Biosimilars
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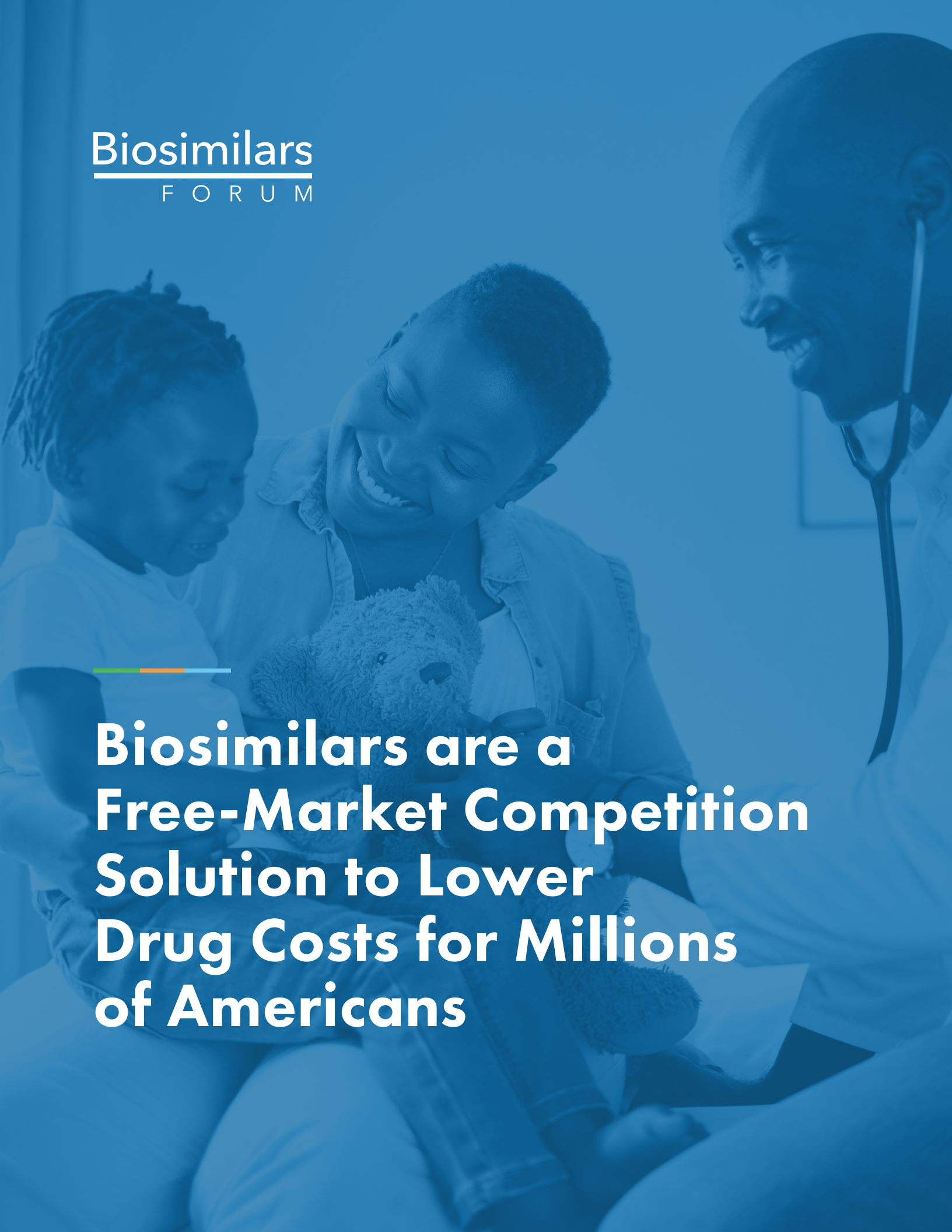

Biosimilars are a Free-Market Competition Solution to Lower Drug Costs for Millions of Americans

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The Anti-Competitive Practices of Pharmacy Benefit Managers (PBMs)

The anti-competitive practices of Pharmacy Benefit Managers (PBMs) significantly impede patient access to biosimilars. While biosimilars have the potential to reduce healthcare costs and increase treatment options for millions of Americans, current PBM practices create barriers that delay or prevent their widespread adoption. These practices undermine both consumer choice and the principles of a competitive marketplace, ultimately harming patients and the healthcare system as a whole.

