The Response of Biologic Prices to Biosimilar Entry: Case Studies of Genotropin and Humira

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INTRODUCTION

Biologics are a class of drugs with complex molecules that generally come from living organisms (ex: bacteria, yeast, animal cells), which is what makes them very difficult and expensive to obtain (https://www.fda.gov/drugs/biosimilars/overview-health-care-professionals). According to the IQVIA Institute for Human Data Science's The Use of Medicines in the U.S. 2024 report, biologics only made up 5% of prescribed drugs in the US, yet contributed to more than 50% of the country's total prescription drug spending (Aitken et al., 2024). To avoid these extreme costs, patients may instead opt for a biosimilar, a kind of biologic drug that is highly similar to an existing biologic. These biosimilars can only be developed and sold after the patent for the original biologic expires, and are on average 60% cheaper than their original biologic (https://www.who.int/news/item/13-02-2025-biosimilars--expanding-access-to-essential-biologic-therapies). Crucially, substituting biologics for cheaper biosimilars helps those in need gain access to important medicines. Within the next decade, 118 biosimilars are expected to lose their patent protections, allowing hundreds of new biosimilar medicines to enter pharmaceutical markets (Aitken et al., 2025). It is currently vital to fully understand how they impact biologic prices.

This paper hopes to identify the real effect of patent protection loss on biologic markets. Biosimilar introduction is expected to drive down biologic prices since when competition is introduced, manufacturers should lower prices in order to remain relevant in their markets. Therefore, the hypothesis is that biosimilar entry drives biologic prices down. In reality, however, executive decision making is influenced by factors such as market monopolies and individual ideals, rendering theoretical predictions imprecise. This paper examines the real-world impact through the case studies of Genotropin and Humira, two widely used biologics, as biosimilars entered their respective markets. The prices of the biologics were observed over time, considering an intervention point of biosimilar entry. Determining prices is beneficial for understanding markets, as it reflects the market equilibrium (Banton, 2025). Price trends were examined using Medicaid's State Drug Utilization Data, and the National Average Drug Acquisition Cost, respectively. This allowed for reliable comparison over time, an approach made necessary by the limited availability of continuous pricing data for most biologic drugs across both databases.

MATERIALS AND METHODS

In order to reveal whether biosimilar entry drives biologic prices down or not, the price of Genotropin was measured alongside the price of Omnitrope (its biosimilar) as Omnitrope entered the market. The same was done for Humira and its respective biosimilars, Hyrimoz and Idacio. Most biologics, including Genotropin and Humira, have multiple biosimilars. This study only requires the measure of prices after the first few, since it is only focused on the initial biosimilar entry that follows patent expiration.

Genotropin is a human growth hormone used to treat growth failure in children and some adults, including people with Turner Syndrome, Prader-Willi Syndrome, or general short stature (Puckey, 2025). Omnitrope works the same way and treats the same things (Thornton, 2025).

Humira blocks a key inflammatory protein in the immune system known as tumor necrosis factor (TNF)-alpha, and is used to treat a massively wide range of inflammation-related diseases, from rheumatoid arthritis to plaque psoriasis to Crohn's disease (Pope, 2025).

Other biologics and their respective biosimilars were examined, such as Epogen and Retacrit, Neupogen and Zarxio, and Lovenox. They were discovered to yield discontinuous data.

Medicaid's State Drug Utilization Data was used in order to collect data on Genotropin / Omnitrope's prices over time. This database is free and accessible to the public. It measures the amount Medicaid reimburses patients, which may not be the most accurate tell of a drug's price, since Medicaid receives rebates that buffer the effects of drug price inflation (Dolan & Tian, 2020). However, it generally has a direct relationship with price trends.

In order to collect data for Genotropin and Omnitrope, the National Totals of State Drug Utilization Data from the years 2008 to 2010 were used (Medicaid began covering Omnitrope in 2009), filtering the state to "XX" (National Overall), filtering the product name to Genotropin or Omnitrope, and filtering the quarter for more precision. The choice was made to filter everything to national and not individual state totals to ensure consistency and for efficiency. For each quarter from 2008 to 2010, the national total amount reimbursed for Genotropin was divided by the national total units reimbursed for Genotropin to calculate the average reimbursement per unit. The same calculation was performed for Omnitrope from the second quarter of 2009 onward. These final values were used to compare the changes of the prices over time.

