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ISSUE BRIEF

Falling Prices: Biosimilar competition has saved billions of dollars, but policy changes can incentivize billions more

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Biosimilar competition has saved billions of dollars, but policy changes can incentivize billions more
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Introduction

Robust competition is the *sine qua non* of an efficient market. Competition fosters positive incentives that encourage firms to consistently increase their efficiencies, improve their quality, and reduce their costs. A 2018 Progressive Policy Institute Paper exemplifies how competition, in this case competition in the tech industry, benefits customers in the form of falling prices and workers in the form of higher real pay and more jobs.[1] The beneficial incentives competition creates in the tech industry include[2]

- a 60 percent rise in tech productivity between 2007 and 2017 compared to 5 percent in the non-health private sector excluding tech (non-tech sector),
- a 15 percent decline in tech prices for customers compared to a 21 percent increase in the non-tech sector, and
- a 15.4 percent increase in real pay per tech worker compared to 7.0 percent increase in the non-tech sector.

The pharmaceutical industry is no different. The development of originator biologic medicines creates tremendous value for patients that significantly improve patient outcomes. Biologics have revolutionized treatment for patients living with autoimmune diseases and osteoporosis.[3] For patients living with many types of cancer, biologic medicines help prevent or slow its spread with fewer toxic side effects than alternative treatments.[4] Given that the costs of developing a new therapy, including post-approval R&D, are estimated to be nearly $2.9 billion,[5] the prices for innovator biologics are initially expensive by necessity.

On average, developers of the originator biologic have 12 years of patent protection left once the drug has been cleared to be sold.[6] This period provides the developers an opportunity to recoup their capital costs. Once this opportunity has been provided, competition in the biologics market is empowered through the introduction of biosimilars. The competition created by biosimilars can generate significant systemic savings in the same manner that competition in the tech space engenders broad-based systemic savings. The Center for Medical Economics and Innovation at the Pacific Research Institute has published several studies documenting biosimilars' potential savings.[7]

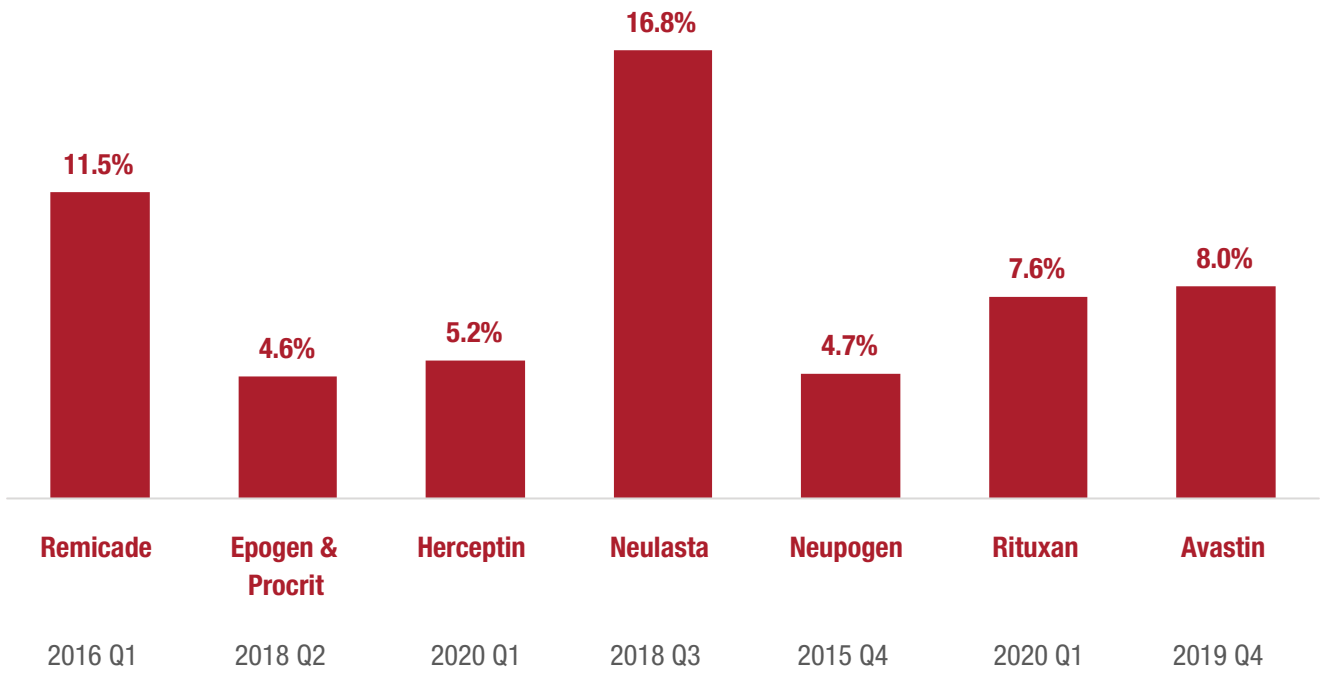
> "The competition created by biosimilars can generate significant systemic savings in the same manner that competition in the tech space engenders broad-based systemic savings.

Over time, as biosimilar competition has increased, these potential opportunities to reduce total costs have become actual systemic savings. In fact, the competitive environment that biosimilars have enabled is generating tens of billions of dollars in cost savings annually. The realization of these opportunities provides important lessons with respect to future biosimilar introductions as well as the benefits competitive markets can deliver for the broader healthcare system. Consequently, it is beneficial to document the size of the realized savings enabled by biosimilar competition and the manner these savings have emerged.

Price and Share Trends Pre- and Post-Biosimilar Competition

As of May 2022, biosimilars provide robust competition across 7 biologic drug classes excluding insulin that include (originator name in parentheses): infliximab (Remicade), rituximab (Rituxan), bevacizumab (Avastin), trastuzumab (Herceptin), filgrastim (Neupogen), pegfilgrastim (Neulasta), and epoetin alfa (Epogen & Procrit). While the competitive pressures manifest themselves differently between these drug classes, an important similarity across all the originator biologics is that their prices were consistently rising prior to the introduction of competitive products. These trends are visualized in Figure 1.

