Second Thoughts on FDA's Covid-Era Mental Health App Policy

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SECOND THOUGHTS ON FDA’S COVID-ERA MENTAL HEALTH APP POLICY

Michael Mattioli

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INTRODUCTION

As the coronavirus pandemic swept across the globe in April 2020, the US Food and Drug Administration (FDA) made an unusual decision. The agency announced that it would relax its enforcement of compliance rules for “digital therapeutics”—smartphone apps designed to address mental health disorders.1 The measure was a response to widely reported upticks in symptoms of anxiety, depression, and substance abuse brought on by the pandemic. As an added benefit, the agency explained, digital therapeutics could promote social distancing by removing patients’ need to visit health care providers.2

This essay explores the possible lasting effects of the FDA’s temporary suspension of its rules. After the FDA put its waiver into effect, makers of unapproved apps branded as “wellness” tools rebranded their products as medical interventions. That rebranding could harm patient privacy. Many “wellness” apps that have rebranded themselves as health interventions operate outside of the confidentiality and privacy laws that bind therapists and other healthcare providers. Many of these apps share user data more liberally than health care providers. The FDA’s temporary suspension of its enforcement could provide a glut of highly sensitive information to app developers and the partners they transmit user data to.

The FDA’s suspension of its rules could also suppress consumer confidence and, by extension, future innovation investments. Clinical studies do not back many wellness apps’ recent medical claims.3 If some of these apps are ineffective, consumers may categorically lose


2 Id. at 7.

confidence in app-based mental health interventions—including treatments that are effective. Suppressed consumer demand could lead to a kind of mental health app “winter”—a period in which investment and research dry up. This possibility highlights the relationship between innovation and consumer behavior. Regulations on advertising could have an unintended impact on innovation.

This essay begins with an explanation of how digital therapeutics fit into the history of mental health treatment. To anchor these concepts, I begin by offering a short introduction to the history and treatment of anxiety disorders—the most common class of mental health disorders in the United States. I then explain how the FDA regulates the marketing of mental health apps. Through before-and-after images of company websites, I show how the FDA’s 2020 suspension enforcement appears to have led app makers to rebrand their devices as medical interventions. Drawing on original interviews, press reports, and legal analysis, I postulate on the potential long-term consequences of the FDA’s temporary waiver.

I. BACKGROUND

In its 2020 announcement, the FDA listed common mental health disorders that it hoped to address by suspending enforcement. Anxiety disorders were the most common among these. For that reason, I begin with a short primer on the history and pathology of anxiety. My goal is to help readers unfamiliar with mental health disorders appreciate what is at stake. I then examine the new field of digital therapeutics (mental health apps) and the potential these technologies have to treat anxiety and other common disorders the FDA cited in its April 2020 announcement.

A. The Shadow Pandemic

In the saliva of every cat, there is a molecule that drives mice senseless with fear. Millions of these molecules, which scientists call

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4 See FDA April 2020 Announcement, supra note 1.
5 See id. at 11-12.
6 See Jeffrey B. Rosen et al., The Smell of Fear: Innate Threat of 2,5-dihydro-2,4,5-
fel d 4, permeate the air whenever a cat sheds. If a nearby mouse inhales a few, its bloodstream floods with a hormone that bears a dire message: “Death is near.” The mouse will flatten itself against the ground, tremble, and, as its heart rate spikes, search for an exit. The mouse’s terror is pitiful but also strange, because strictly speaking, it does not require the presence of a cat. Douse a cotton ball in fel d 4 and present it to a mouse that has never seen a cat before, and the mouse will panic all the same. Some fears are hardwired.

For the 40 million Americans who live with chronic anxiety, the mouse’s distress is familiar. Nearly all forms of this disorder carry similar symptoms, including restlessness, muscle tension, increased heart rate, trembling, and the release of stress-response hormones into the bloodstream. A century ago, a Harvard professor named Walter Cannon coined the term “fight or flight” to describe this response. Although they might sound like opposite reactions to danger, the body prepares for both fight and flight in the same way. Like the mouse, anxiety sufferers can experience these symptoms even when there is no threat present. Some repeatedly relive past trauma, while others dread the future. In both situations, daily life becomes an exercise in vigilance.

What causes anxiety? Ancient people in some parts of the world believed that mental distress was a form of divine punishment. The book of Deuteronomy teaches that God inflicts madness upon those who disobey his commandments. In the Athenian tragedy, Herakles, the God Hera punished Hercules (a demi-god) by “sending madness

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7 *Id.*

8 See *id.*

9 See *id.*


13 See *id.*
upon him.”¹⁴ The Greek God, Pan, meanwhile, gave us the root of the word *panic*.¹⁵ His war cry was said to fill mortals with terror.¹⁶ Similar ideas are woven into countless myths, fables, and legends across many cultures. Accordingly, many early “remedies” for anxiety focused on appeasing the gods.¹⁷ Prayer, chanting, and sacrificial offerings were common “prescriptions” in the ancient world.

