

SMART WEARABLES: THE OVERLOOKED AND  
UNDERRATED ESSENTIAL WORKER

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## INTRODUCTION

Eighty-three thousand deaths, 1.7 million injuries—all linked to medical device malfunction in the decade leading up to 2018.<sup>1</sup> Investigative researchers question if these numbers are entirely accurate; the statistics are likely underrepresentative of the harm caused by medical device malfunctions.<sup>2</sup> Many believe that the Food and Drug Administration (FDA)—the agency that, in part, regulates medical devices—buries evidence of device malfunction in an attempt to retain its reputation as the powerhouse of safety, efficacy, and innovation.<sup>3</sup> But does the FDA weigh one of those characteristics higher than the others? (Hint: it does). Should it? (Hint: it should not). Public safety and product efficacy are important to the FDA, but the tendency for the agency to cover up device malfunction to prevent device recalls suggests that its primary goal is to put devices on the market quickly.<sup>4</sup> Public awareness of these efforts by the FDA has influenced a movement to establish stricter regulations on smart wearables, especially as smart wearables

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1. *Medical Devices Harm Patients Worldwide as Governments Fail on Safety*, INT'L CONSORTIUM OF INVESTIGATIVE JOURNALISTS (Nov. 25, 2018), <https://www.icij.org/investigations/implant-files/medical-devices-harm-patients-worldwide-as-governments-fail-on-safety/> [https://perma.cc/W5EX-XYEE]; see also Christina Jewett, *Hidden FDA Reports Detail Harm Caused by Scores of Medical Devices*, KAISER HEALTH NEWS (Mar. 7, 2019), <https://khn.org/news/hidden-fda-database-medical-device-injuries-malfunctions/> [https://perma.cc/2R5Q-WQFB] (discussing the FDA's internal hidden reporting repository that has prevented the public, including doctors and medical device engineers, from knowing about 1.1 million incidents of medical device malfunction since 2016).

2. See INT'L CONSORTIUM OF INVESTIGATIVE JOURNALISTS, *supra* note 1.

3. See Sasha Chavkin, *Breast Implant Injuries Kept Hidden as New Health Threats Surface*, INT'L CONSORTIUM OF INVESTIGATIVE JOURNALISTS (Nov. 26, 2018), <https://www.icij.org/investigations/implant-files/breast-implant-injuries-kept-hidden-as-new-health-threats-surface/> [https://perma.cc/HVN2-LC78] (detailing the FDA's aiding in burying breast implant malfunctions). When the FDA tightened its enforcement of reporting rules, "reports of injuries soared, and [were] on pace to increase more than 20-fold in the last two years from the previous two-year period." *Id.*

4. See Fergus Shiel, *About the Implant Files Investigation*, INT'L CONSORTIUM OF INVESTIGATIVE JOURNALISTS (Nov. 25, 2018), <https://www.icij.org/investigations/implant-files/about-the-implant-files-investigation/> [https://perma.cc/7ENV-EFS8] (providing evidence that "the average time for a new device to be approved through the FDA's ... approval process has dropped by more than 200 days since 1996" and "[f]aster approvals may yield devices more prone to faults").

become increasingly popular in society.<sup>5</sup> If the FDA requires the regulation of a product as simple as a wooden tongue depressor,<sup>6</sup> there is no question that the agency should require more stringent regulations for complex, continuously evolving devices such as smart wearables.

Smart wearables are capable of monitoring, mitigating issues with, and providing information about an individual's physiological data.<sup>7</sup> Additionally, studies suggest that smart wearables are potentially capable of diagnosing infectious disease.<sup>8</sup> The FDA is not devoid of regulations for smart wearables, but there is ambiguity in the FDA's guidelines that can harm the safety and well-being of society and ultimately hinder innovation.

To keep up with its reputation as "a global leader in setting standards and guidelines for the safety and efficacy of medical technologies," the FDA has introduced initiatives to modernize innovation.<sup>9</sup> This suggests that the agency recognizes its role in properly regulating devices;<sup>10</sup> thus, the FDA's ongoing failure to properly regulate smart wearables is incongruous with its professed goals. However, the FDA is not the only entity to blame for the lack of regulation of smart wearables. Smart wearable manufacturers have realized that they can bypass FDA regulations by strategically marketing their devices with language that falls outside the scope of the definition of a "medical device" under section 201(h) of the

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5. *US Smart Wearable Users (2019-2025)*, INSIDER INTEL. (Feb. 14, 2022), <https://www.insiderintelligence.com/charts/smart-wearables-users/> [<https://perma.cc/F2NW-Z8VD>] (estimating that 93.7 percent of Americans will use smart wearables by 2025).

6. *See* 21 C.F.R. § 880.6230(b) (2023) (classifying tongue depressors as a Class I medical device).

7. *See infra* Part III.B (discussing smart wearables' role in the COVID-19 global pandemic).

8. *See infra* Part III.C (discussing modernized smart wearables and their potential role in presymptomatic detection of the COVID-19 virus).

9. Thomas Sullivan, *PWC Medical Technology Innovation Scorecard: US Falling Behind in the Race for Global Leadership*, POLY & MED. (May 5, 2018), <https://www.policymed.com/2011/01/pwc-medical-technology-innovation-scorecard-us-falling-behind-in-the-race-for-global-leadership.html> [<https://perma.cc/2AA9-R3FK>]; *see also* Scott Gottlieb, *FDA's Comprehensive Effort to Advance New Innovations: Initiatives to Modernize for Innovation*, FDA (Aug. 29, 2018), <https://www.fda.gov/news-events/fda-voices/fdas-comprehensive-effort-advance-new-innovations-initiatives-modernize-innovation> [<https://perma.cc/64LZ-FQCF>].

10. *See* Gottlieb, *supra* note 9 ("In many cases, we've had to refashion our regulatory approach to create more modern platforms.").

Food, Drug, and Cosmetic Act (FDCA).<sup>11</sup> This is not because the device fails to function as a medical device, but rather because loopholes in the FDA's definition of a "medical device" have allowed companies to avoid the often rigorous FDA approval process by simply altering the promotion of their devices.<sup>12</sup> This type of manipulation should not be tolerated by the FDA, especially when it concerns the medical health and safety of people.

Historically, the FDA has been held in high regard among a variety of audiences because of the various and diverse relationships that the agency maintains.<sup>13</sup> For example, both liberal and conservative American politicians "heap praise upon the agency" when making arguments for their policy proposals.<sup>14</sup> Moreover, the FDA's "protective image" has retained its powerful reputation in business and medical disciplines, which amplifies the public's trust in the FDA and consequently in private entities and the products that it regulates.<sup>15</sup> Recently, however, the FDA's reputation is beginning to tarnish,<sup>16</sup> and because so many people rely on the FDA's guidance,<sup>17</sup>

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11. Nicole Wetsman, *Why Apple Needed the FDA to Sign Off on Its EKG but Not Its Blood Oxygen Monitor*, THE VERGE (Oct. 7, 2020, 12:25 PM), <https://www.theverge.com/2020/10/7/21504023/apple-watch-ekg-blood-oxygen-fda-clearance> [<https://perma.cc/L5WY-PYAU>]; see also 21 U.S.C. § 321(h).

12. See Wetsman, *supra* note 11 (discussing Apple's promotion of the Apple Watch's pulse oximeter feature as a "wellness" use, not a "diagnos[ti]c" use).

13. DANIEL CARPENTER, REPUTATION AND POWER 12-14 (2010) ("In numerous ... [public opinion] surveys taken over the past half-century, the FDA has consistently been named or identified as one of the most popular and well-respected agencies in government.").

14. *Id.* at 13.

15. See *id.* at 15 (defining "protective image" as "the diligence of a policing regulator in constraining and ... punishing ... those ... that break basic rules of society, science, and the marketplace").

16. See Daniel Carpenter, *We're Seeing What Happens When the FDA Loses Credibility*, WASH. POST (July 21, 2021, 6:00 AM), <https://www.washingtonpost.com/politics/2021/07/21/were-seeing-what-happens-when-fda-loses-credibility/> [<https://perma.cc/R8BL-39XK>] ("The FDA's reputation for procedural integrity has been damaged.").

17. See, e.g., Robert M. Califf, Margaret Hamburg, Jane E. Henney, David A. Kessler, Mark McClellan, Andrew C. von Eschenbach & Frank Young, *Seven Former FDA Commissioners: The FDA Should Be an Independent Federal Agency*, 38 HEALTH AFFS. 84, 84 (2019) ("The agency's wide-ranging responsibilities ... include over-the-counter medical products, cosmetics, radiological health, veterinary and livestock products, vital aspects of the emergency response system, and blood-related products.").

it must restore its reputation as a reliable agency in order to retain the public's trust.<sup>18</sup>

The ultimate goal is for the FDA to adjust its regulations to re-align with its proclaimed mission statement:

The [FDA] is responsible for protecting the public health by ensuring the safety, efficacy, and security of ... medical devices; and ... is responsible for advancing the public health by helping to speed innovations that make medical products more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medical products ... to maintain and improve their health.<sup>19</sup>

This Note argues that the FDA should revamp its criteria for regulating medical devices to unambiguously include smart wearables. Specifically, this Note calls for the FDA to amend its definition of “medical device” to focus on what a device is technologically *capable of* rather than its intended use.

