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Introduction

Savings From Generics and Biosimilars Continue To Grow, but Face Future Headwinds

More than \$2.6 trillion in savings from medications used to treat nearly every health condition

In 2021, patients in the United States received 6.4 billion prescriptions, 91% of which were generic and biosimilar medicines. The use of these lower-cost medications saved \$373 billion for patients, consumers, employers and taxpayers. Generics and biosimilars continue to provide much-needed financial relief to millions of families.

But these savings, and the competitive market that creates them, are often taken for granted and are increasingly at risk. Today, as a result of pervasive profit-seeking by middlemen, such as pharmacy benefit managers, patients often pay more than they should for generics or are even prevented entirely from receiving lower-cost generics and biosimilars. This is in addition to ongoing brand patent abuses that can delay patient access to new generics and biosimilars.

Our industry's mission is centered around advancing a patient's health through lifesaving and life-changing medicines. We accomplish this by bringing competition to the marketplace. The interaction between branded and generic medicines creates a perpetual cycle where today's new drug is tomorrow's generic, and those generic entrants provide the headroom for investment in further innovation. Overall, when the healthcare system leverages the value of high quality, low cost generics and biosimilars, the entire nation saves considerable sums of money which can be directed to other vital treatments and services.

Policymakers must address these challenges and ensure patient access to more affordable generic and biosimilar medications. This report illustrates the important work that AAM members perform, and I thank all those who have gone the extra mile over the last few years to ensure these savings continue to benefit America's patients.

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Letter From the Biosimilars Council Executive Director

Biosimilars Are Delivering on Their Promise of Patient Access and Savings

More than \$13 billion in savings since 2015

When Congress established a new pathway for the approval of biosimilars in 2011, the goal was clear: greater patient access and lower costs. The approval of the first biosimilar in 2015 generated tremendous excitement. Today, that promise is increasingly becoming a reality. Thanks to new biosimilar competition, more patients are receiving the pharmaceutical care that they need. Biosimilar prices, and the prices of the brand biologics with which they compete, are going down. And savings from biosimilars are continuing to grow, even as the evidence base for the safety and effectiveness of high quality biosimilars expands.

Most importantly, this report shows that patients benefit from biosimilars. In fact, the use of biosimilars has supported 150 million more days of additional patient therapy than would have been possible otherwise. And in the seven years since biosimilars first began to enter the market, they have generated more than \$13 billion in savings.

But new challenges on the horizon demand attention, including the 2023 launch of new pharmacy benefit biosimilars, ongoing gaps in biosimilar adoption, and a continuing need for education to combat misinformation about biosimilars. And, of course, perverse incentives such as pharmacy benefit managers' rebate preferences continue to present obstacles to patient access to lower-cost medicines. The Biosimilars Council remains committed to improving patient access to high-quality, lower-cost therapies and working with stakeholders to make that goal a reality.

Craig Burton
Craig Burton

Executive Director, Biosimilars Council



The Generics and Biosimilars Industry That Works for You



- The Association for Accessible Medicines (AAM) and its member companies and affiliates
 work to make generic and biosimilar medicines accessible to more patients who need them.
 Increased access to medicine requires a comprehensive approach because, after all, we're all
 patients at some point.
- Generic pharmaceutical companies manufacture the medicines used in 9 out of 10
 prescriptions dispensed in the Unites States. Our members are an integral part of the health
 care system, not just in the U.S., but worldwide.
- The Biosimilars Council, a division of AAM, works to create a positive regulatory, reimbursement, and policy environment to encourage biosimilar adoption, as biosimilars provide billions in savings to patients and the health care system.
- This annual report includes a snapshot of the value that generic and biosimilar medicines continue to bring to patients and captures key insights into the dynamics that impact their overall utilization in 2021 and beyond.

Overall Savings Generated by Generics and Biosimilars

Topline Findings

Generic Savings

- The average generic copay: \$6.16¹
- The average brand-name copay: \$56.121
- 93% of generics have a copay less than \$20. Only 59% of brands have a copay less than \$20

Biosimilar Savings

- Savings increased to \$7 billion in 2021
- Biosimilars have been used in over 364
 million days of patient therapy, and have
 been used in over 150 million additional
 days of therapy that otherwise would have
 not been provided
- Generated more than \$13 billion in savings since 2015

