A Shifting Regulatory Framework for Digital Health: The Impact of Silicon Valley on the FDA's Mission to Promote and Protect the Public Health

M. Jason Brooke
AmalgamRx

The FDA has effectively regulated medical device software for more than three decades despite claims that the legal framework for regulation of medical devices in the Food, Drug & Cosmetic Act was not adequately designed to do so. The last decade, however, has seen dramatic growth in the development and proliferation of "software as a medical device" or SaMD products. The growth has been largely driven by the ease with which entrepreneurs can develop SaMD products, the ubiquity of mobile technology, the potential for SaMD products to offer simple and effective solutions to many problems in healthcare, and the attractiveness of the healthcare market to Silicon Valley technology companies and investors. This dramatic growth coupled with the changing technology landscape and the influx of new industry stakeholders has driven the FDA to adapt its thinking about the medical device regulatory framework and its application to SaMD. The FDA has taken an increasingly de-regulatory approach and is shifting to a new paradigm, the basis of which involves promoting innovation and rapid commercialization of SaMD by reducing pre-market regulatory burden while protecting the public health by increasing post-market oversight.

This new paradigm is embodied in the FDA's Software Precertification (Pre-Cert) Program, which relies on a pre-market appraisal of the company developing the SaMD and post-market monitoring of real-world evidence. While the FDA has historically focused its pre-market oversight at the product level, the Pre-Cert Program shifts the focus of the pre-market oversight to an appraisal of the excellence of the company. From a public health perspective, this approach can have dire consequences—being excellent at video game development does not necessarily equate to the ability to develop safe and effective medical devices. Likewise, the reliance on real-world evidence to serve as a surrogate for quality compliance is fraught with public health risk if for no other reason than the fact that what constitutes real-world evidence is not clearly or easily defined and can be presented in a way that paints no better picture of product quality than today's approach. Furthermore, the FDA has not articulated a clear approach to gathering, analyzing, and acting upon real-world evidence and, as such, have not established a fundamental component of its new paradigm, begging the question of whether implementation of the Pre-Cert Program and related policies are in the best interest of the public health.

The objective of this presentation will be to describe the history of and basis for the FDA's new paradigm for regulating digital health, to discuss examples that illustrate the changes in regulatory policy, and to explore the impact of these changes on the public health.