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Digital Home Health During the COVID-19 Pandemic Challenges to Safety, Liability, and Informed Consent, and the Way to Move Forward

Sara Gerke
sgerke@psu.edu

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11.1 INTRODUCTION

Artificial intelligence (AI) and other digital health products, such as smart pills, are rapidly entering clinical practice.[1] We live in the age of big data, where massive amounts of data are collected and used to develop or update digital health products and are shared with third parties for research or commercial purposes. Moreover, we can already see a shift in health care from hospitals to people's homes, for example through the use of medical apps, Fitbits, and other wearables. This line between clinic and home will likely become more and more blurry in the near future. According to one estimate, the smart home health care market size is projected to grow from $6.1 billion in 2018 to over $30 billion in 2025.[2]

In particular, the COVID-19 pandemic has propelled the adoption of health AI and digital health across multiple applications.[3] For example, the development and use of digital home health products have been expedited to reduce exposure to the coronavirus SARS-CoV-2, such as through remote patient monitoring, and to better control its spread, such as through exposure-notification apps.[4] At the same time, the regulation of medical devices is more flexible during the public health emergency. However, the acceleration of launching new digital home health devices on the US

[1] For more information on the ethics and law of health AI, see, e.g., Sara Gerke et al., Ethical and Legal Challenges of Artificial Intelligence-driven Healthcare 295 (Adam Bohr & Kaveh Memarzadeh eds., 1st ed. 2020); for more information on the ethical and legal issues of smart pills, see, e.g., Sara Gerke et al., Ethical and Legal Issues of Ingestible Electronic Sensors, 2 Nature Electron. 329 (2019).

[2] Global Market Insights, Smart Home Healthcare Market, www.gminsights.com/industry-analysis/smart-home-healthcare-market.

[3] MarketsandMarkets, Artificial Intelligence in Healthcare Market, www.marketsandmarkets.com/Market-Reports/artificial-intelligence-healthcare-market-54679303.html.

[4] Sara Gerke et al., Regulatory, Safety, and Privacy Concerns of Home Monitoring Technologies During COVID-19, 26 Nature Med. 1176 (2020). For more information on exposure-notification apps, see, e.g., I. Glenn Cohen et al., Digital Smartphone Tracking for COVID-19: Public Health and Civil Liberties in Tension, 323 JAMA 2371 (2020); Alessandro Blasimme & Effy Vayena, What's Next for COVID-19 Apps? Governance and Oversight, 370 Science 760 (2020).

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market combined with less regulatory oversight also raises some challenges, including post-pandemic questions.

In this chapter, I will first give an overview of the promise of digital home health. I will then discuss the regulation of digital home health before and during COVID-19 in the context of the US Federal Food, Drug, and Cosmetic Act (FDCA). This will be followed by a discussion of three digital home health challenges during the pandemic: 1) safety, 2) liability, and 3) informed consent. In this context, I will also make suggestions on how to move forward.

11.2 THE PROMISE OF DIGITAL HOME HEALTH

The term "digital health" is broadly defined by the US Food and Drug Administration (FDA) and encompasses categories such as telehealth, health information technology, mobile health, AI/machine learning, wearable devices, and precision medicine.[5] Digital health technologies harness software, connectivity, sensor, and computing platforms for health care and associated uses.[6] They are used for several applications, ranging from general wellness to medical devices.[7] The hope is that digital health will revolutionize health care by enabling precision medicine, increasing quality, improving access, and reducing costs and inefficiencies.[8]

I define "digital home health" as digital health that is related to the patient's or consumer's home. The term "home" has a broad scope here. It encompasses patients' or consumers' homes in the narrow sense of the term, such as their apartment, house, and so forth. In addition, it also refers to any other location in which there is no personal contact with and direct supervision by a health care provider. For example, digital home health includes telehealth visits as the conversation between the physician and the patient is virtual. It also refers to general wellness apps, such as an app for weight management,[9] and mobile medical apps, such as an app that detects heart function irregularities,[10] used by consumers or patients. Another example is COVID-19 exposure-notification apps that consumers use – without physicians' supervision – to receive notifications in cases where they may have been exposed to SARS-CoV-2. The term also covers remote patient monitoring – regardless of whether the monitoring takes place in the patient's

[5] US Food & Drug Admin., What is Digital Health?, www.fda.gov/medical-devices/digital-health-center-excellence/what-digital-health.

[6] Id.

[7] Id.

[8] Id.

[9] US Food & Drug Admin., General Wellness: Policy for Low Risk Devices – Guidance for Industry and Food and Drug Administration Staff (2019), at 3, www.fda.gov/media/90652/download.

[10] US Food & Drug Admin., Policy for Device Software Functions and Mobile Medical Applications – Guidance for Industry and Food and Drug Administration Staff (2019), at 5, www.fda.gov/media/80958/download.

apartment or house or even in a hospital – since the data are collected remotely and transferred digitally, and thus there is no personal contact with and direct supervision by a health care provider.[11]

Digital home health holds great promise in enabling patients to self-manage their health issues, keeping them out of the hospital as long as possible, and easing the already overburdened health care system. More than sixty million Americans (who are over sixty-five or younger people with disabilities or certain conditions) are already receiving insurance coverage by Medicare, and it is expected that this number will further increase to more than eighty million beneficiaries in 2030.[12] As the American population is aging, digital home health can serve as a useful tool to help patients to stay independent as long as possible.[13] For example, Best Buy Health offers assisted living technology, including remote patient monitoring devices placed in people's home.[14] A recent study predicts that the global remote patient monitoring market will increase from $23.2 billion in 2020 to $117.1 billion by 2025.[15] Remote monitoring devices can collect a variety of health data, including body temperature, pulse rate, blood pressure, respiration rate, and weight. Digital home health can be used for various applications, such as fall prevention and detection, memory aids, and nutrition, diet, or health status monitoring.[16] For example, researchers at the Massachusetts Institute of Technology developed a radio-frequency-based system, BodyCompass, that provides sleep posture monitoring overnight in a person's home.[17] This system may be applied to track Parkinson's disease progression, reduce apnea events, or avoid bedsores after surgery. In the era of big data, people are also increasingly using apps, fitness trackers, and other wearables to manage their health.

In particular, the COVID-19 pandemic has only highlighted the potential of digital home health. Over the last one and a half years, the development and launching of digital home health products on the US market have been accelerated to ease overcrowding in the hospitals and reduce personal contacts between patients

[11] The umbrella term for remote patient monitoring is "home monitoring"; see Gerke et al., supra note 4, at 1176. The term "digital home health" is broader than home monitoring; it is an umbrella term that also encompasses "home monitoring."

