

FDA’S PRIVACY HALO

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Abstract: Do consumers trust the words “FDA cleared” more than they should? It’s a timely question: In 2017, the US Food and Drug Administration (FDA) began permitting software makers to market smartphone apps as treatments for a range of mental health disorders, including addiction and attention deficit hyperactivity disorder. Although these novel treatments are safe and sometimes effective, they trade on users’ privacy by liberally sharing medical data with third parties. This Article presents an original survey suggesting that the imprimatur of FDA approval on app advertisements leads consumers to ignore these data privacy risks. Rather than informing consumers, the words “FDA cleared” on mental health app ads stimulate vague and sometimes misplaced feelings of goodwill. After laying out the empirical basis for this conclusion, this Article explores its legal implications and presents a set of potential policy solutions.

CONTENTS

- Introduction..... 3
- I. FDA’s App Privacy Gap..... 6
 - A. FDA’s Regulation of Digital Therapeutics 6
 - B. Privacy for Patients Versus “Users” 11
- II. Surveying Consumer Perceptions..... 16
 - A. Methods..... 16
 - B. Results..... 16
- III. Analysis and Recommendations..... 16
- Conclusion 16

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Introduction

America is in the grip of a growing mental health crisis. Anxiety, depression, and substance abuse disorders are at all-time highs. In 2019, an estimated 40 million Americans suffered from clinical anxiety, and 16 million experienced symptoms of depression, making them the two most common mental health disorders in the country.²³ In the same year, over 70,000 Americans died from drug overdoses. Since Covid-19 struck in early 2020, the mental health crisis, already grave, has only deepened. In May 2020, the Center for Disease Control reported that one-third of adult Americans experienced symptoms of clinical anxiety and depression.⁴ Drug use and overdoses reached record levels by the middle of the year.⁵ Mental health has become our shadow pandemic.

A shortage of healthcare professionals is partly to blame. A recent study found that 65% of non-metropolitan counties do not have a single psychologist, and 47% of non-metropolitan areas do not have a psychologist.⁶ The US Department of Health and Human Services has projected that by the year 2025, there will be shortages of between 6,080 and 15,400 psychiatrists; between 8,220 and 57,490 clinical, counseling, and school psychologists; and as many as 26,930 mental health counselors.⁷ Social distancing, which has been necessary to slow the spread of COVID-19, has made mental health care even less accessible to many.

Silicon Valley believes the cure for America's spiraling mental health crisis might be, quite literally, staring us in the

² "Facts & Statistics," The Anxiety and Depression Association of America, available at <https://adaa.org/about-adaa/press-room/facts-statistics>

³ Id.

⁴ The Census Bureau has reported that during the coronavirus pandemic, one-third of Americans show signs of clinical anxiety or depression. "Anxiety and Depression," The Centers for Disease Control and Prevention, available at: <https://www.cdc.gov/nchs/covid19/pulse/mental-health.htm>

⁵ See e.g., Jon Kamp & Arian Campo-Flores, "The Opioid Crisis, Already Serious, Has Intensified During Coronavirus Pandemic" Wall Street Journal, (Sept. 8, 2020) available at: <https://www.wsj.com/articles/the-opioid-crisis-already-serious-has-intensified-during-coronavirus-pandemic-11599557401>

⁶ C. Holly A. Andrilla et al., *Geographic Variation in the Supply of Selected Behavioral Health Providers*, American Journal of Preventive medicine, Vol. 54 (Jun. 1 2018) available at: [https://www.ajpmonline.org/article/S0749-3797\(18\)30005-9/fulltext](https://www.ajpmonline.org/article/S0749-3797(18)30005-9/fulltext).