Biosimilars are a cornerstone, free-market solution to affordable U.S. healthcare—offering patients safe, effective, and lower-cost treatments options for cancer, diabetes, arthritis, Crohn's Disease, and more. Biosimilars are a unique solution for President Trump, his Administration, and Congress to deliver on his mandate they received to promote free market competition and reign in burdensome healthcare bureaucracy and out-of-control spending the healthcare system.

Unfortunately, the biosimilar market is not thriving.
In fact, if market dynamics do not significantly change, the long-term market sustainability is in peril, and the cost-savings potential of biosimilars could be lost forever.

Biosimilars are a free-market competition solution to lowering drug prices for Americans.

Biologics **were 46% of U.S. prescription drug spending in 2022**, despite only making up 3% of prescriptions. Americans **spent** $568 billion on pharmaceuticals in 2022 with $260 billion going toward biologics.

Fifteen years ago, Congress passed the landmark Biologics Price Competition and Innovation Act (BPCIA) to pave the way for biosimilars to lower drug costs for Americans. Since the first biosimilar was approved in 2015 by the FDA, more than **70 biosimilars** have been approved and **saved** the U.S. healthcare system **$56 billion, with the potential to save an additional $181 billion in the next five years**.

Biosimilars also **generate billions in cost-savings** for the Medicare program as prices continue to increase for reference biologic drugs. Biologic drugs—some of the most expensive drugs available—are estimated to **cost Medicare Part B and its enrollees upwards of $32 billion annually**. Making biosimilars more available to the Medicare program has the potential to save billions of dollars each year.

The anti-competitive practices of Pharmacy Benefit Managers (PBMs)

Unfortunately, the American healthcare system faces a major void of biosimilars in the pipeline because of anti-competitive practices by the PBM Monopoly.

This biosimilar void threatens to leave patients without affordable alternatives, forcing them to rely on high-cost brand-name drugs. Over the next decade, **118 biologics are expected to lose patent protection**, and biosimilars could offer significant cost-savings for each of these. This includes a significant wave of oncology drugs, which could lower costs for cancer patients. Only 12 molecules set to lose patent protection from in the next decade have biosimilars in development as of June 2024, with the remaining **106 biologic patent expiries representing a "biosimilar void."** If all products with a patent expiring in the next 10 years were to have a biosimilar in the pipeline, the U.S. healthcare system could **save an additional $189 billion** in addition to savings generated by biosimilars already on the market or expected to enter.

It is important to note that a typical **biosimilar costs $100 million to $300 million to develop** and takes six to nine years to go from analytical characterization to approval.

The PBM Monopoly actively blocks free-market competition and denies patients access to lower-cost, safe, and effective drugs – including biosimilars.

Prescriptions can be more affordable for Americans and eliminate government waste in the American health care system by prioritizing pharmacy benefit manager PBM reforms that require transparency, delink PBM fees from WAC, and allow all patients and health plans to easily access biosimilars. It's unacceptable that PBMs prioritize profits over patients. The **GOP-led House Oversight Committee**, **bipartisan leadership of the Senate Finance Committee** and **federal regulators at the Federal Trade Commission (FTC)** have each separately found that PBMs intentionally misalign incentives to inflate drug prices and deny access to lower-cost drugs to those who want it. Specifically, the FTC in 2025 found that PBMs **hiked the prices of specialty drugs by thousands of percent to generate $7.3 billion in revenue**—all while American patients suffered and the Medicare budget buckled under skyrocketing costs.

PBMs hiked the prices of specialty drugs by thousands of percent to generate $7.3 billion in revenue.

PBMs frequently engage in tactics such as preferential formulary placement of branded biologics over biosimilars, complex rebate structures, and exclusive contracts that limit the inclusion of biosimilars in insurance plans. These strategies incentivize pharmacies and insurers to favor more expensive brand-name biologics, despite the availability of equally effective and more affordable biosimilar options. Such anti-competitive behavior discourages biosimilar manufacturers from entering the market and stifles price competition, leading to higher out-of-pocket costs for patients.

