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Mind the App

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I. INTRODUCTION

American mental health has never been worse.[1] Nearly 50 million Americans experienced a mental illness in 2019, and more than half — over 27 million adults — did not receive treatment for their condition.[2] While a thorough analysis of the COVID-19 pandemic's long-term impact on these already staggering mental health statistics is forthcoming, initial data suggest they will only continue this terrible trend.[3] Financial uncertainty, political strife, and systemic racism contribute to this growing problem.[4]

At the same time, health care in the United States is notoriously expensive and difficult to access.[5] Those barriers are more pronounced for mental and

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[1] *See* Jean M. Twenge et al., *Age, Period and Cohort Trends in Mood Disorder Indicators and Suicide-Related Outcomes in a Nationally Representative Dataset, 2005-2017*, 128 J. ABNORMAL PSYCH. 185, 199 (2019) (discussing the increasing prevalence of mental health disorders and related episodes from 2005 to 2017 and evaluating factors contributing to the increase).

[2] Maddy Reinert et al., *The State of Mental Health in America 2022*, MENTAL HEALTH AM. 1, 28 (Oct. 2021) (data reflective of the COVID-19 pandemic will not be made available until the 2023 report).

[3] *See generally* Jim Clifton, *The Next Global Pandemic: Mental Health*, GALLUP (Dec. 3, 2021), https://www.gallup.com/workplace/357710/next-global-pandemic-mental-health.aspx (reviewing statistics of increased prevalence of depression and anxiety disorders and proposing a mental wellness test which considers five elements of wellbeing – career, social, financial, physical and community); *see also* Nirmita Panchal et al., *The Implications of COVID-19 for Mental Health and Substance Use*, KAISER FAM. FOUND. (Feb. 10, 2021), https://www.kff.org/coronavirus-covid-19/issue-brief/the-implications-of-covid-19-for-mental-health-and-substance-use/ (reviewing statistics showing reported symptoms of anxiety and/or depressive disorder during and following the COVID-19 pandemic, noting that during the pandemic, "4 in 10 adults in the U.S. have reported symptoms of anxiety or depressive disorder").

[4] Claire Gillespie, *America's Mental Health is the Lowest it's Been in Two Decades*, VERYWELLMIND, https://www.verywellmind.com/american-mental-health-lowest-in-two-decades-5093930 (Jan. 4, 2021).

[5] *See* Audrey Kearney et al., *Americans' Challenges with Health Care Costs*, KAISER FAM. FOUND. (Dec. 14, 2021), https://www.kff.org/health-costs/issue-brief/americans-challenges-with-health-care-costs/ (reviewing statistics showing that during the pandemic, many adults in the U.S. cannot access or afford health care, dental services, or prescription drugs, also noting high costs disproportionately affect lower income or uninsured adults).

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behavioral health care.[6] Americans in need of mental health services must deal with high costs, lack of adequate insurance coverage, and long wait times—if they can make an appointment at all.[7] In addition to these structural barriers, the stigma surrounding mental illness could deter even those who can afford care from seeking needed treatment.[8]

Deteriorating mental health, inaccessible health care, and stigma amid a seemingly interminable pandemic create a toxic combination. However, technology may offer a solution. Apple is currently studying ways to improve brain health, such as enlisting smartphones and wearables to identify mental illness and cognitive decline early,[9] using iPhone cameras to detect childhood autism,[10] and uncovering connections between activity, smartphone use, and cognitive function.[11] Beyond these cutting-edge technologies, mental health applications of all kinds are already available for download in smartphone app stores.[12] Their services and functions include,

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[6] NAT'L ALL. ON MENTAL ILLNESS, *The Doctor is Out: Continuing Disparities in Access to Mental and Physical Health Care* 1, 3 (Nov. 2017), https://www.nami.org/Support-Education/Publications-Reports/Public-Policy-Reports/The-Doctor-is-Out/DoctorIsOut.

[7] *Id.* at 6, 9; *see* Cindy Dampier, *Mental Health Care Appointments Often Come with Long Wait: 3 Ways to Cope While Help is Delayed*, CHI. TRIBUNE (Oct. 25, 2018, 4:35 PM), https://www.chicagotribune.com/lifestyles/sc-fam-mental-health-wait-times-1030-story.html (reviewing contributing factors and effects of long delays in accessing mental and behavioral health care services, noting that research shows that "94 million Americans have to wait longer than one week for mental health services").

[8] *See Stigma, Prejudice, and Discrimination Against People with Mental Illness*, AM. PSYCHIATRIC ASS'N (Aug. 2020), https://www.psychiatry.org/patients-families/stigma-and-discrimination (noting "[s]tigma around mental illness especially an issue in some diverse racial and ethnic communities and it can be a major barrier to people from those cultures accessing mental health services").

[9] Bill Kisliuk, *UCLA Launches Major Mental Health Study to Discover Insights About Depression*, UCLA NEWSROOM (Aug. 4, 2020), https://newsroom.ucla.edu/releases/ucla-launches-major-mental-health-study-to-discover-insights-about-depression (describing how UCLA researchers, in collaboration with Apple, will conduct a three-year study to analyze data points from thousands of participants to see if mobile phones and wearables can provide unprecedented insight into mental health, perhaps identifying depression and anxiety early and without a medical professional).

[10] *See* Zhuoqing Chang et al., *Computational Methods to Measure Patterns of Gaze in Toddlers with Autism Spectrum Disorder*, 175 JAMA PEDIATRICS 827, 827 (2021) (evaluating eye-gaze patterns of toddlers with autism versus those with typical development, as captured by an app on iPhone or iPad).

[11] Andrea Park, *Apple Taps Biogen, UCLA to Explore Adding Mental Health Tracking to iPhone: Report*, FIERCE BIOTECH (Sept. 21, 2021, 8:50 AM), https://www.fiercebiotech.com/medtech/apple-taps-biogen-ucla-to-explore-addition-mental-health-tracking-to-iphone-report.

[12] *See* Rebecca A. Clay, *Mental Health Apps are Gaining Traction*, AM. PSYCH. ASS'N (Jan. 1, 2021), https://www.apa.org/monitor/2021/01/trends-mental-health-apps (discussing rise in mental health-related application availability, reviewing benefits and potential downsides).

among others, connecting prospective patients to providers, therapy chatbots, self-diagnosis tools, and "brain training" software.[13]

These innovations have the potential to offer an important and affordable alternative to traditional mental health care, especially given the significant disease burden on digital natives.[14] Further, people may be more willing to be honest when interacting with technology than with other human beings.[15] For individuals hesitant to seek treatment out of the fear of labels, stereotypes, discrimination, or other reasons, mental health apps may prove more appealing than face-to-face clinical encounters.[16] Thus, under certain

