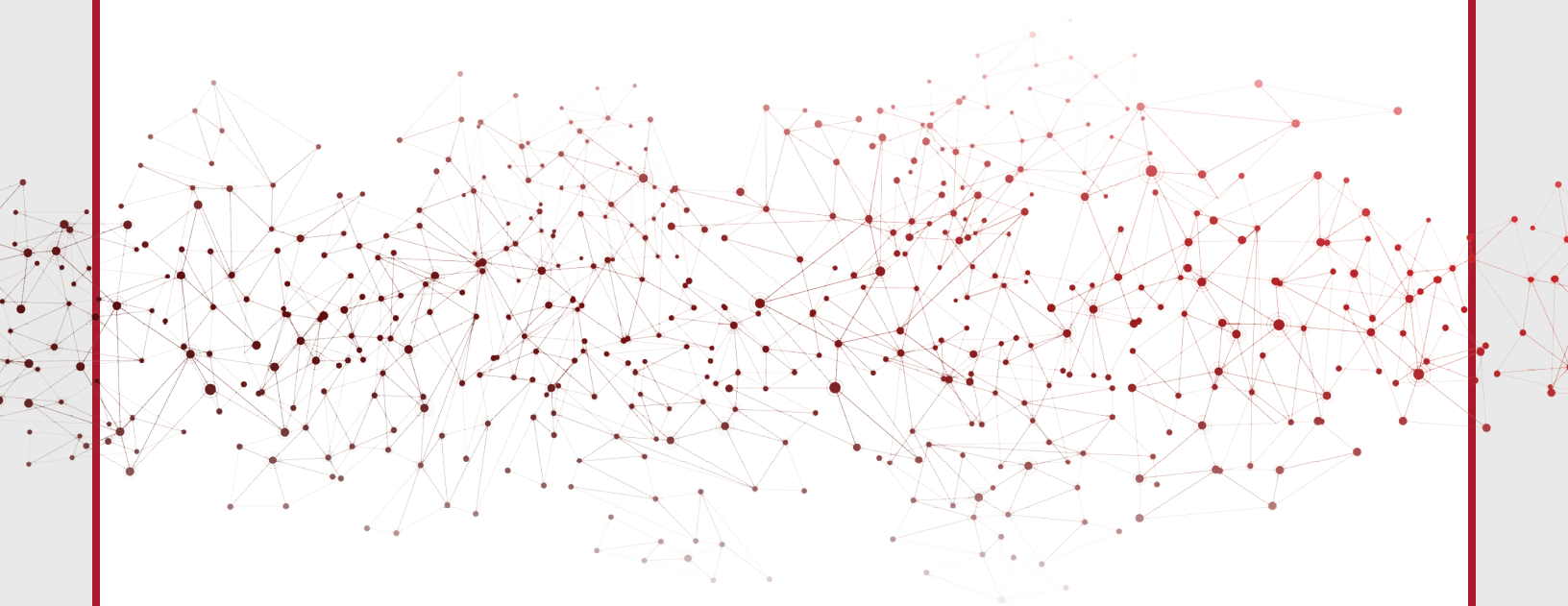


TECHNOLOGY PRIMERS FOR POLICYMAKERS

# Smart Wearables and Health



HARVARD Kennedy School

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Harvard John A. Paulson  
**School of Engineering**  
and Applied Sciences

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#### **AUTHORS**

**Sarith Felber** (Harvard Kennedy School)

**Dawid Maciorowski** (University of Cambridge / University of Wisconsin–Madison)

Ariel Higuchi, *Tech Primers Project Lead* (Harvard Kennedy School)

Amritha Jayanti (Harvard Kennedy School)

#### **REVIEWERS**

Zhenan Bao, PhD (Stanford University)

Lisa Cadmus-Bertram, PhD (University of Wisconsin–Madison)

Charles Odonkor, MD (Yale School of Medicine)

DJ Patil, PhD (GreatPoint Ventures)

Jessica Rich, JD (Kelley Drye & Warren)

David A. Simon, PhD, JD (Petrie-Flom Center, Harvard Law School)

Ariel D. Stern, PhD (Harvard Business School)

#### **FACULTY PRIMARY INVESTIGATOR**

Ash Carter, Faculty Director, Technology and Public Purpose Project, *in memoriam*

Francis J. Doyle III, Dean, Harvard John A. Paulson School of Engineering and Applied Sciences

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The Technology Primers for Policymakers Series was designed to provide a brief overview of each technology and related policy considerations. These papers are not meant to be exhaustive.

## **Technology and Public Purpose Project**

Belfer Center for Science and International Affairs  
Harvard Kennedy School  
79 John F. Kennedy Street, Cambridge, MA 02138

**[www.belfercenter.org/TAPP](http://www.belfercenter.org/TAPP)**

## **Harvard John A. Paulson School of Engineering and Applied Sciences**

29 Oxford Street, Cambridge, MA 02138

**[www.seas.harvard.edu](http://www.seas.harvard.edu)**

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# Executive Summary

Smart wearables in the context of health refer to electronic technologies that are worn on an individual's body to collect physiological information on a real-time basis to help an individual make health-related decisions. There is **no standard definition or classification** of smart wearables.

Smart wearables are quickly becoming the next wave of ubiquitous technologies due to their **vast market penetration and broad utility**. Smart wearables can collect a wide variety of relevant health information from users that may be useful in managing an individual's health, such as to track heart rate, sleep patterns, heart rhythm, body temperature, blood pressure, energy expenditure, and more. In the healthcare setting, smart wearables may be used to advance preventative health measures (identifying amenable health behaviors such as physical activity), emergency medicine (real-time situational data transfer), and primary care (chronic disease management). Smart wearables have the potential to revolutionize the way that healthcare is done, but major technical and nontechnical limitations exist.

The smart wearables market is rapidly growing. In 2020, about **one in five people** in the United States used a smartwatch or other fitness tracker. However, diffusion and retention of smart wearables are relatively lacking due to factors such as cost and technical misunderstandings of the technologies.

The emerging role of smart wearables in healthcare is becoming more evident, but the regulation of these technologies is still **underdeveloped**. Public purpose considerations include challenges related to the protection and security of personal health information, the use of personal health information for marketing purposes, insurance considerations of data gathered, and managing users' expectations of the technologies.

# PART 1: Technology

## What Are Smart Wearables?

There is no standard legal definition of smart wearables,<sup>1</sup> but this term is usually used to describe small software-based electronic products and devices that are placed on or close to the body.

**Examples of wearables include** data-sensing mobile apps, watches, rings, bands, jewelry, patches, textile, hearing aids, etc. They are usually characterized by the following elements: (1) noninvasive or minimally invasive electronic devices; (2) designed to be worn on the user's body (but removable) or incorporated into clothes or other accessories; (3) use sensors that can capture different physiological, behavioral, and environmental data (bodily movements and functions, vital signs, bioelectrical activity, voice tone, etc.); and (4) continuously monitor, track, store, and analyze users' data and have the ability to transmit this information over the internet.

**Smart wearables are mainly used in the health sector and wellness industry:** Wearables monitor and track a person's condition in real time. Through constant monitoring and their connectivity functions, wearables can be used for immediate detection of patient physiological signs and provide exercise guidance, urge for a visit with a medical professional, drug administration reminders, and more.

### COMMON BIOMARKERS TRACKED BY WEARABLES

Heart rate and rhythm, respiratory rate, blood pressure, body temperature, blood oxygen saturation, posture, physical activities, sleep quality, etc.

**Smart wearables - the distinction between medical devices and wellness products:** From a regulatory perspective, smart wearables could be classified as either general wellness products or medical devices. *General wellness products* are not subject to strict Food and Drug Administration (FDA) regulations (but may be subject to other regulations), while *medical devices* are FDA regulated and some might be prescribed by a medical professional. The main distinctions between these two categories are **their intended use and level of risk**. *Wellness products* are low-risk products, that can include software, whose intended use is to encourage a healthy lifestyle. *Medical devices* intended uses are diagnosis, mitigation or treatment of diseases, or health conditions.

