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FDA ISSUES DRAFT GUIDANCE ON MOBILE MEDICAL APPLICATIONS

On July 21, 2011, the Food and Drug Administration (FDA) issued a draft guidance document addressing how it intends to regulate certain software applications intended for use on mobile platforms—termed "mobile medical apps"—as medical devices.[1] According to the draft guidance, a mobile medical app is a mobile software application that meets the definition of "device" in the Food, Drug, and Cosmetic Act (FDCA) and is either (1) "used as an accessory to a regulated medical device," or (2) "transforms a mobile platform into a regulated medical device."[2] If an app qualifies as a mobile medical app, the regulatory requirements of the FDCA apply to the device. For other apps that qualify as devices under the FDCA, but do not meet the mobile medical app definition, FDA intends to apply enforcement discretion.

While the guidance provides the most comprehensive source of FDA's views on the application of the FDCA to mobile apps, it raises a number of significant questions. The agency requested that comments on the draft guidance be submitted by October 19, 2011.

BACKGROUND

Prior to the draft guidance, few sources were available regarding FDA's views on the application of the FDCA to software and mobile apps. In 1989, FDA issued a draft policy regarding the regulation of computer- or software-based medical devices. In that guidance, FDA stated that if computer programs met the definition of device in the FDCA, they were potentially subject to regulation as a device. However, the agency stated that it would exercise enforcement discretion in several key respects. For example, it indicated that it would not regulate software that merely provided "traditional 'library' functions such as storage, retrieval, and dissemination of medical information—functions traditionally carried out through textbooks and journals."[3] Moreover, the policy also exempted software programs that allowed for "competent human intervention"—where clinical judgment and experience can be used to check and interpret a system's output.[4]

Although never finalized, the 1989 draft policy remained FDA's operative policy position on software for more than a decade. FDA withdrew the policy in 2005,[5] later citing in the draft guidance the exponential growth of computer and software products used as medical devices and the diversification and increasing complexity of products.[6] According to the agency, the diversity of

[1] 76 Fed. Reg. 43689 (July 21, 2011); FDA, Draft Guidance for Industry and FDA Staff, Mobile Medical Applications, *available here* (last visited Aug. 1, 2011) (hereinafter Draft Guidance). FDA noted that the draft guidance is limited to identifying mobile medical apps, and that it intends to address "wireless safety considerations, classification and submission requirements related to clinical decision support software, or the application of quality systems to software" through separate guidance(s). *Id.* at 10.

[2] *Id.* at 7.

[3] Draft FDA Policy for the Regulation of Computer Products 1 (Nov. 13, 1989).

[4] *Id.* at 3.

[5] 70 Fed. Reg. 824, 890 (Jan. 5, 2005).

[6] *See* Draft Guidance at 5.

products that use software made it "impractical to prepare an overarching software policy to address all of the issues related to the regulation of all medical devices containing software."[7] In addition, FDA issued guidance on discrete aspects of software used in medical devices. For example, the agency issued guidance on the content of premarket notifications for software contained in devices and guidance on "off-the-shelf" software used in devices.[8]

In its new draft guidance on mobile medical apps, the agency stated that it issued the draft guidance "to inform manufacturers, distributors, and other entities about how the FDA intends to apply its regulatory authorities to select software applications intended for use on mobile platforms."[9] While not intended to answer all questions related to mobile applications for health care purposes, the draft guidance is intended "to clarify the types of mobile apps to which the FDA intends to apply its authority."[10]

DISCUSSION

I. DISTINGUISHING "MOBILE MEDICAL APPS" FROM OTHER APPS

Under FDA's draft guidance, the critical issue is to determine whether an app meets the description of a "mobile medical app." If so, the requirements of the FDCA apply; if not, the app is either not a medical device, or is a medical device that FDA will not actively regulate under an enforcement discretion policy. First, to qualify as a "mobile medical app" an app must be a "device," defined in Section 201(h) of the FDCA as:

> an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or . . . . intended to affect the structure or any function of the body of man or other animals . . . .[11]

Second, the app must either: (1) be used as an accessory to a regulated medical device; or (2) "transform[] a mobile platform into a regulated medical device."[12] To explain these phrases, the guidance document provides examples of mobile medical apps:

- "Mobile apps that are an extension of one or more medical device(s) by connecting"—physically or not—"to such device(s) for purposes of controlling the device(s)"[13] or "displaying, storing, analyzing, or transmitting patient-specific data";[14]

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[7] *Id.*

[8] Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 2005); Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices (September 1999).

