

# THE U.S. MARKET FOR BIOSIMILARS AND BIOLOGICS MEDICINES

Since Congress enacted the Biologics Price Competition and Innovation Act (BPCIA) in 2010, biosimilars have become an important way to bolster competition and increase options for patients. The BPCIA created an abbreviated approval pathway for biosimilars while 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 innovative biologics. Since enactment of the BPCIA, a robust biosimilars market has emerged in the U.S., yielding increased competition and substantial savings for patients and the government. Here's what you should know about the biosimilar market today:

## **While the BPCIA is just over a decade old, it's clear the legislation has been a success in spurring competition in the biologics marketplace.**

Owing to the ongoing implementation of the BPCIA framework, the number of biosimilar approvals in the U.S. biosimilar market has grown faster than the EU biosimilar market over a comparable period of time. In the six years following the EU's first biosimilar approval, there were a total of 11 approved biosimilars.<sup>1,2</sup> By contrast, the U.S. Food and Drug Administration (FDA) has approved 31 biosimilars in the six years following the first biosimilar approval including the first interchangeable biosimilar.<sup>3</sup> As of September 2021, there are 21 biosimilars on the market in the U.S. competing against 8 brand biologics. And there are 9 additional FDA approved biosimilars due to come to market over the next several years.<sup>4</sup>

The Biosimilar User Fee Act (BsUFA) has been vital to the regulatory review of biosimilar and interchangeable biosimilar products in the U.S. As a result of BsUFA, there is tremendous potential for biosimilars to continue to drive competition and savings in the years ahead with nearly 100 biosimilars in development for which sponsors are paying BsUFA fees as of June 2021.<sup>5</sup>

Owing to this successful framework, analysts have noted that we have truly reached "an inflection point," as competition is becoming increasingly robust and initial barriers to adoption and uptake are subsiding.<sup>6</sup>

## **Biosimilars are reducing prices, achieving market uptake, and are increasingly producing cost savings.**

The biosimilars marketplace has become increasingly competitive with annualized savings from biosimilars reaching \$6.5B in 2020.<sup>7</sup> Many biologics are physician-administered medicines reimbursed under Medicare's Average Sales Price (ASP) formula in Part B. In 2021, biosimilar ASPs were as much as 45% less than brand biologic product ASPs were at the time biosimilars were originally launched. And ASP prices for available biosimilars have been decreasing annually at a rate between 9% and 19%.<sup>8</sup> One study highlights the savings brought on by growing biosimilar competition, finding in the absence of biosimilars, by April 2021 every brand name brand biologic would have had a much higher ASP, on average 56% higher.<sup>9</sup> Importantly, increasing biosimilar competition has also resulted in out-of-pocket savings for patients, estimated at \$238 million per year.<sup>10</sup>

Additionally, this year marked a significant milestone for the millions of Americans who require insulin with the introduction of the first interchangeable biosimilar—an insulin—which is expected to further fuel competition in the biosimilar marketplace in the years ahead. Like many generics today, in most states interchangeable biosimilars may be substituted automatically at the pharmacy counter without intervention from the prescriber. Likewise, the savings that are anticipated to result from interchangeable biosimilar insulins are substantial.<sup>11</sup>

More recently launched biosimilars are also reaching much greater market uptake than earlier launched biosimilars, which analysts see as a reflection of the maturing biosimilar market in which we continue to see positive shifts in physicians’ attitudes around prescribing biosimilars as well as increased provider and patient awareness of biosimilars.<sup>12, 13, 14</sup> In fact, biosimilars of a supportive oncology therapy, which first launched in 2013, were only able to achieve a market share of 39% after 2 years on the market. In contrast, biosimilars first launched in 2019 of a commonly used breast cancer therapy reached 42% market share after just 1 year on the market, and analysts project these biosimilars will reach 60% in just 2 years’ time, with greater savings expected as a result.<sup>15</sup>

“This is a momentous day for people who rely daily on insulin for treatment of diabetes, as biosimilar and interchangeable biosimilar products have the potential to greatly reduce health care costs.”

**Acting FDA Commissioner Janet Woodcock, MD**

Importantly, evidence also suggests the increasingly competitive environment is leading to price reductions from both biosimilars and branded biologics, leading to lower costs for patients and Medicare. The Medicare Advisory Commission (MedPAC) found substantial drops in ASP for brand biologics facing biosimilar competition.<sup>16</sup> For example, one brand biologic that dropped its ASP by 46% was able to stave off significant penetration from biosimilars; whereas another brand biologic that dropped its ASP by 6% lost significant market share to biosimilars which garnered 77% of the market by late 2020 (see chart below).