FIGURE 1. Percentage Change in ASP for Originator Biologics Facing Current Biosimilar Competition 8 Quarters Prior to First Biosimilar Launch



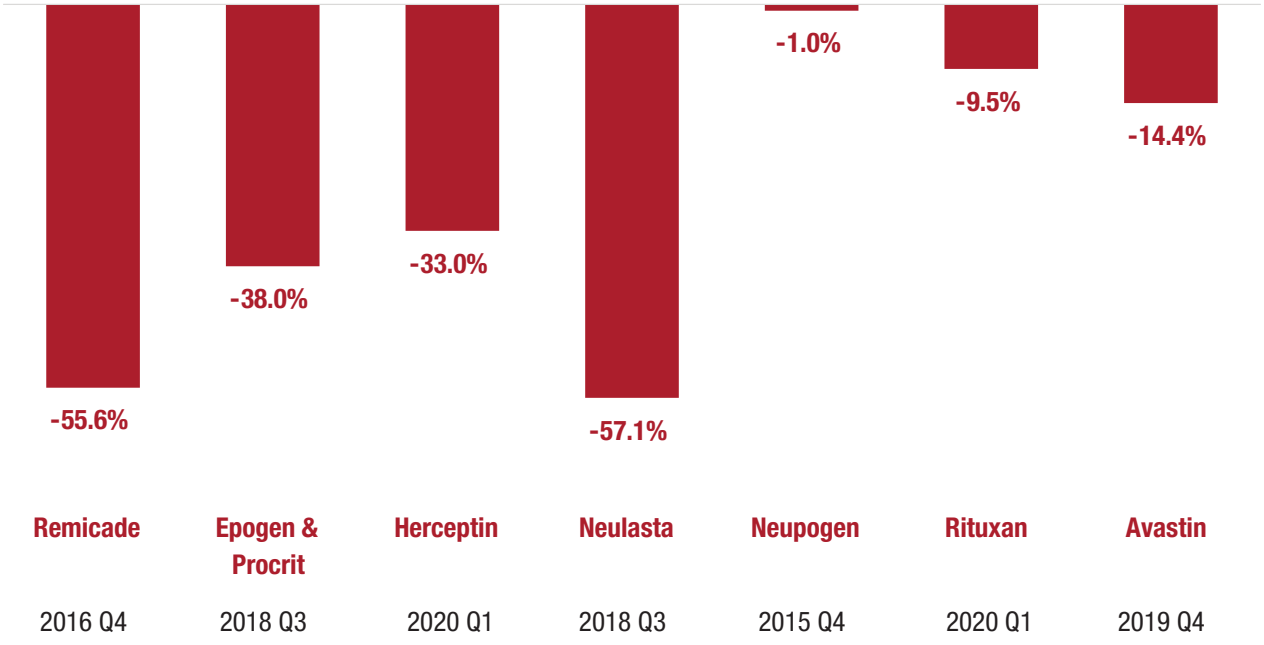
Source: Author calculations based on CMS Medicare Payment Allowance data

Figure 1 presents the percentage change in the average sales price (ASP) for the originator biologic in each one of these drug classes. The ASP reflects the price for the drugs including all rebates and discounts that are privately negotiated between manufacturers and purchasers (excluding Medicaid and select federal discounts and rebates). It is, consequently, a market-based price that reflects the actual price of the drugs that are infused in clinical settings.

Figure 1 compares the ASP that existed in the quarter in which the first biosimilar entered the market for each biologic drug class to the ASP that prevailed 8 quarters prior to the initial biosimilar launch (the approximate initial quarter when significant biosimilar competition began for each biologic drug class is denoted below each column in Figure 1). Figure 1 demonstrates that the prices for the originator biologics were universally rising in all biologic drug classes prior to the introduction of biosimilar competition.

The trend of rising prices changed dramatically once biosimilar competition was introduced, as Figure 2 illustrates. Figure 2 compares the percentage change in prices for the originator biologics from the quarter biosimilar competition was introduced (which varied across the different biologic drug classes) through the second quarter of 2022. While the actual price declines for the originator biologics varied (the price of Neupogen declined a mere 1.0 percent since the introduction of competition), it is noteworthy that the prices for all originator biologics declined once biosimilar competition was introduced. These declining prices starkly contrast with the universal rising price environment that existed prior to the introduction of biosimilar competition.

FIGURE 2. Percentage Change in ASP for Originator Biologics Facing Current Biosimilar Competition From Biosimilar Launch through 2022 Quarter 2



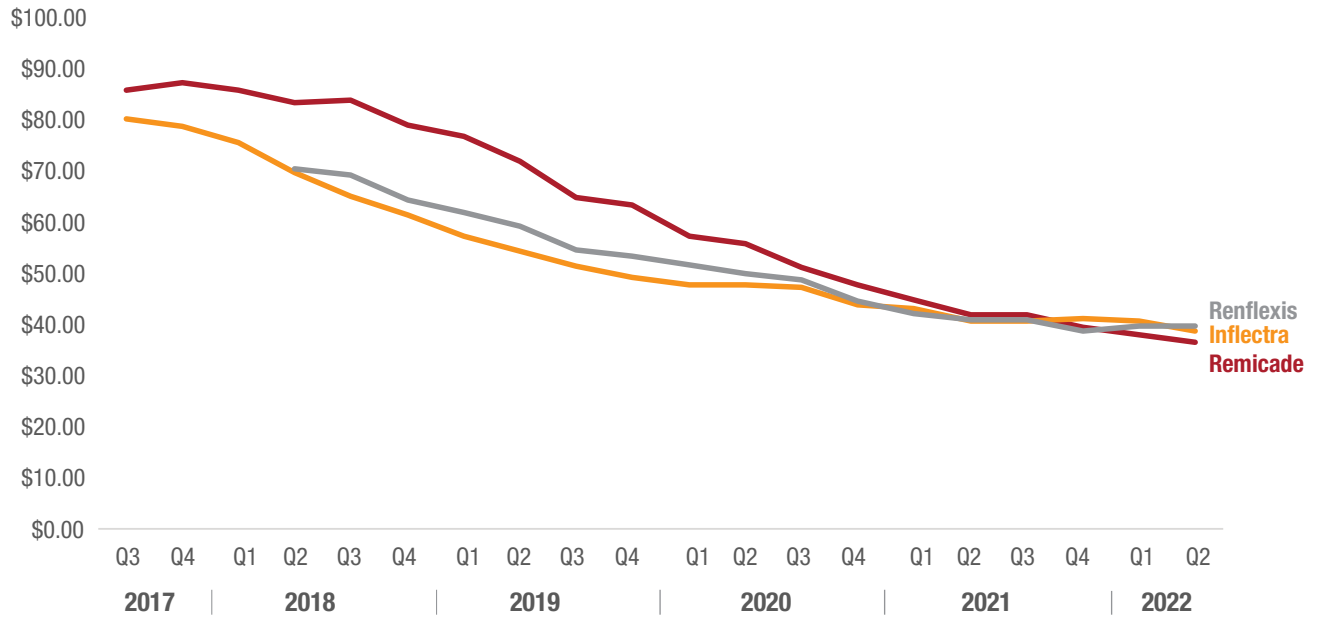
Source: Author calculations based on CMS Medicare Payment Allowance data

This stark change in the pricing trends – from a rising price environment to a flat-to-declining price environment – is an important benefit created by biosimilar competition. Unsurprising, more biosimilars competing against the originator are associated with greater price reduction pressures. To quantify the dollar value of these benefits it is useful to classify the magnitude of the originator price declines for originator biologics into two categories.