Unfortunately, Medicaid's State Drug Utilization Data did not include a lot of biologic/biosimilar groups. The National Average Drug Acquisition Cost (NADAC) database had some that Medicaid data lacked. The National Average Drug Acquisition Cost is the average amount pharmacies pay to wholesale sellers to have specific drugs in their inventories (Myers & Stauffer, 2021). This dataset only started collecting data at the end of 2013, so any biologics with biosimilars introduced before then would not have useful data (ex: Genotropin/Omnitrope). This dataset was used to collect data on Humira and its biosimilars.

To find the required data, all available NADAC observations for each year 2018 to 2025 were included. The "NDC Description" value was filtered to contain either Humira or one of Humira's biosimilars. All available NADAC per unit values for Humira, Hyrimoz, and Idacio were averaged to calculate annual mean prices for each year from 2018 to 2025. The range for the number of observations contributing to each annual average for Humira was 210 - 410, and for Hyrimoz was 24 - 44. For Idacio, 21 data points were averaged in the one year data was collected.

The NADAC database was also used to observe any additional biologics.

After the data was collected, it was entered into graphs in order to visualize the price trends over time. Simple percentages were calculated comparing biosimilar prices to their respective biologic prices over time, and comparing biologic prices before and after biosimilar entry. Interrupted time series analysis was performed on both cases using R programming, which involved using intervention variables to differentiate trends before and after biosimilar introduction in biologic markets.

RESULTS

Tables and Figures

Figure 1: Genotropin (Biologic) and Omnitrope (Biosimilar) Prices 2008-2010

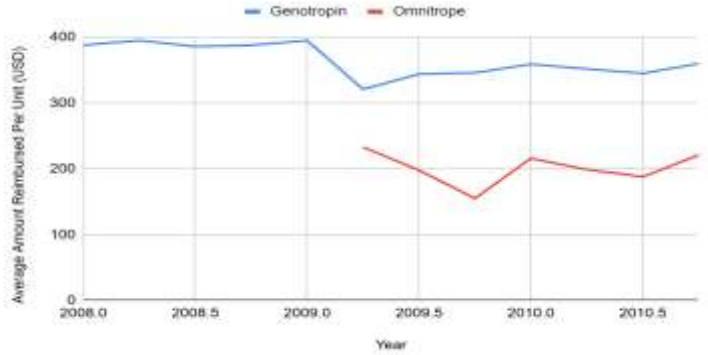


Figure 2: Humira (Biologic), Hyrimoz (Biosimilar), and Idacio (Biosimilar) Prices 2018-2025

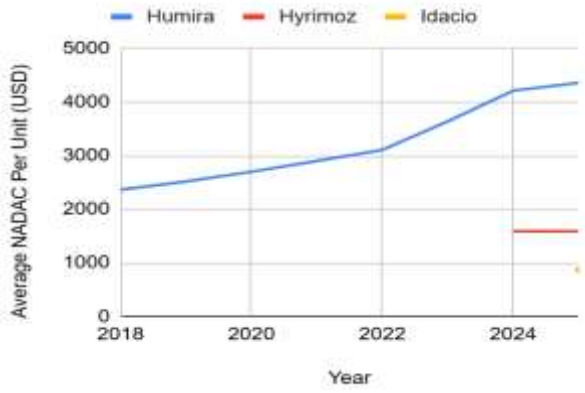


Figure 3: Genotropin Prices Before and After Omnitrope Entry (Interrupted Time Series Analysis) Blue = Data, Red = ITSA fit, Dashed = Omnitrope entry

