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Booming mobile health app market needs more FDA oversight for consumer safety, confidence

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Smart phones and mobile devices are on the cusp of revolutionizing health care, armed with mobile health ("mHealth") apps capable of providing everything from cardiac measurements to sonograms.

While tremendous potential exists to broaden access to medical treatment and control costs, several health law experts say in a just-published *New England Journal of Medicine* (NEJM) report that more oversight is needed by the U.S. Food and Drug Administration (FDA) to ensure consumer confidence and safety. Out of some 100,000 mHealth apps on the market, only about 100 have been cleared by the FDA, while opponents see the FDA as deterrents to innovation—and profits.

"Consumers will be spending a lot of money on these products, and venture capital is flying into the industry," says the article's lead author, SMU Dedman School of Law Associate Dean of Research Nathan Cortez, adding that by 2017 mHealth apps are expected earn $26 billion— up from $2.4 billion in 2013.

The FDA needs "additional funding and in-house technical expertise to oversee the ongoing flood of mHealth products," the authors note. An under-regulated mobile health industry could create "a Wild West" market, says Cortez, who has conducted extensive research into FDA regulation of mobile health technologies.

"Most consumers take mobile health app claims at face value, and think that because they're available through a trusted retailer like the iTunes Store, they must have been reviewed by the FDA, which isn't usually the case," Cortez says.

Cortez, who also serves as an associate professor in SMU's Dedman School of Law, co-wrote the NEJM article with Harvard Law School Professor I. Glenn Cohen, faculty director of the Petrie-Flom Center for Health Law Policy, Biotechnology & Bioethics, and author of Human Subjects Research Regulation: Perspectives on the Future (MIT Press, 2014) and Aaron S. Kesselheim, associate professor of medicine at Brigham and Women's Hospital/Harvard Medical School.

"Although the vast majority of mHealth products are very low-risk, some apps make promises they can't fulfill, and others make errors that could harm patients," Cortez notes, pointing out that life-threatening technical mistakes are not only possible – they also have occurred.

One of several examples cited in the study includes Sanofi Aventis' 2012 recall of a diabetes app that miscalculated insulin dosages.

Several Congressional bills have been proposed to strengthen FDA jurisdiction over mHealth products, with one proposing the creation of a new Office of Wireless Health Technology within the administration, the article notes. Meanwhile, more restrictive bills also have been introduced to keep the FDA from regulating "clinical software" or "applying a complex regulatory framework could inhibit future growth and innovation in this promising market."

"The conventional wisdom is that FDA regulation will stifle innovation, and that's a very short-term way to think about this," Cortez says. "Most Silicon Valley firms aren't used to much federal regulation, and Internet technologies have been subject to very little federal oversight."

If dangerous errors and disproven product benefits are allowed to proliferate, "some very useful products will be undermined by widespread consumer distrust," Cortez contends.

"We're trying to push lawmakers to empower the FDA, not hamstring it," he says. "Clarity will help the industry create products more helpful than harmful."

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