As a more corporeal view of anxiety developed, remedies became more practical. Historians trace the first scientific studies of mental disorders to ancient Greece. There, Hippocrates of Cos, who lived from 460 to 370 BCE, suggested that anxiety originates in the head rather than the heavens.¹⁸ A pivotal Hippocratic text states that the brain is what “makes us mad or delirious, inspires us with dread and fear, . . . brings sleeplessness, inopportune mistakes, aimless anxieties, absent-mindedness, and acts that are contrary to habit.”¹⁹ Unlike earlier spiritual explanations for anxiety, Hippocrates’ views were clinically-based. He and his disciples methodically studied and documented patients who suffered from the disorder.²⁰

Most historians credit Aristotle (384 to 320 BCE) for first describing anxiety as a disease rather than just an unpleasant feeling.²¹ In a famous book on ethics, he wrote, “[T]he man who is by nature apt to fear everything, even the squeak of a mouse, is cowardly . . . while

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¹⁶ See id.


²¹ See Burton, supra note 14.
the man who feared a weasel did so in consequence of disease.”22 In Ancient Greece, this distinction was significant. There, culture demanded that men show bravery regardless of the dangers they faced.23 Courage was a reflection of character and a determinant of social standing.24 An inappropriate display of fear in battle, or worse, outside of battle, could ruin one’s social and professional standing.25 Aristotle’s views helped make anxiety the subject of scientific study, changing how it had been understood and treated.

Scientific analysis has revealed a clearer picture of what causes anxiety. We know today, for instance, that the disorder has no single cause. Rather, it arises from various factors, including genetic predisposition, childhood home environments, isolated traumatic experiences, brain chemistry, and lifestyle factors.26 Researchers have also gained an important understanding of the mechanisms that underlie the problem. Neuroimaging has allowed scientists to identify the brain structures that relate to anxiety.27 (For example, scientists have seen that the brains of Buddhist monks under meditation do not light up in the same ways as people who are panicking.)28 Separately, scientists have known since the 1970s that anxiety and depression are related to the brain’s use of a chemical called serotonin.29 Relatedly, researchers recently identified specific genes that correlate with certain anxiety disorders.30


24 See id.

25 See id.

26 See W. Thomas Boyce et al., Genes and Environments, Development and Time, 117 PNAS (Special Feature: Introduction) 23235, 23235-36 (2020).

27 See Kathrin Holzschneider & Christoph Mulert, Neuroimaging in Anxiety Disorders, 13 DIALOGUES IN CLINICAL NEUROSCI. 453, 453 (2011).


As promising as they are, these advances have not yet made life any easier for patients. Seeking treatment for anxiety today places one in a labyrinth of classifications, acronyms, drug compounds, and theories of the mind. Contradictions seem to arise everywhere, beginning with the diagnosis. To be diagnosed with anxiety, one must meet specific criteria for an anxiety disorder listed in the Diagnostic and Statistical Manual ("DSM"), a book of standards used throughout the mental health profession. Forms of anxiety recognized in the DSM include (i) generalized anxiety disorder, (ii) panic disorder, (iii) social anxiety disorder, (iv) obsessive-compulsive disorder, (v) post-traumatic stress disorder, and (vi) specific phobias. The criteria for diagnosis are precise. For instance, to qualify for having a phobia, a patient must demonstrate:

1. an unreasonable, excessive fear triggered by a specific object or situation
2. an immediate anxiety response out of proportion to any actual danger
3. extreme distress or avoidance of the feared object or situation; and
4. significant impact on school, work, or personal life
5. for at least six months

Critics of the DSM—and there are many—argue that its rigid criteria are out of sync with the fluidity of human psychology. Additionally, there is a lack of uniformity in how medical professionals apply DSM criteria to each patient.

Today, one of the most common treatments for anxiety is cognitive-behavioral therapy ("CBT"). This treatment is grounded in

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34 Cognitive Behavioral Therapy, MAYO CLINIC (Mar. 16, 2019), https://www.mayoclinic.org/tests-procedures/cognitive-behavioral-therapy/about/pac-20384610. This form of psychotherapy is often prescribed in combination with psychotherapeutic medication.
the recent discovery that anxiety is a self-reinforcing behavior that stems from a misunderstanding of the world. Our minds create cognitive structures (constructs) that allow us to apply our past understanding of the world to our ongoing experience of reality. In the mind of a person experiencing anxiety, some of these constructs are faulty. For instance, some anxiety sufferers tend to think about future events in binary or “black-and-white” terms. The results of a routine blood pressure reading or cholesterol test will reveal either perfect health or imminent death. These beliefs can lead to intense feelings of fear both before and after the test. Faulty cognitive constructs are tenacious and persist even if the anxiety sufferer is entirely aware that their fears are unfounded. The body seems to believe even what the brain knows to be untrue. Like the mouse’s response to fel d 4, the fear is hardwired.

