Testimony of Craig Burton
Executive Director, Biosimilars Council
House Ways & Means Committee, Subcommittee on Health
"Lowering Costs for Patients: The Health of the Biosimilar Market"
April 8, 2025

Good morning, House Ways and Means Chairman Smith, Health Subcommittee Chairman Buchanon, Ranking Member Doggett and other members of the Committee. My name is Craig Burton, and I am the Executive Director of the Biosimilars Council.

The Biosimilars Council, a division of the Association for Accessible Medicines, works to increase patient access to lifesaving, affordable biosimilar medicines. Our members include biosimilar manufacturers and stakeholders working for patient access to lower-priced biosimilar medicines.

As you know, biosimilars are lower-cost versions of expensive biologic medicines. They are licensed by the Food and Drug Administration (FDA) as "highly similar to, and with no clinically meaningful differences from"[1] an existing FDA-licensed biologic. I am pleased to join you today to testify on the critical role biosimilar medicines play in ensuring patient access to care, while saving money for taxpayers and employers alike. Unfortunately, the long-term sustainability of the biosimilar market is in doubt–a result of the combination of ill-considered government policies and brand and pharmacy benefit manager (PBM) market abuses. This is evidenced most recently in the shocking fact that many brand biologics with looming patent expiries do not currently have biosimilar competition in development.[2]

I will focus my comments on the opportunity and the challenges facing biosimilar competition, as well as opportunities for Congress and the Administration to help.

The Value of Biosimilar Medicines

Biosimilars represent new competition and savings for the high-priced specialty medicines that drive more than half of all drug spending. In the 10 years since the U.S. launch of the first biosimilar, patients and the healthcare system have saved nearly $36 billion due to the availability of biosimilars.[3] Biosimilars generate savings through robust head-to-head price competition that reduces biosimilar prices as well as brand biologic prices. Today, biosimilar prices are, on average, more than 40 percent lower than their brand biologic's price at the time of biosimilar launch. In addition, due to biosimilar competition, reference biologics' prices have declined an average of 33 percent.[4]

Among self-administered biologic products, there are now 22 versions of adalimumab biosimilars, the lower-cost versions of the biologic Humira®–once deemed the highest-selling pharmaceutical in the

[1] Food and Drug Administration (2024, June 20). 9 Things to Know About Biosimilars and Interchangeable Biosimilars | FDA, located at https://www.fda.gov/drugs/things-know-about/9-things-know-about-biosimilars-and-interchangeable-biosimilars
[2] IQVIA Institute for Human Data Science. (2024). *Assessing the biosimilar void in the U.S.* IQVIA. https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/assessing-the-biosimilar-void-in-the-us
[3] AAM. (September 2024). "2024 U.S. Generic and Biosimilar Medicines Savings Report." Available at: https://accessiblemeds.org/resources/reports/2024-savings-report/
[4] Ibid.

world. These biosimilars have prices as much as 86 percent below the brand biologic's list price. Further, earlier this year, six biosimilar versions of Stelara® launched in the U.S. market with discounts of more than 80 percent below the brand.[5]

Most importantly, biosimilars have resulted in greater patient access to care in almost every therapeutic category in which they are marketed–leading to more than 450 million days of patient therapy than would have occurred without biosimilar competition.[6]

Put simply, biosimilar medicines allow more patients to receive life-altering treatment. But the long-term outlook for a sustainable and competitive biosimilars market is in question. The apparent slowing of investment in new biosimilar competitors should serve as a wake-up call for the need to ensure a sustainable biosimilars market. The reality is that biosimilars face an uneven playing field that discourages competition, and a policy, regulatory and reimbursement landscape that makes it harder—not easier—to gain traction.

Biosimilars Market Today

As of April 1, 2025, there are 69 FDA-licensed biosimilars (with 49 products launched) for 17 reference molecules.[7] Overall, biosimilars hold 80 percent or more of the market in two therapeutic areas. However, the average market share for all biosimilars remains under 20 percent. Within biosimilars, there are two general market types, each with significantly different market incentives and dynamics: (1) the buy-and-bill system for provider-administered biosimilars and (2) the specialty or retail pharmacy model for self-administered biosimilars, such as insulin or adalimumab.