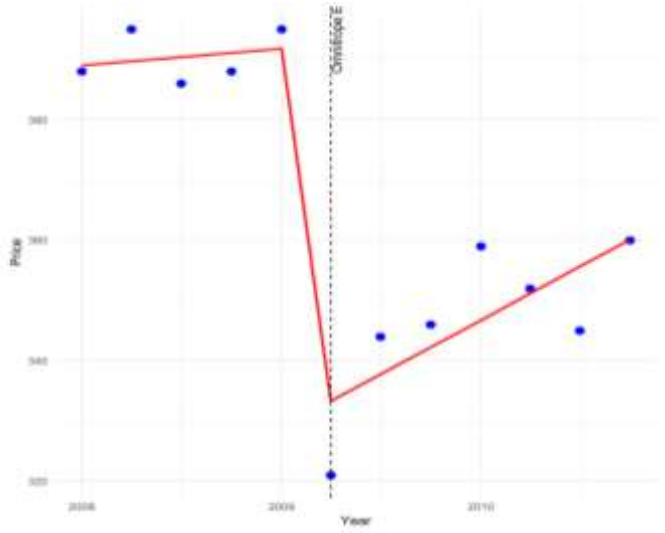
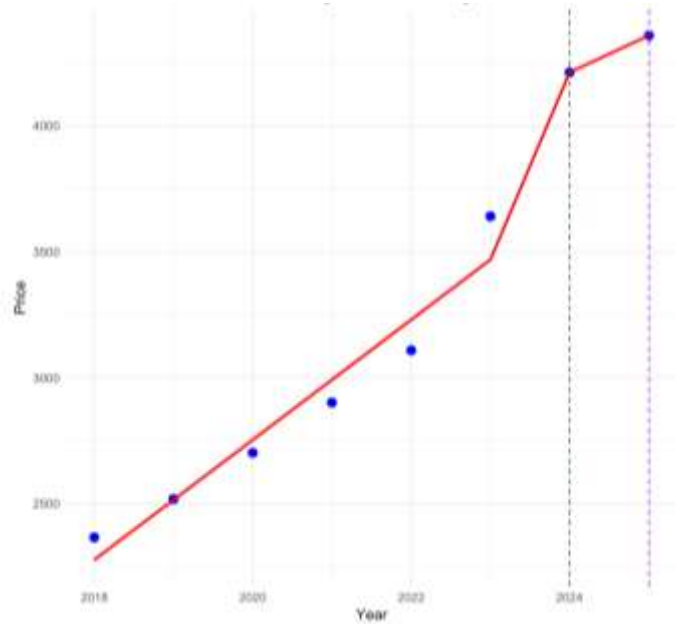


Figure 4: Humira Prices Before and After Hyrimoz/Idacio Entry (Interrupted Time Series Analysis)

Blue = Data, Red = ITSA fit, Green dashed = Hyrimoz entry, Purple dashed = Idacio Entry



It was also noted that 2 additional biologic/biosimilar groups (Epogen/Retacrit and Neupogen/Zarxio) showed very similar patterns, even with discontinuous data. They were both removed from the NADAC database around the same time biosimilars were approved to enter their respective markets. In 2024, both the biologics and biosimilars reappeared, with the biosimilars priced either the same or higher than the original biologic.

STATISTICAL ANALYSES

Descriptive Statistics

Figure 1 shows that after Omnitrope (biosimilar) was introduced in the second quarter of 2009, Genotropin's price decreased by 18.7%. Omnitrope's starting price was 58.99% Genotropin's original price (in 2009) and even after Genotropin's price drop, Omnitrope was still 72.59% of Genotropin's price. While Genotropin's price shifted back up a bit the next half year by 7.79%, Omnitrope's price actually dropped 33.48%. In the 4th quarter of 2009, Omnitrope's price was actually only 44.80% of Genotropin's price.

Figure 2 shows a 17.13% NADAC Per Unit increase for Humira in 2023 (the year Humira's patent expired), and a 15.71% increase in 2024 (the year Hyrimoz (biosimilar) was introduced into the US market). In 2024, the NADAC Per Unit of Hyrimoz was only 37.78% of the NADAC Per Unit of Humira. In 2025, when Idacio was introduced, it was only 20.00% of Humira's cost at the time and 54.83% the cost of Hyrimoz, the other biosimilar in the market at the time.

Inferential Statistics

Interrupted time series analyses (ITSA) were conducted to examine the impact of biosimilar entry on biologic prices. This statistical test was deemed the most appropriate, since it measures the effect an event had on trends over time. The 'event' in these cases was the initial biosimilar entry.

