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Lessons learned from FDA cleared mobile health companies

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"We need to balance our desire for safety with rational risk tolerance and transparency," the West Wireless Health Institute's Chief Medical Officer Dr. Joseph Smith said during his presentation at the Institute's Health Care Innovation day in Washington, DC last week. "And I think — I've not shared this with them — but I think we need to get the FDA out of the business of assuring absolute safety and into one of absolutely assuring transparency around risks and making sure decisions are well-informed as opposed to trying to protect all of us from the rare circumstances of failed technology."

At the event FDA officials confirmed that a draft guidance document focused on how the agency might regulate health apps would likely publish in the coming months. Officials acknowledged that apps included just a small sliver of the activity going on in mobile health, but it is a start. The FDA will seek commentary on the draft document from the industry during a 60 or 90 day period, officials said.

The West Wireless Health Institute gave me the opportunity to moderate a panel of some of those companies that had already navigated the FDA's 510(k) process successfully to secure clearance of mobile health apps and related devices. My panel included commentary from WellDoc Founder/CEO Ryan Sysko, Mobisante CTO David Zar, Airstrip Technologies President/CEO/Co-Founder Dr Cameron Powell and Dr. Jonathan Sackner-Bernstein, Associate Director for Technology and Innovation, CDRH, FDA.

"Our intent was to support both patients and healthcare providers in the management of chronic disease," Sysko said. "As we looked at the regulations as early as 2005 of the software that the FDA had published, it was really clear to us that we were an accessory to a medical device — an accessory to a blood glucose meter… We thought that there were sufficient guidelines from a software perspective to go ahead. Little did we know that it would be a long journey and there were many bumps along the way — many self-inflicted — but we felt that it was absolutely something we would have to do to bring our product to market."

Sysko also said if he could change one part of the process he would have the FDA provide greater clarity around what a successful human factors testing looked like and which types of apps were required to go through such testing.

Mobisante's Zar said that the reason Mobisante didn't wait to submit its product to the FDA was simple: "We're a startup and it was time to market," he said. If his company hadn't, he said others could have beaten them to market.

Airstrip Technologies' Powell said his company had secured five 510(k) clearances over the years: "For our Remote Patient Monitoring platform and Cardiology solution, [the 510(k)] was inherently more difficult" than it was for AirstripOB, he said. "We didn't have the option to wait, we wanted to be first to market again for these products. So we forged ahead, hired really good folks to work for us and made the investment in time, money, sweat and blood."

"I'm sorry you had to pay in both sweat and blood," the FDA's Sackner-Bernstein joked. "We usually just charge fees."

Sackner-Bernstein said that Powell's recognition that the FDA's thinking on mobile health regulation had changed over the years was right on: "I think what is often a misinterpretation of that is that we are becoming inconsistent or changing where the goal line is," he said. "Those representations are unfair because they take a fact that our thinking evolves… and fails to put it on the context that science changes. If [science] is not changing between 2004 and 2011, we may as well hang it up."

Perhaps surprisingly, the panel had fond recollections of the 510(k) experience: "I'm not going to sit here and say that this arduous task that we had to figure out with little guidance from the FDA was detrimental," Powell said. "The guidance was there. It could be better, but it was there. What we went through as a company made us a much better company. It improved our quality systems. The regulatory process and rigor that we had to go through made our software … a lot better … than it would have been if we didn't have to go through it."

As a final question I asked each of the panelists to ballpark the expenses they incurred as a result of their 510(k) experience. The responses demonstrated a difference in opinion as to where costs should be ascribed to the FDA.

"Not only that initial submission but the quality work, ongoing overhead associated with maintaing and following our quality systems," Sysko said, "is without question in the millions of dollars."

Zar admitted that his company was not in full production yet, but to date they have spent "in the low hundreds of thousands of dollars."

"Maybe I'm doing something wrong it wasn't near that expensive for us," Airstrip's Powell said. "I have three full-time people who do the testing and documentation, we have a quality system that we use on a daily basis… fees are not exorbitant. Honestly, I'd be surprised if we spend more than a few hundred thousand dollars on all of our submissions."

Powell said the costs were in the hundreds of thousands for the 510(k) process but the ongoing costs associated with quality assurance might rack up into the millions: "I don't know," Powell said. "I think that's more the costs of running a business and making sure you are doing everything right to deliver your products. I'm not sure how much of that can be directly attributed to the FDA."