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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

¹ See U.S. FOOD & DRUG ADMIN., ENFORCEMENT POLICY FOR DIGITAL HEALTH DEVICES FOR TREATING PSYCHIATRIC DISORDERS DURING THE CORONAVIRUS DISEASE 2019 (COVID-19) PUBLIC HEALTH EMERGENCY: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (2020), <https://www.fda.gov/media/136939/download> [hereinafter FDA April 2020 Announcement].

² *Id.* at 7.

³ See Jessica Davis, *Consumer Adoption of Health Tech Slowed by Privacy, Security Concerns*, HEALTHITSECURITY.COM (Jan. 7, 2020), <https://healthitsecurity.com/news/consumer-adoption-of-health-tech-slowed-by-privacy-security-concerns>; Christina Farr, *Tech Companies See Health Data as a Huge Opportunity, but People Don’t Trust Them*, CNBC.COM (Feb. 13, 2019, 10:36 AM EST), <https://www.cnbc.com/2019/02/13/consumers-dont-trust-tech-companies-with-health-data-rock-health.html>.

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.⁴ Anxiety disorders were the most common among these.⁵ 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.⁶ Millions of these molecules, which scientists call

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.⁷ If a nearby mouse inhales a few, its bloodstream floods with a hormone that bears a dire message: "Death is near."⁸ The mouse will flatten itself against the ground, tremble, and, as its heart rate spikes, search for an exit.⁹ 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,¹⁰ 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.¹¹ A century ago, a Harvard professor named Walter Cannon coined the term "fight or flight" to describe this response.¹² 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.¹³ In the Athenian tragedy, *Herakles*, the God Hera punished Hercules (a demi-god) by "sending madness

TRIMETHYLTHIAZOLINE, A SINGLE MOLECULE COMPONENT OF A PREDATOR ODOR 2 (Markus Fendt et al. eds. 2015), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4548190/pdf/fnins-09-00292.pdf>.

⁷ *Id.*

⁸ *See id.*

⁹ *See id.*

¹⁰ *Facts & Statistics, ANXIETY & DEPRESSION ASS'N OF AMERICA*, <https://adaa.org/understanding-anxiety/facts-statistics#> (Apr. 21, 2021).

¹¹ *See Sadaf Munir, Generalized Anxiety Disorder, STATPEARLS: MEDICAL REF.*, <https://www.statpearls.com/articlelibrary/viewarticle/22130/> (May 8, 2021 12:03:37 PM).

¹² *See David S. Goldstein, Adrenal Responses to Stress Cell*, in 30 *CELLULAR AND MOLECULAR NEUROBIO.* 1433, 1433 (2010).

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

14 See Neel Burton, *A Brief History of Psychiatry*, PSYCH. TODAY: PSYCHIATRY (June 2, 2012), <https://www.psychologytoday.com/us/blog/hidden-and-seeking/201206/brief-history-psychiatry>.

15 See Ben Zimmer, “Panic”: That Wave of Anxiety Is Named After a Partying Greek God, WALL STREET J. (Mar. 12, 2020), <https://www.wsj.com/articles/panic-that-wave-of-anxiety-is-named-after-a-partying-greek-god-11584045370>.

16 See *id.*

17 See Julie Beck, *Diagnosing Mental Illness in Ancient Greece and Rome*, ATLANTIC: HEALTH (Jan. 23, 2014), <https://www.theatlantic.com/health/archive/2014/01/diagnosing-mental-illness-in-ancient-greece-and-rome/282856/>.

18 See Burton, *supra* note 14; see also Marc-Antoine Crocq, M.D., *A History of Anxiety: From Hippocrates to DSM*, 15 DIALOGUES IN CLINICAL NEUROSCI. 319, 320 (2015).

19 ROY PORTER, MADNESS: A BRIEF HISTORY 37 (Oxford Univ. Press 2002).

20 See Eleni Tsiompanou & Spyros G. Marketos, *Hippocrates: Timeless Still*, 106 J. ROYAL SOC’Y OF MED., 288, 289 (2013).

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

22 ARISTOTLE, *NICOMACHEAN’S ETHICS* bk. VII, at para. 5 (W.D. Ross trans., Batoche Books 1999). Stated differently, there’s a difference between being cowardly and having a medical problem.