To date, the majority of licensed and launched biosimilars have been in the buy-and-bill market. Among these provider-administered biosimilars, biosimilar utilization is heavily influenced by how they are distributed and reimbursed. Biosimilars have had a stronger uptake in buy-and-bill, where physicians are incentivized to select one product over another. In addition, patient care models that impact reimbursement can help facilitate the adoption of biosimilars. For example, providers participating in the Oncology Care Model have adopted biosimilars at higher levels compared to non-participants. Of note, biosimilars have fared less well in white bagging, which is when the product is directly delivered from a specialty pharmacy to the provider (e.g., physician's office or hospital).[8]

Meanwhile, adoption of pharmacy-dispensed biosimilars, such as insulin and biosimilar Humira®, remains disappointingly low–due to PBM formulary practices favoring higher-priced brand biologics with high rebates and fees that benefit the PBM and the plan sponsor but are not passed along to the patient.

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[5] Bourgoin Insights Group. (2025). *All Things Biosimilar's U.S. Ustekinumab Biosimilar Label and Pricing Review.* Drug Channels. https://www.drugchannels.net/2025/03/drug-channels-news-roundup-march-2025.html)

[6] AAM. (September 2024). "2024 U.S. Generic and Biosimilar Medicines Savings Report." Available at: https://accessiblemeds.org/resources/reports/2024-savings-report/

[7] U.S. Food and Drug Administration. (April 2025). Biosimilar product information. U.S. Food and Drug Administration. Available at: https://www.fda.gov/drugs/biosimilars/biosimilar-product-information

[8] IQVIA Institute for Human Data Science. (2023). *Biosimilars in the United States: 2023–2027.* IQVIA. https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/biosimilars-in-the-united-states-2023-2027

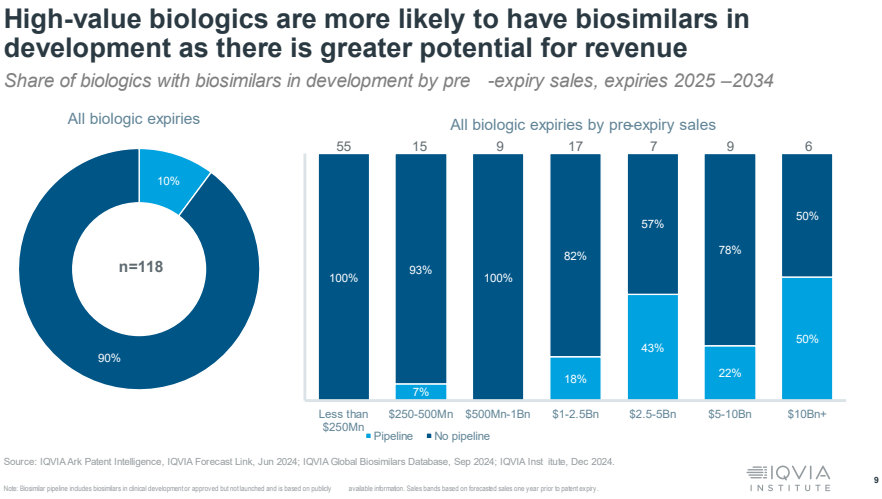
Biosimilar Development is Slowing

Earlier this year, the IQVIA Institute for Human Data Science released a groundbreaking report revealing a massive void in biosimilar development. The highlight: of the 62 reference biologics without patent protection at the end of 2024, only 14 have biosimilar competition. Further, only 12 of the 118 reference biologics expected to lose exclusivity between now and 2034 currently have biosimilars in development. This means that a staggering **90 percent of biologic drugs losing patent exclusivity over the next ten years have no biosimilar competition in the pipeline**.[9]

This isn't just a missed opportunity: it's a direct hit to America's patients who rely on these medicines.

Among Medicare patients, this void in biosimilar development will have drastic impacts:

- **860,000 patients with diabetes** depend on biologics for treatment, yet biosimilar development in this space is virtually nonexistent.
- **102,000 neurology patients**—including those with multiple sclerosis—face the same fate, with no biosimilars in sight.
- **160,000 immunology patients** who could benefit from biosimilars are left waiting as brand-name monopolies remain intact.