Figure 3 is the resulting model for Genotropin. The dataset included 12 values, 4 for each quarter of every year from 2008 - 2010, and was prepared by pairing each value with an intervention variable: 0 for pre-Omnitrope points and 1 for post-Omnitrope points. In the regression model, the dependent variable was Genotropin price and the independent variables were time, the intervention (Omnitrope entry), and time after the intervention. The pre-intervention trend was insignificant, with a slope of 0.70 (standard error = 2.59), a t-value (8 degrees of freedom) of 0.27, and a p-value of 0.79. Genotropin prices during Omnitrope entry had a change of -62.94 (standard error of 9.40), a t-value of -6.70, and a p-value of less than 0.001, displaying an immediate significant decrease in Genotropin prices after Omnitrope entry. The post-intervention trend was also not significant, with a slope of 3.76 (standard error of 3.02), a t-value of 1.25, and a p-value of 0.25. The F-test for the overall model with ⅜ degrees of freedom yielded 30.40 with a p-value less than 0.001, meaning the overall model was statistically significant. The R-squared value was 0.92 for the overall model, meaning that it can explain approximately 92% of the variance in Genotropin prices.

Figure 4 is the resulting model for Humira. The dataset included 8 values: annual average Humira prices from 2018 to 2025. It was prepared with two intervention variables this time, representing the entry of Hyrimoz and Idacio. The regression model had similar independent/dependent variables to Omnitrope's. (The 'intervention' as mentioned below only refers to Hyrimoz. The second intervention corresponding to Idacio entry (2025) couldn't be estimated, since there were no observations after 2025.) Its pre-intervention trend was positive and significant, with a slope of 238.60 (standard error = 30.07), a t-value (4 degrees of freedom) of 7.94, and a p-value of 0.00137. Humira prices during Hyrimoz entry changed by 597.49 (standard error = 295.62), with a t-value of 2.02 and a p value of 0.113, signifying an immediate increase in price corresponding to Hyrimoz entry (although this effect was not statistically significant). The insignificant post-intervention trend had a slope of –92.10 (standard error = 180.40), a t-value of –0.51, and a p-value of 0.637. The overall model was very significant, as F-test for the overall model with ¾ degrees of freedom yielded 84.38 with a p-value of 0.00045). The R-square value was 0.9844 for the overall model, meaning that the model could explain 98.44% of the variance in Humira prices.

DISCUSSION

This research provides a deeper understanding of what happens as biologic patent protection expires, which is vital to know as we enter the most severe patent cliff in history (Raju, Ajay, 2025).

The Case of Genotropin

The Genotropin case supports the hypothesis that biosimilar entry as a result of patent expiration in biologic markets drives prices down. This is because when a patent is in force, the drug is sold as a monopoly, which creates higher prices (Cristian, 2025). Without patent protection, the market becomes competitive, lowering prices. The results of the analysis suggest that Omnitrope entry was associated with an immediate, statistically significant reduction in Genotropin prices, meaning it behaved as expected.

The Case of Genotropin and Competition

The effect of the introduction of Omnitrope aligns with the microeconomic idea of competition. The Oxford Reference defines competition and its results: "Rivalry between suppliers providing goods or services for a market. The consensus of most economic theory is that competition is beneficial for the public, largely because it brings prices down" (https://www.oxfordreference.com/display/10.1093/oi/authority.20110803095628957). This applies to many markets, since without competition, monopolies can charge the maximum price consumers are willing to pay. On the other hand, competitive firms must charge a market price that is usually close to the marginal cost of production, since consumers will tend to purchase the cheaper option. Most substitutes also means that demand will be more elastic, responding more dramatically to price shifts from individual firms, incentivising them to keep prices low. The case of Genotropin and Omnitrope follows this concept flawlessly. Before competition was introduced, Genotropin was the only option in the market, so its prices were higher and consumers were forced to pay those prices. After competition (Omnitrope) was introduced, prices dropped significantly in order to still be competitive in the market. If the prices stayed higher, then consumers may not have purchased any more Genotropin and all switched to Omnitrope.

The Case of Humira

The Humira case rejects the hypothesis. The ITSA results suggest an immediate, non-significant increase in Humira prices associated with Hyrimoz entry. This was completely unexpected, as the original hypothesis predicted a decrease in biologic prices after biosimilar entry. The following paragraphs explore explanations as to why this occurred.

