

The U.S. Biosimilars Market  
Continues to Increase  
Competition and Savings,  
but Reforms are Needed to  
Realize Its Full Potential

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Since Congress enacted the Biologics Price Competition and Innovation Act (BPCIA) in 2010, biosimilars have bolstered competition and increased options for patients. The BPCIA created an abbreviated approval pathway for biosimilars while also providing 12 years of data protection following the first licensure of innovative biologics, balancing the goal of reducing costs with the need to maintain incentives for the development of new biologic medicines. Since the enactment of the BPCIA, a robust biosimilars market has emerged in the U.S., yielding increased competition and substantial savings for patients, employers, insurers and the government.

As of the end of 2022, the U.S. Food and Drug Administration (FDA) has approved a total of 40 biosimilars. There are currently 27 biosimilars on the market competing against 10 brand biologics, with at least seven more biosimilars anticipated to launch in 2023.<sup>1,2</sup> Among these launched biosimilars are the first interchangeable products, which may be substituted at the pharmacy counter without intervention from the prescriber, similar to many generic drugs.

Owing to this successful framework, analysts note that we have truly reached “an inflection point” in the U.S. biosimilar marketplace, as competition has become increasingly robust and initial barriers to adoption and uptake are subsiding.<sup>3</sup> As more biosimilars and interchangeable biosimilars are anticipated to enter the market in the years ahead, competition and savings are expected to grow substantially. But more can be done to realize the full potential of the biosimilar marketplace by addressing market distortions that impede more robust competition and savings from biosimilars, particularly when they could offer lower out-of-pocket costs for patients.

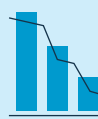
## **BIOSIMILARS ARE REDUCING PRICES, ACHIEVING MARKET UPTAKE AND INCREASINGLY PRODUCING COST SAVINGS**

Increased launches and competition have led to cumulative savings in total drug spending for classes with biosimilar competition estimated at \$21 billion over the past six years.<sup>4</sup> Importantly, biosimilar entry also resulted in an estimated \$238 million in out-of-pocket savings for patients in Medicare and employer plans in 2020.<sup>5</sup>

In the market for small molecule medicines, the introduction of generics often generates savings in the system as patients are swiftly transitioned to generics and use of the original brand product rapidly declines. However, in the biologics market, the introduction of biosimilars commonly produces a more dynamic effect, resulting in savings from both brands and biosimilars as brands often compete with biosimilars to retain market share.

Demonstrating this competitive dynamic, an Xcenda analysis of Medicare Part B payment rates found substantial reductions in the average sales price (ASP) of brand biologics facing competition from biosimilars (see table below). For example, one brand biologic lowered its ASP by 57% and was able to retain majority market share even with significant competition from biosimilars. On the other hand, another brand biologic that lowered its ASP by 1% lost significant market share to biosimilars, which collectively garnered 82% of the market by the middle of 2022.

### **What is ASP?**



Many biologics are reimbursed under Medicare’s average sales price (ASP) formula in Part B. As ASP is a measure of what commercial purchasers pay for drugs, it also reflects saving occurring in the health care market more broadly.



## Trends in Medicare Part B Payment Rates for Brand Biologics and their Biosimilar Products

	First biosimilar entry	Change in brand biologic's ASP since biosimilar entry (through 2022 Q3)	Change in biosimilar's ASP since entry of first biosimilar (through 2022 Q3)	Biosimilar market share (2022 Q2)
<b>Product A</b>	2015 Q3	-1%	-60% to -73%	82%
<b>Product B</b>	2017 Q1	-57%	-41% to -62%	42%
<b>Product C</b>	2018 Q3	-36%	-38%	32%
<b>Product D</b>	2018 Q4	-66%	-56% to -65%	42%
<b>Product E</b>	2019 Q4	-14%	-52% to -63%	82%
<b>Product F</b>	2019 Q4	-21%	-41% to -69%	80%
<b>Product G</b>	2020 Q2	-13%	-44% to -58%	64%

As a result, both brand biologics and biosimilars have experienced significant decreases in their ASPs, with many brand biologic ASPs decreasing by more than 45% following the launch of a biosimilar. In fact, the ASPs of the vast majority of brand biologic products with biosimilar competition have decreased at an annual rate of 4% to 21%, while biosimilar ASPs have declined 9% to 24% over the last few years.<sup>6</sup>

To date, savings from biosimilars have primarily been realized in the market for physician-administered medicines. This is because many of the first biosimilars to launch in the United States have competed against brand biologics that treat certain types of cancers and immunological conditions, which typically require administration by a health care professional in an outpatient clinic or infusion center. As more biosimilars and interchangeable biosimilars are expected to enter the market to compete with brand biologics that are self-administered and dispensed from a pharmacy, the impact and savings of biosimilar competition are projected to grow in the years ahead.



