VICTIMS OF INTROSPECTION: INSUFFICIENT LEGAL PROTECTIONS FOR AT-RISK USERS OF AUTOMATED MENTAL HEALTH APPS

INTRODUCTION

Technology has gone viral. In a society so personally customized, a DIY diagnosis seems only natural, a reflex of our own smartphone self-sufficiency. As one state supreme court quoted with morbid brevity, the "'Norman Rockwell' image of the family doctor no longer exists."[1] The

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[1]. *Perez v. Wyeth Labs. Inc.*, 734 A.2d 1245, 1255 (N.J. 1999) (quoting Lars Noah, *Advertising Prescription Drugs to Consumers: Assessing the Regulatory and Liability Issues*, 32 GA. L. REV. 141, 180 n.78 (2018)).

result is as obvious as the metaphor: the stethoscoped, white-coat-clad American Dream has been filtered and face-tuned into a selfie. As prospective patients become their own doctors, the gradually atrophying role of in-person care likewise affects the legal framework for injuries that occur. The danger of a "Treat Yo['] Self"[2] culture most starkly bleeds into medical fields involving augmented risk of harm to oneself or others—like mental health.[3] But, in actuality, the patients have not become the doctors; technology has. Unaccountable machines increasingly "make decisions for us, about us, or with us."[4]

In response, this Note addresses the emerging use of mobile phone applications as mental health treatment for suicidal ideations and the lack of legal redress for harms to users of these apps. Parts I and II will discuss mental health illness and treatment, detailing the telemedical history of mental health phone applications (MH apps) and culminating in their current impact and usage. Part III will address the lack of legal protection for MH app users. Finally, Part IV will propose a federal regulatory framework to fill the void of legal protections for MH app users.

I. TREATMENT VIA TECHNOLOGY: AN OVERVIEW

The "single most underused person in health care"—the patient—finally found the Wi-Fi, and the health-care industry is heeding the signal.[5] "It seems like every week there is a new headline for an article related to who will see you (the smartphone, robot, avatar, algorithm, or Dr. Siri) for medical care or how you will be seen (cellphone, smartphone, Skype)."[6] But a true grip on this "democratization" of medicine requires a history lesson: "The idea that technology will change medicine is as old as the electronic computer itself. Actually, even older."[7] Indeed, any complete discussion of MH apps necessarily begins with telehealth[8]—its language and its origins—and then narrows to telepsychiatry[9]—its strengths, its challenges, and its future.

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2. *Parks and Recreation: Pawnee Rangers* (NBC television broadcast Oct. 13, 2011).

3. *See infra* Part II.C.

4. Deven R. Desai & Joshua A. Kroll, *Trust but Verify: A Guide to Algorithms and the Law*, 31 HARV. J.L. & TECH. 1, 3–4 (2017).

5. David M. Cutler, *Why Medicine Will Be More Like Walmart*, MIT TECH. REV. (Sept. 20, 2013), https://www.technologyreview.com/s/518906/why-medicine-will-be-more-like-walmart/.

6. ERIC TOPOL, THE PATIENT WILL SEE YOU NOW: THE FUTURE OF MEDICINE IS IN YOUR HANDS 133 (2015) (ebook) [hereinafter THE PATIENT WILL SEE YOU NOW] (citations omitted).

7. Cutler, *supra* note 5 (emphasis omitted).

8. *Infra* text accompanying notes 10–27.

9. *Infra* text accompanying notes 16–18, 28–75.

A. Terminology for Tele-Treatment

To appreciate the landscape of telemedicine, with all its burgeoning branches, one must understand the terminology. Telemedicine's terms—often hastily created by persons chasing to catch up with its relentless progress—vary with each source on the subject: the terminology tends to overlap, contradict, and obviate. For clarity, each relevant term will be outlined in brief here.

Telehealth. Telehealth is used to "encompass a broad[] definition of remote health care," using modes such as "[v]ideoconferencing, transmission of still images, e-health including patient portals, remote monitoring of vital signs and nursing call centers."[10]

Telemedicine. Telemedicine is "the process of providing health care from a distance through technology" or "the use of medical information exchanged from one site to another via electronic communications."[11] Importantly, telemedicine does not constitute a discrete medical discipline but a method by which health care is provided.[12] Telemedicine often involves the use of videoconferencing, but also "includes a wide array of clinical services using internet, wireless, satellite and telephone media."[13] Often telemedicine and telehealth are used synonymously,[14] but telemedicine is distinguished from telehealth in its involvement of clinical services.[15]

Telepsychiatry. Telepsychiatry is a subset of telemedicine particular to psychiatry, and involves a range of psychiatric services, from psychiatry-primary-care consultation to direct psychiatrist-patient interaction.[16] Telepsychiatry can be used to provide therapy, educate patients, manage medications, and perform psychiatric evaluations.[17] In this way, mental health care can be delivered via live, interactive communication (like videoconferencing) or by recording and sending medical information to a distant site to be reviewed.[18]

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10. *What Is Telepsychiatry?*, AM. PSYCHIATRIC ASS'N, https://www.psychiatry.org/patients-families/what-is-telepsychiatry (last visited May 6, 2020) [hereinafter AM. PSYCHIATRIC ASS'N, *Telepsychiatry*].

11. *Id.*

12. *Id.*

13. *About Telemedicine*, AM. TELEMEDICINE ASS'N, http://www.americantelemed.org/main/about/telehealth-faqs- (last visited May 6, 2020) [hereinafter AM. TELEMEDICINE ASS'N].

14. *Id.*

15. *See* AM. PSYCHIATRIC ASS'N, *Telepsychiatry*, *supra* note 10 (explaining that the term *telehealth* is broader than *telemedicine* in that it encompasses forms of care without clinical components).

16. *Id.*

17. *Id.*

18. *See id.* (including teleconferencing when discussing telepsychiatry and possible methods of access).

MHealth. Mobile health (or "mHealth") describes "a form of telemedicine using wireless devices and cell phone technologies."[19] Essentially, mHealth acts as a medium which facilitates the practice of telemedicine.[20] As the most recent evolution of telemedicine, mHealth uniquely influences health care with its ability to deliver clinical care through everyday devices.[21]

B. Origins & Pathology of Telepsychiatry

Notwithstanding the many variations in terminology, the conversations about telemedicine are consistent: everyone concurs as to its significance in today's health-care plane—and the vigor of its recent and continuing growth.[22] Nationally, a majority of hospitals employ telemedicine.[23] Internationally, telemedicine is used to treat millions of patients in hospitals and emergency rooms.[24]

The idea of telehealth has been percolating for centuries. For some scholars, telehealth originated in Medieval Europe with medical professionals spreading information about the bubonic plague.[25] Telehealth's diffusion into American health care, however, harkens back to more recent "old days,"—the 1920s.[26] It was at this time that a Mr. Hugo Gernsback published an article detailing the "teledactyl" in his magazine for science and invention; his imagined—but prophetic—"future instrument" featured a viewscreen and robotic arms which would enable doctors to see and touch patients remotely.[27]

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19. AM. TELEMEDICINE ASS'N, *supra* note 13.
20. *Id.*
21. *Id.*
22. *Id.*
23. *Id.*
24. *Id.*
25. *See* Karen M. Zundel, *Telemedicine: History, Applications, and Impact on Librarianship*, 84 BULL. MED. LIBR. ASS'N 71, 72 (1996) (providing historical examples of medical communication including the hypothesis that medieval people may have transmitted information about the bubonic plague using bonfires or heliographs, as they did when communicating about war and famine).
26. Matt Novak, *Telemedicine Predicted in 1925*, SMITHSONIAN MAG. (Mar. 14, 2012), https://www.smithsonianmag.com/history/telemedicine-predicted-in-1925-124140942/.
27. *Id.* Gernsback prophetically wrote:

> As our civilization progresses we find it more and more necessary to act at a distance . . . . As we progress, we find our duties are multiplied and we have less and less to transport our physical bodies in order to transact business, to amuse ourselves, and so on.
>
> The busy doctor, fifty years hence, will not be able to visit his patients as he does now. It takes too much time, and he can only, at best, see a limited number today. Whereas the services of a really big doctor are so important that he

Telepsychiatry stands as one of the earliest iterations of telemedical technology.[28] Originating in Europe, the first telepsychiatric consultations took place by radio in the 1920s, connecting mainland doctors with sailors at sea and residents of isolated islands.[29] During the 1950s, a Nebraska doctor used telepsychiatry to provide his rural patients with mental health care.[30] The Nebraska Psychiatric Institute started using videoconferencing "to provide group therapy, long-term therapy, and consultation-liaison psychiatry" in 1959.[31] The late 1960s and early 1970s appropriated the invention of the television, which "contributed more to the development of telepsychiatry than any other factor," to allow mental health professionals to conduct consultations, provide care, and educate patients over two-way, closed-circuit televisions.[32] The 1980s saw an increase in telepsychiatry,[33] cementing the telephone as "a mainstay of telehealth, providing physicians and other health professionals with a tool to accurately communicate and transfer medical information."[34]

C. Current Status of Telepsychiatry

Telehealth's ability to provide greater health-care access is its greatest strength. A 2018 review of 145 telemedicine studies revealed that telehealth technology improves access to care.[35] Where televisions first allowed mental health-care providers to treat patients in remote areas, the advent of internet-based communication devices expanded upon those capabilities and their prevalence.[36]

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should never have to leave his office; on the other hand, his patients cannot always come to him. This is where the teledactyl and diagnosis by radio comes in.

Id.

28. Allison N. Winnike & Bobby Joe Dale III, *Rewiring Mental Health: Legal and Regulatory Solutions for the Effective Implementation of Telepsychiatry and Telemental Health Care*, 17 HOUS. J. HEALTH L. & POL'Y 21, 47 (2017).

29. Sy Atezaz Saeed & Irene Pastis, *Using Telehealth to Enhance Access to Evidence-Based Care,* PSYCHIATRIC TIMES, June 2018, at 9.

30. Winnike & Dale, *supra* note 28, at 47.

31. Saeed & Pastis, *supra* note 29, at 9.

32. Tristan Serri, Comment, *An Examination of the Impact of Malpractice Law on Telepsychiatry Clinicians & Clients with Suicidal Ideations*, 50 AKRON L. REV. 933, 937 (2016).

33. Saeed & Pastis, *supra* note 29, at 9.

34. Serri, *supra* note 32, at 937.

35. *In-Depth: Four Major Telemedicine Trends of 2018*, MOBIHEALTHNEWS (June 1, 2018), https://www.mobihealthnews.com/content/depth-four-major-telemedicine-trends-2018 [hereinafter *Four Major Telemedicine Trends*].

36. Serri, *supra* note 32, at 937.

Access to individuals in remote and rural areas was one of the earliest purposes of telehealth and remains one of its foremost objectives.[37] Approximately one in five people in the United States live in rural areas.[38] Telehealth's popularity in all areas of modern life "has been secondary to a direct need to serve these [underserved] areas."[39] Lack of access to care often stems from a shortage of providers.[40] Telepsychiatry, in particular, operates as an effective solution in underserved areas; telepsychiatric services increase efficiency, alleviating the administrative burden on overworked providers, and provide positive clinical outcomes for patients.[41] Telepsychiatry is especially vital in providing basic mental health treatment to individuals with suicidal ideations.[42]

Though telemedicine is a necessity for health-care access in remote and rural areas, other populations, such as schools and disaster zones, also reap its benefits of access.[43] Telepsychiatry, specifically, has succeeded in increasing veteran access to mental health care.[44] For instance, the Department of Veterans Affairs uses video-to-home technology for psychotherapy and is piloting a telehealth program based on patient-provider text-messaging.[45] Similarly, the challenges in treating incarcerated patients are also assuaged by telehealth.[46] Telemedicine services, like provider-to-provider video consultations, are particularly helpful in light of growing issues, in jail populations, of mental illness and opioid addiction.[47] To this end, telepsychiatry's role in increasing access to mental health services has been pivotal.[48]

Indeed, the strengths of telemedicine mean even more in the context of mental health, where rates of access are even lower.[49] Of the 47% of Americans that experience symptoms of mental health conditions, less than

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37. *Four Major Telemedicine Trends*, *supra* note 35.

38. *See* Saeed & Pastis, *supra* note 29, at 9 (estimating, as of 2015, that there are 60 million people living in the rural United States).

39. *Id.*

40. *Id.*

41. *Id.*

42. Serri, *supra* note 32, at 937 (expressing special concern for individuals living in rural areas).

43. *Id.*

44. Saeed & Pastis, *supra* note 29, at 9.

45. *Four Major Telemedicine Trends*, *supra* note 35.

46. *Id.*

47. *Id.*

48. *See* Saeed & Pastis, *supra* note 29, at 9 (discussing the benefits of telepsychiatry in terms of efficient access and effectiveness).

49. Winnike & Dale, *supra* note 28, at 23.

38% have been treated.[50] About one-third of Americans consider mental health care to be inaccessible, according to a survey by the Anxiety and Depression Association of American (ADAA), the American Foundation for Suicide Prevention, and the National Action Alliance for Suicide Prevention.[51] Furthermore, "[n]early 90 percent of Americans value mental health and physical health equally,"[52] and yet, estimates evince only 50% of people suffering from mental illness are treated.[53] More specifically, nearly 40% of adults and 60% of adolescents who suffered a major depressive episode did not receive treatment.[54] Only 36.9% of those suffering from an anxiety disorder receive treatment, and a 2007 ADAA survey found that 36% of people with a social anxiety disorder experienced symptoms for a decade or more before seeking help.[55] These statistics demonstrate what the ADAA's 2015 survey concluded: "although the large majority of Americans are interested in seeking mental health care, they also face great challenges in both finding and affording treatment."[56]

Arguably, such statistics regarding mental health-care access exemplify a societal pressure to ignore mental illness. Yet, do not despair (or do despair, but seek treatment) because telepsychiatry is reducing and combatting the stigma of mental illness.[57] This festering stigmatization boasts a "lengthy history [that] has only recently begun to abate."[58] American society has often viewed the mentally ill as menaces that needed to be restrained, or at least segregated from the mentally healthy.[59] Counterintuitively, the stigma impinged on treatment for mental illness, preventing "patients from getting the best treatment, or at times from getting any treatment at all."[60] This

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50. *Survey Finds that Americans Value Mental Health and Physical Health Equally*, ANXIETY & DEPRESSION ASS'N OF AM. (Aug. 31, 2015), https://adaa.org/survey-finds-americans-value-mental-health-and-physical-health-equally [hereinafter *Survey Finds*].

