# The U.S. Generic & Biosimilar Medicines Savings Report

**SEPTEMBER 2024**

Amgen Exhibit 1068
Amgen v. BMS
IPR2025-00602

# Letter From the President and CEO

## Protecting Patients for the Next 40 Years and Beyond

On the eve of the 40th anniversary of the Drug Price Competition and Patent Restoration Act, commonly known as the "Hatch-Waxman Act," we stand at a critical crossroads. Will we enact policies that support another forty years of a vibrant generic market, enabling patients to access the medicines they need? Or will we allow anti-competitive behavior and the suppression of generic medicines to continue? Will we fight to continue to provide low-cost medications to all patients, including the most vulnerable populations and those who need them most? Or will we force more manufacturers to exit markets and exacerbate shortages of lifes-saving drugs?

I am pleased to share AAM's latest annual savings report highlighting the overall value of the generic and biosimilar industry. This report is the culmination of a continued collaboration with the IQVIA Institute for the past 14 years. Together, generic and biosimilar drugs represent a whopping 90 percent of all U.S. prescriptions for only 13 percent of spending. In the context of all healthcare spending, generics and biosimilars represent only one percent of the U.S. healthcare expenses. With manufacturing facilities located in nearly half of U.S. states — from California, to New Jersey, from Illinois, to North Carolina and beyond — today's generic drug industry makes it easier for patients to afford their medicines. We help employers pay for healthcare to keep our American workforce healthy, and we help health plans contain spending. Generic and biosimilar manufacturers form an integral and essential part of the healthcare system. As a result, the United States leads the world in both pharmaceutical innovation and adoption as well as access to lower-cost generic drugs.

The long-term sustainability and success of these industries and the very health of our nation's patients – hang in the balance. The rate of drug shortages has increased as manufacturers face challenges including rapid price deflation, supply chain challenges, Medicaid rebate policies that harm generic competition, slower adoption of new products due to abusive pharmacy benefit manager (PBM) financial engineering, and brand drug patent thickets.

We cannot afford to take our generic and biosimilar industries for granted.

We must do better!

David R. Gaugh
*Interim President & CEO, Association for Accessible Medicines*

# Letter from the Biosimilars Council Executive Director

## Biosimilars are the Future of Affordable Medicines, but Face Serious Headwinds

Even as the generic drug market exhibits increasing fragility, biosimilar medicines continue to demonstrate their promise of lower costs and greater access for patients, while struggling to fulfill their potential in the face of brand biologic rebate and patent schemes.

The good news: the biosimilars market continues to grow. In 2023, savings from the use of biosimilars increased by more than 30 percent, to $12.4 billion. Since their introduction, biosimilars have generated $36 billion in savings. Biosimilars are demonstrating their safety and effectiveness, with more than 2.7 billion days of patient therapy with no meaningful differences in clinical outcomes. Moreover, biosimilars are increasing patient access to care—495 million more days of patient therapy have occurred because of biosimilar competition.

Despite these positive trends, the biosimilars market faces severe challenges to long-term sustainability. While a few biosimilar products show higher utilization rates, overall, biosimilars achieved only a third of the market versus brand biologics in 2023. Last year we witnessed the PBM challenge facing new biosimilars, as biosimilar versions of best-selling biologic Humira combined to achieve less than two percent of the market despite offering price discounts of greater than 80 percent.

There are still improvements to be made to develop a robust marketplace that supports multiple biosimilar competitors and avoids the “race to the bottom” pricing that has driven generic drug shortages. On top of that, the government price-setting provisions in the Inflation Reduction Act have introduced an additional layer of complexity that manufacturers must navigate when considering future biosimilar development. These challenges to biosimilar adoption, combined with the cost of development, are why more than 80 percent of brand biologics that are eligible for competition do not have biosimilars in development.

This should serve as a wakeup call to policymakers. Without rapid action to streamline the FDA approval process, reduce abusive patent thickets, mitigate the unintended consequences of government price-setting, and remove the perverse incentives of PBM and brand drug rebates, patients will not realize the full value of biosimilars.

Biosimilars have already provided more life-saving medications to more patients, but more savings and access are possible. This depends on swift legislative and regulatory actions to establish a competitive and sustainable biosimilars market for future generations.

Craig Burton

**Craig Burton**
*Executive Director, Biosimilars Council*

BIOSIMILARS COUNCIL™
A DIVISION OF AAM

# About the Association for Accessible Medicines & the Biosimilars Council

- The Association for Accessible Medicines (AAM) is the nation's trade association for manufacturers of generic and biosimilar prescription medicines. AAM's core mission is to improve the lives of patients by advancing timely access to affordable, FDA-approved generic and biosimilar medicines.
- AAM members are manufacturers of finished generic and biosimilar pharmaceutical products, manufacturers of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic and biosimilar pharmaceutical industry.
- The Biosimilars Council, a division of AAM, works to create a positive regulatory, reimbursement, and policy environment to expand patient access to and encourage the utilization of biosimilar medicines.
- AAM and its Biosimilars Council work to expand patient access to safe, quality, and effective generic and biosimilar medicines by educating stakeholders and advancing policies that enable our manufacturers to deliver these medicines to patients.

# The U.S. Generic & Biosimilar Medicines Savings Report

**SEPTEMBER 2024**


| | | |
|---|---|---|
| I. | Introduction | 2 |
| II. | Overall Savings Generated by Generics and Biosimilars | 6 |
| III. | Savings By Category | 12 |
| IV. | Patient Out of Pocket Costs | 17 |
| V. | New Generic Savings | 20 |
| VI. | Drug Shortages | 24 |
| VII. | Biosimilars | 27 |
| VIII. | Conclusion | 36 |
| IX. | Methodology | 37 |
| X. | Endnotes | 39 |
| XI. | Contact Us | 40 |

# Overall Savings Generated by Generics and Biosimilars

# Topline Findings

## Total Savings from Generics and Biosimilars

- Total generic and biosimilar savings in 2023: $445 billion
- Total generic and biosimilar savings for the past ten years: $3.1 trillion
- Total generic and biosimilar savings in Medicare in 2023: $137 billion ($2,672 per beneficiary)
- Total generic and biosimilar savings in the commercial market in 2023: $206 billion
- Share of total U.S. prescriptions filled: 90 percent
- Share of total U.S. prescription drug spending: 13.1 percent
- Share of total U.S. healthcare spending: 1.2 percent

## Total Savings from Biosimilars

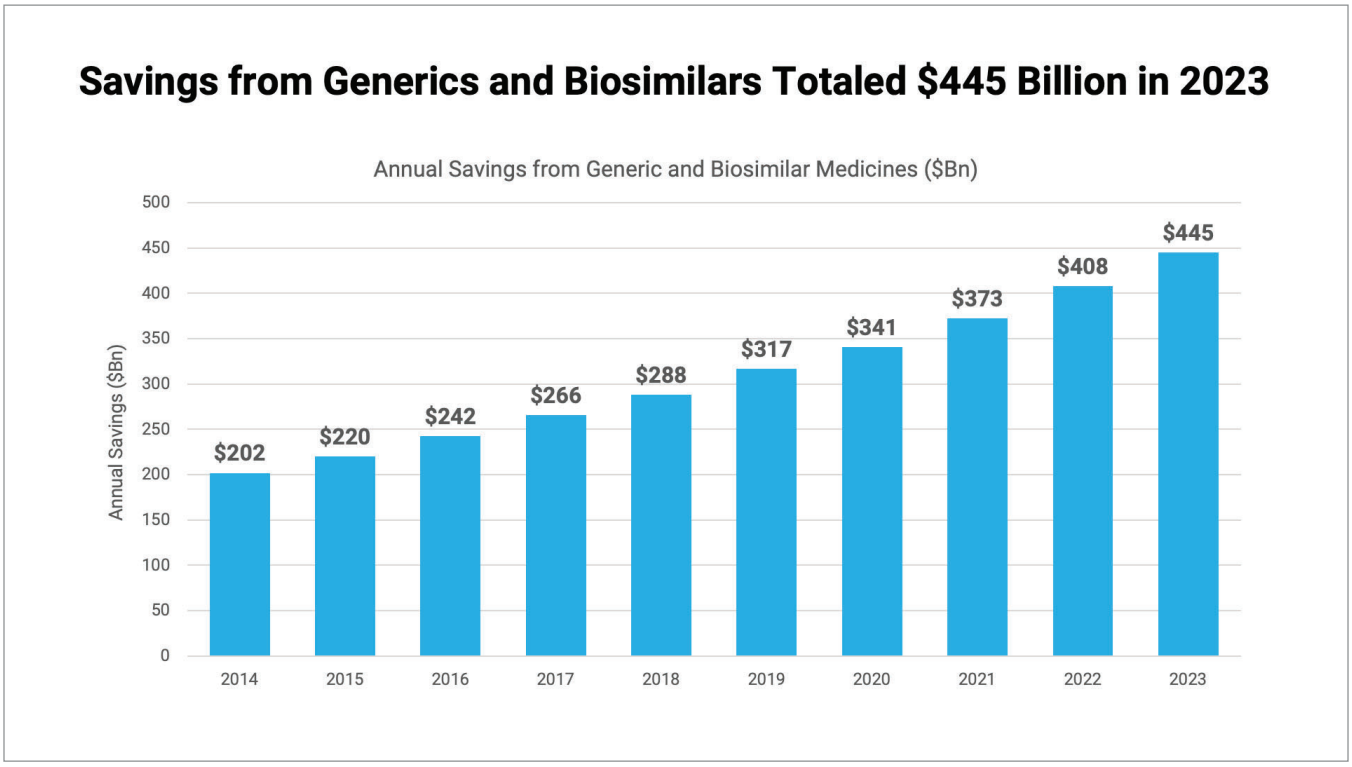
- Savings in 2023: $12.4 billion
- Total savings since first biosimilar entry in 2015: $36 billion
- Total days of patient therapy since 2015: 2.7 billion
- Incremental days of patient therapy that would not have occurred without biosimilar competition: 495 million

## Drug Shortages

- Percentage of shortages affecting generics: 84
- Percentage of shortages related to sterile injectables: 67
- Percentage of shortages for drugs priced at $1/unit or less: 56

# Savings From Generics and Biosimilars Totaled $445 Billion in 2023

## Generic and Biosimilar Savings Increased by $37 Billion




- Generic drugs contain the same active ingredients at the same strength and purity as their brand counterparts but are priced at a fraction of the cost.
- Biosimilars are lower-cost versions of expensive biologic medicines. They are approved by the Food and Drug Administration (FDA) as highly similar to, and with no clinically meaningful differences from, an existing FDA-approved biologic.
- Because of their lower costs, generics and biosimilars represent more than 90 percent of the prescriptions dispensed in the U.S.
- Annual savings from generics and biosimilars exceeded $445 billion in 2023, more than $12 billion of which comes from biosimilar medicines.

