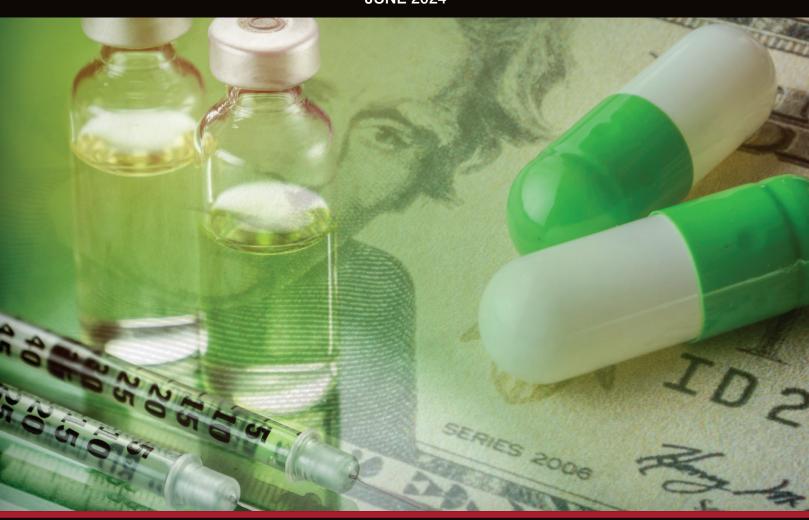


ISSUE BRIEF

The Biosimilar Discount: Growing Biosimilar Market Share Is Driving Down Prices for Expensive Biologic Medicines

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Executive Summary

Despite obstacles, biosimilar competition is meaningfully improving drug affordability. Based on the unit and sales revenue data for ten widely prescribed biologics, which are maintained by IQVIA,

- Biosimilars represent nearly 36 percent of all units sold.
- Relative to 2019, total sales revenues in inflation adjusted dollars are 7.5 percent lower despite
 the 35 percent increase in inflation adjusted Humira sales revenues and 1 percent increase in
 inflation adjusted Enbrel sales revenues (biologics that do not yet face substantial biosimilar
 competition).
- Total unit sales for biologic medicines in 2023 are 4.5 percent higher than 2019, which indicates that falling inflation adjusted prices are driving the realized savings.
- Total inflation adjusted revenues per unit declined from \$1,396 in 2019 to \$1,174 as of the first quarter of 2024.

These results understate the actual benefits from biosimilar competition, however. Enbrel still faces no biosimilar competition as of May 2024 and biosimilar competitors to Humira have endured market obstacles through early 2024. Importantly, there is recent evidence that these constraints may be lessening. CVS Caremark announced on January 3, 2024 that,

Effective April 1, 2024, Humira will be removed from our major national commercial template formularies and Humira biosimilars will be covered. Humira will continue to be an option for its customers with Choice and Standard Opt Out commercial formularies. Commercial formularies are the drug lists used by employers, unions and health plans for prescription drug coverage.

In much the same way that generic drugs are used as alternatives to branded drugs, biosimilars offer quality, safe, and effective treatment options that have no clinically meaningful difference from their reference products. A vibrant and competitive biosimilar market is essential to driving sustainable cost savings and options for consumers over the long term. The biosimilars market in the U.S. is projected to grow from less than \$10 billion in 2022 to more than \$100 billion by 2029.

Excluding these two uncompetitive biologics, the large benefits that a competitive biosimilars market creates are clearer. For the competitive biologics market,

- Biosimilars represent approximately two-thirds of total unit sales of biologic medicines as of the first quarter of 2024.
- Relative to 2019, total sales in inflation adjusted dollars are 51 percent lower through 2023 even though total unit sales are over 1 percent higher.
- Biosimilar competition has reduced the total inflation adjusted unit prices from \$1,111 in 2019 to \$489 as of the first quarter of 2024 (a 56 percent decline).

These falling price trends have generated large savings. As the data on Humira and Enbrel demonstrate, prices for biologics increase without the introduction of competition. In contrast, the data for the other biologics demonstrate that strong biosimilar competition causes prices to decline significantly.

