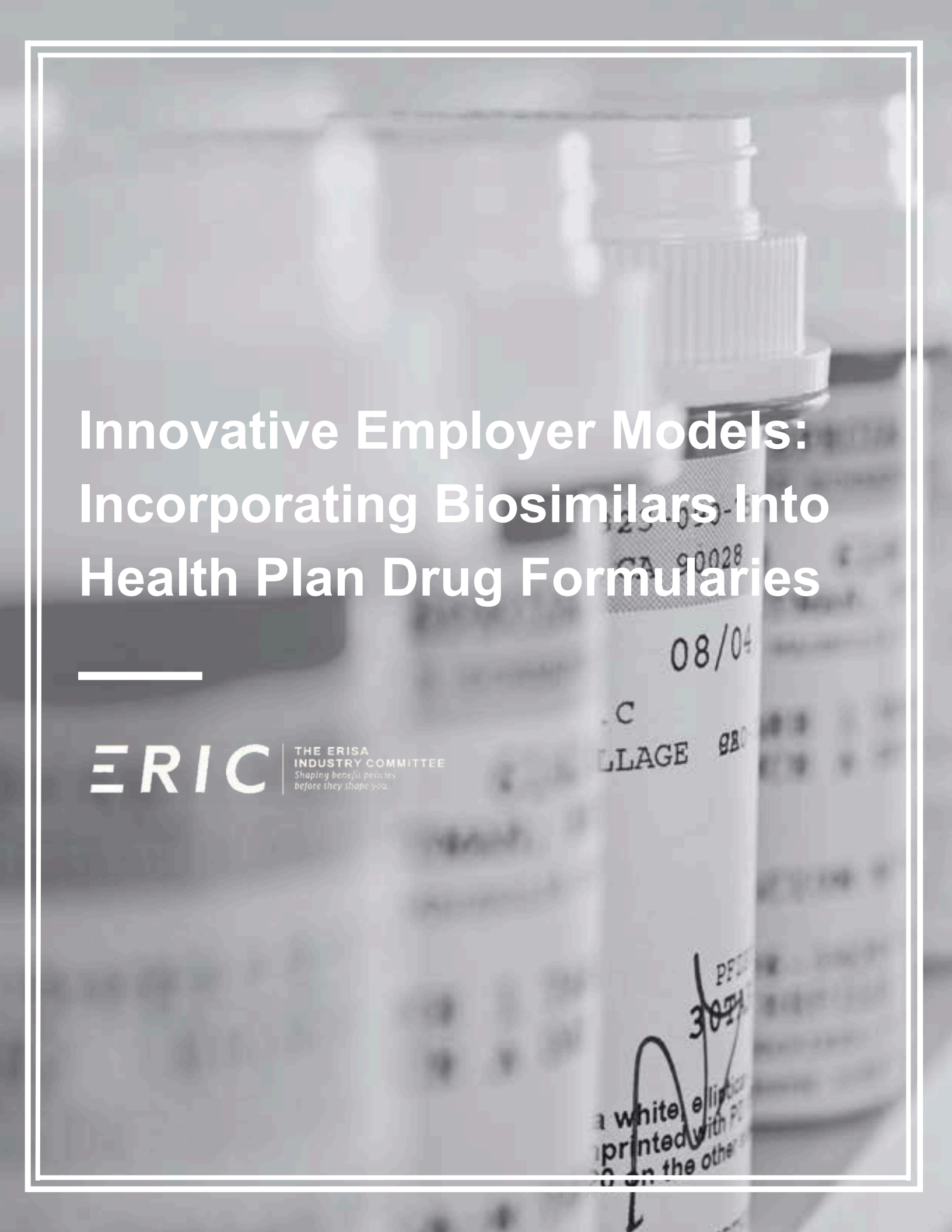
Innovative Employer Models: Incorporating Biosimilars Into Health Plan Drug Formularies



ERIC | THE ERISA INDUSTRY COMMITTEE
Shaping benefit policies before they shape you.

About ERIC

ERIC is a national advocacy organization that exclusively represents large employers that provide health, retirement, paid leave, and other benefits to their nationwide workforces.