51. *Id.*

52. *Id.*

53. *Statistics*, NAT'L INST. OF MENTAL HEALTH, https://www.nimh.nih.gov/health/statistics/index.shtml#OCD (last updated Jan. 2018) [hereinafter *Statistics*].

54. *Major Depression,* NAT'L INST. OF MENTAL HEALTH, https://www.nimh.nih.gov/health/statistics/major-depression.shtml (last updated Feb. 2019) [hereinafter *Major Depression*].

55. *Facts & Statistics*, ANXIETY & DEPRESSION ASS'N OF AM., https://adaa.org/about-adaa/press-room/facts-statistics (last visited May 6, 2020) [hereinafter *Facts & Statistics*].

56. *Suicide and Prevention*, ANXIETY & DEPRESSION ASS'N OF AM., https://adaa.org/understanding-anxiety/suicide (last visited May 6, 2020).

57. Saeed & Pastis, *supra* note 29, at 10.

58. Thomas L. Hafemeister et al., *Parity at a Price: The Emerging Professional Liability of Mental Health Providers*, 50 SAN DIEGO L. REV. 29, 44 (2013).

59. *Id.* at 45.

60. *Id.* at 44–45 (quoting William R. Dubin & Paul Jay Fink, *Effects of Stigma on Psychiatric Treatment*, in STIGMA AND MENTAL ILLNESS 1, 1 (Paul Jay Fink & Allan Tasman eds., 1992)).

stigma, though still present, is beginning to ebb.[61] For instance, younger people are increasingly (and comparatively, to older groups) likely to consider mental health treatment a "sign of strength."[62] This attitude speaks both to telepsychiatry's impact on mental health stigmas and to the amenability of young people to adopt telehealth technologies.[63]

An increasingly dominant societal concern is convenience, and patient behavior is no exception. Fortunately, telehealth also satisfies this key preference. When telehealth acts as an "electronic backbone" to structure health care, "one doesn't need to see a doctor for every issue."[64]As the CEO of one telemedicine provider mused: "If you ask a typical consumer who would they rather see, their primary care doctor that they've seen for five years or some doctor they've never met before, I'm guessing 99 percent would say they'd rather see the doctor they've been seeing for five years."[65] And yet, the CEO postulated, "the context is really important."[66] For instance, a patient's initial preference for the familiar would likely be overcome when given the choice between seeing a different doctor immediately and seeing her regular doctor in a few days.[67]

From the perspective of insurers and employers, telehealth's strength is its ability to lower costs.[68] Consumers agree: nearly half of Americans consider cost an obstacle to obtaining mental health treatment.[69] Quick telemedical consultations on minor health concerns, like a child's cough, could obviate an expensive ER visit.[70] However, this is not always enough to sway health insurers. Health insurers are reticent to embrace widespread use of telemedicine, because some studies have found that telemedicine runs up health-care consumption, while charging only marginally cheaper rates.[71]

Of course, all these benefits would ring hollow if telehealth was not also providing more effective treatment. But it is. The Agency for Healthcare Research and Quality's 2018 report concluded that telehealth "has clinical

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61. *Id.* at 44.

62. *Survey Finds*, *supra* note 50.

63. *See* Jennifer R. Flynn, *Break the Internet, Break the Stigma: The Promise of Emerging Technology & Media in Mental Health*, 20 QUINNIPIAC HEALTH L.J. 1, 17–19 (2017) (professing a belief in technology's capacity to drive social change).

64. Cutler, *supra* note 5.

65. *Four Major Telemedicine Trends*, *supra* note 35.

66. *Id.*

67. *Id.*

68. Reed Abelson, *American Well Will Allow Telemedicine Patients to Pick Their Doctor*, N.Y. TIMES (May 16, 2016), https://www.nytimes.com/2016/05/17/business/american-well-will-allow-telemedicine-patients-to-pick-their-doctor.html.

69. *Survey Finds*, *supra* note 50.

70. Abelson, *supra* note 68.

71. Clifton Leaf, *Why Hasn't Telemedicine Taken off? Hey, Blame This Guy*, FORTUNE (July 3, 2018), http://fortune.com/2018/07/03/whats-holding-up-telemedicine/.

benefits in acute and chronic care," with some evidence of reductions in length of ICU stays, mortality, and costs.[72] In comparing telepsychiatry with traditional care, studies found higher rates of response and remission in participants receiving telepsychiatric treatment.[73] Overall, telepsychiatry— like telemedicine as a whole[74]—is equal to, if not more effective than, in-person evaluations and consultations.[75]

II. MENTAL HEALTH APPS: TELEPSYCHIATRY'S METASTASIS TO MOBILE TECHNOLOGY

"You're More Powerful Than You Think," proclaimed Apple's campaign to debut its Health and Healthkit apps.[76] And due in large part to Apple's earlier introduction of the iPhone, "smartphones are the most rapidly adopted technology in the history of [humankind]."[77] Telehealth grew exponentially with the force of a technologically driven society.[78] And this progress led to mHealth and a "personal metrics movement."[79] This movement is expansive, stretching beyond the obvious markers of diet and exercise: "[i]t's about tracking every facet of life, from sleep to mood to pain, 24/7/365."[80] And this movement is democratized, blindly eluding societal distinctions: it is "capable of spreading among common people, not just the elite or affluent."[81]

Though popular among both the public and practitioners, mHealth is not without its critics or its challenges. With mHealth came MH apps, which may be crucial in today's context of mental illness and mental health care.[82] MH apps use their unique smartphone features to implement traditional mental

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72. *Four Major Telemedicine Trends*, *supra* note 35.

73. Saeed & Pastis, *supra* note 29, at 9.

74. Leaf, *supra* note 71.

75. Saeed & Pastis, *supra* note 29, at 9.

76. Duncan Macleod, *Apple Dreams for iPhone More Powerful Than You Think,* INSPIRATION ROOM (Aug. 8, 2014), http://theinspirationroom.com/daily/2014/apple-dreams-for-iphone-more-powerful-than-you-think/.

77. Eric Topol, *From Patient to Crowdhero: Why Narrative Medicine Can Become a Crowdmedicine,* CTR. FOR DIGITAL HEALTH HUMAN. (July 29, 2015) (emphasis omitted), http:www.centerfordigitalhealthhumanities.com/it/dal-paziente-al-crowdhero-perche-la-medicina-narrativa-puo-diventare-una-crowdmedicine/#more-4485.

78. Rebecca Pifer, *Telemedicine Use Among Commercially Insured Skyrocketed Since 2005*, HEALTHCAREDIVE (Nov. 29, 2018), https://www.healthcaredive.com/news/telemedicine-use-among-commercially-insured-skyrocketed-since-2005/543066/.

79. Eric Topol, *The Wireless Future of Medicine*, TEDMED, at 6:59 (Oct. 2009), https://www.ted.com/talks/eric_topol_the_wireless_future_of_medicine [hereinafter *The Wireless Future*].

80. *Id.* at 7:00.

81. THE PATIENT WILL SEE YOU NOW, *supra* note 6, at 15.

82. 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, 367 (2014).

health treatment, but they are only as effective as the safeguards that surround them.[83]

A. Benefits & Value of MH Apps

The advantages of mHealth and MH apps incorporate those of their telemedicine and telepsychiatry predecessors, including overcoming barriers associated with access, cost, resources, and insurance coverage.[84] MHealth treatment for mental illness also boasts the effectiveness and success rates of telemedicine and telepsychiatry, when compared to in-person care.[85]

Even more than earlier telehealth iterations, MH apps allow users to access treatment at any time and any place, completely circumventing many of the well-known barriers to health care discussed earlier.[86] A typical smartphone user checks their device 150 times per day, making the opportunity for engagement indisputable.[87] In this way, "smartphone apps can generate, reward, and maintain strong habits," in the same way that fitness apps improve physical health.[88] Phones, and related wearable sensors, allow for more accurate assessments of patients, while also being less time-intensive.[89] Real-time monitoring of symptoms and tracking of treatment, buoyed by mHealth's inherent portability and flexibility of use, are powerful advantages for mental health treatment.[90] Patients receiving in-person care may forget psychiatric events between visits, but MH apps can collect random tidbits or crucial reactions in real-time, or at least much closer than traditional care; this feature directly aids in symptom reporting and assessment.[91]

Additionally, MH apps can be relatively inexpensive, compared to other treatment options.[92] Cost stands as a major barrier to treatment, particularly

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83. *See infra* Part III (laying out the risks of underregulating MH apps).

84. Joyce Lui et al., *Evidence-Based Apps? A Review of Mental Health Mobile Applications in a Psychotherapy Context*, PROF. PSYCHOL., Feb. 2017, at 1.

85. Donald M. Hilty et al., *Advances in Mobile Mental Health: Opportunities and Implications for the Spectrum of E-Mental Health Services*, MHEALTH, Aug. 21, 2017, at 8.

86. *Id.* at 2.

87. David Bakker et al., *Mental Health Smartphone Apps: Review and Evidence-Based Recommendations for Future Developments*, JMIR MENTAL HEALTH, Jan.–Mar. 2016, at 2.

88. *Id.*; *see also* Stephanie Schoeppe et al., *Efficacy of Interventions that Use Apps to Improve Diet, Physical Activity and Sedentary Behavior: A Systematic Review*, INT'L J. BEHAV. NUTRITION & PHYSICAL ACTIVITY, Dec. 7, 2016, at 21 (finding, in a systematic review, that health and fitness apps contributed to positive health outcomes in 19 out of 27 studies).

89. Hilty et al., *supra* note 85, at 5.

90. Tara Donker et al., *Smartphones for Smarter Delivery of Mental Health Programs: A Systematic Review*, J. MED. INTERNET RES., Nov. 15, 2013, at 2.

91. Hilty et al., *supra* note 85, at 5.

92. *Id.* at 2.

with respect to mental health.[93] A large majority of the public—76% according to a recent survey—are interested in using a free MH app to manage and monitor their mental health.[94] MHealth also has indirect benefits, including helping patients keep up with medication and avoid emergency room visits, both of which could also reduce overall health-care costs.[95] Similarly, some of the largest hospital chains identify high-risk patients using consumer data.[96] This data has potential "to predict when patients might fall ill due to unhealthy habits and intervene before reaching a point that would require more costly care."[97] This is likely only the iceberg's tip in melting titanic health industry costs; for instance, the insurance industry could embrace mHealth data to expand its risk profiling.[98]

MHealth may also improve patients' adherence to treatment, boasting high rates of engagement and patient retention.[99] A study comparing mHealth care with traditional care found that, while satisfaction rates and success rates for treatment were similar, the mHealth participants had higher rates of engagement in the study.[100] In particular, mHealth attracts young people with mental health issues or developmental challenges; this demographic often feels more at ease when "sharing experiences and trying to learn new behaviors anonymously or at a distance."[101] Social Anxiety Disorder, notably, tends to emerge around age 13,[102] and young people today use technology both as an extension of themselves and as an insight into themselves, communicating with others their internal struggles and emotions.[103] Illustratively, researchers recently reviewed the social media of college students and diagnosed depressive symptoms in 25% of these accounts: "Online reinforcement from their friends may have made them

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93. Bakker et al., *supra* note 87, at 2.

94. *Id.*

95. Barry Liss, *HIPAA and Mobile Health: Where's the App for That?*, N.J. LAW. MAG., Dec. 2016, at 21.

96. J. Frazee et al., *mHealth and Unregulated Data: Is This Farewell to Patient Privacy?*, 13 IND. HEALTH L. REV. 384, 399 (2016).

97. *Id.*

98. *Cf.* Christopher Ingraham, *An Insurance Company Wants You to Hand over Your Fitbit Data So It Can Make More Money. Should You?*, WASH. POST (Sept. 25, 2018), https://www.washingtonpost.com/business/2018/09/25/an-insurance-company-wants-you-hand-over-your-fitbit-data-so-they-can-make-more-money-should-you/ (examining an insurance company's interest in personal fitness data).

99. Donker et al., *supra* note 90, at 8.

100. Dror Ben-Zeev et al., *Mobile Health (mHealth) Versus Clinic-Based Group Intervention for People with Serious Mental Illness: A Randomized Controlled Trial*, 69 PSYCHIATRIC SERVS. 978, 981 (2018), https://ps.psychiatryonline.org/doi/pdf/10.1176/appi.ps.201800063.

101. Hilty et al., *supra* note 85, at 6.

102. *Facts & Statistics*, *supra* note 55.