In the first category, the originator biologic medicines implement steep declines in ASP following the introduction of biosimilar competition and include Remicade, Epogen & Procrit, Herceptin, and Neulasta. Figures 3 through 6 illustrate that these steep price declines for the originator biologic roughly match the ASP trends for their biosimilar competitors. As of the second quarter of 2022, the originator biologic is slightly cheaper than the competitive biosimilars in the infliximab (Figure 3) and Neulasta (Figure 4) cases, approximately the same in the Epogen & Procrit case (Figure 5), and slightly more expensive than the competitive biosimilars in the Herceptin case (Figure 6).

Starting with infliximab, a biosimilar competitor (Inflectra) entered the market around the first quarter of 2017. Since the start of the competitive environment, the price of Remicade (the originator biologic) has followed the lower prices for the biosimilar competitors down and is now slightly lower than the prices for the competitive products. Compared to the price of Remicade prevailing in 2017, the price of Remicade in 2022 is 56 percent lower, the prices of the two biosimilar competitors (Inflectra and Renflexis) in 2022 are 54 percent lower.

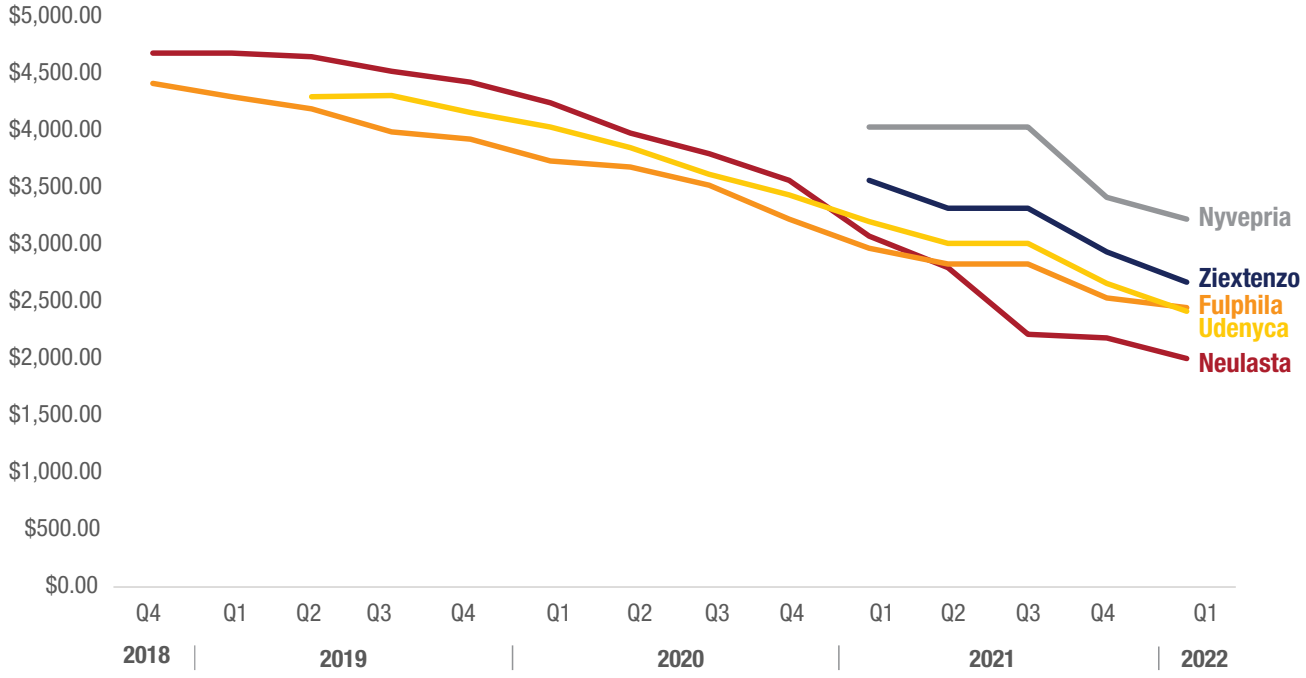
FIGURE 3. Infliximab Price Trends 2017 Quarter 3 through 2022 Quarter 2



Source: CMS Payment Allowance Data

A biosimilar in the Pegfilgrastim drug class entered the market in the fourth quarter of 2018. Since the start of the competitive environment, the price of Neulasta (the originator biologic) has followed the lower prices for the biosimilar competitors down and is now lower than the prices for the competitive products. Compared to the price prevailing in 2018, the price of Neulasta in 2022 is 54 percent lower. The prices of the four biosimilar competitors in 2022 are between 30 percent and 50 percent lower than Neulasta's 2018 price.

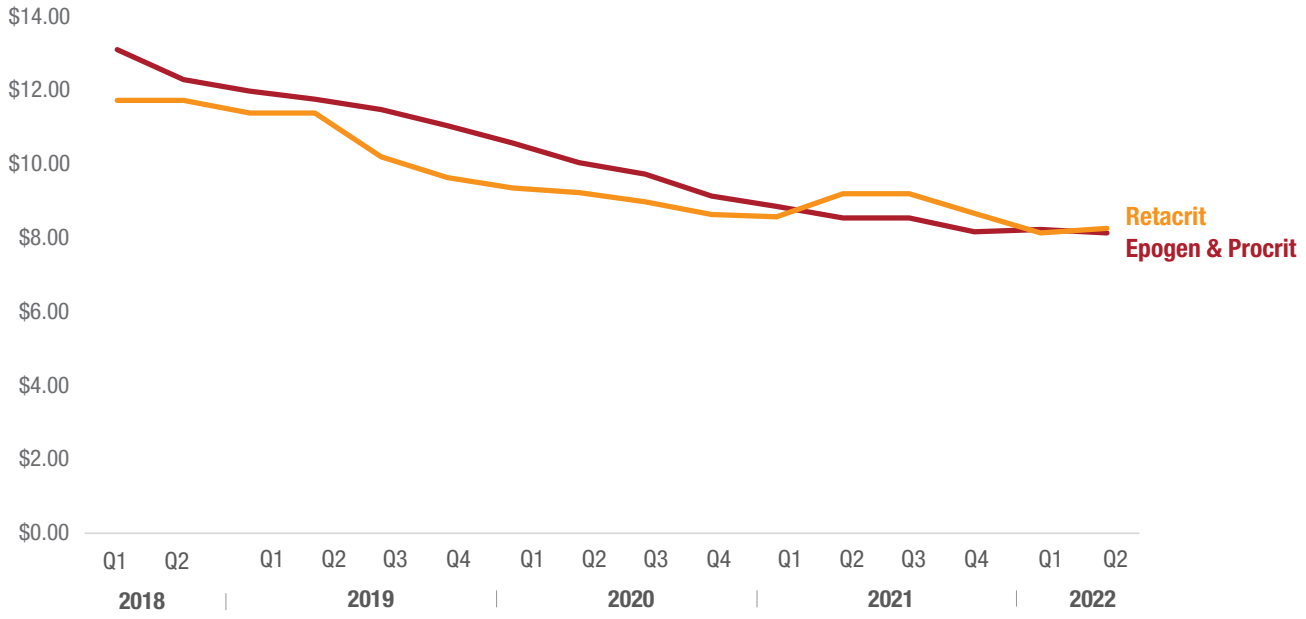
FIGURE 4. Pegfilgrastim Price Trends 2018 Quarter 4 through 2022 Quarter 1



Source: CMS Payment Allowance Data

The biosimilar competitor to Epogen & Procrit (Retacrit) entered the market in the third quarter of 2018. Since the start of the competitive environment, the prices of Epogen & Procrit have followed the price of Retacrit down and is also now approximately the same price as Retacrit. Compared to the prices of Epogen & Procrit prevailing in 2018, current prices in 2022 are 35 percent lower.

