Mobile Health and Wearable Technologies: Systemic Liability

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I. Introduction

In the context of mobile health, “systemic liability” denotes two issues. First, it refers to liability that implicates institutions or enterprises from health care institutions to application developers. Second, it may refer to systemic errors or flaws common to extant processes rather than those that are the product of institution-specific, individual or idiosyncratic behaviors.

Notwithstanding the dearth of decided cases, health care (institutional or direct) and product liability (enterprise) models clearly apply to those involved in mobile development and deployment. This is the case whether the actors are inside or outside the traditional health care system.

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Part II of this paper provides an introduction to the terminology used, and presents a brief typology of the mobile health applications (apps) appearing in the health care space together with some additional terminology. Part III discusses potential health care provider (HCP) liability. Part IV discusses the applicability of product liability to mobile health developers and vendors. The survey concludes by noting that regulation by litigation will be a significant force in app and wearable space. This is a conclusion that is unlikely to cheer neither health care providers nor app developers, given the indeterminacy associated with common law litigation involving emerging technologies.

II. Typology and Terminology

The development of computing hardware, software platforms (operating systems) and the software and services sitting atop them has never been more rapid. It took a while for mainframes to be replaced by personal computers (PC), while the movement to the post-PC world of mobile has been comparatively rapid. However, miniaturization and rapid iteration are now introducing us to the post-mobile future of wearables. In this paper the term mobile health is used to describe health apps running on mobile devices, sensors and software built into mobile devices, and wearable technologies. However, the paper does not consider the use of general mobile technologies, such as email or texting, that may be used in the health care setting.

As explained below, mobile health apps can be roughly categorized by function. At present, however, 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\(^1\) inserted subcutaneously, or otherwise implanted or ingested. In the future, some of our “wearables” will be ocular and, eventually, neural. Such fragmentation may well lead to more differentiation in their regulation. For now, however, wearables as we understand them can be grouped with mobile health apps and the mobile platforms that frequently control or monitor them.

When it comes to developing a typology for mobile health, some deference likely is due to the Food and Drug Administration (FDA) that suggested 10 types in a 2015 Guidance.\(^2\) The 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.” Further, the Guidance identified classes of apps over which the FDA would exercise regulatory discretion (such as fitness trackers). While there have been more sophisticated attempts to categorize mobile apps by function and purpose, the FDA approach is useful for our current task because likelihood of device regulation also may be predictive of liability.

Mobile apps (and wearables) can be roughly divided into two categories, those that are essentially health care provider-facing (and so more part of the “digital health” domain) and those that are consumer-facing. The former include:

1. Apps providing remote control of medical device
2. Apps enabling remote display or analysis of data from medical device
3. Apps/weareables/sensors/attachments providing functions similar to those of currently regulated medical devices
4. Apps/weareables/sensors performing patient-specific analysis/diagnosis/treatment recommendations

In contrast, consumer (or patient-facing) apps include:

1. Apps providing access to health records
2. Consumer versions of existing medical devices
3. Condition monitoring and management apps
4. Fitness trackers and wellness coaches
5. Diagnosis or treatment apps

Obviously, there will be overlaps between the categories. For example, both HCPs may be customers for app-based versions of existing medical devices. Equally, some consumer-facing wearables, such as Google Glass, have migrated over into HCP-facing space.

Of the five consumer-facing apps, those that provide access to health records seem the most benign, with a relatively low risk profile. However, consumer versions of existing medical devices, condition monitoring and management apps, fitness trackers and wellness coaches, and diagnosis or treatment apps all have some risk potential and may lead to liability claims against HCPs or app developers. As I have argued elsewhere, each type of app poses different safety (and, for that matter, privacy) risks. In general terms, HCPs may face some negligence-based claims when they supply or curate apps that cause harm. In

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contrast, developers of defective apps may face strict liability claims for breach of warranty or common law product liability.

III. Health Care Provider Liability for Mobile Health

Institutional health care providers, such as hospitals and managed care organizations, face liability exposure for either the negligence of their employees or their own “direct” or “corporate” wrongs. The former, vicarious liability or respondeat superior, is predicated on a breach of a duty of care (such as medical malpractice) by one of its employees or agents. 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 HCP. This 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, say, apparent agency based on a showing of hospital conduct plus patient reliance. 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.

The potential for direct (a.k.a. corporate) liability of an HCP dates from the famous case of Darling v. Charleston Community Memorial Hospital. Darling articulated two major changes to how the liability system approached institutional liability. First, and running counter to the then prevalent “hotel” doctrine that viewed the hospital as a mere venue in which patients and their physicians interacted, Darling held that an HCP could be directly responsible for aspects of patient care. Second, Darling undermined the dominance of custom as the pro-defense standard of care by permitting surrogates such as accreditation standards and hospital bylaws.