Part I will examine the established legislation regarding medical devices; in particular, it will examine the relationship between FDA regulations and the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule and argue that when taken together, HIPAA creates a strong presumption that smart wearables should be regulated by the FDA. This Part will also discuss a recent legislative proposal that supports the call for smart wearable regulation. Part II will address alternative approaches for the proper regulation of smart wearables. Finally, Part III proposes a unique solution for regulating smart wearables as medical devices and will discuss various policy implications and will address and rebut counterclaims. Additionally, this Part considers the argument that smart wearables fit within the scope of the FDA's current definition of a medical device and identifies loopholes that prevent

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18. See Carpenter, *supra* note 16 (“The ... worry is that if people stop trusting FDA officials, we're likely to find ourselves back in the kind of world that existed before the FDA, where doctors and patients don't know whether to trust new drugs and treatments.”). Distrust in the FDA is demonstrated by the hesitancy surrounding the COVID-19 vaccine. *Id.* (“[W]hen the Trump administration interfered in the agency's decision processes last summer, millions were suddenly less willing to get vaccinated against the coronavirus.”).

19. See *What We Do*, FDA (Mar. 28, 2018), <https://www.fda.gov/about-fda/what-we-do> [<https://perma.cc/ABT4-447M>].

them from being sufficiently regulated. This Part will conclude by providing examples of modernized smart wearables that demonstrate the need for smart wearables to be subject to the FDA's medical device regulations.

### I. CURRENT LEGISLATION

The FDA is not the only entity concerned with smart wearable technology. Legislators and the Department of Health and Human Service's Office for Civil Rights (OCR) are also interested in the regulation of smart wearables.<sup>20</sup> Various legislators have shown their interests in protecting the privacy of smart wearables through the introduction of the Stop Marketing And Revealing The Wearables And Trackers Consumer Health (SMARTWATCH) Data Act, which would be enforced by the OCR.<sup>21</sup> Similarly, the OCR enforces the HIPAA Privacy Rule,<sup>22</sup> with the "major goal of ... assur[ing] that individuals' health information is properly protected while allowing the flow of health information needed to provide and promote high quality health care and to protect the public's health and well being."<sup>23</sup> The introduction of the SMARTWATCH Data Act and the goals of HIPAA demonstrate that multiple intertwined entities are concerned with the proper regulation of medical devices. This Part first explores the FDA's regulation of medical devices, then establishes a nexus between the FDA's safety and efficacy concerns and the OCR's privacy concerns, and ultimately concludes that both regulators are working toward the same goal: protecting the users of smart wearables.

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20. See *HIPAA Enforcement*, U.S. DEP'T OF HEALTH & HUM. SERVS. (July 25, 2017), <https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/index.html> [<https://perma.cc/9WPV-H4HU>].

21. See SMARTWATCH Data Act, S. 500, 117th Cong. (2021).

22. See *HIPAA Enforcement*, *supra* note 20.

23. *Summary of the HIPAA Privacy Rule*, U.S. DEP'T OF HEALTH & HUM. SERVS. (Oct. 19, 2022), <https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html> [<https://perma.cc/ARW9-7GWB>].

### A. FDA Regulations

A product is subject to FDA regulation as a medical device if it satisfies the definition of “medical device” per section 201(h) of the FDCA.<sup>24</sup> The relevant portion of section 201(h) of the FDCA provides that a medical device is “an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component part, or accessory, which is ... intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man.”<sup>25</sup>

Moreover, the FDA recognizes three regulatory classifications—Class I, Class II, and Class III—for generic devices, each with distinct protocols.<sup>26</sup> Every generic device that is introduced to the FDA is assigned to one of the classes based on the level of control needed to ensure that the device is safe and effective.<sup>27</sup> The potential risk to the user if the product fails is a primary factor in determining how the product should be regulated.<sup>28</sup> However, the FDA reserves the right of enforcement discretion—that is, the agency has the authority to regulate devices that are on the cusp of the risk inquiry.<sup>29</sup> The FDA has issued guidance stating that it will not regulate device features that make general wellness claims.<sup>30</sup> General wellness features include calorie trackers and pulse rate trackers for use during exercise.<sup>31</sup> The FDA’s right of enforcement

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24. See *How to Determine if Your Product Is a Medical Device*, FDA (Sept. 29, 2022), <https://www.fda.gov/medical-devices/classify-your-medical-device/how-determine-if-your-product-medical-device> [<https://perma.cc/2LSM-T578>].

25. 21 U.S.C. § 321(h).

26. See *Overview of Medical Device Classification and Reclassification*, FDA (Dec. 19, 2017), <https://www.fda.gov/about-fda/cdrh-transparency/overview-medical-device-classification-and-reclassification> [<https://perma.cc/8ES3-2CGB>]; see also Alex Krouse, Note, *iPads, iPhones, Androids, and Smartphones: FDA Regulation of Mobile Phone Applications as Medical Devices*, 9 IND. HEALTH L. REV. 731, 746 (2012).

27. See *Classify Your Medical Device*, FDA (Feb. 7, 2020), <https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device> [<https://perma.cc/N6DD-TUBN>].

28. See *How to Determine if Your Product Is a Medical Device*, *supra* note 24.

29. Eric Elenko, Austin Speier & Daphne Zohar, Commentary, *A Regulatory Framework Emerges for Digital Medicine*, 33 NATURE BIOTECH. 697, 698 (2015).

30. See *id.*

31. See *id.*

discretion leaves the status of smart wearables as general wellness devices or medical devices up for debate.

### 1. FDA's Classification of Medical Devices

Typically, “Class I devices ... pose the lowest risk to the patient and/or user and Class III devices pose the highest risk.”<sup>32</sup> The necessary dependent factors that determine which class a device belongs to are (1) the intended use of the device and (2) the device’s indications for use.<sup>33</sup>

Class I devices are “general controls”: devices that are “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, and ... do[] not present a potential unreasonable risk of illness or injury.”<sup>34</sup> Class I devices tend to have a simple design and a small potential for harm to the user even if a malfunction or defect occurs and will be subject to the least regulatory restrictions.<sup>35</sup> The general controls that Class I devices must abide by include registration of the company, registration of the device, and tracking of the company’s activities.<sup>36</sup> Generally, for a medical device to be approved for marketing, it must be produced under the Good Manufacturing Practices (GMPs) and submitted to premarket notification; however, Class I medical devices may be exempt from both GMPs and premarket notification requirements.<sup>37</sup>

Class II devices require additional “special controls” because the general controls are “insufficient to assure safety and effectiveness” of the device.<sup>38</sup> Special controls are device-specific and may include heightened performance standards, postmarket surveillance, and

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32. *Overview of Medical Device Classification and Reclassification*, *supra* note 26.

33. *See Classify Your Medical Device*, *supra* note 27.

34. Krouse, *supra* note 26, at 746-47; 21 U.S.C. § 360c(a)(1)(A).

35. *See* Krouse, *supra* note 26, at 746 (providing examples of Class I devices, including bandages, surgical instruments, and surgical gloves).

36. *See id.* at 747.

37. *Id.*; *see also Class I and Class II Exemptions*, FDA (Feb. 23, 2022), <https://www.fda.gov/medical-devices/classify-your-medical-device/class-i-ii-exemptions> [<https://perma.cc/Q6F7-C3V4>].

38. *See* Krouse, *supra* note 26, at 747.



special labeling requirements.<sup>39</sup> Similar to Class I, Class II devices are generally exempt from premarket notification—either automatically or through an easily obtained waiver.<sup>40</sup>

The final category, Class III, includes devices that present the highest risk of illness or injury to the user; thus, Class III devices have the strictest regulatory controls.<sup>41</sup> This category includes devices that are intended to sustain human life, prevent injuries, or have the potential to cause severe harm or injury to the user if a malfunction occurs.<sup>42</sup> Because of the heightened risk, Class III devices are not exempt from premarket approval.<sup>43</sup> Only about 10 percent of medical devices fall under this category.<sup>44</sup>

Many functions of smart wearables, if regulated by the FDA, would likely fall in Class I or Class II.<sup>45</sup> And even the less stringent Class I controls would provide a smart wearable more regulation than it receives with its current status as a general wellness device, thus ensuring increased safety and efficacy.<sup>46</sup>

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39. See *Regulatory Controls*, FDA (Mar. 27, 2018), <https://www.fda.gov/medical-devices/overview-device-regulation/regulatory-controls> [<https://perma.cc/33C9-6TT3>]; see also Krouse, *supra* note 26, at 747 (providing examples of Class II devices, including powered wheelchairs, infusion pumps, and surgical drapes).

40. See *Class I and Class II Exemptions*, *supra* note 37.

41. See *Learn if a Medical Device Has Been Cleared by FDA for Marketing*, FDA (Dec. 29, 2017), <https://www.fda.gov/medical-devices/consumers-medical-devices/learn-if-medical-device-has-been-cleared-fda-marketing> [<https://perma.cc/FMA9-ZX8Y>]; Krouse, *supra* note 26, at 747.

42. See, e.g., Krouse, *supra* note 26, at 747 (“Examples include implantable pacemaker pulse generators and endosseous implants.”); Carrie Hetrick, *How to Classify a Class III Medical Device*, STERLING MED. DEVICES (Apr. 15, 2021), <https://sterlingmedicaldevices.com/medical-device-industry-news-trends/how-to-classify-a-class-iii-medical-device/> [<https://perma.cc/KK6N-RKA9>].

43. See *Classify Your Medical Device*, *supra* note 27.

44. See *Learn if a Medical Device Has Been Cleared by FDA for Marketing*, *supra* note 41 (explaining that 47 percent of medical devices are Class I, 43 percent of medical devices are Class II, and 10 percent of medical devices are Class III).