The anti-competitive practices of Pharmacy Benefit Managers (PBMs)

The PBM Monopoly Actively Denies Patients Access to Lower-cost, Safe, and Effective Drugs – Including Biosimilars for Humira

PBMs are in desperate need of reform. PBMs actively block patients from being able to access lower-cost biosimilars by favoring drugs that pay the PBMs high rebates in exchange for guaranteed market share. This monopolistic system hurts patients by denying them access to lower-cost, safe and effective prescription drugs.

HUMIRA IS A PERFECT EXAMPLE.

There are **ten biosimilars for Humira**, the world's best-selling drug that can cost up to $84,000 annually.

The biosimilars on the market today are **85% lower cost than the brand drug**, yet PBMs have blocked patient access to these lower cost biosimilars.

These biosimilars should have been a watershed year for biosimilars in the United States.

The Biosimilars Forum began sounding the alarm two years before the first Humira biosimilar was released. We knew then that PBMs would block access because they prioritize profits over Americans.

PBMs prioritize profits over patients and favor the higher-cost high-rebate branded Humira® biologic by placing it on a preferable formulary tier relative to its lower-cost biosimilar alternatives. These biosimilars could have offered savings of up to $6 billion to the U.S. health care system if they had formulary access. Yet, the PBM Monopoly deny patients access to adalimumab biosimilars.

The dismal uptake and access for the Humira® adalimumab biosimilars are staggering. Combined Humira biosimilar uptake is only 10% after 2 years for all of the biosimilars.

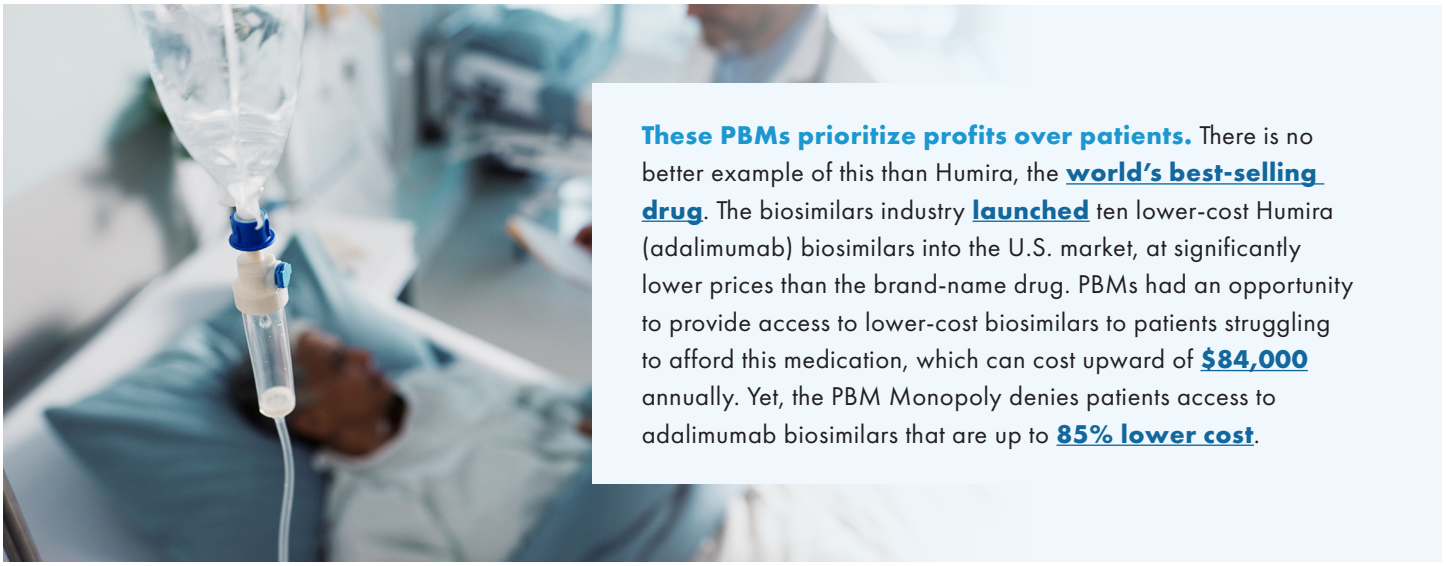
Competition only works to lower prices where there is market access. The cost-savings of biosimilars can only be realized if all biosimilars — especially biosimilars for Humira — are fully available and accessible to the patients who need them.