[12] Centers for Medicare & Medicaid Services, CMS Fast Facts, www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CMS-Fast-Facts/index; Steven Landers et al., The Future of Home Health Care: A Strategic Framework for Optimizing Value, 28 Home Health Care Manag. & Pract. 262 (2016).

[13] Gerke et al., supra note 4, at 1176.

[14] Best Buy Health, Assisted Living Technology, https://healthcare.bestbuy.com/site/bbhealth/products-technology/pcmcat1600181550900.c?id=pcmcat1600181550900.

[15] MarketsandMarkets, Remote Patient Monitoring (RPM) Market, www.marketsandmarkets.com/Market-Reports/remote-patient-monitoring-market-77155492.html.

[16] Global Market Insights, supra note 2.

[17] Shichao Yue et al., BodyCompass: Monitoring Sleep Posture with Wireless Signals, https://people.csail.mit.edu/scyue/projects/bodycompass.

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and physicians and the risk for infection with SARS-CoV-2.[18] For example, physicians can use Alivecor's KardiaMobile 6L, an electrocardiogram device, to measure QTc in patients both at home and in the hospital for the duration of COVID-19.[19] Moreover, telehealth rates have skyrocketed. For example, from March through June 2020, more than 34.5 million telehealth services were delivered to Medicaid and Children's Health Insurance Program's beneficiaries, suggesting a 2,632 percent growth compared to the same time in 2019.[20]

11.3 REGULATION OF DIGITAL HOME HEALTH

11.3.1 *Pre-COVID-19*

The FDA regulates digital home health products if they are classified as medical devices under FDCA Section 201(h). This is usually the case when such a product is

> intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man ... and which does not achieve its primary intended purposes through chemical action within or on the body of man ... and which is not dependent upon being metabolized for the achievement of its primary intended purposes.[21]

Software plays an essential role in digital home health. There are three different software types associated with medical devices:

1. Software as a Medical Device (SaMD) – that is, standalone software that is a medical device on its own;
2. Software in a Medical Device (SiMD) – that is, software, which is integral to a medical device; and
3. software used in the maintenance or manufacture of a medical device.[22]

In particular, a variety of digital home health medical devices are SaMD. For example, AliveCor's Kardia Band System is SaMD that is intended to store, record, and transmit single-channel electrocardiogram rhythms and detect the presence of normal sinus rhythm and atrial fibrillation.[23] The Kardia Band System consists of

[18] See Gerke et al., supra note 4, at 1176.

[19] Alivecor, AliveCor to Provide QTc Measurement for Clinicians Treating COVID-19 Patients, www.alivecor.com/press/press_release/alivecor-to-provide-qtc-measurement-for-clinicians-treating-covid-19-patients.

[20] Centers for Medicare & Medicaid Services, Services Delivered via Telehealth Among Medicaid & CHIP Beneficiaries During COVID-19, www.medicaid.gov/resources-for-states/downloads/medicaid-chip-beneficiaries-COVID-19-snapshot-data-through-20200630.pdf.

[21] Food, Drug, and Cosmetic Act § 201(h), sentence 1 [hereinafter FDCA].

[22] US Food & Drug Admin., Software as a Medical Device (SaMD), www.fda.gov/medical-devices/digital-health-center-excellence/software-medical-device-samd.

[23] Letter from the FDA to AliveCor (Nov. 16, 2017), www.accessdata.fda.gov/cdrh_docs/pdf17/K171816.pdf.

a watchband with a sensor, the Kardia phone app software installed on the Apple iPhone, and the Kardia watch app software installed on the Apple Watch.[24] Other examples are Apple's Electrocardiogram App[25] and Apple's Irregular Rhythm Notification Feature,[26] both of which are SaMD and intended for use with the Apple Watch.

There are three different classes of medical devices – that is, Class I, Class II, and Class III. While Class I medical devices have the lowest risk, Class III medical devices have the highest risk. Depending on the class, medical devices are subject to general controls (all classes), special controls (Class II), and premarket approval (PMA, Class III) to ensure reasonable assurance of their safety and effectiveness.[27] In particular, there are three main premarket pathways for medical devices:

1. 510(k)/clearance – for Class I or II devices, unless exempt;
2. De Novo Classification Request – for novel medical devices of low/moderate risk; and
3. PMA – for Class III medical devices.[28]

Digital home health medical devices can be found in all premarket pathways. For example, AliveCor's Kardia Band System is a Class II medical device that received FDA clearance via the 510(k) pathway in November 2017 as the first device add-on for the Apple Watch.[29] Apple's Electrocardiogram App and Irregular Rhythm Notification Feature are also Class II medical devices, and both received FDA marketing authorization via the De Novo pathway in September 2018.[30]

Some digital home health products are not classified as medical devices under the FDCA and hence are not subject to FDA regulation. The 21st Century Cures Act, signed into law in December 2016, introduced FDCA Section 520(o), which excludes certain medical and clinical decision support software from the medical device definition.[31] In the context of digital home health products, Section 520(o)(1)(B) is relevant:

> The term device, as defined in section 201(h), shall not include a software function that is intended … for maintaining or encouraging a healthy lifestyle and is

[24] Id.

[25] Letter from the FDA to Apple (Sept. 11, 2018), www.accessdata.fda.gov/cdrh_docs/pdf18/DEN180044.pdf.

[26] Letter from the FDA to Apple (Sept. 11, 2018), www.accessdata.fda.gov/cdrh_docs/pdf18/DEN180042.pdf.

[27] FDCA § 513(a)(1).

[28] For more information, see, e.g., US Food & Drug Admin., How to Study and Market Your Device, www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/how-study-and-market-your-device.

[29] Letter from the FDA to AliveCor, supra note 23.

[30] Letters from the FDA to Apple, supra notes 25 & 26. This new competition likely also led to AliveCor's decision in the summer of 2019 to stop selling the Kardia Band System. However, AliveCor intends to continue supporting the system for people who have already bought it. See Dave Muoio, AliveCor Ends Sales of KardiaBand, Its ECG Accessory for Apple Watches, Mobile Health News (Aug. 19, 2019), www.mobihealthnews.com/about.

[31] Pub. L. 114–255, § 3060(a) (2016).

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unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition.

This exception covers digital home health products with a general wellness intended use that maintains or encourages a "general state of health or a healthy activity."[32] For example, apps used by consumers for weight management, relaxation or stress management, physical fitness, self-esteem, sexual function, mental acuity, or sleep management are not considered medical devices, as long as they are not related to "the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition."[33] The FDA also does not regard most software apps and systems for public health surveillance and communication as medical devices, such as COVID-19 exposure-notification apps.[34] Moreover, software for videoconferencing intended for use in telehealth is also not a medical device under the FDCA and thus is not subject to FDA regulation.[35]

For low-risk software functions that are medical devices or may meet the medical device definition, the FDA also intends to practice enforcement discretion and thus does not intend to enforce compliance with the requirements under the FDCA.[36] An example is software functions that guide users through questionnaires of symptoms and signs to recommend the most appropriate health care facility for their needs.[37]

11.3.2 *During COVID-19*

During the COVID-19 pandemic, there are two other pathways for digital home health medical devices available: 1) Emergency Use Authorizations (EUAs) and 2) COVID-19 guidance documents.