[9] Draft Guidance at 4.

[10] *Id.*

[11] FDCA § 201(h); 21 U.S.C.A. § 321(h). The intended use of an app may be determined according to the "labeling claims, advertising materials, or oral or written statements by manufacturers or their representatives." Draft Guidance at 7-8.

[12] *Id.* at 7.

[13] *Id.* at 13. For example, "apps that provide the ability to control inflation and deflation of a blood pressure cuff through a mobile platform." *Id.* at 14.

- "Mobile apps that transform the mobile platform into a medical device by using attachments, display screens, or sensors or by including functionalities similar to those of currently regulated medical devices";[15] and
- "Mobile apps that allow the user to input patient-specific information and - using formulae or processing algorithms - output a patient-specific result, diagnosis, or treatment recommendation to be used in clinical practice or to assist in making clinical decisions."[16]

The draft guidance also provides in an appendix a non-exhaustive, "exemplary list of functionalities to illustrate types of mobile medical apps."[17] The functionalities are grouped into general categories, which generally mirror the examples discussed above.

In contrast, FDA provides examples of mobile apps that it does not consider to be mobile medical apps. It groups these examples according to five general types:

- Apps that are electronic "copies" of medical textbooks (e.g., the electronic Physician's Desk Reference), teaching aids or reference materials (e.g., flash cards or quizzes used for training purposes or as reference material), or "are solely used to provide clinicians with training or reinforce training previously received";[18]
- Apps that "are solely used to log, record, track, evaluate, or make decisions or suggestions" related to general health and wellness development or maintenance (e.g., "decision tools that generally relate to a healthy lifestyle and wellness," such as dietary tracking logs) ("general health and wellness apps");
- Apps that "only automate general office operations with functionalities that include billing, inventory, appointments, or insurance transactions" (e.g., "apps that enable insurance claims data collection and processing");
- Apps that are "not commercially marketed for a specific medical indication," but are generic aids that assist users (e.g., "apps that use a mobile platform as a magnifying glass . . . but not specifically for medical purposes"); and
- Apps that "perform the functionality of an electronic health record system or personal health record system."[19]

For these apps, FDA will apply enforcement discretion—at least for the time being. The guidance states that FDA will monitor these apps and "determine whether additional or different actions are necessary to protect the public health."[20] At its discretion, a manufacturer may "elect to register and list, and to seek approval or clearance for these mobile apps with the FDA."[21] For all mobile apps manufacturers whose apps may meet the device definition, FDA "strongly recommends" that to

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[14] *Id.* at 13. For example, apps that display "previously stored EEG waveforms." *Id.*

[15] *Id.* at 14. For example, "a mobile app that uses a mobile platform for medical device functions, such as attachment of a transducer to a mobile platform to function as a stethoscope." *Id.*

[16] *Id.* For example, mobile apps that "calculate dosage for a specific medication or radiation treatment." *Id.*

[17] *Id.* at 18.

[18] *Id.* at 10. The draft guidance notes that these apps could show examples for a specific medical specialty, but do not contain patient-specific information. *Id.* The guidance states that "mobile apps that allow the user to input patient-specific information along with reference material to automatically diagnose a disease or condition are considered mobile medical apps." *Id.* at 11.

[19] *Id.*

[20] *Id.* at 12.