**Trends in Medicare Part B Payment Rates for Brand Biologics and their Biosimilar Products (Adapted from MedPAC)**

	First Biosimilar Entry	Percent Change in Brand Biologics’ ASP Since Biosimilar Entry (through 2021 Q1)	Biosimilars’ Payment Rate as a Percent of Brand Biologic’s Payment Rate (2021 Q1)	Biosimilar Market Share (2020 Q3)
<b>Brand Biologic A and Biosimilars</b>	2015 Q3	-6%	44%–56%	77%
<b>Brand Biologic B and Biosimilars</b>	2016 Q4	-46%	94%–115%	16%
<b>Brand Biologic C and Biosimilars</b>	2018 Q3	-35%	97%–116%	27%
<b>Brand Biologic D and Biosimilars</b>	2018 Q4	-28%	97%	47%
<b>Brand Biologic E and Biosimilars</b>	2019 Q3	-8%	75%–79%	41%
<b>Brand Biologic F and Biosimilars</b>	2019 Q3	-8%	74%–90%	40%
<b>Brand Biologic G and Biosimilars</b>	2019 Q4	-4%	74%–75%	24%



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 oncology medicines.<sup>17, 18, 19, 20</sup> As awareness and comfortability with biosimilars has 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>21</sup>

## Market distortions may impede more expedient uptake of biosimilars.

Unfortunately, for many hospitals, there are market incentives to use a more costly brand biologic over a lower cost biosimilar due to the significantly higher reimbursements that hospitals obtain from marking up the cost of physician-administered drugs. On average, the reimbursements hospitals receive from commercial insurers are nearly 2.5 times larger than what they paid to acquire the medicines.<sup>22</sup> Additionally, hospitals participating in the 340B program receive an average of 3-4 times what they paid to acquire the medicine.<sup>23,24</sup> That is due, in part, because participation in the 340B program enables hospitals to access deeply discounted drugs which can generate significant profits from high reimbursement rates. Hospitals are not required under the 340B program to reinvest such profit margins in providing care to 340B vulnerable

or uninsured patients. Experts agree the greater profit potential (or “spread”) on 340B discounted drugs creates market distortions that increase costs across the health care system.<sup>25</sup> In fact, the GAO has found hospitals participating in the 340B program prescribe not only more drugs but more expensive drugs.<sup>26</sup> This is because the 340B spread is typically larger for more expensive medicines.<sup>27</sup>

Slower uptake of certain biosimilars at 340B hospitals—with many not even carrying biosimilars at all—calls into question whether 340B-driven market distortions encourage the prescribing of more expensive medicines and discourage uptake of biosimilars in those settings.<sup>28,29,30,31</sup> Ultimately, greater profit margins offered on brand biologics relative to biosimilars, which compete on reduced pricing relative to the brand biologic, may be too attractive for a hospital to pass up.

Looking forward, biosimilars are projected to drive an almost 5-fold increase in savings as new biosimilars launch and existing biosimilars see continued uptake and price declines. These savings are expected to exceed \$100 billion in aggregate between 2020 and 2024.<sup>32</sup> However, there is a wide range of possible savings—from \$69 to \$140 billion—depending on a variety of factors that may influence the evolving landscape.<sup>33</sup> 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 fosters competition.



## Further focus and attention in the following areas is 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 hospitals participating in the program are held accountable for how they use 340B discounts to benefit patients. 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 the rebate system may also reduce barriers to biosimilar uptake and promote access and competition.** Reforming the existing rebate system is expected to redefine the competitive landscape for payers and reshape the contracting relationships between stakeholders.<sup>34,35</sup> As a result, as Milliman has noted, some of these reforms may promote increased uptake of generics and biosimilars which in turn could encourage more biosimilar launches.<sup>36</sup>
3. Additionally, though increasing uptake of biosimilars indicates a positive shift in physician and patient attitudes towards the use of biosimilars, **we need to encourage continued focus on increasing provider and patient education to maximize the benefits of that shift**—this effort should include the development and dissemination of evidence-based materials on the full range of treatment options, including biosimilars, to further support appropriate biosimilar adoption
4. Now and into the future, **ensuring the long-term stability of the BsUFA program through financial transparency, efficiency, and accountability will be critical to further ensuring robust competition in the biosimilar marketplace.**
5. 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.