103. *See* Hilty et al., *supra* note 85, at 6 (explaining that young people are comfortable communicating their thoughts and emotions with online chat groups).

more likely to discuss their depressive symptoms publicly via social networking sites."[104] According to one tech expert, young people's embrace of technology is progress:

> Those who bemoan the perceived decline in deep thinking or engagement, face-to-face social skills and dependency on technology fail to appreciate the need to evolve our processes and behaviors to suit the new reality and opportunities. Young people and those who embrace the new connectedness are developing and evolving new standards and skills at a rate unprecedented in our history.[105]

As more and more people comfortably use online chats and apps to express themselves, mHealth supports the framework of patient-centered care—a concept that underscores "the whole person or person behind the patient" by focusing on quality care.[106]

Lastly, mHealth and MH apps demonstrate a shift to more participatory care—i.e., "moving patients from being mere passengers to responsible drivers of their health by shared decision-making"—might improve the attendance, engagement, and effectiveness of traditional clinical treatment, particularly psychotherapy.[107] Approximately half of all mental health patients receive psychiatric treatment, and attendance infrequency is a common reason such treatments fail.[108] MH apps fill a role of motivation and support that may increase treatment readiness for these patients.[109] MH apps use methods like journalizing, symptom-tracking tools, and psychoeducation to encourage self-reflection; such interactivity ultimately empowers the patient in her own treatment.[110]

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104. *Id.* at 8.
105. JANNA QUITNEY ANDERSON & LEE RAINIE, PEW RES. CTR., MILLENNIALS WILL BENEFIT *AND* SUFFER DUE TO THEIR HYPERCONNECTED LIVES 10 (2012), https://www.pewresearch.org/internet/wp-content/uploads/sites/9/media/Files/Reports/2012/PIP_Future_of_Internet_2012_Young_brains_PDF.pdf.
106. Hilty et al., *supra* note 85, at 1.
107. *Id.* (citation omitted).
108. *Id.* at 6.
109. *Id.*
110. *Id.*

B. Public Impact & Critical Reception of MH Apps

MHealth is integrating mobile technology with social media to revolutionize the mental health-care field.[111] More than 90,000 smartphone apps currently available for download pertain to health.[112] Mental health, in particular, has been a focal point of internet communities for decades, including communities of individuals, such as veterans making the return to civilian life, who see internet socialization as a way to avoid the stigma and isolation of mental illness.[113] The MH apps trend developed slowly at first due to constraints on federal funding, but is now growing exponentially.[114]

The overall public perception of psychiatric apps has been positive.[115] Current users of these apps feel less anxious or isolated, more connected to their doctor, and more confident in making health-related decisions.[116] According to a systematic review of 18 studies, young people reported high satisfaction after seeking online mental health help.[117] Young people prefer internet-based mental health support to the traditional telephone hotlines, and this preference seems to be shared by other demographics.[118]

Public popularity seems likely to increase: 76% of respondents to an online survey reported interest in using a mobile phone for mental health monitoring, as long as the services were free, and those with depression, stress, or anxiety symptoms demonstrated even more interest than those without.[119] Key reasons that respondents identified for their interest in MH apps included the convenience of an app and its potential to combat isolation and enable self-monitoring. [120] On the other hand, a minority of survey respondents attributed their lack of interest in using MH apps to a general dislike for, or disregard of, the technology and concerns that the apps may "be too intrusive."[121] According to focus groups, the key concern—and barrier to wider public adoption—is privacy and security of information.[122]

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111. *Id.* at 2, 4.
112. *Id.* at 2–4.
113. *Id.* at 7. Indeed, 33% of those military personnel preferred technology-based mental health treatment over in-person care. *Id.*
114. *Id.* at 2.
115. *Id.* at 14.
116. *Id.* at 2.
117. *Id.* at 6.
118. Bakker et al., *supra* note 87, at 15.
119. Judith Proudfoot et al., *Community Attitudes to the Appropriation of Mobile Phones for Monitoring and Managing Depression, Anxiety, and Stress*, J. MED. INTERNET RES., Dec. 19, 2010, at 1, 6.
120. *Id.* at 7.
121. *Id.*
122. *Id.* at 10.

The industry reaction (or at least the analysis of the industry reaction) to virtual mental health services has been mixed. According to one source, the MH apps "are remarkably popular with . . . providers—this is a new era of medicine."[123] Yet, another source laments: "Despite empirical evidence for the effectiveness of telepsychiatry when compared with in-person care many psychiatrists are still not at ease with telepsychiatry."[124] Should this collective reluctance actually exist, its origins, at least, are clear: typically, the barriers to medical professionals include anxiety from using the new technology, lack of technical skill, and the time necessary to integrate new services into workflow.[125] Nearly 96% of medical students considered having psychiatry apps with clinical materials useful for their studies, highlighting the younger generation's predilection for—and the correlative increased popularity of—mHealth in mental health care.[126]

Irrespective of its possibly lukewarm regard, those in the psychiatric field are very aware of their impending duty to regulate and evaluate mHealth and MH apps, as well as their current, parallel duty in telehealth.[127] The American Telemedicine Association (ATA) believes telemedicine to be "a safe and cost-effective way to extend the delivery of health care" when "[g]uided by technical standards and clinical practice guidelines."[128] Pursuant to this belief, the ATA developed "a series of standards, guidelines and best practices for health care providers to ensure that they are using telemedicine responsibly."[129] Likewise, the American Psychiatric Association (APA) has created an App Evaluation Model—a rating system and rubric for elevating a clinician's awareness of important considerations when choosing MH apps for treatment.[130] The ADAA, in partnership with PsyberGuide, has published reviews of anxiety, depression, and related apps, using three rating scales: (1) the PsyberGuide Rating Scale, a credibility measurement that assesses the app's research foundation on a five-point scale; (2) the Mobile Apps Rating Scale, a user-experience measurement that assesses, among other things, an app's ease-of-use and aesthetics on a five-point scale; and (3) a Transparency Checklist, an evaluation of the app's

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123.   Hilty et al., *supra* note 85, at 14.

124.   Saeed & Pastis, *supra* note 29, at 9.

125.   Hilty et al., *supra* note 85, at 6.

126*.   Id.*

127*.   See id.* at 14 (expressing concern that, so far, psychiatric organizations have not developed a good way to fulfill the duty to regulate and evaluate mHealth).

128.   AM. TELEMEDICINE ASS'N, *supra* note 13.

129*.   Id.*

130*.   App Evaluation Model*, AM. PSYCHIATRIC ASS'N, https://www.psychiatry.org/psychiatrists/ practice/mental-health-apps/app-evaluation-model (last visited May 3, 2020).

policies on collecting and storing user data.[131] Assessment and evaluation tools like these will shape and improve MH app development and "enable clinicians and consumers to make more informed decisions about their choice of smartphone-based support."[132]

C. Critical Mental Health Care: Stigma & Suicide in Mental Illness

Mental illness sits among us, the silent, ghostly elephant in the Nation's waiting room. Despite recent high-profile hits[133] and celebrity-catalyzed conversations,[134] a self-conscious stigma still stalks mental health and illness, muting a global issue to hushed and hypothetical tones. But the reality of mental illness affects tens of millions of people in the United States each year.[135] According to the National Institute of Mental Health, that number was 46.6 million in 2017.[136] That is nearly one in seven adults in the United States living with a mental illness.[137] In assessing this prevalence, the National Institute of Mental Health (NIMH) found that more women suffer from mental illness than men—22.3% of women to 15.1% of men.[138] Mental illness is also more common in young adults than any other age group.[139]

Anxiety disorders afflict 40 million U.S. adults every year, making anxiety disorders more common than any other mental illness.[140] Approximately one in three people will experience an anxiety disorder during their lifetime.[141] The term *anxiety disorders* denotes a wide range of mental

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131. *Mental Health Apps*, ANXIETY & DEPRESSION ASS'N OF AM., https://adaa.org/mental-health-apps (last visited May 3, 2020).

132. Bakker et al., *supra* note 87, at 17.

133. *See* Alyssa Bailey, *Selena Gomez and Julia Michaels's New Song "Anxiety" Is Here, and It Has Some Very Personal Lyrics*, ELLE (Jan. 24, 2019), https://www.elle.com/culture/music/a26015177/selena-gomez-julia-michaels-anxiety-lyrics-meaning/ (reporting the release of a pop song that addresses mental illness).

134. *See generally Celebrities Highlight Mental Health Issues*, U.S. NEWS & WORLD REP. (May 17, 2018), https://www.usnews.com/news/healthiest-communities/articles/2018-05-17/celebrities-bring-awareness-to-mental-health-issues (listing celebrities who have discussed mental illness publicly). *See also* Amanda J. Calhoun & Jessica A. Gold, *"I Feel Like I Know Them": The Positive Effect of Celebrity Self-Disclosure of Mental Illness*, 44 ACAD. PSYCHIATRY 237, 237–38 (2020) (footnote omitted) ("[C]elebrity disclosures of [mental] health issues help[] to increase knowledge about the disease in the general public, inspire others with the same disease to seek help, and promote advocacy surrounding that particular illness.").

135. *Statistics*, *supra* note 53.

136. *Mental Illness*, NAT'L INST. OF MENTAL HEALTH, https://www.nimh.nih.gov/health/statistics/mental-illness.shtml (last updated Feb. 2019) [hereinafter *Mental Illness*].

137. *Id.*

138. *Id.*

139. *Id.*

140. *Facts & Statistics*, *supra* note 55.

141. *Any Anxiety Disorder*, NAT'L INST. OF MENTAL HEALTH, https://www.nimh.nih.gov/health/statistics/any-anxiety-disorder.shtml (last updated Nov. 2017) [hereinafter *Any Anxiety Disorder*].

illnesses emerging from myriad complex risk factors.[142] A person's genes, brain chemistry, temperament, and circumstances all affect their chance of suffering from anxiety.[143] While each disorder varies in its catalysts, the common qualities to all are "excessive anxiety and related behavioral disturbances."[144]

Depression is also one of the more common mental illnesses: as of February 2019, approximately 17.3 million U.S. adults had experienced at least one episode of major depression.[145] The NIMH defines these depressive episodes as periods of "at least two weeks when a person experienced a depressed mood or loss of interest or pleasure in daily activities; and had a majority of specified symptoms, such as problems with sleep, eating, energy, concentration, or self-worth."[146] Again, depressive episodes demographically affect women and young adults most.[147] Major depression is debilitating, with potential to severely impair, interfere with, or limit a sufferer's ability to take on day-to-day activities.[148]

Aside from being among the most pervasive mental illnesses in the United States, anxiety and depression comingle in their prevalence. The ADAA notes: "It's not uncommon for someone with an anxiety disorder to also suffer from depression or vice versa."[149] Indeed, "[n]early one-half of those diagnosed with depression are also diagnosed with an anxiety disorder."[150] Sufferers of generalized anxiety disorder are especially likely to experience depression.[151]

Depression and anxiety are particularly significant in their common correlation to suicide and *suicidal ideations*,[152] which includes thinking about, considering, or planning suicide.[153] Although many stressed or depressed people experience suicidal thoughts, fortunately, most do not bring those thoughts to fruition.[154] Symptoms of anxiety and depression match

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142. *Facts & Statistics*, *supra* note 55.

143. *Id.*

144. *Any Anxiety Disorder*, *supra* note 141.

145. *Major Depression*, *supra* note 54. These statistics include depressive episodes induced by physical illness, medication, or substance use disorders, which are not included in the DSM-V's diagnostic definition for depression. *Id.*

146. *Id.*

147. *Id.*

148. *Id.*

149. *Facts & Statistics*, *supra* note 55.

150. *Id.*

151. *Id.*

152. Yvette Brazier, *What Are Suicidal Thoughts*, MEDICALNEWSTODAY (June 26, 2010), https://www.medicalnewstoday.com/articles/193026#symptoms-.

153. *Suicide*, NAT'L INST. OF MENTAL HEALTH, https://www.nimh.nih.gov/health/statistics/ suicide.shtml (last updated Apr. 2019).

154. Brazier, *supra* note 152.

many of the signs of suicidal ideation, and both conditions are linked to a higher risk of suicidal ideation.[155] The vast majority—over 90%—of adults who commit suicide suffer from mental illness.[156] And yet, more than half of Americans did not know that people with anxiety or panic disorders are at heightened risk for suicide, despite most understanding that mental health conditions are risk factors.[157]

To be fair to that majority baffled by suicide risk factors, consistent and successful risk assessment standards elude and confound even the most seasoned mental health experts and the most confident legal scholars.[158] Suicide risk assessment involves analyzing a wide variety of triggering factors,[159] but this analysis is complicated because many of the risk factors are common in the general population.[160] Risk factors include substance abuse and exposure to suicide, whether through prior attempts, family history, or media coverage of celebrity suicides.[161] One of the most significant considerations is mental health history.[162] Aside from particular mental illnesses, general mental health indicators include higher levels of impulsivity, hostility, aggression, and hopelessness in suicide attempters.[163] "More than half of all clinically depressed persons have suicidal ideation . . . ."[164] Depression's symptoms of hopelessness, guilt, disinterest, insomnia, and low self-esteem are indicators for suicide risk.[165] "Anxiety disorders are [also] associated with lifetime suicidal ideation and suicide attempts, especially in adolescents and in young adults."[166] "Repeated suicide attempts increase the risk of future suicidal behavior," particularly for individuals with mood disorders.[167] Suicidal ideation by itself may also be a risk factor, "either as an independent risk factor, or as part of a factor

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155. *Id.*

156. Robert I. Simon, *Suicide Risk Assessment: What Is the Standard of Care?*, 30 J. AM. ACAD. PSYCHIATRY & L. 340, 340 (2002).

157. *Survey Finds*, *supra* note 50.

158. *See generally* Simon, *supra* note 156 (discussing the challenges that psychiatric professionals and lawyers face in developing an objective standard to judge the adequacy of suicide risk assessments).

159. Serri, *supra* note 32, at 938 (listing suicide risk factors).

160. Maya Schwartz-Lifshitz et al., *Can We Really Prevent Suicide?*, 14 CURRENT PSYCHIATRY REP. 624, 624 (2012).

161. Serri, *supra* note 32, at 938.

162. *Id.*

163. *See* Schwartz-Lifshitz et al., *supra* note 160, at 624, 626 (reporting that aggression, impulsivity, hostility, and hopelessness—among other symptoms—are health indicators).

164. *Id.* at 625.

