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SYMPOSIUM

Food and Drug Administration Regulation of Diabetes-Related mHealth Technologies

M. Jason Brooke, J.D., M.S.E., B.S.,[1] and Bradley Merrill Thompson, J.D., M.B.A., B.A.[2]

Abstract

mHealth smartphone applications (apps) offer great promise for managing people with diabetes, as well as those with prediabetes. But to realize that potential, industry needs to get clarity from the U.S. Food and Drug Administration (FDA) regarding the scope of its regulatory oversight. Certain smartphone apps, when properly understood, simply help people live healthier lives, assisting with dietary choices, monitoring exercise, and recording other factors important to overall health. The manufacturers of such apps, in an effort to promote their products but also to educate customers, might wish to explain how using the app can help reduce the risk of developing diabetes. Right now, though, the mere mention of the disease "diabetes" would cause the app to be regulated by the FDA. Such regulation, we submit, discourages the kind of education and motivational messages that our country needs to stem the tide of this disease. Further, should the app simply receive data from a blood glucose meter and graph that data for easier comprehension by the patient, the app would become a class II medical device that requires FDA clearance. Again, we submit that such simple software functionality should not be so discouraged. In this article, we identify the issues that we believe need to be clarified by the FDA in order to unleash the potential of mHealth technology in the diabetes space.

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Introduction

Diabetes mellitus is a chronic disease that afflicts an estimated 25.8 million people in the United States—approximately 8.3% of the population.[1] Among other significant clinical complications, the disease ranks as the seventh leading cause of death.[1] The vast majority of diabetes cases are preventable, yet the size of the diabetes population continues to grow. The annual cases of diagnosed diabetes from 1990 to 2010 almost tripled, primarily because of increases in obesity, decreases in physical activity, and the aging of the population.[2] The Centers for Disease Control and Prevention projects that, by 2050, one in three Americans will suffer from diabetes.[3]

Given the dramatic clinical need for more tools to manage this epidemic, medical device manufacturers have sought for decades to design ways to prevent, control, and treat diabetes. As a result, many people with diabetes currently manage their disease through the use of glucometers, continuous glucose monitors, and insulin pumps.

Author Affiliations: [1]Vasoptic Medical Inc., Columbia, Maryland; and [2]Epstein Becker Green, P.C., Washington DC

Abbreviations: (app) application, (CDS) clinical decision support, (FDA) Food and Drug Administration, (MDDS) medical device data system

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Corresponding Author: M. Jason Brooke, M.S.E., J.D., Vasoptic Medical Inc., 9250 Bendix Rd. N., Suite 510, Columbia, MD 21045; email address *Jason.Brooke@VasopticMedical.com*

The initiative to develop a national electronic health record system[4] and the rapid proliferation of mobile technology[5] have revitalized the development of tools to address many of the complications associated with various chronic diseases, particularly diabetes and prediabetes. At their core, these mobile health or "mHealth" tools involve a mobile platform (e.g., a smartphone or tablet) and a software application (app) that allows the patient to perform some aspect of their disease management. In some cases, these mHealth solutions include additional hardware (e.g., a glucometer) and software (e.g., Web-based decision support algorithms).

mHealth solutions for diabetes can vary widely in functionality and complexity. For example, a simple mHealth tool might send daily short message service text messages to remind the user to exercise and eat healthy to reduce the risk of diabetes complications. A more advanced solution might involve the use of a smartphone app to record food intake, exercise activity, daily weight measurements, and periodic blood glucose readings, all of which are stored in an electronic health record for review by the patient, a family member, or a physician. An even more complex system may involve the automatic control of an implantable insulin pump to titrate infusion in real time. These and other examples of mHealth technologies play a vital role in the effort to overcome diabetes and the conditions that lead to the chronic disease.

As important as it is to develop technological solutions for clinical problems, it is equally important to ensure the safety and effectiveness of those technologies. The Food and Drug Administration (FDA) has long been charged with regulating medical devices, including those for use in diabetes management. The question for mHealth developers, however, is whether and to what extent the FDA regulates these novel solutions. This article describes the existing approach to regulation of medical devices for diabetes care and summarizes how this approach impacts diabetes-related mHealth technologies.

Medical Device Definition

In 1976, the U.S. Congress enacted the Federal Food, Drug, and Cosmetic Act, authorizing the FDA to regulate medical devices.[6] The statute defines a device as, among other things, any "instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory" that is "intended for use in the diagnosis … treatment, or prevention of disease" or medical conditions.[7] Hence, a medical device is characterized by two basic elements: (1) a product or accessory that is (2) intended for use in the diagnosis, treatment, or prevention of a disease or medical condition.

The emphasis on instruments and apparatus is to distinguish a medical device from a service. The FDA regulates things put in commerce and not, for example, the practice of medicine. That said, words like "contrivance" are so broad that they have been deemed to include such things as software. Whether a product meets the "intended use" requirement is typically based on an evaluation of what the manufacturer says about the product (e.g., in marketing materials or by sales representatives) and how the manufacturer designs the product. The FDA may imply an intended use by the product design or the marketing practices of the manufacturer, including the types of customers that the manufacturer targets.

