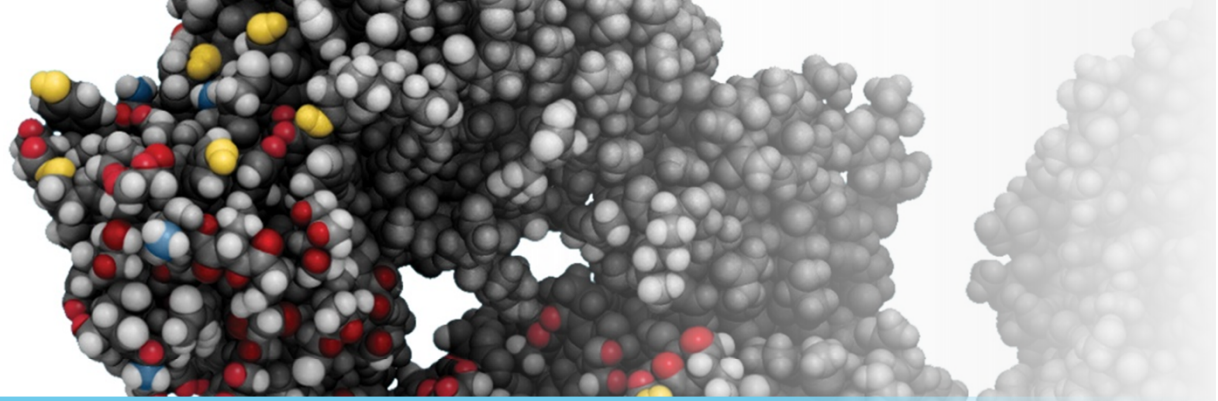
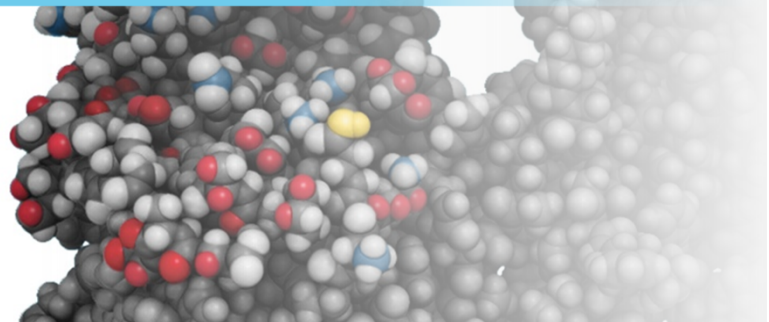
Morgan Lewis



BLOCKBUSTER BIOLOGICS REVIEW ISSUE 23

Legislative and Regulatory Updates



Senators Reintroduce Bill For "Increasing Access To Biosimilars Act" To Encourage Medical Providers To Prescribe Biosimilars

- **In March 2024, senators Michael Bennet (D-Colo.) and John Cornyn (R-Texas) re-introduced the bipartisan "Increasing Access to Biosimilars Act" to boost competition and increase incentives for medical providers to prescribe biosimilars over their more expensive reference agents.**
  - Senators Bennet and Cornyn first introduced this bipartisan bill in April 2021. A similar House bill (HR 1352) was introduced in March 2023.
  - Currently, Medicare Part B medical providers receive higher reimbursement rates for biologic products than for lower-cost biosimilars, resulting in increased out-of-pocket costs for Medicare beneficiaries.
  - This legislation aims to increase patient access to lower-cost biosimilars through the creation of a voluntary shared savings demonstration program in Medicare Part B. The demonstration program is to be a three-year program in which Medicare provides medical providers an additional payment for prescribing lower-cost biosimilars products to Medicare beneficiaries. The extra payments to medical providers won't increase the out-of-pocket expenses for patients.
  - This legislation aims to increase competition, encourage medical providers to prescribe biosimilars, and increase patient access to more affordable drugs that provide the same lifesaving benefits with lower out-of-pocket costs.

Advertising and Promotion of Biologics and Biosimilars

- In April 2024, FDA published a new draft guidance on promotional labeling and advertising considerations for biological reference products, biosimilar products, and interchangeable biosimilar products, replacing a previously published draft on the same subject. The guidance describes specific issues that may be applicable to these products to help ensure that related promotional labeling and advertising meets the FDA's standard of accuracy, truthfulness, and being non-misleading.
- Topics covered in the guidance include:
  - Accurate descriptions of reference products and biosimilar products;
  - Inclusion of studies conducted by a reference-product sponsor in biosimilar sponsor labeling and advertising;
  - Inclusion of biosimilar sponsor data submitted to the FDA in the BLA but not included in the label;
  - Comparisons of reference products and biosimilar products in promotional materials; and
  - Practices when both biosimilar and interchangeable biosimilar products are approved for the same reference product.
- Additional information regarding this guidance can be found at this *As Prescribed* post.

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