165. *Id.*

166. *Id.*

167. *Id.* at 626.

integrating measures of subjective depression, reasons for living, and hopelessness."[168]

In 2017, suicide took the lives of 47,173 people in the United States—more than double the number of homicides—making it the tenth leading cause of death.[169] The NIMH calls suicide "a major public health concern" and notes that rates of suicide are increasing in some populations.[170] According to the CDC, in 2017, "[s]uicide was the second leading cause of death among individuals between the ages of 10 and 34, and the fourth leading cause of death among individuals between the ages of 35 and 54."[171] The American Foundation for Suicide Prevention asserts that, for every reported suicide death in 2017, approximately 12 people go to a hospital for injuries related to self-harm.[172] And in a 2017 survey, a startling 7.4% of high schoolers reported at least one suicide attempt in the past year.[173]

D. Applying Mental Health-Care Treatment to MH Apps

1. Features & Functions of MH Apps

The manifold features of MH apps include video calling, messaging, multimedia functions, sensors, and external device connectivity.[174] The benefits of such features range from the convenience of remote communication and accuracy of data input to innovation in audiovisual psychoeducation and simplification in administering assessments.[175] Through its communicative functions, these apps foster contact between providers, caregivers, social supports, or even other patients.[176] Text-messaging can serve at least four important functions in MH apps: facilitating reminders, delivering information, providing support, and enabling self-monitoring.[177] Remarkably, "[p]ersonalization, caring sentiments, and polite

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168. *Id.* at 627.

169. *Suicide*, *supra* note 153.

170. *Id.*

171. *Id.*

172. *Suicide Claims More Lives than War, Murder and Natural Disasters Combined*, AM. FOUND. FOR SUICIDE PREVENTION, http://afsp.donordrive.com/index.cfm?fuseaction=cms.page&id=1226&eventID=5545 (last visited May 6, 2020).

173. *Suicide Statistics*, AM. FOUND. FOR SUICIDE PREVENTION, https://afsp.org/about-suicide/suicide-statistics/ (last visited May 6, 2020). Perhaps less surprisingly, the number of attempts by female students was almost double that of male students. *Id.* Note, that due to the nature of this data collection, intentional suicide attempts could not be distinguished from non-intentional self-harm behaviors. *Id.*

174. Hilty et al., *supra* note 85, at 4.

175. *Id.*

176. *Id.* at 7.

177. *Id.* at 5.

text are associated with more successful preventative messages."[178] In this way, MH apps allow the flow of information to be continuous, including progress feedback or behavioral or medication reminders.[179]

These features merge to create various functions unique to mHealth and MH apps. First, notifications and reminders "can increase adherence and reduce dropout from self-help CBT interventions."[180] MH apps' notification function can help users engage in an intervention by reminding them throughout the day.[181] In the past, participants in guided self-help treatments for mental illness have stayed on track with the assistance of email or telephone reminders.[182] Similarly, apps can provide reminders via push notifications, which are app-specific notices that pop up on a user's phone screen.[183] MH app notifications are capable of facilitating ecological momentary assessment (EMA), a traditional mental health treatment expounded on in later discussion.[184] The apps can prompt brief self-report questionnaires at various times and automatically record the user's completion time.[185] In this way, EMA via app notifications may reduce self-report bias[186] and can facilitate studies with real-world applications.[187]

Another major function is *gamification*, which is "the use of 'game-based mechanics, aesthetics, and game thinking to engage people, motivate action, promote learning, and solve problems.'"[188] Apps reward users with badges, points, or the like to "remind users that they have achieved something by quantifying their success and allowing users to reflect on their own growth."[189] MH apps often utilize gamification principles in pursuit of increased engagement and retention, motivating game players in pursuit of their goals.[190] Gamification taps into users' own goals to enhance enthusiasm in pursuing treatment and mental health milestones.[191] The stale truism that

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178. *Id.*

179. *Id.* at 4.

180. Bakker et al., *supra* note 87, at 14.

181. *Id.*

182. *Id.*

183. *Id.*

184. *See infra* text accompanying notes 238–45.

185. Bakker et al., *supra* note 87, at 15, 16.

186. *See infra* text accompanying notes 238–42.

187. Bakker et al., *supra* note 87, at 8, 16 (explaining that traditional self-monitoring techniques like reflection and journaling at the end of the day fail to accurately capture a patient's experience of and response to a challenge or stressor, and hypothesizing that MH apps can overcome this problem by enabling self-assessment in nearly real time).

188. *Id.* at 12 (quoting KARL M. KAPP, THE GAMIFICATION OF LEARNING AND INSTRUCTION 23 (2012)).

189. *Id.* at 13.

190. *Id.* at 12.

191. *Id.* at 12, 13.

"fun is the real reward" fits here (insomuch as one believes fun is equivalent to a mentally healthy lifestyle), but the true winner is the user's self-efficacy.[192] Whether winning or losing, the patient maintains feelings of competency.[193] One gamification study found that user's brains released dopamine while navigating a goal-directed task within a game; another concluded "electronic-game-based depression interventions had a moderate effect on depressive symptoms."[194] This neurological evidence substantiates the potential "positive well-being effects" from gamified MH apps.[195]

2. Traditional Treatment Methods in an mHealth Context

Together, these functions of MH apps form "a particularly valuable platform for dissemination of interventions."[196] Intervention, as it pertains to psychological treatment, broadly encompasses "any action intended to interfere with and stop or modify a process," though it can also specifically mean "action on the part of a psychotherapist to deal with the issues and problems of a client."[197] The APA notes that factors like "the nature of the problem, the orientation of the therapist, the setting, and the willingness and ability of the client to proceed with the treatment" guide a psychotherapist's choice of intervention.[198] MHealth's portability and convenience provide the potential to intervene "in the moment of need in any location and time, such as during high-risk or triggering situations, or times of significant distress."[199] Additionally, MH apps could facilitate self-help interventions involving comorbidity; "interventions designed for one disorder are likely to have some efficacy for other emotional disorders."[200] Addressing "shared underlying factors" is effective because "half of all mental illness cases are mixed anxiety and depression."[201]

Cognitive behavioral therapy (CBT) is also a prominent method both in traditional psychiatry and in the mHealth context; a therapist practicing CBT uses cognitive and behavioral interventions "to identify and facilitate a change in an individual's cognitions."[202] CBT treatment focuses on

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192. *Id.* at 13.
193. *Id.*
194. *Id.*
195. *Id.*
196. Lui et al.*, supra* note 84, at 1.
197. *Intervention*, AM. PSYCHOLOGICAL ASS'N, https://dictionary.apa.org/intervention (last visited May 6, 2020).
198. *Id.*
199. Lui et al.*, supra* note 84, at 1.
200. Bakker et al., *supra* note 87, at 6.
201. *Id.*
202. Serri, *supra* note 32, at 938.

"addressing specific cognitive biases and distortions, developing problem solving techniques, accepting and tolerating emotional pain, improving communications, reducing stress, and developing a support system."[203] CBT is commonly used to treat individuals with suicidal ideations.[204] A therapist employing CBT seeks to help the patient understand that the patient's thoughts create and shape her emotions and behavior.[205] In this way, CBT strives to reduce a patient's negative emotions and physiological distress.[206]

A critical component of CBT is psychoeducation, which aids patients in understanding mental health concepts.[207] MH apps succeed in serving this function for MH app users by "present[ing] clients with mental health information in an attempt to teach them about the psychological processes underlying their distress and inform them of resources available to manage it."[208] Psychoeducational interventions have seen success in treating depression: participants of a preventative intervention decreased their probability of developing clinical depression by 38%.[209] MH apps are well-equipped to provide psychoeducation because of the "range of multimedia and audiovisual tools" available to engage users.[210] Evidence illustrates psychoeducation's significant role in improving patients' knowledge and supportive mental health behaviors, particularly via short and passive psychoeducational experiences.[211] Even in a study using the internet to deliver simple psychoeducation visuals and information, researchers found the psychoeducation reduced mental health symptoms.[212] In the context of MH apps, shorter interventions in these studies saw much more success than longer interventions; mobile devices "are well equipped to deliver this kind of brief, passive psychoeducation."[213] However, MH apps can also facilitate longer, more intensive psychoeducation, if necessary, by linking to websites or referring to other sources.[214]

CBT specifically intertwines with e-mental health via its branch of internet-based cognitive behavioral therapy, also called computerized

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203. *Id.* at 939.
204. *Id.* at 938.
205. *Id.*
206. *Id.* at 939.
207. Bakker et al., *supra* note 87, at 10.
208. *See id.* at 10–11 (explaining that MH apps provide a useful platform for sharing mental health information with users).
209. *Id.* at 10.
210. *Id.* at 11.
211. *Id.*
212. *Id.*
213. *Id.*
214. *Id.*

cognitive behavioral therapy (CCBT).[215] Like mHealth, CCBT provides treatment and support to patients via e-mail, websites, and video calls.[216] Evidence strongly supports CCBT in the context of MH apps, as it has been effective in reducing symptoms of the most common anxiety and depressive disorders.[217]

Self-monitoring often works into a CBT-based intervention, wherein patients record their thoughts, feelings, and actions.[218] Regarded as "a core feature of many evidence-based psychological therapeutic techniques," self-monitoring allows the patients to later reflect on these reports.[219] Self-monitoring has potential "to restructure maladaptive anxiety responses, challenge perpetuating factors of depression, and sufficiently treat a small but significant proportion of posttraumatic stress disorder sufferers."[220] And self-monitoring is effective; it improves mood and behavior and enhances treatment compliance.[221] Broader benefits of self-monitoring include reduced symptom severity and increased quality of life.[222]

Traditional paper-and-pencil and computer-based self-monitoring, which require patients to grab journals or sit at computers at scheduled times, can be cumbersome or inconvenient for patients.[223] Because traditional methods impinge on the patient's schedule, they tend to be less effective for many patients.[224] Recall bias also limits self-monitoring, as self-reflection is often far-removed, temporally and geographically, from the day's stressors.[225] Because of these issues, nonadherence to self-monitoring is common,[226] and consequently, so is ineffectiveness: "To be maximally effective, individual self-monitoring needs to take place regularly and in real time to reduce recall bias and increase accuracy."[227]

Alternatively, mHealth and MH apps may cure these issues.[228] Mobile devices are ubiquitous in both developed and developing countries.[229] MH apps advance self-monitoring primarily in two ways.[230] First, the ease of

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215. *Id.* at 3; Serri, *supra* note 32, at 939.
216. Serri*, supra* note 32, at 939.
217. Bakker et al., *supra* note 87, at 3.
218. *Id.* at 8.
219. *Id.*
220. *Id.* (citations omitted).
221. Proudfoot et al., *supra* note 119, at 2.
222. *Id.* at 1.
223. *Id.* at 2.
224. Bakker et al., *supra* note 87, at 8.
225. *Id.*
226. *See infra* text accompanying note 236.
227. Proudfoot et al., *supra* note 119, at 2.
228. *Id.*
229. *Id.*
230. Bakker et al., *supra* note 87, at 8.

integrating a mobile device into a user's daily routine allows MH apps to gather self-monitoring data in—or at least significantly closer to—real-time when the user directly experiences stressors.[231] Using MH apps for self-monitoring "allows for more frequent and broader opportunities for recording reflections, such as while waiting or traveling on public transport."[232] Mobile devices, constantly within reach and armed with inarguable convenience, can thus reduce recall bias and ultimately improve accuracy of self-monitoring.[233]

Second, the apps that automatically format or record the time of an entry can reduce some of self-monitoring's tedium and strain.[234] Self-monitoring via MH apps may also increase help-seeking, especially when the app itself facilitates contact with health professionals.[235] In evaluating self-monitoring's traditionally common noncompliance, researchers found that compliance with a paper diary was 11% (though patient-reported compliance was 90%).[236] On the other hand, researchers have measured compliance with a digital diary above 90%.[237]

Specifically, this evidence of success in self-monitoring demonstrates the capability of mobile devices—via MH apps—in two types of self-monitoring: EMA and experience sampling methods (ESM).[238] ESM involves real-time measurement of a patient's experiences.[239] EMA involves sampling representational activities and behaviors repeatedly.[240] The three most common uses of EMA are daily diary-keeping, when the client reports at the end of the day; "signal-dependent reporting," when the client reports when prompted by an alarm at random times throughout the day; and "event-dependent reporting," when the client reports after "predetermined interpersonal or challenging events during the day."[241] Recall bias and a patient's subconscious urge to report socially desirable behavior make daily diaries inaccurate; whereas, reports based on signal- and event-dependent methods are more accurate.[242] EMA is already widely used by those in mobile mental health who recognized that "EMA is particularly well-suited" for the field; for example, this method enhanced assessments by "capturing

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231. *Id.*
232. *Id.*
233. *Id.*
234. *Id.*
235. *Id.*
236. Proudfoot et al., *supra* note 119, at 2.
237. *Id.*
238. Bakker et al., *supra* note 87, at 8.
239. *Id.*
240. Hilty et al., *supra* note 85, at 5.
241. *Id.*
242. *Id.*

more accurate accounts of a client's emotions, functioning, and activity related to mood anxiety and smoking."[243] One predictive model used EMA data to evaluate what reported changes preceded suicidal ideation risk.[244] With more development progress and clinical validation, EMA data could help patients and doctors identify and respond to suicide risk.[245]

III. DIAGNOSING INADEQUATE LEGAL PROTECTIONS FOR MENTAL HEALTH APP USERS

The danger of MH apps arises at a crossroads of four factors: (1) the risk of harm that accompanies mental illness in users; (2) the presence of direct-to-consumer marketing without intermediary physicians; (3) the ambiguity in industry-wide standards and regulations; and (4) the lack of clinical validation for product safety and efficacy.[246] Without federal intervention, this is a four-way collision zone, an intersection without any warnings or traffic lights:

> The [iTunes app] store demands no verification of medical credentials or license, and some of the apps are available for free. Others are much more expensive, and their cost alone may be a barrier to exclude many non-medical professionals from using the more sophisticated apps. Ultimately, since not all technology users are super-savvy (this author included), and since there are no access barriers between apps for medical professionals and those for everyday consumers, a curious smartphone user could download a confusing app that might lead them to make misinformed health care decisions.[247]

Despite mHealth's rapid growth, popularity, and efficacy, "neither public nor private, top-down nor bottom-up and country-specific nor international approaches related to apps [are] providing a framework to develop, evaluate and regulate . . . mHealth care."[248] Due to this lack of action, danger and

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243. *Id.*

244. *Id.*

245. *Id.*

246. Nathaniel R. Carroll, Comment, *Mobile Medical App Regulation: Preventing a Pandemic of "Mobilechondriacs"*, 7 ST. LOUIS U. J. HEALTH L. & POL'Y 415, 417, 418 n.27, 419, 422 (2014); *see also infra* text accompanying notes 411–14 (explaining that experimental testing and validation is rare for MH apps).