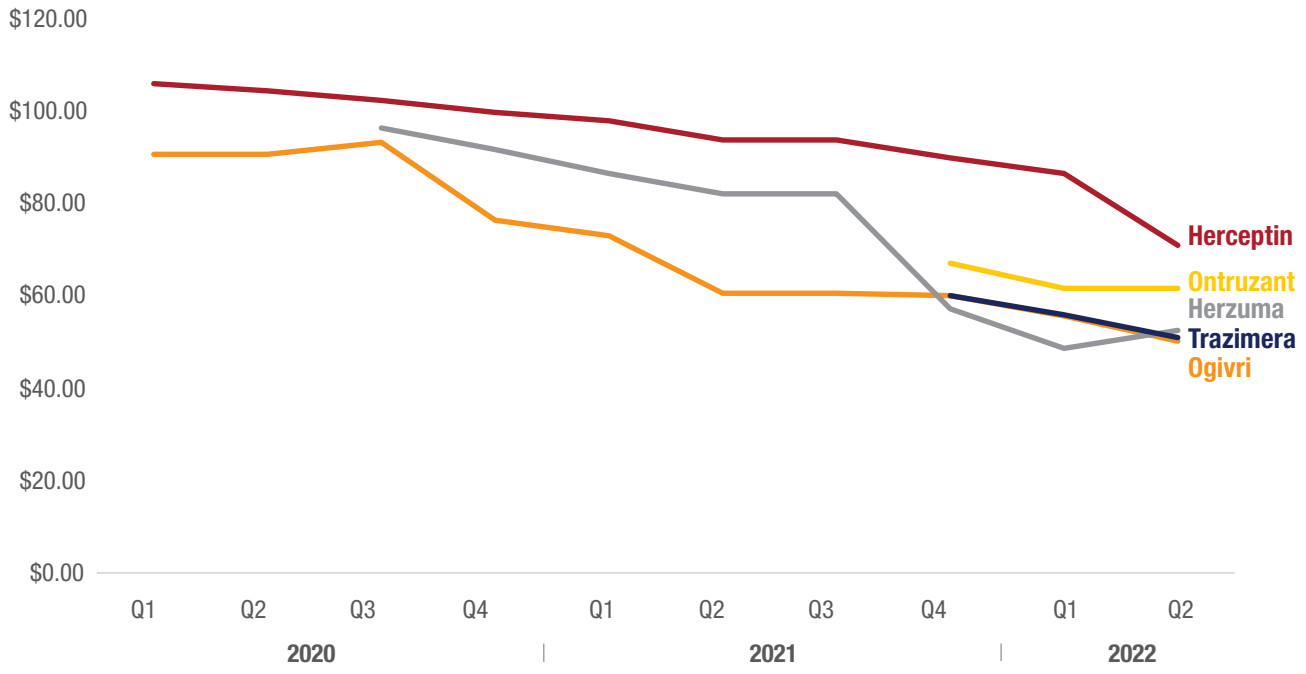
FIGURE 5. Epoetin Alfa Price Trends 2018 Quarter 3 through 2022 Quarter 2



Source: CMS Payment Allowance Data

A biosimilar entered the Trastuzumab market in the first quarter of 2020. Since the start of the competitive environment, the price of Herceptin (the originator biologic) has followed the lower prices for the biosimilars down yet is still higher than the prices for the competitive products. Compared to the price of Herceptin prevailing in 2020, the price of Herceptin in 2022 is 24 percent lower while the prices of the biosimilar competitors in 2022 are between 48 percent and 51 percent lower than Herceptin's 2020 price.

FIGURE 6. Trastuzumab Price Trends 2020 Quarter 1 through 2022 Quarter 2

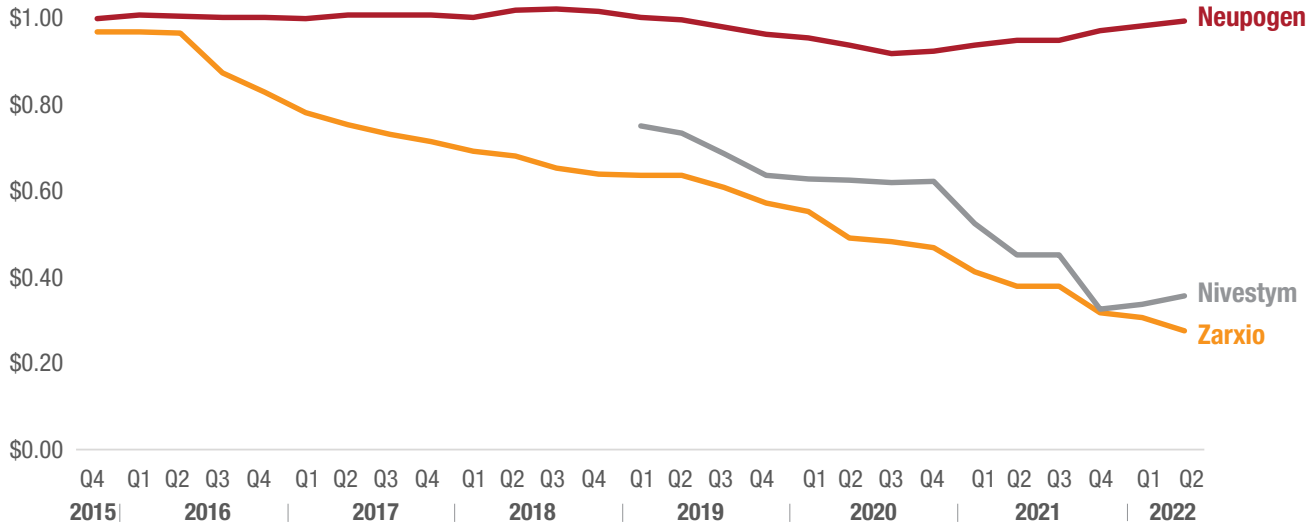


Source: CMS Payment Allowance Data

In the second category of medicines, the originator biologics only decreased their ASP's slightly in response to the introduction of the competitive products. The originator price declines did not come close to matching the significantly lower prices for biosimilars and include Neupogen, Rituxan, and Avastin. These pricing trends are illustrated in Figures 7, 8, and 9, respectively.

