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Casenotes and Comments

THE FDA, CONGRESS, AND MOBILE HEALTH APPS: LESSONS FROM DSHEA AND THE REGULATION OF DIETARY SUPPLEMENTS

NATALIE R. BILBROUGH*

Within the past few years, the mobile health applications (“apps”)¹ industry has exploded, with the number of available apps surpassing 100,000.² One study shows that by 2018, more than half of the 3.4 billion smartphone and tablet users will have downloaded a mobile health app.³ The sheer scope of mHealth,⁴ and particularly mobile health apps, presents exciting possibilities for public health, but also formidable obstacles for the

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1. A mobile app is “a software application that can be executed (run) on a mobile platform . . . or a web-based software application that is tailored to a mobile platform but is executed on a server.” U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF, MOBILE MEDICAL APPLICATIONS 7 (2015), available at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf> [hereinafter MOBILE MEDICAL APP GUIDANCE]. For purposes of this Comment, a “mobile health app” refers generally to any mobile apps that have a health, wellness, or medical function, and should not be confused with “mobile medical apps,” a term used by the FDA to designate a narrower class of mobile health apps. *Id.* at 4. For a description of the history of mobile apps, see Alex Krouse, Note, *iPads, iPhones, Androids, and Smartphones: FDA Regulation of Mobile Phone Applications as Medical Devices*, 9 IND. HEALTH L. REV. 731, 733–35 (2012).

2. RESEARCH2GUIDANCE, MHEALTH APP DEVELOPER ECONOMICS 2014: THE STATE OF THE ART OF MHEALTH APP PUBLISHING 7 (2014), available at <http://research2guidance.com/r2g/mHealth-App-Developer-Economics-2014.pdf>.

3. *Health Information Technologies: Administration Perspectives on Innovation and Regulation: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 113th Cong. 13–14 (2013) (statement of Christy L. Foreman, Director, FDA Office of Device Evaluation), available at <http://www.fda.gov/NewsEvents/Testimony/ucm344395.htm> [hereinafter Statement of Christy L. Foreman].

4. mHealth is “the delivery of healthcare services via mobile communication devices.” Carol E. Torgan, *The mHealth Summit: Local & Global Converge*, KINETICS (Nov. 6, 2009), <http://www.caroltorgan.com/mhealth-summit/>.

federal agencies charged with protecting consumers.⁵ Given that many mobile health apps are not developed with professional medical input, the risks of malfunction or erroneous health advice are great.⁶ For these reasons and others, physicians and other health care providers have generally been reluctant to incorporate mobile health apps and other types of mHealth into their practices.⁷

Recognizing the need for some measure of oversight, the Food and Drug Administration (“FDA”) released a guidance document in September 2013 proposing a risk-based approach in which the FDA would actively regulate only a smaller subset of mobile health apps.⁸ According to the guidance document, the FDA will regulate only “mobile medical apps” (“MMAs”), which are mobile apps that meet “the definition of a device under section 201(h) of the Federal Food, Drug, and Cosmetic Act” (“FDCA”).⁹ However, some stakeholders, scholars, and members of Congress consider FDA interference in this area to be unwarranted or ill-

5. See, e.g., Nathan G. Cortez et al., *FDA Regulation of Mobile Health Technologies*, 4 NEW ENG. J. MED. 371, 372–75 (2014), available at <http://www.law.smu.edu/getmedia/c5412c9e-b58b-4461-a725-f900ddf56127/Nathan-Cortez—NEJM-article-072414> (discussing ways to realize the promise of mobile health technologies but also analyzing the challenges of applying the FDA’s current medical device regulatory framework to mobile health technology); Nicolas P. Terry, *Information Technology’s Failure to Disrupt Health Care*, 13 NEV. L.J. 722, 724 (2013) (arguing that mobile health apps are “the first major success story of health care disruption by IT because they can disorder the high friction, embedded cost of location-specific medicine with a new model of ‘health care everywhere’”); SARAH FELLAY, AMERICAN ENTERPRISE INSTITUTE, CHANGING THE RULES OF HEALTH CARE: MOBILE HEALTH AND CHALLENGES FOR REGULATION 7–9 (2014), available at http://www.aei.org/wp-content/uploads/2014/08/-fellychanging-the-rules-of-health-care_100901289367.pdf (critiquing the inadequacies of the FDA’s approval process as applied to health software).

6. Pamela Lewis Dolan, *What’s Missing from Many Health Apps—Medical Expertise*, AMEDNEWS.COM (May 13, 2013), <http://www.amednews.com/article/20130513/business/130519995/6/> (citing a study conducted at Ohio State University which found that a third of the pain-related apps evaluated had no input from a healthcare professional). App providers such as Apple and Google may ban certain apps, but they do not certify the accuracy or health safety of mobile health apps. Samuel J. Dayton, Note, *Rethinking Health App Regulation: The Case for Centralized FDA Voluntary Certification of Unregulated Non-Device Mobile Health Apps*, 11 IND. HEALTH L. REV. 713, 715–16 (2014).

7. See Dayton, *supra* note 6, at 721–22. Seventy-three percent of doctors do not suggest mobile health apps to patients and 13% discourage them. *Id.* One doctor claimed, “I would never see a patient and make a decision based solely on the records on their phone . . . maybe in 10 years.” Carl Franzen, *Side Effects May Vary: The Growing Problem of Unregulated Medical Apps*, THE VERGE 7 (June 3, 2013), <http://www.theverge.com/2013/6/3/4380244/how-should-medical-apps-be-regulated>.

8. MOBILE MEDICAL APP GUIDANCE, *supra* note 1, at 1, 4. This document was updated in February 2015 to be consistent with changes made to the regulation of medical device data systems, but most of the document is identical to the 2013 version. Compare *id.*, with Mobile Medical Applications; Guidance for Industry and Food and Drug Administration Staff; Availability, 78 Fed. Reg. 59038 (proposed Sept. 25, 2013).

9. *Id.* at 4.

fitting.¹⁰ In 2013 and 2014, several members of Congress proposed bills to amend the FDCA,¹¹ the source of the FDA's authority to regulate medical devices, by excluding certain types of software used in MMAs from the FDA's jurisdiction.¹²

The FDA faced a similar situation in the early 1990s with the dietary supplement industry.¹³ After an outbreak of supplement-related deaths, the FDA suggested stricter regulation of dietary supplements.¹⁴ In response, Congress, spurred by a powerful, industry-driven, lobbying campaign, enacted the Dietary Supplement Health and Safety Act of 1994 ("DSHEA"),¹⁵ which mandated a new, less stringent, regulatory framework for dietary supplements.¹⁶ This congressional preemption of FDA authority hampered the FDA's ability to keep harmful dietary supplements from reaching consumers while simultaneously allowing even more quasi-pharmaceutical substances on the market.¹⁷

Now the question arises: is the FDA again in danger of "being DSHEA'ed"?¹⁸ The FDA and Congress should avoid a repeat of the dietary supplement saga and also draw lessons from the regulatory approach in that field.¹⁹ The field of mobile health apps may be the most disruptive and important development in the health care sector in decades, so it is imperative that consumers can trust the mHealth market and rely on the FDA to protect consumers from faulty or dangerous mobile medical apps.²⁰

10. See, e.g., Vincent J. Roth, *The mHealth Conundrum: Smartphones & Mobile Medical Apps—How Much FDA Medical Device Regulation Is Required?*, 15 N.C. J. L. & TECH. 359, 370 (2014) (determining that the growth of mHealth necessitates a new, streamlined regulatory process that avoids the current regulatory pitfalls that impede innovation); Sen. Deb Fischer & Sen. Angus King, *FDA's Slow Process Hurts Innovation: Column*, USA TODAY (Feb. 15, 2014), <http://www.usatoday.com/story/opinion/2014/02/15/fischer-king-health-information-technology/5464693/> (expressing concern that the FDA's slow, "heavy-handed" regulatory efforts will delay technological development of beneficial mobile health apps).

11. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–399 (2012).

12. See *infra* Part I.A.3.

13. See *infra* Part I.B.

14. See Regulation of Dietary Supplements, 58 Fed. Reg. 33,690, 33,697 (proposed June 18, 1993) (highlighting the new-found risks associated with certain dietary supplements and proposing that they be regulated as drugs).

15. Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325 (codified as amended in scattered sections of 18 and 42 U.S.C.).

16. See *infra* Parts I.B.2–3.

17. See *infra* Part I.B.3.

18. Margaret Gilhooley, *Deregulation and the Administrative Role: Looking at Dietary Supplements*, 62 MONT. L. REV. 85, 89 (2001). In her article, Professor Gilhooley raised the possibility of DSHEA-like congressional deregulation in areas other than dietary supplements and suggested that this prospect may influence the FDA to collaborate more with regulated entities. *Id.*

19. See *infra* Part II.A.

20. See Cortez et al., *supra* note 5, at 372 (insisting FDA oversight is important to help patients and doctors evaluate the usefulness and quality of mobile health apps); Terry, *supra* note

Instead of preempting the FDA in the mobile health app field, Congress should enable the FDA to form an internal sub-agency of experts in mobile technology—the Office of mHealth.²¹ This team of experts should spearhead the FDA’s efforts to regulate mobile health apps, coordinate with other federal agencies, and initiate precedent-making enforcement actions.²² By leveraging this expertise, the FDA can be a more efficient regulator in a developing area of healthcare that is in desperate need of guidance.²³

I. BACKGROUND

Mobile health apps present novel benefits yet also new dangers to consumers and patients.²⁴ Without effective regulation, the mobile health app world could quickly turn into a market for “digital snake oil,” making it difficult for consumers or physicians to trust an otherwise useful technological development.²⁵ Even worse, malfunctioning apps could lead to serious physical harm.²⁶ After receiving stakeholder input, the FDA released a guidance document in 2013 outlining its intended approach to regulate certain “mobile medical apps.”²⁷ However, the FDA faced opposition from industry players and members of Congress who wished to delay FDA action and limit the FDA’s influence on the mobile health app field.²⁸

Wishing to proceed with caution in a new field while also pleasing diverse stakeholders, the FDA continues to recalculate and redefine its role regulating mobile health apps.²⁹ The current state of regulatory

5, at 757–58 (claiming mobile health apps are the exception to HIT’s general failure to disrupt health care).

21. See *infra* Part II.C.1.

22. See *infra* Part II.C.1.

23. See *infra* Part II.C.2.

24. See *infra* Part I.A.1.

25. See Nathan Cortez, *The FDA Needs to Regulate “Digital Snake Oil,”* SLATE (Sept. 24, 2013),

http://www.slate.com/blogs/future_tense/2013/09/24/mhealth_fda_needs_to_regulate_digital_snake_oil.html (comparing ineffective health apps to snake oil and arguing that Congress should empower the FDA to regulate mHealth in order to boost consumer confidence and further innovation).

26. See *infra* Part I.A.1.

27. See MOBILE MEDICAL APP GUIDANCE, *supra* note 1, at 4. The FDA received over 130 comments in response to the draft of the MMA Guidance. See *Examining Federal Regulation of Mobile Medical Apps and Other Health Software: Hearing Before the H. Subcomm. on Health of the H. Comm. on Energy and Commerce*, 113th Cong. 9 (2013) (statement of Jeffrey Shuren, Director, Center for Devices and Radiological Health, U.S. Food & Drug Admin.), available at <http://www.fda.gov/newsevents/testimony/ucm375462.htm> [hereinafter Statement of Jeffrey Shuren].

28. See *infra* Part I.A.3.

29. See *infra* Part I.A.2.

uncertainty³⁰ in the mobile health app landscape parallels another time of upheaval when Congress rejected the FDA's proposed limitations on dietary supplements two decades ago.³¹ Thus an understanding of the enactment and consequences of the Dietary Supplement Health and Education Act of 1994 ("DSHEA") can aid the discussion of possible solutions for the regulation of mobile health apps.³²

A. The FDA's Regulation of Mobile Medical Apps and Congressional Response

Although the FDA regulated mobile health apps before 2013, the dramatic increase in availability and use of mobile health apps led the FDA to more formally define its regulatory approach to those apps.³³ The FDA revealed its intended regulatory strategy in two sources: the Mobile Medical Application Guidance (2013) and the Food and Drug Administration Safety and Innovation Act Health IT Report³⁴ ("FDASIA Health IT Report") (2014), which further outlines the agency's goals for regulating health information technology ("HIT"), including mobile health apps.³⁵ Although some stakeholders responded positively to FDA participation,³⁶ others, including members of both houses of Congress, envisioned a more limited role for the FDA, evidenced by three proposed statutes: the Medical Electronic Data Technology Enhancement for Consumers' Health Act of 2014 ("MEDTECH Act"),³⁷ the Preventing Regulatory Overreach to Enhance Care Technology Act of 2014 ("PROTECT Act"),³⁸ and the Sensible Oversight for Technology which Advances Regulatory Efficiency Act of 2013 ("SOFTWARE Act").³⁹ All of these proposed statutes suggest

30. See, e.g., Letter from Access Integrity et al. to Congress, 1 (Oct. 7, 2014), available at <http://www.healthitnow.org/wp-content/uploads/2014/10/Multi-Group-FDASIA-Letter-to-Congress.pdf> ("We are concerned that there is significant confusion in the market about what technologies may be regulated, by which agencies, and to what standards.").

31. See *infra* Part I.B.

32. See *infra* Part I.B.

33. See Statement of Christy L. Foreman, *supra* note 3, at 17.

34. U.S. FOOD & DRUG ADMIN. ET AL., FDASIA HEALTH IT REPORT: PROPOSED STRATEGY AND RECOMMENDATIONS FOR A RISK-BASED FRAMEWORK 3 (2014), available at <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM391521.pdf> [hereinafter FDASIA HEALTH IT REP.].

35. See *infra* Part I.A.2.

36. For example, Omri Shor, the CEO of MediSafe Project, which sells a medication reminder app, anticipated that the FDA would "take away a lot of the crap that's in the space." Franzen, *supra* note 7.

37. Medical Electronic Data Technology Enhancement for Consumers' Health Act, S. 2977, 113th Cong. (2014).

38. Preventing Regulatory Overreach to Enhance Care Technology Act of 2014, S. 2007, 113th Cong. (2014).

39. Sensible Oversight for Technology which Advances Regulatory Efficiency Act of 2013, H.R. 3303, 113th Cong. (2013).

amending the FDCA to remove certain types of software used in mobile health apps from the FDA's jurisdiction.⁴⁰

1. *What Are Mobile Health Apps and Why Should They Be Regulated?*

Mobile health apps are quickly becoming the darling of the HIT world with major tech companies investing in mHealth products such as wearables.⁴¹ Some mobile health apps allow users to have more control over their own health and wellbeing, while others act as useful tools for medical professionals.⁴² Ranging from calorie counters to mobile ultrasound imaging devices, the wide-ranging capabilities of mobile health apps are astounding.⁴³ While the potential benefits and uses of mobile health apps are many, they are beyond the scope of this Comment.⁴⁴

Mobile health apps also pose significant risks.⁴⁵ Unlike traditional medical devices marketed to and used primarily by trained medical professionals, mobile health apps are widely available to the average consumer who likely has limited medical knowledge.⁴⁶ Consumer access to MMAs through smartphones, tablets, and other mobile platforms continues

40. See *infra* notes 138–141 and accompanying text.

41. See Krouse, *supra* note 1, at 740 (discussing the large corporations such as Verizon, AT&T, and Apple, that have invested in medical technologies); cf. Mike Feibus, *2015: The Year of Health Care for Wearables*, USA TODAY (Jan. 5, 2015), <http://www.usatoday.com/story/tech/columnist/2015/01/02/wearables-fitness-is-name-of-the-game-but-healthcare-is-where-its-at/21190395/> (predicting that apps and wearables will become more oriented toward healthcare, rather than fitness, in the coming year).

42. See RESEARCH2GUIDANCE, *supra* note 2, at 7 (“Today’s mHealth app publishers and Wannabes predominantly target chronically ill patients (31%) and health and fitness-interested people (28%). As primary users, physicians are targeted by 14% of app developers.”).