Assuming that, without competition, inflation adjusted unit prices for the biologics that faced biosimilar competition would have remained flat since 2019, a conservative assumption, robust competition from biosimilars generated \$12 billion in savings between 2019 and 2023. Adding the potential savings that could have arisen had Humira and Enbrel faced biosimilar competition, the potential savings that could have been realized are a much larger \$25 billion.

Due to the price increases that tend to occur without competition, the flat inflation adjusted unit price assumption likely understates the realized savings. Based on the Humira and Enbrel price increases that occurred without meaningful biosimilar competition, it is reasonable to assume that the prices for the other eight biologics would have increased around 2.8 percent annually had there been no biosimilar competition. Judging the realized biosimilar savings against this assumption, biosimilar competition generated \$15.0 billion

in savings between 2019 and 2023. If Humira and Enbrel had faced biosimilar competition, biosimilars could have enabled an additional \$13 billion in savings, for a total of \$28 billion.

The data on biosimilars demonstrate that, when allowed to flourish, competition meaningfully lowers biologics' costs and significantly increases their share of prescriptions. A robust competitive biosimilar market is, consequently, an effective means for improving biologic affordability.

There are several policy changes that will improve the competitiveness of the biosimilars market. As has been the case with Humira, the current rebate system creates perverse incentives that incentivize insurers to prefer the higher cost originator products over the lower cost biosimilars. Other problems include the existence of rebate walls that use volume-based rebates to

Maintaining a
competitive
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the private sector
plays the driving
role developing new
innovative medicines.

lock out lower-priced competition. Addressing these uncompetitive practices can accelerate biosimilars' competitiveness.

Reforming the Inflation Reduction Act (IRA) will also help. The IRA's price controls discourage companies from developing competitive biosimilars due to the \$100 million to \$300 million in research and direct outlays costs required to develop these competitive products.² While significantly less than the development costs for originator medicines, the capitalized costs for developing biosimilars are quite expensive. Price controls create a substantial risk that investors will be unable to recoup their capital costs if they invest in the development of biosimilars. Other alternative investment opportunities will look relatively more attractive, depriving biosimilar developers of the resources they need. The result will be less competition and higher prices.

Addressing these anti-competitive and anti-innovation practices will help improve the competitive landscape for biosimilars. The expected result will be increased competition and, most importantly, lower priced/higher quality care for patients.

Biosimilars Market Performance: Rising Share and Declining Costs

The Center for Medical Economics and Innovation at the Pacific Research Institute has published a series of studies documenting the large and growing savings biosimilars enable.³ Biosimilars are biologic drugs (biologics) that have no "clinically meaningful difference" in safety, purity, and effectiveness relative to its reference originator biologic. Biologics are produced from, or contain, living organisms and are typically much more complicated than chemically based "small molecule" medicines. Unlike small molecule medicines, which are typically sold over the pharmacy counter, biologic medicines are generally administered to patients in a clinical setting. These medicines create enormous benefits for patients that include more efficacious treatments for cancer, psoriatic arthritis, and ulcerative colitis.

Innovative originator biologics exemplify the innovative aspects of the drug development process and are often very expensive because these medicines must cover the large capital costs associated with inventing a new complex therapy. Just like generic medicines, the benefits of biosimilars are the substantial price discounts they enable compared to the price for the originator biologic.

This report analyzes the cost, share trends, and savings for ten widely prescribed biologic medicines (hereafter referred to as biologics market for simplicity). These experiences demonstrate that thriving biosimilar competition drives down costs and generates billions of dollars in savings that, for the eight biologics that have substantial competition (which excludes Humira and Enbrel, thereafter referred to as the competitive biologics market for simplicity) have driven down adjusted unit prices approximately 56% below their 2019 prices as of early 2024.

These data highlight the importance of promoting robust biosimilar competition to ensure that the downward trend in biologic costs continues.

