REGULATING IN THE Connected Health World

U.S. regulators have issued guidances to help bring clarity to companies considering mHealth.

Denise Myshko

Regulation, by its nature, hinders some activity, says Napoleon Monroe, managing director, New Directions.

"But regulation is also necessary to ensure product safety and efficacy, and an efficient, functional capital market," he says. "In the longer term, effective, efficient technology applied ethically in the patient's interest will overcome regulatory barriers."

In September 2013, the FDA issued a final guidance for mobile medical apps. This final guidance was long-awaited by developers of mobile medical apps and will provide clarity regarding which mobile apps are the focus of FDA oversight and which are not.

The FDA will apply the same risk-based approach the agency uses to assure safety and effectiveness for other medical devices. The FDA is taking a tailored, risk-based approach that focuses on the small subset of mobile apps that meet the regulatory definition of "device" and that: are intended to be used as an accessory to a regulated medical device, for example, an application that allows a healthcare 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 transform a mobile platform into a regulated medical device, for example, an application that turns a smartphone into an electrocardiography (ECG) machine to detect abnormal heart rhythms or determine if a patient is experiencing a heart attack.

The FDA intends to focus its regulatory oversight on a subset of mobile apps that present a greater risk to patients if they do not work as intended. In some cases, the risks associated with mobile apps are similar to the risks associated with an already-marketed medical device. For example, mobile apps that affect the programming of a drug infusion pump or computed tomography scanner could lead to a drug or radiation overdose.

An inaccurate or malfunctioning mobile medical app that uses a sensor to diagnose skin cancer or to measure critically low blood oxygen levels in chronic lung disease patients, could delay lifesaving diagnosis and treatment.

The FDA has been regulating medical device software for decades and medical device software on mobile platforms for more than 10 years. The agency has reviewed approximately 100 mobile medical apps, including remote blood pressure, heart rhythm, and patient monitors, and smartphone-based ultrasounds, ECG machines, and glucose monitors.

"The FDA's mandate is to ensure both safety and efficacy," Mr. Monroe says. "The agency has to meet this obligation. FDA Commissioner Hamburg and CDRH Director Shuren have been responsive to considering the advantages and realities of mHealth. Enhanced cooperation and continuing dialogue between stakeholders and the FDA are highly beneficial."

Experts also say the recent draft guidance the agency issued on social media will have an impact on connected health. In January, the FDA issued a draft guidance for how drug companies might approach social media in the promotion of their products. The guidance addresses how companies can submit their materials for interactive promotional media, such as blogs, microblogs, social networking sites, online communities, and live podcasts, to the FDA for review.

Any materials posted to a social media site controlled either directly or indirectly must submit materials to FDA's Office of Prescription Drug Promotion (OPDP). The FDA provided examples of influence being editorial control, preview or review privilege, or collaboration with the poster of the information. But if a pharmaceutical company has given a company unrestricted grant money but otherwise contains no interest in posted materials, then those posted materials do not necessarily have to be submitted.

The issue is how much control a company has over the information. That control also extends to its employees when they are acting on behalf of the company, such as a company-directed tweet from an employee's private account.

For example, if an employee or agent of a firm, such as a medical science liaison or paid speaker, for example as a key opinion leader, acting on the firm's behalf, comments on a third-party site about the firm's product, the firm is responsible for the content its employee or agent provides.

Brian Loew, co-founder and CEO of Inspire, says if this guidance becomes final, it could prompt tremendous change for the better, as pharmaceutical companies would be able to be present amidst patient conversations in third-party mHealth environments without the burden of pharmacovigilance.

SHEILA ROCCHIO ▪ *PHT*

"Concerns about privacy regulations shouldn't prevent sponsors from giving useful data to patients."

Matt Balogh, senior VP, director of technology, Ogilvy CommonHealth, part of Ogilvy CommonHealth Worldwide., says as the FDA guidance for Meaningful Use evolves and companies start hitting some of those milestones, there is going to be a shakeout.

"There are a lot of companies coming into this marketplace now, and it's really hard for anybody to say which companies are going to come out on top," he says.

Another key challenge for connected health is privacy. Concerns about privacy regulations shouldn't prevent sponsors from giving useful data to patients, says Sheila Rocchio, VP of marketing and product management at PHT.

"Companies don't have to know who the patient is to offer education and information," she say. "People are going online more and more to manage their disease and determine what treatments are available. And the emergence of patient advocacy groups demonstrates a willingness on the part of patients to forgo some privacy to create communities and to help them partner with their providers to manage their diseases." PV

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