You are likely to engage with an ERIC member company when you drive a car or fill it with gas, use a cell phone or a computer, watch TV, dine out or at home, enjoy a beverage, fly on an airplane, visit a bank or hotel, benefit from our national defense, receive or send a package, go shopping, or use cosmetics.

With member companies that are leaders in every sector of the economy, ERIC advocates on the federal, state, and local levels for policies that promote flexibility and uniformity in the administration of their employee benefit plans.

ERIC member companies are large, nationwide employers—generally companies with more than 10,000 employees—that provide comprehensive employee benefits to workers and families across the country. ERIC represents member companies exclusively in their capacity as large plan sponsors. By working to preserve the Employee Retirement Income Security Act of 1974, ERIC is helping to maintain national uniformity and fighting against taxes, mandates, and compliance burdens for large plan sponsors. ERIC advocates for policies that make it easier and more cost-effective for employers to provide benefits that support their workforce and families.

Only ERIC provides the combination of intel, expertise, collaboration, and lobbying that exclusively serves the interests of large employers who provide health, retirement, and compensation benefits to their nationwide workforce. Through this work, ERIC helps employers help their employees. ERIC has expanded the availability of telemedicine, improved retirement and health regulations, and reconciled conflicting state and local paid sick and family leave laws.

ERIC works with lawmakers on Capitol Hill and in the states to ensure they and their staff understand legislative policies that impact large employers whether it be policies related to prescription drugs, health insurance premiums, or even mental health benefits. ERIC also meets with regulatory agencies and Administration officials to advance benefit regulations through the political process. ERIC continues to push forward in representing large employers in employee benefit policies at the state and federal levels.

The Value of Biosimilars for Employer Health Plans

What are Biosimilars?

Biosimilars are FDA-approved alternatives to existing biologic medications, including specialty drugs, that match in safety, efficacy, and clinical outcomes.

Robust evidence confirms that biosimilars perform identically to their reference biologic counterparts in treating conditions such as rheumatoid arthritis, cancer, and diabetes.[1] Importantly, both reference biologics and biosimilars must be proven to be safe, pure, and potent under Federal law.[2] In addition, both reference biologics and biosimilars must comply with current Good Manufacturing Practices and FDA facility inspections,[3] and both are monitored with the same FDA pharmacovigilance systems for adverse events.[4]

Why Should Employers Care?

Biosimilars offer a meaningful opportunity for employers to reduce their spending on prescription drugs while maintaining access to high-quality, clinically equivalent treatments for plan participants. This allows the employer to satisfy their ERISA fiduciary duties.

Employers administering self-insured health plans may be considered fiduciaries under the Employee Retirement Income Security Act ("ERISA").[5] ERISA fiduciaries, must, among other things, act prudently and in the best interests of plan participants, and keep health plan administrative costs reasonable.[6]

The Value of Biosimilars for Employer Health Plans, Cont.

Why Should Employers Care?

When an employer affirmatively chooses to include biosimilars in its health plan's drug formulary, the employer is not only lowering costs for the plan and its participants, but the employer is also providing the same value to plan participants, as biosimilars are effectively identical in safety and efficacy to their reference biologic counterparts.

This does not mean that if an employer opts not to incorporate biosimilars in its health plan's drug formulary as a design decision, the employer somehow breached their ERISA fiduciary duties related to administering the plan. This is one of many ways employers can seek to control costs in a plan. Employers should be aware, however, of a series of employee lawsuits alleging that an employer violated ERISA fiduciary duties on account of decisions made (or not made) regarding (1) the health plan's design or (2) how much the plan and plan participants ultimately paid for covered benefits.[7] Although none of these lawsuits have been successful to date, it would be reasonable for employers to undertake a process to (1) consider lower-costing biosimilars and (2) evaluate their efficacy to help control costs to the plan while maintaining access to quality care.

The Value of Biosimilars for Employer Health Plans, Cont.

Do Biosimilars Save Money?

