HEALTH APP LEMONS

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Smartphone health applications (health apps) have the potential to solve seemingly intractable problems with the health care system, improve population and individual health, and democratize medicine. With health apps for everything—from mental health to menstruation to dermatology—the opportunities for disruption and improvement appear boundless. But there is a catch: the vast majority of consumer health apps are not subject to the laws and regulations we expect in a health care context. Yet, these products exist side-by-side with, look like, and even perform similar functions to medical devices and telemedicine tools available for download in the same smartphone app stores. This Article considers the convoluted market that spans everything from highly regulated health apps to worthless or even dangerous "digital snake oil." Using economics, it offers that information asymmetries create an environment in which market failures abound, so consumers cannot tell the difference between products that help and those that harm. It concludes with recommendations for voluntary disclosures incorporated into app store search results to facilitate a move toward a safer overall market for health apps, with fewer bad choices to make.

INTRODUCTION

In January 2022, a news report pointed to a surprising new study with a provocative finding.[1] Researchers systematically evaluating multiple studies of mobile-phone-based interventions for mental health, a booming product category with enormous venture capital backing[2] and (at least temporary, pandemic-related) implicit government endorsement,[3] could find no convincing evidence supporting any mobile phone-based app intervention on

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1. Mario Aguilar, *What Types of Mental Health Apps Actually Work? A Sweeping New Analysis Finds the Data Is Sparse*, STAT NEWS (Jan. 19, 2022), https://www.statnews.com/2022/01/19/mental-health-meditation-app-evidence/.

2. Jenny Gold, *Need Mental Health Help? There Are Apps for That, but Picking the Right One Is Tough*, L.A. TIMES (June 21, 2021, 5:00 AM), https://www.latimes.com/california/story/2021-06-21/mental-health-apps-consumer-challenge-picking-the-right-one.

3. U.S FOOD & DRUG ADMIN., ENFORCEMENT POLICY FOR DIGITAL HEALTH DEVICES FOR TREATING PSYCHIATRIC DISORDERS DURING THE CORONAVIRUS DISEASE 2019 (COVID-19) PUBLIC HEALTH EMERGENCY: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (2020).

any outcome.[4] Instead of safer, more efficacious products, it appears that growing investment and demand have generated a market saturated with apps that do not work—and potentially even cause harm—and consumers are in the dark about the risks.

But mental health apps are just a snapshot of a much larger problem. Health apps, a general term that can include everything from medical devices and telemedicine tools to nothing more than digital snake oil,[5] are widely available in a smartphone user's app store. But it is difficult, if not impossible, for average consumers to distinguish between high-quality and low-quality health apps.[6] Here, misperceptions about safety and efficacy can come with significant secondary health consequences.

Consider a man suffering from depression and anxiety who, while listening to a podcast, hears about *Happify*, a prescription-only digital therapeutic intended to treat major depressive disorder and generalized anxiety disorder through a smartphone app interface.[7] He is excited about a potential alternative to medication and office-based therapy, which make him feel embarrassed and are difficult to incorporate into his already too-busy lifestyle. However, after skimming the app store for mental health apps, he concludes that making an appointment and seeing a medical professional for a prescription-only app seems unnecessary and burdensome when so many free options are already available for download. He observes that the interfaces all look more or less identical based on the app store preview images, and they all have fairly equivalent average star ratings. So, he picks a free mental health app at random because it appears near the top of his search results. However, the app he downloads is not evidence-based and promotes behaviors that increase his social isolation.[8] Even though he follows the app's recommendations, he sinks deeper into his depression.

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4. *See* Simon B. Goldberg et al., *Mobile Phone-Based Interventions for Mental Health: A Systematic Meta-Review of 14 Meta-Analyses of Randomized Controlled Trials*, PLOS DIGIT. HEALTH, Jan. 18, 2022, at 2, https://doi.org/10.1371/journal.pdig.0000002.

5. James Prunty, an FTC attorney, has described some medical apps as "snake oil." *See* Rochelle Sharpe, *Many Health Apps Are Based on Flimsy Science at Best, and They Often Do Not Work*, WASH. POST (Nov. 12, 2012), https://www.washingtonpost.com/national/health-science/many-health-apps-are-based-on-flimsy-science-atbest-and-they-often-do-not-work/2012/11/12/11f2eb1e-0e3711e2-bd1a-b868e65d57ebstory.html.

6. *See generally* David A. Simon et al., *At-Home Diagnostics and Diagnostic Excellence: Devices vs General Wellness Products*, 327 J. AM. MED. ASS'N 523 (2022).

7. *Happify Health Forms Digital Therapeutics Alliance with Sanofi,* MED. DEVICE NETWORK (last updated Nov. 22, 2021, 1:06 PM), https://www.medicaldevice-network.com/news/happify-health-sanofi-alliance/. *Happify* is not FDA-cleared. It is available "by prescription or through an investigational study." Elise Reuter, *Happify Rolls Out Digital Therapeutic for Anxiety, Depression Under Temporary FDA Guidance,* MEDCITY NEWS (July 23, 2021, 2:03 PM), https://medcitynews.com/2021/07/happify-rolls-out-digital-therapeutic-for-anxiety-depression-under temporary-fda-guidance/.

8. *See* Jennifer Nicholas et al., *Mobile Apps for Bipolar Disorder: A Systematic Review of Features and Content Quality*, J. MED. INTERNET RSCH., Aug. 2015, at 65, 74.

Or consider a woman who sees repeated targeted advertisements on *Instagram* for the FDA-cleared digital contraception *Natural Cycles*.[9] Some ads even feature her favorite celebrities and other popular influencers she has come to trust for product recommendations. In searching the app store for a hormone-free form of digital contraception, she notes that many available options identify "fertile days" just like *Natural Cycles*, so she decides a free download would be preferable to *Natural Cycles*'s subscription fee and the hassle of finding the right thermometer. But instead of an evidence-based algorithm synthesizing her unique inputs, her free app predicts fertile days based only on a 28-day average cycle length, which does not account for her irregular periods or other individualized signs and symptoms of ovulation. Despite dutifully entering data about her menstrual cycle and abstaining from unprotected penetrative intercourse on days the app identified as fertile, she unintentionally falls pregnant.

Or, finally, consider a consumer concerned about a new skin lesion who recently read a snappy press release about apps like *SkinVision*, which has CE certification in the European Union.[10] They recently lost their job and are uninsured, so the possibility of getting their lesion looked at without actually seeing a physician feels like their only realistic option. A quick search for "skin check" in their iPhone's app store reveals options for download—some even categorized as "medical" or "health & wellness" in the app store's digital interface. There is even a little picture of a stethoscope above the term "medical." To them, this seems legitimate enough. They download the first available free app, take a quick photo, and the app assures them it is benign. Satisfied with their results, they do not seek follow-up care with a medical professional, and their cancer spreads.

These hypothetical examples are illustrative of a problem in consumer health technologies.[11] Though nearly all smartphone apps are potential sources of confusion, misinformation, and harm,[12] consumer health apps like the three described above create unique challenges due to common

9. Press Release, U.S. Food & Drug Admin., FDA Allows Marketing of First Direct-to-Consumer App for Contraceptive Use to Prevent Pregnancy, (Aug. 10, 2018), https://www.fda.gov/news-events/press-announcements/fda-allows-marketing-first-direct-consumer-app-contraceptive-use-prevent-pregnancy.

10. *CE Marking*, YOUR EUROPE, https://europa.eu/youreurope/business/product-requirements/labels-markings/ce-marking/index_en.htm (last updated July 11, 2022) ("CE marking indicates that a product has been assessed by the manufacturer and deemed to meet EU safety, health and environmental protection requirements. It is required for products manufactured anywhere in the world that are then marketed in the EU." (emphasis omitted)); *For Doctors*, SKINVISION, https://www.skinvision.com/for-doctors/#publications_clinical_evidence (last visited Jan. 29, 2022).

11. Other examples like these have also recently appeared in the news. *See, e.g.*, Ryan Knox & Cara Tenenbaum, *Regulating Digital Health Apps Needs User-Centered Reform,* STAT NEWS (Aug. 3, 2021), https://www.statnews.com/2021/08/03/refor-regulatory-landscape-digital-health-applications/.

12. *See, e.g.*, Georgia Wells et al., *Facebook Knows Instagram Is Toxic for Teen Girls, Company Documents Show*, WALL ST. J. (Sept. 14, 2021, 7:59 AM), https://www.wsj.com/articles/facebook-knows-instagram-is-toxic-for-teen-girls-company-documents-show-11631620739.

misperceptions about the protections that the law affords individuals in a health context. For better or worse (and often mistakenly), when using these apps, people may assume that their information will remain private and secure and that the products they use have been vetted as safe and effective.[13] However, for most consumer health apps, neither assumption is true.

And, beyond common misperceptions about health-related legal protections from recognizable names like the Health Insurance Portability and Accountability Act and the U.S. Food and Drug Administration (FDA), consumer confusion in the health app market is foreseeable because, put simply, the health app market is confusing. It is not just that consumers can and do mistakenly believe these products perform functions they cannot safely or effectively perform, but that they exist in markets alongside more heavily advertised, often fee-based products that do. Most apps are sold in third-party commercial "app stores"—most recognizably the Apple App Store and the Google Play Store.[14] Consumers do not generally download an app from a specific developer's website but rather are presented with a list of all the apps relevant to a given search term. And, aside from sponsored app advertisements putting certain products at the top of the list, there is no readily apparent rationale for the order in which the app store presents search results to a user. Even after selecting an app, the app store's user interface often provides little useful information. Instead, relevant information about a health app's capabilities and limitations may be hidden in the fine print of hard-to-find and even harder-to-understand terms of service (ToS). That is, of course, if it is even available at all.

As a result, average consumers are poorly positioned to know the difference between a pricier app with FDA clearance they saw heavily advertised on social media and a run-of-the-mill wellness tracking health app listed less than a scroll away from it in an app store that looks nearly identical and is available for free, but that cannot reliably perform any of the functions a consumer mistakenly believes it can perform. This information asymmetry—in which developers know the quality of their product and consumers do not—can result in potentially significant secondary health harm.[15]

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13. Leah R. Fowler, *COVID-19 & the Myth of Health Data Privacy*, 31 KAN. J.L. & PUB. POL'Y 373, 381 (2022).

14. Not all app stores are commercial app stores. Consider the Veterans Affairs App Store. *See VA Mobile*, U.S. DEP'T OF VETERANS AFFS., https://mobile.va.gov/appstore (last updated Jan. 12, 2022, 11:15 AM).

15. While privacy harms are a significant concern with digital health technology, this Article focuses on physical harms. In some cases, the two are related. *See, e.g.*, William Ralston, *They Told Their Therapists Everything. Hackers Leaked It All*, WIRED (May 4, 2021, 7:00 AM), https://www.wired.com/story/vastaamo-psychotherapy-patients-hack-data-breach/; *see also* Danielle Keats Citron & Daniel J. Solove, *Privacy Harms*, 102 B.U. L. REV. 793, 816–17 (2022) (noting that the privacy harms may aggregate to become a major imposition while not being fully knowable).

But the problem goes beyond consumers. The resulting market failures can harm developers of high-quality health apps as well.[16] While some app developers invest significant time and resources navigating the FDA regulatory process and providing effective products, other app developers intentionally strive to avoid regulation altogether.[17] For some of these developers, the goal is not to attract consumers with the best product but to enter the market with as few costs as possible, profit off consumer data, and move on. But when consumers lack tools to differentiate between varying levels of quality at the point of download, unsafe apps flying under the regulatory radar benefit from the investments and reputation of their more highly regulated counterparts. The result is a market dominated by lower-quality products and untrustworthy sellers: a health app market for lemons.[18] For producers of health apps, these market failures can create economic disincentives to innovation and ultimately hit a company where it hurts the most—their wallet.

This Article proceeds in three parts, returning to the three product category examples from this introduction to illustrate key concepts. Part I considers mental health apps and app stores to describe the current market. After identifying the potential dangers and the lack of efficacy information available to consumers, it then turns to how those information asymmetries result in market failures and leave consumers to rely on mental shortcuts to make suboptimal health app choices. Part II considers the existing regulatory environment through the lens of period and fertility trackers. It highlights how agency or private enforcement potentially could—but often does not—help remedy existing market failures, underscoring a need for new approaches. Finally, Part III leverages the tools of economics and cognitive psychology to propose voluntary, industry-driven labeling solutions incorporated into app store algorithms that influence the order search results appear in the app store display. It returns to the example of dermatology apps to illustrate how this proposal begins to correct the conditions that can result in market failures and facilitates better health app choices.

16. *See also* Claire E. O'Hanlon et al., *The Business Case for Rigorous Evaluation of Mobile Health Apps*, HEALTH AFFS. (Aug. 30, 2021), https://www.healthaffairs.org/do/10.1377/forefront.20210826.547352/full/.

17. Keith Barritt, *How to Avoid FDA Regulation of Your Mobile Medical App,* MED. DEVICE ONLINE (July 7, 2015), https://www.meddeviceonline.com/doc/how-to-avoid-fda-regulation-of-your-mobile-medical-app-0001; *see also* Ioana Ciopraga, Note, *The FDA Guidance Document for Medical Mobile Apps and Its Impact on Innovation: Bringing the Promise of a New Way to Look at Medicine Closer, or Pushing It Further?* 6 J.L. TECH. & INTERNET 43, 59 (2015).

18. *See generally* George A. Akerlof, *The Market for "Lemons": Quality Uncertainty and the Market Mechanism*, 84 Q.J. ECON. 488 (1970).

I. A FLAWED MARKET FOR HEALTH APPS

The media and public relations view of health apps is often one of a bright future, and many experts have explored the seemingly limitless potential of these consumer health technologies to improve individual and population health.[19] These products could be—or perhaps even already are—great, condensing an entire clinical encounter and medical history into a pocket-sized product a consumer can use anytime and anywhere. The massive venture capital investment backing these technologies reifies this optimistic outlook.[20] But the current reality of health apps is a decidedly mixed picture, and shiny advertisements and industry-driven views can obscure the darker underbelly of the health app market. This Part returns to the first example from the introduction—mental health apps—to illustrate the confusing and conflicting market for health apps and the information asymmetries plaguing how consumers find and select between apps. It then explores how these conditions can result in market failures and the impacts this information environment has on consumer decision-making.

A. Information Asymmetries

Tens of millions of Americans with Internet-capable smartphones[21] know that "there's an app for that,"[22] whatever *that* may be. Sometimes "that" is health, including fitness trackers and wellness apps likely familiar to any smartphone user. There are over 400,000 health apps available,[23] experiencing

19. *See* Nicolas Terry, *Of Regulating Healthcare AI and Robots*, 21 YALE J.L. & TECH (SPECIAL ISSUE) 133, 143 (2019); Nathan G. Cortez et al., *FDA Regulation of Mobile Health Technologies*, NEW ENGL. J. MED. 372, 372–79 (2014); Stephanie J. Mitchell et al., *Internet and Mobile Technology Use Among Urban African American Parents: Survey Study of a Clinical Population*, J. MED. INTERNET RSCH., Jan. 2014, at 155, 156 (2014); Kiona K. Weisel et al., *Standalone Smartphone Apps for Mental Health – A Systematic Review and Meta-Analysis*, NPJ DIGIT. MED., Dec. 2, 2019, at 1. *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 (2020).

20. *mHealth Apps Market Size, Share & Trends Analysis Report by Type (Fitness, Medical), by Region (North America, Europe, Asia Pacific, Latin America, Middle East & Africa), and Segment Forecasts, 2022 – 2030*, GRAND VIEW RSCH. (Jan. 2022), https://www.grandviewresearch.com/industry-analysis/mhealth-app-market; Farah Nayeri, *Is 'Femtech' the Next Big Thing in Health Care?*, N.Y. TIMES (Apr. 7, 2021), https://www.nytimes.com/2021/04/07/health/femtech-women-health-care.html; Gold, *supra* note 2.

21. As of 2021, 97% of Americans owned cell phones. Of those, 85% had Internet-capable smartphones, up from 35% just ten years prior. *Mobile Fact Sheet*, PEW RSCH. CTR. (Apr. 7, 2021), https://www.pewresearch.org/internet/fact-sheet/mobile/.

22. "There's an app for that" first entered the common vernacular after appearing in an Apple iPhone commercial in 2009. CommercialsKid, *iPhone 3g Commercial "There's an App for That" 2009*, YOUTUBE (Feb. 4, 2009), https://www.youtube.com/watch?v=szrsfeyLzyg.

23. Michael Georgiou, *Developing a Healthcare App in 2022: What Do Patients Really Want?*, IMAGINOVATION INSIDER (Feb. 9, 2022), https://www.imaginovation.net/blog/developing-a-mobile-health-app-what-patients-really-want/.

millions of downloads each quarter,[24] and between 10,000 and 20,000 of these apps specifically target mental health.[25] Underscoring its importance, this impressive market for mental-health-focused products is growing alongside a ballooning mental health crisis.[26] In recognition of existing and growing demand, "[v]enture capital firms invested [over] $2.4 billion in digital behavioral health apps in 2020—more than [double] the [year prior]."[27] But setting aside whether mental health apps specifically, and health apps more generally, have, can, or even should become indispensable consumer health tools, this Part acknowledges that apps like these are already commonplace. If consumers do not already have one, they know someone who does. And consumers have likely at least heard of them or seen them heavily advertised on social media or touted by trusted figures like celebrities, influencers, and professional athletes. And this familiarity may distract from how little a consumer actually knows about an app when they mindlessly scroll through the app store, uncritically choose to download one, and use it to manage something as important as their mental health.

1. Health Apps

The research study from the introduction is provocative, but the news report's conclusion does not tell the whole story. Like all health apps, mental health apps perform a range of functions and target various intended audiences.[28] A simple search for "mental health" in the Apple App Store[29] will reveal apps intended to track, target, and even treat a variety of mental health concerns. Even within broad categories of targeted ailments, some are what

24. L. Ceci, *Global Health and Fitness App Downloads as of Q2 2020*, STATISTA (July 6, 2021), https://www.statista.com/statistics/1127248/health-fitness-apps-downloads-worldwide/#:~:text=During%20of%20the%20first%20quarter,have%20generated%20656%20million%20downloads ("During . . . the first quarter of 2020, health and fitness apps were downloaded 593 million times. It is projected that by the end of the second quarter of 2020, health and fitness apps will have generated 656 million downloads. In the same quarter of the previous year, health and fitness apps were only downloaded 446 million times.").

25. Rebecca A. Clay, *Mental Health Apps are Gaining Traction*, MONITOR ON PSYCH., Jan.–Feb. 2021, at 55, 55; *see also* Leah R. Fowler & Jessica L. Roberts, *Mind the App*, 31 ANNALS HEALTH L. & LIFE SCI. 143, 144 (2022).

26. 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, 197 (2019).