45. See *id.* (demonstrating that approximately 90 percent of medical devices are Class I or Class II).

46. See Chris Bowen, *Software as a Medical Device: How HIPAA Security Paves Way for FDA Classification*, HEALTHCARE IT NEWS (Sept. 9, 2015, 6:09 AM), <https://www.healthcareitnews.com/blog/software-medical-device-how-hipaa-security-paves-way-fda-classification> [<https://perma.cc/67JQ-YFTH>] (claiming that “even ... Class I ... requirements are rigorous”).

## 2. *Intended Purpose vs. Actual Use of Smart Wearables*

Although the classification system for medical devices appears straightforward, loopholes in the FDA's guidelines cause ambiguity. The FDA distinguishes between "general wellness" devices and "medical devices."<sup>47</sup> The agency defines general wellness products as products that: "(1) are intended for *only* general wellness use" and "(2) present a low risk to the safety of users and other persons."<sup>48</sup> Most smart wearables are regarded as general wellness devices; however, there are specific features of smart wearables that the FDA classifies as Class II medical devices.<sup>49</sup> For example, the electrocardiogram (ECG) feature on the Apple Watch has FDA clearance as a Class II medical device.<sup>50</sup> Apple promotes the smart watch's ECG feature as a way to detect the condition of atrial fibrillation, which required the company to go through extensive processes to develop and validate this feature—one of which included obtaining FDA clearance.<sup>51</sup>

When determining what type of regulation should cover a product, the FDA focuses on the device's alleged "intended uses."<sup>52</sup> If the device's manufacturer can answer "yes" to the following three questions, then the device will likely be considered a general

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47. See *How to Determine if Your Product Is a Medical Device*, *supra* note 24 ("If your product is intended for wellness use only, and is low risk, it may not be actively regulated by FDA." (emphasis omitted)).

48. See U.S. FOOD & DRUG ADMIN., GENERAL WELLNESS: POLICY FOR LOW RISK DEVICES: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF 1, 2 (2019) [hereinafter FDA GENERAL WELLNESS GUIDANCE], <https://www.fda.gov/media/90652/download> [<https://perma.cc/W4NX-788V>].

49. See Jane E. Blaney, *Hidden in Plain Sight: How COVID-19 Revealed the Need to Incorporate Wearable Devices into Patient Care*, 13 J. HEALTH & LIFE SCIS. L. 41, 61 (2020); U.S. Food & Drug Admin., Off. of Device Evaluation, Ctr. for Device & Radiological Health, Classification Letter on Electrocardiograph Software for Over-the-Counter Use (Sept. 11, 2018), notice provided at 87 Fed. Reg. 2,547 (Jan. 18, 2022) (codified at 21 C.F.R. § 870.2345 (2023)).

50. See Wetsman, *supra* note 11.

51. See *id.*

52. See 21 C.F.R. § 801.4 (2023) (defining "intended use"); see also Paige Papandrea, Note, *Addressing the HIPAA-Potamus Sized Gap in Wearable Technology Regulation*, 104 MINN. L. REV. 1095, 1120 (2019) ("FDA regulations define 'intended use' as how the company marketing the devices objectively intended it to be used, including the claims made about the device." (citing 21 C.F.R. § 801.4)).

wellness device and not subject to the FDA's regulations.<sup>53</sup> The relevant questions are: (1) "Does the product have an intended use that relates to maintaining or encouraging a general state of health or a healthy activity?," (2) "Does the product have an intended use that relates the role of healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions?," and (3) "Is the product low risk?"<sup>54</sup> Apple chose not to answer in the affirmative when marketing the ECG feature; however, they did for the Apple Watch's pulse oximeter monitor in order to "sidestep[]" the FDA approval process.<sup>55</sup> Contrastingly, generic pulse oximeter monitors are classified as Class II medical devices.<sup>56</sup> The FDA's own guidance establishes that "[t]hese classification regulations group together all oximeters intended to measure blood oxygen saturation."<sup>57</sup> Therefore, it is inconsistent that the Apple Watch's pulse oximeter monitor, which "allow[s] you to measure the oxygen level of your blood on-demand directly from your wrist,"<sup>58</sup> is exempt from FDA regulations. This discrepancy is the result of Apple providing a brief disclaimer stating that the feature is not intended to diagnose or treat any diseases, but rather for "general fitness and wellness."<sup>59</sup> Nevertheless, the FDA's own guidance provides that a device "intended for general wellness use *only* ... may not be actively regulated by the FDA"<sup>60</sup>—the key word being "only." Even if Apple claims that the Apple Watch is intended for general wellness use, the pulse oximeter provides an additional medical use.<sup>61</sup> Thus, the Apple Watch should be moved from a general wellness device to a

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53. See Wetsman, *supra* note 11.

54. See FDA GENERAL WELLNESS GUIDANCE, *supra* note 48, at 8-9.

55. See Wetsman, *supra* note 11 ("There's a workaround ... if the company says that the product is just for fun, or for 'general wellness,' they don't have to go through [the FDA approval] process.").

56. U.S. FOOD & DRUG ADMIN., PULSE OXIMETERS—PREMARKET NOTIFICATION SUBMISSIONS [510(K)S]: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (2013), <https://www.fda.gov/media/72470/download> [<https://perma.cc/GB7Y-WFDH>] (classifying pulse oximeters as Class II medical devices).

57. *Id.* at 2.

58. *How to Use the Blood Oxygen App on Apple Watch*, APPLE (Nov. 2, 2022), <https://support.apple.com/en-us/HT211027> [<https://perma.cc/K2B9-XPAV>].

59. *Id.*; see also Wetsman, *supra* note 11.

60. *How to Determine if Your Product Is a Medical Device*, *supra* note 24.

61. See *How to Use the Blood Oxygen App on Apple Watch*, *supra* note 58.

medical device per section 201(h) of the FDCA.<sup>62</sup> The manipulative strategies employed by Apple to evade the FDA approval process should not be tolerated. Until the FDA provides clarity regarding the relationship between smart wearables and medical devices, such dubious scheming from companies like Apple will persist and put the health and safety of users at risk and, ultimately, stall the innovation of medical devices.

*B. Intersection of the SMARTWATCH Data Act, HIPAA Privacy Rule, and FDA Regulations*

The SMARTWATCH Data Act is a bipartisan bill that was most recently introduced by Democratic Senator Jacky Rosen and Republican Senator Bill Cassidy in March 2021.<sup>63</sup> The introduction of the bill acknowledges the modernization of smart wearable technology, especially in response to the recent, large-scale influx of smart wearables as aids in the healthcare industry.<sup>64</sup> This legislative proposal demonstrates that as technology continues to advance, various entities consider smart wearables to be higher risk than once thought.<sup>65</sup> Hence, stricter regulations to cover smart wearables have begun to emerge, such as the SMARTWATCH Data Act.

The SMARTWATCH Data Act is aimed at preventing the sale of personal health information (PHI) gathered through fitness trackers, smart watches, or other similar devices without the user's consent.<sup>66</sup> Although the legislation focuses on data storage and privacy, it is notable that the bill designates the information collected by smart wearables as consumer health information.<sup>67</sup> The bill defines "consumer health information" as "any information about the health status, personal biometric information, or personal

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62. See 21 U.S.C. § 321(h)(1) (defining medical "device[s]" that are subject to FDA regulations).

63. S. 500 (117th): SMARTWATCH Data Act, GOVTRACK, <https://www.govtrack.us/congress/bills/117/s500/summary#ourssummary> [<https://perma.cc/8YZT-VAA5>] (last updated Apr. 20, 2021).

64. Steve Alder, *Smartwatch Data Act Introduced to Improve Privacy Protections for Consumer Health Data*, HIPAA J. (Nov. 21, 2019), <https://www.hipaajournal.com/smartwatch-data-act-consumer-health-data/> [<https://perma.cc/WE6L-MQFJ>].

65. See, e.g., *id.*

66. See *id.*

67. See *id.*

kinesthetic information about a specific individual that is created or collected by a personal consumer device.”<sup>68</sup> Further, the bill defines “biometric information” as any “physiological, biological, or behavioral characteristics of an individual.”<sup>69</sup> Significantly, the bill considers “kinesthetic information,” including “keystroke patterns or rhythms, gait patterns or rhythms, [and] sleep information,”<sup>70</sup> as important data related to an individual’s personal health. The SMARTWATCH Data Act’s privacy concerns of PHI naturally invokes discussion of the HIPAA Privacy Rule (HIPAA).<sup>71</sup>

HIPAA is concerned with physician-patient interactions and prevents the disclosure of a patient’s PHI without their consent.<sup>72</sup> However, HIPAA only applies to certain “covered entities”<sup>73</sup> in the healthcare industry.<sup>74</sup> Neither smart wearable devices nor the companies that manufacture them are subject to HIPAA regulations because they are not one of the defined covered entities,<sup>75</sup> thus leaving the information gathered by smart wearables virtually unregulated. The fact that the SMARTWATCH Data Act provides substantially the same protections to smart wearables that HIPAA affords to certain covered entities that collect medical PHI suggests that smart wearables are collecting medical PHI as well.<sup>76</sup> In fact, the legislators allege just that. One drafter of the bill stated that “[t]his commonsense ... legislation will extend existing health care privacy protections to personal health data collected by ... [smart]

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68. SMARTWATCH Data Act, S. 500, 117th Cong. § 2(6) (2021).