[21] *Id.*

prevent patient and user harm, the manufacturer follow the Quality Systems regulations in 21 C.F.R. Part 820 and "initiate prompt corrections to their mobile medical apps, when appropriate."[22]

II. WHO IS RESPONSIBLE FOR COMPLYING WITH THE REQUIREMENTS OF THE FDCA?

As with all devices, the manufacturer of a mobile medical app is responsible for compliance with the FDCA. A "mobile medical app manufacturer" is defined as any person or entity that manufacturers mobile medical apps in accordance with FDA's regulations. Examples of mobile medical device manufacturers include any person or entity that "[c]reates, designs, develops, labels, re-labels, remanufactures, modifies, or creates a software system from multiple components"; "[p]rovides mobile medical app functionality through a 'web service' or 'web support' for use on a mobile platform"; or "[i]nitiates specifications or requirements for mobile medical apps or procures product development/manufacturing services from other individuals or entities . . . for subsequent commercial distribution."[23]

In contrast, entities that exclusively distribute mobile medical apps, but do not engage in manufacturing functions are not included in this definition and thus are not responsible for compliance with the requirements of the FDCA. The draft guidance identifies owners and operators of "android market," "iTunes store," and "BlackBerry App World" as possible examples.[24]

With respect to mobile platform manufacturers—such as manufacturers of smart phones—the draft guidance indicates that whether such a manufacturer will be considered a device manufacturer depends on the intended use of the mobile platform. If the manufacturer commercially markets the platform with a medical device intended use or to be used with a device, it will be considered a device manufacturer. If, however, the manufacturer "solely distributes or markets its platform with no device intended use [it] is considered a component manufacturer and is exempt from quality systems, registration and listing requirements."[25]

III. REGULATORY REQUIREMENTS FOR MOBILE MEDICAL APPS

For those apps that qualify as mobile medical apps, "manufacturers must meet the requirements associated with the applicable device classification."[26] If the app itself falls within a medical device classification, the manufacturer must meet the requirements associated with that class. If the app adds "medical device functionality to a mobile platform," the manufacturer "must meet the classification requirements applicable to that functionality."[27] FDA sets forth four categories that "identify the types of mobile medical apps" and for each, the associated classifications, including the following:[28]

- Mobile medical apps that display, store, or transmit "patient-specific medical device data in its original format."[29] Such apps are Medical Device Data Systems (MDDS) (21 C.F.R. § 880.6310) subject to Class I requirements (general controls).

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[22] *Id.*

[23] *Id.* at 9.

[24] *Id.*

[25] *Id.* at 10 (internal citation omitted).

[26] *Id.* at 13.

[27] *Id.*

[28] *Id.* at 14.

[29] *Id.*

- Mobile medical apps that control "the intended use, function, modes, or energy source of the connected medical device."[30] Such apps are considered accessories and are required to comply with the controls and regulations applicable to the connected device as the Agency considers such apps to extend the device's use and functionality.
- Mobile medical apps that transform the mobile platform into a regulated medical device. Such apps must comply with the requirements of the platform's device classification. For example, a mobile medical app that uses internal or external mobile platform sensors for electronic stethoscope functions makes the platform an electronic stethoscope and is subject to the electronic stethoscope requirements in 21 C.F.R. § 870.1875(b) (Class II (performance standards)). Similarly, a mobile medical app that displays radiological images for diagnosis transforms the mobile platform into a Picture Archiving and Communications System (PACS).[31]
- Mobile medical apps "[c]reating alarms, recommendations or creating new information (data) by analyzing or interpreting medical device data."[32] Such apps, which analyze or interpret data that is electronically collected or manually entered from another medical device, are considered accessories to that device, are generally required to comply with that device's classification. For example, the draft guidance indicates that "software that analyzes blood glucose readings to help manage diabetes has been classified as part of a 'Glucose Test System' under 21 C.F.R. 862.1345."[33] It also provides examples of mobile medical apps with attachments to a mobile platform and mobile medical apps that use a hardware attachment or interface to a monitoring system that FDA has cleared.[34]

The draft guidance notes although FDA "has typically expected" an accessory manufacturer to "meet the requirements associated" with the connected device's classification, "this approach may not be well-suited for mobile medical apps that serve as" a medical device accessory due to "the wide variety of functions" they "can potentially perform."[35] Accordingly, FDA is seeking comment on how it should approach such apps to reasonably assure safety and effectiveness.[36]

Furthermore, the draft guidance indicates that FDA expects mobile medical app distributors to cooperate with mobile medical app manufacturers with respect to corrections and removal actions and that "[m]obile medical app manufacturers are required to make timely reports of corrections and removals made to reduce a health risk or remedy a violation of the [FDCA] that presents a health risk, and to keep records regarding other corrections and removals."[37]

CONCLUSION

As guidance, the draft document does not establish enforceable requirements. It is, however, the most comprehensive and developed source of guidance on mobile medical apps that FDA has provided to date. The draft guidance helps to clarify how FDA intends to regulate the rapidly changing and growing area of mobile apps and specifically mobile medical apps.