27. Gold, *supra* note 2.

28. The National Institute of Mental Health categorizes mental health apps into six popular development areas. *See Technology and the Future of Mental Health Treatment*, NAT'L INST. OF MENTAL HEALTH (2019), https://www.nimh.nih.gov/health/topics/technology-and-the-future-of-mental-health-treatment/index.shtml; *see also* Joshua August Skorburg & Josephine Yam, *Is There an App for That?: Ethical Issues in the Digital Mental Health Response to COVID-19*, 13 AJOB NEUROSCI. 177, 178–82 (2021) (describing digital mental health tools).

29. Apple has the largest smartphone market share. As a result, the majority of the in-text discussion will focus on Apple products. Team Counterpoint, *US Smartphone Market Share: By Quarter*, COUNTERPOINT (Aug. 25, 2022), https://www.counterpointresearch.com/us-market-smartphone-share/.

we might traditionally think of as medical devices; some provide a portal through which licensed health care providers can offer telemedicine services; and some are even only available with a valid prescription from a licensed provider. Others still are deemed by the FDA to be low-risk wellness trackers, over which the agency exercises enforcement discretion.[30] Perhaps surprisingly, others still are not devices at all.[31] These apps perform ostensibly benign functions posing minimal danger. Some even competently deliver more complex functionalities that resemble more highly regulated devices. However, some of these so-called low-risk wellness trackers or non-device mental health apps are little more than digital snake oil, offering unsuspecting consumers no- or even negative-value products. Put simply: some mental health apps are helpful but some can be harmful.[32] Research supports this pared-down assessment.

Several studies—authored by some of the same scientists as the research identified in the introduction—demonstrate that mental health apps can be efficacious. A meta-analysis of eighteen randomized controlled trials (RCTs) indicated that some mental health apps could reduce symptoms of depression.[33] Another meta-analysis of RCTs investigating mental health apps intended to address anxiety concluded that consumers experienced reductions in total anxiety symptoms and that, promisingly, apps could achieve these results in place of an outpatient patient-therapist session without significant loss of efficacy.[34] Mental health apps also show promise for addressing schizophrenia—a 2015 systematic review showed high levels of adherence, positive user experience, and even some clinical benefits.[35] These studies are a snapshot that helps explain the immense promise of mental health apps, support the media hype, and even provide insight into why, in April of 2020, the FDA explicitly supported their uptake in response to the perfect storm of increased mental distress and reduced medical resources during the coronavirus pandemic.[36] From a certain vantage point, then, mental health apps are poised to disrupt a traditional clinical care system plagued with

30. *See infra* Part II.A.

31. *See* 21 U.S.C. § 360j(o)(1)(A)–(E).

32. This Article focuses on physical health harms. Privacy harms are real and important and can even result in physical (and psychological) harm. However, discussion of privacy harms is outside the scope of this Article. For more information on privacy harms, see Citron & Solove, *supra* note 15.

33. 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, 296 (2017). *But see* Simon B. Goldberg et al., *supra* note 4, at 1.

34. 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, 21 (2017). *But see* Skorburg & Yam, *supra* note 28, at 5–8 (underscoring the underwhelming statistical significance supporting these conclusions in Torous meta-analyses).

35. Joseph Firth & John Torous, *Smartphone Apps for Schizophrenia: A Systematic Review*, JMIR MHEALTH & UHEALTH, Oct.–Dec. 2015, at 36, 38–42.

36. U.S. FOOD & DRUG ADMIN., *supra* note 3.

stigma and often and rightfully criticized for its lack of affordability and accessibility.[37]

But health apps are not all created equal, and mental health apps are no exception. Mixed in with beneficial and scientifically backed mental health apps are those that are ineffective or even dangerous.[38] Some are so surprisingly bad as to shock the conscience. For example, a 2016 systematic review of mental health apps referring to suicide or deliberate self-harm found concerning content including: "[D]escribing or facilitating access to lethal means; providing encouragement to people to end their life" and "portraying suicide in a fashionable or appealing manner."[39] One mental health app excluded from the study suggested self-harm or drug use as a viable alternative to suicide.[40] Two mental health apps included in the review provided users with an enumerated list of ways to cause instant death, albeit in the context of removing access and not using them.[41] Other studies have also flagged concerning content promoting harmful behaviors in other mental health contexts.[42] For example, in a 2015 study of mental health apps targeting eating disorders, fifty percent of the twenty-four apps providing advice included poor or potentially harmful information, including recommendations for how to hide disordered eating at school.[43]

These studies, even if ancient when considered on the relentlessly advancing timeline of technological innovation and app development, provide useful context and highlight memorable problems that persist in varying degrees to this day.[44] For example, a 2021 study flagged that mental health apps are not equipped to help users experiencing a mental health crisis,

37. Fowler & Roberts, *supra* note 25, at 153. *But see* Nicolas P. Terry, *Appification, AI, and Healthcare's New Iron Triangle*, 20 J. HEALTH CARE L. & POL'Y 117, 129 (2018) (noting that, though apps do improve convenience, they are not disruptive—at least not yet); Nicolas P. Terry, *Will the Internet of Things Transform Healthcare?*, 19 VAND. J. ENT. & TECH. L. 327, 348 (2016) [hereinafter *Will the Internet of Things Transform Healthcare?*] (observing that "[t]rue business disruption will occur when traditional providers or their financing mechanisms are replaced, in whole or in part, by new patient-facing technologically mediated models").

38. Though used interchangeably in this Article, Nicolas Terry has argued that whether something benefits a consumer is technically distinct from whether something is said to be efficacious or whether something is safe. *Will the Internet of Things Transform Healthcare?*, *supra* note 37, at 343–45 (distinguishing between whether "fitness apps have shown any overall benefits," the more narrow and legally focused question of efficacy, and the question of safety).

39. Mark Erik Larsen et al., *A Systematic Assessment of Smartphone Tools for Suicide Prevention*, PLOS ONE, Apr. 13, 2016, at 1, 4.

40. *Id.* at 6.

41. *Id.* at 7.

42. Nicholas et al., *supra* note 8.

43. Christopher G. Fairburn & Emily R. Rothwell, *Apps and Eating Disorders: A Systematic Clinical Appraisal*, 48 INT'L J. EATING DISORDERS 1038, 1040 (2015) ("For example, *Anorexia Tips (Free Dev.)*, in a section for people with anorexia nervosa states: 'Make yourself lunch. A big nice sandwich with juice and pack of chips. Then when you get to school, give it away to someone who forgot theirs.'").

44. *See generally* Fowler & Roberts, *supra* note 25 (describing more example deficiencies in mental health apps).

revealing that only thirty-five percent of apps included in the sample provided crisis-specific resources in the app's user interface at all.[45] This finding makes suicide and depression-focused or adjacent apps, like the ones described above, particularly concerning as a product category. Or, consider a 2022 study demonstrating that 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.[46] From the vantage point of this existing and growing body of literature, the excitement about the positive potential of mental health apps is, at best, myopic.

But while some apps are helpful and some can be dangerous, the reality of mental health apps—and, indeed, all health apps—is somewhere in the middle. These examples illustrate the two extremes of mental health apps. On one end, promising and thoughtfully designed technologies show potential to help manage and even treat various mental health concerns from the convenience of a consumer's phone. On the other end of the spectrum, some mental health apps are harmful and can hurt unsuspecting consumers by providing bad or even outright dangerous advice. They are potentially helpful, probably neutral, but possibly risky. But any health app that does not provide benefits may prove problematic if a consumer mistakenly believes the product they are using will help them.

How can a consumer know if he is about to download an app capable of reducing his symptoms of depression or a ready-made menu of suicide modalities? How can he be sure he has selected a mental health app with resources for users in crisis before he is actively experiencing one?[47] Or, even more subtle and difficult to identify, how can he discern between an app that can help improve a condition and one that cannot do anything, but looks similar to one that does, missing a window of opportunity for meaningful intervention and alleviation of suffering? Presently, little information is readily available for even diligent consumers hoping to pick an efficacious health app, and the available information is not always easy to come by if you do not know where to look. Consider some common avenues for consumer-driven research.

Referencing just the information a specific mental health app provides, a consumer might check for general information about acceptable uses, medical disclaimers, and warranties in the ToS—though research suggests this is

45. Emma M. Parrish et al., *Are Mental Health Apps Adequately Equipped to Handle Users in Crisis?*, 43 CRISIS: J. CRISIS INTERVENTION & SUICIDE PREVENTION 289, 289 (2022).

46. Theodora O'Leary & John Torous, *Smartphone Apps for Eating Disorders: An Overview of the Marketplace and Research Trends*, 55 INT'L J. EATING DISORDERS 625, 630 (2022).

47. *See* Parrish et al., *supra* note 45, at 295.

exceedingly unlikely.[48] If they do, they might find the content is unhelpful or, at best, vague or jargon-laden legalese. Most health apps will intentionally avoid making explicit claims about diagnosis, treatment, cure, prevention, or mitigation of diseases.[49] But, more concerningly, many mental health apps do not even have ToS at all, and those that do are often difficult to access and understand.[50] And, more complicated still, even if a consumer can access and understand the ToS, many app developers reserve the right to modify those terms unilaterally, often with little or no notice to consumers.[51] As a result, ToS are unhelpful for average consumers in search of information about health app efficacy.

In addition to (or more likely instead of) consulting ToS, a consumer might consciously or unconsciously seek visual cues about what an app can or cannot do. For example, a consumer might notice medical imagery, like a caduceus, a cross, or other symbols that invoke the idea of medicine, in the pictures of the app's user interface or while searching an app's website. Or, while checking the health app's website, the consumer might notice a corporate advisory board full of members in what appear to be white coats that even includes a chief medical officer. However, these representations may not indicate anything about an app's actual efficacy or medical potential. Instead, those advertisements may signal what app developers believe consumers value[52] while simultaneously seeming to contradict other explicitly written disclaimers in the ToS and other fine print.[53]

Outside the app's ToS, appearance, and website, a consumer may conduct an independent Internet search or consult an online app guide, like the One Mind Psyberguide.[54] This non-profit project recommends mental health apps based on expert reviews of credibility, user experience, and transparency of

48. Yannis Bakos et al., *Does Anyone Read the Fine Print? Consumer Attention to Standard-Form Contracts*, 43 J. LEGAL STUD. 1, 32 (2014).

49. Barritt, *supra* note 17; *see also* Ciopraga, *supra* note 17, at 60–61; David A. Simon et al., Essay, *Skating the Line Between General Wellness Products and Regulated Devices: Strategies and Implications,* J.L. & BIOSCI., July–Dec. 2022, at 1, 2 (describing *Happify* and how using the language of empowerment instead of treatment can help an app avoid regulation).

50. Julie M. Robillard et al., *Availability, Readability, and Content of Privacy Policies and Terms of Agreements of Mental Health Apps*, INTERNET INTERVENTIONS, Sept. 2019, at 1, 6.

51. Jessica L. Roberts & Jim Hawkins, *When Health Tech Companies Change Their Terms of Service*, 367 SCIENCE 745, 745–46 (2020); *see also* Leah R. Fowler et al., *Uncertain Terms*, 97 NOTRE DAME L. REV. 1, 5 (2021).

52. For a series of articles exploring and justifying this claim, see Jim Hawkins & Renee Knake, *The Behavioral Economics of Lawyer Advertising: An Empirical Assessment*, 2019 U. ILL. L. REV. 1005, 1026–32; Jim Hawkins, *Exploiting Advertising*, 80 LAW & CONTEMP. PROBS. 43, 44–45 (2017); Jim Hawkins, *Using Advertisements to Diagnose Behavioral Market Failure in Payday Lending Markets*, 51 WAKE FOREST L. REV. 57, 59 (2016).

53. Fowler et al., *supra* note 51, at 6–7.

54. *Apps and Digital Health Resources Reviewed by Experts*, ONE MIND PSYBERGUIDE, https://onemindpsyberguide.org/ (last visited Jan. 29, 2022).

privacy practices.[55] However, this is not a well-known resource for the average mental health app consumer. It requires research external to the app or app store and may not be a regular part of health app consumer due diligence and app selection, especially for less sophisticated consumers.[56] The guide itself also still struggles to address updates to the apps and literature.[57] Importantly, this resource is also limited to mental health apps, which, though used here as an example, are just one piece of a much larger health app market puzzle.

And finally, a consumer might speak to their health care provider for recommendations or to get an opinion on a specific mental health app of interest. But even if patients talk to their doctors about using apps to manage their health—and that is a big if—the medical system is not always well-positioned to answer questions about whether an app is a good choice for an individual patient.[58] While some apps explicitly recommend discussing the choice to use them with a trusted physician, the education gap surrounding health apps for both providers and patients may make for an ineffective or, worse, a nonexistent conversation.[59] Though some tools exist to help physicians evaluate mental health apps,[60] not all physicians can or will engage in this additional time-consuming (and non-billable) work. And some physicians may be reluctant to do so out of liability concerns.[61] Finally, it is worth mentioning that not every person using an app for health has regular access to a health care provider, and even those that do may not trust them to be supportive of health app use.[62]

To be sure, some minority of highly motivated consumers will exhaust every available avenue of information in pursuit of an effective and well-designed health app. The above examples provide a theoretical path through which fairly diligent consumers might seek information about effectiveness when they have a specific app or app function in mind. Even then, they are subject to significant limitations and may be unrealistic for most people. Every

55. *About One Mind PsyberGuide*, ONE MIND PSYBERGUIDE, https://onemindpsyberguide.org/about-psyberguide/ (last visited Jan. 29, 2022).

56. Mental health app users are most likely to identify apps 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. 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, at 1, 7–8.

57. Martha Neary & Stephen M. Schueller, *State of the Field of Mental Health Apps*, 25 COGNITIVE & BEHAV. PRAC. 531, 536 (2018).

58. Katie Palmer, *How Will Doctors Talk to Patients About Contraception Apps Like Natural Cycles and Clue?*, STAT NEWS (March 12, 2021), https://www.statnews.com/2021/03/12/doctors-talk-contraception-apps-natural-cycles-clue/.

59. *Id.*

60. John Torous et al., *Mental Health Apps: What to Tell Patients*, CURRENT PSYCHIATRY, Mar. 2018, at 21, 22; *see also* John Blake Torous et al., *A Hierarchical Framework for Evaluation and Informed Decision Making Regarding Smartphone Apps for Clinical Care*, 69 PSYCHIATRIC SERVS. 498, 498–99 (2018).

61. *See* Nicolas P. Terry & Lindsay F. Wiley, *Liability for Mobile Health and Wearable Technologies*, 25 ANNALS HEALTH L. 62, 80–97 (2016).

62. Palmer, *supra* note 58.

additional step creates complexity that results in attrition, meaning fewer and fewer consumers will ever encounter useful efficacy information at all. Instead, average consumer choices are more likely to be influenced by what they encounter at the point of download.[63] But what a consumer finds there may prove similarly uninformative.

2. The App Store

For health apps, the point of download is the app store. Smartphone users are familiar with this preloaded portal to search for and download apps of all varieties, turning an individual's smartphone into a highly personalized machine. For consumers interested in health app products like mental health apps, the app store allows users to search for and download desired products with ease.

Mental health app users are most likely to identify apps through social media (think influencers and direct advertisements), followed closely by searches in the app store.[64] With this in mind, some consumers will search by name for a specific app after seeing it advertised online. When a consumer searches for a specific mental health app by name, the app store algorithm[65] will put the sought-after search result at the top and then provide other related results based on variables like keywords or what the algorithm knows about the consumer or other consumers who searched similar terms. Other consumers will type in general search terms into the app store search bar, like "bipolar disorder" or "anxiety," and the app store will list all apps related to those search terms, regardless of the app's intended purpose. For example, a user hoping to find support for eating disorder recovery may search using the term "eating disorder" and receive search results ranging from recovery support apps to food diaries to eating timers and even, problematically, weight loss apps.

But, the app store provides no obviously useful information about health app quality. For example, the app store does not currently place the most effective apps at the top of a search query. In fact, research suggests that search results are highly volatile, both in terms of their visibility in the display order and their availability for download, and will vary from user to user.[66]

Even when an app is available and appears high in a user's search results, identifying even a relevant mental health app is challenging. The app store

63. *See* Neary & Schueller, *supra* note 57.

64. Schueller et al., *supra* note 56.

65. Kristian Lum & Rumman Chowdhury, *What Is an "Algorithm"? It Depends Whom You Ask*, MIT TECH. REV. (February 26, 2021), https://www.technologyreview.com/2021/02/26/1020007/what-is-an-algorithm/.

66. Mark Erik Larsen et al., *Quantifying App Store Dynamics: Longitudinal Tracking of Mental Health Apps*, JMIR MHEALTH & UHEALTH, July–Sept. 2016, at 1, 4–8.

display and descriptions generally do not offer helpful information about mental health app quality.[67] Images are small, and the text in those images is even smaller. As a consumer scrolls through search results, all apps look substantially the same: a small square tile with a logo, three images of the user interface, the rating, and an option to download or open.[68] Given the lack of directly relevant information, at least one published paper documenting one patient's experience suggests individuals will prioritize those apps that appear well-designed, are easy to use, offer appropriate notifications, have sufficient numbers of reviews, and, if an app requires a subscription or fee, that first offers a free trial period.[69] However, most of this information will not be clear until after a user has already downloaded and started using a specific app. Thus, whether an app appears well-designed based on tiny pictures may prove more important than effectiveness in influencing consumer choice.[70] Put differently, a consumer with a debilitating mental illness may make mental health app decisions based on little more than whether they find the color palette of one app appealing relative to another.

If a user decides to click an app to learn more about it, the app store provides more detail but nothing about effectiveness. On an iPhone, the Apple App Store shows a row displaying variables of presumed importance to a consumer: cost, average ratings, age appropriateness, chart rankings, categories, the developer's name, the language, and the file size. Below that, there is a section for "What's New," including recent app updates, user interface previews, the developer's name, ratings and reviews, and, below that, the privacy label (described in greater length in Part III).

App display characteristics in the app store point to three key criteria a consumer is likely to consider when downloading a health app—none of which correlate to efficacy. First, they may opt to download the easiest and cheapest option. For many, this will be the first free app they encounter in their search results that appears to fit the description of the health app they seek.[71]

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67. *Id.* at 4–8.

68. *See* Hsiao-Ying Huang & Masooda Bashir, *Users' Adoption of Mental Health Apps: Examining the Impact of Information Cues*, JMIR MHEALTH & UHEALTH, June 2017, at 1, 2.

69. Emil Chiauzzi & Amy Newell, *Mental Health Apps in Psychiatric Treatment: A Patient Perspective on Real World Technology Usage*, JMIR MENTAL HEALTH, Apr. 2019, at 1, 4–8.

70. Xingwei Chen et al., *How Do We Nudge People to Choose Aesthetically Pleasing Products?*, 32 ARCHIVES DESIGN RSCH. 61, 62 (2019) ("Although theorists view form as important as function, it has been found that people often undervalue form while overvalue function.").