Moreover, this does not begin to count the millions of other patients in Medicare and the commercial market who would benefit from lower cost biosimilar medicines.

Why Are Biosimilars Falling Behind?

Ensuring a vital and sustainable biosimilars market requires aligning policies affecting biosimilars–from development to intellectual property to launch and continued use. Barriers include:

- **Barriers to Development**:
  - The FDA's approval process for biosimilars is still plagued by **redundant and costly requirements**, including unnecessary clinical efficacy studies and confusion about

[9] IQVIA Institute for Human Data Science. (2024). *Assessing the biosimilar void in the U.S.* IQVIA. https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/assessing-the-biosimilar-void-in-the-us

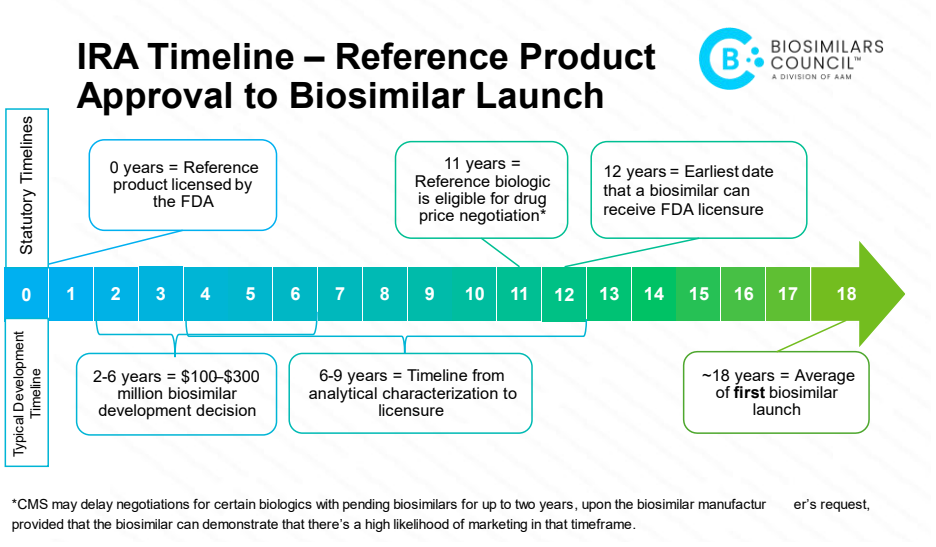
biosimilars versus interchangeable biologics. This slows down development and drives up costs, deterring investment in biosimilar pipelines.
    - Instead of fostering biosimilar adoption, the Inflation Reduction Act's drug pricing policies have **actually discouraged development** by making it less predictable for manufacturers to enter the market.
- **Barriers to Marketing**:
    - Brand-name drug manufacturers use anticompetitive tactics, such as the exploitation of **patent thickets** and legal loopholes to extend monopolies, which keep lower-cost alternatives off the market for years.
- **Barriers to Adoption**:
    - Even when biosimilars are approved, **insurers and PBMs often favor higher-priced brand drugs** over biosimilars, limiting uptake and undercutting competition.
- **Barriers to Continued Sustainability:**
    - Rapid price deflation combined with Medicare reimbursement policies too often **penalize lower-cost biosimilars** and drive healthcare providers to utilize higher-cost alternatives.

Of these critical areas, I will focus on those items most squarely in the Ways and Means jurisdiction.

IRA Price Controls Undermine Biosimilar Competition and Savings

The biosimilar development process is costly and time-consuming, costing between $100-$300 million or more and taking an average of six to nine years to complete. Because of this, the decision to begin the process to develop a biosimilar begins *years* before a brand biologic might ever be subject to the IRA price setting process. This creates a significant timing mismatch that, without Congressional changes, undermines future biosimilar development.

The figure to the right provides a high-level overview of the biosimilar development process, along with the IRA statutory timelines. Biosimilar companies begin their evaluation process to determine development candidates shortly after a brand biologic comes to market. However, the earliest date that a biosimilar can receive FDA licensure is 12 years after the reference biologic is licensed. To date, the average time of the first biosimilar to enter the market, after the respective reference product's licensure, is approximately 18 years–due in large part to patent thickets that delay launch.



