

Digital Health and Regulatory Experimentation at the FDA

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Since the 1980s, the U.S. Food and Drug Administration (FDA) has largely treated medical software like more traditional, tangible medical devices. But the agency—and everyone else—has long suspected that software is *different*. Finally, perhaps spurred by the ongoing revolution in digital health technologies, the agency has started to experiment with novel regulatory frameworks better tailored to software—like mobile applications, clinical decision support (CDS), artificial intelligence (AI), and machine learning—that qualify as medical “devices” under FDA jurisdiction. The agency calls its plans an “entirely new” and “comprehensive approach to the regulation of digital health tools.”

This article identifies and evaluates three important experiments in medical product regulation in the FDA’s new framework. First, the agency is experimenting with a shift from pre-market to post-market review, exempting lower-risk digital health devices from pre-market review, saving such review for higher-risk products. Moreover, spurred by the 21st Century Cures Act, the FDA will rely on “post-market collection of real-world data” to clear new product functions, with help from the forthcoming National Evaluation System for Health Technology, an FDA-led effort to generate and collect such “real-world evidence.”

Second, the FDA is experimenting with firm-level review in lieu of product-level review with a new Software Precertification Pilot Program. Certified companies will enjoy a more streamlined pathway to market. FDA Commissioner Scott Gottlieb explains that “Precertified companies that have demonstrated a culture of quality and organizational excellence could bring certain types of digital health products to market without FDA premarket review or after a streamlined, less-burdensome FDA premarket review.” The agency also promises a “new approach to the review of artificial intelligence,” applying pre-certification to AI so that certain certified companies can make “minor changes to its devices without having to make submissions each time.”

Third, the FDA is experimenting with reviews by independent, non-governmental certifiers. A longstanding observation is that the FDA lacks the internal expertise and resources to give in-depth reviews to sophisticated medical software. In this spirit, the FDA has created a new Digital Health Unit, as well as a new program called “Information Exchange and Data Transformation” (INFORMED), which will conduct regulatory science research to support the FDA’s new initiatives. The program will rely on the “software as a medical device” (SAMD) framework developed through the FDA’s work with the International Medical Device Regulators Forum. In the meantime, non-FDA certifiers will focus on firm-level compliance rather than product-by-product reviews, a genuine innovation at the agency.

This Article will evaluate these new regulatory approaches, explaining how they depart from previous approaches and why these innovations might be important. A swirl of activity as brought us to this point—two acts of Congress, guidance documents, public workshops, inter-agency working groups and reports, culminating in the FDA’s 2017 Digital Health Action Plan. After years of pushing Congress and the agency to think creatively about digital health, this author now can evaluate these experiments in light of the unique challenges of digital health oversight, informed by examples in other areas of risk regulation.