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[13] *See Evaluation of Mental Health Application*, AGENCY FOR HEALTHCARE RSCH. & QUALITY 1, 5, https://effectivehealthcare.ahrq.gov/products/mental-health-apps/protocol (Oct. 15, 2021) (noting "[m]ental health apps span all stages of clinical care provision, including immediate crisis intervention, prevention, diagnosis, primary treatment, supplement to in-person therapy, and post-treatment condition management."); *see also Achieve Your Potential with Talkspace Online Therapy*, TALKSPACE, https://try.talkspace.com/online-therapy (last visited Mar. 12, 2022) (describing Talkspace as "the most comprehensive and convenient way to take care of your mental health and wellbeing."); *see also FAQ*, WOEBOT HEALTH, https://woebothealth.com/faq/ (last visited Feb. 25, 2022) (defining Woebot as an "automated conversational agent (chatbot)" which simulates brief daily conversations with users); *see also* App Store Preview, *Depression Test*, https://apps.apple.com/us/app/depression-test/id666436210 (last visited Feb. 25, 2022) (defining the Depression Test application as one where users can take a test to screen for depression, check the severity of their depression, use self-guided therapy techniques to identify negative thoughts, and access depression resources); *see also Lumosity*, LUMOS LABS, https://www.lumosity.com/en/ (last visited Feb. 25, 2022) (describing Lumosity app as a brain-training application where used can train skills such as memory, processing speed, problem solving, etc.).
[14] *See* Joan Stephenson, *Surgeon General Urges Rapid, Coordinated Response to Mental Health Crisis in US Youth*, JAMA HEALTH FORUM (Dec. 14, 2021), https://jamanetwork.com/journals/jama-health-forum/fullarticle/2787279 (noting Surgeon General's concern surrounding mental health in youth, offering recommendations for media, local governments, and the larger health care sector); *see also* Twenge et al., *supra* note 1 (discussing a study that suggested suicidal trends and recent serious psychological distress is largely attributed to birth cohort, especially among those born from 1982-1999); *see also Digital Natives*, AM. LIBRARY ASS'N (Feb. 19, 2015), https://www.ala.org/tools/future/trends/digitalnatives (describing digital native trends and classifications, defining digital natives as children and young people born into "and raised in a digital world" after 1980.).
[15] *See* Bryan Borzykowski, *Truth be Told, We're More Honest with Robots*, BBC WORKLIFE (Apr. 18, 2016), https://www.bbc.com/worklife/article/20160412-truth-be-told-were-more-honest-with-robots (noting reasons why people are more trustworthy and open when interfacing with robots or automated online technology than they are when interacting with other humans – data shows individuals believe robots are more ethical, will not judge, and are more trustworthy).
[16] Heather Landi, *Demand for Virtual Mental Health Care is Soaring. Here Are Key Trends on Who is Using it and Why*, FIERCE HEALTHCARE (Oct. 23, 2020, 2:05 PM) https://www.fiercehealthcare.com/tech/demand-for-virtual-mental-health-soaring-here-are-notable-trends-who-using-it-and-why (mentioning that "62% of consumers would prefer a virtual visit for their regular mental health visits, even after it is safe to visit a doctor's office in person").

circumstances, mental health apps could be *more* effective than conventional treatments due to increased access to and acceptance of the apps.[17]

However, despite their promise, mental health apps remain poorly and inconsistently regulated, and the market is both expansive and confusing.[18] The technologies currently available range from telehealth tools and U.S. Food and Drug Administration (FDA)-approved medical devices to low-risk wellness apps to the digital equivalent of snake oil.[19] While the Federal Trade Commission (FTC) or state attorneys general may get involved in extreme cases of deception or misrepresentation, industry self-regulation tends to carry the day.[20] Further complicating matters, the FDA relaxed enforcement of compliance rules for "digital therapeutics" in response to the pandemic, allowing mental health wellness apps to subtly rebrand as medical interventions so long as the apps do not create "undue risk."[21] Unfortunately, the current patchwork system does very little to distinguish vastly different quality products.[22] As a result, questionable, ineffective, or, worse yet, dangerous mental health apps exist in app stores alongside their highly regulated, evidence-based counterparts, and these products may be nearly indistinguishable to the average consumer.[23] In fact, research suggests that ineffective mental health apps might predominate the market.[24]

This article proceeds in three parts. Part I considers the promise of apps to address the current mental health crisis. Part II then shows that while these technologies may offer a desirable alternative to traditional treatment, they

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[17] *See id.* (stating that an increase in availability of virtual care is beneficial to certain populations, especially in response to the increase in need after the COVID-19 pandemic).

[18] Nicolas P. Terry & Tracy D. Gunter, *Regulating Mobile Mental Health Apps*, 36 BEHAV. SCI. L. 136, 139 (2018) (reviewing the current regulatory landscape and the disparate impact of many interested agencies as the market for mobile mental health applications grows rapidly); Leah Fowler, *Health App Lemons*, 74 ALA. L. REV. (forthcoming Dec. 2022) (manuscript at 17–21) (on file with author).

[19] *See* Fowler, *supra* note 18 (unpublished manuscript at 3, 10–18) (on file with author) (discussing the disparities in oversight of mental health applications).

[20] Nicolas P. Terry & Tracy D. Gunter, *Regulating Mobile Mental Health Apps*, 36 BEHAV. SCI. L. 136, 140 (2018).

[21] U.S. DEP'T OF HEALTH & HUM. SERVS. ET AL., ENF'T POL'Y FOR DIGIT. HEALTH DEVICES FOR TREATING PSYCHIATRIC DISORDERS DURING THE CORONAVIRUS DISEASE 2019 (COVID-19) PUB. HEALTH EMERGENCY: GUIDANCE FOR INDUSTRY AND FOOD & DRUG ADMIN. STAFF 7–9 (2020).

[22] *See* James A. Armontrout et al., *Current Regulation of Mobile Mental Health Applications*, 46 J AM. ACAD. PSYCH & L. 204, 207 (2018) (discussing the small changes in intended use of an application that can either exempt from or bring an application under government agency regulation).

[23] Kathleen M. Palmer & Vanessa Burrows, *Ethical and Safety Concerns Regarding the Use of Mental Health–Related Apps in Counseling: Considerations for Counselors*, 31 J. TECH. BEHAV. SCI. 137, 138 (Aug. 31, 2020).

[24] Simon B. Goldberg et al., *Mobile Phone-Based Interventions for Mental Health: A Systematic Meta-Review of 14 Meta-Analyses of Randomized Controlled Trials*, 1 PLOS DIGIT. HEALTH 1 (Jan. 18, 2022).

are not uniformly governed, and consumers may be subject to vastly different protections. Part III turns to how these inconsistencies may lead to consumer confusion because potential users cannot easily differentiate between high- and low-quality products. It then offers a voluntary labeling system to combat the information asymmetries that currently exist. The article concludes that policymakers must mind the gaps in mental health app regulation and design consumer-centric solutions that evolve alongside this rapidly developing market.

II. THE AMERICAN MENTAL HEALTH LANDSCAPE

The United States is in the throes of a mental health crisis, exacerbated by our broken health care system and negative attitudes toward mental illness.25 Yet where traditional health care fails, new technologies like mental health apps may offer an innovative path forward.26 Part I gives a brief overview of the current barriers to getting treatment for mental health. It then introduces mental health apps as a possible low-cost, accessible alternative.

A. The American Mental Health Crisis

The National Institutes of Mental Health reports that nearly one in five U.S. adults live with mental illness.[27] While these conditions can be debilitating even with dedicated treatment and support, a majority of Americans go without any care at all.[28] Untreated mental illness contributes to substance use disorders, overdoses, and suicides.[29] This immense disease burden places an enormous toll on individuals, families, and the economy.[30] The cost includes thousands of American lives needlessly lost and billions of dollars spent every year.[31]

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[25] AM. PSYCHIATRIC ASS'N, *supra* note 8, *see generally* U.S. SURGEON GENERAL'S OFF., PROTECTING YOUTH MENTAL HEALTH 16 (2021) (discussing the need for a change in the perception and availability of mental health care for children).

[26] Terry & Gunter, *supra* note 18, at 136.

[27] *Mental Illness*, NAT'L INST. MENTAL HEALTH (last updated Jan. 2022), https://www.nimh.nih.gov/health/statistics/mental-illness.

[28] *See id.* (detailing that only 46.2% of Americans with any mental illness received care for their mental illness in 2020).

[29] Karen Santucci, *Psychiatric Disease & Drug Abuse*, 24 CURRENT OP. IN PEDIATRICS 233, 233 (2012) (discussing hypotheses for dual diagnoses of mental illnesses and substance abuse disorders); Elizabeth Sinclair, *Serious Mental Illness and Suicide*, TREATMENT ADVOC. CTR. (June 13, 2008), https://www.treatmentadvocacycenter.org/fixing-the-system/features-and-news/4011-research-weekly-serious-mental-illness-and-suicide (discussing the presence of an untreated mental illness increases the risk of suicide).

[30] *Facts & Statistics*, NAT'L ALLIANCE ON MENTAL ILLNESS (NAMI) (last visited Apr. 1, 2022), https://namica.org/what-is-mental-illness/facts-statistics/.

