

YANKEE DOODLING **Douglas Kamerow**

Regulating medical apps: which ones and how much?

The US Food and Drug Administration has issued sensible guidance

Close to 100 000 health related apps for smartphones are now available on the two major mobile device software platforms, Apple's iOS and Google's Android. Medical apps have generated more than three million US downloads on iOS alone.¹ By 2015 an estimated 500 million smartphone users worldwide will use some type of medical app,² and the global market for mobile health apps may reach \$26bn (£16bn; €19bn) by 2017.¹

Early apps related to health were designed simply to track exercise or weight loss or to provide instruction on diet or smoking cessation. More recently, though, designers have begun linking smartphones' computing and display power with custom designed hardware to create functioning portable medical devices. Around 15% of these apps are designed for healthcare professionals, but most are being marketed to patients to gather, track, analyze, and transmit medical data.¹

For example, you can now buy an AliveCor device for \$199 that slips over your iPhone and records and transmits a one channel electrocardiogram with its app. For \$15 you can buy "MD EyeCare," an app that turns an iPhone into a "low cost screening tool providing early diagnosis of eye cancer in kids." Or you can order CellScope Oto, a "new approach to visualizing the ear by converting your phone into a connected digital otoscope." (I'll resist making jokes about whether a phone sigmoidoscope is next.)

The Food and Drug Administration, which regulates medical devices in the US, has come under pressure to evaluate and bless all these medical apps and mobile medical devices. App developers have been uncertain whether their products come under FDA jurisdiction. Some have submitted their products to the FDA, of which about 100 have been approved.³ The overwhelming majority of medical app designers,

though, have simply taken their products to market.

The FDA was facing a difficult problem. How could it possibly regulate 100 000 medical apps—and why would it want to? But how could it not regulate apps that have morphed into what seem to be fully fledged medical devices, now available to anyone with a smartphone and a credit card? What type of regulatory requirements could it impose on these new e-devices? And on which devices? After stewing about these and other questions for more than two years the FDA issued its final guidance on mobile medical applications on 25 September.⁴

Firstly, the FDA defined a "mobile medical app" as a software application run on a mobile platform that is either used as an accessory to a regulated medical device or transforms a mobile platform into a regulated medical device. Most health related apps are thus defined as non-devices and will not be subject to regulation. These include electronic versions of medical books and reference materials; educational apps for patients or clinicians; general office apps; and generic tools such as magnifiers, recorders, and communication aids.

Secondly, of the group of apps that do reach the level of "device" and can be used in the diagnosis, treatment, or prevention of disease and thus would be called mobile medical apps, the FDA will not regulate those that pose a low risk to the public. This category includes most disease tracking apps, such as for diabetes, and motivational and educational apps to help with exercise, dieting, smoking cessation, and other behavioral change. Even though these are defined as mobile medical apps, the FDA will exercise "enforcement discretion" and not regulate them. (Incidentally, I love the term "enforcement discretion." It means "choose your battles," and I'm happy to have a name for what



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we were doing all those years with our kids.)

Which brings us to the third group, mobile medical apps that are the focus of the FDA's regulatory oversight. This group includes apps that use an attachment of almost any sort of gizmo to the phone to measure, diagnose, or treat a medical problem, turning the phone into the controller or screen for the device (think ECGs or stethoscopes). It also includes apps that turn the phone itself into a device, such as using the phone's speaker to produce tones for audiometry, and apps that allow remote monitoring by phone of heart tracings. These mobile medical apps will be regulated under the same rules that the FDA applies to other devices.

The good news for developers of the regulated apps is that they will not have to start from scratch with randomized trials to prove that their devices work. They need only show that they have accuracy equivalent to already approved devices to gain acceptance, and the FDA promises quick review of these applications.

All in all, this was a very sensible ruling in a complex area. My only complaint is that we are still left with rafts of health related apps that give advice that is incomplete or plain wrong. For example, a review of 47 iPhone apps for smoking cessation found a low level of adherence to evidence based guidelines.⁵ Few of these apps recommended proven treatments such as pharmacotherapy, counselling, or a quitline.

Regulating these may not be the FDA's job, but it should be someone's.

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References are in the version on bmj.com.

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● News: Experts warn on data security in health and fitness apps (*BMJ* 2013;347:f5600)

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● See the results of our poll on the regulation on mobile medical apps at bmj.com/about-bmj/poll-archive