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

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6 These issues are discussed in a separate paper. See Lindsay Wiley, TBA, AAAS (2015).
7 33 Ill.2d 326 (1965).
9 See e.g., Gafner v. Down E. Community Hosp., 735 A.2d 969 (Me. 1999).
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.\textsuperscript{10}

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

\section*{A. Health Care Provider-Facing Apps}

The hospital-provided, provider-facing apps space is relatively immature. HCPs have concentrated on providing mobile and tablet access to their existing suite of health information technology (HIT) products, such as electronic medical records (EMRs), Clinical Decision Support software (CDS) and imaging products (PACS). Many of these “front-end” apps will have been developed “in-house” or by the developers of the underlying products. However, EMR vendors are opening app stores\textsuperscript{11} and major ‘software as service’ suppliers such as IBM are developing health care-specific apps.\textsuperscript{12} As a result HCPs may soon owe duties to patients regarding the careful selection, deployment, staffing and updating of these new technologies.

Individual employees or credentialed physicians also introduce apps and their hardware platforms into health care institutions. One example of this bring-your-own-device (BYOD) phenomenon is the use of Google 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.\textsuperscript{13} 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

\begin{footnotesize}
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  \item \textsuperscript{10} Thompson v. Nason Hospital, 591 A.2d 703, 708 (Pa. 1991).
  \item \textsuperscript{11} Judy Newman, \textit{Epic Systems to open its own app exchange}, Wis. State J. (Feb 18, 2015, 9:05 AM), \url{http://host.madison.com/wsj/business/epic-to-open-its-own-app-exchange/article_fc7e8b94-b1ec-59f4-9065-1e6143fe351c.html}.
  \item \textsuperscript{13} Nicolas Terry, Chad Priest, & Paul Szotek, Google Glass and Health Care: Initial Legal and Ethical Questions, 8(2) J. Health & Life Sci. L. 93 (2015).
\end{itemize}
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images of patients.™ Again, good risk management suggests that HCPs update their social media policies to prohibit app uses that may involve legal or ethical risks.\(^{15}\)

**B. Patient-Facing Apps**

In general, consumers drive the processes of choosing and using mobile apps. However, an HCP might insert itself into such processes by recommending or prescribing apps. Consider, for example, the pitch made by one HCP for its health app curation:

The O Bar shares physician-recommended health apps at its state-of-the-art 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 O 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.\(^{16}\)

Clearly, HCPs that recommend or curate apps or coach patients in their use will have increased exposure if their choices or techniques are negligent and damage-causing. Some HCPs 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. That leads to a broader observation as to the standard of care appropriate for app recommending or curating. There are very few prescription-only apps currently available (typically for diabetes or other chronic disease monitoring\(^{17}\)), and, as with other prescribing duties, a professional standard of care would seem appropriate.\(^{18}\) 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.\(^{19}\)

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\(^{14}\) See e.g., Virginia Hughes, *Is This Doctors App A Digital Classroom — Or Medical Porn?*, BuzzFeed News (Apr. 17, 2015, 6:04 PM), [http://www.buzzfeed.com/virginiahughes/is-this-doctors-app-a-digital-classroom-or-medical-porn](http://www.buzzfeed.com/virginiahughes/is-this-doctors-app-a-digital-classroom-or-medical-porn).


\(^{18}\) See generally Hall v. Hilbun, 466 So. 2d 856 (Miss. 1985).

\(^{19}\) See e.g., Helling v. Carey, 519 P.2d 981 (Wash. 1974).
C. Informed Consent

Liability assertions involving recommendation or curation are essentially informational. That begs the question whether the broadly recognized informed consent duty would have a role to play. Consider, for example, an HCP approving the use of an innovative, augmented or virtual reality wearable during surgery or one recommending a novel disease monitoring app. Is the patient entitled to additional risk disclosure? Some courts have held the fact of experimental or novel use of a device to be relevant to informed consent allegations. A related question would be whether the HCP should provide additional disclosure if a prescription app was prescribed for an off-label use. Again, this is an area where the authorities are mixed but some courts have allowed those facts to reach the jury.

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. However, this avenue of liability may be moot. The conventional (albeit somewhat nonsensical) wisdom is that the risk disclosure duty is exclusively owed by physicians and not by institutional providers. However, 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."

IV. 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. By 2010, the FDA was collecting reports of HIT-related safety concerns, classifying them as follows:

21 See e.g., DeNeui v. Wellman, 2008 WL 4065816 (D. S.D. 2009). See also 40 Pa. Stat. § 1303.504(a)(5) (requiring informed consent for “using an experimental device or using an approved medication or device in an experimental manner”).
25 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 SLU LJ 37 (2002).
(1) errors of commission, such as accessing the wrong patient’s record or 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.26

Additionally, there has been considerable critical research regarding “alarm fatigue” and other problems with the interfaces used by HIT products.27

There is little doubt that product liability models would apply to HIT devices and their mobile extensions.28 Indeed, the HIT industry has been heavily criticized for attempting to shift such risks to HCPs.29 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”30 by analogy to liability found in cases involving defective aeronautical charts.31

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.32 However, substantial limitations apply with regard to FDA-regulated

32 See Restatement (Third) of Torts: Products Liability §2, §6 (1998). Parallel claims may also be brought for breach of the implied warranty of merchantability, UCC §2-314.
medical devices because of application of the preemption doctrine. A private right of action may exist at federal law for harms caused by products regulated by the Consumer Product Safety Commission.