Contrast this with the timelines established in the IRA that allow a reference biologic to be eligible for price negotiation at 11 years after the reference product is licensed, and that establishes the maximum fair price (MFP) for implementation at 13 years after the reference product's licensure.

This occurs years *after* the biosimilar developer has made its investment decision, and yet, will almost certainly take effect *before* the biosimilar even has a chance to come to market.

This mismatched timing does not appear to be solved by the biosimilar delay process. To date, the earliest a biosimilar has launched after the licensure of a reference product is 12 years, 11 months.[10] Moreover, the launch of that biosimilar product was "at risk"–while litigation was pending. But Centers for Medicare and Medicaid Services (CMS) guidance notes that a biosimilar delay request will only be considered once litigation has ended, except in limited circumstances. Thus, "at risk" launches do not meet the required marketing requirement for a delay or exemption, even though such pro-competitive behavior should be encouraged and applauded.

Because the IRA provides no predictability as to what a selected drugs MFP will ultimately be, only that the Secretary should pursue the lowest price possible, the resulting unpredictability has a direct effect on the ability of a biosimilar developer to assess a future market opportunity to the extent necessary to support an investment of $300 million or more. As a result, it is likely there will be fewer biosimilar launches in the future as well as a delay in the development or launch of some biosimilars. This would mean lost savings for the Medicare program, taxpayers, employers and patients.

To compound the challenge facing biosimilars, the law virtually guarantees an additional year of Medicare coverage *even after* the biosimilar is on the market. Consider the case of Stelara®, a brand biologic used to treat autoimmune diseases such as Crohn's disease, that was selected for price negotiation as part of the initial price applicability year (IPAY) 2026. Even though there are six biosimilars on the market today, with prices significantly lower than the list price,[11] under the IRA, Stelara® is *guaranteed* formulary coverage in Medicare next year, regardless of the availability of lower-cost biosimilars. This not only denies Medicare patients access to lower-cost biosimilars, but it makes it more difficult for biosimilar manufacturers to justify the $300 million or more investment needed to bring a biosimilar to market.[12]

Thus, the legislation intended to impose price controls on high-priced brand-drugs could have the perverse effect of *extending* the very brand-drug monopolies it sought to end. Without Congressional action to better align the timing for imposition of price controls only as a last resort when a generic or

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[10] Association for Accessible Medicines. (2024, March 27). *IRA hurts generic and biosimilar medication competition.* Accessible Medicines. https://accessiblemeds.org/resources/blog/ira-hurts-generic-biosimilar-medication-competition/

[11] The MFP announced by CMS on August 15, 2024 is 66 percent lower than the list price. (https://www.cms.gov/newsroom/fact-sheets/medicare-drug-price-negotiation-program-negotiated-prices-initial-price-applicability-year-2026). Biosimilar list prices range from 80-85 percent less than the list price. (Bourgoin Insights Group. (2025). *All Things Biosimilar's U.S. Ustekinumab Biosimilar Label and Pricing Review.* Drug Channels. https://www.drugchannels.net/2025/03/drug-channels-news-roundup-march-2025.html)

