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**Featured Article**

## Mobile Medical Apps: Understanding and Defending Against Products Liability Challenges

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Healthcare on the go? There's an app for that. In fact, there are thousands of them, and, while the technology is not exactly new, the number of these applications on the market, the services they provide and the functions they perform has skyrocketed over the last several years. Indeed, mobile healthcare or "mHealth" was determined to be an $8 billion industry in 2018 and expected to grow to $111.1 billion by 2025. (Globe Newswire, *Global mHealth Apps Market Will Reach USD 111.1 Billion By 2025: Zion Market Research* (Jan. 2019)) With the rapid growth of this market, we have seen new and innovative mobile medical apps (or "MMAs") to monitor, track, treat, and educate on patient health, including those that store health data or medical records, measure physical activity, monitor nutrition, and even apps that connect to implantable or other external devices.

Along with the growing profitably comes increasing legal risk. Even the existing players in the healthcare industry may not fully understand how MMAs are or can be regulated, or the full extent of the risk their "products" (to the extent they can be considered products) may pose to consumers. Not only are existing healthcare companies moving in this direction, but so are smaller start-up companies who may not be intimately familiar with the laws and regulations in the medical device context. In fact, according to market research, approximately 28 percent of digital health practitioners have little experience in the industry. (*See* Research 2 Guidance, *mHealth App Economics 2017/2018: Current Status and Future Trends in Mobile Health* (Nov. 2017).)

If deemed a "medical device" under federal law, an MMA would hav e to undergo FDA review and would be subject to existing regulatory requirements. But not all mobile health apps will be regulated as a "medical device"—this ultimately depends on the app's intended use and risk to consumer safety. According to FDA, it "intends 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." (*See generally* FDA, Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff (Feb. 9, 2015). In recent years, FDA has demonstrated its commitment to more efficient and effective regulation of MMAs, having "recognized the need for a new approach for digital health oversight" and the benefit derived from innovation in the industry. (FDA, Digital Health Innovation Action Plan at 2 (July 2017). As part of its Digital Health Program, FDA plans to implement a modern, more carefully tailored review of MMAs through its "Software Precertification (Pre-cert) Program," which is intended to streamline the regulatory review process.

### Product Liability Scheme

While the FDA regulatory review process may provide some comfort to the healthcare industry and patients as to the safety and effectiveness of MMAs, increasing use and reliance on MMAs could pose additional risk to consumer/patient safety. Apps that malfunction, have undiscovered defects, or are affected by external factors could significantly impact consumer health and result in product liability litigation—regardless of FDA approval. And while medical devices have been the subject of product liability litigation for years, there are a number of challenges with trying to map the traditional product liability scheme onto these types of cases. For one, the question of *who* will be sued is a complicated one. Not only could a plaintiff sue the product manufacturer, but also the software developer and any third-party service providers in the supply chain. The nature of the lawsuit will also be unpredictable—plaintiffs' attorneys may attempt to manipulate their clients' claims to fit within existing product liability frameworks by bringing claims of negligence or

strict liability based on design defect, manufacturing defect, and/or failure to warn, or they could attempt to bring other product or warranty-related claims.

## Considerations in Product Liability Litigation

When companies do find themselves confronted with product liability litigation surrounding an alleged malfunction or some other claimed defect, careful consideration should be paid to the potential vulnerabilities of plaintiffs' claims in these types of cases.

### *Causation*

Causation is a significant potential area to exploit when faced with product liability claims in this context. In many cases, there may be various external events that must occur or factors that exist for an MMA's proper functionality. For example, a user may have to manually input data or read app data or results. For apps that connect to external devices, the proper function and user operation of those devices may also be a separate but integral factor in the app's function. Moreover, when a healthcare professional uses an app to provide patient care, any resulting injury from that care is one further step removed from the app itself. Each of these could be "superseding" or "intervening" causes breaking the causal chain necessary to plaintiff's claims, in which case a good argument exists against the imposition of liability. This is especially true where plaintiff brings related medical malpractice claims, or if there are criminal or tortious intervening acts. The strength of the argument will, of course, depend on the nature of the product, claimed injury, and legal precedent in a particular jurisdiction. However, lack of causation will certainly be an argument worth considering and pursuing in some cases—both as a potential way to defeat an element of plaintiff's product liability claims and to attempt to challenge standing (which requires sufficient causation) in federal courts.