<sup>1</sup> See definitions at Jan Benedikt Brönneke et al., "Regulatory, Legal, and Market Aspects of Smart Wearables for Cardiac Monitoring," *Sensors* 21, no. 14 (July 2021); and at Matthew Smuck et al., "The Emerging Clinical Role of Wearables: Factors for Successful Implementation in Health-care," *Npj Digital Medicine* 4, no. 1 (2021): 45, <https://doi.org/10.1038/s41746-021-00418-3>.

Drawing the line between these two categories becomes more challenging as smart wearables become “smarter” and can provide health-related services to their users.<sup>2</sup> The narrowing distinction between smart wearable wellness products and medical devices is discussed in greater detail in Part 3: Governance and Regulation.

## Related Technologies

Wearable devices deploy several technologies to collect and deliver data and insights, including:

**Big data:** As wearables continuously monitor users’ activities and other bodily signals, they collect vast and varied data that cannot be collected from a limited clinical setting. This data is often analyzed by machine learning algorithms that can learn useful patterns.

**Artificial intelligence and machine learning:**<sup>3</sup> Machine learning (ML) is a subset of artificial intelligence (AI) through which computer programs (algorithms) run statistical models on vast quantities of data to learn associations between different data points, identify patterns, and make predictions.<sup>4</sup>

There are ongoing discussions about the ways AI/ML could improve the healthcare industry and healthcare delivery.<sup>5</sup> Wearables play a part in this transformation as an important source of data to train algorithms. Data from wearables help the development of ML models to associate certain biomarkers with a risk of medical conditions. These models can then detect anomalies that may indicate a risk of infection. AI/ML are also at the core of some wearable functions. For example, Apple Watch’s algorithm was trained on historical data to distinguish between “normal” electrocardiogram (ECG) results and those that may indicate increased risk.

**Internet of Things (IoT):** In the health context, IoT refers to the ability of wearables to connect to each other and to the internet. Internet connection enables sending and receiving data collected from wearables and the transmission of the data to a cloud where it is stored and analyzed (most wearables do

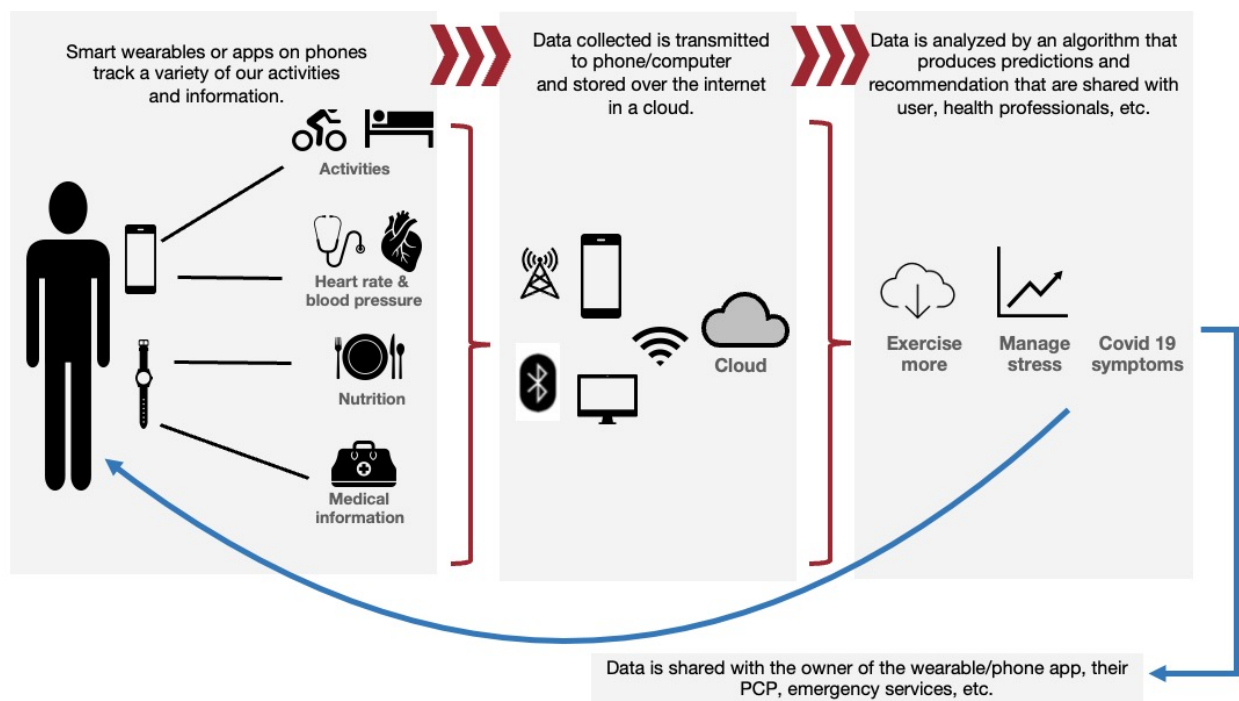
- 
- 2 For an elaborated discussion about the “blurry line” between general wellness products and medical devices, see David A. Simon, Carmel Shachar, and Glenn Cohen, “Skating the Line between General Wellness Products and Regulated Devices: Strategies and Implications,” *Journal of Law and the Biosciences* 9, no. 2 (July 2022).
  - 3 For a more detailed overview of AI and ML, see Eddine Abail, Issam, Gopal Nadadur, Enrico Santus, Ariel Higuchi and Amritha Jayanti. “Technology Primer: Artificial Intelligence & Machine Learning.” Edited by Nicolas Christin, Susan Ritchie and Daniel Zhang. Belfer Center for Science and International Affairs, Harvard Kennedy School, April 6, 2023.
  - 4 Solveig Badillo et al., “An Introduction to Machine Learning,” *Clinical Pharmacology & Therapeutics* 107, no. 4 (2020): 871–85.
  - 5 Samantha F. Sanders, Mats Terwiesch, William J. Gordon, and Ariel D. Stern, “How Artificial Intelligence Is Changing Health Care Delivery,” *NEJM Catalyst* (October 2019); Thomas Davenport, and Ravi Kalakota, “The Potential for Artificial Intelligence in Healthcare,” *Future Healthcare Journal* 6, no. 2 (2019): 94–98; Timo Minssen et al., “Regulatory Responses to Medical Machine Learning,” *Journal of Law and the Biosciences* 7, no. 1 (July 2020).

not have the computational power to run a complex analysis).<sup>6</sup> Connectivity to the internet also permits notifications to healthcare teams who can remotely monitor the user and identify possible worrisome changes in a user's vital signs.

**Cloud computing:** As the volume of data collected through wearables increases, and due to the devices' limited storage, there is a need for more storage space and computational power to run analytics processes. Cloud computing technologies grant access to data storage and computational capabilities.

**Sensors:** Advanced wearables aim to continuously monitor various physiological and environmental information such as movement, distance, or heart rate to provide meaningful information to users and sometimes to clinicians. To do so, wearables deploy advanced sensors that are equipped with transmitting capabilities through the internet or cellular networks.<sup>7</sup> The type of sensors often used in wearable products are pedometers that function as step counters, accelerometers or gyroscopes. By sensing and measuring the user's different movements, sensors provide information about speed, distance covered, rate (sometimes combined with a GPS), sedentary time, and sleep patterns.<sup>8</sup> Heart rate sensors (optical or electrical, such as an ECG) measure heart rhythm and can detect cardiovascular abnormalities. Pulse oximeter sensors measure levels of oxygen in the blood.<sup>9</sup> There are also sensors to measure skin temperature, blood glucose, etc.<sup>10</sup>

**Figure 1.** The Lifecycle of Smart Wearables



<sup>6</sup> Ibid.

<sup>7</sup> Ibid., table 1.

<sup>8</sup> Vini Vijayan et al., "Review of Wearable Devices and Data Collection Considerations for Connected Health," *Sensors* 21, no. 16 (August 2021).

<sup>9</sup> Wearables and the IoT. We address the limitation of pulse oximeters in medical devices and in wellness products in the limitations section.

<sup>10</sup> Aroganam Ibid, Gobinath, Nadarajah Manivannan, and David Harrison. "Review on Wearable Technology Sensors Used in Consumer Sport Applications," *Sensors* 19, no. 9 (April 2019).

