FDA Regulation of Mobile Medical Apps

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Introduction
The past decade has witnessed rapid advancement in telecommunication and computer technologies. The smartphone is one result of that technological development and has been adopted by hundreds of millions of people worldwide. Innovators in the medical device industry quickly recognized the potential to use smartphones to expand the capabilities of healthcare professionals via mobile medical applications (“apps”) resident on these devices. These apps raise unique challenges for regulation by the Food and Drug Administration (FDA).

FDA responded to the industry’s growing interest in commercializing mobile medical apps in a July 19, 2011 news release introducing the Agency’s Draft Guidance for Industry and Food and Drug Administration Staff - Mobile Medical Applications. The news release read, in part, as follows:

The U.S. Food and Drug Administration today announced it is seeking input on its proposed oversight approach for certain mobile applications specific to medicine or health care called mobile medical applications (“apps”) that are designed for use on smartphones and other mobile computing devices.

The agency’s draft guidance defines a small subset of mobile medical apps that impact or may impact the performance or functionality of currently regulated medical devices. This subset includes mobile medical apps that:

a. are used as an accessory to medical devices already regulated by FDA (for example, an application that allows a health care professional to make a specific diagnosis by viewing a medical image from a picture archiving and communication system [PACS] on a smartphone or a mobile tablet); or

b. transform a mobile communications device into a regulated medical device by using attachments, sensors, or other devices (for example, an application that turns a smartphone into an ECG machine to detect abnormal heart rhythms or determine if a patient is experiencing a heart attack).

Review of FDA’s Draft Guidance on Mobile Medical Apps

Definition of a Medical Device

Section III of the draft guidance is devoted to definitions. The most challenging definition discusses what makes a mobile medical app a medical device subject to FDA regulation. As the draft guidance explains:
The intended use of a mobile app determines whether it meets the definition of a “device.” As stated in 21 CFR 801.4,5 intended use may be shown by labeling claims, advertising materials, or oral or written statements by manufacturers or their representatives. When the intended use of a mobile app is for the diagnosis of disease or other conditions, or the cure, mitigation, treatment, or prevention of disease, or is intended to affect the structure or any function of the body of man, the mobile app is a device.

To illustrate the issue, consider an app that measures heart rate (sensed by a chest strap) and can both display the data on the smartphone and transmit the data to a remote computer server. Let us assume the app shows the following statement on the smartphone display whenever the app is used:

This app is intended to monitor heart rate for use as a health and fitness tool.

On the basis of this information, the app is not a medical device. Heart rate monitoring is a common tool for fitness training and the intended use statement clearly makes no medical claims.

But if the company provides sales and marketing literature that suggests the heart rate information can be sent to a physician or other healthcare professional, FDA can determine that the app is now a medical device.

Now consider a similar app, one which can display and transmit electrocardiographic (ECG) tracings and provide alarms when arrhythmia is detected. Let us assume the app displays the following statement when turned on:

This app is for monitoring heart activity for use as a health and fitness tool and is not for medical use.

FDA will consider the app to be a medical device in spite of the above statement, since arrhythmia detection has well-known medical utility, is not commonly used for health and fitness, and requires the skills of a medical professional for correct interpretation. A company can sometimes avoid regulation as a medical device by disavowing medical use, but when it is clear that the app serves as a medical device, such disavowals are ineffective.
Section V of the draft guidance details which apps FDA will regulate. FDA discusses its plans to regulate four categories of mobile medical apps as summarized below.

1. **Displaying, storing or transmitting patient-specific medical device data in its original format**

These mobile medical apps constitute Medical Device Data Systems (MDDSs) as per 21 CFR 880.6310. They are subject to Class I general controls (e.g., design control, establishment registration, device listing, adverse event reporting, and corrections and removals) and do not require a premarket notification [510(k)] for commercialization. Details on the definition of MDDSs can be found at [FDA’s website](http://www.fda.gov) and associated links.

Note that FDA stipulates that:

An MDDS does not modify, interpret, or add value to the data or the display of the data.

Accordingly, even minor embellishments (such as converted data from table form to chart form) can exceed the limitations of an MDDS and trigger a Class II designation and require a 510(k) submission.

2. **Controlling the intended use, function, modes, or energy source of the connected medical device**

Such apps are considered an accessory to the connected device and must comply with the controls applicable to that connected device. For example, an app that controls the inflation of a blood-pressure cuff would be considered such an accessory.

3. **Transforming or making the mobile platform into a regulated medical device**

As described by FDA:

Mobile medical devices that use attachments, display screens, sensors, or other such similar components to transform a mobile platform into a regulated medical device are required to comply with the device classification associated with the transformed platform. For example, a mobile medical app that uses sensors (internal or external) on a mobile platform for electronic stethoscope functions is considered to convert the mobile platform into an electronic stethoscope; manufacturers of such a mobile medical app are required to follow the requirements of 21 CFR 870.1875(b) (Electronic Stethoscope).
4. Creating alarms, recommendations, or creating new information (data) by analyzing or interpreting medical device data

These kinds of mobile medical apps are considered an accessory to the medical device that supplies the data and typically must comply with the requirements of that device. For example, software that analyzes blood glucose readings has been classified as an accessory to “Glucose Test System” under 21 CFR 862.1345.

**Appendices** of the draft guidance provide additional useful information. Appendix A of the draft guidance provides many examples to illustrate the categories. Appendix B lists device classifications that are especially relevant to mobile medical apps. Appendix C gives a quick overview of FDA regulations.

**Discussion**

FDA’s draft guidance provides much useful information for companies developing mobile medical apps. Having said this, the industry needs to keep in mind the caveat included in the black box under the title of the draft guidance:

>This draft guidance when finalized will represent the Food and Drug Administration’s (FDA’s) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public.

Whether in draft or final form, an FDA guidance document can only point you in the right direction. FDA cannot anticipate the nature of every future mobile medical app and small details in a product’s design and/or intended use can have a dramatic effect on how the agency decides to regulate that particular device.
In addition, FDA’s own understanding of how best to regulate mobile medical apps will grow and evolve over time, as has the agency’s approach to the regulation of countless older technologies. The pre-submission (formerly “pre-IDE”) process is one means of obtaining a better understanding of FDA’s expectations for your specific mobile medical app.

At the time of drafting this white paper (July 2013), the July 2011 draft guidance is still in place. It is expected FDA will eventually issue an updated draft guidance, or a final guidance, which will then replace the 2011 draft document. Before a final guidance is published, industry can influence FDA’s regulatory approach by direct interaction with the agency, by participation in trade groups, or by working with Congressional members. FDA has invited interested parties to send their comments and will give thoughtful consideration to such input.

Resources

July 2011 FDA draft guidance on mobile medical apps:
http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm263280.htm

FDA “It Has Come to Our Attention” letter to app developer Biosense Technologies (uChek Urine Analyzer) requesting FDA clearance of the analyzer app:
http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/ucm353513.htm (5/21/13)
Some industry responses:

http://www.mddionline.com/blog/devicetalk/wanted-fda-app-enforcement
(3/13/13)

(5/25/13)

(5/29/13)

(5/31/13)

http://www.fdanews.com/qmn/newsletter/article?issueId=16857&articleId=155944
(5/31/13)

http://www.mondaq.com/unitedstates/x/244126/food+drugs+law/FDA+Letter+To+Mobile+App+Developer+Signals+Regulatory+Scheme
(6/10/13)
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Ted Gorski, NAMSA Founder

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