

As seen in the

*New Jersey Law Journal – Product Liability & Toxic Tort Supplement*

December 14, 2015

---

## **Uncharted Territory: Mobile Medical Apps and Product Liability Collide**

---

**By: Beth S. Rose, Esq.**

What types of applications do you have on your smartphone? Besides the usual—Facebook, Google and Instagram, chances are that you have a health-related app as well. Think Fitbit (counting steps per day), MyFitnessPal (tracking calories and exercise) or Hello Heart (monitoring blood pressure). Perhaps you know someone with diabetes who uses an app to remotely monitor glucose data. We routinely obtain these apps “free” or at minimal cost from the iTunes App Store.

News flash—the Food and Drug Administration (FDA) considers some of these apps to be medical devices subject to agency regulation and oversight. Indeed, earlier this year, the FDA published its final guidance document which explains when it considers mobile apps to be mobile medical applications (MMA) and thus, medical devices subject to regulation. This article examines the FDA’s current approach to MMAs and explores the potential implications for product liability litigation if they malfunction.

---

### **Overview of FDA Guidance**

---

On Feb. 9, 2015, the agency issued Mobile Medical Applications: Guidance for Food and Drug Administration Staff (the “Guidance”). At the outset,

the FDA acknowledged the nuances between a mobile app and a MMA. It defined a mobile app as a “software application that can be executed or run on a mobile platform, i.e., handheld commercial off-the-shelf computing platform (with or without wireless connectivity) or a Web-based software application that is tailored to a mobile platform but is executed on a server.” The FDA then defined an MMA as a mobile app that meets the definition of device in section 201(h) of the Federal Food Drug and Cosmetic Act and is either intended: “to be used as an accessory to a regulated medical device; or to transform a mobile platform into a regulated device.” Guidance at 7. Under the act, a medical device is an “instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar related article including any component, part or accessory,” “that is ... intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease in man.” Id. at 7, n 4. The FDA’s position is that the intended use of the mobile app determines whether it meets the definition of a medical device. Intended use is shown through labeling claims, advertising materials, and written statements by manufacturers or their

representatives. Establishing intended use depends on the function of the device, not the platform on which it is run. Id. at 8.

The focus of the FDA’s oversight is only those mobile apps that qualify as MMAs and “whose functionality could pose a risk to a patient’s safety if the mobile app were to not function as intended.” Id. at 13. Included in this category are mobile apps that are connected to one or more medical devices and are therefore considered to be an accessory (MMA controlled delivery of insulin through an infusion pump); mobile apps that transform the mobile platform into a regulated medical device (electronic stethoscope); and mobile apps which become regulated medical device software by performing patient-specific analysis, diagnosis or treatment (calculation or creation of dosage plan for radiation therapy). Id. at 13-15.

By contrast, there are mobile apps which may meet the definition of medical device but pose low risk to patients. For this category of mobile apps, the FDA will exercise its enforcement discretion only, meaning the FDA does not intend to enforce the requirements of the act. Id. at 15. Examples in this category include mobile apps that provide: (1) supplemental clinical care by coaching

or prompting patients to help manage their health; (2) tools to organize and track health information; (3) access to information related to a patient's health conditions; (4) tools to help patients document, show or communicate potential medical conditions; and (5) perform simple calculations routinely used in clinical practices. *Id.* at 15-18.

Finally, there are numerous mobile apps that the FDA does not consider to meet the definition of a medical device, and therefore will not regulate them. *Id.* at 12. Examples include mobile apps that are intended: (1) to provide access to medical texts or other reference material (medical dictionaries or the PDR); (2) for health-care providers to use as educational tools or medical training (surgical training videos); (3) for general patient education and to facilitate patient access to commonly used reference information (tutorials on how to administer first aid or CPR); (4) to automate general office operations (generate reminders for scheduled medical appointments or blood donation); and (5) as generic aids (magnifying glass not specifically intended for medical purposes). *Id.* at Appendix A.

An MMA subject to FDA regulation must meet all of the requirements associated with the applicable device classification whether it is Class I (general controls), Class II (special controls) or Class III (premarket approval). *Id.* at 13. The FDA also strongly recommends that all mobile apps that may meet the definition of a medical device follow the Quality System regulations, which include good manufacturing practices.