The Case of Humira and AbbVie's Monopoly

Humira was the number one top-selling drug in the US for a long time up until around 2020. It was also the highest grossing drug of all time with $21 billion in annual global sales as of 2021 (Contreras, 2023). This is because of both its utility and price. On the ZoomRx blog, Healthcare Market Research Expert Karni Medth compared the drug to a swiss army knife due to its versatility, "Humira, a name synonymous with swiss knife. It is a drug that could treat all conditions…" (Medh, 2023). It was approved by the FDA on Dec. 31, 2002, with its patent originally set to expire in 2016 (Pope, 2025; Constantino & Capoot, 2024). AbbVie, Humira's manufacturer, managed to extend its patent out many years longer until 2023. Large pharmaceutical companies manage to do this through a process known as evergreening. This is when companies patent "new inventions" that are really just slight modifications of old drugs (Collier, 2013). As a result, the companies get to keep their patents for longer and have the opportunity to keep prices high and make a lot of money in their monopoly as the only drug in their specific market. AbbVie applied for 311 Humira-related patents, of which 165 were granted (Robbins, 2023). A few of these did benefit patients, such as the formulation of a drug that reduced the pain of getting the injections, however the majority simply evergreened previous patents. All of this suggests that AbbVie did not want to lose its monopoly over a drug as successful as Humira, so in 2022, the year before the foreseen end of their patents, as seen on the graph, they began implementing strategic entry deterrence strategies such as price hikes in order to ensure their future competitors as little success as possible. According to ICER (Institute for Clinical and Economic Review), between 2021 and 2022, Humira was the drug with the most price

increases unsupported by clinical evidence, with a 7.11% increase in wholesale acquisition cost, resulting in a net price increase in drug spending of 386 million dollars (Rind et al., 2023).

The Case of Humira and Pharmacy Benefit Managers

Another big way companies limit their competition is through PBMs (Pharmacy Benefit Managers). It's because of these PBMs that even though there were many biosimilars released into the market in 2023, they only captured 4% of AbbVie's share (Constantino & Capoot, 2024). PBMs were originally meant to help health insurers save money on drugs: they handled negotiating drug prices and managing drug supplies. Now, they also negotiate with drug makers to decide which drugs are "preferred" by insurance companies. Drug makers can pay rebates to PBMs to be labelled as preferred, leading them to steer consumers towards drugs sold by companies who pay them more money. PBMs also earn administrative fees based on a percentage of a drug's price, meaning the more expensive the drug, the more PBMs make. It is a system set up to prefer more expensive drugs from more monopolistic companies. So, even if there are dozens of significantly cheaper biosimilars in the market, insurance companies will recommend the more expensive Humira to patients. Speaking of monopolies, PBMs are also run under 3 companies that control 89% of the market: Express Scripts, CVS Caremark, and OptumRx (Pinder, 2023). After CVS Caremark switched to recommending Humira's biosimilars instead, the market share for Humira biosimilars rose from 5% to 36% within a week (Constantino & Capoot, 2024). In 2024, it was only the 14th best-selling drug in the US (Rashid, 2025).

Manufacturer Influence

Humira's price trends can be explained by the way its manufacturer responded to its patent's expiration, which suggests that market structure alone may be insufficient to explain pricing behavior, and that firm-level strategic decision-making may play a critical role. An alternative hypothesis rises: biologic price behavior depends on the company behind the drug. The additional cases of Neupogen and Epogen support this hypothesis. While these data were too discontinuous for formal interrupted time series analysis, the observed pattern—both drugs disappearing from the NADAC database around the time of biosimilar approval (2015 for Neupogen and 2018 for Epogen) and both reappearing in 2024 with biosimilars priced at or above the original biologic—is consistent with the manufacturer influence hypothesis, as both are manufactured by Amgen Inc. However, these observations should be considered exploratory rather than confirmatory.

