

# Skating the line between general wellness products and regulated devices: strategies and implications

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## ABSTRACT

Health technology is advancing at a rapid clip, with many of these technologies appearing on consumer products like smartphones and tablets. Federal regulators have responded to these changes with a flexible approach that allows firms to manufacture a ‘general wellness product’ (‘GWP’) without being subject to regulation typically applied to ‘devices’ that diagnose or treat a disease or condition. Using currently available medical products and devices from across a spectrum of diseases, we describe how firms can use this existing regulatory framework to develop innovative products by ‘skating the line’ between mostly unregulated GWPs and regulated devices. On the one hand, we find that skating the line offers a variety of benefits, including potential improvements to product development, innovation, and patient access to medical technologies. On the other hand, we show that this technique has potential costs to patient safety, competition, and data sharing. Skating the regulatory line between GWP and devices, in other words, offers important benefits but is not without risks. Any further regulatory action to address such risks should be careful to leave significant unregulated space for product development.

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Developing a new medical device and bringing it to market can be costly for devices that are new or present safety risks that require some review by the Food & Drug Administration ('FDA').<sup>1</sup> Compounding the problem, laboratory conditions may not be a sufficiently robust testing ground to obtain information needed to determine market share, assess product viability, or perfect product performance, particularly for technologies that utilize artificial intelligence or machine learning ('AI/ML'). To avoid these problems, a firm may take a different strategy: debut a low-risk general wellness product ('GWP'), which is not regulated by FDA, to generate sufficient market data to determine whether FDA review is a viable business option. Once a sufficient amount of information is collected and a viable business model is developed, manufacturers can then perform a regulatory switch, applying to FDA for clearance or approval to market their product as a device. At the same time, the firm can maintain a presence in the wellness market to capitalize on existing customer bases, consumer expectations, advertising, and brand goodwill—and continue to hone existing products and develop new ones.

Consider Happify Health ('Happify'), which markets its 'Happify Wellness app' as a platform 'with science-backed activities that build essential skills for life'.<sup>2</sup> Happify uses 'Kopa—[its] core, non-FDA cleared platform—to attract and retain people with specific medical conditions that are comorbid with mental health challenges, and educate them on their various therapeutic options'.<sup>3</sup> In particular, Kopa promises to connect patients to care, but also to other Happify services.

It is not hard to see the line Happify is skating. By offering its product in language of patient empowerment, Happify hopes to stay on the non-regulatory side of it. In April 2021, however, the FDA issued new guidance loosening restrictions on digital health devices that treated psychiatric disorders during the pandemic emergency ('COVID-19 Guidance').<sup>4</sup> Under the COVID-19 Guidance, some digital devices used to treat psychiatric disorders—such as a prescription-only 'computerized behavioral therapy device for psychiatric disorders'—would not be required to comply with certain normally applicable regulations, including regulatory clearance under the 510(k) pathway (Figure 1, Box 1).<sup>5</sup>

After FDA released its guidance, Happify leveraged its existing user base, data, and analytics to skate over the line into the device space, launching Ensemble, 'the first and only transdiagnostic prescription digital therapeutic for the treatment of patients who have major depressive disorder ('MDD'), or generalized anxiety disorder

1 *Medical Devices and the Public's Health: The FDA 510(k) Clearance Process at 35 Years*, INSTITUTE OF MEDICINE OF THE NATIONAL ACADEMIES (2011). Of all devices subject to FDA premarket review, 90 per cent pass through the 510(k) pathway—but only about one-third of all devices entering the market pass through the 510(k) pathway. *Id.* at 4, 170.

2 HAPPIFY HEALTH, <https://www.happifyhealth.com/wellness-app> (accessed May 6, 2022). Happify was not the only firm to make the switch—a variety of mental health apps did as well. Michael Mattioli, *Second Thoughts on FDA's Covid-Era Mental Health App Policy*, 21 HOUS. J. HEALTH L. & POL'CY 9 (2021).

3 HAPPIFY HEALTH, <https://www.happifyhealth.com/solutions> (accessed May 6, 2022).

4 U.S. FOOD & DRUG ADMINISTRATION, *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* [hereinafter *COVID-19 Guidance*] <https://www.fda.gov/media/136939/download> (accessed May 6, 2022).

5 *Id.*

(‘GAD’).<sup>6,7,8,9,10</sup> It then prepared an investigational device exemption (‘IDE’) submission to FDA for Kopa to treat MDD and GAD, which FDA granted; an early-stage trial is currently ongoing.<sup>11</sup> At the same time, it has continued to offer services that fall on the non-device side of the regulatory line.

Box 1.   Exempt and non-exempt software functions under the 21st Century Cures Act	
<p>The 21st Century Cures Act (the Act), Pub. L. No. 114-255, § 3037, 130 Stat. 1033 (2016), codified at 21 U.S.C. § 360j(o), exempted from the definition of device certain software functions and, in the process, defined what kinds of software functions counted as devices. These are summarized below, with the bolded text signifying the relevant statutory provision that covers “general wellness products,” which is located at 21 U.S.C. § 360j(o)(1)(B).</p>	
Exempt	Non-Exempt
<p>A software function</p> <ul style="list-style-type: none"> <li>• for “<b>maintaining or encouraging a healthy lifestyle and is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition</b>”;</li> <li>• for providing information related to diagnostic or screening tests/results that is not intended to interpret or analyze such tests/results to for the purposes of the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition;</li> <li>• for serving as an electronic health record provided such record is not analyzed and is stored under supervision of medical professionals; or</li> <li>• for transferring, storing, or converting formats or displaying device data or lab results by a health care professional.</li> </ul>	<p>A software function</p> <ul style="list-style-type: none"> <li>• for interpreting or analyzing clinical laboratory test or other device data, results, and findings even when the software function is also intended for transferring, storing, converting ats, or displaying clinical laboratory test or other device data and results, findings by a health care professional with respect to such data and results, general information about such findings, and general background information about such laboratory test or other device.</li> <li>• for the purposes of being used as clinical decision support software that a clinician cannot review and for which the clinician relies on exclusively; or</li> <li>• for the purpose of being used as clinical decision support software that a clinician <u>can</u> review and on which the clinician does <u>not</u> exclusively rely <u>if</u> the software function is intended to “acquire, process, or analyze a medical image or signal from an invitro diagnostic device or pattern or signal from a signal acquisition system.”</li> </ul>

6 Laura Lovett, *Happify Health Rolls Out First PDTx for Depression and Anxiety*, MOBIHEALTHNEWS, July 22, 2021. <https://www.mobihealthnews.com/news/happify-health-rolls-out-first-pdtx-depression-and-anxiety#:~:text=The%20product%20is%20able%20to,decision%20a%20few%20days%20ago> (accessed May 6, 2022). It is currently exploring a variety of the conditions it provides information to consumers about.

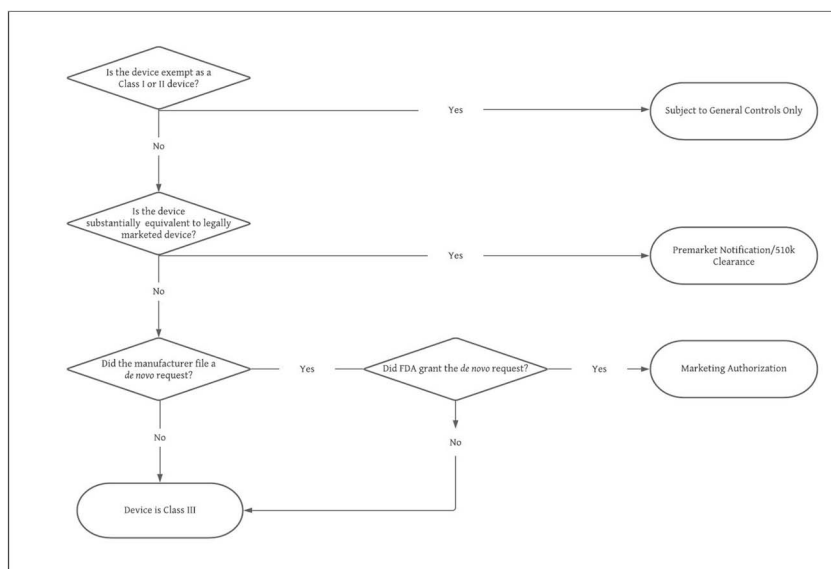
7 The firm plans to seek FDA clearance for its product. Videoconference communication with David A. Simon, Jan. 20, 2022.