Biosimilars can generate significant savings for both employers and plan participants through lower net costs and out-of-pocket spending. **Case-in-point**: ERIC asked Johns Hopkins to analyze pricing and utilization data from 13 ERIC members for purposes of comparing the spending on the biologic reference of two particular drugs – *Filgrastim* (which is a drug utilized by cancer patients) and *Infliximab* (which is a drug used to treat rheumatoid arthritis) – as compared to their biosimilar counterparts. The purpose of the study was to analyze the savings potential if these ERIC members fully adopted the biosimilar counterpart in place of the reference biologic (i.e., the employer fully replaced the biologic reference with the biosimilar). According to data from the 2018 plan year, the study found that:

- *Infliximab* biosimilar cost 32% less than the reference biologic, while the *Filgrastim* biosimilar cost 26% less.
- Full biosimilar replacement could have saved these employers $1.5 million annually on *Infliximab* and $17,838 on *Filgrastim.*
- Employee out-of-pocket costs would have also dropped by $300 (12%) for *Infliximab* users and $600 (45%) for *Filgrastim* users.

The analysis also suggested that if all self-insured employers offered biosimilars in lieu of the reference biologic *Infliximab* and *Filgrastim*, this action alone could have saved between $407 million and $1.4 billion annually. Medicare savings could have also reached $279 million upon full replacement.[8]

The Value of Biosimilars for Employer Health Plans, Cont.

Do Biosimilars Save Money?

Humira® – the world's best-selling drug – has seen a price increase of 470% since the brand-name drug first entered the market in 2003.[9] Recently, a wave of *Humira*® biosimilars were finally introduced in the market with list prices up to 85% lower than the cost of the reference biologic.[10] Although a recent report found that Humira® biosimilars competition has occurred in less than 2% of the U.S. market,[11] industry experts suggest that in the first 18 months of biosimilar competition, the U.S. healthcare system accrued approximately $11 billion in savings attributable to adalimumab, a *Humira*® biosimilar.[12]

By way of example, if *Humira*® costs $84,000, but a *Humira*® biosimilar discounted at 85% costs $12,600, a participant paying a 20% co-pay out-of-their-own-pocket for the *Humira*® biosimilar would save about $14,200 annually. Another example: Lower costing *Humira*® biosimilars like adalimumab aqvh can be purchased through Mark Cuban's Cost Plus for almost a 92% discount.[13]

The bottom-line is this: Biosimilars lower costs in two ways: (1) The list price for biosimilars is significantly lower than the net price for the reference biologic and (2) biosimilars promote competition, forcing reference biologic manufacturers to compete with biosimilars which leads to lower costs for prescription drugs for the entire health care system. Both mechanisms to lower costs were responsible for $56 billion in savings from 2013 to 2022, as biosimilars began to establish their presence in the market.[14] Importantly, the availability of biosimilars writ-large has the potential to save the health care system up to $133 billion in 2025.[15]

Rethinking Pharmacy Benefit Design to Support Biosimilars

Challenges With Traditional Rebate Models and Biosimilar Adoption

The dominant business model among PBMs is the "Traditional Rebate Model" in which the PBM generates the lion's share of its revenue through the receipt of "rebate" payments from drug manufacturers. Here, the drug manufacturer develops a "list price" for a particular drug and the amount of the rebate is typically based on a percentage of the drug's list price – and the PBM generally retains a percentage of this list price, treating it as compensation from the employer. This means that the higher the list price of a particular drug, the higher the rebate (and revenue) paid to the PBM. This results in a perverse incentive for PBMs to favor high-cost drugs, which ultimately results in PBMs choosing to include these high-cost drugs on their preferred formulary. This results in increased health care spending for both the plan and its participants, especially in cases where a PBM retains the full amount of the rebate for their own gain and does not pass through any portion of the rebate to the plan or its participants.

Despite the overwhelming data indicating that biosimilars can save employers millions of dollars (as discussed above), **PBMs have shown resistance to placing biosimilars on a health plan's drug formulary.** This resistance is largely driven by profit motives concerning rebates. For example, because biosimilars carry a lower list price, biosimilars generate smaller rebates for PBMs. As a result, PBMs have little incentive to replace high-cost biologics with their biosimilar counterparts under a rebate-driven model. In some cases, PBMs and drug manufacturers even enter into agreements to exclude biosimilars from the PBM's drug formularies in exchange for larger rebates offered by the manufacturer for the continued placement of the reference biologic.[16] This slows biosimilar adoption, undercuts competition, and limits savings for employers and plan participants.

