FDA Announces New Steps to Empower Consumers and Advance Digital Healthcare

Posted on July 27, 2017 by FDA Voice

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When people think about personalized medicine, they often think of genetic testing and sequencing of the human genome. But the concept of personalized medicine is much broader. It includes the re-imagination of healthcare delivery. It includes empowering consumers to take more control of their own healthcare information to make better informed decisions about their medical care and healthy living.

This opportunity is enabled by a new technological paradigm of digital health tools, like apps, that enable consumers to have more active engagement and access to real-time information about their health and their activities. These tools allow consumers and providers to supersede the traditional, physical constraints of healthcare delivery and exploit the opportunities offered by mobile technology.

Historically, healthcare has been slow to implement disruptive technology tools that have transformed other areas of commerce and daily life. One factor that's been cited, among many, is the regulation that accompanies medical products. But momentum toward a digital future in healthcare is advancing. Not all of these tools are subject to FDA regulation. For the devices we are asked to evaluate, we know that our policies must continue to empower consumers and facilitate innovation.

Today, I'm excited to announce, as part of our broader Medical Innovation Access Plan, a new component focused on digital health innovation—the formal launch of our Pre-Cert for Software Pilot Program. This new program embraces the principle that digital health technologies can have significant benefits to patients' lives and to our healthcare system by facilitating prevention,

treatment, and diagnosis; and by helping consumers manage chronic conditions outside of traditional healthcare settings.

At the same time we are announcing this pilot, FDA's Center for Devices and Radiological Health (CDRH) is publishing its Digital Health Innovation Action Plan to provide details and timelines for our integrated approach to digital health technology and the implementation of the 21st Century Cures Act. We're telling consumers and the digital health industry how we will establish clear and consistent expectations for the products FDA regulates.

The challenge FDA faced in the past is determining how to best regulate these non-traditional medical tools with the traditional approach to medical product review. We envision and seek to develop through the Pre-Cert for Software Pilot a new and pragmatic approach to digital health technology. Our method must recognize the unique characteristics of digital health products and the marketplace for these tools, so we can continue to promote innovation of high-quality, safe, and effective digital health devices.

FDA's traditional approach to medical devices is not well suited to these products. We need to make sure our approach to innovative products with continual updates and upgrades is efficient and that it fosters, not impedes, innovation. Recognizing this, and understanding that the potential of digital health is nothing short of revolutionary, we must work toward establishing an appropriate approach that's closely tailored to this new category of products. We need a regulatory framework that accommodates the distinctive nature of digital health technology, its clinical promise, the unique user interface, and industry's compressed commercial cycle of new product introductions.

Our new, voluntary pilot program will enable us to develop a tailored approach toward this technology by looking first at the software developer or digital health technology developer, rather than primarily at the product (as we currently do for traditional medical products). This pilot will help us establish the most appropriate criteria for standing up a firm-based pre-certification program for these new tools.

The goal of our new approach is for FDA to, after reviewing systems for software design, validation and maintenance, determine whether the company meets the necessary quality standards and pre-certify the company. Pre-certified companies could submit less information to us than is currently required before marketing a new digital health tool. In some cases, pre-certified companies could not submit a premarket submission at all. In those cases, the pre-certified company could launch a new product and immediately begin post-market data collection. Pre-certified digital health companies could take advantage of this approach for certain lower-risk devices by demonstrating that the underlying software and internal processes are sufficiently reliable. The post-market data could help FDA assure that the new product remains safe and effective as well as supports new uses.

FDA designed the new digital health pilot program to include up to nine software firms of various sizes. Initial participants in this new pilot will range from small startups to large companies that develop both high- and low-risk software products that are devices. We want to include medical product manufacturers as well as non-traditional software developers. Given the amount of attention we're getting, and the ongoing innovation in this space, I'm confident we'll have strong participation in the new pilot.

Digital health product developers will be selected for the program based on the following:

- The company must be in the process of developing or planning to develop a software product that meets the definition of a medical device;
- The company must have an existing track record in developing, testing, and maintaining software products and demonstrating a culture of quality and organizational excellence measures that are tracked by Key Performance Indicators (KPI) or other similar measures;
- And during participation of the pilot, companies must agree to:
    - Provide access to measures for developing, testing and maintaining software products and demonstrating a culture of quality and organizational excellence measures by KPI;
    - Collect real-world post-market data and provide it to FDA;
    - Meet with FDA for real-time consultation;
    - Be available for site visits from FDA officials; and,
    - Provide information about the firm's quality management system.

We have intentionally left the initial criteria broad because this pilot is purposely designed to be inclusive and flexible. We want to be able to accommodate a broad range of participants and technologies. We appreciate that the experience and capabilities of a small company will be different from that of a large company and recognize that we need a pre-certification program that accommodates both.

The initiative will begin immediately. Starting on August 1, companies can submit a statement of interest that includes the qualities listed above, requesting participation in the pilot to FDAPre-CertPilot@fda.hhs.gov. Then, during the month of August, FDA's Digital Health Team will evaluate submissions and select companies that reflect the broad range of software developers. A critical component is that we will include small and large companies, traditional and non-traditional medtech companies, and products that range in risk. This approach will create opportunities for more dynamic entrepreneurship and competition and help continue to drive product innovation.

We expect that the first four months of the pilot will better inform our regulatory team as well as product developers. FDA will hold a public workshop in January 2018 to report on and review our initial findings. The goal is to inform product developers who are not participating in the pilot, so they can understand our process and findings, to help better inform development programs underway outside of the pilot.

As we launch our Digital Health Innovation Action Plan, I am conscious of the fact that apps and app updates come to market every day. But the most powerful feature of this market may not be one revolutionary app but rather a combination of apps that provides consumers and providers with the information they need. This can help people better manage their chronic diseases, which could result in less trips to the doctor for checkups, or better awareness of illness, like prompts to a parent with a sick child on when they need to see a provider. I'm delighted to be helping lead FDA at a critical moment, when I have the opportunity to help advance innovation in digital health and to make sure patients can benefit from these remarkable technologies.

Scott Gottlieb, M.D., is Commissioner of the U.S. Food and Drug Administration