8 ENSEMBLE, *Get Ensemble*, <https://getensemble.com/> (accessed May 6, 2022).

9 Happify publishes research based on real world implementation. E.g., Acacia C. Parks et al., *The Effects of a Digital Well-Being Intervention on Patients With Chronic Conditions: Observational Study*, 22 J. MED. INTERNET RESEARCH e1621 (2020).

10 Jordan Carpenter et al., *Seeing the “Big” Picture: Big Data Methods for Exploring Relationships Between Usage, Language, and Outcome in Internet Intervention Data*, 18 J. MED. INTERNET RESEARCH e241 (2016).

11 Digital Therapeutic for Major Depressive Disorder (MDD) and Generalized Anxiety Disorder (GAD), [ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/NCT05016050) Identifier: NCT05016050, Posted Aug. 23, 2021. <https://clinicaltrials.gov/ct2/show/NCT05016050> (accessed May 6, 2022).



**Figure 1.** Device classification and pathways to market.

We call this technique *skating the line* because firms launch products on the low-risk general wellness side of the regulatory line (which FDA does not have jurisdiction to regulate) but may eventually skate across that line and market them as devices (which FDA does have jurisdiction to regulate). A producer may use the wellness space as a testing ground or launchpad for an eventual regulated device, refining and testing the product to ‘maturity’. Even products that never mature into a device may nevertheless yield valuable commercial insights for the firm, all without the cost and inconvenience of FDA scrutiny.

Another motivation for skating the line may lie in the producer’s expectation that the product eventually will move through the regulatory process, but only after the firm or product is sold to another entity.<sup>12</sup> In such cases, the product may be marketed cheaply in the wellness space to allow founders and/or venture capital to establish proof of concept and develop a sufficient (potential) consumer base to make the producer an attractive acquisition target.<sup>13</sup> To be clear, the term ‘skating the line’ is meant to be purely descriptive; we do not intend it to mean something nefarious—in fact, we think that in some instances the phenomenon may be neutral or even beneficial for users and society.

12 Mark A. Lemley & Andrew McCreary A., *Exit Strategy*, 101 B.U. L. REV. 1 (2021).

13 It is also possible that third party firms develop software or applications that process data from GWP’s to provide diagnostic-like outputs. Andrew Y. Paek, Justin A. Brantley, Barbara J. Evans, Jose L. Contreras-Vidal, *Concerns in the Blurred Divisions Between Medical and Consumer Neurotechnology*, 15 IEEE Sys. J. 3069 (2021). In such cases, the original product developer may have no intention or plan to skate the line and would not be liable for harms caused by third party applications that the original developer played no part in making, marketing, selling, or distributing. Although this kind of ‘GWP creep’ and the issues it raises are interesting, our focus in this paper is on cases where the manufacturer or a partner or purchaser of the manufacturer skates the line.

Although firms have always used disclaimers and other language to skate close to the line, they have not, until recently, been able to leverage their ability to stake on one side it to gain momentum to cross over to the other.<sup>14</sup> After describing how this technique works and FDA's response to it, we argue that skating the line offers important benefits to innovation, businesses, and consumers—benefits that, as noted by critics in other contexts like mobile health generally, have sometimes been difficult to see.<sup>15</sup> Once we have made the case that skating the line is an important tool to drive innovation, we explain that it also raises several issues of concern policymakers should consider: consumer safety, regulatory uncertainty, competition, and data governance.

### I. THE WELLNESS-DEVICE LINE AND HOW TO SKATE IT

Bringing a new device to market can be complicated. FDA has authority to regulate 'devices': products '*intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man . . . or intended to affect the structure or any function of the body of man*'.<sup>16</sup> Determining the intended use of a product is therefore critical to determining whether federal laws and regulations apply to it. Devices intended for uses that pose a high risk must pass through more demanding regulatory pathways than those that pose a low risk (Figure 1).

If a product falls within the definition of device stated in the Food, Drug, and Cosmetic Act ('FDCA'), FDA classifies it into one of three categories depending on the risk of their intended use.<sup>17</sup> Classification often determines the relevant scope of regulatory compliance required by the manufacturer. Class I devices are low-risk, and most can be marketed without any review by FDA (exempt devices).<sup>18</sup> Class II devices are moderate risk, and most require a lesser review—Premarket Notification, also known as 510(k) clearance ('510(k)')—that is focused on equivalence, rather (or perhaps more) than safety.<sup>19</sup> The 510(k) pathway is the most common route to market for non-low-risk devices, which requires the manufacturer to submit information to the FDA demonstrating the device is 'substantially equivalent' to a legally

14 If a firm is using the platform to obtain information to sell to a third party, it may be considered part of a two-sided market. Mark Armstrong, *Competition in Two-Sided Markets*, 37 RAND J. ECON. 668 (2006).

15 Nathan Cortez, *The Mobile Health Revolution*, 47 U.C. DAVIS L. REV. 1173–1270 (2014) [hereinafter Cortez, *The Mobile Health Revolution*].

16 21 U.S.C. § 321(h)(1)(B).

17 21 U.S.C. § 360c. Classification is not simply about whether 'general controls'—statutory provisions governing the manufacturing and marketing of devices, 21 USC § 360c(h)(1)—can provide 'reasonable assurance of safety and effectiveness', but also what is known about the potential risks and benefits. Not much may be known about a new device, for example, but it will fall within Class I if it 'is not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health'. *Id.* at § 360(a)(1)(A)(ii)(I). General controls, however, are not sufficient to provide reasonable assurance of safety and effectiveness for Class II devices, and thus requires special controls, such as postmarket surveillance and FDA-promulgated regulations. *Id.* at § 360(a)(1)(B). For a device where insufficient information exists to develop special controls that would provide reasonable assurance of safety and effectiveness, the device is classified as Class III. *Id.* at § 360(a)(1)(C).

18 21 U.S.C. § 360(l) (exempt and exempt Class I devices). This exception 'does not apply to any class I device that is intended for a use which is of substantial importance in preventing impairment of human health, or to any class I device that presents a potential unreasonable risk of illness or injury'. 21 U.S.C. § 360(l)(1).

19 21 U.S.C. § 360(k); 21 U.S.C. § 360(m) (exempt Class II devices); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 471 (1996).

marketed device, a so-called ‘predicate device’.<sup>20</sup> A manufacturer can satisfy this standard by showing that its device is equivalent to (i) a device marketed prior to the effective date of the Medical Device Amendments of 1976<sup>21</sup> (‘MDA’) (a ‘pre-amendment device’), (ii) a device marketed after the MDA (a ‘post-amendment device’) that was equivalent to a pre-amendment device, or (iii) a post-amendment device that is equivalent to a post-amendment device that was equivalent to a pre-amendment device. Upon successful review, the FDA ‘clears’ these devices for their intended uses.

Class III devices are the highest risk, and usually require the most extensive review for safety and efficacy, known as Premarket Approval (‘PMA’). Any new device that lacks a predicate device is automatically shunted into Class III unless it is substantially equivalent to a new device that has been reclassified as Class I or II. (For purposes of the above diagram, the term ‘legally marketed devices’ is meant to include § 513(f) ‘new’ devices reclassified to Class I or II). To avoid this automatic assignment to Class III, a manufacturer of a new device that lacks a predicate device can request the FDA classify their device as Class I or II—this is the so-called ‘de novo’ pathway.

All of these pathways to market (Figure 1), as well as others,<sup>22</sup> are designed to impose safety and efficacy requirements commensurate with the risks posed by the device. And although there are limited data on the cost of device development, the information that does exist suggests that increasing regulatory requirements will, on average, increase development costs and time to market.<sup>23</sup> Higher development costs, particularly for novel technologies with no existing analogue (predicate device), may also increase barriers to market entry, reducing innovation.<sup>24</sup>

In 2016, Congress tried to provide more flexibility to developers of software intended ‘for maintaining or encouraging a healthy lifestyle’, and not intended to diagnose diseases or conditions, including, according to FDA’s interpretation, low-risk ‘GWPs’<sup>25</sup> (Box 1).