23 See THOMAS VAN NORTWICK, *IMAGINING MEN: IDEALS OF MASCULINITY IN ANCIENT GREEK CULTURE* 93 (Bella Vivante ed., Praeger Publishers 2008).

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).

28 Matt Danzico, *Brains of Buddhist Monks Scanned in Meditation Study*, BBC NEWS (Apr. 24, 2011), <https://www.bbc.com/news/world-us-canada-12661646>.

29 See RL Carhart-Harris & DJ Nutt, *Serotonin and Brain Function: A Tale of Two Receptors*, 31 J. *PSYCHOPHARMACOLOGY* 1091, 1091-92 (2017).

30 Jordan W. Smoller, *Anxiety Genetics Goes Genomic*, *AM. J. PSYCHIATRY* 192 (Mar. 1, 2020).

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.³¹ 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.³² 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 months³³

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”).³⁴ This treatment is grounded in

³¹ *Anxiety Diagnosis*, HEALTHLINE (July 15, 2017), <https://www.healthline.com/health/anxiety-diagnosis>.

³² *What Are The Five Major Types of Anxiety Disorders?*, U.S. DEP’T OF HEALTH & HUMAN SERVS. (Feb. 12, 2014), <https://www.hhs.gov/answers/mental-health-and-substance-abuse/what-are-the-five-major-types-of-anxiety-disorders/index.html>

³³ See Lisa Fritscher, *DSM-5 Diagnostic Criteria for a Specific Phobia*, VERYWELL MIND (May 28, 2021), <https://www.verywellmind.com/diagnosing-a-specific-phobia-2671981>.

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.³⁵ Our minds create cognitive structures (constructs) that allow us to apply our past understanding of the world to our ongoing experience of reality.³⁶ 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.³⁷ 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.³⁸ 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.³⁹ 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.*

³⁷ *Clinical Practice Guideline for the Treatment of Posttraumatic Stress Disorder: What Is Cognitive Behavioral Therapy?*, AM. PSYCH. ASS’N (July 2017), <https://www.apa.org/ptsd-guideline/patients-and-families/cognitive-behavioral>.

³⁸ *See id.*

³⁹ *See* Courtney E. Ackerman, *25 CBT Techniques and Worksheets for Cognitive Behavioral Therapy*, POSITIVEPSYCHOLOGY.COM (May 20, 2021), <https://positivepsychology.com/cbt-cognitive-behavioral-therapy-techniques-worksheets/>.

mind.⁴⁰ CBT is used to treat a range of mental health disorders beyond anxiety, including depression, substance abuse, and more.⁴¹

B. The Rise of Digital Therapeutics

In the mid-2010s, software makers began developing and selling smartphone apps that apply various forms of CBT.⁴² 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.⁴³ Many such apps administer CBT through interactive lessons, games, and journaling software.⁴⁴ Most recently, AI-driven chatbots (“conversational agents”) have been developed to administer CBT and other established forms of treatment through apps.⁴⁵ Most conversational agents play a therapist-like role by asking users to share information about themselves and their thinking patterns.⁴⁶ These systems then lead users through sets of structured lessons designed to identify and challenge common cognitive distortions.⁴⁷ Recently, some app developers have started reaching beyond textual input by applying machine learning algorithms to identify facial expressions and vocal cues.⁴⁸

⁴⁰ *Id.*

⁴¹ *Id.*

⁴² Grant I. Christie, et al., *Gamifying CBT to Deliver Emotional Health Treatment to Young People on Smartphones*, 18 *INTERNET INTERVENTIONS* 1, 1-2 (2019); See Sabine Wilhelm, *Cognitive-Behavioral Therapy in the Digital Age: Presidential Address*, 51 *BEHAV. THERAPY* 1, 3 (2020).

⁴³ Simon Makin, *The Emerging World of Digital Therapeutics*, *NATURE* (Sept. 25, 2019), <https://www.nature.com/articles/d41586-019-02873-1>.

⁴⁴ *Id.*

⁴⁵ Kien Hoa Ly et al., *A Fully Automated Conversational Agent for Promoting Mental Well-being: A Pilot RCT Using Mixed Methods*, 10 *INTERNET INTERVENTIONS* 39, 40 (2017).

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.*

⁴⁸ Madhumitha Loganathan, *How to Make Empathetic Bots With Emotion Technology*, *MEDIUM.COM* (Feb. 15, 2019), <https://medium.com/intuit-engineering/how-to-make-empathetic-bots-with-emotion-technology-e61fdc0a3309>.