43. See, e.g., Katie Matlack, *5 Medical Peripherals for the iPad or iPhone*, THE PROFITABLE PRACTICE (Jan. 26, 2012), <http://profitable-practice.softwareadvice.com/5-medical-peripherals-for-the-ipad-or-iphone-1012612/> (describing the MobiUS SP1 Ultrasound Imaging Device, a portable ultrasound device that connects to a phone or other mobile platform to scan and send images). Another example is the iPhoneECG Electrocardiogram, an app that uses electrodes built into a smartphone cover that you can place on your heart or finger to record and transmit data into the smartphone to later send to an expert to analyze. *Id.* For a description of the different categories of mobile health apps, see Nathan Cortez, *The Mobile Health Revolution?*, 47 U.C. DAVIS L. REV. 1173, 1182–90 (2014).

44. For a discussion of the benefits of mobile health apps see Cortez, *supra* note 43, at 1190–1200.

45. See MOBILE MEDICAL APP GUIDANCE, *supra* note 1, at 6–7 (“As is the case with traditional medical devices, certain mobile medical apps can pose potential risks to public health.”).

46. See Cortez, *supra* note 43, at 1187–88 (“Notably, many customizer apps generally target medical professionals and students, though nothing prevents lay users from downloading them.”); Dayton, *supra* note 6, at 721–22 (citing study that found that fifty-nine percent of mobile health users said apps and other mobile technologies have replaced visits to health care providers, suggesting increased vulnerability to inaccurate or deceptive mobile health apps).

to increase, creating heightened opportunities for both risks and benefits.⁴⁷ Not all apps present the same level of risk.⁴⁸ An app that tracks a runner's steps may not pose a significant health risk if it makes a mistake, but an app that acts as the "central command" for a glucose meter for a diabetic patient may have deadly consequences were it to malfunction.⁴⁹ Similarly, an app that functions as a medical device normally only found in a hospital may pose more risk to an untrained consumer than a health clinician who is trained to use that sort of a device.⁵⁰ Without the need for a prescription or professional input, mobile apps provide health advice and treatment to consumers in an unregulated space.⁵¹ Indeed, this ease of access is one of the benefits of mobile health apps, but also one of its dangers.⁵²

Many apps are developed without any clinician or expert input, posing the risk of erroneous or malfunctioning apps that may harm patients.⁵³ "Virtually any app that claims it will cure someone of a disease, condition or mental health condition is bogus," says John Grohol, an expert in online health technology, pointing out that the vast majority of apps have not been scientifically tested.⁵⁴ According to Morgan Reed, the Executive Director

47. See Roth, *supra* note 10, at 364–65, 415–18 (identifying a phenomenon called "marketplace interposition" which "occurs where commerce (in this case technological advancement) encourages society to tacitly permit self-treatment and the unauthorized practice of medicine through consumer access and actual use" and using that phenomenon to explain the risks of the consumer-focused aspect of the mobile health app market).

48. See Statement of Jeffrey Shuren, *supra* note 27, at 12 ("While many mobile apps carry minimal or no risk to patients, a small subset of these apps can pose significant risks to patients if they don't operate correctly.").

49. See U.S. FOOD & DRUG ADMIN., FDA NEWS RELEASE, FDA ISSUES FINAL GUIDANCE ON MOBILE MEDICAL APPS (2013), available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm369431.htm> (discussing the different levels of risk presented by different mobile health apps).

50. See Morgan Reed, Exec. Dir. of ACT, Remarks at Public Workshop: Proposed Risk-Based Regulatory Framework and Strategy for Health Information Technology 21 (May 13, 2014), available at <http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM405509.pdf> ("So, the exact same sensor, the same functionality, the same capability in different hands has different implications to the patient safety and to improving patient outcomes.").

51. Roth, *supra* note 10, at 415 (finding that the marketplace is "rejecting the federal prohibition against self-treatment" and "state prohibition of the unauthorized practice of medicine").

52. See Cortez, *supra* note 43, at 1178–79 (arguing that the benefits of mobile health apps, such as their consumer focus, will not reach their full potential unless the apps are "subjected to a healthy dose of skepticism from federal regulators").

53. See Thomas Lorchan Lewis & Jeremy C. Wyatt, *mHealth and Mobile Medical Apps: A Framework to Assess Risk and Promote Safer Use*, 16 J. MED. INTERNET RES. 210 (2014), available at <http://www.jmir.org/2014/9/e210/> ("[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.").

54. Rochelle Sharpe, *Many Health Apps Are Based on Flimsy Science at Best, and They Often Do Not Work*, WASH. POST (Nov. 12, 2012), <http://www.washingtonpost.com/national/health-science/many-health-apps-are-based-on-flimsy->

of ACT, an app-developer association,⁵⁵ the thousands of apps that make these types of claims set “a really dangerous expectation that this device will cure you.”⁵⁶ This type of misinformation may lead users to not seek medical help even when it is desperately needed.⁵⁷

Even when apps are developed with adequate professional input, malfunctions are still a real danger.⁵⁸ For example, in 2011, Pfizer conducted a voluntary recall for its rheumatoid arthritis calculator app because it gave faulty results.⁵⁹ And in 2012, Sanofi Aventis voluntarily recalled its Diamago diabetes app through an Apple “push notification” because of a software error that could cause the app to “miscalculate an insulin dose potentially resulting in dangerously low or high blood glucose levels in diabetic patients.”⁶⁰ In February 2010, the FDA revealed it had reports of 260 malfunctions, 44 injuries, and 6 deaths related to HIT, which, although not entirely attributable to mobile health apps, illustrate the potential and indeed, real, risks of software-enabled medical devices.⁶¹

Still, the push for medical clinicians to incorporate mobile technologies and mobile health apps into their practices is increasing.⁶² Dr. Peter Pronovost, the senior vice president for patient safety and quality for

science-at-best-and-they-often-do-not-work/2012/11/12/11f2eb1e-0e37-11e2-bd1a-b868e65d57eb_story.html. One study found that a significant percentage of therapeutic apps tested relied on a cellphone’s sounds, light, or phone vibrations for treatments—all methods which scientists claim are useless in treating the intended conditions. *Id.*

55. ACT | The App Association is “an international grassroots advocacy and education organization representing more than 5,000 small and mid-size app developers and information technology firms.” ACT | THE APP ASSOCIATION, <http://actonline.org/about/> (last visited Jan. 4, 2015).

56. Reed, *supra* note 50, at 40.

57. See Statement of Jeffrey Shuren, *supra* note 27, at 12 (“An inaccurate or malfunctioning mobile medical app that uses a sensor to diagnose skin cancer or to measure critically low blood oxygen levels in chronic lung disease patients, could delay lifesaving diagnosis and treatment.”).

58. See Cortez et al., *supra* note 5, at 373 (giving examples of apps that have been recalled due to malfunctions). During 2014, the FDA recalled at least five medical devices involving software, including an ARKON Anesthesia Delivery System with 2.0 Software (software defect caused system to stop working) and a Puritan Bennett 840 Series Ventilator (software problem). U.S. FOOD & DRUG ADMIN., 2014 MEDICAL DEVICE RECALLS, available at <http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm384921.htm> (last updated Mar. 5, 2015).

59. Veronica Hackethal, *10 Top Mobile Apps for Rheumatoid Arthritis*, RHEUMATOLOGY NETWORK (Sept. 6, 2013), <http://www.rheumatologynetwork.com/rheumatoid-arthritis/10-top-mobile-apps-rheumatoid-arthritis>.

60. Cortez, *supra* note 43, at 1210 (internal quotation marks omitted); see also U.S. FOOD & DRUG ADMIN., CLASS 2 RECALL: SANOFI AVENTIS DIAMIGO IPHONE APP, (2012), available at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=114792> (announcing the recall).

61. Cortez, *supra* note 43, at 1228.

62. Cf. Nayana Davis, *The RX You Fill at the App Store*, FAST COMPANY (Aug. 13, 2014), <http://www.fastcompany.com/3034306/healthware/the-rx-you-fill-at-the-app-store> (describing the development of a prescription app and viewing how it is incorporated into professional practice).

Johns Hopkins Medicine, “hear[s] pitches for several [apps] every week.”⁶³ Nevertheless, physicians and other health care providers have generally been reluctant to incorporate mobile health apps and other types of mHealth into their practices because of some of the same risks explained above.⁶⁴ However, as a younger, more tech-savvy generation of health care professionals enters the field, new technologies such as mobile health apps will begin to play a more prominent role.⁶⁵ This increased reliance on mobile health app technology worries some interest groups who ask, “what happens when software ends up making very complex decisions and the physicians, either because time does not permit or because the software does not reveal enough to be evaluated, end up deferring to the software?”⁶⁶ This very question led some stakeholders to ask for more, rather than less, FDA oversight.⁶⁷

2. *The FDA Suggests a Limited Regulatory Approach to Mobile Medical Apps*

Recognizing the challenge posed by mobile health apps, the FDA attempted to clarify its position on these devices.⁶⁸ The FDA first released the final Mobile Medical Application Guidance (“MMA Guidance”) in 2013, declaring that it would regulate a subset of mobile health apps that posed the most risk to patients and users.⁶⁹ Additionally, the FDASIA

63. *Id.*

64. See Dayton, *supra* note 6, at 721; see also Ryan Faas, *Why Your Doctor Doesn't Want You Using iPhone and iPad Health Apps*, CULT OF MAC (June 20, 2012), <http://www.cultofmac.com/174776/why-your-doctor-doesnt-want-you-using-iphone-and-ipad-health-apps/> (identifying physicians' concerns that they would not be able to ensure that patients properly use mobile health apps and that patients would soon avoid regular healthcare visits).

65. Katie Hafner, *Redefining Medicine with Apps and iPads*, N.Y. TIMES (Oct. 8, 2012), <http://www.nytimes.com/2012/10/09/science/redefining-medicine-with-apps-and-ipads-the-digital-doctor.html?pagewanted=all> (“The proliferation of gadgets, apps and Web-based information has given clinicians—especially young ones like Dr. Rajkomar, who is 28—a black bag of new tools: new ways to diagnose symptoms and treat patients, to obtain and share information, to think about what it means to be both a doctor and a patient.”).

66. See MHEALTH REGULATORY COAL. & CDS COAL., EXAMPLES OF SOFTWARE THAT WOULD BE DEREGULATED UNDER THE PROTECT ACT 3 (2014), available at <http://assets.fiercemarkets.com/public/newsletter/fiercehealthit/protectactexamplesV1.pdf> [hereinafter EXAMPLES].

67. See Letter from the Patient, Consumer, and Public Health Coalition to Sen. Tom Harkin, Chairman of the S. Comm. on Health, Education, Labor and Pensions (Feb. 14, 2014), available at <http://assets.fiercemarkets.com/public/newsletter/fiercehealthit/protectconsumer.pdf> (opposing proposed restrictions of FDA authority under the PROTECT Act of 2014).

68. See generally MOBILE MEDICAL APP GUIDANCE, *supra* note 1 (non-binding guidance document for agency and industry use).

69. See *infra* Part I.A.2.a.

Health IT Report, released in early 2014, reiterated the agency's view that the FDA should limit its oversight to only a small portion of apps.⁷⁰

a. FDA Mobile Medical App Guidance

The FDA's approach in the area of HIT and mobile health app regulation has been characterized as informal, incremental, and restrained.⁷¹ By the time the FDA released the MMA Guidance in September 2013⁷², the agency was already regulating mobile-based software and had reviewed over 100 mobile health apps.⁷³ The MMA Guidance declares that the FDA will actively regulate only a limited category of apps that fit the FDCA's definition of a "device."⁷⁴ The MMA Guidance also describes a risk-based regulatory scheme that stresses what the FDA will *not* regulate.⁷⁵ For example, the FDA will not regulate the sale of mobile platforms⁷⁶ such as smartphones, and it will not apply any regulatory requirements to companies that solely distribute apps, such as the iTunes App Store or Google Play.⁷⁷ According to the MMA Guidance, the FDA will only regulate "mobile medical app[s]," which are mobile apps that (1) act "as an accessory to a regulated medical device" or (2) "transform a mobile platform into a regulated medical device."⁷⁸

Using these parameters, the MMA Guidance separates all mobile health apps into three categories: (1) apps that do not meet the definition of "device" and will not be regulated, (2) apps that may meet the definition of "device" but pose such low risk that the FDA will exercise "enforcement

70. See FDASIA HEALTH IT REP., *supra* note 34, at 4 (claiming the "FDA would focus its attention and oversight on medical device health IT functionality, such as computer aided detection software, remote display or notification of real-time alarms from bedside monitors, and robotic surgical planning and control").

71. See, e.g., Nathan Cortez, *Regulating Disruptive Innovation*, 29 BERKELEY TECH. L.J. 175, 190-91, 194 (2014) (arguing that the FDA's use of "threats" to regulate software has been counterproductive).

72. MOBILE MEDICAL APP GUIDANCE, *supra* note 1, at 1.

73. Statement of Christy L. Foreman, *supra* note 3, at 17. The FDA-approved MMAs included "remote blood pressure, heart rhythm, and patient monitors, and smartphone-based ultrasounds, EKG machines, and glucose monitors." *Id.*

74. MOBILE MEDICAL APP GUIDANCE, *supra* note 1, at 4.

75. The MMA Guidance spends approximately twelve pages covering apps and manufacturers that will not be regulated by the FDA. *E.g., id.* at 12-13, 20-25. See also Statement of Jeffrey Shuren, *supra* note 27, at 14-15 ("Just as important as what the policy does is what the policy does not do.").

76. Mobile platforms are "commercial off-the-shelf (COTS) computing platforms, with or without wireless connectivity, that are handheld in nature," including smartphones, tablet computers, and portable computers. MOBILE MEDICAL APP GUIDANCE, *supra* note 1, at 7.

77. *Id.* at 9.

78. *Id.* at 4, 7. The FDA will provide "regulatory oversight to only those mobile apps that are medical devices and whose functionality could pose a risk to a patient's safety if the mobile app were not function as intended. This subset of mobile apps the FDA refers to as mobile medical apps." *Id.* at 4.

discretion”⁷⁹ over them, and (3) apps that *will* be regulated because they meet the definition of “device” and may pose a higher risk to patients were the app to malfunction.⁸⁰ Using this scheme, the FDA has cleared over forty MMAs⁸¹ and taken one enforcement action related to MMAs since 2011.⁸²

The FDA declares it will *not* regulate simple educational or administrative apps.⁸³ If an app is not intended to diagnose or treat a patient, the FDA does not consider it to be a medical device.⁸⁴ Similarly, the FDA will not enforce regulations against the “enforcement discretion” category of low-risk apps, which includes apps that provide access to electronic health records, communicate information to providers, or provide tools to users to organize and track health information.⁸⁵

Instead, the FDA will focus its oversight on the subset designated as mobile medical apps.⁸⁶ This category includes mobile apps that *connect* to medical devices in order to control the device, such as an app that controls a

79. *Id.* at 15. Enforcement discretion means the FDA “does not intend to enforce” the regulatory requirements of the FDCA on this category of apps for now. *Id.*

80. *Id.* at 13.

81. CTR. FOR DEVICES AND RADIOLOGICAL HEALTH, U.S. FOOD & DRUG ADMIN., NARRATIVE BY ACTIVITY 86 (2014), *available at* <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM394762.pdf>. For example, the FDA cleared BlueStar, a prescription-only mobile app designed to assist patients with Type-II diabetes to manage their disease. Davis, *supra* note 62.

82. In May 2013, the FDA sent an “It Has Come to Our Attention” Letter to Biosense Technologies Ltd., developer of an app called uChek that allows users to take a picture of urinalysis test strips with a smartphone and then identifies substances to deliver a result to the patient. uChek had not been submitted to the FDA for clearance even though the FDA thought it fit the definition of a medical device. Letter from James L. Woods, Deputy Dir., Patient Safety and Prod. Quality, U.S. Food & Drug Admin., to Myshkin Ingawale, Biosense Technologies Private Ltd. (May 2013), *available at* <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/ucm353513.htm>; *see also* Christian Farr, *The FDA Launches First Inquiry into Medical iPhone App*, VENTUREBEAT.COM (May 29 2013), <http://venturebeat.com/2013/05/29/the-fda-launches-first-inquiry-into-medical-iphone-app/> (discussing the FDA’s letter to Biosense). The FDA only addressed uChek’s non-conformance after the app was featured in a TED talk even though the app had been offered for years without FDA clearance. This example highlights the FDA’s current inability to adequately police the mammoth-sized world of mobile health apps. The company eventually recalled uChek and retreated to foreign markets because it could not afford to go through the regulatory process. FELLAY, *supra* note 5, at 6.