# PART 2: Applications and Market Overview

## How Are Smart Wearables Being Used?

The scope of use of wearables is substantially broad and spans from research and wellness purposes to the diagnosis and treatment of health conditions. The challenges and limitations of these applications will be addressed in the next section.

### Applications

**Physical activity and healthy lifestyle:** Physical inactivity is considered a threat to the population's health, as it increases the risks for major diseases and is even considered a contributor to premature morbidity. Wearables, such as smartwatches or fitness trackers, can play a part in encouraging a healthier lifestyle that includes more physical activity. Research has shown that using wearables and trackers is associated with positive physiological results, such as lower body mass index, reduced blood pressure, etc.<sup>11</sup>

The increased popularity of these products and their potential to contribute to a healthier lifestyle might be linked to their accessibility and techniques deployed. In terms of **accessibility**, there are a variety of products at a wide range of prices; they are easy to carry as they are usually small and aesthetic, and, to some extent, user-friendly. Wearables deploy **behavioral techniques** to encourage people to engage in healthier lifestyles, such as goal setting, self-monitoring, or group interactions. Lastly, wearables **reduce monetary and psychological barriers** associated with more structured forms of fitness (such as gyms, fitness classes, etc.).<sup>12</sup>

### DEEPER DIVE: THE USE OF SMART WEARABLES TO MEASURE PHYSICAL ACTIVITY

Physical activity is essential for a healthy lifestyle;<sup>13</sup> how should we measure it and how do wearables help?

**Without smart wearables** physical activity measurement is mainly based on subjective

11 Ty Ferguson, et al., "Effectiveness of Wearable Activity Trackers to Increase Physical Activity and Improve Health: A Systematic Review of Systematic Reviews and Meta-Analyses," *Lancet Digital Health* 4, no. 8 (2022).

12 Ibid. Though it might not be effective in the long term, see Emily Fawcett, Michelle Helena Van Velthoven, and Edward Meinert, "Long-Term Weight Management Using Wearable Technology in Overweight and Obese Adults: Systematic Review," *JMIR MHealth and UHealth* 8, no. 3 (March 2020). In addition there are also concerns that it may encourage obsessive and unhealthy behaviors.

13 See, for example, the recommendations by the American Heart Association: "Life's Essential 8™: Your Checklist for Lifelong Good Health," American Heart Association, accessed September 2, 2022, <https://www.heart.org/en/healthy-living/healthy-lifestyle/lifes-essential-8>.

assessments or direct observations:<sup>14</sup>

- **Subjective assessments:** “I walk three times a week for 30 minutes.”
  - The problem: subjective assessments lack information such as intensity, rest time, etc.
- **Direct observations:** Running on a treadmill at a clinic or wearing a designated device.
  - The problem: Limited scope and time period, not easily accessible (requires arriving at the clinic).

**Smart wearables** can improve the way we assess a person’s level of physical activity and whether it is satisfactory considering the specific characteristics of each user:

- **Objective and continuous assessment:**
  - A smartwatch, for example, could be worn throughout the day and detect all kinds of activities in a real-life environment (sedentary time, sleep, etc.). Some are suited for long-term data collection (months or years), providing information about trajectories of change over time.
- **Variety of information:**
  - Smart wearables record a range of relevant information through the user’s input and their sensors: motion, heartbeat, symptoms, etc.
  - Connectivity to the internet and with other products or apps allows for the integration of even more information about the user.
- **Analysis and predictions:**
  - Using algorithms, a smart wearable could identify patterns and provide personal feedback about the desirable level of physical activity and can raise specific concerns about the user’s health.

**Sleep regulation:** These technologies allow users to confer their sleep data without extensive engagement from the users. The health benefits of sleep are becoming more understood, from immune system regulation and memory processing to weight management. Some of the major components of sleep health include: a) the number of hours of sleep you need each night (7–9); b) the quality of sleep; and c) types of sleep cycles, all of which can be measured with several wearable devices.

**Early detection and the spread of disease:** Wearables can potentially monitor users’ physiological signs continuously. If accurate enough, they can detect subtle changes in the user’s physiological markers that otherwise may go unnoticed,<sup>15</sup> and lead to faster diagnosis (and treatment) of diseases.<sup>16</sup> For example, recent research shows that data retrieved from smartwatches, such as heart rate, physical activity, and sleep patterns, could detect pre-symptomatic cases of COVID-19.<sup>17</sup>

14 Karim Bayoumy, et al., “Smart wearable devices in cardiovascular care: where we are and how to move forward,” *Nature Reviews Cardiology* 18, no. 8 (2021): 581–99.

15 “Wearable Devices Measure a Growing Array of Health Indicators,” *Economist*, May 2, 2022, <https://www.economist.com/technology-quarterly/2022/05/02/wearable-devices-measure-a-growing-array-of-health-indicators>.

16 Jessilyn Dunn, Ryan Runge, and Michael Snyder, “Wearables and the Medical Revolution,” *Personalized Medicine* 15, no. 5 (2018): 429–48.

17 For a review of the research see: H. Ceren Ates, Ali K. Yetisen, Firat Güder, and Can Dincer. “Wearable Devices for the Detection of COVID-19,” *Nature Electronics* 4, no. 1 (2021); Arash Alavi et al., “Real-Time Alerting System for COVID-19 and Other Stress Events Using Wearable Data,” *Nature Medicine* 28, no. 1 (2022).

Wearables could also contribute to the early detection of disease dispersion. Widely used wearables provide data about the population and help create a baseline for the population. Real-time data from the same wearables could show an uptick in measurements that may indicate the spread of certain diseases, such as the flu.<sup>18</sup>

**Mental health:** Data collected by wearables could also provide information about the user's mental health (anxiety, depression, stress, etc.). Such information includes physiological signs such as sleep patterns, heart rate, blood pressure, etc. Wearables could also detect contextual behavioral data:<sup>19</sup> changes in the tone of voice, erratic use of phone, etc.<sup>20</sup> Analysis of the combined data can assist in detecting mood disorders or other symptoms associated with mental health conditions.

**Remote patient monitoring:** Virtual health service gained some momentum even before the COVID-19 pandemic due to the growing recognition of the benefit of remote care, including the potential to improve care for populations with barriers to in-person care (due to travel limitations, health risks, etc.). This trend and recognition expanded during the COVID-19 pandemic, especially for chronic conditions.<sup>21</sup> Wearables are part of this transformation. Physicians are integrating data from wearables to help patients make sense of this data and to assess their conditions.<sup>22</sup> In addition, wearables could facilitate recovery in outpatient settings by allowing doctors to monitor patients in real time and follow their recovery, their reactions to medical treatments, etc. Continuous monitoring by wearables helps in monitoring patients with chronic conditions, such as diabetes or epilepsy,<sup>23</sup> or other at-risk populations, such as the elderly. Wearables can detect signs of instability or other relevant physiological signs and quickly alert a primary care physician, family, or even first responders.<sup>24</sup>

**Electronic health records:** Some companies, such as Apple, have created health apps that integrate health data from different sources, including verified health records and information from wearables. The data

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18 Jennifer M. Radin, Nathan E Wineinger, Eric J Topol, and Steven R Steinhilbl, "Harnessing Wearable Device Data to Improve State-Level Real-Time Surveillance of Influenza-like Illness in the USA: A Population-Based Study," *Lancet Digital Health* 2, no. 2 (2020): e85–93; "Data from Wearable Devices Are Changing Disease Surveillance and Medical Research," *Economist*, May 2, 2022, <https://www.economist.com/technology-quarterly/2022/05/02/data-from-wearable-devices-are-changing-disease-surveillance-and-medical-research>.

19 Shruti Gedam, and Sanchita Paul. "A Review on Mental Stress Detection Using Wearable Sensors and Machine Learning Techniques," *IEEE Access* 9 (2021).

20 Maulik Majmudar, "A New Tool to Help You Understand and Improve Your Social Wellbeing," August 27, 2020, <https://www.aboutamazon.com/news/devices/a-new-tool-to-help-you-understand-and-improve-your-social-wellbeing>. A blog post by Amazon's medical officer describing the company's wrist band functions regarding wellbeing and mental health.