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.⁴⁹ 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.⁵⁰ The FDA calls these "Class I" devices.⁵¹ Moderate-risk "Class II" devices, by contrast, must meet higher safety performance standards.⁵² Makers of higher-risk "Class III" devices can receive FDA approval only by providing the agency with robust scientific evidence of safety and efficacy.⁵³ 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.⁵⁴ This process is called a "510(K) premarket submission."⁵⁵ 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.⁵⁶

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.

⁵⁰ *Is It Really 'FDA Approved?'*, U.S. FOOD & DRUG ADMIN. (last updated Jan. 17, 2017), <https://www.fda.gov/consumers/consumer-updates/it-really-fda-approved>. This is called FDA's Premarket approval process (PMA). See "Premarket Approval" at <https://www.fda.gov/medical-devices/premarket-submissions/premarket-approval-pma>.

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.

⁵⁵ See *Premarket Notification 510(k)*, U.S. FOOD & DRUG ADMIN. (last updated Mar. 13, 2020), <https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k>.

⁵⁶ See, e.g., *FDA in Brief: FDA Proposes Improvements to the De Novo Pathway for Novel Medical Devices to Advance Safe, Effective, and Innovative Treatments for Patients*, U.S. FOOD & DRUG ADMIN. (Dec. 4, 2018), <https://www.fda.gov/news-events/fda-brief/fda-brief-fda>.

The FDA cleared the first digital therapeutic app that uses CBT in 2018.⁵⁷ Called “reSET,” the app is sold by Pear Therapeutics to treat substance abuse disorder.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.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.”⁶⁰ Pear supplied the FDA with the results of a 12-week clinical trial of 399 patients.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.”⁶² The study participants experienced no side effects from using the app.⁶³

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

proposes-improvements-de-novo-pathway-novel-medical-devices-advance-safe-effective-and.

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.”)

⁵⁸ *FDA Permits Marketing of Mobile Medical Application for Substance Use Disorder*, U.S. FOOD & DRUG ADMIN. (Sept. 14, 2017), <https://www.fda.gov/news-events/press-announcements/fda-permits-marketing-mobile-medical-application-substance-use-disorder>.

⁵⁹ *Id.*

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

⁶¹ *Id.*

⁶² Press Release, FDA Permits Marketing of Mobile Medical Application for Substance Use Disorder (Sept. 14, 2017), <https://www.fda.gov/news-events/press-announcements/fda-permits-marketing-mobile-medical-application-substance-use-disorder>.

⁶³ *Id.* (suggesting that there were no notable side effects following the use of reSet).

hyperactivity disorder (ADHD).⁶⁴ ADHD is a neurodevelopmental condition that, left untreated, can significantly interfere with a child's growth and healthy development into adulthood.⁶⁵ Talk therapy, commonly prescribed, is often expensive and in short supply.⁶⁶ By comparison, EndeavorRx runs on any modern iPad.⁶⁷ 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."⁶⁸ 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.⁶⁹ Like reSET, the app presented no serious side effects.⁷⁰

⁶⁴ Press Release, FDA Permits Marketing of First Game-Based Digital Therapeutic to Improve Attention Function in Children with ADHD (June 15, 2020), <https://www.fda.gov/news-events/press-announcements/fda-permits-marketing-first-game-based-digital-therapeutic-improve-attention-function-children-adhd>; see also Sean Hollister, *The FDA Just Approved the First Prescription Video Game – It's for Kids with ADHD*, THE VERGE (June 15, 2020), <https://www.theverge.com/2020/6/15/21292267/fda-adhd-video-game-prescription-endeavor-rx-akl-t01-project-evo>; Callum Borchers, *This Won't Hurt A Bit: A New Prescription Medicine Is . . . A Video Game*, WBUR (June 16, 2020) <https://www.wbur.org/bostonmix/2020/06/16/this-wont-hurt-a-bit-a-new-prescription-medicine-is-a-video-game>.

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.

⁶⁷ *Frequently Asked Questions*, AKILI, <https://my.akili.care/akiliassist/endeavor-faqs> (last visited July 18, 2021).