69. *Id.* § 2(2).

70. *Id.* § 2(9).

71. See Standards for Privacy of Individually Identifiable Health Information, 67 Fed. Reg. 53,182 (U.S. Dep’t of Health & Hum. & Servs. Aug. 14, 2002) (codified at 45 C.F.R. pts. 160, 164).

72. See *Summary of the HIPAA Privacy Rule*, *supra* note 23.

73. 45 C.F.R. § 164.500(a) (2023).

74. *Id.* § 160.103 (defining “covered entity” as a “health plan ... health care clearinghouse ... [or] health care provider who transmits any health information in electronic form in connection with a [covered] transaction”).

75. Jesse Rifkin, *SMARTWATCH Data Act Would Protect Privacy of Personal Health Info Stored on Wearable Devices Like Fitbit and Apple Watch*, GOVTRACK INSIDER (Apr. 20, 2021), <https://govtrackinsider.com/smartwatch-data-act-would-protect-privacy-of-personal-health-info-stored-on-wearable-devices-like-d3f9b3c54249> [<https://perma.cc/S563-7H7L>].

76. See *id.* (“The SMARTWATCH ... Data Act would protect personal health data stored on a device with the same HIPAA privacy protections as personal health information shared in person with a doctor.”).

wearables.”<sup>77</sup> While the bill is directed towards protecting smart wearable users’ PHI privacy, the numerous references to HIPAA indicate an emerging trend to view smart wearables as part of the healthcare industry.<sup>78</sup>

The SMARTWATCH Data Act does not intend to supersede HIPAA; in fact, the legislation is aimed at filling the gaps that HIPAA fails to address, specifically by providing regulations for smart wearable manufacturers—entities not covered by HIPAA.<sup>79</sup> Notwithstanding the trend to consider smart wearables as part of healthcare, neither the SMARTWATCH Data Act nor HIPAA address the problem of consumer safety and device efficacy; the FDA is needed to tackle that problem.

The FDA’s regulation of medical devices has broader applicability than HIPAA restrictions because the FDA is concerned with the manufacture of devices, whereas HIPAA only concerns a narrow list of covered entities.<sup>80</sup> Because of the narrow path for HIPAA safeguards to apply to a device, a device that is “designed to comply with the technical safeguards of the HIPAA [Privacy] Rule has a head start for ... FDA [regulations].”<sup>81</sup> Therefore, the SMARTWATCH Data Act is the nexus that bridges the gap between HIPAA and FDA protocols, and the bill should persuade the FDA to classify smart wearables as medical devices.

## II. ADDRESSING ALTERNATIVE APPROACHES

Although this Note focuses on the FDA’s role in regulating medical devices, there are other entities that have interests in regulation as well. This Part discusses alternative pathways for the regulation of smart wearables: (1) the Digital Health Software Precertification (Pre-Cert) Program, and (2) amending the HIPAA Privacy Rules to include smart wearables. The former is an area of

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77. Alder, *supra* note 64 (quoting Sen. Jacky Rosen).

78. *See id.*

79. *See id.*; 45 C.F.R. § 160.102(a) (2023) (providing HIPAA’s scope of applicability). For an argument to expand the HIPAA privacy rule’s definition of “covered entity” to include smart wearable manufacturers, see generally Papandrea, *supra* note 52.

80. *See* Nicolas P. Terry, *Will the Internet of Things Transform Healthcare?*, 19 VAND. J. ENT. & TECH. L. 327, 343 (2016).

81. Bowen, *supra* note 46.

control that the FDA reaches, and the latter implicates the OCR.<sup>82</sup> This Part will ultimately conclude that neither the Pre-Cert Program nor amending the HIPAA Privacy Rules goes far enough in providing safe and effective regulations of smart wearables.

#### A. *FDA Pilot Program: Digital Health Software Precertification Program*

In partnership with the Federally Funded Research and Development Center, the FDA introduced initial testing phases of the Pre-Cert Program.<sup>83</sup> The Pre-Cert Program was created to “help inform the development of a future regulatory model that will provide more streamlined and efficient regulatory oversight of software-based medical devices.”<sup>84</sup> Overall, the program is intended to expedite the FDA’s regulatory process of medical devices.<sup>85</sup> The program’s “Action Plan” involves redesigning policies and procedures to better reflect modernized digital health technology and to provide manufacturers clarity regarding the policies so that they know how to proceed.<sup>86</sup>

Moreover, the scope of the Pre-Cert Program is digital health software, or “Software as a Medical Device (SaMD)”;<sup>87</sup> therefore, the program does not cover devices that are considered medical devices under section 201(h) of the FDCA.<sup>88</sup> In fact, in some instances, the Pre-Cert Program and section 201(h) of the FDCA are in direct conflict with each other; the FDA admits this problem exists and concedes that they do not have a solution.<sup>89</sup> For example, the FDA recognizes that “the product types that may benefit from

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82. See *supra* Part I.B.

83. *Digital Health Software Precertification (Pre-Cert) Program*, FDA (Sept. 26, 2022), <https://www.fda.gov/medical-devices/digital-health-center-excellence/digital-health-software-precertification-pre-cert-program> [https://perma.cc/W8SE-6MTC].

84. *Id.*

85. Theodore T. Lee & Aaron S. Kesselheim, *U.S. Food and Drug Administration Precertification Pilot Program for Digital Health Software: Weighing the Benefits and Risks*, 168 ANNALS INTERNAL MED. 730, 730 (2018).

86. U.S. FOOD & DRUG ADMIN., DIGITAL HEALTH INNOVATION ACTION PLAN 1-3 (2017), <https://www.fda.gov/media/106331/download> [https://perma.cc/WRL5-5GBN].

87. See *Digital Health Software Precertification (Pre-Cert) Program*, *supra* note 83.

88. See U.S. FOOD & DRUG ADMIN., THE SOFTWARE PRECERTIFICATION (PRE-CERT) PILOT PROGRAM: TAILORED TOTAL PRODUCT LIFECYCLE APPROACHES AND KEY FINDINGS 4-6 (2022), <https://www.fda.gov/media/161815/download> [https://perma.cc/HM5V-URVW].

89. See *id.*

precertification might include all software that meets the definition of medical device in section 201(h),<sup>90</sup> but because the Pre-Cert Program's focus is on SaMD technologies *apart* from hardware medical devices,<sup>91</sup> section 201(h) medical devices are ineligible.<sup>92</sup> Additionally, the program claims that its scope covers “[o]rganizations that are developing or planning to develop a software that could be subject to FDA oversight,”<sup>93</sup> but as long as the FDA continues to allow companies to categorize their devices as intended merely for general wellness rather than as medical devices, companies will continue to bypass both the FDA approval process and the Pre-Cert Program.

Although the Pre-Cert Program encourages innovation, innovation is not the FDA's only goal; the agency must also enforce regulations that promote safety and efficacy.<sup>94</sup> This issue is amplified by concerns raised by skeptics of the program: the Pre-Cert Program “may reduce incentives for developers to study the safety and effectiveness of their software products before patients start to rely on them,” “the FDA does not have as much authority after a product's widespread use to enforce data collection deadlines,” and “Pre-Cert may also create confusion for patients and physicians, who may believe that marketed products were subject to rigorous study.”<sup>95</sup> An expedited approval process that does not cover all medical devices—or even a majority—is not the proper solution. The Pre-Cert Program should not be abandoned altogether, but its scope does not cover most smart wearable devices;<sup>96</sup> therefore, it is not a solution to the ongoing ambiguities surrounding the regulation of smart wearables as medical devices. Eventually, smart

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90. See U.S. FOOD & DRUG ADMIN., SOFTWARE PRECERTIFICATION PROGRAM: REGULATORY FRAMEWORK FOR CONDUCTING THE PILOT PROGRAM WITHIN CURRENT AUTHORITIES 2 (2019), <https://www.fda.gov/media/119724/download> [<https://perma.cc/M9D8-DZY6>]; see also 21 U.S.C. § 321(h) (providing that certain software functions are excluded as a “device” pursuant to section 520(o) of the FDCA).

91. See U.S. FOOD & DRUG ADMIN., DEVELOPING A SOFTWARE PRECERTIFICATION PROGRAM: A WORKING MODEL 10 (2019), <https://www.fda.gov/media/119722/download> [<https://perma.cc/V7YB-6MV2>] (defining SaMD “as software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device”).

92. *Id.* at 9.

93. *Id.*; see *supra* Part I.A.2.

94. See *What We Do*, *supra* note 19.

95. Lee & Kesselheim, *supra* note 85, at 730.

96. See *supra* Part I.A.2.



wearable technology may be included in the scope of the Pre-Cert Program; however, the first step in ensuring safe, effective, and innovative medical devices is for the FDA to unambiguously classify smart wearables as medical devices under section 201(h) of the FDCA.<sup>97</sup>

*B. Amending HIPAA Privacy Rules to Extend Applicability to Smart Wearables*

A separate approach to regulating smart wearables is to amend the HIPAA Privacy Rules to apply to smart wearables. One legal scholar advanced this very idea because she was concerned with how “wildly unregulated” wearable technology is “[d]espite the significant risks posed by wearable technology.”<sup>98</sup> The first step in this approach is to expand HIPAA’s definition of “covered entities,” specifically by amending the definition to include the phrase, “[a] company that manufactures wearable technology.”<sup>99</sup> Arguably, amending the HIPAA Privacy Rule “has the potential to properly regulate wearable technology and protect consumers with minimal changes.”<sup>100</sup> Admittedly, these changes would likely allow for smart wearables to be covered by HIPAA Privacy Rules; however, this approach is primarily concerned with privacy and confidentiality of patient records, rather than the safety and efficacy of the actual smart wearable device.<sup>101</sup> When data collected on a medical device is faulty or misleading due to failures in regulating the device, there is no need for HIPAA to protect the data—it is not actually the patient’s accurate physiological information. Thus, the FDA must first regulate smart wearables as medical devices, and then discussions about the HIPAA Privacy Rule protecting the devices will naturally follow.