11.3.2.1 EUAs

The FDA can issue EUAs for medical devices during COVID-19. In February 2020, the then Secretary of Health and Human Services Alex Azar determined a public health emergency[38] and, based on this determination, has issued the following three EUA Declarations related to medical devices:

[32] US Food & Drug Admin., supra note 9; US Food & Drug Admin., Changes to Existing Medical Software Policies Resulting from Section 3060 of The 21st Century Cures Act – Guidance for Industry and Food and Drug Administration Staff (2019), at 4–5, www.fda.gov/media/109622/download.

[33] US Food & Drug Admin., 21st Century Cures Act – Guidance, supra note 32, at 5.

[34] US Food & Drug Admin., Digital Health Policies and Public Health Solutions for COVID-19, www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/digital-health-policies-and-public-health-solutions-covid-19; Gerke et al., supra note 4, at 1177.

[35] US Food & Drug Admin., supra note 34; See also US Food & Drug Admin., supra note 10, at 19.

[36] US Food & Drug Admin., supra note 10, at 2, 9, 12.

[37] Id. at 23.

[38] Determination of Public Health Emergency, 85 Fed. Reg. 7316, www.federalregister.gov/documents/2020/02/07/2020-02496/determination-of-public-health-emergency.

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1. "in vitro diagnostics for detection and/or diagnosis of the novel coronavirus";[39]
2. "personal respiratory protective devices";[40] and
3. "medical devices, including alternative products used as medical devices."[41]

Due to the broad scope of the latter EUA Declaration, the FDA can issue EUAs under FDCA Section 564 for unapproved or uncleared digital home health medical devices for commercial distribution or for unapproved or uncleared uses of approved or cleared digital home health medical devices.[42] This is the case if the following four criteria are fulfilled:

1. serious or life-threatening condition or disease;
2. evidence of effectiveness;
3. benefit/risk analysis; and
4. no alternatives.[43]

The first criterion is met during the COVID-19 pandemic – SARS-CoV-2 can cause COVID-19, a serious or life-threatening disease. The second criterion requires a "may be effective" standard as evidence, and thus a lower level than an "effectiveness" standard.[44] More precisely, it must be "reasonable to believe" that the digital home health medical device "may be effective" to treat, diagnose, or prevent COVID-19.[45] The third criterion is given if it is "reasonable to believe" that the potential and known benefits of the digital home health medical device outweigh its known and potential risks, taking into account the material threat posed by SARS-CoV-2.[46] For both the second and third criteria, the assessment must be "based on the totality of scientific evidence available," including – if available – data from well-controlled and adequate clinical trials.[47] Lastly, the fourth criterion is fulfilled when there is "no adequate, approved, and available alternative" to the digital home health medical device for treating, diagnosing, or preventing COVID-19.[48] An

[39] Id.
[40] Emergency Use Declaration, 85 Fed. Reg. 13907, www.federalregister.gov/documents/2020/03/10/2020-04823/emergency-use-declaration.
[41] Emergency Use Authorization Declaration, 85 Fed. Reg. 17335, www.federalregister.gov/documents/2020/03/27/2020-06541/emergency-use-authorization-declaration; see also FDCA § 564(b); Gerke et al., supra note 4, at 1177.
[42] See FDCA § 564(a)(2).
[43] FDCA § 564(c); see also US Food & Drug Admin., Emergency Use Authorization of Medical Products and Related Authorities, Guidance for Industry and Other Stakeholders (2020), at 7–8, www.fda.gov/media/97321/download.
[44] US Food & Drug Admin., supra note 43, at 8.
[45] FDCA § 564(c)(2)(A).
[46] FDCA § 564(c)(2)(B).
[47] FDCA § 564(c)(2).
[48] FDCA § 564(c)(3).

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approved alternative may be considered "unavailable" if there are insufficient supplies to fully encounter the emergency need and may be considered "inadequate" if SARS-CoV-2 is or may be resistant to it.[49]

With the issuance of an EUA, the FDA may also, for example, waive the requirements concerning current good manufacturing practice.[50] An EUA can be revised or revoked under specific conditions, such as when the issuance criteria are no longer met.[51] In general, an EUA also becomes ineffective with the termination of the Secretary of Health and Human Services' corresponding EUA Declaration.[52]

The FDA has already issued EUAs for digital home health medical devices, namely for certain wearable or remote patient monitoring devices to help reduce personal contacts between patients and health care providers and thus exposure to COVID-19.[53] For example, in April 2020, the FDA issued an EUA for VitalConnect's VitalPatch Biosensor.[54] This wireless remote monitoring system is intended to be used by health care professionals to detect QT interval changes of an electrocardiogram in adult COVID-19 patients who are not in the ICU but are undergoing treatment with drugs that may cause arrhythmias.[55] The device is used in the hospital setting to remotely monitor such patients to decrease health care professionals' exposure to SARS-CoV-2.[56] VitalPatch Biosensor is a 510(k)-cleared device for continuous collection of physiological data in health care settings and in the patients' homes.[57] However, its clearance does not include the use for automated arrhythmia detection of an electrocardiogram's QT interval.[58] Thus, the FDA authorized here an emergency use of a cleared device for an uncleared use.

11.3.2.2 COVID-19 Guidance Documents

The FDA has released numerous enforcement discretion guidance documents related to digital home health medical devices that apply during the COVID-19 pandemic.[59] These guidance documents represent the agency's current thinking

49 US Food & Drug Admin., supra note 43, at 8.
50 FDCA § 564(e)(3).
51 FDCA § 564(f)–(g).
52 FDCA § 564(f), (b)(2).
53 US Food & Drug Admin., Remote or Wearable Patient Monitoring Devices EUAs, www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/remote-or-wearable-patient-monitoring-devices-euas.
54 Letter from the FDA to VitalConnect (Apr. 26, 2020), at 1, www.fda.gov/media/137397/download.
55 Id.
56 Id.
57 Id.
58 Id.
59 For all guidance documents related to medical devices, including digital home health medical devices, see US Food & Drug Admin., Coronavirus (COVID-19) and Medical Devices, www.fda.gov/medical-devices/emergency-situations-medical-devices/coronavirus-covid-19-and-medical-devices#guidance.

