FDA 2.0: Initial upgrade complete — federal legislative action is necessary to regulate Dr. Robot

By Abbye E. Alexander, Esq., Christopher J. Tellner, Esq., and Talya Van Embden, Esq., Kaufman Dolowich Voluck LLP

NOVEMBER 14, 2022

Technology and science have the potential to fundamentally transform the health care industry. As artificial intelligence and machine learning advance, medical devices will detect disease earlier, diagnose more accurately, target better therapies and improve personalized medicine. However, the current regulatory framework implemented by the U.S. Food and Drug Administration (FDA) is not well suited to the adoption of digital health products.

In July 2017, the FDA launched the Software Precertification Pilot Program (Pre-Cert Program) to replace the current FDA product-by-product premarket review process and "fast-track" the process for medical device developers that the FDA trusts to produce consistently high-quality, safe and secure products, thereby removing the necessity to undergo the full review process.

The current regulatory framework implemented by the U.S. Food and Drug Administration (FDA) is not well suited to the adoption of digital health products.

After five years of collecting data from nine volunteer companies considered to be the leading developers of digital health products, the FDA issued a final report — "The Software Precertification (Pre-Cert) Pilot Program: Tailored Total Product Lifecycle Approaches and Key Findings," Sept. 26, 2022 (https://bit.ly/3EkgHRm) — discussing the results of its revolutionary Pre-Cert Program, which concluded that rapidly evolving medical device software technologies could benefit from an updated regulatory framework. Most importantly, however, the recent report notes that the FDA lacks the legal authority to fully implement the program.

FDA oversight and digital health

For decades, the FDA has been charged with the responsibility of regulating medical devices, and its incorporated software, to ensure safety for its consumers. There are two different ways that such software is categorized: (1) a 'software in a medical device' (SIMD); or (2) a 'software as a medical device' (SaMD).

SIMD incorporates software into a traditional medical device to aid functionality, such as a robotic surgical device that implements software for a surgeon to control navigation features while conducting surgery. On the other hand, when the software itself is the medical device, it is classified as a SaMD. For example, a software program that analyzes X-rays and engages in computer-assisted diagnosis is considered an SaMD.

While the FDA's regulatory process regarding these innovative technologies still requires a great deal of fine-tuning, it is encouraging to see the hurdles have been recognized.

Over the last decade, SaMDs have exploded in both demand and popularity resulting in a new category of health care products coined as "digital health" encompassing the development of wearables such as Apple Watches and Fitbits to mobile health care applications aimed at assisting physicians and patients. However, a widely recognized challenge to the growth and advancement of digital health is the FDA's premarket review requirements as it is a lengthy and expensive process. The current FDA premarket review process requires developers of SaMDs to understand the FDA requirements, gather necessary data, prepare voluminous submissions and answer the FDA's stringent criteria.

As such, the FDA's outdated premarket review process severely hampers the speed at which the medical device industry can innovate — a necessary trade-off to ensure that medical devices are marketed to the consumer with a great degree of assured safety and effectiveness. The digital health medical device industry simply cannot thrive within the traditional regulatory structure, a challenge that has previously been addressed by Congress in 2016.

The 21st Century Cures Act

In 2016, the 21st Century Cures Act (the Cures Act) was enacted by Congress clarifying, among other various purposes, the FDA's regulatory oversight over digital health and medical devices.

Pursuant to the Act, digital health — under the purview of the FDA and subject to regulatory authority — includes machines or devices that use artificial intelligence such as machine learning to provide diagnostic information to patients.

Most importantly, the Cures Act provides that devices classified as low-risk medical software that serve as electronic patient records or data storage are to be excluded from the lengthy premarket review process. To put it simply, if the AI algorithm does not provide a diagnosis or predict a course of treatment, the FDA does not need to regulate it.

Before Apple Watches, Fitbits and other mobile medical devices were utilized to track steps or monitor hearts, a medical device was traditionally only thought of and used to provide measurements or give treatments. Considering the increasing popularity and demand of SaMD, and the imperfect fit between technology development and federal regulation, the FDA pitched a pilot program to *pre-certify* eligible health developers who could market their devices to consumers without additional FDA review.