# Biosimilars Are Delivering Savings and Expanding Patient Access

## Biosimilars Are Also Driving Brand Prices Down

### Biosimilars Market Overview

**57**
APPROVED

**41**
MARKETED

**17**
REFERENCE PRODUCTS

Biosimilar savings since 2015
**$36 BILLION**

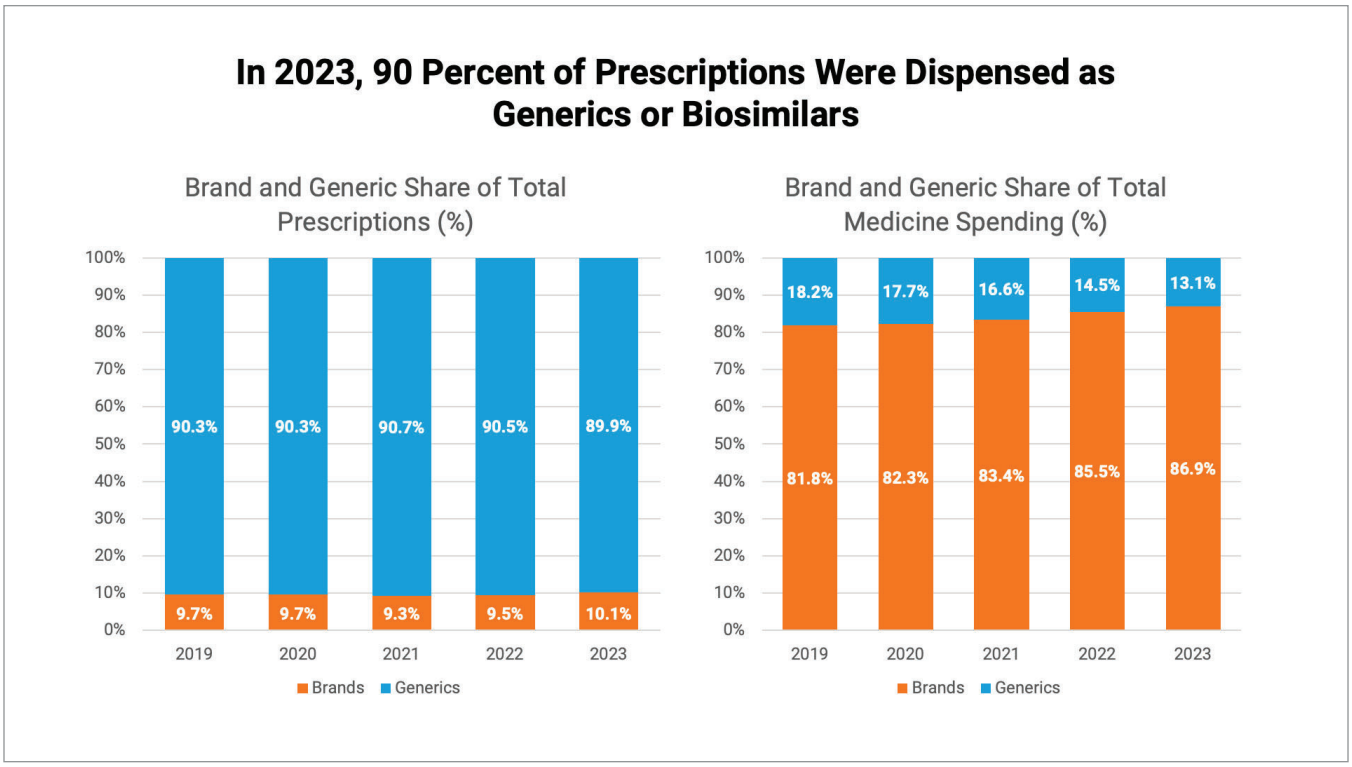
Biosimilars have been used in almost **2.7 BILLION DAYS** of patient therapy and have resulted in more than **495 MILLION INCREMENTAL DAYS** of therapy

Biosimilar competition is driving lower prices among biosimilars and their reference products

- The biosimilar market is rapidly growing, with 57 approved biosimilars for 17 reference biologics. Forty-one biosimilars are now available to patients.
- Biosimilars have been used in 2.7 billion days of patient therapy with no clinically meaningful differences in safety or efficacy.
- Patients have received 495 million more days of therapy than if no biosimilar was available. Put simply, biosimilars are making it possible for more patients to receive care.
- Robust biosimilar price competition results in lower prices – today more than 40 percent lower than the brand biologic price at the time of biosimilar launch.
- Biosimilar competition also lower prices on brand biologics — by more than one-third lower since biosimilar market entry.
- But more remains to be done. Biosimilar adoption has been slower than anticipated due to brand biologic rebate barriers, and the majority of brand biologics do not have a biosimilar in development.
- Policymakers must reduce the cost of development and ensure more rapid adoption of lower-price biosimilars.

# Generics and Biosimilars Are More Than 90 Percent of All Prescriptions but Only 13 Percent of Spending

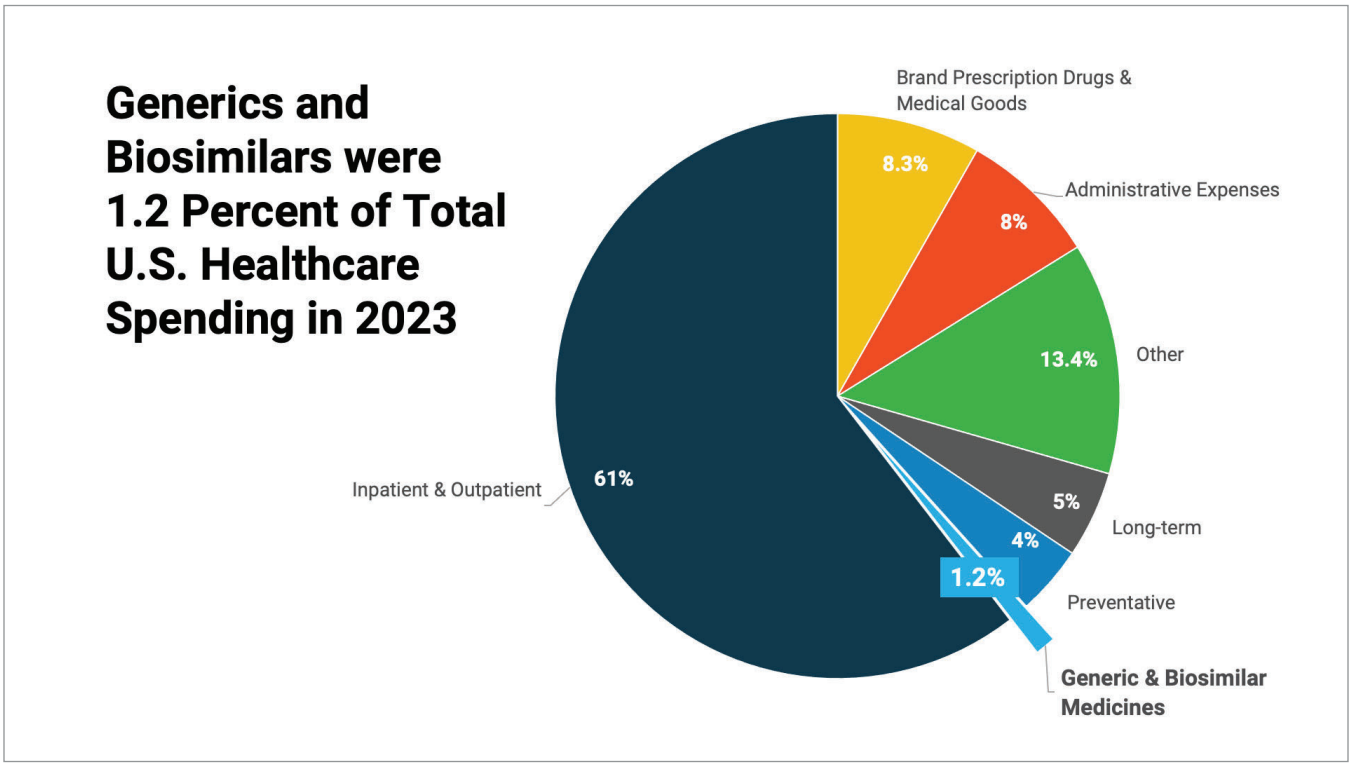
## Generic Prices Have Fallen 20 Percent Since 2019[1]




- In 2023, generics and biosimilars continued to demonstrate their value proposition – representing 90 percent of all prescriptions but only 13.1 percent of prescription drug spending.[2]
- Generic and biosimilar medicines are the only segment of healthcare that consistently deliver lower costs.
- In 2023, the average out-of-pocket cost for a generic was $7.05, while the average out-of-pocket cost for a brand drug was nearly four times higher — at $27.10.[3]
- In fact, generic prices continue to experience severe deflation; the overall value of all generic sales in the U.S. has declined by $6.4 billion since 2019 despite increased volume and new generic launches.[2, 4]

# Generics and Biosimilars Account for Less Than 2 Percent of Total U.S. Spending on Healthcare

## Generic and Biosimilar Medicines Provide Patient Access to High-Value Care




- Although patients receive a generic or biosimilar 90 percent of the time, these lower cost medications are less than two of every 100 dollars spent on healthcare in the U.S.
- The U.S. healthcare system has saved nearly $3.1 trillion in the last 10 years due to the availability of affordable generic and biosimilar medicines. In 2023, competition from generics and biosimilars resulted in more than $445 billion in savings to the healthcare system, including more than $137 billion in savings for Medicare.
- This continues a years-long trend of generic price deflation. In fact, the share of spending attributable to brand drugs continues to increase even as the total number of prescriptions filled by brand drugs has declined by half in the past 10 years.[2, 5]

# Savings by Category

# The 10 Most Dispensed Generics of 2023 Saved $89.5 Billion

## The Top 10 Generics by Volume Represent 20 Percent of Savings in the Past 10 Years

| Top 10 Products by Volume, 2023 | | | | | | |
|---|---|---|---|---|---|---|
| Products | Generic Entry Year | Brand Pre-Expiry Price (Per Unit) | Price of Generic Equivalent 2023 (Per Unit) | 2023 Savings ($Bn) | Percent Savings | 2023 Volume Units Dispensed (Mn) |
| Glucophage | 2021 | $0.66 | $0.04 | $5.6 | 94% | 9910 |
| Neurontin | 2023 | $1.02 | $0.06 | $7.5 | 95% | 7736 |
| Lipitor | 2010 | $3.29 | $0.08 | $24.8 | 97% | 7736 |
| Toprol XI | 1993 | $0.41 | $0.06 | $2.1 | 86% | 5872 |
| Norvasc | 2006 | $1.54 | $0.02 | $8.4 | 99% | 5544 |
| Zestril | 1998 | $0.67 | $0.03 | $3.2 | 96% | 4920 |
| Amoxil | 1993 | $0.04 | $0.04 | $0.0 | 5% | 4399 |
| Cozaar | 2009 | $1.51 | $0.07 | $6.1 | 96% | 4237 |
| Prilosec | 2001 | $3.31 | $0.05 | $12.1 | 98% | 4094 |
| Crestor | 2015 | $5.78 | $0.08 | $19.07 | 99% | 3467 |

- Generic competition continues to generate billions of dollars in savings each year. This year's data highlights the larger impact of generics for Amoxil and Crestor.
- Generics provide savings through new launches, through widely-used medicines for chronic conditions, and through generics used in low-volume markets.
- The 10 most commonly prescribed generic medicines accounted for $89.5 billion in savings in 2023. These medicines provide care for patients with the most prevalent chronic health conditions.
- The 10 generics with the highest total savings achieved $127 billion in savings in 2023 (28 percent of total generic savings).

