RETHINKING THE FDA'S REGULATION OF
MOBILE MEDICAL APPS

By Scott D. Danzis and Christopher Pruitt

Smartphones and mobile devices have rapidly become part of everyday life in the United States. It is no surprise, therefore, that such devices have also become part of our health care system. In fact, it could be said that health care in the United States is becoming digitized, as patients and health care professionals turn to mobile applications (or apps, as they are commonly known) for a wide variety of medical uses. Apps can identify pills, perform medical calculations, and screen for diseases, among many other functions. And they are proliferating at a breathtaking pace: according to a recent estimate, there are now 13,000 health

and medical applications available to consumers and an additional 5,000 marketed to medical professionals—a number that grows by 150 percent each year.[1]

Despite the growing importance of mobile apps and other software in health care, the regulatory requirements that pertain to these programs remain unclear—particularly those relating to the authority of the US Food and Drug Administration (FDA) to regulate apps as medical devices. The FDA has asserted for more than 25 years that certain software can be subject to regulation as a medical device, yet the agency has never

articulated a formal and coherent regulatory framework for these products. App developers are merely the latest to face the questions of whether and how their software products will be regulated—critical questions that can mean the difference between very modest compliance expenses at one end of the spectrum, and spending hundreds of thousands of dollars on the premarket approval process at the other end of the spectrum. To solve this problem, the FDA should take short- and long-term steps to clarify and streamline its regulatory policies. These steps should include announcing a clear policy of enforcement discretion for low-risk

apps and beginning the process of classifying other apps into the FDA's risk-based tier system.

The FDA's Historic Policies on Software

Section 201(h) of the federal Food, Drug, and Cosmetic Act (FDCA) defines a device in relevant part 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." Although not expressly identified in the statute, the FDA has long considered software products to meet the definition of a device when they are intended for use in diagnosing and treating diseases and other conditions.

The concept of "intended use" is crucial to the FDA's regulation of devices. Generally speaking, an article—such as software—will be considered a device if its intended use is for a medical purpose. The FDA does not, however, consider an item to be a device when it is intended for general health or wellness purposes, such as treadmills intended for able-bodied users. The FDA generally determines the intended use of a product according to the promotional claims made by the manufacturer or other party

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legally responsible for the labeling of the product.

Since 1976, devices have been subject to FDA regulation in a three-tier system. Class I devices are considered the lowest risk and generally can be marketed without any premarket review. Class II devices represent an intermediate level of risk, and FDA regulations generally require the manufacturer to file a premarket notification (called a "510(k) notification") showing that the device is "substantially equivalent" to another Class II device. Class III devices are the highest-risk devices and generally require premarket approval, a complex and expensive process that typically requires the manufacturer to submit clinical data in a premarket approval application (PMA). Importantly, the law states that any device marketed for the first time after 1976 is *automatically* placed into Class III, unless the FDA has classified the device type into a lower classification, the device type existed before 1976 and is undergoing classification, or the device is "substantially equivalent" to a device in one of these categories. Manufacturers can petition for a Class III device to be classified in Class II or I, but the process can be expensive and time-consuming.

Over the years, the FDA has recognized that software products—especially standalone products—may warrant a more nuanced regulatory approach than traditional medical devices. The FDA first discussed its approach to regulating software in a 1989 draft policy document entitled "FDA Policy for the Regulation of Computer Products 11/13/89 (Draft)." In the draft policy, the FDA stated its intent to not enforce the requirements of the FDCA on "computer products (e.g., 'expert' or 'knowledge-based' systems, artificial intelligence and other types of decision support systems) 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)." The reasoning

underlying the FDA's approach was that such programs posed less risk to patients; physicians would be able to challenge the program's outputs and consider them in conjunction with the physician's clinical experience.