71. Frank A. Pasquale, *Rankings, Reductionism, and Responsibility*, 54 CLEV. STATE L. REV. 115, 129 (2006) ("Though literally thousands or millions of results can appear in response to a query, only about ten to fifteen can appear on the first page. Of these, the first unpaid result is likely to get ten times the traffic as the tenth, and twice that of the second. The resulting competition has created various strategies to influence rankings, which in turn drive search engines to make their ranking algorithms more opaque. Rankings can also generate self-fulfilling prophecies, whereby the top-ranked site may become the most popular and successful one, regardless of its merits.").

Second, a consumer may pick an app based on the average number of star ratings and quantity of ratings or reviews. Unfortunately, these ratings, which presently offer the greatest opportunity for comparison between health apps at the point of download, show little relationship with evaluations of app quality when scientifically scrutinized.[72]

Third, and probably least likely, a consumer might select an app based on how frequently it is updated. Surprisingly, a study attempting to find proxies for app quality has suggested that the best indicator of app quality is the number of days since the last update. However, this unintuitive method for app selection is likely unhelpful for individual users and impractical at scale.[73]

In sum, the point of download does not help consumers pick safe and effective health apps as currently designed. The result is a consumer looking for a health app—maybe one like the kind he saw heavily advertised by his favorite Internet celebrity that boasts FDA clearance and is available for a fee—may instead unintentionally end up with a free digital snake oil look-alike. And while this may be a common app store feature for any app, these challenges are unique for health apps where consumer expectations about baseline protections may be different and the risks higher.

B. Market Failures

The market for health apps is confusing.[74] Health apps perform a variety of functions and target a variety of health concerns. A small percentage of these apps are very good, and a small percentage are very bad. This heterogeneity in the market is not in itself a problem. Instead, the problem arises when consumers cannot distinguish between products that help and products that hurt. Current health app and app store design and configurations do not provide users with helpful information about health app safety and efficacy. As a result, the developer is the only party to the health app transaction with actual knowledge of how, and if, a health app works. When only developers know the quality of their product, the result is an information asymmetry. Information asymmetries lead to market failures. This Subpart takes into consideration economic models that assume humans are

72. John Torous et al., *The Emerging Imperative for a Consensus Approach Toward the Rating and Clinical Recommendation of Mental Health Apps*, 206 J. NERVOUS & MENTAL DISEASE 662, 663–65 (2018); Jamie M. Marshall et al., *Clinical or Gimmickal: The Use and Effectiveness of Mobile Mental Health Apps for Treating Anxiety and Depression*, 54 AUSTL. & N.Z. J. PSYCHIATRY 20, 25 (2020); *see also* Chiauzzi & Newell, *supra* note 69.

73. Hannah Wisniewski et al., *Understanding the Quality, Effectiveness and Attributes of Top-Rated Smartphone Health Apps*, 22 EVIDENCE-BASED MENTAL HEALTH 4, 7 (2019) ("A longer duration without updates also suggests that an app is no longer being maintained and may be what is known as a 'zombie app'—alive in its availability but dead in terms of updates and support.").

74. The term itself is somewhat ambiguous. "Digital health" can mean everything from an app to personalized medicine. *See* Ravi N. Shah et al., *The Rise of Digital Health and Innovation Centers at Academic Medical Centers: Time for a New Industry Relationship Paradigm*, J. AM. MED. ASS'N HEALTH F., Mar. 2021, at 1, 1.

rational actors and behavioral economic theories that understand that, in reality, humans often behave irrationally. It considers how health app market failures hurt good-faith developers of quality health apps and, ultimately, force consumers to rely on ineffective proxies and heuristics to choose between facially similar apps.

1. Impact on Developers

Many have written about how the digital health revolution and health apps can harm or benefit consumers, but the scholarly literature has paid considerably less attention to the risks faced by the companies that develop these products. However, information asymmetries and market failures subject health app developers to two potential sources of harm. First, most high-quality health apps have no easy or meaningful way to distinguish themselves from lower-quality apps, especially within the category of minimally regulated wellness apps. Second, mistaken association with low-quality health apps that have failed to help or even outright harmed consumers may diminish consumer goodwill in high-quality apps. This is partly because health apps themselves do not provide standardized, easy-to-understand efficacy information, and app stores do not require or incorporate efficacy information into how search results are displayed to consumers.

In some ways, this informational environment creates a free-rider problem. In economics, a free-rider problem is a market failure that occurs when people do not pay their fair share, and it is most commonly thought of in the context of public goods.[75] Because an individual can benefit without necessarily assuming any of the burdens, the tendency will be that they will choose not to assume any burdens at all. Over time, a smaller and smaller subset of individual actors will continue to bear the cost and the expense of the public good. When this happens, it can result in underproduction or degradation.

Economic theorists have described this phenomenon for private goods as well. When a seller decides to improve a product, it assumes the full cost of those improvements.[76] But all sellers in that market will benefit from the resultant increase in overall average quality due to the increased value of the goods sold.[77] This uniformly distributed benefit is not universally good, especially for those sellers who have assumed the costs of improvement without solely appreciating the benefits of those investments. But for low-quality products with little or no investment in product development, the value of their product goes up anyway. They reap the benefits of the

75. Public goods are non-rivalrous and non-excludable—for example, clean air.

76. Hayne E. Leland, *Quacks, Lemons, and Licensing: A Theory of Minimum Quality Standards*, 87 J. POL. ECON. 1328, 1339 (1979).

77. *Id.*

considerable effort that goes into developing high-quality products by enjoying an increase in the overall average value of their own. The high-quality products, however, do not likewise benefit across all metrics. Instead, the low-quality products flooding the market bring down the average value, which dilutes the financial benefits of investing in improvements in the first place.

Consider this free-rider problem by using mental health apps as an example. A small subset of companies may assume the costs of having an FDA-cleared and well-developed mental health app. The cost of navigating these processes is not insignificant.[78] To maximize consumer exposure to their product to increase downloads and recoup the investment in development costs, the health app developer will likely heavily advertise their product on social media, creating additional and often considerable expenses. They then charge a fee for their app. However, the cost for entry into the app market can be extremely low—especially for mental health apps that intentionally avoid regulatory oversight and instead brand themselves as wellness trackers. Seeing that people are interested in mental health apps, smaller but visually indistinguishable apps of low-to-poor quality enter the market alongside the expensive, but effective, mental health apps. This second category of developers does not have the same high, up-front development costs and can offer their products for free. A consumer may see the impressive advertisements for the good product, be turned off by the cost when they search for it in the app store, and opt for the low-quality, but free, mental health app listed for download right below it.

The regulation of a similar product can create the appearance that an unregulated product has been likewise evaluated.[79] As a result, low-quality apps benefit from the reputations of better apps but provide no comparable functionality. Nevertheless, they draw consumers away from those better apps because they can offer their products at lower financial costs,[80] reducing profit for the developers that invested the up-front costs and disincentivizing others from innovating.[81]

Though the very best health apps may keep getting better, market failures may mean that most apps are poor or simply ineffective despite the market's overall average quality. For consumers, this poses significant problems because discerning between low- and high-quality products can be difficult or impossible depending on the type of good in question. Unfortunately, health apps are a type of so-called "credence good," meaning consumers cannot

78. *See infra* Part II.A.

79. Patricia J. Zettler, *The FDA's Power over Non-Therapeutic Uses of Drugs and Devices*, 78 WASH. & LEE L. REV. 379, 382 (2021) (using the example of decorative and corrective contact lenses).

80. It is commonly said of technology that if a product is free, you are the product. I use the term "financial cost" here to underscore that all apps come with a cost. Sometimes, users pay with their data instead of their money.

81. This further creates a shadow cost. Reputable producers never create health apps that provide maximal benefits. Over time, they do not even try, which eliminates potential benefits.

ascertain their quality through inspection or prior experience with other health apps.[82] One must download a health app to learn its quality. Credence goods create "lemon problems."[83]

In his now-famous 1970 article, Nobel Prize laureate George A. Akerlof describes a "Market for 'Lemons,'"[84] a term familiar to anyone who has ever purchased used cars. Akerlof notes that in these circumstances there is an "incentive for sellers to market poor quality merchandise, since the returns for good quality accrue mainly to the entire group . . . rather than to the individual seller."[85] The concept of a market for lemons begins with a good product. Buyers want this product, so they buy it. Less reputable sellers see this transaction and want a piece of the profit, so they flood the market with glitzy, similar-looking but lower-quality products at lower prices to undercut the original good product. In these circumstances, the buyer does not and cannot know the difference between good and bad products. But the cost to a seller for a good product is much higher. As a result, the bad products drive out the good because they are available at the same or lower prices. The result—the market for lemons—is a smaller market dominated by lower-quality products and untrustworthy sellers.[86]

This economic phenomenon exists outside of the market for cars. For example, within the health space, it exists for pharmaceuticals.[87] But similar reasoning applies to health apps. High-quality products—say, an app that has undergone FDA clearance for marketing for a specific health purpose—is available alongside facially similar apps of uncertain quality. The app developers know the quality of their apps. But, as many studies have demonstrated, the buyer has no meaningful or convenient way of discerning the quality or the risks posed among the vast majority of apps—specifically the thousands of unregulated wellness apps without some kind of obvious indicator of quality.[88] This is especially true if the consumer is only

82. Daniel Carpenter, *Confidence Games: How Does Regulation Constitute Markets?*, *in* GOVERNMENT AND MARKETS: TOWARD A NEW THEORY OF REGULATION 164, 174 (Edward J. Balleisen & David A. Moss eds., 2010).

83. *Id.*

84. *See generally* Akerlof, *supra* note 18.

85. *Id.*

86. As many scholars note, this is similar to "Gresham's Law," or the concept that "bad money drives out good money." *See* Noel Sullivan, *Gresham's Law, Fact or Falsehood?*, 19 STUDENT ECON. REV. 17, 17 (2005) (emphasis omitted).

87. *See* Ariel Katz, *Pharmaceutical Lemons: Innovation and Regulation in the Drug Industry*, 14 MICH. TELECOMMS. & TECH. L. REV. 1, 11–12 (2007). *See generally* Amy Kapczynski, *Dangerous Times: The FDA's Role in Information Production, Past and Future*, 102 MINN. L. REV. 2357, 2362 (2018).

88. *See* François Modave et al., *Low Quality of Free Coaching Apps With Respect to the American College of Sports Medicine Guidelines: A Review of Current Mobile Apps*, JMIR MHEALTH & UHEALTH, July–Sept. 2015, at 126, 126; Nicholas et al., *supra* note 8; Britt Lunde et al., *An Evaluation of Contraception Education and Health Promotion Applications for Patients*, 27 WOMEN'S HEALTH ISSUES 29, 34 (2017) ("More than one-third of identified apps were excluded from this review for containing inaccurate information."); *see also* Michelle L. Moglia et al., *Evaluation of Smartphone Menstrual Cycle Tracking Applications Using an Adapted APPLICATIONS*

considering downloading free health apps, which are available in the same store as the (often) paid, regulated, and higher-quality apps.[89] Here, the market that disappears is not the health app market altogether, but the health app market for well-researched and thoughtfully developed wellness apps—those that require considerable time and investment to bring to market but for which no meaningful indicator of effectiveness is available to a consumer should the developer choose, as most do, not to obtain FDA approval.[90]

Compounding this problem is the fact that there is little added incentive to provide high-quality products because app downloads are usually one-time activities, obviating the need for the average (non-Google, non-Meta, non-Apple) app developer to build a trusting relationship expected to endure over time.[91] And, because the real business model here may actually be collecting and monetizing user data instead of selling a high-quality product that users want, we have all the more reason to be suspicious of whether the current health app market truly encourages the development of safe products that actually work.

2. Impact on Consumers

But what about the consumer? The market failures described above contribute to a market predominated by suboptimal choices, which is certainly not an ideal place for the economic ideal of a rational actor to shop. But additionally, the information asymmetries that cause those market failures limit how real human consumers can make choices. Absent useful information, the average irrational consumer will rely on cognitive biases and heuristics to decide which health app to download. When this happens, consumers are more likely to make choices counter to their preferences or best interests.

The point of download is one of the greatest windows of opportunity to influence health app decision-making.[92] This fact results from how our brain

Scoring System, 127 OBSTETRICS & GYNECOLOGY 1153, 1153–56 (2016) (noting that of the 108 apps that fit the study criteria, 88 apps were eliminated due to the inclusion of misinformation and other inaccuracies).

89. "[T]he power of free can get us to make many foolish decisions." Karen Yeung, *'Hypernudge': Big Data as a Mode of Regulation by Design*, 20 INFO., COMMC'N & SOC'Y 118, 126 (2017) (citing DAN ARIELY, PREDICTABLY IRRATIONAL: THE HIDDEN FORCES THAT SHAPE OUR DECISIONS 44 (Harper Collins ed., 2008)).

90. The FDA process is expensive and takes a long time. Even high-resource developers, like Apple, are not interested. *Will the Internet of Things Transform Healthcare?*, *supra* note 37, at 346. Initially entering the market as a general wellness product may also be a deliberate business strategy. Simon et al., *supra* note 49.

91. Sarah Duranske, *This Article Makes You Smarter! (Or, Regulating Health and Wellness Claims)*, 43 AM. J.L. & MED. 7, 22 (2017). *But see* Simon et al., *supra* note 49, at 12 (arguing that the ability for general wellness products to "skate the line" between unregulated wellness products and regulated devices offers important benefits in addition to possible risks and forms the basis of a business strategy for debuting devices before seeking regulatory approval).

92. Neary & Schueller, *supra* note 57.

works and the heuristics that influence how we make choices.[93] These heuristics, or beliefs about how likely an event or outcome might be, lead to cognitive biases, which are unconscious errors.[94] Heuristics are not necessarily bad—they are shortcuts that allow us to navigate the world more easily. They allow us to rely on things like what we have already experienced so we do not have to process every moment as an onslaught of brand-new information. In other words, when they work well, they make us more efficient thinkers. However, when they do not, these shortcuts result in bad choices.

The power these heuristics and cognitive biases wield over our behaviors is so significant and predictable that so-called choice architects can use them to influence how individuals make decisions via something called a "nudge."[95] A nudge is a term used to describe scenarios designed to influence choice, encouraging a person to act in their own best interest while still preserving the full array of options.[96] Put differently, nudges can address behavioral market failures—like those resulting from cognitive tendencies and biases—by using the tools of behavioral economics to influence how real people think and act.[97] Nudges enable economically and individually preferable choices by making them easier than those that provide less social and personal benefit.[98]

A classic example of a nudge is presenting healthier food in a workplace cafeteria at eye level, where it is easy to see and grab, and placing unhealthy food in harder-to-reach places. In this scenario, a cafeteria customer interested in eating more fruits and vegetables will see them earlier and be able to access them easier than the lower-quality food he may crave in the short term. In presenting food this way, the employer—acting as the choice architect—can influence the employee–diner's choice. This approach is considered libertarian

93. Amos Tversky and Daniel Kahneman originally identified three heuristics: representativeness, availability, and adjustment and anchoring. Amos Tversky & Daniel Kahneman, *Judgment Under Uncertainty: Heuristics and Biases*, 185 SCIENCE 1124, 1124, 1127–28 (1974). But the list has since grown to over nineteen. J. S. Blumenthal-Barby & Heather Krieger, *Cognitive Biases and Heuristics in Medical Decision Making: A Critical Review Using a Systematic Search Strategy*, 35 MED. DECISION MAKING 539, 539 (2015).

94. In addition to biases, heuristics can result in noise, which "consists of unwanted variability in judgments." Cass R. Sunstein, *Governing By Algorithm? No Noise and (Potentially) Less Bias*, 71 DUKE L.J. 1175, 1178 (2021).

95. *See* RICHARD H. THALER & CASS R. SUNSTEIN, NUDGE: IMPROVING DECISIONS ABOUT HEALTH, WEALTH, AND HAPPINESS (2008); CASS R. SUNSTEIN, WHY NUDGE? THE POLITICS OF LIBERTARIAN PATERNALISM 34–50 (2014).

96. *See* SUNSTEIN, *supra* note 95. *But see* Henrik Skaug Sætra, *When Nudge Comes to Shove: Liberty and Nudging in the Era of Big Data*, TECH. SOC'Y, Nov. 2019, at 1, 4–9.

97. Since the introduction of "nudge" to the literature, the effectiveness of nudges has been subject to testing and ongoing debate. *See, e.g.*, Stefano DellaVigna & Elizabeth Linos, *RCTS to Scale: Comprehensive Evidence from Two Nudge Units*, 90 ECONOMETRICA 81, 114 (2022) (finding a small impact of nudges on outcomes). *But see* Maximilian Maier et al., *No Evidence for Nudging After Adjusting for Publication Bias*, 119 PROC. NAT'L ACAD. SCI., July 19, 2022, at 1, 2 (finding that "after correcting for this bias, no evidence remains that nudges are effective as tools for behavior [sic] change").

98. By contrast, they can also be used to trick or otherwise influence people to act against their best interests. Instead of a nudge, this is a "sludge." Richard H. Thaler, *Nudge, Not Sludge*, 361 SCIENCE 431, 431 (2018). In technology, this often manifests as a "dark pattern."

paternalism because the choice architect still preserves all available options but encourages one that is more consistent with desired ends: a healthier employee.

Nudges *intentionally* harness cognitive biases, but these biases still exist and influence behavior even without the intervention of a choice architect. A health-app-focused example can clarify how these concepts play out in the app store. App selection is a heuristic process, meaning that it is a process-oriented strategy using information cues rather than systematic evaluation.[99] For example, a consumer goes to the app store to search "mental health" and finds a meditation app displayed at the top as the first search result. The order effects, or primacy/recency bias,[100] in which people are more likely to choose the option presented first (or last) rather than in the middle, may result in a consumer picking the first mental health app they encounter rather than searching for additional information or seeking out one that better fits their needs. So, instead of one better targeted to the consumer's actual condition, they simply download the first one that looks relevant at the price they want to pay. Of course, this is a simplistic example pointing to just one mental shortcut. In reality, multiple heuristics and biases can bear on any given choice at any given time and can depend on the consumer's unique situation and prior experiences.[101] Relevantly, it does not depend on actual knowledge of the health app's efficacy at all. For unlucky consumers, this can potentially mean selecting a harmful mental health app instead of one that provides some benefit simply because it was the easiest choice.

These cognitive quirks can negatively influence not only how we pick a health app but also how we use it. For example, we are all subject to "[a]utomation bias" or "the tendency to over-rely on" computer-generated recommendations over and beyond our own conclusions.[102] Consequently, even if a user has reason to pause when reviewing a health app's output, automation bias may lead him to rely on its recommendations against his better judgment. Moreover, how average consumers misunderstand probability is likely to result in those consumers putting more weight on diagnostic app predictions than is warranted in light of actual disease prevalence.[103]

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99. Huang & Bashir, *supra* note 68.