# Generics And Biosimilars Save Billions for Patients

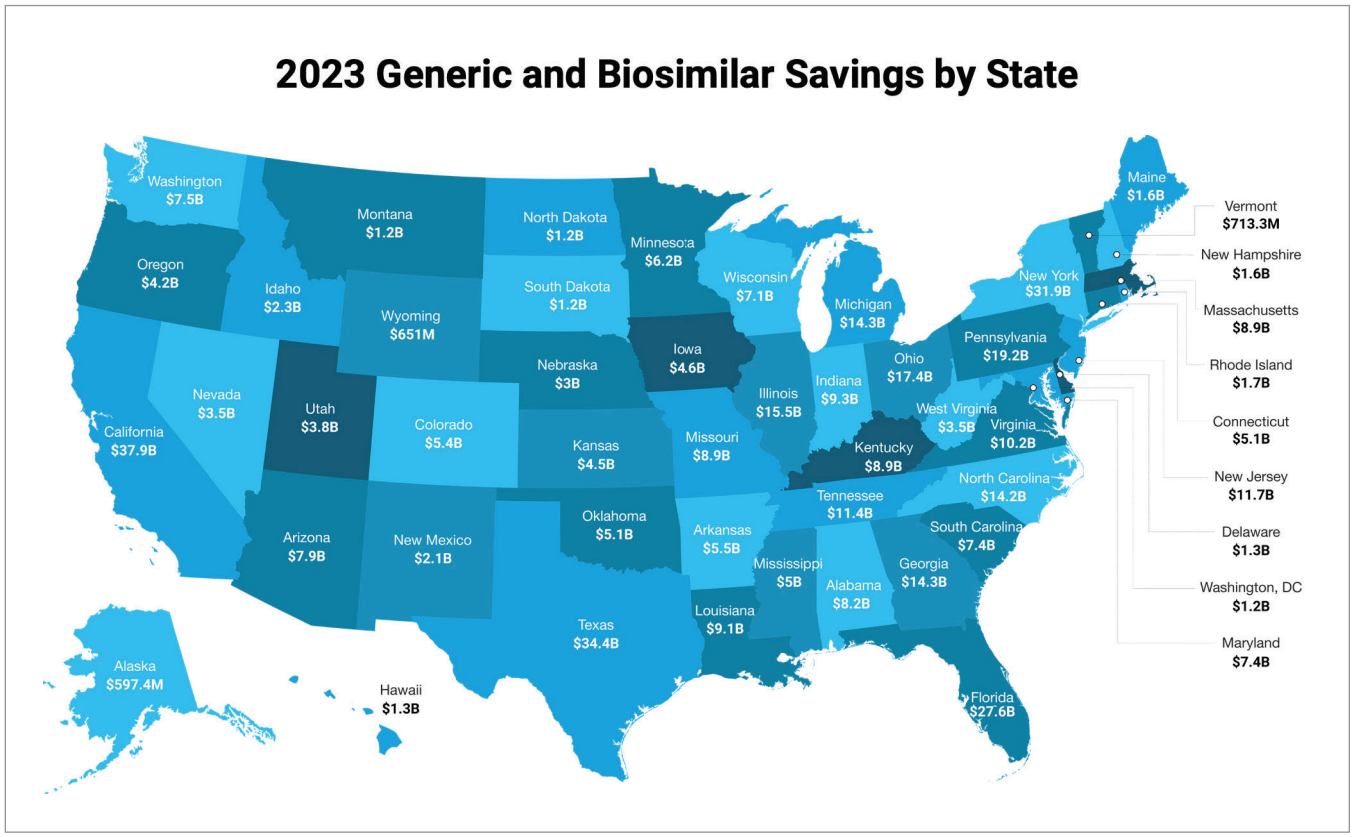
## Generic and Biosimilar Medicines Provide Significant Relief for Patients With Chronic and Acute Conditions Alike

| Savings by Condition | |
|---|---|
| **Condition** | **Total Savings (Primary Condition + Comorbidities)** |
| Heart Disease | $118.1 billion |
| Mental Illness | $76.4 billion |
| Diabetes | $61 billion |
| Cancers | $25.5 billion |
| Allergies & Asthma | $13 billion |
| Arthritis | $5.6 billion |
| Multiple Sclerosis | $4.6 billion |
| Crohn's & Colitis | $2.4 billion |
| Bone Disease (Osteoporosis, Osteoarthritis, etc.) | $2.2 billion |
| Autoimmune Diseases | $350 million |

- To better understand the value of generic drugs, one can examine the savings by some of the most common patient conditions and comorbidities.
- For example, in 2023, patients were protected from higher prescription medicine costs for:
  - Heart Disease: Generics saved patients $118.1 billion.
  - Mental Health: Generics saved patients with anxiety and depression almost $76.4 billion.
  - Cancers: Generics and biosimilars saved patients $25.5 billion.
- These savings are found both in treatment for the underlying condition as well as in treatments for some of the most common comorbidities of each of these conditions.
- Biosimilars promise additional savings for complex conditions, such as cancer and autoimmune diseases. Just as generics offer savings over brand-name drugs, these safe, effective alternative versions of biologic medicines promise to improve the quality of life for America's patients, while at the same time saving the health system billions of dollars.

# Savings by State

## Patients Across the U.S. Can Find Relief From Prescription Drug Costs Through Generics and Biosimilars



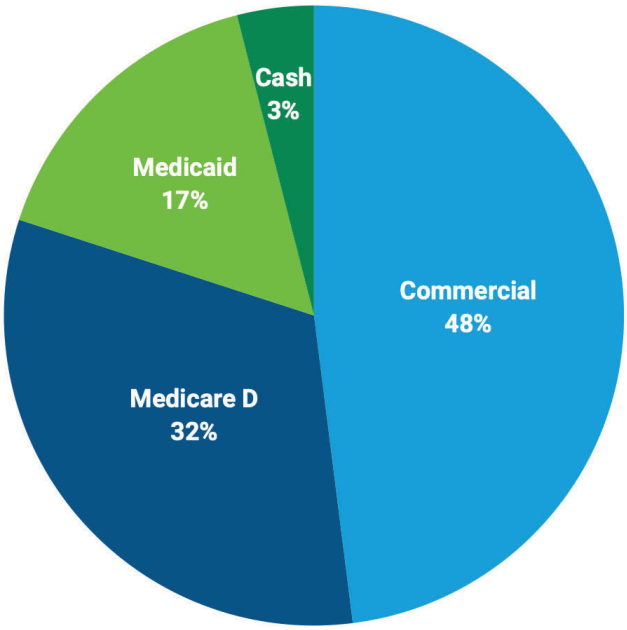

- Encouraging use of lower-cost generic and biosimilar medicines is a way for employers and states to ensure access and manage spending for states with patients diagnosed with chronic and complex conditions.
- On average, the use of generics and biosimilars saved more than $8 billion per state in 2023, with savings ranging from approximately $600 million (Alaska) to nearly $38 billion (California).
- Because more populous states often experience higher healthcare costs, such states also often realize greater savings through the use of generic and biosimilar medications.

# Generic and Biosimilar Savings Benefit Commercial Insurance and Medicare

## Use of Generics and Biosimilars in Medicare Saved $137 Billion in 2023

### 2023 Generic and Biosimilar Savings by Payer

Savings by state and by pay type were estimated using the share of each molecule dispensed via retail pharmacies to patients paying with cash and those covered by Medicare, Medicaid, and commercial insurance.



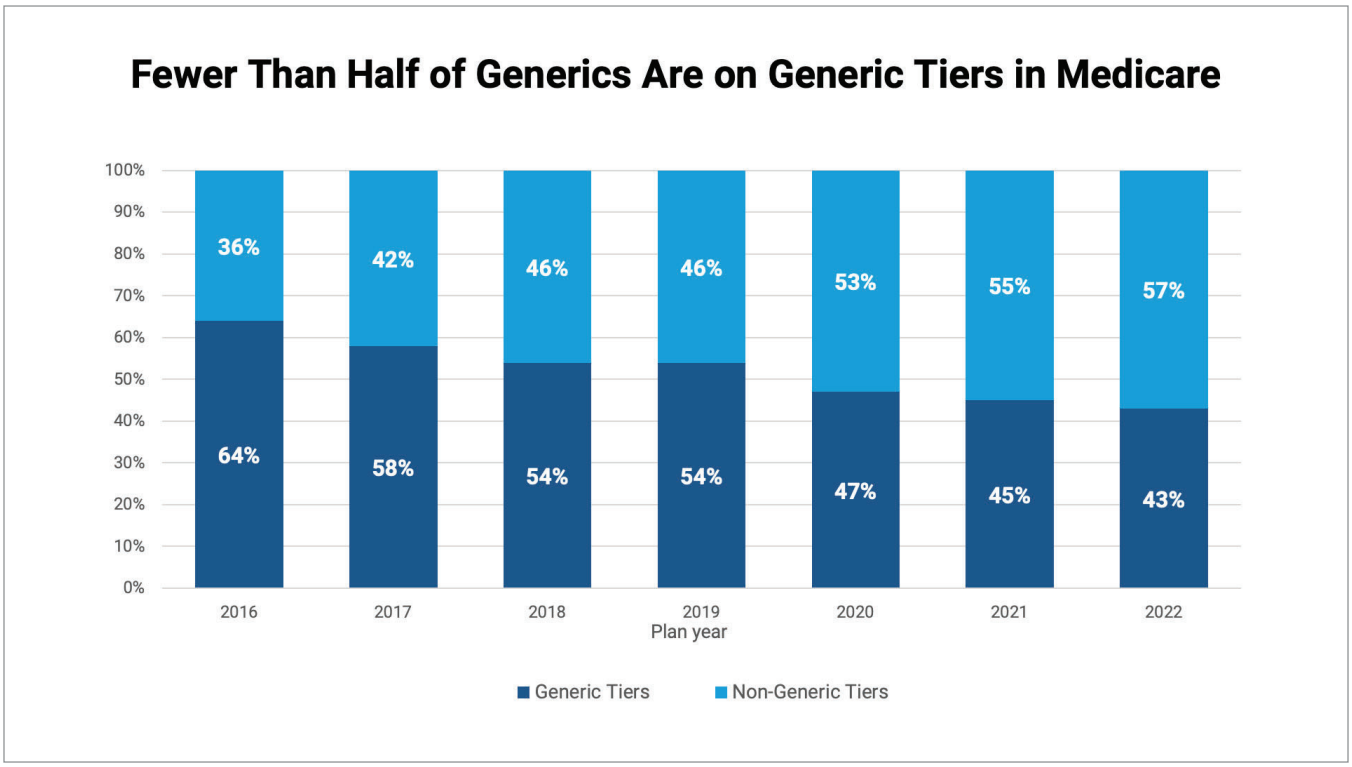

Generics and biosimilars provide critical savings throughout the healthcare system and are particularly valuable to Medicare and employer-sponsored health insurance and the patients they serve.

