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Analyzing Risk in Mobile Medical Apps

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Technological innovations are changing the way people learn, entertain themselves, and do business as computers, smartphones, and software expand into every aspect of modern life. Health care providers, pharmaceutical manufacturers, and medical device companies also are making great leaps forward in using mobile devices and platforms to change the way patients and doctors communicate, especially with mobile medical applications (MMAs). Government regulators are starting to catch up, and as they do, MMA developers face a complicated regulatory landscape with overlapping agencies eyeing the risks that these new devices could pose to users. While the Food and Drug Administration (FDA) views these apps with a focus on protecting patient safety, the Federal Trade Commission (FTC) has an

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interest in protecting consumer privacy and preserving truth in marketing. The Office of the National Coordinator for Health Information Technology (ONC) and the Federal Communications Commission (FCC) also have roles to play in both coordinating and regulating the MMA field. MMA developers have a broad horizon of opportunity, but need to be prepared to clear the regulatory hurdles along the way.

1. FDA Regulation

Last year, the FDA released an MMA guidance document after more than two years of debate and discussion. Instead of creating hard-and-fast rules for most mobile apps, the FDA took a risk-based approach and announced its intention to focus on apps that pose the most danger to patient safety. With this philosophy, FDA is choosing to use "enforcement discretion" and allow many apps to move forward without direct FDA regulation. Apps that fall into the medical device or "enforcement discretion" categories require a careful risk analysis to ensure that MMA developers do not run into unnecessary regulatory challenges.

A. MMA Guidelines and "Enforcement Discretion"

The FDA defines an MMA as a mobile app that meets the definition of a medical device,[1] which is any app intended to be used to diagnose, cure, mitigate, treat, or prevent disease, or affect the body's structure or function. The FDA also considers an app to be a medical device if it is intended to be used as an accessory to a regulated medical device or to transform a mobile platform into a regulated medical device.[2] To determine the intended use of the device, the FDA looks to the labeling claims, advertising materials, or oral or written statements by the manufacturers.[3]

MMAs are broadly defined, but the agency is primarily focused on apps that pose the greatest risk to patient safety if they do not function the way they are intended. These regulated MMAs will be required to follow the traditional FDA controls on medical devices.[4] However, FDA also released draft guidance in June for Medical Device Data Systems (MDDS) to clarify that the agency would not enforce regulatory controls on MMAs that act as MDDS because of the low risk they pose to patients and the important role they play in advancing digital health by allowing inter-communication of health data between devices.[5]

The FDA's concentration on the functionality of MMAs means that it will use "enforcement discretion" with the bulk of MMAs, which pose a low risk to patients if they do not properly perform their function.[6] It is this gray area of "enforcement discretion" that could leave some MMA developers unsure of the features that may attract FDA attention.

B. Other FDA Guidelines

While traditional medical device manufacturers may be acutely aware of the FDA regulations that govern their products, app developers, especially those who have been developing non-health care apps, may not be as aware of the overlapping layers of FDA guidance that will apply to their MMAs.

Developers of regulated MMAs must register their establishments and provide a list of the devices they market, just as any other traditional medical device manufacturer is required to do.[7] MMAs that are categorized as medical devices must comply with labeling requirements, including conspicuously specifying the name and place of business of the manufacturer.[8] If an MMA developer becomes aware that its app may have malfunctioned or the app may have caused or contributed to an injury or death, FDA requires the developer to report such events.[9] Some recalls or corrections to an app – if they could pose a risk to user health – also must be reported to FDA.[10]

The FDA has signaled that it may rely more on Quality System Regulations (QSRs) for apps that fall into the enforcement discretion category. The FDA Guidance on QSRs is more than ten years old,[11] and updating it could meet the FDA's goal of retaining safety oversight while allowing more industry flexibility to avoid the burdensome and time-consuming premarket approval process.[12] QSRs require developers to demonstrate that they have a process in place to ensure that their app consistently meets safety standards, not only in design, production, and operation, but also in distribution and installation.[13] In a report to Congress earlier this year, FDA said it "intends to adopt a policy that will leverage existing quality system requirements to reduce premarket burden, facilitate continual device improvement, and provide reasonable assurance of the safety and effectiveness of [ ] devices."[14] As part of this move, in August, FDA identified "low-risk" medical devices that it would exempt from premarket review,[15] including some mobile applications, which some analysts believe may encourage "faster innovation and incentivize[ ] development of products that pose little risk to patients, while raising the quality and efficiency of the care patients receive."[16]

Just as the mobile market is moving quickly to adapt to changing technology, FDA also is considering new guidance and regulations that may affect MMAs. For example, the agency has issued a

draft guidance document that provides recommendations for how prescription drug manufacturers can use social media to promote their drugs,[17] an area that may overlap with an MMA developed to support a drug. FDA is still considering guidelines to update its adverse event reporting requirements for medical devices.[18] For MMAs that must go through the FDA premarket approval process, developers should consider the FDA's draft guidance on managing cybersecurity issues and how to present risk information for MMAs that operate as medical devices.[19] These layers of guidance documents may not affect all MMAs entering the market, but the savvy developer will anticipate whether or how they may impact its MMA rollout.