83. *See id.* at 20–22. Appendix A of the MMA Guidance provides examples of apps that will not be regulated by the FDA, such as apps that provide electronic copies of medical reference books or automate office functions. *Id.*

84. *Id.* at 20.

85. *Id.* at 15–18, 23–25. Under these guidelines, daily exercise and calorie trackers apps may technically be medical devices, but will nevertheless not be regulated. *Id.* at 24–25. Appendix B of the MMA Guidance provides examples of apps that fall under the enforcement discretion category. *Id.* at 23–26.

86. *Id.* at 13.

blood pressure cuff.⁸⁷ The FDA considers this sort of app to be an accessory that falls under the same regulations as the parent device.⁸⁸ The MMA may also be an app that *transforms* a mobile platform, like a smartphone or tablet, into a medical device using sensors, display screens, or attachments.⁸⁹ The MMA Guidance gives examples of apps that use attachments of a glucose strip reader to transform a mobile platform into a glucose meter or apps that use a smartphone's built-in accelerometer to measure movement to monitor sleep apnea.⁹⁰ Lastly, any mobile app that *analyzes* or *diagnoses* patients using patient-specific data will fall under FDA oversight.⁹¹ For instance, an app that uses radiation therapy treatment software to calculate dosages of radiation for a particular patient would be considered a mobile medical app.⁹² Apps that fall into the MMA category will be classified under the three-class system just as any other medical device according to the risk they present.⁹³

In general, the FDA places all regulated medical devices into three classes according to the level of risk presented by the intended use of the device.⁹⁴ A mobile app will be regulated under this medical device class system only “[w]hen the *intended use* of a mobile app is for the diagnosis of disease or other conditions, or the cure, mitigation, treatment, or prevention of disease, or is intended to affect the structure or any function of the body of man.”⁹⁵ Class I devices are those that pose no “potential unreasonable risk of illness or injury.”⁹⁶ Class II devices pose more risk of injury to patients and must be under general and “special controls,” including post-market surveillance.⁹⁷ Lastly, Class III devices are “represented to be for a use in supporting or sustaining human life” or present “a potential

87. *Id.* at 14.

88. *Id.*

89. *Id.* at 14–15.

90. *Id.* at 15.

91. *Id.*

92. *Id.*

93. *Id.* at 13. Appendix C provides examples of apps that are considered mobile medical apps and will be regulated by the FDA. *Id.* at 27–29.

94. 21 U.S.C. § 360c (2012).

95. MOBILE MEDICAL APP GUIDANCE, *supra* note 1, at 8 (emphasis added). Intended use is the “objective intent of the persons legally responsible for the labeling of devices. . . . shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives.” MOBILE MEDICAL APP GUIDANCE, *supra* note 1, at 8 n.5 (citing 21 C.F.R. § 801.4 (2014)). A mobile medical app manufacturer is “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.” MOBILE MEDICAL APP GUIDANCE, *supra* note 1, at 9. For example, an app that makes an LED operate may or may not fall under regulation as a device. If the app is intended to be a general light source, it will not be regulated. However, if the app is labeled and marketed to be used by doctors as a light source to examine patients, similar to an ophthalmoscope, then it will fall under the FDA’s oversight. *Id.* at 8.

96. 21 U.S.C. § 360c(a)(1)(A).

97. *Id.* § 360c(a)(1)(B).

unreasonable risk of illness or injury.”⁹⁸ Most manufacturers attempt to avoid Class III classification and pre-market approval because it is often a long, expensive process requiring substantial amounts of testing and clinical trials.⁹⁹

To summarize, if a mobile health app does not fall under the definition of a “mobile medical app” it will not be regulated by the FDA.¹⁰⁰ Furthermore, some mobile health apps will fall under the “enforcement discretion” category and not be regulated either.¹⁰¹ Finally, even the mobile health apps that do fall under the riskier, regulated “mobile medical app” category will be classified under the general Class I–III system that applies to all medical devices, meaning they may only be subject to minimal controls.¹⁰²

b. FDASIA Health IT Report

The much-anticipated FDASIA Health IT Report, released in April 2014, provided further insight into how federal agencies are approaching mobile health apps and HIT in general.¹⁰³ Section 618 of the Food and Drug Administration Safety and Innovation Act of 2012 (“FDASIA”)¹⁰⁴ commissioned the FDA to write the Report in conjunction with the Federal Communications Commission (“FCC”) and the Office of the National Coordinator for Health Information Technology (“ONC”).¹⁰⁵ Congress

98. *Id.* § 360c(a)(1)(C).

99. *See* FELLAY, *supra* note 5, at 9–10. In fact, any type of FDA approval process is often a hindrance to device manufacturers. The first sponsor to submit a new device, especially, is at a disadvantage because the new device must go through more initial testing to enter the market, whereas future similar devices only have to prove “substantial equivalence” to the first device to receive FDA approval. *Id.*

100. *Id.* at 4.

101. *Id.* at 15–16.

102. *Id.* at 13. All MMA manufacturers must meet the generally applicable device regulatory requirements such as registering and listing the MMAs they market with the FDA. *Id.* at 33. MMA manufacturers must also comply with Quality System regulations, which mandate the development of safety requirements, procedures to design, produce, and distribute MMAs, and verification processes for the MMAs on various mobile platforms. *Id.* at 34. For more information on Quality System regulations, see Quality System Requirements, Management Responsibility, 21 C.F.R. § 820.20 (2014).

103. *See* FDASIA HEALTH IT REP., *supra* note 34, at 3 (recommending a four-pronged approach of fostering safety, leveraging standards, using industry-led testing and certification, and creating a learning environment for HIT).

104. Food and Drug Administration Safety and Innovation Act of 2012, Pub. L. No. 112–144, 126 Stat. 993 (codified as amended in scattered sections of 21 U.S.C.). FDASIA amended the FDCA. *Id.* § 2(b).

105. *Id.* § 618. The ONC, an office within the Department for Health and Human Services, was first created by executive order in 2004 and later established by the Health Information Technology for Economic and Clinical Health (HITECH) Act in 2009. The ONC oversees the development of standards and certification criteria for HIT and supports two federal advisory committees. FDASIA HEALTH IT REP., *supra* note 34, at 6.

instructed these agencies to address “an appropriate, risk-based regulatory framework pertaining to HIT, *including mobile medical applications*, that promotes innovation, protects patient safety, and avoids regulatory duplication.”¹⁰⁶ Under the direction of the statute, the agencies formed a FDASIA Workgroup consisting of a representative of each of the three agencies involved, plus twenty-eight individuals from the general public.¹⁰⁷

Overall, the Report continued the theme of deemphasizing the FDA’s role in HIT regulation.¹⁰⁸ Again, the Report stressed that no “new or additional *mandatory* conformity assessments” should be required before a new HIT device is allowed to be marketed or used.¹⁰⁹ The Report concluded that “a limited, narrowly-tailored approach that primarily relies on ONC-coordinated activities and private sector capabilities is prudent,” implying these options were preferred over FDA oversight.¹¹⁰ Other methods, such as industry-led certification and development of best practices, were emphasized, rather than a regulation-first approach.¹¹¹ The Report’s authors also envisioned more cooperation with stakeholders and the private sector.¹¹² For example, the Report suggests that non-governmental entities may manage the testing, inspection, and certification of mobile health app manufacturers to insure they meet certain minimum standards.¹¹³

The authors of the FDASIA Health IT Report also recommended the creation of a Health IT Safety Center, a public-private entity formed by the ONC, FDA, FCC, and Agency for Healthcare Research and Quality with input from other agencies and IT stakeholders.¹¹⁴ The Center is meant to involve stakeholders in gathering the scientific evidence and data necessary to create HIT safety goals and educate the HIT community on best practices and patient safety.¹¹⁵ Beyond mentioning that the Center would require “a

106. FDASIA § 618(a) (emphasis added).

107. FDASIA HEALTH IT REP., *supra* note 34, at 7. The public members included “experts representing patients, consumers, health care providers, startup companies, health plans, venture capitalists, IT and health IT vendors, small businesses, purchasers, and employers.” *Id.*

108. *Id.* at 3 (“[N]o new or additional areas of FDA oversight are needed.”).

109. *Id.* at 20 (emphasis added). Rather, the assessment tools will simply distinguish between the products and organizations that create high quality products meeting the minimum standards and those that do not. *Id.*

110. *Id.*

111. *See id.* (“[A] better approach is to foster the development of a culture of safety and equality; leverage standards and best practices; employ industry-led testing and certification; and selectively use tools such as voluntary listing, reporting, and training to enable the development of a healthcare environment that is transparent and promotes learning to foster continual health IT improvement.”).

112. *See id.* at 29 (“[T]he Agencies intend to continue active engagement with stakeholders in an ongoing collaborative effort to implement a health IT framework . . .”).

113. *Id.* at 21.

114. *Id.* at 14–15.

115. *Id.*

strong governance mechanism,” the Report did not specify how this entity would be formed, what its authority would be, if any, and how it would operate.¹¹⁶ Ultimately, the FDASIA Report demonstrated that there is no consensus on who should be making the guidelines or standards for regulation of mobile health apps—the FDA, non-governmental entities, or perhaps both—and that more information on mHealth is needed.¹¹⁷

After the release of the FDASIA Health IT Report, the FDA began adjusting its regulation of HIT. In June 2014, the FDA issued another guidance document (“MDDS Guidance”), which it finalized in February 2015,¹¹⁸ declaring it would not enforce its prior regulations of medical device data systems (“MDDS”),¹¹⁹ medical image storage devices, and medical image communication devices.¹²⁰ The MDDS Guidance stated “the FDA has gained additional experience with these types of technologies, and has determined that these devices pose a low risk to the public.”¹²¹ The MDDS Guidance also affected the MMA Guidance since the latter originally contemplated the regulation of apps that served MDDS functions.¹²²

Even after the FDA explained its regulatory intentions through the MMA Guidance, the FDASIA Report, and public workshops,¹²³

116. *Id.*

117. *See id.* at 22 (questioning the role of the government and non-governmental entities in making decisions about possible assessment tools for HIT); *accord* Transcript of Panel B at 148–49, Public Workshop—Proposed Risk-Based Framework and Strategy for Health Information Technology (May 13, 2014), *available at* <http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM405509.pdf> (discussing the possible role of stakeholders versus the federal agencies to write accountability rules for HIT).

118. U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF: MEDICAL DEVICE DATA SYSTEMS, MEDICAL IMAGE STORAGE DEVICES, AND MEDICAL IMAGE COMMUNICATIONS DEVICES (2015), *available at* <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM401996.pdf> [hereinafter MDDS GUIDANCE].

119. Medical Device Data Systems are “hardware or software products that transfer, store, convert formats, and display medical device data. . . . MDDS are not intended to be used in connection with active patient monitoring.” *Id.* at 5.

120. *Id.* at 4.

121. *Id.* The MDDS Guidance affected the 2011 Medical Device Data Systems Final Rule that lowered MDDS from Class III to Class I. Medical Device Data System Rule, 21 C.F.R. § 880.6310 (2014).

122. The MMA Guidance was updated and reissued on February 9, 2015, to reflect the changes relating to MDDS. MOBILE MEDICAL APP GUIDANCE, *supra* note 1, at 1.

123. The FDA hosted public workshops in 2011 and 2014 to discuss the FDA’s proposed regulatory framework for HIT and MMAs. *See* U.S. FOOD & DRUG ADMIN., PUBLIC WORKSHOP—MOBILE MEDICAL APPLICATIONS DRAFT GUIDANCE (2011), *available at* <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm267821.htm> (last visited Jan. 14, 2015); U.S. FOOD & DRUG ADMIN., PUBLIC WORKSHOP—PROPOSED RISK-BASED REGULATORY FRAMEWORK AND STRATEGY FOR HEALTH INFORMATION TECHNOLOGY (2014),

stakeholders still believe the mobile health app regulatory landscape is unstable.¹²⁴ Multiple healthcare and technology organizations wrote a letter to Congress in October 2014 calling for increased “statutory clarity and a stable foundation” for the continued growth of HIT innovation in contrast to the “[c]urrent regulatory uncertainty [that] stifles health care innovation.”¹²⁵ In fact, Congress had already been considering different measures that would affect the regulation of mobile health apps.¹²⁶

3. *Congress and Stakeholders React to FDA Regulation of Mobile Health Apps*

As the FDA works to solidify MMA regulation, stakeholders and Congress are unsure how much authority the FDA should have in that area. While the FDA was still receiving stakeholder comments on the proposed MMA Guidance in 2012, some members of Congress attempted to slow down the regulatory process out of fear that regulation would halt innovation and expansion.¹²⁷ Many stakeholders encouraged these congressional slow-down efforts.¹²⁸ Individuals within the HIT industry “believe[d] that any new set of regulations, no matter how well-intentioned in development, [would] likely have unintended consequences or lead to a regulatory land grab.”¹²⁹ Not all stakeholders, however, supported these efforts to stall the MMA Guidance.¹³⁰ For example, the mHealth

<http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm392877.htm> (last visited Jan. 14, 2015).

124. *See, e.g.*, Letter from Access Integrity, *supra* note 30, at 1 (informing Congress that uncertainties in the HIT market are creating barriers to innovation).

125. *Id.* at 1–2.

126. *See infra* Part I.A.3.

127. *See* Brian Dolan, *How Congress Almost Delayed the FDA’s Mobile Medical App Guidance*, MOBIHEALTHNEWS (July 5, 2012), <http://mobihealthnews.com/17707/how-congress-almost-delayed-the-fdas-mobile-app-guidance/>. Senator Michael Bennet (D) proposed an amendment that would impose a “year-long moratorium on [the MMA Guidance] so that HHS and an outside working group of various stakeholders can work together on a report to Congress to help us do the proper due diligence on this issue.” *Id.* *But see Health Information Technologies: Harnessing Wireless Innovation: Hearing Before the H. Subcomm. on Comm’n and Techn. of the Comm. on Energy and Commerce*, 113th Cong. 5 (2013) (statement of Rep. Doris O. Matsui) (stating that the FDA MMA Guidance *should* be finalized quickly in order to provide clarity and boost investor confidence).

128. *See* Dolan, *supra* note 127 (interviewing Joel White, Executive Director of the Health IT Now Coalition, which represents large corporations such as Verizon and Aetna, who supported the Bennet-Hatch Amendment’s requirement to seek stakeholder advice, asserting “external input is critical”).

129. *Id.* One industry representative made the following comment: “Does the FDA really have any teeth? Do we really need a finalized guidance document? Look at how quickly mobile health has grown in the past year, the past two years.” *Id.*

130. *See* Letter from Bradley Merrill Thompson, mHealth Regulatory Coalition, on Bennet-Hatch Amendment to Senator Tom Harkin, Chairman, Comm. on Health, Educ., Labor, and Pensions, and Senator Michael B. Enzi, Comm. on Health, Educ., Labor, and Pensions 1–2 (May 17, 2012), *available at* <http://mhealthregulatorycoalition.org/wp-content/uploads/2010/06/MRC->

Regulatory Commission (“MRC”)¹³¹ believed a finalized MMA Guidance would actually benefit the HIT industry because it would decrease the uncertainty that halted further innovation.¹³² Ultimately, the resulting legislation, FDASIA, did not stall the FDA’s issuance of the MMA Guidance.¹³³

Still, Congress continued to attempt to craft a statutory barrier to diminish FDA regulation of mobile health apps. The release of the final MMA Guidance was preceded by a bill proposed in the House of Representatives, the SOFTWARE Act of 2013,¹³⁴ and followed by a similar bill in the Senate, the PROTECT Act of 2014.¹³⁵ Both bills concerned the FDA’s authority to regulate mobile health apps. Bradley Merrill Thompson, counsel for the MRC and part of the FDASIA workgroup, surmised that Congress was trying to frustrate the efforts of the FDA with these bills, particularly because the PROTECT Act was introduced so soon after the MMA Guidance and shortly before the release of the expected FDASIA Health IT Report.¹³⁶ Then, on December 4, 2014, Senators Orrin

Letter-to-Senate-HELP-Committee-on-Proposed-Moratorium-FINAL.pdf (opposing the amendment that would stall FDA action, claiming that the amendment would stall job creation and innovation in the HIT sector because of regulatory confusion).

