Gottlieb Announces New Regulatory Paradigm for Digital Health Software

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Medical Device Alert

The rapid development of medical software products continues to create regulatory challenges for the Food and Drug Administration (FDA).

Recognizing both the opportunities and the potential regulatory challenges presented by such rapid development, the FDA – under the leadership of recently confirmed Commissioner Dr. Scott Gottlieb – is spearheading a new “Digital Health Innovation Plan” intended to encourage innovation in the digital health technology space while continuing to ensure that products brought to market are safe and effective. In a recent FDA blog post, Dr. Gottlieb reiterated that the Agency's policies must be clearly communicated to avoid creating uncertainty, noting in particular that industry should not need to seek FDA's position on "every individual technological change or iterative software development."

Read the full "Gottlieb Announces New Regulatory Paradigm for Digital Health Software" client alert.

Contacts

Suzanne Levy Friedman
Senior Associate

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