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Liability for Mobile Health and Wearable Technologies*

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I. INTRODUCTION

Notoriously, health care is relatively immune to traditional market forces[1] and is more difficult to disrupt than other industries.[2] Instead, change has been reliant on massively compromised and politically fraught interventions, such as the Affordable Care Act.[3] Mobile health offers a different, parallel path. It promises better and more personalized care combined with improved convenience and lower cost.[4]

Many, if not most, mobile health applications ("apps") and wearable devices that track fitness, wellness, or other physiological data do not support existing models of health care.[5] Rather, developers are delivering a novel consumer-centric aesthetic and functionality that traditional healthcare policymakers are only now beginning to conceptualize.[6] Notwithstanding, the division between traditional health care and mobile health is anything but

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* © 2016 Nicolas Terry & Lindsay Wiley. All rights reserved. This paper is based on presentations we prepared for a workshop sponsored by the American Association for the Advancement of Science (AAAS). We thank all the workshop participants and, in particular, Deborah Runkle, Senior Program Associate at AAAS for her valuable comments. We also thank Mark Levy and Maya Frazier, American University Washington College of Law JD candidates, for their helpful research assistance and Kelci Dye, Indiana University Robert H. McKinney School of Law JD candidate, for her diligent editing.

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1. Alain C. Enthoven, *Market Forces and Efficient Health Care Systems*, 23 HEALTH AFF. 25, 25 (2004).

2. *See* Nicolas P. Terry, *Information Technology's Failure to Disrupt Health Care*, 13 NEV. L.J. 722, 723 (2013) (noting the difficulties faced by one possible health care disruptor, health information technology (HIT)).

3. *See generally* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010) (codified as amended at 42 U.S.C. § 18001 (Supp. 2010)).

4. Nicolas Terry, *Innovation in Mobile Health Impacts Law*, IND. LAW. (July 15, 2015), http://www.theindianalawyer.com/innovation-in-mobile-health-impacts-law/PARAMS/article/37699.

5. *Id.*

6. *Id.*

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clean.[7] Some mobile health apps are "provider-facing," targeting the traditional physician-patient relationship designed to improve data access or efficiency.[8] Other apps, while designed for consumers, may be developed by traditional healthcare providers or their business partners.[9] Many patients will acquire apps or wearables with the intention of presenting the data to their providers, looking for professional approval, further recommendations, or even technical assistance.[10] Some providers may attempt to manage the app onslaught by recommending only certain apps or even curating their own app formularies.[11]

Much of the mobile health revolution likely will play out in lightly regulated spaces bereft of most of the privacy, security, and safety rules associated with traditional health care.[12] The non-provider actors at most risk of legal liability are the developers and app vendors who may have only a cursory knowledge of the exceptional legal rules and protections to which patients and providers are accustomed.

Most of the legal commentary regarding mobile health has focused on direct regulation.[13] Congress and several federal agencies have begun to

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7. *See id.* (noting that there is a "health care revolution" going on and that mobile health is "poised to upset the model").

8. *See generally* Pragati Verma, *How Electronic Health Records Will Be More Helpful to Doctors – And Patients*, FORBES (April 27, 2015, 10:00 AM), http://www.forbes.com/sites/cit/2015/04/27/how-electronic-health-records-will-be-more-helpful-to-doctors-and-patients/#45480d777a15 (predicting flexible, mobile cloud-based acute care electronic health records will enable better integration, allowing physicians to view a patient's information, respond to patient messages using quick text and assess a patient's refill requests).

9. *See* Bob Spoerl, *6 Trends in an Era of Consumer-Driven Healthcare*, BECKER'S HOSP. REV. (June 6, 2012), http://www.beckershospitalreview.com/strategic-planning/6-trends-in-an-era-of-consumer-driven-healthcare.html (stating, "The fact that hospitals are seeking to make more intimate connections with patients and treating them as consumers is not a new phenomenon. But now, in an era when mobile access and social media brings a sense of hyper-connectivity to life, the trend may seem more pronounced than ever before.").

10. *See* Joseph Conn, *Easy on Those Apps: Mobile Medical Apps Gain Support, but Many Lack Clinical Evidence*, MODERN HEALTHCARE (Nov. 28, 2015), http://www.modernhealthcare.com/article/20151128/MAGAZINE/311289981 (explaining that approximately sixteen percent of health care professionals currently use mobile applications with their patients, but that forty-six percent plan to do so in the next five years).

11. *See id.* (recommending home blood-pressure apps because patients' blood pressure often rises when they enter the office).

12. *Mobile Medical Applications*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/MedicalDevices/DigitalHealth/MobileMedicalApplications/default.htm#e (last updated Sept. 22, 2015).

13. *See, e.g.*, Nathan Cortez, *The Mobile Health Revolution?*, 47 U.C. DAVIS L. REV. 1173, 1179 (2014) (focusing on the mobile health's potential of mobile health by examining regulators such as the FDA); *see also* Nicolas P. Terry, *Mobile Health: Assessing the Barriers*, 147 CHEST 1429, 1430-33 (2015) (focusing on the potential of mobile health apps in the context of safety and privacy, discussing regulations in mobile health apps).

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address the risks posed by these technologies.[14] Some commentators have urged the Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) to provide more meaningful oversight to ensure that mobile health technologies are safe and effective,[15] while others have cautioned that regulatory overreach may stifle innovation.[16] This article focuses on another means for ensuring that mobile health technologies are developed and used in a safe, effective, and data-protective manner: indirect regulation through liability models applied to healthcare professionals, healthcare institutions, and app developers.

The areas of malpractice, product liability, and privacy liability remain primarily case law driven, but at this stage in the development of mobile health, there is little case law directly on point. We extrapolate from cases addressing analogous issues to assess potential liability concerns for health care providers who: (1) participate in the design of mobile health products;[17] (2) use—or decline to use—mobile health products for patient care; and (3) recommend or even prescribe the use of mobile health products by patients.[18] We further suggest that the advent of mobile health technologies does not necessitate the development of novel legal doctrines. Rather, existing doctrines are adequate to apply tort and privacy law to the development, use, recommendation, and prescription of mobile health products by healthcare professionals.[19]

Like any other new medical technology, mobile health products are likely to amplify existing uncertainties in the tort liability context, at least in the short term.[20] In particular, the standard of care for professional malpractice—which is based on the customary or prevailing practices of the professional

14. *See* Cortez, *supra* note 13, at 1201 ("[C]ongress and the FDA have prioritized which devices deserve more regulatory attention based on the risks they present."); *see also* 21 C.F.R. § 860.7 (2008) (ruling that the FDA will review evidence concerning the safety and effectiveness of a medical device).

15. Cortez, *supra* note 13, at 1230; Stephen McInerney, *Can You Diagnose Me Now? A Proposal to Modify FDA's Regulation of Smartphone Mobile Health Applications with a Pre-Market Notification and Application Database System*, 70 FOOD & DRUG L.J. 161, 179 (2015).

16. Brady Donnelly, *While Healthcare Apps Are on the Rise, the FDA Threatens to Stifle Innovation in the U.S.*, TNW NEWS (June 9, 2012, 1:20 PM), http://thenextweb.com/insider/2012/06/09/while-healthcare-apps-are-on-the-rise-the-fda-threatens-to-stifle-innovation-in-the-u-s/#gref.

17. *See* Beth S. Rose, *Uncharted Territory: Mobile Medical Apps and Product Liability Collide*, N.J. L.J. (Dec. 9, 2015), http://www.njlawjournal.com/id=1202744463977/Uncharted-Territory-Mobile-Medical-Apps-and-Product-Liability-Collide (noting that liability regarding mobile health will likely "turn on the performance or design of the app itself").

18. Pam Baker, *Mobile Health Apps, Part 4: Life, Death and Lawsuits*, TECH NEWS WORLD (May 5, 2011, 5:00 AM), http://www.technewsworld.com/story/72394.html.

19. Rose, *supra* note 17.

20. Baker, *supra* note 18.

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community—could act as a temporary drag on the adoption of new mobile health technologies by professionals, who may prefer to proceed with caution until prevailing professional practices emerge with respect to mobile health use.[21] Over time, however, if these technologies prove useful and reliable, they could be incorporated into the standard of care in some contexts.[22] At that point, the customary-practice standard of care might accelerate adoption of mobile health technologies by recalcitrant physicians who would otherwise face potential liability for failing to make use of applications that have been incorporated into the prevailing practices of the profession.[23] Similar conclusions apply to our treatment of product liability-based exposure of app developers and vendors. Notwithstanding the dearth of decided cases, direct institutional healthcare liability or product liability theories could be applied to those involved in mobile development and deployment. This is the case whether the actors are inside or outside the traditional healthcare system.

Part II of this paper provides an introduction to the terminology used, and presents a brief typology of the apps appearing in the health care space. Part III discusses the potential liability of physicians and other healthcare professionals. Part IV discusses the potential liability of institutional healthcare providers such as hospitals (that, in many cases are dependent upon the finding of fault in an individual professional). Part V discusses the applicability of product liability to mobile health developers and vendors. Part VI explains some of the issues that may arise when patients or consumers seek damages following privacy or security breaches. The survey concludes by noting that regulation by litigation will be a significant force in the app and wearable arena during a period of light regulation by traditional

21. *See* Deven McGraw et al., *Going Digital with Patients: Managing Potential Liability Risks of Patient-Generated Electronic Health Information*, 5 J. PARTICIPATORY MED. (Dec. 18, 2013), *available at* http://www.jopm.org/perspective/narratives/2013/12/18/going-digital-with-patients-managing-potential-liability-risks-of-patient-generated-electronic-health-information/ (noting the reluctance of some physicians to receive patient data through digital forms because of professional liability concerns and the lack of a clear standard of care).

22. The disadvantage of the customary-practice standard of care, its indeterminacy, is linked to its advantage, flexibility. The customary-practice standard is flexible enough to accommodate changes in technology and professionals' use of it. New technology—whether it be MRI, pulse oximetry, or an app—challenges health care professionals to adapt their practice. When adoption of such a technology becomes prevailing practice among the relevant profession, it is more or less automatically incorporated into the customary-practice standard of care.

23. Overall the literature is murky when it comes to physicians and the adoption of health information technologies. For example, there is some evidence that physicians who adopt EHRs have a lower malpractice rate, Mariah A. Quinn et al., *The Relationship Between Electronic Health Records and Malpractice Claims*, 172 ARCH INTERN MED. 1187, 1187-89 (2012). However, any impact does not seem to be factored into medical malpractice premiums, Hye Yeong Kim & Jinhyung Lee, *Effects of Health Information Technology on Malpractice Insurance Premiums*, 21 HEALTHCARE INFORMATICS RES. 118, 118-19 (2015).

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regulators. This is a conclusion that is unlikely to encourage either healthcare providers or app developers, given that the indeterminacy associated with common law litigation is only exacerbated when applied to novel or emerging technologies.

II. TYPOLOGY AND TERMINOLOGY

The development of computing hardware, software platforms (operating systems), and the software and services sitting atop them has been extraordinary, with "Moore's law provid[ing] an unprecedented combination of blistering progress and certainty about the near future."[24] It took a while for mainframes to be replaced by personal computers (PC), while the movement to the post-PC world of mobiles has been comparatively rapid.[25] However, increased miniaturization and rapid iteration are now delivering the post-mobile future of wearables.[26] In this article the term mobile health is used to describe several overlapping technologies: health apps running on mobile devices, sensors and software built into mobile device platforms, and wearable technologies. However, the article does not consider the use of general mobile technologies, such as email or texting that may be used in the healthcare setting.

Tens of thousands of mobile health products are already available on the market.[27] A typology developed by Nathan Cortez, which organizes these products according to function, is a useful starting point for our analysis.[28] "Connectors" connect "smartphones and tablets to FDA-regulated devices,"

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24. *Double, Double, Toil and Trouble*, ECONOMIST: TECH. Q. 3 (March 12, 2016), *available at* http://www.economist.com/technology-quarterly/2016-03-12/after-moores-law.

