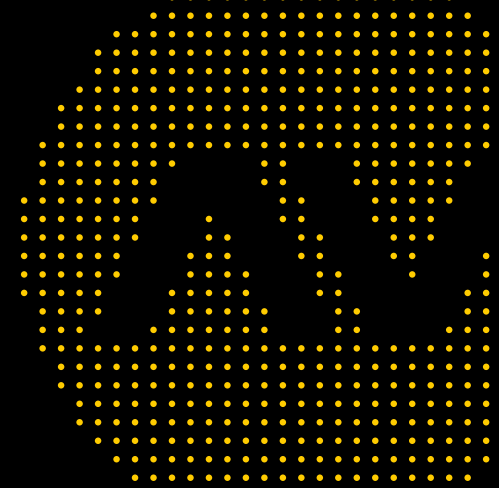


Biosimilars Policy Brief



HEALTH POLICY BRIEF:

Biosimilar competition leads to lower prices and lower spending.¹ Policy solutions must encourage biosimilar adoption by providing the US Food and Drug Administration (FDA) with the tools and authorities necessary to improve its biosimilar approval process and by mitigating brand manufacturer tactics that discourage the uptake of biosimilar products. Thoughtful solutions will help drive competition and lower prices.

The Issue: Biologic products – larger molecules that are often grown with biological processes, like Humira – face far less effective competition than generic “small molecule” drugs like Lipitor, which are chemically synthesized.

The biosimilar approval pathway, created in 2010 by the Biologics Price Competition and Innovation Act (BPCIA) within the Affordable Care Act, was intended to bring about low-cost competitors to biologic products much in the same way that the Hatch-Waxman Act created the generic, small molecule drug market in America. Since implementation, several structural challenges have emerged and continue to hinder the approval and utilization of biosimilar products that could offer significant savings to patients, employers, and taxpayers.

The Evidence: Increased competition generally drives prices down. The Drug Price Competition and Patent Term Restoration Act of 1984, often referred to as the Hatch-Waxman Act, created an abbreviated pathway for FDA approval of generic drugs in exchange for patent and exclusivity rights for brand-name drug products. In 2020, generic prescriptions represented 90% of all prescriptions but only 18% of drug expenditures, saving the US health care system more than \$300 billion dollars in that year alone.^{2, 3}

The BPCIA created an FDA approval pathway for biosimilars. Unlike generics, which can be exact chemical matches to their brand-name counterparts, it is more difficult to establish bioequivalence between brand-name “reference biologics” and biosimilars. FDA approves biosimilars once they are shown to be highly similar to the reference biologic and do not produce any clinically meaningful differences.⁴ BPCIA also requires manufacturers to meet additional requirements to be deemed interchangeable– a designation that, depending on state law, allows pharmacists to substitute the brand reference biologic with the biosimilar at the pharmacy counter in the same manner as generic drugs are substituted for brands.

The potential for savings from biosimilars is significant. Brand-name biologics represented only 2% of total prescriptions and more than half of drug spending.⁵ Early estimates of savings from biosimilars ranged from \$24 to \$150 billion in the US from 2017 to 2026.⁶ Actual uptake has lagged behind these savings estimates. By 2020, twenty-two biosimilars had launched in the US market, but sales for these products represented only 20% of volume sold and only about 16% of total biologic sales.⁷ In Europe, more than 50 biosimilars have been approved and most of them



**IN 2020, GENERIC PRESCRIPTIONS REPRESENTED
90% OF ALL PRESCRIPTIONS BUT ONLY 18%
OF DRUG EXPENDITURES, SAVING THE
US HEALTH CARE SYSTEM MORE THAN**

\$300 BILLION

have successfully launched commercially.⁸ Importantly, these European biosimilars have launched with discounts of frequently more than 70% compared to their reference products and have seen broad utilization by prescribers and patients.⁹

There are a variety of reasons why the biosimilar market in the US has not lived up to its expected potential. Patent practices by brand-name manufacturers – including patent thickets, where brand-name manufacturers obtain hundreds of patents on a single product – present a significant barrier to biosimilar commercialization. Once launched, biosimilars also face two distinct challenges with provider and patient uptake. Restrictive contracts with insurers keep biosimilars off formulary. For example, Janssen, the maker of Remicade, was sued by Pfizer for using this tactic to block biosimilar competition in a lawsuit that dragged on for nearly four years before both parties settled outside of court—on undisclosed terms.¹⁰ Finally, there is often reluctance from providers to shift stabilized patients taking brand reference biologics to biosimilars and many are skeptical about the idea of automatic substitution of biosimilars for brand reference biologics.¹¹

Other barriers to uptake include the following:

- **Complexity of Manufacturing:** The complicated and costly process for manufacturing biosimilars greatly reduces the number of potential manufacturers with the technical expertise and market capitalization to make a product

that would pass the FDA's exacting standards. One of the main outcomes of the manufacturing complexity related to biosimilars is that a separate and robust industry of biosimilar developers with large-scale manufacturing capacity has not emerged since the 2010 passage of the BPCIA.

