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FDA Shows Deft Touch With 1st Mobile App Enforcement

By **Jeff Overley**

Law360, New York (May 22, 2013, 7:27 PM ET) -- The U.S. Food and Drug Administration's Tuesday move to rein in a developer of iPhone urinalysis software marked a perfectly balanced foray into stronger oversight of the fledgling mobile medical apps industry, experts say, addressing frustration among app makers that already work closely with regulators while taking care not to scare off potential innovators.

Experts had complained for months that India-based Biosense Technologies Pvt. Ltd.'s uChek app, which is being sold on Apple Inc.'s App Store to screen for diabetes and urinary tract infections, was clearly a medical device and had improperly failed to seek the FDA's blessing before going to market. More broadly, the app became a symbol for the FDA's hands-off approach toward mobile medical apps, thousands of which are available for smartphones and tablets.

By releasing a letter informing Biosense that it's expected to file a so-called premarket notification, the FDA likely calmed nerves among app developers that have long sought the agency's endorsement before selling their high-tech wares, said Michele L. Buenafe, an apps specialist at Morgan Lewis & Bockius LLP.

"For those companies that have been very diligent in trying to comply with the appropriate FDA regulatory requirements, it does help to some degree that FDA has issued an enforcement letter," Buenafe said.

At the same time, the FDA chose a notably mild way to conduct that enforcement, issuing an "it-has-come-to-our-attention" letter that experts described as an unusually cordial method of cracking down. In addition to giving Biosense 30 days to respond, the FDA specifically identified a similar device that's already been approved, which would allow the company to seek speedier approval under the 510(k) process.

"The agency is actually being quite gentle with the app developer," said Marc C. Sanchez, an Atlanta-based consultant and attorney on FDA matters. "Most warning letters carry a much harsher tone and shorter windows to reply."

While many observers have been calling for the FDA to get tougher with app companies, the agency has also been under tremendous pressure to treat the youthful industry with kid gloves.

House Republicans earlier this year took the extraordinary step of staging three consecutive days of hearings in which they decried the risks of regulatory overreach. Rep. Marsha Blackburn, R-Tenn., went so far as to float the idea of legislation stripping away the FDA's power to regulate mobile medical apps.

With that in mind, the FDA likely wanted to speak softly in its first enforcement action, delivering a message that compliance is expected without sending software companies into panic mode, said Bradley Merrill Thompson, an FDA specialist at Epstein Becker Green PC who was among the first to sound an alarm over uChek.

"It's accommodating, and I think the philosophy is that they're dealing with a nontraditional medical device company ... and so they're trying to be more educational," he said.

The likely upshot is that the FDA gets the best of all worlds: more safety without appearing to be a bully, and more innovation from companies that want to develop apps but can't compete if rivals are flying under the radar and avoiding costly compliance, according to Thompson

"If I were FDA, that's exactly the balance I'd be trying to strike — not scaring the bejesus out of the little guys, but bringing enough consistency ... that those willing to invest are able to do so," he said.

While the FDA has cleared about 100 mobile apps, experts say the lack of any punishment for those that didn't bother with regulatory approval ran the risk of encouraging scofflaws.

"As an attorney advising clients in this area, it can be difficult sometimes because clients will point to competitors who have not jumped through these same hoops," said Christopher H. Pruitt, an FDA enforcement expert at Covington & Burling LLP. "It's difficult as an attorney to say, 'These are the consequences if you don't comply,' if you can't point to any [examples]."

The FDA doesn't appear to have taken enforcement action before, although the Federal Trade Commission in 2011 ordered a halt to sales of two apps that claimed to fight acne using colored light emitted from smartphones.

The choice of uChek as an initial target makes sense because it had received tremendous publicity, both from news outlets intrigued by the idea of using a phone to analyze urine and in reports about whether the app was inappropriately ducking regulators. During testimony before Congress, Thompson specifically mentioned the Biosense app in criticizing lax enforcement.

In addition, attorneys say the app very likely constitutes a medical device, making it a good bet the FDA won't appear to be policing run-of-the-mill software that poses little risk to human health. In its letter to Biosense, the agency said the dipsticks used by uChek had been cleared only for direct visual reading, whereas the smartphone and app are functioning as an "automated strip reader."

"I don't think FDA wanted to choose a controversial or borderline case to make its first enforcement statement," Pruitt said.

While Tuesday's letter is a step forward, significant questions still surround the FDA's app oversight, mainly because draft guidance issued nearly two years ago has yet to be finalized. The FDA has said it won't be concerned with mundane apps, such as calorie counters, and has also made clear that advanced diagnostic apps will fall under its purview. But there's still a sizable gray area that includes health-and-fitness apps that might be meant to reduce risks of disease, and so uncertainty remains the name of the game for now, according to experts.

“The letter shows that FDA’s enforcement will be case-by-case for now without a great deal of written guidance or categorical rules,” said Jeffrey K. Shapiro of Hyman Phelps & McNamara PC.

As a result, app corporations still have to “think carefully about FDA regulation and whether their particular application is one that might cause FDA to conclude that device requirements should be applied,” he said.

--Editing by Elizabeth Bowen and Lindsay Naylor.