25. *See generally* Gina Smith, *Post PC Era Buzzword: Net Pioneer and MIT Futurist David Clark Used it First in 1999*, A NEW DOMAIN, http://anewdomain.net/2012/10/13/post-pc-era-buzzword-mit-david-clark-used-it-first-in-1999/ (last visited March. 12, 2016) (describing the characteristics of the post-PC world); *see generally* THE NIELSEN CO., THE U.S. DIGITAL CONSUMER REPORT (Feb. 10, 2014), *available at* http://www.nielsen.com/us/en/insights/reports/2014/the-us-digital-consumer-report.html.

26. *See generally* Jeanne Meister*, The Wearable Era Is Here: Implications for the Future Workplace*, FORBES (June 16, 2014, 10:15 AM), http://www.forbes.com/sites/jeannemeister/2014/06/16/the-wearable-era-is-here-implications-for-the-future-workplace/#5ffe995f17bd (noting that the Wearable Era is "a time when smart accessories will in turn push aside regular old phones and Tablets."). For a general definition of what a wearable is and is not, *see* Dan Sung, *What is Wearable Tech? Everything You Need to Know Explained*, WAREABLE (Aug. 3, 2015), http://www.wareable.com/wearable-tech/what-is-wearable-tech-753 ("The new age of wearables tap into the connected self – they're laden with smart sensors, and make sue use of a web connection, usually using Bluetooth to connect wirelessly to your smartphone.").

27. Matt Goodman, *Study Argues Booming Mobile Health Industry Would Benefit from Increased FDA Regulation*, DALLAS/FORT WORTH HEALTHCARE DAILY (Aug. 5, 2014), http://healthcare.dmagazine.com/2014/08/05/study-argues-booming-mobile-health-industry-would-benefit-from-increased-fda-regulation/ (noting there were more than 97,000 mobile health apps on the market as of March 2013).

28. Cortez, *supra* note 13, at 1179.

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enabling clinicians to view scans and other biometric readings, and/or act as wireless remote controls for medical devices, raising the possibility of patient injuries.[29] "Replicators" turn "the smartphone or tablet itself into a medical device" using "attachments or sensors to send data directly to the smartphone, which then processes and displays the results," and in some cases recommends, diagnoses or provides treatment options.[30] "Automators" and "customizers" use surveys, algorithms, and the like to aid clinical decision-making but could lead to faulty diagnosis or treatment decisions.[31] "Informers" and "educators," which make up a significant portion of the hundreds of mobile health apps now on the market, are digital versions of resources that are also available in print or would have been in the past.[32] "Administrators" are the mobile health equivalent of practice management software—to the extent that they are confined to scheduling patient appointments and performing billing functions; there would not appear to be any significant liability concerns regarding administrator apps.[33] Yet, as they start to incorporate automator and customizer functions to triage patients for appointments,[34] they could expose healthcare providers to liability.[35] "Loggers" and "trackers" allow users to record and analyze information about their diet, physical activity, sleep patterns, and so on.[36]

The FDA has its own, somewhat less transparent mobile health app typology, suggesting ten types of apps in recently-published guidance for the medical application industry and FDA.[37] That guidance identified mobile apps that *could* be regulated under section 201(h) of the Federal Food, Drug, and Cosmetic Act either "as an accessory to a regulated medical device; or to transform a mobile platform into a regulated medical device."[38] The guidance then identified classes of apps over which the FDA would exercise regulatory

29. *Id.* at 1182.
30. *Id.* at 1184.
31. *Id.* at 1186.
32. *Id.* at 1188.
33. *Id.* at 1189.
34. *Id.*
35. Ken Terry, *A Physician's Guide to Prescribing Mobile Health Apps*, MED. ECON. (Oct. 8, 2014), http://medicaleconomics.modernmedicine.com/medical-economics/content/tags/2014-ehr-scorecard/physicians-guide-prescribing-mobile-health-apps?page=full (discussing the fear physicians have when dealing with medical mobile apps causing them to be very general when recommending apps to patients).
36. Cortez, *supra* note 13, at 1189.
37. *See generally* U.S. DEP'T OF HEALTH & HUMAN SERVS., MOBILE MEDICAL APPLICATIONS: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF 13–18 (2015) [hereinafter FDA 2015 GUIDANCE], http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf (superseding the original Guidance issued in September 2013, but the 2015 Guidance is primarily consistent with the original Guidance).
38. *Id.* at 12.

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discretion (such as fitness trackers).[39] The FDA approach remains useful for our current task because the agency's risk-based approach to regulation or the exercise of its regulatory discretion should be loosely predictive of harm and liability exposure.[40]

Mobile apps and wearables can be roughly divided into two categories: those that are essentially healthcare provider-facing, a greater part of the "digital health" domain, and those that are patient or consumer-facing.[41] The former includes:

(1) apps providing remote control of medical device or enabling remote display or analysis of data from medical device (connectors);[42] (2) apps, wearables, sensors, or attachments providing functions similar to those of currently regulated medical devices (replicators);[43] and (3) apps, wearables, or sensors performing patient-specific analysis, diagnosis, or treatment recommendations (automators and customizers).[44]

In contrast, consumer apps include: (1) apps providing access to health records,[45] (2) consumer versions of existing medical devices,[46] (3) condition monitoring and management apps,[47] (4) fitness trackers and wellness coaches,[48] and (5) diagnosis or treatment apps.[49]

Obviously, there will be overlaps between the categories. Both patients

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39. *Id.* at 23–26.

40. *See id.* at 13 (noting the FDA's intent to "apply its regulatory oversight to only those mobile apps that are medical devices and whose functionality could pose a risk to a patient's safety if the mobile app were to not function as intended.").

41. *See generally* U.S. FOOD & DRUG ADMIN., MOBILE MEDICAL APPLICATIONS, http://www.fda.gov/MedicalDevices/DigitalHealth/MobileMedicalApplications/default.htm (discussing the FDA regulations for mobile medical apps and how these apps assist providers and consumers, and also discussing that consumers can use both mobile medical apps and mobile apps so manage their own health and wellness) [hereinafter FDA MEDICAL APPS].

42. Cortez, *supra* note 13, at 1182.

43. *Id.* at 1184.

44. *Id.* at 1186.

45. *See generally Medfusion Launches First Consumer Mobile App to Simplify Healthcare Records*, MEDFUSION (Sept. 16, 2015), http://www.medfusion.com/press-releases/medfusion-launches-first-consumer-mobile-app-to-simplify-healthcare-records/.

46. *See generally* FDA MEDICAL APPS, *supra* note 41 (stating that, "Mobile medical apps are medical devices that are medical apps, meet the definition of a medical device, and are in accessory to a regulated medical device or transform a mobile platform into a regulated medical device.").

47. *See generally* Julie Bird, *7 Mobile Apps for Chronic Condition Management*, FIERCE MOBILE HEALTHCARE, (Sept. 25, 2012), http://www.fiercemobilehealthcare.com/slideshows/7-mobile-apps-chronic-condition-management (discussing the top consumer mobile apps for chronic condition management).

48. *See generally* FDA, MEDICAL APPS, *supra* note 41 (stating that, "Consumers can use both mobile medical apps and mobile apps to manage their own health and wellness, such as to monitor their caloric intake for healthy weight maintenance.").

49. *See id.* (discussing how some apps are used for diagnostic purposes for diagnosing and treating different patient conditions).

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and providers may be customers for app-based versions of existing medical devices. For example, both patients and providers might make use of a blood pressure cuff that plugs into an iPhone.[50] Equally, some consumer-facing wearables, such as Google Glass, have migrated over into provider-facing space.[51] To put it another way, an app that allows a physician to access a hospital's clinical decision system reflects the steady march of miniaturization, while putting a diagnostic app in the hands of a consumer is potentially disruptive.

Although mobile health apps can be roughly categorized by function, at present wearables are relatively undifferentiated. The overwhelming majority are attachments, and occasionally fashion statements, and most of those use the wrist as their attachment point. However, in the near future that picture is likely to change as "wearables" are applied as temporary tattoos,[52] or technology is incorporated into contact lenses.[53] Future generation devices likely will be inserted subcutaneously, or otherwise implanted or ingested, challenging the current nomenclature. In the future, some of our "wearables" may even be neural.[54] Such fragmentation may well lead to more differentiation in their regulation. For now, however, wearables as they are currently understood, can be grouped with mobile health apps and the mobile platforms that frequently control or monitor them.

Each type of app poses different safety and privacy risks,[55] and exposure to liability varies depending on the role of the potential defendant. In general terms, healthcare providers may face negligence-based claims when they supply or curate apps that cause harm.[56] In contrast, developers of defective

50. One such example is already available. *See, e.g. Withings Wireless Blood Pressure Monitor*, WITHINGS, https://www.withings.com/us/en/products/blood-pressure-monitor (last visited March 23, 2016).

51. Nicolas Terry et al., *Google Glass and Health Care: Initial Legal and Ethical Questions*, 8 J. HEALTH & LIFE SCI. L. 93, 95 (2015).

52. Lydia Ramsey, *Stick-On Tattoo Measures Blood Sugar Without Needles*, POPULAR SCI. (Jan. 20, 2015), http://www.popsci.com/temporary-tattoos-could-monitor-diabetes-less-invasively (researchers at the University of California San Diego have designed a needle-free blood sugar reading device that uses electrodes on temporary tattoo paper).

53. Quinten Plummer, *Google Smart Contact Lens to Hit The Market Soon?*, TECH TIMES (June 28, 2016, 3:38 AM), http://www.techtimes.com/articles/63868/20150628/google-smart-contact-lens-to-hit-the-market-soon.htm.

54. Emotiv is an example of a company producing neural devices. EMOTIV, https://emotiv.com (last visited April 13, 2015, 2:50 PM). For a discussion of the potential benefits, as well as initial critiques of such devices, *see* Mark Honigsbaum, *Could this $300 Headset Transform the Lives of 'Locked-In' Patients?*, THE GUARDIAN (July 11, 2014, 6:00 AM), http://www.theguardian.com/technology/2014/jul/11/kickstarter-headset-locked-in-syndrome-communication.

55. *See generally* Terry, *supra* note 13, at 1430–33 (discussing the various risks).

56. Nathaniel R. Carroll, *Mobile Medical App Regulation: Preventing a Pandemic of "Mobilechondriacs"*, 7 ST. LOUIS U.J HEALTH L. & POL'Y 415, 429 (2014).

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apps may face strict liability claims for breach of warranty or common law product liability.[57]

III. HEALTH CARE PROFESSIONAL LIABILITY

To hold a physician or other healthcare professional liable for malpractice, a plaintiff must establish four elements.[58] First, duty—the plaintiff must establish that a treatment relationship was in effect at the time of breach, and such that the defendant health care professional owed a duty of care to plaintiff patient.[59] Second, breach—the plaintiff must establish that the defendant professional's conduct fell below the standard of care.[60] Third, damages—the plaintiff must establish that she or he suffered physical harm.[61] Fourth, causation—the plaintiff must establish a sufficient nexus between the defendant's breach and the plaintiff's harm.[62] As discussed in detail below, for physicians or other health care professionals who participate in the design or development of mobile health products, the primary issue is likely to be duty.[63] For those who use mobile health products in the context of patient care or who recommend or prescribe the use of such products by patients, the primary issue is likely to be breach.[64]

A. Professionals Contributing to Design of Apps

Some, but far from all, mobile health products are developed with input from healthcare professionals.[65] In addition to the strict liability exposure faced by all app developers and marketers, healthcare professionals who participate in product development may also face professional malpractice liability. Ultimately, healthcare professionals who participate in the design of

57. Kevin M. Henley, *Tracking the Likelihood of Liability from Health Apps*, LAW360 (Mar. 11, 2015), http://www.law360.com/articles/629313/tracking-the-likelihood-of-liability-from-health-apps.

58. *E.g.,* B. Sonny Bal, *An Introduction to Medical Malpractice in the United States*, 467 CLINICAL ORTHOPEDICS & RELATED RES. 339, 342 (2009), *available at* http://doi.org/10.1007/s11999-008-0636-2.