21 Mitchell Tang, Ateev Mehrotra, and Ariel D. Stern. "Rapid Growth of Remote Patient Monitoring Is Driven by a Small Number of Primary Care Providers: Study Examines the Growth of Remote Patient Monitoring," *Health Affairs* 41, no. 9 (September 2022): 1248–54.

22 Ken Abrams, Urvie Shah, Casey Korba, and Natasha Elsner, "How the Virtual Health Landscape Is Shifting in a Rapidly Changing World - Findings from the Deloitte 2020 Survey of US Physicians," *Deloitte Insights* (New York: Deloitte, 2020), [https://www2.deloitte.com/content/dam/insights/us/articles/6668\\_CHS-virtual-health/DI\\_CHS-virtual-health.pdf](https://www2.deloitte.com/content/dam/insights/us/articles/6668_CHS-virtual-health/DI_CHS-virtual-health.pdf).

23 For a discussion about the reasons patients might be reluctant to adopt apps for managing chronic disease see: Robert S. Huckman, and Ariel D. Stern, "Why Apps for Managing Chronic Disease Haven't Been Widely Used, and How to Fix It," *Harvard Business Review*, April 4, 2018, <https://hbr.org/2018/04/why-apps-for-managing-chronic-disease-havent-been-widely-used-and-how-to-fix-it>; Christine E. King, and Majid Sarrafzadeh, "A Survey of Smartwatches in Remote Health Monitoring," *Journal of Healthcare Informatics Research* 2, no. 1 (June 2018).

24 Gerald Wilmink et al., "Artificial Intelligence-Powered Digital Health Platform and Wearable Devices Improve Outcomes for Older Adults in Assisted Living Communities: Pilot Intervention Study," *JMIR Aging* 3, no. 2 (September 2020).

integrated into the app can be made available to the user's clinician who can review the patient's heart rate, sleep or exercise routine. Viewing this information allows the clinician to make more informed decisions regarding certain aspects of their patient's health.

**Precision health and personalized medicine:**<sup>25</sup> Precision health is an approach that seeks to develop personalized solutions to health conditions, namely disease detection, prevention, and treatment. According to this approach, a broad range of individual factors, such as genetics, environment, and behaviors (physical activity or eating habits) can affect a person's health. Precision health aims to use data to "tailor" an intervention that will fit each person's characteristics rather than using a "one-size-fits-all" approach.<sup>26</sup> Aggregated data collected from wearable technologies that continuously monitor different signs, together with additional data (medical history, etc.), may improve the understanding of individuals' health,<sup>27</sup> and thus help "tailor" treatments to the specific characteristics of each patient.<sup>28</sup> Furthermore, personalized risk profiles in combination with wearables that may detect changes or deviations from an individual's baseline could contribute to better and faster detection of health conditions that require treatment.<sup>29</sup>

The advancement of precision health (and medicine) requires comprehensive and diverse health data from large populations for clinical research. Traditionally, a small sample size and a lack of diversity among participants in medical research led to treatments that were designed for the "average patient." These restrictions decreased the generality of research findings and may have also led to wrong interpretations of examination results.<sup>30</sup>

There are several initiatives to create wider and more inclusive data sets for medical research, such as the All of Us Research Program administered by the National Institutes of Health. This program aims to engage one million participants who have agreed to share their health data toward research. Acknowledging the potential of wearables to contribute to the advancement of precision health, the program also collects data from smartphone apps and wearables (participants can receive a free Fitbit). The use of smart wearables will also help to expand existing data sets to explore "the relationship between physical activity, heart rate, sleep, and other health metrics, along with health outcomes."<sup>31</sup>

25 The terms "precision health" and "precision medicine" are both used in this context. We use the term "precision health" to go along with the Centers for Disease Control and Prevention's distinction between the two terms, however, we acknowledge that some of the concepts in this section also apply to precision and personalized medicine.

26 "Precision Health: Improving Health for Each of Us and All of Us,," Centers for Disease Control and Prevention, September 13, 2022, [https://www.cdc.gov/genomics/about/precision\\_med.htm](https://www.cdc.gov/genomics/about/precision_med.htm); Jillian C. Ryan, John Noel Viana, Hamza Sellak, Shakuntla Gondalia, and Nathan O'Callaghan, "Defining Precision Health: A Scoping Review Protocol," *BMJ Open* 11, no. 2 (2021).

27 Sanjiv S. Gambhir et al., "Continuous Health Monitoring: An Opportunity for Precision Health," *Science Translational Medicine* 13, no. 597 (June 2021).

28 J.M. Radin et al., "The Hopes and Hazards of Using Personal Health Technologies in the Diagnosis and Prognosis of Infections," *Lancet Digital Health* 3, no. 7 (2021).

29 Ibid.

30 All of Us Research Program Investigators, "The 'All of Us' Research Program," *New England Journal of Medicine* 381, no. 7 (August 2019).

31 Scripps Research Institute "Through 'All of Us' Program, Scripps Research Launches Wearable Technology Study to Accelerate Precision Medicine." Press release, February 24, 2021 <https://www.scripps.edu/news-and-events/press-room/2021/20210224-aou-fitbit-study.html>

## Technical and Nontechnical Limitations of the Technology

**Accuracy:** This refers to the wearable's ability to produce a reliable and accurate measurement of physiological and other signs, similar to “gold standard” devices utilized in clinical settings. Inaccurate measurements cannot be used as a source for decision-making by users and clinicians.<sup>32</sup> Several studies examining the accuracy of wrist-worn consumer-grade wearables found that their level of accuracy varies between devices and functions. A meta-analysis from 2020 found that products such as Apple Watch, Fitbit, and Garmin were relatively reliable when counting steps and measuring heart rate, however, they were less accurate during rest and when measuring energy expenditure.<sup>33</sup> These results are consistent with a newer study that examined products such as Apple Watch and Fitbit.<sup>34</sup> Wearable companies release new models periodically that might improve accuracy relative to products examined in the aforementioned studies, however, they acknowledge in their terms of service that the accuracy of their products “is not intended to match that of a medical device.”<sup>35</sup>

Accuracy concerns (and regulatory barriers) are one of the main reasons why the use of wearable products that are not FDA-cleared remain limited in clinical settings.<sup>36</sup> Accuracy limitations are associated with several factors:

- a. **Technological limitations.** The advantage of wearables is their accessibility and **noninvasiveness**, but that may limit their measurement. Consumer-grade wearables also have to take into consideration aesthetics and comfort of use, which can lead to **suboptimal design**, such as measurement from a single point on the body,<sup>37</sup> or measuring heart rate from the wrist rather than from the chest. There are concerns that accuracy might be influenced by the **skin tone** and weight of the user due to sensor limitations (consumer-grade wearables using photoplethysmography sensors to measure heart rate might be less accurate when used on darker skin tones).<sup>38</sup>
- b. **Lack of diversity** in the training and validation of smart wearables. For example, pulse oximetry

32 Jason D. Stone et al., “Assessing the Accuracy of Popular Commercial Technologies That Measure Resting Heart Rate and Heart Rate Variability,” *Frontiers in Sports and Active Living* 3 (March 2021).

33 Daniel Fuller et al., “Reliability and Validity of Commercially Available Wearable Devices for Measuring Steps, Energy Expenditure, and Heart Rate: Systematic Review,” *JMIR MHealth and UHealth* 8, no. 9 (September 2020).

34 Guy Hajj-Boutros et al., “Wrist-Worn Devices for the Measurement of Heart Rate and Energy Expenditure: A Validation Study for the Apple Watch 6, Polar Vantage V and Fitbit Sense,” *European Journal of Sport Science* 23, no. 2. (January 2022): 1–13.

35 For example, Fitbit clarifies that “the accuracy of the data collected and presented through the Fitbit Service is not intended to match that of medical devices or scientific measurement devices”. Fitbit Terms of Service, July 2021, <https://www.fitbit.com/global/us/legal/terms-of-service>.

36 William J. Gordon, Adam Landman, Haipeng Zhang, and David W. Bates, “Beyond Validation: Getting Health Apps into Clinical Practice,” *Npj Digital Medicine* 3, no. 1 (2020): 14, <https://doi.org/10.1038/s41746-019-0212-z>.