## MARKET DISTORTIONS IMPEDE MORE EXPEDIENT UPTAKE OF BIOSIMILARS

### *Market Distortions Associated with Medicines Administered in Hospital Outpatient Settings*

While evidence clearly demonstrates a well-functioning and robustly competitive biosimilar marketplace is increasingly at work today, uptake of biosimilars may vary significantly by setting, particularly for physician-administered medicines.<sup>7 8 9 10</sup> As awareness and comfort with biosimilars have grown tremendously among both physicians and patients, this variability indicates that other factors may be influencing hospital-based purchasing decisions beyond obtaining the lowest-priced option for delivering appropriate care to patients.<sup>11</sup>

Evidence suggests the 340B Drug Pricing Program may be interfering with the growth of biosimilar competition in the market today and distorting the market in the process. The program was designed to help improve access to medicines for vulnerable, low-income patients through discounts to specific qualifying hospitals and federally funded clinics. Unfortunately, the program has strayed far from its purposes with more and more hospitals using these discounts for themselves. Research shows 340B hospitals are more likely to prescribe more expensive medicines and significantly mark up the price of medicines.<sup>12</sup> This is in part because participation in the 340B program enables hospitals to keep the difference between the discounted 340B price and the reimbursement amount, which, in general, allows covered entities to earn more revenue from medicines with higher prices. For example, 340B hospitals received nearly five times what they paid, on average, to acquire oncology medicines through the 340B program.

As biosimilars generally enter the market with lower list prices compared to their corresponding brand biologic, they may offer smaller margins to hospitals than higher list price alternatives, which may influence patient access and out-of-pocket costs. In fact, a Milliman analysis found that 340B hospitals have lower utilization of biosimilars than non-340B hospitals among their commercially insured patients, potentially leading to higher patient out-of-pocket costs.<sup>13</sup> The study found that among commercially insured patients who paid cost sharing, those who received biosimilar products had 16% lower out-of-pocket costs compared to patients who received the brand biologic at 340B hospitals in 2020. In other words, if 340B hospitals had biosimilar utilization rates that were in line with non-340B hospitals, patient out-of-pocket costs at 340B hospitals would generally have been lower.

Slower uptake of biosimilars at 340B hospitals indicates that 340B-driven market distortions are encouraging the prescribing of medicines with higher list prices and discouraging uptake of biosimilars in those settings.<sup>14 15 16 17 18</sup> It is particularly concerning that the potential for greater 340B hospital mark-ups and profits is undermining the competitive market for biosimilars and resulting in higher out-of-pocket costs for some patients.

### ***Market Distortions Associated with Medicines Dispensed from a Pharmacy***

2021 marked a significant milestone with the launch of the first interchangeable biosimilar, an insulin product. As insulin is most often self-administered by patients, it is generally dispensed from a retail pharmacy. Due to the potential for interchangeable products to be automatically substituted at the pharmacy, the impact of competition from interchangeable products has been anticipated to drive substantial savings.

However, the market dynamics surrounding the launch of this first interchangeable insulin demonstrate there are significant barriers patients must overcome to access these products, despite the potential for biosimilars to lower out-of-pocket costs. The three largest pharmacy benefit managers (PBMs) control 80% of all prescriptions and own, or are owned by, some of the largest health insurers in the country. As a result, PBMs have significant leverage over which medicines are covered and how much patients pay out of pocket.

According to experts, PBMs may have incentives to prefer medicines with high list prices and high rebates.<sup>19 20 21</sup> These dynamics are thought to have prompted the manufacturer of the first FDA-approved interchangeable insulin to simultaneously introduce two identical versions—a branded version with a higher list price and rebates, and an unbranded version with a lower list price (and low rebates), giving payers the option of which to cover.<sup>22 23</sup> Not one of the three largest PBMs included the lower list price version as a preferred option on their 2022 standard formulary.<sup>24</sup> The situation will persist in 2023 as the three largest PBMs continue to prefer products with higher list prices and high rebates over lower list price versions, even though coverage of these products could dramatically lower out-of-pocket costs for many patients with deductibles or coinsurance.<sup>25</sup> As pharmacies cannot substitute a biosimilar if that biosimilar is excluded from coverage by the PBM, these dynamics can impose a significant barrier to the uptake of interchangeable products and the potential for these medicines to lower patient out-of-pocket-costs.<sup>26</sup>

***“PBMs have an incentive for manufacturers to keep list prices high, since the rebates, discounts and fees PBMs negotiate are based on a percentage of a drug’s list price—and PBMs retain at least a portion of what they negotiate.”<sup>32</sup>***

**—Senate Finance Committee**

This year, the anticipated launch of multiple biosimilars competing against a widely used biologic product used to treat autoimmune conditions is expected to have a significant impact on the market, particularly since multiple entrants are expected to obtain interchangeability designations.<sup>27</sup> However, the recent launch of the first of these biosimilars (which also launched with two versions: one with a high list price and high rebates and one with a lower list price and low rebates) highlights the distortions that exist in the market today, as biosimilar manufacturers fear they may not be able to successfully compete in the market if they cannot provide options that align to PBM preferences.<sup>28</sup> Meanwhile, the largest PBMs thus far have declined to provide more favorable coverage for the biosimilar over the brand biologic, suggesting PBM preferences may continue to distort the market in the years ahead.<sup>29</sup> Reforms to address PBMs' incentives to prefer higher-priced products are needed to bolster the impact of biosimilar competition and increase access to medicines that can lower out-of-pocket costs for patients.