FDA’s guidance document explains that it will not treat as devices low-risk GWPs, which it defines as products that ‘(i) are intended for only general wellness use, as defined in this guidance, and (ii) present a low risk to the safety of

20 21 U.S.C. § 360c(i)(1)(A).

21 PUB. L. No. 94–295, Sec. 2, § 521, 90 STAT. 539, 574 (codified at 21 U.S.C. § 360 k (1988)).

22 E.g., 21 U.S.C. § 360bbb–3; 21 U.S.C. § 360j(h) (humanitarian device exemption pathway); 21 U.S.C. 360c(f)(2) (de novo pathway); 21 U.S.C. § 360e–3 (breakthrough device pathway).

23 Josh Makower et al., FDA IMPACT ON U.S. MEDICAL TECHNOLOGY INNOVATION (2010); Garber, Steven, Susan M. Gates, Emmett B. Keeler, Mary E. Vaiana, Andrew W. Mulcahy, Christopher Lau, and Arthur L. Kellermann, REDIRECTING INNOVATION IN U.S. HEALTH CARE: OPTIONS TO DECREASE SPENDING AND INCREASE VALUE (RAND Corporation, 2014, 33–34). [https://www.rand.org/pubs/research\\_reports/RR308.html](https://www.rand.org/pubs/research_reports/RR308.html) (accessed May 6, 2022); David A. Simon, *Off-Label Innovation*, 56 GEORGIA L. REV. \_\_\_ (forthcoming 2022).

24 W. Nicholson Price, *Regulating Black-Box Medicine*, 116 MICH. L. REV. 421–747 (2017); Rachel Sachs, *Innovation Law and Policy: Preserving the Future of Personalized Medicine*, 49 U.C. DAVIS L. REV. 1881–1940 (2016).

25 21 U.S.C. § 360j(0)(1)(B). Compare CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, U.S. FOOD AND DRUG ADMINISTRATION, Clinical Decision Support Software: Draft Guidance for Industry and Food and Drug Administration Staff (Sept. 27, 2019) with CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, U.S. FOOD AND DRUG ADMINISTRATION, Policy for Device Software Functions and Mobile Medical Applications—Guidance for Industry and Food and Drug Administration Staff, at \*45 (Sept. 27, 2019).

users and other persons'.<sup>26</sup> Notably, this policy applies only to 'low-risk' GWPs— invasive, implantable, or other non-low-risk devices are excluded. FDA explains that there are two types of GWPs, which it categorizes based on the claims the product makes: products that make general claims about health (eg 'enhance learning capacity', 'promote relaxation and manage stress') and products that make reference to diseases or conditions (eg 'may help reduce the risk of' or 'may help living well with'). The former claims are usually acceptable, and the latter are acceptable if they are 'well understood' and 'generally accepted'.<sup>27</sup> For example, software that tracks and helps an individual manage diet can advertise that it promotes a healthy weight, which, along with 'balanced diet may help living well with high blood pressure and type 2 diabetes'.<sup>28</sup> But products that make claims to diagnose or treat specific diseases or conditions—for example, the same software that claims to help 'prevent diabetes and high blood pressure'—are never included in the definition of GWP.<sup>29</sup> By exempting GWPs, Congress provided further room for low-risk consumer products that do not require FDA oversight while still constraining space for higher risk products that do.

But regulatory flexibility has also allowed producers to modify and improve upon a strategy they have perfected over many decades: offering device-like products as non-devices using a variety of tactics, including disclamatory language.<sup>30</sup> What is different this time around is that advances in digital technologies have changed what firms can do with the products once they are on the market. In the past, a product may have been able to avoid FDA scrutiny by disclaiming diagnostic functions, but the firm's involvement in the product usually ended with the sale to a consumer. Now, however, once a GWP is sold the product lifecycle is just beginning: the manufacturer uses the product itself to gather vast amounts of consumer information, which it can use at some later date, potentially to help shepard the product through regulatory review. And unlike many of their analog predecessors, new digital products are continually developed *after* they reach the consumer. This means the benefits of skating the line accrue to the manufacturer not just up to the point of sale but also after it.

Both Congress' and FDA's approach to GWP has enabled a large quantity of innovation to occur without strict controls. But where FDA is more concerned with the quality of innovation, such as in software that functions as a device, it has tried to implement a flexible approach that encourages companies to ensure their products also meet certain quality controls. FDA hoped that the Software Precertification ('Pre-Cert') pilot program for Software-as-a-Medical-Device ('SaMD'), for example, 'could replace the need for a premarket submission for certain products and allow for decreased submission content and/or faster review of the marketing submission for other products'.<sup>31</sup> The approach, at least in part, inverts the current FDA strategy of evaluating products and instead focuses on manufacturers. For its Pre-Cert pilot, FDA selected large and

26 CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, U.S. FOOD AND DRUG ADMINISTRATION, *General Wellness: Policy for Low Risk Devices* (2019), <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-wellness-policy-low-risk-devices> (accessed Apr. 23, 2021).

27 *Id.*

28 *Id.*

29 *Id.*

30 Cortez, *The Mobile Health Revolution*, *supra* note 15, at 1173, 1188, 1194; Sachs, *supra* note 24, at 1897.

31 U.S. FOOD & DRUG ADMINISTRATION, *Digital Health Innovation Action Plan*; 2018 <https://www.fda.gov/media/106331/download> (accessed May 6, 2022).

small manufacturers with certain characteristics, including ‘an existing track record in developing, testing, and maintaining software products demonstrating a culture of quality and organizational excellence measured and tracked by key performance indicators or other similar measures’.<sup>32</sup> Because the program is still new, no data exist on its performance.

Pre-Cert is, however, one regulatory experiment relevant to the skating the line problem—it attempts to balance the need for safe and effective devices against the often countervailing need to experiment with technologies early and often, uninhibited by the cost of regulatory compliance. Although Pre-Cert is not a direct response to the GWP problem, it may provide a useful framework—one that is flexible and attuned to problems inherent in software development—that FDA could carry forward to evaluate GWPs. Yet the full panoply of options available to address skating the line, and the reasons one might pursue them, become clear only after one has a more comprehensive view of the phenomenon and its potential impacts. Below we explain in more detail how firms can skate the line, as well as potential responses to the problems it raises, including those inherent in using FDA’s limited Pre-Cert pilot program to regulate GWPs.

## II. EXAMPLES OF SKATING THE LINE

In this Section, we describe examples of skating the line.<sup>33</sup> While the article began with the example of Happify, other firms are also well-positioned to skate the line, and examining these additional cases can give one a better sense of the phenomenon.<sup>34</sup> One firm following a similar path to Happify is BigHealth, which offers two ‘digital health therapeutic[s]’: a ‘revolutionary’ one for insomnia (Sleepio)<sup>35</sup> and ‘life-changing’ one for anxiety (Daylight)<sup>36</sup>—both of which it advertises as ‘safe and effective non-drug alternatives for mental health’, though it is quick to qualify that statement in a disclaimer.<sup>37</sup> BigHealth started, however, in 2012 with only Sleepio, which at the time was designed as a GWP (or at least as a non-device) to help users with insomnia and improve sleep habits.<sup>38</sup> It launched Daylight in 2019. After the FDA’s 2021 COVID-19 Guidance, BigHealth, like Happify, began promoting both the wellness and device-like qualities of its products.

Other firms have taken a slightly different road, choosing to skate the line only to cross it once a willing partner was found. Take, for example, Headspace, a meditation app that offers subscription-based meditation services. The app itself is not meant to diagnose or cure any disease. But the firm claims its product is ‘the most science-backed meditation app’ with ‘[p]ublished studies, external scientists, prestigious research orga-

32 82 FED. REG. 35216, 35216–35218, July 28, 2017.

33 To be clear, we are not making any claims about the nature or existence of the motives or decisions of any of the firms mentioned in this article. We are just reporting steps they took that might be thought of as indicative of this phenomenon.