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and should be seen as nonbinding recommendations, unless particular statutory or regulatory requirements are cited.[60]

For example, the FDA issued a guidance document for certain legally marketed noninvasive remote monitoring devices to help expand the capability and availability of such devices to facilitate patient monitoring, while decreasing health care provider and patient contact and exposure to SARS-CoV-2.[61] This guidance document contains a list of applicable device types, such as breathing frequency monitors, noninvasive blood pressure measurement systems, cardiac monitors, and oximeters.[62] All of these devices can be connected to a wireless network through, for example, Wi-Fi or Bluetooth to transfer a patient's collected health data directly to the health care provider or another monitoring party.[63] Some of these devices also apply algorithms.[64] The guidance document states that, during the public health emergency, the FDA does not intend to disapprove of limited modifications to claims, functionality, indications, software, or hardware of the listed devices, without prior 510(k) submission, where this premarket notification submission would usually be necessary.[65] Suppose a noninvasive remote monitoring device was previously marketed exclusively for use in hospitals. During the COVID-19 pandemic, the manufacturer can modify the device for use in the home setting without submitting a 510(k).[66] In addition, the FDA also clarifies that the agency does not anticipate to enforce compliance with the special controls for two device types listed in the guidance document, namely non-electroencephalogram physiological signal-based seizure monitoring systems and computerized cognitive assessment aids.[67] The guidance document also contains recommendations, such as on labeling, and emphasizes that the modification of a legally marketed noninvasive monitoring device must not create an undue risk.[68]

Another example of a COVID-19 guidance document related to digital home health medical devices is for certain noninvasive maternal and fetal monitoring devices.[69] This enforcement policy aims to foster monitoring of pregnant women at home during COVID-19, while decreasing potential exposure for health care

[60] See, e.g., US Food & Drug Admin., Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (Revised), at 5, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-non-invasive-remote-monitoring-devices-used-support-patient-monitoring-during.

[61] Id.

[62] Id. at 6–7.

[63] Id. at 7.

[64] Id. at 8.

[65] Id.

[66] Id.

[67] Id.

[68] Id. at 9–11.

[69] US Food & Drug Admin., Enforcement Policy for Non-Invasive Fetal and Maternal Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency, www.fda.gov/media/137286/download.

providers and their patients to SARS-CoV-2.[70] Some of these devices can be connected to Wifi or Bluetooth to directly transmit the measurements, such as the fetal or maternal heart rate, to the patient's health care provider or another monitoring party.[71] The FDA clarifies that 510(k)-cleared noninvasive maternal and fetal monitoring devices listed in the guidance document can be modified to a limited extent in their functionality, indications, software, and/or hardware without submitting a new 510(k).[72] This only applies, however, when the modification of the device does not create an undue risk.[73] This guidance document also contains recommendations, such as on labeling.[74] Other examples of COVID-19 enforcement discretion guidance documents related to digital home health medical devices include guidance for digital health devices for treating psychiatric disorders[75] and guidance for remote ophthalmic assessment and monitoring devices.[76]

11.4 DISCUSSION

While the acceleration of launching new digital home health products on the US market or modifying legally marketed devices is needed to address the COVID-19 pandemic, it also raises several challenges. In the following, I will discuss three of them, namely safety, liability, and informed consent,[77] and make suggestions on how to move forward.

11.4.1 *Safety*

The two additional regulatory pathways available during the COVID-19 public health emergency, namely EUAs and COVID-19 enforcement discretion guidance documents, are vital to act swiftly and combat COVID-19, but at the same time also pose safety risks. In particular, digital home health medical devices that are FDA authorized for emergency use concerning COVID-19 under an EUA have not undergone a "full" review that intends to provide reasonable assurance of their

[70] Id. at 4–5.
[71] Id. at 5, 7.
[72] Id. 7.
[73] Id.
[74] Id. 11–12.
[75] US Food & Drug Admin., Enforcement Policy for Digital Health Devices for Treating Psychiatric Disorders During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency, www.fda.gov/media/136939/download.
[76] US Food & Drug Admin., Enforcement Policy for Remote Ophthalmic Assessment and Monitoring Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency, www.fda.gov/media/136733/download.
[77] Other issues beyond this article's scope include privacy, surveillance, security, and access. For more information, see, e.g., Gerke et al., supra note 4, at 1180–1; Marcello Ienca & Effy Vayena, On the Responsible Use of Digital Data to Tackle the COVID-19 Pandemic, 26 Nature Med. 463; Carmel Shachar et al., AI Surveillance during Pandemics: Ethical Implementation Imperatives, 50 Hastings Cent. Rep. 18 (2020).

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safety and effectiveness, as is the case of FDA-cleared or approved medical devices. Instead, as seen above,[78] the FDA can already issue an EUA when the digital home health medical device "may be effective" to treat, diagnose, or prevent COVID-19. Thus, an EUA does not suggest that the device is safe and effective.[79]

It is imperative that – even in times of a pandemic – the FDA does not make too many tradeoffs when carrying out the benefit/risk analysis and determining whether the digital home health medical device's potential and known benefits outweigh its known and potential risks.[80] For example, the agency has recently been criticized for its decision in March 2020 to issue an EUA for chloroquine phosphate and hydroxychloroquine sulfate for the treatment of COVID-19, when used under certain conditions, due to a lack of adequate scientific evidence at the time of issuance.[81] The FDA revoked the EUA in June 2020 after case reports in April 2020 have shown death and serious heart-related adverse events in COVID-19 patients receiving these medicines.[82] This case example also holds valuable lessons for EUAs for digital home health medical devices as it highlights the importance of a robust benefit/risk analysis based on the totality of scientific evidence even in times of crisis. In particular, more transparency in the decision-making process of EUAs is needed. For example, the FDA has issued EUAs for wearable or remote patient monitoring devices "based on bench testing and reported clinical experience," but without giving any further information on such reports in the letters of authorization.[83] Thus, it would be helpful if the FDA disclosed the scientific evidence used to reach an EUA decision in more detail in its letter of authorization.[84] Transparency is crucial to promote public trust in the agency, which has been tremendously shaken during the COVID-19 pandemic, such as most recently in vaccines.[85]

[78] See supra Section 11.3.2.1.

[79] See letter from the FDA to VitalConnect, supra note 54, at 7; Gerke et al., supra note 4, at 1178.

[80] For more information on the criteria of issuance an EUA, see supra Section 11.3.2.1.

[81] See, e.g., Liam Bendicksen et al., Increase Transparency at the FDA: We Need Sunlight to Fight the Pandemic, STAT (Sept. 29, 2020), www.statnews.com/2020/09/29/increase-transparency-at-the-fda-we-need-sunlight-to-fight-the-pandemic; see also letter from the FDA to the Biomedical Advanced Research and Development Authority (Mar. 28, 2020), www.fda.gov/media/136534/download.