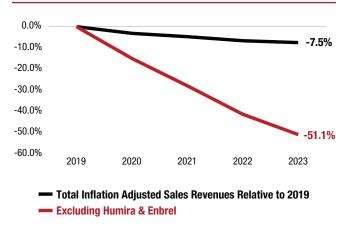
Biosimilar Revenues, Units and Share of Prescriptions: An Overview

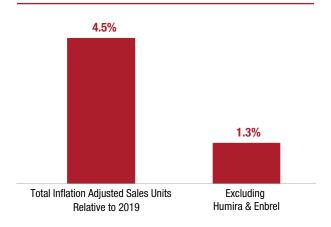
To see the impact on costs and prices from robust biosimilar competition, Figure 1 presents the sales revenue data for the biologics market relative to the total inflation adjusted sales revenues as of 2019.⁵

The data are presented for the entire biologics market as well as just for the competitive biologics market (excluding Humira and Enbrel). As Figure 1 illustrates, the total inflation adjusted revenues for the biologics market in 2023 was 7.5 percent less than the total inflation adjusted value in 2019. The total inflation adjusted value for the competitive biologics market in 2023 was 51.1 percent less than 2019.

Figure 1
Inflation Adjusted Sales Revenues for Biologics
Market Relative to 2019
2019–2023

Figure 2
Inflation Adjusted Sales Units 2023
Compared to 2019





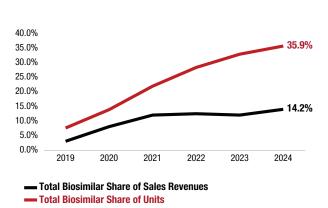
Source: Author calculations based on IQVIA data

Source: Author calculations based on IQVIA data

Total inflation adjusted sales revenues could have declined because prices fell, or the total number of units sold declined. Figure 2 demonstrates that sales revenues were lower because inflation adjusted unit prices fell, not because fewer units were sold. Compared to 2019, a total of 4.5 percent more units were sold in 2023 for the entire biologics market and 1.3 percent more units were sold in 2023 for the competitive biologics market. The 1.3 percent increase in total units sold in the competitive biologics market coupled with the 51.1 percent decline in total inflation adjusted sales revenues indicates that biologic prices have declined precipitously since 2019.

Large declines in inflation adjusted unit prices occurred because the share of lower cost biosimilars have been growing since 2019. Figure 3 presents these share trends for the entire biologics market, while Figure 4 presents the trends for the competitive biologics market. Figure 3 demonstrates that biosimilars' share of the total market has increased over four-fold between 2019 and 2024. The growth illustrated in Figure 4 is even more impressive as biosimilars now comprise over two-thirds of the market for the eight biologics where actual competition is occurring.

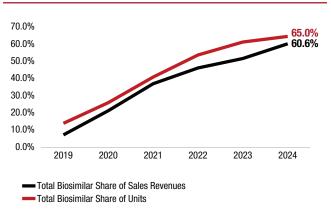
Figure 3
Biosimilars' Share of the Biologics Market by Units and Revenues
2019–2024



Source: Author calculations based on IQVIA data

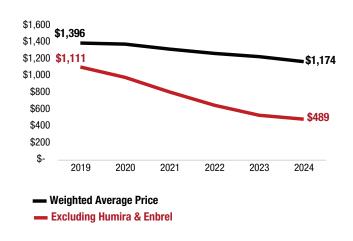
Figure 5 presents the actual inflation adjusted prices per unit, which are measured as inflation adjusted total sales revenue divided by total units. These prices will vary from actual patient costs for these medicines. As illustrated in Figure 5, the inflation adjusted weighted average price per unit for biologic medicines (including both originator and biosimilar competitors) has declined 16 percent between 2019 and 2024 (from \$1,396 to \$1,174), which includes the rising inflation adjusted prices per unit for Humira and Enbrel which lack biosimilar competition. The competitive biologics market has seen larger declines in prices per unit due to the positive incentives created by robust biosimilar competition. Inflation adjusted prices per unit for the competitive biologics market declined 56 percent between 2019 (\$1,111) and 2024 (\$489).