37 “Unlocking Our Personal Health Through Smart(Er) Wearables,” University of Massachusetts, Amherst, accessed October 4, 2022, <https://www.umass.edu/gateway/article/unlocking-our-personal-health-through-smarter-wearables>.

38 Tananant Boonya-Ananta Ajmal, Andres J. Rodriguez, V. N. Du Le, and Jessica C. Ramella-Roman, “Monte Carlo Analysis of Optical Heart Rate Sensors in Commercial Wearables: The Effect of Skin Tone and Obesity on the Photoplethysmography (PPG) Signal,” *Biomedical Optics Express* 12, no. 12 (December 2021).

devices are less accurate in people with darker skin. This inaccuracy may be influenced by the fact that “its original development [was] in populations that were not racially diverse.”<sup>39</sup> The FDA requires reporting of demographic subgroups to mitigate such risks,<sup>40</sup> but as most wellness products are not FDA-cleared, they do not need to adhere to this requirement, which may increase the risk of inaccurate results among different subgroups (pulse oximeters are also available for “wellness purposes” in smartwatches).<sup>41</sup>

- c. **User errors:** Accuracy is also dependent on how users utilize them. Some wearable products depend on inputs from the user (height, weight, food) or are influenced by the way users are wearing the product; a misuse or an error in the inputs could lead to inaccuracies. Errors can also occur when the operating system is not updated correctly.<sup>42</sup>

**Battery:** A significant feature of smart wearables is their continuous monitoring. The need to charge the wearable, separately from the user, might interrupt the measurement sequence. One of the challenges of wearables is extending battery life or providing other charging methods. Batteries also present some safety concerns as they might overheat and harm the user or lose effectiveness.<sup>43</sup>

**Interoperability:** Data from wearables are not typically interoperable as there is no clear standard for data-sharing that limits its research and clinical use. Interoperability is based on whether interconnected devices can perform connections, transfer data, and then function successfully after the data is transferred. If smart wearables are to have a more significant role in medicine, standardization of interoperability will need to be explored.

**Equity:** Access to digital health technologies in lower-income households lags behind middle and upper-income households. Low-income households are less likely to have a smartphone, wearable, and broadband.<sup>44</sup> This may lead to a lack of diversity in clinical research using smart wearables and phone apps.<sup>45</sup> It could also increase the already existing health gaps in the United States.

39 Michael W. Sjoding et al., “Racial Bias in Pulse Oximetry Measurement,” *New England Journal of Medicine* 383, no. 25 (December 2020).

40 “FDASIA Section 907: Inclusion of Demographic Subgroups in Clinical Trials,” U.S. Food and Drug Administration (FDA), March 28, 2018, <https://www.fda.gov/regulatory-information/food-and-drug-administration-safety-and-innovation-act-fdasia/fdasia-section-907-inclusion-demographic-subgroups-clinical-trials>.

41 Health, Center for Devices and Radiological, “Pulse Oximeter Accuracy and Limitations: FDA Safety Communication,” FDA, June 21, 2022, <https://www.fda.gov/medical-devices/safety-communications/pulse-oximeter-accuracy-and-limitations-fda-safety-communication>.

42 Carmel Shachar et al., “When Is a Change Significant? The Update Problem of Apps in Medical and Behavioral Research,” *Ethics & Human Research* 44, no. 3 (2022).

43 For example, recently Fitbit recalled its Ionic smartwatch due to a burn hazard. “Fitbit Recalls Ionic Smartwatches Due to Burn Hazard; One Million Sold in the U.S.,” U.S. Consumer Product Safety Commission, March 02, 2022, <https://www.cpsc.gov/Recalls/2022/Fitbit-Recalls-Ionic-Smartwatches-Due-to-Burn-Hazard-One-Million-Sold-in-the-U-S>.

44 Emily A. Vogels, “Digital Divide Persists Even as Americans with Lower Incomes Make Gains in Tech Adoption,” *Pew Research Center* (blog), June 22, 2021, <https://www.pewresearch.org/fact-tank/2021/06/22/digital-divide-persists-even-as-americans-with-lower-incomes-make-gains-in-tech-adoption/>.

45 Michelle Holko et al., “Wearable Fitness Tracker Use in Federally Qualified Health Center Patients: Strategies to Improve the Health of All of Us Using Digital Health Devices,” *Npj Digital Medicine* 5, no. 1 (2022).

**Low user retention:** Surveys indicate low retention and adoption particularly among older populations who stand to gain from this technology. Low retention is linked to costs, lack of persistence and understanding of how these devices work, or full engagement with device features.<sup>46</sup>

**Privacy:** The scope of data collected by wearables is broad and includes sensitive data. This massive data collection raises concerns and challenges regarding users' privacy, such as the use of information by third parties, security breaches, ownership of data, etc. These concerns may decrease users' engagement with these products.

**Regulation:** There are several federal and state regulations governing aspects related to wearables (privacy, IoT, health, consumer protections, etc.), but there is no specific law for wearables products, which generates uncertainty among developers and users regarding their rights and obligations. (The authors expand on this issue in Part 3: Governance and Regulations and Part 4: Public Purpose Considerations).

## Product Market Landscape

**Wearables are popular among consumers and investors:** In 2020 about one in five Americans used a smartwatch or other fitness tracker.<sup>47</sup> It is reasonable to assume that this number has increased as shipments of smartwatches and fitness trackers increased from 158M in 2019 to 197M in 2021 worldwide,<sup>48</sup> and is expected to increase even more as seen in figure 2. As also seen in figure 2, this trend is not unique to wellness products but also to wearable medical devices. Health-related wearables companies gained traction from investors. The investment in these companies increased by 78 percent from 2019 to 2020.<sup>49</sup> In addition, wearables sensors technology was among the top-funded digital health technologies in 2020; telemedicine led the funding with \$3.2B and wearables sensors technology was in fourth place with \$703M.<sup>50</sup> While these trends have slowed down in 2022 there are still significant investments in this technology.<sup>51</sup>

<sup>46</sup> Statista, "Digital Health Trends 2022."

<sup>47</sup> Emily A. Vogels, "About One-in-Five Americans Use a Smartwatch or Fitness Tracker," *Pew Research Center* (blog), January 9, 2020, <https://www.pewresearch.org/fact-tank/2020/01/09/about-one-in-five-americans-use-a-smart-watch-or-fitness-tracker/>.

<sup>48</sup> CCS insights "Wearables: Turning the Lens on Wearable Tech," 2020, accessed March 15, 2023.

<sup>49</sup> "Digital Health Wearable Makers Raised \$815 Million in 2020," *Mercom Capital Group* (blog), February 24, 2021, <https://mercomcapital.com/digital-health-wearable-makers-raised-815-million-in-2020/>.

<sup>50</sup> Mercom Capital Group, "9M and Q3 2020 Digital Health (Healthcare IT) Funding and M&A Report," <https://mercomcapital.com/product/9m-and-q3-2020-digital-health-healthcare-it-funding-and-ma-report/>, accessed March 15, 2023.