34 To be clear, we have no insider knowledge of what any of the firms discussed in this section intends and instead merely describe what we are seeing in the market.

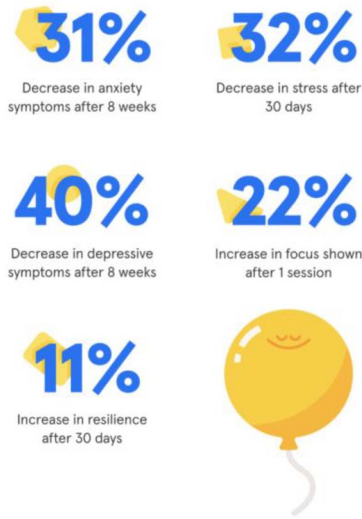
35 BIGHEALTH, *Sleepio*, <https://www.bighealth.com/sleepio/> (accessed May 6, 2022).

36 BIGHEALTH, *Daylight*, <https://www.bighealth.com/daylight/> (accessed May 6, 2022).

37 BIGHEALTH, <https://www.bighealth.com/> (accessed May 6, 2022).

38 Dave Muoio, *Big Health Hauls in \$75M to Ramp Up Commercialization, Launch New Digital Mental Health Therapeutics*, FIERCE HEALTHCARE, Jan 19, 2022. <https://www.fiercehealthcare.com/digital-health/big-health-hauls-75m-to-ramp-up-its-digital-mental-health-therapeutics-business> (accessed May 6, 2022).





**Figure 2.** Image from Headspace website.

nizations, and our science team . . . show[ing] that Headspace can improve mental, emotional, and social health'.<sup>39</sup> Other benefits are touted, though they are not sourced—what these statistics refer to (meditation in general or the app in particular) is unclear (Figure 2).

Headspace is not approved, cleared, or authorized by FDA. But it developed an existing network of patients and potential research that positioned it to make a regulatory switch or to sell the information to a third-party who will. And that is exactly what the firm has done. Recently, Headspace merged<sup>40</sup> with Ginger to offer behavioral health coaching and licensed therapists and psychiatrists,<sup>41</sup> and partnered with Capsule to provide (delivery) pharmacy services.<sup>42</sup> It apparently plans to leverage this network of subscribers—all of whom may have medical mental health issues—to satisfy demand in another market. In effect, the firm has created a dual market: one for the GWP-version(s) or features of the app and a device-version of the app (or services on the app), which could be marketed alongside the retail GWP-version.

In developing a new product and then merging with another firm, Headspace is likely to gather and own new data, which it may then both exclude others from using and use to develop additional products and marketing techniques. The firm can then also push patients back-and-forth to its various products without having them ever leave the app. As explained below, this and other aspects of the platform model raise competition issues that policy makers should consider.

39 BIGHEALTH, <https://www.bighealth.com/> (accessed May 6, 2022).

40 BUSINESSWIRE, *Ginger and Headspace Will Merge to Meet Escalating Global Demand for Mental Health Support*, August 25, 2021. <https://www.businesswire.com/news/home/20210825005262/en/Ginger-and-Headspace-Will-Merge-to-Meet-Escalating-Global-Demand-for-Mental-Health-Support> (accessed May 6, 2022).

41 GINGER, [ginger.com/experience](https://ginger.com/experience) (accessed May 6, 2022).

42 CAPSULE, [capsule.com/locations](https://capsule.com/locations) (accessed May 6, 2022).

Tools do not need to be especially sophisticated, at least when they launch, to leverage this technique—nor do they need to target mental health. Patients with epilepsy, for example, are often instructed to keep a diary to help track seizures. App developers have brought this simple technique onto a smartphone. Epi & Me 2, which was developed with support from UCB Pharma S.A., launched with minimal features that included an ability for patients to self-record seizure activity and medication changes (such as types and titration).<sup>43</sup> The second version of the app integrated a ‘seizure detection algorithm’ that made easier tracking seizures, ‘creating seizure models’, and sending ‘reports’ of seizures to a physician.<sup>44</sup>

As this progression shows it takes only a small leap to layer on additional services and functions—and it is likely that the firm will develop and test such services and functions using the data harvested from users who signed up for the previous version(s) of the app. For example, Epi & Me could use seizure-diary data and other data collection to develop a predictive algorithm to detect and respond to seizures, potentially in concert with the manufacturers of compatible devices<sup>45</sup> some of which may alert emergency contacts or responders,<sup>46</sup> or administer medication.

Such a development may be very welcome in the end, but the journey from simple GWP to diagnostic device can be a slow-burn—it may happen gradually and iteratively, each change moving the product closer to, but still short of, the device-wellness line. Because the product’s development was gradual, its final step across the line may happen without much fanfare or clear delineation. The pace and nature of this process makes regulating the product at any one phase of its development challenging until regulation is all but imminent and many of the potential worries are in the rearview mirror.

Similar concerns apply to apps that skate even closer to the line. Helpiepsy (developed by Neuroventis) offers similar seizure-tracking services with an added ability to link to seizure-detection devices.<sup>47</sup> Another example is SeizAlarm, a smartphone app that ‘can detect seizure-like/abnormal movement and/or elevated/low heart rate (if using the Apple Watch) and automatically notify emergency contacts’.<sup>48</sup> Although the app is framed in terms of seizure detection, the firm is also quick to disclaim its ability to diagnose seizures, noting ‘SeizAlarm does not prevent seizures, should not be used for diagnosis and is not a substitute for medical care’.<sup>49</sup> One can easily imagine, however, SeizAlarm leveraging its existing consumer base to develop data it could use to submit its product to FDA for review, potentially opening up a new market (insurance reimbursement), to work with a third-party (either by contract or by selling its data to it) to do so.

43 EPIANDME, <http://epiandme.com/> (accessed May 6, 2022).

44 EPI & ME 2, APPLE, APP STORE, <https://apps.apple.com/us/app/epi-me-2/id1004604219> (accessed May 6, 2022).

45 Rosalind W. Picard et al., *Wrist Sensor Reveals Sympathetic Hyperactivity and Hypoventilation before Probable SUDEP*, 89 *NEUROLOGY* 633–635 (2017).

46 *Id.*

47 Helpiepsy App, APPLE APP STORE, available at <https://apps.apple.com/us/app/helpiepsy/id1276141618> (accessed May 6, 2022). Currently can connect only to NightWatch (by LivAssured), which is a medical device under European regulation. <https://www.nightwatchepilepsy.com/>.

48 SEIZALARM, FAQ <http://seizalarm.com/faq/> (accessed May 6, 2022).

49 *Id.* (‘Use of SeizAlarm should be a supplement to other medical treatments you are already using.’).

Again, while these improvements may benefit users, they could also pose significant risk if the applications are inaccurate, or less accurate than they would be if they had undergone FDA review. This, coupled with the slow-burn described above, may complicate efforts to regulate the products in a meaningful way before data about them are submitted to FDA (if they are submitted at all).

Although the firms described so far are private and have relatively modest footprints, the technique is not limited to private or small firms. New FitBit and Amazon products in the health sphere arguably provide further illustrations of this technique. FitBit is a firm that began producing wearable technology that tracked user heart rate and steps. Since its launch, it has sold worldwide over 116 million products and currently boasts 31 million active users<sup>50</sup> and migrated deeper into the wellness and device space. On the wellness front, FitBit offers a variety of diagnostic-adjacent tools that it markets to individuals, employers, and insurers to track various aspects of an individual's health on a 'Health metrics dashboard', including skin temperature and blood oxygen saturation ('SpO2') levels, though it expressly states that 'this feature should not be relied on for any medical purposes'.<sup>51</sup> On the device side of the line, FitBit (like Apple), has received 510(k) clearance for an electrocardiogram (ECG) function on its watch, which is a GWP with a device *function*.<sup>52</sup>

Amazon also has marketed its BMI tool, which is part of the Halo product umbrella, as a GWP. Halo is 'a suite of AI-powered health features that provide actionable insights into overall wellness . . .'.<sup>53</sup> The BMI tool is one such AI-powered product, which Amazon touts as making information more accessible for the average consumer.<sup>54</sup> Sophisticated devices that accurately measure BMI can be used to screen for and potentially identify a variety of diseases, but they are expensive, ranging from \$5,000 to \$20,000.<sup>55</sup> Amazon's tool is much cheaper—and, it claims, just as accurate.<sup>56</sup> But, like FitBit, it is careful not to say that it can be used in the diagnosis or treatment of a disease or condition. Its marketing is framed in terms of patient empowerment.

