



## **FDA approval of mobile diabetes tracker may herald era of 'personal health management'**

By Neil Versel  
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Two weeks ago, we reported that WellDoc had received FDA approval [1] to sell DiabetesManager, a remote monitoring system for patients with Type 2 diabetes. We didn't think too much of it, burying the news in the "Also Noted" section of the newsletter. Others saw the approval as slightly more significant.

"This signals the regulator's openness to mobile health solutions--a market moment that may usher in the new-and-improved era of personal health management," health economist Jane Sarasohn-Kahn writes on her Health Populi blog. "While an "N" of 1 = 1, and WellDoc's approval is for one product from one company, the approval of DiabetesManager represents a positive sign for the many developers of mobile health applications waiting in the wings for market approval."

Sarasohn-Kahn continues: "The week that the FDA approved WellDoc's DiabetesManager, the agency also published a report [2] on its 510(k) approval process for medical devices. The agency understands the process isn't ready for primetime when it comes to evaluating innovations--including but not limited to m-health applications.

"The more clarity the FDA offers in the area of mobile applications for health, the more investors will back these important new products and services and the sooner patients and health consumers will be empowered by these tools. That's when both healthcare and health costs will be better managed."

In case you're wondering, DiabetesManager is a blood-glucose measuring system that links to a mobile phone app for patients to collect, track and share readings. Baltimore-based WellDoc has developed algorithms to help deliver personalized health management tips to the user based on specific data and trends.

WellDoc expects to launch the product early next year.