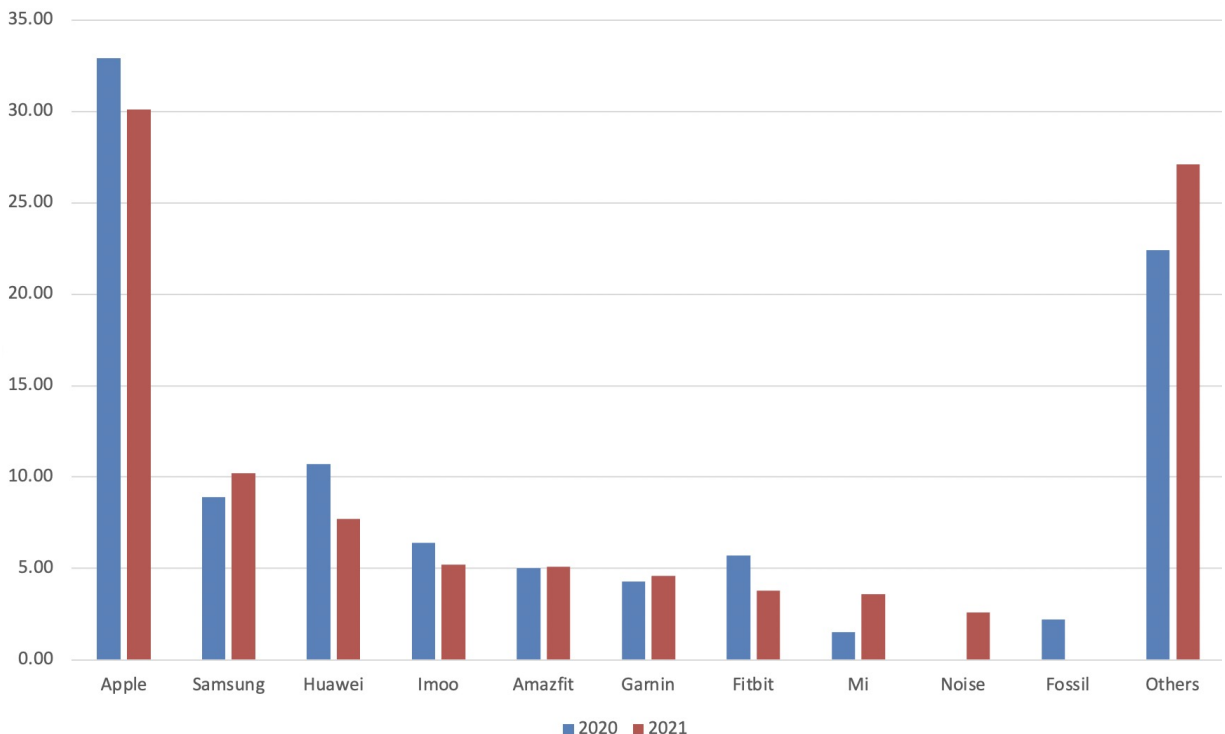
<sup>51</sup> Brock E. W. Turner, "5 Takeaways from the Q3 Digital Health Funding Report," *Digital Health Business & Technology*, October 18, 2022, <https://digitalhealth.modernhealthcare.com/digital-health/q3-digital-health-funding-has-new-york-surpassed-california>.

**Figure 2.**<sup>52</sup> Number of Units Shipped Globally (Millions)



**Leading companies and technologies:** The conversation regarding wellness wearables usually involves popular U.S. devices such as Fitbit and Apple Watch, although market research shows that other companies are prevalent in the global market (see figure 3).

**Figure 3.** Global Smartwatch Market Share 2020–2021, by Vendor<sup>53</sup>



52 Jeff Loucks, Duncan Stewart, Ariane Bucaille, and Gillian Crossan, “Wearable Technology in Health Care: Getting Better All the Time,” *Deloitte Insights*, December 2021. <https://www2.deloitte.com/us/en/insights/industry/technology/technology-media-and-telecom-predictions/2022/wearable-technology-healthcare.html>.

53 Andrew Wooden, “The Smartwatch Market Hit Record Levels in 2021,” *Telecomms.com*, March 14, 2022, <https://telecoms.com/514060/the-smartwatch-market-hit-record-levels-in-2021/>.

**Figure 4.**<sup>54</sup> Landscape of Leading Products and Health-Related Features

Company & Product	Product Category	Health-related Function	Technology Used and Battery Life (BL) <sup>55</sup>	Market
<b>Apple</b> Apple Watch Series	Smart watch	-1 lead ECG/HR measurements -Blood oxygen saturation -Pedometer & calorimeter -Sleep patterns -Fertility tracking	IMU, blood oxygen sensor, electrical heart sensor, optical sensors BL: 1 day	Widely available
<b>Fitbit</b> Sense/Verse	Smart watch	-1 lead ECG/HR measurements -Blood oxygen saturation -Pedometer & calorimeter -Sleep patterns	IMU, blood oxygen sensor, electrical heart sensor, optical sensors BL: 6 days	Widely available
<b>Samsung</b> Watch	Smart watch	-1 lead ECG/HR measurements -Blood oxygen saturation -Pedometer & calorimeter	IMU, blood oxygen sensor, electrical and optical sensors BL: 2 days	Widely available
<b>AliveCor</b> KardiaBand	Electronic wristband attached to an Apple Watch	-ECG for detecting heart conditions (atrial fibrillation, tachycardia, etc.) -HR measurement	Electrical heart sensor BL: 9 days	Widely available
<b>Ava</b> Ava Fertility Tracker	Electronic bracelet	-Skin temperature -HR and respiratory rate -Fertility tracking	Blood oxygen sensor, thermometer, heart monitor BL: 12 hours	Widely available
<b>Omron</b> Heart Guide	Smart watch	-Blood pressure -HR measurement -Sleep tracker -Pedometer & calorimeter	Sphygmomanometer, IMU, heart monitor BL: 3 days	Widely available
<b>Motiv</b> Motiv Ring	Electronic ring	-Sleep tracker -Pedometer & calorimeter -HR measurement	IMU, heart monitor BL: 3 days	Widely available
<b>Oura</b> Oura Ring	Electronic ring	-Sleep tracker -Pedometer & calorimeter -HR and respiratory rate -Body temperature	IMU, heart monitor, thermometer BL: 7 days	Widely available
<b>Xiaomi</b> Xiaomi Mi Band	Smart watch	-Sleep tracker -Blood oxygen saturation -HR, respiratory output velocity	IMU, blood oxygen sensor, heart monitor BL: 14 days	Widely available
<b>ArchiMed</b> ActiGraph	Electronic watch	-Sleep tracker -Fall detection -Sleep quality analysis	IMU BL: 14 days	Widely available
<b>Garmin</b> vivoactive	Smart watch	-Blood oxygen saturation -HR and respiratory rate -Sleep tracker -Pedometer & calorimeter	IMU, blood oxygen sensor, heart monitor BL: 8 days	Widely available
<b>Upright</b> GO 2	Posture corrector	-Vibrations to notify user to fix posture	Biofeedback sensors BL: 12 days	Widely available

Acronyms: IMU, inertial measurement unit which is an accelerometer sensor; ECG, Electrocardiogram; HR, heart rate.

\*Updated as of February 17, 2023.

<sup>54</sup> Information extracted from companies' websites.

<sup>55</sup> "Battery Life" refers to the number of hours or days that battery lasts after a full charge.

## Looking Forward with Smart Wearables

**Studies are showcasing hints at how the future of medicine will look, and that future is deeply integrated with smart wearables.**

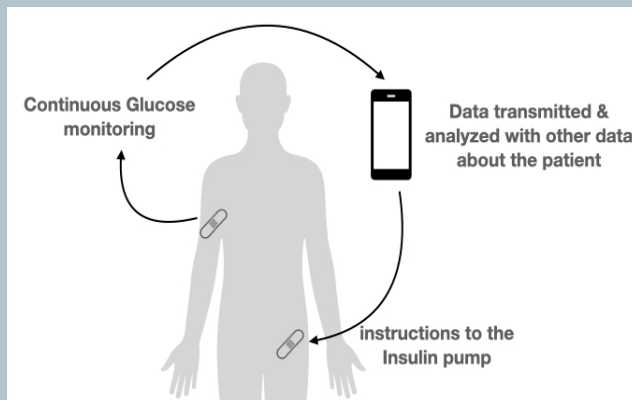
The previously mentioned capabilities is only the beginning of how these technologies can modernize healthcare. Smart wearables are tracking more complicated human markers of health such as cognitive function and early signs of inflammation and infection. The relative youth of this field opens the door for a dramatic innovation potential of smart wearables to track and integrate other physiologic signs over the next several years.

Smart wearables may serve as a powerful preventative health tool. People may be given real-time information about their health, possibly making them more inclined to change negative modifiable risk factors. This may add to the current major shift in healthcare in giving individuals the decision-making autonomy of their health, with the support of healthcare providers. Integrated and automated wearables, such as the automated insulin delivery (AID) systems, have the potential to improve health care as it does not rely on the individual to take needed actions (such as taking insulin shots) and relieves some of the burden of daily management of health routines. Also, smart wearables with long battery lives can allow primary care providers access to patient health data over longer periods and in real time, providing a greater panoramic view rather than just a snapshot when the patient is physically in the room with the physician, thus allowing the provider to see the overall health of the patient.