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97. See U.S. FOOD & DRUG ADMIN., *supra* note 91, at 10 (“As FDA gains insights from implementation of Version 1.0 [of the Pre-Cert Program], we hope to expand the program to be able to leverage a software manufacturer’s precertification status to the review of all medical device software products.”).

98. Papandrea, *supra* note 52, at 1097.

99. *Id.* at 1122.

100. *Id.* at 1121.

101. See *supra* notes 86-90 and accompanying text.

Significantly, one of the main reasons why proponents of amending the HIPAA Privacy Rule favor that solution rather than amending the FDA's definition of "medical device" is due to concerns about the FDA being "administratively overburdened."<sup>102</sup> However, the implementation of the Pre-Cert Program suggests that the FDA is willing to address these problems, and an issue as important as the proper regulation of medical devices should not be dismissed merely because of speculative administrative burdens.

### III. SOLUTION: THE FDA SHOULD AMEND THE DEFINITION OF "MEDICAL DEVICE" TO UNAMBIGUOUSLY INCLUDE SMART WEARABLES

The FDA has a broad definition for "medical device"; on its face, the definition appears to already include smart wearable technology, and at a minimum, it reasonably includes *modernized* smart wearables. The ambiguity arises when companies that manufacture smart wearables claim that their device is intended for general wellness rather than one of the categories covered in section 201(h)—diagnosing, curing, mitigating, preventing, or treating a disease.<sup>103</sup> The FDA has stated that it will not regulate devices that are only intended to promote general fitness or healthy lifestyle maintenance and that have no reference to a particular disease or diagnosis.<sup>104</sup> These limitations include general wellness claims, such as weight management, stress management, mental acuity, sleep management, and sexual function.<sup>105</sup> The confusion regarding the status of smart wearables as a general wellness device or a medical device imposes a duty on the FDA to provide explicit guidance with regard to the regulation of smart wearables.<sup>106</sup> The FDA has

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102. *E.g.*, Papandrea, *supra* note 52, at 1128.

103. *See* 21 U.S.C. § 321(h)(2); *supra* Part I.A.2.

104. *See* FDA GENERAL WELLNESS GUIDANCE, *supra* note 48, at 3 (defining "general wellness product[s]").

105. *Id.*

106. *See, e.g.*, Papandrea, *supra* note 52, at 1107 (discussing the "blurr[ed] ... line between wearable technology as a consumer good and wearable technology as a medical good"); Nathan Cortez, *The Mobile Health Revolution?*, 47 U.C. DAVIS L. REV. 1173, 1217 (2014) (criticizing the FDA's equivocal posture towards medical device software by relying only on "nonbinding guidance documents and spotty case-by-case enforcement," and calling for meaningful regulatory oversight to address past regulatory failures).

discretionary power to enforce regulatory control over any potential medical device; thus, it is not an unwarranted nor hugely disruptive ask to have the agency unambiguously include smart wearables as a medical device.<sup>107</sup>

*A. Proposed Amendment to the FDA's Definition of "Medical Device"*

While the FDA's definition of "medical device" is broad,<sup>108</sup> the ambiguous language creates loopholes that narrow the scope of the definition significantly. Amending the definition of "medical device" is the best approach to provide clarity to what types of devices are covered by the FDCA. Specifically, the phrase "intended use" is problematic and needs to be omitted from the definition.<sup>109</sup> The relevant portion of section 201(h) currently defines a medical "device" as a "machine ... or other similar or related article ... intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man."<sup>110</sup> To provide clarity to manufacturers of smart wearables, and to provide consistent regulation of medical devices, the definition in section 201(h) should be amended by replacing the "intended use" standard with an objective phrase that focuses on the actual functions of a device. In particular, replacing "intended use" with the phrase "capable of" would provide an objective standard. Thus, the amended definition of "medical device" should read as follows:

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107. See generally Elenko et al., *supra* note 29.

108. See, e.g., Bill Sutton, *Overview of Regulatory Requirements: Medical Devices—Transcript*, FDA (Nov. 2011), <https://www.fda.gov/training-and-continuing-education/cdrh-learn/overview-regulatory-requirements-medical-devices-transcript> [<https://perma.cc/8CYD-F9J3>] (stating that the definition of medical device per section 201(h) is "a very broad definition").

109. See, e.g., Scott Danzis, *FDA Proposes Amending the Definition of "Intended Use,"* 5 NAT'L L. REV. (Sept. 28, 2015), <https://www.natlawreview.com/article/fda-proposes-amending-definition-intended-use> [<https://perma.cc/H5C6-A2Y4>] (discussing the realization that the phrase "intended use" is ambiguous).

110. 21 U.S.C. § 321(h)(1).

An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is—

(A) recognized in the official National Formulary, or in the United States Pharmacopoeia, or any supplement to them,

(B) *capable of* use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(C) *capable of affecting* the structure or any function of the body of man or other animals, and which does not achieve its primary *capability* through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary *capability*.<sup>111</sup>

The proposed language would prevent a smart wearable manufacturer from being able to work around the FDA regulatory process simply by claiming its smart wearable is intended for general wellness. Under the proposed amendment, insincere claims would be substituted for the actual functions and capabilities of the device. Therefore, a device that is capable of providing medical functions to users will be regulated as a medical device per section 201(h), regardless of how the company promotes and markets the device. This clarification is necessary because the current definition leaves unregulated many smart wearables that have medical functions because the manufacturer promotes the device as being intended for general wellness use.<sup>112</sup>

This puts consumers at risk because it assumes that a consumer will ignore the medical functions that the smart wearable provides. When companies that manufacture smart wearables that, in reality, have medical functions claim that they *intend* the device to be used for general wellness, it is clear that it is a strategy to bypass the

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111. See 21 U.S.C. § 321(h) (proposed language emphasized).

112. Becca Caddy, *Wearable Tech and Regulation: What Laws Do Wearables Need to Follow?*, WAREABLE (Sept. 19, 2019), <https://www.wearable.com/health-and-wellbeing/wearable-tech-and-regulation-5678> [<https://perma.cc/S3ZJ-DMJ4>].

FDA's regulatory process.<sup>113</sup> Not every individual who uses a smart wearable device knows that they have been assigned the task of deciphering between a general wellness use and a medical use; the user simply relies on the physical capabilities of the device, and likely believes the information on the device is representative of their physiological medical health. The FDA has even admitted that "consumer intent could be relevant" to the consideration of how a device is properly used.<sup>114</sup> The discrepancies between a device's intended use and actual function places too large of a burden on consumers; there is too much at stake, and the FDA is in the best position to protect consumers by unequivocally categorizing smart wearables with medical capabilities as medical devices.

This Note is not the first to argue that the phrase "intended use" is ambiguous. The FDA proposed a rule to clarify the meaning of "intended use" and received several comments arguing that the phrase is ambiguous.<sup>115</sup> However, this Note presents a novel solution that can be implemented with minimal changes.

Under the proposed language, smart wearables that provide medical functions would be covered by section 201(h) of the FDCA and subject to FDA regulations as Class I, Class II, or possibly—although unlikely—Class III medical devices.<sup>116</sup> For example, the Apple Watch's pulse oximeter feature, which objectively functions as a medical device, would be subject to FDA regulations.<sup>117</sup>

The FDA contends that the phrase "intended use" is not ambiguous.<sup>118</sup> In response to arguments that the phrase "intended use" is too subjective and narrows the scope of section 201(h) to "promotional claims ... made in the marketplace," the FDA asserts that view is misguided: "Nothing in the statute requires the [suggested] narrow scope."<sup>119</sup> According to the FDA, a device's "label, accompanying labeling, promotional claims, advertising, and any other

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113. *See id.*

114. Regulations Regarding "Intended Uses," 86 Fed. Reg. 41,383, 41,386 (Aug. 2, 2021) (codified at 21 C.F.R. pts. 201, 801) (quoting *United States v. Travia*, 180 F. Supp. 2d 115, 119 (D.D.C. 2001)).

115. *See id.* at 41,385.

116. *See id.* at 41,390-91.

117. *See supra* notes 72-76 and accompanying text.

118. *See* Regulations Regarding "Intended Uses," 86 Fed. Reg. at 41,386.

119. *Id.*

relevant source” are additional evidence of intended use.<sup>120</sup> The arguments advanced by the FDA do provide clarity as to what types of evidence fall under the category of “intended use,” but they do not address the ambiguities that are present in the context of smart wearables.

*B. Smart Wearables Fall Within the Scope of the FDA’s Current Definition of “Medical Device”*

Even if the FDA is adamant about preserving the current “intended use” language of section 201(h), modernized smart wearables already fall within the scope of the definition. The realm of technology is constantly evolving, and smart wearable technology is not exempt from this evolution; in fact, smart wearables are at the forefront of innovation. Utilizing smart wearables in patient care can act as “a catalyst towards the ultimate triple aim of health care: to increase patient access, reduce overall costs, and increase the quality [of] care.”<sup>121</sup> As proof of their role in the healthcare industry, the following Subsection will discuss the essential role that smart wearables have played in the mitigation efforts of the COVID-19 pandemic, highlighting the rapid advancements in smart wearable technology.

