Association for Accessible Medicines

The U.S. Generic & Biosimilar Medicines Savings Report

SEPTEMBER 2023

Letter From the President and CEO

Generic Savings: Significant Impact, Fragile Future

Generic and biosimilar competition saved more than $408 billion, but sustainability is under threat

Amid daily news coverage of prescription drug pricing lies the under-appreciated success story of generic medicines. Generic medicines are an integral part of our health care system, expanding patient access through competition and lower prices. And a new wave of lower-priced biosimilars is also delivering value and savings.

Together, generics and biosimilars represent a whopping 90 percent of all U.S. prescriptions but less than 18 percent of spending. This is indisputable proof of the value of generics and biosimilars for patients, employers and taxpayers.

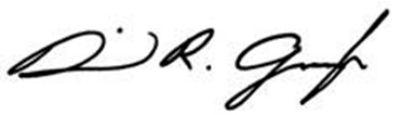
The price of generics has fallen by approximately twenty percent since 2019 and these savings translate into significant financial relief for millions of patients and families.

But as we approach the 40-year anniversary of the Hatch-Waxman Act that created the modern generic drug framework, the recent surge in drug shortages has highlighted an increasingly fragile industry. And its long-term sustainability faces significant challenges with dire implications.

If government policies continue to penalize low-cost generic medicines and highly consolidated purchasers continue to impose unsustainably low prices and onerous contractual terms, more manufacturers will exit the market. If the Medicare program continues to reward middlemen for using high-priced brands with high rebates, patients will continue to lack access to new generics and biosimilars. And if regulatory challenges are not addressed, manufacturers will continue to struggle to prevent and recover from shortages. The result will leave America's patients without access to many generic medicines.

Patients depend on generic and biosimilar medicines for their physical health and financial well-being. Likewise, our health care system relies on generic medicines, the only sector of the health care system that consistently reduces spending. It is vital that policymakers take a comprehensive approach to remedy the systemic challenges facing the industry.

This report reflects the important work that AAM members perform. I thank all those who are dedicated to delivering these savings for patients.



David Gaugh

Interim President & CEO, Association for Accessible Medicines

Letter from the Biosimilars Council Executive Director

Biosimilars are delivering on their promise of expanded patient access but face challenges to adoption and sustainability

Use of biosimilars has saved nearly $24 billion since 2015

Prescription drug spending is increasingly driven by a small group of biologic and specialty medicines that, although less than three percent of all prescriptions, are more than half of all spending. Biosimilars are lower-cost, equally effective versions of those high-cost brand biologics. Biosimilars provide meaningfully lower prices. The average biosimilar price is more than 50 percent less than the brand price was at the time of biosimilar launch. Moreover, biosimilar competition is forcing brand biologics to reduce their prices.

Most importantly, the introduction of biosimilar competition is expanding patient access to care.

Nonetheless, although some biosimilars have seen significant adoption and the use of biosimilars has risen, not all biosimilars have been able to achieve substantial market use. There remain significant challenges to achieving a biosimilars market that can deliver lower prices for patients over the long term.

Ultimately, ensuring that every patient benefits from biosimilars means ensuring that all biosimilar markets achieve rapid patient access to and adoption of multiple biosimilar competitors.

The Biosimilars Council remains dedicated to expanding access to lower cost biosimilars so that patients can live longer, healthier lives.

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) and the Biosimilars Council work to make generic and biosimilar medicines accessible to more patients who need them.
- 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 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 advancing education regarding the safety and effectiveness of generic and biosimilar medicines.

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OVERALL SAVINGS GENERATED BY GENERICS AND BIOSIMILARS

Topline Findings

Total Savings from Generics and Biosimilars

- Total generic and biosimilar savings in 2022: $408 billion
- Total generic and biosimilar savings for the past ten years: $2.9 trillion
- Total generic and biosimilar savings in Medicare in 2022: $130 billion ($2,563 per beneficiary)
- Total generic and biosimilar savings in the commercial market in 2022: $194 billion
- Share of total U.S. prescriptions filled: 90 percent
- Share of total U.S. prescription drug spending: 17.5 percent
- Share of total U.S. health care spending: 1.5 percent

Generic Savings

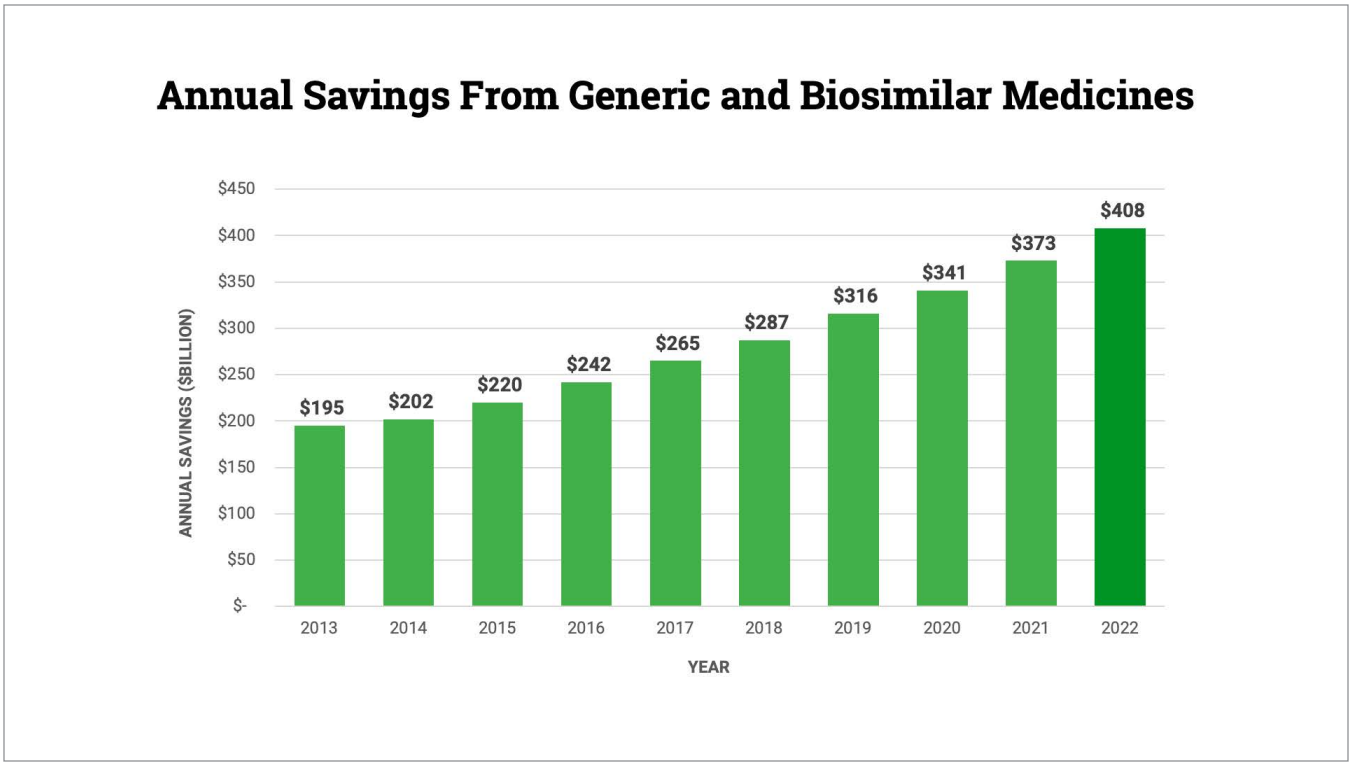
- Average generic copay: $6.16
- Average brand-name copay: $56.12
- 92 percent of generics have a copay less than $20; 53 percent of brands have a copay less than $20

Biosimilar Savings

- Savings in 2022: $9.4 billion
- Total savings since first biosimilar entry in 2015: $23.6 billion
- Total days of patient therapy since 2015: 694 million
- Incremental days of patient therapy that would not have occurred without biosimilar competition: 344 million

Savings From Generics and Biosimilars Totaled $408 Billion in 2022

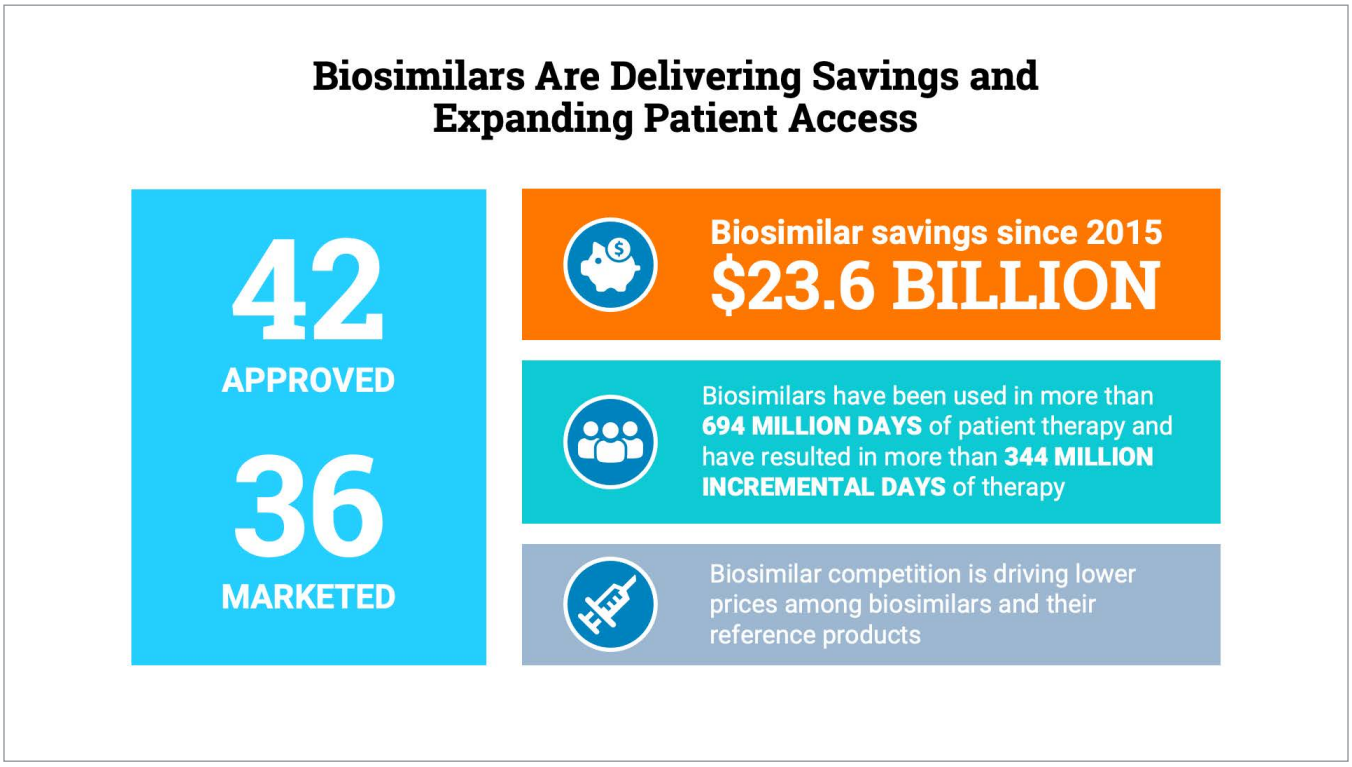
Generic and Biosimilar Savings Increased by $35 Billion from 2021 to 2022