100. George F. Loewenstein & Dražen Prelec, *Preferences for Sequences of Outcomes*, 100 PSYCH. REV. 91, 93 (1993).

101. Huang & Bashir, *supra* note 68.

102. Kate Goddard et al., *Automation Bias: A Systematic Review of Frequency, Effect Mediators, and Mitigators*, 19 J. AM. MED. INFORMATICS ASS'N 121, 121–27 (2012).

103. Boris Babic et al., *Direct-to-Consumer Medical Machine Learning and Artificial Intelligence Applications*, 3 NATURE MACH. INTEL. 283, 284–85 (2021).

As a result, the lack of available efficacy information can (indirectly) physically harm consumers.[104] This potential for secondary health harm is because all health apps are, regardless of nuanced regulatory distinctions, designed to help consumers manage health states through their various functionalities. And, problematically, expectations are particularly significant in a health context, where consumers likely assume—though often incorrectly—that the product they are using will be safe and effective. First, consider a user who relies on information obtained from a health app. He may seek invasive treatment based on inaccurate data provided by an app[105] or avoid treatment required for a condition obscured by information from app data.[106] Even wellness-tracking apps that only provide information are subject to errors and misinformation, even if physical harm can only result if the user does or does not take a specific action based on the information provided.[107] Second, and relatedly, a user primarily depending on an app for health management may also miss out on opportunities for secondary diagnoses resulting from routine clinical encounters.[108] If a consumer has selected a dangerous health app, given the lack of useful information available and his own subconscious decision-making, the potential for these types of harms increases.

And finally, because of yet another form of market failure—high switching costs and status quo bias—consumers may be unwilling or unable to move themselves and, relevantly, their historical information to a more efficacious app.[109] This limits a consumer's ability to use their purchasing power to drive the market in a different direction. As a result, the market for

104. Scholars have noted that "there [are] no direct physical risk[s]" related to the types of health apps that fall outside the FDA's purview. Duranske, *supra* note 91, at 19. Indeed, if a health app were capable of physically harming an individual user, it would be regulated by the FDA as a high-risk mobile medical app. However, there are indirect harms possible.

105. An example may be helpful in clarifying this point. Consider a user trying to get pregnant using fertile window prediction from a poor-quality period- and fertility-tracking app. If the app inaccurately predicts fertile days, a couple may focus their sexual efforts on non- or less-fertile days. Research has shown that targeted intercourse on non- or less-fertile days may lessen the chances of conception as compared to random intercourse throughout the month. Alexander Freis et al., *Plausibility of Menstrual Cycle Apps Claiming to Support Conception*, FRONTIERS PUB. HEALTH, Apr. 3, 2018, at 1, 2. As a result, a woman may seek out medical assistance under the mistaken assumption she is infertile when she has really been relying on incorrect information. Duranske, *supra* note 91, at 27.

106. Even if a physician is ultimately able to correct a health app user's misunderstanding of a health state informed by a low-quality health app, it still involves real costs to the consumer. For example, the costs include taking time off work to see a physician, arranging for childcare, obtaining transportation, and other logistical challenges. These situations also have an emotional cost.

107. Duranske, *supra* note 91, at 27.

108. 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 Program*, 48 U. MICH. J.L. REFORM 1073, 1079 (2015).

109. *See generally* Hal R. Arkes & Catherine Blumer, *The Psychology of Sunk Cost*, 35 ORGANIZATIONAL BEHAV. & HUM. DECISION PROCESSES 124, 124–40 (1985); Oren Bar-Gill & Omri Ben-Shahar, *Exit from Contract*, 6 J. LEGAL ANALYSIS 151, 153–54 (2014); MARGARET JANE RADIN, BOILERPLATE: THE FINE PRINT, VANISHING RIGHTS, AND THE RULE OF LAW 3, 27 (2013); Fowler et al., *supra* note 51, at 19–22.

low-quality health apps flourishes, drowning out better, safer, and more effective products. Between more bad apps and the limits of consumer decision-making, the odds of making a bad choice go up.

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The conditions in the market for health apps make it ripe for market failure. Thoughtful and well-developed health apps with the demonstrated potential to help consumers manage their health are difficult to distinguish from those that do nothing—or worse. Consumers are essentially powerless to tell the difference between these products, and the app store does nothing to help distinguish between those that work and those that do not. These information asymmetries result in market failures that harm innovative developers of high-quality health apps as well as innocent consumers. But this problem is uniquely challenging: the health app market is dynamic, and mistakes arise not only from obvious fraud or misrepresentations—areas where the law is poised and eager to intervene—but from reasonable confusion and the limits of flawed human decision-making processes. As a result, existing regulatory and legal approaches may only provide potential but incomplete solutions.

II. THE CHALLENGE OF REGULATING HEALTH APPS

Lawmakers and regulators are not ignorant of health app risks. They are acutely aware of the challenges of intervening in this space.[110] As a result, only a small subset of health apps and some developer behaviors are well-controlled. However, as described in Part I, the distinctions between apps that have been subjected to more significant oversight and those that have not are murky, and the actions or statements that may trigger additional scrutiny are hard to define and easy to avoid.[111] Even health apps exhibiting more egregious behaviors may fly under the radar due to the size and evolving

110. The FDA's regulatory approach to smartphone health apps is at least ten years in the making as it has struggled to make sense of appropriate risk categorizations and levels of required oversight for a new, but booming, market. The FDA recognizes the risk of these products and current approaches and, in response, solicits input to develop a series of biennial reports on the impact of these types of exclusions on patient safety. Despite these iterations, ambiguity, it seems, is unavoidable. *FDA Calls for Input on Benefits, Risks of Software Excluded from Regulation as Devices by CURES Act Agency to Develop the First Biennial Report Mandated by Statute on Five Non-Device Software Functions*, GUIDE TO MED. DEVICE REGUL. NEWSL. (Thompson FDA), July 2018, at 1. That the FDA continually refines its position is reflective of what some people have characterized as the "first existential challenge" to the FDA's regulatory paradigm from mobile health apps. Jeffrey K. Shapiro, *When It Comes to Software as a Medical Device, FDA Acknowledges that New Technology No Longer Fits the Old Regulatory Paradigm*, HYMAN, PHELPS & MCNAMARA, P.C. (Sept. 19, 2017), https://hpm.com/publications/when-it-comes-to-software-as-a-medical-device-fda-acknowledges-that-new-technology-no-longer-fits-the-old-regulatory-paradigm/.

111. A more in-depth discussion about what is and is not a device is a complex and interesting question, but unfortunately outside the scope of this Article.

nature of the market. This Part returns to the second example from the introduction—period and fertility trackers—to give a high-level overview of the health app regulatory and legal environments. It identifies where existing regulations and laws are well equipped to intervene and, more importantly, where they are not.

A. Agency Enforcement

To date, a host of federal agencies have addressed mobile health.[112] However, the FDA and the Federal Trade Commission (FTC) are the primary federal regulators of consumer health technologies and are intimately involved in the health app space, including so-called "femtech" apps.[113] Femtech[114]—a term encompassing software and technology targeting women's health issues like menstruation, menopause, and pregnancy—is a popular health app category. In 2019 alone, this industry generated $820.6 million in global revenue and benefitted from enormous venture capital investment.[115] One facet of this product category is period and fertility trackers, which includes everything from FDA-cleared digital contraception to wellness products dubiously purporting to link a user's menstrual cycle predictions to the phases of the moon and other celestial bodies.[116]

When these products work, they can provide a reliable form of hormone-free birth control that is comparable in effectiveness to other forms of fertility-awareness-based contraception.[117] For example, the apps *Natural Cycles* and *Clue* cite a "typical use" annual pregnancy rate of 6.5% and 5.2%, respectively.[118] Used incorrectly, they result in concerningly high rates of unintended pregnancies.[119]

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112. Nathan Cortez, *The Mobile Health Revolution?*, 47 U.C. DAVIS L. REV. 1173, 1179 (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. *See* Duranske, *supra* note 91, at 52–53.

113. DAN KRACOV ET AL., ARNOLD & PORTER, MEDICAL DEVICES & CONSUMER HEALTH PRODUCTS 2021: USA: LAW AND PRACTICE 21 (CHAMBERS GLOB. PRAC. GUIDES 2021).

114. This term was coined by Ida Tin. Tin is the founder of *Clue*, a period and ovulation tracking app. Lindsay Dodgson, *The Entrepreneur Who Coined the Term 'FemTech' Founded a Period Tracking App That's Helping Women Understand and Accept Their Bodies*, INSIDER (June 5, 2020, 9:24 AM), https://www.insider.com/founder-of-clue-ida-tin-coined-the-term-femtech-2020-6.

115. Nayeri, *supra* note 20.

116. KRACOV ET AL., *supra* note 113, at 21.

117. Palmer, *supra* note 58; *see also* Megan McCluskey, Bachelor *Stars Are Promoting a Birth Control App on Instagram that Experts Say Uses One of the Least Effective Contraceptive Methods*, TIME (Feb. 5, 2021, 12:15 PM), https://time.com/5933696/bachelor-natural-cycles-fertility-app/.

118. Palmer, *supra* note 58.

119. Research shows that unintended pregnancies occur in up to 25% of individuals using fertility-awareness-based methods of contraception annually. *Id.*; *see also* McCluskey, *supra* note 117.

Using a poorly designed period and fertility tracking app, even correctly, can similarly result in unintended pregnancies. As of 2021, only two apps have obtained FDA clearance for marketing as digital contraception.[120] While not explicitly marketed as contraception, other period tracking apps may also provide predicted ovulation dates or identify "fertile windows" that a consumer may then use for family planning.[121] The FDA exercises enforcement discretion over these so-called "proceptive" apps.[122] But there is ample reason to believe unvetted apps may provide inaccurate predictions. Multiple studies designed to evaluate the accuracy of period trackers have called into question accuracy and efficacy.[123] Some have ultimately needed to exclude a large percentage of available apps because they did not meet even basic requirements for accuracy.[124] And accuracy is of paramount importance for all individuals interested in fertility awareness, whether they are using them for contraception or conception.[125] For those individuals, selecting an accurate app from the array of app choices is a critical consideration.

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120. De novo or 510(k) approval for health apps is rare when considered from a percentage of total health app market share. At the time of writing, only two period trackers have FDA clearance for marketing as digital contraception; for those interested in mental health apps from Part I, as of writing, "[o]f the estimated 20,000 mental health apps available for download[,]" the FDA has only formally vetted and approved five. Gold, *supra* note 2; *see also* 21 C.F.R. § 884.5370(a) (2019) (defining software application for contraception).

121. *See* Megan Falk, *The Best Ovulation Tracker Apps to Identify Your Fertile Window,* SHAPE (Feb. 21, 2022), https://www.shape.com/health/sexual-health/ovulation-tracker-apps.

122. *See Product Classification*, U.S. FOOD & DRUG ADMIN., (Aug. 15, 2022), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=LHD. Apps associated with wearables are more likely to accurately predict fertile windows and ovulation. Tracy Y Zhu et al., *Accuracy of a Wrist-Worn Medical Device to Identify Fertile Window and Ovulation Day*, 116 FERTILITY & STERILITY (SUPPLEMENT) 292, 292 (2021).

123. *See, e.g.*, Lunde et al., *supra* note 88, at 34 ("More than one-third of identified apps were excluded from this review for containing inaccurate information."); *see also* Moglia et al., *supra* note 88, at 1153–55 (noting that of the 108 apps that fit the study criteria, 88 apps were eliminated due to the inclusion of misinformation and other inaccuracies); Marguerite Duane et al., *The Performance of Fertility Awareness-Based Method Apps Marketed to Avoid Pregnancy*, 29 J. AM. BD. FAM. MED. 508, 508 (2016); Sarah Johnson et al., *Can Apps and Calendar Methods Predict Ovulation with Accuracy?*, 34 CURRENT MED. RSCH. & OP. 1587, 1587–94 (2018); Roshonara Ali et al., *Do Fertility Tracking Applications Offer Women Useful Information About Their Fertile Window?*, 42 REPROD. BIOMED. ONLINE 273, 273–281 (2021) (finding that 54.4% of apps included in a sample of ninety used only calendar dates to predict ovulation, which the author notes is "impossible"); Lauren Worsfold et al., *Period Tracker Applications: What Menstrual Cycle Information Are They Giving Women?* WOMEN'S HEALTH, Oct. 9. 2021, at 1, 1–8 (showing that apps struggle to make predictions when presented with irregular menstrual cycle data and finding that the top ten period trackers gave conflicting information on period dates, ovulation day, and the fertile window).

124. *See* Moglia et al., *supra* note 88, at 1154–55 ("Our primary criterion for ongoing inclusion in this study was accuracy. Ninety-nine percent of regular menstrual cycles range from 21 to 35 days, and only one in eight or nine women have 28-day cycles. Because women may not know their average cycle length, we decided that the ability to predict the next menstrual cycle based on averages of past cycles and not on a default (often 28-day) cycle length would be an important element of our accuracy criteria." (footnote omitted)).

125. This is problematic for those using these technologies to assist in conception as well. If the app inaccurately predicts fertile days, a couple may focus their sexual efforts on non- or less-fertile days, which may lessen the chances of conception as compared to random intercourse throughout the month. Freis et al., *supra* note 105, at 2.

However, much like the mental health apps described above, both effective and ineffective products look alike and are available for download in a smartphone's app store.[126] In light of these concerns and considerations, FDA and FTC actions centering on femtech products provide a rich illustration through which to explore these agencies' respective (and combined) powers to address health app information asymmetries and the potential for consumer harm.

1. Regulating Health Apps

The FDA is the primary premarket regulator of the small percentage of health apps it believes qualify as medical devices.[127] The FDA has long been concerned with claims of a medical nature and has historically broadly interpreted what constitutes "instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals."[128] While it seems plausible that all health apps could fall under an expansive reading of "for use in the diagnosis . . . cure, mitigation, treatment, or prevention of disease . . . ,"[129] it only applies to health apps that the FDA believes are *intended* to perform a medical device function.[130] And for those apps that qualify as medical devices, the FDA takes a risk-based approach.[131]

The example of period and fertility trackers shows how the FDA can regulate health apps as medical devices. Consider *Natural Cycles* and *Clue*, which have received FDA clearance for marketing as a contraceptive after

126. Palmer, *supra* note 58 (quoting Raoul Scherwitzl, *Natural Cycles*'s CEO and co-founder, in discussing app confusion: "There's always a disclaimer somewhere that says 'do not use for contraception,' and the user can decide to use it the way she wants to. But I think that's not clear enough . . . .").

127. This Part is intended to provide a high-level overview of the FDA's regulatory powers to regulate medical devices.

128. United States v. 23, More or Less, Articles, 192 F.2d 308, 309–10 (2d. Cir. 1951) (quoting Federal Food, Drug & Cosmetic Act, 21 U.S.C. § 321(h)) (holding that a phonograph record is a "contrivance" and that a phonograph record intended for use in the treatment or prevention of insomnia was a device intended to affect a function of the body (inducing sleep) within the meaning of the Act, and that labeling which conveys the impression that the record is a cure-all for insomnia was false and misleading, and thus a misbranding within the meaning of the Federal Food, Drug, and Cosmetic Act).

129. 21 U.S.C. § 321(h) (defining "device").

130. *See infra* notes 164–173 and accompanying text (discussing intended use controversies); *see also* U.S. FOOD & DRUG ADMIN., POLICY FOR DEVICE SOFTWARE FUNCTIONS AND MOBILE MEDICAL APPLICATIONS: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (2022).

131. *See* 21 U.S.C. § 360(c) (defining Class I as devices with the lowest risk and subject to the least regulatory control; Class II as those with an intermediate level of risk; Class III as devices with the highest risk and that generally require premarket approval); *see also* Simon et al., *supra* note 49, at 5–6 (describing how the FDA classifies devices into risk categories and how those categorizations influence regulatory requirements).

review through the de novo premarket review and the abbreviated 510(k) approval pathway, respectively.[132]

In 2018, the FDA announced that it had cleared *Natural Cycles* to market itself as the first mobile medical app that could be used as a method of contraception to prevent pregnancy.[133] The FDA reviewed the app through the de novo premarket review pathway intended for novel, low-to-moderate risk devices of a new type.[134] To obtain this clearance, *Natural Cycles* provided documentation from clinical studies that included over 15,000 women evaluating the effectiveness of their product at preventing pregnancy for an average of eight months. By paving the way, *Natural Cycles* also prompted the FDA to establish criteria (also called special controls) to clarify the agency's expectations regarding accuracy, reliability, and effectiveness for apps intended to prevent pregnancy.[135]

This action also created a new regulatory classification, meaning that subsequent similar devices can use the 510(k) process to obtain authorization by demonstrating substantial equivalence to the legally marketed predicate device.[136] In other words, the devices that come later do not have to clear as high of a hurdle as those that come first. And this is also true for substantial equivalence to "pre-amendments devices," which are products that were on the market before the medical device amendments to the Food, Drug, and Cosmetics Act (FDCA) in 1976.[137] Perhaps surprisingly, this includes some health apps and associated devices.[138]

Setting aside products that are grandfathered in,[139] the 510(k) approval pathway is not available unless a similar product has already obtained de novo review, as the process requires submitters to compare their device to one or more similar legally marketed devices and make and support their substantial equivalence claims.[140] In 2021, *Clue* availed itself of this process[141] shortly after

132. *See* Press Release, *supra* note 9; *see also* Letter from Jason Roberts, U.S. Food & Drug Admin., to Yarmela Pavlovic, Partner, Manatt, Phelps & Phillips, LLP (Feb. 18, 2021), https://www.accessdata.fda.gov/cdrh_docs/pdf19/K193330.pdf.

133. Press Release, *supra* note 9.

134. *Id.*

135. *Id.*

136. *Id.*

137. Madelyn Lauer et al., *FDA Device Regulation*, 114 MO. MED. 283, 283–85 (2017).

138. Cara Tenenbaum & Genevieve Grabman, *FDA Regulation Must Uphold Women's Health*, 77 FOOD & DRUG L.J. (forthcoming 2022) (manuscript at 29) (on file with author) (describing how a digital pelvic floor trainer with accompanying smartphone app "can still be considered substantially equivalent to devices invented before the dawn of personal computing").

139. U.S. FOOD & DRUG ADMIN., PREMARKET NOTIFICATION 510(K): PREAMENDMENT DEVICES, https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-notification-510k#preamend (last updated Oct. 3, 2022) (describing preamendment devices).