## THE POTENTIAL FOR BIOSIMILARS TO CONTINUE TO DRIVE SAVINGS IS THREATENED BY THE INFLATION REDUCTION ACT

Unfortunately, in addition to the barriers to biosimilar uptake described thus far, a new threat has now emerged: the Inflation Reduction Act's (IRA's) drug price setting provisions. These IRA provisions threaten to undermine the progress that has been made in building a robust biosimilar marketplace and its potential to drive future cost containment across our health care system, for Medicare and for patients. Under the IRA, the Secretary of Health and Human Services is directed to select certain brand drugs and biologics in both Medicare Part B and Part D for government price setting. Biologics that have been on the market for 11 years or longer may be selected for government price setting (at a price known as the maximum fair price, or MFP) as long as they do not have a marketed biosimilar competitor.

Though Congress enacted a "Special Rule" enabling certain biosimilar manufacturers to obtain a "pause" before the brand biologic product is selected for price-setting to allow time to launch before the set price is imposed, the timelines under the "pause" may still be insufficient to provide predictability for biologic and biosimilar manufacturers. Biosimilar development can take seven to eight years and an investment of \$128 million to \$320 million, adjusted for inflation.<sup>30</sup> Given the complexity of developing and launching biosimilars within the timeframes specified in the IRA, even with the "pause" there may be circumstances where the biosimilar manufacturer would need additional time to launch beyond the two years after approval allowed under the "pause." If the brand biologic has its price set before the biosimilar can launch, the biosimilar would be entering a market where it must compete against a biologic with an aggressively reduced price. By decreasing the ability of the biosimilar manufacturer to recoup its investment, this scenario disincentivizes the continued development of future biosimilars.

Under the IRA, biosimilar manufacturers are not able to predict, with any accuracy, which biologics will be subject to price setting, creating significant uncertainty regarding whether there will be an opportunity to recoup the investments required to develop a biosimilar competitor. The IRA substitutes price setting for market competition and upends the incentives for the development of biosimilars. Chilling biosimilar development at a time when the marketplace is poised to demonstrate the value of competition in controlling health care costs is shortsighted and threatens the projected savings for the years ahead.

## WE NEED POLICY SOLUTIONS TO ENSURE A ROBUST BIOSIMILAR MARKETPLACE MOVING FORWARD

Over the next five years, savings attributable to biosimilars are projected to exceed \$180 billion, a more than four-fold increase from the last five years.<sup>31</sup> However, future savings depend on a variety of factors that may influence the evolving landscape—including many of the misaligned payer incentives which impede uptake of biosimilars and the threat of the IRA chilling biosimilar competition in the years ahead. In order to harness the full potential of the biosimilars marketplace and realize the savings they offer to our health care system and patients, we need a balanced approach that reduces barriers to uptake of biosimilars and continues to foster a competitive biologics and biosimilars marketplace.

*Further focus and attention in the following areas are needed to continue to foster a robust biosimilar market:*

- 1. We need to reduce perverse incentives driven by the 340B program.** Policymakers should reform the 340B program to ensure patients benefit more directly from the discounts provided by manufacturers and that the program is more focused on helping rural and safety net providers. This will not only help patients as intended but can also help reduce the financial incentives which may discourage use of biosimilars.
- 2. Meaningful reforms to realign PBM incentives may also reduce barriers to biosimilar uptake and promote access and competition.** To address misaligned incentives which may lead PBMs to favor medicines with high list prices and high rebates, PBMs should be prohibited from receiving compensation calculated as a percentage of a medicine's price. Instead, PBMs should receive flat fees based on the services they provide. Requiring the rebates, discounts and other price concessions that PBMs receive from pharmaceutical manufacturers to be passed on to patients at the point of sale also realigns the incentives that may encourage PBMs to favor higher-priced medicines. It also ensures that patients receive the benefit of those negotiated discounts when paying their cost sharing, the way they do with every other medical or provider service for which they must pay an out-of-pocket cost.
- 3.** To help ensure the preservation of the competitive biosimilar marketplace, CMS should **implement the “Special Rule” in the IRA using clear and consistent criteria** and with as much flexibility as possible.
- 4.** Lastly, to continue to foster the rapid emergence of the robust market for biosimilars we are seeing today, **we need to maintain a balanced approach to reimbursement policy to ensure there are adequate incentives for continued innovation and facilitating patient choice.**

In enacting the BPCIA over a decade ago, U.S. policymakers rightly sought to balance increased competition with policies that support the United States' leading role in finding new treatments for patients. By allowing the market to continue to evolve and enacting policies that support this evolution, we'll continue to see biosimilars' benefits for patients and society.

Learn more at [PhRMA.org/Biosimilars](https://PhRMA.org/Biosimilars)

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