In the Filgrastim drug class the price of the originator biologic (Neupogen) is approximately the same today as it was back in 2015 whereas the price of the biosimilar Zarxio – the market leader in this drug class – is 71 percent below the pre-competition prices.

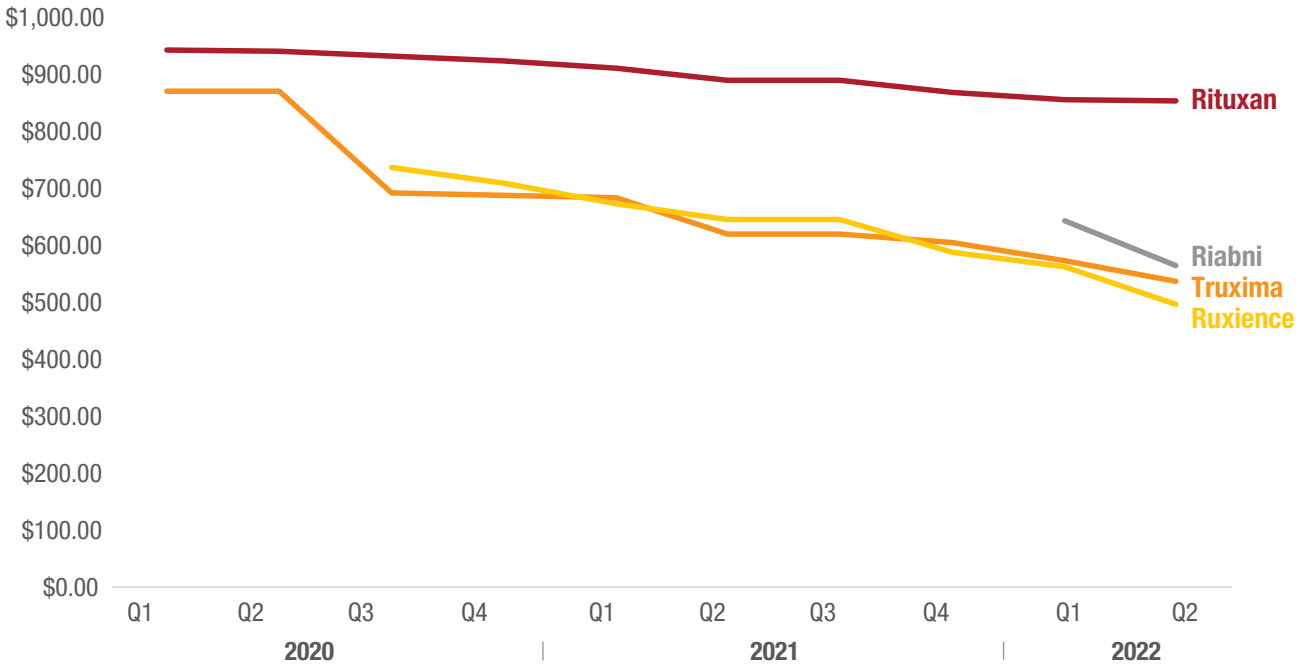
FIGURE 7. Filgrastim Price Trends 2015 Quarter 4 through 2022 Quarter 2



Source: CMS Payment Allowance Data

In the Rituximab drug class, the price for the originator biologic (Rituxan) has declined 9 percent compared to its 2020 average price, which is a significantly smaller price decline compared to its biosimilar competitors that are between 35 percent and 41 percent lower than Rituxan's pre-competition price.

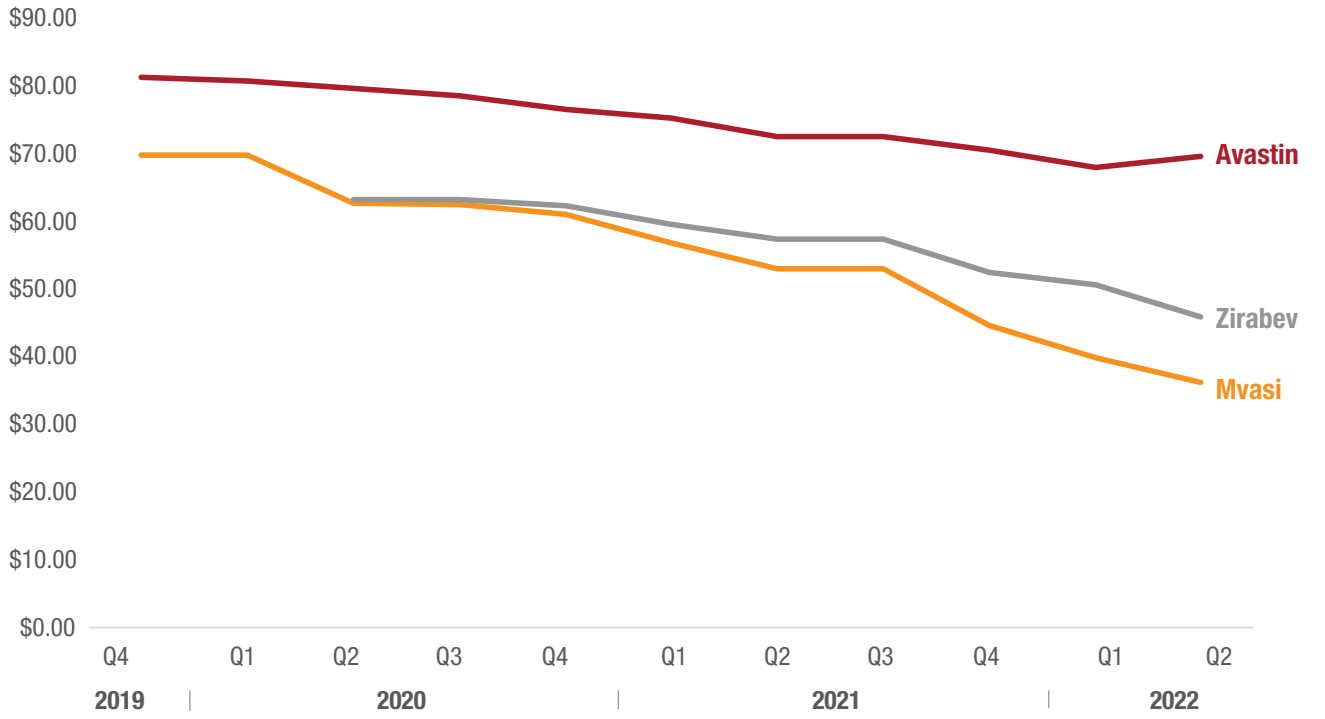
FIGURE 8. Rituximab Price Trends 2020 Quarter 1 through 2022 Quarter 2



Source: CMS Payment Allowance Data

The price trends in the bevacizumab drug class are similar to rituximab. Whereas the prices for Avastin (the originator biologic) have declined 15 percent compared to the pre-competition price, the prices for the two biosimilar competitors are down a much larger 41 percent to 53 percent.

