Introduction

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Even prior to the COVID-19 pandemic, health care delivery was already shifting away from the clinic and into the home, utilizing telehealth, wearable sensors, ambient surveillance, and other products. Patients often prefer the convenience and comfort of care in the home, and the health system can benefit in terms of the lower cost of care. The COVID-19 pandemic further crystallized the value that can be gained when "health care comes home." Trends such as facilitating aging at home for seniors, keeping patients out of the clinic as much as possible, and telehealth have only been accelerated by the pandemic. However, this transition is not without its risks and potential unintended consequences.

So, what does this post-pandemic new world of at-home digital health care delivery look like? Patients will increasingly interact with digital products from the start of their health care journey, using wearable sensors to monitor changes in temperature or blood pressure, conducting home or self-directed testing before virtually meeting with a physician for a diagnosis, and then using smart tools to document their adherence to the prescribed treatment. Some of these products may be direct-to-consumer, while others will be designed to be integrated into the existing models of health care delivery. Some medical care may be relatively easier to translate from the clinic to the home, due to factors such as pre-existing clinician/patient relationships. Other services, such as diagnostics, may prove more complicated to shift into the home, perhaps because the individual is unaware that they might be developing a condition or because there are no established care relationships. Consider the difference in translating diabetes detection into the home, with the challenges of educating individuals about why they should test without a previous history of diabetes, and translating ongoing diabetes care, with patients who have physicians monitoring them and experience in managing their conditions.

This volume reflects on the explosion of at-home digital health care and explores the ethical and legal challenges and opportunities of this shift. These issues are substantial and complex – in part because this care can straddle the line between consumer wellness products and medical devices – but also because moving care into the home raises privacy questions and the challenge of integrating home devices

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with medical practices, among other issues. The integration of this new category of products will depend on the thoughtfulness and insightfulness of the solutions to these ethical and legal questions. By characterizing (and in some cases offering solutions to) these complex issues, this volume offers new insights into what it would truly mean to leave the twenty-first century focus on the clinic and the hospital for a more modern model, one of medical "touching at a distance."[1] Our volume has a significant grounding in health law and public health law, with leading legal experts exploring topics such as post-market surveillance for digital health products and the role of the FDA in ensuring safety and efficacy. But this work is not exclusively legal in nature, with social scientists, physician leaders, and political scientists also providing their analysis of digital health opportunities, challenges, and changes. The goal of this interdisciplinary volume is to identify the right questions for readers looking to engage with the ethical and regulatory implications of developments in digital diagnostics and therapeutics outside of traditional clinical settings.

A NOTE ON THE SCOPE OF THIS VOLUME

A challenge of editing this volume was defining and categorizing the domain of digital at-home health that this project examines. Digital at-home health products are proliferating, and this rapidly expanding domain covers many different technologies. There is no settled definition for "at-home digital diagnostics," and yet, it is important to demarcate the scope of the inquiry. While others might arrive at slightly different definitions, for the purposes of this book project, the term "at-home digital diagnostics" is interpreted broadly, with each constituent part understood in the following way.

At-Home: Outside of traditional health care settings. Traditional health care settings include, for example, physician offices, brick-and-mortar hospitals, medical centers, and stand-alone testing facilities. When the product is used primarily or only in these settings or locations, the definition excludes them. An in-home sleep study device would, by contrast, qualify as "at-home," as would a smartphone application, like Hyfe, an app that produces a cough report by tracking user cough patterns whenever the user initiates the app. At the same time, for our purposes, "at-home" might also include a traditional health care service, such as an office visit, if performed remotely through video or telephone.

Diagnostics: Any device that can aid in the identification of a particular disease or condition, or an event associated with that disease or condition. This definition covers not only the initial diagnosis of a particular disease or condition, but also the "diagnosis" (or identification) of events caused by a particular disease or condition. Glucose monitors, for example, would fit within this definition because they can aid

[1] Robert D. Truong, Of Slide Rules and Stethoscopes: AI and the Future of Doctoring, 49 *Hastings Center Report* 3 (2019).

