

The FDA's Regulation of Mobile Technology as Medical Devices

Raakhee Kumar, J.D., LL.M. Candidate (Health Law)
rbkumar@central.uh.edu

In the last few years, a phenomenon has begun to take shape that has the ability to transform medical practice and health care as we know it. Mhealth or “mobile health” is the use of mobile devices such as cell phones, PDAs, and other wireless technology to collect health data and transmit that information between medical personnel, caregivers, and even researchers.¹ Similarly, mHealth devices can assist patients in the detection and management of their health conditions and adherence to treatment protocols. With an estimated 3.3 billion individuals carrying mobile devices, out of an estimated 6.6 billion people in the world, the reach of mHealth is profound.² The development of mHealth has enormous potential to enhance the decision-making process of health professionals as well as patients, promote healthy lifestyles, improve healthcare quality by facilitating access to medical information, and expand access to health care through instantaneous communication in remote and/or underserved locations.

Background

The scope of mHealth benefits varies depending on where and how it is used. In more medically-advanced locations, mHealth can allow medical professionals to access medical data more efficiently and, with some mHealth applications, in real-time.³ Particularly, where daily or hourly monitoring of vital signs or glucose levels is required, medical professionals can access, monitor and direct treatment and transmit prescriptions readily, without having to be in or around the same location as the patient.⁴ In rural areas of the United States, the same benefit of decentralization of care is particularly far-reaching. Where many such areas are afflicted by a dearth of medical providers, mHealth applications can allow the limited number of available medical providers to reach and treat a much more expansive pool of patients. While the benefits of mHealth such as maximizing access and efficiency in health care delivery are clear, it also has the potential, if unregulated, to result in errors in the delivery of care. Therefore, there is a logical role for the U.S. Food and Drug Administration (FDA) to play in the mHealth arena.

This article focuses on the FDA's mandate to regulate medical devices, including mHealth applications on cell phones and associated products. The FDA's existing framework for medical device regulation is ideal for regulation of, and necessary for, vetting of mHealth devices; however, the FDA should be careful not to over-regulate mHealth devices by requiring regulatory approvals for not only the health software or applications, but also the entire mobile technology product. Rather, the FDA should

¹ Vonda J. Sines, *Why Mhealth is Important*, (May 15, 2009), available at http://www.associatedcontent.com/pop_print.shtml?content_type=article&content_type_id=1750096.

² *Id.*

³ *Id.*

⁴ *Id.*

continue to focus on how integral and intertwined the medical function is to the cell phone or PDA's use. In this way, the FDA will regulate the necessary accessory or component of the product and its developer, and not unduly restrict placement of these products in the marketplace by over-regulation of all aspects of a product, which is not properly considered a medical device in its entirety.

FDA Regulation of Medical Devices

The FDA has jurisdiction over medical devices and must approve medical devices before they are made available to the public.⁵ Under section 201(h) of the Federal Food, Drug and Cosmetic Act (the "FDCA"), a medical device is defined to include an instrument, implement, or machine, including a component part or accessory which is used in the diagnosis, cure, prevention or treatment of disease or affects the structure of any body function.⁶ The FDCA's definition of a device is broad and includes a range of items, from simple tongue depressors to pacemakers.⁷ Additionally, accessories to products can be considered medical devices. This aspect of the definition is particularly important when considering mHealth technology because to the extent an application or software is construed as an accessory, it will be regulated; but to the extent it is considered a component of a product where the parent device is the medical device, only the finished product and the manufacturer of the finished product are regulated.⁸

To date, the FDA has approved wireless products as medical devices in two categories.⁹ First, the FDA has approved mHealth medical devices *that have a primary purpose to measure and transmit patient data*.¹⁰ For example, Motorola's HealthPal places wireless chips in patient data-gathering devices. Patient information is transmitted via the devices to a monitoring company, where the data is reviewed, interpreted, acted upon where necessary and stored.¹¹ The HealthPal product serves only one function – to act as a wireless transmitter-receiver of patient data.¹² Second, the FDA has begun to regulate mHealth applications that are used on wireless phones, but do not alter the phone's primary function of mobile telecommunication.¹³ Examples include the software Pill Phone, a mobile medication reminder and LifeWatch's Ambulatory Cardiac Telemetry devices that monitor patient data and, in the event of an abnormality, transmit the data to the patient's cell phone, alerting a LifeWatch monitoring call center.¹⁴ Notably, the FDA has construed these devices as accessories, such that the accessory or software developer, rather than the wireless provider that facilitates the availability of these applications to

⁵ Bradley Merrill Thompson, *FDA May Regulate Certain Mobile Phones, Accessories*, MOBIHEALTHNEWS, July 13, 2009, available at <http://mobihealthnews.com/3177/fda-may-regulate-certain-mobile-phones-accessories/>.