An overview of the pre-cert pilot program

The FDA launched the Pilot Program as an initial step forward in developing a new regulatory framework that accommodates the distinctive nature of Software as a Medical Device (SaMD) and replaces the FDA's current product-by-product premarket review process with a "pre-certify" process for SaMD developers who demonstrate sufficient quality performance. In other words, SaMD developers would be able to forgo the current FDA premarket review process.

Pilot program results and future legislation

Under the Pre-Cert program, the FDA provided nine companies, including Apple, Samsung, Verily, Johnson & Johnson, Roche and Fitbit, with the voluntary opportunity to partake in a "pre-certification" process and forgo the FDA's stringent premarket review by demonstrating in-house adherence to objective criteria related to software design, development, testing and validation.

During the Pilot Program, the FDA conducted ongoing "Excellence Appraisals" of the nine participants and evaluated each company's ability to develop safe and effective devices, instead of monitoring the medical device itself as currently required under the FDA's 510(k) process. The FDA also collected data throughout the Pilot Program concerning the volunteer companies' capacity to monitor and improve a SaMD during its life cycle.

The FDA report states that the current medical device regulatory approach is far too rigid and impractical to efficiently evaluate the safety and effectiveness of modern medical technology and digital health devices.

The Pilot Program resulted in various findings related to excellence principles and key performance indicators (KPI) that may be useful to SaMD manufactures.

Some of the KPI objectives identified by the Pilot Program and considered as the best practices for implementation of a quality management system in compliance with the Quality System Regulation (21 C.F.R. Part 820) are:

(1) development of well-characterized software, i.e., "the software behaves as expected";

(2) deployment and monitoring of such software, i.e., "the software behaves as expected in the real-world";

(3) a patching process that ensures timely resolution of issues, i.e., "software can be fixed when it does not behave as expected;" and

(4) a process to ensure modifications meet user needs through real-world use.

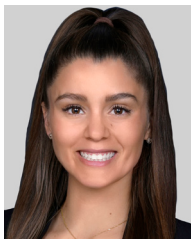
Ultimately, innovation aside, the FDA concluded that under current statutory authorities there are significant challenges to implement the Pilot Program. However, the report offers no guidance or detail about what type of regulatory framework would be useful to achieve the goals of the Pilot Program. Instead, the FDA provides that the rate at which digital health develops requires that a flexible and risk-based approach to regulation of medical devices be considered.

While the FDA's regulatory process regarding these innovative technologies still requires a great deal of fine-tuning, it is encouraging to see the hurdles have been recognized. Hopefully in time, the legislative action necessary to allow for the FDA to move at — or close to — the speed of these developing technologies will be executed.

Abbye E. Alexander and Christopher J. Tellner are regular, joint contributing columnists on health care litigation for Reuters Legal News and Westlaw Today.

About the authors





Abbye E. Alexander (L) is co-managing partner of **Kaufman Dolowich Voluck**'s Orlando, Fla., office and co-chair of the firm's health care and managed care practice group. She focuses her practice on issues affecting national and local businesses to include health care professionals, organizations and facilities, including long-term care facilities, assisted living facilities, rehabilitation centers and doctors. She may be reached at aalexander@kdvlaw.com. **Christopher J. Tellner** (C) is a co-managing partner of the firm's Blue Bell, Pa., office and co-chair of the firm's health care and managed care practice group. He specializes in professional liability defense, including the defense of health care facilities and practitioners; prior to entering the legal profession, he worked as a health care professional. He may be reached at ctellner@kdvlaw.com. **Talya Van Embden** (R) is an associate attorney in the firm's Fort Lauderdale, Fla., office and is a member of the firm's health care and managed care practice group. She focuses her practice on labor and employment, general liability, and health care and managed care defense. She can be reached at tvanembden@kdvlaw.com.

This article was first published on Reuters Legal News and Westlaw Today on November 14, 2022.