Health Care System Savings

- Total generic and biosimilar savings in 2021: \$373 billion
- Total generic and biosimilar savings for past 10 years: more than \$2.6 trillion
- Total generic and biosimilar savings to Medicare in 2021 average: \$119 billion (\$2,447 per enrollee)
- Total generic and biosimilar savings in commercial plans for 2021: \$178 billion
- Generics and biosimilars represent 91% of prescriptions filled, but only 18.2% of prescription drug spending
- Generics represent only 3% of all health care spending²

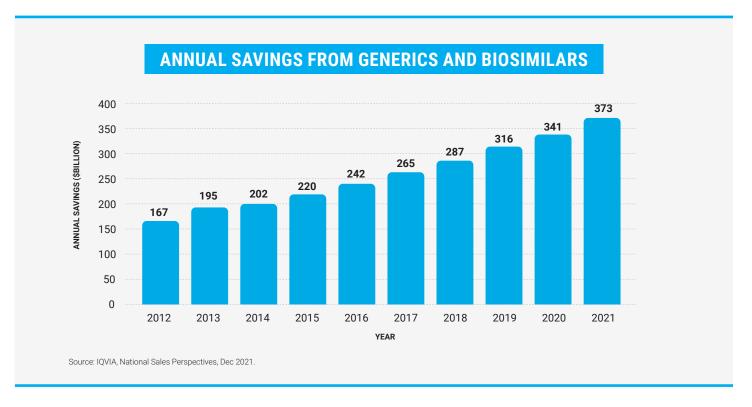
Note: Unless otherwise referenced, the data in this report reflects the methodology described at the conclusion of this publication.

¹ IQVIA LAAD dataset. (May 2021) U.S. Market Access Strategy Consulting Analysis.

² Peterson-KFF Health System Tracker. "What drives health spending in the U.S. compared to other countries." September 25, 2020. Note: Generic and brand drug share of prescription drug spending was calculated using an analysis of the 2018 Medical Expenditures Panel Survey. Total drug spending was segmented into generics and brans. Those percentages were then applied to the Peterson -KFF Health System Tracker analysis of spending by type of expenditure in the U.S. health care system.

Savings From Generics and Biosimilars Totaled \$373 Billion in 2021

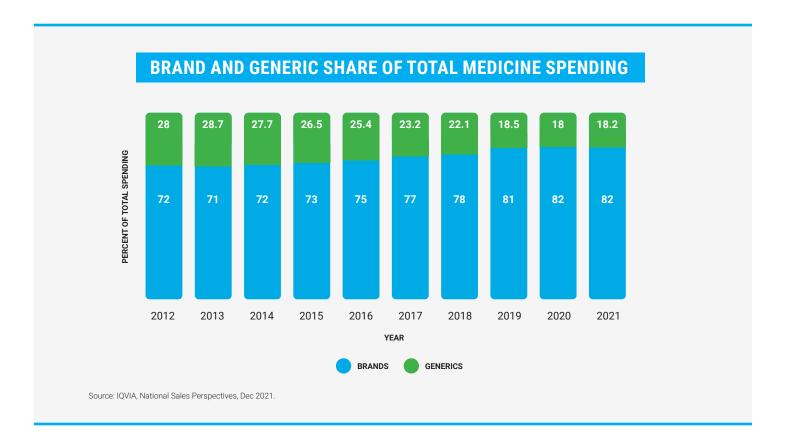
GENERIC AND BIOSIMILAR SAVINGS INCREASED BY \$32 BILLION FROM 2020 TO 2021



- 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.
- Likewise, biosimilars are lower-cost versions of expensive biologic medicines and 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 cost and high value to patients, generics and biosimilars represent 91% of the prescriptions dispensed in the United States
- Annual savings from generics and biosimilars have exceeded \$373 billion — an increase of about \$33 billion more than 2020 — and yearly savings have consistently increased by 7-10%.
- Biosimilars are contributing a growing share of savings, with \$7 billion in 2021.

Generics and Biosimilars Account for 18.2% Of Total Medicine Spending

GENERICS AND BIOSIMILARS ARE 91% OF ALL PRESCRIPTIONS



- Generics and biosimilars continued to demonstrate their value proposition representing 91% of all prescriptions, but only 18.2% of spending.
- This continues a years-long trend of generic price deflation contrasted with brand price inflation. In fact, the share of spending attributable to brand drugs has risen even as the total number of prescriptions filled by brand drugs has declined.
- While spending on brand drugs continued to increase in 2021, spending on generic drugs declined. This continued a multi-year period during which spending on generic drugs declined by more than 5%.
- Spending on biosimilars increased as a result of higher provider and patient adoption, generating \$7 billion in savings.
- The U.S. health care system has saved more than \$2.6 trillion in the last 10 years due to the availability of affordable generics and biosimilars.