⁶ *Id.*

⁷ Russell Fox, *Understanding mHealth Regulation: FCC and FDA*, MOBIHEALTHNEWS, June 26, 2009, available at <http://mobihealthnews.com/2960/understanding-mhealth-regulation-fcc-and-fda/>.

⁸ See Bradley Merrill Thompson, *supra* note 5.

⁹ *Id.*

¹⁰ *Id.* (emphasis added).

¹¹ *Id.*

¹² *Id.*

¹³ *Id.*

¹⁴ See Bradley Merrill Thompson, *supra* note 5.

subscribers, is required to obtain FDA approval.¹⁵ So far, the FDA has followed a logical analysis, examining the primary function of the product as the key indicator of whether the item, in its entirety, should be regulated as a medical device. This distinction, as seen when comparing the HealthPal from a cell phone with health software available on it, is essential to FDA regulating the proper entity.

However, the potential for over-regulation has come to light in the recently-expressed views of FDA officials considering *mobile phones* that contain and facilitate use of mHealth applications, to be medical devices subject to regulatory approval. This view suggests a shift by FDA officials to now view healthcare software or applications as components to cellular medical devices, rather than medical accessories to a non-regulated product. If the FDA fails to consider whether the product is indeed primarily a medical device in terms of functionality, rather than a cellular device with medical functions, over-regulation can result. The FDA should not make the assumption that any phone with health software falls within its reach. However, a device such as LG Electronics' phone which contains a blood glucose monitor and has the ability to monitor readings and forward results to a medical facility, is a clearer example of a medical device.¹⁶ Relying solely on whether the software placed on a phone or PDA device is a component of the product and how the product is marketed without regard to the actual, primary function of the product can lead to approval delays by the FDA seeking information from the wrong source, i.e., the cell phone manufacturer, rather than the developer. Where the mHealth software is a perk included by the cell phone manufacturer, rather than a fundamental feature of the product, requiring the developer of that software to clear regulatory requirements makes more sense as it will likely streamline the process. Indeed, the developer will better understand the nuances and implications of the software and more effectively answer regulators' questions. Furthermore, it doesn't make much sense to have the FDA approve the entire mobile product if only one aspect of the item has the ability to perform a medical function.

Mobile technology manufacturers seem to be taking a similar position. In an attempt to bypass the burden of regulatory approval, some mobile device manufacturers are taking preemptive measures to contractually place compliance hurdles on mHealth application developers. For example, Apple includes in its iPhone developer agreement a section entitled "Regulatory Compliance for Health, Medical and Related Apps," whereby the developer agrees that it "will not seek any regulatory marketing permissions or make any determinations that may result in any Apple products being deemed regulated or that may impose any obligations or limitations on Apple . . . You represent and warrant that You are in full compliance with any applicable laws, regulations, and policies, including but not limited to all FDA laws, regulations and policies. . ." ¹⁷ This provision must be agreed to by developers of medical apps and peripheral devices such as Lifescan's

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ Brian Dolan, *Apple Puts Onus of FDA Clearance on iPhone Developers*, MOBIHEALTHNEWS, June 9, 2009, <http://mobihealthnews.com/2641/apple-puts-onus-of-fda-clearance-on-iphone-developers>.

glucometer and AirStrip's cardiac monitoring application.¹⁸ Whether such an abdication of regulatory responsibility will suffice in the eyes of the FDA is another matter.

Conclusion

While many mHealth manufacturers and application carriers (e.g., cellular phone companies) may not have previously thought carefully about FDA regulation of their products, it is clear that the FDA is scrutinizing these products. To the extent that the FDA can regulate a developer of mHealth software or applications, rather than or in addition to regulating the manufacturer of the product that embodies it, FDA should follow that route. Developers of mHealth software are likely to understand the purpose, function and safety/effectiveness of the device better than a cell phone manufacturer that merely includes the software in its product. Focusing on the developer then serves to streamline the process instead of creating a middle-man that needs to seek the requested information from the developer. The exception to this rule should be for products which contain a medical function that is so integral and intertwined to the handset that it could not be considered an accessory or component that could be separately regulated. In such instances, the cell phone manufacturer has become so intricately involved in the medical application of the product that regulation of the device in its entirety is warranted.

Health Law Perspectives (April 2010)

Health Law & Policy Institute

University of Houston Law Center

<http://www.law.uh.edu/healthlaw/perspectives/homepage.asp>

The opinions, beliefs and viewpoints expressed by the various Health Law Perspectives authors on this web site do not necessarily reflect the opinions, beliefs, viewpoints, or official policies of the Health Law & Policy Institute and do not constitute legal advice. The Health Law & Policy Institute is part of the University of Houston Law Center. It is guided by an advisory board consisting of leading academicians, health law practitioners, representatives of area institutions, and public officials. A primary mission of the Institute is to provide policy analysis for members of the Texas Legislature and health and human service agencies in state government.

¹⁸ *Id.*