

Morgan Lewis



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Legislative and Regulatory Updates

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- > **On May 25, 2022, Senator Tim Kaine (D-VA) introduced, with Senators Susan Collins (R-ME) and Maggie Hassan (D-NH), the Interchangeable Biologics Clarity Act**
 - > Objective is to more efficiently usher drugs to the market by making key improvements to the FDA review process for interchangeable biosimilars.
- > **On May 27, 2022, the Senate Committee on Health, Education, Labor and Pensions (HELP) released the latest version of its FDA user-fee reauthorization bill**
 - > Would allow for tentative interchangeable approvals and shared first interchangeable exclusivity for multiple first filers.

Contacts



Christopher J. Betti, Ph.D.
Chicago
T: +1.312.324.1449
christopher.betti@morganlewis.com



Maria E. Doukas
Chicago
T: +1.312.324.1454
maria.doukas@morganlewis.com



Kelly A. Plummer, Ph.D.
Chicago
T: +1.312.324.1490
kelly.plummer@morganlewis.com