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FDA Commissioner Forecasts New, Modernized Digital Health Regulatory Framework

In his first public statement as Commissioner of the Food and Drug Administration ("FDA") on the regulation of digital health technologies, Scott Gottlieb, M.D., signaled that FDA is contemplating significant changes. In a June 15, 2017, blog post on FDA's website, Dr. Gottlieb announced that FDA will be modernizing its regulation of digital health products to make it more efficient. risk-based, and predictable, in an effort to provide greater regulatory certainty and help reduce the development costs of innovating new and beneficial medical technologies. Dr. Gottlieb cites to the boom in the development and availability of mobile medical applications, noting that last year there were over 160,000 health-related apps available for download on smartphones.

As part of an FDA-wide initiative to foster medical innovation, FDA will create a program specific for digital health, to be known as the Digital Health Innovation Plan. Although the blog post is relatively short on details, Dr. Gottlieb announced that the Plan will include a "novel, post-market approach to how [FDA] intends to regulate these digital medical devices."

This announcement follows on the heels of the recent enactment of the 21st Century Cures Act, which amended the Federal Food, Drug, and Cosmetic Act to remove certain software functions that generally present a low risk from the statutory definition of a "device." For more information on the software-related provisions of 21st Century Cures Act, see our alert here. In the blog post, Dr. Gottlieb states that FDA will be issuing implementing guidance in the coming months to explain what software functions are outside of FDA's jurisdiction, and how the 21st Century Cures Act provisions relate to FDA's pre-existing policies on regulation of medical software. Dr. Gottlieb also states that certain other low-risk software technologies and functions not addressed by 21st Century Cures Act will not be subject to FDA's premarket requirements, although the blog post does not address what those device types might be.

In addition, Dr. Gottlieb's blog post discusses an upcoming pilot program, to be unveiled in the fall of 2017, to evaluate a novel approach to regulating digital health. The pilot program, which is still under development, would establish a third-party certification program under which lower risk digital health products could be marketed without FDA premarket review and higher risk products could be marketed with a streamlined form of FDA premarket review. Under the pilot program, FDA would rely on third-party certification to assess firms' regulatory programs and compliance, rather than the safety and effectiveness profiles of individual products. For example, the certification process might evaluate whether a company consistently engages in high quality software design and testing, as well as continuing product maintenance. FDA believes that this approach could reduce the financial and time resources necessary to bring digital health technologies to market. Such a third-party certification program, if it were piloted and ultimately adopted on a broad scale, would create an entirely new approach to FDA regulation of medical software.

Dr. Gottlieb also emphasizes the role of postmarket collection of real-world data to help streamline the introduction of new and iterative digital health products. To underscore this point, Dr. Gottlieb cites to the real-world data collection being conducted by the National Evaluation System for health Technology ("NEST"), which is operated by the Medical Device Innovation Consortium ("MDIC"), an independent public-private partnership. NEST is expected to launch a fully operational system by the end of 2019, which would make available postmarket data that companies can rely on to demonstrate product performance at the premarket stage, and thereby expedite the market

entry of the new product, or an expanded indication of a marketed product. With all of these initiatives in place, Dr. Gottlieb believes that "this firm-based approach, rather than the traditional product-based approach, combined with leveraging real-world evidence, would create market incentives for greater investment in and growth of the digital health technology industry."

Ropes & Gray will continue to monitor developments in this area. If you have any questions, please contact any member of Ropes & Gray's FDA regulatory practice or your usual Ropes & Gray Advisor.