59. *E.g., id.*

60. *E.g., id.*

61. *E.g., id.*

62. *See e.g. id.*; *see also* Provost v. Fletcher Allen Health Care, 2005 VT 115, ¶ 16, 890 A.2d 97, 100; Giles v. Anonymous Physician I, 13 N.E.3d 504, 510 (Ind. Ct. App. 2014).

63. *See infra* Part III. A (discussing physicians who could be found liable for contributing to the design of a medical app).

64. Carroll, *supra* note 56, at 429.

65. *See e.g.,* Maged N. Kamel Boulos et al., *Mobile Medical and Health Apps: State of the Art, Concerns, Regulatory Control and Certification*, 5 ONLINE J. PUB. HEALTH INFORMATICS 1, 9 (2014), https://www.researchgate.net/publication/261222082_Mobile_medical_and_health_apps_State_of_the_art_concerns_regulatory_control_and_certification (noting various apps had between 32-34% professional involvement).

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mobile health products for use by the general public are unlikely to be held liable on the basis of professional malpractice for injuries caused to individuals with whom they have not entered into a treatment relationship. A physician who exercises medical judgment in designing or developing a diagnostic automator or customizer, for example, might fall below the standard of care and her negligence might cause injury to patients whom are misdiagnosed or mistreated by providers relying on the app. However, in the absence of a physician-patient relationship between the developer-physician and the injured plaintiff-patient, the plaintiff will not be able to establish the duty element of a malpractice claim.[66] Other kinds of tort liability, such as products liability or ordinary negligence, could be a concern, but not professional malpractice.[67]

Where there is no nexus at all between the patient-plaintiff and the developer-physician, the duty element would not be satisfied.[68] On the other hand, if the developer is also the treating physician (i.e., a physician develops an app and then uses it for the care of her own patients) then the duty element would be met and the court would move on to breach and causation to determine whether the case should be brought before a jury.[69] There is, perhaps, a murky middle ground where a physician develops an app and then shares it with other physicians in her practice or network, who then rely on it for diagnosis and treatment or prescribe it for use by their patients. As detailed below, in analogous situations, courts often find that a physician-patient relationship is formed based on minimal interaction between the two parties, but some form of engagement of the physician with a particular patient is generally required.[70]

1. Cases Suggestive of Liability

A physician-patient relationship can be formed with quite minimal contact between the physician and patient, or even in the absence of any physical contact between the two at all.[71] The question is typically whether medical judgment has been exercised with regard to a particular patient's case.[72] For

66. *See* Bal, *supra* note 58, at 342.

67. *See* Rose, *supra* note 17.

68. *See* Giles v. Anonymous Physician I, 13 N.E.3d 504, 510-11 (Ind. Ct. App. 2014) (discussing duty of care and the relationship between the physician and patient).

69. *Id.*

70. *Id*.

71. *See, e.g.,* Adams v. Via Christi Reg'l Med. Ctr., 19 P.3d 132, 139-40 (Kan. 2001) (discussing various cases where a relationship between the physician exists or does not exist); *see also* Bienz v. Cent. Suffolk Hosp., 557 N.Y.S.2d 139, 139-40 (App. Div. 1990).

72. *See, e.g.,* Bienz, 557 N.Y.S.2d at 139.

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example, in *Bienz v. Central Suffolk Hospital,* an individual who called the physician's office "for the purpose of initiating treatment" sued the physician for malpractice.[73] The physician moved for summary judgment, arguing that a telephone call to initiate treatment does not form a physician-patient relationship.[74] The court affirmed the denial of summary judgment, finding that a relationship may have formed and that more fact-finding was necessary to determine whether any medical advice had been given during the call.[75] Similarly, in *Adams v. Via Christi Regional Medical Center,* a malpractice claim was filed against an obstetrician following the death of a woman due to an undetected ectopic pregnancy.[76] Although the defendant physician had treated the woman previously, he had not seen her as a patient for several years.[77] On the evening she died, her mother called the physician and asked questions about her daughter's abdominal pain.[78] The physician explained to the patient's mother that such pain is typical during pregnancy, recommended she go to the emergency room if her condition worsened, and to go see physician in the morning.[79] Later that evening, she was taken to the hospital and died.[80] The physician moved for judgment as a matter of law, arguing that he had not re-formed a physician-patient relationship based on the conversation with the girl's mother over the phone.[81] The court affirmed the judgment against the physician, finding that, because he did not decline to provide his medical opinion on her case, he cannot say that he declined to form a physician-patient relationship.[82]

Where physicians have provided telemedicine consults, courts have sometimes allowed the jury to determine, based on the specific facts of the case, that a physician-patient relationship was formed.[83] In *White v. Harris*, for example, the parents of a psychiatric patient who committed suicide sued a psychiatrist who had one online video consultation with the girl as part of a research study on telemedicine.[84] The court reversed the lower court's grant of summary judgment, finding that the one-time consultation was sufficient

73. *See id.*
74. *Id.*
75. *Id.* at 139-40.
76. Adams, 19 P.3d at 132.
77. *Id.* at 134.
78. *Id.*
79. *Id.*
80. *Id.* at 134-35.
81. *Id.* at 139-40.
82. *Id.* at 141-42.
83. *See, e.g.*, Bovara v. St. Francis Hosp., 700 N.E.2d 143, 144 (Ill. App. Ct. 1998); *see also,* White v. Harris, 2011 VT 115, ¶ 1, 36 A.3d 203, 204 (Vt. 2011).
84. White, VT 115, at ¶ 1-2, 36 A.3d at 203.

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to form a physician-patient relationship, giving rise to a duty of care.[85] The court remanded for the lower court to permit discovery on the scope of the duty and whether the physician's conduct satisfied the standard of care.[86] Another example, *Bovara v. St. Francis Hospital,* involved a malpractice claim against two physicians who reviewed a patient's film from an angiogram and informed the treating physician that the plaintiff was a candidate for angioplasty.[87] The court found that the physicians, despite their lack of direct contact with the patient, could have formed a physician-patient relationship with him.[88] Because the question was one for the jury, the court reversed the granting of summary judgment in favor of the physicians.[89]

2. Cases Suggesting No Liability

On the other hand, courts have sometimes declined to find that a treatment relationship exists in cases where the consulting physician did not have sufficient contact with the patient.[90] In *Jennings v. Badgett* for example, the parents of a prematurely delivered child sued, among others, Dr. Schlinke, who had consulted over the phone with the treating physician.[91] The parents contended that Schlinke was liable because his advice prompted the treating physician to deliver the baby prematurely.[92] The court found that no physician-patient relationship was formed and that "even though Dr. Badgett chose to rely on Dr. Schlinke's opinion, Dr. Badgett was free to exercise his independent judgment."[93] Similarly, in *Hill by Burston v. Kokosky*, the mother of a child born with cerebral palsy sued the physicians who had consulted with her treating physician about alternative birthing options.[94] The plaintiff alleged that the physicians provided substandard advice to the treating physician.[95] The court found that the consulting physicians could not be held liable based on a telephone call with the treating physician because neither of the consulting physicians had talked with the patient, examined her, or reviewed her chart.[96]

The courts are divided as to whether a remote consultation with the

85. *Id.* at ¶ 10, 36 A.3d at 207.
86. *Id.* at ¶ 14-15, 36 A.3d at 208-09.
87. Bovara, 700 N.E.2d at 144.
88. *Id.* at 148.
89. *Id.* at 149-50.
90. *See generally* Hill ex rel. Burston v. Kokosky, 463 N.W.2d 265, 266-67 (Mich. Ct. App. 1990); *see also* Jennings v. Badgett, 2010 OK 7, ¶ 20, 230 P.3d 861, 867.
91. Jennings, 2010 OK 7, at ¶ 9, 230 P.3d at 864-65.
92. *Id.* at ¶ 7, 230 P.3d at 864.
93. *Id.* at ¶ 25, 230 P.3d at 868.
94. Kokosky, 463 N.W.2d at 265-266.
95. *Id.* at 266.
96. *Id.* at 267.

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treating physician is sufficient in the absence of interaction between the consulting physician and the patient.[97] However, it appears that *engagement by the physician on a specific patient's case* as evidenced by contact or record review, is a *sine qua non*.[98] As a result, it is unlikely that a physician, who participates in the design or development of a mobile health product for use by the general public, rather than one destined for her own patients, would be subject to professional malpractice liability.[99] Development of an app for use by patients within a particular physician group practice or network might be considered a gray area, based on the existence of the nexus between the defendant-physician and the plaintiff's treating physician, but liability remains unlikely in the absence of the defendant-physician's exercise of medical judgment with respect to an identifiable patient, as opposed to a general patient population.[100]

3. Disciplinary Action for Provision of Medical Services in the Absence of a Physician-Patient Relationship

Although malpractice liability for developer-physicians is unlikely in the absence of a physician-patient relationship, it is worth noting that there are several telemedicine cases in which medical boards have taken disciplinary action against physicians who performed medical services—especially prescription writing—without forming a physician-patient relationship.[101]

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97. *Id.* (finding that, "whether a physician-patient relationship arises from a treating physician's solicitation of a colleague's informal opinion on patient treatment is an issue of first impression," but other jurisdictions have considered this question in other ways).

98. Miller v. Martig, 754 N.E.2d 41, 46 (Ind. Ct. App. 2001) ("Generally, where a doctor does not treat, see, or in any way participate in the care or diagnosis of the plaintiff-patient prior to or during surgery, a doctor-patient relationship will not be found to exist."); *see also* Irvin v. Smith, 31 P.3d 934, 942 (Kan. 2001); *see generally* Sterling v. Johns Hopkins Hosp., 802 A.2d 440 (Md. Ct. Spec. App. 2002).

99. Kokosky, 463 N.W.2d at 268 (finding that the consulting physician did not have a duty because he remotely provides advice based on limited information about a specific patient).

100. *Id.* at 267 (holding that a "limited and remote connection to the case cannot be equated with 'treatment'").

101. *See* Jones v. N. D. State Bd. of Med. Exam'rs, 2005 ND 22, ¶¶ 21-22, 691 N.W.2d 251, 259 (finding that Jones acted unethically and provided inappropriate, harmful prescriptions over the Internet without examining patients in person first); *see also* Golob v. Ariz. Med. Bd., 176 P.3d 703, 705 (Ariz. Ct. App. 2008) (finding that the board could discipline a physician that failed to establish a physician-patient relationship with his patients); *see also* FED'N OF STATE MED. BD.S, INTERNET PRESCRIBING-STATE MEDICAL BOARD POLICIES/STATE LEGISLATION, http://www.fsmb.org/Media/Default/PDF/FSMB/Advocacy/SMB_Policies-State_Laws_INTERNET.pdf (last visited Mar. 18, 2016) (exhibiting a map and listing policies and laws limiting the use of Internet-based prescriptions). For a representative but controversial medical board rule, *see* 22 Tex. Admin. Code § 190.8(1)(L) (2015), which prompted the filing of an antitrust suit by a large provider of telemedicine services; *see also* Eric Wicklund, *Federal Judge Sides with Teladoc in Texas Telemedicine Debate*, MHEALTH

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These cases suggest that while the absence of a treatment relationship is likely to protect physician-developers from tort liability when consumers are injured, the absence of a treatment relationship may expose physician-developers to disciplinary action.[102]

In *Jones v. North Dakota State Board of Medical Examiners-Investigative Panel B*, Dr. Jones worked for an online prescription service, providing prescriptions for non-narcotic medications (mostly erectile dysfunction drugs) to individuals who filled out the company's online survey.[103] Dr. Jones reviewed the survey responses and occasionally operators made personal calls for further information.[104] The State Board revoked the physician's license for writing prescriptions without establishing a physician-patient relationship and Dr. Jones appealed, arguing he did not violate the state medical statute.[105] The court agreed with the board's findings, that writing approximately seventy-two prescriptions per hour made it impossible for him to spend sufficient time evaluating a patient's medical needs to establish a physician-patient relationship.[106]

Similarly, in *Golob v. Arizona Medical Board*, the Arizona Medical Board censured and put Dr. Golob on probation for providing prescriptions to individuals through an online prescription service without forming a physician-patient relationship.[107] Individuals filled out an online form and paid a fee for the questionnaire to be reviewed by the physician.[108] In some cases, the individuals would answer questions over the phone, but operators working for the company, rather than the physician, would ask the questions.[109] Dr. Golob purportedly "directed" the operators to ask the questions, forming the alleged basis for the suspension.[110] The court upheld the board's decision, finding that these acts did not establish a physician-patient relationship.[111]

These cases suggest that in an analogous situation, developer-physicians

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NEWS (Jun. 1, 2015), http://www.mhealthnews.com/news/federal-judge-sides-teladoc-texas-telemedicine-debate.