- Generic drugs contain the same active ingredients at the same strength and purity as their brand-name counterparts but come 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 United States.
- Annual savings from generics and biosimilars exceeded $408 billion in 2022, an increase of $35 billion from 2021. Yearly savings have consistently increased by 7–10 percent.

Biosimilars Are Delivering Savings and Expanding Patient Access

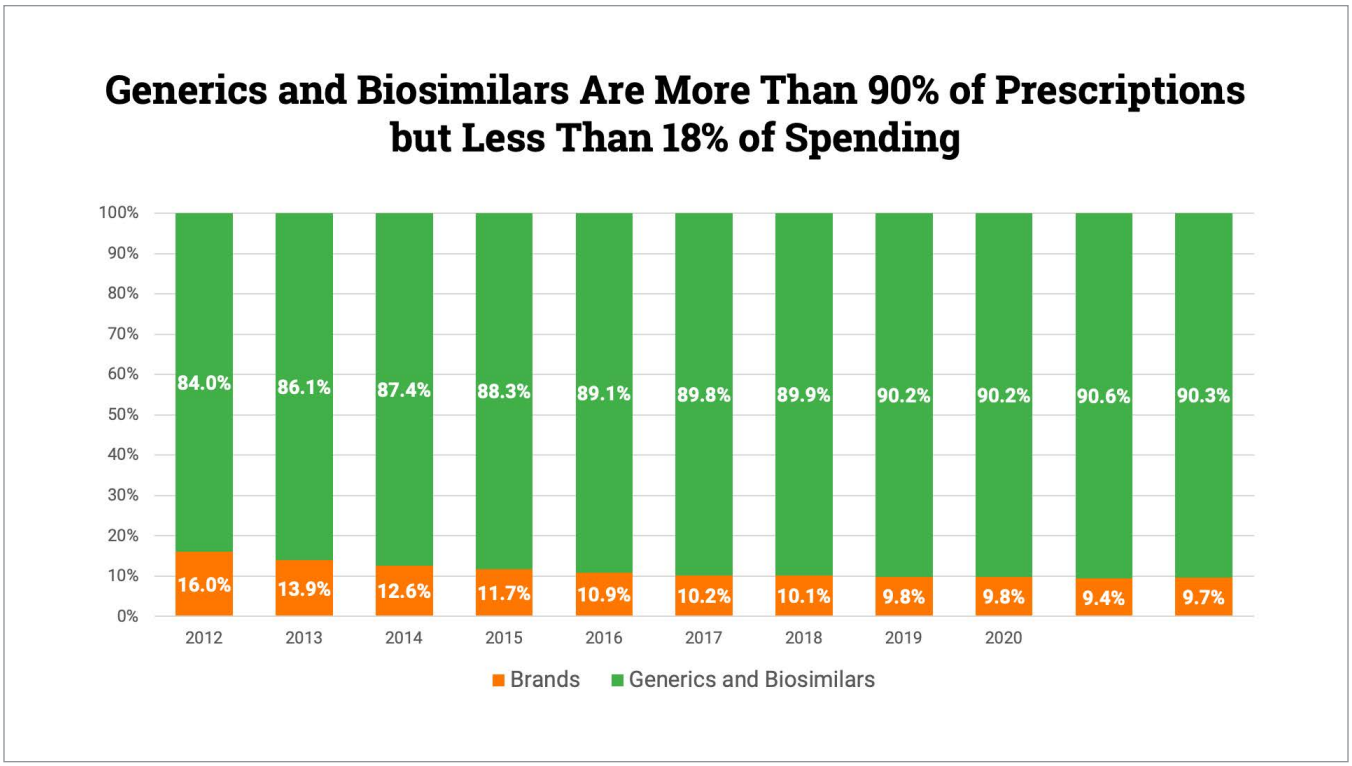
Biosimilars Are Also Driving Brand Prices Down



- The biosimilar market is rapidly growing. Thirty-six biosimilars are now available to patients.
- Biosimilars have been used in 694 days of patient therapy. And patients have received 344 million more days of therapy than if no biosimilar was available. Put simply, biosimilars are making it possible for more patients to receive care.
- This occurs as a result of robust biosimilar price competition that creates not only lower prices on biosimilars, but also lower prices on brand biologics.
- In fact, biosimilar average sales prices today are more than 50 percent lower than the brand biologic price at the time of biosimilar launch. And brand prices are also lower—more than one-quarter lower since biosimilar market entry.

Generics and Biosimilars Are More Than 90 Percent of All Prescriptions but Less Than 18 Percent of Spending

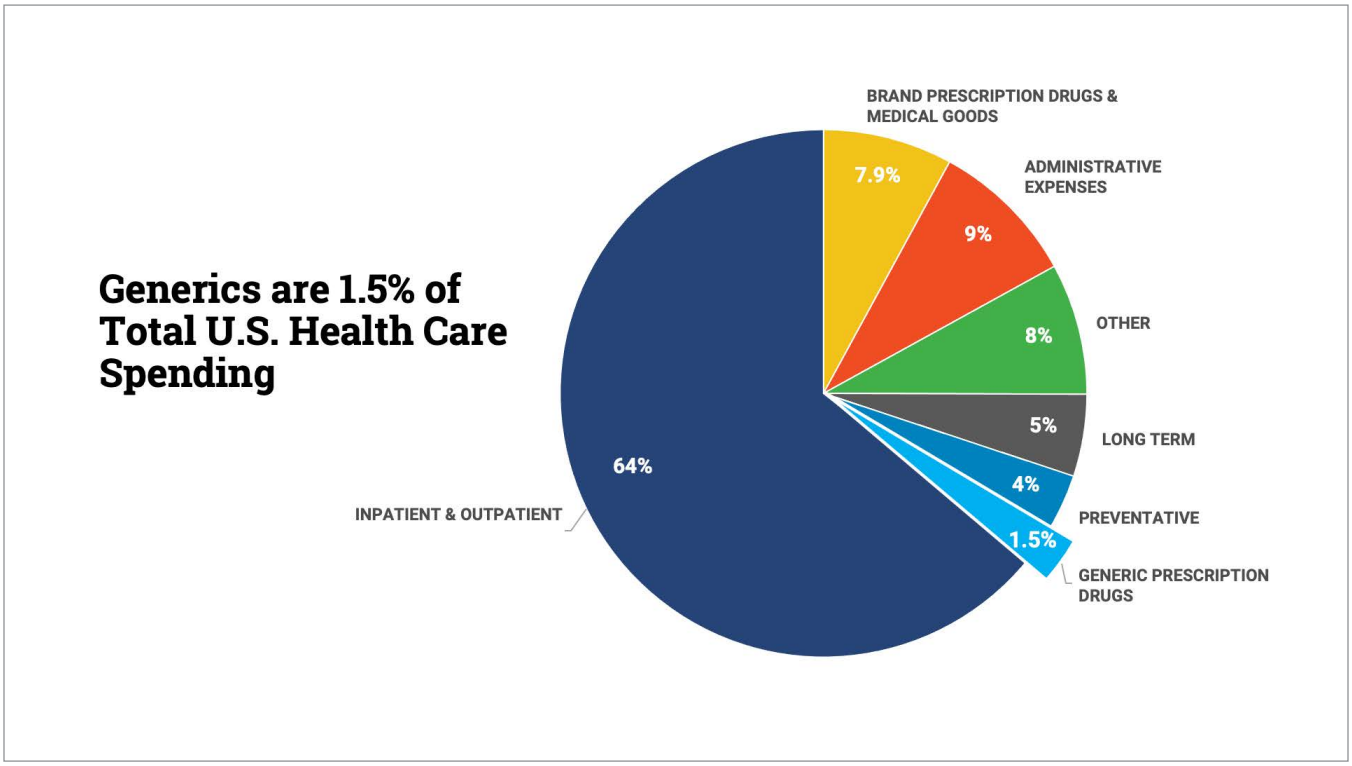
Generic prices have fallen 20 percent since 2019



- In 2022, generics and biosimilars continued to demonstrate their value proposition — representing 90 percent of all prescriptions but only 17.5 percent of prescription drug spending.[1]
- Generics and biosimilars are the only classes of medicine that consistently deliver lower costs.
- In fact, generic prices have been deflating and the overall value of all generic sales in the U.S. has declined by $6.4 billion since 2019 in spite of increased volume and new generic launches.[1, 2]

Generics Account for Less Than 2 Percent of Total U.S. Spending on Health Care

Generic medicines provide patient access to high-value care



- Polling consistently ranks prescription drug prices as one of the most important issues to the American public, and generic and biosimilar medicines offer a proven track record of savings.
- Despite making up more than 9 out of every 10 prescriptions, generics are less than two of every ten dollars spent on medicines in the U.S.
- This is why spending on generic medicines accounts for roughly 1.5 percent of total U.S. health care spending.[1, 3]