*1. Essential Aids for COVID-19 Contact Tracing*

The COVID-19 pandemic has brought about a multitude of changes in society, but one of the most intrusive changes is the lack of accessibility that many people have to medical care.<sup>122</sup> This is especially disruptive during a global pandemic where a highly contagious, and often, fatal virus is spread rapidly. At the beginning of the pandemic, people would steer clear of doctors’ offices and hospitals unless it was absolutely essential (hence, the title “essential workers” given to healthcare providers); however, not

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120. *Id.* (quoting *United States v. Travia*, 180 F. Supp. 2d 115, 119 (D.D.C. 2001)).

121. Blaney, *supra* note 49.

122. See, e.g., Reed Abelson, *Covid Overload: U.S. Hospitals Are Running Out of Beds for Patients*, N.Y. TIMES (Sept. 22, 2021), <https://www.nytimes.com/2020/11/27/health/covid-hospitals-overload.html> [<https://perma.cc/TWN3-3Y7H>].

everyone has the privilege to choose to avoid the doctor.<sup>123</sup> Fortunately, when state governments began implementing stay-at-home orders,<sup>124</sup> many governors also promulgated emergency orders to increase access to telehealth services.<sup>125</sup> One week before the stay-at-home orders took effect, only 13,000 telehealth visits were reported per week nationwide; after the stay-at-home orders began, the number of telehealth visits jumped to 1.7 million.<sup>126</sup> This exponential increase in demand for telehealth services has exposed previously overlooked needs in the healthcare industry: patients' desires to receive healthcare services virtually and healthcare providers' ability to monitor them remotely.<sup>127</sup> Encouragingly, smart wearables provide solutions to fulfill these needs because they provide an easily accessible system for contact tracing, and they can monitor existing COVID-19 symptoms and detect presymptomatic cases of COVID-19.<sup>128</sup> The significant role that smart wearables have continuously played during the COVID-19 pandemic indicates that smart wearables unequivocally function as a medical device as defined in section 201(h) of the FDCA.<sup>129</sup>

One role that smart wearables have played during the COVID-19 pandemic is their ability to advance the mitigation efforts of COVID-19, including the prevention of subsequent COVID-19 waves

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123. *Interim List of Categories of Essential Workers Mapped to Standardized Industry Codes and Titles*, CDC (Mar. 29, 2021), <https://www.cdc.gov/vaccines/covid-19/categories-essential-workers.html> [<https://perma.cc/PL8Y-U5DK>].

124. *See, e.g.*, Jennifer Kates, Josh Michaud & Jennifer Tolbert, *Stay-At-Home Orders to Fight COVID-19 in the United States: The Risks of a Scattershot Approach*, KAISER FAM. FOUND. (Apr. 5, 2020), <https://www.kff.org/policy-watch/stay-at-home-orders-to-fight-covid19/> [<https://perma.cc/PYD8-GMY3>] (explaining stay-at-home orders and providing a timeline of state-mandated stay-at-home orders in March of 2020).

125. *See Telehealth Guidance by State During COVID-19*, AM. PSYCH. ASS'N SERVS., <https://www.apaservices.org/practice/clinic/covid-19-telehealth-state-summary> [<https://perma.cc/S2RT-KSL7>] (last updated Apr. 2021).

126. Dana Shilling, *Telemedicine in the Age of COVID-19*, 353 *ELDER L. ADVISORY NL* 1, 2 (2020).

127. *See* Blaney, *supra* note 49.

128. *See infra* Parts III.B.1-B.2; *see, e.g.*, Tejaswini Mishra, Meng Wang, Ahmed A. Metwally, Gireesh K. Bogu, Andrew W. Brooks, Amir Bahmani, Arash Alavi, Alessandra Celli, Emily Higgs, Orit Dagan-Rosenfeld, Bethany Fay, Susan Kirkpatrick, Ryan Kellogg, Michelle Gibson, Tao Wang, Erika M. Hunting, Petra Mamic, Ariel B. Ganz, Benjamin Rolnik, Xiao Li & Michael P. Snyder, *Pre-Symptomatic Detection of COVID-19 from Smartwatch Data*, 4 *NATURE BIOMED. ENG'G* 1208, 1208 (2020) (investigating whether smart wearables can detect presymptomatic cases of COVID-19).

129. *See* 21 U.S.C. § 321(h).

and variants. Before a vaccine was created for COVID-19, contact tracing was the primary mitigation effort for stopping the spread of the virus.<sup>130</sup> Copious evidence shows that contact tracing helps prevent people from contracting infectious diseases like COVID-19.<sup>131</sup> Contact tracing is used to stop the spread of infectious diseases, and in the case of COVID-19, contact tracing tells individuals if they have been exposed to the virus, which allows the individual to get tested and to self-isolate or self-quarantine if necessary.<sup>132</sup> As discussed in Part I, the FDA defines a medical device as an “implement” or “machine” that is “intended for use in the ... mitigation ... or prevention of disease.”<sup>133</sup> And the Centers for Disease Control and Prevention (CDC) provides guiding principles for how to “mitigate” COVID-19.<sup>134</sup> The CDC explicitly listed contact tracing as one of the *mitigation* strategies used to “minimize morbidity and mortality of COVID-19” especially “before a vaccine or therapeutic drug becomes widely available.”<sup>135</sup> Contact tracing becomes even more crucial when COVID-19 mutates into highly

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130. Heather Hollingsworth & Bobby Caina Calvan, *Contact Tracing Revs Up in Some States as Omicron Reaches US*, U.S. NEWS & WORLD REP. (Dec. 4, 2021, 11:52 AM), <https://www.usnews.com/news/health-news/articles/2021-12-03/contact-tracing-revs-up-in-some-states-as-omicron-reaches-us> [<https://perma.cc/8CTG-8FHQ>] (stating that “[c]ontact tracing is a vital tool in the pandemic response” and quoting former New York Mayor Bill de Blasio, saying that “contact tracing is absolutely crucial”).

131. See Beth Duff-Brown, *Model Shows Potential Contact Tracing Impact Against COVID-19*, STAN. MED. (Aug. 24, 2020), <https://med.stanford.edu/news/all-news/2020/08/model-shows-potential-contact-tracing-impact-against-covid-19.html> [<https://perma.cc/46JK-H2L3>].

132. *Contact Tracing for COVID-19*, CDC, <https://www.cdc.gov/coronavirus/2019-ncov/php/contact-tracing/contact-tracing-plan/contact-tracing.html> [<https://perma.cc/GMF2-KLDK>] (last updated Feb. 10, 2022).

133. 21 U.S.C. § 321(h).

134. *Implementation of Mitigation Strategies for Communities with Local COVID-19 Transmission*, CDC, <https://www.cdc.gov/coronavirus/2019-ncov/community/community-mitigation.html#print> [<https://perma.cc/PK4H-7NTU>] (last updated May 23, 2021).

135. *Id.*



contagious variants,<sup>136</sup> such as the Omicron variant.<sup>137</sup> Smart wearables were undeniably included in the contact tracing efforts to mitigate and prevent the spread of COVID-19.<sup>138</sup>

As evidence of smart wearables being involved in the mitigation efforts of the COVID-19 pandemic, two leaders of innovation, Apple Inc. and Google LLC, established a contact tracing initiative with the claimed intention to “help combat the virus and save lives.”<sup>139</sup> The companies stated that this initiative is “a joint effort to enable the use of Bluetooth technology to help governments and health agencies reduce the spread of the virus” in order to “solve one of the world’s most pressing problems.”<sup>140</sup> When two powerhouses of technological advancements claim that smart wearables have the potential to mitigate a deadly global pandemic, the FDA should listen.<sup>141</sup>

Furthermore, during the COVID-19 pandemic, the terms “mitigation” and “prevention” have been used almost synonymously with

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136. See, e.g., Antonio Olivo, *Amid Omicron Surge, Contact Tracing Is More Complicated, Officials Say*, WASH. POST (Jan. 7, 2022, 1:36 PM), <https://www.washingtonpost.com/dc-md-va/2022/01/07/omicron-contact-tracing-covid-surge/> [<https://perma.cc/QB3H-ZDE6>] (“[H]ealth officials are prioritizing their contact tracing efforts ... as a way to limit the damage caused by [Omicron] ... [and] urging ... residents who have tested positive to inform close contacts about potential exposure on their own as soon as possible, or to use smartphone apps that allow those alerts to go out anonymously.”). See generally Hollingsworth & Caina Calvan, *supra* note 130.

137. See *Update on Omicron*, WORLD HEALTH ORG. (Nov. 28, 2021), <https://www.who.int/news/item/28-11-2021-update-on-omicron> [<https://perma.cc/AD2U-WSGE>] (providing an update on the COVID-19 Omicron variant that was discovered on November 26, 2021).

138. See, e.g., Olivo, *supra* note 136.

139. *Privacy-Preserving Contact Tracing*, APPLE, <https://covid19.apple.com/contacttracing> [<https://perma.cc/SX52-PQXE>].