⁷ See US Dept. of Health and Human Services, Projections for Demand of Behavioral Health Practitioners, available at <https://bhw.hrsa.gov/sites/default/files/bhw/health-workforce-analysis/research/projections/behavioral-health2013-2025.pdf>.

face. Today, smartphone apps called “digital therapeutics”⁸ purport to treat a wide range of mental health disorders, including anxiety, depression, substance abuse, and even attention deficit hyperactivity disorder (ADHD) in children. Many of these apps administer cognitive behavioral therapy (“CBT”), an intervention that challenges some common thoughts and behaviors that perpetuate mental health disorders. In place of a human therapist, CBT apps usually administer their treatment through interactive lessons, games, journaling software, and AI chatbots. A different type of digital therapeutic uses AI and machine learning to monitor patient behavior and predict the onset of mental health episodes such as panic attacks. In 2017, the FDA began permitting digital therapeutics to be marketed as medical treatments. Patients are hopeful. Investors are bullish.⁹

Digital therapeutics seem to directly address some of the problems bedeviling health care policy in the US. Because the apps are automated, they can treat a virtually unlimited number of patients in any geographic region. This reach could address the national workforce shortage of clinicians. Equally important, these apps allow people to receive help without visiting a therapist’s office. This convenience could be especially helpful to people who feel reluctant to seek medical treatment due to feelings of stigma. The ability to be treated at home is also uniquely well-suited to the social distancing rules required in the age of COVID-19. Finally, some users have reported feeling more comfortable disclosing their problems to an app than to a human clinician.

Digital therapeutics come up short in a critical respect, however: privacy. A 2019 study of the privacy policies in sixty-one mental health apps reported that “[n]early half of the apps (25/61, 41%) did not have a privacy policy to inform users about how and when personal information would be collected

⁸ See Press Release, FDA Permits Marketing of First Game-Based Digital Therapeutic to Improve Attention Function in Children with ADHD, available at: <https://www.fda.gov/news-events/press-announcements/fda-permits-marketing-first-game-based-digital-therapeutic-improve-attention-function-children-adhd>.

⁹ See Callum Burroughs, The coronavirus lockdown has made mental health startups more important than ever, according to founders and investors. Here's why the sector is exploding, Business Insider (May 19, 2020) available at: <https://www.businessinsider.com/mental-health-startups-and-vc-investors-see-positives-amid-covid-pandemic-2020-5>.

and retained or shared with third parties.”¹⁰ One app recently cleared by the FDA states in a privacy policy that it will disclose non-anonymous user data with marketing partners.¹¹ Because FDA oversees only app safety and efficacy, these data-sharing practices don’t conflict with receiving the agency’s permission. Because mental health apps operate outside the legal framework that governs patient privacy in clinical settings, app makers are free to collect and share user data more liberally. Mental health apps turn patients into “users.”

Could the FDA’s stamp of approval on an app’s advertising materials dampen consumer attentiveness to these privacy issues? There’s good reason to think so. Recent studies reveal that consumers think FDA authorization carries more assurances than it does. In a 2011 Dartmouth study surveying 2,944 participants, 39% believed that the FDA approves only “extremely effective” drugs, and 25% believed incorrectly that the FDA doesn’t approve drugs that carry side-effects.¹² A 2020 study conducted by the Department of Health and Human Services revealed that consumers have a similarly inflated view of what “FDA approval” means.¹³ At least one legal scholar has noted with concern that pharmaceutical and biotechnology firms have tried to trade on this “halo effect” by using the term “FDA Approved” as a marketing device.¹⁴

This Article examines whether consumers are less attentive to data privacy concerns when they see that FDA has cleared an app. In October 2020, we surveyed [TK] consumers to determine their understanding of FDA’s role in this new industry, as well as their understanding of terms like “FDA cleared” and “FDA authorized.” We used Facebook as a study recruitment device to reach potential subject participants where they would be most likely to encounter ads for mental health apps. The survey suggests that the imprimatur of FDA approval on app advertisements leads consumers to ignore these data privacy risks. Rather than informing consumers, the

¹⁰ Lisa Parker et al, *How private is your mental health app data? An empirical study of mental health app privacy policies and practices*, International Journal of Law and Psychiatry 64 (2019) 198-204.

¹¹ The app, reSET, is sold by Pear Pharmaceuticals and discussed in greater detail later in this article. See “Privacy Policy” at <https://peartherapeutics.com/privacy-policy/>.

¹² Lisa M. Schwartz, MD, MS & Steven Woloshin, MD, MS, *Communicating Uncertainties About Prescription Drugs to the Public: A National Randomized Trial*, 171 Arch Intern Med (Sep 12, 2011).