[82] Letter from the FDA to the Biomedical Advanced Research and Development Authority (June 15, 2020), www.fda.gov/media/138945/download; US Food & Drug Admin., Coronavirus (COVID-19) Update: FDA Revokes Emergency Use Authorization for Chloroquine and Hydroxychloroquine, www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-revokes-emergency-use-authorization-chloroquine-and; US Food & Drug Admin., Hydroxychloroquine or Chloroquine for COVID-19: Drug Safety Communication – FDA Cautions Against Use Outside of the Hospital Setting or a Clinical Trial Due to Risk of Heart Rhythm Problems, www.fda.gov/safety/medical-product-safety-information/hydroxychloroquine-or-chloroquine-covid-19-drug-safety-communication-fda-cautions-against-use.

[83] See letter from the FDA to VitalConnect, supra note 54, at 2; letter from the FDA to PhysiolGuard Corporation (May 5, 2020), at 2, www.fda.gov/media/137693/download.

[84] See also Bendicksen et al., supra note 81.

[85] See, e.g., Michael Barbaro, The Vaccine Trust Problem, www.nytimes.com/2020/07/21/podcasts/the-daily/coronavirus-vaccine.html?showTranscript=1.

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There are likely additional safety risks when the development of digital home health products – devices and non-devices – is rushed to quickly put them on the market in response to the COVID-19 pandemic. In particular, digital home health products are prone to false-positive results that may be caused, for example, by inaccurate measurements.[86] Suppose an authorized remote monitoring device for emergency use under an EUA is used in the hospital to monitor a COVID-19 patient remotely, thereby reducing clinicians' exposure to SARS-CoV-2, and has too many false positives due to its rapid development. Suppose the device alerts the patient's physician each time it detects an irregular heart rhythm. Thus, due to the high false-positive ratio, the device sends several false alerts, which can easily lead to alert fatigue of the physician.[87] Moreover, digital home health products also bear the risk of false-negative results. If the device in the hypothetical example fails to detect an irregular heart rhythm, the patient's treatment may be delayed, and this can have adverse effects on the patient's health.[88]

The COVID-19 guidance documents related to digital home health medical devices mainly apply to certain limited modifications of particular legally marketed devices.[89] Thus, in general, the risks associated with such modifications may likely be lower than the risks associated with EUAs, which may also authorize emergency use of uncleared or unapproved medical devices.[90] In addition, the COVID-19 guidance documents contain an additional safeguard as the limited modifications must not create an undue risk.[91] Nevertheless, one also needs to acknowledge that accelerated modifications of devices in compliance with the COVID-19 guidance documents bring additional risks, especially when such devices are now used in people's homes. For example, even if patients receive instructions for home use with appropriate lay terminology,[92] patients may over-rely on the device's output, mishandle the device, and also not know when to seek medical help.[93]

Many digital home health products are not considered medical devices, and thus the FDA did not review them – even before the COVID-19 pandemic.[94] Thus, it is essential that – irrespective of whether a product undergoes no review, a "light"

[86] Gerke et al., supra note 4, at 1178.

[87] For more information on alert fatigue, see, e.g., Sara Gerke et al., The Need for a System View to Regulate Artificial Intelligence/Machine Learning-Based Software as Medical Device, 3 npj Digit. Med. (2020).

[88] See also Gerke et al., supra note 4, at 1178.

[89] For more information on COVID-19 guidance documents, see supra Section 11.3.2.2. An exception of a COVID-19 guidance document that applies to specific uncleared devices is US Food & Drug Admin., Enforcement Policy for Clinical Electronic Thermometers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency, www.fda.gov/media/136698/download. For more information on this guidance, see also Gerke et al., supra note 4, at 1179.

[90] Gerke et al., supra note 4, at 1179. For more information on EUAs, see supra Section 11.3.2.1.

[91] Gerke et al., supra note 4, at 1179; see also US Food & Drug Admin., supra note 60, at 9; FDA, supra note 69, at 7–9.

[92] See, e.g., FDA, supra note 60, at 10; US Food & Drug Admin., supra note 69, at 11.

[93] Gerke et al., supra note 4, at 1178.

[94] For more information, see supra Section 11.3.1.

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review, or a "full" review – digital home health companies should mitigate safety risks to patients and consumers as much as reasonable. They should – during the pandemic and post-pandemic – practice "ethics by design."[95] This approach requires, among other things, that the companies develop products that mitigate biases, adequately protect individuals' privacy, and have proper security safeguards in place. Moreover, digital home health companies should also practice "ethics maintenance" of their products during and after the COVID-19 pandemic. This is particularly important for so-called adaptive algorithms that can learn and adapt to new conditions and therefore hold great promise to realize the full potential of AI in the future.[96] However, since these algorithms constantly learn and change, it will be crucial to make sure that the products will remain safe and effective. An "ethics maintenance" approach ensures, for instance, that companies monitor their digital home health products continuously and that the monitoring is carried out by a department other than the one that developed it.[97]

On January 8, 2021, the then Secretary of Health and Human Services Alex Azar signed a proposal making some regulatory flexibilities provided during the COVID-19 pandemic permanent.[98] This proposal was published in the Federal Register on January 15, 2021, only five days before President Joe Biden's inauguration. It intended, among other things, to exempt eighty-three Class II medical devices from the 510(k) premarket notification requirement, including several devices related to digital home health such as fetal cardiac monitors and computerized behavioral therapy devices for psychiatric disorders.[99] The proposal suggested that the 510(k) premarket notification requirement was no longer necessary for such devices to assure their safety and effectiveness because they were apparently associated with few adverse event reports.[100] But few adverse event reports should not be a primary reason to justify 510(k) exemptions. Digital home health medical devices interact with their user, and it can be challenging to detect issues with them straightaway.[101] As we have seen above, digital home health medical devices are,

[95] Gerke et al., Ethical and Legal Issues of Ingestible Electronic Sensors, supra note 1; see also Gerke et al., supra note 4, at 1180.

[96] Boris Babic et al., Algorithms on Regulatory Lockdown in Medicine: Prioritize Risk Monitoring to Address the "Update Problem," 366 Science 1202 (2019).

[97] Id. at 1204 (where Babic et al. suggest an appropriate division of labor for AI/machine learning systems).

[98] Department of Health & Human Services, Making Permanent Regulatory Flexibilities Provided During the COVID-19 Public Health Emergency by Exempting Certain Medical Devices From Premarket Notification Requirements; Request for Information, Research, Analysis, and Public Comment on Opportunities for Further Science and Evidence-Based Reform of Section 510(k) Program, 86 Fed. Reg., 4088, www.govinfo.gov/content/pkg/FR-2021-01-15/pdf/2021-00787.pdf.