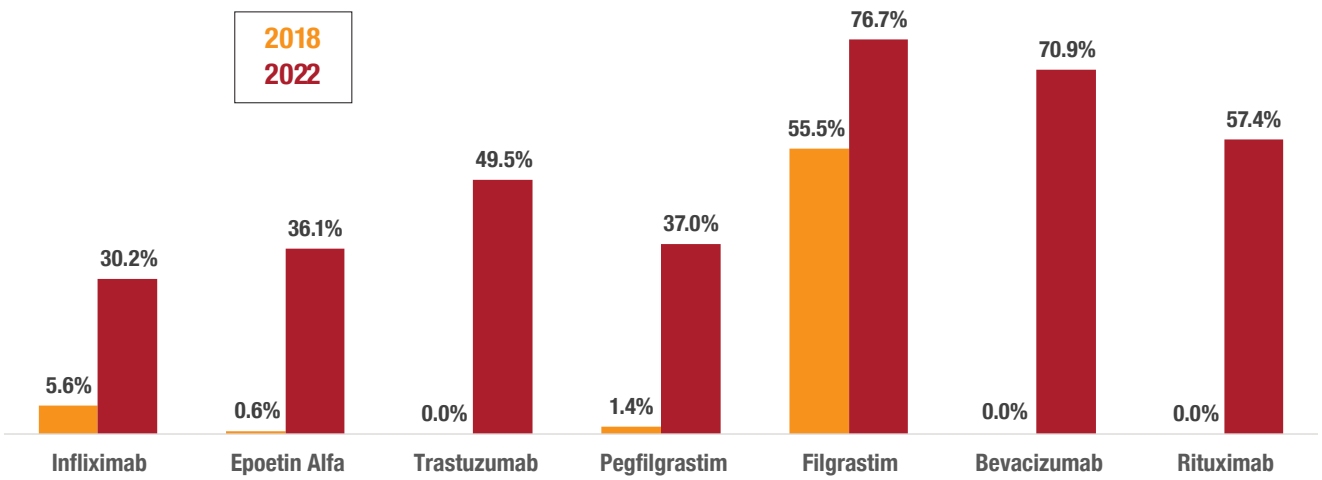
FIGURE 9. Bevacizumab Price Trends 2019 Quarter 4 through 2022 Quarter 2



Source: CMS Payment Allowance Data

Not surprisingly, there is a strong correlation between the market share maintained by the originator biologic and whether the originator reduced its price in line with the biosimilar competitors (category 1) or only implemented slight price declines (category 2). Figure 10 illustrates these impacts by presenting biosimilars' share of total units dispensed for each drug class. For perspective on the tremendous growth in the sales of biosimilars over the past several years, the share of sales in 2018 is presented in addition to biosimilars share of sales as of the second quarter of 2022. Just four years ago in 2018, sales of biosimilars were negligible across all the drug classes except for Filgrastim where the biosimilar Zarxio reached a 55.5 percent share of the market. The situation has changed dramatically. The latest volume data reported as of this writing demonstrates that most of the sales for the category 2 [e.g., rituximab (Rituxan), bevacizumab (Avastin), and filgrastim (Neupogen)] drug classes are biosimilars. Alternatively, the originator biologics in the category 1 drug classes [inflectra (Remicade), epoetin alfa (Epogen & Procrit), trastuzumab (Herceptin), and pegfilgrastim (Neulasta)] still maintain a dominant market share.

FIGURE 10. Biosimilar Market Share by Biologic Drug Class 2018 Quarter 4 versus 2022 Quarter 2



Source: Author calculations based on data from IQVIA

These figures demonstrate that biosimilar competition can generate systemic savings through two different competitive environments. In the first competitive environment, the originator biologic responds to the new entrants by matching (or beating) the lower prices offered by biosimilars, category 1. In these cases, competition generates significant systemic healthcare savings regardless of the market share of the biosimilar because the benefits of competition are also reflected in the price of the originator biologic.

When the originator biologic medicines do not attempt to match the pricing offered by biosimilars, category 2, a significant price discrepancy between the originator and biosimilar competitors emerges and systemic savings are only realized when biosimilars gain significant market share. As Figure 10 illustrated, this has been the case indicating that biosimilar competition creates large benefits in the drug classes that fall into competition category 2.

Competition Requires Competitors

It is important to note that whether biosimilars generate beneficial competition depends on their access to the drug formularies. Formularies are the list of approved drugs typically managed by pharmacy benefit managers (PBMs) on behalf of payers. Due to the opacity of the drug pricing system coupled with the inefficient drug rebate system that often benefits payers while increasing patients' out of pocket costs, competitive products will often receive disadvantaged formulary placements, or outright exclusion from the drug formulary.

Although the Federal Trade Commission (FTC) allows "exclusive dealing contracts" when such contracts expand the services customers receive, anticompetitive concerns arise when a company uses exclusivity contracts "to prevent smaller competitors from succeeding in the marketplace. For instance, exclusive contracts may be used to deny a competitor access to retailers or distributors without which the competitor cannot make sufficient sales to be viable."[8] Formulary obstacles play this obstructive role with respect to biosimilars and thwart the pricing benefits they can enable.

Reducing the number of effective biosimilar competitors should be expected to dampen the price decreases competition can enable. For instance, with respect to small molecule drugs, the FDA found that

> for products with a single generic producer, the generic AMP is 39% lower than the brand AMP before generic competition, compared to a 31% reduction using invoice prices. With two competitors, AMP data show that generic prices are 54% lower than the brand drug price before generic competition, compared to 44% when calculated using invoice-based drug prices. With four competitors, AMP data show that the generic prices are 79% less than the brand drug price before generic entry, compared to 73% when calculated using invoice-based drug prices. With six or more competitors, generic prices using both AMP and invoice prices show price reductions of more than 95% compared to brand prices.[9]

The market dynamics for the biologics market are no different. Larger numbers of biosimilars with equal formulary access to the originator biologic will engender a more competitive market environment that will benefit patients by improving affordability. Consequently, as discussed later, it is important that the formularies do not discriminate against biosimilars and instead promote a robust competitive environment.

Significant Price Declines Are Driving Large Dollar Savings

The different market processes have important implications with respect to the development of future competitive biosimilar medicines (an issue discussed in the next section). However, the pricing trends unequivocally demonstrate that the introduction of biosimilars has injected beneficial competitive pressures into the current biologics market to the benefit of overall healthcare expenditures.