[31] *See Health Reform & Mental Illness*, NAT'L ALLIANCE ON MENTAL ILLNESS (NAMI), https://www.nami.org/getattachment/Get-Involved/NAMI-National-Convention/Convention-

This crisis impacts certain groups more than others. Racial and ethnic minorities bear a disproportionately high burden of disability from mental disorders.[32] Suicide is the second leading cause of death among people aged 10-34.[33] Males are significantly less likely than females to seek mental health treatment.[34] The annual prevalence of mental illness among LGBTQIA adults is as high as 37.4%.[35] Rural communities have fewer resources than their urban counterparts.[36] Yet these disparities aside, the crisis is far-reaching enough that it has the potential to touch all Americans.[37]

Despite America's steadily worsening mental health, needed medical resources remain difficult to access.[38] With some exceptions, existing mental health parity laws aim to ensure that group health plans and insurance issuers that provide mental health or substance use disorder benefits do so equitably.[39] Regardless, significant barriers persist in mental health care that

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Program-Schedule/Hill-Day-2017/FINAL-Hill-Day-17-Leave-Behind-all-(1).pdf (describing the costs of untreated mental health issues, and proposing policy-based solutions); *see also* Megan Leonhardt, *What You Need to Know About Cost and Accessibility of Mental Health Care in America*, CNBC (May 10, 2021), https://www.cnbc.com/2021/05/10/cost-and-accessibility-of-mental-health-care-in-america.html (describing spending on mental health treatment, both through direct financial costs and indirect costs like lower workforce participation and decreased productivity).

[32] *Mental Health Disparities: Diverse Populations*, AM. PSYCH. ASS'N (2017), https://www.psychiatry.org/File%20Library/Psychiatrists/Cultural-Competency/Mental-Health-Disparities/Mental-Health-Facts-for-Diverse-Populations.pdf (discussing racial and ethnic disparities for mental health diagnosis and care).

[33] *Facts & Statistics, supra* note 30.

[34] *Id.*

[35] *Id.*

[36] Dawn A. Morales et al., *A Call to Action to Address Rural Mental Health Disparities*, 4 J. CLINICAL TRANSLATIONAL SCI. 463, 463 (2020); *see also* Facts & Statistics, *supra* note 30 (stating that one in five adult Americans have reported experiencing mental illness each year and one in six American youths experiencing mental illness); *see also* Press Release, The White House, FACT SHEET: President Biden to Announce Strategy to Address Our National Mental Health Crisis, As Part of Unity Agenda in his First State of the Union (Mar. 1, 2022), https://www.whitehouse.gov/briefing-room/statements-releases/2022/03/01/fact-sheet-president-biden-to-announce-strategy-to-address-our-national-mental-health-crisis-as-part-of-unity-agenda-in-his-first-state-of-the-union/ (noting that President Biden's FY23 budget will invest millions in programs to address mental health in rural and underserved communities).

[37] Press Release, The White House, FACT SHEET: President Biden to Announce Strategy to Address Our National Mental Health Crisis, As Part of Unity Agenda in his First State of the Union (Mar. 1, 2022), https://www.whitehouse.gov/briefing-room/statements-releases/2022/03/01/fact-sheet-president-biden-to-announce-strategy-to-address-our-national-mental-health-crisis-as-part-of-unity-agenda-in-his-first-state-of-the-union/ (quoting "our country faces an unprecedent mental health crisis among people of all ages").

[38] Facts & Statistics, *supra* note 30 (noting the treatment gaps among different groups of people, demonstrating disparities in access).

[39] *The Mental Health Parity and Addiction Equity Act* (MHPAEA), CTRS. FOR MEDICAID & MEDICARE, https://www.cms.gov/CCIIO/Programs-and-Initiatives/Other-Insurance-Protections/mhpaea_factsheet (last visited May 29, 2022).

are absent in other areas of care.[40] For example, patients seeking outpatient mental health treatment are more likely to use an out-of-network provider.[41] Just finding an in-network therapist can be harder than other types of services.[42] And should someone be lucky enough to find an in-network provider, insurance companies are more likely to deny claims for mental health services or to charge higher out-of-pocket costs.[43] As a result, people with otherwise good insurance could still find themselves paying more for mental health services.[44]

Beyond just navigating insurance, millions of Americans may have trouble finding nearby mental health care professionals.[45] Only twenty-seven percent of mental health needs are currently met in underserved areas, affecting more people than the primary care and dental care shortages combined.[46] Given that the number of mental health professionals is expected to shrink, the availability of these already scarce services will likely continue to diminish over time, just as they are needed most.[47]

Sadly, mental health stigma in the United States remains high, resulting in the compounding of pervasive structural barriers.[48] A person who is aware of negative beliefs about mental illness or has internalized those beliefs may forgo treatment to avoid the label and its ensuing social consequences. For example, they may feel shame or fear that their situation is hopeless.[49] Thus, in addition to cost and access, stigma about mental illness may also deter people from seeking needed treatment or from fully engaging when they do.[50]

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[40] NAT'L ALL. ON MENTAL HEALTH, *supra* note 6 at 2.

[41] *Id.* at 4.

[42] *Id.*

[43] *Id.* at 6.

[44] *New Report Reveals Worsening Disparities in Access to Behavioral Healthcare for Employer-Sponsored Health Plans*, GLOBE NEWSWIRE, (Nov. 20, 2019, 10:16AM), https://www.globenewswire.com/news-release/2019/11/20/1950219/0/en/New-Report-Reveals-Worsening-Disparities-in-Access-to-Behavioral-Healthcare-for-Employer-Sponsored-Health-Plans.html.

[45] *Mental Health Care Professional Shortage Areas* (HPSAs), KAISER FAM. FOUND. (Sept. 30, 2021), https://www.kff.org/other/state-indicator/mental-health-care-health-professional-shortage-areas-hpsas/? (displaying the Health Professional Shortage Area (HPSA) designations used to identify areas and population groups within the United States that are experiencing a shortage of health professionals, as well as displaying the numbers of practitioners needed to remove the HPSA).

[46] MADDY REINHERT ET AL., 2022: THE STATE OF MENTAL HEALTH IN AMERICA 39 (2021).

[47] U.S. DEP'T OF HEALTH & HUM. SERVS. ET AL., NATIONAL PROJECTIONS OF SUPPLY AND DEMAND FOR SELECTED BEHAVIORAL HEALTH PRACTITIONERS: 2013–2025, 3 (2016).

[48] Angela M. Parcesepe & Leopoldo J. Cabassa, *Public Stigma of Mental Illness in the United States: A Systematic Literature Review*, 40 ADMIN. & POL'Y MENTAL HEALTH 384, 384 (2013).

[49] *Id.* at 43 (discussing self-stigma as the internalization of prejudice against seeking mental health care and its adverse impact on care-seeking).

[50] 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, 37 (2014).

To summarize, the mental health crisis in America is reaching new heights, compounded by old problems. Care can be expensive and difficult— if not impossible—to access. Stigma and shame create additional hurdles to treatment. But even if we could overcome those barriers, traditional mental health resources are limited and shrinking. Perhaps, then, an entirely new approach to mental health care may prove the most promising.

B.   Mental Health Apps as a Solution

The mental health space is ripe for disruptive innovation. Not surprisingly, the market for mental health apps is booming.[51] This growth can generate incredible innovation when developers compete to offer consumers the best product.[52] But, it can also incentivize unsavory developers to enter the market with a low-quality product to make a quick buck at the expense of vulnerable consumers.[53] As a result, both effective and dangerous mental health apps are available for download in smartphone app stores.[54] As we discuss at greater length in Part II, this wide range of products is largely due to the inconsistent regulation of health care technologies.[55] However, we begin with a more optimistic view of mental health apps.