Rethinking Pharmacy Benefit Design to Support Biosimilars, Cont.

Challenges With Traditional Rebate Models and Biosimilar Adoption

ERIC member companies recognize the short-comings of the Traditional Rebate Model, and some may be poised to make a change.

- For example, according to a recent ERIC survey, a majority of our member-companies that currently rely on the Traditional Rebate Model would consider shifting away from this Model if they were able to achieve savings by including lower list price drugs on their formulary. The vast majority of ERIC members also responded that they would consider abandoning their reliance on rebates if plan expenditures for the year were lower without rebate guarantees.

  In other words, if an alternative model was available that did not include rebates, thereby eliminating the perverse incentive to favor high-cost drugs to the detriment of lower costing biosimilars, while also allowing employers to include lower list price drugs on their plans' drug formulary, our members appear open to making the change.

But, just about half of our ERIC members are undertaking efforts to analyze whether making such a change is appropriate.

- But, just about half of our ERIC members are making efforts to analyze whether making such a change is appropriate. For example, about half of our member companies are mapping out whether plan costs will go down if, instead of relying on rebate guarantees, their plan's drug formulary includes "preferred" lower costing biosimilars relative to their high-cost biologic counterparts.

  However, separate and apart from any reliance on rebates and/or efforts to shift away from the Traditional Rebate Model, a number of ERIC members are successfully lowering their health care spending by adopting innovative strategies to encourage biosimilar utilization by (1) re-evaluating formulary placement and tiering and (2) reducing their reliance on PBMs, as discussed more fully below.

Rethinking Pharmacy Benefit Design to Support Biosimilars, Cont.

Emerging Employer Strategies to Encourage Biosimilar Utilization

1. Re-Evaluating Formulary Placement – Tiering and Other Strategies

In cases when an employer successfully includes biosimilars in their health plan's drug formulary, the employer may take steps to steer plan participants to utilize biosimilars instead of the high-costing biologic. These steps may include formulary tiering and varying the cost-sharing (e.g., co-pay and co-insurance) levels for particular drugs placed on a particular tier within the drug formulary. For example, the employer-sponsor may establish three separate tiers:

- **Tier #1** includes low-cost generics.
- **Tier #2** includes preferred brand-name drugs and their biosimilar counterparts.
- **Tier #3** includes non-preferred brands and specialty drugs.

The employer will then establish lower co-pays or co-insurance for the biosimilars included in **Tier #2**, making the biosimilars financially attractive compared to the high-cost reference biologic.

Other employers have placed biosimilars on their preferred tier (with lower cost-sharing), while moving the high-cost reference product to a different tier (with no favorable cost-sharing). These employers also incorporated utilization management into the formulary; in particular, prior authorization and step therapy. Here, the only way participants could access the brand-name drug over the biosimilar counterpart to get confirmation from a licensed physician that the biosimilar was not performing and providing the prescribed outcome.

Some employers have gone so far as to remove the brand-name drug from the plan's formulary entirely, only offering biosimilars on the formulary. And, only in very limited circumstances would the employer allow access to the brand-name biologic (like a life-or-death reaction to the biosimilar).

Rethinking Pharmacy Benefit Design to Support Biosimilars, Cont.

Emerging Employer Strategies to Encourage Biosimilar Utilization

A number of ERIC members have already taken steps to steer their employees to "preferred" lower costing drugs through the same tiering and drug placement strategies discussed above.

However, when it comes to the "selection" of drugs included in the drug formulary in the first place, a majority of ERIC members have signaled that their PBM "controls" the drug selection, while only a minority of ERIC members actually review the (1) list price of particular drugs and/or (2) rebates associated with the selected drugs. Employers also face challenges regarding which drugs will be stocked and dispensed by PBM-owned specialty pharmacies.

Interestingly, a majority of ERIC members note that they are at least "aware" of their PBM's decisions to include certain drugs on their plan's formulary. But, despite being aware of their PBM's decisions, virtually all ERIC member companies surveyed explained that they want more "involvement" in their plan's formulary design, including comparing (1) formulary offerings and (2) net costs vs. rebates associated with particular drugs. Some employers appear to be satisfied with the traditional rebate model, but many other employers would like to see full transparency so they can readily compare whether they are saving more from a rebate model as compared to, for example, a pass-through model, and whether or not there are "rebate walls" that limit the employer's savings.