SAVINGS BY CATEGORY

The 10 Most Dispensed Generics of 2022 Saved $68 Billion

The top 10 generics by volume represent 18 percent of savings in the past 10 years

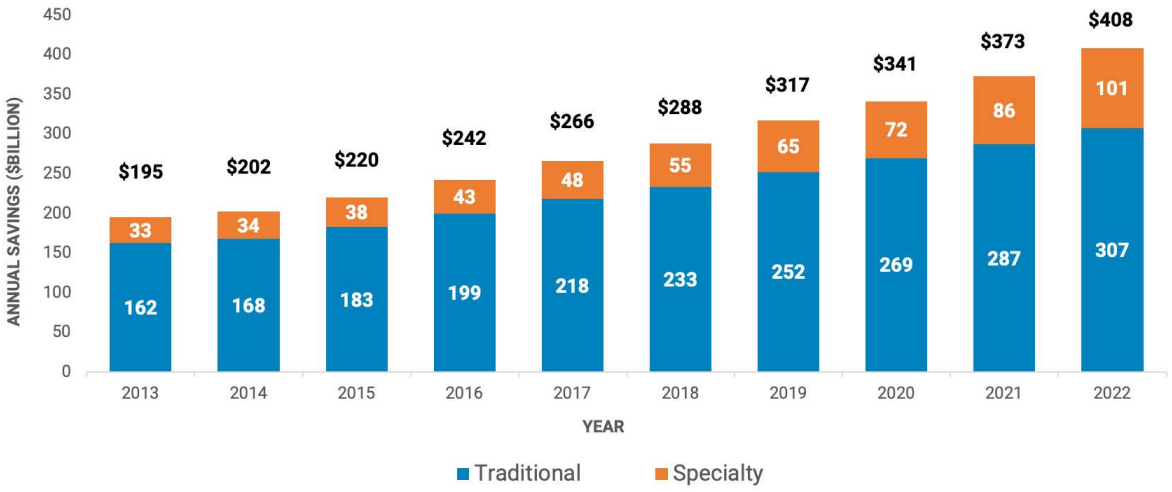
Top 10 Generic Products with Greatest Savings in 2022

PRODUCTS	GENERIC ENTRY YEAR	BRAND PRE-EXPIRY PRICE (PER UNIT)	PRICE OF GENERIC EQUIVALENT 2020 (PER UNIT)	2021 SAVINGS ($BILLION)	PERCENT SAVINGS
Glucophage	2021	$0.66	$0.04	$5.63	94%
Neurotin	2023	$1.02	$0.06	$7.60	95%
Lipitor	2010	$3.29	$0.08	$22.38	97%
Toprol XI	1993	$0.41	$0.06	$2.09	85%
Norvasc	2006	$1.54	$0.02	$7.92	99%
Zestril	1998	$0.67	$0.03	$3.18	96%
Cozaar	2009	$1.51	$0.08	$5.85	95%
Prilosec	2001	$3.31	$0.04	$12.87	99%
Amoxil	1993	$0.04	$0.03	$0.02	14%
Cephulac	1993	$0.02	$0.01	$0.03	41%

- Generic competition continues to generate billions of dollars in savings each year. Generics for medicines such as Crestor and Abilify are notable recent launches providing significant savings.
- 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 $68 billion in savings in 2022. These medicines provide care for patients who suffer from the most prevalent chronic health conditions.
- The 10 generics with the highest total savings achieved $119 billion in savings in 2022 (29 percent of total generic savings).
- Regardless of the particular medicine or indication, generics are often sold at a loss. This fact, combined with government policies that make continued production challenging, places generics at risk of shortage.

Savings from Specialty Generics and Biosimilars Reached $101 Billion in 2022

As specialty medicines take on a larger role, generic and biosimilar savings are vital



- Specialty medicines are therapies used to treat chronic, complex or rare diseases, and often possess additional distribution and administration characteristics that require special management.
- Over the past ten years, the share of prescription drug spending on specialty medicines has increased from 32 percent to 51 percent, even though specialty medicines are used only 3 percent of the time.[1]
- This means that generic and biosimilar competition is vital to controlling costs.
- In spite of challenges to market adoption, biosimilar competition cut spending growth for oncology drugs by half and is projected to reduce the spending growth rate for autoimmune therapies to zero.[4]
- Building on this will require alignment of reimbursement and coverage policies to expand patient access and reward health care providers, plans and pharmacy benefit managers for use of lower-cost specialty biosimilars and generics.

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

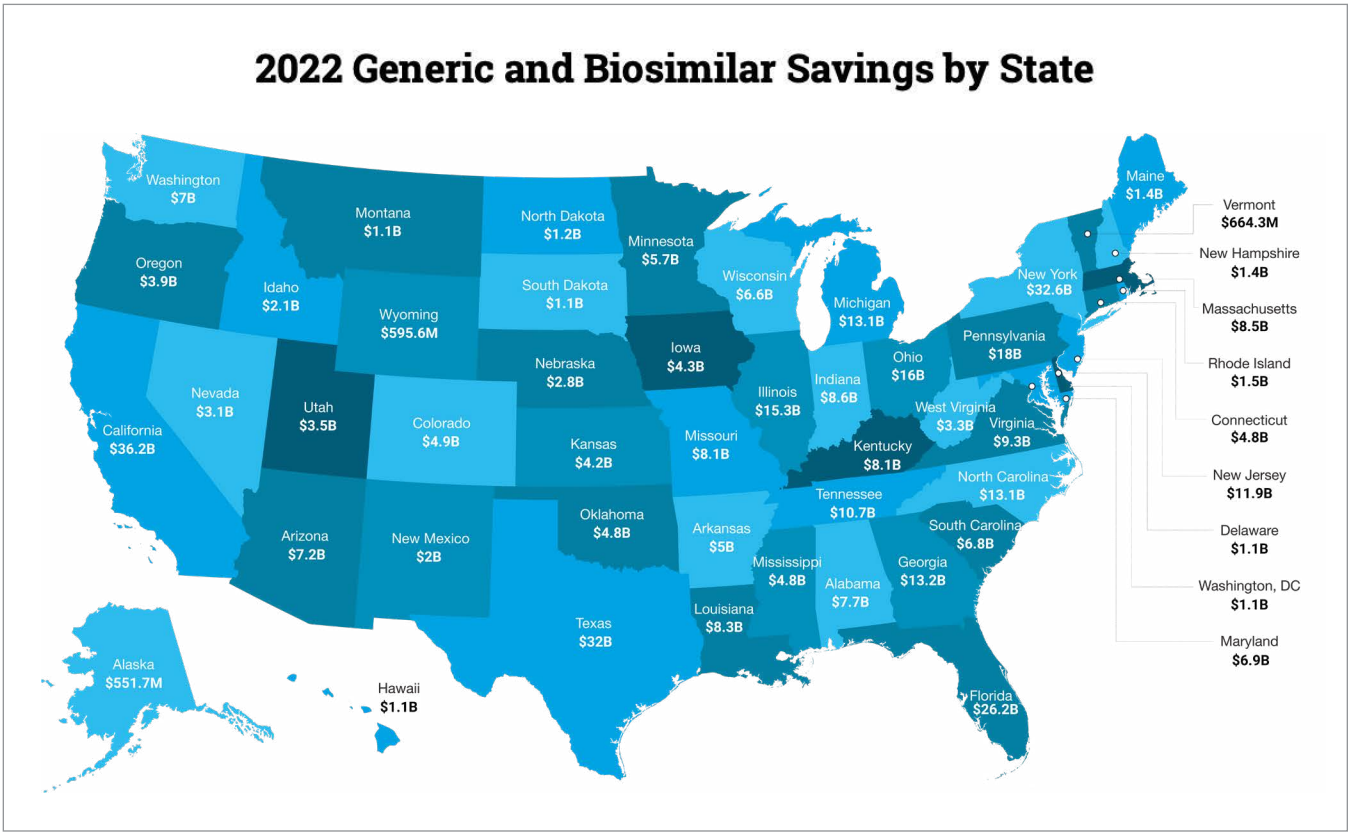
CONDITION	TOTAL SAVINGS (PRIMARY CONDITION + COMORBIDITIES)
Heart Disease	$104.5 Billion
Anxiety and Depression	$60.5 Billion
Diabetes	$59.5 Billion
Epilepsy	$42.2 Billion
Allergies and Asthma	$11.3 Billion
Breast Cancer	$8.9 Billion
Parkinson's Disease	$6.4 Billion
Alzheimer's Disease	$6.2 Billion
Chronic Obstructive Pulmonary Disease (COPD)	$6.1 Billion

- 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 2022 patients were protected from higher prescription medicine costs for:
  - Heart Disease: Generics saved patients $105 billion.
  - Mental Health: Generics saved patients struggling with anxiety and depression almost $61 billion.
  - Cancer: Generics and biosimilars saved patients $21 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.

  For example:
  - Arthritis: Forty-seven percent of patients also take medications for diabetes, and generic medicines saved $656 million.
  - Crohn's and Colitis: Twenty-eight percent of patients also take medications for hypertension, and generic medicines saved $125 million.
  - Autoimmune Disease: Thirty-three percent of patients also take medications for depression, and saved $125 million.
- Biosimilars promise additional savings for other complex conditions. 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

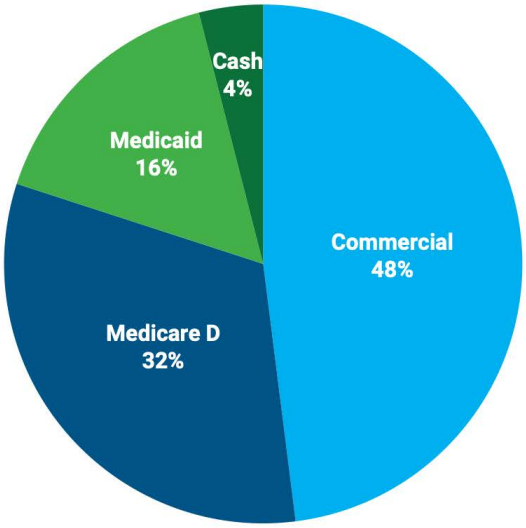


- Encouraging use of lower-cost generic and biosimilar medicines is a critical tool to manage spending within states with populations suffering from chronic and complex conditions.
- On average, states saved $8 billion from the use of generics in 2022.
- Although larger states had greater overall savings, generics and biosimilars benefit all states. In fact, some smaller states with smaller populations (e.g., Louisiana, West Virginia, Indiana, Georgia, and Kentucky) had higher per capita savings.