⁶⁸ Press Release, Akili Announces FDA Clearance of EndeavorRX™ for Children with ADHD, the First Prescription Treatment Delivered Through a Video Game (June 15, 2020), <https://www.akiliinteractive.com/news-collection/akili-announces-endeavortm-attention-treatment-is-now-available-for-children-with-attention-deficit-hyperactivity-disorder-adhd-al3pw>.

⁶⁹ *Id.*

⁷⁰ See Scott H. Kollins et al., *A Novel Digital Intervention for Actively Reducing Severity of Paediatric ADHD (STARS-ADHD): A Randomised Controlled Trial*, 2 LANCET DIGIT. HEALTH 168 (2020) (suggesting that digital intervention did not result in notable side effects).

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 In

⁷¹ FDA April 2020 Announcement, *supra* note 1.

⁷² *Id.*

⁷³ *Id.*

⁷⁴ Public Health Service Act, Pub. L. No. 108-276, 118 Stat. 835 (2004) (codified at 21 U.S.C.A. § 360bbb-3(a) (2017)).

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 (EAU) 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.⁷⁷ Unlike some drugs, the FDA believes that mental health apps categorically present low risks to consumers.⁷⁸

Under certain circumstances, the FDA has also provided a one-year “grace period” of non-enforcement.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.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.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.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.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.

FOR DISEASE CONTROL & PREVENTION (June 24, 2010, 10:00 AM), <https://www.cdc.gov/h1n1flu/eua/>.

⁷⁷ See *Emergency Use Authorization – Archived Information*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization-archived-information#ebola> (last visited July 18, 2021).

⁷⁸ See FDA April 2020 Announcement, *supra* note 1, at 6.

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>.

⁸⁰ *Id.*

⁸¹ *Id.*

⁸² *Id.*

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.⁸⁴ 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.⁸⁵ Since then, the company's CEO has announced that it will launch all its apps currently in development before winter.⁸⁶

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!"⁸⁷

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

[O]ur 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.⁸⁸

In the past, Woebot has avoided branding itself as a replacement for traditional therapy.⁸⁹ Following the FDA's announcement, however, the company branded the app as a solution to help fill the gap in mental health treatment.⁹⁰ By February 2021, the website more

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.

⁹⁰ <https://woebothealth.com>, INTERNET ARCHIVE, [http://web.archive.org/web/20200729072927/https://woebothealth.com/\(click on "129](http://web.archive.org/web/20200729072927/https://woebothealth.com/(click%20on%20%22129)

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

captures” link and select dates to view captures after July 29, 2020); See Allison Darcy, *The Role of Digital Mental Health in the Healthcare Journey*, HIT CONSULTANT (June 14, 2021), <https://hitconsultant.net/2021/06/14/role-digital-mental-health-healthcare-journey/#.YPG-fGhKhEY>.

⁹¹ <https://woebothealth.com>, INTERNET ARCHIVE, <http://web.archive.org/web/20200729072927/https://woebothealth.com/> (click on “129 captures” link and select dates to view captures after February 2021).

⁹² *About Us*, WOEBOT HEALTH, <https://woebothealth.com/about-us/> (last visited July 16, 2021).

⁹³ *Products & Pipeline*, WOEBOT HEALTH, <https://woebothealth.com/products-pipeline/> (last visited July 16, 2021).

⁹⁴ <https://www.youper.ai/>, INTERNET ARCHIVE, <http://web.archive.org/web/20200417071330/https://www.youper.ai/> (click on “143 captures” link and select dates to view captures before April 2020); see *infra* Appendix, Youper Website – April 17, 2020 screenshots.

⁹⁵ <https://www.youper.ai/>, INTERNET ARCHIVE, <http://web.archive.org/web/20200417071330/https://www.youper.ai/> (click on “143 captures” link and select dates to view captures in October 2020); see *infra* Appendix, Youper Website – October 2020 screenshots.

⁹⁶ *Infra* Appendix, Youper Website – October 2020 screenshots.

offered “tools & insights to shape up your mood.”⁹⁷ After, it became “Fitness for Your Mental Health.”⁹⁸

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.⁹⁹ 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.”¹⁰⁰ 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

⁹⁷ <https://www.getmoodfit.com/>, INTERNET ARCHIVE, <http://web.archive.org/web/20200406162735/https://www.getmoodfit.com/> (click on “44 captures” link and select dates to view captures in April 2020).

⁹⁸ MOODFIT, <https://www.getmoodfit.com/> (last visited July 16, 2021).