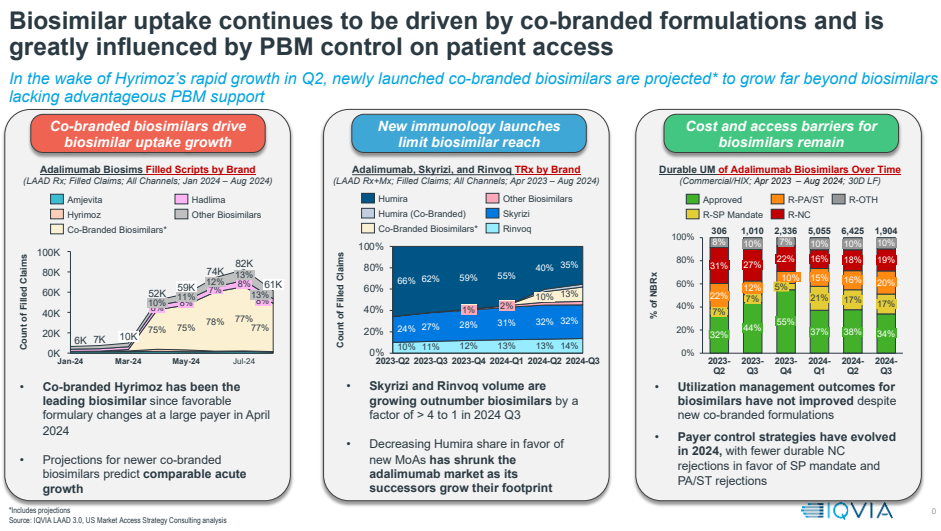
[12] This is not an isolated example. For IPAY 2027, the most recent round of fifteen selected drugs announced in January 2025, there were 152 approved ANDAs, tentatively approved ANDAs, or pending ANDAs. Competition is ready for 13 of those 15 drugs. Association for Accessible Medicines. (2024, March 27). *IRA hurts generic and biosimilar medication competition.* Accessible Medicines. https://accessiblemeds.org/resources/blog/ira-hurts-generic-biosimilar-medication-competition/

biosimilar is unlikely to come to market, it is likely there may be fewer, and they may be slower to market. As such, employers, health plans and taxpayers will pay the cost while waiting longer for lower cost biosimilars.

To be clear, this is not to say that biosimilars cannot or should not face price competition. Quite the opposite: biosimilars promise lower prices and greater access than what is provided in the CMS-imposed prices to date. However, the uncertainty in considering the return on investment based on an unpredictable and inherently political price setting process will invariably affect biosimilar investment. The result will not only be higher prices in the Medicare program, but also in the employer-sponsored insurance market.

Barriers to Adoption

Unfortunately, as previously described, biosimilars continue to face massive challenges within the pharmacy benefit, as evidenced by adoption of biosimilar versions of Humira® and insulin. Despite 22 biosimilar versions offering prices as low as 86 percent below that of the top-selling brand biologic Humira®, the brand still retains a majority market share, largely due to preferred PBM coverage decisions.[13] Further, as noted below, those same PBMs have helped switch more patients to newer, high-priced branded alternatives to Humira® than to all the biosimilars in the therapeutic area combined.



Rebate and administrative fee revenue tied to the list price continues to maintain a stranglehold on coverage decisions, to the detriment of patients, and ultimately, payers. Even when plans cover the Humira® biosimilars, they frequently place the biosimilar on parity with the higher-priced brand, which removes any incentive for patients to use the lower-cost biosimilar.

The impact of these coverage trends are plainly seen in biosimilar products–most recently in biosimilar adalimumab and biosimilar insulin.[14] In 2023, AAM found that commercial plans, employers and

[13] Drug Channels. (2024, Sep 4). Humira Biosimilar Price War Update: Should We Be Glad that CVS Health and Express Scripts Are Using Private Label Products to Pop the Gross-to-Net Bubble? https://www.drugchannels.net/2024/09/humira-biosimilar-price-war-update.html
[14] Biosimilars Council. (2024, March 18). *PBM rebate suppress biosimilar Humira competition.* Biosimilars Council. https://biosimilarscouncil.org/news/pbm-rebate-suppress-biosimilar-humira/

patients missed out on savings up to $6 billion because of rebate schemes by PBMs.[15] The report highlights the strategy created by PBMs to protect $2 billion in profits by suppressing adoption of lower-cost versions of Humira® and identifies several factors that ultimately limited biosimilar market share, including:

- Humira® remained a costlier option than adalimumab biosimilar products for health plans even after discounts, with a net price of approximately $2,100 for one month's supply compared to <$1000 for some biosimilar versions.
- Slow biosimilar uptake was driven by Humira® contracting and rebating practices and large PBM payer controls. A transition to biosimilar products would disrupt the traditional PBM profit model, as they would take in less in rebates and WAC-based administrative fees, losing up to 84 percent of profit.
- Additionally, since nearly 80 percent of Humira® volume is dispensed by large, PBM-affiliated specialty pharmacies, lost revenue from dispensing Humira® biosimilars would negatively impact large PBMs with vertically integrated pharmacies.
- This combined loss of PBM and affiliated specialty pharmacy profits exceeding $2 billion annually may have driven PBM contracting and rebating practices, leading to the slow adoption of biosimilar adalimumab in favor of Humira®.

