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FDA Efforts to Balance Health IT Innovation and Safety

The US FDA looks to adopt a flexible approach to mobile medical app and Health IT regulation that will both foster innovation and protect the public health. By M Elizabeth Bierman of Morgan Lewis & Bockius.

As smartphones and tablets have become more a part of everyday life, their use for health care applications has also become more common. Some have expressed concern that the development and use of health information technology (health IT) may have outpaced the US Food and Drug Administration's (FDA) ability to regulate this product category. There are predictions that 500 million smartphone users worldwide will be using a healthcare application (app) by 2015.

The uses of health IT cross all diagnostic and therapeutic categories. Apps that appear on app store websites include those that help physicians and patients monitor symptoms to help adjust the dosing of medications, the diagnosis of potentially cancerous moles, assess the disease risk of patients with pulmonary arterial hypertension, and enable physicians to remotely monitor labor and delivery patients. In addition, smartphones are being adapted with accessories to perform certain diagnostic functions. For example, through the addition of accessories, a smartphone can be used as a stethoscope, otoscope, diagnostic camera, or blood glucose-testing device.

With these important advances in healthcare—many of which enable lay users to perform some level of self-diagnosis and physicians to diagnose and treat patients remotely—come new safety concerns. The FDA, however, has largely been in catch-up mode over the last several years with respect to regulation of health IT and has not evaluated the majority of the hundreds of health IT-related products that have flooded the market during this time period. As a result, the FDA and other federal agencies are now grappling with how to strike the right balance between promoting innovation and ensuring safety, for both products already on the market and new products in development.

Overview of Past FDA Regulation of Health IT

The term "health IT" can be broadly defined, but for purposes of this article, health IT means software-based products intended for medical uses and under FDA's jurisdiction, including medical device data systems, mobile medical applications and clinical decision support software. While electronic health records (EHRs) also are commonly understood to be a subset of health IT, the FDA has stated that, at present, it does not intend to regulate EHRs and, thus, EHRs are not addressed in this article.

Many of the products that fall within the category of health IT are considered "medical devices" regulated by the FDA. Under the Federal Food, Drug, and Cosmetic Act, a "device is an instrument, apparatus, implement, machine, . . . or other similar or related article, including any component, part, or accessory, which is—(1) recognized in the official National Formulary, or The United States Pharmacopeia . . . (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease . . . , or (3) intended to affect the structure or any function of the body of man," provided that such product does not meet the statutory definition of a "drug." While many health IT products fall within the scope of this statutory definition, FDA regulation in this area has been ambiguous, confusing, or absent.

FDA first sought to regulate standalone software products that met the statutory definition of "device" in 1989 with issuance of its draft "FDA Policy for the Regulation of Software Products." This guidance was withdrawn in 2005, but included principles that are relevant to current discussions on balancing innovation and safety. Specifically, the draft policy outlined a risk-based approach, stating that 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 would be considered medical devices but would not be "actively regulated." The phrase "competent human intervention before any impact on human health occurs" meant that there is time and opportunity for clinical judgment and experience to be used to check and interpret a system's output before such output is used in the diagnosis or treatment of a patient. Products meeting this description would be considered medical devices but would be exempt from FDA regulatory requirements (i.e., registration, listing, premarket review, labeling, good manufacturing practices, and adverse event reporting). These principles were further refined in a software workshop held by the FDA in 1996.

Between 1996 and 2008, the FDA did not initiate any rulemakings or issue any guidance specifically applicable to standalone software or health IT products. During this same time period, the marketplace saw the launch of personal digital assistants, the early smartphones, and the iTunes store, followed shortly by the iPhone and other advanced smartphones. All of these advances provided convenient platforms and a marketplace for mobile medical apps, triggering their rapid growth. This created increased pressure on the FDA to establish a regulatory framework.

Given how far technology had advanced, from 2007 to 2008 the FDA decided to move iteratively, tackling first those systems that were easiest to regulate and the lowest risk to patients. In February 2008, the FDA issued a proposed rule

to classify "medical device data systems" or "MDDS" as Class I devices. This rule was issued in final form three years later in 2011.

MDDS are systems that electronically transfer and store medical data; electronically convert medical data from one form to another in accordance with preset specifications, and electronically display medical device data. Medical device data are any electronic data available directly from a medical device or that were obtained originally from a medical device. An MDDS, therefore, is a device through which medical device data are passively transferred or communicated, but does not interpret or alter such medical device data or create or generate any of its own data—except data related to its own functioning. For example, software that collects output from a ventilator about a patient's CO^2 level and transmits the information to a central patient data repository is an MDDS.

Safety Issues Presented by Health IT

While MDDS present a relatively low risk, other software-based systems meeting the definition of "device" present potentially greater risk. For example, systems that are used to control infusion pumps present a risk of medication overdose, and the interpretation of radiological images on a mobile device could be adversely affected by the smaller screen size. Safety concerns also are presented by some software apps relied upon by physicians in making diagnostic and treatment decisions in acute, critical situations—possibly from a remote site.