Looking to the future, plaintiffs’ attorneys no doubt will consider a plethora of product liability allegations against app sellers (such as app developers or wearable manufacturers). Thus, it might be argued that fitness/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.’ 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, sued the developer of a bicycle GPS app that awarded “King of the Mountain” status to top performers.

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

As the wearable market matures, devices will increasingly be built into clothing or in other ways brought into direct contact with the skin, increasing risk. For example, in 2014, Fitbit recalled its Fitbit Force wearable after more than 10,000 purchasers complained of skin blisters and rashes. The company only avoided a recall of its Flex product by agreeing to warn of allergens such as nickel.

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

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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/.
and wearable cases. For example, the FTC, while exercising its discretion and not applying divide 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.  

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. The same company also publishes developer guidelines on designing interfaces and optimizing usability, and has published detailed rules as to how the third party watchbands should ensure that its Watch sensors are in contact with a user’s skin.

B. Efficacy, Effectiveness and Warranty Claims

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

A good example of an effectiveness issue, albeit one pursued by the Federal Trade Commission and not a private action for damages, was raised against two developers who made “mole apps.” 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

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40 Id at 13, referring to 21 CFR part 820 (references omitted).
44 See e.g., East River S.S. Corp. v. Transamerica, 476 U.S. 858 (1986).
45 E.g., under UCC §2-313.
information. The apps then purported to calculate the risk of the skin imperfection being pre-cancerous or cancerous. The FTC argued that the developers deceptively claimed the apps could detect symptoms of melanoma and assess early stage risk. 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.47

In a dissenting statement, Commissioner Ohlhausen complained that her colleagues had imposed an “inappropriately high substantiation requirement on a relatively safe product.”48 Hewing to the majority, FTC approach is a class action claim that argues Fitbit devices overestimated sleep by 67 minutes per night compared to polysomnography and 43 minutes compared to the less-accurate actigraphy.49 The claim, which alleges the breach of various state statutes, fraud and breach of warranty, is largely predicated on the findings published in a peer-reviewed sleep journal.50

C. App Certifiers and Health Care Providers

47 In the Matter of Health Discovery Corporation at 3.
50 Montgomery-Downs HE, Insana SP, Bond JA. Movement toward a novel activity monitoring
device. Sleep Breath. 2012 Sep;16(3):913-7
Product liability and warranty claims primarily apply to “commercial sellers.”51 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. Specifically, some older cases have imposed liability on actors who recommended or certified products.52 This has particular salience given the proposal by Powell and colleagues that organizations should undertake the review or certifications of mobile health apps. They further recommend that such “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...” 53 In the mobile health space, one company, Happtique, has attempted a certification process. However, it quickly suspended the program after a third party cast doubts on the security of two of the products it certified.54

Although courts have a relatively broad sense of who can be a defendant in a product liability action,55 they have not extended liability to HCPs. 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.56

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51 See Restatement (Third) of Torts: Products Liability §1(1998).
53 In Search of a Few Good Apps, Adam C. Powell, PhD; Adam B. Landman, MD; David W. Bates, MD. JAMA. 2014;311(18):1851-1852.
55 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. Restatement (Third) of Torts, Products Liability § 20(a) (1998).
56 San Diego Hospital Ass’n. v. Superior Court, 30 Cal.App.4th 8, 16 (1994).
This should shield most HCPs from strict liability when they provide a third party app to a patient. The answer might be different if the HCP is the app developer or commissioned it from one, an issue likely to be tested as major medical centers produce branded apps for their patients. In any case, and as discussed above, the HCP may still face liability in negligence for, say, recommending apps.

V. Conclusion

As I have noted:

The mHealth narrative combines the decentralization of health care with patient centeredness. Because it is patient facing, mHealth is consistent with contemporary calls to reform health care from a push model to one where patients pull only necessary resources. Operationally, mHealth places “tools for monitoring health and medical diagnosis...increasingly...in the hands of consumers” together with “online services for them to report and analyze data.” Mature mHealth apps and services could provide actionable information, coaching, or alerts at a fraction of the cost of conventional health care.57

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.58 In any event, regulation by litigation currently does apply to the mobile health space. However, common law doctrines such as malpractice and product liability 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.

57 Nicolas Terry, Mobile Health: Assessing the Barriers, Chest. 2015;147(5):1429, 1433 (references omitted).