102. *See Jones*, 2005 ND, 22 at ¶¶ 21-22, 691 N.W.2d at 259 (finding that Jones acted unethically and provided inappropriate, harmful prescriptions over the Internet without examining patients in person first); *see also Golob*, 176 P.3d at 705(finding that the board could discipline a physician that failed to establish a physician-patient relationship with his patients).

103. *Jones*, 2005 ND 22 at ¶ 3, 691 N.W.2d at 253-54.

104. *Id.* at ¶ 3, 691 N.W.2d at 253-54.

105. *Id.* at ¶¶ 58 & 16, 691 N.W.2d at 254-255, 257.

106. *Id.* at ¶¶ 20-22, 691 N.W.2d at 258.

107. Golob v. Ariz. Med. Bd., 176 P.3d 703, 705 (Ariz. Ct. App. 2008).

108. *Id.* at 706.

109. *Id.* at 708.

110. *Id*.

111. *Id.* at 709.

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could face professional disciplinary action—which is akin to malpractice liability in that it is based on deviation from the customary-practice standard of care, but distinct, in that it does not rely upon establishment of a duty of care owed by the physician to the patient—for providing medical services in the absence of a physician-patient relationship.[112] Notably, unlike malpractice liability, disciplinary action would be possible even if no identifiable patient has been harmed by the defendant-physician's actions.[113] Disciplinary action of this sort is rare, but may be more likely in situations in which a professional board perceives the physician to be engaged in a commercial enterprise, such as app development, solely for financial gain, undermining the reputation of medicine as a calling.[114]

B. Professionals Relying on Apps for Patient Care

Healthcare professionals who use mobile health technologies directly in the context of patient care may be held liable for malpractice if a patient is harmed.[115] Conversely, a health professional who declines to make use of data provided by a patient via mobile health technology, which is likely to be overwhelming in its volume, could be held liable if she misses important information, delaying diagnosis and harming the patient.[116] But in either case, the plaintiff must establish the breach element by showing that the defendant failed to exercise sound professional judgment in the use, or non-use, of mobile health technologies.[117]

The customary-practice standard of care adopted by courts[118] to adjudicate the breach element of malpractice claims requires that, when diagnosing a condition, a physician exercises:

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112. *Id.* (finding that the board could sanction a physician even though the physician failed to establish a physician-patient relationship).

113. N.D. CENT. CODE § 41-17-31 (West 2015) (listing grounds for disciplinary action, including conduct that does not necessarily harm an identifiable individual).

114. *See* Golob, 176 P.3d at 705 (supporting the board's decision to sanction a physician for profiting by doing business over the Internet without establishing relationships with patients).

115. *Medical Malpractice and Liability*, Teleheath Res. Ctrs., http://www.telehealthresourcecenter.org/toolbox-module/medical-malpractice-and-liability (last visited Mar. 18, 2016) (explaining that medical malpractice cases arise when a patient is harmed or injured and telehealth presents unique issues in malpractice).

116. *See* Hoffer v. Johnson, 2003 ND 79, ¶ 9, 660 N.W.2d 909, 914 (finding that there is no remedy for malpractice without an injury).

117. *See McCourt ex rel. McCourt v. Abernathy*, 457 S.E.2d 603, 607-08 (S.C. 1995) (holding that a physician breaches the standard of care duty by failing to exercise the same degree of care and skill as a competent physician in the same field of medicine).

118. *See* Peter Moffett & Gregory Moore, *The Standard of Care: Legal History and Definitions: the Bad and Good News*, 12 W. J. EMERGENCY MED. 109, 111 (2011) (stating that McCourt is one of the three major cases defining the modern standard of care).

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> [T]he degree of skill and care . . . that which would be exercised by competent practitioners in the defendant physicians' field of medicine . . . Negligence may not be inferred from a bad result. Our law says that a physician is not an insurer of health, and a physician is not required to guarantee results. He undertakes only to meet the standard of skill possessed generally by others practicing in his field under similar circumstances.[119]

If a physician's use or non-use of a mobile health product reflects reasonable medical judgment, then she or he is unlikely to be held liable, even if the product malfunctions or is poorly designed, or if key information buried in masses of irrelevant data (collected by the app more or less continuously as opposed to during discrete clinical encounters) is missed.[120] In a case of misuse, a court might consider whether the physician should have known how to use the technology properly or should have refrained from using it if she was not sufficiently informed regarding its proper use.[121] In the case of product malfunction, the question would be whether the physician knew or had reason to know that the product was defective, poorly designed, or otherwise prone to malfunction.[122] In the case of non-use of patient data provided via mobile health products, the question would be whether a reasonably competent physician could have and would have taken hours to sort the wheat from the chaff.[123]

It is worth noting that in about half of jurisdictions, the standard of care is defined differently for informed consent claims.[124] If the basis of a claim by an injured patient is that the physician failed to inform him adequately of the risks associated with the use of a mobile health product or failed to inform him of the availability of a mobile health product as an alternative to the recommended treatment, these jurisdictions adopt a patient-centered, rather than a physician-centered, standard of care.[125] In these courts:

> [T]he patient's right of self-decision shapes the boundaries of the duty to reveal….Thus the test for determining whether a particular peril must be divulged is its materiality to the patient's decision: all risks potentially affecting the decision must be unmasked. And to safeguard the patient's

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119. *McCourt ex rel. McCourt*, 457 S.E.2d at 607 (approving trial court instructions).

120. *See id.* (explaining that, "negligence may not be inferred from a bad result").

121. *See id.* (stating that a physician's duty is determined by the skill and care that a competent physician in the same field of medicine would do under the circumstances).

122. *See id.*

123. *See id.*

124. *See* Jamie S. King & Benjamin Moulton, *Rethinking Informed Consent: The Case for Shared Medical Decision-making*, 32 AM. J.L. & MED. 429, 430 (2006).

125. *See id.* at 438-39 (explaining the importance of a patient's knowledge of risks, benefits, and alternatives of a procedure).

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> interest in achieving his own determination on treatment, the law must itself set the standard for adequate disclosure.[126]

Instead of asking whether the defendant's actions conformed to the customary practice of a competent physician under the circumstances, these courts ask whether information about mobile health products that the defendant-physician failed to provide would have been material to a reasonable patient's decision about whether to consent to treatment.[127]

In some jurisdictions, this materiality issue can also play out at the "duty" level (that is, courts will determine the issue as a matter of law on a fact-pattern basis). For example, in *Arato v. Avedon*, the Supreme Court of California ruled that as a matter of law, a physician did not have a duty to disclose statistical life expectancy data or information material to a patient's non-medical interests.[128] Thus, a physician might successfully argue that she was under no duty to discuss the risks disclosed by a patient-acquired data-collecting app.

Under either the patient-centered or physician-centered standard of care, the malpractice doctrine obligates physicians to take reasonable steps to inform themselves regarding the limitations of the resources available to them and adjust their conduct accordingly.[129] For example, in *Hall v. Hilbun,* the defendant-physician argued that the hospital-provided nursing staff members were incompetent.[130] The court found that the defendant was obligated to adjust his conduct in light of what he knew or should have known about the competence of the nursing staff—declining to rely on their independent judgment if he knew them to be incompetent.[131] Another case from the same court, *Boyd v. Lynch*, illustrates the importance of the reasonableness standard as applied to a physician's reliance on available resources.[132] Although an expert witness suggested that a physician should generally work with a nurse for at least six months before justifiably relying on that nurse to independently assess patients, the Mississippi Supreme Court affirmed a directed verdict for the defendant.[133] The court found that, under the circumstances, the physician's reliance on the independent assessment of a nurse he had known for only one month was insufficient to show that the

126. *See, e.g.* Canterbury v. Spence, 464 F.2d 772, 786-87 (D.C. Cir. 1972).
127. *See id.*
128. Arato v. Avedon, 858 P.2d 598, 607 (Cal. 1993).
129. *See* Hall v. Hilbun, 466 So.2d 856 (Miss. 1985), *superseded by statute*, Miss. Code Ann. § 85-5-7 (2004), *as recognized in* Narkeeta Timber Co., Inc. v. Jenkins, 777 So.2d 39 (Miss. 2000).
130. *Id.* at 878-79.
131. *Id.* at 870, 878-79.
132. Boyd v. Lynch*,* 493 So.2d 1315, 1317-18 (Miss. 1986).
133. *Id.* at 1317, 1320.

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defendant had breached the standard of care for general practitioner physicians.[134] Similarly, in *Forsberg v. Edward Hospital and Health Services,* another state court found that the defendant physician *reasonably* relied on nurses who were responsible for collecting surgical sponges during a surgery.[135] In *Pacheco v. Ames*, however, the court found that, under the circumstances, the defendant oral surgeon unreasonably relied on a referring dentist's handwritten notation on an x-ray, resulting in a procedure performed on the wrong side of the patient's mouth.[136] The relevant inquiry, then, is whether the defendant professional's reliance on any given resource (be it a nurse, a medical record, or a mobile health product) was reasonable under the circumstances.[137]

By implication, if, for example, a physician using a connector product misreads a patient scan on a mobile device due to poor lighting conditions, the appropriate question for purposes of the physician's malpractice liability is whether she conformed to the prevailing standard of care and exercised reasonable medical judgment under the circumstances.[138] This is not much different from a situation where a physician misreads a scan at a time when she is experiencing blurry vision—should she have realized that conditions were inadequate and adjusted her conduct appropriately? Was it reasonable for her to rely on her vision, which she knew to be compromised?

Similarly, a physician's reliance on an informer or educator app in the course of researching a patient's condition is not fundamentally different from reliance on a print publication. Would a reasonably prudent physician have known that the product was unreliable? If a physician relies on a replicator product to serve as a stethoscope, or an automator product to determine the appropriate dose of anesthesia and that product is poorly designed or malfunctions, the question will be whether the physician's reliance on the product reflects sound professional judgment in light of what she knew or should have known about it. Did the physician take reasonable steps to inform herself of the limitations of the product?

The standard of care is typically quite forgiving, holding physicians liable in situations where the dangers of the defendant's approach were widely known among peer physicians or should have been evident to her under the circumstances,[139] but generally not requiring that physicians take extraordinary steps to exhaustively research every technology or resource on

134. *Id.* at 1318.
135. Forsberg v. Edward Hosp. & Health Servs., 906 N.E.2d 729, 737 (Ill. App. Ct. 2009).
136. Pacheco v. Ames, 69 P.3d 324, 330 (Wash. 2003).
137. *Id*.
138. *E.g.,* Bal *supra* note 58, at 342.
139. *See, e.g.*, Estate of Kurstin v. Lordan, 25 A.3d 54 (D.C. 2011) (holding physician liable for ordering administration of Lovenox during surgery, contrary to hospital policy and widely recognized safety concerns).

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which they rely.

The adoption of a new technology may introduce some uncertainty as to what physicians know or should know about the design and appropriate use of that technology. Like any other treatment innovation, the customary-practice standard of care for malpractice—which boils down to what other physicians in good standing would have done under the circumstances[140]—can lead to liability concerns acting as a drag on adoption of innovative approaches. Doing things "the old way" can appear safer from a liability standpoint, but that is true only up to an ill-defined tipping point at which the innovation becomes the prevailing standard of care. In any case, the basic inquiry is the same; there is no need for the development of new mobile health-specific doctrines.