2. Reducing Reliance on PBMs

Some ERIC members have taken other innovative approaches to providing plan participants with meaningful access to prescription drugs by limiting – or in some cases eliminating – their reliance on a PBM. These actions can save employer plan-sponsors millions of dollars, and increase value to plan participants, especially in cases where the employer offers preferred access to biosimilars.

EMPLOYER HIGHLIGHT – Contracting With Retail Pharmacies

Company X adopted a **direct contracting model** with retail pharmacies, **effectively bypassing PBMs entirely**. In doing so, Company X took steps to **de-construct the prescription drug supply-chain** to identify:

1. Where in the supply chain costs for prescription drugs are the most economical.
2. Where in the chain the prices of the drugs are inflated.

These steps included:

- **First**, identifying the manufacturer of a particular drug, and then **identifying the price charged by the drug manufacturer**. Here, the cost was the lowest, as the drug manufacturer sits at the beginning of the supply chain.
- **Second**, identifying the drug wholesaler and the **price of the drug charged by the wholesaler**. Here, there was a slight mark-up in price relative to the drug manufacturer's price.
- **Third**, identifying the retail pharmacies that are selling the drugs to plan participants, and then **identifying the price charged at the pharmacy counter**. At this point in the supply-chain, the cost of the drug is higher than what the drug manufacturer and wholesaler charged, but still economical.
- **Fourth**, identifying the PBM that may be hired to manage the employer health plan's drug formulary and drug placement, and then **identifying the price charged by the PBM**. Because this is the end of the supply-chain, the price of the drug is the highest, especially when factoring in spread pricing and rebates that were not passed-through to Company X or Company X employees participating in the health plan.

Upon the identification of these price mark-ups, Company X made a strategic decision to **directly contract with retail pharmacies** (such as Walmart). As noted, although retail pharmacies are three steps into the supply chain, costs are lower relative to the prices charged by PBMs, as Company X discovered.

You may be asking: Why contract directly with retail pharmacies instead of going directly to the wholesaler or drug manufacturer, which are the first and second steps in the supply chain?

***Answer*:** Company X discovered that drug manufacturers and wholesalers typically do not have the same distribution capabilities as the retail pharmacies, and thus, the drug manufacturers and wholesalers cannot offer employees the same wide-spread access to the drugs that retail pharmacies can. In addition, the sales capabilities and customer service inherent in the retail pharmacies also provide significant value to plan participants. Company X has, however, recently begun contracting directly with a drug manufacturer on two biosimilar equivalent medications that recently entered the market, thereby further reducing the margin within the supply chain. These first two agreements are intended to serve as the template for additional products in the future.

SETTING PRECEDENT – Blue Shield of California and Multi-Vendor Partnership

Blue Shield of California ("Blue Shield") has taken steps to **eliminate their reliance** on one of the three major PBMs operating today, and instead, has chosen to **contract with multiple vendors** to perform many of the same services a PBM would provide, but at a significantly lower cost, and in a much more transparent and equitable way.

Through this **multi-vendor partnership**, Blue Shield works with specified companies to:

- **Negotiate the prices** of the prescription drugs covered under Blue Shield's plan.
- **Disclose the prices** of covered prescription drugs to participants through a mobile app.
- **Deliver prescription drugs** directly to participants.
- **Process claims and other payments** for covered prescription drugs.

With regard to negotiating prices, Blue Shield partnered with Prime Therapeutics (a PBM created and owned by Blue Cross/Blue Shield plans) to support rebates for Blue Shield's Commercial and Medicare formularies. Although Prime Therapeutics ("Prime") operates under the Traditional Rebate Model, Blue Shield retains oversight and control over formulary and utilization management to ensure the best value and experience for members. The formulary placement for a particular drug is influenced by efficacy and health outcomes instead of the drug's ability to earn rebates. By doing so, Blue Shield ensures decisions are made to improve patient outcomes, while lowering health care spend.