131. The MRC represents mHealth stakeholders including medical device manufacturers, app developers, telecommunications providers, and non-profit health associations, such as AT&T, Verizon Wireless, Continua Health Alliance, Voxiva, MedApps, and many more. *Id.* at 2. *About Us*, MHEALTH REGULATORY COMMISSION, <http://mhealthregulatorycoalition.org/about-us/> (last visited Jan. 4, 2015).

132. *See* Letter from Bradley Merrill Thompson, mHealth Regulatory Coalition, on FDA Guidance to Kathleen Sebelius, Secretary, Dept. of Health and Human Services (June 21, 2013), available at <http://mobihealthnews.com/wp-content/pdf/MRCforFDAfinalguidance.pdf> (“writing on behalf of the mHealth Regulatory Coalition (“MRC”) to encourage HHS, through FDA, to publish the final guidance on mobile medical apps as soon as reasonably possible”).

133. Food and Drug Administration Safety and Innovation Act of 2012, Pub. L. No. 112–144, § 618(a), 126 Stat. 993 (codified as amended in scattered sections of 21 U.S.C.). Instead FDASIA required the FDA, ONC, and FCC to work with external stakeholders to create and publish a report advising how to regulate health IT so that the government could keep tabs on the agency’s regulatory efforts. *See supra* Part I.A.2.b. *See also* Dolan, *supra* note 127 (discussing the result of Senator Bennet’s proposed moratorium).

134. Sensible Oversight for Technology which Advances Regulatory Efficiency Act of 2013, H.R. 3303, 113th Cong. (2013). *See* Christina Farr, *Congress Wants to Kick the FDA out of Digital Health with This New Bill*, VENTUREBEAT, (Feb. 26, 2014), <http://venturebeat.com/2014/02/26/new-digital-health-bill-proposes-to-undermine-the-fda-draws-mixed-reactions/>. Representative Blackburn stated that she plans to reintroduce an updated version of the SOFTWARE Act in 2015. Dan Bowman, *Orrin Hatch: MEDTECH Act Vital to Protecting Healthcare Innovation*, FIERCEHEALTHIT (Dec. 5, 2014), <http://www.fiercehealthit.com/story/orrin-hatch-medtech-act-vital-protecting-healthcare-innovation/2014-12-05>.

135. Preventing Regulatory Overreach to Enhance Care Technology Act of 2014, S. 2007, 113th Cong. (2014) (introduced Feb. 10, 2014).

136. Farr, *supra* note 134. Thompson stated, “[t]he September guidance was greeted with relief and fanfare. . . . Most people who read [the Guidance] said it’s a sensible approach, [so] why are we legislating to undo that?” *Id.*

Hatch (R) and Michael Bennet (D) introduced another bill concerning the regulation of mobile health apps, the MEDTECH Act of 2014.¹³⁷

All three bills seek to amend the FDCA, the FDA's source of authority to regulate medical devices, by placing certain types of medical software out of the FDA's regulatory reach.¹³⁸ The SOFTWARE Act proposed to limit the FDA's jurisdiction to "medical software," excluding "clinical" or "health software."¹³⁹ If enacted, the SOFTWARE Act would limit the FDA's enforcement discretion and prevent it from regulating software products marketed to health care professionals.¹⁴⁰ Similarly, the MEDTECH Act excludes certain types of low-risk software and mobile health apps from FDA regulation.¹⁴¹

Under the PROTECT Act, at least some MMAs, such as those with clinical decision support ("CDS") software, would not fall under the FDA's jurisdiction.¹⁴² Examples of CDS apps include sports concussion apps, melanoma detection apps, and drug dose calculator apps that are marketed

137. Medical Electronic Data Technology Enhancement for Consumers' Health Act, S. 2977, 113th Cong. (2014).

138. See S. 2007 § 3(b) (giving the following prohibition: "Clinical software and health software shall not be subject to regulation under [the FDCA]"); H.R. 3303 § 4 (amending Section 201 of the FDCA to exclude health and clinical software); S. 2977 § 2 (defining "device" under the FDCA to exclude administrative software, software used for health and conditioning outside of a clinical setting, electronic patient records, and more).

139. H.R. 3303 § 2. Medical software is partially defined as:

software . . . intended to be marketed for use by consumers and makes recommendations for clinical action that—(i) includes the use of a drug, device, or procedure to cure or treat a disease or other condition without requiring the involvement of a health care provider; and (ii) if followed, would change the structure or any function of the body of man or other animals; (2) [but] is not software whose primary purpose is integral to the functioning of a drug or device; and (3) is not a component of a device.

Id.

140. See *id.* § 3(a). Clinical software, which is removed from the FDA's jurisdiction under the SOFTWARE Act, is defined as:

clinical decision support software . . . intended for human or animal use that—(A) captures, analyzes, changes, or presents patient or population clinical data or information and may recommend courses of clinical action, but does not directly change the structure or any function of the body of man or other animals; and (B) is intended to be marketed for use only by a health care provider in a health care setting.

Id.

141. S. 2977 § 2. Specifically, Sen. Hatch, the MEDTECH Act's author, said, "the bill limits and clarifies the FDA's role regarding regulation of administrative and financial software, wellness and lifestyle products, certain aspects of electronic health records and software that aids healthcare providers in developing treatment recommendations for their patients." Bowman, *supra* note 134.

142. See MHEALTH REGULATORY COAL. & CDS COAL., *supra* note 66, at 1–3 (listing different software and mobile medical apps that are presently regulated by the FDA but would not be under the PROTECT Act of 2014).

to consumers to use without involving medical professionals.¹⁴³ These apps pose unique risks to patients, especially when used in an emergency setting, leading some HIT stakeholders to object to the bill's deregulation of CDS software.¹⁴⁴

So why is Congress considering overriding the FDA's current MMA framework? First, some elected officials argue that the FDA's old regulatory methods and statutory mandate are incompatible with new technological advances.¹⁴⁵ Specifically, the authors of the PROTECT Act wrote that the FDCA definition of medical device is "overly broad," "dated," and "bad news for health IT innovation."¹⁴⁶ The PROTECT Act discusses the importance of HIT innovation and the economic impact of mobile health: mobile health apps have created over 500,000 new jobs in the United States, and it is projected that the market will reach \$26 billion by 2017.¹⁴⁷ Proponents of the Act think Congress must "intervene" in order to focus "agency efforts on fostering health information technology and mobile health innovation while better protecting patient safety, improving health care, and creating jobs in the United States."¹⁴⁸ The PROTECT Act names specific agencies, such as the National Institute of Standards and Technology, the ONC, and the FCC, to "work on next steps . . . such as collaborating with nongovernmental entities to develop certification processes and to promote best practice standards."¹⁴⁹ Noticeably absent from this list of regulators is the FDA.¹⁵⁰

Not everyone, however, supports these congressional efforts. Specifically, the MRC, CDS Coalition, and the Patient, Consumer, and Public Health Coalition, oppose the PROTECT Act.¹⁵¹ The latter, a patient

143. *Id.* at 1–2. Melanoma detection apps are a particularly worrisome category of apps since one study found that three out of four melanoma apps incorrectly classified thirty percent of melanomas as "unconcerning," which could potentially leave a dangerous skin condition undiscovered and untreated. Joel A. Wolf et al., *Diagnostic Inaccuracy of Smartphone Applications for Melanoma Detection*, 149 JAMA DERMATOLOGY 422, 422 (2013).

144. See MHEALTH REGULATORY COAL. & CDS COAL., *supra* note 66, at 3 (giving the example of Emergency Care Predictive Analytics Software, which processes large amounts of healthcare and vital sign data to make a recommendation in an emergency care setting and claiming that because "the volume of information that the software considers and the little time available to the doctor or EMT, there is no practical way for the physician or EMT to read, understand and critically evaluate the basis for the computer's recommendation").

145. See, e.g., Fischer & King, *supra* note 10 ("The FDA's regulatory footprint is growing beyond its statutory shoe size.").

146. *Id.*

147. S. 2007 § 2(a).

148. *Id.* § 2(b).

149. *Id.*

150. *Id.*

151. See MHEALTH REGULATORY COAL. & CDS COAL., *supra* note 66, at 1–3 (posing the risks presented by the PROTECT Act's removal of certain software from FDA jurisdiction); Letter from the Patient, Consumer, and Public Health Coalition to Sen. Harkin, *supra* note 67 (claiming that millions of Americans may be put at risk if software-reliant devices like MRIs were

advocacy group, wrote to Senator Tom Harkin, the Chairman of the Senate Committee on Health, Education, Labor and Pensions, that “[w]e are extremely concerned that this bill will deregulate a broad swath of medical devices that rely on software and will create opportunities for rampant ‘gaming’ to avoid regulation.”¹⁵² The group thinks that FDA intervention is necessary to protect consumers:

Without [the] FDA to carefully scrutinize the risks and benefits of a device, patients’ health may be seriously harmed. Even if the device itself is not harmful, if it is not proven effective, then patients could be harmed by inaccurate results that are either anxiety-producing or erroneously reassuring; these outcomes could result either in unnecessary testing or serious illness or death.¹⁵³

Yet opponents of the PROTECT Act reacted more positively to the more recent MEDTECH Act because it preserved FDA authority over medium-risk and high-risk apps.¹⁵⁴ Currently, the bills are still in committee.¹⁵⁵

B. FDA Regulation of Dietary Supplements and the Dietary Supplement Health and Education Act

Congress’s concerns and the FDA’s current unstable position in the mobile health context are reminiscent of an earlier debate over the regulation of dietary supplements in the 1990s. In 1993, the FDA proposed more stringent regulation of certain dietary supplements after they were

no longer regulated by the FDA under the PROTECT Act’s restrictions); *see also* Greg Slabodkin, *Industry Group Voices ‘Extreme’ Concern with PROTECT Act*, FIERCEMOBILEHEALTHCARE (Feb. 19, 2014), <http://www.fiercemobilehealthcare.com/story/industry-group-voices-extreme-concern-protect-act/2014-02-19> (summarizing the groups’ opposition to the PROTECT Act).

152. Letter from the Patient, Consumer, and Public Health Coalition to Sen. Harkin, *supra* note 67.

153. *Id.*

154. *See* Christina Farr, *Draft U.S. Legislation Would Curb FDA Medical Software Oversight*, REUTERS (Nov. 24, 2014), <http://www.reuters.com/article/2014/11/25/fda-technology-idUSL2N0TE22020141125>. Bradley Thompson called the MEDTECH Act “a straightforward and clean approach” that “is less likely to have unintended consequences.” *Id.*

155. The SOFTWARE Act died in the House Committee on Energy and Commerce: Health, but it will likely be reintroduced in 2015. *H.R. 3303 (113th): Sensible Oversight for Technology which Advances Regulatory Efficiency Act of 2013*, GOVTRACK.US, <https://www.govtrack.us/congress/bills/113/hr3303> (last visited Feb. 5, 2015). The PROTECT Act of 2014 also remains unenacted after being referred to the Senate Committee on Health, Education, Labor, and Pensions. *S. 2007 (113th): Preventing Regulatory Overreach to Enhance Care Technology Act of 2014*, GOVTRACK.US, <https://www.govtrack.us/congress/bills/113/s2007> (last visited Feb. 5, 2015). The MEDTECH Act was also referred to the Senate Committee on Health, Education, Labor, and Pensions. *S. 2977 (113th): Medical Electronic Data Technology Enhancement for Consumers’ Health Act*, GOVTRACK.US, <https://www.govtrack.us/congress/bills/113/s2977> (last visited Feb. 5, 2015). Sen. Hatch plans to reintroduce the bill in 2015. Bowman, *supra* note 134.

linked to serious injury and death.¹⁵⁶ The FDA's proposal was followed by industry pushback¹⁵⁷ and a swift congressional response—the passage of the Dietary Supplement Health and Education Act of 1994.¹⁵⁸ DSHEA completely changed the way dietary supplements were regulated and hampered the FDA's ability to protect the public from dangerous and ineffective dietary supplements.¹⁵⁹

1. *The FDA Regulated Dietary Supplements Before DSHEA*

The FDA has regulated dietary supplements since 1938.¹⁶⁰ Dietary supplements include vitamins, minerals, herbal remedies, and amino acids¹⁶¹ and can be in gel, capsule, drink, powder, or even energy bar form.¹⁶² Historically, the FDA classified each dietary supplement either as a drug, food additive, or food product based on the claims for intended use made by the manufacturer on the labeling.¹⁶³ If a label made a “drug” claim or fell into the food additive category, the FDA required stricter controls such as pre-market approval of the supplement, which meant the manufacturer had to substantiate its claims by “adequate and well-controlled investigations.”¹⁶⁴ Otherwise, supplements making mere nutrition claims could be regulated as foods, which were presumed to be safe.¹⁶⁵

Throughout the 1960s and 1970s, the extent of regulation over dietary supplements fluctuated as the FDA created new regulatory classification schemes which were later abandoned due to industry pressure,

156. See Regulation of Dietary Supplements, 58 Fed. Reg. at 33,690 (citing the thousands of injuries caused by L-tryptophan as motivation to reassess dietary supplement regulation).

157. See Gilhooley, *supra* note 18, at 93 (describing the dietary supplement industry's reaction to the FDA's Notice of Proposed Rulemaking and how industry efforts led to the passage of DSHEA); see also *infra* Part I.B.2.

158. Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325 (codified as amended in scattered sections of 21 U.S.C.).

159. See *infra* Part I.B.3.

160. For a brief historical overview of the legislative and regulatory history of dietary supplements, see COMM'N ON DIETARY SUPPLEMENT LABELS, REPORT OF THE COMM'N ON DIETARY SUPPLEMENT LABELS 11–13 (1997), available at <http://www.health.gov/dietsupp/final.pdf>.

161. See 21 U.S.C. § 321(ff)(1). Dietary supplements are defined as “dietary substance[s] [used] by man to supplement the diet by increasing the total dietary intake.” *Id.*

162. OFFICE OF DIETARY SUPPLEMENTS, NAT'L INST. OF HEALTH, DIETARY SUPPLEMENTS: WHAT YOU NEED TO KNOW 1 (2011), available at http://ods.od.nih.gov/HealthInformation/DS_WhatYouNeedToKnow.aspx.

163. Jennifer Akre Hill, Comment, *Creating Balance: Problems Within DSHEA and Suggestions for Reform*, 2 J. FOOD L. & POL'Y 361, 366–67 (2006).

164. 21 U.S.C. § 355(d) (1994). See Gilhooley, *supra* note 18, at 89–95 (summarizing the pre-DSHEA regulatory framework for dietary supplements). Food additives were required to show that the ingredient was “generally recognized as safe” in order to receive pre-market approval by the FDA. Hill, *supra* note 163, at 367–68.

165. Hill, *supra* note 163, at 367–68.

congressional interference, judicial decrees, or all three.¹⁶⁶ Following the backlash, the FDA exercised “regulatory restraint” in the 1980s and early 1990s, which led to an increase in the number of dietary supplements on the market.¹⁶⁷ In the 1990s, however, when 38 deaths and 1500 other adverse events were traced to the uses of L-tryptophan, a non-essential amino acid used in supplements, the FDA initiated an investigation into new ways to handle the safety issues associated with dietary supplements.¹⁶⁸ The FDA released an Advance Notice of Proposed Rulemaking that sought stronger regulatory features, such as pre-market review for a range of supplements, to combat the safety risks posed by many supplement ingredients.¹⁶⁹

2. *Industry Anger and Congressional Pushback: The Enactment of DSHEA*

The supplement industry saw the FDA’s recommendations as an attempt to drastically reduce the sale and marketing of dietary supplements, and the industry started a campaign to ensure that the FDA would not succeed.¹⁷⁰ For example, retailers held a “Blackout Day” in which they covered in black crepe all of the supplements which could potentially be taken off the market under a broad FDA regulatory scheme.¹⁷¹ Responding to the industry’s concern, members of Congress introduced DSHEA, and

166. *See id.* at 368–70 (giving the history of the FDA’s regulation of dietary supplements during the 1960s and 1970s). For example, when the FDA began regulating high dosages and “irrational combinations” of supplements previously treated as “foods,” lobbyists convinced Congress to pass the Proxmire Amendment. *Id.* at 369. The Amendment restricted the FDA’s authority to regulate supplements based on potency or combination, Pub. L. No. 94-278, § 501, 90 Stat. 410 (1976) (codified at 21 U.S.C. § 350 (1976)). The Amendment was followed by a decision by the U.S. Court of Appeals for the Tenth Circuit holding that the FDA could not limit potency of supplements under its current authority. *Nat’l Nutritional Foods Ass’n v. Matthews*, 557 F.2d 325, 336 (2d Cir. 1977).