247. *Id.* at 425 (footnote omitted).

248. Hilty et al., *supra* note 85, at 14.

confusion overshadow the potential of MH apps.[249] More pressing than the uncertainty for providers or app creators is the concern for users arising from the apps' lack of evidence-based studies or substantiations; "digital psychiatric therapies often do not conform to existing standards of care for the specific conditions they claim to treat."[250] Typically, fundamentals of law and economic policy call upon the self-regulatory functions of the tort system, a system which "should maximize social welfare by creating incentives that deter some, but not all, accidents."[251] However, the tort system is ill-equipped to deal with the intricacies of MH app invention; neither malpractice nor product liability provide solid protection or remedies for MH app users.[252] Where self-regulation fails, the government usually succeeds (or more accurately, at least participates).[253] But the Food and Drug Administration (FDA) refuses to fill the abyss of MH app protection with any guidance or oversight for the vast majority of MH apps, despite MH apps falling within its jurisdiction.[254] Ultimately, the lack of regulation for MH apps creates risks for app creators and leaves app users without protection.[255]

A. 404 Error for MH Apps: Tort Claim Not Found

To determine the necessity of administrative regulation, the failure of both malpractice and product liability in controlling MH apps must be demonstrated. In theory, the tort system acts "by requiring the tortfeasor to pay damages that fully compensate victims of accidents caused by risks that are cost-effective to eliminate."[256] Eliminating the risks of MH apps is certainly cost-effective because they involve significant mental health risks: "For accidents with health effects, the award should be equivalent to the

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249. *Id.*; *see generally* Winnike & Dale, *supra* note 28, at 23 (analyzing the spectrum of laws, regulations, and policy issues related to telemedicine).

250. Theodore T. Lee, *Recommendations for Regulating Software-Based Medical Treatments: Learning from Therapies for Psychiatric Conditions*, 73 FOOD & DRUG L.J. 66, 75 (2018).

251. W. Kip Viscusi et al., *Deterring Inefficient Pharmaceutical Litigation: An Economic Rational for the FDA Regulatory Compliance Defense*, 24 SETON HALL L. REV. 1437, 1448 (1994).

252. *Infra* Part III.A.

253. *Cf. infra* text accompanying notes 303–06 (summarizing the ways in which federal regulation is more effective than private regulation through the tort system).

254. *Infra* Part III.B; *see also* U.S. FOOD & DRUG ADMIN., POLICY FOR DEVICE SOFTWARE FUNCTIONS AND MOBILE MEDICAL APPLICATIONS: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF 9 (2019), https://www.fda.gov/media/80958/download [hereinafter U.S. FDA, POLICY FOR MOBILE MEDICAL APPLICATIONS] (describing the limited scope of the FDA guidance with respect to mobile medical devices).

255. *See infra* Part III.A (discussing the obstacles to holding app creators liable in tort actions).

256*.* Viscusi et al., *supra* note 251, at 1448.

amount a firm would have to pay all persons exposed to the risk in order to induce such persons to accept the risk voluntarily."[257]

This idealized tort system minimizes the risk of accidents because "financial incentives will force firms to invest in safety to the extent necessary to eliminate all awards of damages and all inefficient risk."[258] Socially irresponsible risks become fiscally irresponsible risks, and the prospect of compensatory damages deter such risks.[259] But such a perfect result requires a perfect process: tort law must have "perfect information about both the costs of accidents and the costs of avoiding them" to achieve its goal;[260] this gives the tort system the ability "to distinguish between accidents that should be avoided and, therefore, compensable, and accidents that should not be deterred because the social cost of reducing the accident is greater than the cost of the accident itself."[261] If the tort system cannot so distinguish, "tort law can easily create perverse incentives, thereby harming social welfare by reducing overall efficiency."[262]

Due to the role of MH apps in telepsychiatry, the first remedy considered is likely a medical malpractice claim. When a person receiving treatment is harmed, or inflicts harm, the immediate legal reaction is often a negligence claim against the health providers.[263] One problem is that MH app creators do not fall within the role of a physician or licensed professional, making it difficult for an app's remote user to bring a professional liability claim.[264] The first element in a suicide liability case requires that the defendant had a duty to prevent the suicide.[265] Practically speaking, courts have held that

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257. *Id.* at 1448–49.

258. *Id.* at 1449 (emphasis omitted).

259. *Id.*

260. *Id.*

261. *Id.*

262. *Id.*

263. *See generally* Serri, *supra* note 32, at 940–45 (describing the legal elements of a medical malpractice case before applying it to CBT). In mental health treatment, the provider-defendant role could be played by both physicians and non-physicians. Hafemeister et al., *supra* note 58, at 36. Depending on the identity of the provider, the recipient-plaintiff could be considered either a client or a patient. *Id.* Patients file medical malpractice claims against physicians (psychiatrists); clients file professional liability claims against non-physicians (psychologists, social workers, various counselors). *Id.* Despite the variances in terminology, the nature of these claims is similar—as is their unworkability for harm caused by mental health apps. *Id.*

264. *See* Daven Lowhurst & Brian McDonald, *What to Know About Liability and Legal Costs for Apps*, Ins. J. (July 25, 2016), https://www.insurancejournal.com/magazines/mag-features/2016/07/25/420535.htm (listing the legal theories on which app creators can be held liable).

265. Barry A. Lindahl, Modern Tort Law: Liability and Litigation § 3:36 (2d ed.), Westlaw (database updated June 2019).

liability rests upon the existence of a special relationship between the decedent and defendant and upon the foreseeability of the suicidal act.[266]

Foreseeability, while directly pertinent to the causation element of the claim, is also a factor in determining whether a special relationship existed; other factors in this determination include public policy and the case-specific interactions in the parties' relationship.[267] Judges determine whether a special relationship exists as a matter of law.[268] Significant dissimilarities between a traditional psychiatrist-patient relationship and a virtual one further complicate the legal determination: "In traditional psychiatry, the practitioner-patient relationship is temporal, as each session lasts for a specific period of time, but in telepsychiatry, this relationship is more fluid, as telepsychiatry requires the patient to engage in other activities assigned by the therapist outside of each session."[269] Telepsychiatry's "fluidity" muddies the already-murky relationship element, further distressing the courts.[270] The complexity leads to a fairly simple result: courts are likely to treat telepsychiatry patients as outpatients—a status which rarely compels liability.[271]

However, the element of duty, and of a special relationship, may not be the most difficult hurdle faced by a plaintiff.[272] Even if the proper relationship existed, the second problem is that the claim would likely fail. Negligence torts based upon liability for suicidal acts or attempts are historically unsuccessful, despite the fact that patient suicide sparks more malpractice claims against psychiatrists than any other injury.[273] And while purely electronic interaction could still establish a negligence claim against a mental health-care provider,[274] a malpractice claim for a suicide has less potential.[275] Liability for failure to prevent suicide traditionally arises only with the presence of a decedent's suicidal tendencies, of which the defendant was actually or constructively aware, and in response to which the defendant had

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266. 1 JAMES E. ROOKS, JR., RECOVERY FOR WRONGFUL DEATH § 2:8 (4th ed.), Westlaw (database updated July 2018).

267. Serri, *supra* note 32, at 949.

268. *Id.*

269. *Id.*

270. *Id.*

271. *Id.* at 955.

272. *See* ROOKS, *supra* note 266, § 2:8 (explaining that even if a plaintiff successfully establishes a duty of care and a special relationship, suicide is generally held to be unforeseeable).

273. Simon, *supra* note 156, at 340, 342.

274. *See, e.g.*, White v. Harris, 2011 VT 115, ¶ 15, 190 Vt. 647, 650, 36 A.3d 203, 207 (holding that one 90-minute video conference as part of a telepsychiatry research study sufficiently established a psychiatrist-patient relationship).

275. Serri, *supra* note 32, at 954–55.

a duty to act.[276] As with any general malpractice suit, a generally-applicable, specifically-defined duty is virtually impossible to formulate—let alone maintain.[277] Despite suicide's role as the most common basis of psychiatric malpractice claims, "[t]he rarity of suicide and the complexities of its causes have not allowed for a professional standard of care."[278]

Another reason these claims often fail is the difficulty in proving proximate causation. Proximate cause analysis focuses on foreseeability, because "[i]t is only the risk of suicide that can be assessed, and therefore only the risk of suicide that is reasonably foreseeable."[279] The question of foreseeability goes to the nature of the risk that a patient could commit suicide.[280] That a suicide appears preventable in retrospect is not relevant.[281] Predictability does not have an applicable standard—preventability, predictability, and foreseeability are not mutually interchangeable in this context.[282] A general principle of traditional tort law is that suicide is an intervening act that breaks the chain of causation.[283] This historical principle is derived in part from the view that suicide is "abnormal and not in accord with human experience"—some jurisdictions still view suicide as immoral or unlawful.[284] Though modern application of suicide liability is evolving,[285] about half the states continue to enforce the common-law view that suicide is an intervening act.[286] Other jurisdictions have abolished this rule, but some have simply made exceptions to its application, for example, when a custodial or special relationship exists.[287] The one clarity in the otherwise muddled sphere of suicide liability is that users of MH apps are not likely to find solace there.

Product liability is another failure in tort regulation of MH apps. As the app economy boomed from $1.9 billion to $143 billion between 2008 and

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276. ROOKS, *supra* note 266, § 2:8.

277. Hafemeister et al., *supra* note 58, at 42–43 (explaining that duties of care have to be defined on a case-by-case basis using expert testimony).

278. Serri, *supra* note 32, at 952. *See* Simon, *supra* note 156, at 340 (reporting that suicide is the most common impetus behind claims of psychiatrist malpractice).

279. Simon, *supra* note 156, at 341.

280. *See* Serri, *supra* note 32, at 955–56 (describing risk factors that the court would find legally sufficient to establish foreseeability in a suicide case).

281. Simon, *supra* note 156, at 341–42.

282*. Id.*

283. ROOKS, *supra* note 266, § 2:8.

284. *Id.*

285*. Id.*

286. J. Shahar Dillbary et al., *Why Exempting Negligent Doctors May Reduce Suicide: An Empirical Analysis*, 93 IND. L.J. 457, 457 (2018).

287. Serri, *supra* note 32, at 955.

2016, so did product liability exposures.[288] Consequently, "liability concerns have become a critical issue for software designers, hardware manufacturers and their insurers."[289] MH apps are often used without the oversight—or even recommendation—of mental health-care providers, leaving only one party to turn to when use of the app goes awry—the app creator.[290] Product liability protects consumers by creating "the framework for seeking remedies when a defective product (or misrepresentations about a product) causes harm to persons or property."[291]

There are two problems with using product liability to compensate harmed users of MH apps: (1) product liability law's inability to deal with the autonomous (and often automated) nature of the apps and (2) app creators' uncertainty in governing law and its requirements for compliance.[292] The example of self-driving cars may help demonstrate the difficulties of these automated MH apps. Thus far, autonomous vehicles have been legally assessed in terms of product liability principles.[293] But the novelty of autonomous vehicles causes uncertainty, as "[l]iability constantly bounces between accused parties based on varying levels of autonomy, human intervention, and algorithm diagnostics."[294]

A less obvious legal issue is choice-of-law, an issue steadily defying resolution since the advent of MH apps' predecessor, telepsychiatry.[295] Two suggestions arose in the context of virtual psychiatric care.[296] One suggested using the law of the physician's jurisdiction on the theory that telepsychiatry "electronically transport[s]" the patient to the physician's location.[297] The other would apply the law of the patient's jurisdiction on the theory that the physician "personally availed" herself of the jurisdiction's laws.[298] The latter

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288. Sara J. Papasidero, *Mobile Apps—Has the Marketplace Downloaded Potential Product Liability Risk?*, WILSON ELSER (Aug. 5, 2016), https://www.productliabilityadvocate.com/2016/08/mobile-apps-%E2%88%92-has-the-marketplace-downloaded-potential-product-liability-risk/.

289. *Id.*

290. *See id.* (explaining that injuries incurred by mobile app users while using apps have given rise to liability questions for app creators).

291. John Villasenor, *Products Liability and Driverless Cars: Issues and Guiding Principles for Legislation*, BROOKINGS INST. (Apr. 24, 2014), https://www.brookings.edu/research/products-liability-and-driverless-cars-issues-and-guiding-principles-for-legislation/.

292. *See generally* Papasidero, *supra* note 288 (describing how the evolution of medical apps results in vague FDA guidance, which produces a liability risk to app creators).

293. Melissa L. Griffin, Comment, *Steering (or Not) Through the Social and Legal Implications of Autonomous Vehicles*, 11 J. BUS. ENTREPRENEURSHIP & L. 81, 91 (2018).

294. *Id.*

295. *See* Serri, *supra* note 32, at 947 (explaining that lawsuits claiming harm from telepsychiatry involve complicated questions of choice-of-law and personal jurisdiction).