Patients who undergo CBT treatment learn to identify and challenge common patterns of faulty thinking. Rather than learning to push fearful thoughts away, CBT requires patients to make a habit out of noting and considering their thoughts and feelings, as well as the events that give rise to anxiety-inducing thoughts and feelings. The patient must then systematically consider evidence that challenges the thoughts or feelings and apply it to their situation. Therapists typically tell their patients to keep a daily journal and practice workbook exercises that focus on common patterns of distorted thinking. Repetition of this process, combined with relaxation breathing techniques, can restructure the faulty constructs in the

35 Michael Mattioli, Pooling Mental Health Data with Chatbots, in GOVERNING PRIVACY IN KNOWLEDGE COMMONS 70, 75 (Katherine Strandburg et al. eds., Cambridge Univ. Press 2020).
36 See id.
38 See id.
mind. CBT is used to treat a range of mental health disorders beyond anxiety, including depression, substance abuse, and more.

**B. The Rise of Digital Therapeutics**

In the mid-2010s, software makers began developing and selling smartphone apps that apply various forms of CBT. Because the FDA did not authorize the marketing of these “digital therapeutics” until 2017, such apps have long been branded as promoting “wellness” or well-being rather than treatments for medical conditions. Many such apps administer CBT through interactive lessons, games, and journaling software. Most recently, AI-driven chatbots (“conversational agents”) have been developed to administer CBT and other established forms of treatment through apps. Most conversational agents play a therapist-like role by asking users to share information about themselves and their thinking patterns. These systems then lead users through sets of structured lessons designed to identify and challenge common cognitive distortions. Recently, some app developers have started reaching beyond textual input by applying machine learning algorithms to identify facial expressions and vocal cues.

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40 Id.
41 Id.
44 Id.
46 See Kathleen Kara Fitzpatrick et al., *Delivering Cognitive Behavior Therapy to Young Adults with Symptoms of Depression and Anxiety Using a Fully Automated Conversational Agent (Woebot): A Randomized Controlled Trial*, 4 JMIR MENTAL HEALTH 1, 3 (2017).
47 Id.
Prior to FDA’s April 2020 announcement, software makers that wished to market their apps as medical interventions had to demonstrate safety and efficacy to the FDA. There are a few ways to do this. Some medical devices pose such a low risk to consumers that the FDA will clear them for sale as long as they are manufactured according to standard practices and labeled appropriately for consumers. The FDA calls these “Class I” devices. Moderate-risk “Class II” devices, by contrast, must meet higher safety performance standards. Makers of higher-risk “Class III” devices can receive FDA approval only by providing the agency with robust scientific evidence of safety and efficacy. Alongside this three-tiered classification system are special rules that relate to how “novel” a device is. If a device is “substantially equivalent” to a device that the FDA has already approved, the manufacturer can request a streamlined form of marketing clearance. This process is called a “510(K) premarket submission.” If a device is of a new kind, the manufacturer can request that the FDA classify and authorize its sale through the agency’s “De Novo” review pathway.

49 21 C.F.R. § 801.4 (2018). The FDA’s authority to oversee these apps stems from the expansive definition of “medical device” in the 1976 amendments to the Federal Food, Drug, and Cosmetic Act (FDCA). “[A]n instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease . . . or intended to affect the structure or any function of the body . . .” 21 C.F.R. § 801.4 (2016). Intent is a fact-based inquiry.


51 Id.

52 Id.

53 Id. at 2; see also Premarket Approval (PMA), U.S. FOOD & DRUG ADMIN. (May 16, 2009), https://www.fda.gov/medical-devices/premarket-submissions/premarket-approval-pma.

54 U.S. FOOD & DRUG ADMIN., supra note 50.


The FDA cleared the first digital therapeutic app that uses CBT in 2018.\textsuperscript{57} Called “reSET,” the app is sold by Pear Therapeutics to treat substance abuse disorder.\textsuperscript{58} reSET works by administering a form of cognitive-behavioral therapy (”CBT”) tailored to help overcome thought patterns that lead people to abuse harmful drugs such as cocaine.\textsuperscript{59} As the company explained in an FDA filing, “reSET consists of several therapy lessons (modules) that are intended to teach the user . . . skills to aid in the treatment of substance use disorder. These lessons teach users to avoid substance use, cope with thoughts about substance use, take responsibility, and more.”\textsuperscript{60} Pear supplied the FDA with the results of a 12-week clinical trial of 399 patients.\textsuperscript{61} According to an FDA press release, the data “showed a statistically significant increase in adherence to abstinence for the patients with alcohol, cocaine, marijuana, and stimulant SUD in those who used Reset.”\textsuperscript{62} The study participants experienced no side effects from using the app.\textsuperscript{63}

In June 2020, the FDA permitted the marketing of another CBT-based app, EndeavorRX, designed to treat childhood attention-deficit

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\textsuperscript{57} The FDA decided to clear reSET through the de novo premarket review pathway. See FDA Clears Mobile Medical App to Help Those with Opioid Use Disorder Stay in Recovery Programs, U.S. FOOD & DRUG ADMIN. (Dec. 10, 2018), https://www.fda.gov/news-events/press-announcements/fda-clears-mobile-medical-app-help-those-opioid-use-disorder-stay-recovery-programs. (“The reSET-O is an app that can be downloaded directly to a patient’s mobile device after they receive a prescription to do so from their doctor. It is intended to be used while participating in an outpatient OUD treatment program. . . It includes a compliance reward system– such as earning special icons on a prize wheel within the app.”)