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in the diagnosis of low blood sugar, even though a patient typically uses one only *after* an initial diabetes diagnosis. The majority of the contributions in this volume focus on diagnostics, but we have also included contributions across the entire care cycle, including monitoring and therapeutics, to provide the reader with a broader sense of the implementation of digital at-home health.

This volume's special emphasis on diagnostics stems from our belief that this is an especially exciting frontier for health care. Early attempts at digital health care have tended to focus on existing patient–provider relationships, such as using video conferencing for follow-up visits. Pre-diagnostic and diagnostic digital health products have the potential to integrate health care into daily living but also to move patients into treatment and care at earlier points, improving outcomes and saving on costs. To truly revolutionize health care, digital health needs to embrace the earlier portions of the medical cycle and deliver on monitoring and diagnostics.

Digital: Significantly incorporates a novel, technology-enabled component not traditionally found in health and medical devices. A self-testing kit that allows users to view their results online would not satisfy this definition of "digital," since the digital component does not significantly alter the analog self-test. By contrast, a self-testing kit that enables the user to run a tissue sample through a machine-learning application on a phone or tablet to process the results, or to assist the user in understanding and interpreting the results, would fall within this definition. This flexible definition captures the breadth of technologies where the digital component *significantly changes* the nature of the device.

A ROADMAP FOR READERS

The book is divided into four parts. Part I, "Questions of Data Governance for Data from Digital Home Health Products," dives into the digital side of this new products category. Introduced by Carmel Shachar, these chapters demonstrate how the digital aspect of these new technologies has revolutionized at-home care. But these chapters also address the challenges raised by using data gleaned from the home. In an age where digital data streams have turned into roaring rivers, how do we respect the privacy of consumers and patients? The authors of these chapters note that the products we focus on are embedded in the home, making the data more sensitive and privacy violations more concerning. Each of the chapters in Part I provides different approaches and solutions to the unique challenge of data governance when the data is both topically sensitive (health and medical data) and situationally sensitive (coming from the home).

Barbara J. Evans opens our volume with her chapter, "In the Medical Privacy of One's Own Home: Four Faces of Privacy in Digital Home Health Care." Evans's contribution is an expansive look at the concept of privacy. She contextualizes the unique privacy challenges raised by moving the medical panopticon into the home. We chose to open our volume with this contribution to remind the reader

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that digital at-home health products are not simply medical devices transplanted from the hospital to the home. Instead, because they are designed for and placed within our houses, worn on our bodies, or otherwise part of our daily lives, they are a new beast entirely. Evans suggests that there is a need for legislation specifically addressing these types of products to create a new data governance scheme for at-home digital health.

Charles Duan and Christopher J. Morten's chapter, "Patient Access to Health Device Data: Toward a Legal Framework," also articulates a new data governance framework for digital at-home health products. In this chapter, the authors focus on the problem of data silos, a data governance problem that appears time and time again in the digital at-home health field as developers purposefully design wellness products and medical devices to lock data away in manufacturers' cloud services. Duan and Morten argue that limiting access to data is especially problematic when that data is health and medical data. Additionally, they are concerned that this siloing undermines medical research by preventing researchers from building "real-world evidence" data sets. Duan and Morten argue for a patients' "bill of rights" with incentives for developers to build data interoperability into their products, technical standards to promote data sharing and access, and guidelines for data aggregation.

"Challenges of Remote Patient Care Technologies under the General Data Protection Regulation: Preliminary Results of the TeNDER Project," Danaja Fabcic Povse's contribution, provides a European-focused framing to questions of data governance for digital at-home health products. Povse aims to "bridge the gap between the high-level frameworks and practical, micro-level application of these technologies by providing an overview of the challenges under European Union (EU) law when developing and using" remote care technologies. She draws upon her experience with the TeNDER project, which builds technology that alerts caregivers when patients with complex diseases, such as Parkinson's and Alzheimer's fall. Povse's work is a great example of the challenge of distilling larger data governance principles and regulatory requirements into workable guidelines for those building innovative new technologies. She acknowledges that there are tensions between particular technologies and abstract legal frameworks in general, and that it is the work of lawyers and ethicists to determine how to bridge the gap.