The anti-competitive practices of Pharmacy Benefit Managers (PBMs)

To ensure the sustainability of the biosimilar market and the savings and affordability benefits are fully realized by the healthcare system and patients, anti-competitive practices by PBMs must be addressed.

Unfortunately, the massive savings from biosimilars are being completely left on the table because PBMs have prioritized high-cost, high-rebate drugs over lower-cost biosimilars. This stifles free market competition and forces Americans to pay more for the prescription drugs they need. Patients are then left to choose between their critical medications and other life expenses.

PBMs exclude generic drugs and biosimilars from formularies in exchange for higher profits. These exclusionary schemes cut off patient access to lower-cost medicines. PBMs **control 80% of the prescription drug marketplace**. This monopolistic system hurts patients and denies them access to lower-cost, safe and effective prescription drugs. Unfortunately, biosimilar competition is not a certainty for all biologics. Increasing pressures on biosimilar developers and barriers to access continue to limit the future cost-savings potential of biosimilars.



These PBMs prioritize profits over patients. There is no better example of this than Humira, the **world's best-selling drug**. The biosimilars industry **launched** ten lower-cost Humira (adalimumab) biosimilars into the U.S. market, at significantly lower prices than the brand-name drug. PBMs had an opportunity to provide access to lower-cost biosimilars to patients struggling to afford this medication, which can cost upward of **$84,000** annually. Yet, the PBM Monopoly denies patients access to adalimumab biosimilars that are up to **85% lower cost**.

Rebate schemes and formulary exclusions by PBMs have hindered biosimilar access while maximizing PBMs' own profits within the healthcare system. PBM reform must require transparency, delinks business practices from the Medicare program, and allows all patients and health plans to easily access biosimilars.

It is unacceptable that PBMs prioritize higher-priced prescriptions because it is more lucrative than providing lower cost medicines to patients.

The anti-competitive practices of Pharmacy Benefit Managers (PBMs)

The Biosimilars Forum supports market competition in the pharmaceutical industry.

The Biosimilars Forum is a non-profit organization working on a consensus basis to develop policy positions to ensure the United States has a competitive, safe, and sustainable biosimilars market that provides more options to patients and physicians. Our members represent the majority of companies with the most significant U.S. biosimilars development and on-market portfolios. We believe it is clear that biosimilars are the commonsense, free-market solution to skyrocketing prescription drug prices.

We stand ready to work with both sides of the aisle and the administration to prioritize American patients and provide more choices for lower-cost drugs.

The Forum stands ready to work with the Administration to further our shared goals – from promoting free market competition to providing lower expenditures for government healthcare programs to ensuring taxpayers, veterans, and small businesses have the treatment options they need at prices they can afford. The Administration has an opportunity to support the biosimilars industry as a key component to make American Healthy Again and save Americans and the government billions of dollars.

We must do everything in their power to address the anti-competitive behaviors of the PBM Monopoly. Time is of the essence: every day without reform deepens the affordability crisis for Americans dealing with a convoluted, misaligned system for their prescription drugs.

The PBM system must be reformed. It is time we put patients first.

Biosimilars: Lowering Prescription Drug Costs

The Biosimilars Forum

We are a nonprofit dedicated to expanding patient access to life-saving biosimilar drugs. We work with policymakers and stakeholders to create public policies that encourage biosimilar awareness and education and increased use.

LOWER
prescription drug costs for millions of Americans that need them

INCREASE
access to lifesaving, lower-cost treatments

EDUCATE
patients, providers, employers, and payers on the safety and efficacy of biosimilars

ENGAGE
with the Administration and lawmakers to implement policies that promote biosimilars

WORK
with regulatory bodies to advance biosimilars

The Biosimilars Savings Opportunity

Biosimilars have the potential to save money for patients and bring access to the healthcare system.

Biosimilars have **saved** the U.S. healthcare system **$56 billion**, with the **potential to save an additional $181 billion in the next five years**.

