U.S. CARES Act Enables Long-Awaited OTC Drug Regulatory Modernization: Key Highlights



Subtitle F of the recently enacted U.S. CARES Act substantially reforms the regulatory framework for non-prescription drugs, representing the most significant update of the review process for over-the-counter (OTC) drugs since that process was first established in 1972. The Act draws from recent legislative proposals to reform OTC regulation, incorporating a modified version of the "Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2019" (S. 2740, H.R. 3443) that was passed 91-2 by the U.S. Senate in December 2019. At that time, Senate Health Committee Chairman Lamar Alexander (R-Tenn.) described the legislation as "the most important new law affecting the safety, innovation, and affordability of over-the-counter drugs since the 1970s."

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