167. Hill, *supra* note 163, at 370; *see also* Regulation of Dietary Supplements, 58 Fed. Reg. at 33,690 (discussing the growth and change in the dietary supplement industry in the early 1990s).

168. *See* Gilhooley, *supra* note 18, at 92; *see also* Regulation of Dietary Supplements, 58 Fed. Reg. at 33,690–91 (explaining that the Dietary Supplement Task Force was created to investigate the safety of supplements).

169. *See* Regulation of Dietary Supplements, 58 Fed. Reg. at 33,697 (suggesting treating dietary supplements containing amino acids as drugs or food additives, which require additional FDA oversight); *see also* COMM’N ON DIETARY SUPPLEMENT LABELS, *supra* note 160, at 13 (summarizing the FDA’s advanced notice of proposed rulemaking).

170. *See* Gilhooley, *supra* note 18, at 93 (discussing the dietary supplement industry’s reaction to the FDA’s investigation and proposals); *see also* COMM’N ON DIETARY SUPPLEMENT LABELS, *supra* note 160, at 13 (calling the FDA’s advanced notice of proposed rulemaking a “significant motivating factor” in the efforts to secure the enactment of DSHEA).

171. The Tan Sheet, *Dietary Supplement Blackout Day to Support Hatch/Richardson Bills*, PHARMA & MEDTECH BUS. INTELLIGENCE (Aug. 9, 1993), <https://www.pharmamedtechbi.com/publications/the-tan-sheet/01/024/dietary-supplement-blackout-day-to-support-hatchrichardson-bills>. The Blackout Day campaign’s slogan was “Don’t Let Health Freedom Follow the Dinosaur.” *Id.*

represented the bill as protection for patient autonomy and consumer choice.¹⁷²

The lobbying efforts paid off. Passed unanimously by Congress¹⁷³ and signed into law by President Clinton, DSHEA classified dietary supplements as food rather than drugs or food additives under the FDCA¹⁷⁴ and established a special regulatory framework for dietary supplements that limited the FDA's ability to regulate them.¹⁷⁵ Congress enacted DSHEA for a number of reasons, but namely because it thought the FDA had erected "unreasonable regulatory barriers"¹⁷⁶ that could prevent consumers from receiving dietary supplements—products that were widely used, generally safe, and available at a lower cost than traditional medicines.¹⁷⁷ DSHEA was meant to rectify the FDA's inadequate, "ad hoc, patchwork regulatory policy"¹⁷⁸ and "bring common sense to the treatment of dietary supplements under regulation and law."¹⁷⁹ With the enactment of DSHEA, Congress ultimately foreclosed much of the FDA's power in dietary supplement regulation.¹⁸⁰

3. *DSHEA's Negative Impact on Dietary Supplement Regulation and Public Health and Safety*

DSHEA drastically changed the regulation of dietary supplements and has since been labeled "the most important example of deregulation of a federal health and safety program."¹⁸¹ Dietary supplements are now treated as a category of food, and thus do not undergo agency scrutiny before they are marketed directly to the consumer.¹⁸² Only "new dietary ingredients,"

172. See Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, § 2, 108 Stat. 4325 (codified as amended in scattered sections of 21 U.S.C.) ("[C]onsumers should be empowered to make choices about preventive health care programs based on data from scientific studies of health benefits related to particular dietary supplements.").

173. Hill, *supra* note 163, at 371.

174. See DSHEA § 3 (codified at 21 U.S.C. § 321(ff)) ("[A] dietary supplement shall be deemed to be a food within the meaning of this [Act].").

175. See DSHEA § 4 (codified at 21 U.S.C. § 342) (adding new standards for determining whether a supplement is adulterated and placing the burden of proof on the FDA to show that a supplement is adulterated).

176. DSHEA § 2 (legislative findings).

177. *Id.* At that time, almost fifty percent of Americans regularly used dietary supplements for nutrition purposes. *Id.*

178. *Id.*

179. William J. Clinton, President, Statement upon Signing S. 784 (Oct. 25, 1994), *reprinted in* 1994 U.S.C.C.A.N. § 3523-1.

180. See Hill, *supra* note 163, at 363 (charging DSHEA with failing to provide the FDA with adequate regulatory power to protect consumers).

181. Gilhooley, *supra* note 18, at 85.

182. See 21 U.S.C. § 321(ff) (2012) (defining dietary supplements as "food" within the meaning of the statute); see also David Kessler, *Cancer and Herbs*, 342 N. ENG. J. MED. 1742, 1742-43 (2000) (discussing how supplements are regulated under the DSHEA).

dietary supplement ingredients not marketed prior to October 15, 1994, need FDA approval—all other ingredients were grandfathered in by DSHEA.¹⁸³ Supplements sold before 1994 may only be regulated if the FDA can prove that they are adulterated and present an “unreasonable risk of illness or injury.”¹⁸⁴ If the FDA desires to remove a product from the market, it must prove that the product is an “imminent hazard to public health or safety,” a process that requires the FDA to use its limited resources to conduct testing and studies on a supplement.¹⁸⁵

Since its enactment DSHEA has faced criticism from academics and medical professionals who claim that the Act’s regulatory framework leaves the public vulnerable to dangerous dietary supplements.¹⁸⁶ Many scholars call for DSHEA’s repeal or amendment because it placed the FDA in a reactive role, led to an increase of drug-like products posing as dietary supplements, and made it difficult for the FDA to remove dangerous supplements from the market.¹⁸⁷

Much of the criticism is directed at the fact that the FDA now has a purely reactive role and can only act after it has found proof that substantial

183. 21 U.S.C. § 350b(d) (2012).

184. 21 U.S.C. § 342(f)(1) (2012).

185. *Id.*; see also Richard Potomac, *Are You Sure You Want to Eat That?: U.S. Government and Private Regulation of Domestically Produced and Marketed Dietary Supplements*, 23 LOY. CONSUMER L. REV. 54, 66 (2010) (noting that initiating a ban of a dietary supplement is impractical for the FDA because it is “incredibly onerous, expensive, and time-consuming”); Hill, *supra* note 163, at 381–84 (describing the FDA’s long, arduous effort to ban ephedra from the dietary supplement market).

186. See, e.g., Interview by Ira Flatow, NPR, with Paul Offit, Chief of the Division of Infectious Diseases, Children’s Hospital in Philadelphia (July 5, 2013), available at <http://www.npr.org/2013/07/05/199025493/is-alternative-medicine-really-medicine> (“[DSHEA] is an education act that has nothing to do with education and everything to do with the consumer not knowing what they’re buying because the industry is now allowed to, frankly, sell products under this wink and nod”); Letter from Michael D. Maves, Am. Medical Ass’n, to Sen. Richard J. Durbin (Feb. 17, 2004), reprinted in *10 Years After the Implementation of DSHEA: The Status of Dietary Supplements in the United States: Hearing Before the Subcomm. on Human Rights and Wellness of the H. Comm. on Gov’t Reform*, 108th Cong. 30 (2004) (stating that the American Medical Association believes that DSHEA fails to give the FDA “adequate regulatory oversight” of dietary supplements and supports amendments to the statute).

187. See, e.g., Peter J. Cohen, *Science, Politics, and the Regulation of Dietary Supplements: It’s Time to Repeal DSHEA*, 31 AM. J.L. & MED. 175, 181 (2005) (“DSHEA gutted much of what had been accepted as integral to the states’ protection of consumers.”); Potomac, *supra* note 185, at 55 (claiming the current dietary supplement regulatory framework puts the public in “substantial risk”); Hill, *supra* note 163, at 364 (joining other academics in arguing that DSHEA needs to be amended in order to protect consumers). But see Lars Noah & Barbara A. Noah, *A Drug by Any Other Name . . . ? Paradoxes in Dietary Supplement Risk Regulation*, 17 STAN. L. & POL’Y REV. 165, 167–68 (2006) (arguing that DSHEA grants the FDA adequate “regulatory muscle” to implement “aggressive” risk-management and needs not be repealed); Joshua H. Beisler, Note, *Dietary Supplements and Their Discontents: FDA Regulation and the Dietary Supplement Health and Education Act of 1994*, 31 RUTGERS L.J. 511, 512–13 (2000) (arguing that DSHEA plays an important role in maintaining consumer access to dietary supplements).

harm has occurred.¹⁸⁸ David Kessler, former FDA Commissioner, agrees that DSHEA is inadequate:

The safety standard may sound as if the FDA has all the authority it needs to protect the public. The problem is that the burden of proof lies with the FDA. Even when the agency is able to act, how is it supposed to know which products contain [harmful substances], and who sells them?¹⁸⁹

After the passage of DSHEA, the number of available dietary supplements increased dramatically, from 4000 to 55,000 in 2012, making it even more difficult for the FDA to keep tabs on the changing industry.¹⁹⁰ Exempt from providing the initial information required of their pharmaceutical counterparts, dietary supplement manufacturers and their products are relatively unknown entities until an adverse event or other red flag garners FDA attention.¹⁹¹ For example, before it was voluntarily recalled in 2009, the weight-loss supplement Hydroxycut was linked to one death and twenty-three instances of liver failure.¹⁹² Neither the FDA nor the millions of consumers who used Hydroxycut had any way to determine the safety of the product beforehand because DSHEA so limited the FDA's role in overseeing dietary supplements.¹⁹³ Without a reliable source ensuring a product's integrity, consumers cannot be sure dietary

188. See, e.g., Richard E. Nowak, *DSHEA's Failure: Why a Proactive Approach to Dietary Supplement Regulation Is Needed to Effectively Protect Consumers*, Comment, 2010 U. ILL. L. REV. 1045, 1068, 1076 (2010) (critiquing the FDA's "limited, reactive authority" to regulate dietary supplements under DSHEA and recommending a proactive approach modeled after the European Union's Food Supplement Directive).

189. Kessler, *supra* note 182, at 1743; see also Potomac, *supra* note 185, at 65 (echoing the claim that the FDA lacks knowledge about what supplements are being produced, which is a major barrier to effective regulation under DSHEA).

190. Pieter A. Cohen, *Assessing Supplement Safety—The FDA's Controversial Proposal*, 366 N. ENG. J. MED. 389, 389 (2012); see also *Dietary Supplement Health and Education Act: Is the FDA Trying to Change the Intent of Congress?: Hearing Before the H. Comm. on Gov't Reform*, 106th Cong. 17 (1999) (statement of Jane Henney, Comm'r., FDA), available at http://commdocs.house.gov/committees/gro/hgo57333.000/hgo57333_of.htm (commenting on the significant changes in the dietary supplement industry since the passage of the DSHEA).

191. See Gilhooley, *supra* note 18, at 118 (stating that the "important problem with supplements is the unknown").

192. Nowak, *supra* note 188, at 1048.

193. *Id.* A more recent example of an unsafe ingredient being marketed as a "natural" dietary supplement is DMAA (also known as dimethylamylamine, methylhexanamine or geranium extract). *Consumer Updates: Stimulant Potentially Dangerous to Consumers, FDA Warns*, U.S. FOOD & DRUG ADMIN. (Apr. 11, 2013), <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm347270.htm>. The ingredient is illegal to include in dietary supplements and has been linked to causing heart attacks and death. *Id.* In an effort to get DMAA out of the marketplace, the FDA issued warning letters to manufacturers whose products contained DMAA. *Id.*

supplements are what they claim to be, and the FDA is unable to act until a serious problem occurs.¹⁹⁴

DSHEA also incentivized manufacturers to market their products as dietary supplements in order to take advantage of the Act's relaxed restrictions.¹⁹⁵ Manufacturers of products that previously were not considered food supplements can now take advantage of DSHEA's broad definition of dietary supplement and make claims about the structure of the body as long as the label includes a disclaimer.¹⁹⁶ Products with no nutritive value that use the same ingredients as pharmaceuticals are slipping under the regulatory radar by posing as dietary supplements.¹⁹⁷ In a hearing before Congress, former FDA Commissioner Jane E. Henney testified: "[P]roducts that contain substances similar to those found in prescription drugs are marketed for children as dietary supplements. Likewise, products with ingredients that simulate illicit street drugs are marketed as dietary supplements to adolescents"¹⁹⁸ Because DSHEA uses such broad definitions, many substances that would otherwise be regulated are being marketed to consumers with little to no agency oversight.¹⁹⁹

The FDA also faces difficulties in identifying the cause of problems linked to dietary supplements because supplement use takes place outside of a health care setting.²⁰⁰ In its initial enactment, DSHEA did not require supplement manufacturers to report adverse events to the FDA, a feature that garnered much criticism.²⁰¹ Even though Congress enacted legislation in 2006 requiring supplement manufacturers to report serious adverse

194. See Interview by Ira Flatow, NPR, with Paul Offit, *supra* note 186 (expressing concerns about trusting even low-risk supplements "because this is an unregulated industry, [and] you don't know what's in that bottle").

195. See Hill, *supra* note 163, at 378–79 (noting that DSHEA has given manufacturers leverage to negotiate with the FDA in order to get borderline products, such as cholesterol-lowering margarine, admitted as a dietary supplement, rather than a food additive).

196. Gilhooley, *supra* note 18, at 95. Specifically the supplement's label must state: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease." 21 U.S.C. § 343(r)(6)(C) (2012). If an ingredient is new, the FDA will require a manufacturer to provide "reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury" before it allows the supplement to be marketed. 21 U.S.C. § 342(f)(1)(B).

197. See Gilhooley, *supra* note 18, at 95–96, 117–18.

198. Statement of Jane Henney, *supra* note 190.

199. See Hill, *supra* note 163, at 373–74 (discussing the ambiguity of the definition of the catch-all term "dietary substance," which allows items such as shark cartilage to be marketed under DSHEA even though they do not otherwise "supplement the diet").

200. See Kessler, *supra* note 182, at 1743 (remarking that the difficulty in pinpointing adverse effects is exacerbated in the supplement context).

201. See, e.g., Cohen, *supra* note 201, at 184 (noting a report from the Institute of Medicine that found that "the lack of adverse event reporting" hindered the FDA's ability to "monitor supplement safety"); Hill, *supra* note 163, at 393 (recommending mandatory adverse event reporting for dietary supplement manufacturers).

events to the FDA,²⁰² the FDA estimates it receives reports on only two percent of adverse events related to dietary supplements.²⁰³

Even when the FDA learns of adverse events, the proof required by the statutory scheme is a major obstacle to enforcement action, a feature which jeopardizes public health.²⁰⁴ The FDA's decade-long struggle to ban the use of ephedra, a substance used in dietary supplements linked to numerous deaths and over 1600 reported adverse events, has become symbolic of the FDA's relative impotence to effectively protect the public under DSHEA's scheme.²⁰⁵ Years of testing, reports, litigation, and state-issued bans preceded the final enforceable FDA ban of the product.²⁰⁶ It continues to be difficult, time-consuming, and costly for the FDA to prove that a dietary supplement is adulterated or poses an "imminent hazard" to public health.²⁰⁷ Furthermore, the FDA does not have the resources to enforce compliance with even the limited requirements placed on supplement manufacturers, and many companies decide to risk being investigated rather than comply with regulations.²⁰⁸ The statutory standard for marketplace removal has been labeled as merely "cautionary language" that gives the FDA no real power to enforce compliance with good manufacturing practices.²⁰⁹

II. ANALYSIS

DSHEA removed much of the FDA's regulatory power over dietary supplements at a time when supplement use was increasing and replaced the

202. See Dietary Supplement and Nonprescription Drug Consumer Protection Act, Pub. L. No. 109-462, § 760 (a)(3), 120 Stat. 3469 (2006) (codified as amended at 21 U.S.C. § 379aa-1(2) (2012)) (defining a "serious adverse event" as one that results in death, a life-threatening experience, inpatient hospitalization, significant disability or incapacity, or a birth defect).

