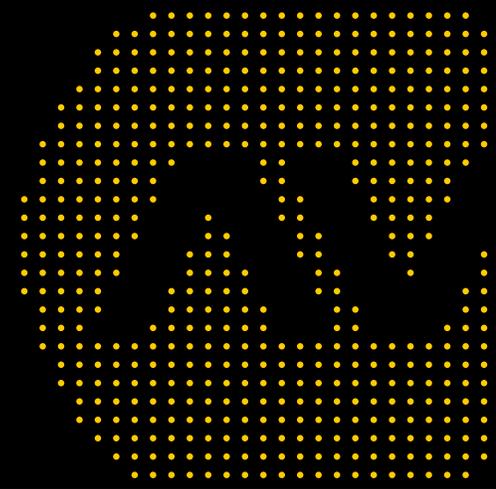


Biosimilars Policy Brief



HEALTH POLICY BRIEF

Policy solutions must encourage biosimilar adoption by providing the US Food and Drug Administration (FDA) tools and authorities necessary to improve its biosimilar approval process and by mitigating brand manufacturer use of 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. One reason for this is that biologics are typically more difficult to replicate and manufacture than traditional drugs. The biosimilar approval pathway was created by the Biologics Price Competition and Innovation Act (BPCIA), which passed as part of the Affordable Care Act in 2010 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. However, several structural challenges have emerged over the last decade that continue to hinder the approval and utilization of biosimilar products, and in turn, significantly reduce potential 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 2018, generic prescriptions have grown to represent roughly 90% of all prescriptions written, saving the US health care system nearly \$300 billion dollars.

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 this bioequivalency and interchangeability between biologics, known as reference biologics, and biosimilars. Because of this, FDA approves biosimilars once they are shown to be highly similar to their reference brand-name biologic and do not produce any clinically meaningful differences. BPCIA also created a second pathway – the interchangeable biologic – which, if a biosimilar manufacturer shows that there is no risk in switching between one biologic product and another biologic product, allows pharmacists to substitute the interchangeable product at the pharmacy counter, subject to state law.

The potential for savings from biosimilars is significant. While brand-name biologics represented only 2% of total prescriptions in 2017, they represented 37% of net drug spending. Early estimates of savings from biosimilars ranged from \$24 to \$150 billion in the US from 2017 to 2026. Actual uptake has lagged behind these savings estimates. By the end of 2018, seven biosimilars had launched in the US market, but sales for these products represent less than 1% of all US biologic sales volume. In Europe, more than 50 biosimilars have been approved and most of them have successfully launched commercially. Importantly, these European biosimilars have launched with discounts up to 70% compared to their reference products and have seen much broader utilization by prescribers and patients.



**BIOSIMILARS COULD POTENTIALLY
SAVE THE US HEALTH CARE SYSTEM
UPWARDS OF \$54 BILLION DOLLARS
OVER THE NEXT 10 YEARS**

\$54 BILLION

There are several reasons for this. While the FDA has approved an increasing number of products in recent years, patent practices by brand-name manufacturers – often referred to as patent thickets where brand-name manufacturers obtain hundreds of patents on a single product – present a significant barrier to biosimilar commercialization. By 2020, only 15 of the 26 FDA-approved biosimilars have launched commercially. Once launched, biosimilars also face two distinct challenges with provider and patient uptake. First, reference biologic products that have established markets may be able to use restrictive contracts with insurers to keep biosimilars off formulary. Janssen, the maker of Remicade, is currently being sued by Pfizer for using this tactic to block biosimilar competition. Second, there may be reluctance from providers to prescribe and patients to use these products either because of misinformation or distrust of the highly similar nature of the product. This may be exacerbated by confusion over statutory interchangeability designations or FDA-driven suffixes added to biosimilar product names.

The Solutions: A number of policy solutions are available both 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 as well as the interchangeability designation as a whole, which does not exist in other markets. Research has shown that these conventions can create confusion among providers and patients.
- 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. One option would be to provide a reimbursement increase for biosimilars to encourage provider adoption. A version of this has been proposed in S. 2543 which would provide a temporary increase of 2% over 5 years. Another option would be to combine reimbursement codes for reference biologic products and biosimilars similar to how generics are treated in Part B. Finally, Congress could require that the least costly option be used in Part B first before trying more expensive treatments.
- Congress could direct the Federal Trade Commission (FTC) 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.