Morgan Lewis

BLOCKBUSTER BIOLOGICS REVIEW ISSUE 31
Legislative and Regulatory Updates

Senate Committee on Health, Education, Labor and Pensions Advances Drug Disclosure and Biosimilar Bills

- On June 17, 2026, the US Senate Committee on Health, Education, Labor and Pensions (HELP) advanced two bipartisan bills concerning drug disclosure and biosimilars to the full Senate.
  - The **Medication Affordability and Patent Integrity Act**, if passed, would require applicants for the Food and Drug Administration (FDA) approval of drugs to certify that information submitted to the FDA and the US Patent & Trademark Office is consistent.
  - The **Biosimilar Red Tape Elimination Act**, if passed, would automatically deem biosimilars interchangeable with their name-brand counterpart once the biosimilar receives FDA approval.

New Biosimilar Guidance: Container Closure System and Device Constituents

- In July 2026, the FDA published a draft guidance titled "Biosimilar and Interchangeable Biosimilar Products: Considerations for Container Closure Systems and Device Constituent Parts." Highlights of the guidance include:
  - A reminder that the proposed presentation of a product must not include a condition of use (or dosage form, strength or route of administration) that has not been previously approved from the reference product.
  - However, within these limitations, the FDA guidance suggests that container closure and device constitutent components of a biosimilar product may differ from the reference product, if the applicant can establish that potential use errors related to the design differences do not preclude the product otherwise meeting the biosimilar or interchangeable standards.
  - The FDA recommends an assessment of the biosimilar and reference products with respect to (1) a physical comparison of the device constituent parts, (2) a comparative task analysis, and (3) a labeling comparison, with a subsequent focus on any resulting differences that may impact a design feature relied upon by a user to perform a critical task in the use of the 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