The National Institutes of Mental Health groups mental health apps into six popular development areas.[56] The first is self-management, which provides feedback based on user-inputted information.[57] The second is improved thinking skills, which often targets those with serious mental illness.[58] Third is skills training, which frequently gamifies[59] interventions intended to help users learn coping or thinking skills.[60] Fourth is illness management and supported care, which provides an avenue for interaction

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[51]Rebecca Clay, *Mental Health Apps are Gaining Traction*, 52 APA (Jan. 1, 2021), https://www.apa.org/monitor/2021/01/trends-mental-health-apps; *see also* Nichols, *supra* note 88 (describing different components of popular apps available to individuals today).
[52] Gold, *infra* note 89 (discussing how tech companies compete with one another in a saturated marketplace).
[53] *Id.*
[54] Jamie M. Marshall et al., *Apps with Maps – Anxiety and Depression Mobile Apps with Evidence-Based Frameworks: Systematic Search of Major Apps Stores*, 7 J. MED. INTERNET RSCH. MENTAL HEALTH 1, 6 (2020), https://mental.jmir.org/2020/6/e16525/.
[55] *Id.* at 6.
[56] Technology and the Future of Mental Health Treatment, NAT'L INST. OF MENTAL HEALTH (Sept. 2019), https://www.nimh.nih.gov/health/topics/technology-and-the-future-of-mental-health-treatment/.
[57] *Id.*
[58] *Id.*
[59] *Gamify*, MERRIAM-WEBSTER.COM, https://www.merriam-webster.com/dictionary/gamification (last visited May 15, 2022) (defining the word "gamify" as "the process of adding games or gamelike elements to something (such as a task) so as to encourage participation").
[60] NAT'L INST. OF MENTAL HEALTH, *supra* note 56

with other people, like peer support groups.[61] Fifth is passive symptom tracking, which uses smartphone sensors to record things like movement patterns.[62] Finally, there is passive data collection, which can gather data without user input.[63]

When designed well, mental health apps can perform these functions alone or in combination to target an array of symptoms and illnesses.[64] Existing apps aim to address everything from self-awareness and relaxation to more significant disorders with serious prognoses, like anxiety, bipolar disorder, depression, and schizophrenia.[65] Some gamify treatment, others provide virtual approximations of what we would recognize as cognitive behavioral therapy or exposure therapy.[66] Some popular press articles go as far as to frame mental health apps as an alternative to therapy.[67]

Yet the framing of apps as completely detached from provider involvement is not entirely accurate. Mental health apps may work in conjunction with more traditional treatments. While most deliver standalone self-help tools for managing mental health symptoms,[68] others are supported apps, used in concert with professional care providers.[69] And in some cases, mental health apps are part of blended care to improve the efficacy and efficiency of traditional treatment.[70]

Research suggests that at least some mental health apps are efficacious.[71] A meta-analysis of eighteen randomized controlled trials (RCTs) indicated that apps have the potential to help reduce users' depressive symptoms and that the results were greatest in those with mild to moderate depression.[72]

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[61] *Id.*

[62] *Id.*

[63] *Id.*

[64] *See id.* (discussing potential benefits to leveraging different functionalities of mental health apps).

[65] Jessica Truschel & Jennifer Tzeses, *Top Mental Health Apps: An Effective Alternative for When You Can't Afford Therapy?* PSYCOM (Dec. 22, 2021), https://www.psycom.net/25-best-mental-health-apps.

[66] Theodore T. Lee, *Recommendations for Regulating Software-Based Medical Treatments: Learning from Therapies for Psychiatric Conditions,* 73 FOOD & DRUG L. J. 66, 71–72 (2018) (describing different types of mental health apps).

[67] Truschel & Tzeses, *supra* note 65.

[68] *See id.* (showcasing various apps that address mental health issues using self-management).

[69] *See id.* (discussing apps that utilize professional care providers in their care model).

[70] *See id.* (reflecting accounts of professionals who used mental health apps in concert with traditional therapy sessions).

[71] *See generally* Joseph Firth et al., *The Efficacy of Smartphone-Based Mental Health Interventions for Depressive Symptoms: A Meta-Analysis of Randomized Controlled Trials,* 16 WORLD PSYCHIATRY 287, 287–88 (2017) (discussing the efficacy of some mental health apps in treating depressive symptoms); *but see* Goldberg et al., *supra* note 24 at 2.

[72] Joseph Firth et al., *The Efficacy of Smartphone-Based Mental Health Interventions for Depressive Symptoms: A Meta-Analysis of Randomized Controlled Trials,* 16 WORLD PSYCHIATRY 287, 287–88 (2017).

Another RCT meta-analysis that explored mental health apps providing anxiety interventions showed that the apps could reduce consumers' total anxiety and replace outpatient patient-therapist sessions without significant loss of efficacy.[73] Finally, a systematic review of mental health apps for schizophrenia also showed high levels of adherence, positive user experience, and even some clinical benefits.[74]

In addition to potential clinical benefits, these technologies compare favorably to conventional health care in other important ways. Mental health apps are both cheaper and easier to access.[75] A person with employer-provided health insurance pays over six thousand dollars more annually to treat major depression than a similarly employed person without that condition.[76] Apps, by contrast, are often very low-cost or even free.[77] They are, therefore, significantly more affordable than conventional treatment.

Mental health apps can also provide greater access to treatment and care.[78] Smartphones are already well-embedded in our daily lives, creating a natural point of contact, and can scale up to reach underserved areas.[79] For individual consumers, smartphone apps enjoy a low threshold for use. People can use apps to access portable and flexible mental health resources.[80] Mental health apps may then have clear advantages over in-person treatment, such as increased capacity, constant availability, improved equity, immediate support, anonymity, personalized approaches, links to other technology systems, and lowered costs.[81] Apps could also provide continuous support to individuals as they apply newly learned skills in real-life situations,[82] thus

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[73] *See generally* Joseph Firth et al., *Can Smartphone Mental Health Interventions Reduce Symptoms of Anxiety? A Meta-Analysis of Randomized Controlled Trials*, 218 J. AFFECTIVE DISORDERS 15, 20–21 (2017) (outlining results of study showing efficacy of smartphone mental health apps in treating anxiety).

[74] Joseph Firth & John Torous, *Smartphone Apps for Schizophrenia: A Systematic Review*, 3 JMIR MHEALTH UHEALTH 36, 41 (2015), https://mhealth.jmir.org/2015/4/PDF.

[75] *See generally* Debra Lerner et al., *The High Cost of Mental Disorders: Facts for Business Leaders*, TUFTS MED. CTR. PROGRAM ON HEALTH, WORK & PRODUCTIVITY (2020), https://secureservercdn.net/198.71.233.213/e47.77e.myftpupload.com/wp-content/uploads/2020/09/OMaW_Tufts-Study_High-Cost-of-Mental-Disorders-1.pdf (outlining high costs for mental health care); *see also* Miranda Olff, *Mobile Mental Health: A Challenging Research Agenda*, 6 EUR. J. PSYCHOTRAUMATOLOGY (2015) (outlining the affordability of mental health apps).

[76] Lerner et al., *supra* note 75.

[77] Olff, *supra* note 75.

[78] *Id.*

[79] *Id.*

[80] *Id.*

[81] *Id.*

[82] Kiona K. Weisel et al., *Standalone Smartphone Apps for Mental Health – A Systemic Review and Meta-Analysis*, 2 NPJ DIGIT. MED. 1, 1 (2019).

improving the management of chronic diseases.[83] As a result, these digital tools hold considerable promise to improve accessibility, affordability, engagement and retention, increase youth participation at times when mental illness is most likely to present, and support patient-driven care and shared decision-making.[84]

Finally, although not addressing mental illness stigma at its core, these technologies could mitigate the effects of stigma on seeking treatment.[85] Users can download mental health apps privately, and apps do not give diagnoses the same way a provider would.[86] Thus, mental health apps have the potential to be less stigmatizing than more conventional approaches to mental health care.[87]

III. REGULATING MENTAL HEALTH APPS

Apps, at least in theory, have the potential to alleviate the mental health crisis.88 However, for mental health apps to live up to this enormous promise, consumers must be able to select apps that are effective and appropriate for their mental health needs. Unfortunately, current approaches to health app regulation and app store displays may leave consumers confused or misled. To start, most mental health apps are not health care or medical devices, per se.89 Separate sets of laws and regulations govern these technologies, and the rigorousness of the standards depends largely on the kinds of functions the apps purport to perform.90 The result is that consumers of mental health apps have inconsistent protection from potentially harmful products, and they may not know whether a product is

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[83] *See generally* Alayna M. Frauhiger, *Mobile Health Apps and Wearable Technology: Addressing Emerging Risks Without Derailing Chronic Care Management,* 29 ANNALS HEALTH L. ADVANCE DIRECTIVE 145, 148 (2020) (discussing the opportunities for technology to improve chronic diseases).