¹³ Helen W. Sullivan et al., *Consumer Understanding of the Scope of FDA’s Prescription Drug Regulatory Oversight: A Nationally Representative Survey*, 29 Pharmacoepidemiol Drug Saf. (February 2020).

¹⁴ Jonathan J. Darrow, *Pharmaceutical Gatekeepers*, 47 Ind. L. Rev. 363 (204).

words “FDA cleared” on mental health app ads work like a slogan, stimulating vague and sometimes misplaced feelings of goodwill.

Part I of this Article explains what it means for the FDA to clear or otherwise authorize an app as a medical intervention. The discussion then presents the hypothesis that consumers may trust FDA cleared apps more than they should. Part II of the Article presents the methodology and results of an original survey of American consumers conducted in October 2020. We tailored this survey to gauge whether consumers mistakenly trust FDA cleared apps due to a “halo effect” of goodwill that extends from positive associations with the FDA. Part III of the Article explores the study’s law and policy implications and presents a set of potential policy solutions.

I. FDA’s App Privacy Gap

This background discussion begins with the FDA’s recent move to authorize the marketing of mental health apps. The agency evaluates apps’ safety and efficacy, but it does not consider the privacy-related harms they might cause. The discussion then explains why laws that ordinarily govern patient data privacy don’t necessarily restrict the trading of mental health data collected from apps. The discussion concludes by explaining why the FDA’s stamp of approval might dampen consumers’ attentiveness to these privacy risks.

A. FDA’s Regulation of Digital Therapeutics

When Congress authorized the FDA to oversee the safety of medical devices in 1976, few could have imagined the agency would someday evaluate the functions of mobile phones.¹⁵ At the time, handheld portable phones were a prototype technology with no meaningful connection to medicine. Over the next four decades, sweeping technological advances brought smartphones and the software they run squarely under the FDA’s jurisdiction as medical devices, however. The Federal Food, Drug, and Cosmetic Act (FDCA) defines a medical device as:

[A]n instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any

¹⁵ 1976 amendments to The Federal Food, Drug, and Cosmetic Act of 1938 (FDCA), granted FDA the authority to oversee the safety of food, drugs, and cosmetics.

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
. . .¹⁶

The word “intended” in this definition is important. For FDA purposes, a “medical device” isn’t just a tool – it’s a tool that’s intended for a particular use. In this context, the term means “objective intent of the persons legally responsible for the labeling of devices.”¹⁷ The upshot is that the FDA’s jurisdiction to regulate a device often stems from advertising claims made by the device’s manufacturer or service provider. The claim that consumers can use a smartphone app to treat a specific medical condition is likely to invoke FDA oversight, while more generalized statements about promoting “wellness” are not.¹⁸

Companies must demonstrate to the FDA that their medical devices are safe and effective.¹⁹ 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 were manufactured according to standard practices and are labeled appropriately for consumers. The FDA calls these “Class I” devices. Moderate-risk “Class II” devices, by contrast, must meet higher safety performance standards.²⁰ Higher-risk “Class III” devices can obtain FDA approval only by providing the agency with robust scientific evidence of safety and effective.²¹ Alongside this three-tiered classification system, there are special rules that relate to how novel a device is. If a device is “substantially equivalent” to a device the FDA has already approved, the manufacturer can request a streamlined form of marketing clearance. This process is called a “510(K) premarket submission.”²² If a device is of a new kind, the manufacturer can

¹⁶ Id.

¹⁷ 21 C.F.R. § 801.4 (2016). Intent is a fact-based inquiry.

¹⁸ See Theodore T. Lee, *Recommendations for Regulating Software-Based Medical Treatments: Learning from Therapies for Psychiatric Conditions*, 73 Food & Drug L.J. 66, 77 (2018).

¹⁹ Schwartz, *supra* at note 125.

²⁰ This is called FDA’s Premarket approval process (PMA). See “Premarket Approval” at <https://www.fda.gov/medical-devices/premarket-submissions/premarket-approval-pma>.

²¹ Id. See also “Is it really approved” at <https://www.fda.gov/consumers/consumer-updates/it-really-fda-approved>.