Figure 4
Biosimilars' Share of Biologics Market by Units and Revenues
Excluding Humira and Enbrel
2019–2024



Source: Author calculations based on IQVIA data

Figure 5
Inflation Adjusted Weighted Average Price Per
Unit for Biologic Medicine
2019–2024



Individual Biologic Price and Biosimilar Share Trends

The connection between rising biosimilar market share and falling biologic prices are not driven by one or two biologics. Reviewing the average inflation adjusted price per unit for all ten of the biologics evaluated demonstrates this relationship.

Figure 6 demonstrates these impacts for Adalimumab (Humira). Since there were no biosimilar competitors against Humira between 2019 and 2022, the inflation adjusted weighted average price equaled Humira's price. Without biosimilar competitors, prices per unit rose through 2023 at a 3 percent annual rate.

Starting in 2023 biosimilar competitors were introduced, although through early 2024 biosimilar market share remains minimal. The continued dominance of the originator biologic has been due, in large part, to pharmacy benefit managers (PBMs) continuing to prefer the more expensive originator product – a policy consistent with PBM's financial interest despite the cost to the broader healthcare system. Even this minimal biosimilar market share has put downward pressure on inflation adjusted unit prices in 2024. The decision by CVS Caremark to prefer biosimilars may accelerate their use and, subsequently, accelerate the decline in prices. Such an outcome, based on the experiences of the other biologics, should cause inflation adjusted prices for Adalimumab to decline significantly over the next several years.

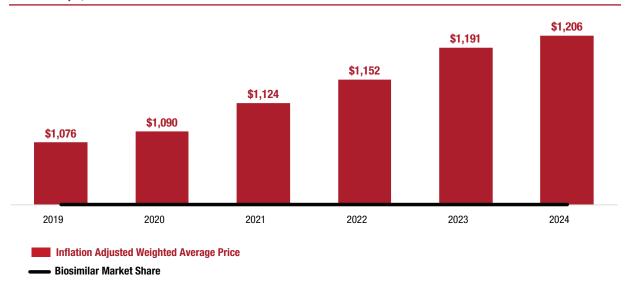
Figure 6Weighted Average Price Per Unit Compared to Biosimilar Market Share Adalimumab
2019–2024



Source: Author calculations based on IQVIA data

Etanercept (Enbrel) is the only biologic considered in this analysis that, as of May 2024, still faced no biosimilar competition – the weighted average price reflects the price for Enbrel. Not surprisingly, Enbrel's inflation adjusted prices per unit have increased 12.0 percent between 2019 and 2024.

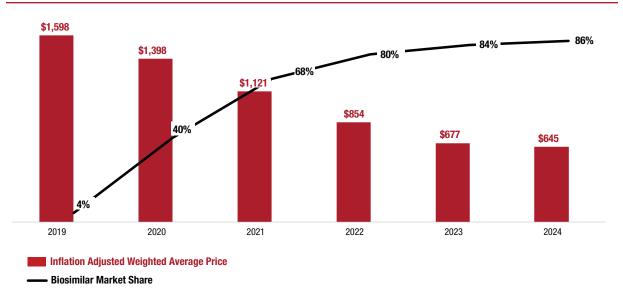
Figure 7Weighted Average Price Compared to Biosimilar Market Share Etanercept, 2019–2024



Source: Author calculations based on IQVIA data

Unlike Humira and Enbrel, biosimilar competitors for Avastin (bevacizumab) have been steadily increasing their share of total prescriptions between 2019 and 2024, see Figure 8. In 2019, biosimilars represented 4 percent of total units administered. By 2024, biosimilars dominated the market having obtained an 86 percent share. Not surprisingly, the weighted average price for bevacizumab declined 59.6 percent from \$1,598 in 2019 to \$645 per unit in 2024.