In recent years, members of the US Congress began to express concerns about the safety of health IT systems. Senator Grassley sent letters to Kathleen Sebelius, the Secretary of the Department of Health and Human Services, in early 2010 questioning the safe use of health IT and the FDA's role in regulating this technology. In particular, Senator Grassley expressed concern about the "lack of discussion about patient safety concerns" when health IT products function incorrectly or are used incorrectly. In response to these concerns, the Institute of Medicine held a public meeting on Dec.14, 2010 on the topic of patient safety and health IT. These hearings and meetings led to further regulatory activities by the FDA, and legislation requiring a multi-agency initiative to identify a coordinated strategy for regulation of health IT.

FDA's Recent Efforts to Balance Innovation and Safety in the Regulation of Health IT

The Director of FDA's Center for Devices and Radiological Health, Jeffrey Shuren, MD, JD, has described the Agency's approach to regulation of health IT as "smart regulation." Agency officials have described smart regulation as involving (1) a focus on higher patient risk technology and software (2) selective use of regulatory tools appropriate for the technology (3) a scaling back from the traditional risk classification scheme for devices (Class I, II, and III) and (4) relying on a quality systems approach. As examples of this approach, they have cited the MDDS rule, which does not require premarket submissions for this technology; and the draft FDA guidance issued in July 2011 on mobile medical applications.

The draft guidance on mobile medical applications, which is expected to issue in final before Oct. 1, 2013, is intended to address only a small subset of mobile medical applications that meet the statutory definition of "device": "(1) apps that will be used as an accessory to a regulated medical device; and (2) apps that transform a mobile platform into a regulated medical device." Other apps that meet the definition of device that are not covered by the draft guidance will be subject to enforcement discretion. These may include patient self-management apps and simple tracking or trending apps that are not intended to impact treatment. FDA has stated that it intends to monitor the performance of these other apps to assess whether further regulation is necessary to protect the public health.

What's Next for FDA Regulation of Health IT?

When it passed the Food and Drug Administration Safety and Innovation Act in 2012 (FDASIA), Congress included a provision requiring that the FDA, in consultation with ONC and the Federal Communications Commission, prepare a report setting forth a "proposed strategy and recommendations on an appropriate, risk-based regulatory framework pertaining to health information technology, including mobile medical applications, that promotes innovation, protects patient safety, and avoids regulatory duplication." The report is required to be completed by January 2014. Although an FDASIA Workgroup and various subcommittees have been formed and meetings have been held, it is too early at this point to predict what the proposed recommendations will be. Preliminarily, however, the FDASIA Workgroup Regulations Subcommittee has indicated that one objective is not to diminish the FDA's jurisdiction with respect to its sphere of expertise and experience (e.g., premarket review and regulation of medical devices). Accordingly, the Workgroup's recommendations for health IT products could focus on improvements in existing and new regulations that will avoid duplication and ambiguity, improve efficiency, and address gaps in patient safety and innovation needs.

FDA's development of a guidance document on clinical decision support software (CDS) will further signal how the Agency intends to use its existing authority to balance innovation and safety for health IT products. In the *federal register* notice that issued on July 21, 2011 announcing the availability of the draft guidance on mobile medical applications, FDA stated that a separate guidance would address CDS. As of the date of this article, an estimated date for its issuance has not been announced. FDA's notice on the mobile medical applications draft guidance described CDS as "standalone software (mobile or traditional workstation) that analyzes, processes, or interprets medical device data (collected electronically or through manual entry of the device data) for purposes of automatically assessing patient-specific data or for providing support in making clinical decisions." Examples of CDS are software programs that (1) assist in diagnosis of a disease or condition, or assess the status of a disease or condition; (2) direct where to biopsy; and (3) suggest a cancer treatment based on a proprietary algorithm. These products, therefore, present both important benefits as well as significant risks.

Early, informal discussions regarding how to regulate CDS have focused on a risk-based approach, consistent with the "smart regulation" approach described by Dr. Shuren. This approach also is reminiscent of FDA's 1989 draft software policy. For example, the extent of regulatory oversight required for CDS may correspond to the level of risk presented by the software. For low risk CDS, where there is no independent effect on diagnosis or treat-

ment (e.g., an Apgar score calculator that calculates a score at the birth of a baby), FDA could determine to apply a lower level of regulatory oversight than for high-risk CDS, where the information is relied upon for final clinical decisions (e.g., determining radiation therapy, identifying anomalies in medical images). Other factors that might affect the risk calculation include the extent of reliance on CDS and whether there is time and opportunity for "competent human intervention," the degree of acceptance of the methodology in clinical practice, the complexity of the clinical condition, and the ability to easily identify erroneous output (i.e., the transparency of the calculation or algorithm). Applying this approach, FDA could decide, for example, that compliance with device registration/listing and labeling requirements (or possibly enforcement discretion) is appropriate for CDS that is lower on the risk spectrum; compliance with device quality systems and adverse event reporting requirements is appropriate for moderate risk CDS; and premarket review and clearance/approval are necessary for high risk CDS.

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Although FDA has been slow to develop a regulatory framework for health IT, there are indications that the Agency is now attempting to adopt a flexible approach for this product category that will both foster innovation and protect the public health. By taking an iterative approach to regulation of health IT, selectively using the regulatory tools available to it (e.g., guidance documents, existing regulations, and rulemaking), and exercising its enforcement discretion, the FDA has the ability to address any risks that may arise, while allowing innovation to continue.

The forthcoming final guidance on mobile medical apps and draft guidance on CDS will reveal further the extent to which the FDA will adopt a smart regulation approach.