[99] Id. at 4088, 4096–8.

[100] Id. at 4096.

[101] For medical AI tools, see also Casey Ross, "Slippery Slope Territory": Health Officials Propose Waiving Regulatory Review of Medical AI Tools, STAT (Jan. 16, 2021), www.statnews.com/2021/01/16/slippery-slope-territory-health-officials-propose-waiving-regulatory-review-of-medical-ai-tools.

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for example, prone to false-positive and false-negative results. Patients and consumers may also over-rely on their outputs and may unknowingly not seek medical care although necessary. In a Notice from April 16, 2021, the Department of Health and Human Services and the FDA luckily withdrew, among other things, the proposed exemptions for the eighty-three Class II medical devices.[102] The main reason for the withdrawal was "that the proposed exemptions and bases for them are flawed."[103]

11.4.2 *Liability*

The use of digital home health products during the COVID-19 pandemic also raises questions of liability. Suppose a remote monitoring device that is authorized for emergency use concerning COVID-19 under an EUA fails to detect an irregular heart rhythm in a COVID-19 patient, and the patient dies as a result. Can the manufacturer be held liable under current law? The then Secretary of Health and Human Services Alex Azar issued a Declaration under the Public Readiness and Emergency Preparedness Act (PREP Act), effective as of February 4, 2020, "to provide liability immunity for activities related to medical countermeasures against COVID-19."[104]

[102] Department of Health & Human Services & FDA, Making Permanent Regulatory Flexibilities Provided During the COVID-19 Public Health Emergency by Exempting Certain Medical Devices From Premarket Notification Requirements; Withdrawal of Proposed Exemptions, 86 Fed. Reg. 20174, www.govinfo.gov/content/pkg/FR-2021-04-16/pdf/2021-07760.pdf.

[103] Id. at 20174.

[104] Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198, www.govinfo.gov/content/pkg/FR-2020-03-17/pdf/2020-05484.pdf; see also Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 21012, www.govinfo.gov/content/pkg/FR-2020-04-15/pdf/2020-08040.pdf; Second Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 35100, www.govinfo.gov/content/pkg/FR-2020-06-08/pdf/2020-12465.pdf; Department of Health and Human Services, Third Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 52136, www.govinfo.gov/content/pkg/FR-2020-08-24/pdf/2020-18542.pdf; Fourth Amendment to the Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 and Republication of the Declaration, 85 Fed. Reg. 79190, www.govinfo.gov/content/pkg/FR-2020-12-09/pdf/2020-26977.pdf; Fifth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 86 Fed. Reg. 7872, www.govinfo.gov/content/pkg/FR-2021-02-02/pdf/2021-02174.pdf; Sixth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 86 Fed. Reg. 9516, www.govinfo.gov/content/pkg/FR-2021-02-16/pdf/2021-03106.pdf; Sixth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 86 Fed. Reg. 10588, www.govinfo.gov/content/pkg/FR-2021-02-22/pdf/2021-03526.pdf; Seventh Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 86 Fed. Reg. 14462, www.govinfo.gov/content/pkg/FR-2021-03-16/pdf/2021-05401.pdf; Eighth Amendment to

Under the PREP Act,

> a *covered person* shall be immune from suit and liability under Federal and State law with respect to all *claims for loss* caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a *covered countermeasure* if a declaration … has been issued with respect to such countermeasure (emphasis added).[105]

However, there is no immunity in cases of willful misconduct that proximately caused serious injury or death.[106] A covered person is, for example, a manufacturer of a covered countermeasure or a "qualified person" (for example, a licensed health professional or other person who is authorized to administer, prescribe, or dispense covered countermeasures under the State law in which the countermeasure was administered, prescribed, or dispensed).[107] The term "loss" includes, for instance, death and personal injury.[108] Covered countermeasures are, for example, FDA cleared or approved medical devices used to prevent, mitigate, treat, cure, diagnose, or limit the harm of COVID-19, medical devices authorized for emergency use concerning COVID-19 under an EUA, and investigational medical devices that are permitted to be used under an investigational device exemption to treat COVID-19.[109] Consequently, PREP Act immunity may apply in cases of digital home health medical devices authorized for emergency use concerning COVID-19 under an EUA. However, devices that are modified under the COVID-19 enforcement discretion guidance documents are not covered countermeasures, and thus there is a priori no PREP Act immunity.[110] Further, digital home health

Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 86 Fed. Reg. 41977, www.govinfo.gov/content/pkg/FR-2021-08-04/pdf/2021-16681.pdf; Ninth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 86 Fed. Reg. 51160, www.govinfo.gov/content/pkg/FR-2021-09-14/pdf/2021-19790.pdf; Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19; Correction, 86 Fed. Reg. 54696, www.govinfo.gov/content/pkg/FR-2021-10-04/pdf/2021-21652.pdf.

105 42 U.S.C. § 247d–6d(a)(1).

106 42 U.S.C. § 247d-6d(c)(3); see also Department of Health and Human Services, Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, supra note 104; Department of Health and Human Services, Advisory Opinion on the Public Readiness and Emergency Preparedness Act and the Mar. 10, 2020 Declaration under the Act (Apr. 17, 2020, as Modified on May 19, 2020), at 7, www.hhs.gov/sites/default/files/prep-act-advisory-opinion-hhs-ogc.pdf.

107 42 U.S.C. § 247d–6d(i)(8); see also Department of Health and Human Services, Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, supra note 104; Department of Health and Human Services, supra note 106, at 5–6.

108 42 U.S.C. § 247d–6d(a)(2)(A).

109 42 U.S.C. 247d–6d(i)(1) and (7); see also Department of Health and Human Services, Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, supra note 104; Department of Health and Human Services, supra note 106, at 3–5.

110 See also Peter S. Spivack & Emily M. Lyons, Liability Immunity Under the Prep Act for COVID-19 Countermeasures: What Manufacturers Need to Know, at 6, www.hoganlovells.com/~/media/hogan-lovells/pdf/2020-pdfs/2020_03_23_liability_immunity_under_the_prep_act_for_covid_19_countermea

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products that are not classified as medical devices are likewise not covered countermeasures, and PREP Act immunity does not apply from the outset.[111] Such products will likely be governed under product liability law if they are defective.[112]

The Department of Health and Human Services Office of the General Counsel (Counsel) has emphasized in its first Advisory Opinion from May 2020 the broad scope of the PREP Act immunity.[113] Even in cases where not all of the requirements are fulfilled, a "reasonably-could-have-believed" standard may confer immunity.[114] For instance, suppose the medical product is not a covered countermeasure (for example, is counterfeit), but an individual or entity "reasonably could have believed" that it was a covered countermeasure (for example, the individual or entity has taken reasonable steps to substantiate the product's authenticity).[115] Such an individual or entity will not lose PREP Act immunity so long as the individual or entity complies with all other conditions of the Secretary of Health and Human Services' Declaration and the PREP Act.[116]

If all conditions of the Secretary of Health and Human Services' Declaration and the PREP Act are fulfilled, immunity will cover claims for loss sounding in contract and tort and claims for loss relating to compliance with federal, state, or local laws, regulations, or other legal conditions.[117] The Counsel clarifies in its first Advisory Opinion that

> immunity applies when a covered person engages in activities *related to an agreement or arrangement with the federal government, or when a covered person acts*

sures.pdf; Gerke et al., supra note 4, at 1178. For more information on COVID-19 enforcement discretion guidance documents, see supra Section 11.3.2.2.