C. Healthcare Professionals Recommending Apps

Healthcare professionals who recommend the use of mobile health technologies to their patients, without using them directly, could similarly be held liable if the recommendation to use mobile health products for the purposes of patient self-care does not reflect sound professional judgment or deviates from the prevailing standard of care.[141] Again, this is not fundamentally different from low-tech scenarios. If a nurse practitioner recommends that a patient use a logger and tracker physical fitness app, she must take reasonable steps to inform herself regarding the regimen that the app will urge the patient to adopt and must apply sound medical judgment to determine whether that regimen is appropriate in light of the patient's condition. There are probably more permutations, and perhaps more unknowables, in this scenario compared to a nurse practitioner recommending that a patient start a particular exercise regimen such as P90X, because the app is personalized and may allow for nearly endless permutations. This problem is amplified if we are talking about a pediatrician recommending that parents use a customizer product that amounts to an all-in-one diagnostic tool before calling the physician. It would be harder for a physician to evaluate all of the possible recommendations of a customizer app than to read a book that gives basic advice on whether to call a pediatrician or take a child to the emergency room based on particular symptoms. But again, the basic doctrinal approach—according to which the relevant questions are what the professional should have known about the product she was recommending or prescribing and what, if any, warnings or instructions regarding self-care should the professional have conveyed to the

140. *See McCourt ex rel. McCourt*, 457 S.E.2d at 607.
141. *Id.*

Preprint not peer reviewed

This preprint research paper has not been peer reviewed. Electronic copy available at: https://ssrn.com/abstract=2725450

patient—remains the same.[142]

IV. HEALTH CARE INSTITUTIONAL LIABILITY

Institutional healthcare providers, such as hospitals and managed care organizations, face liability exposure for either the negligence of their employees or their own corporate or direct wrongs.[143] A plaintiff pursuing such a claim must prove not only a breach by the individual, but also that there was a principal-agent or employer-employee relationship between the individual and the institutional provider.[144] Inserting this additional requirement that plaintiff must prove an employment or agency relationship causes an additional layer of indeterminacy in cases involving adverse events caused by a non-employee, such as a credentialed physician. In such cases, the plaintiff would have to prove the existence of apparent agency based on a showing of hospital conduct, plus patient reliance.[145] Only then can the plaintiff move on to the heart of the allegation, that the hospital employee or agent negligently approved, recommended, or prescribed an app or wearable.[146]

The potential for direct, or corporate, liability of healthcare institutions dates from the famous[147] case of *Darling v. Charleston Community Memorial Hospital.* Darling articulated two major changes to how the liability system

142. *Id*. at 607-08.

143. *See e.g.,* Barkes v. River Park Hosp., Inc., 328 S.W.3d 829, 833 (Tenn. 2010) ("Tennessee law clearly recognizes that hospitals owe a duty of reasonable care to their patients and may be directly liable to patients independent of any liability based on the hospital's employees or agents."); *see generally* Gregory T. Perkes, *Medical Malpractice—Ostensible Agency and Corporate Negligence— Hospital Liability may be Based on Either Doctrine of Ostensible Agency or Doctrine of Corporate Negligence*, 17 ST. MARY'S L.J. 551 (1986).

144. *See* Ramone v. Mani, 535 S.W.2d 654, 656 (Tex. Civ. App. 1975) (explaining that if nurses were found to be employees, employer would be held jointly liable for their negligence).

145. *See e.g.*, Kashishian v. Al-Bitar, 535 N.W.2d 105 (Wis. Ct. App. 1995) (concluding that the trial court was wrong in holding that the physician in question was not the hospital's agent, finding that when a patient enters a hospital, they rely on the reputation of the hospital itself); *see generally* Burless v. W. Va. Univ. Hosps., Inc., 601 S.E.2d 85 (W. Va. 2004) (finding that the Plaintiff's established a genuine issue of material fact on the issue of their reliance on the apparent agency relationship between the hospital and their treating physicians); *see generally* Sanchez v. Medicorp Health Sys., 270 Va. 299 (2005) (holding that the theory of agency by estoppel was not sufficient to hold the defendant hospital system vicariously liable for the alleged negligence of its independent contractor).

146. *See Burless,* 601 S.E.2d at 95-96.

147. *See generally* Mitchell J. Wiet, *Darling v. Charleston Community Memorial Hospital And Its Legacy*, 14 ANNALS HEALTH L. 399 (2005) (discussing the impact that *Darling*, a landmark Illinois Supreme Court case, has had on hospital liability cases over the past four decades).

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approached institutional liability.[148] First, *Darling* held that an institutional provider could be directly responsible for aspects of patient care.[149] This ran counter to the then prevalent "hotel" doctrine, which viewed hospitals as a mere venues in which patients and physicians interacted.[150] Second, *Darling* undermined the customary practice standard of care in medical malpractice cases, because it permitted accreditation standards or hospital bylaws as alternative standards of care.[151]

States continue to refine the corporate liability doctrine's reach.[152] For example, today most jurisdictions recognize *Darling*'s standard as it applies to maintaining safe and adequate facilities and equipment, selection and retention of only competent physicians, general oversight of those who practice medicine within its walls, and promulgation and enforcement of quality/safety rules and policies.[153] However, some jurisdictions stop short of going beyond such meta-care duties.[154] In contrast, a smaller set of jurisdictions, including Pennsylvania, have gone further as expressed by one state high court as follows:

> Today, we take a step beyond the hospital's duty of care delineated in [earlier case law] in full recognition of the corporate hospital's role in the total health care of its patients. In so doing, we adopt as a theory of hospital liability the doctrine of corporate negligence or corporate liability under which the hospital is liable if it fails to uphold the proper standard of care owed its patient.[155]

This formulation places broad responsibility on healthcare institutions for all aspects of a patient's care and treatment. Subject to the above jurisdictional variations, institutional liability exposure with regard to apps could arise to both provider-facing and patient-facing apps.

A. Healthcare Provider-Facing Apps

Hospital-provided, provider-facing apps space is relatively undeveloped. Providers have concentrated on providing mobile and tablet access to their existing suite of health information technology (HIT) products, such as electronic medical records (EMR), Clinical Decision Support software

148. Darling v. Charleston Cmty. Mem'l Hosp., 211 N.E.2d 253 (Ill. 1965).
149. *Id.* at 337.
150. *Id.*
151. *Id.* at 332.
152. *See*, *e.g.*, Gafner v. Down E. Cmty. Hosp., 1999 ME 130, 735 A.2d 969 (Me. 1999).
153. *See*, *e.g.,* Darling, 211 N.E.2d at 326; *see also* Thompson v. Nason Hosp., 591 A.2d 703, 707 (Pa. 1991).
154. *See*, *e.g.*, *Gafner*, 735 A.2d at 969 (providing that Maine would be such a jurisdiction which stops short of going beyond meta-care duties).
155. *Thompson*, 591 A.2d at 708.

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(CDS) and imaging products (PACS). Many of these "front-end" apps will have been developed "in-house" or by developers of the underlying products. However, EMR vendors are opening app stores[156] and major "software as service" suppliers such as IBM are developing health care-specific apps.[157] As a result, providers may soon owe duties to patients regarding the careful selection, deployment, staffing, and updating of these new technologies.[158]

Individual employees or credentialed physicians also introduce apps and their hardware platforms into healthcare institutions. One example of this bring-your-own-device (BYOD) phenomenon is the use of Google Glass ("Glass") in surgery and other tasks within an institution. In the case of Glass, serious ethical and legal risks are raised because of the potential of the device to capture video and images, and the doubts about its ability to satisfy HIPAA security requirements.[159] Hospitals that have not updated their BYOD policies or otherwise controlled the use of unauthorized apps or wearables could face liability in the event of an adverse event. A related concern arises with regard to apps with social media characteristics that, for example, encourage health care professionals to post images of patients.[160] We suggest that due consideration for good risk management practices should necessitate that hospitals update their social media policies to prohibit app uses that may involve legal or ethical risks.[161]

B. Patient-Facing Apps

In general, consumers drive the processes of choosing and using mobile apps. However, an institutional provider, like the physician discussed above might insert itself into such processes by recommending or prescribing apps. Consider, for example, the pitch made by one provider for its health app

156. Judy Newman, *Epic Systems to Open its Own App Exchange*, WIS. ST. J. (Feb 18, 2015), http://host.madison.com/wsj/business/epic-to-open-its-own-app-exchange/article_fc7e8b94-b1ec-59f4-9065-1e6143fe351c.html.

157. *IBM MobileFirst for iOS*, IBM, http://www.ibm.com/mobilefirst/us/en/mobilefirst-for-ios/ (last visited Feb. 22, 2016).

158. *See generally* Am. Health Info. Mgmt. Ass'n. *The Implementation and Management of Patient Portals*, 86 J. OF AHIMA 50–55 (April 2015), http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_050877.hcsp?dDocName=bok1_050877; *see also* Sandeep S. Mangalmurti, Lindsey Murtagh, and Michelle M. Mello, *Medical Malpractice Liability in the Age of Electronic Health Records*, 363 NEW ENG. J. OF MED. 2060, 2060 (2010).

159. Terry et al., *supra* note 51.

160. *See e.g.*, Meera Senthiligram, *'Instagram for Doctors' Lets Medics Share Photos to Solve Mystery Cases*, CNN (Feb. 10, 2015, 5:23 AM), http://www.cnn.com/2015/02/10/tech/figure1-photos-medical-app/.

161. *See generally* Nicolas Terry, *Fear of Facebook: Private Ordering of Social Media Risks Incurred by Healthcare Providers*, 90 NEB. L. REV. 703-51 (2012); *Social Media Guidelines for Employees*, USC UNIV. HOSP., http://www.uscuniversityhospital.org/connect/wp-content/uploads/Social-Media- Guidelines-for-Employees.pdf.

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curation through a hospital-branded app and iPad "bar":

> Patients with diabetes, high cholesterol or smoking cessation needs can test the best apps to manage their health and wellness . . . For those who find the process overwhelming, the [bar] is staffed by a technology specialist who can assist in choosing the right product or app for your lifestyle as well as providing setup guidance and support.[162]

Clearly, providers that recommend or curate apps or coach patients in their use will have increased exposure if their choices or techniques are negligent and cause damage. Some institutional providers may seek to make curation more manageable by maintaining limited app formularies, although that could backfire if the contents of the formulary do not keep pace with the rapidly changing app ecosystem.[163] That leads to a broader observation as to the standard of care appropriate for app recommending or curating. The very few prescription-only apps currently available are typically for diabetes or other chronic disease monitoring,[164] and as with other prescribing duties, a professional standard of care would seem appropriate.[165] However, a court could view recommending or curating apps as more of a ministerial task and use a more general standard of care with regard to keeping abreast of technical developments.[166]

C. Informed Consent

Liability assertions involving recommendation or curation are essentially informational, which raises the issue of whether and to what extent informed consent duties are implicated by health care app use. Consider, for example, a provider approving or endorsing the use of an innovative, augmented or virtual reality wearable during surgery or a provider recommending a novel

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162. *Ochsner's O Bar Makes it Easier for Patients to Manage their Health*, OCHSNER HEALTH SYSTEM (Nov. 17, 2014), http://blog.ochsner.org/articles/ochsners-o-bar-makes-it-easier-for-patients-to-manage-their-health.

163. *See* FED. TRADE COMM'N, PROTECTING CONSUMER PRIVACY IN AN ERA OF RAPID CHANGE (2010), https://www.ftc.gov/sites/default/files/documents/reports/federal-trade-commission-bureau-consumer-protection-preliminary-ftc-staff-report-protecting-consumer/101201privacyreport.pdf.

164. *See*, *e.g.*, Roberto A. Ferdman, *The World's First Prescription-Only Smartphone App*, QUARTZ (Jan. 6, 2014), http://qz.com/163792/the-worlds-first-prescription-only-smartphone-app/.

165. *See* Hall v. Hilbun, 466 So.2d 856 (Miss. 1985) (discussing the higher standard of care for physicians).

166. *See*, *e.g.*, Helling v. Carey, 519 P.2d 981, 983 (Wash. 1974) ("Under the facts of this case reasonable prudence required the timely giving of the pressure test to this plaintiff. The precaution of giving this test to detect the incidence of glaucoma to patients under 40 years of age is so imperative that irrespective of its disregard by the standards of the opthalmology profession, it is the duty of the courts to say what is required to protect patients under 40 from the damaging results of glaucoma.").

