

Morgan Lewis



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Legislative and Regulatory Updates

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- **On November 22, 2022, Sen. Mike Lee introduced draft legislation titled the “Biosimilar Red Tape Elimination Act”**
 - Would stop the FDA from requiring biosimilars to conduct “unnecessary” switching studies in order to obtain an interchangeability designation.
- **On December 22, 2022, the US Congress passed the Consolidated Appropriations Act for 2023 that funds the federal government through September 2023**
 - Includes key improvements to the FDA’s review process for interchangeable biosimilars.

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