When a biosimilar enters the market, it drops biologic prices by 50% or more

3%
Of all prescriptions are for biologic drugs

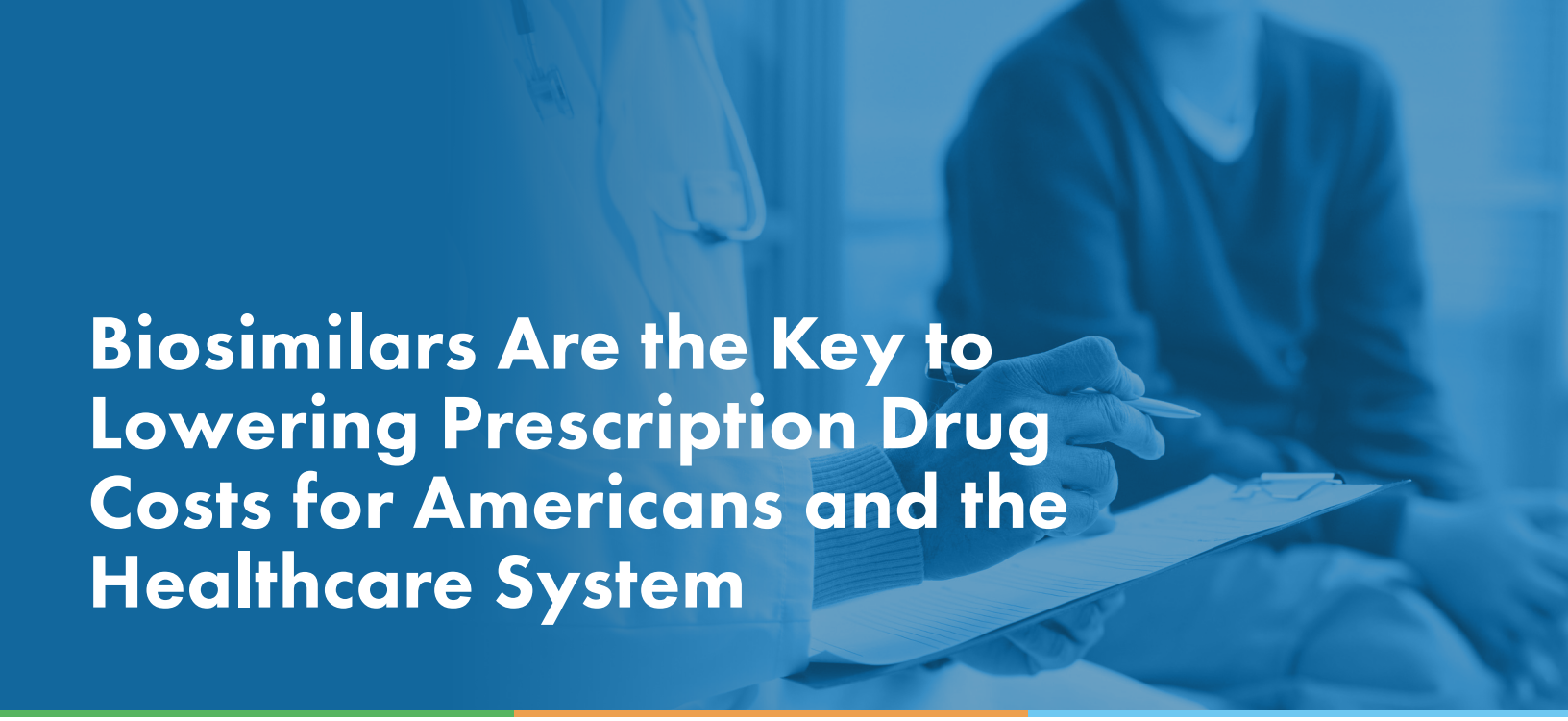
46%
Of all prescription drug spending is for biologic drugs

Barriers to Access Still Exist

- **PBMs Blocking Patient Access**
- **Rebate Walls**
- **Lengthy IP Challenges**

* Wayne Winegarden. Pacific Research Institute. ".Promoting Biosimilar Competition to Reduce Patients' Out-of-Pocket Costs" March 2020. https://medecon.org/new-issue-brief-expanding-biosimilars-use-could-save-patients-reduce-out-of-pocket-costs-by-17-percent

** The ERISA Industry Committee. "BIOSIMILARS: COST SAVINGS & COMPETITION." https://www.eric.org/biosimilar-initiative



Biosimilars Are the Key to Lowering Prescription Drug Costs for Americans and the Healthcare System

The biosimilars industry continues to prioritize cost-savings to both patients and the healthcare system as the **healthcare affordability crisis worsens**.

