

Morgan Lewis



BLOCKBUSTER BIOLOGICS REVIEW ISSUE 20

Legislative and Regulatory Updates

Senator Reintroduces Biosimilar Red Tape Elimination Act to Push for Biosimilars to Become Interchangeable

- **In July 2023, Senator Mike Lee (R, Utah) reintroduced a bipartisan bill “The Red Tape Elimination Act,” a follow-up to his earlier submission to remove the class of biosimilars labeled as an “interchangeable biosimilar.”**
 - The new version of the bill would:
 - Amend the federal code to state that all biosimilars, upon approval, will be deemed interchangeable.
 - Remove the current requirement in the code that has been used to justify “switching studies.”
 - Require the FDA to conduct a private briefing if they want to require a “switching study” for a particular biosimilar.

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