OPINION | COMMENTARY

Open Your App and Say 'Ahh'

Smartphones and better electronic health records have the potential to revolutionize medicine.

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No one wants to sit in an exam room while the doctor spends precious minutes entering billing information into an electronic health record. But frustrations like this don't mean we should give up on technology's potential to improve health outcomes. The data collected by a new generation of digital health products—including smart watches, smartphones and fitness trackers—could help the medical community learn about treatments that might work for a patient like you, and which ones to avoid. The first step is enabling them to stream data wirelessly to your doctor's EHR.

At the Food and Drug Administration, we're modernizing our regulations and establishing clear standards for the use of these tools and the data they generate. This will make it easier for innovators to develop smart, user-friendly mobile technologies that capture the data most important to patients and doctors. We are also making it possible for real-world evidence collected by smart devices to be included on drug and product labels.

This information—in FDA jargon, evidence for a product's clinical benefits and risks—can help patients and physicians match treatments to patient's needs and preferences. It's also important to FDA regulators because it can help us maintain our mission of assuring the safety and effectiveness of the products we regulate.

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In some ways, the data generated by wearable devices can be more valuable than the data generated by traditional clinical trials, which are typically conducted at specialized medical centers and not always representative of the experience of the larger population. In the real world, the patient experience doesn't happen only in the doctor's office. Being healthy or sick isn't a one-shot deal; it's a continuous process that spans a lifetime.

Today, we have the tools to take continuous health measurements—like your heart rate and steps—during the course of a day, whether you're on your way to work or out for an evening jog. EHRs can incorporate more of these data through an ecosystem of mobile apps, evaluating that information against a baseline drawn from office visits, lab tests and even genomic sequencing.

Your doctor can use all of it to create a personalized dashboard for your health, guiding your treatment, diet and exercise—and calling you in for a checkup if something seems off.

An app-enabled health dashboard that exists in your smartphone and is connected to your doctor's office isn't a far-flung aspiration. In many respects it's already here, thanks to the 21st Century Cures Act, passed by Congress in late 2016. The Cures Act directed the Health and Human Services Department to modernize the nation's health information technology infrastructure, including the EHR systems. The new law empowers patients to access, exchange and use their health information "without special effort."

The FDA is developing a framework for the use of real-world evidence. This will affect product approval and labeling decisions, spurring demand among patients for apps that permit their own health data to flow from their smart devices to their EHR and back again.

Tech companies are already betting on this trend. Apple recently announced it will open its newly developed health-records app to developers and researchers. If you have an iPhone in your pocket, you can download medical records from a participating health-care system right now. Dozens of other technology companies, including Google, Fitbit and Amazon, are venturing into similar territories.

Going forward, patients can willingly choose to share their anonymized information with hospitals, doctors, and drug companies, receive tailored health-care services, enroll in clinical trials or simply contribute to research. When shared with the FDA, these data can provide a long-term view of the experiences of diverse patients who use products the agency regulates. That puts each patient at the center of FDA's mission.

Unleashing new technologies and paring back unnecessary regulations will make medicine less about having doctors enter billing data into the EHR and more about liberating them to focus on the needs of individual patients.

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