### *Duty to Warn/Learned Intermediary*

In a similar vein, a product manufacturer's duty to warn of risks must only extend so far. And there is a lack of clear legal guidance as to what that duty looks like, who exactly owes that duty, and to whom it runs in this context. Plaintiffs may attempt to impose a broad duty to warn, but courts may have a difficult time defining this duty given the inherent complexity of software and chance for malfunction/unauthorized access. Courts should be unwilling to extend a manufacturer's duty beyond what would typically be imposed on a non-software product manufacturer, especially where a particular malfunction is not reasonably foreseeable or, conversely, a danger obvious to the user—which would be consistent with traditional common law principles of product liability claims. Moreover, in jurisdictions that have adopted the learned intermediary doctrine, a device manufacturer's duty may only run to the healthcare provider. As such, for MMAs that are to be prescribed or operated by a doctor, this doctrine may preclude liability in failure to warn cases.

### *Preemption*

While it may be tempting for companies to avoid being classified as a medical device by FDA and going through the required regulatory processes, the review and approval by FDA may actually foreclose some product liability claims against certain MMA developers. The Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act expressly preempt state law claims challenging the safety or effectiveness of devices that have undergone pre-market approval by FDA. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008). This defense is frequently asserted and successful in device litigation and should equally apply where an app goes through the premarket approval process. However, it is possible that many apps and devices on the market have not been subject to that process (*e.g.*, those that seek 510(k) clearance, in which case preemption may not be a viable argument). It also remains to be seen how this preemption argument would be impacted by the pre-certification program that FDA will be implementing.

### *Personal Jurisdiction*

Another consideration is whether a court in one state would even have personal jurisdiction over an MMA defendant located in another. Given the relatively few barriers to entry and distribution, apps can be quickly and easily made available nationwide no matter where the developer is considered "headquartered." In the case of internet defendants, courts may look at various factors to determine a defendant's contact with the forum and thus whether there is personal jurisdiction over an internet defendant (including interactivity of a website, whether goods or services are offered, and the location of the servers). In theory, taking those factors, MMAs could be subject to personal jurisdiction in a large number of states—they are interactive, offer both goods and services, and are located in the hardware of each user's phone. But personal jurisdiction must also be reasonable, so the pressure point here is whether the MMA actually targeted the particular state in which jurisdiction is sought. *See Bristol-Myers Squibb Co. v. Superior Court of California, San Francisco Cty.*, – U.S. –, 137 S. Ct. 1773, 1785–86 (2017); *J. McIntyre Mach., Ltd. v. Nicastro*, 564 U.S. 873 (2011) (plu-

rality); *Advanced Tactical Ordnance Sys. LLC v. Real Action Paintball Inc.*, 751 F.3d 796, 801-02 (7th Cir. 2014).

### *Contractual Defenses*

End-user licensing or other agreements with app users may incorporate disclaimers, waivers of liability, assumption of risk clauses, or other clauses that attempt to limit legal liability to the extent permitted by law. The validity and enforceability of these agreements can vary widely from state to state, but where permitted and shown to be a valid, enforceable contractual provision, this can be a powerful defense. Even before any litigation arises, companies should consider to what extent such contracts can be used to limit liability, and should consult with counsel regarding the legal requirements to ensure enforceability.

### *Other Considerations*

To further prevent or reduce the risk of this sort of litigation, MMA manufacturers/developers should ensure strict compliance with FDA and any other safety and health regulations as applicable. Functionality of software and devices should, of course, be beta-tested and validated on a frequent basis, especially with the roll-out of new updates, analyzing not only user experience, but safety, accuracy, efficacy, quality, and security. The development and approval of marketing materials and claims made within the apps and/or on connecting devices will also be hugely important, as such claims are consumer/facing and may serve as a basis for alleged consumer fraud class actions. Written agreements with appropriate indemnity provisions should be in place among the various parties in the supply chain. Adequate procedures should also be established—or updated to the extent they already exist—to govern routine software testing, development and review of product claims, and development and review of licensing and other consumer and third-party agreements, and to account for the impact of these new technologies on recalls and complaint or adverse event handling, so as to confine the risk and ultimate scope of liability.

Ultimately, MMAs are revolutionizing the healthcare industry and can provide significant benefits to patients and physicians alike. Companies wishing to get a piece of the action should properly plan and keep the aforementioned legal considerations front of mind for when something inevitably goes awry.

Any opinions expressed in this publication are solely those of the authors.

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