- In 2023, the use of generics and biosimilars saved:
  - $137 billion in Medicare; and
  - $206 billion in commercial health insurance.
- Regardless of changing beneficiary dynamics due to an aging population and plan eligibility or enrollment policies, generics and biosimilars offer sustained cost relief.
- Medicines taken by older adults account for the majority (78 percent) of total savings:
  - Adults aged 40-64 accounted for $194 billion in savings.
  - Seniors over age 65 accounted for $151 billion in savings.
- But many patients are being denied access to new generics and biosimilars or are forced to pay too much for their generic prescription. In fact, almost two-thirds of all Medicare beneficiaries were forced to pay the full cost for at least one generic in 2021.[6] This is why patients increasingly resort to paying cash for their medicines.[7]

# Patient Out-of-Pocket Costs

# Nearly 60 Percent of Generic Drugs in Medicare Are Not on Generic Tiers

## Plans Shift Generics Onto Higher Tiers and Increase Patient Costs

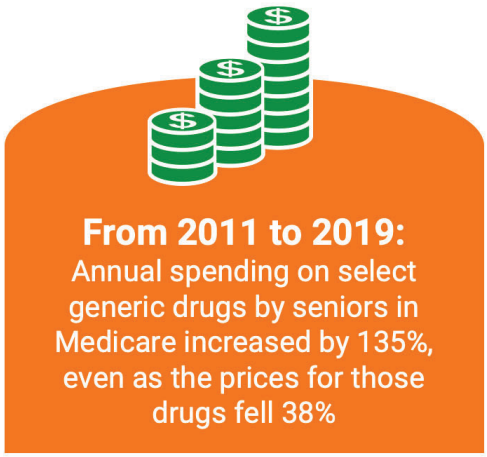


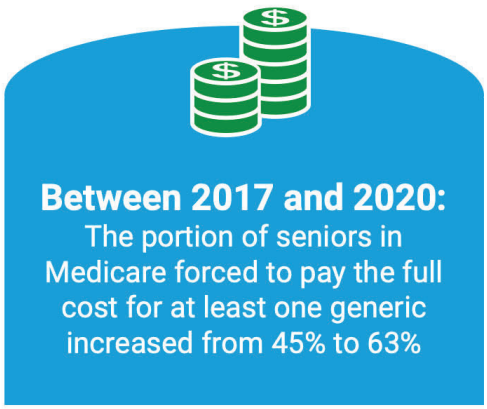

- Many patients face unnecessarily high costs due to PBM and health plan formulary decisions that place generics on non-generic tiers.
- Formulary tiers are intended to reward patients when they use the lowest-cost option possible. In recent years, as prices for generic medicines continue to fall, many Medicare Part D plans continue to place generics on higher tiers with higher copays. This forces seniors to pay more for lower-cost generic medications, often more than the cost of the medication.
- The result is that patients are paying more for their generics — even as those generic prices have declined.[6]
- This drives up patient spending on the lowest-priced medicines, and forces many insured patients to abandon their insurance and instead pay cash using pharmacy discount cards to afford their generic medicine.[7]

# Patients Overpay for Generics Due to Improper Formulary Placement

## Patients Are Paying More Even As Generic Prices Are Going Down

### Medicare Plans Are Making Patients Pay More for Generics



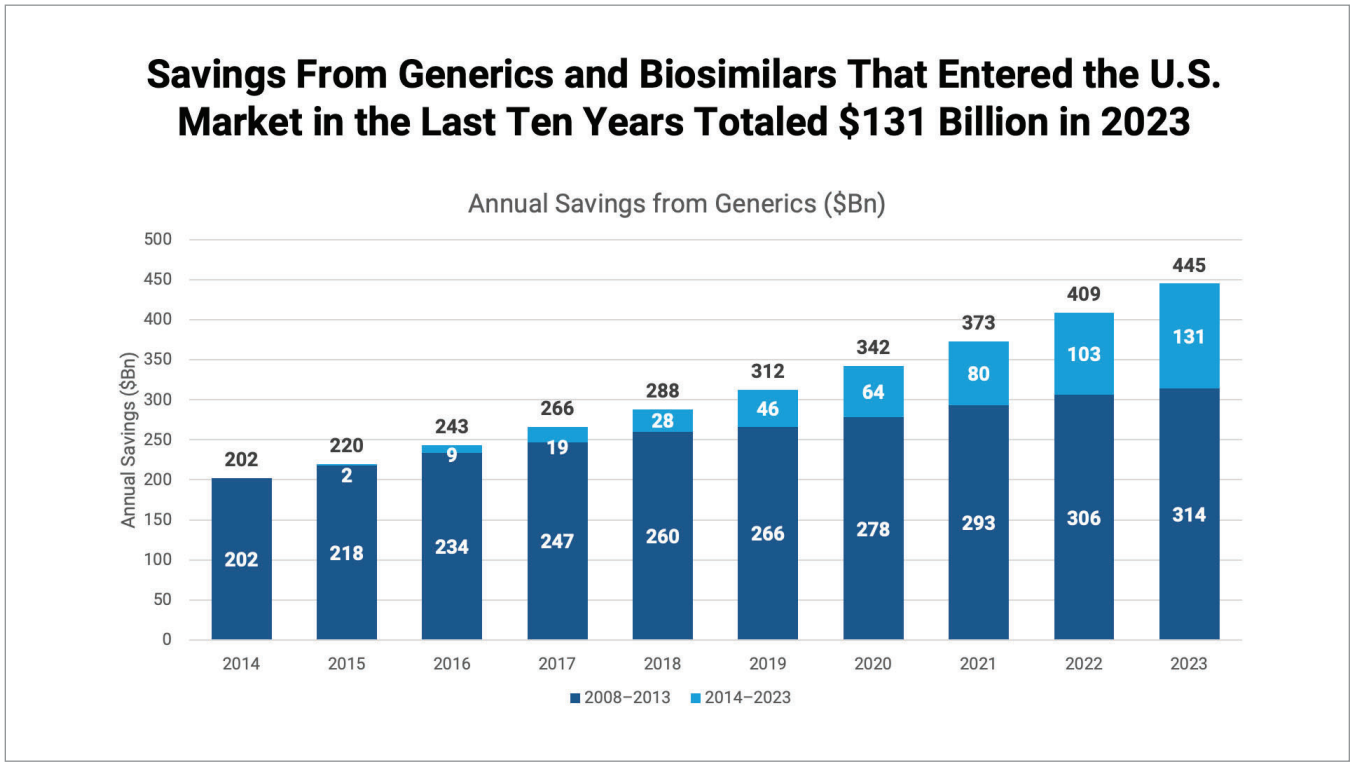




- Decisions by PBMs and health plans to shift generics to non-generic tiers increases copays and imposes higher costs on patients.
- An analysis of generic drugs covered from 2011 to 2019 found that shifting generics to brand tiers resulted in a 135 percent increase in annual patient spending, even as the average price of those medicines fell by 38 percent.[8]
- The number of patients forced to pay the full cost of the drug is growing.
- In 2017, 45 percent of patients in Medicare paid the full cost of their generic at least once. But by 2020, almost two-thirds of Medicare patients bore the full cost of their generic medicine.[8]

# New Generic Savings

# New Generics and Biosimilars Bring Lower Prices But Many Patients Lack Access

## New Generics and Biosimilars Generated $131 Billion in Savings in 2023




- Brand drug manufacturers enjoy years of regulatory exclusivity prior to a generic or biosimilar company's ability to enter the market. During this time, patients often experience repeated price increases.
- New generics and biosimilars generate lower costs and greater access to care for patients.
- Biosimilars and first generics come to market as a result of successful patent challenges, settlement agreements permitting earlier entry, or patent expiry.
- However, greater savings are being stymied by patent thickets and PBM rebate practices. Increasingly, new generics and biosimilars face challenges to delays in health plan coverage. For instance:
  - Biosimilars continue to face challenges to adoption.
  - New generics were only dispensed 75 percent of the time in 2023.

# New Generics Face Delays in Coverage

## Many PBMs and Health Plans Delay Coverage of New Lower-Cost Generics

### Medicare Plans Are Particularly Slow to Cover New Generics

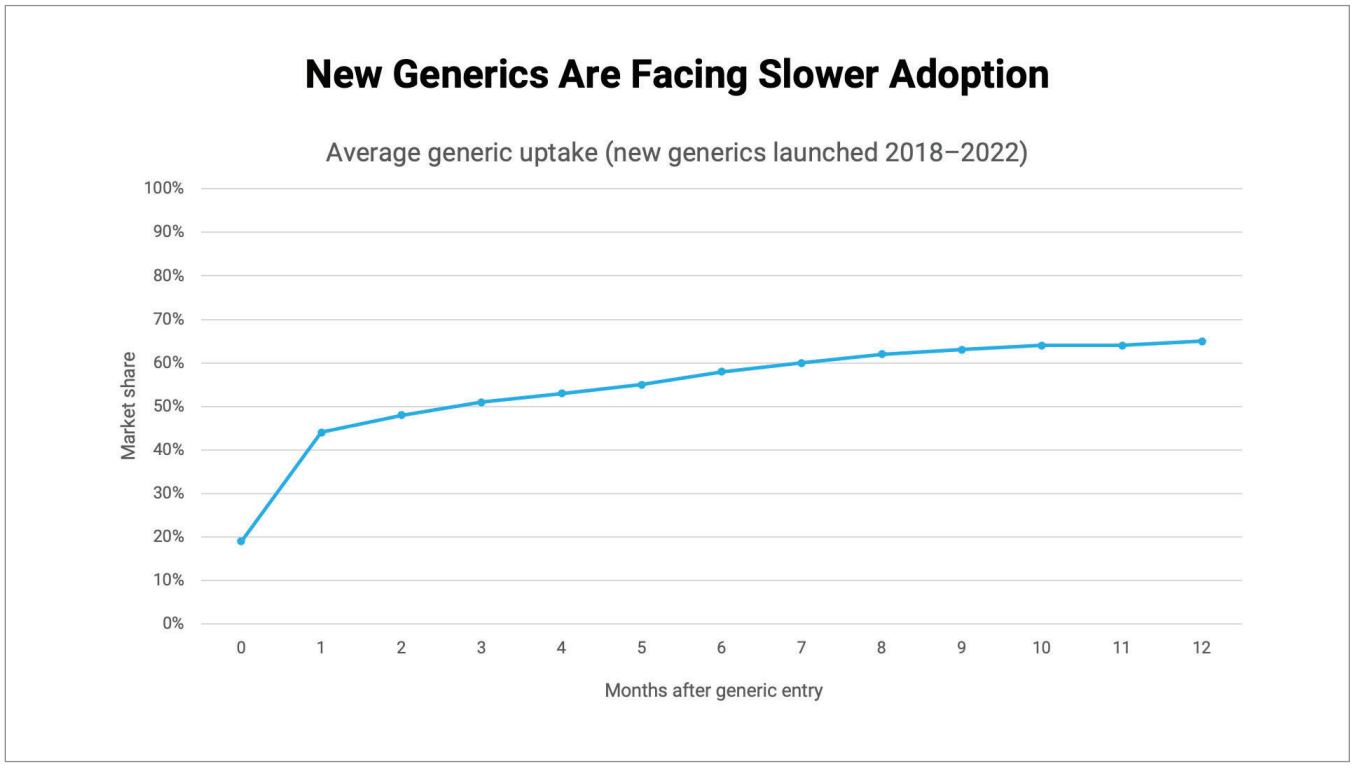
| Launch year | 2016 | | 2017 | | 2018 | | 2019 | | 2020 | | 2021 | | 2022 | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | M | C | M | C | M | C | M | C | M | C | M | C | M | C |
| 2016 | 22% | 46% | 31% | 68% | 63% | 72% | 58% | 72% | 60% | 76% | 62% | 78% | 61% | 90% |
| 2017 | | | 12% | 58% | 25% | 73% | 58% | 73% | 65% | 76% | 65% | 76% | 64% | 89% |
| 2018 | | | | | 17% | 39% | 27% | 49% | 51% | 59% | 54% | 60% | 54% | 84% |
| 2019 | | | | | | | 31% | 44% | 59% | 60% | 72% | 61% | 72% | 88% |
| 2020 | | | | | | | | | 21% | 55% | 41% | 66% | 60% | 90% |
| 2021 | | | | | | | | | | | 23% | 86% | 46% | 89% |

Medicare Part D (M) Commercial (C)

- Slower adoption and lower efficiency rates for new generics is driven in part by slower coverage decisions by PBMs and health plans. These entities benefit from rebates on high-priced brand drugs, even though patients would save through lower-cost generics or biosimilars.
- For instance, it appears to take roughly three years before new generics are covered by more than half of all Medicare drug plans. During this time, lack of coverage restricts patient access to lower-cost generics.[9]
- This means that pharmacies cannot provide a patient with a lower-cost generic if the plan formulary blocks it in favor of the higher-priced brand with high rebates.
- Although an average of 50 percent or more of commercial plans typically cover first generics the year after launch, this coverage appears to plateau over time.
- Although the Inflation Reduction Act included changes to Medicare that may encourage plans to cover new generics, it retained the perverse incentives for PBMs to prefer high-priced brand drugs that provide high rebates and fees.