²² See “Premarket Notification 510(K)” at <https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k>

request that the FDA classify and authorize its sale through the agency's "De Novo" review pathway.²³

The FDA requires manufacturers to label medical devices in particular ways. Product labels include printed statements about risks and benefits, instructions for use, and other safety information.²⁴ Labels also include advertising materials under the FDCA. As the 9th Circuit has held, "The term 'labeling' is defined in the Act as including all printed matter accompanying any article.⁶ Congress did not, and we cannot, exclude from the definition printed matter which constitutes advertising."²⁵ Device manufactures can make advertising statements that are not false, misleading, or harmful to consumers.²⁶ The law generally permits truthful statements such as "FDA Cleared," "FDA Approved," and "FDA authorized" on advertising materials.

The FDA cleared the first digital therapeutic app in 2017.²⁷ Called "reSET," the app is sold by Pear Pharmaceuticals to treat substance abuse disorder.²⁸ 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. 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

²³ 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" available at: <https://www.fda.gov/news-events/fda-brief/fda-brief-fda-proposes-improvements-de-novo-pathway-novel-medical-devices-advance-safe-effective-and>

²⁴ See FDA, "Guidance on Medical Device Labeling" available at <https://www.fda.gov/media/71030/download> (April 19, 2001).

²⁵ *United States v. Research Labs.*, 126 F.2d 42, 45 (9th Cir. 1942)

²⁶ False or misleading statements are forbidden under the FDCA and may implicate other areas of law and regulation, such as the Lanham Act or FTC. See, e.g., *Misbranded drugs and devices* 21 U.S.C.A. § 352 (West).

²⁷ The FDA decided to clear reSET through the de novo premarket review pathway. See Press Release, "FDA clears mobile medical app to help those with opioid use disorder stay in recovery programs" (Dec. 10, 2018) at <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.")

²⁸ <https://www.fda.gov/news-events/press-announcements/fda-permits-marketing-mobile-medical-application-substance-use-disorder>;

substance use, to take responsibility, and more.”²⁹ Pear supplied the FDA with the results of a 12-week clinical trial of 399 patients. 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.” The study participants experienced no side effects from using the app.

The FDA’s decision to permit the sale of reSET was a milestone in two ways. First, it marked a departure from the agency’s longstanding reluctance to regulate mobile phone apps;³⁰ Second, it opened the door for other apps targeting mental health disorders. Because reSET was unlike any previously authorized device at the time, the FDA approved it through its de novo review process and classified it as “class II.” The FDA codified this classification decision under the Code of Federal Regulations titled, “Computerized behavioral therapy device for psychiatric disorders.”³¹ The classification stated, “A computerized behavioral therapy device for psychiatric disorders is a prescription-only device intended to provide a computerized version of condition-specific behavioral therapy as an adjunct to clinician supervised outpatient treatment to patients with psychiatric conditions.”³² The FDA relied on this classification two years later when it cleared a “reSET-O” – a version of reSET specially designed “to increase patient retention in outpatient treatment programs” for opioid use disorder.³³

In June 2020, the FDA permitted the marketing of a cheerful racing video game called “EndeavorRX” to treat childhood attention-deficit hyperactivity disorder (ADHD).³⁴

²⁹ https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN160018.pdf;

³⁰ See Nathan Cortez, *Analog Agency in a Digital World*, in *FDA IN THE 21ST CENTURY* (eds. Holly Fernandez Lynch and I. Glenn Cohen) (Columbia University Press 2015).

³¹ 21 CFR 882.5801.

³² *Id.*

³³ *Id.* The FDA classified reSET-O as a Class II “Computerized behavioral therapy device for psychiatric disorders.”

³⁴ See Sean Hollister, “The FDA just approved the first prescription video game – it’s for kids with ADHD,” *THE VERGE* (Jun. 15, 2020) available at: <https://www.theverge.com/2020/6/15/21292267/fda-adhd-video-game-prescription-endeavor-rx-akl-t01-project-evo>; Press Release, “FDA Permits Marketing of First Game-Based Digital Therapeutic to Improve Attention Function in Children with ADHD” (Jun. 15, 2020) available at: <https://www.fda.gov/news-events/press-announcements/fda-permits-marketing-first-game-based-digital-therapeutic-improve-attention-function-children-adhd>; Callum Borchers, “This Won’t Hurt A Bit: A New Prescription Medicine Is ... A Video Game” *WBUR* (Jun. 16, 2020) available at:

ADHD is a neurodevelopmental condition that left untreated, can significantly interfere with a child's growth and healthy development into adulthood.³⁵ Drugs are the most common therapeutic intervention, but they often carry side-effects.³⁶ Talk therapy, also commonly prescribed, is 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."³⁷ 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.