\textsuperscript{59} Id.

\textsuperscript{60} U.S. FOOD & DRUG ADMIN., DE NOVO CLASSIFICATION REQUEST FOR RESET (2016), https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN160018.pdf.

\textsuperscript{61} Id.


\textsuperscript{63} Id. (suggesting that there were no notable side effects following the use of reSet).
hyperactivity disorder (ADHD). ADHD is a neurodevelopmental condition that, left untreated, can significantly interfere with a child’s growth and healthy development into adulthood. Talk therapy, commonly prescribed, is often expensive and in short supply. By comparison, EndeavorRx runs on any modern iPad. According to Akili Interactive, which makes and sells the app, EndeavorRX “is designed to directly target and activate neural systems through the presentation of sensory stimuli and motor challenges to improve cognitive functioning.” The FDA approved the app after reviewing five clinical studies involving over 600 children, many of whom exhibited improvements in attention after using the app. Like reSET, the app presented no serious side effects.


65 See, e.g., About ADHD – Overview, CHADD.ORG, https://chadd.org/about-adhd/overview/. This specifically addresses Children and Adults with Attention-Deficit/Hyperactivity Disorder (CHADD).

66 Mattioli, supra note 36, at 75.


69 Id.

II. COVID-19: FDA Enforcement and Product Marketing

In April 2020, the FDA announced that it would temporarily suspend its usual enforcement practices against “computerized behavioral therapy devices and other digital health therapeutic devices for psychiatric disorders.”\(^{71}\) The agency explained its rationale as follows:

In the context of the COVID-19 public health emergency, the use of digital health technologies, including software as a medical device or other digital therapeutics solutions, may improve mental health and well-being of patients with psychiatric conditions during periods of shelter-in-place, isolation, and quarantine. In addition, the use of such technologies has the potential to facilitate “social distancing” by reducing patient contact with, and proximity to, health care providers, and can ease the burden on hospitals, other health care facilities, and health care professionals that are experiencing increased demand due to the COVID-19 public health emergency.\(^{72}\)

The agency also stated that it would not demand clinical data to validate the efficacy of such apps.\(^{73}\)

This is not the first time that the FDA has exercised its discretionary authority to make certain products more available to the public in emergencies. Under a 2004 law, the agency may, during public emergencies, authorize the use of medical products that have not been “approved, licensed, or cleared for commercial distribution.”\(^{74}\) The following year, the agency exercised this authority to permit an anthrax vaccine to be administered to certain people who were at risk of exposure.\(^{75}\) In 2009, shortly after the H1N1 virus had been confirmed to be circulating in the U.S., the agency again exercised this authority to permit the use of certain tests and medications.\(^{76}\)

\(^{71}\) FDA April 2020 Announcement, supra note 1.

\(^{72}\) Id.

\(^{73}\) Id.


\(^{75}\) Authorization of Emergency Use of Anthrax Vaccine Adsorbed for Prevention of Inhalation Anthrax by Individuals at Heightened Risk of Exposure Due to Attack With Anthrax; Availability, 70 Fed. Reg. 5452 (Feb. 2, 2005).

\(^{76}\) Termination of the Emergency Use Authorization (EUA) of Medical Products and Devices, Ctrs.
2015, the agency again called upon its emergency use authority to permit the use of certain drugs for the Ebola virus.\textsuperscript{77} Unlike some drugs, the FDA believes that mental health apps categorically present low risks to consumers.\textsuperscript{78}

Under certain circumstances, the FDA has also provided a one-year “grace period” of non-enforcement.\textsuperscript{79} The agency does so when a company has received approval to market a product that is being marketed by other companies that do not have approval.\textsuperscript{80} Typically, the agency gives the non-approved companies a one-year window (beginning from the date of approval) before it initiates enforcement actions such as seizure or injunctions.\textsuperscript{81} This grace period is not set in stone, however. The agency handles such situations on an ad hoc basis and in light of factors such as public safety, the difficulty of completing clinical studies, and the burdens on affected parties, among other circumstances.\textsuperscript{82}

It seems that app makers took notice of the FDA’s enforcement suspension. Since April 2020, app makers have introduced new products and changed the marketing of existing “wellness” apps to include more medical language, and in some cases, to explicitly claim certain medical benefits.\textsuperscript{83} While there is no direct evidence that these changes (which are documented in the following paragraphs) were responses to the FDA’s enforcement rollback, the timing and context suggest a causal relationship.


