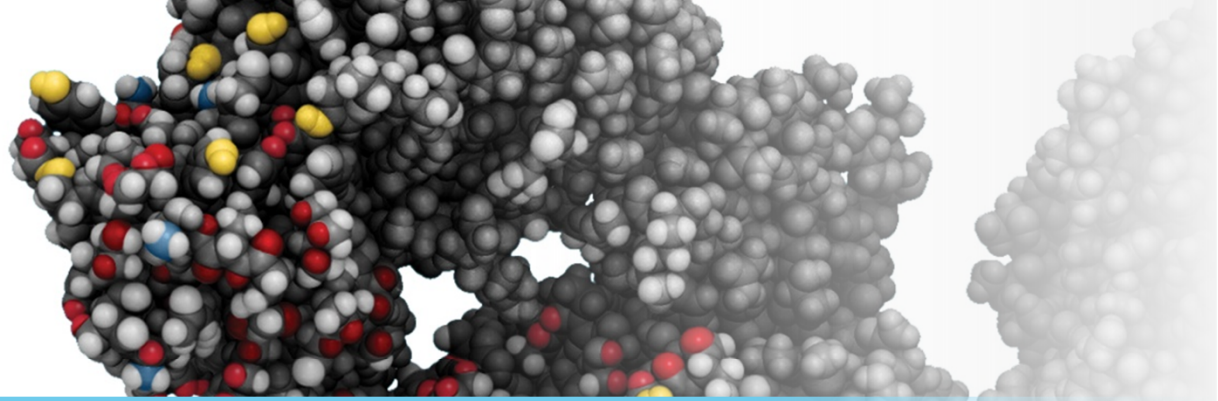
Morgan Lewis



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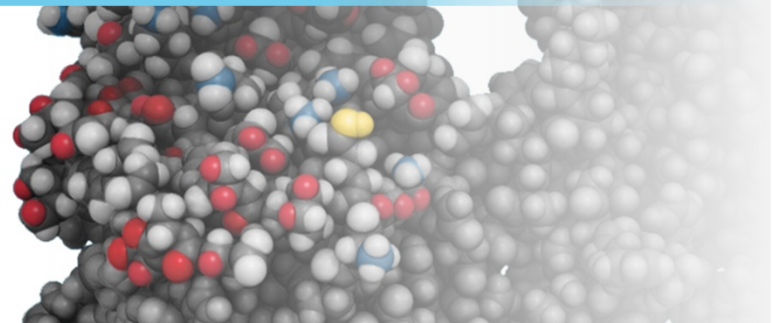
Legislative and Regulatory Updates



Representatives Introduce "Biosimilar Red Tape Elimination Act"

- On September 19, 2025, Representatives August Pfluger (R-Tex.) and Greg Landsman (D-Ohio) introduced the bipartisan Biosimilar Red Tape Elimination Act.
  - If passed, the Biosimilar Red Tape Elimination Act would automatically deem biosimilars interchangeable with their name-brand counterpart once the biosimilar receives FDA approval.
  - A similar bill was introduced in June 2025 in the Senate by Senators Mike Lee (R-Utah), Rand Paul (R-Ky.), Maggie Hassan (D-N.H.), and Ben Ray Luján (D-N.M.).

FDA Issues Draft Guidance Limiting Need for Comparative Efficacy Studies

- FDA recently published a draft guidance "***Scientific Considerations in Demonstrating Biosimilarity to a Reference Product: Updated Recommendations for Assessing the Need for Comparative Efficacy Studies***."
- The draft proposes eliminating the need for biosimilar sponsors to conduct and submit comparative efficacy clinical studies, providing a path for biosimilar sponsors to rely only on analytical, pharmacokinetic/pharmacodynamic (PK/PD), and immunogenicity data to inform biosimilarity determinations, when appropriate.
- The draft proposes **three parameters** in which this may be employed:
  - the reference and proposed biosimilars are manufactured from clonal cell lines, are highly purified, and are well-characterized analytically;
  - the relationship between quality attributes and clinical efficacy is generally understood and evaluable in the comparative analytical assessment; and
  - a human PK similarity study is feasible and clinically relevant.

FDA Signals Additional Ongoing Evolution of the Biosimilars Program

- Citing recent advancements in analyticial characterization, public statements from FDA leadership have signalled that ongoing streamlining of biosimilar evidentiary requirements is under consideration within FDA.
- FDA leadership has also signalled that it plans to finalize recommendations included in a 2024 draft guidance that moved away from requiring the conduct and submission of switching studies to establish a biosimilar as interchangeable with its reference product.

Contacts

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

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

Maarika L. Kimbrell
Washington, DC
T: +1.202.739.5348
maarika.kimbrell@
morganlewis.com

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

Margaret C. Harney
Chicago
T: +1.312.324.1727
margaret.harney@
morganlewis.com