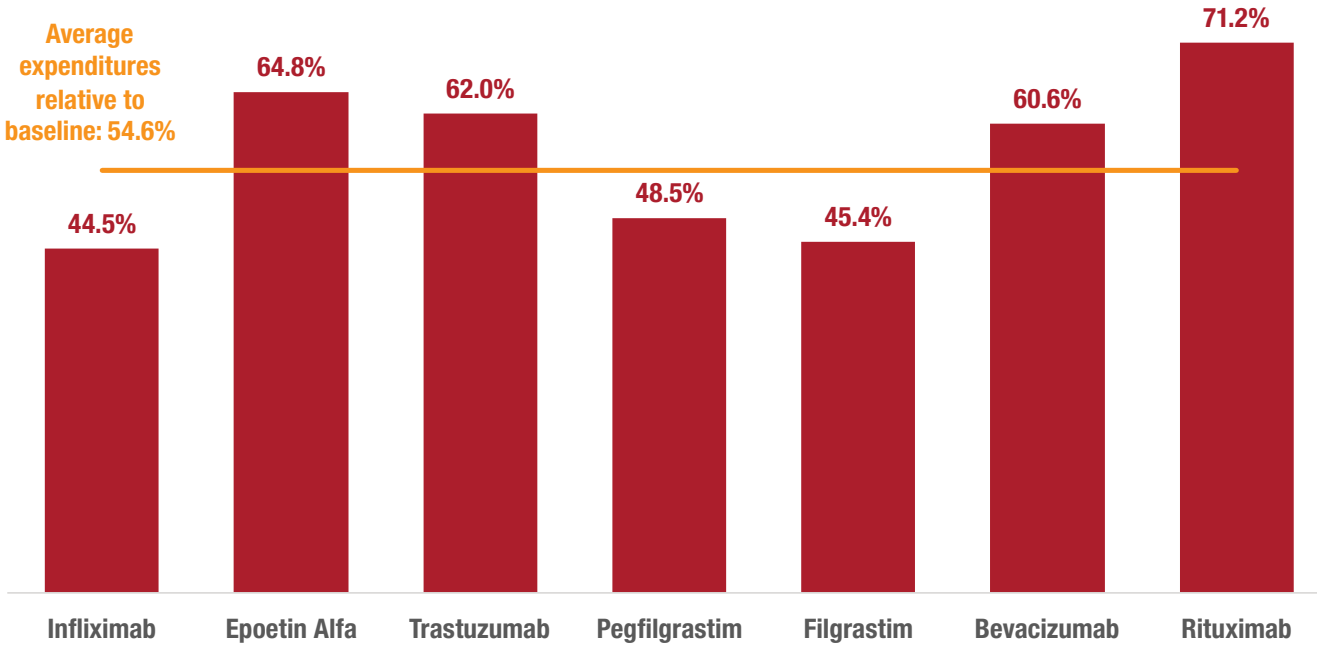
These beneficial outcomes can be visualized by comparing the expenditures for each drug class that are currently incurred to the expenditures that would have been incurred if the current unit sales were valued at the pre-competition originator prices. Given that prices were universally rising over time prior to the introduction of competition, this baseline valuing methodology establishes a conservative benchmark for evaluating the savings generated by biosimilar competition.

> “...the pricing trends unequivocally demonstrate that the introduction of biosimilars has injected beneficial competitive pressures into the current biologics market to the benefit of overall healthcare expenditures.

To estimate the realized savings, the 12-month shipment data through February 2022 for the seven biologic drug classes with current biosimilar competition is valued using two different methodologies.[10] The first methodology values the shipments of each originator and biosimilar drug at its current price, which provides an estimate of the total current expenditures for these seven biologic drug classes.

The second methodology values the total shipments for each biologic drug class at the price of the originator biologic in the quarter when biosimilar competition began. This methodology provides an estimate for the expenditures that would have been incurred had biosimilar competition not occurred – referred to as the baseline scenario. Figure 11 presents the expenditure discount that are currently being realized due to biosimilar competition as a share of total baseline expenditures.

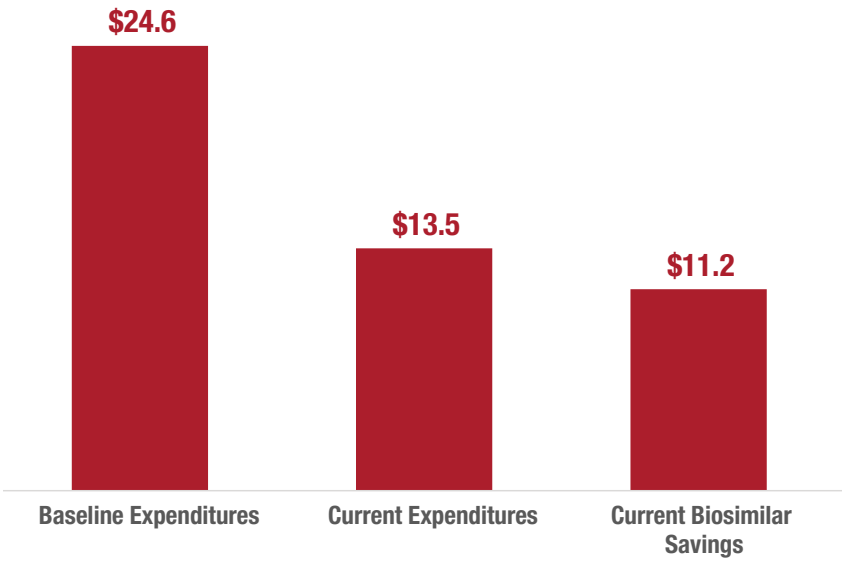
FIGURE 11. Current Expenditures as a Percentage of Baseline Expenditures by Biologic Drug Class



Source: Author calculations based on IQVIA and CMS data

Figure 11 illustrates that the competitive environment enabled by biosimilars has reduced total expenditures by a significant amount. At the low end, competition reduced expenditures to 71.2 percent of baseline expenditures on rituximab. At the high end, competition reduced expenditures on infliximab to 44.5 percent of baseline expenditures. The orange line at 54.6 percent is the average current expenditures relative to baseline expenditures across all drug classes. Due to these price discounts, total current expenditures on these seven drug classes are $13.5 billion, or a savings of $11.2 billion relative to the baseline expenditures of over $24.6 billion, see Figure 12.