Even today, although more of the big PBMs have begun to adopt biosimilar adalimumab, the total biosimilar market share is only 13 percent, despite their lower prices. Of note, during the same time period that biosimilars have been on the market, more patients have been switched to newer, high-price brands instead of the biosimilar, leaving biosimilar products outnumbered by the brand manufacturer's product portfolio by approximately 9 to 1.[16] This product hopping could not have occurred without the buy-in of major PBMs.

An analysis by Avalere Health on behalf of the Biosimilars Council found that, across the five largest Medicare Part D parent organizations in 2023 (i.e., United Healthcare, Humana, CVS, Centene, and Cigna), biosimilars were substantially less likely to be covered than their reference products. More specifically, while brand Humira® was covered 99 percent of the time by these MA-PD and PDP plans, lower-priced biosimilars were only covered six percent of the time.[17]

Likewise, PBMs also significantly restricted access to biosimilar insulin, with the five major payers offering better coverage for the brand, while blocking or limiting coverage for the lower-cost biosimilar.[18] And a review of the biosimilar insulin market, performed by IQVIA on behalf of the Biosimilars Council, found that, if not for PBM formulary controls, six out of every 10 prescriptions for

[15] IQVIA Institute for Human Data Science. (2024, November 2). *Humira biosimilar tracking: Executive summary.* Biosimilars Council. https://biosimilarscouncil.org/wp-content/uploads/2024/04/04022024_IQVIA-Humira-Tracking-Executive-Summary.pdf
[16] IQVIA Institute for Human Data Science. (2024, August). *Adalimumab biosimilar launch tracking: Q3 report.* Biosimilars Council. https://biosimilarscouncil.org/wp-content/uploads/2024/08/202408-IQVIA-AAM-Adalimumab-Biosimilar-Launch-Tracking-Q3-Report.pdf
[17] Avalere Health Contributors. (2024, March 27). *PBMs block patient access to lower-priced biosimilar insulin.* Biosimilars Council, Analysis Prepared for AAM. https://biosimilarscouncil.org/resource/pbms-block-patient-access-lower-priced-biosimilar-insulin/
[18] Ibid.

the reference insulin or its biosimilars would have been filled by a biosimilar.[19] The rejection of biosimilars in favor of the brand was most prominent in the Medicare market.

There are recent announcements that suggest that the big PBMs may be more aggressive in adopting biosimilar versions of ustekinemab (Stelara®), although it remains too early to draw any definitive conclusions on this market.

Nonetheless, the experiences to date demonstrate the distortionary effects of plan and PBM coverage and rebating practices in Medicare Part D, and spotlight a straightforward pathway to improve patient access to these products –namely for Congress and CMS to ensure that Medicare beneficiaries have access to lower-cost biosimilars.

Barriers to Continued Sustainability

When Congress revised the Medicare Part B prescription drug payment policy to move away from reimbursement based on Wholesale Acquisition Cost (WAC) to Average Sale Price (ASP), the intent was to address rising prescription drug costs, with little consideration given to determining appropriate biosimilar reimbursement or what a sustainable biosimilar market might entail.

As such, the current payment system is designed to help decrease overall drug costs, not provide sustainable reimbursement when prices of drug products are on a rapid decline. Prior to biosimilar entry, brand-biologics take significant price increases. After biosimilar entry, brand-biologic prices tend to go down. After a biosimilar enters the market, brand-biologic prices have typically dropped 33 percent. Biosimilars, on average, are priced more than 40 percent lower than the brand-biologic's price at the time of biosimilar launch and decline from there.[20] This results in savings from both the originator biologics and the biosimilars.

