Client Alert

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FDA Letter to Mobile App Developer Signals Regulatory Scheme

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Last week, the U.S. Food and Drug Administration (FDA) sent an enforcement letter to a mobile medical app developer for failing to obtain a 510(k) clearance before marketing the app, which the FDA said appears to be a "device" under section 201(h) of the Federal Food, Drug, and Cosmetic Act (FDCA). The mobile app—the uChek Urine Analyzer developed by Biosense Technologies Private Limited and available through the iTunes App store—allows a user to read urine dipsticks using a camera phone to screen for diabetes and urinary tract infections. The FDA's letter signals the type of oversight the FDA intends to exercise over mobile medical app developers, although the agency has not released final guidance in this murky area.

FDA PREVIOUSLY INDICATED LIGHT REGULATION OF MEDICAL MOBILE APPS

In March, Congress urged the FDA to clarify the regulation of mobile medical apps in three days of hearings before the House Energy and Commerce Committee. The FDA generally relieved concerns raised by the mobile communications industry, which had feared heavy regulation of mobile phones and tablets as medical devices. Christy Foreman, the Director of the Office of Device Evaluation in the Center for Devices and Radiological Health (CDRH) at the FDA, testified before the committee that the FDA intends to limit regulation to a small subset of apps, in accordance with the FDA's July 2011 draft guidance on mobile medical apps.

The FDA proposed a narrowly tailored approach focusing on apps that could threaten patient safety if they do not work as intended. These include apps that either: (1) affect the performance or functionality of a currently regulated medical device or (2) have traditionally been considered medical devices. Consistent with this philosophy, the agency does not intend to regulate mundane apps that help people achieve a healthier lifestyle, such as pedometers or calorie counters. Nor does the agency plan to regulate apps that track medical data but otherwise do not meet the definition of "device" in section 201(h) of the FDCA because they are not intended to diagnose, treat, or cure conditions or diseases.

Specifically, the 2011 draft guidance indicated that the FDA will regulate mobile apps that qualify as medical devices under section 201(h) *and* that are intended to perform one of two functions: (1) serve as an accessory to a regulated medical device—for example, an app that allows doctors to diagnose patients by viewing medical images on a tablet; or (2) transform a mobile platform into a regulated medical device—for example, an app that allows a patient to measure blood glucose with a smartphone. The FDA's recent enforcement letter to Biosense falls squarely in line with this proposed regulatory scheme. As the FDA noted in its letter, the uChek app is intended for use with urinalysis dipsticks that have received 510(k) clearance for "direct visual reading." However, the app allows a mobile phone to analyze the dipsticks and that means "the phone and device as a whole functions as an automated strip reader" that requires new clearance.

FDA DOES NOT INTEND TO REGULATE OTHER MOBILE TECHNOLOGY

In a prepared statement released on the day of her testimony, Foreman laid out the boundaries of the FDA's proposed mobile medical app policy. The statement made clear that the FDA does *not* intend to regulate mobile technology apart from the medical apps themselves. Thus, the FDA will not regulate the sale or general consumer use of smartphones or tablets. Entities that solely distribute mobile medical apps (such as owners and operators of the "iTunes App store" or the "Android market") will not be considered medical device manufacturers. And mobile platform manufacturers will not be deemed medical device manufacturers simply because their platforms support mobile medical apps regulated by the FDA. Based on these statements, smartphone manufacturers and app distributors can put to rest for now any concerns they might have had about FDA oversight regarding health-related mobile apps.

FDA'S STATEMENTS ON MOBILE APP REGULATION EASE UNCERTAINTY IN INDUSTRY

Congress held the recent hearings in response to uncertainty among mobile app developers, which the House Energy and Commerce Committee voiced in a letter to the FDA Commissioner in early March. The letter relayed industry fears of widespread regulation by the FDA and concerns over the lack of final guidance on the regulation of mobile medical apps. At the hearing, the committee also inquired whether the FDA intends for smartphones, tablets, and other devices that display mobile medical apps to be taxed as medical devices under the Patient and Protection and Affordable Care Act (PPACA). Foreman deflected these questions, noting that the IRS, not the FDA, has the authority to impose taxes on medical devices.

Though the mobile medical app market has been growing, Foreman's testimony showed that the industry is still in its infancy. Foreman stated that the FDA receives fewer than 20 submissions per year for mobile medical apps, which amounts to approximately 0.5% of all medical device applications the agency reviews each year. All mobile medical apps cleared thus far have gone through the 510(k) process, which in 2011 and 2012 took an average of 67 days to complete. The agency has not yet deemed any mobile medical apps to be Class III medical devices.

FURTHER GUIDANCE EXPECTED LATER THIS YEAR

Mobile medical app developers should look for a final guidance from the FDA on regulation of mobile medical apps later this year. Though Foreman initially projected that the guidance would be published in "the coming months," when pushed to be more specific she narrowed her projection to the end of the FDA's fiscal year in September. Technological developments in mobile medical apps have far outpaced the FDA's sluggish timing in releasing its final guidance. Congress and mobile app developers will be watching closely to see if the FDA's final guidance brings the clarity and light regulation of mobile medical apps that the agency has proposed. In the meantime, developers whose apps work in tandem with regulated medical devices should pay attention to the FDA's enforcement letter to Biosense and consider whether FDA clearance is appropriate. We will continue to monitor this topic and provide relevant updates.

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