Pear Pharmaceuticals and Akili Interactive refer to FDA authorization in their marketing materials for reSET, reSET-O, and EndeavorRX. The reSET app on the iOS app store, for instance, states, "reSET®, for individuals with substance use disorder, is the first FDA-authorized treatment shown to increase abstinence and retention over a 12-week trial period."³⁸ The iOS app store page for reSET-O states, "reSET-O® is the only FDA-authorized prescription digital therapeutic that's clinically proven to help people with opioid use disorder stay in treatment over 12 weeks."³⁹ The website for EndeavorRX similarly states, "EndeavorRX™ is the first-and-only FDA cleared prescription treatment for attention in children with ADHD delivered through a digital therapy."⁴⁰

The FDA has taken extraordinary steps to encourage the distribution and use of mental health apps. As the coronavirus pandemic swept across the globe in 2020, the FDA announced

<https://www.wbur.org/bostonmix/2020/06/16/this-wont-hurt-a-bit-a-new-prescription-medicine-is-a-video-game>

³⁵ See e.g., Children and Adults with Attention-Deficit/Hyperactivity Disorder (CHADD), "About ADHD - Overview," at <http://www.chadd.org/about-adhd/overview>.

³⁶ *Id.*

³⁷ See Press Release, "Akili Announces FDA Clearance of EndeavorRX™ for Children with ADHD, the First Prescription Treatment Delivered Through a Video Game," (Jun. 15 2020) at <https://www.akiliinteractive.com/news-collection/akili-announces-endeavortm-attention-treatment-is-now-available-for-children-with-attention-deficit-hyperactivity-disorder-adhd-al3pw>.

³⁸ See "reSET" and "reSET-O" at <https://www.resetforrecovery.com/patient/>.

³⁹ See "Pear reSET-O" at <https://apps.apple.com/us/app/pear-reset-o/id1270975804>.

⁴⁰ See "EndeavorRX" at <https://www.akiliinteractive.com/get-endeavorrx>.

that it would temporarily relax enforcement of compliance rules for mental health apps “for the duration of the pandemic.”⁴¹ The agency stated it hoped this step would help relieve widely-reported upticks in symptoms of anxiety and depression. At the same time, the agency explained, the apps could promote social distancing by removing the need for patients to be in close proximity to health care providers. Investors and industry analysts believe these steps have spurred many consumers to use these technologies, which in turn could lead the FDA to authorize many more mental health apps after the pandemic. In October 2020, hundreds of clinical trials were in progress to evaluate mobile apps designed to treat mental health disorders.⁴²

The age of FDA-authorized mental health apps is here. These technologies could help address many of the problems bedeviling mental healthcare in the US. As the next section explains, however, mental health apps raise new privacy concerns.⁴³

B. Privacy for Patients Versus “Users”

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?⁴⁴ 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 might be the easiest to answer. In many cultures, people with mental health disorders have historically

⁴¹ FDA, “Enforcement Policy for Digital Health Devices For Treating Psychiatric Disorders During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency” (April 2020) available at: <https://www.fda.gov/media/136939/download>.

⁴² Data obtained from ClinicalTrials.gov on September 26, 2020.

⁴³ Theodore W. Ruger, “*After the FDA: A Twentieth-Century Agency in a Postmodern World*,” in *FDA in the 21st Century* (eds. Holly Fernandez Lynch and I. Glenn Cohen) (Columbia University Press 2015).

⁴⁴ 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* 109 (Harvard University Press 2008).

suffered stigma.⁴⁵ The law has contributed to this. As recently as the 1960s and 1970s, many states had laws that automatically branded people 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.⁴⁶ 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.⁴⁷

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 don't seek treatment because they experience feelings of shame.⁴⁸ 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."⁴⁹ Recent studies show that these concerns vary by gender, age, ethnicity, religion, and other cultural lines.⁵⁰

US 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).⁵¹ This statute permits health care providers to disclose an individual's

⁴⁵ See generally, William R. Dubin & Paul Jay Fink, *Effects of Stigma on Psychiatric Treatment*, in *Stigma and Mental Illness* 1 (Paul Jay Fink & Allan Tasman eds., 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.").