Generic and Biosimilar Savings Benefit the Commercial Insurance and Medicare Market

Use of generics in Medicare saved $130 billion in 2022

2022 Generic and Biosimilar Savings by Payer

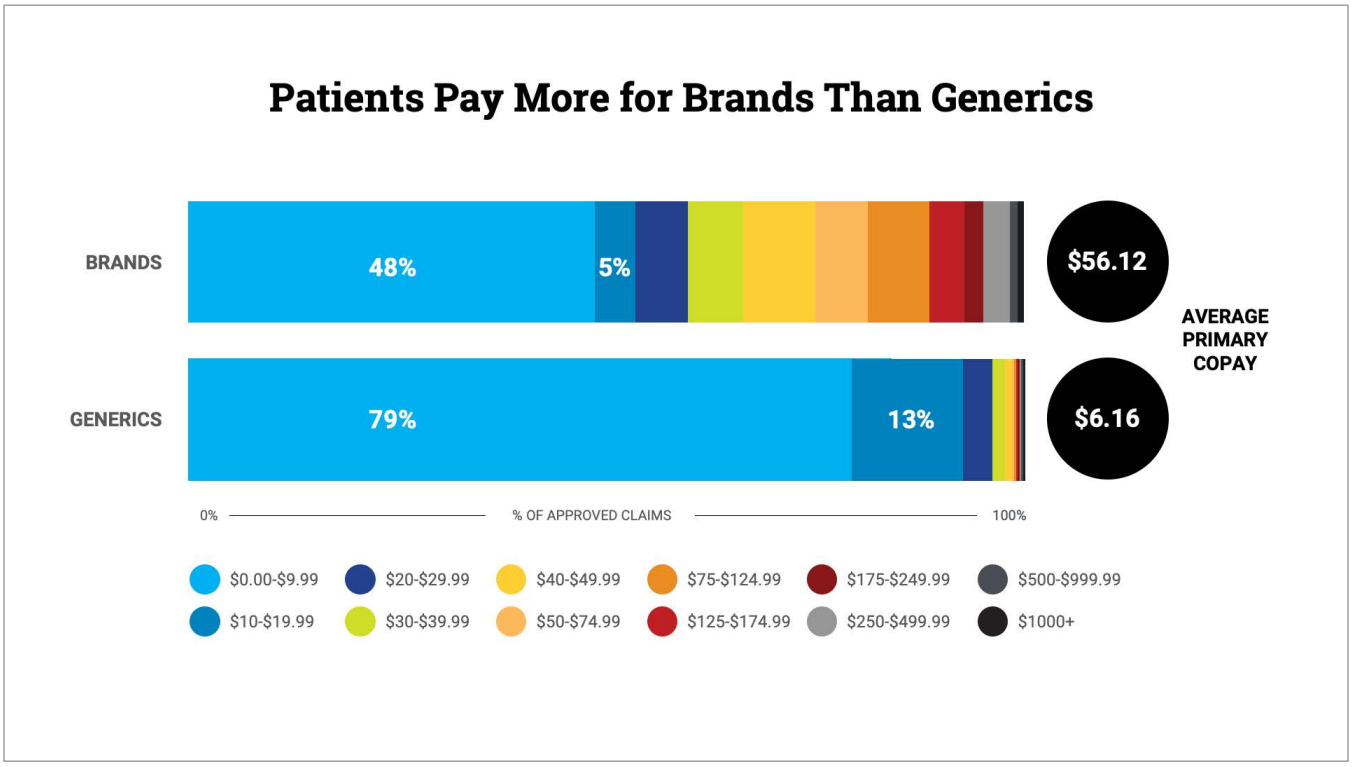


- Generics and biosimilars provide critical savings throughout the health care system and are particularly valuable to Medicare and employer-sponsored health insurance and the patients they serve.
- In 2022, the use of generics and biosimilars saved:
  - $130 billion in Medicare
  - $194 billion in commercial 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 (approximately 80 percent) of total savings:
  - Adults aged 40-64 accounted for $167 billion in savings.
  - Seniors over age 65 accounted for $147 billion in savings.
- But many patients are being denied access to new generics and biosimilars or 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.[5] This is why some Medicare and commercially-insured patients are using discount cards to pay cash for their medicines.[6]

PATIENT OUT-OF-POCKET COSTS

92 Percent of Generic Prescriptions Had a Copay of Less Than $20

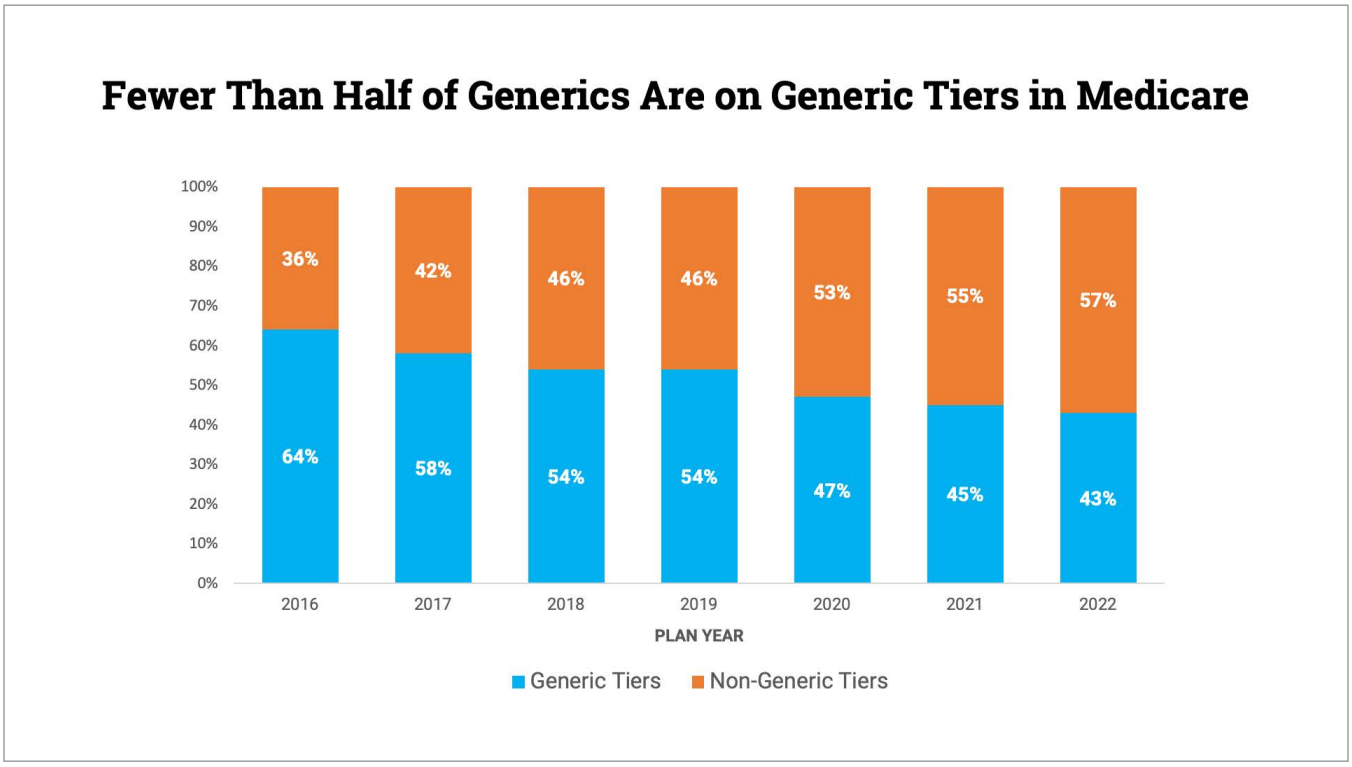
On average, patients pay nearly 10x more for brands



- Use of generic medicines is driven by their low costs allowing each segment of the supply chain to profit from their use.
- Even after markups driven by middlemen, patients still pay less in absolute terms (although more in percentage terms) for generic drugs.
- The average copay for a generic prescription was $6.16, compared with the average brand copay of $56.12.[6]
- Nonetheless, there are many instances when patients are forced to pay too much for a generic.
- Many health plans and PBMs are shifting generics onto formulary tiers with brand drugs and higher patient copays. The result is that patients are paying more for their generics—even as those generic prices have declined.
- This is why, in 2020, nearly two-thirds of patients in Medicare were forced to pay the full cost of at least one generic medicine.[5]
- As a result, many patients with commercial insurance or Medicare coverage turn to pharmacy discount cards and pay cash for their generic to avoid high copays.[6]