140. U.S. FOOD & DRUG ADMIN., PREMARKET NOTIFICATION 510(K): WHAT IS SUBSTANTIAL EQUIVALENCE, https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-notifications-510k#se (last visited Feb. 5, 2022).

learning that 20% of users were already using *Clue*'s menstrual tracking features for birth control—just like its FDA-cleared counterpart *Natural Cycles*.[142]

These two products illustrate how apps can work through the FDA-defined process, both as an initial concept and then later as a similar product. But the FDA's jurisdiction does not end at premarket approval or clearance. Once a product has entered the market, the FDA shares oversight responsibilities with the FTC.[143]

The FTC is tasked with the dual mission of protecting consumers and promoting competition.[144] Among other functions, the FTC regulates health claims in advertising.[145] Under Section 5 of the FTC Act, the FTC can regulate unfair and deceptive acts or practices.[146] Under Sections 12–15, the FTC prohibits the dissemination of any false or misleading advertisement in or affecting commerce "for the purpose of inducing, or which is likely to induce . . . the purchase of food, drugs, devices, services, or cosmetics."[147] The FTC requires that claims in advertising "be truthful, cannot be deceptive or unfair, and must be evidence-based."[148] Section 13(b) authorizes the FTC to file suit to enjoin an act or practice that violates these provisions.[149] State attorneys generally have similar consumer protection powers over deceptive trade practices within their jurisdictions.

The FTC and, to a lesser extent, state attorneys general have taken a prominent role in policing health apps. For example, FTC settlements can prohibit defendant companies from making health claims unless supported by scientific evidence.[150] It can also prevent health apps from fabricating or

141. Letter from Jason Roberts, *supra* note 132.

142. Palmer, *supra* note 58 ("Brayboy said the impetus for creating *Clue*'s upcoming feature was the company's discovery that 20% of its users were using the menstrual tracking app for birth control. In late February, *Clue* removed a feature called the 'fertile window' that could have encouraged users to employ the uncleared app as birth control; now, they can only see their predicted day of ovulation.").

143. *See infra* notes 159–160 and accompanying text (explaining enforcement discretion and the 21st Century Cures Act); *see also* SOLOMON CTR. FOR HEALTH L. & POL'Y & STRATHMORE HEALTH STRATEGY, A PATH TO PATIENT-CENTERED DIGITAL HEALTH REGULATION (Ryan Knox and Cara Tenenbaum eds. 2021).

144. FED. TRADE COMM'N, *Mission*, https://www.ftc.gov/about-ftc/mission (last visited May 9, 2021).

145. The FTC also regulates privacy and security.

146. Federal Trade Commission Act, 15 U.S.C. § 45.

147. *Id.* §§ 52–55.

148. FED. TRADE COMM'N, *Advertising and Marketing Basics*, https://www.ftc.gov/business-guidance/advertising-marketing/advertising-marketing-basics (last visited May 9, 2021).

149. 15 U.S.C. § 53.

150. *See generally* FTC v. Lasarow, No. 15-cv-1614 (N.D. Ill. 2015), https://www.ftc.gov/system/files/documents/cases/150223avromorder.pdf (considering an app that claimed to detect melanoma, risk of melanoma, and evaluation of moles). Further, it requires such testing shall be both "randomized, double-blind, and adequately controlled" as well as "conducted by researchers qualified by training and experience to conduct such testing." In the Matter of Carrot Neurotech. Inc., No. C-4567, 2016 WL 807980, at *35 (F.T.C. Feb. 22, 2016) (involving an app that claimed to improve a user's

otherwise influencing user reviews.[151] States can likewise act to stop these behaviors. For example, in 2017, the New York Attorney General brought an action against three health apps to prevent similar deceptive practices.[152]

The FTC also holds health apps to the promises they make consumers. For example, in 2021, the FTC made news by settling a case against *Flo*, another period- and fertility-tracking app, because it broke clearly stated privacy promises to consumers.[153] In this case, *Flo* repeatedly promised its users that it would keep their health data private and that *Flo* only utilized users' data to provide the app's services.[154] The privacy policy even specified that, among other protections, when sharing any data with third parties, *Flo* "exclud[ed] information regarding your marked cycles, pregnancy, symptoms, notes and other information that is entered by you and that you do not elect to share."[155] However, despite those explicit representations, the FTC alleged that *Flo* nevertheless shared this data with third parties through software development kits—and did so until a news exposé revealed the deception in the *Wall Street Journal* in 2019.[156] While this is an example of a privacy claim and not a health claim, one can extend the logic to claims regarding health. For example, if a period- or fertility-tracking app claimed to employ state-of-the-art artificial intelligence to predict the date of the user's next period using an in-depth analysis of her historical menstruation data and other user-entered signs and symptoms but instead relied on a simple twenty-eight-day count, the FTC or a state agency would likely have grounds to bring a claim.

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vision or reverse, delay, or correct aging eye or presbyopia); *see also* POM Wonderful, LLC v. FTC, 777 F.3d 478, 483 (D.C. Cir. 2015) (upholding the FTC's substantiation standards).

151. FTC v. Lumos Labs Inc., No. 3:16-cv-00001, at 8 (N.D. Cal. Jan. 8, 2016), https://www.ftc.gov/system/files/documents/cases/160105lumoslabsstip.pdf (charging the defendants with failing to disclose that some consumer testimonials featured on the website had been solicited through contests that promised significant prizes, including a free iPad, a lifetime Lumosity subscription, and a round-trip to San Francisco); *see also* Press Release, Fed Trade Comm'n, FTC Puts Hundreds of Businesses on Notice about Fake Reviews and Other Misleading Endorsements (Oct. 13, 2021), https://www.ftc.gov/news-events/news/press-releases/2021/10/ftc-puts-hundreds-businesses-notice-about-fake-reviews-other-misleading-endorsements.

152. Press Release, N.Y. State Off. Att'y Gen., A.G. Schneiderman Announces Settlements with Three Mobile Health Application Developers for Misleading Marketing and Privacy Practices (Mar. 23, 2017), https://ag.ny.gov/press-release/2017/ag-schneiderman-announces-settlements-three-mobile-health-application-developers.

153. Press Release, Fed. Trade Comm'n, Developer of Popular Women's Fertility-Tracking App Settles FTC Allegations That It Misled Consumers About the Disclosure of Their Health Data (Jan. 13, 2021), https://www.ftc.gov/news-events/press-releases/2021/01/developer-popular-womens-fertility-tracking-app-settles-ftc.

154. In the Matter of Flo Health, Inc., No. C-4747, at 3 (F.T.C. Jan. 13, 2021), https://www.ftc.gov/system/files/documents/cases/192_3133_flo_health_complaint.pdf.

155. *Id.* (emphasis omitted).

156. Sam Schechner & Mark Secada, *You Give Apps Sensitive Personal Information. Then They Tell Facebook.*, WALL ST. J. (Feb. 22, 2019), https://www.wsj.com/articles/you-give-apps-sensitive-personal-information-then-they-tell-facebook-11550851636.

2. The Problem of Inaction

The FDA and FTC thus appear to be well-positioned to protect health app consumers. The FDA and FTC thus appear to be well positioned to protect health app consumers. But perhaps more importantly for present-day considerations, there is a difference between what the FDA and the FTC have jurisdiction over now and how they choose to enforce their authority at this time.[157]

Recall that the FDA regulates health apps when they qualify as medical devices. However, the FDA exercises its powers over only a small percentage of health apps. Instead, from a regulatory perspective, the vast majority of health apps pose minimal risks to users. While some may technically qualify as medical devices, the FDA does not expect developers to receive pre-market review or register their apps.[158] To use a term of art, the FDA exercises "enforcement discretion" over a subset of so-called low-risk health apps, meaning that they will not enforce applicable regulatory requirements. The 21st Century Cures Act places yet another subset of these products outside of the agency's regulation and oversight altogether.[159] Section 3060(a) of the 21st Century Cures Act amended Section 520 of the FDCA to remove certain software functions from the FDCA definition of a device, including those that "maintain[] or encourag[e] a healthy lifestyle."[160]

Central to determining what the FDA will or will not regulate is an important and controversial question: what is a health app's intended use? "Intended use" is statutorily defined as the "objective intent of the persons legally responsible for the labeling of an article."[161] Evidence of intended use may include, among others, labeling claims, advertisements, and statements.[162] But "intended use" is a deceptively simple term.[163] Although the FDA has indicated—at least as recently as 2013—that they do not plan to use *actual use*

157. In fairness to the FDA and FTC, at the time of writing, both are confronting much larger issues. The FDA is responding to the ongoing coronavirus pandemic, and the FTC has its sights on Big Tech giants like Facebook/Meta and antitrust issues. Health Apps are understandably lower priorities.

158. U.S. FOOD & DRUG ADMIN., EXAMPLES OF SOFTWARE FUNCTIONS FOR WHICH THE FDA WILL EXERCISE ENFORCEMENT DISCRETION, https://www.fda.gov/medical-devices/device-software-functions-including-mobile-medical-applications/examples-software-functions-which-fda-will-exercise-enforcement-discretion (last updated Sept. 29, 2022).

159. 21st Century Cures Act, Pub. L. No. 114-255, 130 Stat. 1131 (2016).

160. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360j(o)(1)(A)–(E). The other four are the following: provide administrative support for a health care facility; serve as electronic patient records; transfer, store, or display data for converting data formats; and provide limited clinical decision support. *Id.*

161. 21 C.F.R. § 801.4 (2020).

162. Barbara Zabawa, *FDA Regulation of mHealth and Wellness Devices: What You Need to Know*, HEALTH LAW., Dec. 2017, at 38, 39.

163. What constitutes intended use is a subject of much debate, and in-depth exploration of this subject is outside the scope of this Article. Patricia J. Zettler et al., *Closing the Regulatory Gap for Synthetic Nicotine Products*, 59 B.C. L. REV. 1933, 1938 (2018) (noting that this issue has long been controversial).

to determine "intended use,"[164] a variety of evidence, including actual use, may be relevant to this determination.[165] They can even look beyond explicit labels.[166] For example, the FDA might consider subjective claims[167] and advertising,[168] *past* claims,[169] and even product design,[170] among others.[171] A seller may not even have to make any affirmative representations at all.[172] Notably, the FDA reaffirmed its ability to rely on *any relevant source of information* to determine intended use in the preamble to the August 2021 final rules.[173]

There may be evidence that almost all health apps—including run-of-the-mill period and fertility trackers—are arguably within the FDA's jurisdiction even after considering the "for maintaining or encouraging a healthy lifestyle"

164. *Health Information Technologies: Administration Perspectives on Innovation and Regulation: Hearing Before the Subcomm. on Oversight and Investigations of the Comm. on Energy and Com.*, 113th Cong. 58–59 (2013) (citing Letter from Michele Mital, Acting Assoc. Comm'r for Legis., U.S. Food & Drug Admin., to The Hon. Tim Murphy, Chairman, Subcomm. on Oversight & Investigations of the Comm. of Energy & Com. (Mar. 20, 2013)), https://purl.fdlp.gov/GPO/gpo39105; *see infra* Part II.

165. *See* Zettler et al., *supra* note 163, at 1956 (citing United States v. Storage Spaces Designated Nos. 8 & 49, 777 F.2d 1363, 1366 (9th Cir. 1985)) ("This intent may be derived or inferred from labeling, promotional material, advertising, or any other relevant source." (internal quotation marks omitted)).

166. United States v. Travia, 180 F. Supp. 2d 115, 119 (D.D.C. 2001) ("Labeling is not exclusive evidence of the sellers' intent. Rather . . . 'it is well established "that the intended use of a product, within the meaning of the [FDCA], is determined from its label, accompanying labeling, promotional claims, advertising, and any other relevant source."'") (emphasis omitted)).

167. Nat'l Nutritional Foods Ass'n v. FDA, 504 F.2d 761, 789 (2d Cir. 1974) ("[A] factfinder should be free to pierce all of a manufacturer's subjective claims of intent . . . to find actual therapeutic intent on the basis of objective evidence . . . .").

168. United States v. An Article . . . Consisting of 216 Cartoned Bottles, More or Less, of an Article Labeled in Part: Sudden Change, 409 F.2d 734, 739 (2d Cir. 1969) ("It is well settled that the intended use of a product may be determined from its label, accompanying labeling, promotional material, advertising and any other relevant source.").

169. Allergan, Inc. v. Athena Cosms., Inc., 738 F.3d 1350, 1356 (Fed. Cir. 2013); United States v. 789 Cases, More or Less, of Latex Surgeons' Gloves, an Article of Device, 799 F. Supp. 1275, 1285 (D.P.R. 1992) ("[W]hen a manufacturer has created a market for a product to be used as a device, he or she cannot avoid the reaches of the [FDCA] by stating that the product has a different—and non-regulated use. The [Courts] have recognized the 'carry-over effect' that is created by a manufacturer's original representations about the product."); United States v. Undetermined Quantities of an Article of Drug Labeled as Exachol, 716 F. Supp. 787, 791 (S.D.N.Y. 1989) (noting that "[c]ourts have recognized that where years later customers purchase a product in reliance on the therapeutic claims of the previous literature marketed with that product, the court may use such literature to determine the intent in marketing the product despite a later disclaimer").

170. *See, e.g.*, Clarification of When Products Made or Derived from Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding "Intended Uses," 82 Fed. Reg. 2193, 2208 (Jan. 9, 2017) (providing examples of when the FDA has relied on product design as circumstantial evidence of intended use).

171. Zettler et al., *supra* note 163, at 1956–70 (describing evidence of intended use in the context of synthetic nicotine).

172. United States v. Travia, 180 F. Supp. 2d 115, 119 (D.D.C. 2001) ("The environment provided the necessary information between buyer and seller.").

173. Regulations Regarding "Intended Uses," 86 Fed. Reg. 41383, 41388 (Aug. 2, 2021) (to be codified at 21 C.F.R. pts. 201, 801).

Cures Act carve-out.[174] However, that determination is product-specific, and each product must be assessed individually.[175] Thus, the theoretical ability of the FDA to do something that impacts the entire health app market is meaningless when confronted with the reality that, to date, they have chosen not to.

The FTC's potential to take a more prominent role in regulating the health app space encounters similar roadblocks. Recall that the FTC regulates health claims in advertising. They have, among other things, prevented health apps from lying to consumers,[176] misrepresenting evidence,[177] making unsupported health claims,[178] and influencing product reviews.[179] However, despite this broad authority, deceptive behaviors may still be common practice for health apps. One 2019 study found that even though none of the health apps in the study's sample had been approved by the FDA to make medical claims, almost half made claims that could potentially be construed as medical.[180] Another study of highly ranked health apps found that the majority (64%) made positive claims about effectiveness, appealing to scientific language,[181] technical expertise, "appeals to the 'wisdom of the crowd,'" or "lived experience."[182] Importantly, however, only two apps (2.7%) provided direct evidence for their app—one from a pilot study and one from user-reported results after app use.[183] And what about health apps that are simply silent on evidence and effectiveness? Research suggests that silence may even be the most common approach for health app developers. One study evaluating a subset of health app quality claims noted that the single largest category of apps consisted of those apps that did not make claims about effectiveness at all, more than half of which did not include any supporting

174. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360j(o)(1)(A)–(E). The other four are the following: provide administrative support for a health care facility; serve as electronic patient records; transfer, store, or display data for converting data formats; and provide limited clinical decision support. *Id.*

175. Zettler et al., *supra* note 163, at 1958; Patricia J. Zettler, *What Lies Ahead for FDA Regulation of tDCS Products*, 3 J.L. & BIOSCI. 318, 319 (2016).

176. Federal Trade Commission Act, 15 U.S.C. §§ 45, 52–55.

177. *See infra* note 219 (discussing Acne App).

178. Press Release, Fed. Trade Comm'n, Lumosity to Pay $2 Million to Settle FTC Deceptive Advertising Charges for Its "Brain Training" Program (Jan. 5, 2016), https://www.ftc.gov/news-events/press-releases/2016/01/lumosity-pay-2-million-settle-ftc-deceptive-advertising-charges.

179. FTC v. Lumos Labs Inc., No. 3:16-cv-00001, at 8 (N.D. Cal. Jan. 8, 2016), https://www.ftc.gov/system/files/documents/cases/160105lumoslabsstip.pdf.

180. Wisniewski et al., *supra* note 73, at 7.

181. The authors note, however, that "a third of apps whose descriptions included scientific techniques referred to principles that had no evidence available in the scientific literature." Mark Erik Larsen et al., *Using Science to Sell Apps: Evaluation of Mental Health App Store Quality Claims*, NPJ DIGIT. MED., Mar. 22, 2019, at 1, 4.

182. *Id.*

183. *Id.*

statements.[184] Instead, these apps rely on consumer assumptions and benefit from marketing invoking the imprimatur of science.[185]

Whether these marketing approaches rise to the level of false or misleading statements from the FTC's perspective is fact-specific, but it is also up to the FTC whether they want to pursue it. Given previous enforcement actions, it seems likely that if the FTC wanted to intervene and bring an enforcement action against a specific health app for engaging in any of those behaviors, it probably could. But, much like the FDA, it usually does not.

B. Private Enforcement

While certainly the most powerful and far-reaching actors, the FDA and the FTC do not wield the singular authority to keep a health app accountable. When the law works as intended, consumers can also seek redress in the courts. A health app's ToS is a contract, and contract law can provide possible avenues for holding health apps to their word. Health apps are also products, and harmed consumers could theoretically bring products liability tort claims. Thus, there remains a potential for health app regulation through litigation.[186]

1. Terms of Service and Contract Law

Health app consumers—and consumers of all digital technologies—have likely scrolled through and clicked "I accept" to a product's ToS. These ToS and End User License Agreements (EULA)[187] are contracts.[188] Absent other applicable or intervening laws, these contracts likely govern any disputes that may arise between a health app developer and users of its product. As a result,

184. *Id.* at 3; *see also* Weisel et al., *supra* note 19; Carolina Rodriguez-Paras et al., *Posttraumatic Stress Disorder and Mobile Health: App Investigation and Scoping Literature Review*, JMIR MHEALTH & UHEALTH, Oct. 2017, at 1, 3 (finding that in another study of mental health apps for PTSD specifically, searching for apps to include in the study sample did "not reveal information on how the apps were designed and evaluated, or whether studies had analyzed their usability."); L.S. van Galen et al., *Eczema Apps Conformance with Clinical Guidelines: A Systematic Assessment of Functions, Tools and Content*, 182 BRIT. J. DERMATOLOGY 444, 450 (2019) ("Most apps failed to cite their source of educational information, and even apps with cited claims or information provided by qualified doctors contained content inconsistent with guidelines.").

185. Anna Wexler & Peter B. Reiner, *Oversight of Direct-to-Consumer Neurotechnologies: Efficacy of Products Is Far from Clear*, 363 SCI. 234, 235 (2019); *see also* Larsen et al., *supra* note 181.

186. *Will the Internet of Things Transform Healthcare?*, *supra* note 37, at 346.

187. Jennifer Laird, *EULA Versus Terms and Conditions*, PRIV. POLICIES (July 1, 2022), https://www.privacypolicies.com/blog/eula-vs-terms-conditions/#:~:text=Here's%20an%20easy%20way%20to,them%20to%20behave%20in%20return ("An EULA sets out what end users can and can't do with your *software*. A Terms and Conditions agreement set [sic] out what services you agree to offer the end user and how you expect them to behave in return." (emphasis omitted)).