[84] Jena M. Richer, *Victims of Introspection: Insufficient Legal Protections for At-Risk Users of Automated Mental Health Apps,* 44 VT. L. REV. 893, 902–904 (2020).

[85] *Id.* at 900.

[86] *Id.* at 899.

[87] *Id.*

[88] *See* Hannah Nichols, *The Top 8 Mental Health Apps,* MED. NEWS TODAY (Jan. 12, 2022), https://www.medicalnewstoday.com/articles/320557 (discussing how apps can improve the mental health crisis).

[89] Jenny Gold, *Need Mental Health Help? There Are Apps for That, but Picking the Right One is Tough,* L.A. TIMES (June 21, 2021), https://www.latimes.com/california/story/2021-06-21/mental-health-apps-consumer-challenge-picking-the-right-one (stating how certain apps claim they are something they are not and describing the vast amount of mental health apps to choose from on the consumer's end).

[90] James A. Armontrout et al., *Current Regulation of Mobile Mental Health Applications,* 46 J. AM. ACAD. PSYCHIATRY L. 204, 207 (2018).

effective or harmful until it is too late.91 This Part briefly describes the laws and regulations that govern mental health apps in the United States, including how the FDA further dialed back its enforcement during the pandemic.

A. Laws and Regulations

A handful of mental health apps have received FDA approval or clearance, but the vast majority of health apps available in smartphone app stores enter the market without FDA involvement.[92] For example, in 2020, the FDA authorized *Somryst* as the first and only prescription digital therapeutic for chronic insomnia using cognitive behavioral therapy techniques.[93] However, not all insomnia app developers seek FDA approval for their products. A quick search for "insomnia" in the Apple App Store reveals several available health apps that the FDA does not regulate.[94] This outcome is possible because the FDA takes a risk-based approach to regulation. While it categorizes some health apps as medical devices requiring approval or clearance, the agency designates others as low-risk devices and exercises enforcement discretion based on the intended use of the product in question.[95] Others still do not meet the definition of a medical device at all.[96] Most apps fall into one of these latter categories. This light regulatory touch is intended to spur innovation by enabling products that are unlikely to harm consumers to enter the market more easily.

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[91] Gold, *supra* note 89 (discussing how consumers fall through the cracks because of a lack of regulation).

[92] *Id.*; 21 U.S.C. §360j(o)(1)(A)–(E) (2011). Moreover, the 21st Century Cures Act places yet another subset of these low-risk products outside of the agency's regulation and oversight altogether. Specifically, section 3060(a) of the 21st Century Cures Act amended section 520 of the FD&C Act to remove certain software functions from this definition. Section 3060 excludes five software functions from the FDCA definition of a device, including those that: provide administrative support for a health care facility; maintain or encourage a healthy lifestyle; serve as electronic patient records; transfer, store, or display data for converting data formats; and provide limited clinical decision support.

[93] Charles M. Morin, *Profile of Somryst Prescription Digit. Therapeutic for Chronic Insomnia: Overview of Safety and Efficacy*, 17 EXPERT REV. MED. DEVICES 1239, 1239 (2020), https://doi.org/10.1080/17434440.2020.1852929.

[94] *See* Amy Marschall, *Which Mental Health Apps are FDA-Approved*, VERYWELLMIND (Oct. 1, 2021), https://www.verywellmind.com/fda-approval-and-mental-health-apps-5193123 (stating the few apps that are approved as of October 2021).

[95] *Device Software Functions Including Mobile Medical. Applications*, U.S. FOOD & DRUG ADMIN. (Nov. 5, 2019), https://www.fda.gov/medical-devices/digital-health-center-excellence/device-software-functions-including-mobile-medical-applications#c; "Enforcement discretion" means the FDA will not enforce applicable regulatory requirements. Determining a product's intended use is a complex question and more complete analysis is outside the scope of this paper.

[96] *Id.* (explaining that software functions are not medical devices (meaning such software functions do not meet the definition of a device under section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)), and FDA does not regulate them as devices).

Once a product has entered the market, the FDA still has regulatory authority. For instance, the agency retains some jurisdiction over labeling for certain types of devices.[97] It also investigates potential violations of the Federal Food, Drug, and Cosmetics Act.[98] Typically, the FDA will communicate with a product's developer to gather information and encourage voluntary compliance before initiating an enforcement action.[99]

The FDA shares oversight of some products with the FTC.[100] The FTC is responsible for protecting consumers and promoting competition in the market.[101] This includes the regulation of deceptive or unfair claims in advertising.[102] For example, *Lumosity* claimed the ability to improve cognitive function, delay age-related cognitive decline, and "reduce cognitive impairment associated with health conditions, including stroke, traumatic brain injury, [post-traumatic stress disorder], [attention deficit hyperactivity disorder], the side effects of chemotherapy, and Turner syndrome," and it advertised that "scientific studies proved these benefits."[103] However, the FTC brought an action against the developer because the evidence did not support those assertions.[104] *Lumosity* ultimately settled the claim.[105]

Beyond these federal agencies and others, consumer and contract laws protect consumers of mental health apps.[106] State attorneys general may file

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[97] *See Device Labeling*, U.S. FOOD & DRUG ADMIN. (Oct. 23, 2020), https://www.fda.gov/medical-devices/overview-device-regulation/device-labeling (describing FDA labeling practices).

[98] *Inspection of Cosmetics*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/cosmetics/cosmetics-compliance-enforcement/inspection-cosmetics.

[99] *Letters to Industry*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/medical-devices/industry-medical-devices/letters-industry.

[100] *Health Claims*, FED. TRADE COMM'N (Apr. 4, 2016), https://www.ftc.gov/news-events/media-resources/truth-advertising/health-claims; *see also infra* note 97 and accompanying text (detailing some of the relevant FTC statutory oversight authority).

[101] *What We Do*, FED. TRADE COMM'N, https://www.ftc.gov/about-ftc/what-we-do (last visited May 29, 2021).

[102] *See* 15 U.S.C § 45 (noting that the FTC Act authorizes the FTC to regulate unfair and deceptive acts or practices; *see also* 15 U.S.C. §§ 52–55 (noting that section 12–15 prohibits the dissemination of any false or misleading advertisement); *see also Advertising and Marketing*, FED. TRADE COMM'N, https://www.ftc.gov/tips-advice/business-center/advertising-and-marketing (last visited Jan. 20, 2021) (stating that the FTC requires that claims in advertising are "truthful, cannot be deceptive or unfair, and must be evidence-based"); *see also* 15 U.S.C. § 53 (noting that section 13(b) authorizes the FTC to file suit to enjoin an act or practice that violates these provisions).

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

[104] *Id.*

[105] *Id.*

[106] Leah R. Fowler et al., *Uncertain Terms*, 97 NOTRE DAME L. REV. 1, 26–27 (2021); *see also* Nathan Cortez, *The Mobile Health Revolution?* 47 U.C. DAVIS L. REV. 1173, 1179

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actions for unfair or deceptive practices, and individuals or classes may bring legal claims handled in courts or through arbitration.[107] An app's terms of service (ToS) or End Users License Agreement (EULA), which are contracts that specify the rights and responsibilities of developers and consumers and enumerate the app's capabilities, limitations, and disclaimers, generally govern these disputes.[108]

B. FDA's Pandemic Waivers

If the patchwork regulatory system described above was not confusing enough, the FDA further dialed back its efforts to police mental health apps in light of the pandemic.[109] Though mental health apps predate the 2020 spread of COVID-19, the coronavirus pandemic gave these tools increased importance.[110]   When many clinics shut their doors to in-person appointments, commentators recognized that mental health apps could provide a promising solution to the lack of available care.[111]

The FDA was among those that recognized the promise of mental health apps. In April 2020, the agency issued guidance to help "facilitate consumer and patient use [of digital health therapeutic devices for psychiatric disorders] while reducing user and healthcare provider contact and potential exposure to COVID-19."[112] Part of this effort was reducing enforcement. The FDA specified that it would not "object to the distribution and use of" mental health apps, including both regulated devices and low-risk apps, so long as they did not "create an undue risk in light of the public health

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(2014) ("Congress and over half a dozen federal agencies, including the FDA, the Federal Communications Commission ("FCC"), the Federal Trade Commission ("FTC"), the Department of Commerce, the Department of Defense, and various subagencies of the Department of Health and Human Services ("HHS"), have addressed mobile health"); Others have argued that health apps blur the division between the FDA and the FTC, and that their functions are both overlapping and complementary.; Sarah Duranske, *This Article Makes You Smarter! (Or, Regulating Health and Wellness Claims)*, 43 AM. J. L. & MED. 7, 8 (2017).