Biosimilars Have the Potential to Save Patients Billions of Dollars If They Are Accessible

Biosimilars are, on average, **more than 50% lower-cost** than the biologics they reference.

Biosimilars Offer Cost-Savings at a Critical Time for the U.S. Healthcare System

Lower-cost biosimilars are a key tool to end the prescription drug affordability crisis once and for - all while **saving Medicare billions of dollars**.

Biosimilars have the **potential to save hundreds of billions of dollars** in 2025 alone—cost-savings that are critical for providing access and coverage for millions of Americans for new innovations, such as GLP-1s and new treatments for conditions like cancer.

American taxpayers lose when Medicare, Veterans Affairs, the Children's Health Insurance Program, and other government medical programs cannot realize cost savings from lower-cost biosimilars.

Biosimilars Promote Free Market Competition that Lowers Drug Costs for Everyone

Free market competition is the best way to achieve lower-cost drug prices for Americans. Biosimilars promote competition that lowers prices and increases access for patients through lower-cost drugs, like biosimilars. Since the first biosimilar was approved in 2015 by the FDA, more than **70 biosimilars** have been approved and **saved** the U.S. healthcare system **$56 billion, with the potential to save an additional $181 billion in the next five years**.

Biosimilars also **generate billions in cost-savings** for the Medicare program as prices continue to increase for reference biologic drugs. Biologic drugs—some of the most expensive drugs available—are estimated to **cost Medicare Part B and its enrollees upwards of $32 billion annually**.

The Biosimilars Forum Supports a Free Market Competitive Landscape that Benefits Patients

Biosimilars Forum Priorities to Lower Drug Costs

- Market Access
- IRA Revision & Implementation
- Streamlined Development
- Industry Sustainability

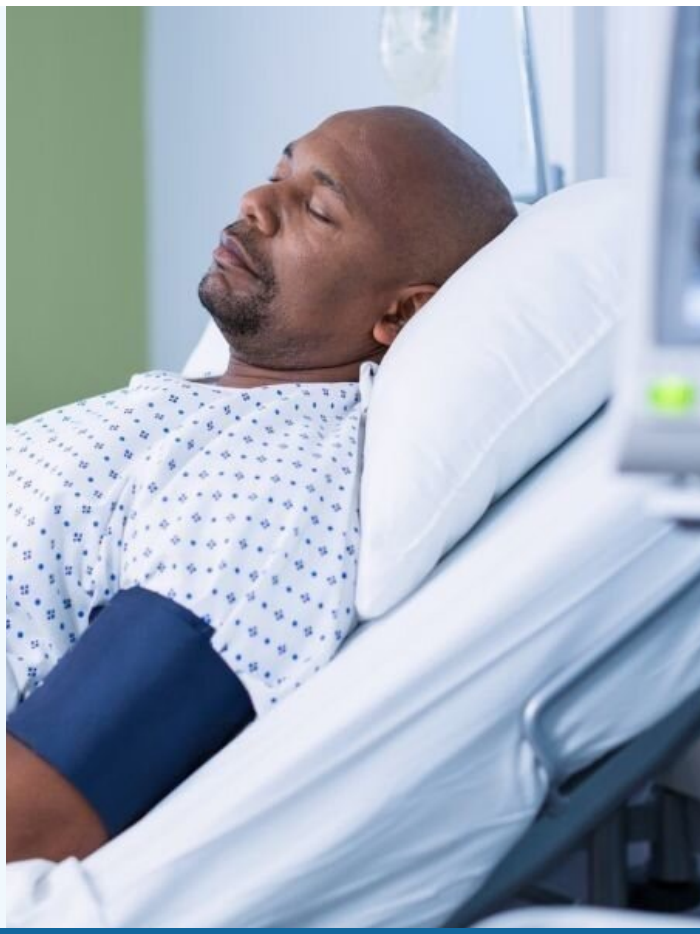
Market Access Is Vital for the Biosimilars Industry

Pharmacy Benefit Managers (PBMs) are blocking access to lower-cost medicines for millions of patients that need them.