111 See also Gerke et al., supra note 4, at 1180.

112 Id.

113 Department of Health and Human Services, supra note 106, at 4. For other advisory opinions, see Department of Health and Human Services, Advisory Opinion 20-02 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration under the Act (May 19, 2020), www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/advisory-opinion-20-02-hhs-ogc-prep-act.pdf; Department of Health and Human Services; Advisory Opinion 20-03 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration under the Act (Oct. 22, 2020, as modified on Oct. 23, 2020), www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/AO3.1.2_Updated_FINAL_SIGNED_10.23.20.pdf; Department of Health and Human Services, Advisory Opinion 20-04 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration under the Act (Oct. 22, 2020, as modified on Oct. 23, 2020), www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/AO%204.2_Updated_FINAL_SIGNED_10.23.20.pdf; Department of Health and Human Services, Advisory Opinion 21-01 on the Public Readiness and Emergency Preparedness Act Scope of Preemption Provision (Jan. 8, 2021), www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/210108l078-jo-advisory-opinion-prep-act-complete-preemption-01-08-2021-final-hhs-web.pdf; Department of Health and Human Services, Advisory Opinion 21-02 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration under the Act (Jan. 12, 2021), www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/AO-21-02-PREP-Act_1-12-2021_FINAL_SIGNED.pdf.

114 Department of Health and Human Services, supra note 106, at 4–5; see also 42 U.S.C. § 247d–6d(a)(4)(B).

115 Department of Health and Human Services, supra note 106, at 2, 4, 5, 7.

116 Id.

117 Id at 2.

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according to an Authority Having Jurisdiction to respond to a declared emergency (emphasis added).[118]

The Counsel interprets such two conditions broadly.[119] The first condition includes "any arrangement with the federal government."[120] The second condition means "any activity that is part of an authorized emergency response at the federal, regional, state, or local level."[121] These activities can be authorized, for example, through agreements, requests for assistance, guidance, or other arrangements.[122]

The Fourth Amendment to the Declaration under the PREP Act, published in the Federal Register on December 9, 2020, added a third distribution channel that extends liability coverage to additional private-distribution channels.[123] To qualify for this channel, the "Covered Person must manufacture, test, develop, distribute, administer, or use the Covered Countermeasure pursuant to the FDA licensure, approval, clearance, or authorization (or pursuant to an Investigational New Drug Application or Investigational Device Exemption), or the NIOSH approval."[124]

If liability immunity is provided to covered persons, individuals who die or suffer a serious physical injury as a direct outcome of the use or administration of a covered countermeasure may receive compensation under the Countermeasures Injury Compensation Program.[125] In order to assess whether PREP Act immunity applies, each case will need to be evaluated individually, taking into account the particular circumstances and facts. The Fourth Amendment to the Declaration under the PREP Act also clarified that the Declaration must be construed pursuant to the Counsel's advisory opinions.[126] However, the advisory opinions only set forth the Counsel's current views.[127] It is thus highly recommended that digital home

[118] Id.; see also Department of Health and Human Services, Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, supra note 104.

[119] Department of Health and Human Services, supra note 106, at 2.

[120] Id.

[121] Id.

[122] Id.

[123] Department of Health and Human Services, Fourth Amendment to the Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 and Republication of the Declaration, supra note 104, at 79191.

[124] Id. at 79194. For more information on the Fourth Amendment to the Declaration, see, e.g., Cortney M. Godin & Kaitlyn M. Hansen, Fourth Amendment to the PREP Act Expands Protection and Adopts Guidance, www.peabodyarnold.com/fourth-amendment-to-the-prep-act-expands-protection-and-adopts-guidance.

[125] Department of Health and Human Services, Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, supra note 104; Department of Health and Human Services, supra note 106, at 8.

[126] Department of Health and Human Services, Fourth Amendment to the Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 and Republication of the Declaration, supra note 104, at 79191.

[127] See, e.g., Department of Health and Human Services, Advisory Opinion 21-02 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration under the Act, supra note 113, at 3.

health companies, for example, continue to apply best record-keeping practices and recording justifications for decision-making concerning devices that could be used as countermeasures to fight COVID-19.[128]

Digital home health products will also continue to raise liability questions post-pandemic. In particular, health AI presents new challenges for the liability ecosystem,[129] and it will be decisive to figure out how to ensure a balanced liability system in the future.

11.4.3 *Informed Consent*

Informed consent is important to respect the patient's autonomy and includes that health care providers disclose relevant information to competent patients who can voluntarily decide whether they want to accept or refuse a treatment, research study, and so forth.[130] For example, during the COVID-19 pandemic, a meaningful discussion between the physician and the patient is crucial in cases in which a wearable or remote patient monitoring device that is authorized for emergency use under an EUA shall be used in the treatment of a COVID-19 patient (for example, in a hospital setting) to help reduce personal contacts.[131] Most prominently, the physician should inform the patient that the device has not undergone a "full" FDA review and that the EUA does not suggest that it is safe and effective.[132] The physician should also explain to the patient, among other things, the significant known and potential risks and benefits of the use of the device, the patient's option to refuse or accept its use, and available alternatives, including their benefits and risk.[133]

The FDA requires sponsors to develop two fact sheets – one for health care providers and one for patients – that contain relevant information, such as on COVID-19, the device and its use, the device's potential and known risks and benefits, alternatives, length of the monitoring, the device's limitations, and an

[128] See Duane Morris, Department of Health & Human Services Clarifies Broad Scope of Immunity Protection Under the PREP Act, www.duanemorris.com/alerts/department_health_human_services_clarifies_broad_scope_immunity_protection_prep_act_0420.html; Department of Health and Human Services, supra note 106, at 8.