As these examples illustrate, there is a dynamic and robust market for products that skate the line. But, as commentators have noted previously, unregulated, device-like products also raise concerns,<sup>57</sup> including those about a potential deluge of worthless

50 STATISTA, Fitbit—statistics & facts, <https://www.statista.com/topics/2595/fitbit/#:~:text=Since%202010%2C%20Fitbit%20has%20sold,worldwide%20in%20the%20same%20period>, (accessed May 6, 2022).

51 FITBIT, *Device Comparison Chart*, available at [https://pages.fitbit.com/2021\\_08-DeviceComparisonSheet\\_LP.html](https://pages.fitbit.com/2021_08-DeviceComparisonSheet_LP.html) (accessed May 6, 2022).

52 FOOD & DRUG ADMINISTRATION, *Clearance Letter for Fitbit ECG App*, K200948, Sept. 11, 2020, <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K200948> (May 6, 2022).

53 *Press Release: Introducing Amazon Halo and Amazon Halo Band—A New Service that Helps Customers Improve Their Health and Wellness*, AMAZON PRESS CENTER, Aug. 27, 2020, <https://press.aboutamazon.com/news-releases/news-release-details/introducing-amazon-halo-and-amazon-halo-band-new-service-helps> (accessed May 6, 2022).

54 *Id.*

55 *Id.*

56 Nicole Wetsman, *Amazon's Halo Body Fat Percentage Calculator Outperforms Lab Devices*, THE VERGE, June 17, 2021. <https://www.theverge.com/2021/6/17/22538610/amazon-halo-body-fat-percentage-a-ccurate-study> (accessed May 6, 2022).

57 This has included and may include websites that function similar to or as part of GWPs. Happify, for example, started as a rather rudimentary website. Historically, however, stand-alone websites could not offer the same type of product made possible by advances in technology. Nevertheless, to the extent that the website plays a role in the GWP or the suite offered by the GWP, it may be of concern as well.

devices,<sup>58</sup> consumer data predation,<sup>59</sup> potential confusion about whether the products are actually medical grade,<sup>60</sup> and a potential suboptimal ossification of soft-pedaled regulation.<sup>61</sup> Because many of these concerns apply generally to GWP products, they also to many products that skate the line.

### III. BENEFITS OF SKATING THE LINE

Despite the importance of these risks, however, a focus on how they arise in an underregulated marketplace can obscure the benefits of fewer regulatory burdens. Here, we attempt to show that some degree of freedom to skate the line can provide space to support product development, small and medium-sized enterprises ('SMEs'), new business models, and otherwise unrealized consumer benefits.

*Product Development.* As the examples above illustrate, there is much for firms to find attractive in skating the line: lower regulatory burdens in the wellness space translate to lower development costs. For example, bringing to market a smartwatch that measures activity generally is easier and cheaper than bringing to market one that can perform an ECG, which requires running tests and quality checks to ensure 'substantial equivalence' to a predicate device (Figure 1).<sup>62</sup>

Lower costs increase failure tolerance, which can lead to more product innovation in several ways. First, it frees firms to invest more in product technology that would otherwise have gone to regulatory compliance. Although this may occur at the start of the product lifecycle, the wellness space also enables a different, iterative investment to occur. During the 'wellness phase' producers may also acquire information that can support a later decision to apply to FDA for clearance, approval, or authorization. Happify's app, for example, acquired many users, including information about their mental health and daily habits—information that can be used to improve the quality of the product they offer. The same is true for applications like Epi & Me 2 and SeizAlarm. The more consumers use the app, the more the firm can refine and improve it. As the firm refines the product, it can evaluate both whether it is viable and, if so, whether it makes sense to submit the product to FDA. This is especially important for smaller firms (discussed below), that may not be able to compete with Amazon and Google if all GWP have to undergo FDA review—or even something akin to the review involved in the Pre-Cert program.

Second, starting in the wellness space—or straddling or crisscrossing the wellness-device line—may allow firms to do market research for a subsequent product or to buy time to perfect its product without incurring regulatory compliance costs while maintaining a market presence and acquiring market share. This could include identifying the pool of existing and potential users/patients, disease profiles amendable to the

58 Cortez, *The Mobile Health Revolution*, *supra* note 15, at 1173–1230.

59 Elizabeth Brown, *The FitBit Fault Line*, 16 YALE J. OF HEALTH POLICY, LAW, & ETHICS 1–50 (2016). Nurgalieva, L, O'Callaghan, D, Doherty, G, *Security and Privacy of mHealth Applications: A Scoping Review* 8 IEEE ACCESS 104247–104268 (2020).

60 David A. Simon, Carmel Shachar, & I. Glenn Cohen, *At-Home Diagnostics and Diagnostic Excellence Devices vs General Wellness Products*, 327 JAMA 523–524 (2022).

61 Nathan Cortez, *Regulating Disruptive Innovation*, 29 BERKELEY TECH. L.J. 175–228 (2015).

62 FOOD & DRUG ADMINISTRATION, *Clearance Letter for ECG 2.0 App*, K201525, Oct. 8, 2020. [https://www.accessdata.fda.gov/cdrh\\_docs/pdf20/K201525.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf20/K201525.pdf) (accessed May 6, 2022).

technology at issue, and user/patient demographics and socioeconomic status. It might even allow the firm to devise a strategy to segment their technology, simultaneously marketing general wellness functions to higher-paying clients while shifting lower-income clients to the world of insurance reimbursement. Large institutional customers, such as insurance companies, that are not interested in device-grade information but are interested in cheaper options can also provide a rich testing ground for the product.<sup>63</sup> If a firm eventually performs the regulatory switch and markets the product as a device, at least for some uses, the producer may be able to maintain retail market share by engaging in two-track product sales: one wellness, one device. Firms can then continue to refine the retail product to either support the existing device or to develop new devices, capabilities, or products.

In some cases, then, skating the line has the potential to improve access to certain patient populations. Products that start as unaffordable GWP (limiting access) may become regulated devices that both public and private insurance programs reimburse (enabling greater access). Even when consumers are not priced out of the GWP, a two-track product strategy allows consumers to sort themselves according to their needs and motivations (assuming the products are clearly labeled).

*Supporting Small and Medium-Sized Enterprises.* Freedom to experiment and market also means firms can skate the line to establish proof of concept, either for existing management or investors. This is particularly important for startups, which tend to be heavily dependent on investors, including venture capital funding.<sup>64</sup> For these firms, skating the line is likely to be an important business strategy tool. Raising regulatory obstacles to these firms—by imposing more stringent FDA oversight of products that skate the line, for example—can systematically alter the characteristics of market entrants. Some (perhaps many) SMEs, who typically have less capital, will not have the funding to develop and push a product through FDA review before bringing the product to market. Seed funding and subsequent funding rounds for devices, moreover, may require larger sums of money and greater demonstrated non-retail business models, which can raise costs for the firm and increase risks to investors.

Large firms, on the other hand, can absorb regulatory costs better than SMEs because their coffers are, at present, overflowing with capital.<sup>65</sup> While more stringent regulation will favor large incumbents and likely drive out less proven GWP produced by SMEs, it may also reinforce the dominance of large incumbents *both* in the GWP *and* the device space. Large players have more resources to launch GWP and fight over whether the product falls on the wellness or device side of the line. At the same time, eliminating the flexibility for small firms entrenches the role of large firms like, Apple, Google, and Medtronic, potentially strangling disruptive innovations by SMEs.

To the extent that this unregulated/gray space enables firms to collect information about how well a product is working, or to improve the product, at substantially lower cost compared to the same product subject to device regulations, skating the line may offer a method of spurring innovation by SMEs. This could potentially have important

63 Anya E. R. Prince, *Hidden Trade-Offs in Insurance Wellness Programs*, 2021 MICH. ST. L. REV. 341 (2021).

64 Carmen Cotei & Joseph Farhat, *The Evolution of Financing Structure in U.S. Startups*, 19 J. ENTREPRENEURIAL FINANCE 1 (2017).