140. *Id.*

141. See, e.g., Sarah Kellogg, *Every Breath You Take: Data Privacy and Your Wearable Fitness Device*, 72 J. MO. BAR 76, 77 (2016) (“The Apple Watch, like most Apple products, became a wearable industry leader even before it was shipped to stores in April 2015.”); Mike Peterson, *Apple Keeps Lead in Growing Smartwatch Market as Fitness Bands Decline*, APPLE INSIDER (Sept. 2, 2021), <https://appleinsider.com/articles/21/09/02/apple-keeps-lead-in-growing-smartwatch-market-as-fitness-bands-decline> [<https://perma.cc/A4XY-N5XJ>] (“In the smartwatch category ... Apple is still the top player.”); Kevin J. Ryan, *4 Things Google Does to Remain One of the World’s Most Innovative Companies*, INC. (June 3, 2016), <https://www.inc.com/kevin-j-ryan/how-google-remains-one-of-the-worlds-most-innovative-companies.html> [<https://perma.cc/D3L9-ZVJ4>] (“Google manages to innovate with the kind of dexterity and creativity that most young startups would love to have.... [T]he company [takes] on projects that are both ambitious and game-changing—and that, if successful, could impact humanity for the better.”).

the phrase “contact tracing,” and the FDA’s definition of medical device plainly reaches devices that perform such functions.<sup>142</sup> While smart wearables are not used, as of right now,<sup>143</sup> to diagnose COVID-19, the word “diagnos[e]” is not the only term provided in the FDA’s definition of medical device.<sup>144</sup> Significantly, the terms “mitigation” and “prevention” are included in the definition and must be given equal weight as the term “diagnos[e].”<sup>145</sup> Thus, as stated by the FDA’s own regulations and guidance, a medical device is one that is “intended for use in ... the ... mitigation ... or prevention of disease.”<sup>146</sup> Ergo, smart wearables that aid in mitigating and preventing a global pandemic clearly fall within the scope of the definition and should be regulated accordingly.

## 2. *Essential Aids for Monitoring COVID-19 Symptoms*

In addition to mitigation efforts, smart wearables have played an important role during the COVID-19 pandemic by monitoring COVID-19 patients and providing continuous, real-time physiological data regarding the patients’ existing symptoms. This allows for healthcare providers to work remotely with their patients, which has proven crucial during the COVID-19 pandemic.<sup>147</sup> Although it may seem unreliable to allow patients to have this much control over their healthcare data, “[t]he concept of patients wearing devices to connect with their healthcare data and treatment is not new.”<sup>148</sup> Even healthcare providers are becoming increasingly accepting of smart wearables as aids in their treatment plans.<sup>149</sup> The Healthcare

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142. See 21 U.S.C. § 321(h).

143. See *infra* Part III.C.2.

144. 21 U.S.C. § 321(h).

145. See *id.* The statute uses the word “or” when providing the different uses of a medical device; therefore, a device can be classified as a medical device if it is “intended for use in the diagnosis of disease ... or in the cure, *mitigation*, treatment, or *prevention* of disease.” *Id.* (emphasis added).

146. See *id.*

147. See Shilling, *supra* note 126, at 2.

148. *The Endless Possibilities of Wearable Technology in Healthcare*, HEALTHCARE INFO. & MGMT. SYS. SOC’Y (Apr. 28, 2021), <https://www.himss.org/resources/endless-possibilities-wearable-technology-healthcare> [<https://perma.cc/7TJA-RCBJ>] (“Diabetics wear glucose monitors. Implanted devices such as pacemakers and defibrillators provide a life-saving, intimate connection with patients.”).

149. See *id.*

Information and Management Systems Society conducted a survey that revealed “more than half of providers found wearable technology in healthcare helpful.”<sup>150</sup> The providers in the survey believed that the smart wearable devices were capable of assisting with the care they provide to their patients, but they demonstrated an interest in having more reliable methods of collecting and transmitting the data.<sup>151</sup> These concerns are the exact kind that the FDA is equipped to address.<sup>152</sup>

If smart wearables were classified as a medical device and subject to FDA regulations accordingly, then healthcare providers would trust the devices because they know that they have been subject to rigorous scrutiny and regulatory controls.<sup>153</sup> Thus, the FDA’s regulation of smart wearables would allow for the devices to be utilized more commonly and more effectively in the medical field, and providers, patients, the public at large, and the FDA would benefit from the increase in safety, innovation, and reliability.

### C. *The Future of Smart Wearables*

The future of smart wearables is here, and as smart wearable technological innovation progresses, devices will inevitably become more complex, and therefore potentially dangerous if not regulated appropriately. Many recently developed smart wearables undeniably function as medical devices per section 201(h) of the FDCA, and recent studies have even reported that smart wearables are able to detect diseases in humans.<sup>154</sup>

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150. *Id.* (discussing a survey regarding healthcare providers’ thoughts on commercial and personal smart wearables).

151. *See id.* (providing a list of the top concerns for patients using wearables, including patient technical issues, data not being accurate, and false alarms on the device).

152. *See What We Do, supra* note 19 (“The [FDA] is responsible for protecting the public health by ensuring the safety, efficacy, and security of ... medical devices ... [and] for advancing the public health by ... mak[ing] medical products more effective, safer, and more affordable.”).

153. *See Papandrea, supra* note 52, at 1109, 1111-12.

154. *See infra* Part III.C. *See generally* Xiao Li, Jessilyn Dunn, Denis Salins, Gao Zhou, Wenyu Zhou, Sophia Miryam Schüssler-Fiorenza Rose, Dalia Perelman, Elizabeth Colbert, Ryan Runge, Shannon Rego, Ria Sonecha, Somalee Datta, Tracey McLaughlin & Michael P. Snyder, *Digital Health: Tracking Physiomes and Activity Using Wearable Biosensors Reveals Useful Health-Related Information*, 15 PLOS BIOLOGY 1 (2017) (detailing the research methods and results for a study that found that “wearable devices were useful in

### 1. *Examples of Modernized Smart Wearable Technology*

As the FDA continues to resist regulating modernized smart wearables as medical devices, the agency will lag in innovation and technological progress. The medical field and the FDA appear to have discrepancies as to what they classify as medical conditions versus general health; this affects what types of devices are considered medical devices or general wellness devices. For example, the FDA issued guidance stating that the agency will not regulate devices that claim to encourage healthy eating, assist with weight loss goals, or improve mental acuity, instruction-following, concentration, decision-making, or logical ability.<sup>155</sup> Further, the FDA typically views conditions such as mental health, obesity, menstruation, and sexual function as relating to general wellness.<sup>156</sup> Despite the fact that many smart wearables are successful in mitigating the aforementioned conditions, the FDA considers them general wellness devices as long as the manufacturing company provides a disclaimer that they only intend for the device to “promote” or “encourag[e] a general state of health.”<sup>157</sup> However, this is an outdated mindset that the FDA needs to address.<sup>158</sup> Mental health and mental illnesses are a subgroup of medical conditions,<sup>159</sup> and many smart wearables are extremely effective in mitigating, preventing, and treating mental illnesses.<sup>160</sup> For the FDA to regard

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identification of early signs of Lyme disease and inflammatory responses”); Mishra et al., *supra* note 128 (describing a study that found that smart wearables are able to detect COVID-19 in presymptomatic individuals).

155. See FDA GENERAL WELLNESS GUIDANCE, *supra* note 48, at 3.

156. See, e.g., *id.*

157. *Id.*; see also *supra* Part I.A.2.

158. See Ranna Parekh, *What Is Mental Illness?*, AM. PSYCHIATRIC ASS'N (Aug. 2018), <https://www.psychiatry.org/patients-families/what-is-mental-illness> [<https://perma.cc/F4H7-M27Z>] (“We are continually expanding our understanding of how the human brain works, and treatments are available to help people successfully manage mental health conditions.”).

159. See *id.* (“Mental illness is nothing to be ashamed of. It is a medical problem, just like heart disease or diabetes.”). The article defines “mental health” as “involv[ing] effective functioning in daily activities resulting in [p]roductive activities[,] ... [h]ealthy relationships ... [and] [a]bility to adapt to change and cope with adversity” and further defines “mental illness” as “all diagnosable mental disorders—health conditions involving ... [s]ignificant changes in thinking, emotion and/or behavior ... [and] [d]istress and/or problems functioning.” *Id.*

160. Recall that a device that “mitigat[es]” and/or “prevent[s]” a disease or condition falls within the scope of the FDA’s definition of medical device. See 21 U.S.C. § 321(h) (defining medical “device”).

mitigation efforts against mental illness as nonmedical functions unworthy of regulation is unfair, out of touch, and flies in the face of its own definition of “medical device.”

Section 201(h) of the FDCA provides that a device that is “intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man” is a medical device subject to FDA regulation.<sup>161</sup> The following examples of smart wearables are capable of aiding in the *mitigation, treatment, prevention*, and possibly, the *diagnosis* of disease, as required by the statute. Thus, it is uncontestable, according to the plain language of the statute, that these smart wearables are medical devices according to section 201(h).

First, the Oura Ring (Oura) is a health-tracking wearable device worn on a person’s finger that monitors an individual’s vital signs.<sup>162</sup> The Oura has seven “precise research-grade”<sup>163</sup> infrared light sensors on the finger arteries to measure body temperature.<sup>164</sup> Subsequently, this data is used to “help [the user] predict [their] period each month, visualize [their] cycle, and even discover when [they] may be getting sick—sometimes even before [they] experience any symptoms.”<sup>165</sup> The Oura requires two weeks of use to establish a user’s baseline body temperature measurement, and then it continuously compares fluctuations in body temperature to the baseline.<sup>166</sup> By monitoring a user’s body temperature, the Oura tracks changes in hormone levels throughout a person’s menstrual cycle to customize the user’s daily health goals.<sup>167</sup> The Oura also has a blood pulse oximeter feature,<sup>168</sup> which in its generic form is regulated as a Class II medical device, but it remains unregulated when in the form of a smart wearable.<sup>169</sup>

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161. *Id.* § 321(h)(2).