# New Generic Market Adoption Has Slowed

## High Prices and Rebates Allow Brand Drugs to Retain Market Share Against Lower Net Priced Generics




- While nearly half of the small molecule generics reached over 75 percent market share by the end of 12 months, that is less than in prior years. This is in large part due to the recent trend of PBMs preferring brand drugs with high list prices, even when the generic or biosimilar would cost less for patients.
- For instance, the entry of biosimilar versions of insulin and Humira boasting discounts of more than 80 percent has been stymied by PBM decisions to continue preferred coverage of the higher-priced brand.
- Further, two class action lawsuits recently filed by employees of two large corporations allege PBM formulary practices caused employees to overpay for prescription drugs. And a whistleblower lawsuit describes how a major vertically-integrated PBM blocked coverage of new generics and ensured that its in-house pharmacies did not purchase the generic.
- Such practices and incentives favoring higher-cost brand drugs are a significant barrier to the sustainability of low-priced generic and biosimilar competition.

# Drug Shortages

# Drug Shortages Continue to Hamper Patient Care

## Generic Drug Shortages Are a Symptom of Challenges Facing Generic Sustainability

### Drug Shortages Present Challenges to Patient Care

There are many drugs in shortage, increasing from 61 in 2019 prior to the COVID-19 pandemic to 132 molecules as of June 2023.

**360**
**Molecules with active shortages or planned discontinuations**
Distinct molecules with active shortages **132** down from **168** in 2011

**Key therapies**
Mostly in oncology, mental health, ADHD, diabetes/obesity, and antibacterials.

**6.7%**
**Single-source**
6.7% of all single-source generics in the U.S. are in shortage, compared to 9.5% of multi-source genericized molecules and 1.8% of brands

**84%** **Generics**
Shortages disproportionately affecting generics

**11** **Cancer shortages**
11 oncology molecules with more than 10% of volume in shortage over the past 18 months

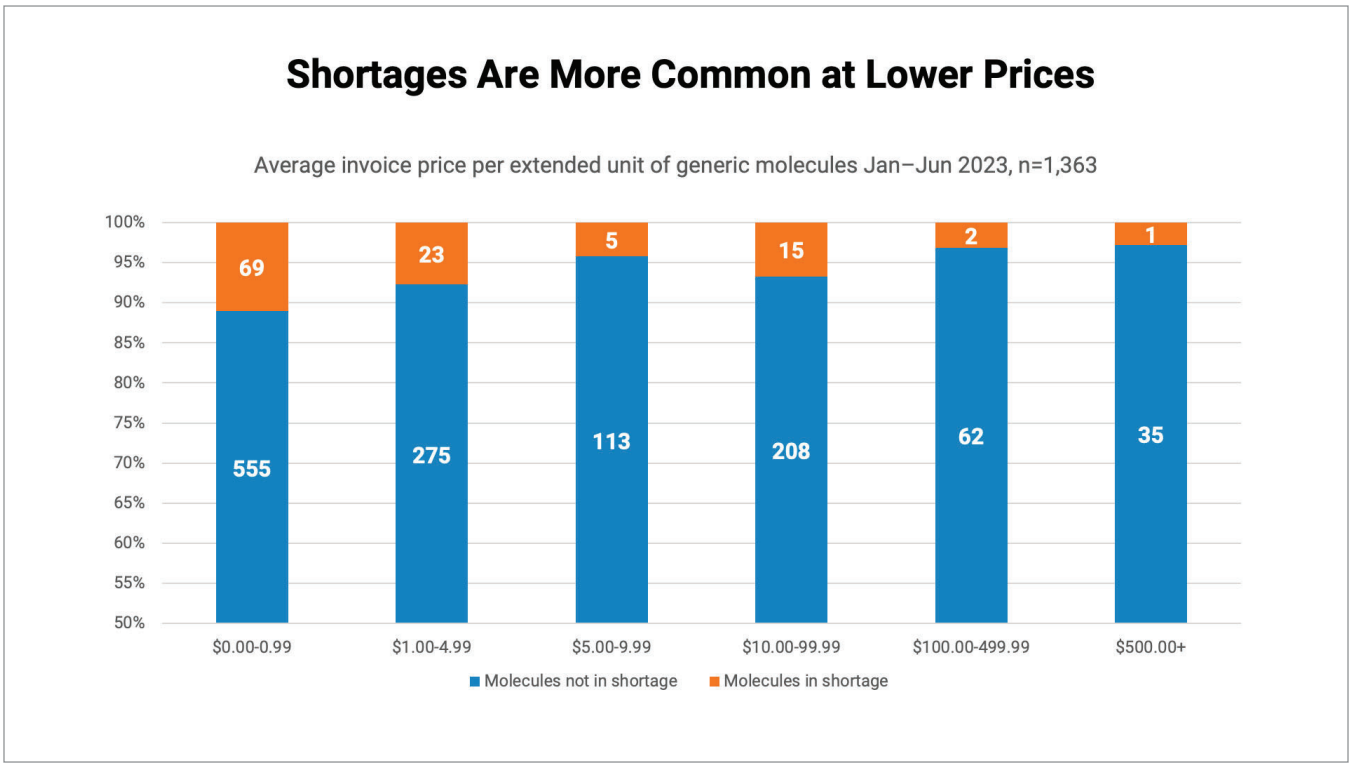
**Injectable** **67%**
Sterile injectables are the majority of shortages

**56%** Products in shortage are typically low-price, with 56% of molecules in shortage priced at $1 per unit or less and three-quarters of molecules priced below $5 per unit

- Although drug shortages affect both brand and generic drugs, generic drugs may be at greater risk of shortages.
- The increase in generic drug shortages is closely correlated with unsustainably low prices, new government policies that harm generic competition, supply chain challenges, as well as regulatory and manufacturing challenges.
- In fact, more than 6 of 10 generic drugs that are in shortage have a price of $1 per unit or less.
- Reducing future drug shortages requires a comprehensive set of policies to improve the long-term sustainability of generic drug competition through earlier adoption of new generics, ending abusive purchasing practices, preventing a 'race-to-the-bottom' in prices, and reforming government policies that penalize low-cost generic manufacturing.

# Shortages Are More Common for Lower-Priced Drug Products

## 60% of Generic Molecules in Shortage Are Priced Less Than $1.00 per Unit

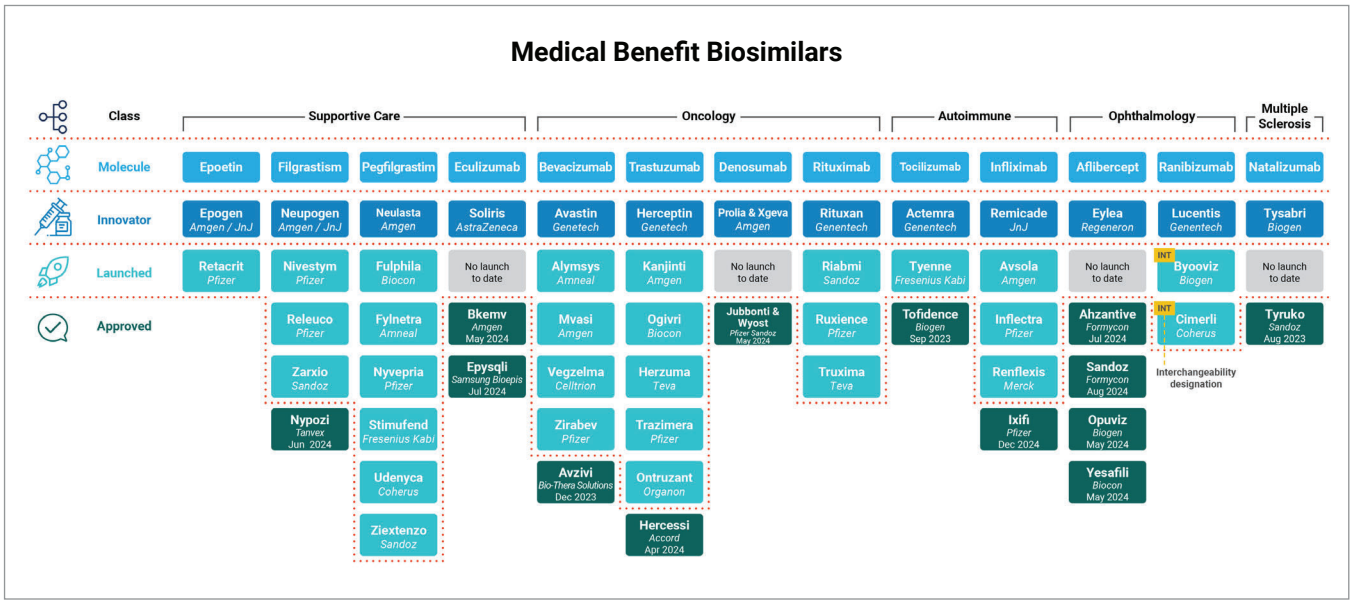


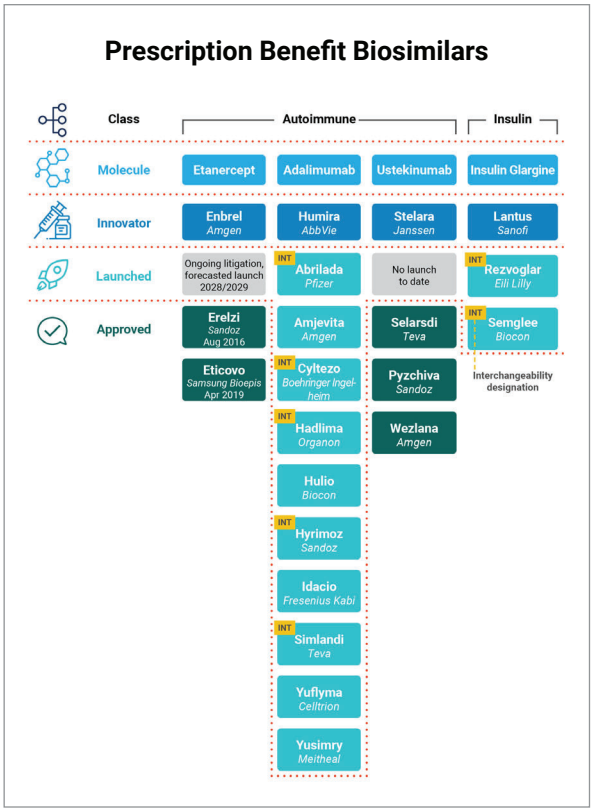

- While each drug shortage is unique, a common thread among shortages is unsustainably low generic prices further exacerbated by new government policies that undermine competition.
- The result can strain supply chains and leave providers without sufficient supply for patients.
- Policymakers can reduce future shortages by creating incentives for earlier adoption and more sustainable pricing of generic medicines.
- As FDA Commissioner Dr. Robert Califf recently noted, “We have got to fix the core economics if we’re going to get this situation fixed.”[10]