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

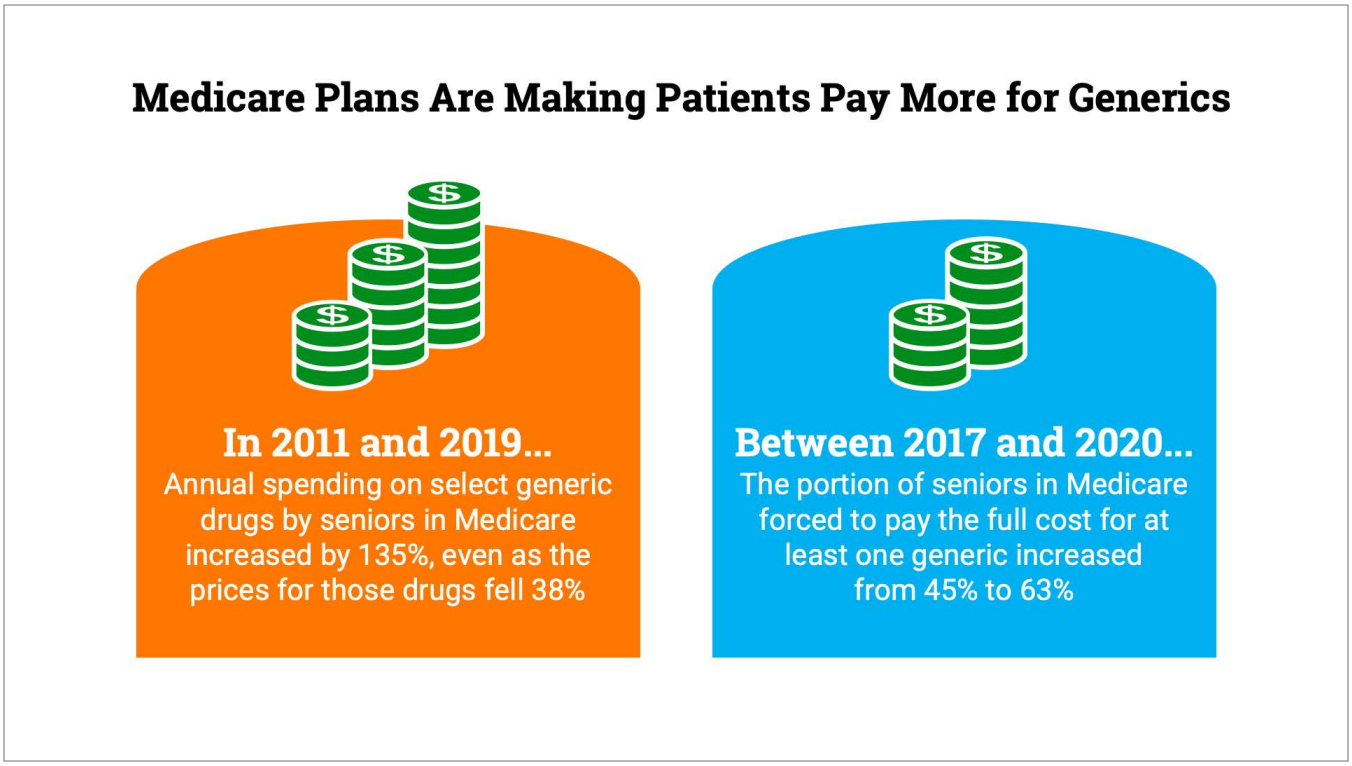
Plans shift generics onto higher tiers and increase patient costs



- Many patients face unnecessarily high costs as a result of formulary decisions that place generics on non-generic tiers.
- In recent years, even as the cost of generics continues to decrease, many Medicare Part D plans have chosen to place generics on higher tiers with higher copays.[7]
- The result is that patients are paying more for their generics — even as those generic prices have declined.
- 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.[6]

Patients Overpay for Generics Due to Improper Formulary Placement

Patients are paying more even as generic prices are going down

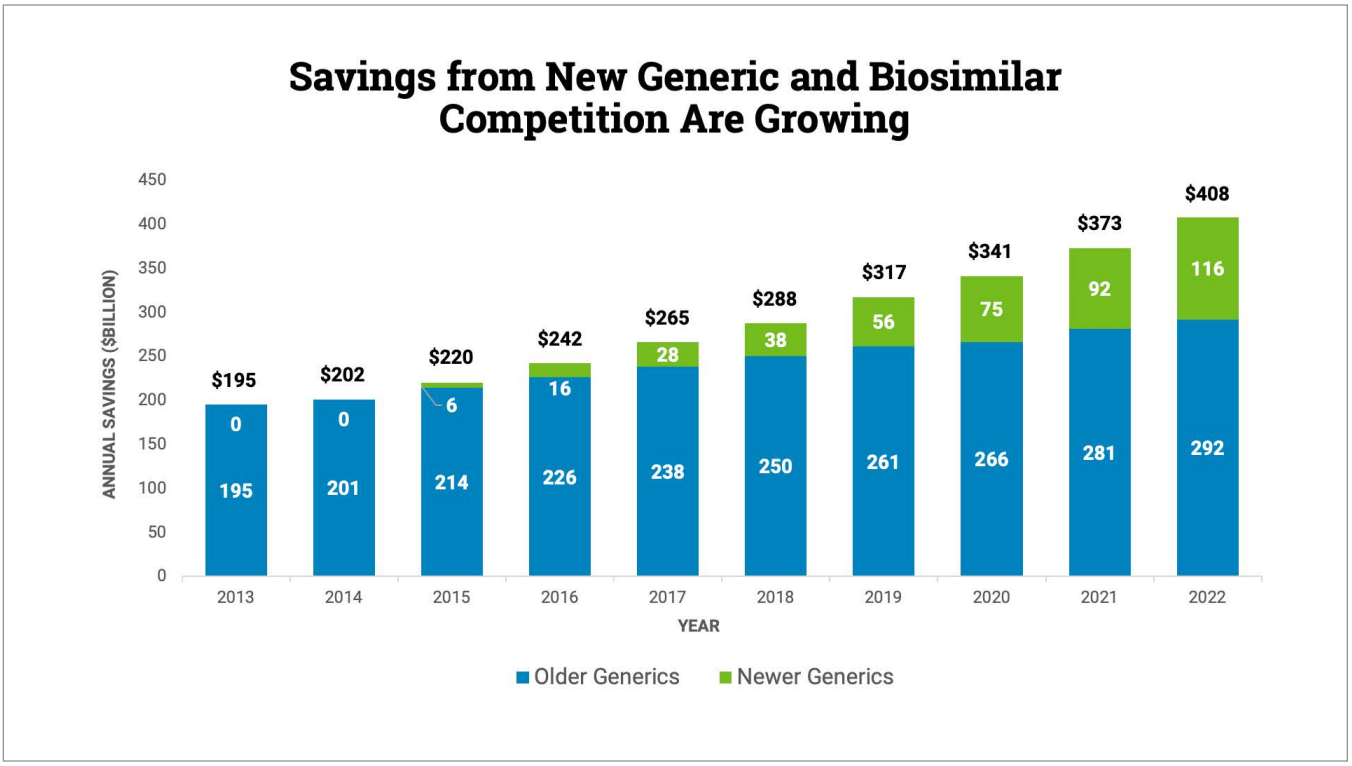


- Shifting generics in Medicare to non-generic tiers with higher copays has a significant impact on patients. An analysis of generic drugs covered in 2011 and 2019, found that shifting generics to brand tiers resulted in a 135 percent increase in annual patient spending, even as the average price of those medicines fell by 38 percent.[8]
- Medicare policy prohibits Part D plans from charging beneficiaries a cost-sharing amount that exceeds a product's negotiated price, but this nonetheless leaves patients to pay for more than the manufacturer's price for the drug.
- This is why 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, that figure had risen to almost two-thirds of Medicare patients.[8]

NEW GENERIC SAVINGS

New Generics Bring Lower Prices But Are Blocked From Many Patients

New generic and biosimilar competition saved $116 billion in 2022



- Brand name manufacturers enjoy years of regulatory exclusivity prior to a generic or biosimilar company's ability to enter the market. During this time, patients often see repeated brand drug price increases.
- New generics and biosimilars generate lower costs and greater access to care for patients.
- These include biosimilars, first generics and new generics with a 180-day exclusivity period due to successfully challenging brand patents prior to approval.
- Although these savings are important, they are less than what is possible. Increasingly, new generics and biosimilars face challenges to adoption due to delays in health plan coverage. For instance,
  - Biosimilars continue to face challenges to adoption in critical disease states.
  - The average efficiency rate (the rate at which a generic or biosimilar is used instead of the brand) for new products entering the market in 2021 was only 72 percent.

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

(Percent of First Generics Covered by Medicare Part D and Commercial Plans by Formulary Year)

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%

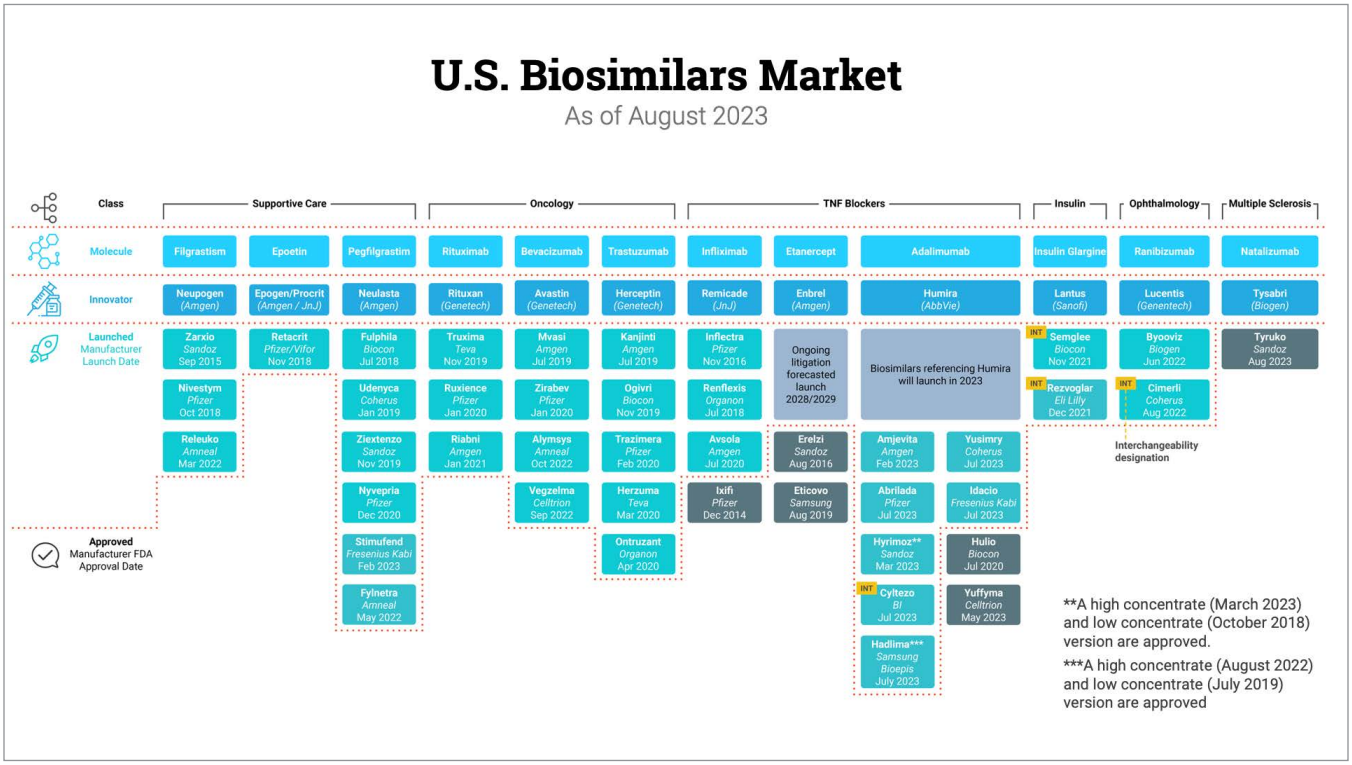
Medicare Part D (M) Commercial (C)