Figure 8Weighted Average Price Compared to Biosimilar Market Share Bevacizumab, 2019–2024



Figures 9 through 15, which present the data for the remaining seven biologics, all tell the same story that is illustrated in Figure 8. Rising biosimilar share of prescriptions is associated with declining inflation adjusted weighted average prices. The precise relationship between share growth and declines in inflation adjusted weighted average price varies across each biologic, see Table 1 and Figures 8 through 15. On average, inflation average unit prices have declined 56 percent and biosimilars have obtained approximately two-thirds market share as measured by units (see Figures 4 and 5).

Table 1Market Share, 2024 and Percentage Change in Inflation Adjusted Unit Prices, 2019–2024
Eight Biologics Facing Biosimilar Competition

	Biosimilar Market Share 2024	Percentage Change Inflation Adjusted Unit Prices 2019 - 2024
Bevacizumab	86%	-59.6%
Filgrastim	84%	-35.0%
Infliximab	55%	-57.8%
Pegfilgrastim	55%	-62.7%
Ranibizumab	50%	-49.0%
Rituximab	80%	-50.2%
Teriparatide	56%	-32.9%
Trastuzumab	73%	-25.3%

Figure 9Weighted Average Price Compared to Biosimilar Market Share Filgrastim, 2019–2024

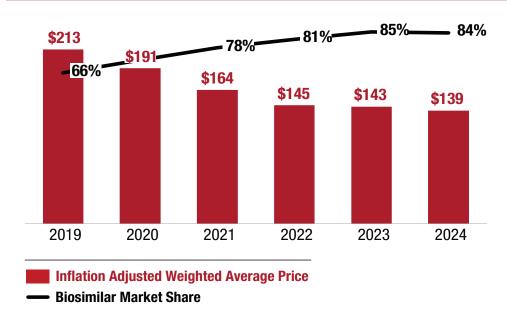


Figure 10
Weighted Average Price Compared to Biosimilar
Market Share
Infliximab, 2019–2024

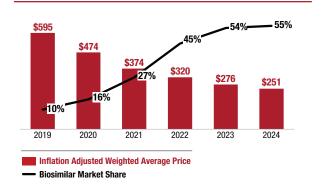


Figure 11
Weighted Average Price Compared to
Biosimilar Market Share
Pegfilgrastim, 2019–2024



Figure 12
Weighted Average Price Compared to Biosimilar
Market Share
Ranibizumab, 2019–2024

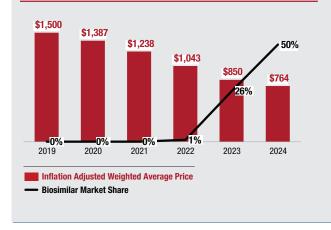


Figure 13
Weighted Average Price Compared to
Biosimilar Market Share
Rituximab, 2019–2024

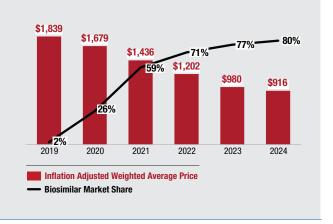


Figure 14
Weighted Average Price Compared to Biosimilar
Market Share
Teriparatide, 2019–2024

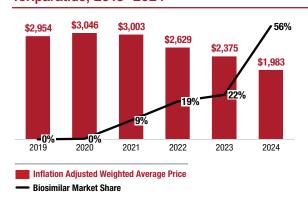
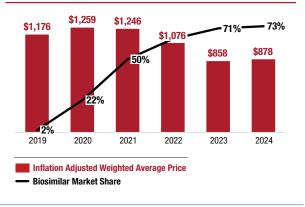


Figure 15
Weighted Average Price Compared to
Biosimilar Market Share
Trastuzumab, 2019–2024



Source: Author calculations based on IQVIA data

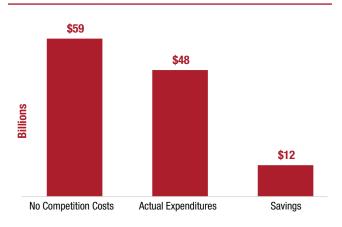
11

Estimating Biosimilars' Savings Potential

The data summarized in Figures 6 through 15 illustrate that there is a close relationship between growing market share for biosimilars and declining weighted average prices for biologic medicines. Alternatively, in those instances where biosimilar competition has not yet been introduced or remains small (Enbrel and Humira), weighted average prices continue to increase. These trends indicate that robust biosimilar competition generates large savings on expensive biologic medicines. The extent of those savings depends on a counterfactual: What would the prices for the eight biologics that currently have a substantial biosimilar share be in the absence of competition?