Biosimilars are a bipartisan solution to lower drug costs for millions of Americans.

Much more work is needed to make lower-cost biosimilars accessible to the patients that need them.

PBMs have assured patients and their families suffer by blocking access to biosimilars and denying fair competition.



The Biosimilars Forum Supports a Free Market Competitive Landscape that Benefits Patients

PBMs Stifle Free Market Competition and Block Patients from Having Access to Lower-Cost Biosimilars

- PBMs are profiting off higher-cost drugs. PBMs actively favor the higher-cost biologics by placing them on a preferred formulary tier or requiring fewer restrictions for a patient to access them – and this increases the PBMs' earnings.
- Lack of access to lower-cost treatment options limits consumer choice, stifles market competition and only serves to raise the cost of prescription medicines.

Patients deserve access to biosimilars.

The three largest PBMs control 80% of the prescription drug marketplace.

Biosimilars have saved the U.S. healthcare system $56 billion, with the potential to save an additional $181 billion in the next five years.

Yet these savings are being completely left on the table because PBMs have prioritized in their formularies high-cost, high-rebate drugs over lower-cost biosimilars.

The IRA and Biosimilars Special Rule Benefit Patients

The Inflation Reduction Act Biosimilar Special Rule provides a 2-year negotiation pause for the reference biologic to allow for a potentially stable marketplace for the biosimilar to launch into and compete.

Biosimilars must be able to compete in a competitive free market system for market access.

Early clarity of the "high likelihood of approval" rule is essential to support biosimilar development and encourage further investment.

The 2-year pause in the Special Rule supports lowering drug costs through free-market competition from biosimilars.

The Biosimilars Forum Supports a Free Market Competitive Landscape that Benefits Patients

The Special Rule Supports a Thriving and Sustainable Biosimilars Industry

- A biosimilar cannot be approved by the FDA until 12 years after the reference biologic has been approved.
- A biosimilar generally will not launch until the patent walls of the reference biologic are litigated and resolved which has been 3-4+ years post approval (or longer in most cases). The fastest biosimilar launch in U.S. history occurred at year 15.
- The Inflation Reduction Act Biosimilar Special Rule provides a 2-year negotiation pause for the reference biologic to allow for a potentially stable marketplace for the biosimilar to launch into and compete.
- The Special Rule pause creates a window for biosimilar applicants to get across the regulatory finish line, recognizing the number of complex steps FDA must take to get to approval.
- The Special Rule pause recognizes the complexity of the patent challenges for biosimilar applicants. It encourages reference biologics to reduce patent walls and settle patent challenges with the biosimilar applicant to avoid price negotiation.
- The 2-Year pause supports lowering drug costs through free-market competition from biosimilars.
- CMS has imposed an extra-statutory bona fide marketing requirement. Without caveat or limitation, the IRA refers to whether the biosimilar is "marketed." The term "marketed" has a well-understood meaning in the context of drugs and biologics. The Forum has asked CMS to abandon this artificial concept and adhere to the statute.
- The criteria CMS is requiring to determine high-likelihood is tantamount to certainty and does not adhere to statutory intent.
  - By restricting eligibility for the Biosimilar Special Rule to biosimilar manufacturers with a filed or approved 351(k) BLA, CMS truncates that two-year period for demonstrating high likelihood of licensure to a one-year period.
  - The criteria required to show high-likelihood of marketing is incompatible with the patent litigation process and timeline for biosimilars. The Forum has proposed numerous alternative options to CMS.
- Some of the dates CMS is using in guidance are contrary to those in the statute.
- The Forum has requested additional transparency from CMS so it can best work within the requirements it has set forth.

Prioritizing Biosimilar Streamlined Development

The biosimilar development, approval, and launch process is lengthy and expensive – and must be prioritized by federal regulators.

Biosimilar development can take between 6-9 years and can cost $100 million to $300 million.

FDA review and approval can take 12 months or longer.