188. *See generally* Fowler et al., *supra* note 51 (whether privacy policies are contracts is debatable). For an excellent discussion, see Daniel J. Solove & Woodrow Hartzog, *The FTC and the New Common Law of Privacy*, 114 COLUM. L. REV. 583, 595–96 (2014).

courts hearing cases against digital health tech companies would likely turn to contract doctrines to interpret these materials.

Within the confines of the ToS, consumers can find information about medical disclaimers, waivers of liability, and various warranties about the accuracy of any information provided by the app, to name a few. For example, the ToS may include language indicating that the product is offered as-is and not intended to be a substitute for medical advice; disclaim liability for errors, omissions, and technical inaccuracies; and claim that using the app is done solely at the user's own risk.[189] *Flo* even disclaims liability for violations of "ethical or moral standards applicable in your community."[190]

The average consumer encounters these types of warnings all the time in the physical world, and they are common in a variety of products. For example, consumers are likely familiar with the labels on hair dryers warning them not to use the hair dryers in the bathtub and other types of risk warnings on common household objects.[191] In general, this reflects the rationale behind manufacturers' duties: manufacturers of dangerous products must warn users of hidden dangers that may be present as well as instruct users on how to use a product in a way that is safe.[192] When a manufacturer fails to do so, a consumer may have a product liability case.

If a health app violates its terms or does not warn users of foreseeable dangers, a user may be able to sue them. At first blush, this seems like a possible fix for some of the existing health app information asymmetries: developers could include everything a consumer needs to know about a product in the ToS, along with necessary disclaimers and warranties. A consumer wishing to use a health app for a specific purpose could theoretically consult the detailed and lengthy ToS to determine if that is an acceptable use of the product. If the product later harms the consumer for some reason the developer should have disclosed, they may have a cause of action.

2. The Problem of Fine Print

Even though ToS are contracts in the most basic sense, they are complicated and controversial documents. Many of their common criticisms are likely familiar to anyone who has ever tried to read one. For example,

189. Fowler et al., *supra* note 51, at 28.

190. *Terms of Use: Medical Services Disclaimer*, FLO (May 1, 2022), https://flo.health/terms-of-service.

191. U.C.C. § 2-316 requires warranty disclaimers to be conspicuous. U.C.C. § 2-316 (AM. L. INST. & UNIF. L. COMM'N 2002); *see also* Omri Ben-Shahar & Carl E. Schneider, *The Failure of Mandated Disclosure*, 159 U. PENN. L. REV. 647, 657–58 (2011).

192. Warnings are generally required when: the product presents a danger; the manufacturer knows about the danger; the danger is present when the product is reasonably used in its intended manner; and the danger is not obvious to the reasonable user. *Defects in Warnings*, FINDLAW (Dec. 2, 2018), https://www.findlaw.com/injury/product-liability/defects-in-warnings.html.

some scholars have condemned them for being difficult to understand,[193] notoriously ignored,[194] and in some cases even unavailable to the most diligent and motivated consumers.[195] As a result, their considerable criticism appears well-earned.[196]

ToS for period trackers are no exception and help illustrate the extent of the problem. Prior research into period and fertility tracking apps found that app developers often write ToS well above the eighth-grade reading level recommended for improved population-wide comprehension.[197] Moreover, this same research showed that they were cumbersome to review and exhausting to read, even for the most motivated consumer. For example, one app would require nearly eighty-five scrolls on an iPhone 8 to read to completion.[198] And, of course, that is if the consumer can find the ToS at all. In this study, the team noted that, in attempting to access ToS for one period tracking app, an author received emails from the listed developer that the app owner had recently sold the app. The new company representative (not listed on the app at the time of data collection) acknowledged that they did not know which terms would apply.[199] In another instance, two different ToS were available for one period tracker, and the study team was never able to clarify with a company representative about which terms applied, though the representative did thank the author for drawing attention to the issue.[200] Both apps were available for consumer download and use, despite this uncertainty.

As a result, contract law may prove inadequate to remedy information asymmetries given the unique nature of health apps and the problem with the ToS contracts themselves. Core contract law doctrines—like mutual assent[201] and duty to read[202]—emerged in a world in which the ubiquity of health apps and the existence of interminable digital boilerplate terms were

193. Leah R. Fowler et al., *Readability and Accessibility of Terms of Service and Privacy Policies for Menstruation-Tracking Smartphone Applications*, 21 HEALTH PROMOTION PRAC. 679, 682 (2020); *see also* Ali Sunyaev et al., *Availability and Quality of Mobile Health App Privacy Policies*, 22 J. AM. MED. INFORMATICS ASS'N (SPECIAL ISSUE) e28, e31–e32 (2015).

194. Bakos et al., *supra* note 48, at 31–32.

195. Fowler et al., *supra* note 193, at 682.

196. Bakos et al., *supra* note 48, at 31–32; Ben-Shahar & Schneider, *supra* note 191. *See generally* Florencia Marotta-Wurgler, *Will Increased Disclosure Help? Evaluating the Recommendation of the ALI's "Principles of the Law of Software Contracts,"* 78 U. CHI. L. REV. 165 (2011); Uri Benoliel & Shmuel I. Becher, *The Duty to Read the Unreadable*, 60 B.C. L. REV. 2255 (2019); Ian Ayres & Alan Schwartz, *The No-Reading Problem in Consumer Contract Law*, 66 STAN. L. REV. 545 (2014).

197. Fowler et al., *supra* note 193, at 681–82.

198. *Id.* at 681.

199. *Id.*

200. *Id.*

201. ATACS Corp. v. Trans World Commc'ns, Inc., 155 F.3d 659, 666 (3d Cir. 1998) ("[T]he decisive inquiry in contract formation is the 'manifestation of assent of the parties to the terms of the promise and to the consideration for it . . . .'") (quoting 1 SAMUEL WILLISTON, A TREATISE ON THE LAW OF CONTRACTS § 23, at 51 (Walter H.E. Jaeger ed. 1957); then citing RESTATEMENT (SECOND) OF CONTRACTS § 22 (AM. L. INST. 1981)).

202. NANCY KIM, WRAP CONTRACTS: FOUNDATIONS AND RAMIFICATIONS 65 (2013).

unimaginable.[203] Some scholars have even theorized that if courts were to apply contract law in its classical formulation, it would be unlikely to offer much protection for health tech users.[204] And this focus on theoretical outcomes is intentional: to date, no existing case law exists, from period trackers or other types of health apps, in which a consumer sues a health app developer for specific health harms she experiences as a result of using a product, regardless of whether the developer disclaimed those functionalities in their ToS. However, it is unclear if this lack of case law is a function of mandatory arbitration agreements so often contained in ToS or if there are simply no plaintiffs. Circumstantial evidence from wearables and other consumer health products suggests it is not the latter.

Consider *McLellan v. Fitbit, Inc.*, a case concerning Fitbit's line of PurePulse heart rate trackers.[205] From the flurry of filings, it is clear that the plaintiffs looked at the entire product and created an impression based on everything from advertising to design, including prominent slogans like "Every Beat Counts." What those consumers saw was a piece of technology that promised accurate heart rate monitoring. But the tracker was off by a considerable amount—and it appeared to get worse as the intensity of activity increased.[206]

Plaintiffs sued, claiming that Fitbit's popular heart-rate tracker did not work as advertised.[207] But where plaintiffs saw guarantees of accuracy, Fitbit claimed inactionable puffery.[208] And more importantly, Fitbit also pointed to the ToS and removed to arbitration.[209]

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203. *See* Robin Bradley Kar & Margaret Jane Radin, *Pseudo-Contract and Shared Meaning Analysis*, 132 HARV. L. REV. 1135, 1155 (2019) (explaining how in many modern cases, "boilerplate text creates only pseudo-contract (as in many cases of unread and unreadable boilerplate text in online consumer transactions)"); *see also* Madelyn Tarr, *Accountability Is the Best (Privacy) Policy: Improving Remedies for Data Breach Victims Through Recognition of Privacy Policies As Enforceable Agreements*, 3 GEO. L. TECH. REV. 162, 192 (2018) (discussing contracting practices in health tech contracts). Commentary has already lamented this normative degradation of the legal system. MARGARET JANE RADIN, BOILERPLATE: THE FINE PRINT, VANISHING RIGHTS, AND THE RULE OF LAW 15 (2013) ("'Normative degradation' refers to the fact that our system is committed to the moral premise that justifies our legal structure of contract enforcement, that premise being that people who enter contracts are *voluntarily* giving up something in exchange for something they value more.").

204. Fowler et al., *supra* note 51, at 40.

205. McLellan v. Fitbit, Inc., No. 3:16-CV-00036, 2018 WL 2688781 (N.D. Cal. June 5, 2018).

206. EDWARD JO & BRETT A. DOLEZAL, VALIDATION OF THE FITBIT SURGE AND CHARGE HR FITNESS TRACKERS 22–23, http://www.lieffcabraser.com/pdf/Fitbit_Validation_Study.pdf (last visited Feb. 5, 2022). Fitbit countered that the attorneys representing the plaintiffs commissioned the study and that it lacked scientific rigor. Rachel Dicker, *Fitbit Devices Are Inaccurate, Study Says*, US NEWS (May 24, 2016, 1:02 PM), https://www.usnews.com/news/articles/2016-05-24/fitbit-devices-are-inaccurate-cal-poly-study-says.

207. *McLellan*, 2018 WL 2688781, at *1.

208. *Id.* at *2. Plaintiffs sued under the California False Advertising Law, the California Unfair Competition Law, common-law fraud, fraud in the inducement, unjust enrichment, breach of express warranty, breach of implied warranties under the Magnuson-Moss Warranty Act, and the Arizona Consumer Fraud Act. *Id.* at *1.

209. And a messy arbitration it was. *McLellan*, 2018 WL 3549042, at *1.

Or consider a lawsuit involving a different direct-to-consumer product. In *Tompkins v. 23andMe, Inc.*, a class of plaintiffs brought claims against 23andMe for "unfair business practices, breach of warranty, and misrepresentations about the health benefits of 23AndMe's services."[210] As part of the claims about warranties and misrepresentations, the plaintiffs claimed that 23andMe "represented and advertised that their DNA Kits would improve consumers' health."[211] In their response, 23andMe noted that "[c]ontrary to the litigation assertions reprised in Plaintiffs' Statement of the Case, the Company's website and TOS made abundantly clear that the health-related component was for informational purposes only, did not constitute medical advice or diagnoses, and could not be used by customers for diagnostic purposes."[212] Unfortunately, the court did not make it to that argument when evaluating the claims. Ultimately, they stopped short of reaching the issues of breach of warranty and misrepresentations of health benefits when they held that the challenged arbitration agreement was not unconscionable under California law and that their "authority to review portions of the contract outside the arbitration provision [was] limited."[213]

As *McLellan* and *Tompkins* further illustrate, confusion resulting from a disconnect between user interfaces and marketing and the information in the fine print of the ToS and EULA for direct-to-consumer health products is foreseeable and possibly even common. The plaintiffs in these cases thought the product would improve their health, but the ToS—that, realistically, they did not read—said otherwise. However, as the law stands, contract law will likely only hold developers responsible for explicit statements about their products' capabilities, and developers will often be protected by the warranties and disclaimers included in their ToS and EULA—documents at which the average consumer has likely never even looked.[214] As a result, private actions to enforce ToS hold little promise to remedy existing market failures or influence consumer decisions. More complicated still, it is not clear that any private law mechanism exists to protect a consumer who is confused about the capabilities of one health app because of something they understand to be true about a completely different health app.[215] And from a public policy perspective, it is not even clear that private enforcement is the best approach, given that legal recourse is only available to consumers after they have already experienced harm.

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210. Tompkins v. 23andMe, Inc., 840 F.3d 1016, 1021 (9th Cir. 2016).

211. First Amended Class Action Complaint at 8, Guthrie v. 23andMe, Inc., Nos. 2:14-cv-00168, 14CV01258 (N.D. Cal. Mar. 13, 2014), 2014 WL 10450399.

212. Brief of Defendant-Appellee at 20, Tompkins v. 23andMe, Inc., 840 F.3d 1016 (9th Cir. 2016) (No. 14-16405).

213. *Tompkins*, 840 F.3d at 1032.

214. Other doctrines might protect future theoretical plaintiffs. Fowler et al., *supra* note 51, at 56–58.

215. Confusion is also an important concept in trademark law but is outside the scope of this paper. *See generally* David A. Simon, *Trademark Law & Consumer Safety*, 72 FLA. L. REV. 673 (2020).

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Whatever the law may permit the FDA and FTC to regulate, they only enforce those requirements for a small subset of health apps. But, given the size and dynamic nature of the health app market, even increased scrutiny of individual bad actors may do little to address the systemic problems identified in Part I. Contract and consumer law, at first blush, at least appear as though they should either provide meaningful protections or act as some kind of deterrent to bad behavior. However, to date, private law likewise shows little evidence of protecting health app consumers from the types of harms resulting from information asymmetries. Traditional contract law approaches to ToS may further reinforce the information asymmetries between consumers and developers. As a result, information asymmetries persist under our current regulatory and legal regimes, preventing health app consumers from making choices in line with their preferences and best interests. Absent meaningful changes on these fronts, new approaches are needed that provide the missing information at the heart of the problem and use that information to influence downloading decisions.

III. INCENTIVIZING AND LEVERAGING VOLUNTARY DISCLOSURES

Part I detailed the information asymmetries that pervade the health app market. It then theorized how those information asymmetries result in market failures and prevent consumers from making decisions based on much more than guesswork and assumptions. In an ideal world, existing enforcement mechanisms would hold health app developers accountable for providing factually accurate information about the efficacy and accuracy of their products. As discussed in Part II, the FDA and the FTC (and even state agencies) likely could—and perhaps should—intervene in the health app market to help accomplish those ends. But the simple fact of the matter is that, for various reasons, they generally do not.[216] At the same time, reliance on private enforcement would likely only worsen existing problems with already impenetrable ToS and do nothing to help the vast majority of consumers. New solutions are necessary. This Part returns to the third and final example from the introduction—dermatology apps—to explore how creating a voluntary labeling regime[217] incorporated into the app store display

216. Nicolas P. Terry, *Appification, AI, and Healthcare's New Iron Triangle*, 20 J. HEALTH CARE L. & POL'Y 117, 171 (2018) (referring to it as a "long game of whack-a-mole").

217. Voluntary labeling is likely the most realistic, and potentially only legal, approach to such a label. Oren Bracha & Frank Pasquale, *Federal Search Commission – Access, Fairness, and Accountability in the Law of Search*, 93 CORNELL L. REV. 1149, 1151 (2008) ("[T]wo of these courts found that search results are opinions 'entitled to full constitutional protection' under the First Amendment.").

order can work with existing oversight mechanisms to correct market failures and support an overall trend toward better health app choices.[218]

A. How Voluntary Disclosures Work

Skin-focused apps have long been part of the health app market.[219] And with good reason—some researchers suggest that dermatological conditions are a particularly suitable focus for health apps, given their reliance on visualization for diagnosis and determining the severity of conditions.[220] This promise has translated into modest popularity. For example, skin cancer smartphone applications grew 544% between 2017 and 2020.[221] But though the market may be growing, it is not clear that skin-focused apps reliably work. While the science has improved over time, the jury is still out on their ability to accurately identify cancerous lesions, especially if the end-user is not white.[222] And beyond identifying cancer, these products also show mixed results for other types of dermatological concerns. For example, eczema management is a popular health app category. However, a systematic assessment of eczema self-management apps showed that 34% of the apps included in the sample provided false or misleading information, and only 15% provided correct information on pharmaceutical therapies supported by

218. While mandatory labeling is also a potential avenue, it comes with significant drawbacks and ongoing legal challenges. *Philip Morris USA Inc. and Sherman Group Holdings, LLC v. U.S. Food and Drug Administration et al. (2020)*, PUB. HEALTH L. CTR. (Aug. 4, 2020), https://www.publichealthlawcenter.org/litigation-tracker/philip-morris-usa-inc-and-sherman-group-holdings-llc-v-us-food-and-drug. "The graphic warning rule's effective date has already been postponed by the court in the parallel *R.J. Reynolds v. FDA*. Further briefing in this case has been suspended while the parallel litigation proceeds." *Id.*; *see also* Nathan Cortez, *Do Graphic Tobacco Warnings Violate the First Amendment?*, 64 HASTINGS L.J. 1467, 1470 (2013). Further, it may be subject to First Amendment challenges. Zauderer v. Off. of Disciplinary Couns. of Supreme Ct. of Ohio, 471 U.S. 626, 651 (1985). For additional discussion on the history and further consideration of the distinction between commercial and noncommercial speech for FDA-regulated entities, see Nathan Cortez, *Can Speech by FDA-Regulated Firms Ever Be Noncommercial?*, 37 AM. J. L. & MED. 388 (2021).

219. Interestingly, skin-focused health apps were the first health app category against which the FTC brought a case targeting health app claims in 2011. Press Release, Fed. Trade Comm'n, *"Acne Cure" Mobile App Marketers Will Drop Baseless Claims Under FTC Settlements* (Sept. 8, 2011), https://www.ftc.gov/news-events/news/press-releases/2011/09/acne-cure-mobile-app-marketers-will-drop-baseless-claims-under-ftc-settlements.

220. Galen et al., *supra* note 184; Aisha Masud et al., *Mobile Medical Apps for Patient Education: A Graded Review of Available Dermatology Apps*, 101 CUTIS 141, 141 (2018).

221. Ann M. John et al., *Mobile Applications in Skin Cancer Detection: A Descriptive Analysis*, 47 DERMATOLOGIC SURGERY 1285, 1285 (2021) (identifying 277 mobile applications related to skin cancer detection as of December 2020); *see also* Hania K. Flaten et al., *Growth of Mobile Applications in Dermatology – 2017 Update*, DERMATOLOGY ONLINE J., Feb. 2018, at 1, 1.