However, there are some pitfalls that could arise from FDA's current policies on MMAs. On the anti-regulatory side, members of the House of Representatives and Senate have introduced two bills to strip FDA of oversight authority over many apps,[20] arguing that any regulatory oversight stifles innovation. On the other side, doctors are warning about the dangers of apps marketed as "recreational" or "for entertainment only" that could harm patients who attempt to substitute these untested apps for legitimate medical devices.[21]

2. FTC Enforcement

Another agency watching the development of MMAs as closely as the FDA is the FTC. As the agency charged with protecting consumers from deceptive and unfair trade practices,[22] the FTC has two major concerns with mobile apps – how they are marketed and how they protect consumer data and privacy. As the value of healthcare data increases, MMA developers and the healthcare industry as a whole should give careful attention to security and marketing claims.[23]

C. Marketing

The FTC considers as advertising "anything a company tells a prospective buyer or user – expressly or by implication – about what a product can do."[24] With such a broad mandate, the FTC has carefully scrutinized MMAs for overpromising or making false claims about their effectiveness. For an MMA developer to make an objective claim about her app, she needs "competent and reliable evidence" to back those statements up.

If FTC finds an MMA label or claim to be false or misleading, the agency has the authority to charge MMA developers with a violation of the Federal Trade Commission Act and seek civil penalties and cease-and-desist orders.[25] In 2011, FTC exercised that power against the makers of "AcneApp," an MMA sold by DermApps, and the maker of "Acne Pwner," both of which purported to treat acne by use of the colored blue and red lights emitting from the screens of smartphones or mobile devices.[26] To avoid more prosecutions of MMA developers, FTC has provided marketing guidelines that encourage developers to "get it right from the start"[27] – not only with marketing, but also with data security and privacy.

D. Data Security/Privacy

A growing target of FTC action is data security and consumer privacy online, and MMAs are a ripe field for potential action by FTC because of the sensitivity of users' personal health information. In May, FTC called for more transparency and accountability in how consumers' data are being used and sold by data brokers, who have a burgeoning business in trading personal information collected online.[28] MMAs that do not provide clear privacy settings and upfront information about how securely they store users' data may soon be under FTC's microscope.

FTC has targeted both mobile app developers and businesses in the health care industry. In February, FTC settled a case against Accretive Health, Inc., a company offering medical billing and revenue management services to hospitals, which had been charged with providing inadequate data security for consumer information.[29] FTC is currently pursuing action against LabMD, alleging that the medical testing laboratory exposed consumers' personal information on a peer-to-peer file-sharing network.[30] FTC also has brought negligence actions against mobile device makers and app developers who failed to install sufficient security controls or who created programs that exposed users' personal information without authorization.[31] Other FTC actions have targeted mobile app developers who failed to disclose to users that their personal data was being collected without consent.[32]

While FTC is not currently drafting new regulations on health care data privacy, the agency is encouraging the development of best practices within the health data industry.[33] With FTC maintaining a close eye on the security and privacy settings of all mobile apps, as well as their labeling and what they promise to deliver, MMA developers must monitor FTC guidelines and actions.

3. ONC Oversight

ONC is a relatively new player in the health care field, but is the leading agency for managing health IT. It is charged with coordinating the federal government's health IT initiatives and advancing the use of electronic health records (EHR) to improve access to medicine.[34] ONC's impact on MMAs has not yet

been felt, but it will likely play a role in working with FDA to develop clearer definitions of regulations governing MMAs and Clinical Decision Support (CDS) software. For MMA developers whose apps are designed to keep track of a patient's health data – for example, medication management – and communicate it to treating physicians for patient-specific analysis, ONC may play a role in helping FDA define what regulations should apply, if any.[35] The overlap between MMAs and CDS remains a huge regulatory question mark for app developers.[36]

Through its Office of Interoperability and Standards, ONC is working to develop technology standards and harmonize security and privacy practices in health IT.[37] A recently announced initiative between FDA, ONC, and FCC is the creation of a Health IT Safety Center, which would promote quality management principles, develop standards, encourage certification, and accreditation of health IT products,[38] which could include some MMAs. Some private organizations could also play a role in standard-development and accreditation.[39] However, until ONC and FDA provide more detail on the operation and governance of the Health IT Safety Center, MMA developers should be aware these initiatives are underway.

4. FCC Office of Engineering and Technology

The FCC is likely the smallest player in the MMA regulatory sphere, but its impact is felt in the regulation and licensing of operational infrastructure for wireless devices. FCC's mHealth initiatives are focused on ensuring that the technology and bandwidth exist to enable MMAs, and other tools that rely on or use health care networks, to operate efficiently and securely.[40] FCC and FDA signed a Memorandum of Understanding in 2010 to coordinate their regulatory efforts, which at FCC are led by the Office of Engineering and Technology (OET).

The OET is in charge of allocating spectrum for use by wireless health devices, including MMAs. One initiative is to dedicate bandwidth to Medical Body Area Networks, groups of wireless sensors that can transmit patient health data to treating physicians.[41] The FCC also has overseen rule changes to permit the development of wireless medical devices to restore function to paralyzed limbs, retinal implants to treat the profoundly blind, and types of body-worn or implanted devices to diagnose and treat heart conditions.[42] For MMA developers working with wireless radio technology, an awareness of FCC rules is crucial.

5. Conclusion

The possibilities are limitless for the development of new technology to diagnose and treat humankind's most intractable diseases and health conditions. Mobile medical applications are a new frontier that government agencies are only just beginning to address. MMA developers can best manage the risk of bringing their products to market by gaining a clear understanding of what agencies are involved with MMAs and how to navigate each agency's regulations and expectations.

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