⁴⁶ See also, e.g., the Americans with Disabilities Act (ADA).

⁴⁷ Dubin & Fink, *supra* note 45.

⁴⁸ See nami.org.

⁴⁹ See also *Jaffee v. Redmond*, 518 U.S. 1 (1996).

⁵⁰ *Id.*

⁵¹ This is not an exhaustive analysis of every federal or state law that could discourage disclosure.

health information only for a narrow set of purposes.⁵² The Act includes within its definition of “health information” any information received by health care providers that “relate to a person’s past, present, or future physical or mental health or condition.” Permitted disclosures include responding to law enforcement requests, providing treatment, obtaining reimbursement from insurers, and preventing imminent public safety threats. “Psychotherapy notes” are subject to heightened protections. These records may be disclosed only through a rigorous process of patient authorization.⁵³ Importantly, HIPAA applies only to health care providers (including mental health professionals) and their business associates.

Many states limit the disclosure of mental health information even more stringently than HIPAA.⁵⁴ 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.⁵⁵ Other states, including Nebraska and New Mexico, have absolute obligations of confidentiality.⁵⁶ 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.”⁵⁷

Digital therapeutics collect the same mental health information that mental health professionals collect, and sometimes much more. This information includes their users’ names, email addresses, phone numbers, and the specific mental health conditions they seek to treat. Many apps 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’

⁵² 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 a person’s past, present, or future physical or mental health or condition,” as well as details of treatment. 45 CFR Part 160.103.

⁵³ 45 C.F.R. § 164.508(a)(2);

⁵⁴ See *Privacy and Confidentiality in Mental Health Care* (eds. John J. Gates & Bernard S. Arons) (2001). See also *Improving the Quality of Health Care for Mental and Substance-Use Condition* (2006).

⁵⁵ Mass. Gen. Laws. ch. 112 § 129A.

⁵⁶ See also Neb. Rev. Stat. § 71-1,335(1); N.M. Stat. Ann. § 61-9A27; Utah Code. Ann. 58-61-602(2)(c).

⁵⁷ Restatement (Second) of Torts §652D.

written descriptions of their thoughts. Some CBT-based apps also collect and store user responses to periodic quizzes and check-ins. Motion-based apps such as EndeavorRX, meanwhile, store and analyze data directly from a tablet's sensors, detecting a user's movements.⁵⁸ Collecting, storing, and analyzing such information in cloud servers is integral to how many of these apps work.⁵⁹ 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.⁶⁰

Digital therapeutics have greater freedom than mental health professionals to disclose user data to third parties. The FDA places no restrictions on the data that cleared and approved apps can share. With few exceptions, state statutes designed to prevent disclosure of medical data don't 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.⁶¹

The same is likely true of prescription-only digital therapeutics like those the FDA has cleared so far. HIPAA's rules apply not only to covered entities but also to their "business associates." Due to the phrasing of the Act, it is unclear whether a software firm that produces a mental health app could, under some circumstances, fall under this definition.⁶² It seems unlikely, though. For HIPAA to apply, an app would need to transmit protected health information "on behalf of" a treating doctor. Even an app met this definition, the company wouldn't be subject to many state-level laws and confidentiality requirements that apply to therapists.⁶³ From a privacy perspective, prescription-only apps turn patients into "users."

This is evident in the privacy policies that digital therapeutics publish on their websites. Akili Interactive, which

⁵⁸ https://my.akili.care/endeavor/IFU/Endeavor_IFU_1_5_0.pdf; As the app developers explain, "The game algorithm continues to challenge the child at a specific and consistent level of difficulty throughout the game..."

⁵⁹ See, e.g., Michael Mattioli, Mental Health Chatbots, in *PRIVACY AS KNOWLEDGE COMMONS GOVERNANCE* (eds. Katherine Strandburg, Brett Frischmann, and Michael Madison) (forthcoming, Cambridge University Press, 2020).