296. *Id.* at 948.

297. *Id.*

298. *Id.*

option gives weight to the jurisdiction's strong interest in protecting its citizens, including patients.[299] The choice-of-law question must also take into account a mental health patient's vulnerability and the therapist's fiduciary duty to the patient.[300] This leads some scholars to favor applying the law of the patient's jurisdiction.[301] The solution of applying the law from the jurisdiction where the patient received treatment would help patients, but it would likely not help app creators. Since the apps are downloadable wherever mobile technology is available, this place-of-treatment approach would subject app creators to liability under every state's law.[302] Without federal guidance—and the accompanying relief of federal preemption—app creators would have to comply with *all* state laws, and potentially even foreign law. Until federal regulation speaks to these concerns, however, product liability cannot serve as a reliable source of redress for users of MH apps. Because "tort law does not operate in a vacuum," direct regulation like this "can sometimes achieve the social goal of deterring inefficient accidents more economically and accurately than the indirect incentives provided through tort law."[303] In simpler terms, "*laissez faire* pharmaceutical litigation often creates perverse incentives" that "can lessen the value or even countermand the judgments of the FDA, thereby overturning the agency's well-considered risk-benefit assessments."[304] Between the two, the FDA is much better equipped to determine the proper balance of risks and benefits than our tort system.[305] As such, tort law's role, conclusively, "needs to be refocused."[306]

Regulatory chaos forestalls effective implementation of MH apps as treatment tools and further complicates any redress for harms from use of the apps.[307] Central to this chaos are "inharmonious federal and state laws and regulations" and "unresolved policy issues."[308] The FDA springs to mind first, as the choice agency to ensure the safety of MH apps. However, regulatory jurisdiction of mHealth falls within the purview of many other agencies as well.[309] The list of government entities exercising authority over

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299. *Id.* at 948–49.

300. *Id.* at 949.

301. *Id.* (citing Jeffrey L. Rensberger, *Choice of Law, Medical Malpractice, and Telemedicine: The Present Diagnosis with a Prescription for the Future*, 55 U. MIAMI L. REV. 31 (2000)).

302. *Id.* at 947.

303. Viscusi et al., *supra* note 251, at 1450.

304. *Id.* at 1475.

305. *Id.*

306. *Id.*

307. Winnike & Dale, *supra* note 28, at 23; *see infra* Part III.B (describing the FDA's current approach to regulating MH apps).

308. Winnike & Dale, *supra* note 28, at 23.

309. Frazee et al., *supra* note 96, at 386.

MH apps includes Congress, the Federal Trade Commission (FTC), and state attorneys general, which adds to the regulatory complexity more than it appropriately protects the app users or creators.[310] In fact, the first mHealth consumer protection case, involving a claim for deceptive marketing practices against a health app, can be attributed to the FTC.[311] Also, the Office of the National Coordinator for Health Information Technology, the Federal Communications Commission (FCC), and the FDA jointly received congressional direction in 2012 to issue a collaborative report; per section 618 of the Food and Drug Administration Safety and Innovation Act, this report was to include "a proposed strategy and recommendations on an appropriate, risk-based regulatory framework pertaining to health information technology, including mobile medical applications, that promotes innovation, protects patient safety, and avoids regulatory duplication."[312] The confluence of agencies at play leave app creators and users confused as to where to look for guidance and protection, respectively.[313] These questions varnish complexity over the simple answer: there is none.

B. An App a Day Keeps the FDA Away

The FDA's wariness in treading into the MH app field is noticeable, albeit understandable, "[g]iven the sheer number of products, the dynamic nature of software applications that can change with each update, the flexibility required to oversee them, and the potential ethical issues involved."[314] But the FDA has both the authority and the duty to regulate MH apps. The FDA derives its authority to regulate food, drug, and cosmetic safety from the Federal Food, Drug, and Cosmetic Act of 1938 (FDCA).[315] In 1976, Congress amended the statute to grant further FDA authority over safety of high-risk devices.[316] Decades later, the FDA's public health responsibility to supervise medical device safety and efficacy now extends to mobile medical apps.[317]

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310. Lee, *supra* note 250, at 76.

311. Anne Marie Helm & Daniel Georgatos, *Privacy and mHealth: How Mobile Health "Apps" Fit into a Privacy Framework Not Limited to HIPAA*, 64 SYRACUSE L. REV. 131, 162 (2014).

312. Frazee et al., *supra* note 96, at 386–87 (citation omitted).

313. Winnike & Dale, *supra* note 28, at 101–02.

314. Anna Wexler & Peter B. Reiner, *Oversight of Direct-to-Consumer Neurotechnologies; Efficacy of Products is Far from Clear*, 363 SCI. 234, 235 (2019).

315. Lee, *supra* note 250, at 77.

316*. Id.*

317*. Device Software Functions Including Mobile Medical Applications*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/medicaldevices/digitalhealth/mobilemedicalapplications/default.htm#a (last updated Nov. 5, 2019) [hereinafter *Device Software Functions*].

The congruence between MH apps and other medical devices—both may operate without direct or ongoing medical supervision[318]—implicates the FDA.[319] Fortunately, MH apps arguably already fit into the FDA regulatory framework. The FDA's statutory definition of "device" is broad, inclusive, and focuses on "intended use" of the device; FDA regulations define "intended use . . . as objective intent of the persons legally responsible for the labeling of devices."[320] MH apps could be categorized as either "intended for use . . . in the cure, mitigation, treatment, or prevention of disease" or "intended to affect the structure or any function of the body of man or other animals."[321] Thus, by its plain language, this definition brings digital mental health therapy within the FDA's purview.[322]

If the FDA exercises jurisdiction to regulate a device, the agency must determine the device's risk classification, as required by the Medical Device Amendments of 1976.[323] At the low end of the risk spectrum, the FDA puts Class I devices, which are subject to only general controls, like adulteration and registration.[324] Class III devices lie at the high-risk end and are generally subject to premarket approval.[325]

The FDA interprets its regulatory jurisdiction to include mobile applications.[326] According to the agency itself, "[t]he FDA encourages the development of mobile medical apps (MMAs) that improve health care and provide consumers and health care professionals with valuable health information."[327] The FDA's authority to regulate mobile applications strongly suggests that the FDA also has authority over MH apps because both can qualify as *medical devices* if statutory criteria are satisfied.[328] Unsurprisingly—given the very basis of this Note—"the administrative actions that build upon the statute (including FDA regulations and guidance) are less clear," in terms of their application to digital medical treatments like MH apps.[329] One author succinctly diagnoses the issue: "Under the existing regulatory framework, it is difficult to determine whether a medical app is a device and, if so, what is required for [the] FDA to authorize marketing for

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318. *Id.*
319. *See* U.S. FDA, POLICY FOR MOBILE MEDICAL APPLICATIONS, *supra* note 254, at 2.
320. Lee, *supra* note 250, at 77 (quoting 21 U.S.C. § 321(h) (2012) and 21 C.F.R. § 801.4 (2016)).
321. 21 U.S.C. § 321(h) (2018).
322. Lee, *supra* note 250, at 77.
323. *Id.* at 79.
324. *Id.*
325. *Id.* at 80.
326. *Id.* at 76.
327. *Device Software Functions*, *supra* note 317.
328. Lee, *supra* note 250, at 76.
329. *Id.*

that device."[330] Further, "[the] FDA's existing guidance fails to distinguish digital psychiatric therapies and other software-based medical treatments from mobile applications that serve other purposes."[331] These ambiguities ultimately spotlight the difficulty in knowing "whether [the] FDA will exercise enforcement discretion over software treatments."[332]

The FDA often relies on guidance—with its inherent regulatory flexibility—to implement its policies, rather than rulemaking, and its action aimed at regulating software is no exception to this practice.[333] In 2015, the FDA released updated guidance regarding mHealth apps: the Mobile Medical Applications Guidance for Industry and Food and Drug Administration Staff.[334] The FDA issued this document to delineate its oversight of mobile medical apps as *devices*.[335] The FDA specified its focus as "only on the software that presents a greater risk to patients if it doesn't work as intended and on software that causes smartphones, computers, or other mobile platforms to impact the functionality or performance of traditional medical devices."[336] As such, "the document divides the world of [mobile medical applications] into two categories: (1) mobile apps that are the focus of FDA's regulatory oversight and (2) mobile apps for which FDA intends to exercise enforcement discretion."[337] The FDA chose the term "mobile medical applications" to encompass both consumer- and professional-grade software, while also acknowledging that "not all mobile applications are medical devices."[338] According to the FDA, generic "[m]obile apps are software programs that run on smartphones and other mobile communication devices," accessories that attach to such devices, or "a combination of accessories and software."[339] The FDA then defines "mobile medical apps" as "medical devices that are mobile apps, meet the definition of a medical device, and are an accessory to a regulated medical device or transform a mobile platform into a regulated medical device."[340] The FDA specifies that it will not enforce regulations for mobile apps which are covered by the regulatory definition but nonetheless "pose minimal risk to patients and consumers," meaning that FDA will not require

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330. *Id.*
331. *Id.*
332. *Id.*
333. *Id.* at 81.
334. *Id.* at 82.
335. *Device Software Functions*, *supra* note 317.
336. *Id.*
337. Lee, *supra* note 250, at 82.
338. *Id.*
339. *Device Software Functions, supra* note 317.
340. *Id.*

manufacturers of such apps to register their apps with the FDA, or submit to premarket review.[341] Included in this promise of enforcement discretion are mobile medical apps that "[h]elp patients/users self-manage their disease or condition without providing specific treatment suggestions . . . or [a]utomate simple tasks for health care providers."[342] This reference to self-management implicates MH apps that use coaching or provide data analysis because "the line between information or self-management and treatment is not always an obvious one."[343] Thus, FDA guidance suggests that this type of medical device will not be regulated via FDA enforcement, because MH apps do not fit neatly into MMA categories.[344] However, "assuming developers make disease-specific treatment claims," MH apps do more than inform—they treat conditions, a focus which "suggests they should be subject to enforcement."[345]

The key inquiry here becomes whether MH apps are therapies or medical devices, because the FDA does not regulate therapies.[346] The dissimilarity between a scalpel and a smartphone is obvious. The dissimilarity between orating about your childhood while lying on a couch and typing your most personal emotions into a phone while lying on your bed is less so. One crucial distinction exists, though.[347] The person wielding the health-care tools is not a licensed therapist.[348] The patient's care quite literally rests in her own hands. And when the patient controls the medical instruments, "there is less opportunity to correct operating errors before they cause injuries."[349] When digital psychiatric therapies employ unsupervised and unchecked algorithms, the software itself is the health-care provider.[350] This discrepancy and the resulting concerns are both particular to digital psychiatric therapies.[351] Under the FDCA, the FDA can regulate *devices*, which are "non-metabolized articles that affect the structure or function of a person's body."[352] MH apps are such articles: "Because digital psychiatric therapies are an 'article,' rather

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341. *Id.*

342. *Id.*; *see generally*, *Examples of Mobile Apps for Which the FDA Will Exercise Enforcement Discretion*, U.S. FOOD & DRUG ADMIN. (last updated Sept. 26, 2019), https://www.fda.gov/MedicalDevices/ DigitalHealth/MobileMedicalApplications/ucm368744.htm (providing a detailed list of examples of medical apps that the FDA does not intend to regulate).

343. Lee, *supra* note 250, at 84.

344. *Id.*

345. *Id.*

346. *Id.* at 79.

347. Barbara Fox, *Mobile Medical Apps: Where Health and Internet Privacy Law Meet*, 14 HOUS. J. HEALTH L. & POL'Y 193, 199 (2014).

348. *Id.*

349. *Id.*

350. Lee, *supra* note 250, at 79.

351. *Id.*

352. *Id.* (citing 21 U.S.C. § 321(h) (2018)).

than a process or mode of treatment, and they act directly on the function of a human's brain, they are more similar to a traditional regulated device than therapy itself."[353] The fact that some health-care providers may use these digital psychiatric therapies under supervision or in conjunction with in-person therapy is not enough to abandon all FDA involvement over these apps.[354]

However, this nonbinding—and frankly, idealistic—guidance "has left both legal and medical professionals with more questions than answers."[355] App creators—a group with much less experience navigating FDA regulation than attorneys or physicians[356]—join in this confusion.[357] The creators' uncertainty of FDA regulations could hinder development, as "[c]ompanies may be reluctant to invest significant resources in a particular area if those investments will become moot due to a shift in regulation."[358]

And the FDA continues to congratulate itself on its narrow regulatory scope; in January 2019, the FDA announced developments to continue "advancing several meaningful initiatives and policy proposals aimed at enhancing the safety of medical devices."[359] Psychiatric medical devices, and their dangers, were again ignored. Ultimately, the FDA has done little more than "pay[] lip service to innovation."[360] Refusing "to alter its regulatory approval processes to catalyze the ways that each individual can assume a greater role in their medical care," the FDA ensures that the "smartphone isn't as smart as it could be," and patients are not as smart as they could be.[361] Undeniably, mHealth's "potential benefits for patients and health care providers are limitless, but so too may be the potential pitfalls."[362]

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353. *Id.*

354. *Id.*

355. Sean Palmer, *Swipe Right for Health Care: How the State May Decide the Future on the mHealth App Industry in Wake of FDA Uncertainty*, 37 J. LEGAL MED. 249, 250 (2017).

356. Lee, *supra* note 250, at 68.

357. *Id.* at 84.

358. *Id.* at 68–69.

359. *Statement from FDA Commissioner Scott Gottlieb, M.D. and Jeff Shuren, M.D., Director of the Center for Devices and Radiological Health, on Latest Steps to Strengthen FDA's 510(k) Program for Premarket Review of Medical Devices*, U.S. FOOD & DRUG ADMIN. (Jan. 22, 2019), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm629686.htm.