FIGURE 12. Current Expenditures, Baseline Expenditures, and Estimated Total Biosimilar Savings (Billions)



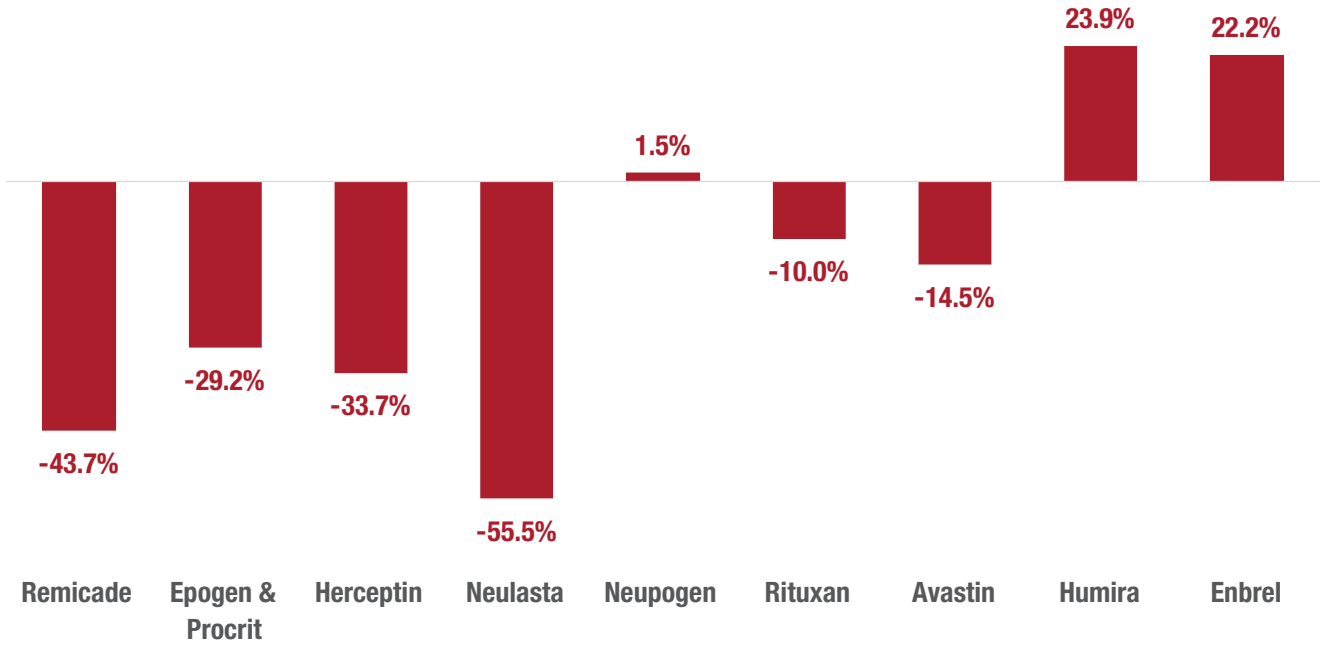
Source: Author calculations based on IQVIA and CMS data

Ensuring the Future Vibrancy of the Biosimilars Market

The 45 percent cost reduction relative to the expenditure baseline demonstrate that biologic competition has enabled large systemic benefits. Past achievements do not guarantee future success, however. Ensuring that the benefits enabled by biosimilar competition continue requires an understanding of the future savings opportunities and the broader barriers to future competition.

In dollar terms, there is a tremendous savings opportunity from introducing biosimilar competition into the etanercept (Enbrel) and adalimumab (Humira) markets. As Figure 13 demonstrates, unlike the prices for the originator biologics facing biosimilar competition, which have been declining, the prices for the originator biologics that do not face competition (Humira and Enbrel) continue to rise. Biosimilar competitors to Humira will be introduced in 2023, while it will take another six years before a competitor to Enbrel is released.

FIGURE 13. Latest 3-Year Percentage Change in Price for Originator Biologics 2019 Quarter 3 through 2022 Quarter 2



Source: Author calculations based on CMS Payment Allowance Data

If these competitive products are priced at 50 percent of the current prices for Humira and Enbrel and gain a 75 percent share of the market, then based on the same methodology as above, these biosimilars would generate $5.0 billion and $1.4 billion in savings compared to current expenditures. In other words, successful competitors to these drugs can expand the realized savings by over 57 percent.

There are several barriers that should be addressed to ensure that these significant potential savings can be realized. Paramount among these barriers is the current opaque pricing and rebate system that create anti-competitive obstacles. The practice referred to as a "rebate wall" exemplifies the problem as I documented in a 2020 analysis,

> One of the top reform priorities should address the anti-competitive practice that is commonly referred to as a "rebate wall" or a "rebate trap". Rebate walls occur when rebates are tied to specified volume targets. When the dollar sales of a drug are large enough, which often occurs when a drug treats multiple indications, losing these dollar rebates overwhelms the potential savings that lower-priced competitive drugs can offer insurers and PBMs. In order to avoid this penalty, insurers will, essentially, block patient access to lower-priced medicines. The lack of competition between drugs causes prices to remain excessively high, which impose large costs on patients who require expensive medicines and do not benefit from the rebates. As a result, successful rebate walls worsen the drug affordability problem by denying patients access to drugs that would be just as efficacious but cost less.[11]

Both Humira and Enbrel are well positioned to create rebate walls to minimize the reach of biosimilar competitors. The most effective way to address this problem is to fix the broader problems with the current rebate system, which should require greater price transparency and ensure that all rebates directly benefit patients when they receive their medications. Such reforms would fundamentally change the incentives that drive the pharmaceutical market. Instead of competing based on the size of the rebates paid, drug companies would compete based on the actual market prices of medicines. With rebates no longer driving the market process, the ability to game the system via rebate wall tactics would disappear because new competitors would compete with established brands by selling their drugs at a lower net price, and insurers would be able to include these drugs on their formularies without risking losing the sizable rebate revenues.

Should broad-based reform be politically infeasible, then reforms should prohibit, or significantly restrict, exclusionary- and volume-based rebates that enable firms to establish anti-competitive rebate walls.

Another consideration is the disincentives that can arise when originator biologics match biosimilars' lower prices. For current patients, these price declines are both welcome and an expected result from the increased competitive pressures. There are implications for the development of the next generation of biosimilars, however.

As the sales data demonstrate, biosimilars market share is significantly lower when the originators match biosimilars lower prices. The reduced market share decreases the expected value from future biosimilar investments, which reduces the incentive to invest in future biosimilars. Consequently, originators weaken the future competitive environment when they match biosimilars lower prices today, indicating that there will be fewer savings enabled by biosimilar competition in the future. While such considerations are irrelevant for most markets, the exclusivity period that is rightly granted to the developers of the originator biologic makes this concern relevant to the biologics market.

Addressing this concern requires reforms that counterbalance the reduction in the expected future value from investing in biosimilar development. Such reforms could include providing preferential placement for biosimilars on the drug formularies – or the list of approved drugs covered by an insurer. However, to gain access to any preferential treatment, biosimilars should be required to price their products at discounts that exceed set cost reduction thresholds.

Conclusion

Competition promotes affordability for consumers of biologic medicines just as it does in most other markets. Compared to the prices that prevailed pre-competition, biosimilar competition generates tens of billions of dollars in annual savings. Successful launches of biosimilars in the adalimumab and etanercept market can increase these savings by nearly 60 percent.

The biosimilars case study provides important perspective for policymakers because the savings generated by a competitive biologics market does not disincentivize future innovation. Consequently, policies that improve the competitive incentives in the biologics market will promote the dual goals of continued drug innovation and greater drug affordability. Recognizing these benefits, the goal of government drug policies should be to remove current barriers to competition, promote a transparent drug pricing system, and ensure that formularies do not block patients from accessing the widest available number of biosimilars.

Endnotes

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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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