Biosimilars Deliver on Their Promise of Access and Savings

39
APPROVED

MARKETED

\$13.3 BILLION

BIOSIMILARS HAVE BEEN USED IN MORE THAN
364 MILLION DAYS OF PATIENT THERAPY AND
HAVE RESULTED IN MORE THAN 150 MILLION
INCREMENTAL DAYS OF THERAPY

BIOSIMILAR COMPETITION IS DRIVING LOWER PRICES AMONG BIOSIMILARS AND THEIR REFERENCE PRODUCTS

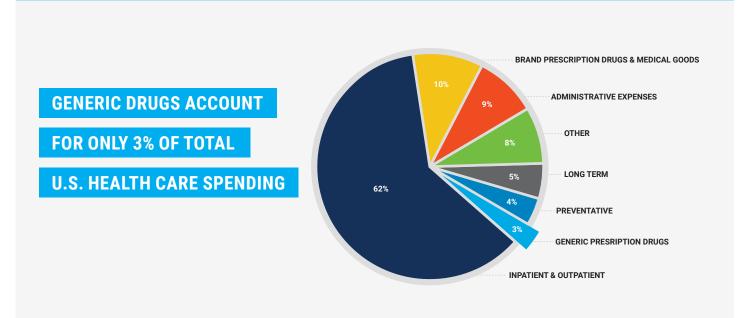
Approval / Marketing data as of September 2022.
Source: U.S. FDA and AAM Commercial Assessment. Savings and patient day data developed by Biosimilars Council with IQVIA.

- The biosimilar market is rapidly growing.
 Twenty-two biosimilars are now available to patients, with at least seven more scheduled to launch in 2023.
- Since biosimilar entry, medicines with biosimilar competition have experienced greater patient adoption equaling more than 150 million days of patient therapy. Put another way, more patients are receiving care because of competition from lower-cost biosimilars.
- This is occurring as a result of robust biosimilar price competition. The result is not only lower biosimilar prices, but also lower prices on brand biologics.

- In fact, biosimilar average sales prices today are more than 50% 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.
- These lower prices are critical to overall affordability, as brand biologics and specialty medicines today account for 55% of all spending, despite being only 3% of all prescriptions.
- Biosimilars will continue to deliver on their promise, and policymakers can maximize savings by enacting policies to support timely biosimilar availability and adoption.

Generics and Biosimilars Reduce Health Care Spending

GENERICS REPRESENT THE SMALLEST PORTION OF OVERALL SPENDING ON HEALTH



Source: IQVIA LAAD dataset. (May 2021) U.S. Market Access Strategy Consulting Analysis.

IQVIA Institute for Human Data Science. (May 2021) "The Use of Medicines in the U.S. - Spending and Usage Trends and Outlook to 2025."

Peterson-KFF Health System Tracker. "What drives health spending in the U.S. compared to other countries." September 25, 2020. Note: Generic and brand drug share of prescription drug spending was calculated using an analysis of the 2018 Medical Expenditures Panel Survey. Total drug spending was segmented into generics and brans. Those percentages were then applied to the Peterson-KFF Health System Tracker analysis of spending by type of expenditure in the U.S. health care system.

- Although highly scrutinized, the reality is that pharmaceutical costs are only a small portion of total health care costs in America.
- And generic drugs are a fraction of that. In fact, spending on generic medicines represents only 3% of total U.S. health care spending.
- From 2021 to 2022, hospital spending growth is projected to accelerate substantially from 5.7% to 6.9% while prescription drug spending is expected to decrease from 4.7% to 4.3%

 primarily as a result of the use of lower-cost generic and biosimilar medicines.³

³ Poisal, John A et al. "National Health Expenditure Projections, 2021–30: Growth To Moderate As COVID-19 Impacts Wane." Health affairs. 41.4 (2022): 474–486. Web.