203. Potomac, *supra* note 185, at 91. Furthermore, dietary supplement companies do not have to report mild or moderate adverse events or side effects, depriving the FDA of an important set of information. *Id.* at 66.

204. See Cohen, *supra* note 201, at 189 (noting that DSHEA's enforcement requirements make criminal prosecutions under the statute rare).

205. See, e.g., *id.* at 190 (claiming that the "history of the ban on ephedra . . . illustrates significant enforcement impediments inherent in DSHEA"); Potomac, *supra* note 185, at 60 (using the FDA's struggle to ban ephedra despite "overwhelming evidence" of its dangers as an example of the difficulties of banning a supplement from the market).

206. See Hill, *supra* note 163, at 381-84 (discussing the events leading up to the FDA's ban of ephedra).

207. See 21 U.S.C. § 342(f)(1) (providing the statutory standard to remove dietary supplement ingredients from the market); Potomac, *supra* note 185, at 60 (noting that the FDA has developed other methods to police the supplement industry since instituting a ban of a product is so difficult).

208. Potomac, *supra* note 185, at 92 (estimating that as few as eighteen percent of dietary supplement companies are in compliance with FDA regulations).

209. Nowak, *supra* note 188, at 1067.

FDA's system with a weak regulatory scheme.²¹⁰ This congressional preemption led to growth in the dietary supplements industry,²¹¹ but also an increase in adverse events linked to supplement use²¹² and a federal agency which is almost powerless to remove harmful products from the market.²¹³ Steps must be taken to prevent a similar result in the mobile health app context.

There are several similarities between dietary supplements and mobile health apps and the FDA's struggle to effectively regulate both.²¹⁴ Because of these similarities the FDA and Congress can learn important lessons from DSHEA that can be applied to the current efforts to regulate MMAs.²¹⁵ First, Congress should not significantly narrow the FDA's authority over medical devices in a way that leaves the agency powerless to adjust to changes in the MMA industry.²¹⁶

Second, instead of using legislation to prematurely limit FDA regulation of dietary supplements in a DSHEA-like fashion, Congress should create a new FDA sub-agency, the Office of mHealth, which can direct the FDA's mobile health efforts.²¹⁷ The Office of mHealth could be modeled off of similar sub-agencies and committees, including one created by DSHEA,²¹⁸ but it also must focus on acquiring personnel with expertise in mobile technologies in order to be truly effective.²¹⁹ The new Office of mHealth would address Congress's concerns about mobile health app regulation and enable the FDA to provide confident, flexible oversight to the growing mobile health app industry.²²⁰

210. See *supra* note 175; Regulation of Dietary Supplements, 58 Fed. Reg. at 33,690 (discussing the state of the dietary supplement industry in 1993); see also Kessler, *supra* note 182, at 1743 (explaining flaws in DSHEA's regulatory scheme).

211. Gilhooley, *supra* note 18, at 85 (attributing the expansion of the dietary supplement market to DSHEA).

212. See Potomac, *supra* note 185, at 91 (pointing out the rise in supplement-related illnesses and death). There were four reported supplement-caused deaths in 1994 and twenty-seven recorded deaths in 2005. *Id.*

213. See *id.* at 93 (blaming DSHEA's regulatory scheme for allowing harmful substances to remain on the market while federal agencies are unable to adequately police them).

214. See *infra* Part II.A.

215. See *infra* Part II.A.

216. See *infra* Part II.B.

217. See *infra* Part II.C.

218. See Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, § 13, 108 Stat. 4325 (creating the Office of Dietary Supplements within the National Institute of Health).

219. See *infra* Part II.C.1.

220. See *infra* Part II.C.2.

A. *The DSHEA Saga Is Relevant to the Regulation of Mobile Health Apps Because of Similarities Between Dietary Supplements and Mobile Health Apps*

Because dietary supplements and mobile health apps possess analogous features, it seems that Congress may be building up to another DSHEA-like statute, and thus similar consequences could result. First, the dietary supplement industry shares many features with the mobile health app industry. Both are multi-billion dollar industries²²¹ with powerful lobbying presences in Washington, making it more likely that Congress will want to appease the industry and keep regulatory barriers to a minimum.²²² Both involve products that can be marketed directly to and used by consumers without any professional guidance, thus presenting unique risks to consumers.²²³ Lastly, both supplements and mobile health apps offer alternatives to the conventional health care model.²²⁴ Many dietary supplements and mobile health apps present little to no risk to users, making it easier for opponents of regulation to ignore the risks created by the minority of supplements and apps that could cause serious harm in certain circumstances.²²⁵ Many of these shared characteristics, such as

221. More than 100 million Americans collectively spend more than \$35 billion on dietary supplements. Press Release, Senator Orrin Hatch, Hatch Marks 20th Anniversary of the Dietary Supplement Health and Education Act (DSHEA) (Oct. 27, 2014), <http://www.hatch.senate.gov/public/index.cfm/2014/10/hatch-marks-20th-anniversary-of-the-dietary-supplement-health-and-education-act-dshea>. The mobile health app market is expected to exceed \$26 billion by 2017. Preventing Regulatory Overreach to Enhance Care Technology Act of 2014, S. 2007, 113th Cong. § 2 (2014).

222. See Ashley Gold, *Tech Giants Move to Protect Wearables*, POLITICO (Sept. 24, 2014), <http://www.politico.com/story/2014/09/health-applications-wearables-congress-111299.html> (discussing the lobbying activities of tech companies concerned with regulation of wearable health technology). Large corporations, such as IBM and Athena Health, support the passage of the PROTECT Act. Press Release, Senator Angus King, King, Fischer Introduce Legislation to Protect Jobs, Prevent Overregulation in Growing Health IT Industry (Feb. 10, 2014), <http://www.king.senate.gov/newsroom/press-releases/king-fischer-introduce-legislation-to-protect-jobs-prevent-overregulation-in-growing-health-it-industry>.

223. Compare Noah & Noah, *supra* note 187, at 193 (noting that dietary supplements present “serious risks” because they are typically used without physician supervision or “the ameliorating influence of expert oversight”), with Dayton, *supra* note 6, at 721–22, and Krouse, *supra* note 1, at 745 (both discussing the risks of unsupervised consumer use of mobile health apps).

224. See Cortez, *supra* note 43, at 1197–99 (exploring the potentials for mobile health technology and its ability to “democratize” medicine); Beisler, *supra* note 187, at 511–12 (grouping dietary supplements in the same category as other “alternative” medicines).

225. See Noah & Noah, *supra* note 187, at 173–74 (comparing the low risk of daily multivitamins to the serious risk presented by products containing substances such as kava, ephedra, and L-tryptophan). Similarly, a medical flashcard app would present little health risk to a user, whereas an app that controlled the functions or settings of an infusion pump could present serious risks to a patient were it to malfunction. See MOBILE MEDICAL APP GUIDANCE, *supra* note 1, at 20, 29 (categorizing the mentioned apps in different categories because of their different levels of risk); see also Paul Brown, Gov’t Relations Manager, Nat’l Res. Center for Health Research, Remarks at Public Workshop: Proposed Risk-Based Framework and Strategy for Health Information Technology 99 (May 13, 2014), *available at*

widespread use, relative safety, and the potential to offer alternatives to traditional medicine, are significant because they were cited in DSHEA's legislative findings as motivation for the Act and could similarly be used to support restrictive mobile health app legislation.²²⁶

Second, even though the FDA has proposed modest oversight of MMAs, there have already been signs of pushback from the mobile health industry and Congress, similar to the backlash seen in the dietary supplement context.²²⁷ Just as the FDA's regulation of supplements fluctuated throughout the twentieth century leading Congress to refer to it as an "ad hoc, patchwork regulatory policy,"²²⁸ the FDA's attempt at regulating software enabled devices, the precursors to mobile health apps, has also been inconsistent and uncertain.²²⁹ This type of agency instability provides more reason for stakeholders to petition Congress to intervene.²³⁰ Now the proposed PROTECT Act, SOFTWARE Act, and MEDTECH Act are attempting to place strict boundaries on what types of software the FDA can regulate.²³¹ Again, as in DSHEA, these bills' supporters appeal to "common sense" and the ways that apps have affected consumers.²³² Moreover, the number of mobile health apps has already surpassed the number of dietary supplements on the market²³³ and has the potential to be

<http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM405509.pdf> (noting that even though the MMA Guidance characterized the risk of mobile health apps as "generally low" "doesn't mean they are all low").

226. Compare Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, § 2(10), (12)(A), 108 Stat. 4325 (mentioning increased consumer reliance on nontraditional healthcare and the dietary supplements industry's "integral" place in the economy), with Preventing Regulatory Overreach to Enhance Care Technology Act of 2014, S. 2007, 113th Cong. § 2(a) (2014) (commenting similarly on the expansion of mobile health apps and their transformative potential).

227. See *supra* notes 170–180 and accompanying text; Cortez, *supra* note 43, at 1216–17 (commenting that the FDA has been "upbraided by skeptical members of Congress for daring to regulate [medical apps]"). Senator Orrin Hatch, one of the authors of DSHEA, also introduced the MEDTECH Act. Bowman, *supra* note 134.

228. DSHEA § 2.

229. Cortez, *supra* note 43, at 1220–23 (describing the beginning and eventual demise of the FDA's Draft Software Policy and ultimately concluding that "[s]oftware does not stand on terra firma with the FDA"). Furthermore, the FDA has already made changes in its MMA regulatory approach since the release of the MMA Guidance. See *supra* notes 118–122 and accompanying text.

230. See, e.g., Letter from Access Integrity, *supra* note 30, at 1 (asking Congress to provide statutory clarity for mobile health regulation).

231. See *supra* Part I.A.3.

232. Fischer & King, *supra* note 10 ("We believe Congress must act and codify the common sense that you can't regulate new technology with old rules.").

233. There are now over 100,000 available mobile health apps, RESEARCH2GUIDANCE, *supra* note 2, at 7, and approximately 55,000 different dietary supplements as of 2013, *Dietary Supplement Label Database (DSLDB)*, NAT'L INST. OF HEALTH, OFFICE OF DIETARY SUPPLEMENTS, http://ods.od.nih.gov/Research/Dietary_Supplement_Label_Database.aspx (last visited Feb. 7, 2015).

more transformative to health care.²³⁴ For these reasons, the pressure on Congress to promote innovation and consumer access to mobile health apps will likely be as strong as it was prior to the enactment of DSHEA.²³⁵

Overall, these similarities demonstrate that it is very possible that Congress could again preempt the FDA as it did with DSHEA and that the negative effects of DSHEA could forecast the possible negative impact a similar mobile health app bill could have on both the FDA and public health.²³⁶

B. Congress Should Not Apply DSHEA-like Preemption to the FDA's Regulation of Mobile Medical Apps

The failures of DSHEA discussed in Part I.B. demonstrate that Congress should not preempt FDA authority in a dynamic, consumer-focused industry.²³⁷ Furthermore, mobile health apps are still an evolving technology, making them ill-suited to be defined or confined by concrete legislation.²³⁸ Lastly, unlike its earlier approach to dietary supplements, the FDA's current cooperative, risk-based approach to regulating mobile health apps closely mirrors that suggested by members of Congress, making the proposed amendments to the FDCA unnecessary at this time.²³⁹ Thus Congress should not use legislation to limit the FDA's authority in the MMA context.²⁴⁰

234. Cf. Terry, *supra* note 5, at 751–56 (explaining how mobile health apps have the potential to disrupt healthcare in ways that other consumer health products do not).

235. Cf. Cortez et al., *supra* note 5, at 372 (recognizing that momentum for congressional legislation in the mobile health app field is building).

236. Although the proposed HIT-related bills differ from DSHEA, the idea behind the bills and DSHEA is the same: Congress thinks it can improve the FDA's regulatory framework and wants to decrease the FDA's impact on the field. Compare Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, § 2(15)(B), 108 Stat. 4325 (“[A] rational Federal framework must be established to supersede the current ad hoc, patchwork regulatory policy on dietary supplements.”), with Preventing Regulatory Overreach to Enhance Care Technology Act of 2014, S. 2007, 113th Cong. § 2(a)(5) (2014) (“Consumers and innovators need a new risk-based framework . . . that improves on the framework of the Food and Drug Administration.”).

237. See *supra* Part I.B.3.

238. See Bakul Patel, Senior Policy Advisor to the Director of the CDRH, Remarks at Public Workshop: Proposed Risk-Based Framework and Strategy for Health Information Technology 74 (May 13, 2014), available at <http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM405509.pdf> (expressing the problem with drawing a “concrete” line to define different types of HIT and suggesting a more flexible approach to adapt to the “continuous learning environment”).

239. Compare FDASIA HEALTH IT REP., *supra* note 34, at 29 (recommending a narrowly-tailored, risk-based health IT regulatory framework based on input from stakeholders), with Preventing Regulatory Overreach to Enhance Care Technology Act of 2014, S. 2007, 113th Cong. § 2(b)(2) (calling for risk-based approach to regulating software that decreases regulatory burdens and fosters innovation).

240. See *supra* notes 137–141 and accompanying text (explaining how the proposed acts would remove different types of software from the FDA's jurisdiction under the FDCA).

As DSHEA demonstrates, when Congress interferes with agency discretion it can prevent the FDA from being the protective body it was designed to be.²⁴¹ The FDA is frequently criticized for taking a reactive rather than a proactive role—for responding to health disasters rather than preventing them.²⁴² Proposed legislation, such as the PROTECT Act and SOFTWARE Act, however, go even further than DSHEA, and instead of placing the FDA in a reactive role, they completely remove certain classes of mobile health apps from the FDA’s jurisdiction.²⁴³ This interference could create problems. For example, removing clinical decision support apps from the FDA’s jurisdiction would create a huge risk to patients²⁴⁴ and “would provide scant oversight to products that might evolve into some of the more innovative and important mHealth products in the near future.”²⁴⁵ Furthermore, by broadly defining certain types of software and placing it beyond the FDA’s reach, Congress may incentivize app developers to erroneously claim their high-risk apps fall under one of the unregulated categories, just as DSHEA did with supplement manufacturers.²⁴⁶ Congressional legislation that delays FDA regulation or enforcement could lead to consumer mistrust of mobile health apps or even injury caused by a faulty app.²⁴⁷

Moreover, the novelty of mobile health applications makes it even more imperative that the FDA’s authority over MMAs not fall under a premature, DSHEA-like statute.²⁴⁸ Unlike dietary supplements, with which

241. See *supra* notes 187–189 and accompanying text (explaining how DSHEA placed the FDA in a reactive role).

242. See, e.g., Cortez, *supra* note 43, at 1218–20 (critiquing the FDA’s restrained treatment of software in the past). Professor Cortez gives the example of the first software-enabled radiation machine, the Therac-25, a device that was recalled after it literally burned through patients’ bodies with radiation overdoses. Not until after this tragedy occurred did the FDA begin to develop a separate policy for regulating software. *Id.*

243. See, e.g., PROTECT Act § 3 (removing all clinical and health software from regulation under the FDCA).

244. MHEALTH REGULATORY COAL. & CDS COAL., *supra* note 66, at 1–3 (discussing possible risks presented by CDS apps).

245. Cortez et al., *supra* note 5, at 376. Cortez et al. give examples of CDS apps such as symptom checkers and drug dose calculators and state that “it is crucial that the algorithms are safe and work as intended—the twin goals of FDA oversight.” *Id.*

246. See *supra* notes 195–199 and accompanying text (commenting on the tendency of manufacturers to market their products as dietary supplements to escape harsher regulations even though the products may be more similar to pharmaceuticals).

247. See Robert Jarrin, Qualcomm, Inc., Remarks at Public Workshop: Proposed Risk-Based Framework and Strategy for Health Information Technology 99 (May 13, 2014), available at <http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM405509.pdf> (claiming that patients are exposed to safety risks while the government and stakeholders experiment with standards and regulations for mobile health technologies).