162. See Danielle Dresden, *Oura Ring Review: What to Know*, MED. NEWS TODAY (Nov. 2, 2022), <https://www.medicalnewstoday.com/articles/oura-ring-review-brand-and-product> [<https://perma.cc/CJC8-QBLK>].

163. OURA, <https://ouraring.com/> [<https://perma.cc/PRJ4-6VK4>].

164. See Dresden, *supra* note 162.

165. OURA, *supra* note 163.

166. See Dresden, *supra* note 162.

167. See OURA, *supra* note 163.

168. See *Blood Oxygen Sensing (SpO2)*, OURA, <https://support.ouraring.com/hc/en-us/articles/7328398760851-Blood-Oxygen-Sensing-SpO2> [<https://perma.cc/F3T3-CVE2>].

169. See *supra* notes 56-57 and accompanying text.

Oura consistently promotes its device as a “science-backed,” “research grade” device that predicts bodily functions and prescribes treatment plans.<sup>170</sup> Significantly, Oura’s website details an ongoing study that is investigating whether the Oura Ring can predict COVID-19 in pre- and asymptomatic people.<sup>171</sup> The aim of the study is “to build an algorithm to identify patterns of, onset of, progression of, and recovery from, COVID-19.”<sup>172</sup> Despite the overwhelming evidence that the Oura Ring functions as a medical device, the Oura website provides a disclaimer (ironically, directly under the explanation of the study investigating whether the Oura can diagnose COVID-19): “Oura ring products and services are not medical devices, and are not intended to mitigate, prevent, treat, cure or diagnose any disease or condition. If you have any concerns about your health, please consult your doctor.”<sup>173</sup> And that simple statement, hidden on the website, is enough to bypass FDA regulations.

Neuroscientists and physicians developed a second smart wearable, the Apollo Neuro (Apollo), that “provides scientifically proven touch therapy” and is worn on the user’s wrist or ankle.<sup>174</sup> The Apollo website claims that the device is “proven to actively improve your health” by strengthening and rebalancing the autonomic nervous system.<sup>175</sup> Moreover, studies suggest that Apollo touch therapy “improve[d] the balance between the parasympathetic and sympathetic [nervous] systems” by increasing the user’s heart rate variability and cognitive performance.<sup>176</sup> Once again,

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170. See OURA, *supra* note 163.

171. See *UCSF TempPredict Study*, OURA (Aug. 31, 2020), <https://ouraring.com/blog/ucsf-tempredict-study/> [<https://perma.cc/3UGW-FNBX>].

172. *Id.*

173. *Id.*

174. APOLLO NEURO, <https://apolloneuro.com/> [<https://perma.cc/6Q6G-5RWL>]. For a full discussion of the neuroscience behind the Apollo device, see generally *Science*, APOLLO NEURO, <https://apolloneuro.com/pages/science> [<https://perma.cc/4UW8-54LF>].

175. See APOLLO NEURO, *supra* note 174.

176. *Clinical Study Validates that Apollo Improves Cognitive Performance and Heart Rate Variability (HRV)*, APOLLO NEURO (Mar. 22, 2021), <https://apolloneuro.com/blogs/news/clinical-study-validates-that-apollo-improves-cognitive-performance-and-heart-rate-variability-hrv#:~:text=Under%20the%20Apollo%20Test%20Group&text=With%20Apollo%20vibration%20patterns%20C%20participants,within%203%20minutes%20under%20stress> [<https://perma.cc/5NJW-SWKJ>]; Robert H. Shmerling, *Harvard Health Ad Watch: Can a Wearable Device Reduce Stress?*, HARV. HEALTH PUBL’G (Sept. 22, 2021), <https://www.health.harvard.edu/blog/harvard-health-ad-watch-can-a-wearable-device-reduce-stress-202109222601> [<https://perma.cc/QK8Z-GKMB>] (“Other preliminary studies reportedly show that [Apollo] users

unfortunately, the Apollo website provides a disclaimer stating that their device is not a medical device; thus, the Apollo is not subject to FDA regulations.<sup>177</sup>

The Oura and the Apollo devices are only two examples of the many modernized smart wearable technologies advanced in recent years. They are backed with robust scientific research because of their advanced and complex features, and they certainly satisfy the FDA's definition of medical device.<sup>178</sup> Failing to classify smart wearables, such as the Oura and Apollo, simply because their respective websites provide a disclaimer does not dispose of the fact that the devices satisfy the requirements of section 201(h) in that the smart wearables are used "in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease."<sup>179</sup> Subjecting smart wearables to FDA regulations follows naturally from the agency's fundamental goal: to place safe and effective medical devices on the market.<sup>180</sup> Therefore, in accordance with their own definition, the FDA should regulate smart wearables as medical devices.

## *2. Smart Wearables Are Capable of Detecting Infectious Diseases*

Researchers are on the verge of proving that smart wearables are capable of detecting infectious diseases, such as COVID-19, which will provide consequential aid during ongoing and future global pandemics. A primary danger of COVID-19 is how difficult it is to track the patterns of spread, especially for pre- and asymptomatic cases; however, current research suggests that smart wearables can be used to detect COVID-19 in presymptomatic individuals.<sup>181</sup>

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achieved deeper states of meditation, improvements in PTSD symptoms, and reduced use of narcotics and sleeping pills.”)

177. See *Science*, *supra* note 174.

178. See 21 U.S.C. § 321(h).

179. *Id.*

180. See *What We Do*, *supra* note 19; see also Shmerling, *supra* note 176 (arguing that the Apollo device puts consumers at risk because it essentially functions as a medical device yet has not been studied enough, and “none of the evidence presented would be adequate for FDA approval”).

181. See ‘*Stealth Transmission*’ Fuels Fast Spread of Coronavirus Outbreak, COLUM. PUB. HEALTH (Mar. 16, 2020), <https://www.publichealth.columbia.edu/public-health-now/news/>

Researchers used the heart rate monitor, steps, and sleep data from smart watches to investigate whether the devices could be used to detect presymptomatic cases of COVID-19.<sup>182</sup> The study resulted in several important findings: (1) “[a]bnormal resting heart rate (RHR) and heart rate-to-steps ratio are associated with COVID-19 illness,” (2) “COVID-19 illness alters steps and sleep patterns, which can be tracked using a wearable device,” and (3) there is an “[a]ssociation between heart rate signals and [COVID-19] symptoms.”<sup>183</sup> In conclusion, the study asserts that other types of physiological measurements obtained from smart wearables, such as “heart rate variability, respiration rate, skin temperature, blood oxygen saturation and electrocardiogram readings” will likely be able to “increase diagnostic sensitivity and perhaps even predict illness severity and symptoms.”<sup>184</sup> The established empirical data clearly suggests that smart wearables are—or eventually will be—capable of “the diagnosis of disease or other conditions, or in the ... mitigation, treatment, or prevention of disease, in man.”<sup>185</sup> Thus, smart wearables are unequivocally within the plain language of the definition of “medical device” per section 201(h) of the FDCA.<sup>186</sup>

## CONCLUSION

The modern world has exposed the dire need for smart wearables to be regulated as medical devices. The COVID-19 pandemic, the rise of telehealth services, and continuously evolving, increasingly complex technological advancements have established smart wearables as aids in the medical field. Particularly, physicians, scientists, and consumers consider—and utilize—smart wearables in the same manner as recognized medical devices. Regardless, the FDA maintains that smart wearables do not fall within the definition of

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stealth-transmission-fuels-fast-spread-coronavirus-outbreak[<https://perma.cc/83J3-8GKT>] (explaining that “stealth transmission” refers to undocumented cases of asymptomatic COVID-19 promoting the rapid spread of COVID-19); *see, e.g.*, Mishra et al., *supra* note 128, at 1208; H. Ceren Ates, Ali K. Yetisen, Firat Güder & Can Dincer, *Wearable Devices for the Detection of COVID-19*, 4 NATURE ELECS. 13, 13 (2021).

182. *See generally* Mishra et al., *supra* note 128.

183. *Id.* at 1209-13.

184. *Id.* at 1218.

185. 21 U.S.C. § 321(h) (defining a “medical device” subject to FDA regulations).

186. *See id.*



“medical device” per section 201(h) of the FDCA, but rather are only general wellness devices. However, loopholes exist in the FDA’s guidelines that cause smart wearables to remain virtually unregulated.

The FDA is in the best position to implement an objective standard clarifying that smart wearables will be regulated as medical devices. This Note proposes an amendment to the definition of “medical device.” The amendment includes replacing the subjective phrase “intended use” with objective language, such as “capable of.” This would provide an objective standard for determining the types of devices that qualify as medical devices by focusing on a device’s actual capabilities rather than the fickle, subjective intent of manufacturers. Overall, the amendment would provide clarity to smart wearable manufacturers and users. Finally, regulating smart wearables as medical devices would realign the FDA with its professed fundamental mission: protecting and advancing public health by ensuring safe, effective, and secure medical devices as well as encouraging innovation.<sup>187</sup>

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187. See *What We Do*, *supra* note 19.

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