The FDA never codified or formalized this policy. In 2005, the FDA formally withdrew the 1989 draft policy without comment. The FDA later explained that, due to the "history, complexity, and diversity of computer systems and controlling software, it would be impractical to adopt one 'software' or 'computer' policy to address all computer and software medical devices."[2]

The FDA has, however, classified a number of stand-alone medical device software products into Class I and II. For example, it placed laboratory information systems (LIS) into Class I, and picture archiving and communications systems (PACS) into Class II. In 2011, the FDA released a final rule classifying Medical Device Data System (MDDS) software as Class I, 510(k) exempt devices. That rule defined MDDS software as a narrow category of products that transfer, store, convert, or display medical device data without providing analysis, alarms, or active patient monitoring. The FDA also has regulated a number of software programs, including some mobile apps, as "accessories" to traditional medical devices like glucose meters. Under the FDA's "accessory rule," these devices typically are classified and regulated in the same manner as the parent device.

Draft Guidance on Mobile Medical Apps

In July 2011, the FDA released a draft guidance document setting forth a proposal for regulating mobile applications.[3] According to the draft guidance, the FDA planned to regulate only a subset of apps that both meet the definition of a medical device and (1) are used as an accessory to a "regulated medical device" *or* (2) transform a mobile platform into a "regulated medical device." The FDA termed these apps "mobile medical apps." According

to the FDA, this category included apps that connect to and act as an extension of a medical device (e.g., remotely displaying data from a bedside monitor), apps that transform a mobile platform into a traditionally regulated medical device (e.g., an iPhone as a stethoscope), and apps that allow the user to enter patient-specific information and, using formulae or processing algorithms, output a patient-specific result. The draft guidance stated that apps in this last category included apps that perform calculations resulting in an index or score, calculate dosage for a specific medication or radiation treatment, or provide recommendations that aid a clinician in making a diagnosis or selecting a specific treatment for a patient.[4] Examples included apps that automate a Glasgow Coma Scale, pain index, Apgar score, or NIH stroke scale.[5]

The draft guidance met with significant criticism. Stakeholders in the mobile app industry were happy that the FDA would exercise enforcement discretion toward some apps. The draft guidance failed to make clear, however, where that enforcement discretion line existed. One source of confusion was footnote 13, which appeared to discuss mobile apps subject to enforcement discretion (i.e., not subject to device regulatory requirements) but then described those apps as "mobile medical apps," which indicated that the FDA actually would regulate them.

Another significant issue with the draft guidance document was its proposal for the FDA to regulate apps that perform very basic clinical analysis by merely automating simple and well-understood clinical calculations and algorithms. The example of an Apgar scoring app was particularly puzzling, given that an Apgar app would simply add together five variables that could range from 0–2. Requiring an app of this sort to comply with the host of regulatory requirements applicable to medical devices would seem excessive.

The draft guidance also proposed to apply the FDA's "accessory rule"—by which the FDA regulates accessories

to medical devices in the same manner as the parent device—in a rigid and counterproductive manner. Accessories were traditionally regulated in the same manner as the parent device under the theory that a malfunction in the accessory could cause the parent device to malfunction. This conception of risk does not necessarily apply to software, however. An app may interface with a blood pressure cuff, for example, by downloading stored data and charting values, without altering the functions or parameters of the connected device. This would not be a Class I intended use under the MDDS rule, because the charting and analysis would exceed the narrow scope of that rule. As a result, the app likely would be regulated as an accessory to the Class II blood pressure cuff. However, it seems unlikely that the FDA should need to review the safety and efficacy of a simple, low-risk app such as this before it is marketed.[6]

More recently, section 618 of the Food and Drug Administration Safety and Innovation Act (FDASIA) directed the FDA to hold a public meeting with a diverse set of stakeholders and issue a report to Congress setting forth a "risk-based regulatory framework pertaining to health information technology, including mobile medical applications." Section 618 reportedly was a compromise from a provision in an earlier version of the bill that would have prohibited the FDA from finalizing the draft guidance until it issued a report to Congress. Despite the compromise, however, section 618 represents a clear indication that Congress is monitoring the FDA's trajectory.