[107] Fowler et al., *supra* note 106 at 38.

[108] Jennifer Laird, *EULA versus Terms and Conditions*, PRIVACY POL'YS (Sept. 17, 2020), https://www.privacypolicies.com/blog/eula-vs-terms-conditions/#:~. ("An EULA sets out what end users can and can't do with your *software*. A Terms and Conditions agreement set out what services you agree to offer the end user and how you expect them to behave in return.").

[109] 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 1, 4 (Apr. 2020), https://www.fda.gov/media/136939/download.

[110] Robert L Longyear & Kostadin Kushlev, *Can Mental Health Apps Be Effective for Depression, Anxiety, and Stress During a Pandemic?*, 6 PRAC. INNOVATIONS 131, 131 (2020).

[111] *Id.*

[112] U.S. FOOD & DRUG ADMIN., *supra* note 109

emergency."[113] While the guidance was in effect, the agency would not investigate "low-risk" products making mental health claims or, if the technology qualified as a medical device, enforce the applicable standards.[114] The FDA did not, however, relax its oversight for certain software functions intended for treatment.[115] Unfortunately, whether a technology offers treatment per se, is not always obvious to consumers, especially when an app developer is creative with the claims made in advertising and disclaimers.

The effect was nearly instantaneous, with mental health apps modifying their marketing to present a more medical façade to attract customers.[116] Developers also poured money into mental health apps: venture capital firms invested over $2.4 billion in digital behavioral health apps in 2020—more than double from the year prior.[117] While the motivation behind the guidance was positive—to encourage mental health app use in the face of a pandemic that closed many providers' offices and spiked emotional distress—the long-term effects of this decision on the market and on consumers of mental health apps remain unknown.[118]

Put briefly, the patchwork regulation of mental health apps leaves consumers vulnerable.[119] High-quality, highly regulated products appear alongside untested and unregulated ones in an app store.[120] However, as discussed in the following Part, it may not be clear to the average consumer which ones are evidence-based or -informed and high-quality and which are not.

IV. IDENTIFYING & ADDRESSING CONSUMER CONFUSION

The regulatory approaches described in Part II can promote innovation or give people access to needed care during a public health crisis. Yet the current system may also confuse vulnerable consumers who rely on apps to manage their mental health but lack useful information about product efficacy. This Part explores the dangers this information gap can create in a market predominated by ineffective—and potentially harmful—products. It then offers solutions that incorporate scientific evaluation of mental health

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[113] *Id.* at 7, 10.

[114] *See id.* at 10 (explaining that the FDA would not "(a) examine low-risk digital health products that make certain claims for mental health or psychiatric conditions to determine whether they are devices as described in section 201(h) of the [Food Drug & Cosmetic] Act, or (b) if they are devices, enforce applicable regulatory requirements.").

[115] *Id.* at 12.

[116] Michael Mattioli, *Second Thoughts on FDA's COVID-Era Mental Health App Policy*, 21 HOUS. J. HEALTH L. & POL'Y 9, 22 (2021).

[117] Gold, *supra* note 89.

[118] Mattioli, *supra* note 116, at 33.

[119] *See* Gold, *supra* note 89 (discussing the absence of FDA regulation for mental health apps).

[120] *Id.*

apps into app store displays and search results and discusses how this approach can help promote informed choices as a first step to broader industry change.

A.   Opportunities for Consumer Confusion

As explained in Part II, mental health apps may provide a viable alternative to expensive, inaccessible, and potentially stigmatizing traditional mental health care.[121]   However, not all apps are created equal, and the average consumer lacks the tools to distinguish between this wide range of products.[122]

While the very best of mental health apps may have FDA approval or clearance, those represent only a fraction of the larger market for mental health apps. Researchers have raised the criticism that many existing studies of health app efficacy are deficient, and those that are scientifically rigorous are not generally available to consumers.[123] The result is what some scholars have referred to as a market with "high availability but low evidence base."[124] This lack of evidence may mean that many, perhaps even the vast majority of mental health apps, provide no clinical benefit.[125] However, it may also mean that some mental health apps are harmful.[126]

Mental health apps may offer dangerous advice to vulnerable consumers. Consider a 2016 systematic review of mental health apps referring to suicide or deliberate self-harm.[127] As part of the research, the study team coded for harmful content, which included: "describing or facilitating access to lethal means; providing encouragement to people to end their life" and "portraying suicide in a fashionable or appealing manner."[128] Notably, two mental health apps provided users with a list of ways to cause instant death, though the research team noted that they were presented as suggestions for *removing*

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[121] Martha Neary & Stephen Schueller, *State of the Field of Mental Health Apps*, 25 COGNITIVE BEHAV. PRAC. 531, 531 (2018).
[122] *Id.* at 533 (explaining how consumers often use unreviewed, unsupported apps because few apps have efficacy data available to consumers, and those with tools—such as app ratings— are often biased).
[123] *Id.* (noting most studies use weak control groups such as waitlist or non-treatment design); *see also* Longyear & Kushlev *supra* note 110 (discussing the lack of oversight for all apps).
[124] Neary & Schueller, *supra* note 121 at 532; Simon Leigh & Steve Flatt, *App-based psychological intervention: friend or foe?*, 18 EVIDENCE BASED MENTAL HEALTH 97, 97 (Nov. 2015).
[125] Neary & Schueller, *supra* note 121.
[126] John Torous et al., *Mental Health Apps: What to Tell Patients*, 17 CURRENT PSYCHIATRY 21, 21 (Mar. 2018).
[127] *See* Mark Erik Larsen et al., *A Systematic Assessment of Smartphone Tools for Suicide Prevention*, 11 PLOS ONE 1, 14 (Apr. 13, 2016) (describing studies investigating apps referring to suicide or deliberate self-harm).
[128] *Id.* at 4.

access to those means instead of using them.[129]   However, consumers experiencing suicidal intent may find this to be a distinction without a difference. A mental health app excluded from the study also suggested non-lethal self-harm or drug use as viable alternatives to suicide.[130] Further, a 2015 study of mental health apps targeting eating disorders found that fifty percent of the twenty-four apps providing advice included poor or potentially harmful information.[131] For example, one app for presumably young people with anorexia nervosa provides the following tip: "make yourself a lunch. A big, nice sandwich with juice and a pack of chips. Then when you get to school, give it away to someone who forgot theirs."[132]   Based on these reviews, it is not surprising then that, according to a 2021 study, many mental health apps are not equipped to help users in the throes of a mental health crisis.[133]

Setting aside the sensational yet likely small percentage of mental health apps that provide dangerous advice, neutral mental health apps can also cause harm.[134] Some apps may have no impact whatsoever. But even a mental health app that is helpful as a general matter may not be meaningfully clinically effective.[135] A consumer who uses an ineffective health app in place of professional care may forgo important opportunities for intervention.[136] This can result in symptom worsening—or at the very least a failure to improve—regardless of whether the mental health app itself creates a threat.[137]

Furthermore, apps may work differently across populations. Studies of mental health app effectiveness have lacked diversity, making it difficult to generalize any possible benefits to racial minorities and populations with low