## Endnotes

1. PhRMA analysis of EMA. [“Biosimilar medicines.”](#) Accessed December 2020.
2. Article 10(4) Directive 2001/83/EC of the European Parliament and of the council of 6 November 2001 (OJ L311 p67), as amended; in particular by Directive 2004/27/EC (OJ L136 p34).
3. PhRMA analysis of FDA, [Biosimilar Product Information.](#); IQVIA Institute, [“Biosimilars in the United States 2020 – 2024.”](#) (October 2020).
4. PhRMA analysis of [Pink Sheet FDA Performance Tracker: Review Pathways – Biosimilars.](#) As of September 2021.
5. [FDA-TRACK: Center for Drug Evaluation & Research - Pre-Approval Safety Review - Biosimilars Dashboard.](#)
6. E Munoz, [“A positive road ahead for biosimilars?”](#) IQVIA, January 2021.
7. IQVIA Institute Report (2020). [Biosimilars in the United States 2020 – 2024.](#)
8. Amgen, [2021 Biosimilar Trends Report,](#) September 2021.
9. Xcenda, [“Biosimilars Have Significantly Lowered Prices of All Biologics”](#) 2021.
10. Winegarden W. [Promoting biosimilar competition to reduce patients’ out-of-pocket costs.](#) PRI Center for Medical Economics and Innovation. March 2020.
11. FDA Statement, [“FDA Approves First Interchangeable Biosimilar Insulin Product for Treatment of Diabetes,”](#) July 2021.
12. Fein, Adam. (2019). [We Shouldn’t Give Up on Biosimilars – And Here Are the Data to Prove It.](#) Drug Channels.
13. Amgen, [2021 Biosimilar Trends Report,](#) September 2021.
14. Wilde S, Schapiro L, Fletcher M, Pearson C. [Understanding stakeholder perception of biosimilars.](#) April 2021.
15. E Munoz, [“A positive road ahead for biosimilars?”](#) IQVIA, January 2021.
16. MedPac, A Databook: [Health Care Spending and the Medicare Program, Chart 10-5. Trends in Medicare Part B payment rates for originator biologics and their biosimilar products,](#) July 2021.
17. G Bai et al., [“Biosimilar Uptake in Medicare Part B Varied Across Hospital Outpatient Departments and Physician Practices: The Case of Filgrastim,” Value in Health, Volume 23, Issue 4, April 2020, Pages 481-486.](#)
18. AD Stern et al., [“Biosimilars And Follow-On Products In The United States: Adoption, Prices, And Users,”](#) Health Affairs, VOL. 40, NO. 6, June 2021.
19. Dean EB, Johnson P, Bond AM. [Physician, Practice, and Patient Characteristics Associated With Biosimilar Use in Medicare Recipients.](#) JAMA Netw Open. 2021;4(1):e2034776.
20. E Munoz, [“A positive road ahead for biosimilars?”](#) IQVIA, January 2021.
21. Wilde S, Schapiro L, Fletcher M, Pearson C. [Understanding stakeholder perception of biosimilars.](#) April 2021.
22. The Moran Company. [Hospital Charges and Reimbursement for Drugs: Analysis of Markups Relative to Acquisition Cost.](#) October 2017; [Hospital Charges and Reimbursement for Medicines: Analysis of Cost-to Charge Ratios.](#) September 2018.
23. A. Bunker, M.T. Hunter and C. Kim, [“Analysis of 340B Hospitals’ Outpatient Department Acquisition Cost and Commercial Reimbursement for Physician-Administered Brand Medicines.”](#) Milliman. December 2019.
24. R Gal, Moto Advisors, [“Examining Hospital Price Transparency, Drug Profits, & the 340B Program,”](#) September 2021.
25. R. Conti and M. Rosenthal, [“Pharmaceutical Policy Reform — Balancing Affordability with Incentives for Innovation,”](#) N Engl J Med 2016; 374:703-706.
26. GAO, [“Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals,”](#) June 2015.
27. R Conti and P Bach, [“Cost Consequences of the 340B Drug Discount Program,”](#) JAMA. 2013 May 15; 309(19): 1995–1996.
28. T Hagan, [“Biosimilars Advance in the Oncology Space,”](#) AJMC, April 2021.
29. T Hagan, [“COA’s Okon Takes Aim at Biosimilar Misconceptions,”](#) AJMC, April 2021.
30. R Gal, Moto Advisors, [“Examining Hospital Price Transparency, Drug Profits, & the 340B Program,”](#) September 2021.
31. P Kolchinsky. [“When drug prices are a Trojan Horse for other costs, we all lose,”](#) July 14, 2021. Rapport.
32. IQVIA Institute Report (2020). [Biosimilars in the United States 2020 – 2024.](#)
33. E Munoz, [“A positive road ahead for biosimilars?”](#) IQVIA, January 2021.
34. 84 Fed. Reg. at 2355.
35. The proposed rule addresses the existing rebate framework, which OIG and others have noted may incentivize PBMs and insurers to favor medicines that carry higher rebates. Outside of the U.S., these dynamics do not exist – PBMs do not negotiate price concessions on behalf of private payers and patients do not pay cost sharing based on prices that exceed the net cost to their insurers. In countries where these specific dynamics are absent, net price transparency is not likely to have similar benefits.
36. Klaisner J, Holcomb K, Filipek T. [Impact of Potential Changes to the Treatment of Manufacturer Rebates.](#) Milliman. January 31, 2019, at 12. Available at: <https://www.regulations.gov/document?D=HHSIG-2019-0001-0002>; Bell D, Carioto J, Hayes M. [An End to Manufacturer Rebates as We Know Them Today?.](#) Milliman. February. 15, 2019.