The Problem for App Developers

The current regulatory framework leaves open two fundamental questions for app developers:

- Is my product subject to regulation?
- If so, what requirements apply to my product?

The draft guidance was an attempt to answer the first of these questions

(at least for mobile apps) but was inadequate in many respects. As mentioned above, the draft guidance offered little clarity about the very large category of apps that allow users to enter patient-specific information and output a patient-specific result.

Aside from a brief discussion of general requirements that apply to devices, the draft guidance did not attempt to answer the second of these questions, leaving open a critical question for developers. Keep in mind that new devices are automatically classified into Class III—subject to the premarket approval process. The draft guidance stated that a number of apps that analyze patient-specific data would be subject to regulation, but the FDA did not provide a classification regulation that would apply to most apps. This means, for example, that an Apgar or pain scale app could be a Class III device, requiring premarket approval or a petition for down-classification. That expense could be prohibitive for many, if not all, innovative app developers.

Short-Term and Long-Term Solutions

The FDA cannot classify the universe of mobile apps and software into its risk-based tiers overnight. The agency faces serious resource constraints, and a variety of procedural obligations slow the pace at which the FDA can act. Nevertheless, the FDA can take several important steps in the short term to help clarify and streamline its regulatory policies.

Most importantly, the FDA should significantly rewrite the draft guidance. Despite the FDA's intentions, the draft guidance has caused more confusion than clarity—especially for devices that analyze patient-specific data. Accordingly, the FDA should issue a new draft guidance that addresses the areas of confusion described above and incorporates many of the agency's historic concepts, such as competent human intervention. In addition, the FDA should state that it will exercise enforcement discretion toward several specific types of low-risk apps and software that

allow the user to enter patient-specific information and, using well-understood, nonproprietary formulae or processing algorithms, output a patient-specific result. These basic analytical apps and software include the following:

- **Basic clinical analysis programs.** Apps and software that merely automate well-understood, nonproprietary clinical algorithms are inherently low risk; physicians already understand how to use the information provided, and familiarity with the calculations and algorithms would allow a physician to second-guess an incorrect result. This "competent human intervention," as termed by the 1989 draft software policy, provides an adequate safeguard to assure that these types of apps will not lead to medical errors. Programs of this sort have existed unregulated in web-based forms for years—including an oncology drug-dosing calculator that formerly resided on the FDA's own website and a number of similar calculators on other federal government websites.[7] There is no reason for the FDA to regulate them now.
- **Basic disease-management analysis programs.** Another low-risk category is apps and other software that consider patient-specific data to help patients manage a disease, in conjunction with professional care and according to well-understood guidelines. This category would include, for example, an app that helps heart disease patients create a diet based on published nutritional guidelines. To meet the criteria for enforcement discretion, such apps should be intended to operate in tandem with professional care and not encourage a patient to self-treat or diagnose a disease. Because these apps pose a low risk to patients and can meaningfully improve public health, they

should be subject to enforcement discretion.
- **Programs that use downloaded medical device data for basic disease management.** The FDA also should consider apps and software to be within the scope of the MDDS rule if they perform charting, trending, and basic disease-management analysis of medical device data from a connected device (e.g., blood pressure cuff or glucose monitor). For example, this would include apps that chart glucose monitor values and identify trends. Again, to meet the criteria for enforcement discretion, such programs should be intended to operate in tandem with professional care.