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[129] *Id.* at 7.
[130] *Id.* at 6.
[131] Christopher G. Fairburn & Emily R. Rothwell, *Apps and Eating Disorders: A Systematic Clinical Appraisal*, 48 INT'L J. EATING DISORDERS 1038, 1040 (2015).
[132] *Id.*
[133] *See generally* Emma M. Parrish et al., *Are Mental Health Apps Adequately Equipped to Handle Users in Crisis?* CRISIS: THE J. OF CRISIS INTERVENTION & SUICIDE PREVENTION 5, 10 (May 2021) (discussing the pitfalls of mental health apps including the lack of in-app crisis resources and inconsistencies in crises management plans and privacy protections).
[134] *See* Stephen McInerney, *Can You Diagnose Me Now: A Proposal to Modify FDA's Regulation of Smartphone Mobile Health Applications with a Pre-Market Notification and Application Database System*, 70 FOOD & DRUG L. J. 161, 166 (2015) (explaining that facially low-risk applications can provide users with information that informs their subsequent self-treatment, risking self-diagnosis and treatment).
[135] Renwen Zhang et al., *Clinically Meaningful Use of Mental Health Apps and Its Effects on Depression: A Mixed Methods Study*, 21 J. MED. INTERNET RSCH. 1, 8 (2019) (suggesting mental health apps could be designed to incorporate just the right amount of "intervention components and promote use at the right amount").
[136] McInerney, *supra* note 134 at 167.
[137] *Id.*

socioeconomic status.[138]   One qualitative content analysis of sixty-one prominent mental health apps demonstrated that, though many apps normalized the existence of mental illness for everyone, "everyone" was often depicted as individuals who are "employed, white, and in a family."[139] This lack of representation may alienate consumers who already experience systemic barriers to care, racism, and social marginalization. It is also unclear how app effectiveness varies across age groups, particularly adolescent and preadolescent users.[140] This lack of data is concerning, given that digital natives may be the most obvious target consumer demographic for these technologies and indeed shoulder some of the largest burdens of mental illness.

In short, mental health apps may not always live up to their enormous promise.   Instead, they may prevent meaningful improvement or even exacerbate mental illness in those already most at risk.[141]   Given the technology industry's immense reach, the negative health-altering capabilities of these technologies are often underappreciated, but they may still be substantial. Indeed, in the context of suicide risk, picking the right mental health app can be a matter of life and death.[142]

B.   Informing Mental Health App Consumers

When prospective users search for mental health apps, the app store results will include everything from reputable—even prescription-only—products to potentially harmful ones. Consumers are unlikely to extensively research an app before they download it. One survey of mental health app users revealed that the users rely more on informal information sources than on formal sources (e.g., medical providers) when trying to identify mental health apps to download.[143] Mental health app users are most likely to identify apps

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[138] Longyear & Kushlev, *supra* note 110 at 131.

[139] Lisa Parker et al., *Mental Health Messages in Prominent Mental Health Apps*, 16 ANNALS OF FAM. MED. 338, 338 (July 2018).

[140] Rebecca Grist et al., *Mental Health Mobile Apps for Preadolescents and Adolescents: A Systematic Review*, J. MED. INTERNET RSCH. (May 25, 2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5465380/.

[141] *See* Jena M. Richer, *Victims of Introspection: Insufficient Legal Protections For At-Risk Users of Automated Mental Health Apps*, 44 VT. L. REV. 893, 916 (2020) (stating "[t]he danger of MH apps arises at a crossroads of four factors: (1) the risk of harm that accompanies mental illness in users; (2) the presence of direct-to-consumer marketing without intermediary physicians; (3) the ambiguity in industry-wide standards and regulations; and (4) the lack of clinical validation for product safety and efficacy.").

[142] *Id.* at 929, 933–38 (describing suicide risk and calling for regulation of mental health apps to include suicide risk assessment).

[143] Stephen M. Schueller et al., *Discovery of and Interest in Health Apps Among Those with Mental Health Needs: Survey and Focus Group Study*, J. MED. INTERNET RSCH. (June 11, 2018), https://www.jmir.org/2018/6/e10141/ (listing informal sources of information used to select mental health apps and percentage of respondents claiming to have relied on each).

through social media, followed closely by searches in the app store, Google, and web forums, with fewer identifying apps based on provider, friend, or family recommendations.[144] Thus, whether a consumer picks an effective app may simply be a function of app store displays, search result order, and luck.

Apps developers have discretion regarding how they present their app services to consumers, and search results look virtually indistinguishable in the app store prior to download. This can create information asymmetries, in which the developer knows a product's quality, but the consumer does not.[145] But for mental health apps to help address the mental health crisis in the United States, consumers must be able to sort the effective apps from the ineffective ones. Leah R. Fowler has argued for voluntary evidence labels that appear in the app store display and influence search results order to reduce the information asymmetries found in the health app market generally.[146] Her recommendations apply with equal force to mental health apps.

Incorporating voluntary labeling into app store displays and search algorithms could help consumers choose wisely between products. Such labeling requires that developers provide information about what a health app specifically does, "how it does it, and [also requires that the developer] point[s] to the scientific evidence supporting those functionalities" where appropriate.[147] Three aspects of Fowler's proposed solution are critical: (1) the evidence label, while voluntary in the sense that the app developer itself provides the information and it is not legally mandated, would be required for listing in the app store; (2) it should be available to the consumer at the point of download; and (3) the app store should then incorporate label information into algorithms that determine the order in which the app store displays search results to consumers.[148] The first element helps overcome the logistical and partisan challenges of legislative actions and obviates potential First Amendment concerns. The final two elements help take advantage of how consumers experience and use information in decision-making and help address information asymmetries in the health app market. A key benefit of the proposed solution is providing consumers with needed

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[144] *Id.*

[145] Eric H. Franklin, *Mandating Precontractual Disclosure*, 67 U. MIAMI L. REV. 553, 561 (2013) (stating "Information asymmetry exists whenever a party to a contract does not enjoy the same level of access to information as the party's contracting counterpart.").

[146] Fowler, *supra* note 18 (manuscript at 43–50).

[147] *Id.* (manuscript at 47).

[148] *Id.* (manuscript at 51–54).

information at the point of download, where many people will choose a mental health app.[149]

As currently configured, consumers can search app stores for a specific mental health app by name, putting the sought-after app (or a sponsored app) at the top and then providing other related results below that.[150] Alternatively, consumers may type in general search terms like "depression" or "schizophrenia." The app store's search algorithm will then list apps related to those search terms, revealing results that reflect the algorithm's selection criteria and not necessarily the consumer's individual needs.[151] For example, a user hoping to find help with an eating disorder may search for an app and receive dozens of results, only seven percent of which offer any research support and only four apps that have been studied at all.[152] Incorporating evidence labels into app store search results algorithms can help consumers identify the small percentage of evidence-informed apps by placing those apps higher in search results.

Moreover, the proposed solution can also help consumers differentiate between mental health apps of varying quality. At present, app store displays and descriptions do not offer helpful, uniformly presented information about whether a mental health app is effective or evidence-informed beyond what an app developer chooses to advertise.[153] It can be difficult for consumers to make informed decisions when scrolling through app search results in the Google Play or Apple App Store.[154] Given the lack of directly relevant efficacy information, individuals may prioritize those apps that appear well

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[149] *See* Stephen M. Schueller et al., *Discovery of and Interest in Health Apps Among Those with Mental Health Needs: Survey and Focus Group Study*, J. MED. INTERNET RSCH. (June 11, 2018), https://www.jmir.org/2018/6/e10141/ (identifying app stores as a common place where users search for apps).

[150] *See Optimizing for App Store Search*, APPLE DEVELOPER, https://developer.apple.com/app-store/search/#:~:text=app's%20search%20ranking.-,Search%20ranking,%2C%20keywords%2C%20and%20primary%20category (last visited May 29, 2022) (listing "your app's title" as the first text-relevance factor in search ranking).

[151] *See, e.g.*, Jonathan Fishman, *Ranking Factors for App Store and Google Play*, STOREMAVEN (July 14, 2020), https://www.storemaven.com/academy/app-store-and-google-play-algorithms/ ("Search results and rankings on the App Store and Play Store are grounded in complex and dynamic algorithms. A combination of user search queries and keywords determine search results and rankings, yet the details of both the App Store and Play Store algorithms are shrouded in secrecy.").

[152] Fairburn & Rothwell, *supra* note 131 at 1039–40, 1043; Theodora O'Leary & John Torous, *Smartphone apps for eating disorders: An overview of the marketplace and research trends*, INT'L J. EATING DISORDERS 1, 6 (2022), https://doi.org/10.1002/eat.23690.

[153] Mark Erik Larsen et al., *Quantifying App Store Dynamics: Longitudinal Tracking of Mental Health Apps*, JMIR MHEALTH UHEALTH (Aug. 9, 2016), https://mhealth.jmir.org/2016/3/e96/.

