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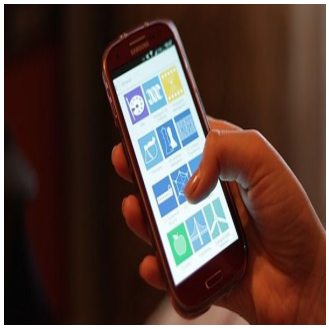
Government Oversight Needed for Booming Health Apps Market



An under-regulated mobile health industry could create “a Wild West” market, says law professor, Nathan Cortez, writing in the New England Journal of Medicine. Cortez, who has conducted extensive research into FDA regulation of mobile health technologies argues that while mHealth holds great promise, there is a role for government oversight. Out of around 100,000 mHealth apps on the market, around 0.1% (100) have been cleared by the FDA. However, free market proponents see regulation as a deterrent to innovation and profits.

When mobile devices can already collect more granular patient data than can be collected from devices that are typically used in hospitals or physicians’ offices the promise is clear. With momentum toward legislation building, the article, co-authored by I. Glenn Cohen from Harvard Law School and Aaron S. Kesselheim of Brigham and Women’s Hospital/Harvard Medical School, focuses on the public health benefits and risks of mHealth devices under the jurisdiction of the FDA and discusses how to best use the FDA’s authority.

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

“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.

“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.”

Source: SMU
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