---

### Implications for Product Liability Litigation

---

As MMAs become central to medical

care, litigation is inevitable. A threshold issue in such litigation is likely to be whether or not a mobile app is, in the first instance, an MMA subject to FDA regulation. The FDA's Guidance provides a laundry list of mobile apps that it deems not to be MMAs, but the agency makes clear that its lists are not exhaustive and will evolve over time.

Who has potential exposure when an MMA malfunctions causing or contributing to an injury? Look for both the MMA manufacturer and health-care provider to be named as defendants in what used to be a garden variety medical-malpractice case. See Pam Baker, "Mobile Health Apps, Part 4: Life, Death and Lawsuits (TechNewsWorld, May 5, 2011). The Guidance defines a "mobile medical app manufacturer" as any person or entity who "initiates specifications, designs, labels, or creates a software system or applications for a regulated medical device in whole or from multiple software components." Guidance at 9.

The "author" of the MMA, meaning that person who created the original idea and who initiated and developed the specifications, is considered to be a mobile medical app manufacturer. But a software developer, who merely takes the author's specifications and transforms them into an MMA, is not. *Id.* at 10. The FDA identified the persons/entities it does not consider to be mobile medical app manufacturers, including: (1) manufacturers and distributors of mobile platforms who do not intend (by virtue of labeling and advertising claims) for their platforms to be used for medical device functions; and (2) third parties who solely provide market access to the mobile medical app ("Google play," the iTunes App store and Blackberry App World), but play no role in the manufacture of the MMA. Time will tell whether MMAs

will spawn a new group of potential defendants in product liability litigation.

In the event that an MMA does not perform as intended and allegedly causes personal injury, what legal theories are available to a plaintiff? Are such mobile apps products or services? *The Restatement (Third) of Torts: Product Liability*, Section 19 (1998), specifically excluded "services" from the definition of products. Comment d to the Restatement observed that when courts ultimately reached the question of whether to extend strict liability to computer software, they might "draw an analogy between the treatment of software under the Uniform Commercial Code and under products liability law." Courts have generally found that mass-produced, standardized or generally available software are goods covered by the UCC. *Advent Systems Limited v. Unisys Corp.*, 925 F.2d 670 (3d Cir. 1991). It is therefore reasonable to expect courts to consider MMAs to be products, and as such, subject them to the same theories of tort liability that apply to traditional medical devices (i.e., strict liability, breaches of express warranty, etc.). The gravamen of such claims, however, is likely to be different. Whereas product liability claims involving traditional medical devices often focus on the adequacy of the product warnings, claims involving MMAs are more likely to turn on the performance or design of the app itself.

The defenses available to defendants in MMA-related products liability litigation would be the same as well. In the event the MMA were a PMA-approved device, the defendant could argue that failure to warn and possible other related claims were pre-empted. *Riegel v. Medtronic*, 55 U.S. 312 (2008) (state law failure-to-warn claims against PMA approved device pre-empted by Medical Device Amendments). For the

time being, the availability of the pre-emption defense to MMAs is likely to be limited given that most, if not all, of them are 510(k) devices which are not subject to premarket approval.

Finally, the burden of proving a design defect in an MMA is both technical and substantial. See *In re: Alloderm Litigation*, CaseCode295, *Memorandum of Decision on Defendant's Motions for Partial Summary Judgment as to Plaintiffs' Claims for Design Defect* (N.J. Sup. Ct., Aug. 14, 2015). Establishing proximate cause may be challenging as well, especially in a case with competing and related medical malpractice claims. Consider

the case of *Luther v. IOM Company*, 130 So.3d 817 (La. 2013), where the plaintiff's medical malpractice claim was premised on alleged defects of a remote monitoring software intended to provide monitoring reports to the surgeon during the operation. Instead of reporting a "significant loss of function to critical neurological structures," the software reported functioning within normal limits, depriving the surgeon of the opportunity to take appropriate corrective action. *Id.* at 819. The plaintiff settled with the software manufacturer, but this case presents a good example of possible product liability scenarios yet to come.

---

*Rose is a member of Sills Cummis & Gross in Newark. She is chairperson of the firm's Product Liability Practice Group. The views and opinions expressed in this article are those of the author and do not necessarily reflect those of the firm or its clients.*

---