- **Interchangeability Designation Challenges:** Unlike brand-name small molecule products and their generic counterparts, originator biologics and biosimilar products cannot be automatically substituted at the pharmacy counter without the biosimilar receiving an interchangeability designation. This is further complicated by the fact that originator biologics and biosimilars are marketed as if they are entirely different products. To date, no FDA-approved, non-insulin biosimilar is on the market with this designation.¹² Without such designation, the biosimilar cannot automatically be substituted for the originator biologic at the pharmacy counter and physician prescribing of biosimilars is hampered.
- **Misaligned Payment Incentives:** In both public and private programs, biologic manufacturers often engage in so-called “rebate traps” by conditioning rebates on exclusivity of sales to curb biosimilar uptake. This strategy makes it costlier for an insurer to cover a biosimilar.¹³

The Solutions: A number of policy solutions are available to the FDA, the Centers for Medicaid and Medicare Services (CMS), and to Federal and State lawmakers to help encourage development and uptake of biosimilars.



- Congress and FDA should revisit the need for naming conventions used to distinguish biosimilars.
- FDA should utilize its full regulatory flexibility to ensure that safe and effective biosimilars are not being held to higher standards than the reference biologic products they are intended to compete with. This includes the standards necessary to show interchangeability, if that pathway is going to be used.
- In Medicare Part B, the Federal government could take steps to encourage the use of lower-cost biosimilar products. Options include:
 - Change payment structures to incentivize biosimilar use, such as increasing reimbursements for biosimilars relative to reference biologics to encourage provider adoption.
 - Combine reimbursement codes for reference biologic products and biosimilars similar to how generics are treated in Part B.
 - Require that the least costly option be used in Part B first before trying more expensive treatments.¹⁴
- Congress could direct the Federal Trade Commission to proactively investigate the use of anticompetitive behaviors in the biologics market. This includes pay-for-delay deals between reference products and biosimilar manufacturers, rebating practices that discourage uptake (often called rebate traps), and misleading advertising by biologics manufacturers. Advertising enforcement should include coordination with FDA.
- State policymakers should ensure that substitution laws provide maximum flexibility for pharmacists to substitute the lowest cost biologic for patients at the pharmacy counter.

Endnotes

1 Frank R, Shahzad M, Kesselheim A, Feldman W. "Biosimilar Competition: Early Learning." *Health Economics* Vol. 31 (4, 647 – 663). 12 January 2022. Retrieved from <https://onlinelibrary.wiley.com/doi/10.1002/hec.4471>

2 <https://accessiblemeds.org/sites/default/files/2021-10/AAM-2021-US-Generic-Biosimilar-Medicines-Savings-Report-web.pdf> (Page 6)

3 <https://healthpolicy.usc.edu/research/u-s-consumers-overpay-for-generic-drugs/>

4 <https://www.fda.gov/drugs/biosimilars/biosimilar-and-interchangeable-products>

5 <https://accessiblemeds.org/sites/default/files/2021-10/AAM-2021-US-Generic-Biosimilar-Medicines-Savings-Report-web.pdf> (Page 19)

6 <https://www.rand.org/pubs/periodicals/health-quarterly/issues/v7/n4/03.html>

7 <https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/iqvia-institute-biosimilars-in-the-united-states.pdf>

8 <http://www.gabionline.net/Biosimilars/General/Biosimilars-approved-in-Europe>

9 <http://www.gabionline.net/Biosimilars/General/Huge-discounton-biosimilar-infliximab-in-Norway>

10 <https://www.fiercepharma.com/pharma/pfizer-johnson-johnson-agree-to-a-settlement-terms-undisclosed-biosimilar-lawsuit>

11 https://www.norc.org/PDFs/Biosimilars/20210405_AV%20-%20NORC%20Biosimilars%20Final%20Report.pdf

12 Cyltezo, a Humira biosimilar, received interchangeability designation but won't be commercially available until at least 2023 due to a patent settlement agreement.

13 <https://jamanetwork.com/journals/jama/fullarticle/2625049>

14 <https://www.crfb.org/papers/injecting-price-competition-medicare-part-b-drugs>