65 STATISTA, *Leading Companies in the World in 2020, by Net Income*, <https://www.statista.com/statistics/269857/most-profitable-companies-worldwide/> (accessed May 6, 2022).

pro-competitive effects by combating the already-significant market dominance from existing technology and medical device firms.<sup>66</sup> On the other hand, if not monitored closely, it could also have the reverse effect, described below, with large firms skating the line more quickly and deftly than smaller firms, outcompeting them but with more adverse consequences for competition. Because we are quite early in the technological revolution, it may be prudent to adopt a wait-and-see approach. Understanding the potential benefits of the approach, along with its risks, is an important component of this strategy.

*Supporting New Business Models, Expanding Access.* Skating the line can help firms solve the ‘chicken-or-egg’ problem of attracting users in what economist call a ‘two-sided market’—markets where the benefit to users on one side of the platform depends on attracting users on the other side.<sup>67,68</sup> For example, Ginger’s benefit to physicians depends both on attracting a sufficient number of patients, and the benefit to patients depends on attracting a sufficient number of physicians.

Attracting either side of the market can be difficult, however, because the success of the platform depends on both sides adopting it. Since one side is unlikely to adopt the product without the other side doing so, neither side has a sufficient incentive to adopt the product. Skating the line with a GWP can help solve this problem by attracting a wide audience for limited or no fees. Once a sufficient number of users join the platform, the firm can then advertise this fact to the other market segment to persuade them to adopt it. After adoption, the firm can slide out of the GWP market or offer it alongside other products on its platform. Headspace, for example, attracted users with its GWP, obtaining one side of the market (consumers), and then merged with Ginger to obtain the other market segment (physicians). In the meantime, the firm can (like Facebook) ‘charge’ the users by harvesting and selling their data to third parties (eg advertisers and other manufacturers).

Skating the line in this way can provide opportunities to integrate care and expand access to populations who, for technological, social, economic, or cultural reasons, may be unable or hesitant to engage in traditional healthcare delivery. It may also encourage synergistic relationships to form at a more natural point in the business cycle, reducing costs to each firm by allowing for more efficient division of labor and forcing regulation at a more natural point in the business cycle, where scale and integration raise issues not presented by the GWP alone.

*Other Consumer Benefits.* Although we have focused on the benefits to producers, many of the innovation benefits redound to consumers in the form of more diverse products and an overall increase in products to meet consumer demand. This includes having ‘wellness grade’ and ‘device grade’ options at different price and access points. In addition, GWP may have direct positive effects on consumers, including increasing exercise and awareness of their own physical well-being. For example, epileptic patients may benefit from keeping a journal of their seizure activity, and even understanding

66 Large firms, even large public firms, also benefit from this strategy since they have to devote fewer firm resources to developing new products. This somewhat tempers this potential benefit.

67 Armstrong, *supra* note 14, at 668–691.

68 David S. Evans, *Two-Sided Market Definition*, ABA SECTION OF ANTITRUST LAW, MARKET DEFINITION IN ANTITRUST: THEORY AND CASE STUDIES (forthcoming). <https://papers.ssrn.com/abstract=1396751> (accessed May 6, 2022).

when seizures have occurred in the past through an app's visualization or analysis features. In some cases, the application simply makes it easier to do something the patient could, in theory, do herself using a computer program (eg Excel) or simple math. In other cases, the application may perform an analysis function that the patient would be unlikely to be able to perform but is nevertheless useful. Skating the line, in other words, may provide useful products to consumers that they would not otherwise have.

#### IV. COSTS OF SKATING THE LINE

Despite its potential benefits, skating the line is not without costs. And the examples above illustrate four key concerns that policymakers should consider for products that skate the line: consumer safety, regulatory uncertainty, competition, and data governance. In this section, we explain these costs and offer some directions that watchful policy makers should consider moving forward.

*Regulation, Safety, & Uncertainty.* Although skating the line enables nimble and lean business operations, it can also increase the risk to consumers and the health system more generally. To some degree, the ability to skate the line incentivizes firms to avoid regulatory approval and pursue low-cost GWP and marketing strategies. As a result, more products will reach the market that are unsafe or ineffective compared to a regime where all or more products underwent FDA review to ensure a measure of safety and efficacy.<sup>69</sup> To put things slightly differently, the current approach produces more innovation but with greater variation in quality than would be expected under a system where GWPs did not exist (or were regulated).

One strategy to address concerns over safety and effectiveness is to more strictly regulate all products, including those that market themselves as GWP. Too much regulation, however, would destroy the benefits provided by an ability to skate the line. Another strategy, one which FDA is pursuing (even if not strongly enough) is to pay most attention to the highest risk GWP and the least attention to the lowest-risk GWP. To some extent, FDA has done this by taking a risk-based approach to enforcement, defining GWP narrowly and excluding from the definition of GWP products that are high-risk or purport to be a device. Any product that is invasive or implanted, for instance, is a high-risk.<sup>70</sup> FDA also has shown adaptability by launching the Pre-Cert program and issuing guidance on SaMD and mental health apps during the COVID-19 emergency.

Yet there is still room for improvement. Some have suggested a more nuanced risk-based approach that focuses on the 'nature' of products, allocating oversight priorities according to the risk and benefits created by the nature and function of the product itself.<sup>71</sup> We also note that FDA's existing approach does not factor in some of the innovation benefits skating the line produces.

As FDA considers adjusting its regulatory approach, it should be mindful of how adjustments will affect the nature of innovation. Even a nuanced approach like the one described above can have adverse innovation consequences if FDA treats all product categories the same way, or cracks down too hard on one category rather than another.

69 Leah Fowler, *The Health App Market for Lemons*, ALA. L. REV. (forthcoming 2022) (on file with authors).

70 FDA, *General Wellness*, *supra* note 26.

71 Cortez, *The Mobile Health Revolution*, *supra* note 15.

These effects also can exist in novel regulatory paradigms like the Pre-Cert program, which we commend. However, the Pre-Cert program, while laudable and innovative, may not be a good fit for the innovation enabled by skating the line because it focuses on vetting established manufacturers. Allowing startups to participate in the program would necessarily undermine the manufacturer-based approach it is hoping to cultivate.

One potential solution is to develop an alternative model of regulatory monitoring (rather than review) for startup firms that anticipate making a regulatory switch, perhaps focusing on startups and SMEs that do not have established track records but may have important product lines.<sup>72</sup> Other options include modifying the Pre-Cert program by implementing an opt-in lottery system for startups and SMEs, though this would exclude many startups. Prizes could also be offered in addition to market clearance or PMA.<sup>73</sup> The problem, however, is that the government is not well-equipped to identify which technologies will be the most useful, and market distortions may arise from advantages bestowed upon participants or from deterrence of new market entrants.

Another solution is to design a more nimble and less costly pathway that focused on startups originating in well-known ‘labs’, such as Langer Lab at the Massachusetts Institute of Technology.<sup>74</sup> Like the Pre-Cert program, this regulatory approach would rely on a programmatic track record as a proxy for future quality. Again, however, this has the potential to privilege certain classes of individuals, technologies, and product lines at the expense of others that might be more innovative precisely because they do not make it past these ‘alternative methods of quality screening’, which the government has now altered to suit its regulatory goals.<sup>75</sup> Perhaps that is a cost worth bearing, but the potential for negative or unintended consequence should be identified and mitigated as much as possible.

Although attempting to be flexible, however, FDA should also be mindful of its potential to create uncertainty. Consider FDA’s 2021 COVID-19 Guidance, which is based on a cost–benefit analysis *in the pandemic* where the benefit of using products covered by its guidance outweigh its costs, as well as the costs associated with in-person treatment modalities. But when that risk calculus changes—when the pandemic ends or risks posed by in-person visits diminish substantially—will Happify and Headspace/Ginger have to stop offering their products?