⁹⁹ Eric Rosenbaum, *A COVID-19 Surge of Depression and Anxiety Is Being Treated by Robots*, CNBC (Nov. 13, 2020, 10:00 AM), <https://www.cnbc.com/2020/11/11/people-with-depression-anxiety-want-to-reveal-pain-to-a-robot.html>.

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"¹⁰¹—it is important to be specific. What does mental health information comprise?¹⁰² 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.¹⁰³ 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

¹⁰¹ Lillian R. Bevier, *Information About Individuals in the Hands of Government: Some Reflections on Mechanisms for Privacy Protection*, 4 WM. & MARY BILL RTS. J. 455, 458 (1995).

¹⁰² Conceptualizing and defining privacy as a legal right has occupied generations of scholars and lawmakers. From its roots in Warren and Brandeis' 1899 law review article, "The Right to Privacy," to its role at the center of policy debates over reproductive rights, facial recognition, and "surveillance capitalism," privacy has denoted a wide range of interests. Lillian BeVier has called privacy "chameleon-like;" Fred Cate dubbed it "antisocial;" The scholar Daniel Solove subtitled a book chapter about privacy, "a concept in disarray." See DANIEL J. SOLOVE, *UNDERSTANDING PRIVACY* 1 (Harvard Univ. Press 2008).

¹⁰³ See generally *STIGMA AND MENTAL ILLNESS* 1 (Paul Jay Fink & Allan Tasman eds., 1st ed. 1992). ("We define stigmatization of mental illness as the marginalization and ostracism of individuals because they are mentally ill... Stigma associated with mental illness can cause those afflicted to delay seeking treatment or to conceal the illness in an attempt to escape the shame and isolation of being labeled "disturbed" and "other.").

to enter into contracts, vote, or make treatment decisions for themselves.¹⁰⁴ Federal and state laws now prohibit such discrimination.¹⁰⁵ 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.¹⁰⁶

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.¹⁰⁷ 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.”¹⁰⁸

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).¹⁰⁹ This statute permits health care providers to disclose an individual’s health information only for a narrow set of purposes.¹¹⁰ The Act includes within its definition of

¹⁰⁴ Richard C. Boldt, *The “Voluntary” Inpatient Treatment of Adults Under Guardianship*, 60 VILL. L. REV. 1, 17 (2015).

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.

¹⁰⁷ *StigmaFree Company*, NAT’L ALL. ON MENTAL ILLNESS (2021), <https://www.nami.org/Get-Involved/Pledge-to-Be-StigmaFree/StigmaFree-Company>

¹⁰⁸ See also *Jaffee v. Redmond*, 518 U.S. 1 (1996).

¹⁰⁹ See generally Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-101, 110 Stat. 1936 (codified as amended in scattered sections of 18, 26, 29, and 42 U.S.C.) (this is not an exhaustive analysis of every federal or state law that could discourage disclosure).

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.

¹¹³ 45 C.F.R. § 164.508(a)(2) (2019).

¹¹⁴ 45 C.F.R. § 160.102.

¹¹⁵ See PRIVACY AND CONFIDENTIALITY IN MENTAL HEALTH CARE (John J. Gates & Bernard S. Arons eds., 2001); see also IMPROVING THE QUALITY OF HEALTH CARE FOR MENTAL AND SUBSTANCE-USE CONDITIONS (Nat’l Academies Press 2006).

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).

¹¹⁸ RESTATEMENT (SECOND) OF TORTS § 652D (AM. L. INST. 1977).

addresses, phone numbers, unique identifiers tied to their smartphones, and the specific mental health conditions they seek to treat.¹¹⁹ 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.¹²⁰ 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."¹²¹ Apps used solely by consumers outside of any therapeutic context don't fall under the Act's definition of a covered entity.¹²²

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.¹²³ A recent comprehensive study of mental health app data practices

¹¹⁹ Thomas Germain, *Mental Health Apps Aren't All As Private As You May Think*, CONSUMER REPS. (Mar. 2, 2021), <https://www.consumerreports.org/health-privacy/mental-health-apps-and-user-privacy/>.

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

¹²¹ *Business Associates*, U.S. DEP'T OF HEALTH & HUMAN SERVS. (May 24, 2019), <https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/business-associates/index.html>.