Products that might not on their own be intended for a medical use might nonetheless become a regulated medical device by virtue of the fact that the manufacturer of the product intends for it to connect to, or be used in conjunction with, a regulated medical device. These products are called *accessories* and are typically regulated in the same way as the medical device to which it connects, unless the product fits squarely within a separate classification regulation of its own. In the mHealth context, what constitutes an accessory becomes particularly important because widespread use of interoperable technologies and movement of health information creates a complex web of "accessory" relationships that turns the FDA's historical regulatory approach on its head.

Risk-Based Regulation of Medical Devices

Based on this general framework, the FDA takes an expansive view of its legal authority and mission to protect public health. To achieve this mission, the agency regulates medical devices based on the risk associated with a device.

To break this scheme down further, the FDA designates devices as either class I (lowest risk), class II (moderate risk), or class III (highest risk), applying increased levels of regulatory oversight for devices with increased levels of risk.

For approximately 1700 generic product types, the FDA has established "classification regulations" that define the level of risk associated (i.e., class I, II, or III). For example, the FDA has classified glucometers[8] and infusion pumps[9] as class II devices. New and novel devices that do not fit squarely within a classification regulation are automatically placed in class III, as are devices used for life-sustaining purposes (e.g., artificial pancreas device systems). The agency has issued a number of guidance documents that describe how specific types of devices are regulated.[10]

The Developing Regulatory Framework for mHealth Technologies

The FDA has begun developing a regulatory approach specifically for mHealth technologies based on the existing general framework for medical devices. In February 2011, the FDA issued a regulation for what it called "medical device data system" (MDDS) devices.[11] These devices include any hardware or software products that are intended to electronically transfer, store, convert (in accordance with preset specifications), or display medical device data "without controlling or altering the function or parameters of any connected medical device."[11] In other words, a MDDS device is a product through which medical device data are passively transferred or communicated.[11] These devices do not modify, interpret, or add value to the data or the display of the data.[11]

Importantly, MDDS devices are not treated as accessories to the devices to which they connect. (The FDA defines medical device data as any electronic data that are available directly from a medical device or that were obtained originally from a medical device. Data that are manually entered into a medical device are not medical device data unless the manually entered data are subsequently transmitted from a medical device as electronic data.)[11] Equally importantly, MDDS devices may not be intended for use in *active patient monitoring* (see **Figure 1**).[11] For example, a software app that displays blood glucose measurements collected by a glucometer (i.e., a class II device) could be regulated as a class I MDDS device if the app does not display the measurements for immediate clinical action. However, if the manufacturer intends the app to be used, for example, in a critical care setting, the FDA would regulate the app as a class II accessory to the glucometer.

The FDA describes a device as involving *active patient monitoring* if it meets any of the following three criteria:

- Is intended to be relied upon in deciding to take immediate clinical action;
- Involves detection, measurement, or recording of patient data and other functions of a patient monitoring device; or
- Transmits, stores, converts, or displays medical device data that are intended to be relied upon in deciding to take immediate clinical action or that are to be used for continuous monitoring by a health care professional, user, or the patient.

Figure 1. Characteristics of active patient monitoring.[11]

In July 2011, the FDA published draft guidance on the regulation of mobile medical apps,[12,13] which described its current thinking on the regulation of software that meets the definition of a medical device and is designed for use on a mobile platform. A mobile app may be subject to regulation if it is intended (1) for use as an accessory to a medical device or (2) to transform a mobile platform into a regulated medical device. Mobile apps intended for general health and wellness purposes are excluded from FDA regulation.[12] For example, a smartphone app designed to allow a physician to perform a remote assessment of a patient with diabetes might be regulated as a mobile medical app if it connects to a medical device (e.g., an infusion pump) or uses the smartphone's built-in camera for diagnostic or treatment purposes (e.g., for viewing diabetic ulcers).

	FDA Regulated	Uncertain Regulatory Status	Non-FDA Regulated
Exercise	To monitor exercise activity for treatment of obesity.	To allow a physician to review exercise activity.	To monitor exercise activity to improve general health.
Diet	To alter dietary habits for purposes of managing glucose levels in a diabetes patient.	To promote weight loss through diet control for individuals with chronic disease.	To record calorie consumption for a healthy individual.
Other	To manage insulin levels through continuous monitoring of blood glucose.	To allow a physician to monitor diet and exercise activity of a patient.	To allow a diabetes patient to manually log daily blood glucose measurements.

Figure 2. Regulatory status of example intended use claims for diabetes-related devices.

In the mobile medical apps draft guidance, the FDA also expressed its view that any mobile app that is intended to produce a patient-specific result for diagnosis or treatment purposes is also a medical device. So in the previous example, if the smartphone app incorporates an algorithm that analyzes the patient's diabetic ulcers to assess disease progression or to recommend a treatment plan, the FDA would consider the app to be a medical device. In fact, the agency has expressed specific concern about these types of apps—so-called clinical decision support (CDS) software—because, although they may seem innocuous, clinicians could become reliant on them to the potential detriment of their patients.