Blue Shield also contracted with Amazon to **deliver prescription drugs** directly to a plan participant's home, effectively creating their own mail-order distribution as opposed to being forced to rely on a PBM-owned mail-order pharmacy, which often times steers participants to pay higher prices for their prescription drugs.

Separately, Blue Shield **contracts directly with drug manufacturers**. One examples is with (Fresenius Kabi, where Blue Shield made available to its participants adalimumab-aacf, a *Humira*® biosimilar at a cost that is one-fourth the cost PBMs charge for the brand-name. The direct purchase agreement is facilitated through Evio Pharmacy Solutions ("Evio"), an entity co-founded by Blue Shield.

Evio is an **important component** to Blue Shield's approach to deciding (1) which drugs to include on the plan's formulary and (2) how much Blue Shield pays for these drugs. Evio's capabilities around data analytics, real-world evidence, and innovative contracting model, allows Blue Shield to evaluate **patient outcomes and re-direct incentives away from rebates, and toward clinical effectiveness**.

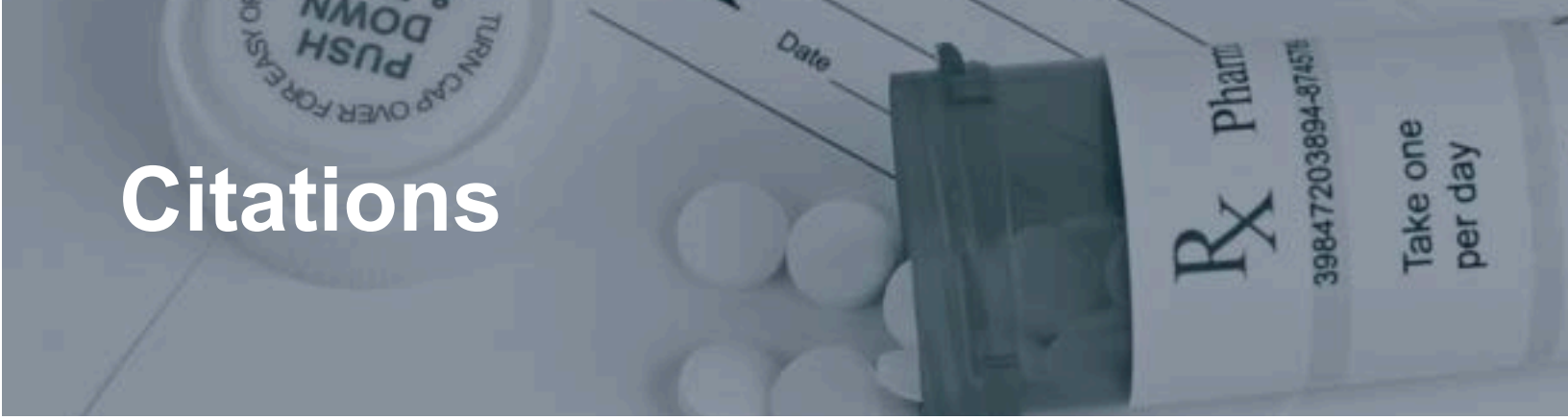
CASE-IN-POINT –
Amazon and Data-Driven Analyses

Amazon employs a data-centric strategy for healthcare decision-making that prioritizes cost reduction and evidence-based outcomes, though it doesn't necessarily eliminate pharmacy benefit administrators entirely.

Amazon's integrated teams—comprising data analytics, pharmaceutical benefits, and health benefits specialists — dive deep into transparent claims data and pharmacy benefit performance metrics. This continuous data evaluation enables Amazon to glean valuable insights into net drug pricing. Amazon translates these insights into lower costs for members and the Plan through emerging contractual innovations with pharmacy benefit administrators, and other entities supporting pharmacy benefits including formulary management, rebate administration, mail order, and specialty.

Ultimately, while Amazon may partner with pharmacy benefit administrators for prescription drug management when advantageous, the company maintains flexibility in its approach. Amazon's decisions regarding drug coverage and pricing are fundamentally driven by data analysis rather than traditional industry partnerships. Amazon's clinical pharmacists and actuaries can develop drug formularies that optimize the balance between cost-effectiveness and patient health outcomes.