[154] Hsiao-Ying Huang & Masooda Bashir, *Users' Adoption of Mental Health Apps: Examining the Impact of Information Cues*, JMIR MHEALTH UHEALTH (June 28, 2017) https://mhealth.jmir.org/2017/6/e83/ (characterizing the app market as "difficult and overwhelming" and describing the "heuristic approach" of choosing apps).

designed, easy to use, offer appropriate notifications, have sufficient numbers of reviews, and, if a paid app, offer free trial periods.[155] Including an evidence label alongside other pertinent information, like Apple's Privacy Label[156] in the Apple App Store, can help improve app selection.

A succinct label in an easily accessible location can also counter some of the challenges arising from already too-long Terms of Service (ToS) or Privacy Policies (PP).[157] Readability and ease of access are crucial: one study showed that a "tiny fraction" of consumers read standard-form contracts before using the associated products.[158] Providing succinct efficacy information in the app store before a consumer selects an app to download can better inform consumers.

Further, the proposed labeling system is beneficial for a variety of key stakeholders, including consumers, care providers, developers, and regulators. First, and perhaps most importantly, individual consumers benefit from improved app store labeling and display. Research shows that consumers value user-friendly, versatile apps.[159] The absence of empirical validation may explain, in part, the gap between interest in mental health apps and actual use, at least for some user populations.[160] Giving consumers the tools they need to make informed choices allows them to choose the best option for themselves. Irrespective of whether the vast majority of mental health apps are not actively harmful, the benefit of helping even one consumer experiencing suicidal intent to avoid downloading a mental health app with potentially harmful content is obvious.[161]

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[155] Emil Chiauzzi & Amy Newell, *Mental Health Apps in Psychiatric Treatment: A Patient Perspective on Real World Technology Usage*, JMIR MENTAL HEALTH (Apr. 22, 2019), https://mental.jmir.org/2019/4/e12292/.

[156] *See* APPLE, https://www.apple.com/privacy/labels/ (last visited May 29, 2022) (displaying Apple's Privacy Nutrition Labels, which contain information on how an app handles data).

[157] *See* Yannis Bakos et al., *Does Anyone Read the Fine Print? Consumer Attention to Standard-Form Contracts*, 43 J. LEGAL STUD. 1, 4 (2014) ("[T]he lack of a significant informed minority is due to high search and reading costs of standard form contracts.").

[158] *Id.* at 3 (finding that only one or two per one thousand customers access product end user license agreements for at least one second).

[159] *See* Felwah Alqahtani & Rita Orji, *Insights from User Reviews to Improve Mental Health Apps*, 26 HEALTH INFORMATICS J. 2042, 2043 (2020) (finding that apps with adaptive functionalities and that are very user-friendly receive high ratings).

[160] Adam Kern et al., *Mental Health Apps in a College Setting: Openness, Usage, and Attitudes*, MHEALTH 1, 8 (June 30,2018), https://mhealth.amegroups.com/article/view/20127/19966 ("The results of this study demonstrate appreciable interest among college students in the use of MHAs (with over one-quarter of respondents indicating that they would be open to using a MHA) ... However, only a small proportion of students in the present study reported actually using MHAs. The gap between the interest in and actual use of MHAs points to a need for further research ...").

[161] *See* Larsen et al., *supra* note 127 at 11 (finding "[j]ust under 90% of the apps identified in the app stores contained no suicide prevention strategies, and some contained potentially harmful content").

Second, the proposed labeling system can benefit mental health care providers who incorporate mental health apps into blended or supported care and require better tools to make recommendations with confidence.[162] As experts note, "the vast majority of commercially available apps are not appropriate for clinical care."[163] Discerning between those that can help and those that can hurt will be a growing part of psychiatry practice—whether providers want to incorporate them into treatment or not.[164] Inevitably, some patients will ask about apps, and they will expect clinicians to respond knowledgeably.[165]   The American Psychiatric Association (APA) recommends that physicians base mental health app recommendations on potential risk and harm, including privacy, evidence of efficacy, usability, and the ability to share data with clinicians if necessary.[166] Taking the APA criteria into account, an evidence label could inform a health care provider's advice, support buy-in to mental health apps, and help providers incorporate apps into their practices by making evidence of efficacy easier to evaluate.

The third benefit of the proposed labeling system is the potential for market improvement. At its most basic, a product label could help consumers feel confident in selecting an app.[167] A prior study of mental health app users revealed that the most common barrier to downloading a mental health app is that consumers are unaware of how effective the app is.[168] Moreover, under the current system, good faith developers who invest considerable resources into building higher-quality mental health apps have limited ways of distinguishing their products from lower-quality and even harmful products when consumers are browsing the app store.[169] While developers could pay for more intense advertising, that cost is likely ultimately shifted to the consumer and reflected in the cost of the app, which may further disincentivize downloads.[170] If consumers could discern between products

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[162] *See* Grist et al., *supra* note 140 (finding insufficient efficacy and safety evidence on whether any mental health app can be used effectively with young people).

[163] Torous et al., *supra* note 126 at 22.

[164] *See id.* (explaining that psychiatrists will need to be knowledgeable about apps even if they decide not to implement them).

[165] *Id.*

[166] *See id.* at 22–23 (suggesting clinicians take a risk-based approach to evaluating mental health apps by considering context, risk of harm, potential for benefit, usability and adherence, and interoperability).

[167] *See* Kevin Keating, *Why Food Transparency is a Vital Issue for Consumers (Part 1 of 2)*, PKG BRAND DESIGN: "WELISTEN" BLOG (Apr. 28, 2021, 11:46 AM), https://www.pkgbranding.com/blog/why-food-transparency-has-become-a-vital-issue-for-consumers-part-1 (explaining how food labels foster consumer trust and confidence).

[168] Schueller et al., *supra* note 143

[169] *See* Mattioli, *supra* note 116 at 31–33 (noting the potential impact of mental health applications on innovation in the market).

[170] *Id.*

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of varying quality, these barriers to use could diminish, and app developers could realize a larger return on their investments.

Finally, creating a labeling mechanism by which mental health apps could explicitly signal quality can help agencies responsible for product regulation and consumer protection. Labels could provide clear evidence of intended use for the FDA and help the FTC and state attorneys general target scarce resources. If mental health apps self-disclose and publicly indicate a level of quality and effectiveness, the task of government oversight will become more manageable. This remains true even—and perhaps especially—if app developers misrepresent the evidence underlying their product as those will appear at the top of the search results and enjoy closer scrutiny.

V. CONCLUSION

Mental health apps have the potential to be an important tool to address our current mental health crisis. Investment in mental health apps and the growing popularity of these products is, in many ways, a positive trend. The increasing use of mental health apps points to societal recognition that psychological wellbeing is an inseparable part of overall health and that individuals want and need products that help them achieve their best mental health. However, the news is not all positive. For better or worse, the ubiquity of these products also means that mental health apps are likely to influence public perceptions concerning mental illness and appropriate symptom and treatment management.[171] But not all apps are up to the task. Many available mental apps are ineffective, and the current market is opaque, made increasingly so by the FDA's pandemic waiver. Thus, without improved consumer protections, this trend is also alarming.[172]

The good news is that the information needed to facilitate consumer choice is already available, it is just not used in a way that improves decision-making at the point of download. The proposed labeling and search result solution we describe is far from perfect, but it is a good initial step. Moving forward, more research is needed to understand the impact of the FDA's pandemic waiver on consumer understanding of mental health apps. And ultimately, universal standards will be necessary, including, at a minimum, data security and privacy, app effectiveness, usability, and data integration.[173] However, we should not let perfection get in the way of meaningful progress. The technology industry can take interim steps now to promote consumer safety

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[171] Parker et al., *supra* note 139, at 341.
[172] *See id.* (explaining the widespread use of mental health apps might lead to overdiagnoses and overtreatment).
[173] John Torous et al., *Towards a Consensus Around Standards for Smartphone Apps and Digital Mental Health*, 18 WORLD PSYCHIATRY 97, 98 (2019).

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until state and federal legislators can make broader, more enforceable changes.