In fact, across all biosimilars, within the first three years of an initial launch, ASP declines an average of 50 percent.[21] Those ASP declines are driven by two key factors–reductions in provider acquisition costs and rebates to payers. To remain competitive, biosimilar manufacturers offer lower provider acquisition costs while simultaneously increasing rebates to payers. These competitive strategies, which are essential to drive volume, also decrease ASP.

Thus, despite not receiving any payer rebates, providers are paid based on an ASP that includes rebates the manufacturer provides to the payer. This can result in providers being "underwater"–being paid by Medicare less than the acquisition cost of the biosimilar. Similarly, biosimilar manufacturers may be "underwater" with a zero or negative ASP.

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[19] Biosimilars Council. (July 2023). "Pharmacy Benefit Managers Are Blocking Patient Access to Biosimilar Insulin". Available at: https://biosimilarscouncil.org/resource/pharmacy-benefit-managers-are-blocking-patient-access-to-biosimilar-insulin/

[20] AAM. (September 2024). "2024 U.S. Generic and Biosimilar Medicines Savings Report." Available at: https://accessiblemeds.org/resources/reports/2024-savings-report/

[21] Cardinal Health. (2024). *10 years of biosimilars: A retrospective and forward-looking perspective*. Cardinal Health. https://www.cardinalhealth.com/content/dam/corp/web/documents/whitepaper/cardinal-health-10-years-of-biosimilars.pdf

To help encourage provider adoption and address rapidly declining ASPs, the Biosimilars Council recommends CMS or Congress create a shared savings demonstration program in Medicare Part B to reward providers for new biosimilar adoption. The program would be optional for providers and apply only to patients initially starting with that drug. Participants would continue to be reimbursed at current Part B payment rates, but when they choose a biosimilar that has a lower price than the reference biologic, they would become eligible for enhanced shared savings payments. A shared savings program is a first step to help ensure providers are not "underwater" and to increase adoption of lower-cost biosimilars.

Policymakers Must Act—Now

We cannot afford to let biosimilars stagnate. Policymakers must take bold action to correct course and close the biosimilar void before it's too late. Here's what needs to happen:

1. **Eliminate Unnecessary Regulatory Barriers**
    - The FDA must remove outdated requirements, such as unnecessary clinical efficacy trials, and permit use of global comparators to streamline biosimilar development and bring new competition to market faster.
    - And Congress should follow the FDA's recommendation to remove the statutory distinction between biosimilars and interchangeable biologics.
2. **Reverse the Damage Done by the Inflation Reduction Act**
    - Congress must adjust drug pricing policies to ensure biosimilar competition is encouraged—not punished. The arbitrary and unpredictable nature of the IRA's price control framework discourages new investments in biosimilars — the end result of which will be fewer and slower biosimilar competitors and higher prices for America's employers and patients.
3. **End Abusive Patent Thickets**
    - Congress must curb the abuse of the patent system, preventing brand manufacturers from using patent thickets to block competition indefinitely.
4. **Ensure Rapid Patient Access**
    - Congress and CMS should ensure that Medicare PBMs and health plans cover biosimilars at launch—no more favoring higher-priced drugs at the expense of patients—unless the brand-name drug has lowered its price and costs less at the unit level.
5. **Create a Shared Savings Program**
    - CMS could create or Congress could authorize a demonstration program to help incentivize the utilization of biosimilars.

The Cost of Inaction

If nothing changes, patients and the healthcare system will pay the price. A fully competitive biosimilar market could save the U.S. an additional $189 billion over the next decade[22]—but those savings will vanish if biosimilars remain trapped in the void. This isn't just a theoretical discussion; it's a crisis that will impact real people: the diabetic patient struggling to afford their insulin, the cancer survivor burdened by high treatment costs, the retiree on a fixed income choosing between life-sustaining medicines and rent.

As the U.S. biosimilars market has evolved over the last decade, challenges and policy priorities have as well. However, one thing remains clear–America's patients and healthcare system rely on biosimilar medicines. We have the tools to fix this. Now, I implore policymakers to use them. The future of biosimilar competition—and the health of millions of Americans—depends on it.

[22] IQVIA Institute for Human Data Science. (2024). *Assessing the biosimilar void in the U.S.* IQVIA. https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/assessing-the-biosimilar-void-in-the-us