Jodyn Platt and Sharon Kardia provide a different sort of case study in their chapter, "Renegotiating the Social Contract for Use of Health Information: Lessons Learned from Newborn Screening and Implications for At-Home Digital Care." Platt and Kardia analyze the experience of setting up the Michigan BioTrust for Health, which included Michigan's newborn screening bloodspots, to help guide the implementation of future technologies, including at-home digital health products. Platt and Kardia use consumer preferences and expectations for the BioTrust for Health to develop recommendations for the governance of at-home digital health care products. In doing so, they draw the reader's attention to the implicit

and explicit social contract between patients, providers, and developers when it comes to data use.

Part II, "Digital Home Diagnostics for Specific Conditions," introduced by Daniel B. Kramer, focuses on the application of digital at-home health products to specific conditions, namely cardiovascular disease, reproductive health, and neurodegenerative diseases. Each chapter, on its own, provides a real-world case study of the challenges and opportunities of incorporating new technologies, such as sensors, data transmission, artificial intelligence (AI), and data science, to the diagnoses, treatment, and management of a particular condition. The chapters in Part II, when read together, allow the reader to consider the commonalities and contrasts in the ethical, legal, and regulatory questions raised when these products are used to address these conditions. What questions are universal when incorporating digital health technology into the home? What questions are specific to certain conditions?

Patrik Bächtiger, Mihir A. Kelshiker, Marie E.G. Moe, Daniel B. Kramer, and Nicholas S. Peters, in their chapter, "Patient Self-Administered Screening for Cardiovascular Disease Using Artificial Intelligence in the Home," explore the application of at-home digital technologies to cardiovascular disease, using data from a UK attempt to address late or missed diagnoses of congestive heart failure. Bächtiger and his co-authors explore questions of equity, agency, data rights, and responsibility. Drawing from the UK experience, they argue that the incorporation of digital at-home technologies with the monitoring and treatment of cardiovascular disease requires a rethinking of the roles and responsibilities of each stakeholder, including patients, providers, and regulators.

Greer Donley and Rachel Rebouché, in their chapter, "The Promise of Telehealth for Abortion," likewise consider questions of equity, agency, and data governance. In their case, these questions arise in their legal and regulatory analysis of medical abortion services provided without direct in-person care. This chapter was written at a very specific point in the timeline of reproductive care regulations, shortly after the US Supreme Court declared that there was not a constitutionally protected right to an abortion in *Dobbs* v. *Jackson Women's Health Organization*. The reader should consider their chapter as an early response to the upheaval caused by *Dobbs* and an attempt to flag the challenges and risks borne by patients seeking abortion care and providers of abortion services. Additionally, their contribution reminds us that inviting digital health into the home can mean inviting unwanted digital surveillance into our private lives as well. Are the benefits of digital at-home health worth the invasion of privacy? As such, Donley and Rebouché's chapter harkens back to Part I, with its broader discussions of privacy and data governance.

Claire Erickson and Emily A. Largent close this section with their contribution, "Monitoring (on) Your Mind: Digital Biomarkers for Alzheimer's Disease," which explores the complexity of using digital at-home health products with Alzheimer's disease. Erickson and Largent argue that some of the questions raised by

incorporating these products into the diagnosis, care, and treatment of Alzheimer's are unique because Alzheimer's affects the mind. In contrast to physical ailments, using digital surveillance for people with preclinical or clinical dementia raises unique and challenging questions around consent. Alzheimer's is also differentiated from cardiovascular disease because of the absence of effective therapies for cognitive impairment. In light of the challenges of consent and the questionable value of early detection, how do we ethically incorporate these monitoring products into everyday life?

Part III, "The Shape of the Elephant for Digital Home Diagnostics," introduced by I. Glenn Cohen, reminds us that these technologies are designed to be products, sold on the market and bought by consumers. What happens when at-home digital health products are released into the wild? How should our legal and regulatory systems monitor and manage these technologies once they have passed the research and development stages? The chapters in Part III seek to illuminate the ways we can ensure the safety and efficacy of these products, both *ex-post* and *ex-ante*. Read together, these chapters remind the reader of the breadth of tools our regulatory system has to "keep an eye" on various at-home digital health products.

