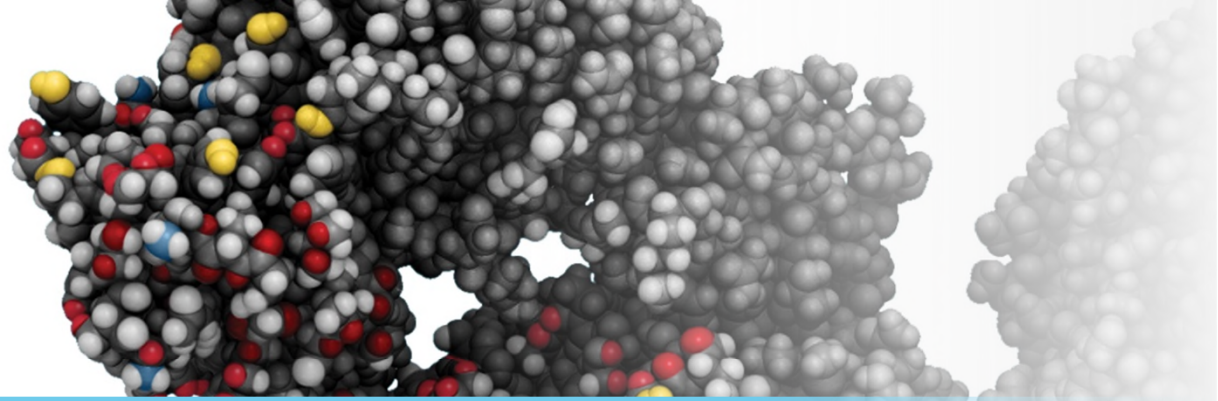
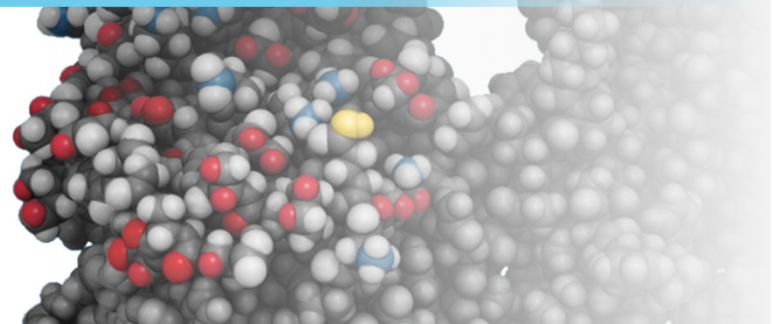
Morgan Lewis



BLOCKBUSTER BIOLOGICS REVIEW ISSUE 30

Legislative and Regulatory Updates



Senate Report Highlights Potential Biosimilar Reforms

- On February 17, 2026, Senator Cassidy, chair of the Senate Health, Education, Labor and Pensions (HELP) Committee released a report detailing potential legislative and regulatory reforms to modernize the FDA. The report could indicate potential policy riders that could be considered by Congress in connection with anticipated FDA user-fee reauthorizations in 2027.
- Within the proposed reforms, two focus on biosimilars:
  - *Reducing Evidentiary Burdens.* The report considers whether legislative action should be taken to codify or otherwise address indications from the FDA that certain biosimilar data requirements may in many cases be unnecessary, including (1) comparative clinical studies for biosimilarity determinations and (2) switching studies for interchangeability designations.
  - *Pathway Flexibility.* The report suggests that a new biologic approval pathway should be added to the FDA's authorities. This pathway would be a hybrid pathway between a full 351(a) biologic application and a 351(k) biosimilar and would permit partial reliance on a previous licensure, akin to the 505(b)(2) pathway for small molecules. This pathway could enable an abbreviated path for "biobetters."

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