- Slower adoption and lower efficiency rates for new generics is driven in part by slower coverage decisions by Medicare, commercial health plans and pharmacy benefit administrators. PBMs often 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 commercial plans typically cover first generics the year after launch, this coverage appears to plateau over time.
- While the recently enacted Inflation Reduction Act included changes to Medicare that may encourage plans to cover new generics, it left in place incentives for use of high-priced brand drugs that provide rebates and fees.

BIOSIMILARS

The U.S. Biosimilars Market

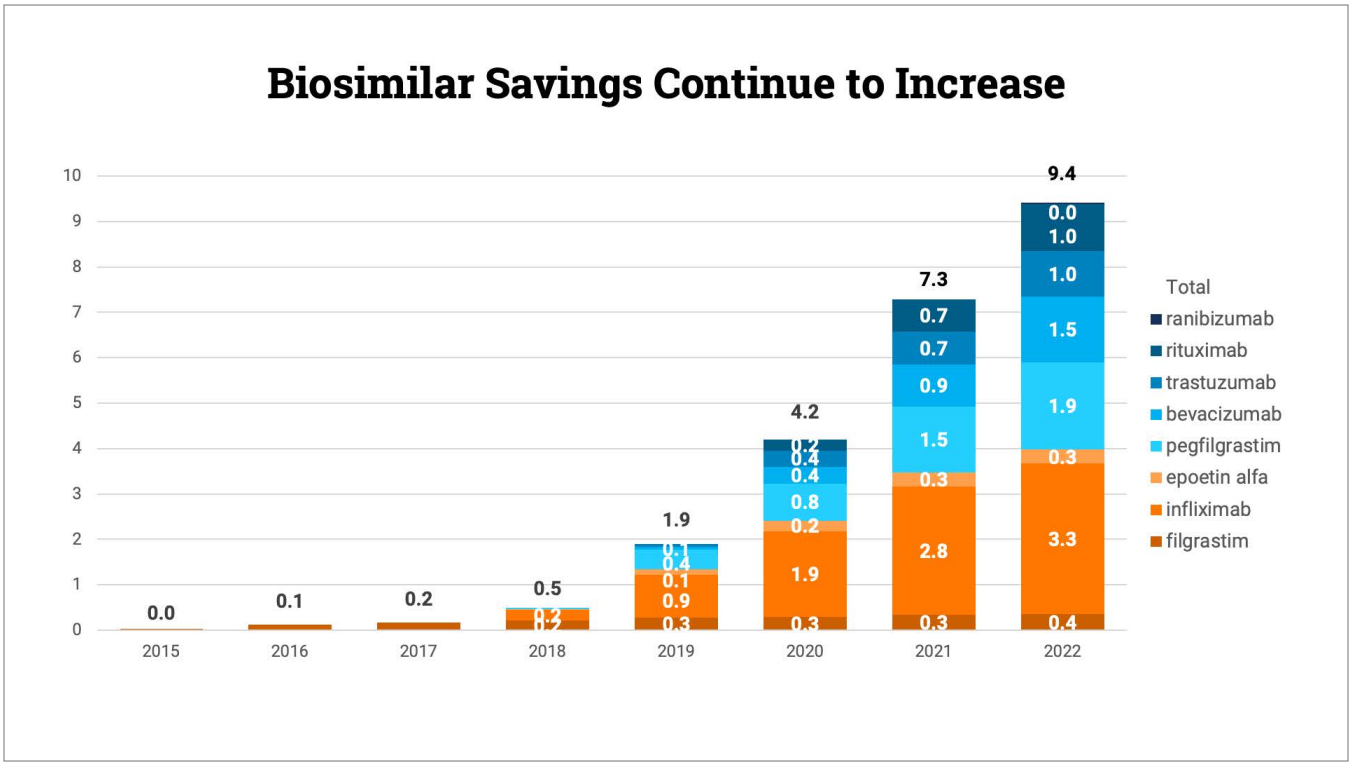
The biosimilars landscape is growing



- To date, the FDA has approved 42 biosimilars across 15 molecules.
- Thirty-six biosimilars are on the market with prices averaging more than 50 percent less than the reference brand biologic price at launch.[10]
- Although there are currently 106 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.[4]
- 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 health care providers (medical benefit or buy-and-bill).
- New biosimilar launches in insulin and adalimumab represent the first entry of pharmacy-dispensed biosimilars.

Biosimilars Have Generated $23.6 Billion in Savings Since 2015

Savings reflect provider confidence and robust price competition

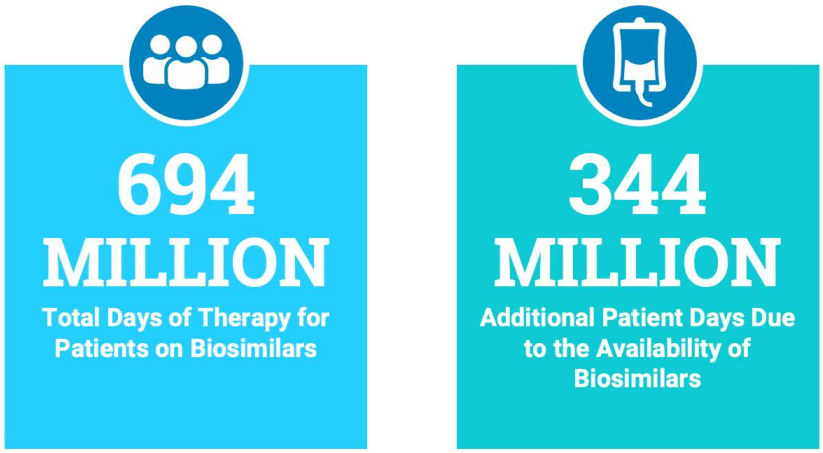


- Since the first biosimilar launch in 2015, patients and the health care system have saved nearly $24 billion.
- Nearly 40 percent of total savings from biosimilar entrants has occurred in the past year with over $9.4 billion in savings in 2022 alone.
- Biosimilar savings increased by $2 billion year over year, with oncology biosimilars – namely bevacizumab, rituximab, and trastuzumab – leading the charge.
- However, biosimilar adoption continues to trail expectations as a result of misaligned incentives within the market that slow adoption.
- Although two biosimilars have adoption rates exceeding 80 percent, others are far less, as low as 13 percent.[4]

Biosimilars are Delivering Safe Therapy

Biosimilar introduction often results in greater patient access overall

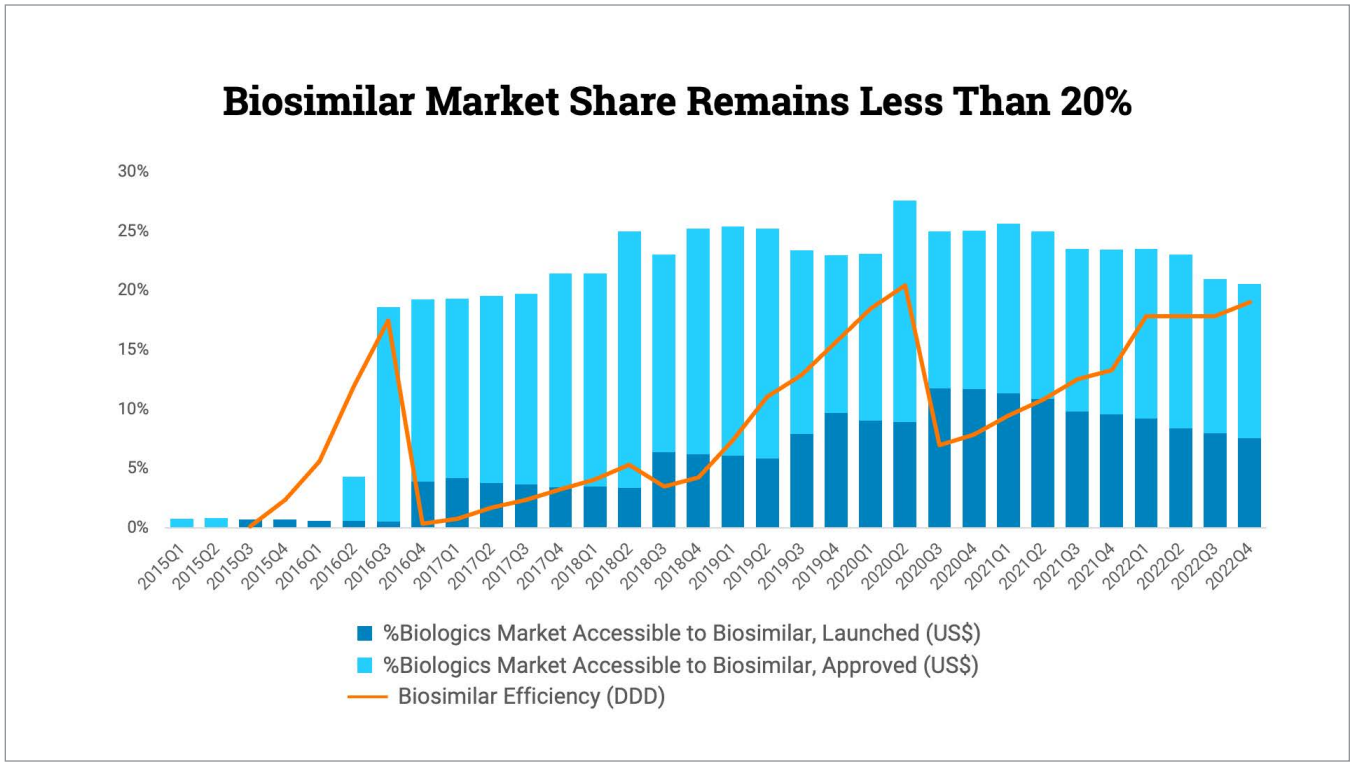
Biosimilars Are Now a Core Element of Patient Care



- The increasing use of biosimilars has quickly put to rest any questions about their safety and efficacy.
- Since 2015, biosimilars have been used in almost 700 million days of patient therapy with no unique clinical challenges.
- 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 20 percent more doses of filgrastim, 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 344 million incremental days of therapy—care that patients would not have received otherwise.