David A. Simon and Aaron S. Kesselheim open Part III with their contribution, "Physician and Device Manufacturer Tort Liability for Remote Patient Monitoring Devices." Simon and Kesselheim give the reader a whirlwind tour of the US tort system. They note the value of torts as "a major tool to hold these actors [device manufacturers and physicians] accountable for injuries they cause to patients." At the heart of this chapter is the question: How can torts be used to *ex-post* regulate at-home digital health products? To answer this question, Simon and Kesselheim evaluate various regulatory pathways that could be used to bring these products to market and their implications on subsequent tort claims. They also evaluate the application of the tort system to at-home digital health products by considering the application of US tort law to various stakeholders, including prescribing physicians, patients/consumers, and others who interact with the products, such as caregivers.

Alexander O. Everhart and Ariel D. Stern use a different approach to illustrate another approach to the *ex-post* regulation of at-home digital health products in their chapter, "Post-Market Surveillance of Software Medical Devices: Evidence from Regulatory Data." Everhart and Stern explore the FDA's post-market surveillance of remote patient monitoring devices that are categorized as medical devices. They use a dataset of all 510(k)-track and premarket notification approval medical devices approved by the FDA between 2008 and 2018 to demonstrate that "software-drive medical devices" had higher rates of adverse events and recall probabilities than devices that did not have a software component. They argue that this discrepancy suggests that post-market surveillance is not sufficient for software-drive medical devices and that our regulatory system needs further tools to ensure the safety of these products as they become more and more common.

While the first two chapters in Part III focus on *ex-post* regulatory mechanisms, Sara Gerke's chapter, "Labeling of Direct-to-Consumer Medical Artificial Intelligence Applications for 'Self-Diagnosis'" considers *ex-ante* regulatory mechanisms for at-home digital health products. Gerke focuses on direct-to-consumer medical self-diagnosing artificial intelligence apps. She argues that these apps have been largely mislabeled as "information-only" rather than diagnostic tools. The mislabeling is partially by design, because manufacturers have strong regulatory incentives to present their products as information-only, despite evidence suggesting that most consumers assume these apps are actually diagnostic. Gerke suggests that direct-to-consumer apps require better labeling, reducing user confusion, but that some apps should be prescription-only. Gerke provides suggestions for how the FDA can exercise leadership in this space but also calls for a new regulatory agency to be responsible for mobile health apps.

Zhang Yi and Wang Chenguang turn the focus of Part III away from the US approach to regulating digital at-home health products to the Chinese approach in their chapter, "'Internet Plus Health Care' as an Impetus for China's Health System Reform." Chinese regulation focuses on these products as being within the continuum of health care and, therefore, properly regulated within the context of health care regulation. China has created a regulatory category, "internet plus health care" (IPHC), for these products that the chapter describes in some depth. While the authors acknowledge that there are still many open questions when it comes to regulating these products, they also note that China has successfully integrated these technologies into their health care delivery and regulatory systems. This chapter will hopefully prompt US and European readers to consider whether the FDA and its European counterparts focus perhaps too much on digital health technologies as devices, rather than as integrated tools of medical practice.

Part IV, "Reimbursement Considerations for Digital Home Health," introduced by Julia Adler-Milstein, shifts the focus from regulation to reimbursement and financing for digital at-home health products. Despite the fact that digital at-home health products are an increasingly significant part of the health care landscape, American insurers and governmental programs are still struggling to articulate consistent reimbursement policies and approaches. As one chapter in this section makes clear, European regulators and policymakers likewise struggle to articulate clear and concise reimbursement pathways for these new care modalities. Clear and consistent pathways to reimbursement are important for this product category to continue to thrive, however. But what is a workable reimbursement approach for these new technologies? The authors of the chapters in Part IV agree that the current, scattershot approach risks undermining the impact that digital at-home health products can have on expanding access and improving quality of care.