\textsuperscript{78} See FDA April 2020 Announcement, supra note 1, at 6.

\textsuperscript{79} CTR. FOR DRUG EVALUATION & RESEARCH, CPG § 440.100, MARKETED NEW DRUGS WITHOUT APPROVED NDAS AND ANDAS (Sept. 2011), https://www.fda.gov/media/72007/download.

\textsuperscript{80} Id.

\textsuperscript{81} Id.

\textsuperscript{82} Id.

\textsuperscript{83} Tom Simonite, The Therapist Is In – And It’s a Chatbot App, WIRED (June 17, 2020, 07:00 AM), https://www.wired.com/story/therapist-in-chatbot-app.
A Swedish pharmaceutical company called Orexo, for instance, had been seeking FDA clearance for three CBT apps that target substance abuse when the agency suspended its enforcement of such apps. The policy change led the company to launch all three apps and to offer its app to U.S. patients. Pear Therapeutics, the developer of reSET and reSET-O, was running clinical trials on an app designed to treat schizophrenia when the FDA’s announcement came. Since then, the company’s CEO has announced that it will launch all its apps currently in development before winter.

Woebot Labs, which makes a conversational agent that implements CBT, seems to have responded to the agency’s announcement as well. Before the announcement, the company’s website made claims that steered clear of specific medical terminology. For instance, the website stated, “We want to help you feel the best, no matter how you’re feeling on a given day. Sign up and give Woebot a try for free now!”

After the FDA’s announcement, the company launched a new website with what appeared to be unambiguously medical claims:

[Our company and products... deliver expert emotional support and tools in an easily-accessible app to help reduce anxiety and depression symptoms. Woebot, our chat-based tool, is the delivery mechanism for a suite of clinically-validated therapy programs that address many of today’s mental health challenges, from generalized anxiety and depression to specific conditions like postpartum depression, adult and adolescent depression, and substance abuse.

In the past, Woebot has avoided branding itself as a replacement for traditional therapy. Following the FDA’s announcement, however, the company branded the app as a solution to help fill the gap in mental health treatment. By February 2021, the website more

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84 Id.
85 Id.
86 Id.
87 See infra Appendix, Woebot Website – April 21, 2020 screenshots.
88 See infra Appendix, Woebot Website – Summer 2020 screenshots.
89 See infra Appendix, Woebot Website – April 21, 2020 screenshots.
deliberately presented the technology as a mental health intervention, stating that it offered “highly targeted therapeutics that address users’ specific symptoms.”91 The website also claimed the product is designed to make therapy more accessible.92 Finally, the 2021 version of the site listed “adult mental health,” “adolescent mental health,” and “substance abuse” among the conditions it could treat.93

The branding for another popular CBT conversational agent called “Youper” underwent a similar change. Before the FDA’s announcement, the app’s website called the app an “Emotional Health Assistant” and told visitors, “Understand yourself, track your mood and monitor your emotional health.”94 Following the FDA’s announcement, the website called the app “AI Therapy” and explained that “AI Therapy is modern mental health care.”95 Like Woebot, Youper has explicitly rebranded itself as a mental health intervention that has benefits over traditional therapy. The website explicitly claims that the product can help users experiencing anxiety, depression, and a range of other mental health disorders.96 Similarly, before the FDA’s announcement, another popular app called Moodfit...
offered “tools & insights to shape up your mood.” After, it became “Fitness for Your Mental Health.”

It is unclear whether these branding changes have had, or will have, any influence on consumer decision-making. Since the summer of 2020, there have been some reports of increased downloads of such apps. But this data is largely anecdotal. Any uptick in download might have merely been a reflection of the widespread anxieties of living through a global pandemic rather than changes to marketing on websites and app stores. There is, then, good reason to be skeptical about how much of a difference these advertising changes have on consumer behavior. Before considering the possible policy effects of the FDA’s April 2020 enforcement rollback, it is important to keep this in mind.

III. CONCERNS ABOUT PRIVACY AND INNOVATION

An important motivation for FDA’s April 2020 decision was the agency’s belief that mental health apps do not pose substantial safety risks to consumers. In their April 2020 announcement, FDA stated its belief that they “present a low risk to the safety of users and other persons.” Many such apps pose an important non-medical risk to users, however, in the form of data privacy. In this section, I explore the nature of these privacy risks. I then postulate on a risk facing companies in this new industry. A glut of ineffective apps could weaken consumer confidence and, by extension, innovation investments in this new and promising field of technology.

It’s important to highlight what we don’t know. The following discussion is based on two inferences for which no evidence exists: first, that the branding changes documented in Part II of this essay.

100 FDA April 2020 Announcement, supra note 1, at 6
were responses to the FDA’s enforcement rollback; second, that these branding changes might influence consumer decision making. At the moment, we can only infer that there’s some truth to these hypotheses based on the available context. This includes the timing of the branding changes and the likelihood that corporations have changed their branding language because they believed doing so would attract more users. In the future, scholars may be able to test the first inference by interviewing corporate principals and brand managers; the second inference could be examined through a carefully designed study. The discussion below aims to show that these are questions worth exploring.