Current Limitations and Future Research

This study attributes Humira's price increase to its manufacturer, but assumes that Genotropin's price decrease was solely because of competition. A deeper dive into the company behind Genotropin would yield results that could be better compared to other cases, especially while exploring the alternative hypothesis of manufacturer influence. While investigating this hypothesis, continuing to observe Humira's manufacturer may yield interesting results. At the moment, Humira is AbbVie's only biologic drug with biosimilars in the market, but they have a few more up-and-coming drugs (such as immunology treatments Skyrizi and Rinvoq) that are expected to become monopolies similar to Humira (Constantino & Capoot, 2024). Skyrizi climbed up to the 7th best-selling drug in the US in 2024 (Rashid, 2025).

Because this study examines a limited number of biologics, the generalizability of these findings to the broader biologics market remains uncertain. Analyzing a greater number of cases and performing a correlational study comparing biologics whose prices increase and decrease could be useful in finding what causes different outcomes. Continuing to track prices into the future could reveal if biologic prices end up decreasing more after biosimilars become more competitive, or if they increase back to their original prices. Overall, there is much more to be studied in order to help economic and healthcare experts predict important price trends in the future.

Previous Research

Previous Research Questions the Impact of Biosimilar Entry on Biologic Prices

Grabowski et al., emphasizes why prices for biosimilars may not always be as low as expected. Fewer biosimilars are created because of high development and manufacturing costs, uncertain regulatory pathways, and few

incentives for firms to enter small markets. They must also compete on quality, reputation, and marketing, making it tough to lower prices and allowing original biologic manufacturers to differentiate their product, prolonging their monopolies. Because of this, it can be concluded that biosimilar introduction may not have as significant of an impact on biologic prices as expected. (Grabowski et al., 2014). This challenges conventional understanding, but it could also explain why biologic prices may not decrease after their patents expire.

Previous Research Supports the Case of Omnitrope

The percent of change in the average price of biologics with and without biosimilar competition was studied by Pacific Research Institute Senior Fellow of Business & Economics Wayne H. Winegarden. He observed that in markets with biosimilar competition, the average price of biologics fell by 56% and overall spending dropped by 51%. He noted that biosimilars do not reach the extremely low prices of traditional generics due to their expensive and time-consuming development (often taking 6–9 years and costing $100–300 million). Still, he argued the large impact of biosimilars on the affordability of their original biologics. Winegarden's analysis demonstrates how the introduction of a competitor can tend to lower prices, pointing to the conclusion that the introduction of biosimilars will significantly lower the prices of their original biologics, which was reached by Genotropin's case (Winegarden, 2024).

Previous Research Explains the Case of Humira through Strategic Entry Deterrence

In 2011, Ellison and Ellison found evidence suggesting the existence of deterrence strategies, although identifiable cases were relatively rare. This evidence mostly involved small-molecule drug companies, but the underlying logic still applies to biologics, providing a reason as to why Humira's prices surprisingly increased instead of decreased after biosimilar competition was introduced. Alongside the many struggles biosimilar manufacturers have to endure, biologic companies might also try to sabotage their success. Strategic entry deterrence is the purposeful discouragement of generic entry by pharmaceutical companies through calculated moves such as advertising shifts, pricing changes, and "presentation proliferation" (proliferating package sizes or formulations) (Ellison & Ellison, 2011). An example of a strategic entry deterrence strategy is temporarily reducing marketing activity to make a drug appear less profitable to potential competitors.

CONCLUSION

This investigation set out to understand the real impact of biosimilar entry on biologic markets. However, additional research with more biologics is needed to determine the exact factors that influence price changes and future correlational studies could yield clearer results, potentially leading to ways to predict future price behaviors. The understanding this paper reveals on biologic price behavior is applicable to aid pharmaceutical companies, individuals, and monetary and fiscal decision-making, especially as we enter a time of massive shifts in our pharmaceutical market. The results of this research merge the claims made from different economists: biosimilar entry can decrease or increase biologic prices depending on numerous factors. It introduces a new hypothesis that biologic price behavior may relate to company management as well, which can be explored by comparing different biologics from the same manufacturers to each other and to outside biologics.

The conclusion is that biosimilar entry alone is insufficient to predict biologic price behavior. Genotropin's price decreased significantly in response to the introduction of biosimilar competition, while Humira's price increased insignificantly in response due to its manufacturer implementing monopolistic practices such as abusing pharmacy benefit managers or using entry deterrence strategies to limit competition. Based on these results, it can be assumed that these two variables aren't as related as many economists believe.

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