¹²² See W. Nicholson Price II & I. Glenn Cohen, *Privacy in the Age of Big Data*, 25 NATURE MED. 37, 39 (2019). The FDA cleared a non-prescription digital therapeutic in 2017 for the treatment of diabetes. See Press Release, WellDoc Receives FDA 510(k) Clearance to Offer a Non-Prescription Version of Bluestar® Digital Therapeutic for Type 2 Diabetes (Jan. 19, 2017), <https://www.welldoc.com/news/welldoc-receives-fda-510k-clearance-to-offer-a-non-prescription-version-of-bluestar-digital-therapeutic-for-type-2-diabetes/>.

¹²³ Lisa Parker et al., *How Private Is Your Mental Health App Data? An Empirical Study of Mental Health App Privacy Policies and Practices*, 64 INT'L J. L. & PSYCH. 198, 200 (2019).

concluded, “[t]he field of mental health apps is beset by risks to user privacy.”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.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.¹²⁶ (To be sure, many patented inventions are ultimately not commercialized – an important issue that Ted Sichelman has carefully called attention to.)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.

¹²⁴ *Id.* at 203.

¹²⁵ See, e.g., Benjamin N. Roin, *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...”).

¹²⁶ *Id.*

¹²⁷ Ted Sichelman, *Commercializing Patents*, 62(2) STAN. L. REV. 341, 343 (2010).

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

¹²⁸ Peter Lee, *Toward A Distributive Commons in Patent Law*, 2009 WIS. L. REV. 917, 1000 (2009).

¹²⁹ Peter Lee, *Social Innovation*, 92 WASH. U. L. REV. 1, 6 (2014).

¹³⁰ Ofer Tur-Sina, *Technological Progress and Well-Being*, 48 LOY. U. CHI. L.J. 145, 147 (2016).

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.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 1854.¹³⁴ 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.¹³⁵ (At this point, Otis reportedly would announce, "All safe, ladies and gentlemen. All safe.")¹³⁶ Successfully commercializing his distrusted invention was for Otis literally an uphill climb.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.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."¹³⁹ Studies show that another app called Wysa has promise in reducing anxiety symptoms, particularly in assisting children.¹⁴⁰ It is important to note that some

¹³³ Michael Brick, *Celebrating Effort to Make the Elevator a Dull Ride*, N.Y. TIMES (Apr. 2, 2003), <https://www.nytimes.com/2003/04/02/nyregion/celebrating-effort-to-make-the-elevator-a-dull-ride.html>.

¹³⁴ *Id.*

¹³⁵ *Id.*

¹³⁶ *Id.*

¹³⁷ *Who Made America? Elisha Otis*, PBS, http://www.pbs.org/wgbh/theymadeamerica/whomade/otis_hi.html (last visited Feb. 27, 2021); Olivia B. Waxman, *This Is the Patent for the Device That Made Elevators a Lot Less Dangerous*, TIME (Mar. 23, 2017), <https://time.com/4700084/elevator-patent-history-otis-safety/>

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

¹³⁹ Press Release, Youper Wants Everyone on the Planet to Have an AI Emotional Health Assistant (June 11, 2019), <https://www.youper.ai/press-release>.

¹⁴⁰ See also VICE News, *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.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.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.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.¹⁴⁴ In short, suppressed innovation in the mental health app industry could lead us to miss out on much-needed new technologies.

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.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

<https://www.youtube.com/watch?v=AE966uR09es>.

¹⁴¹ Interview with anonymous source (Summer 2020).

¹⁴² *Id.*

¹⁴³ Patrick W. Corrigan et al., *The Impact of Mental Illness Stigma on Seeking and Participating in Mental Health Care*, 15 PSYCH. SCI. PUB. INT. 37, 40 (2014).

¹⁴⁴ Emily Dreyfus, *LGBTQ+ Youth Prefer to Seek Mental Health Help Digitally*, WIRED (June 11, 2019, 5:41 PM), <https://www.wired.com/story/lgbtq-mental-health-digital-outreach/>.

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.