A. Data Privacy

What does it mean to say that mental health information is, or should be, “private?” Because privacy is an amorphous idea—one scholar aptly called it “chameleon-like”—it is important to be specific. What does mental health information comprise? Who has a burden to keep such information secret, and in what contexts? How are these responsibilities encoded in the law? What policy goals do such laws promote?

The last question is the easiest to answer. In many cultures, people with mental health disorders have historically suffered stigma. The law has contributed to this. As recently as the 1960s and 1970s, many states had laws that branded people who had been hospitalized for mental health treatment as incompetent, making it impossible for them
to enter into contracts, vote, or make treatment decisions for themselves. Federal and state laws now prohibit such discrimination. Thankfully, popular culture has also helped to destigmatize some common disorders such as anxiety and depression in recent years. Even so, stigma and the anticipation of stigma are a reality for many.

The privacy concern is about disclosure. For people who face or fear stigma, the disclosure of a mental health disorder or the mere fact they have sought treatment could cause distress and embarrassment. Beyond stigma, disclosure of some mental health conditions can lead to financial or reputational harm. Fears about disclosure can also impede treatment. The National Alliance on Mental Health estimates that eight out of every ten employees with a mental health problem do not seek treatment because they experience feelings of shame.

As the Supreme Court noted in a 1996 decision concerning the confidentiality of therapy records, “[T]he mere possibility of disclosure may impede development of the confidential relationship necessary for successful treatment.”

U.S. laws that prohibit the disclosure of mental health information often focus on the source of disclosure as well as the content. The most relevant federal law is the Health Insurance Portability and Accountability Act of 1996 (HIPAA). This statute permits health care providers to disclose an individual’s health information only for a narrow set of purposes. The Act includes within its definition of

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105 See also, e.g., Americans with Disabilities Act of 1990 (ADA) 42 U.S.C. § 12101(b) (1990).
106 See generally STIGMA AND MENTAL ILLNESS, supra note 104.
110 45 C.F.R. §160.103 (2019). (The statute defines “health information” as “any information, including genetic information, that is created or received by a health care provider, health plan, public health authority, employer, life insurance company, school or university, or health care clearinghouse; and relates to the past, present, or future physical or mental health
“health information” any information received by health care providers that “relates to the past, present, or future physical or mental health or condition of an individual.”111 Permitted disclosures include responding to law enforcement requests, providing treatment, obtaining reimbursement from insurers, and preventing imminent public safety threats.112 “Psychotherapy notes” are subject to heightened protections. These records may be disclosed only through a rigorous process of patient authorization.113 Importantly, HIPAA applies only to health care providers (including mental health professionals) and their business associates.114

Many states limit the disclosure of mental health information even more stringently than HIPAA.115 For example, Massachusetts law requires psychologists to keep their records private but, unlike HIPAA, does not permit information to be shared with third parties for treatment-related purposes.116 Other states, including Nebraska and New Mexico, have absolute obligations of confidentiality.117 Mental health care providers are also subject to confidentiality rules imposed by state licensing boards. Finally, torts such as the public disclosure of private facts could prevent certain disclosures. This cause of action can be asserted against someone who publicly discloses a private matter of no legitimate concern to the public and “highly offensive to a reasonable person.”118

Many mental health and wellness apps collect the same mental health information that healthcare professionals collect, and sometimes much more. This information includes users’ names, email

or condition of an individual; the provision of healthcare to an individual . . . “).

111 Id.
112 45 C.F.R. § 164.512.
114 45 C.F.R. § 160.102.


116 MASS. GEN. LAWS ch. 112 § 129A (2019)
117 See also NEB. REV. STAT. ANN. § 38-2136 (West); N.M. STAT. ANN. § 61-9A27(West); UTAH CODE. ANN. § 58-61-602(2)(c)(LexisNexis).

addresses, phone numbers, unique identifiers tied to their smartphones, and the specific mental health conditions they seek to treat. Many apps also capture information that would ordinarily be contained in psychotherapy notes. Apps that administer CBT to treat mental health disorders, for instance, often collect and store users’ written descriptions of their thoughts. Some CBT-based apps also collect and store user responses to periodic quizzes and check-ins. Collecting, storing, and analyzing such information in cloud servers is integral to how many of these apps work. App providers can use such data to tailor the app to an individual user, train machine learning algorithms, or gain general new insights about how people use an app.

Mental health and wellness apps have greater freedom than mental health professionals to disclose user data to third parties. With few exceptions, state statutes designed to prevent disclosure of medical data do not appear to apply to apps. HIPAA, meanwhile, applies only to health information collected by “covered entities.” Apps used solely by consumers outside of any therapeutic context don’t fall under the Act’s definition of a covered entity.