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disease monitoring app. Would such a patient be entitled to additional risk disclosures? Some courts have held that when a device is used in an experimental or novel way, informed consent from patients must be obtained.[167] Should a provider offer additional disclosures if a prescription app was prescribed for an off-label use?[168] Some courts have allowed that question to reach a jury.[169]

An informed consent theory especially would be of particular value to plaintiffs in the slight minority of jurisdictions that apply a patient expectations approach to informed consent rather than the professional standard used elsewhere.[170] However, the informed consent avenue of liability may be moot. The conventional wisdom suggests that the risk-disclosure duty is exclusively owed by physicians and not by institutional providers.[171] Although one recent case held that a "hospital has an independent duty to obtain informed consent" when it allowed "the use of equipment that is not part of the hospital's usual inventory,"[172] any more generalized informed consent duty owed by hospitals seems to remain problematic.

V. PRODUCT LIABILITY, WARRANTY, UCC, & RELATED CLAIMS

Many provider-facing apps are essentially extensions of traditional HIT devices, such as EMRs and CDS products that already have risk profiles.[173] By 2010, the FDA was collecting reports of HIT-related safety concerns, classifying them as follows:

> (1) errors of commission, such as accessing the wrong patient's record or

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167. *See*, *e.g.*, Estrada v. Jaques, 321 S.E.2d 240, 254 (N.C. Ct. App. 1984).

168. *See* Osburn v. Danek Med., Inc., 520 S.E.2d 88, 95 (N.C. Ct. App. 1999); *see* Yadin David & William Hayman, *Issues Associated with Off Label Use of Medical Devices*, INST. OF ELECTRICAL AND ELECTRONICS ENGINEERS 3556, 3356-57 (Aug. 2007).

169. *See*, *e.g.*, DeNeui v. Wellman, 2008 WL 4065816, at *7 (D.S.D. 2008); *see also* 40 PA. STAT. § 1303.504(a)(5) (2002) (requiring informed consent for "using an experimental device or using an approved medication or device in an experimental manner").

170. *See* Culbertson v. Mernitz, 602 N.E.2d 98, 101 (Ind. 1992) (applying majority "professional standard" rule and discussing authorities in detail); *cf*. Largey v. Rothman, 540 A.2d 504, 506 (N.J. 1988) (applying patient standard).

171. *See, e.g.*, Pauscher v. Iowa Methodist Med. Ctr., 408 N.W.2d 355 (Iowa 1987); Ward v. Lutheran Hosps. & Homes Soc'y of Am., 963 P.2d 1031, 1034 (Alaska 1998) (stating, "Alaska is the only state that imposes on hospitals a non-delegable duty to provide quality emergency medical care. Unless the patient selects the physician herself, a general acute care hospital will be liable for the physician's negligence in the emergency room").

172. Nguyen v. IHC Med. Servs., 288 P.3d 1084, 1092 (Utah Ct. App. 2012).

173. Although the app/wearable space is new, many of the liability issues are similar to those raised by the deployment of more conventional health information technologies. *See, e.g.,* Nicolas Terry, *When the Machine That Goes 'Ping' Causes Harm: Default Torts Rules and Technologically-Mediated Health Care Injuries*, 46 ST. LOUIS U. L.J. 37, 47–59 (2002).

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> overwriting one patient's information with another's; (2) errors of omission or transmission, such as the loss or corruption of vital patient data; (3) errors in data analysis, including medication dosing errors of several orders of magnitude; and (4) incompatibility between multi-vendor software applications and systems, which can lead to any of the above.[174]

Additionally, there has been considerable critical research regarding "alert fatigue" and other problems with the interfaces used by HIT products.[175] There is little doubt that product liability models would apply to HIT devices and their mobile extensions.[176] Indeed, the HIT industry has been heavily criticized for attempting to shift such risks to providers.[177] There is slightly less certainty that product liability-type theories apply to stand-alone apps (i.e., software without hardware) or to consumer-facing apps. However, the few courts that have faced the issue seem to agree that there is potential liability for "[c]omputer software that fails to yield the result for which it was designed"[178] by analogy to liability found in cases involving defective aeronautical charts.[179]

A. Product Liability

State law product liability actions may be brought for personal or property injury caused by product defects associated with manufacture, design or inadequate warning.[180] However, substantial limitations apply with regard to FDA-regulated medical devices because of application of the preemption

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174. Testimony of Jeffrey Shuren, Health Information Technology (HIT) Policy Committee Adoption/Certification Workgroup (Feb. 25, 2010), http://www.cchfreedom.org/pr/Health%20IT%20Deaths%20%20FDA%20jeffrey%20Shuren.pdf; *see generally* U.S. FOOD & DRUG ADMIN., FDASIA HEALTH IT REPORT (2014), http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM391521.pdf.

175. *See generally* Nicolas Terry, *Foreword: Drug-Drug Interaction Warnings as Technological Iatrogenesis*, 5 ST. LOUIS U. J. HEALTH L. & POL'Y, 251, 251–55 (2012); *see also* Nicolas Terry, *Pit Crews With Computers: Can Health Information Technology Fix Fragmented Care?* 14 HOUS. J. HEALTH L. & POL'Y, 129 (2014).

176. *See generally* Sharona Hoffman & Andy Podgurski, *E-Health Hazards: Provider Liability and Electronic Health Record Systems*, 24 BERKELEY TECH. L.J. 1523, 1579 (2009).

177. Ross Koppel & David Kreda, *Health Care Information Technology Vendors' "Hold Harmless" Clause: Implications for Patients and Clinicians*, 301 JAMA 1276, 1276 (2009).

178. Winter v. G.P. Putnam's Sons, 938 F.2d 1033, 1036 (9th Cir. 1991); *cf.* Wilson v. Midway Games, Inc., 198 F. Supp. 2d 167, 172 (D. Conn. 2002) (ruling against plaintiff in video game case but not necessarily disagreeing with liability in *Winters*-type cases involving "harm resulting from reliance on instruction manuals, cookbooks, navigational charts and similar materials").

179. *See generally* T. Randolph Beard et al., *Tort Liability for Software Developers: A Law & Economics Perspective*, 27 J. MARSHALL J. COMPUTER & INFO. L. 199, 208–09 (2009).

180. *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY §2, §6 (AM. LAW INST. 1998); *cf.* U.C.C. §2–314 (AM. LAW INST. & UNIF. LAW COMM'N 1977) (explaining that parallel claims may also be brought for breach of the implied warranty of merchantability).

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doctrine.[181] In contrast, a private right of action may exist at federal law for harms caused by products regulated by the Consumer Product Safety Commission rather than the FDA.[182]

Looking to the future, plaintiffs' attorneys no doubt will consider a plethora of product liability allegations against app developers, wearable manufacturers, and their distributors. It is anticipated that arguments will be made that fitness and wellness apps recommended either over-exercise or under-exercise, and it is unlikely to be long before some plaintiff alleges a new syndrome such as "exercise addiction."[183] Other quantified-self apps have faced such exposure. For example, in 2012, the family of an "obsessed" cyclist, who died trying to break a record, unsuccessfully sued the developer of a bicycle GPS app that awarded "King of the Mountain" status to top performers,[184] with the trial court concluding that the cyclist "assumed the risks of bicycling and that the defendant (Strava) has shown that bicycling is an inherent risky activity."[185]

Annually there are large numbers of deaths and injuries caused by exercise equipment.[186] Increasingly, health apps will either control that equipment or potentially cause distractions for users.[187]

As the wearable market matures, devices will increasingly be built into

181. *See* Rodriguez v. Am. Med. Sys., 597 F. Appx. 226, 228 (5th Cir. 2014).

182. 15 U.S.C. § 2072 (1981); *see also* Zepik v. Tidewater Midwest, Inc., 856 F.2d 936, 943 (7th Cir. 1988).

183. *See* Kristina Berczik et al., *Exercise Addiction: Symptoms, Diagnosis, Epidemiology, and Etiology*, 47 SUBSTANCE USE & MISUSE 403 (2011).

184. Liz Gannes, *GPS App Strava Sued Over Cyclist's Death*, ALL THINGS D (Jun. 19, 2012), http://allthingsd.com/20120619/gps-app-strava-sued-over-cyclists-death/; Helen Pidd, *Strava – The App That Turns Cyclists Into Racers*, THE GUARDIAN (Jul. 31, 2013), http://www.theguardian.com/lifeandstyle/shortcuts/2013/jul/31/strava-app-cyclists-racers-smartphone.

185. Flint v. Strava, 2013 WL 9744334, *1 (Cal. Super. Ct. June 24, 2013) (order granting motion for summary judgment); *see also One-Year-Old Lawsuit Against Strava Dismissed*, BICYCLE RETAILER (June 4, 2013), http://www.bicycleretailer.com/north-america/2013/06/04/one-year-old-lawsuit-against-strava-dismissed#.VtWs2sfp38t.

186. *See Research & Statistics: Injury Statistics*, U.S. CONSUMER PROD. SAFETY COMM'N, http://www.cpsc.gov/en/Research—Statistics/Injury-Statistics/ (last visited Mar. 16, 2016) (providing, for example, that between 2012 and 2014 there were approximately 72,900 injuries seen in hospital emergency rooms).

187. *See, e.g.*, Michael E. Miller, *Dave Goldberg's Death Points to Rise and Risks of Treadmills in Era of Smartphones*, WASH. POST (May 5, 2015), http://www.washingtonpost.com/news/morning-mix/wp/2015/05/05/dave-goldbergs-death-points-to-rise-and-risks-of-treadmills-in-era-of-smart-phones/?tid=hp_mm&hpid=z3 ("[Dave] Goldberg slipped and fell while using one of the [treadmills] [. . .] He hit his head and died from brain trauma and blood loss."); Aamer Madhani, *Treadmill Injuries Send Thousands to the ER Every Year,* USA TODAY (May 5, 2015, 5:45 PM), http://www.usatoday.com/story/news/2015/05/04/treadmill-emergency-room-injuries-exercise-equipment/26898487/ (describing injuries caused by exercise equipment).

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clothing[188] or have sensors or other mechanisms that more directly contact the skin, arguably increasing risk. For example, in 2014, Fitbit recalled its Fitbit Force wearable after more than 10,000 purchasers complained of skin blisters and rashes.[189] The company only avoided a recall of its Flex product by agreeing to warn of allergens such as nickel.[190]

In an emerging field, courts likely will look to a broad array of expert evidence and other normative sources to flesh out the meaning of defectiveness in app and wearable cases. For example, the FDA, while exercising its discretion and not applying device regulation to most apps, nevertheless,

> [S]trongly recommends that manufacturers of all mobile apps that may meet the definition of a device follow the Quality System regulation (which includes good manufacturing practices) in the design and development of their mobile medical apps and initiate prompt corrections to their mobile medical apps, when appropriate, to prevent patient and user harm.[191]

Similarly, platform owners may help courts understand safe practices. For example, Apple's App Store Developer Guidelines already set a reasonably high bar for app privacy and security standards.[192] The same company also publishes developer guidelines on designing interfaces and optimizing usability,[193] and has published detailed rules as to how the third party

188. *See* Zach Miners, *Under Armour Snaps Up MyFitnessPal to Become Largest Health Tracker*, PCWORLD (Feb 5, 2015, 7:32 AM), http://www.pcworld.com/article/2880312/under-armour-buys-two-fitness-apps-builds-trove-of-health-data.html (referencing popular devices like Fitbit and Jawbone).

189. *Fitbit Recalls Force Activity-Tracking Wristband Due to Risk of Skin Irritation*, U.S. CONSUMER PROD. SAFETY COMM'N (Mar. 12, 2014), http://www.cpsc.gov/en/Recalls/2014/Fitbit-Recalls-Force-Activity-Tracking-Wristband/.

190. *See* Rachel Abrams, *After One Product Recall, Fitbit Faces a New Safety Inquiry*, N. Y. TIMES (Sept. 26, 2014) http://www.nytimes.com/2014/09/27/business/after-product-recall-fitbit-faces-a-new-safety-inquiry.html?_r=0 (explaining United States requirements to warn consumers about the risks of nickel exposure from Fitbits and of wearing the device too tightly).