222. Manu Goyal et al., *Artificial Intelligence-Based Image Classification Methods for Diagnosis of Skin Cancer: Challenges and Opportunities*, COMPUTS. BIOLOGY & MED., Dec. 2020, at 1, 7 (explaining that AI algorithms used to identify skin cancer are less accurate on non-Caucasian people); *see also* Seung Seog Han et al., *Classification of the Clinical Images for Benign and Malignant Cutaneous Tumors Using a Deep Learning Algorithm*, 138 J. INVESTIGATIVE DERMATOLOGY 1529, 1532 (2018) (finding that skin cancer identification AI trained on images of Asian skin were less accurate than when used on Caucasian skin).

international guidelines.[223] Despite the inconsistent data about dermatology app quality, some remain optimistic that someday the diagnostic technology available in a smartphone app may be just as good—if not better—than an actual dermatologist.[224] As a result, experts have long eyed them as potentially beneficial tools for both consumers and health care providers.[225]

But skin conditions are more than an aesthetic nuisance; they can also be lethal. And even when they are not, they can dramatically affect a user's quality of life. As a result, selecting an effective dermatology app is critical. But recall that, as a consumer scrolls through search results in the app store, all apps look substantially the same: a small square tile with a logo, three images of the user interface, the rating, and an option to download or open.[226] After clicking through to see app details, they encounter more indistinguishable content. The Apple App Store has rows displaying variables of presumed importance to consumers. Below that, there is a section for "What's New," including recent app updates, previews of the user interface, the developer, ratings and reviews, and, below that, the privacy label.[227]

This privacy label includes three key domains: data used to track users, data linked to users, and data not linked to users.[228] It is presented in short, easy-to-read sentences and includes pictures to enhance user understanding. This display allows a user to click the "App Privacy" section of the app's description after selecting it in the App Store to learn more and appreciate that even apps that look alike can vary widely in what information they collect and what they do with it.[229] Using dermatology apps as an example, this Subpart introduces an easy-to-read evidence label akin to Apple's "privacy label," which app stores can incorporate into search algorithms that influence the order in which the app store presents health app search results to consumers.[230]

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223. *See* van Galen et al., *supra* note 184, at 444.

224. Lisa M. Abbott & Saxon D. Smith, *Smartphone Apps for Skin Cancer Diagnosis: Implications for Patients and Practitioners*, 59 AUSTRALASIAN J. DERMATOLOGY 168, 168 (2018).

225. Ann Chang Brewer et al., *Mobile Applications in Dermatology*, 149 JAMA DERMATOLOGY 1300, 1303 (2013).

226. Hsiao-Ying Huang & Masooda Bashir, *Users' Adoption of Mental Health Apps: Examining the Impact of Information Cues*, JMIR MHEALTH & UHEALTH, June 2017, at 1, 3 (discussing App Adoption Flow).

227. *See supra* Part I.A.2 (describing app store design and user interface).

228. *Privacy*, APPLE, https://www.apple.com/privacy/labels/ (last visited Feb. 5, 2022).

229. Brian X. Chen, *What We Learned from Apple's New Privacy Labels*, N.Y TIMES (Aug. 18, 2021), https://www.nytimes.com/2021/01/27/technology/personaltech/apple-privacy-labels.html.

230. Some have argued for voluntary or mandated labeling requirements for privacy terms. *See generally* J. Frazee et al., *mHealth and Unregulated Data: Is This Farewell to Patient Privacy?*, 13 IND. HEALTH L. REV. 384 (2016); Elizabeth A. Brown, *The Fitbit Fault Line: Two Proposals to Protect Health and Fitness Data at Work*, 16 YALE J. HEALTH POL'Y, L. & ETHICS 1, 40 (2016).

1. The Evidence Label

The first part of the proposed voluntary labeling regime is the evidence label to remedy existing information asymmetries. At a high level, the label would require that health app developers make explicit claims about the extent to which scientific evidence supports the product they offer and its obvious uses.[231] The developer would provide this information when listing an app for download in the app store, and the app store would display this information to consumers in easily accessible ways. This label would target health app developers that wish to categorize their product as "medical" or "health & wellness" in the app store.[232] Importantly, it would apply regardless of whether a health app is a regulated medical device, low-risk and subject to enforcement discretion, or not a device at all.

A promising template for an evidence label is Apple's privacy label, which appears to be a successful way to facilitate consumer knowledge about relevant information.[233] Apple's privacy label provides a template for how and where developers can display information about health app safety, efficacy, predictive ability, and the underlying evidence. This information can then help users assess whether and how an app works for their desired purpose. For health apps, it would explain how it calculates whatever health-related predictions it generates. For apps that have undergone more rigorous evaluation, this could also include links to scientific studies, providing users—or, more likely, health care providers and researchers—with the chance to click and review published articles related to the app or other indicators regarding compliance with quality frameworks.[234]

Much like the privacy label, the proposed evidence label would be mandatory insofar as Apple requires software developers to provide the information before the app is made available in the App Store. Though Apple[235] requires the label, developers self-report all information included in the label. The ability of health app developers to self-report information into

231. The FTC has considered similar labeling requirements in the past to address privacy terms, but the proposal did not advance beyond planning. Brown, *supra* note 230, at 40. While outside the scope of this Article, the proposed app store ordering solution could be expanded to incorporate privacy label information.

232. These category examples come from Apple's App Store. The Google Play Store would apply it to its own categorization regime.

233. Sarah Lagan et al., *Assessing Mental Health Apps Marketplaces with Objective Metrics from 29,190 Data Points from 278 Apps*, 144 ACTA PSYCHIATRICA SCANDINAVICA 201, 208 (2021); Transparency is a critical tool in addressing the potential harms of consumer technology. Rebecca Kelly Slaughter et al., *Algorithms and Economic Justice: A Taxonomy of Harms and a Path Forward for the Federal Trade Commission*, 23 YALE J.L. & TECH. (SPECIAL PUBL'N) 1, 48–49 (2021).

234. Larsen et al., *supra* note 181.

235. Apple was the first to introduce a privacy label. Google will roll out a similar feature, which is expected to debut in 2022. Sarah Perez, *Following Apple's Launch of Privacy Labels, Google to Add a 'Safety' Section in Google Play*, TECHCRUNCH (May 6, 2021, 1:58 PM), https://techcrunch.com/2021/05/06/following-apples-launch-of-privacy-labels-google-to-add-a-safety-section-in-google-play/.

an evidence label is important. A key feature of any workable solution is preserving the ability of companies to update their products, given the dynamic nature of the health app market. This proposed solution is consistent with the concern that developers continue to be able to make necessary changes.[236]

Similar to Apple's privacy label—which includes data used to track consumers, data linked to consumers, and data not linked to consumers—evidence labels should include at least three categories of information.[237] In simplest terms, an evidence label should tell a consumer what a health app does, how it does it, and point to the scientific evidence supporting those functionalities. Like the privacy label, this information would be available at the point of download and not in the app itself.

First, the evidence label should state what the app does. Here, the developer would provide a brief, plain-language explanation of the app's functionalities. For example, a consumer with eczema will encounter a variety of apps when searching in an app store for "eczema."[238] However, the functionalities of those apps may vary.[239] Some may be intended for taking photos, tracking progression, or otherwise documenting skin lesion changes. Others may be reference apps, providing information about available treatments. Others still may be dietary trackers, allowing users to look for patterns between foods consumed and skin flare-ups. Some may provide a combination of functionalities. However, health app users should be able to identify an app's functionalities without downloading it and using it first. So, if a patient merely wants an app suitable for tracking allergens, the app should describe this functionality in a way that allows users to identify an app that meets their specific needs.

Second, the evidence label should describe how the health app comes by its predictions or from what source it bases its information. What this entails will vary depending on the health app's functionalities. As described above, this might include photo documentation, digital reference tools, and trackers, among others. So, if a dermatology app is primarily a reference resource for eczema treatments, it would indicate where it sources the reference information and as of what date it remains current. Or, if the app can scan skin lesions, it should indicate what aspects of the image it considers in generating predictions (e.g., measurements or uniformity of color). More

236. *But see* Lagan et al., *supra* note 233.

237. Empirical research should illuminate final recommendations for information to include in an evidence label and optimal manner of presentation.

238. Galen, *supra* note 184.

239. *Id.*

complex apps that utilize machine learning or artificial intelligence could likewise indicate that capability in this section of an evidence label.[240]

Finally, the evidence label should include information about any competent and reliable scientific evidence that substantiates an app's health-related claims.[241] The FTC has defined "competent and reliable scientific evidence" to mean evidence "consist[ing] of human clinical testing . . . that is sufficient in quality and quantity, based on standards generally accepted by experts in the relevant field, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true."[242] The FTC also requires that such testing shall be both "randomized, double-blind, and adequately controlled" as well as "conducted by researchers qualified by training and experience to conduct such testing."[243] This section of an evidence label should reflect this high standard when such studies are available—which will likely be rare.[244] So, for example, if a randomized clinical trial demonstrates that a mole scanning app competently detects skin cancer, the developer could note that information, including citations, in this section. Other studies that fail to clear the FTC's high bar are still relevant to consumers, and this section of the evidence label can accommodate other types of evidence. And while the specific scholarly papers referenced in this section of an evidence label may be too complex for the average consumer or even hidden behind paywalls, including this information can nevertheless help app stores catalog higher-quality products and clinicians research and recommend better health apps to their patients.

To be clear, this proposed solution does not require that all apps undertake rigorous clinical trials. It recognizes that no such research will exist for most health apps, nor will studies be appropriate or even feasible.[245] For example, an eczema app that functions as a reference resource will likely have no associated research studies demonstrating its efficacy. That is not fatal to its success in the health app market. Where no such research exists, app developers can indicate that in the relevant section of the evidence label or

240. In-depth discussion of the unique challenges associated with labeling artificial intelligence and machine learning products in a health context are beyond the scope of this Article. For more information, see W. Nicholson Price II, *Regulating Black-Box Medicine*, 116 MICH. L. REV. 421 (2017).

241. Recall that the FTC prohibits defendant companies from making health claims unless supported by scientific evidence. *See supra* notes 129–131.

242. FTC v. Lasarow, No. 15-cv-1614 (N.D. Ill. 2015) (considering an app that claimed to detect melanoma, risk of melanoma, and evaluation of moles).

243. In the Matter of Carrot Neurotech. Inc., No. C-4567, 2016 WL 807980, at *35 (F.T.C. Feb. 22, 2016) (involving an app that claimed to improve a user's vision or reverse, delay, or correct aging eye or presbyopia).

244. Even if rare, such studies are increasingly likely to become available. Goldberg et al., *supra* note 4 ("As interest and uptake of mobile phone-based intervention and mobile mental health interventions generally has increased, so has research on their efficacy. From fewer than five studies per year in 2011 to now hundreds per year–there exist thousands of research studies on mobile health interventions.").

245. Aguilar, *supra* note 1 ("[E]ven scientists and companies committed to rigorous evaluation are still sorting out what a good trial of an app looks like.").

check a box for "not applicable" or "no evidence." Similar, competing apps will all be on level playing fields, as these types of limitations will uniformly apply. Scientific evidence, while informative, is not a requirement to list an app for download in the app store. However, the absence of scientific evidence may be relevant to a prospective consumer for certain types of health app functionalities. While it will not impact a consumer's choice when seeking a digital eczema resource, it may be a key determining factor for a consumer wanting to scan a skin lesion.

Finally, it is worth acknowledging that a voluntary evidence label does not prevent an app from misrepresenting data. Nor does it prevent an app from outright lying. Indeed, a major criticism of Apple's privacy labels is that much of the included information is false because the information is voluntary and self-entered.[246] This is a potential scenario for evidence labels as well, as health apps have previously misrepresented scientific literature for their own gain. For example, *AcneApp* and *Acne Pwner* once claimed to be able to treat acne and used advertisements that claimed, for example, that *Acne Pwner* could "Kill ACNE with this simple, yet powerful tool!"[247] Similarly, *AcneApp* marketing claimed, "This app was developed by a dermatologist. A study published by the *British Journal of Dermatology* showed blue and red light treatments eliminated p-acne bacteria (a major cause of acne) and reduces skin blemishes by 76%."[248] However, the apps misrepresented the Journal's findings in an attempt to mislead consumers and trick them into purchasing an ineffective app.

Notwithstanding the risk that other health apps might similarly misrepresent available scientific evidence or overstate technological capabilities to boost downloads, a voluntary label still provides a valuable function—even, and perhaps especially, if the information entered is a lie. Importantly, an evidence label forces health app developers to make a statement about their products. And, like *AcneApp* and *Acne Pwner*, these statements may then draw the attention of existing regulatory agencies like the FTC.[249] To borrow an analogy from Ryan Calo, "[a] traffic light camera does not prevent individuals from running the light. It just makes it harder to run the light without getting a ticket."[250] Like a traffic light, a required evidence label creates a mechanism for those responsible for enforcement to take note and, when necessary, act.

246. Geoffrey A. Fowler, *I Checked Apple's New Privacy 'Nutrition Labels.' Many Were False.*, WASH. POST (Jan. 29, 2021, 7:00 AM), https://www.washingtonpost.com/technology/2021/01/29/apple-privacy-nutrition-label/.

247. Press Release, *supra* note 219.

248. *Id.*

249. *Id.*

250. Ryan Calo, *Code, Nudge, or Notice?*, 99 IOWA L. REV. 773, 779 (2014).

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One way to address an information asymmetry is to provide the missing information. Evidence labels can achieve that. But, as numerous studies have demonstrated, more information is not always better. To be effective, consumers must be able to receive, comprehend, and act on the information that a disclosure conveys.[251] Too much information can overwhelm consumers and make them even less likely to read the information presented.[252] Consequently, simply providing additional health app information via an evidence label is, on its own, not sufficient to address the problem of health app information asymmetries and flawed decision-making. A comprehensive solution requires an additional step.

2. App Store Order

Remedying information asymmetries through labels alone is not always possible, especially when it is hard to communicate the relevant information to the public.[253] Current app store user interfaces offer little to help consumers choose between available apps based on effectiveness or accuracy.[254] In short, other than paid advertisements, it is not clear what factors app stores consider when deciding to present a health app high on the list in a prominent location or hundreds of scrolls and pages of search results away. To fully realize the power of evidence labels, the entities responsible for the point of download must incorporate the evidence label into features that help users make the best decisions, recognizing the very human tendency to ignore the fine print and rely instead on cognitive biases.

In simplest terms, smartphone app stores should show consumers the best apps first. Under the proposed solution, app stores would present health apps with the most robust self-reported evidence base before those with less or no information about their safety and efficacy. App store algorithms are complex and can incorporate information about the user's downloading habits or the downloading habits of other users who search similar terms, among other data points. App stores should modify this algorithm to prioritize evidence-based apps, displaying those with stronger evidence higher in the search order. So, for example, a skin-scanning app backed by clinical trials that evaluates moles should appear before an equivalent-looking app with no

251. Howard Latin, *"Good" Warnings, Bad Products, and Cognitive Limitations*, 41 UCLA L. REV. 1193, 1195 (1994).

252. Ben-Shahar & Schneider, *supra* note 191, at 687.

253. Leland, *supra* note 76, at 1341 n.15 ("For example, a drug which has complicated side effects might better be banned than offered for sale carrying a technical warning label, if consumers cannot properly assess the warning.").

254. *See supra* Part I.A.

similar evidence base. Or a digital medical reference app, for which no clinical trials are available, should list the app with the most current data before other potentially out-of-date apps. App stores can automate this process. It does not require a living person at Apple or Google to evaluate or verify research or developer inputs, which would create additional legal and logistical hurdles—simply that the interface in which a developer enters this data be designed with this ultimate purpose in mind.

Incorporating labels into search results is critical to avoid common and justifiable criticisms of labeling as a standalone approach. Scholars have made several credible arguments against mandated disclosures, including that the underlying premise of mandated disclosures—that more information is better—is divorced from reality.[255] Of particular concern is that mandated disclosures fail to convey information, their presentation is lacking, and they do not improve the disclosee's decisions.[256] Some scholars have observed these problems and many other well-documented challenges and concluded that mandatory disclosures are failures. This conclusion, however, may be premature.

When considering the sheer amount of information the average consumer encounters while engaging with digital contracts, it is easy to agree with arguments against adding even more for consumers to read and process via an evidence label. Unquestionably, the app store is already full of copious but dubiously relevant information. There are pictures and numbers and stars. There is already a privacy label. Walls of text fill ToS and privacy policies, and most people are more than happy to check "I Accept" without ever seeing any of these things.[257] However, just because evidence labels add to the ever-growing list of information that consumers are expected to sift through[258] does not make disclosures bad in general, nor does it establish that evidence labels, in particular, pose unique problems. Even those who are understandably critical of *more words* and *more stuff* admit that labeling can be more effective if policymakers deliberately pair disclosures with efforts to influence consumer behavior and modify their expectations about the benefits of becoming informed.[259] Incorporating an evidence label system into how the app store presents search results to users is responsive to this need because search order can influence consumer behavior and increase awareness of the varying quality of similar-looking products in the health app market.[260]

255. *See generally* Ben-Shahar & Schneider, *supra* note 191, at 679.

256. *Id.*

257. Whether other ubiquitous disclosures of questionable utility that distract from more salient information should remain in ToS and privacy policies is a question outside the scope of this Article.

258. *See* Ben-Shahar & Schneider, supra note 191, at 686–90 (describing the "quantity problem").

259. Bakos et al., *supra* note 196, at 169.

260. *See infra* Part III.B.2 (discussing nudges).

As a result, evidence labels and improved app store search results can help create more informed consumers. However, markets do not need all consumers to have perfect information to function well. Some have theorized that to be competitive, sellers would need to vie for the business of the most well-informed consumers.[261] This theory postulates that the "informed minority"—a small group of dedicated consumers that actually do their research and read the fine print—can compensate for an uninformed majority by putting in the effort to learn about competing products.[262] That informed minority then selects the best product, influencing what others purchase and, ultimately, forcing the market to trend toward better or, at least, more popular products.

However, there is reason to believe the informed minority hypothesis does not hold in digital environments replete with standard-form contracts (like ToS) because, realistically, not even a minority of consumers will consult these documents.[263] Even if they do, those terms are generally industry-standard and non-negotiable.[264] For this reason, evidence labels that influence the order in which app stores present search results to consumers may offer the greatest opportunity to influence consumer choice and market trends regardless of whether an informed minority is ever possible for consumer technologies at all.

This solution, however, is incomplete. It does not address the remaining problem of notifying users who have already downloaded an app. Interacting with a label, be it an existing privacy label or the proposed evidence label, happens when a user searches for an app to download in the app store, which is a one-time activity for most users. But there are hundreds of thousands of health apps available,[265] experiencing millions of downloads each quarter.[266] For users who have already downloaded a health app, developers should generate an email and in-app notification[267] to alert existing users of the creation of the label and its contents. It should also notify a user how the health app they have chosen to download would compare to other similar apps by referencing the order in which it would appear in search results.[268] Of

261. Yonathan A. Arbel & Roy Shapira, *Consumer Activism: From the Informed Minority to the Crusading Minority*, 69 DEPAUL L. REV. 233, 234 (2020).

262. *Id.* at 240.

263. *See* Bakos et al., *supra* note 48, at 1–2.

264. KIM, *supra* note 202, at 65.

265. Georgiou, *supra* note 23.

266. Ceci, *supra* note 24 ("During . . . the first quarter of 2020, health and fitness apps were downloaded 593 million times. It is projected that by the end of the second quarter of 2020, health and fitness apps will have generated 656 million downloads. In the same quarter of the previous year, health and fitness apps were only downloaded 446 million times.").

267. Empirical research shows that notifications are promising mechanisms for changing app choice and download behavior in a privacy context. *See generally* Denise de Ridder et al., *Nudgeability: Mapping Conditions of Susceptibility to Nudge Influence*, 17 PERSPS. ON PSYCH. SCI. 346, 354 (2021).

