Former FDA director: mHealth shouldn't wait

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By Brian Dolan

In an opinion piece published in the Wall Street Journal this week, US President Barack Obama wrote that the US Food and Drug Administration (FDA) is set for reform: "Tomorrow the FDA will lay out a new effort to improve the process for approving medical devices, to keep patients safer while getting innovative and life-saving products to market faster," President Obama wrote Tuesday.

The next day Dr. Dan Schultz, former Director of the Center for Devices and Radiological Health at the FDA participated in a webinar moderated by Dr. Leslie Saxon, the Executive Director of the University of Southern California's Center for Body Computing. Saxon asked Schultz if mHealth companies should wait to bring products to market while the FDA figures out how best to tackle the new challenges brought about by connected health devices.

"I would not say that people should be sitting and waiting," Schultz said. "I think that obviously there are a lot of good beneficial technology being developed, but what the agency would expect is that companies have a thoughtful process in terms of defining what it is they are and providing a rationale as to whether they are or are not a regulated product… until there is greater clarity, there is an opportunity for companies to do their own self-assessment and document the results of that assessment. Then, should there be changes and more specific regulatory policies then at least they have something to go back to and say that they didn't just go out there willy-nilly and market a product that was a device without going to the [FDA]."

Saxon also asked Schultz about one of the stickiest wickets in FDA regulation: the accessory rule. Is that likely to change for mHealth?

"This is not really necessarily a new question or something that is specific to mHealth," Schultz said. "With accessories the general mantra is that the accessory to a medical device is regulated to the same standard as the device itself. If you have an ECG and it's regulated as a Class II device and you add a wireless component to that ECG, then that too would be regulated as an ECG. The question is, how far do you take that? If there is a program that allows you to view these waveforms on your iPhone or PC or some other electronic device, does that mean those devices are now an accessory? I think that it is unlikely, again depending on the particulars, that the FDA is going to want to get into regulating these general use products as medical devices."

Schultz said device makers will likely have to demonstrate that their device is "compatible" with these other devices like mobile phones, but that the FDA is unlikely to regulate all of them as accessories.

"That's my sense anyway," Schultz said. "There are some things that will be black and white and others that will be more gray."

At least one mobile health company is excited about President Obama's move to nudge the FDA along:

"WellDoc applauds President Obama's executive order, which will help the FDA ensure safety and efficacy, while fulfilling their complete mission of advancing public health. The safe and accelerated approval of new genres of medical devices — especially those which enable more effective and cost-

efficient healthcare — drives our nation's innovation potential and global competitive advantage," WellDoc President Dr. Anand Iyer told InformationWeek in an interview.

For a couple of years now the mobile health industry has pushed the FDA to improve its regulatory processes and provide medical device makers with a better of understanding of how it regulates connected health devices. FDA regulation expert and co-founder of the mHealth Regulatory Coalition Bradley Merrill Thompson penned a number of essays on the topic for MobiHealthNews over the course of the past year (be sure to download the free report on FDA's regulation of mHealth in our Research section if you haven't read it yet. This document is the primer on why mobile health challenges the current FDA regulatory process.)

And if you haven't read our interview with the inventor of iPhone ECG, Dr. David Albert, be sure to do so. He believes the current FDA process is unlikely to change — and it doesn't need to — most of the noise about mHealth regulation is trumped up by "enterprising laywers" in Dr. Albert's estimation.