Stephanie Zawada, Nels Paulson, Margaret Paulson, Michael Maniaci, and Bart Demaerschalk open Part IV with "A Pathway for High-Value Home Hospital Care in the United States: Statutory, Reimbursement, and Cybersecurity Strategies in

the Age of Hybrid Care." The authors draw upon their experiences at the Mayo Clinic of building a hospital at-home (H@H) program to keep lower-acuity patients at home during the COVID-19 pandemic. Zawada and her co-authors describe a program that had many benefits, including increased access, lower utilization, and easier transitions to post-acute care. They note that a critical factor in establishing and expanding this program and in making it a success was payment parity. That is, patients within the H@H program were reimbursed as if they were inpatients at the Mayo Clinic. Payment parity for telehealth and other at-home digital care modalities has been hotly contested. Here, Zawada and her co-authors argue that, while some costs are lowered by home-based care, such as the physical infrastructure costs, the increased technology and staffing needs mean that these programs are only financially workable if reimbursement is at parity with inpatient programs. This chapter is informative to the reader because it dissects a real-world experience, delivering insights on what is needed to make at-home digital health care a success overall.

Kathryn Huber and Tara Sklar also consider the necessity of payment parity and other reimbursement incentives in building up at-home digital health care in their chapter, "Digitally Enabled Medicaid Home and Community-Based Services." Huber and Sklar focus on home and community-based services (HCBS) for older adults who otherwise might be candidates for skilled nursing facilities or other institutional settings. HCBS are currently limited, and demand far outstrips supply. Technology, such as remote patient monitoring, home telehealth, and self-administered diagnostics, could help bridge this gap and support aging in place. Huber and Sklar argue that leadership from the Centers for Medicare and Medicaid is vital, especially when it comes to innovative reimbursement policies to support the incorporation of at-home digital health technologies into long-term care. Huber and Sklar also flag challenges in the utilization of digital technologies to care for aging patients, such as ensuring equitable access, the mitigation of risks, and supported decision-making.

Kaat Van Delm then directs our attention to the need for united European reimbursement policies for these technologies in her chapter, "EU In-Home Digital Diagnostics – Cross-Border Patient Reimbursement under Threat?" Cross-border reimbursement for health care remains a challenge for the EU, where telehealth cross-border reimbursement is even more complicated and poorly defined. And cross-border reimbursement for digital diagnostics is almost entirely unmapped as of yet. Van Delm explains why cross-border reimbursement of telehealth remains such a challenge under the EU regulatory scheme that must attempt to harmonize its different member states' approaches. She warns that the status quo can discourage innovation by making it difficult for developers to achieve scale by operating across the EU. She also flags that EU policymakers should consider modernizing and simplifying the legal frameworks to better support the adoption and growth of digital health, including at-home diagnostics.

CONCLUSIONS

The authors of the chapters in this volume map out the opportunities of these new products alongside the ethical, legal, and regulatory challenges of integrating new technologies that have the potential to be so disruptive. We begin this volume with some of the questions that immediately come to mind when thinking of digital health products: questions of data governance, data ownership, and privacy. We then consider three case studies of different conditions, which demonstrate that digital at-home health products have the potential to be revolutionary for a variety of medical specialties. Our attention then turns to how to regulate these products when they are released to market, using both *ex-post* and *ex-ante* approaches. Lastly, we consider an aspect that is often overlooked when people consider how to integrate digital at-home health products into the health care landscape: The need for consistent and sensible reimbursement policies. Not every question raised in this volume has an answer, but, overall, the authors of this volume provide the reader with a roadmap toward a twenty-first-century model of medicine.

At-home digital health products are vital for moving health care from a twentieth-century model of care – largely based within the physician's office or the hospital – to a twenty-first-century modality in which monitoring, diagnosis, treatment, and follow-up are integrated into daily living. The development of at-home digital health products that can monitor and diagnose is especially exciting because, until recently, most at-home digital health care efforts have focused on translating ongoing, already-established care relationships. Bringing care into the home at earlier and earlier points in the medical cycle means making health care more accessible and delivering care at earlier intervention points. But whatever the medical cycle point, this product category has the potential to be transformative at a time when labor shortages, rising costs, and limited resources mean that health care can no longer be "business as usual."

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