248. See Statement of Jeffrey Shuren, *supra* note 27, at 22–23 (testifying that legislation regarding mobile health apps is “premature” and would risk “lock[ing]” regulation into a new, untested framework); cf. Cortez et al., *supra* note 5, at 376 (“If Congress passes legislation, it

the FDA and consumers were already somewhat familiar, mobile health app technology is relatively new and the market itself is evolving rapidly.²⁴⁹ Professor Nathan Cortez warns that fixed statutory definitions that anchor the FDA's jurisdiction to software as it now exists could cause problems in the future as mHealth continues to develop.²⁵⁰ Congress should give the FDA time to effectively implement its proposed strategy, especially since the FDA has manifested an intention to work with stakeholders.²⁵¹ The FDA can respond to changes in app technology and consumer use of MMAs more readily than Congress could if the statutory definitions proved to be inadequate.²⁵² The pervasiveness of mobile technology and general uncertainty over where this industry is heading should give Congress pause before it paralyzes one of the key federal agencies charged with assuring public health and safety.²⁵³

Lastly, it is simply unnecessary for Congress to exercise its preemptive prerogative at this time because the FDA is taking a limited regulatory approach to MMAs that aligns with that envisioned by Congress—something it did not do with dietary supplements in the 1990s.²⁵⁴ When enacting DSHEA, the Senate noted that the FDA “twist[ed] the statute” and “distort[ed] the law” in efforts to prevent the marketing and sale of certain supplements.²⁵⁵ Here however, the FDA has *not* manipulated the definition of “device” under the FDCA in an analogous way in order to pull mobile health apps under its jurisdiction.²⁵⁶ Furthermore, the FDA has already stated in the MMA Guidance that it will not regulate or enforce regulations against some of the types of apps, such as electronic health records, that the PROTECT Act and MEDTECH Act wish to officially remove from its

should update the FDA's authority to better fit mHealth and preserve the FDA's discretion to address emerging risks.”).

249. See *supra* Part I.A.1; see generally Cortez, *supra* note 43 (examining the technological revolution of mobile health apps and the challenges they present to regulation).

250. Cortez et al., *supra* note 5, at 376.

251. FDASIA HEALTH IT REP., *supra* note 34, at 29; see also Cortez, *supra* note 71, at 213–14 (remarking on the “collaborative mood” exhibited by the FDA at its HIT public workshops).

252. Cf. Tim Wu, *Agency Threats*, 60 DUKE L.J. 1841, 1848–50 (2011) (arguing that lawmaking in a dynamic, uncertain industry can be premature and cripple future innovation).

253. See Cortez et al., *supra* note 5, at 372 (arguing that the FDA's oversight of mobile health technology is “increasingly important”).

254. See *supra* Part I.A.2 (outlining the FDA's proposed limited framework for regulating mobile health apps).

255. S. REP. NO. 103-410, at 16, 22 (1994) (“[T]he FDA has disregarded the congressional intent underlying the law regulating food and food additives.”).

256. For instance, the FDA could have attempted to regulate the sale of mobile platforms, such as smartphones, by saying that the addition of a mobile health app turned them into medical devices; instead, the FDA has taken a narrow view by only regulating a small portion of the apps themselves. MOBILE MEDICAL APP GUIDANCE, *supra* note 1, at 12–13.

jurisdiction.²⁵⁷ Since congressional interference is not necessary at this time, Congress should not enact statutes, such as the proposed PROTECT Act, that interfere with the types of software and apps that fall under the FDA's jurisdiction.²⁵⁸ To do so would risk the serious consequences which followed DSHEA's preemption of FDA authority over dietary supplements.²⁵⁹

C. Alternative to Premature Preemption by Congress: Create an Expert Sub-Agency on Mobile Health Apps

Although this Comment argues that DSHEA provides examples of what Congress should *not* do in its quest to promote mHealth innovation, DSHEA does offer one positive lesson that Congress should pursue as an alternative to preemption. Instead of creating new statutory definitions that unnecessarily limit the FDA's discretion in an unfamiliar industry, Congress should create an expert sub-agency within the FDA—the Office of mHealth.²⁶⁰ The Office of mHealth can lead the agency in its efforts to regulate MMAs and model itself on other sub-agencies or committees, including the Office of Dietary Supplements, created by DSHEA.²⁶¹ By creating an office with the requisite technical expertise, Congress will enable the FDA to provide effective, up-to-date regulation suitable to a dynamic industry while avoiding the pitfalls of DSHEA.²⁶²

1. The Office of mHealth

This Comment is not the first to suggest some sort of department or office dedicated to software or mobile health within the FDA.²⁶³ In fact,

257. *Id.* at 16 (placing electronic health records in the enforcement discretion category). Moreover, the FDA already declared that it will not enforce regulations of MDDS, MDDS GUIDANCE, *supra* note 118, which would fall under the PROTECT Act's definition of "clinical software." MHEALTH REGULATORY COAL. & CDS COAL., *supra* note 66. Likewise, the MEDTECH Act proposes removal of administrative software and products intended to be used for health and fitness outside of the clinical setting, Medical Electronic Data Technology Enhancement for Consumers' Health Act S. 2977, 113th Cong. § 2 (2014), but the FDA already stated that it does not consider these types of software to fall under the mobile medical app category and thus will not regulate them, MOBILE MEDICAL APP GUIDANCE, *supra* note 1, at 21, 25.

258. See *supra* notes 142–144 and accompanying text.

259. See *supra* Part I.B.3.

260. *Cf.* Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, § 13, 108 Stat. 4325 (codified as amended at 42 U.S.C. 287c-11 (2012)) (creating the Office of Dietary Supplements). The Office of mHealth could perhaps be under the Center for Devices and Radiological Health ("CDRH"), which currently manages MMA regulation. See *generally* MMA GUIDANCE, *supra* note 1.

261. See *infra* Part II.C.1.

262. See *infra* Part II.C.2.

263. See, e.g., FDASIA HEALTH IT REP., *supra* note 34, at 14–15 (proposing the creation of a Health IT Safety Center); Scott D. Danzis and Christopher Pruitt, *Rethinking the FDA's*

Representative Michael Honda suggested the creation of an Office of Wireless Health Technology within the FDA in his bill, the Healthcare Innovation and Marketplace Technologies Act.²⁶⁴ Although the bill died in committee, Representative Honda insisted that the funding, interest, and need for such an office exists.²⁶⁵ Currently, the FDA has no sub-agency or office dedicated to mHealth or software, so looking at the structures, missions, successes, and failures of similar offices in other federal agencies can provide a guide for the formation of an expert sub-agency for mHealth within the FDA.²⁶⁶ The Office of Dietary Supplements, a sub-agency within the National Institute of Health (“NIH”),²⁶⁷ and the Federal Trade Commission’s (“FTC”) Mobile Technology Unit, can be used as guidelines for the establishment of the FDA’s Office of mHealth.²⁶⁸

a. Office of Dietary Supplements

The Office of Dietary Supplements (“O.D.S.”), created by DSHEA, provides a better model than the rest of the Act’s provisions for the successful congressional treatment of a growing or unfamiliar industry.²⁶⁹ According to DSHEA, the purposes of the O.D.S. were to (1) “explore more fully the potential role of dietary supplements” in improving health care and (2) “promote scientific study of the benefits of dietary supplements in maintaining health and preventing chronic disease and other health-

Regulation of Mobile Medical Apps, 9 SCITECH LAWYER 4 (2013) (proposing that the FDA should have an Office of Software, similar to the Office of In Vitro Diagnostics, allowing the FDA to grow its expertise in the area of mobile medical apps); Email from Bradley Merrill Thompson, Counsel to MRC, to Bakul Patel, Senior Policy Advisor to the Director of the CDRH, 10 (Oct. 19, 2011), available at <http://mhealthregulatorycoalition.org/wp-content/uploads/2010/06/MRC-Comments-on-FDA-Draft-MMA-Guidance.pdf> (suggesting the creation of a mHealth-specific Regulatory Division within the FDA).

264. Health Care and Innovation and Marketplace Techs. Act of 2013, H.R. 2363, 113th Cong. § 1 (2013). The bill died in committee. *H.R. 2363 (113th): Health Care Innovation and Marketplace Technologies Act of 2013*, GOVTRACK.US, <https://www.govtrack.us/congress/bills/113/hr2363> (last visited Feb. 7, 2015).

265. See Timothy Hay, *Q&A: Rep Mike Honda on Proposed Office of Wireless Health*, VENTURE CAPITAL DISPATCH (Feb. 6, 2013), <http://blogs.wsj.com/venturecapital/2013/02/06/qa-rep-mike-honda-on-proposed-fda-office-of-wireless-health/> (“There is money, and there should be the will. My job is to create that political will. This could create jobs, and help innovators.”).

266. *Consumer Updates: FDA 101: Advisory Committees*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm048040.htm> (last visited Feb. 9, 2015). The FDA has approximately fifty federal advisory committees or panels that it uses to obtain expert advice, but there is no committee established to work solely on issues of mobile health. *Id.*

267. See *infra* Part II.C.1.a.

268. See *infra* Part II.C.1.b.

269. See Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, § 13, 108 Stat. 4325 (statutory provisions for O.D.S.); see also *Office of Dietary Supplements (ODS)*, NIH DIVISION OF NUTRITION RESEARCH COORDINATION, <http://dnrc.nih.gov/reports/programs/ods.asp> (last visited Feb. 7, 2015) (providing an overview of the O.D.S.).

related conditions.”²⁷⁰ The Office of mHealth should adopt this research-oriented mission, especially since the full potential of mobile health apps has not yet been fulfilled.²⁷¹ To capitalize on the benefits that mobile health apps could provide in the professional medical setting, doctors and other professionals will need to know that the products are safe and legitimate, just as they do with prescription pharmaceuticals.²⁷²

The Office of mHealth could also adopt the duties of the O.D.S. The O.D.S. Director’s duties include conducting scientific research relating to supplements, collecting results from that research, and serving as principal advisor to the Secretary of Health and other agency directors on issues relating to dietary supplements.²⁷³ Because mobile health apps and HIT fall under the regulatory jurisdiction of many federal agencies, it would be prudent to have a well-informed individual, the Director of the Office of mHealth, to serve as an advisor within the FDA and to collaborate with other agencies engaged in regulating mHealth and HIT, such as the ONC, FCC, and FTC.²⁷⁴ The O.D.S. is made up of fifteen programs, each of which interacts with one or more stakeholder communities including research investigators, educators, health practitioners, educational institutions, food-related industries, consumer and public interest groups, and members of the public.²⁷⁵ Similarly, the Office of mHealth should create different programs aimed at working with different stakeholders, such as patient advocacy groups, health care professionals, app developers, mobile technology companies, legal professionals, and consumer interests groups.²⁷⁶ This approach would continue the collaborative environment already begun by the FDA in the mobile health app context.

b. FTC’s Mobile Technology Unit

The FTC’s Mobile Technology Unit (“M.T.U.”) provides another possible model for the Office of mHealth since it was created specifically to

270. DSHEA § 13.

271. See Cortez et al., *supra* note 5, at 372–73 (explaining the transformative potential of mobile health apps).

272. See *id.* at 376 (claiming that without FDA oversight, doctors are put in a “precarious position” because they will not know whether they can trust what apps tell them).

273. DSHEA § 13(c).

274. Congress instructed the FDA, FCC, and ONC to work together on a HIT regulatory framework. Food and Drug Administration Safety and Innovation Act of 2012, Pub. L. No. 112–144, § 618, 126 Stat. 993 (codified as amended in scattered sections of 21 U.S.C.).

275. See *Budget*, NAT’L INST. OF HEALTH, OFFICE OF DIETARY SUPPLEMENTS, <http://ods.od.nih.gov/About/Budget.aspx> (last visited Feb. 7, 2015) (describing the O.D.S. programs).

276. The FDASIA Workgroup provides a good representation of the types of stakeholders mentioned who could contribute to the Office of mHealth. For a membership list see *FDASIA*, HEALTHIT.GOV, <http://www.healthit.gov/FACAS/health-it-policy-committee/itpc-workgroups/fdasia> (last visited Feb. 7, 2015).

address mobile technologies.²⁷⁷ Realizing the growing prevalence of deceptive practices in the app world, the unit was created to harness the technological expertise needed to exercise the FTC's jurisdiction, an approach the FDA should follow.²⁷⁸ In addition to holding public workshops and creating educational materials and reports on mobile finance issues, the unit acts as a resource for the FTC as it develops policies and regulatory guidance that relate to mobile technology.²⁷⁹ Likewise, the Office of mHealth should include an educational component to bring awareness to the public and the FDA about the risks and benefits of MMAs, a goal discussed in the FDASIA Health IT Report.²⁸⁰ The M.T.U. also incorporates an enforcement aspect by examining mobile products and identifying parties who engage in unfair practices for enforcement action.²⁸¹ Because of its lack of personnel and resources, the M.T.U. concentrated on filing complaints against highly visible actors, such as Facebook and Snapchat, in order to set enforcement precedents for the rest of the app

277. The M.T.U. is organized under the Bureau of Consumer Protection's Financial Practices group. *Division of Financial Practices*, FED. TRADE COMM'N, <http://www.ftc.gov/about-ftc/bureaus-offices/bureau-consumer-protection/our-divisions/division-financial-practices> (last visited Feb. 7, 2015).

278. Peter Maass, *Your FTC Privacy Watchdogs: Low-Tech, Defensive, Toothless*, WIRED (June 28, 2012), <http://www.wired.com/2012/06/ftc-fail/> (explaining the creation of the M.T.U. to oversee the expanding mobile phone sector).

279. See, e.g., FED. TRADE COMM'N, *MARKETING YOUR MOBILE APP: GET IT RIGHT FROM THE START*, (2013), available at <http://business.ftc.gov/documents/bus81-marketing-your-mobile-app> (providing information to app developers about good privacy and data collection practices); FED. TRADE COMM'N, *Understanding Mobile Apps*, ONGUARDONLINE.GOV (June 2011), <http://www.onguardonline.gov/articles/0018-understanding-mobile-apps> (giving basic information to consumers about mobile apps and privacy concerns).

280. FDASIA HEALTH IT REP., *supra* note 34, at 22–24 (explaining goals to “creat[e] [] an environment of learning and continual improvement” in the realm of HIT).

281. *Division of Financial Practices*, FED. TRADE COMM'N, <http://www.ftc.gov/about-ftc/bureaus-offices/bureau-consumer-protection/our-divisions/division-financial-practices> (last visited Jan. 8, 2015) (describing the role of the M.T.U.). Already, the FTC has brought enforcement actions against mobile app developers and negotiated settlements with app providers such as Google in order to make them establish privacy policies for all mobile services. FED. TRADE COMM'N, *PAPER, PLASTIC . . . OR MOBILE?: AN FTC WORKSHOP ON MOBILE PAYMENTS 2* (2013), available at http://www.ftc.gov/sites/default/files/documents/reports/paper-plastic-or-mobile-ftc-workshop-mobile-payments/p0124908_mobile_payments_workshop_report_02-28-13.pdf.

industry.²⁸² The Office of mHealth could follow a similar strategy in order to maximize its own limited resources.²⁸³

Although the M.T.U.'s aspirations provide a good model for the FDA to follow, the reality of the M.T.U. also provides an example of pitfalls to avoid—namely, the M.T.U. suffers from a lack of resources and experienced personnel.²⁸⁴ For example, the M.T.U. consists merely of six people, including only one technologist, which seems very inadequate when compared to the type of expertise present in the regulated industry itself.²⁸⁵ This is exactly the image of impotency that the FDA wants to avoid; therefore, the Office of mHealth should include personnel with expertise in HIT and app development who can ferret out bad actors.²⁸⁶

In summary, the Office of mHealth, though similar to the offices suggested by the FDASIA Health IT Report and the Healthcare Innovation and Marketplace Technologies Act, could also borrow features from existing offices, such as the M.T.U. and the O.D.S. The Office first needs to gather expertise in the area of mobile technologies, and then leverage this expertise through different enforcement techniques.²⁸⁷ The Office of mHealth could be established by legislation, such as Healthcare Innovation Marketplace Technologies Act, and would help the mobile health app industry navigate the often confusing regulatory process, something that would appeal to many regulated parties and members of Congress who want to simplify this process.²⁸⁸

282. See, e.g., Press Release, Fed. Trade Comm'n, Facebook Settles FTC Charges That It Deceived Consumers by Failing to Keep Privacy Promises (Nov. 29, 2011), <http://www.ftc.gov/news-events/press-releases/2011/11/facebook-settles-ftc-charges-it-deceived-consumers-failing-keep> (describing the FTC's case against Facebook); Press Release, Fed. Trade Comm'n, Snapchat Settles FTC Charges That Promises of Disappearing Messages Were False (May 8, 2014), <http://www.ftc.gov/news-events/press-releases/2014/05/snapchat-settles-ftc-charges-promises-disappearing-messages-were> (describing the FTC's case against Snapchat, an app that allows the user to send pictures).