This is evident in the privacy policies that mental health apps publish on their websites and in app stores. Thousands of wellness apps that have not received FDA approval (but someday might) contain expansive privacy policies or no privacy policies at all. A recent comprehensive study of mental health app data practices


120 See, e.g., Mattioli, supra note 36.


concluded, “[t]he field of mental health apps is beset by risks to user privacy.”\textsuperscript{124}

Might some mental health app users have an expectation of greater privacy? This seems like a reasonable possibility. It is widely known that the information one shares with a therapist is confidential. It might not be widely known, however, that the same rules do not apply to app developers. (Recall that many privacy laws focus not just on the information disclosed but also the source.) A user could be forgiven for assuming that an app that brands itself as a replacement for medical care has more stringent privacy protections than Instagram.

B. Consumer Confidence and Innovation Investments

In addition to its impact on user privacy, the FDA’s enforcement rollback could have consequences for innovation. The concern is easy to appreciate: a glut of ineffective apps marketed to the public as health interventions could erode consumer confidence in mental health apps. If this occurs, market demand for such apps may be weakened, in turn weakening innovation investments in this area.

Intellectual property scholars have long recognized that market demand is often a necessary precondition for innovation.\textsuperscript{125} Arguably, the U.S. patent system is premised on this notion. Incentive theory holds that the limited exclusive rights patents confer encourage inventors an opportunity to recoup their investments by commercially exploiting their inventions.\textsuperscript{126} (To be sure, many patented inventions are ultimately not commercialized – an important issue that Ted Sichelman has carefully called attention to.)\textsuperscript{127} But, in broad strokes, the patent system assumes that a market either already exists at the time of the invention or that one can be developed.

\textsuperscript{124} Id. at 203.

\textsuperscript{125} See, e.g., Benjamin N. Roin, \textit{Intellectual Property Versus Prizes: Reframing the Debate}, 81 U. CHI. L. REV. 999, 1008 (2014) (noting that intellectual property “introduces artificial scarcity into the market for inventions, forcing consumers to reveal their willingness to pay for those products. As a result, it allows the government to link the profits from innovation to consumer demand—a market-based metric…”).

\textsuperscript{126} Id.

Peter Lee is one of the leading voices that has called attention to the relationship between market demand and innovation, writing, “it is ultimately the pull of market demand that motivates private innovation.”128 Expanding on this theme, Lee later wrote, “Among its other virtues, the patent system is often extolled as a neutral platform in which the market—rather than a government entity—determines the allocation of resources for technological development.”129 Writing in a similar vein, Ofer Tur-Sina has noted, “market demand appears to have a leading role in driving technological innovation in society.”130

What happens when a consumer discovers that an app that claims to treat anxiety or depression is ineffective? Because the FDA has enabled unapproved apps to make such claims, it is reasonable to think that some, or perhaps many, consumers will have this experience. Will some disappointed consumers in this group seek out higher quality apps that bear the words “FDA Approved” or “FDA Cleared?” It’s possible. It seems likely, though, that many such consumers will lose confidence in the idea that a smartphone can help them to feel better. In the aggregate, this could diminish consumer demand for mental health apps. This, in turn, could diminish future innovation investments in the field.

If this possibility seems remote, it is worth knowing that executives and researchers I have recently interviewed voiced this very concern to me. The CEO of a company that makes one of the most popular mental health apps stated, “I would love to see more regulation, honestly, because the fact is, there hasn’t been any. And if health and wellness apps with no support for efficacy [are quickly adopted] … that threatens the public’s confidence.”131 A prominent researcher echoed the concern. Commenting on “digital phenotyping” apps that assemble a portrait of user mental health, the researcher stated, “Consumer trust is essential. Without it, we could have a digital phenotyping winter.”132

131 Interview with anonymous source (Summer 2020).
132 Id.
A lack of consumer trust doesn’t always signal the death knell for innovation, of course. Some products have succeeded in overcoming public distrust. Often though, regaining the public’s confidence is difficult. For Elisha Otis, the inventor of the elevator, it famously took a public stunt.\textsuperscript{133} In an attempt to quell the public’s fear of elevators, he repeatedly rode one that had been specially constructed for public display at the New York World’s Fair in 1854.\textsuperscript{134} To the shock of crowds, he slashed the suspension ropes with a saber, causing himself to momentarily plummet before his patented safety brakes kicked in.\textsuperscript{135} (At this point, Otis reportedly would announce, “All safe, ladies and gentlemen. All safe.”)\textsuperscript{136} Successfully commercializing his distrusted invention was for Otis literally an uphill climb.\textsuperscript{137}

We should want continued innovation investments in mental health apps. Although the technology is fairly new, there is some evidence that smartphones can serve a meaningful role in the treatment and diagnosis of mental health problems.\textsuperscript{138} In fairness, much of the existing evidence is reported in clinical studies that app providers prominently post on their websites. Youper, for instance, claims that more than 80% of its users “experience a reduction in negative moods after just one conversation.”\textsuperscript{139} Studies show that another app called Wysa has promise in reducing anxiety symptoms, particularly in assisting children.\textsuperscript{140} It is important to note that some


\textsuperscript{134} Id.

