

The FDA Allows an App for That

Here's some good news: your smartphone is safe. The U.S. Food and Drug Administration has announced that it will not be regulating mobile apps that help you count calories. Nor will it regulate apps that remind you to floss your teeth, provide motivational tips for relieving stress, or allow you to track how much (or how little) your new baby is sleeping.

The bad news is that the FDA *could* regulate all those apps—and many more besides—since such programs often qualify as medical devices under the FDA's expansive definitions. The agency has so far chosen to use its discretion mercifully. It is giving these apps a pass, allowing consumers to take a bold risk on unregulated suggestions to improve their posture and brazenly unchecked games that encourage them to practice physiotherapy exercises at home.

But it's depressing that such patently benign (and potentially helpful) innovations legally fall squarely within the agency's purview by default.

Am I glad that the FDA won't be regulating the iTunes App store? You bet I am. But it says something about the current state of affairs that the agency feels the need to clarify this fact on its website. (In case you're wondering, the agency also states that it will not regulate the Google Play store either. No favoritism.)

Still, let's do as a cheerful unregulated mental health promotion app might suggest and try to look on the bright side. Regulating medical apps that empower people to take charge of their own health

in simple, safe ways would have been a colossal waste of time and money. The FDA actually recognized as much—or perhaps just sensed how ridiculous it would have looked if it had started regulating food diaries and illustrations of yoga poses—and chose the reasonable course.

In a world of attempted bans on super-size soda, this act of regulatory self-restraint comes as a surprise. But maybe it shouldn't. Given the speed and ease with which technology is putting health monitoring and maintenance into the hands of individuals, it would be practically impossible for regulators to step in effectively in all these areas, even if they wanted to.

It's one thing to identify, track, and approve every pacemaker being used in the country. It's quite another to identify, track, and approve every mobile “diet coach” program being used for weight loss or diabetes management. Programmers probably designed a thousand of them in the time it took you to read that sentence. And if the supply of such apps were being held up by an FDA pre-approval bottleneck, what do you suppose the odds are that contraband mobile “diet coaches” would begin appearing on the black app market? (Unapproved diet apps would likely become just as impossible to obtain as—oh I don't know—*marijuana*.)

One of the ostensible purposes of regulation has always been to serve as a stand-in expert, providing information that people couldn't obtain easily on their

own. How could a patient know if a particular pacemaker would be safe and effective without the FDA's help? But technology has been eroding that argument to a great degree, connecting regular people with previously unimaginable stores of data, records, and reviews. People can use that information to judge how well a product has performed in the past and what true experts have written about it.

I'm not saying the average Joe is going to be comfortable choosing a pacemaker based on user comments. But a mobile app that helps monitor the frequency of asthma attacks or offers information on drug interactions? Most people would be perfectly content to select one of those based on the assurances or warnings of other customers—information that is readily available in an app store in the form of star-ratings, reviews, and information for which a regulator is unnecessary.

The most exciting thing about mobile health apps is their ability to foster self-sufficiency. Diabetics can monitor and track their own blood glucose levels (though the FDA does regulate apps in that particular case—bureaucrats still need jobs, you know). Elderly patients can organize their own medication schedules and receive reminders from their smartphones. Everyday reliance on doctors, pharmacists, and caregivers is reduced, giving people greater autonomy. But the ultimate autonomy is being able to choose those emancipating programs on one's own, unfettered by a government monopoly's views on which ones are worthy and which ones aren't.

So far, the FDA has deigned to allow us this luxury in at least some cases. If technology continues progressing apace, the agency will have less and less choice in the matter.

When that happens, some bureaucrats may find themselves out of work. But not to worry—they'll have plenty of positive-thinking and learned-optimism apps to turn to. **R**

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