360. THE PATIENT WILL SEE YOU NOW, *supra* note 6, at 228.

361. *Id.*

362. Carroll, *supra* note 246, at 417–18.

IV. PRESCRIPTION FOR LIMITED FEDERAL INVOLVEMENT: FDA OVERSIGHT
& FTC ATTENTION

The solution to the problematic lack of regulation seems too obvious: regulation. Though perhaps simplistic as a fix, a federal regulatory framework is never simple. But the FDA does have the authority to regulate these apps.[363] And the FDA does have the tools to regulate these apps, including its warning label standards,[364] evidence-based testing requirements,[365] and suicide assessment framework.[366] Critics try to argue that regulation will deter innovation,[367] ultimately harming more patients than those helped, but the FDA's requirements need only apply to apps that treat—or at least, profess to treat—mental illness. No one questions that "[e]nsuring the safety and efficacy of mobile medical apps requires regulation that balances consumer safety and freedom to innovate."[368] But invention is most effective when efficacy may be proven. And if the apps cannot make such claims of efficacy in mental health treatment, they need not be removed from the market[369]: they need only not make such claims.[370] To accomplish this result, the FTC should play an interstitial supporting role in penalizing fraudulently marketed MH apps.[371] Working together, this limited regulatory framework can protect MH app users until tort and product liability develop enough to self-regulate these self-managing apps.

A. Why Should the FDA Regulate MH Apps?

Regulatory oversight by the FDA, bolstered by litigious attention by the FTC, can act as legal sutures to the wounding gaps in tort law. Specifically, this regulatory structure could "alter the actions of the regulated community

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363. Lee, *supra* note 250, at 76.

364. *Infra* Part IV.B.1.

365. *Infra* Part IV.B.2.

366. *Infra* Part IV.B.3.

367. Jordan Roberts, *Health Care Delivery is Changing; Regulations Shouldn't Stand in the Way*, CAROLINA J. (Feb. 14, 2020), https://www.carolinajournal.com/opinion-article/health-care-delivery-is-changing-regulations-shouldnt-stand-in-the-way/.

368. Carroll, *supra* note 246, at 417.

369. *See* Emma Margolin, *Why Choosing a Mental Health App is Harder Than You Think,* NBC NEWS (May 30, 2018), https://www.nbcnews.com/know-your-value/feature/why-choosing-mental-health-app-harder-you-think-ncna832051 (explaining that research and clinical testing is not a requirement for developing a mental health app and releasing it into the market, but clarifying that this lack of testing does not mean all apps are ineffective and dangerous).

370. *See infra* text accompanying notes 451–57 (discussing the legal issues Lumosity experienced by making unsubstantiated claims about the product's efficacy).

371. *Infra* Part IV.C.

by imposing criminal or other sanctions on socially harmful behavior."[372] As federal regulation by administrative agencies seems to be the last remedy standing, the question of regulation progresses from *what* to *who* and *how*.

Criticism of FDA regulation, in general, tends to collect at the corners of fearing regulation's effect on innovation or access and disdaining superfluous costs of time, money, and effort.[373] These arguments are not without merit. For instance, FDA review of pre-market testing is notably lengthy; usually the evaluative process spans between five and seven years.[374] And the drugs that do not withstand that process are lost to consumers, according to critics who lament the resultant deprivation to patients of such innovative and potentially useful drugs.[375] One may argue that fewer standards may allow for smoother operations in marketing, advertising, and supply, which, in turn, provides greater access for users.[376] In fact, this seems to be the rationale behind the FDA's current framework, or at least the rationale pressed upon the FDA by Congress and stakeholders.[377] Congressional "concern that regulation could stifle the industry in its infancy" conveniently matches stakeholders' solicitude "that a flexible regulatory scheme is necessary to allow for the development of new technologies."[378]

These arguments, like most against increasing liability, cannot compare with the potential life-and-death harm that surrounds the use of MH apps. But we need not rest on the patient care benefits to sway the more capitalistically inclined critics. While deliberate regulatory ignorance correlates with economic benefits, regulatory uncertainty likely has the opposite effect.[379] In a technological upheaval of incessant updates and downloads, regulators are confronted with the difficult choice between "reckless action (regulation without sufficient facts) or paralysis (doing nothing)."[380] In early 2018 reflections, the FDA recognized the challenge of digital health, and the FDA stressed its resolve in "allowing beneficial new

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372. Viscusi et al., *supra* note 251, at 1450.

373. *See id.* at 1445 (describing how FDA drug licensing provisions affect patients by denying them useful drugs).

374. *Id.* at 1444.

375. *Id.* at 1445.

376. Flynn, *supra* note 63, at 36.

377. Frazee et al., *supra* note 96, at 390–91.

378. *Id.*

379. Mark Fenwick et al., *Regulation Tomorrow: What Happens When Technology Is Faster Than the Law?*, 6 AM. U. BUS. L. REV. 561, 561 (2018).

380. *Id.* at 582.

technologies to advance, while continuing to protect consumers."[381] But for MH apps, the FDA chose—and is choosing—to do nothing, and the paralysis is spreading.[382] Inaction actually disincentivizes innovation.[383] Inaction actually encumbers new treatment technologies attempting, not just blindfolded but also mapless, to reach the market.[384] Some commentators "assert that more stringent regulation could provide economic benefit to stakeholders."[385] The FDA's euphemistically-termed "light touch" also discourages medical professionals from adopting mHealth.[386]

B. How Should the FDA Regulate MH Apps?

Not only does the FDA have the statutory freedom to regulate MH apps,[387] its current regulation in other areas can be applied easily to MH apps.[388] This will aid the FDA in ultimately comporting with its statutory mandate and in restraining itself only to necessary regulation. Whereas the FTC's consumer protection actions, discussed *infra*,[389] will likely be punitive in nature, the FDA's accountability over MH apps should be more preventative.

A key consideration in MH app regulation has been, and will continue to be, the breakneck rapidity of updates. "More has been learned about the underpinnings of disease in the last two and a half years than in the history of [humankind]."[390] Thus, "the rate of innovation vastly surpasses the timeline and barriers accompanied by current regulation and oversight structures."[391] And this pace only quickens. To its credit, the FDA recently streamlined its process for reviewing medical software.[392] However, other

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381.   Scott Gottlieb, *Reflections on a Landmark Year for Medical Product Innovation and Public Health Advances and Looking Ahead to Policy in 2018*, U.S. FOOD & DRUG ADMIN (Jan. 9, 2018), https://www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/reflections-landmark-year-medical-product-innovation-and-public-health-advances-and-looking-ahead.

382.   *See* THE PATIENT WILL SEE YOU NOW, *supra* note 6, at 228 (lamenting the FDA's inaction).

383.   Fenwick et al., *supra* note 379, at 582.

384.   *Id.*

385.   Frazee et al., *supra* note 96, at 391.

386.   *Id.*

387.   *See* Lee, *supra* note 250, at 77 (explaining how the FDCA's 1976 amendment gave the FDA authority to regulate devices like MH apps).

388.   *See infra* Part IV.B.1–3 (highlighting existing tools the FDA can use to regulate MH apps).

389.   *Infra* Part IV.C.

390.   *The Wireless Future*, *supra* note 79, at 15:16.

391.   Carroll, *supra* note 246, at 446.

392.   Lee, *supra* note 250, at 87. In 2017, the FDA launched a pilot program that allows an accelerated regulatory review for pre-certified companies. *Id.* An FDA statement explains that the program was started "so that these fast-evolving technologies can similarly undergo the rapid product evolution that's the hallmark of software tools like medical apps, while [the] FDA maintains the ability to make sure that these digital health tools are being reliably produced." Gottlieb, *supra* note 381.

more comprehensive responses have failed.[393] One such solution that could be revisited is the proposed creation of a new FDA Office of Mobile Health: "Creating an Office of Mobile Health would establish a branch of the agency sensitive to the dynamic changes in mobile medical technology that could provide a quicker turnaround scheme for premarket approval that is not time and cost prohibitive."[394]

Despite acknowledgement of the industry's rapid evolution, the FDA's focus still misses the point. The foreseeable risks in MH app use "differ in kind depending on the app's intended *user*."[395] But the FDA regulates based on intended *use*.[396] Instead, the FDA needs to be more attentive to the difference between apps intended for use by patients and those intended for medical professionals.[397]

1. Warning Labels

The field of current FDA regulation perhaps best analogized to MH apps is that of pharmaceutical antidepressants. Like MH apps, these drugs often comprise treatment for mental illnesses, like anxiety or depression.[398] The FDA's primary regulation of pharmaceutical drugs is through standardized warning labels, using "a standardized warning vocabulary and structure to ensure that safety information is readily accessible to health care professionals."[399] Drug labels divide information into three sections, each addressing a particular subject.[400] The first section of the label generally describes the product, and the second explains how the pharmaceutical functions.[401] "[I]ndications and usage" are the third component of the label, importantly summarizing "the particular situations in which the medicine has

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393. *See, e.g.*, Efthimios Parasidis, *Clinical Decision Support: Elements of a Sensible Legal Framework*, 20 J. HEALTH CARE L. & POL'Y 183, 199 (2018) (relating the short history of the FDA's regulation of clinical decision support software, which ended after the industry successfully lobbied Congress for an exception).

394. Carroll, *supra* note 246, at 446. Per two experts' suggestion that regulation of direct-to-consumer neurotechnologies be guided by that of analogous dietary supplements, creation of such an office would not be unlike that of the National Institutes of Health (NIH) Office of Dietary Supplements: "which conducts scientific research on dietary supplements and translates knowledge for the public and policy-makers." Wexler & Reiner, *supra* note 314, at 235.

395. Carroll, *supra* note 246, at 419 (emphasis added).

396. *Id.*

397. *Id.*

398. *See* John Alan Cohan, *Psychiatric Ethics & Emerging Issues of Psychopharmacology in the Treatment of Depression*, 20 J. CONTEMP. HEALTH L. & POL'Y 115, 169 (2003) (warning that antidepressant drugs are not a substitute for psychotherapy).

399. Viscusi et al., *supra* note 251, at 1441.

400. *Id.*

401. *Id.*

been shown to be effective."[402] The efficacy of the FDA's label requirements derives not only from the helpful information contained therein, but also from the structure itself: "This standardized format significantly assists risk information processing."[403] Additionally, "the regulatory process and institutional memory also ensure that the language used in drug labeling is consistent and appropriate to the degree of known risks posed by the drug."[404] Overall, this regulatory centralization allows for a uniformity otherwise not possible through less-centralized means.[405]

Such an argument applies just as well to MH apps, though these "labels" would be more appropriately presented on the app's download page within an app store. Creating uniformity among app "labels" will allow users to know what to look for and where to look; this is comparably more vital for MH app users, who likely do not have a prescribing doctor or pharmacist to explain the treatment.[406]

2. Pre-Marketing Testing

Another FDA tool that would work well in the MH app arena is pre-marketing testing. Specifically, this would appease the concerned scholars and practitioners within the psychiatric field who want to see more evidentiary support for MH apps.[407] The FDA requires pre-marketing testing to ensure "that 'substantial evidence' of efficacy be demonstrated for the drug's proposed uses."[408] This involves a risk-benefit analysis: Pharmaceutical companies "must generate substantial pre-marketing safety and efficacy information through human clinical trials."[409] The FDA uses this evidence to weigh the costs and benefits of approving a drug for marketing and sale.[410]

The lack of experimental testing and validation in mHealth and MH apps is one of mHealth's biggest challenges.[411] The process of thorough experimental testing is of the utmost necessity for an effective mental health

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402. *Id.*

403. *Id.* at 1442.

404. *Id.*

405. *Id.*

406. *Cf. id.* at 1441 (assuming, without so stating, that medical professionals are the primary audience for FDA-mandated labels).

407. *See, e.g.*, Bakker et al., *supra* note 87, at 2 (criticizing MH app creators for eschewing experimental validation and for failing to use existing research-backed guidelines for similar self-help products).

408. Viscusi et al., *supra* note 251, at 1444.

409. *Id.* at 1442–43.

410. *Id.* at 1439.

411. Bakker et al., *supra* note 87, at 2.

intervention; this process guides development of the treatment itself.[412] And yet, MH app creators are not publishing, let alone conducting, experimental trials to validate their apps: one systematic review "revealed that there is a complete lack of experimental evidence for many of the hundreds of [MH apps] available."[413] Another review identified only five apps, out of the hundreds available, that had been tested in randomized, controlled trials, and none of the five apps were intended for consumer use.[414]

At the very least, MH apps need to follow evidence-based guidelines developed and used to protect participants in other self-help mental health interventions.[415] This preliminary step could aid in building a more comprehensive framework for evaluating apps.[416] But these guidelines are not being applied to MH apps.[417] As an illustration of the problem this creates, look no further than the categorization of MH apps by specific diagnosis or disorder; research establishes that labeling users in this way can cause them additional harm.[418]

The ADAA provides a convenient feature that the FDA could appropriate for its analysis of whether an app requires pre-marketing testing: a six-factor rating system for MH apps.[419] The ADAA factors include personalization and interactivity, which could be balanced with the research factors of evidence supporting treatment efficacy and evidence supporting the app's efficacy in an FDA risk analysis.[420]

3. Suicide Assessment

The danger of automated MH apps as treatment for depression or anxiety necessarily bleeds from their conceivable convergence with suicide. As MH apps intertwine with and intervene in the role of a mental health clinician, the apps' inattention to one key mental health-care duty becomes apparent: suicide risk assessment. However, whether users of these apps are more likely to commit suicide due to extrinsic factors or if company negligence or an app played a meaningful role is not a conundrum exclusive to MH apps.[421]

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412. *Id.*
413. *Id.*
414. *Id.*
415. *Id.*
416. *Id.*
417. *Id.*
418. *Id.*
419. *See Finding Help: Mobile Apps*, ANXIETY & DEPRESSION ASS'N OF AM., https://adaa.org/finding-help/mobile-apps (last visited May 6, 2020) (listing the six factors).
420. *Id.*
421. *See, e.g.*, Jean M. Tweange et al., *Increases in Depressive Symptoms, Suicide-Related Outcomes, and Suicide Rates Among U.S. Adolescents After 2010 and Links to Increased New Media*

The FDA currently has a suicidality framework in place,[422] ostensibly allowing for a convenient insertion of MH apps into that framework.