\textsuperscript{135} Id.

\textsuperscript{136} Id.


\textsuperscript{138} Tara Donker et al., \textit{Smartphones for Smarter Delivery of Mental Health Programs: A Systematic Review}, 15 J. MED. INTERNET RSCH. 1, 7-8 (2013).


\textsuperscript{140} See also \textit{VICE} News, \textit{AI Won’t Replace Therapy – Yet}, YOUTUBE (Dec. 17, 2018),
experts are doubtful about such positive claims, however. One nationally recognized academic researcher in the field commented in an interview for this article that the claims of efficacy are supported by weak evidence that has not been replicated.\textsuperscript{141} This expert went on to opine, however, that there is evidence that these interventions can work as adjuncts to (rather than replacements for) traditional medical care.\textsuperscript{142}

Apps could also offer some special benefits as compared to traditional therapy. Many people afflicted with mental health disorders neglect to seek out therapy due to feelings of stigma.\textsuperscript{143} These feelings might be lessened by an app that can be used in the privacy of one’s home—assuming the app provides meaningful privacy to the user, of course. These apps could reach populations that are both in great need of care and who also tend to decline it. LGBTQ+ youth, for example, reportedly prefer to seek mental healthcare on apps and websites.\textsuperscript{144} In short, suppressed innovation in the mental health app industry could lead us to miss out on much-needed new technologies.

\section*{Looking Ahead}

Generally, emergencies are when we are least likely to think about the long-term consequences of our decisions. The FDA had surely hoped that its April 2020 enforcement rollback would address the country’s spiraling mental health crisis.\textsuperscript{145} But this short-term decision could have harmful long-term effects. First, the temporary measure has provided companies with a resource that will long outlive the COVID-19 emergency: patient data. Many of these apps collect data of all kinds pertaining to individual mental health struggles. Because wellness apps exist outside the legal framework that traditionally

\textsuperscript{141} Interview with anonymous source (Summer 2020).
\textsuperscript{142} Id.
\textsuperscript{143} Patrick W. Corrigan et al., \textit{The Impact of Mental Illness Stigma on Seeking and Participating in Mental Health Care}, 15 PSYCH. SCI. PUB. INT. 37, 40 (2014).
\textsuperscript{144} Emily Dreyfus, LGBTQ+ Youth Prefer to Seek Mental Health Help Digitally, \textit{Wired} (June 11, 2019, 5:41 PM), https://www.wired.com/story/lgbtq-mental-health-digital-outreach/.
\textsuperscript{145} See FDA April 2020 Announcement, supra note 1.
governs patient privacy, they are free to share it with third parties in ways that conflict with consumer expectations. This risk about unexpected disclosure of mental health information existed before the FDA’s 2020 rule, of course. But, by permitting unapproved apps to make healthcare advertising claims, the agency may have worsened it.

The agency’s decision could also harm the very population that it appears to benefit. A glut of ineffective apps could dampen market demand and, over time, dampen innovation investments in this space, leading to a mental health app winter. This would be bad for companies and for the public. This technology shows great promise.

This essay aims to call attention to a potential problem. The next step is for policymakers at the FDA and interested industry parties to begin exploring solutions. Privacy concerns could be addressed immediately if the industry was only willing to find business models that don’t depend so much on user data. Mental health app makers should search for ways to turn a profit while providing the same level of data privacy and confidentiality that therapists offer. The tech industry should also search for new ways to signal app quality to consumers. Perhaps Apple and Google, the gatekeepers of the app stores that serve us, should play a greater role in communicating efficacy. (As of this writing, Apple has already taken a similar step by offering privacy “nutrition labels” to consumers.\footnote{Samantha Murphy Kelly, \textit{Apple Rolls out Privacy ‘Nutrition Labels’ on Apps}, CNN (Dec. 14, 2020, 1:41 PM), https://www.cnn.com/2020/12/14/tech/apple-privacy-labels/index.html.} Another route would be for the mental health app industry to develop an independent organization that scores apps for efficacy and privacy. Today, it’s unknown if these or other approaches would be most useful. It seems time, though, that policymakers, app makers, and the public begin thinking long-term about mental health apps.
APPENDIX: EXAMPLES OF MARKETING CHANGES FOLLOWING FDA’S SUSPENSION OF ENFORCEMENT

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In the last decade alone, we’ve seen a 13% rise in mental health conditions and substance use disorders worldwide. More than 264 million people of all ages and geographies suffer from depression, while 1 in 5 of the world’s children and adolescents have a mental health condition. Alcohol abuse kills 3 million people every year, 31 million who use drugs suffer from substance abuse disorders.

Significant barriers exist to getting care, chief among them the longstanding stigma associated with mental illness. But there’s an even more dire reality: as recent events push more people to the brink, there simply aren’t enough clinicians and specialists to treat everyone who needs help.

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