To reduce uncertainty for firms like Headspace, FDA could explain how it expects to change, eliminate, or phase out its existing guidance. For example, the COVID-19 Guidance imposes on product manufacturers labeling and disclosure statement requirements, such as explaining whether the device is available with or without a prescription and what to do if symptoms do not improve.<sup>76</sup> Shoring up post-pandemic guidance now, or at least foreshadowing the possible direction of the agency, could

72 Sara Gerke, Boris Babic, Theodoros Evgeniou, & I. Glenn Cohen, *The Need for a System View to Regulate Artificial Intelligence/Machine Learning-based Software as Medical Device*, 53 NPJ DIGIT. MED. 1–4 (2020).

73 For a detailed sketch of prizes in the domain of IP, see Michael Abramowicz, *Perfecting Patent Prizes*, 56 VAND. L. REV. 115 (2003).

74 LANGER LAB, MIT DEPARTMENT OF CHEMICAL ENGINEERING. <https://langerlab.mit.edu/> (accessed Feb. 22, 2022).

75 Nathan Cortez, *The Evolving Law and Ethics of Digital Health*, in HOMERO RIVAS & KATARZYNA WAC (eds.), DIGITAL HEALTH: SCALING HEALTHCARE TO THE WORLD 249–269 (2018).

76 U.S. FOOD & DRUG ADMINISTRATION, *COVID-19 Guidance*, *supra* note 4.



provide greater certainty for firms like Happify and Headspace/Ginger as they look to expand their product offering or potentially skate across the line into regulated device space.

Some regulatory uncertainties—and consumer safety issues—may be trickier to tackle. The gradual development of applications like Epi & Me 2, Hepilepsy, and to a lesser extent SeizAlarm, present FDA with a kind of Sortes Paradox: a GWP may morph into a device, but the process could be so gradual that no individual change is significant enough to render it a device until most of the potential risk has materialized. FDA, in other words, cannot regulate until all of the risks have materialized because there was no previous point at which it could say *this particular change* rendered the GWP a device. Other actors, such as hospitals and health systems, may be able to fill some of this void, but clinicians pushing to bring technology into the clinic face significant pushback from administration because of liability concerns.<sup>77</sup>

One potential means of addressing uncertainty is to create an incentive for firms to market their products in a manner more consistent with their diagnostic- or treatment-related functions without requiring them to undergo 510(k) or PMA review. The Pre-Cert program is an attempt to address this type of uncertainty. Besides the shortcomings mentioned above, the Pre-Cert program is designed to encompass the entire lifecycle of the product. In a sense, it is a choreographed process where the FDA carefully monitors the product lifecycle. While this has obvious safety benefits, it does not account for less structured experimentation and product perfection that occurs in the open market. An alternative approach would offer some kind of incentive to producers to declare an intent to make the switch, such as increased marketing leeway.

Whatever approach FDA takes, it will confront a tradeoff. The more lenient the standard, the more likely that the quantity and diversity of innovation will increase. At the same time, however, a more restrictive regulatory stance will likely produce innovation of better overall quality, even if the type and amount of innovation is less than it would be under a lenient regulatory approach. Balancing this tradeoff will be a challenge for any regulatory regime.

In our view, however, these ends are not always mutually exclusive. Ensuring space for a large and diverse set of innovations can be achieved while simultaneously ensuring certain types of products meet quality standards. We do recognize, however, that at some level the tradeoff cannot be avoided. While we consider desirable a diverse array and quantity of innovations, we do not comment here on precisely what level of regulation would create benefits of such innovation that exceed the costs of compliance with regulation.

*Competition & Antitrust.* Skating the line may also have anticompetitive consequences that current antitrust law could address. Antitrust law prohibits practices that unreasonably restrain trade. Broadly speaking, unreasonable restraints on trade fall into two categories. The first occurs under Section 1 of the Sherman Act when firms enter into anticompetitive agreements.<sup>78</sup> While some kinds of agreements, by themselves, violate antitrust laws, other conduct requires a more nuanced ‘rule of reason analysis’

77 E.g., David A. Simon, Alan Leviton, & I. Tobias Luddenkemper, *Liability Issues for Validating and Implementing New Remote Patient Monitoring Technology in Hospital Care* (working paper 2022) (draft on file with authors).

78 15 U.S.C. § 1; Clayton Act in 1914 (15 U.S.C. §§ 12 to 27); 15 U.S.C. § 5.

that focuses on whether firm practices unreasonably restrain competition in a given market.<sup>79</sup> Firms offering mental health GWP or apps, for example, may decide to fix prices to eliminate competition. Or they could enter into agreements with health care companies to reimburse only their products. Although there are laws prohibiting certain referral arrangements, the legal restrictions generally apply only if a device is reimbursable by federal or state health care programs—and are subject to other exceptions as well.<sup>80</sup> This leaves open the possibility that GWP firms could enter into agreements that harm competition by limiting the market for new products. Presently, however, these do not appear to be the primary means by which antitrust concerns would arise.

The second category of antitrust violation occurs under Section 2 of the Sherman Act when a firm monopolizes trade (or conspires to do so) by using market dominance to exclude rivals and harm competition.<sup>81</sup> In this context, antitrust laws apply to firms that exercise ‘monopoly’ power, usually defined as firms that have a large market share. Other factors can also determine monopoly power, such as barriers to entry, the size and strength of competing firms, industry pricing, ability of customers to switch goods/services and the strength of demand—with barriers to entry being one of the most significant factors.<sup>82</sup>

This can also include ‘tying’, which occurs when firms with ‘market power’ harm competition by forcing the consumer to purchase products from the firm (rather than a competitor).<sup>83</sup> For example, tying may exist when a firm uses a patent covering a product to require consumers buy a firm’s unpatented product.<sup>84</sup> Simply performing the competition through better service, innovation, or products, however, is does not fall within this category of antitrust violation—that is just good old-fashioned competition.

Skating the line may pose several potential Section 2 problems. One is tying, which might exist if firms obtain a patent over their GWP technology and use it to require consumers purchase other firm services. For example, large firms like Amazon or Apple in theory could obtain large market share and patent or copyright protection over aspects of their GWPs. If they have sufficient market power, these firms they could force consumers to purchase firm-only unpatented products required to use their patented products. Although this is a possibility, the current fragmentation of the GWP marketplace suggests it will not happen for some time.

As noted above, some GWPs may be integrated with or part of a platform that is a two-sided market. Such two-sided platforms, in particular, can give rise to antitrust

79 *Continental T. V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 49 (1977).

80 42 U.S.C. § 1320a-7b(b)(3)(A)–(J) (SSA § 11288(b)(3)).

81 15 U.S.C. § 2.

82 *Redwood Theatres, Inc. v. Festival Enterprises, Inc.*, 200 Cal. App. 3d 687, 710 (Cal. App. Ct. 1988).

83 *Jefferson Par. Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2, 12 (1984), abrogated by *Illinois Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28 (2006) (‘Our cases have concluded that the essential characteristic of an invalid tying arrangement lies in the seller’s exploitation of its control over the tying product to force the buyer into the purchase of a tied product that the buyer either did not want at all, or might have preferred to purchase elsewhere on different terms’).

84 *Illinois Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28, 40 (2006) (noting ‘the patent misuse doctrine and our antitrust jurisprudence became intertwined’ but subsequently holding they are not identical); 35 U.S. Code § 271 (2022) (patent misuse).

concerns because they often involve concentrated markets.<sup>85</sup> Within these markets, pricing strategies can affect competition. For example, suppose a platform offers to connect patients to therapists, using a free GWP to draw them into the network. Once both sides of the market have been captured, the firm can reprice either side of the market to prevent competitors from entering. Happify, for example, may be able to reprice either its app, its subscription fees, or the amount it pays participating physicians to block an encumbant from entering the market. Doing so could hinder the very innovation made possible by skating the line.

Some of these concerns may be offset if the only impediment to entering the market is a lack of consumer interest, rather than a platform with strong network effects. It would be hard, for example, to argue that barriers to entry exist when the only barriers imposed result from economies of scale. Additionally, the Supreme Court's recent decision in *Ohio v. American Express Co.*,<sup>86</sup> which held that certain two-sided platforms can be treated as single markets, may reduce the threat of antitrust violations, though the case is distinguishable.<sup>87</sup> But regulators should pay close attention to the activity of firms that skate the line to reduce the risk of anticompetitive practices.