# Biosimilars

# The U.S. Biosimilars Market

## The Biosimilars Landscape Is Growing



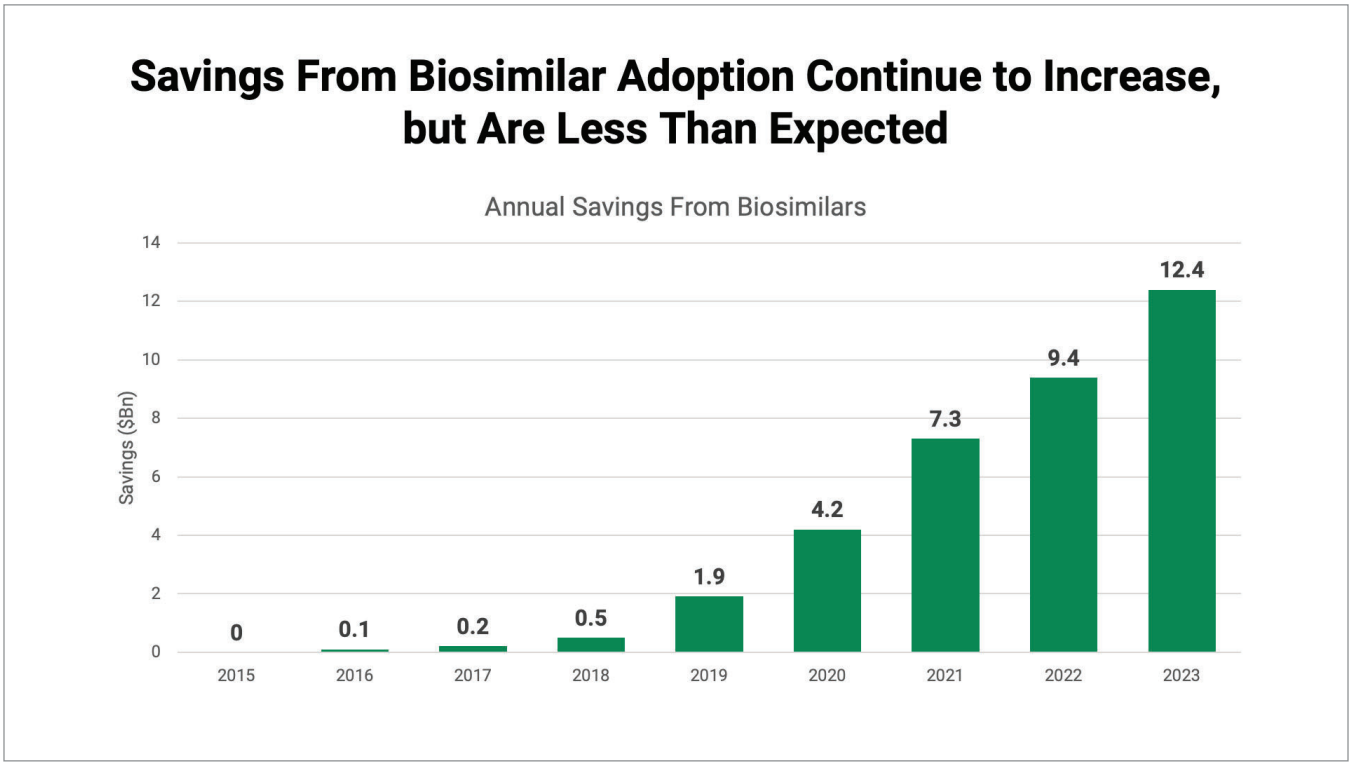




*As of November 2024*

- To date, the FDA has approved 57 biosimilars across 17 molecules.
- Forty-one biosimilars are on the market with prices averaging more than 40 percent less than the reference brand biologic price at launch.[11]
- Although there are currently 97 biosimilar development programs underway, there are nonetheless too many potential biosimilars that are not being developed.[11] In fact, 86 percent of brand biologics that are eligible for biosimilar competition do not have a biosimilar under development.[12] This is a reflection of the cost of development and the uncertainty regarding the future of the biosimilar market in the United States.
- To date, the bulk of biosimilar competition involved products that are directly purchased and administered by healthcare providers (medical benefit or buy-and-bill).
- New biosimilar launches in insulin and adalimumab represent the first entry of pharmacy-dispensed biosimilars, although PBM adoption has been slower than hoped.

# Biosimilars Have Generated $36 Billion in Savings Since 2015

## Savings Reflect Provider Confidence and Robust Price Competition

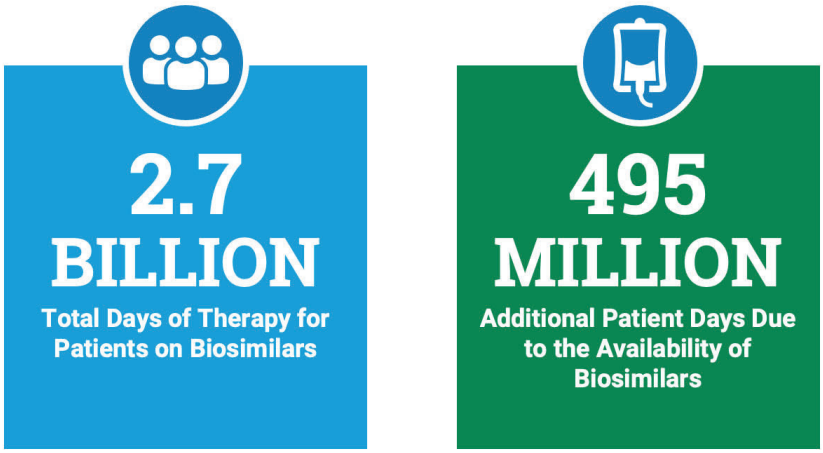



- Since the first biosimilar launch in 2015, patients and the healthcare system have saved nearly $36 billion.
- Savings are increasing as biosimilar adoption has grown. Sixty percent of total savings from biosimilar entrants has occurred in the past two years, with over $12.4 billion in savings in 2023 alone.
- However, biosimilar adoption continues to trail expectations because of misaligned incentives and PBM practices that slow adoption.
- Although biosimilar adoption has been higher among medical benefit biosimilars, it remains too low in many instances. And even markets with robust biosimilar adoption remain unable to support multiple competitors.
- Adoption of pharmacy-dispensed biosimilars such as insulin and biosimilar Humira remains disappointing due to PBM formulary practices favoring high-priced brand biologics with high rebates and fees that benefit the PBM but that are not shared with patients.

# Biosimilars are Delivering Safe Therapy

## Biosimilar Introduction Often Results in Greater Patient Access

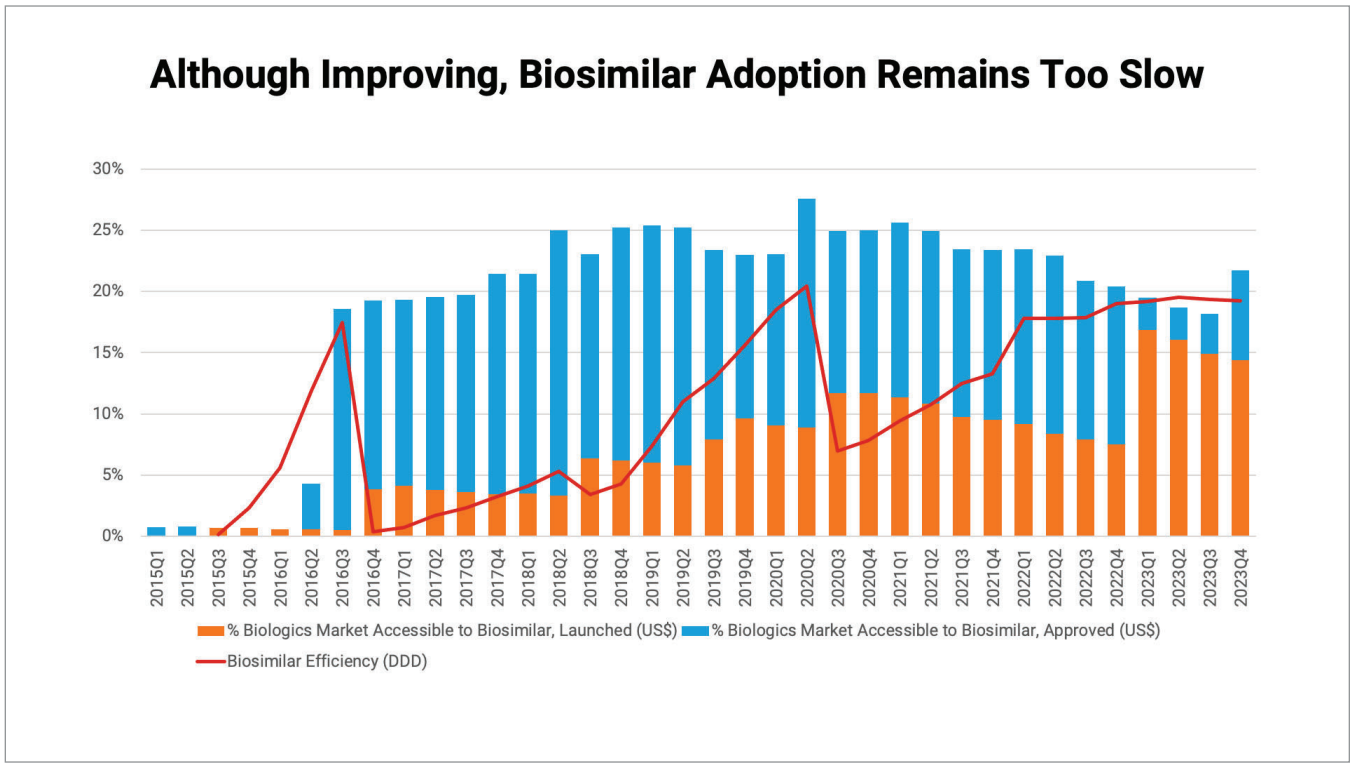
### Biosimilars Are Now a Core Element of Patient Care




- The increasing use of biosimilars should put to rest any questions about their safety and efficacy.
- Since 2015, biosimilars have been used in almost 2.7 billion days of patient therapy with no meaningful differences in safety or clinical outcomes.
- Moreover, overall use of molecules with biosimilar competition has increased. This means that more patients use medicines when a biosimilar is available.
- For instance, over 25 percent more doses of pegfilgrastim, used to generate new white blood cells for patients fighting cancer, have been dispensed since its biosimilar entered the market.
- In fact, biosimilar competition has now supported more than 495 million incremental days of therapy—care that patients would not have received otherwise.