Longer term, the FDA should consider the following actions:

- The FDA should create an Office of Software, akin to the Office of In Vitro Diagnostics (OIVD).[8] The creation of OIVD helped the FDA grow its expertise regarding in vitro diagnostics; an Office of Software may provide similar benefits, including more consistent enforcement and application of regulatory requirements.
- The FDA should promulgate additional classification regulations that describe generic categories of apps and their regulatory treatment, including clinical decision support apps. Given the wide range of intended uses for apps, the FDA may need to draft these classification regulations to describe general characteristics of types of apps, rather than specific intended uses. For example, the FDA could designate a "disease-risk calculator" as a Class I device, except when intended to be used for certain serious or life-threatening conditions. The FDA took this functional approach to classification with the MDDS rule, which considers all MDDS software to

be Class I, regardless of the type of medical device data the software handles.
- The FDA should develop guidance documents addressing the regulation of clinical decision support apps and software that use proprietary calculations and algorithms to provide analysis of patient-specific data—in other words, programs that move beyond performing the basic clinical or basic disease-management analysis that would be subject to enforcement discretion. Developers of these types of programs lack clarity regarding their likely classification and data expectations for regulatory submissions.
- For software programs subject to 510(k) clearance or PMA approval, the FDA also should clarify how routine updates to software affect the obligation to file a new 510(k) or a PMA supplement. The FDA should explore ways to allow developers to update and patch software without triggering the need for regulatory submissions. For example, the design control requirements of the FDA's Quality System Regulation (QSR) could provide the necessary level of FDA oversight.

A Balanced Regulatory Approach

The rapidly growing universe of mobile apps has challenged the FDA, as the agency struggles to apply its complex regulatory framework to these products. The cornerstone of the FDA's approach should be to maximize the public health benefits of its limited regulatory resources. Attempting to do too much—by declaring broad categories of apps subject to regulation without the resources necessary to issue clear guidelines and consistently enforce regulatory requirements—likely will lead to two results. First, the legitimacy of the FDA's oversight will be called into question, as noncompliant developers simply ignore the agency. Second, innovation will be stifled, as compliant

developers will be hesitant to invest in product development without a clear understanding of the likely regulatory expenses. The FDA therefore should adopt balanced policies that include identifying low-risk apps subject to enforcement discretion and providing clear guidance to the remaining higher-risk apps subject to regulation. ◆

Endnotes

1. Dina ElBoghdady, *Health-Care Apps for Smartphones Pit FDA Against Tech Industry*, Wash. Post, June 22, 2012, *available at* http://www.washingtonpost.com/business/economy/health-care-apps-for-smartphones-pit-fda-against-tech-industry/2012/06/22/gJQAHCcBvV_story_1.html. The statistics quoted in the article were compiled by *MobiHealthNews*, a trade publication for app developers and other members of the mHealth industry.

2. FDA, Medical Devices; Medical Device Data Systems, 76 Fed. Reg. 8637, 8638 (Feb. 15, 2011).

3. FDA, Draft Guidance for Industry and Food and Drug Administration Staff: Mobile Medical Applications (2011), *available at* http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf.

4. *Id.* at 14.

5. *Id.* at 19–20.

6. In a Federal Register notice announcing a public meeting on the draft guidance, the FDA acknowledged that the traditional accessory rule may not be appropriate for mobile apps and requested that stakeholders comment on the issue. 76 Fed. Reg. 50,231, 50,233 (Aug. 12, 2011). As a result, the FDA may already be reexamining this issue.

7. *See, e.g.*, The National Heart, Lung, and Blood Institute, part of the National Institutes of Health (NIH), U.S. Department of Health and Human Services (DHHS), offering a "10 Year Heart Attack Risk Calculator," *available at* http://www.nhlbi.nih.gov/educational/hearttruth/lower-risk/tools.htm#risk (visited Sept. 25, 2012); National Institute of Diabetes and Digestive and Kidney Diseases, NIH, DHHS, offering a "GFR Calculator for Children," *available at* http://nkdep.nih.gov/lab-evaluation/gfr-calculators/children-conventional-unit.shtml; The U.S. Department of Veterans Affairs, linking to a "Model for End-Stage Liver Disease Calculator" offered by the Mayo Clinic, *available at* http://www.hepatitis.va.gov/provider/tools/meld-calculator.asp.

8. The mHealth coalition, which represents mobile app developers, suggested in comments to the FDA that the agency create a division within the Center for Devices and Radiological Health that focuses on mHealth specifically.