The utility of real-time data of smart wearables may drastically change some medical fields such as emergency medicine, where data from the patients can provide diagnostic and treatment foresight before the patient even comes through the doors. Rather than having emergency medical services log patient details, we can imagine emergency medical services having access to a patient's smart wearable with extensive physiological tracking. The real-time team at the hospital would have the patient information in a timely manner to prepare for immediate intervention, and the smart wearable data may also give information that allows more precise elucidation of the medical emergency at hand, increasing the chance of a successful life-saving intervention.

## INTEGRATED SMART WEARABLES: AUTOMATED INSULIN DELIVERY SYSTEM

AID systems are approved medical devices. An app or handset is connected to a continuous glucose monitoring wearable (a patch) and to an insulin pump in a closed-loop system. An algorithm analyzes the blood glucose data and other data about the user and calculates the dose of insulin to be administered. The device then gives the order to the pump to deliver insulin automatically or with little intervention from the user.



# PART 3: Governance and Regulation

## Federal Regulation

While there is no specific or distinct regulation for smart wearables, these products and devices are subject, to some extent, to health-related regulation by the FDA and to privacy and consumer protection regulation. In this section, we will address key aspects of the federal regulation related to smart wearables.

### FDA Regulation: Medical Devices and Wellness Products

Wearables can be broadly classified into two categories, *medical devices* and *wellness products*.

**General wellness products** include products with minimal risk whose intended use relates to “maintaining or encouraging a general state of health or healthy activities,” “or to the role of a healthy lifestyle in helping to reduce the risk or impact of certain chronic diseases or conditions.”<sup>56</sup> Wellness products with low risk are exempted from FDA regulation. Software with similar intended use and risk is subject to this exemption as well. A wellness device that is not low risk will be subject to FDA regulation.<sup>57</sup>

**Medical devices** are “intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease.”<sup>58</sup> A product that falls within this definition is subject to regulation by the FDA that aims to ensure the safety and efficacy of the device. The scope of supervision depends on the level of risk assigned to the device.

<sup>56</sup> FDA guidance for wellness products.

<sup>57</sup> An invasive or implantable device, even if used for wellness purposes, will not be considered low risk.

<sup>58</sup> Food, Drug, and Cosmetic Act, 21 USC § 321(h)(1).

- ↘ **Low-risk** (class I): low-risk general wellness products are mostly exempted from review (examples: fitness or weight management apps).
- **Moderate risk** (class II): products mainly undergo a premarket notification process that could be satisfied if the device is “substantially equivalent” to an existing FDA-cleared device (examples: smart watches that can detect arrhythmias or glucose monitoring devices)
- ↗ **High-risk** (class III): products undergo a premarket approval process.

**These distinct categories are challenged by the increasing capabilities of wearables.** Companies might “game” the intended use to stay in the “wellness realm” instead of a “medical device” to avoid the regulatory burden.<sup>59</sup>

#### WEARABLES CLASSIFICATION APPLE WATCH CASE STUDY

An Apple Watch has both medical device and general wellness functions

- **An ECG function that measures heart rhythm:**

Intended use: Diagnosis of a heart condition, alerts the user if it detects atrial fibrillation (a heart condition).

Classification (by FDA): A medical device that required FDA-clearance (De Novo classification).

- **A function that measures blood oxygen saturation:**

Intended use: “Measurements . . . are not intended for medical use and are only designed for general fitness and wellness purposes.”

Classification (unofficial): General wellness product, does not require approval.<sup>60</sup>



## Privacy and Health-Data Protection

**Protection of private health information:** The United States has legal and regulatory regimes to guard health data, however, not all protections fully apply to wellness wearables.<sup>61</sup>

**HIPAA** (Health Insurance Portability and Accountability Act of 1996) includes rules to protect the

<sup>59</sup> Simon, Shachar, and Cohen refer to this as “Skating the Line.”

<sup>60</sup> There are pulse oximeters that serve the same function and are classified as devices. See Health, Center for Devices and Radiological, “Pulse Oximeter Accuracy and Limitations: FDA Safety Communication,” FDA, June 21, 2022.

<sup>61</sup> David A. Simon, Barbara J. Evans, Carmel Shachar, and I. Glenn Cohen, “Should Alexa Diagnose Alzheimer’s?: Legal and Ethical Issues with at-Home Consumer Devices,” *Cell Reports Medicine* (July 2022): 3–4, <https://doi.org/10.1016/j.xcrm.2022.100692>; Kenny Gutierrez, “Privacy in Wearables: Innovation, Regulation, or Neither,” *Hastings Sci. & Tech.* LJ 13 (2022).

privacy of individualized health information when possessed by covered entities and their business associates. Covered entities, according to HIPAA rules, are mainly health care providers, health plans, and health care clearinghouses. It is widely accepted that tech companies that develop and sell wellness wearables are not “covered entities” unless they are business associates of a covered entity (i.e., help the covered entity to carry out its health care activities and functions).<sup>62</sup> Their exclusion applies even if they store personal health information (unless the data they collect was integrated into a medical record).<sup>63</sup>

**Some states have adopted stricter policies than HIPAA:** California, for example, imposes health-data privacy obligations beyond traditional healthcare entities to also include companies that offer products that maintain medical information, including “a mobile application or related device.”<sup>64</sup> Recently the legislature in Washington state passed the “My Health My Data” Act.<sup>65</sup> If signed into law, this act will protect health data that is not covered under HIPAA as it will apply to non-healthcare entities such as mobile apps and possibly to the manufacturers of wellness wearables. It also expands the definition of consumer health data to include information that might reveal (even through inference) information about the consumer’s mental or physical health. Additionally, companies establish their own privacy protection policies, manifested in their terms of service, that might clarify whether they should comply with HIPAA or not, but this information may be less accessible and understandable by a lay customer.

#### **Federal Trade Commission (FTC):**

- **Health Breach Notification Rule:** This rule requires notifying an individual if there is a breach of their health data. Though the rule applies to vendors of personal health records and associated companies, the FTC announced that this rule also applies to health apps and similar products that collect information on U.S. consumers.<sup>66</sup>
- **Unfair and deceptive practices:** FTC has the statutory authority to bring enforcement actions and develop rules to prevent and remedy “unfair or deceptive acts or practices.” Such practices may include sharing sensitive data without adequate consumer notice and consent or the misrepresentation or omission of information that might mislead consumers. In addition, the FTC could charge companies who do not comply with their own privacy policies or companies who

<sup>62</sup> For a list of covered entities see: <https://www.hhs.gov/hipaa/for-professionals/covered-entities/index.html>.

<sup>63</sup> There is a bill in Congress that proposes to strengthen the protection on health-related data: Bill Cassidy, “Cassidy, Baldwin Introduce Legislation to Begin Modernization of Health Privacy Laws,” press release, February 9, 2022, <https://www.cassidy.senate.gov/newsroom/press-releases/cassidy-baldwin-introduce-legislation-to-begin-modernization-of-health-privacy-laws>.

<sup>64</sup> Cal. Civ. Code § 56.06 (California Confidentiality of Medical Information Act).

<sup>65</sup> WA. HB 1155 Addressing the collection, sharing, and selling of consumer health data: <https://lawfilesexternal.wa.gov/biennium/2023-24/Pdf/Bills/House%20Passed%20Legislature/1155-S.PL.pdf?q=20230421070449>

<sup>66</sup> “Complying with FTC’s Health Breach Notification Rule,” Federal Trade Commission January 21, 2022, <https://www.ftc.gov/business-guidance/resources/complying-ftcs-health-breach-notification-rule-0>.

deceptively present themselves as HIPAA compliant.<sup>67</sup>

- **Business guidelines and educational materials:** The FTC has issued business education materials, reports, and “best practices” guides for various types of businesses that collect data regarding the use and dissemination of personal information. These guides and best practices could apply to wellness wearables as well.<sup>68</sup>

## Self-Regulation

Companies could **choose to adhere to stricter regulations than the ones relevant to their product**. Samsung, for example, previously registered a version of its watch as a medical device in the European Union even though it is intended for wellness purposes, due to some of its functions (blood pressure, etc.).<sup>69</sup> **Companies adopt security protocols to govern the data retained from these devices that are not necessarily required** by the above-mentioned regulation. Companies may use such protocols to: (1) overcome privacy concerns that might deter consumers from using a wearable, or (2) encourage consumers to prefer their product over a different company’s product. In addition, companies might up their privacy protection to be able to cooperate with health providers who are subject to higher standards.<sup>70</sup>

As we will discuss in the next section, the use of wearables, especially those intended for wellness, raises several ethical, legal, and public-purpose concerns. Even if the regulator is slow to respond to these concerns, companies could still address them in their product design and take into consideration principles and values, such as transparency, privacy, diversity, and societal well-being.<sup>71</sup> In the smart wearables context this will include, for example, finding salient ways to clarify the intended use of the product’s function, reminding users when monitoring is taking place, providing clear explanations about how the data may be used, and avoiding biases.<sup>72</sup>

67 See, for example, the FTC held proceedings against a company that provide transportation or evacuation services for injured or ill people that deceptively used a HIPAA seal: [https://www.ftc.gov/system/files/documents/cases/skymed\\_-\\_complaint.pdf](https://www.ftc.gov/system/files/documents/cases/skymed_-_complaint.pdf).