In September 2011, the agency presented an unofficial definition of CDS software, which includes any software—whether designed as a mobile app, Web-based service, or desktop app—that uses an individual's information from various sources (electronically or manually entered) and converts this information into new information that is intended to support a clinical decision.[14] The FDA gave examples of CDS functionality, including look-up databases, comparison algorithms, and simple calculators based on known formulas. This expansive definition suggests that the FDA may regulate *any* software that interprets *any* information from virtually *any* source if the information or the result of the interpretation is intended for use in a clinician's decision-making process. In short, software that produces any "actionable information" may be regulated. To what extent the FDA actually applies this broad view remains to be seen but will certainly impact the use of mHealth technologies in the diagnosis, treatment, and prevention of diabetes.

Regulation of Diabetes-Related Technologies

The diversity of diabetes-related technologies currently under development and on the market is not surprising, given the significance of the clinical need. The FDA currently regulates many of these technologies, including glucometers, continuous glucose monitors, infusion pumps, and artificial pancreas devices. Indeed, the agency has even cleared a number of mHealth products used for diabetes management, many of which involve the use of mobile apps that connect to a glucometer for daily management purposes.[15,16,17] Whether and to what extent those other technologies are regulated is currently the subject of much discussion.

Recall that the determining factor for regulatory oversight is the manufacturer's intended use for a given product. Intended use in the mHealth context, however, is not often as clearly defined as with traditional medical devices.

For example, many devices are intended to affect the precursors to diabetes (e.g., diet and exercise). The FDA does not regulate products that are intended for general health and wellness.[12] Therefore, the regulatory status of these types of devices will depend on the language employed to promote their use. In some cases, the intended use may be ambiguous, such that the product does not clearly meet the definition of a medical device (see **Figure 2**). Developers of these types of technologies would be best served by enhanced guidance from the agency that further defines the types of claims that may be made without crossing into the regulated territory.

Even in cases where the intended use puts the product clearly within FDA regulatory authority, there are scenarios where the agency may not actively enforce the regulations—particularly where the risk is sufficiently low to be outweighed by the benefit of the product's use. For example, the FDA has suggested that the following types of mobile apps will not likely be actively regulated, despite the fact that they might technically meet the definition of a medical device:

- Educational tools (e.g., apps that provide a list of questions to ask physicians);
- Simple, common calculators (e.g., for tabulating an Apgar score);
- Body mass index calculators;
- Drug–drug interaction formulas;
- Diabetes management guides (e.g., nutritional guides or prediabetes risk assessments); and
- Substance abuse behavior guides.[18]

Similarly, the FDA has stated their intention to delay (for an unknown period) the regulation of mobile apps that:

- Automate common knowledge available in the medical literature,
- Allow individuals to self-manage their disease or condition, or
- Automate common clinician's diagnostic and treatment tasks using simple general-purpose tools.[12]

Therefore, a significant number of diabetes-related mHealth technologies may escape FDA oversight, at least in the near term.

Conclusion: A Need for Clarity

Despite the existing guidance from the FDA on its approach to regulation of mHealth products, the agency needs to provide more clarity to developers of diabetes-related technologies whether and to what extent their products are regulated. As noted earlier, added clarity from the FDA is required to better define the types of intended use claims that a manufacturer can make without triggering regulation. It would be a shame to miss out on the clinical benefits that result from the use of low-risk, diabetes-related mHealth products simply because the manufacturer refers, for example, to prediabetes or diabetes.

What's more, the FDA has not specified how it will address accessories in an mHealth system. Would an unregulated personal health record become an accessory if it connects to a patient's glucometer? Even less certain is the FDA's thinking on CDS software. As indicated earlier, the preliminary scope of the CDS approach is extremely broad. To encourage development of an interconnected health care system where medical data can move freely and rapidly throughout the system and where we can take advantage of the opportunities that software presents to enhance patient care, the FDA needs to focus on moderate- to high-risk CDS software, as it appears to be doing with mobile medical apps.

It is commonly understood that continued regulatory uncertainty will hinder—if not paralyze—investment and innovative thinking in mHealth, ultimately hurting, rather than protecting, the public health. Patients with diabetes would be particularly hurt by any delay in the proliferation of mHealth technologies, given the clinical need to attack the epidemic by fundamentally changing daily behaviors.

That is also why it is so important that the FDA clarify the distinction between unregulated mobile apps that simply encourage healthy living versus regulated apps that are used in the treatment or management of diabetes. Modernizing the rules to allow device makers to draw well-understood connections between lifestyle—including exercise and diet—and the management of diabetes as they promote their apps is essential to stemming the tide of this terrible disease. Industry stands ready to help with the education of the American people regarding diabetes prevention and management, with the goal of leading Americans to live healthier lives. We have to figure out a way to reform the regulatory system to encourage public health education without reflexively subjecting all of the associated products to stringent regulatory requirements.

Disclosures:

Epstein Becker and Green, P.C., represents the mHealth Regulatory Coalition and numerous individual manufacturers who have an interest in this topic. Vasoptic Medical Inc. is a medical device manufacturer developing a low-cost mobile health solution for the early detection of diabetic retinopathy at primary care.

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