# Biosimilars

**AV Health Policy Brief**

Prescription drugs and therapies must be affordable and accessible for patients, employers, and taxpayers.

**THE ISSUE:** Biologic products, or biosimilars – larger molecules that are often grown with biological processes, like Keytruda (used for cancer) – 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 lower-cost competitors to brand biologic products (biosimilars) much in the same way that the Hatch-Waxman Act created the generic, small molecule drug market in America.

The Food and Drug Administration (FDA) approves biosimilars once they are shown to be highly similar to their reference biologics and do not produce any clinically meaningful differences. Unlike generics, which can be exact chemical matches to their brand-name counterparts, brand-name "reference biologics" and biosimilars have minor differences, which are not clinically meaningful, due to natural variability. Reference biologics and biosimilars are held to high regulatory standards – most trials supporting the FDA approval of biosimilars appear to be as rigorous as and often larger, longer, and more costly than pivotal trials for new molecular entities. 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. In June 2024 the FDA released updated draft guidance that removes the requirement of a switching study to demonstrate biosimilar interchangeability. Addressing just one of the many barriers that hinders the approval and utilization of biosimilars.

**THE EVIDENCE:** The potential for savings from biosimilars is significant and has not been fully realized. Biologics comprise only about 3% of prescriptions in the U.S. but more than half the spending. Early estimates of potential savings from biosimilars range from $24 to $150 billion in the U.S. between 2017 to 2026. Actual savings, to date, have lagged behind these estimates. Unlike the EU, which has about 90 approved biosimilars on the market, the U.S. has about 40 biosimilars on the market (as of 2024).

There are a variety of reasons why the biosimilar market in the US has not lived up to its expected potential, including:

- ***Patent Thickets:*** Manufacturers employ complex patent thickets on biologics to extend monopoly protections and keep competitors out of the market. Patent thickets consist of patents for the active ingredient in addition to secondary patents on manufacturing processes, methods of use, delivery devices, and other aspects of a product. Because of the uncertainty and litigation cost for biosimilar manufacturers to challenge each patent, competitors often opt to settle with the originator manufacturers instead.
- ***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. In Medicare, the program design has blunted price competition, creating incentives for use of the originator biologics.
- ***Interchangeability Designation Challenges:*** Pharmaceutical companies are required to perform additional "switching studies" to receive an interchangeability designation. Without such designation, the biosimilar cannot automatically be substituted for the originator biologic at the pharmacy counter. Implementation of FDA's updated draft guidance to remove the switching study requirement reduces some of these challenges.
- ***Complexity of Manufacturing:*** The complicated and costly process for manufacturing biosimilars reduces the number of potential manufacturers with the technical expertise and market capitalization to develop biosimilars.

**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 remove unnecessary naming policies that cause confusion among users, including the 4-letter suffixes given exclusively to biosimilars for the sole purpose of distinguishing them from their originators.
- Congress should codify FDA's guidance that no longer requires an additional clinical trial to demonstrate a biosimilar's interchangeability with its reference product. Legislation should continue to provide flexibility to FDA to require these studies in certain instances.
- Regulators should consider policies supporting indication extrapolation, such as a default rule approving biosimilars for all reference biologic indications. This could streamline FDA's review of biosimilar applications and enhance patient access.
- In Medicare Part B, the Federal government should take steps to encourage the use of lower-cost biosimilar products. Options include:
  - Implement a budget-neutral policy by changing 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.
- Congress should address patent thickets by minimizing the use of terminal disclaimers by capping the number of patents that brand-name biologic manufacturers can assert against biosimilar firms.
- Congress should 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.
- The FDA should publish timely updates to the Purple Book and ensure that the Purple Book includes more complete data on FDA-licensed biological products, such as patents and exclusivities from the time of licensure going forward.
- State policymakers should ensure that substitution laws provide maximum ability for pharmacists to substitute the lowest cost biologic for patients at the pharmacy counter.