⁶⁰ *Id.*

⁶¹ See W. Nicholson Price II & I. Glenn Cohen, Privacy in the age of medical big data, 25 *Nature Medicine* (January 2019). The FDA cleared a non-prescription digital therapeutic in 2017 for the treatment of diabetes. See <https://www.welldoc.com/news/welldoc-receives-fda-510k-clearance-to-offer-a-non-prescription-version-of-bluestar-digital-therapeutic-for-type-2-diabetes/>.

⁶² 45 C.F.R. § 160.103.

⁶³ 45 C.F.R. § 164.504.

markets EndeavorRX, for instance, states that it will share personally identifying information collected by its ADHD app “for any purpose that is communicated to you or others when we collect or process any data or information.”⁶⁴ The policy also states, “Akili employees and our partners who need to know your data for the purposes described above will have access to your personally identifiable data.”⁶⁵ (The company states that employees are subject confidentially requirements, however.) Information subject to these rules includes a user’s name, email address, age, gender, “responses to app-related questionnaires including cognitive assessments,” “disclosed medical information or diagnosis, including that of your child,” and more.⁶⁶ Users of reSET and reSET-O can expect their medical data to be shared with marketing partners. A privacy policy on Pear Pharmaceuticals website states:

We disclose your Personal Data and non-Personal data to third party vendors who help us operate the Site. . . . We share Analytics with Clinicians, Clinical and Pharmacy Partners for their internal use and with other third parties to market and promote Pear Therapeutics and the Service.⁶⁷

As mentioned in the Introduction, thousands of wellness apps that have not received FDA approval (but someday might) contain similarly expansive privacy policies or no privacy policies at all. A recent comprehensive study of mental health app data practices concluded, “[t]he field of mental health apps is beset by risks to user privacy.”⁶⁸

Might some mental health app users have an expectation of greater privacy? This seems like a reasonable concern. 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 don’t always apply to app developers. (Recall that many privacy laws focus not just on the *information* disclosed, but also the *source*.) The problem might be more acute when a doctor prescribes an app. A patient could be forgiven for assuming that an app prescribed in the course of medical treatment has more stringent privacy protections than Instagram.

⁶⁴ <https://my.akili.care/privacy>.

⁶⁵ *Id.*

⁶⁶ *Id.*

⁶⁷ <https://peartherapeutics.com/reset-o-pt-privacy/>

⁶⁸ Parker et al., *supra* 2019.

There's good reason to think that the FDA's stamp of approval might contribute to skewed privacy expectations. Consumers trust the agency. Ted Ruger has noted, FDA "ranks highly in public opinion polls of the most trusted, effective, and independent federal agencies."⁶⁹ Daniel Carpenter has similarly written that FDA has "consistently been named or identified as one of the most popular and well-respected agencies in government" in recent decades.⁷⁰ Meanwhile, consumers lack a nuanced understanding of what, exactly, the FDA does. In a 2011 Dartmouth study surveying 2,944 participants, 39% believed that the FDA approves only "extremely effective" drugs, and 25% believed incorrectly that the FDA doesn't approve drugs that carry side-effects. At least one legal scholar has noted with concern that pharmaceutical and biotechnology firms have sometimes tried to trade on this "halo effect" by using the term "FDA Cleared" as a marketing device.⁷¹

Consumers and policymakers can benefit from knowing if an FDA privacy halo effect exists. The FDA has long sought to ensure that consumers have relevant and accurate information about the products that fall within its jurisdiction.⁷² Moreover, the agency's proper role is to ensure that medical devices are safe and effective – not to allow firms to stimulate generalized feelings of consumer goodwill. The following section of this Article reports the results of an original consumer survey designed to examine this question.

II. Surveying Consumer Perceptions

A. Methods

B. Results

III. Analysis and Recommendations

Conclusion

⁶⁹ Ruger, *supra*.

⁷⁰ Daniel Carpenter, Reputation and Power: Organizational Image and Pharmaceutical Regulation at the FDA

⁷¹ Darrow, *supra*.

⁷² Neal Hooker et al., "Natural" Food Claims, Food and Drug Law Journal, Vol. 73, No. 2 (2018) pp. 319-337 (noting that the FDA has "underscored the important role that labels play in providing consumers with relevant and accurate product information to make informed decisions on the purchase of food and beverages.)