Lastly, Amazon recognizes that transforming pharmacy benefit administration must align with its customer-focused philosophy by providing members with superior care coordination services and affordable access to high-value medications for chronic condition management.



Citations

[1] See, e.g., National Library of Medicine, Therapeutic Equivalence of Biosimilar and Reference Biologic Drugs in Rheumatoid Arthritis at https://pmc.ncbi.nlm.nih.gov/articles/PMC10220520/. (finding that a systematic review involving 25 randomized clinical trials and over 10,600 patients demonstrated that biosimilars of adalimumab, etanercept, and infliximab produced equivalent clinical responses and functional outcomes compared to their reference biologics in rheumatoid arthritis treatment); see also, JAMA Network, Cancer Biosimilars Similar and Significant Enough to Deserve More Attention? athttps://jamanetwork.com/journals/jamanetworkopen/fullarticle/2810586 and National Library of Medicine, A Randomized Pharmacokinetic and Pharmacodynamic Trial of Two Regular Human Insulins Demonstrates Bioequivalence In Type 1 Diabetes and Availability of Biosimilar Insulin May Improve Access to This Medication at https://pmc.ncbi.nlm.nih.gov/articles/PMC10146588/.
[2] See Sections 351(a) and 351(i) of the Public Health Service Act ("PHSA").
[3] See, e.g., PHSA sections 351(a)(2)(B) and 351(k).
[4] See Section 505(k) of the Federal Food, Drug, and Cosmetic Act.
[5] Section 3(16)(B) of the Employee Retirement Income Security Act ("ERISA").
[6] See ERISA section 404(a).
[7] See Lewandowski v. Johnson & Johnson, No. 3:24-cv-00671 (filed in Feb. 2024, dismissed for lack of standing and never ruled on the merits); see also, Navarro v. Wells Fargo & Co., No. 0:24-cv-03043 (filed July 2024, dismissed for lack of standing and never ruled on the merits) and Barbich & Lindvall v. Northwestern University, et al., No. 25-cv-6849 (filed June 2025, still pending).
[8] See Johns Hopkins University, Center for Hospital Finance and Management, Biosimilar Medications – Savings Opportunities for Large Employers: A Report for The ERISA Industry Committee at https://www.eric.org/wp-content/uploads/2020/03/JHU-Savings-Opportunities-for-Large-Employers.pdf.
[9] See Committee on Oversight & Reform, U.S. House of Representatives, Drug Pricing Investigation: AbbVie–Humira and Imbruvica at https://docs.house.gov/meetings/GO/GO00/20210518/112631/HHRG-117-GO00-20210518-SD007.pdf.
[10] See Managed Healthcare Executive, 8 Humira Biosimilars Are on the Market, July 4, 3023 at https://www.managedhealthcareexecutive.com/view/8-humira-bosimilars-are-on-the-market.
[11] See Biospace, AbbVie's Humira Maintains Market Dominance Amid Biosimilar Launches: Report, Jan. 18, 2024 at https://www.biospace.com/article/abbvie-s-humira-maintains-market-dominance-amid-biosimilar-launches-report/.
[12] See Biosimilars Review & Report, 18 Months of US Adalimumab Biosimilar Competition Yields $11 Billion in Savings at https://biosimilarsrr.com/2024/08/12/18-months-of-us-adalimumab-biosimilar-competition-yields-11-billion-in-savings/.
[13] For example, a box for two Humira® pen injectors could cost around $7,300, while the price for a box of two Humira® biosimilar (i.e., adalimumab-aqvh) pen injectors at Cost Plus is $526.75. See, e.g., https://www.costplusdrugs.com/medications/yusimry-40mg-0_8ml-box-of-2-pen-injectors/.
[14] See IQVIA Institute for Human Data Science, Biosimilars in the United States 2023-2027at https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/biosimilars-in-the-united-states-2023-2027.
[15] See Biosimilars Council, Biosimilar Medicines Produce Billions in Savings in U.S., Dramatically Reduce Oncology Spending Growth: Report at https://biosimilarscouncil.org/news/biosimilar-medicines-produce-billions-in-savings-in-u-s-dramatically-reduce-oncology-spending-report/.
[16] See Federal Trade Commission, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies, July 2024 at https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.

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