Here regulators other than FDA, such as the Federal Trade Commission ('FTC'), may have better expertise to evaluate competitive practices and the problems they raise. At the same time, however, FDA regulatory and enforcement decisions may affect the practices FTC is charged with regulating. Here, it may be helpful for FDA and FTC (and perhaps the Department of Justice ('DOJ')) to coordinate policy—much in the way the Patent & Trademark Office ('PTO') has attempted to begin coordinating with FDA on drug pricing—to improve market conditions and regulatory certainty.<sup>88</sup> Not only could such coordination improve the competitive marketplace, it could also reduce waste by targeting reforms to encourage competition in those sectors where its wanting and discourage anticompetitive practices in sectors particularly susceptible to them.

85 David S. Evans, *Competition and Regulatory Policy for Multi-Sided Platforms with Applications to the Web Economy*, 2 CONCURRENCES 57–62 (2008).

86 *Ohio v. Am. Express Co.*, 138 S. Ct. 2274 (2018).

87 The Court in *American Express* examined whether an 'anti-steering' provision constituted a vertical restraint on trade under Section 1 of the Sherman Act. The provision required merchants accepting American Express credit cards not to steer customers to other credit cards, which charged lower transaction fees than American Express but also provided fewer benefits to its cardholders. The Court's holding treated the credit card platform, despite it being two-sided, as a single market—meaning effects on both sides of the market must be evaluated to determine whether an antitrust violation occurs. Just pointing to '[e]vidence of a price increase on one side of a two-sided transaction platform cannot by itself demonstrate an anticompetitive exercise of market power.' *Id.* at 2288. This meant that unlike the district court, the Supreme Court found no anticompetitive effects, without additional evidence, from charging merchants higher fees because American Express cardholders also received a benefit within that market in the form of cardholder perks. Two facts, then, make the case distinguishable. First, because the case involved an actual agreement to restrain trade, the Court in *American Express* focused on the competitive effect of under Section 1, not Section 2, of the Sherman Act. Second, it concerned what amounts to a single platform (a 'transaction platform') all merchants could use in the relevant market. But the two-sided market described in the example focuses on how platforms can leverage both sides of the market to *prevent competitors from entering the market at all*. This is different from the *American Express* case, where market harm was evaluated with respect to both sides of a *single* platform and not with regard to how competition within the platform might affect competition by another, similar 2-sided platform.

88 JANET WOODCOCK, LETTER TO MR. ANDREW HIRSHFELD, <https://www.fda.gov/media/152086/download> (accessed May 6, 2022).

*Data Siloing, Competition, and Data Access.* As firms skate the line, they accumulate large quantities of data. Firms may sell these data to other firms, treating the data as property in doing so.<sup>89</sup> Since firms view themselves as owning user data, they guard them preciously, even when sharing the data would provide more societal benefit (eg for research or future innovation). Firms are likely, then, to acquire and maintain data silos inaccessible by others who could make productive use of the data. So while skating the line may generate innovation, that innovation may produce excessive waste or stifle future advances in technology and treatment.

Propertized data collected when skating the line, for example, may raise barriers to entry. If firms that raise barriers to entry by maintaining proprietary data sets acquire monopoly power, their actions may trigger antitrust concerns. A firm, like SeizAlarm, that perfects its product while marketing it as a GWP may develop a proprietary dataset and algorithm that is difficult, if not impossible, to replicate without gathering similar amounts of data.<sup>90</sup> Although theoretically possible, new market entrants will have difficulty obtaining the same data for the same costs because a superior product already exists.<sup>91</sup> What is more, the incumbent may continue to offer its GWP to progressively update and refine its product—whether its free, subscription-based, or prescription-based. This could occur because a firm already exercises sufficiently large market power that it can quickly scale up its GWP and raise barriers for competitors. Amazon, for example, already maintains large, proprietary datasets it could leverage to scale up its GWP faster than a startup, potentially raising barriers to entry before smaller firms have a chance to get off the ground. In either case, the initial innovator may use its dominant market position anticompetitively to raise costs on competitor firms that wish to enter the same product market.

These issues highlight the dynamic nature of competition concerns for firms that skate the line. On the one hand, skating the line offers a short-term innovation benefit by allowing smaller firms to develop a product that would otherwise be prohibitively expensive because of regulatory compliance costs. On the other hand, once a product is developed, data siloing may create a competition problem that skating the line initially solved. For this reason, regulators should monitor the GWP-device space carefully to ensure that anticompetitive business practices do not undermine the innovation benefits created by skating the line.

Beyond antitrust concerns, there is something of an irony in the process of protecting information as property by firms skating the line. Because the main federal privacy law concerning medical information—the Health Insurance Portability and Accountability Act of 1996 (‘HIPAA’)—generally does not apply to these firms, the firms are free to use and sell information provided they do not do so in a deceptive manner. At the same time, however, the freedom to disclose generates a private market for information as property that incentivizes protection, rather than disclosure of information.

Happify, SeizAlarm, or BigHealth might be able to collect vast amounts of information about its users, and can potentially use and sell that information in ways it could not

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89 See generally, Kathleen Liddell, David A. Simon, & Anneke Lucassen, *Patient Data Ownership: Who Owns Your Health?*, 8 J. L. & BIOSCI. 1 (2021).

90 Werden, G, *Network Effects and Conditions of Entry: Lessons from the Microsoft Case*. 69 ANTITRUST L.J. 87, 89–90 (2001).

91 *Los Angeles Land Co. v. Brunswick Corp.*, 6 F.3d 1422, 1427–28 (9th Cir. 1993).

if HIPAA applied<sup>92</sup>. But because firms can appropriate value from user data, they might not be inclined to share that data unless they are paid. And, even then, one can expect some firms to sell information in a way that maintains the value of the underlying asset, either by licensing limited access to the information or by selling only certain data sets.

Users may also have no meaningful access to the data in the application. Recently, the federal government issued a final rule providing patients access to health care records.<sup>93</sup> But these protections do not apply to GWP firms unless the GWP data appear in the patient's medical record. Perhaps more concerning, GWP manufacturers are governed by terms of service and contracts that *they* draft.<sup>94</sup> Terms of service may lock users out of the application or prohibit them from accessing certain parts of data. The risk that patients may not be able to use their own information, or to transfer it elsewhere, looms large as GWP skate the line.

To improve access to data, FDA may consider a modified regulatory regime (like the one described above) that conditions certain marketing permissions on data access and disclosure. At a minimum, stakeholders—consumer groups, firms, policy makers, and academics—should think carefully about developing best practices or uniform access rules for all GWP. Minimum requirements should include data access, uniformity, usability, and portability. Existing regulatory regimes can also be designed to incentivize information disclosure and access.

## V. CONCLUSION

As more diagnostics move outside the hospital or physician's office, the line between wellness products and devices is becoming blurred. We have shown that although these products provide some benefits to consumers, they also pose risks that can put pressure on the health care system. Furthermore as the examples we have provided suggest, firms have a strong incentive to skate the wellness-device line. Rather than radically changing regulation of this space, we have canvassed a number of alternatives designed to reduce risks posed by products that skate the line while allowing room to experiment and innovate. We believe that any further action to reduce the risks posed by skating the line should carefully weigh the concomitant costs of imposing regulation.

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92 While HIPAA probably does not apply to many of the examples discussed in this paper, it could apply to these firms or some of their data depending on how the firms generate, collect, and transmit the patient information.

93 ONC Cures Act Final Rule, 85 FED. REG. 25642–25961, May 1, 2020.

94 Leah Fowler, Jim Hawkins, & Jessica Roberts, *Uncertain Terms*, 97 NOTRE DAME L. REV 1–65 (2021).

**CONFLICT OF INTEREST DISCLOSURES**

Dr. Simon and Ms. Shachar declare no conflicts of interest. Mr. Cohen reports that he serves as a bioethics consultant for Otsuka on the Abilify MyCite product, is a member of the Illumina and Bayer ethics advisory boards, and serves as an ethics consultant for DawnLight.