The draft guidance, moreover, clarifies several areas for which FDA will exercise enforcement discretion. For example, FDA limited the scope of the definition of mobile medical apps to exclude

[30] *Id.*

[31] 21 C.F.R. § 892.2050.

[32] *Id.* at 15.

[33] *Id.*

[34] *Id.*

[35] *Id* at 13.

[36] *Id.*

[37] *Id.* at 16-17.

health and wellness apps and apps that serve traditional library and reference functions—both of which are likely to present a low potential for risk. In addition, FDA clarified the roles and responsibilities for compliance with FDA regulations, excluding "entities that exclusively distribute mobile medical apps, without engaging in manufacturing functions" as well as mobile platform manufacturers that solely distribute or market their platforms with no device intended use, from the meaning of mobile medical app manufacturer.[38]

However, the draft guidance raises several potential issues and questions. For example, prior to the draft guidance FDA had indicated that it intended to exempt computer products "that are intended to involve competent human intervention before any impact on human health occurs, (e.g., where clinical judgment and experience can be used to check and interpret a system's output)" from certain regulatory requirements.[39] However, the draft guidance does not appear to contain a similar exception. Accordingly, apps that use simple algorithms to look up or automate common medical knowledge and are likely to present a low potential risk, could be subject to regulation by FDA under the principals articulated in the draft guidance. In addition, the draft guidance does not address how currently marketed mobile medical apps, which companies had previously assumed would be subject to enforcement discretion, will be treated. For example, the guidance is silent with respect to whether such apps may stay on the market if their manufacturers commit to submitting a premarket notification or application, if such is required.

The draft guidance is also ambiguous in other important respects. For example, how FDA will regulate a number of decision support mobile apps remains unclear. According to the draft guidance, mobile apps that analyze data from a single medical device will be considered accessories to that device and are "generally required" to comply with the classification of the associated device.[40] For mobile apps that analyze data from more than one device, however, the draft guidance notes that the app may present a greater or lesser risk than the associated devices.[41] FDA states that it will address in a separate document how these devices will be regulated and recommends that manufacturers of such mobile medical apps to contact the agency to determine the regulatory classification of their mobile app. FDA also requested comment on this issue.

Finally, the agency provides little guidance to companies that may need additional clarification regarding specific apps. The draft guidance states that "FDA encourages manufacturers of such mobile medical apps to contact the Agency to determine the classification of their mobile app,"[42] but provides no mechanisms on how manufacturers may obtain the agency's input in a timely manner. The agency's typical tools for obtaining such guidance—such as pre-IDE meetings and requests for classification under Section 513(g) of the FDCA—may be impractical tools for the rapidly evolving app industry.

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[38] *See* Draft Guidance at 8-10.

[39] *See* Draft FDA Policy for the Regulation of Computer Products (Nov. 13, 1989) (withdrawn). In a document issued in connection with a public workshop held by FDA in 1996, FDA expressed concern about over-reliance on the "competent human intervention" criteria, calling this "one of the most frequently misunderstood aspects of the 1989 draft policy." *See* Food And Drug Administration & National Library of Medicine, Software Policy Workshop (September 3 and 4, 1996).

[40] Draft Guidance at 15.

[41] To illustrate, the draft guidance notes that "analysis of class I device information along with other demographic information can result in an interpretation of a highly acute patient condition, which presents a greater risk than the connected class I device" while "an analysis or interpretation of data from class II or class III devices can lead to a simple informational result with . . . a level of risk more characteristic of a class I device." *Id.*

[42] *Id.*

In the Federal Register notice announcing the availability of the draft guidance, FDA notes that it welcomes comments on all aspects of the draft guidance as well as a number of specific issues (as noted in the above discussion). If you are interested in commenting on the draft guidance or discussing its application, please feel free to contact any of the attorneys listed below.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our food & drug practice group:

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