268. *See infra* Part III.A.2.

course, it may be too naïve or ambitious to assume that a health app developer would ever alert a consumer that different, better products might be available. So, at a minimum, app stores should notify consumers of the new feature upon installing the update, prompting users to independently assess how their already-downloaded health apps compare to other available products. But in some ways, whether notifications reach people will eventually become irrelevant. The health app market is growing at such a rate that legacy users will eventually switch health apps as older, unprofitable products fall away.

Finally, this approach need not stand alone as an intervention. For example, an evidence label could be paired with mandatory evaluation—by an agency, a technology company, or some other third-party consumer protection group—at predetermined intervals, producing incentives to generate new data about the existing product.[269] This evaluation could specifically include reviewing the information provided in the evidence label, prompting developers to keep the information up to date. However, periodic evaluation might merely incentivize short-term players to enter the market, profit off user data while providing an ineffective app, and vanish before any review is required. Given the current ease of entering and exiting the market for apps, such a problem is entirely foreseeable. Notwithstanding this possibility, a voluntary evidence label and modified search-order system could also make such behavior more difficult and less profitable. And solutions need not be perfect to be worthwhile.

B. Why Voluntary Disclosures Work

Left unaddressed, health app information asymmetries have real-world implications. First, it may result in markets in which bad products predominate and create economic disincentives for developers of higher-quality products, ultimately stifling innovation. Second, consumers suffer the consequences by being forced to pick a health app in an environment where making a good choice is hard, and the odds of a bad choice are high. More complicated still, the problem here is not just one of a singular bad health app, but how an individual may interpret an app's capabilities in the broader context of the market for similar products with varying levels of oversight, approval, and evidence bases—nuanced problems that existing enforcement mechanisms are unlikely to remedy, even if scaled up.

But, the proposed evidence label and search result system are feasible and beneficial. It balances the advancement of a promising and still rapidly evolving industry with the light-touch regulation required for it to thrive. This

269. Nathan Cortez, *Digital Health and Regulatory Experimentation at the FDA*, 21 YALE J.L. & TECH. (SPECIAL ISSUE) 4, 21 (2019).

Subpart explores why it works by evaluating how this approach can help correct market failures and nudge stakeholders to better health app choices.

1. Correcting Market Failures

The market for health apps includes products of varying and inconsistent quality. The developers of high-quality health apps backed by the best available evidence compete with developers of visually similar but ineffective products that are faster and cheaper to bring to market. At present, quality is difficult to determine, making it hard for consumers to distinguish good products from bad and for developers to recoup the cost of those investments. Evidence labels help provide a form of quality assurance.

According to some interpretations of traditional economic theory, there is no justification for regulating quality.[270] Critics have panned it as "misguided economic paternalism"[271] or merely a "means—tacitly controlled by industry or professional representatives—to capture monopoly profits."[272] However, while it might be reasonable to suggest that limited (or no) changes in regulation or intervention make more sense in a nascent market, it is harder to imagine that any preferred economic solution permits thousands of poor-quality, ineffective, or dangerous apps to proliferate unchecked indefinitely. There are already hundreds of thousands of available health apps on the market. It is difficult to articulate a compelling argument for why the principles of capitalism demand that the market for health apps continues to grow as it has for over a decade with no added benefit—and potential harm—to developers or consumers. While efficiency may support an unregulated market, it is not always the only—or even the most important—consideration.

An alternate view of the underlying justification for changes in the health app market is the belief that we should correct information asymmetries between consumers and producers as a means of quality assurance.[273] Economic theory also demonstrates that minimal quality standards can be advantageous.[274] This is true for all kinds of markets. Even assuming perfect competition, markets can benefit if the quality of a product is important

270. Leland, *supra* note 76, at 1329.

271. Some scholars have argued that paternalism is indeed a valid justification for regulation in this space. *See* Duranske, *supra* note 91, at 22–23; Kapczynski, *supra* note 87, at 2358.

272. Leland, *supra* note 76, at 1329.

273. Ariel Katz has described this for pharmaceuticals and the FDA. *See generally* Katz, supra note 87. In Katz's view, regulation and other interventions are a benefit rather than a burden because they create a mechanism for quality assurance. Evidence labels perform a similar quality assurance function. *Id.*

274. Leland, *supra* note 76, at 1336 (noting that minimal quality standards are advantageous, particularly in markets that satisfy four conditions: (1) they are sensitive to quality variations; (2) they have a low elasticity of demand; (3) there is a low marginal cost of providing quality; (4) and there is a low value placed on low-quality service).

enough to consumers relative to the cost of implementing those standards.[275] Voluntary labeling provides low-cost and minimally burdensome quality assurances, and the potential benefit can sometimes be the difference between life and death. But it is especially important for markets, like the one for health apps, where the conditions of perfect competition cannot be assumed.

As a general matter, implementing quality standards can have one of two possible effects. What happens depends primarily on who finds it easier to enter a market based on the requirements imposed. In general, developers with the highest opportunity costs will be eliminated from the market.[276] When the opportunity costs of entering decrease as the quality of the product goes up, the market improves.[277] When the opportunity costs of entering decrease as the quality of the product goes down, the market gets worse. But the motivation to improve will also shrink as a market grows large and average improvements approach zero.[278] In these cases, anyone undertaking quality improvements will experience no benefit, sellers will find that the optimal level of such quality improvement investments is zero, and the overall quality of the products offered will stagnate or diminish.[279]

The latter scenario, in which quality stays the same or worsens, is one we want to avoid. Voluntary evidence labels incorporated into app store display orders is a possible solution that helps avoid such an outcome. For example, entering supporting evidence into an evidence label will be easier for a health app developer that has thoughtfully designed a health app based on the best available science or has conducted clinical trials. The evidence is easily available because the developer used the study or possibly even conducted it. For a bad-faith developer with a low-quality product, fabricating that evidence will be more difficult. It will also be riskier, as it may draw the attention of regulatory agencies like the FTC as it polices health app misrepresentations. In other words, the opportunity cost will be highest for the lowest-quality health apps, meaning fewer will enter the market.

With evidence labels as a form of quality assurance coupled with the proposed changes in search result display order, the conditions now motivate a race to the top for the remaining smaller market of higher-quality health app developers. Producing an effective product with a robust evidence base

275. *Id.* at 1336–37.

276. *Id.* at 1340. This also happens in the app market. Rebecca Janßen et al., *GDPR and the Lost Generation of Innovative Apps* 2 (Nat'l Bureau of Econ. Rsch. Working Paper No. 30028, 2022) ("We have [found that] . . . GDPR precipitated the exit of over a third of available apps; and following its enactment, the rate of new entry fell by 47.2 percent, in effect creating a lost generation of apps."). While many economists have argued that these data support the proposition that regulation stifles good innovation, others also argue—and I agree—that the apps unable to enter the market are more likely ones primarily designed to exploit user data, not those representing beneficial improvements in products.

277. Leland, *supra* note 76, at 1340.

278. *Id.*

279. *Id.*

ultimately results in a more impressive evidence label and, in turn, the opportunity to appear higher in more users' search results. As a result, the proposed requirement creates an economic incentive for app developers to innovate, as those that appear higher in an app store search are more likely to benefit from a higher volume of downloads.

But these market-level justifications are only compelling if commercial app stores and health app developers are willing to adopt a voluntary evidence label approach in the first place. Though the technology industry loathes regulation, a voluntary evidence label is likely an appealing option. In addition to the economic rationale for quality assurance, several other practical reasons support this underlying assumption.

App stores benefit from the proposed solution. Both Apple and Google, proprietors of the largest smartphone app stores, offer their own consumer health products. As a result, they have a financial interest in ensuring that their products are not crowded out of the health app marketplace by lower-quality apps that diminish the value of their investment. They are also high-resource app developers with high-quality products, and the ability to promote those products above others using otherwise neutral metrics is legally and financially advantageous.[280] Additionally, from the perspective of the technology industry, voluntary steps are preferable to mandated government proposals. Finally, it is consistent with other voluntary actions, as an evidence label would not be the first time app stores have intervened to ensure that the products they offer do not harm their users.[281] In light of recent scrutiny into Big Tech's behaviors, the ability to demonstrate a commitment to public health and safety is also simply good public relations. As a result, it is reasonable to believe that the two largest app stores on the market would likely be amenable to a voluntary evidence label and updated app store algorithm.

Developers of good and bad products alike would likewise welcome this approach because warnings place the ultimate responsibility for preventing harm on the product's users and not the developer.[282] Labeling performs a similar function.[283] For example, consider an evidence label indicating that a health app provides a digital reference guide of treatment modalities using a medical reference text published on a specific date. If a consumer wants to

280. For example, neutral ranking mechanisms can help avoid potential liability for proposed legislative attempts to rein in health misinformation. David McCabe, *Lawmakers Target Big Tech 'Amplification.' What Does That Mean?*, N.Y. TIMES (Dec. 1, 2021), https://www.nytimes.com/2021/12/01/technology/big-tech-amplification.html.

281. Bennett Cyphers, *App Stores Have Kicked Out Some Location Data Brokers. Good, Now Kick Them All Out.*, ELEC. FRONTIER FOUND. (Mar. 10, 2021), https://www.eff.org/deeplinks/2021/03/apple-and-google-kicked-two-location-data-brokers-out-their-app-stores-good-now.

282. Latin, *supra* note 251, at 1194.

283. This consumer-focused responsibility is appropriate in the circumstances like those with so-called low-risk health apps, where health harm is secondary or indirect.

use this app, they are on notice of its acceptable uses, source of information, and limitations. This, in turn, alleviates some of the legal risks of private enforcement.[284]

2. Nudging Stakeholders

The current state of the health app market makes identifying high-quality apps difficult for anyone. The conditions are so bad they have caught the attention of scientists who study health apps. As a result, researchers have documented a need for "(1) public-facing efforts to facilitate informed decision-making around app choices for patient[s], clinicians, and policy makers and (2) wider efforts to map the space and understand the quality, content, and gaps in apps publicly offered today."[285] The proposed solution accomplishes these goals by helping address these two important considerations through the potential power of nudges.

First, an evidence label incorporated in the app store ordering helps consumers and other stakeholders make and recommend better, more informed choices. Recall that all people use heuristics to make decisions. For example, a consumer may be more likely to pick an option presented first than one existing somewhere in the middle. Sometimes those heuristics result in quick, good choices. Sometimes, however, they result in suboptimal decision-making. However, though heuristics and cognitive biases contribute to the unique health risks of health apps, they can also inform how app stores can leverage evidence labels to help address the problem. A powerful tool to counteract the very human tendency to avoid reading the fine print and reach for the easiest, prettiest, or cheapest option is to nudge. This is especially true for consumers who do not strongly prefer a specific choice, either due to doubt or ambivalence.[286] By utilizing the concept of nudges to inform algorithms[287] that make better decisions easier, app stores can help consumers and health care providers pick and recommend more effective health apps.

Under the current app store approach, the example in which a consumer searches for an app and picks the first one[288] may result in that consumer selecting an ineffective or even potentially harmful app. But this scenario has a different outcome under an evidence-informed labeling and ordering scheme. Instead, a user skimming her smartphone app store for a health app searches using keywords for a general health-promoting function (e.g., "skin check" or "acne"). Under the proposed solution, apps with robust evidence bases would

284. *See supra* Part II.B.

285. Lagan et al., *supra* note 233, at 202.

286. de Ridder et al., *supra* note 267, at 354.

287. Sunstein, *supra* note 94, at 1177 ("Algorithms do not use mental short-cuts; they rely on statistical predictors, which means that they can counteract or even eliminate cognitive biases.").

288. Loewenstein & Prelec, supra note 100.

appear earlier in the search results while apps with limited or no information would still be available but require additional scrolls to view. In this way, app stores can use facilitator nudges[289] to encourage users to download better apps by presenting them with evidence-based or evidence-informed apps at the top of their search results and presenting apps with less or no self-reported evidence more scrolls away.

Nudging is important because it is a tool that still respects the fact that consumers want—and should be allowed to access—different things.[290] By analogy, some people may prefer traditional medical care, and others may consciously choose to pursue complementary and alternative interventions. To the greatest extent feasible, and within the bounds of safety and reasonability, the market should accommodate this heterogeneity. Creating nudges through ordering apps in the app store preserves user preferences. Here, some consumers may want a specific health app regardless of how or whether it does what the consumer thinks it does. This proposed solution leaves room in the market for these preferences, so long as they are informed. This is consistent with approaches to potentially dangerous products across other industries.[291]

It also helps key stakeholders like clinicians and professional organizations make better recommendations. In addition to the possibility of nudging consumers, the proposed regime can nudge doctors as well. For these groups, the added detail of the evidence label that prompts developers to disclose information about published studies that may seem unnecessary for average consumers takes on additional importance. For more sophisticated groups such as these, access to scholarly literature about efficacy can help these groups make informed recommendations and eventually even incorporate health apps into clinical practice.[292] It also helps efforts to catalog health apps.[293] The evidence label shifts the evidentiary burden to the developer and away from those attempting to systematically evaluate industry-leading apps for consumers. When done honestly, this can help avoid high-profile misclassifications of apps, as even government-supported efforts to create public lists of high-quality apps have failed in the past.[294]

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289. Ana Caraban et al., *23 Ways to Nudge: A Review of Technology-Mediated Nudging in Human-Computer Interaction*, 2019 CHI CONF. ON HUM. FACTORS COMPUTING SYS., May 2019, at 1, 11.

290. *But see* Yeung, supra note 89, at 118–36.

291. Tort law has long permitted manufacturers to continue to make and market unsafe products so long as consumers are warned of the dangers. Latin, *supra* note 251, at 1195–96.

292. To help bridge the gap between the quality of apps, the American Psychiatric Association (APA) provides guidance on how to assess and evaluate apps before recommending them to patients. *App Advisor*, AM. PSYCHIATRIC ASS'N, https://www.psychiatry.org/psychiatrists/practice/mental-health-apps (last visited May 8, 2021).

293. E.g., *About One Mind Psyberguide*, *supra* note 55.

294. Kit Huckvale et al., *Unaddressed Privacy Risks in Accredited Health and Wellness Apps: A Cross-Sectional Systematic Assessment*, BMC MED., Sept. 25, 2015, at 1, 10.

Second, incorporating evidence labels into displays and search result order helps map the quality of the space. As previously discussed, this is beneficial for consumers, providers, and professional organizations who can more readily ascertain the relative quality of the desired health app. But doing so also offers key benefits to the state and federal actors ultimately responsible for consumer protection by simplifying their role in investigations. Under this approach, health apps making claims about the safety and efficacy of their product have now identified themselves explicitly, nudging agencies toward an easily identifiable pool of products with which to target their enforcement efforts.

Finally, a key benefit of the proposed solution is its simplicity: it works within the framework of existing laws and regulations. The proposal does not require backtracking on the 21st Century Cures Act or giving the FDA any added responsibility regarding even apps over which it chooses to exercise enforcement discretion. It does not ask that the FTC's approaches to these apps fundamentally change either. This solution recognizes that requiring the FDA to consider the safety and efficacy of all health apps is wasteful of their limited time and resources and further burdens app developers based on the bad behavior of others. Likewise, it respects that requiring the FTC to consider every health app systematically is unrealistic given the state of the market, other agency priorities, and their own limited resources. However, voluntary evidence labels incorporated into app store search result order is helpful should the FDA, FTC, or state attorneys general ever develop a heightened interest in health apps capable of harming consumers. Should a regulatory agency later choose to look into specific apps, the proposed approach allows it to focus enforcement attention and resources on health apps making certain kinds of explicit evidence-based or efficacy-related claims.

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Labels are not a silver bullet,[295] but they are a good first step and they need not stand alone. And best of all, the proposed solution can happen now with no change in existing law or agency priorities, and it does not preclude further action in the health app space should future developments require it.[296] The simple fact is that health apps are already here and here to stay. But

295. For example, labels have done little to rein in the dietary-supplement market.

296. Scholars and industry experts have suggested several possibilities to remedy market failures in the digital space in both the safety and privacy contexts. These include, to name a few, legal liability for health care professionals, institutions, and app developers, a Consumer Subject Review Board, a paid option regime, and public and private precertification. *See generally* Terry & Wiley, *supra* note 61; Ryan Calo, *Consumer Subject Review Boards: A Thought Experiment*, 66 STAN. L. REV. ONLINE 97 (2013); Ryan Calo, *Digital Market Manipulation*, 82 GEO. WASH. L. REV. 995, 1047–48 (2014); Andrew Neiman, *A Policy of Trust: Software Developer Precertification As a Viable Solution To Protect Patients and Promote Innovation for 'mHealth'*

without new approaches, the health app market will continue to grow unchecked, information asymmetries will worsen, and promising innovation may simply be drowned out by cheap and ineffective products that harm consumers. But while this outcome is not inevitable, the time is now to reverse our course.

CONCLUSION

The popularity of health apps is undeniable. And with the right changes to alleviate information asymmetries, the future of these consumer health technologies is indeed bright. A man managing depression will find an app that allows him to engage in symptom management from the comfort of his home, helping stave off the darkness that previously consumed him. A woman interested in getting off her hormonal birth control but still not ready to start a family can find an app that accurately predicts her fertile window, allowing her to avoid conception (until she is ready). A person can discern between a cancerous skin lesion and eczema and, if the latter, even find tools that help them track allergens and recommend evidence-based, over-the-counter treatments that alleviate discomfort and make them feel more confident in their appearance. These categories of consumers are not just theoretical; they already exist. Unfortunately, the conditions that would facilitate informed choices about health apps best suited to their needs do not.

In the same news article highlighting the surprising ineffectiveness of mental health apps, experts also looked forward with cautious optimism. They speculated that within five years, trials would show convincing evidence for some of the more promising app interventions.[297] But even the best-designed study will mean little if it cannot be used to separate the best products from the worst and, more importantly, influence consumer behavior. Building the infrastructure necessary to leverage this research must start today. Short-term, voluntary actions can help ensure that the future course of the health app market is toward better products and healthier consumers. The result is fewer information asymmetries, helping correct the market failures that have led to a health app market for lemons.

Applications, 17 COLO. TECH. L.J. 213 (2018); Samuel J. Dayton, *Rethinking Health App Regulation: The Case for Centralized FDA Voluntary Certification of Unregulated Non-Device Mobile Health Apps*, 11 IND. HEALTH L. REV. 713 (2014); Sarah Jean Kilker, *Effectiveness of Federal Regulation of Mobile Medical Applications*, 93 WASH. U. L. REV. 1341 (2016). International approaches, such as those in Germany, may further incentivize health developers to innovate. Sara Gerke et al., *Germany's Digital Health Reforms in the COVID-19 Era: Lessons and Opportunities for Other Countries*, NPJ DIGIT. MED., July 10, 2020, at 1, 5.

297. Aguilar, *supra* note 1.