To answer this question, Figure 16 makes the conservative assumption that, in the absence of biosimilar competition, the inflation adjusted unit prices for the eight biologics with competition would have remained constant at 2019 prices (rather than declining 56 percent). With the further assumption that Humira's and Enbrel's inflation adjusted unit prices were unaffected, total biologic expenditures in 2023 would have been \$59 billion, or \$12 billion higher than the actual total spending of \$48 billion.

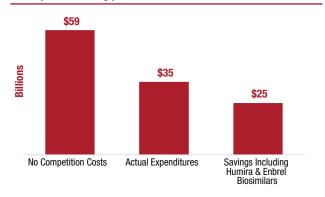
Figure 16
Estimated Biosimilar Savings Relative to 2019
Cost Baseline, 2023



Source: Author calculations based on IQVIA data. Numbers may not add due to rounding.

The savings could be even higher, however, because the potential savings biosimilar competition can enable for Humira and Enbrel have not been considered. If the relationship between rising biosimilar market share and declining inflation adjusted weighted average unit prices holds, then there are exceptionally large biologic savings that would have arisen had the biosimilar market share for Humira and Enbrel equaled the average of the share for the other eight biologics. Based on these assumptions, a total of \$25 billion in additional savings were possible – more than double the realized savings due to the widespread use of Humira and Enbrel, see Figure 17.

Figure 17
Estimated Biosimilar Savings Relative to 2019
Cost Baseline
Including Humira and Enbrel Biosimilar
Competition Hypothetical, 2023



Source: Author calculations based on IQVIA data. Numbers may not add due to rounding.

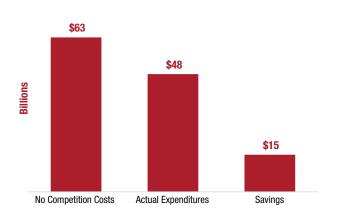
Assuming that the originator prices for competitive biologics would not have increased since 2019 potentially understates the savings. The growth in the inflation adjusted unit prices for Humira and Enbrel during this period argues that without competition, inflation adjusted unit prices increase over time.

If the inflation adjusted unit prices had increased similar to the actual increases for Humira and Enbrel, then total biologic expenditures in 2023 would have been \$63 billion, or \$15 billion higher than the actual total spending of \$48 billion, see Figure 18.

12

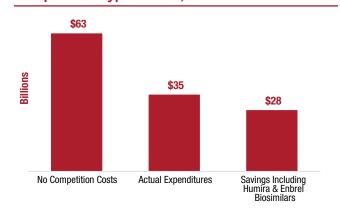
Applying the potential savings from Enbrel and Humira as estimated in Figure 17, a total of \$28 billion in additional savings were possible, see Figure 19.

Figure 18
Estimated Biosimilar Savings Relative to Growing Cost Baseline 2019–2023



Source: Author calculations based on IQVIA data

Figure 19
Estimated Biosimilar Savings Relative to Growing
Cost Baseline
Including Humira and Enbrel Biosimilar
Competition Hypothetical, 2023



Conclusion

The market share of biosimilars has increased substantially for many biologic medicines between 2019 and 2024. For the eight biologic medicines that faced robust competition, biosimilars have gained approximately two-thirds of the market while inflation adjusted unit prices have declined 56 percent. These significant price declines have generated billions of dollars in savings – depending on the assumptions, realized savings could be as large as \$15 billion. The potential savings – including the savings that would have been realized had effective biosimilar competition developed for Humira and Enbrel – are a much larger \$28 billion.