[129] See., e.g., W. Nicholson Price II, Medical Malpractice and Black-Box Medicine 295 (I. Glenn Cohen et al. eds., 1st ed. 2018); A. Michael Froomkin et al., When AIs Outperform Doctors: Confronting the Challenges of a Tort-Induced Over-Reliance on Machine Learning, 61 Ariz. L. Rev. 33 (2019); W. Nicholson Price II et al., Potential Liability for Physicians Using Artificial Intelligence, 322 JAMA 1765 (2019); A. Selbst, Negligence and AI's Human Users, 100 B.U. L. REV. 1315 (2020); W. Nicholson Price II et al., How Much Can Potential Jurors Tell Us about Liability for Medical AI?, 62 J. Nucl. Med. 15 (2021); Kevin Tobia et al., When Does Physician Use of AI Increase Liability?, 62 J. Nucl. Med. 17 (2021).

[130] Paul S. Appelbaum, Assessment of Patients' Competence to Consent to Treatment, 357 N. Eng. J. Med. 1834 (2007).

[131] For more information on EUAs, see supra Section 11.3.2.1.

[132] See also Gerke et al., supra note 4, at 1179.

[133] Id.; see also FDCA § 564(e).

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EUA.[134] An informed consent conversation between the physician and patient may also be carried out via telehealth, such as by phone or video call, to discuss, inter alia, the patient's questions concerning the fact sheet or any other questions.[135] In particular, the current fact sheets are only available in English, and their translation in other languages would be helpful for patients who may not be fluent in English.[136] The physician also needs to communicate with the patient through a qualified interpreter to ensure that a patient with limited English proficiency can give voluntary and informed consent.[137]

Transparency about the EUA and its criteria for issuance is essential to promote trust in the physician-patient relationship. The same applies to post-pandemic scenarios. Regardless of the legal requirements, the clinical translation of new technologies like AI and wearable or remote patient monitoring devices can only succeed if health care providers are frank with their patients from the outset about the technology's use, its benefits, and shortcomings.[138] The era of big data also requires that physicians are adequately educated about AI and digital health, including scientific, ethical, and legal considerations. Education in this field is crucial so that physicians can, for instance, explain to their patients what AI is, with what type of data the algorithm was trained, what data is collected and shared with third parties, and why it is shared. Moreover, this knowledge will not only help physicians to identify the best available treatment option for their patients but also to recognize potential biases in an AI/machine learning system.

Another challenge of most digital home health products is user agreements. For example, in response to COVID-19, Apple developed together with the White House, the Centers for Disease Control and Prevention, and the Federal Emergency Management Agency, a COVID-19 screening tool app. This app aims to help users understand what steps to take next about COVID-19, such as self-isolating. However, with the app's installation or use, users also agree to be bound by

[134] See, e.g., Letter from the FDA to VitalConnect (Apr. 26, 2020), supra note 54, at 4. For examples of such fact sheets, see, e.g., VitalConnect, Fact Sheet for Healthcare Providers, www.fda.gov/media/137399/download; VitalConnect, Fact Sheet for Patients, www.fda.gov/media/137400/download. For a best-practice list with information that fact sheets of EUA home monitoring devices should contain, see Gerke et al., supra note 4, at 1179.

[135] For more information on telehealth coverage policies during COVID-19 and post-pandemic considerations, see Sara Gerke et al., Germany's Digital Health Reforms in the COVID-19 Era: Lessons and Opportunities for Other Countries, 3 npj Digit. Med. (2020); Carmel Shachar et al., Implications for Telehealth in a Postpandemic Future: Regulatory and Privacy Issues, 323 JAMA 2375 (2020).

[136] See also Gerke et al., supra note 4, at 1179.

[137] For more information on the right to language services, see Gaurab Basu et al., Clinicians' Obligations to Use Qualified Medical Interpreters When Caring for Patients with Limited English Proficiency, 19 Am. J. Ethics 245 (2017).

[138] See, e.g., I. Glenn Cohen, Informed Consent and Medical Artificial Intelligence: What to Tell the Patient? 108 Geo. L. J. 1425 (2020) (who concludes that "the existing legal doctrine of informed consent does not robustly support an obligation to disclose the use of medical AI/ML," at 1467). For the importance of transparency concerning ambient intelligence in hospitals, see Sara Gerke et al., Ethical and Legal Aspects of Ambient Intelligence in Hospitals, 323 JAMA 601 (2020).

the terms of Apple's software license agreement. The issue with user agreements is that they are lengthy and difficult to understand, especially for nonlawyers. In contrast to an informed consent conversation between a physician and patient, a user agreement is nonnegotiable, and the user either accepts it or has to refrain from using the app.[139] In addition, user agreements often change. Moreover, in most cases of digital home health apps, such as in the case of Apple's screening tool app, sensitive data are collected. Such data may then be shared with third parties for different purposes, including commercial ones.[140]

Thus, during the COVID-19 pandemic and after the pandemic, more transparency is needed concerning software license agreements and the respective privacy policies when users install and use digital home health apps, such as COVID-19 exposure-notification apps, wellness apps, and mobile medical apps. App developers can do a better job in making the terms more accessible to the average user. For example, icons and a few sentences with lay terminology could be additionally used to present relevant information – such as the app's goal, information to data collection, use and sharing, and cybersecurity safeguards – to users once they have installed and opened the app. If this key information changes (for example, the app is now sharing data with third parties for commercial purposes), users should be notified in a similar manner so that they can make an informed decision about whether to continue using the app. User-friendly design options not only increase transparency, but also promote user trust in companies, which is necessary to ensure the success of digital home health in the future.

11.5 CONCLUSION

Digital home health holds great promise in enabling individuals to manage their own health. However, the adoption of digital home health products has been hastened during the COVID-19 pandemic to reduce exposure to SARS-CoV-2. This acceleration has also raised several challenges, including safety, liability, and informed consent. It is important that the identified issues are dealt with as best as possible during the COVID-19 public health emergency and will be overcome post-pandemic to release digital home health's full potential in the future.

[139] For more information on user agreements and their relationship to informed consent, see, e.g., Craig M. Klugman, The Ethics of Smart Pills and Self-Acting Devices: Autonomy, Truth-Telling, and Trust at the Dawn of Digital Medicine, 18 AJOB 38, 40–1 (2018).

[140] The Health Insurance Portability and Accountability Act of 1996 (HIPAA), for example, has gaps and may not adequately protect the health data privacy of individuals. Most users currently need to rely on the privacy laws of the states in which they live as to whether their privacy is adequately protected when using apps. For more information on such data privacy issues, see, e.g., I. Glenn Cohen & Michelle M. Mello, Big Data, Big Tech, and Protecting Patient Privacy, 322 JAMA 1141 (2019); Gerke et al., Ethical and Legal Challenges of Artificial Intelligence-Driven Healthcare, supra note 1, at 317–19; Gerke et al., supra note 4, at 1180–1; W. Nicholson Price II & I. Glenn Cohen, Privacy in the Age of Medical Big Data, 25 Nature Med. 37 (2019); Shachar et al., supra note 77, at 18–19.