The FDA BsUFA III Regulatory Science Roadmap is a start to achieving streamlined development

https://www.mckinsey.com/industries/life-sciences/our-insights/three-imperatives-for-r-and-d-in-biosimilars

The Biosimilars Forum Supports a Free Market Competitive Landscape that Benefits Patients

The Forum Encourages FDA to Support Innovation through Streamlined Development of Biosimilars

- Fifteen years ago, Congress passed the landmark Biologics Price Competition and Innovation Act (BPCIA) to pave the way for biosimilars to lower drug costs for Americans. The first biosimilar was **approved** in 2015 by the FDA.
- The Forum is working with FDA to implement new policies and tools that will streamline the development of biosimilars in the U.S. These efforts will increase efficiencies in development and approval of biosimilars with no change in their quality, safety, or efficacy.
- To lower costs for patients and the healthcare system, streamlined development advancements should be implemented by BsUFA IV, if not sooner.
- It is time to lower costs using increased efficiency.

The Biosimilars Industry Is at a Watershed Moment

Without reforms to PBMS that support free market competition, the cost-savings potential of the biosimilars industry may be lost forever.

Biosimilars must be able to compete in a competitive free market system for market access.

Without support, the biosimilars industry could cease to exist, leaving patients with higher-cost medicines.

PBMs must be reformed to mandate transparency and access for biosimilars.

A Robust, Sustainable Biosimilars Industry Is Vital for Patients and the American Healthcare System

- It is unacceptable that biosimilars face many hurdles threatening their ability to help patients. Patients must be able to fully access FDA-approved, lower-cost biosimilars. When PBMs prioritize high cost, high rebate products, patients suffer. We must prioritize access to lower-cost biosimilars to those who need them.
- Biosimilar manufacturers are doing their part in bringing lower-cost products to market – requiring millions of dollars and years of development – but PBMs are denying patients access to them.
- Ultimately, without a fair biosimilars marketplace that is built on competition, patients will continue to have fewer options for the treatments they need. And without a significant increase in uptake, the promise of biosimilars could be lost forever.

More Work Must Be Done to Realize the Tremendous Cost-Savings Potential of Biosimilars

The Promise of Humira® Biosimilars NOT Met

The largest-selling prescription drug in history, Humira®, is an excellent example of the opportunity and cost-savings that biosimilars represent.

For 20 years, patients suffering from debilitating chronic diseases, such as Crohn's disease or rheumatoid arthritis, had one primary treatment option when it came to this drug.

That changed when biosimilars for Humira® hit market last year.

The Cost of Humira®

Humira® is incredibly expensive. In fact, it can cost upward of **$84,000 annually** and has had a **470% price increase** since it was launched in 2003. Multiple Humira® biosimilars are being offered at discounts of -85%, but consumers do not have access to these lower-cost products.

This can have a real effect on consumers – even if they have insurance. Consumers who have to pay a 20% co-pay would see significant cost savings between Humira and the highly-discounted biosimilars.

Multiple Humira® biosimilars are being offered at discounts of 85%, but consumers do not have access to these lower-cost products.

More Work Must Be Done to Realize the Tremendous Cost-Savings Potential of Biosimilars

Biosimilars Can Provide Significant Cost Savings

HUMIRA® → **20% COPAY** → $16,800 co-pay/year

$84,000

Biosimilars → **85% DISCOUNT** → $2,520 co-pay/year

If Humira® costs $84,000, a patient with a 20% copay would pay $16,800 a year. However, a biosimilar that is discounted at 85% would cost approximately $12,600, with a co-pay of $2,520 for that year. This is a significant savings.

Consumers deserve a right to lower-cost medicines that will have significant ripple effects across their personal finances – especially for those who have multiple conditions and treatments for each.

The Biosimilars Forum

The Biosimilars Forum is a nonprofit organization working to advance biosimilars in the United States with the goals of expanding access and availability and improving healthcare outcomes. Since its inception, the Forum has worked to expand the uptake of biosimilars throughout the healthcare system through policies that will increase access for patients and lower costs through increased competition. Forum members represent companies with the most significant U.S. biosimilars development portfolios.

Notes

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For more information on the Biosimilars Forum's work to increase access to lower-cost biosimilars, visit **www.biosimilarsforum.org**.

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