68 The specific law that governs the collection of information from children under the age of 13 is the Children’s Online Privacy Protection Act of 1998, 15 U.S.C. 6501–6505.

69 “Samsung Expands Vital Blood Pressure and Electrocardiogram Tracking to Galaxy Watch3 and Galaxy Watch Active2 in 31 More Countries.” Accessed March 18, 2023. <https://news.samsung.com/global/samsung-expands-vital-blood-pressure-and-electrocardiogram-tracking-to-galaxy-watch3-and-galaxy-watch-active2-in-31-more-countries>; “Are Galaxy Watch Medical Devices?” Accessed March 18, 2023. [https://www.samsung.com/africa\\_en/support/mobile-devices/are-galaxy-watch-medical-devices/](https://www.samsung.com/africa_en/support/mobile-devices/are-galaxy-watch-medical-devices/). <https://www.sconline.com/blog/post/2022/06/14/fitness-wearables-and-the-law-in-eu/>.

70 Paige Papandrea, “Addressing the HIPAA-potamus sized gap in wearable technology regulation,” *Minn. L. Rev.* 104 (2019): 1095.

71 Alexandra Kapeller et al., “Implementing Ethical, Legal, and Societal Considerations in Wearable Robot Design,” *Applied Sciences* 11, no. 15 (July 2021).

72 Simon, Evans, Shachar, and Cohen, “Should Alexa Diagnose Alzheimer’s.”

# PART 4: Public Purpose Considerations

Smart wearables pose certain noteworthy areas of concern. These include:

## Privacy and Security Threats

Wearable devices collect, store, and transfer vast amounts of data about their users. These products are usually connected to an extended eco-system (cloud storage, other apps) that increases its exposure and vulnerabilities to data leaks or hacks. Nevertheless, these products are not subject to strict privacy or security regulation.

- **Cyberattacks pose a risk to a user's health:** For example, if health information was intentionally distorted without a user's knowledge, this could mislead the user and result in risky behavior (e.g., not seeing a doctor, overexercising, distorting one's diet, etc.).
- Cyberattacks could interfere with a user's medical care and compromise their safety. For example, the FDA warned about potential cybersecurity risks to a specific type of insulin pump noting that unauthorized access could compromise the pump's communication protocol, which could cause the pump to deliver too much or too little insulin.<sup>73</sup>
- **Cyberattacks pose a threat to a user's privacy:** A user's data could be (legally) sold or leaked and used in a malicious manner, such as aggressive marketing by a third-party platform or for surveillance purposes.
  - Recent concerns have had to do with possible hacking into the accelerometer software of smart wearables where agents could track hand motions that can lead to exploiting passwords and pin information. Another example is the tracking of individuals' daily routines to track their locations.<sup>74</sup>

## Managing Users' Expectations

As previously discussed, the regulatory classification of wearables is not determined according to the nature of the wearable itself but rather according to its intended use. The "average" consumer might not

<sup>73</sup> "FDA Warns of Cybersecurity Risk with Certain Medtronic Insulin Pumps," *Reuters*, September 21, 2022, <https://www.reuters.com/business/healthcare-pharmaceuticals/fda-warns-cybersecurity-risk-with-certain-medtronic-insulin-pumps-2022-09-20/>.

<sup>74</sup> Xiangyu Liu, Zhe Zhou, Wenrui Diao, Zhou Li, and Kehuan Zhang, "When Good Becomes Evil: Keystroke Inference with Smartwatch," In *Proceedings of the 22nd ACM SIGSAC Conference on Computer and Communications Security*, 1273–85. Denver, CO:: Association for Computing Machinery, 2015, <https://doi.org/10.1145/2810103.2813668>.

know the exact “intentions” of their wearable functions and could improperly rely on their smartwatch instead of consulting a medical professional.<sup>75</sup> This blurry line may also raise legal challenges in terms of liability.<sup>76</sup>

Furthermore, without clear standardization or external quality assurances, some wellness wearables may not provide complete accurate information, which might lead users to take unwarranted actions (change diet, habits, etc.) leading to negative health consequences. This is particularly true for endpoints that are challenging for smart wearables to measure accurately, such as energy expenditure (calories).

### **Use of Personal Information for Marketing Purposes**

Wearables track our daily routines and collect meaningful data about our fitness, diet, sleep, web browsing, shopping habits, etc. This data can be very valuable for marketing purposes as it gives insights into consumers’ habits. What should the boundaries be regarding the use of data for marketing purposes? For example, if a user’s vital signs show some kind of distress that might affect their judgment, should there be limitations on marketing at this time? Or if a user enters their eating habits into a health app, and it indicates unhealthy eating habits, should we limit the ability to use this information? This consideration is critical as many data brokers operate in this market.

### **Insurance Exclusion**

As previously mentioned, wearables could improve health outcomes through “tailoring” treatments to a specific patient’s needs. However, we should also consider the risks of “overly” personalized medicine. For example, if insurance companies have access to such data, they might engage in “selective practices” or even discrimination against certain users. There was a similar concern when genetic testing became more available; the resulting regulation determined that refusing insurance to individuals with risks of a genetic disease, or increasing their premiums, would be considered discrimination. We should consider how personalized medicine could affect access to insurance and other medical treatments, especially when this data is shared with third parties.

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<sup>75</sup> Simon, Shachar, and Cohen, “Skating the Line.”

<sup>76</sup> David A. Simon, Carmel Shachar, and I. Glenn Cohen, “Unsettled Liability Issues for ‘Prediagnostic’ Wearables and Health-Related Products,” *JAMA* 328, no. 14 (October 2022): 1391.

# Selected Readings and Additional Resources

*The list below highlights some of the citations in this document or comprehensive documents on specific topics and is not meant to be exhaustive.*

## On the Technology

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# About the Technology and Public Purpose (TAPP) Project

*The arc of innovative progress has reached an inflection point. It is our responsibility to ensure it bends toward public good.*

Technological change has brought immeasurable benefits to billions through improved health, productivity, and convenience. Yet as recent events have shown, unless we actively manage their risks to society, new technologies may also bring unforeseen destructive consequences.

Making technological change positive for all is the critical challenge of our time. We ourselves - not only the logic of discovery and market forces - must manage it. To create a future where technology serves humanity as a whole and where public purpose drives innovation, we need a new approach.

Founded by former U.S. Secretary of Defense Ash Carter, the TAPP Project works to ensure that emerging technologies are developed and managed in ways that serve the overall public good.

## **TAPP Project Principles:**

1. Technology's advance is inevitable, and it often brings with it much progress for some. Yet, progress for all is not guaranteed. We have an obligation to foresee the dilemmas presented by emerging technology and to generate solutions to them.
2. There is no silver bullet; effective solutions to technology-induced public dilemmas require a mix of government regulation and tech-sector self-governance. The right mix can only result from strong and trusted linkages between the tech sector and government.
3. Ensuring a future where public purpose drives innovation requires the next generation of tech leaders to act; we must train and inspire them to implement sustainable solutions and carry the torch.

For more information, visit: [www.belfercenter.org/TAPP](http://www.belfercenter.org/TAPP)