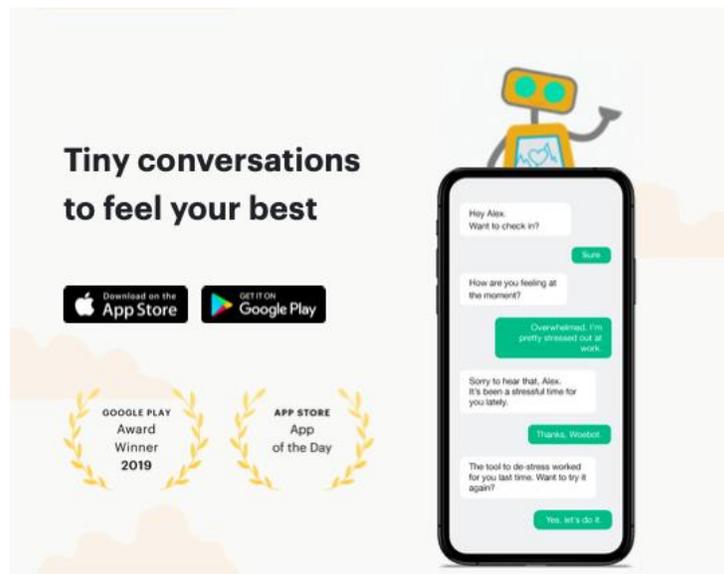
The agency's decision could also harm the very population that it appears to benefit. A glut of ineffective apps could dampen market demand and, over time, dampen innovation investments in this space, leading to a mental health app winter. This would be bad for companies and for the public. This technology 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.)¹⁴⁶ 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.

¹⁴⁶ Samantha Murphy Kelly, *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>.

**APPENDIX: EXAMPLES OF MARKETING CHANGES FOLLOWING
FDA'S SUSPENSION OF ENFORCEMENT**

Woebot Website - April 21, 2020



Woebot Website - April 21, 2020

Woebot has something to offer everyone

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!

4.7



On App Store

4.7



On Play Store

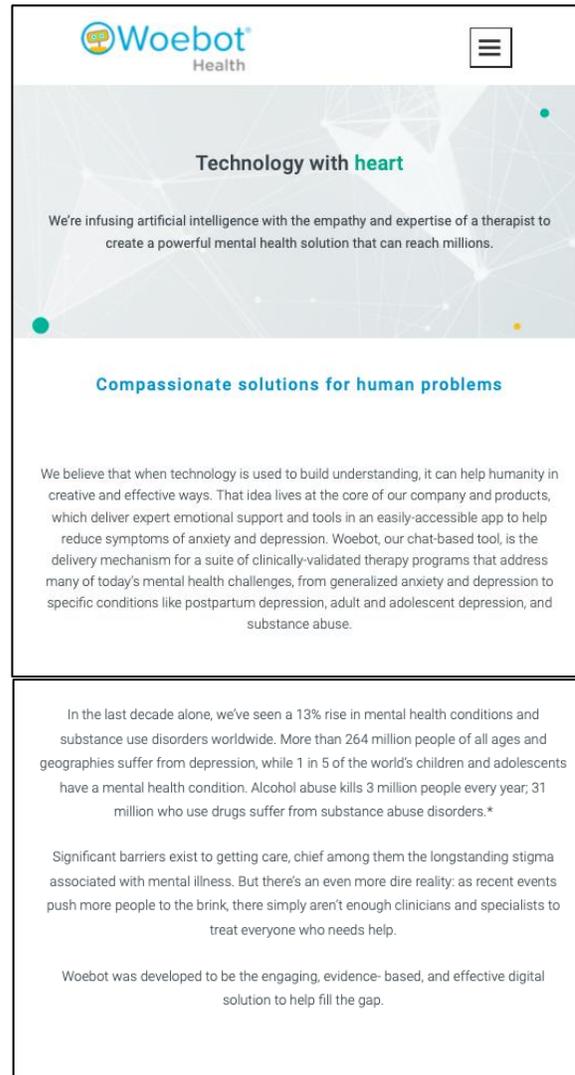
"In my first session with Woebot, I found it immediately helpful."



Nick Douglas
Lifehacker



Woebot Website – Summer 2020



The screenshot shows the top portion of the Woebot Health website. At the top left is the Woebot Health logo, and at the top right is a hamburger menu icon. The main content area has a light blue background with a network diagram. The headline is "Technology with heart". Below it is a paragraph: "We're infusing artificial intelligence with the empathy and expertise of a therapist to create a powerful mental health solution that can reach millions." The next section is titled "Compassionate solutions for human problems" and contains a paragraph: "We believe that when technology is used to build understanding, it can help humanity in creative and effective ways. That idea lives at the core of our company and products, which deliver expert emotional support and tools in an easily-accessible app to help reduce symptoms of anxiety and depression. 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." The bottom section contains two paragraphs: "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.*" and "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." The final paragraph states: "Woebot was developed to be the engaging, evidence-based, and effective digital solution to help fill the gap."