# Although Improving, Biosimilar Adoption Remains Too Slow

## Biosimilar Adoption Is Hindered by Incentives for Using Costly Brands

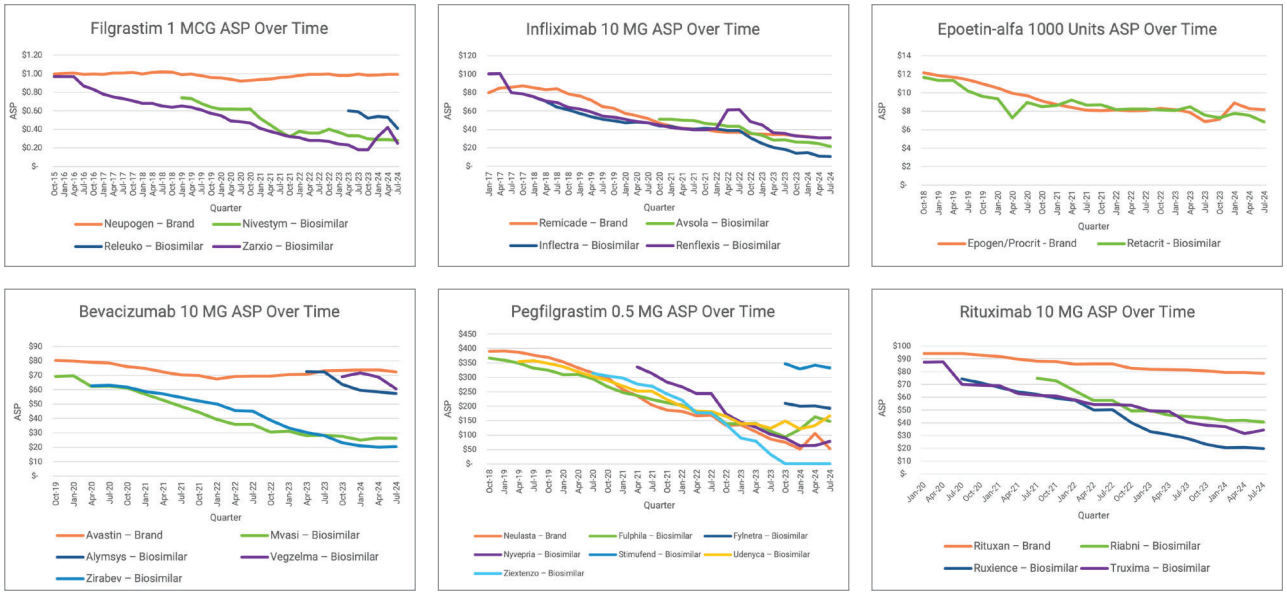



- The biosimilar efficiency rate, the rate at which biosimilars are dispensed when available, is growing but remains too low.
- While biosimilars are 80 percent or more of the market in two therapeutic areas, the average market share for all biosimilars remains under 20 percent.
- Even where biosimilars have been adopted, the majority of the market share is concentrated among one or two competitors. The market is not yet supporting multiple biosimilars within a molecule, leading to a winner-takes-all dynamic that could dampen future development.
- A sustainable biosimilars market is one that supports rapid adoption by multiple competitors.

# Biosimilars Launch at a Discount and Continue to Decrease Their Prices

## Biosimilars Also Drive Down Brand Prices

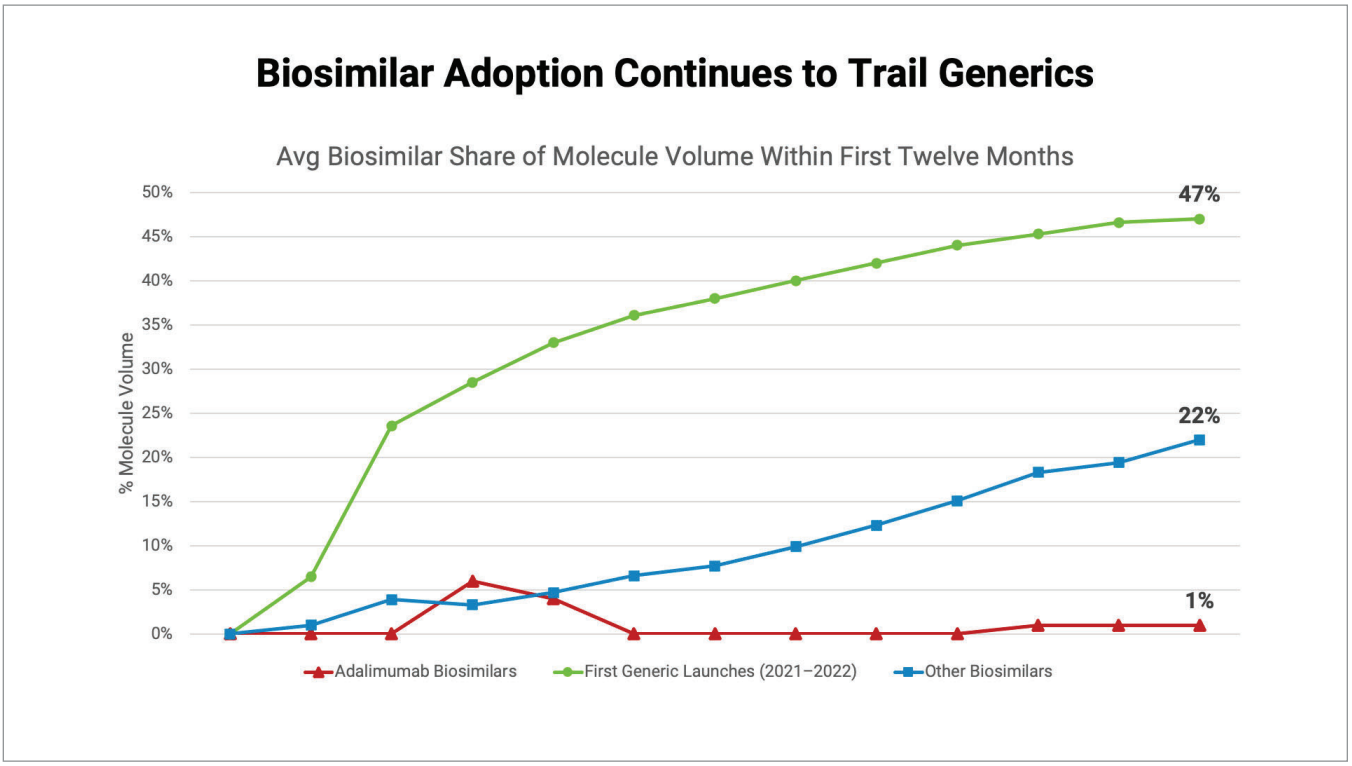
### Biosimilars Consistenly Drive Down Costs




- Prior to biosimilar entry, brand biologics take significant price increases. After biosimilar entry, brand prices tend to go down.[13, 14]
- Brand biologics have reduced by 33 percent on average. This results in savings from both the originator biologic and biosimilars.[13]
- Today, biosimilars, on average, are priced more than 40 percent lower than the brand biologic's price at the time of biosimilar launch.[13]
- Properly aligning incentives to support biosimilar adoption could save as much as $42.9 billion in medical costs by 2027.[15]
- However, the long-term sustainability of the biosimilars industry is in doubt, given the costs of development, the slow adoption by health plans and PBMs, and the uncertainty created by the government price setting approach established in the Inflation Reduction Act.
- Achieving the full promise of lower-cost biosimilars requires streamlining the development and approval process, removing the patent thickets that delay market introduction, and aligning coverage and reimbursement policies to encourage use of these lower-cost medicines.

# Biosimilars Adoption Remains Too Slow

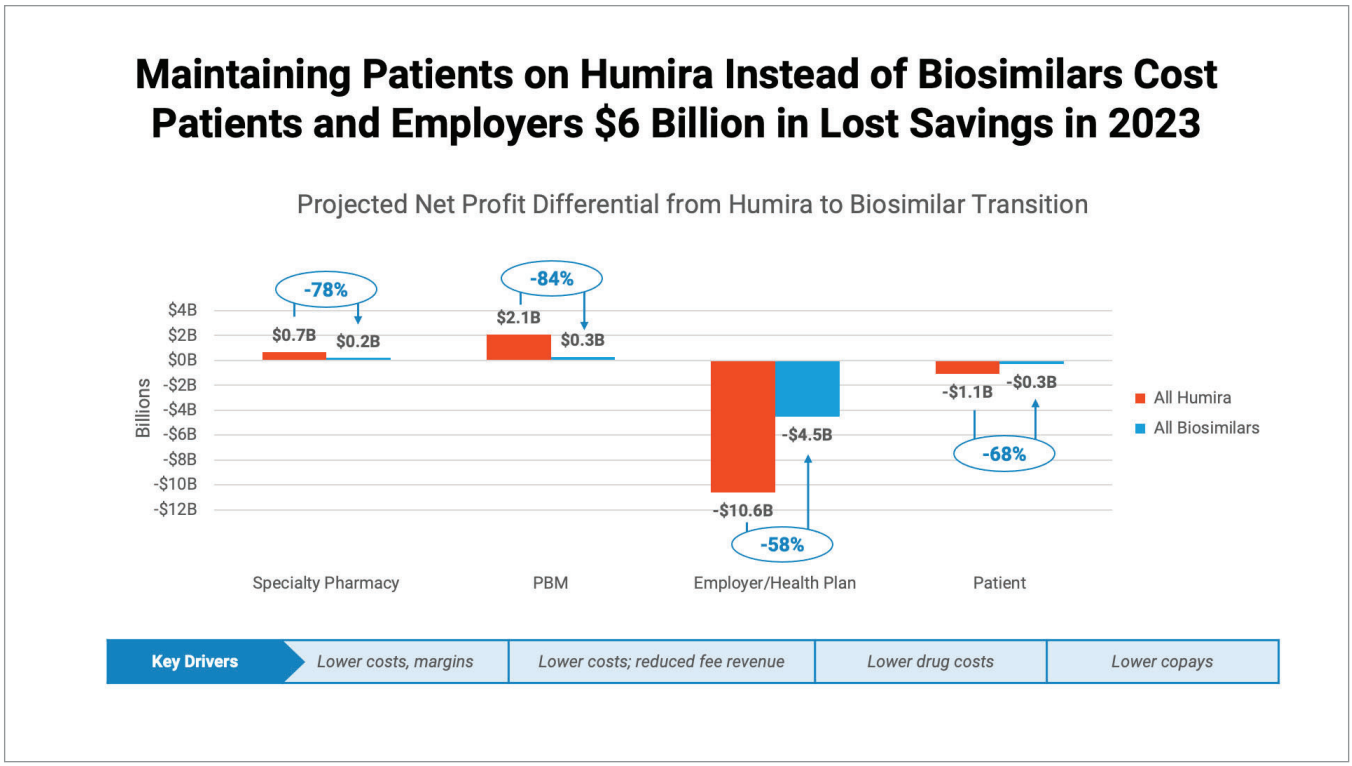
## Biosimilars Face Obstacles to Adoption




- Although they face challenges, small molecule generics fare better than biosimilars in gaining market share when brand product loses exclusivity. First generics launched in 2021 and 2022 typically achieved 47 percent of the market share within one year of the loss of exclusivity.
- Among biosimilars, there is wide variation in market share, with the average around 20 percent at one year.
- Adoption of adalimumab biosimilars has been particularly low—at one percent, due to insurer coverage decisions that fail to prioritize lower-cost treatments for patients.

# Maintaining Patients on Humira Comes at a Cost of Up to $6 Billion per Year for Patients and Employers

## Many PBMs and Health Plans Continued Use of Brand Humira Instead of Biosimilars With Lower Net Costs



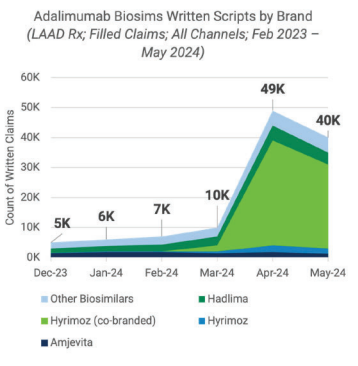

- PBM rebates and fees tied to high brand list prices continues to maintain a stranglehold on coverage decisions, to the detriment of patients. Despite price discounts of greater than 80 percent, adoption of biosimilar versions of Humira has been disappointingly slow, achieving less than two percent market share in their first year on the market.
- Even when rebates are taken into account, biosimilar options have lower net costs for employers and patients.
- IQVIA found that adalimumab biosimilars offer up to $6 billion in potential savings; however, switching all U.S. patients would lead to an estimated 84 percent decrease in PBM profits.
- This is a result of:
  - Continued PBM reliance on rebates and fees that are tied to brand drug high list prices; and
  - PBM practice of rewarding their vertically-integrated in-house specialty pharmacy networks compared to independent specialty and retail pharmacies.
- The vast majority of biosimilar Humira adoption in 2023 was by PBMs that are not reliant on rebate revenue and that prioritize use of lower-priced medicines.