Experts describe systematic suicide risk assessment as "a process, not an event."[423] Accuracy requires frequency, as "[t]ime rapidly diminishes the clinical usefulness of suicide risk assessments."[424] Such systematic assessments require a life-and-death level of induction from the clinician, but do not require perfect or even comprehensive evaluations.[425] Even with the best risk assessment, "[p]rediction of suicide remains opaque to the clinician."[426] This fact makes it all the more important that medical professionals conform any suicide risk assessment to the legal standard of foreseeability.[427]

If identifying risk factors for suicide is difficult, conducting an actual assessment of suicide risk is even more challenging. Despite "a variety of suicide risk assessment methods available to the clinician,"[428] pertinent research depicts a grim picture: therapists often underestimate their patients' suicide risk.[429] A standardized or objective assessment method, like use of a checklist, may fail to "capture the dynamic interplay between suicide risk and protective factors."[430] However, assessment based purely in clinical judgment is also insufficient.[431] Successful suicide prevention strategies include more "responsible media coverage," an increase in public psychoeducation, and use of risk-identification methods;[432] these identification methods include using questionnaires to screen students and adults, training "gatekeepers" to recognize and refer at-risk individuals, and providing psychoeducation for primary care providers.[433] Mental health clinicians can save lives, but they first must understand "what's going on inside the suicidal person's mind, recogniz[e] warning signs, hav[e] a

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Screen Time, 6 CLINICAL PSYCHOL. SCI. 3 (2018) (studying the link between adolescent suicide and social media use, as well as other social factors).

422.   *See infra* text accompanying notes 435–40.

423.   Simon, *supra* note 156, at 342.

424*.   Id.*

425*.   Id.*

426*.   Id.* at 341.

427*.   Id.*

428*.   Id.* at 342.

429.   Laurie Meyers, *Facing the Specter of Client Suicide*, AM. COUNSELING ASS'N (Oct. 19, 2015), https://ct.counseling.org/2015/10/facing-the-specter-of-client-suicide/.

430.   Simon, *supra* note 156, at 343.

431.   Lisa Firestone, *Suicide: What Therapists Need to Know*, AM. PSYCHOLOGICAL ASS'N, https://www.apa.org/education/ce/suicide.pdf (last visited Apr. 17, 2020).

432.   Schwartz-Lifshitz et al., *supra* note 160, at 627 (explaining that sensational or detailed media coverage of a suicide can spur others to commit suicidal acts).

433.   *Id.* at 28 (explaining that "gatekeepers" are people in positions of trust—e.g., family, friends, teachers, pastors, care-givers—who can influence a suicidal person).

decision tree for assessing and managing suicide risk, and know[] which treatments are most effective."[434]

The FDA currently classifies suicide events using an eight-category classification system, the Columbia Classification Algorithm for Suicide Assessment (C-CASA).[435] The system arose after 2003, when the FDA responded to findings implicating certain drugs in suicidal reactions by directing researchers conducting FDA clinical trials to collect data on suicidal ideation and behavior.[436] The FDA used C-CASA to assess antidepressants, also known as selective serotonin reuptake inhibitors (SSRIs).[437] Despite the well-known difficulties in accurate suicidality assessments,[438] C-CASA represents the FDA's effort to better identify suicidal events through an "methodical, anchored approach."[439] C-CASA employs suicidality definitions "derived from empirical findings on the phenomenology of suicidality and identified predictive and risk factors;" its eight categories distinguish between events that are suicidal, nonsuicidal, potentially suicidal, and indeterminate.[440]

The FDA's guidance certainly seems to allow for application of its suicidal assessment criteria to MH apps: "[T]he heightened risk of suicide in most psychiatric illnesses strongly suggests that suicidal ideation and behavior should be assessed as part of the evaluation of any drug being developed for a psychiatric condition . . . ."[441] The FDA guidance notes: "Past experience specifically indicates that assessment of suicidal ideation and behavior should be a regular part of development programs involving antidepressants and antiepileptic drugs."[442]

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434. Firestone, *supra* note 431, at 1.

435. David V. Sheehan et al., *Current Assessment and Classification of Suicidal Phenomena Using the FDA 2012 Draft Guidance Document on Suicide Assessment: A Critical Review*, INNOVATION CLINICAL NEUROSCIENCE, Sept.–Oct. 2014, at 55.

436. *Id.*

437. U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY—SUICIDALITY: PROSPECTIVE ASSESSMENT OF OCCURRENCE IN CLINICAL TRIALS 3 (Draft Guidance, Sept. 2010); Cohan, *supra* note 398, at 116. For example, Prozac, Paxil, and Zoloft are well-known SSRIs. *Id.*

438. Cohan, *supra* note 398, at 146 (explaining that there is no reliable test for predicting suicide).

439. Kelly Posner et al., *Columbia Classification Algorithm of Suicide Assessment (C-CASA): Classification of Suicidal Events in the FDA's Pediatric Suicidal Risk Analysis of Antidepressants*, 164 AM. J. PSYCHIATRY 1035, 1035 (2007).

440. *Id.* at 1036.

441. U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY—SUICIDAL IDEATION AND BEHAVIOR: PROSPECTIVE ASSESSMENT OF OCCURRENCE IN CLINICAL TRIALS 9 (Draft Guidance, Revision 1, Aug. 2012), https://www.fda.gov/media/79482/download.

442. *Id.*

In fact, some of the MH apps specifically assess a user's mental health in ways similar to C-CASA.[443] This could portend FDA utilization of these apps to monitor the trials themselves, or even the usage of FDA-regulated, risk-prone drugs.

C. When Should the FTC Regulate MH Apps?

To the extent that the FDA will be only standardizing evidentiary bases for mental health treatment via the apps, it follows that the FTC should interstitially exercise its regulatory power to bring actions against apps making claims of mental health treatment without the requisite support of research and trials.[444] In particular, the FTC's involvement will provide an alternative that allows apps to circumvent the often-costly (in both temporal and fiscal senses) compliance with FDA efficacy-proving requirements, while still reducing risk to the users.[445] In simpler terms, attention from the FTC's Consumer Protection division counters critics who may argue that FDA restrictions will work against the very tenets of telehealth by raising costs to the app creators—costs that will in turn, be passed to the consumer—ultimately reducing access and innovation.[446]

Such action would fit within the FTC's work as a member of the National Prevention Council.[447] The National Prevention Council "provides coordination and leadership at the federal level regarding prevention, wellness, and health promotion practices," and the FTC has used its powers to "advance[] the National Prevention Council's goal of increasing the number of Americans who are healthy at every stage of life."[448] Direct-to-consumer "neurotechnologies," like MH apps, are sold directly to consumers

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443. *See* Jamie Ducharme, *Artificial Intelligence Could Help Solve America's Impending Mental Health Crisis,* TIME (Nov. 20, 2019), https://time.com/5727535/artificial-intelligence-psychiatry/ (describing a mobile app that evaluates mental health using repetitive verbal exercises and assesses patients by comparing clips of their responses).

444. FTC regulation is also relevant to mHealth and mental health apps in areas of cybersecurity and HIPAA, but such topics are unfortunately outside the scope of this Note. For more information regarding those issues, see Frazee et al., *supra* note 96, and see Helm & Georgatos, *supra* note 311.

445. *See* Helm & Georgatos, *supra* note 311, at 159 (discussing the FTC's authority to regulate deceptive advertising).

446. *See* Frazee et al., *supra* note 96, at 390–91 (describing criticisms from industry stakeholders and members of Congress who want to limit FDA regulation of mHealth); *see also* Helm & Georgatos, *supra* note 311, at 162 (describing an FTC action against a health app developer for deceptive advertising).

447. *Lumosity to Pay $2 Million to Settle FTC Deceptive Advertising Charges for Its "Brain Training" Program*, FED. TRADE COMM'N (Jan. 5, 2016), https://www.ftc.gov/news-events/press-releases/2016/01/lumosity-pay-2-million-settle-ftc-deceptive-advertising-charges [hereinafter *Lumosity to Pay*].

448. *Id.*

without a physician's provision or guidance.[449] Dangerously, "the imprimatur of science is often an integral part of their marketing."[450]

One particularly analogous example is recent FTC action against an app called Lumosity.[451] In its consumer protection struggle against misleading advertising, the FTC filed a complaint against the people behind the Lumosity "brain training" app.[452] The complaint centered around allegations of Lumosity's false or deceptive advertising, specifically that the app's employees "deceived consumers with unfounded claims that Lumosity games can help users perform better at work and in school, and reduce or delay cognitive impairment associated with age and other serious health conditions."[453] According to Jessica Rich, Director of the FTC's Bureau of Consumer Protection: "Lumosity preyed on consumers' fears about age-related cognitive decline, suggesting their games could stave off memory loss, dementia, and even Alzheimer's disease."[454] As Director Rich states, the FTC took issue because "Lumosity simply did not have the science to back up its ads."[455] To resolve this, the settlement included a stipulated court order, requiring Lumosity "to have competent and reliable scientific evidence before making future claims about any benefits for real-world performance, age-related decline, or other health conditions."[456] The FTC described the settlement as "the latest in a series of cases reminding advertisers that claims like that need solid scientific support."[457]

The settlement of Lumosity is akin to the situation of MH apps. The Lumosity app centered around gamification, "consist[ing] of 40 games purportedly designed to target and train specific areas of the brain."[458] While Lumosity boasted benefits to test scores and even athletic performance, it notably tailored its marketing to attract people with serious medical conditions, claiming "stroke patients and cancer survivors could regain cognitive abilities" and people with ADHD could "develop sustained attention and focus."[459] Similarly, MH apps utilize gamification, as well as other similar features explicitly intended to reduce or manage anxiety and

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449. Wexler & Reiner, *supra* note 314, at 234.
450. *Id.*
451. *Lumosity to Pay*, *supra* note 447.
452. *Id*.
453. *Id.*
454. *Id.*
455. *Id.*
456. *Id.*
457. Lesley Fair, *Mind the Gap: What Lumosity Promised vs. What It Could Prove*, FED. TRADE COMM'N (Jan. 5, 2016), https://www.ftc.gov/news-events/blogs/business-blog/2016/01/mind-gap-what-lumosity-promised-vs-what-it-could-prove.
458. *Lumosity to Pay*, *supra* note 447.
459. Fair, *supra* note 457.

depression.[460] In fact, Lumosity advertised its app to "improve outcomes in combat veterans suffering from traumatic brain injuries,"[461] not unlike the way MH apps have been specifically utilized with veteran PTSD.[462] Additionally, Lumosity emphasized consistent use for short daily periods,[463] similar to the EMA features of MH apps.[464]

<div align="center">CONCLUSION</div>

Dr. Eric Topol, a fierce advocate for digitalized medicine, prophesizes "a time ahead when every human being has the potential for the same access to medical care, provided they have a mobile signal, when medicine is no longer paternalistic and autocratic, when a reformation and a renaissance of medicine can take hold."[465] But until then, MH apps occupy an uneasy position in current legal frameworks. The consequences for continued inaction are life and death, so the users of these apps should compel more regulatory attention and fewer law review notes describing the lack thereof. Users of MH apps have no legal protection or remedy for preventable harm from use of these apps, and their very use of the apps speaks to their vulnerability. The FDA must download a system update to implement safeguards for users of MH apps, backed up by the FTC's consumer protection regulation.

Perhaps contextualizing this issue will speak louder, if not more convincingly. Reader, this is not an abstract concern. This is a lawyer's concern: as the country's "most frequently depressed occupational group,"[466] "lawyers suffer from the highest rate of depression" among all U.S. professionals[467] and "rank [fifth] in incidence of suicide by occupation."[468] This is a law student's concern: upon "[e]ntering law school, law students have a psychological profile similar to that of the general public. After law

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460. *See supra* Part II.D.1 (describing the features and functions of mental health apps).

461. Fair, *supra* note 457.

462. *See generally* Jason E. Owen et al., *VA Mobile Apps for PTSD and Related Problems: Public Health Resources for Veterans and Those Who Care for Them*, MHEALTH, July 2018, at 1 (describing how public health agencies, including the Department of Veterans Affairs, have used mobile technologies for treatment of PTSD).

463. *Lumosity to Pay*, *supra* note 447.

464. *See supra* notes 238–45 and accompanying text.

465. THE PATIENT WILL SEE YOU NOW, *supra* note 6, at 230.

466. *Lawyers & Depression*, DAVE NEE FOUND., http://www.daveneefoundation.org/scholarship/lawyers-and-depression/ (last visited May 6, 2020) [hereinafter DAVE NEE FOUND.].

467. Todd David Peterson & Elizabeth Waters Peterson, *Stemming the Tide of Law Student Depression: What Law Schools Need to Learn from the Science of Positive Psychology*, 9 YALE J. HEALTH POL'Y L. & ETHICS 357, 358 (2009).

468. DAVE NEE FOUND., *supra* note 466.

school, 20–40% have a psychological dysfunction."[469] And beyond this Author's claustrophobically self-preservational anxieties, this is a societal concern. As one, notably suicidal, writer noted: "Happiness in intelligent people is the rarest thing I know."[470] Another suicidal writer wrote: "There is an increasing market for mental-hospital stuff."[471] The mental health "market" increases all the while, as does its potential to cause injury. And until further action is taken, MH apps remain legally neglected, another illegible prescription for tragedy.

–Jena M. Richer[*]