These data indicate that promoting more efficient biosimilar competition can meaningfully bend the cost curve for expensive biologic medicines. There are several policy changes that will improve the competitiveness of the biosimilars market. As has been the case with Humira, the current rebate system creates perverse incentives that incentivize insurers to prefer the higher cost originator products over the lower cost biosimilars. Other problems include the existence of rebate walls that use volume-based rebates to lock out lower-priced competition. Addressing these uncompetitive practices can accelerate biosimilars' competitiveness.

Reforming the Inflation Reduction Act (IRA) will also help. The IRA's price controls discourage companies from developing competitive biosimilars due to the \$100 million to \$300 million in research and direct outlays costs required to develop these competitive products. While significantly less than the development costs for originator medicines, the capitalized costs for developing biosimilars are

Addressing these anti-competitive and anti-innovation practices will help improve the competitive landscape for biosimilars.

quite expensive. Price controls create a substantial risk that investors will be unable to recoup their capital costs if they invest in the development of biosimilars. Other alternative investment opportunities will look relatively more attractive, depriving biosimilar developers of the resources they need. The result will be less competition and higher prices.

Addressing these anti-competitive and anti-innovation practices will help improve the competitive landscape for biosimilars. The expected result will be increased biosimilar competition. Toward this end, recent developments promoting greater biosimilar use for the adalimumab (Humira) biologic are encouraging. Should the recent changes start the same beneficial competitive processes that generated broad based savings for other biologics, substantial savings opportunities will be realized over the next several years.

Endnotes

- "CVS Caremark accelerates biosimilars adoption through formulary changes" CVS Caremark, January 3, 2024, https://www.cvshealth.com/news/pbm/cvs-caremark-accelerates-biosimilars-adoption-through-formulary-changes.html.
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- Winegarden W "Falling Prices: Biosimilar competition has saved billions of dollars, but policy changes can incentivize billions more" Pacific Research Institute, Center for Medical Economics and Innovation, August 2022; Winegarden W "Promoting Biosimilar Competition to Reduce Patients' Out-of-Pocket Costs" Pacific Research Institute, March 2020; Winegarden W "The Biosimilar Opportunity: A State Breakdown" Pacific Research Institute, October 2019; Winegarden W "Incenting Competition to Reduce Drug Spending: The Biosimilar Opportunity" Center for Medical Economics and Innovation at the Pacific Research Institute, July 2019; and, Winegarden W "Impediments to a Stronger Biosimilars Market: An infliximab case study" Pacific Research Institute, June 2018.
- The biologic medicines evaluated were Adalimumab, Bevacizumab, Etanercept, Filgrastim, Infliximab, Pegfilgrastim, Ranibizumab, Rituximab, Teriparatide, and Trastuzumab.
- Nominal sales revenues are measured as IQVIA sales dollars. The nominal sales revenues are adjusted for inflation based on the GDP Price Index, www.bea.gov.
- 6 Units are measured as eaches, or the number of single items including vials, syringes, bottles, or packet of pills that are contained in a unit or shipping package.

About the Author

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Wayne H. Winegarden, Ph.D. is a Senior Fellow in Business and Economics at the Pacific Research Institute and director of PRI's Center for Medical Economics and Innovation. He is also the Principal of Capitol Economic Advisors.

Dr. Winegarden has 25 years of business, economic, and policy experience with an expertise in applying quantitative and macroeconomic analyses to create greater insights on corporate strategy, public policy, and strategic planning. He advises clients on the economic, business, and investment implications from changes in broader macroeconomic trends and government policies. Clients have included Fortune 500 companies, financial organizations, small businesses, state legislative leaders, political candidates and trade associations.

Dr. Winegarden's columns have been published in the *Wall Street Journal, Chicago Tribune, Investor's Business Daily*, Forbes.com, and Townhall.com. He was previously economics faculty at Marymount University, has testified before the U.S. Congress, has been interviewed and quoted in such media as CNN and Bloomberg Radio, and is asked to present his research findings at policy conferences and meetings. Previously, Dr. Winegarden worked as a business economist in Hong Kong and New York City; and a policy economist for policy and trade associations in Washington D.C. Dr. Winegarden received his Ph.D. in Economics from George Mason University.

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