# PBM Strategies 'Product Hopping' Are Suppressing Uptake of Lower-Cost Biosimilars

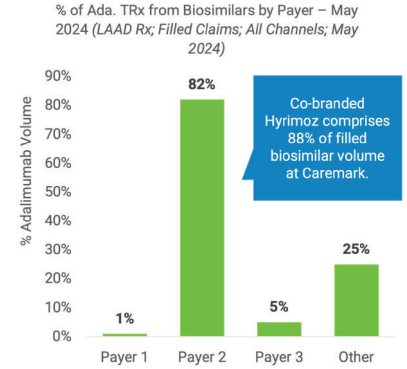
## Many PBMs and Health Plans Continued Use of Brand Humira Instead of Biosimilars With Lower Net Costs

### PBMs Continue to Play a Large Role in Patient Access to Biosimilars

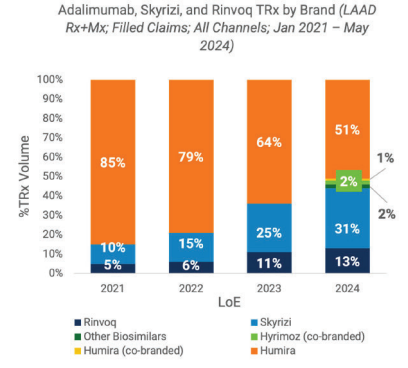
**Co-Branded Hyrimoz is Driving Increased Biosimilar Utilization**




**Large PBMs Continue To Favor Humira or Co-branded Options**




**Product Hopping Outpaces Biosimilars**




- Despite price discounts of greater than 80 percent, biosimilar adoption has been disappointingly slow.
- In their first year on the market, biosimilars achieved less than two percent of total market share, primarily through adoption by non-rebate dependent, smaller PBMs.
- Adoption increased in the spring of 2024 when a major vertically integrated PBM adopted and began driving use of a biosimilar.
- Nonetheless, large PBMs continue to prefer the high-priced brand over biosimilars.
- In fact, the major PBMs have partnered with the brand company to shift more patients to newer high-priced brands than to biosimilars.
- As a result, the brand manufacturer's immunology portfolio, consisting of three products, currently outnumbers all adalimumab biosimilar dispensing by a factor of 24 to 1.

# Conclusion

Generic medicines continue to provide value to patients, taxpayers, employers, and the healthcare system. And biosimilars are increasingly delivering on their promise of lower prices and expanded access for patients.

Generic and biosimilar medicines serve patients, ensuring that each one receives the medicine they need, when they need it. Moreover, they are expanding patient access, making life-savings medicines more affordable for patients, enabling patients to better adhere to their therapies, and ultimately saving lives.

But the continued savings achieved through use of lower-cost generics and biosimilars can no longer be taken for granted. The long-term outlook for generic and biosimilar competition hinges on addressing the barriers to development and adoption and, ultimately, sustainability of this vital industry. Without action to strengthen the generic and biosimilars markets, many of these lower-cost medicines may disappear, and patients' access to care will suffer.

# Methodology

The value of generics currently on the market was estimated using the pre-expiry prices of the brands they replaced. The current dataset includes pre-expiry brand prices for 1,302 generic molecules. The value of each generic molecule was determined by multiplying its pre-expiry brand price by the generic volume sold in each of the last ten years. This value represents what would have been spent on brand medicines in the absence of generic competition.

The savings attributed to each of the 1,302 generic molecules was determined by subtracting historic generic spending from the estimated brand spending in the absence of generic competition.

This analysis was refreshed with annual sales and volume data for all medicines sold in the United States between 1993 and 2023, focusing on the 10-year savings for the period 2014 to 2023. Savings from generics launched in the 1994 to 2023 study period are based on the most current knowledge of their pre-expiry prices.

Generic savings were calculated at the molecule-class level using a single average price for each molecule across all formulations (oral solid, liquid). Molecules that are available in multiple formulations are assumed to have the same pre- and post-expiry utilization patterns. Molecules with injectable formulations were calculated related to specific formulations to appropriately measure the cost differences between brands and equivalent generic forms.

State level generic savings was estimated by apportioning total savings for each molecule by each state's share of the national retail prescription volume. This method embeds two assumptions: first, that prices are uniform across the country, and second, that retail prescription activity mirrors prescription activity in other channels, notably mail order.

Savings generated by children, young adults, older adults, and seniors were estimated based on national prescription trends captured in the IQVIA New to Brand Audit. These figures represent the portion of the national savings generated by each age group, not the sum of the patients' personal savings.

Savings by pay type were estimated using the share of each molecule dispensed via retail pharmacies to patients paying with cash and those covered by Medicare, Medicaid, and commercial insurance. After calculating savings at the molecule, state, and payer level, results were summed to the state-payer level. This method does not analyze the cost to the patient who may have a copay or discount card; rather it divides generic savings equally amongst patients based on prescription use, regardless of insurance plan.

Patients with Medicaid, Medicare, and commercial insurance pay different prices for their medications based on their insurance benefit design. This analysis did not attempt to estimate savings to individual patients based on their method of payment. Instead, total generic savings for each molecule was divided evenly based on the number of prescriptions filled by patients of each pay type.

In previous editions of this study, the IQVIA Institute has employed not previously available historic archives. The prior versions of this study were based on archives and live data covering periods 2004-present. The current edition of the study includes archives extending a further 12 years to 1992. The calculation of generic savings depends upon the brand's pre-expiry price, or

the oldest available brand price if the pre-expiry price is not available. Older generics, particularly those first launched 1992-2004, and even those first launched before 1992, now have improved accuracy in the study. Brand prices change post-expiry, and therefore the more complete and accurate prices have improved the accuracy of the savings estimated in the study.

In the study released in 2024, molecules with >25 percent of prescriptions flowing through a single method of payment in a single state were excluded. These molecules are generally non-retail but may flow through unusual channels in specific states, potentially skewing savings data. Sixty unique molecules were excluded from state and method of payment calculations. The average share of TRx for non-excluded molecules in the largest states is only one percent.

Generic and brand drug share of prescription drug spending was calculated using an analysis of CMS National Health Expenditure data and IQVIA National Sales Perspective data. Total drug spending was segmented into generics and brands. Those percentages were then applied to the National Health Expenditure estimates of spending by type of expenditure within the CMS data.

This report estimates condition level savings from generics as a single year estimate for 2023. The base savings were calculated by IQVIA. Avalere generated condition-level savings by assigning drugs to a list of common conditions. Avalere then aggregated savings for all drugs that are used to treat these conditions. Importantly, many products treat multiple conditions. For purposes of this analysis, Avalere relied on internal subject matter expertise to determine the primary use of the product when assigning it to a condition. Avalere calculated comorbidity savings estimates for the three most common comorbidities for each of the index conditions and based on publicly available epidemiology data. Avalere calculated the base savings for the primary condition in the same manner as described above, and then assigned a weighted savings to each of the three selected comorbid conditions based on published prevalence data. Because the IQVIA data offers units rather than patients, Avalere used units as a proxy for the number of patients treated and adjusted the units, and thus savings, in proportion to the published prevalence of each comorbid condition. This methodology, due to the differences in units utilized by patients for specific conditions, could lead to estimates of comorbidity savings that exceed the total savings for that stand-alone condition. In these cases, the comorbidity savings were capped at the savings for that stand-alone condition to ensure a lower savings estimate.

# Endnotes


1 Long, D. (February 2024). US Generics & Biosimilars Trends, Issues & Outlook, *IQVIA*.

2 IQVIA Contributors. (May 2023). The Use of Medicines in the U.S. 2023. https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/the-use-of-medicines-in-the-us-2023

3 IQVIA Contributors. (May 2024). The Use of Medicines in the U.S. 2024: Usage and Spending Trends and Outlook to 2028. https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/the-use-of-medicines-in-the-us-2024

4 Long, D. (August 2023). US Pharmaceutical Trends, Issues and Outlook, *IQVIA*.

5 Fiore JA, Madison AJ et al. (June 2024). National Health Expenditure Projections, 2023–32: Payer Trends Diverge As Pandemic-Related Policies Fade. *Health Affairs*. https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2024.00469

6 Avalere Health Contributors. (July 2022). Some Medicare Part D Beneficiaries Pay Full Price for Generic Drugs. https://avalere.com/insights/some-medicare-part-d-beneficiaries-pay-full-price-for-generic-drugs

7 Association for Accessible Medicines Contributors. (October 2022). The U.S. Generics and Biosimilar Medicines Savings Report. https://accessiblemeds.org/sites/default/files/2022-09/AAM-2022-Generic-Biosimilar-Medicines-Savings-Report.pdf

8 Association for Accessible Medicines Contributors. (October 2022). Patients Pay More When Generic Drugs Are Placed On Non-Generic Tiers, Even Though Prices for Generics Are Going Down. https://accessiblemeds.org/resources/blog/patients-pay-more-when-generic-drugs-are-placed-non-generic-tiers

9 Association for Accessible Medicines Contributors. (January 2023). Middlemen Increasingly Block Patient Access to New Generics. https://accessiblemeds.org/sites/default/files/2023-01/AAM-Middlemen-Block-Patient-Access-New-Generics-2023.pdf

10 Kansteiner, Fraiser. (August 2023). A tale of 2 industries: FDA's Robert Califf weighs in on 'fundamental problem' causing so many shortages. *Fierce Pharma*. https://www.fiercepharma.com/pharma/tale-two-industries-fdas-califf-rails-against-innovator-and-generic-drug-pricing#:~:text=There's%20the%20%E2%80%9Cinnovator%20industry%2C%E2%80%9D,the%20drug%2C%E2%80%9D%20he%20said

11 U.S. Food & Drug Administration Contributors. (August 2023). Biosimilars. https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/biosimilars

12 IQVIA Contributors. (January 2023). Biosimilars in the United States 2023–2027. https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/biosimilars-in-the-united-states-2023-2027

13 Centers for Medicare & Medicaid Services Contributors. (July 2023). ASP Pricing Files. https://www.cms.gov/medicare/payment/part-b-drugs/asp-pricing-files

14 MEDPAC Contributors. (June 2023). Addressing high prices of drugs covered under Medicare Part B. *Report to the Congress: Medicare and the Health Care Delivery System*. https://www.medpac.gov/wp-content/uploads/2023/06/Jun23_Ch1_MedPAC_Report_To_Congress_SEC.pdf

15 PWC Contributors. (2024). Medical Cost Trend: Behind the Numbers 2025. https://www.pwc.com/us/en/industries/health-industries/library/assets/pwc-behind-the-numbers-2025.pdf

# Contact Us

## Association for Accessible Medicines

601 New Jersey Ave NW
Suite 850
Washington, D.C. 20001
202-249-7100
accessiblemeds.org

Follow AAM on social media

/accessiblemeds

---

## Biosimilars Council

A division of the Association for Accessible Medicines
biosimilarscouncil.org

Follow the Council on social media

/biosimscouncil

---

accessiblemeds.org

biosimilarscouncil.org