283. Cf. Cortez et al., *supra* note 5, at 377 (explaining that the FDA needs more resources in order to keep up with its growing responsibility over MMAs).

284. Maass, *supra* note 278 ("But the agency's ambitions are clipped by a lack of both funding and legal authority, reflecting a broader uncertainty about the role government should play in what is arguably America's most promising new industry.").

285. See *id.* ("For the FTC, the unit represents an important allocation of resources to protect the privacy rights of more than 100 million smartphone owners in America. For Silicon Valley, a six-person team is barely a garage startup.").

286. Cortez et al., *supra* note 5, at 377 ("With potentially thousands of mHealth products under the FDA's domain, agency authority will be undermined if the FDA cannot enforce its requirements. The agency needs additional funding and in-house technical expertise to oversee the ongoing flood of mHealth products.").

287. *Id.*

288. See Neil Versel, *Bill Would Create FDA Office of Mobile Health, HHS Support for App Developers*, MOBIHEALTHNEWS (Sept. 28, 2012), <http://mobihealthnews.com/18580/bill-would-create-fda-office-of-mobile-health-hhs-support-for-app-developers/> (interviewing an officer of a startup health app company who expressed hope that a FDA Office of Mobile Health "could help smaller companies like his navigate the 'confusing' and often expensive regulatory process").

2. *The Office of mHealth Could Address Barriers to Effective Regulation*

The creation of the Office of mHealth could address and overcome several critiques of FDA regulation that led some stakeholders and members of Congress to be concerned about the agency's capabilities, including the FDA's lack of expertise in mobile technologies,²⁸⁹ the agency's inability to keep pace with the fast-evolving technological sector,²⁹⁰ and the FDA's inadequate or nonexistent enforcement methods.²⁹¹

289. *See infra* Part II.C.2.a.

290. *See infra* Part II.C.2.b.

291. *See infra* Part II.C.2.c.

a. Lack of Expertise

The Office of mHealth could rectify the FDA's lack of expertise in mobile technologies, specifically mobile health apps.²⁹² Although the FDA has been regulating medical device software since the 1980s, mobile health apps have not been in existence long enough for the agency to have acquired sufficient experience with them.²⁹³ The shortage of expert personnel, or "brain drain" within government agencies is problematic, especially for an agency charged with overseeing an innovative field.²⁹⁴ Without knowledgeable experts sitting on agency review panels and evaluating regulatory proposals, the public, Congress, and the courts will have little faith in the decisions the agency makes.²⁹⁵

This shortage of expertise is true for the underfunded and frequently criticized FDA.²⁹⁶ Within the FDA's Center for Devices and Radiological Health ("CDRH"), which oversees MMA regulation, reviewer and manager turnover is almost twice that of the FDA's other centers.²⁹⁷ This turnover is problematic because as the number of increasingly sophisticated and ambitious MMAs grows, so will the need for regulators with mobile app experience.²⁹⁸ An understanding of medical devices alone is not enough; rather, the FDA needs the input of individuals and organizations with knowledge and experience of systems of information technology, mobile

292. See Cortez, *supra* note 43, at 1206 ("FDA is well aware that it lacks technical expertise on mobile technologies."); Hay, *supra* note 265 (comparing the FDA's lack of familiarity with mobile health technologies to the judiciary's inexperience during early lawsuits involving technology).

293. See MOBILE MEDICAL APP GUIDANCE, *supra* note 1, at 6 (giving the background of the FDA's history of regulating software).

294. Sidney A. Shapiro, *Why Administrative Law Misunderstands How Government Works: The Missing Institutional Analysis*, 53 WASHBURN L.J. 1, 11 (2013).

295. See *id.* at 25 ("As politicians and others denigrate the agencies, talented people no longer want to work for the government and the government loses expertise. As the government loses expertise, there is less reason for the public to accept its judgments. And as the public grows more distrustful of the agencies, they become less attractive places to work and talented people do not want to work there.").

296. See *Wyeth v. Levine*, 555 U.S. 555, 578 n.11 (2009) (documenting reports of the FDA's inability to fulfill its responsibilities due to underfunding and lack of resources and "serious scientific deficiencies"). Peter Barton Hutt, former FDA Chief Counsel, warned, "F.D.A. has become a paradigmatic example of the 'hollow government' syndrome—an agency with expanded responsibilities, stagnant resources, and the consequent inability to implement its statutory mandates." Peter Barton Hutt, *The State of Science at the Food and Drug Administration*, 60 ADMIN. L. REV. 431, 432 (2008).

297. Beth Simone Noveck, *If We Only Knew What We Know: Open Regulatory Review at the FDA*, 32 YALE L. & POL'Y REV. 545, 551–52 (2014).

298. See Cortez et al., *supra* note 5, at 377 (calling for more expertise within the FDA to handle mHealth); Noveck, *supra* note 297, at 553 ("The proliferation of mobile health devices such as heart monitors that leverage the sensors in a cellphone has further complicated the regulatory process and driven the demand for more knowledgeable and effective regulatory review.").

apps, and their application to medicine.²⁹⁹ By creating an office of personnel with the requisite technological knowledge to draw from, the FDA will no longer be dependent on external advisors or temporary workshops like the one formed to make the FDASIA Health IT Report, which slows down the regulatory process.³⁰⁰ A more permanent, internal entity with actual regulatory authority, such as the Office of mHealth, can provide stability and clarity within and without the agency, making further congressional intervention unnecessary.³⁰¹

b. Tension Between Fast-paced Innovation and Regulation

Another objection to FDA regulation of MMAs is that slow-moving regulatory processes are obstacles for fast-paced technology, but an Office of mHealth can help to mitigate this problem.³⁰² The tension between innovation and regulation is a major theme in the literature surrounding FDA regulation.³⁰³ FDA clearance of medical devices inevitably frustrates an app manufacturer's desire to quickly reach the market before a competitor.³⁰⁴ For example, the average clearance time for a mobile medical application is 110 days, but this may be preceded by several years of discussions.³⁰⁵ One app creator believes that creating an FDA-approved MMA would cost ten times the amount of creating one that did not need FDA approval.³⁰⁶ When faced with these potential delays and costs, many

299. See Jeffrey Shuren, Dir. of the CDRH, FDA, Remarks at Public Workshop: Proposed Risk-Based Framework and Strategy for Health Information Technology 11 (May 13, 2014), *available at* <http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM405509.pdf> (“[W]e deal with product that doesn’t stand in isolation, but is part of a system, and really systems within systems.”).

300. See Noveck, *supra* note 297, at 551 (discussing how the FDA’s reliance on external expertise contributes to slower review of medical devices).

301. See Cortez et al., *supra* note 5, at 377 (“A dedicated center would also help to build regulatory capacity for a future that will be much more digitized than it is even now.”).

302. See Preventing Regulatory Overreach to Enhance Care Technology Act of 2014, S. 2007, 113th Cong. § 2 (2014) (“Clinical and health software innovation cycles evolve and move faster than the existing regulatory approval processes.”).

303. See, e.g., Fischer & King, *supra* note 10 (“The FDA’s work is important, but its processes are often painstakingly slow and based on outdated assumptions. This halting regulatory pace, along with a lack of bureaucratic incentives to embrace disruptive technological change, has often held back progress.”); Franzen, *supra* note 7 (asking whether the FDA can regulate “phony medical apps without killing innovation”).

304. FELLAY, *supra* note 5, at 7–8 (“With 20,000 applications being added to the Apple Store each month, competition for consumers’ attention and for their wallets is fierce. Application developers need to engage in marketing efforts and receive consumer feedback to promote their products, but they cannot do so until they have received FDA clearance.”).

305. *Id.* It took the FDA four years to clear MIMvista, a diagnostic imaging app. *Id.* at 8.

306. Lauren Silverman, *Your Smartphone Will See You Now: The Wild West of Medical Apps*, KERA BREAKTHROUGHS (Aug. 12, 2014), <http://breakthroughs.kera.org/the-smartphone-will-see-you-now-medical-apps-have-lawyers-doctors-worried/>.

app developers prefer to release their apps elsewhere, such as Europe or South Korea, where the regulatory schemes are more favorable.³⁰⁷ Without maximizing speed and efficiency in its regulatory approach, the FDA risks diverting promising and beneficial apps from the American public.³⁰⁸

The FDA acknowledges this problem, and in an interview, Bakul Patel, a Senior Policy Advisor within the Center for Devices and Radiological Health, stated that the MMA Guidance actually “scale[d] back” the FDA’s regulatory reach to make more room for innovation.³⁰⁹ A streamlined office staffed with both medical and technical experts should be able to make the premarket approval process more efficient.³¹⁰ Additionally, the personnel with mobile app backgrounds should be able to better understand the goals and motivations of other mobile health app manufacturers and developers, creating a more harmonious regulatory environment.³¹¹ While some delay is inevitable, ultimately, an Office of mHealth dedicated to facilitating FDA oversight of MMAs will likely encourage, not stifle, innovation.³¹²

c. Lack of Enforcement Power

Lastly, the Office of mHealth would need to be vested with authority to enforce and implement its policies and regulations in order to overcome the failings identified both in the dietary supplement context and the regulatory world at large.³¹³ Several stakeholders have questioned how the

307. See FELLAY, *supra* note 5, at 7 (noting that large companies such as Samsung often introduce their mobile health products abroad well before breaking into the United States market). Some app developers will simply change the intended use of their product and “experiment[] with less-regulated markets,” such as veterinary science, to escape the FDA regulations. *Id.*

308. See Nina A. Mendelson, *Regulatory Beneficiaries and Informal Agency Policymaking*, 92 CORNELL L. REV. 397, 417 (2007) (“In some settings, a particular regulatory beneficiary’s loss of expected benefits may not be as serious as the loss suffered by a regulated entity possibly facing fines or stringent permit requirements. In other settings, however, such as those involving health, beneficiary losses might be the significant ones.”).

309. Greg Slabodkin, *FDA’s Bakul Patel: For Mobile Medical Apps, Patient Safety First*, FIERCEMOBILE HEALTHCARE (May 23, 2013), <http://www.fiercemobilehealthcare.com/story/fdas-bakul-patel-mobile-medical-apps-patient-safety-first/2013-05-23>.

310. *Cf.* Noveck, *supra* note 297, at 567 (concluding that by bringing in the right kinds of experts, the FDA will be able to make quicker and better decisions).

311. *Cf.* Cortez, *supra* note 43, at 1206. Cortez commented on the lack of FDA expertise in mobile technology and the app developers’ ignorance of federal regulations exhibited in an FDA-hosted public workshop. *Id.* A good way to remedy this disconnect, then, would be with individuals who understand both the world of mobile technology and the world of the FDA and administrative law.

312. See Cortez et al., *supra* note 5, at 377 (“Congress must recognize that robust FDA oversight is not necessarily incompatible with innovation in the mHealth industry. In fact, the industry’s long-term potential may depend on it.”).

313. See Cortez, *supra* note 43, at 1181 (explaining that “regulators will need to provide genuine oversight, not just cheerleading” in order to fulfill their mandate of promoting public

FDA intended to enforce regulation of MMAs and expressed concern that there seemed to be no overarching accountability for bad actors.³¹⁴ Even though stakeholders seem open to different methods of enforcement, potential tort or contract liability is not enough to keep companies accountable.³¹⁵

As a sub-agency, rather than a federal advisory committee, the Office of mHealth could be given authority to set and enforce clear regulatory standards while mobile health apps are still in the developing stages.³¹⁶ The FDA should not have to wait for an outside party to discover wrongdoing in the mHealth sector; instead, the Office of mHealth should be able to identify bad actors and bring precedent-setting enforcement actions.³¹⁷ There may be more than one effective enforcement method: stakeholders have suggested alternatives to fines or recalls, including an official agency list of compliant companies made available to consumers, a promise of a faster registration process for meeting the suggested standards, or simply public shaming of bad actors with inferior products.³¹⁸ As one stakeholder has aptly noted, however, “shame or praise may be incentive enough to bring in the developer community, but it also may not be. In the meantime, while it is not happening, patients are at risk.”³¹⁹ Therefore, it is essential

safety). Perceived impotency is not a problem unique to the FDA. *Cf.* Maass, *supra* note 278, at 5 (“The FTC doesn’t strike fear into the heart of tech companies. . . . They know that as long as they stay within lax boundaries, it’s unlikely the FTC will bring enforcement actions against them.”).

314. *See, e.g.*, Meg Marshall, Cerner Corp., Remarks at Public Workshop: Proposed Risk-Based Framework and Strategy for Health Information Technology 59 (May 13, 2014), *available at* <http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM405509.pdf> (asking “[W]ho is going to be the accountable oversight” “when an event happens” and explaining “there needs to be some sort of an enforcement mechanism”).

315. *See id.* (“And whether it is a safety center with teeth or whether it is a nod to the regulatory, there needs to be something, some sort of a recourse other than a provider or a consumer’s private rights of action through contract or tort law.”). It is likely that many start up app developers would not have the funds to make pursuing certain tort or contract suits worthwhile.

316. *See id.* at 9 (advocating that the FDA needs to quickly develop an enforcement method to apply in the HIT sector, and ultimately, “[t]he results must be more than words on paper”).

317. *See supra* notes 281–282 and accompanying text (discussing the M.T.U.’s method of enforcing privacy standards in the app world); *see also* Cortez et al., *supra* note 5, at 377 (“As experience with the dietary-supplement market has shown, manufacturers will have few incentives to comply with FDA requirements that lack enforcement teeth.”).

318. *See* Joel White, Executive Dir., Health IT Now Coalition, Remarks at Public Workshop: Proposed Risk-Based Framework and Strategy for Health Information Technology 92–93 (May 13, 2014), *available at* <http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM405509.pdf> (suggesting positive and negative incentives for industry accountability and enforcement).

319. Robert Jarrin, Qualcomm, Inc., Remarks at Public Workshop: Proposed Risk-Based Framework and Strategy for Health Information Technology 99 (May 13, 2014), *available at* <http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM405509.pdf>.

that the FDA's regulatory scheme for MMAs include ways to ensure compliance, and the Office of mHealth would be uniquely situated to determine the best methods for such a regime.

III. CONCLUSION

The question of how the FDA should regulate mobile health apps without sacrificing innovation or public safety is an important one currently being considered by federal agencies, stakeholders, and Congress.³²⁰ Although some industry lobbyists want Congress to use legislation to limit the FDA's authority over mobile health apps, this type of statutory preemption is premature because the industry is still evolving and the FDA needs flexibility to be able to respond adequately to new risks to patients and consumers.³²¹ When Congress limited FDA authority over dietary supplements, another consumer-oriented industry, with the enactment of the Dietary Supplement Health and Education Act of 1994, the result was increased risk to consumers and an agency that was unable to effectively respond.³²² Because of the similarities between mobile health apps and dietary supplements, DSHEA offers an important model of what can happen if Congress again uses a statute to interfere with agency discretion.³²³ Instead of taking regulatory jurisdiction from the FDA, Congress should form a mobile health focused sub-agency, the Office of mHealth, within the FDA.³²⁴ This is a better approach because such an office would equip the FDA with the expertise and tools necessary to overcome regulatory barriers and to be an effective and efficient mobile medical app regulator.³²⁵

320. *See supra* Part I.A.

321. *See supra* Part I.A.3.

322. *See supra* Part I.B.

323. *See supra* Parts II.A–B.

324. *See supra* Part II.C.

325. *See supra* Part II.C.2.