Woebot[®]
Health

Technology with heart

We're infusing artificial intelligence with the empathy and expertise of a therapist to create a powerful mental health solution that can reach millions.

Compassionate solutions for human problems

We believe that when technology is used to build understanding, it can help humanity in creative and effective ways. That idea lives at the core of our company and products, which deliver expert emotional support and tools in an easily-accessible app to help reduce symptoms of anxiety and depression. 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 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.

Woebot was developed to be the engaging, evidence-based, and effective digital solution to help fill the gap.

Youper Website – April 17, 2020

youper

Your Emotional Health Assistant

Feel your best with Youper

Download for free

Download on the App Store

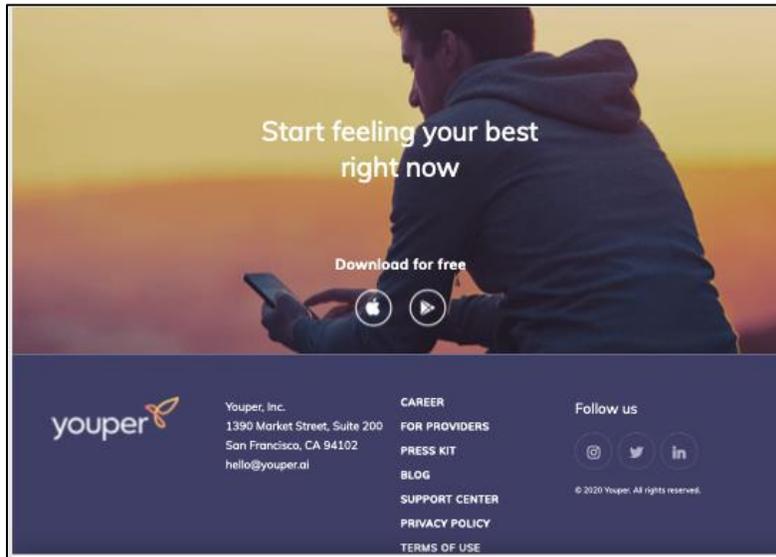
GET IT ON Google Play

HOW IT WORKS

Youper helps you take control of your emotional health

- Have quick conversations that can change your day
- Listen to Youper guiding you through personalized meditations
- Understand yourself, track your mood, and monitor your emotional health

Youper Website – April 17, 2020



Youper Website – October 2020

youper 

Created by therapists

Feel your best with Youper AI Therapy

- ✓ Get immediate help
- ✓ Start with a free mental health checkup
- ✓ Talk with Youper 24/7

I'M READY 

Andrea Niles, PhD
Director of Science and Clinical Psychologist

Featured in

YAHOO! Forbes Health TechCrunch

AI Therapy is modern mental health care

Youper is an AI Therapy platform that supports your mental health anytime and anywhere.

You'll have conversations guided by our empathetic Artificial Intelligence (AI) using therapy exercises scientifically proven to improve well-being. Youper is affordable, private, and always available.

How it works

- 
Complete a Mental Health Checkup to personalize Youper to you.
- 
Start talking to Youper like texting a therapist or caring friend.
- 
Talk whenever you need or set Youper to check in on you every day.
- 
Monitor anxiety, depression, panic, PTSD, and other conditions.
- 
Get regular checkups to gain insights into symptom reduction.

I'M READY

Youper Website – October 2020



A graphic with a dark blue background. On the left is a portrait of Jose Hamilton, MD, a man in a white lab coat and tie. To the right of the portrait is the text "Jose Hamilton, MD, CEO and Psychiatrist". The main heading is "Benefits of AI Therapy". Below the heading are four bullet points, each with a checkmark icon:

- ✓ **Available 24/7**
No more wait times to see a therapist
- ✓ **Safe and private**
Talk about anything without judgment
- ✓ **At your pace**
Respects your needs and timing
- ✓ **Affordable**
Save money while accessing world-class, science-based techniques



A graphic with a background image of a person in a hoodie looking at a smartphone against a sunset sky. The text reads: "Take our free Mental Health Checkup and see how you can improve". Below the text is an orange button with the text "I'M READY".