Although Improving, Biosimilar Adoption Remains Too Slow

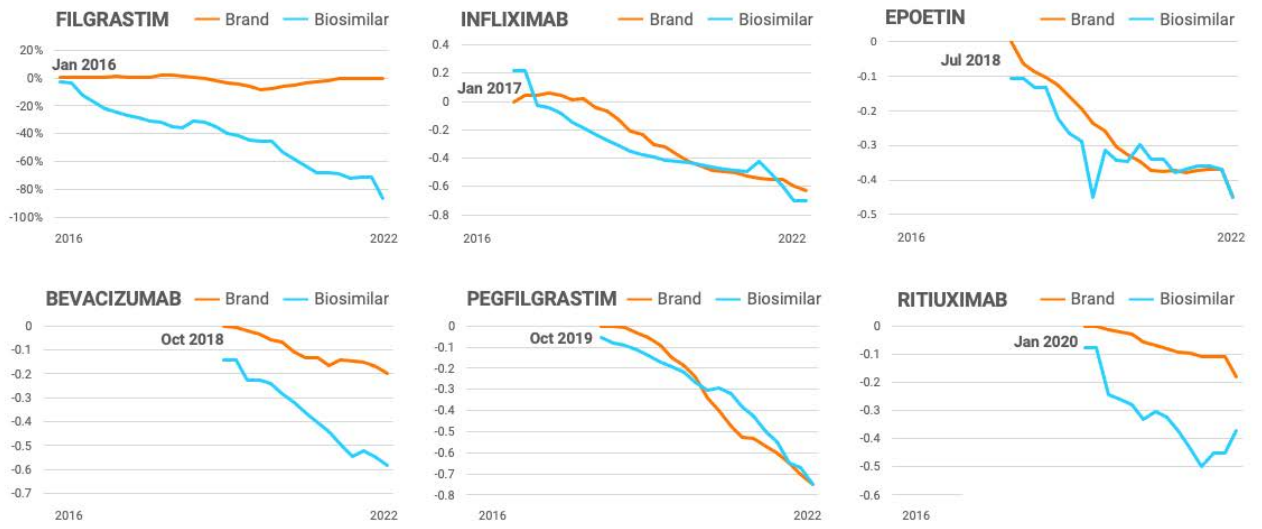
Biosimilar adoption is hindered by incentives for using costly brands



- 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 areas, the average market share for biosimilars broadly is barely 20 percent.
- And 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

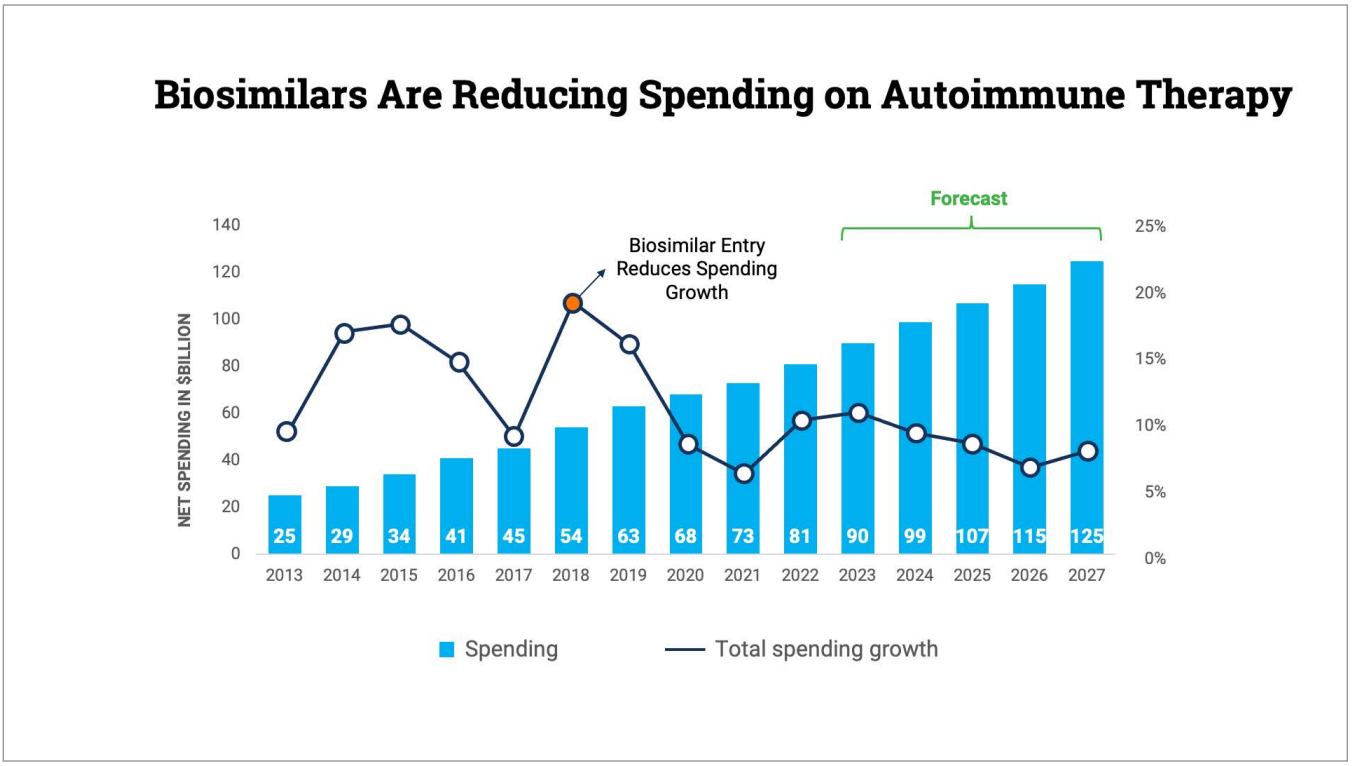


- Prior to biosimilar entry, brand biologics take significant price increases. After biosimilar entry, brand prices go down.[12, 13]
- Brand biologics respond to biosimilar entry by lowering their prices to date, by 25 percent on average. This results in savings from both the originator biologic and biosimilars.[12]
- Today biosimilars, on average, are priced more than 50 percent lower than the brand biologics price at the time of biosimilar launch.[12]

	Percent Change in Originator Biologic's ASP in 10 Years Before Biosimilar Entry	Percent Change in Originator Biologic's ASP in 10 Years Before Biosimilar Entry (Through 2023 Q1)
Filgrastim	+71	−2
Infliximab	+54	−58
Pegfilgrastim	+117	−66
Epoetin Alfa	+35	−33
Bevacizumab	+42	−13
Trastuzumab	+69	−23
Rituximab	+68	−14

Biosimilars Have Slashed Spending Growth for Cancer

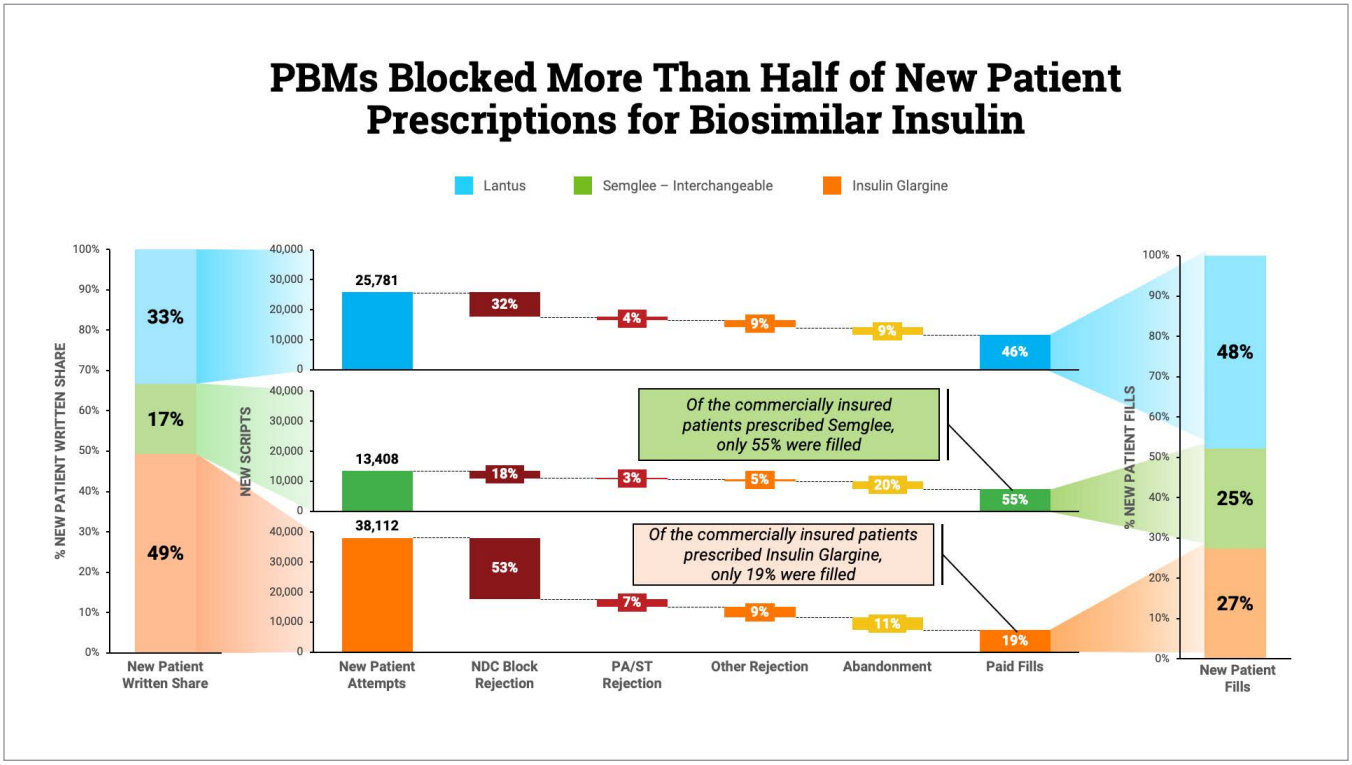
Biosimilar and generic competition has reduced oncology spending growth by 50 percent