191. U.S. FOOD & DRUG ADMIN., MOBILE MEDICAL APPLICATIONS: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF 13 (2015) (referring to 21 C.F.R. § 820 (2011)).

192. *See App Store Review Guidelines*, *HealthKit and Human Subject Research*, APPLE, https://developer.apple.com/app-store/review/guidelines/#healthkit (last visited Feb. 16, 2016) (outlining privacy guidelines in Section 17) ("Apps cannot transmit data about a user without obtaining the user's prior permission and providing the user with access to information about how and where the data will be used."); *see* Terry, *supra* note 13, at 1431.

193. *iOS Human Interface Guidelines: HealthKit*, APPLE, https://developer.apple.com/library/ios/documentation/UserExperience/Conceptual/MobileHIG/HealthKit.html (last visited March 18, 2016) (explaining that "apps built with HealthKit can use data from the Health app to provide health and fitness services that are more powerful and integrated").

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watchbands should ensure that its Watch sensors are in contact with a user's skin.[194]

Overall, the extent of a product manufacturer's liability for privacy, but more ominously, security breaches, is an open question. How should manufacturers react to potential cyberattacks?[195] At least in the near term manufacturer compliance or non-compliance with store or sub-regulatory guidance[196] may influence the applicable norms.

B. Efficacy, Effectiveness, and Warranty Claims

In general terms, strict product liability does not apply to pure economic harms or complaints about product performance.[197] Rather, plaintiffs in such cases must bring contractual or express warranty claims.[198] In some states, consumer protection statutes grant private rights of action for such product "disappointments."[199]

A good example of an effectiveness issue, albeit one pursued by the FTC and not a private action for damages, was raised against two developers who made "mole apps."[200] Defendants' apps (going by names such as MelApp and Mole Detective) leveraged a smartphone platform's camera to capture a picture of a mole and then requested the user to input other information.[201]

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194. *Band Design Guidelines for Apple Watch*, APPLE 5-6 (May 6, 2015), https://developer.apple.com/watch/bands/Band-Design-Guidelines-for-Apple-Watch.pdf ("Bands must not prevent the user's skin from maintaining direct contact with the Apple Watch heart rate sensors and back of Apple Watch, and must incorporate sufficient margin to compensate for shifting or dimensional changes of the band material. Failure to do so may interfere with Apple Watch wrist detect and Apple Pay features.").

195. *See generally* John Villasenor, *If a Cyberattack Causes a Car Crash, Who Is Liable?*, SLATE MAG. (Aug. 11, 2015), http://www.slate.com/blogs/future_tense/2015/08/11/if_a_cyberattack_causes_a_car_crash_who_is_liable.html?wpsrc=fol_tw (questioning who is liable in cyberattacks).

196. *See, e.g.*, U.S. FOOD & DRUG ADMIN., POSTMARKET MANAGEMENT OF CYBERSECURITY IN MEDICAL DEVICES: DRAFT GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (2016) (providing FDA guidance on how to handle cyberattacks); U.S. FOOD & DRUG ADMIN., CONTENT OF PREMARKET SUBMISSIONS FOR MANAGEMENT OF CYBERSECURITY IN MEDICAL DEVICES: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (2014) (providing additional FDA guidance on medical premarket submissions for effective cybersecurity management).

197. E. River S.S. Corp. v. Transamerica, 476 U.S. 858, 872-73 (1986).

198. For example, a plaintiff can bring a claim under UCC §2-313. *Id.* at 872 ("The maintenance of product value and quality is precisely the purpose of express and implied warranties.").

199. *See, e.g.*, WIS. STAT. § 402.314 (2015) (implied warranty, merchantability, usage of trade).

200. Health Discovery Corp. & FTC v. Avrom Boris Lasarow, 2015-1 Trade Cases P 17280, 2015 WL 926509 ¶ 1 (Feb. 23, 2015) (referring to mobile apps that provide automated analyses of moles and skin lesions for symptoms of melanoma).

201. *Id.*

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The apps then purported to calculate the risk of the skin imperfection being pre-cancerous or cancerous.[202] Crucially, the FTC applied a "competent and reliable scientific evidence" standard for the substantiation of claims:

> [H]uman clinical testing of the Device that is sufficient in quality and quantity, based on standards generally accepted by experts in the relevant field, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. Such testing shall be blinded, conform to actual use conditions, and include a representative range of skin lesions; be conducted by researchers qualified by training and experience to conduct such testing; and all underlying or supporting data and documents generally accepted by experts in the relevant field as relevant to an assessment of such testing . . . must be available for inspection and production to the Commission.[203]

In a dissenting statement, Commissioner Ohlhausen complained that her colleagues had imposed an "inappropriately high substantiation requirement on a relatively safe product."[204] However, the majority's approach to the substantiation standard was upheld by the DC Circuit in *POM Wonderful, LLC v. FTC*.[205] Subsequently, the FTC has applied the same substantiation standard in the Carrot Neurotechnology case ordering an app developer to cease making scientifically unsubstantiated claims that its app could improve users' vision or vision rest results.[206]

Increasingly, apps and wearables are being tested for effectiveness against established baselines.[207] For example, a recent study tested thirty popular mobile apps for programming physical activity.[208] Their performance was weighed against guidelines and fitness principles established by the American College of Sports Medicine (ACSM).[209] The study concluded that

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202. *Id.*

203. Analysis of Proposed Consent Order to Aid Public Commitment, at Part I, Health Discovery Corp. & FTC v. Avrom Boris Lasarow, et al., Trade Reg. Rep. ¶ 17280 (Feb. 23, 2015).

204. *Id.*

205. *See generally* Pom Wonderful, LLC v. F.T.C., 777 F.3d 478 (D.C. Cir. 2015) (alleging false claims that POM products could treat, prevent, or reduce the risk of heart disease, prostate cancer, and erectile dysfunction, although seventeen of thirty-six ads had qualifying language).

206. *See* Complaint, Carrot Neurotechnology, Inc., F.T.C. No. 142-3132 (Feb. 22, 2016), https://www.ftc.gov/system/files/documents/cases/160223carrotneurodo.pdf.

207. *See, e.g.,* François Modave et al., *Low Quality of Free Coaching Apps With Respect to the American College of Sports Medicine Guidelines: A Review of Current Mobile Apps*, 3 J. MED. INTERNET RES. 125, 125 (2015) ("[N]o systematic assessment has been performed about [the quality of apps and wearables as they relate to sound fitness principles] . . . [t]he aim of this paper is to fill this gap and asses the quality of mobile coaching apps . . . ").

208. *Id.*

209. *Id.*

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"very few" of the apps "are evidence based, and respect the guidelines for aerobic activity, strength/resistance training, and flexibility, set forth by the ACSM."[210] Indeed, only one app even scored over fifty percent in the comparison.[211]

A California class action may be the liability "canary in the coalmine." The complaint argues Fitbit devices overestimated sleep by sixty-seven minutes per night compared to polysomnography and forty-three minutes compared to the less-accurate actigraphy.[212] The claim, which alleges the breach of various state statutes, fraud, and breach of warranty,[213] is largely predicated on the findings published in a peer-reviewed sleep journal.[214]

C. App Certifiers and Healthcare Providers

Product liability and warranty claims primarily apply to "commercial sellers."[215] However, in this evolving space, it may be that regulators and litigators seek to extend responsibility to emerging entrants such as app stores (that either do or do not curate or police their offerings), or computing clouds that offer not only data storage but, increasingly, cloud-based analytic services.

There have been a few cases that have extended liability, typically using a negligence standard, to others not directly in the stream of commerce.[216] Specifically, some older cases have imposed liability on actors who recommended or certified products.[217] This has particular salience given a proposal that organizations should undertake the review or certifications of mobile health apps.[218] The proposal further recommend that such

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210. *Id.*

211. *Id.*

212. Class Action Complaint & Demand for Jury Trial at ¶ ¶ 20-21, Brickman v. FitBit, Inc., No. 3:15-cv-2077 (N.D. Cal. May 8, 2015).

213. *Id.* at ¶ ¶ 47-143.

214. *See* Hawley E. Montgomery-Downs et al., *Movement Toward a Novel Activity Monitoring Device*, 16 SLEEP & BREATHING: INT'L J. SCI. & PRAC. SLEEP MED. 913, 916 (2011).

215. *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY §1 (AM. LAW INST. 1998).

216. *See generally* Robert C. Feldmeier, *The Risk of Negligence Liability for Trade Association Engaged in Standards Setting or Product Certification*, 34 TORT & INS. L. J. 785 (1999).

217. *See, e.g.*, Hanberry v. Hearst Corp., 81 Cal. Rpt. 519 (Cal. Ct. App. 1969) (involving a plaintiff magazine company that recommended and certified shoes); Hempstead v. Gen. Fire Extinguisher Corp., 269 F. Supp. 109 (D. Del. 1967) (involving a defendant fire extinguisher manufacturer's hired testing company that certified and proscribed standards with which to operate its fire extinguisher); *cf.* Dekens v. Underwriters Lab. Inc., 132 Cal. Rptr. 2d 699 (Cal. Ct. App. 2003) (involving a plaintiff consulting firm that recommended employment safety practices).

218. Adam C. Powell et al., *In Search of a Few Good Apps*, 311 JAMA 1851, 1851-52

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"organizations would likely need to include in their reviews a certification process to ensure that apps do not pose potential harm to their users or have significant security and privacy vulnerabilities."[219] In the mobile health space, one company, Happtique, did attempt a certification process for app privacy and security.[220] However, it quickly suspended the program after a third party cast doubts on the security of two of the products it certified.[221]

Although courts have a relatively broad sense of who can be a defendant in a product liability action, they have not extended liability to healthcare providers.[222] The general rule is that:

> The hospital is not in the business of selling or even leasing, bailing or licensing equipment to the physician. It is in the business of providing medical services to its patients and of providing the environment in which physicians may provide their own medical treatment to the patients. Rather than being a supplier or an entity that places a product in "the stream of commerce," the hospital, as well as the physician, is an ultimate consumer of hospital equipment which is used in the treatment of the patient.[223]

This rule should shield most physicians and hospitals from strict liability when they provide a third-party app to a patient.[224] The answer might be different if the institution is the app developer or commissioner, an issue likely to be tested as major medical centers produce branded apps for their patients.[225] In any case, and as discussed above, the provider may still face liability in negligence for recommending apps, but is unlikely to under strict products liability.[226]

(2014). On certification models in health care, *see generally* Frank A. Pasquale, *Private Certifiers and Deputies in American Health Care*, 92 N.C. L. REV. 1661 (2014).

219. Powell et al., *supra* note 218, at 1851.

220. Stephanie Baum, *Happtique Suspends mHealth App Certification Program After Software Developer Exposes Security Shortcomings*, MED. CITY NEWS, Dec. 12, 2013, 4:10 PM, http://medcitynews.com/2013/12/happtique-suspends-mhealth-certification-program-software-developer-exposes-security-flaws/.

221. *Id*.

222. *See* RESTATEMENT (THIRD) OF TORTS, PRODUCTS LIABILITY § 20(a) (AM. LAW INST. 1998) ("One sells a product when, in a commercial context, one transfers ownership thereto either for use or consumption or for resale leading to ultimate use or consumption. Commercial product sellers include, but are not limited to, manufacturers, wholesalers, and retailers.").

223. San Diego Hosp. Ass'n. v. Superior Court, 35 Cal. Rptr. 2d 489, 493 (Cal. Ct. App. 1994); *see generally* Laura Pleicones, Note, *Passing The Essence Test: Health Care Providers Escape Strict Liability For Medical Devices*, 50 S.C. L. REV. 463, 464 (1999).

224. *See generally* Pleicones*, supra* note 223.

225. *See generally id.*

226. *See* Patricia M. Danzon, *Liability for Medical Malpractice*, 5 J. ECON. PERSP. 51, 51 (1991).