- Treatments for cancer are a leading driver of health care costs with oncology spending set to reach $125 billion by 2027.[4]
- There were nearly 2 million new diagnoses for cancer cases reported in 2022.[14] As diagnoses rise, cancer treatments may be started earlier due to advances in early identification. Further, treatment may be extended due to increased patient survival, further increasing the cost burden.
- Oncology biosimilars are a prime example of biosimilar competition's ability to reduce spending. Altogether, the use of new biosimilars and generics has saved patients with cancer more than $22 billion.
- Biosimilars have cut the growth rate in oncology spending by nearly half and are expected to continue to stifle costs going forward.

Patient Demand for Biosimilar Insulin Is Blocked by PBMs

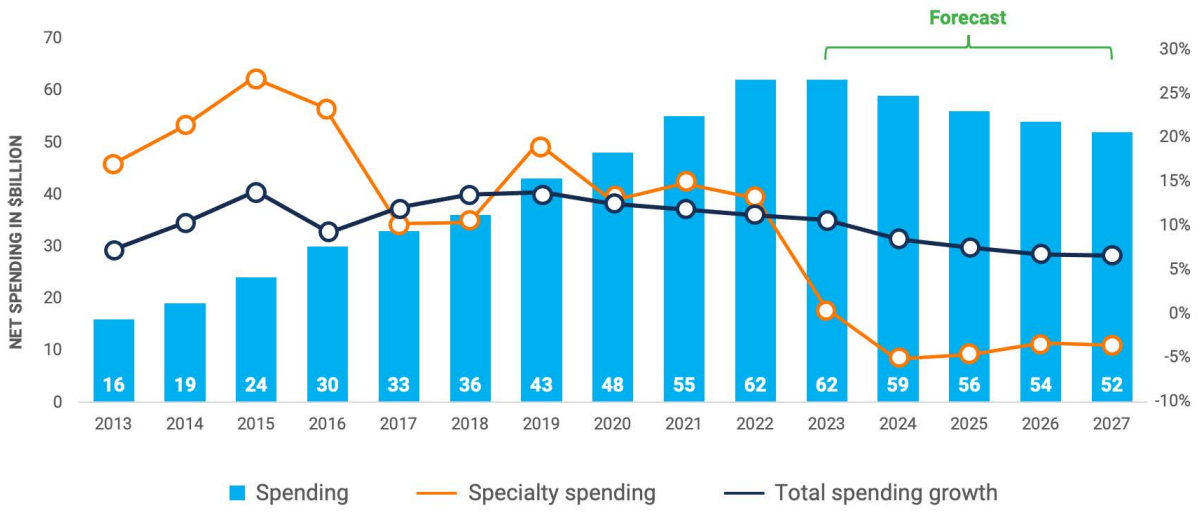
More than half of low-priced biosimilar insulin prescriptions were rejected



- The launch of Semglee, a biosimilar insulin glargine, points to the role of PBMs and health plans in biosimilar adoption.
- Biosimilar Semglee is available at either a slight decrease in price with a high rebate or a lower flat price that is approximately 65 percent lower than the brand list price.
- The biosimilar has seen high demand—accounting for 60 percent of all new written prescriptions. But because of formulary rejections, new patients receive the biosimilar insulin only 37 percent of the time.[15]
- Among the four health plans that account for almost two-thirds of all newly written insulin glargine prescriptions, three still cover the brand in full, while the biosimilars are either blocked or only partially covered.
- This reflects ongoing preferences of PBMs for higher priced products with high rebates. Unfortunately, those rebates are not often shared with the patient using the medicine who frequently faces high cost-sharing based on the list price of the drug.

Biosimilars are Reducing Spending Growth in Treatments for Autoimmune Disorders

But patients are not receiving the value of biosimilar competition



- Treatment for autoimmune disorders like Rheumatoid Arthritis, Lupus and Multiple Sclerosis is expected grow by 45 percent by 2027.[4]
- Prior to entry of biosimilars, spending on immunology treatment was growing by more than 25 percent a year.
- The highly anticipated launch of biosimilar adalimumab (Humira ®) and ustekinumab (Stelara ®) represent the introduction of biosimilars to the pharmacy-benefit market, which has distinctly different dynamics from the medical-benefit market.
- Biosimilars are projected to reduce the growth rate for spending in immunology to negative 3 percent and total autoimmune spending by 41 percent.[4]
- These launches are facilitated by procompetitive patent settlements that allow the biosimilars to launch sooner.
- But patients are not yet benefiting from these products as PBMs and health plans take advantage of high rebates instead of preferring the lower cost biosimilars.

Conclusion

Generic medicines continue to provide value to patients, taxpayers, employers, and the health care 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. Generics and biosimilar medicines expand patient access, making life-saving medicines more affordable for patients, enabling patients to better adhere to their therapies, and ultimately saving lives.

But generics and biosimilars should not be taken for granted, nor should the access and savings they create. Unfortunately, significant challenges threaten the long-term outlook. Without action to strengthen the generic and biosimilars markets, many of these lower-cost medicines may disappear. And patients' access to care will suffer.

A foundation of good health allows people to do more, be more and reach their potential. The generics and biosimilars industry stands ready to contribute to optimizing the health of America patients' daily lives.

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 1,283 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 name medicines in the absence of generic competition.

The savings attributed to each of the 1,283 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 1992 and 2022, focusing on the 10-year savings for the period 2013 to 2022. Savings from generics launched in the 1993 to 2022 study period are based on the most current knowledge of their pre-expiry prices. Savings from generics launched prior to 1993 were calculated using brand prices from 1992 which is the oldest archived data period retained by IQVIA.

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 co-pay 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 2003-present. The current edition of the study includes archives extending a further 11 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 1992-2003, 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 2023, 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. 49 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 1 percent.

Generic and brand drug share of prescription drug spending was calculated using an analysis of the 2022 Medical Expenditures Panel Survey and IQVIA National Sales Perspective data. Total drug spending was segmented into generics and brands. Those percentages were then applied to the Medical Expenditures Panel Survey analysis of spending by type of expenditure within the Panel Survey.

This report estimates condition level savings from generic as a single year estimate for 2022. The base savings were calculated by IQVIA. Avalere generated condition-level savings by assigning drugs to a list of common conditions, based off a list of conditions provided by AAM. 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 3 most common comorbidities for each of the index conditions provided by AAM 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 3 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 IQVIA. (April 2023) "The Use of Medicines in the U.S. 2023: USAGE AND SPENDING TRENDS AND OUTLOOK TO 2027." Accessible at: https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/the-use-of-medicines-in-the-us-2023/the-use-of-medicines-in-the-us-2023.pdf.

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

3 Keehan, SP, Fiore JA (June 2023) "National Health Expenditure Projections, 2022–31: Growth To Stabilize Once The COVID-19 Public Health Emergency Ends." Health Affairs Accessible at: https://www.healthaffairs.org/doi/10.1377/hlthaff.2023.00403#:~:text=National%20health%20expenditures%20are%20projected,the%20end%20of%20that%20period; IQVIA (December 2022) National Sales Perspective.

4 IQVIA Institute for Human Data Science (January 2023) "Biosimilars in the United States 2023–2027." Accessible at: https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/biosimilars-in-the-united-states-2023-2027/iqvia-institute-biosimilars-in-the-united-states-2023-usl-orb3393.pdf.

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

6 Association for Accessible Medicines.2022 Generics and Biosimilar Medicines Savings Report (October 2022) Accessible at: https://accessiblemeds.org/sites/default/files/2022-09/AAM-2022-Generic-Biosimilar-Medicines-Savings-Report.pdf.

7 Avalere Health (January 2022) "57 percent of Generic Drugs Are Not on 2022 Part D Generic Tiers." Accessible at: https://avalere.com/insights/57-of-generic-drugs-are-not-on-2022-part-d-generic-tiers.

8 Association for Accessible Medicines (October 2022) "Patients Pay More When Generic Drugs Are Placed On Non-Generic Tiers, Even Though Prices for Generics Are Going Down." Accessible at: https://accessiblemeds.org/resources/blog/patients-pay-more-when-generic-drugs-are-placed-non-generic-tiers-even-though-0.

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

10 Food and Drug Administration. Biosimilar Product Information (August 2023) Accessible at: https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/biosimilars.

11 Food and Drug Administration. Biosimilar Product Information (August 2023) Accessible at: https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/biosimilars.

12 Centers for Medicare and Medicaid Services. ASP Pricing Files. (July 2023) Accessible at: https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/asp-pricing-files (comparison of current biosimilar prices and reference prices at launch of first biosimilar).

13 MEDPAC (June 2023) "Addressing high prices of drugs covered under Medicare Part B." Accessible at: https://www.medpac.gov/wp-content/uploads/2023/06/Jun23_Ch1_MedPAC_Report_To_Congress_SEC.pdf.

14 American Cancer Society (2022) Cancer Facts & Figures. Accessible at: https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2022/2022-cancer-facts-and-figures.pdf.

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

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