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VI. PRIVACY-SECURITY LIABILITY EXPOSURE

The Privacy and Security Rules authorized by the Health Insurance Portability and Accountability Act of 1996 (HIPAA), present a compliance-oriented regulatory model and do not provide for a private right of action.[227] In 2009, the HIPAA-amending Health Information Technology for Economic and Clinical Health (HITECH) Act included a provision that would allow persons injured by privacy or security breaches to receive compensation based on a "percentage of any civil monetary penalty or monetary settlement."[228] However, this provision has not been acted upon, for reasons that are unclear.[229] In contrast to federal law, a small number of state privacy statutes allow for a private right of action. For example, California's Confidentiality of Medical Information Act (CMIA) provides:

> In addition to any other remedies available at law, a patient whose medical information has been used or disclosed … and who has sustained economic loss or personal injury therefrom may recover compensatory damages, punitive damages not to exceed three thousand dollars ($3,000), attorneys' fees not to exceed one thousand dollars ($1,000), and the costs of litigation.[230]

Notwithstanding, most plaintiffs injured by a provider or developer data breach will have to rely on common law causes of action.

A. Causes of Action

The traditional common law privacy torts, such as intrusion on seclusion or public disclosure of private facts, are discrete, limited causes of action that provide damage remedies for a limited range of unlawful data collection.[231] Dependent on a showing of specific intent, they are also quite difficult to prove.[232]

Of considerably more utility is the breach of confidence tort that applies to those who disclose information that had been given to them in privacy.[233]

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227. *See* 45 C.F.R. § 160 (2013); 45 C.F.R. § 164 (2013).
228. 42 U.S.C. § 17939 (2010).
229. *Id.*
230. CAL. CIV. CODE § 56.35 (West 2000).
231. RESTATEMENT (SECOND) OF TORTS § 652A-652B, 652H (AM. LAW INST. 1977).
232. *See, e.g.*, Knight v. Penobscot Bay Med. Ctr., 420 A.2d 915 (Me. 1980) (rejecting plaintiff's appeal of lower court's ruling that defendants, a hospital, a doctor, a nurse, and an observer, invaded plaintiffs' privacy); *cf.* Estate of Berthiaume v. Pratt, 365 A.2d 792 (Me. 1976) (sustaining the administratrix' appeal of the grant of a directed verdict in favor of the surgeon and ordered a new trial as to the administratrix' invasion of privacy and assault and battery causes of action involving the photographs of her deceased husband which were taken by the surgeon while her husband was dying).
233. *See, e.g.*, Johns v. Firstar Bank, NA, No. 2004-CA-001558-MR, 2006 Ky. App.

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This contextual requirement of a confidential relationship could be established against providers via the traditional physician-patient relationship and against developers with an implied contract argument. Most jurisdictions now recognize the breach of confidence as a tort.[234] It is essentially a strict liability action[235] and, at least in this regard, is similar to HIPAA and state health privacy statutes. To prevail against a provider, the plaintiff would have to prove "unprivileged disclosure to a third party of nonpublic medical information that a physician or hospital has learned within a physician-patient relationship."[236]

Recently, a further limitation was recognized by the New York Court of Appeals, which held that a claim for unauthorized disclosure of medical information could not run directly against medical corporations when the employee responsible for the breach was not a physician and was acting outside the scope of her employment.[237] Beyond issues arising in breach of confidence cases, there is a growing body of fact-intensive case law dealing with the responsibility of healthcare data custodians for the misfeasance of their employees.[238]

A common issue in privacy and security litigation is how such state's causes of action interact with the HIPAA privacy and security rules. As decisively stated by the Fifth Circuit in *Acara v. Banks*:

> HIPAA does not contain any express language conferring privacy rights upon a specific class of individuals. Instead, it focuses on regulating persons that have access to individually identifiable medical information and who conduct certain electronic health care transactions. HIPAA provides both civil and criminal penalties for improper disclosures of medical information. However, HIPAA limits enforcement of the statute to the Secretary of Health and Human Services. Because HIPAA specifically delegates enforcement, there is a strong indication that

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Unpub. LEXIS 85, at *8-9 (Ky. Ct. App. Mar. 24, 2006).

234. *See, e.g.*, Biddle v. Warren Gen. Hosp., 715 N.E.2d 518, 523 (Ohio 1999).

235. *See generally* Vassiliades v. Garfinckel's, Brooks Bros., 492 A.2d 580, 590 (D.C. 1985) (reasoning that the "limited duty conveys a standard that is more strict than the reasonable man test").

236. *See Biddle*, 715 N.E.2d at 528.

237. Doe v. Guthrie Clinic, Ltd., 5 N.E.3d 578, 582 (N.Y. 2014).

238. *See, e.g.*, Walgreen Co. v. Hinchy, 21 N.E.3d 99, 103 (Ind. Ct. App. 2014) (ruling on question of fact as to whether pharmacist acting within scope of employment when she looked up prescription records belonging to girlfriend of ex-partner); *cf.* Robbins v. Trs. of Ind. Univ., No. 49A04-1412-CT-583, 2015 Ind. App. LEXIS 663 (Ct. App. Oct. 2, 2015) (holding that while the nurse's employer, the trustees, authorized her to access patient information for business reasons, she was expressly not authorized to access, use, or disclose the information for personal, unauthorized, unethical, or illegal reasons, and the nurse's actions were not sufficiently associated with her employment duties so as to have fallen within the scope of her employment); *cf.* Sheldon v. Kettering Health Network, 40 N.E.3d 661, 675 (Ohio Ct. App. 2015).

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> Congress intended to preclude private enforcement….
>
> > While no other circuit court has specifically addressed this issue, we are not alone in our conclusion that Congress did not intend for private enforcement of HIPAA. Every district court that has considered this issue is in agreement that the statute does not support a private right of action. . . .[239]

Thus a private right of action may not be implied in HIPAA nor may the federal regulatory scheme be used to fashion a state negligence per se action. However, it does not follow that all jurisdictions will treat HIPAA as irrelevant to state tort claims such as breach of confidence, negligent infliction of emotional distress, negligent misrepresentation, or even simple negligence. For example, in the recent case of *Byrne v. Avery Center for Obstetrics and Gynecology, P.C*., the court not only denied the defendant's argument that HIPAA preempted state common law causes of action but also stated:

> [T]o the extent it has become the common practice for Connecticut health care providers to follow the procedures required under HIPAA in rendering services to their patients, HIPAA and its implementing regulations may be utilized to inform the standard of care applicable to such claims arising from allegations of negligence in the disclosure of patients' medical records.[240]

Notwithstanding that HIPAA is a "compelled" custom, it has been adopted by most health care providers suggesting that HIPAA-derived norms will be increasingly important in privacy and security litigation.[241]

B. Causation and Damages Issues

Strict liability breach of confidence actions and HIPAA-informed negligence actions undoubtedly help plaintiffs hold defendants liable for privacy and security breaches. However, plaintiffs still face two linked and persistent problems: proving causation and damages. Many of these issues surface in security breach class actions where they are magnified by Article III standing issues[242] and the certification requirements of commonality and

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239. Acara v. Banks, 470 F.3d 569, 571 (5th Cir. 2006).

240. Byrne v. Avery Ctr. for Obstetrics & Gynecology, P.C., 102 A.3d 32, 49 (Conn. 2014).

241. Karen J. Maschke, *The Implications of the HIPAA Privacy Rule for Quality-Improvement Activities*, *in* HEALTH CARE QUALITY IMPROVEMENT: ETHICAL AND REGULATORY ISSUES 107, 122 (Bruce Jennings, et al. ed., 2007).

242. *See generally* Susan B. Anthony List v. Driehaus, 134 S. Ct. 2334, 2347 (2014) (hearing a suit brought by advocacy organizations challenging an Ohio statute that criminalized false statements about candidates during political campaigns); Clapper v.

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predominance.[243]

Resnick v. AvMed, Inc., is a rare case decided in plaintiffs' favor on this issue.[244] Thieves stole two unencrypted laptops containing information on 1.2 million patients from a health insurer.[245] The plaintiff class representatives, two plan members who had histories of being particularly careful with their personal or sensitive information, alleged *inter alia* negligence, negligence per se, and breach of contract.[246] Within a year of the theft both plaintiffs had been victims of identity theft.[247] The Eleventh Circuit Court held that the pleading of causation was sufficient to avoid dismissal.[248] Specifically, the court noted that the plaintiffs had "pled a cognizable injury and have pled sufficient facts to allow for a plausible inference that [defendant's] failures in securing their data resulted in their identities being stolen.[249] They have shown a sufficient nexus between the data breach and the identity theft beyond allegations of time and sequence."[250]

In some cases, a state data protection statute that provides for nominal damages may throw plaintiff a lifeline. However, in *Sutter Health v. Superior Court,* even that was insufficient.[251] The California statute in question, part of the CMIA, provided for nominal damages of $1,000.00, noting that, "[i]n order to recover under this paragraph, it shall not be necessary that the plaintiff suffered or was threatened with actual damages."[252] Given that four million medical records had been stolen, the stakes were high.[253] The court ruled that the theft of the data was insufficient and that the statutory damage provision was not triggered until, the plaintiffs demonstrated that the confidentiality of their records had been lost, by showing the thief had viewed the stolen information.[254]

Amnesty Int'l USA, 133 S. Ct. 1138, 1151 (2013) ("[R]espondents cannot manufacture standing merely by inflicting harm on themselves based on their fears of hypothetical future harm that is not certainly impending."); *see also,* Green v. eBay Inc., No. 14-1688, 2015 U.S. Dist. LEXIS 58047, at *6 (E.D. La. May 4, 2015); *see, e.g.*, Remijas v. Neiman Marcus Grp., LLC, 794 F.3d 688, 697 (7th Cir. 2015) (holding victims of cyber theft of credit card information plausibly alleged standing to bring class action).

243. FED. R. CIV. P. 23.
244. Resnick v. AvMed, Inc., 693 F.3d 1317, 1321 (11th Cir. 2012).
245. *Id*. at 1322.
246. *Id.* at 1321.
247. *Id*.
248. *Id.*
249. *Id*. at 1330.
250. *Id*.
251. Sutter Health v. Superior Court, 174 Cal. Rptr. 3d 653, 655 (Cal. Ct. App. 2014).
252. CAL. CIV. CODE § 56.36 (West 2016).
253. *Sutter*, 174 Cal. Rptr. 3d at 655.
254. *Id*. at 662.

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VII. CONCLUSION

Physicians and healthcare institutions are accustomed to adapting as new technologies and methods are introduced. In particular, emerging technologies often introduce uncertainty as to the applicable knowledge base and their appropriate deployment or use. Mobile health and wearables may prove particularly challenging because of their hybrid existence, sometimes inside and sometimes outside, the traditional provider-patient relationship and its relatively tightly regulated domain.

In this context the private liability model, or regulation by litigation, is particularly troublesome. A case-by-case liability decision-making model will tend to exhibit particular indeterminacy when faced with novel issues. As with any other treatment innovation, the customary-practice standard of care for malpractice can chill or accelerate adoption of new approaches. Doing things "the old way" can appear safer from a liability standpoint. But that is true only up to an ill-defined tipping point at which the innovation becomes the prevailing standard of care. Malpractice liability for healthcare providers who participate in the design of, rely on, or recommend and prescribe mobile health products does not raise *novel* legal issues. However, *existing* legal doctrines will likely influence the development and adoption of mobile health products by healthcare professionals.

The FDA has decided on a very "light" approach to the regulation of mobile health apps and wearables, in all probability based on a determination that any perception of over-regulation would stifle innovation. An alternative argument is that regulatory certainty would reduce market anxiety and spur development.[255] When it comes to the more dignitary losses that occur when privacy or security are breached, traditional regulatory systems such as HIPAA do not provide remedies for individuals. Here too, relatively underdeveloped common law analogs will be applied, bringing with them another set of indeterminacies.

What is clear is that regulation by litigation currently *does* apply to the mobile health space. However, the applicable common law doctrines are by nature fact-intensive and, at least in the early days of application to novel fact patterns, tend to exhibit high levels of indeterminacy.

255. Cortez, *supra* note 13, at 1179.

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