The Top 10 Generics of 2021 Saved \$110 Billion

THE TOP 10 PRODUCTS OF 2021 REPRESENT 26% OF THE OVERALL SAVINGS IN THE PAST 10 YEARS

TOP 10 PRODUCTS WITH GREATEST SAVINGS IN 2021

Products	Generic Entry Year	Brand Pre-Expiry Price (Per Unit)	Price of Generic Equivalent 2020 (Per Unit)	2021 Savings (\$Bn)	Percent Savings
Lipitor	2010	\$3.29	\$0.07	\$21.4	98%
Zofran	2005	\$8.47	\$0.19	\$16.1	222%
Crestor	2015	\$5.78	\$0.08	\$12.6	99%
Prilosec	2001	\$3.31	\$0.06	\$12.4	98%
Abilify	2014	\$21.68	\$0.29	\$10.3	99%
Norvasc	2006	\$1.54	\$0.02	\$9.1	99%
Neurontin	2003	\$1.02	\$0.07	\$7.4	94%
Protonix	2006	\$2.83	\$0.07	\$7.3	97%
Cymbalta	2012	\$4.61	\$0.16	\$6.8	97%
Lyrica	2019	\$6.93	\$0.12	\$6.7	99%

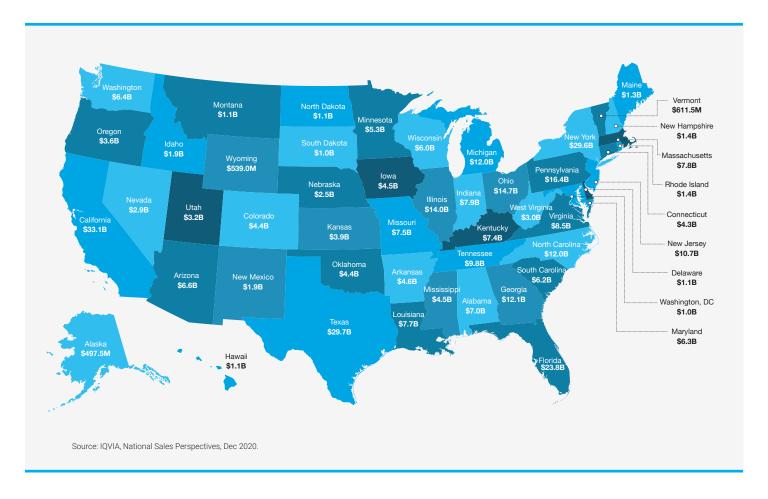
Source: IQVIA, National Sales Perspectives, Dec 2021.

- Generic competition continues to generate billions of dollars in savings each year for highpriced brand drugs. Generics for medicines such as Crestor (a blockbuster cholesterol reducing medication) and Abilify (a first of it's kind antidepressant), are notable recent launches providing significant savings.
- Generics consistently deliver savings both for those highly utilized and for smaller volume products.
- For instance, the top ten generics in total savings represented \$110 billion in savings, and the ten generics with the highest sales volume in 2021 represented \$66 billion in savings.

- But generics also accumulate savings daily through thousands of small-volume and low-margin products. These medicines are essential for maintaining equitable access to pharmaceutical care across a variety of health conditions.
- Importantly, new generics also contribute important savings for patients, although these products have experienced slower adoption and lower savings in recent years due to health plan formulary tactics that can delay patient access to new generics.

Savings by Category

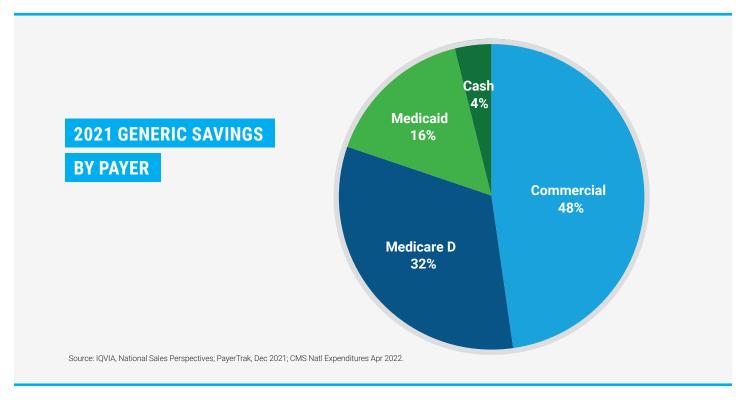
2021 Savings by State



- Encouraging use of lower-cost generic and biosimilar medicines is a critical tool to manage spending within states with populations compromised in various manners.
- On average, states saved \$7.3 billion from the use of generics in 2021.
- Although larger states had greater overall savings, generics and biosimilars benefit all states. In fact, some smaller states (Mississippi, Louisiana, West Virginia, Kentucky, Nebraska, Arkansas, Alabama) had higher per capita savings.

2021 Generic Savings by Payer

A MAJORITY OF PRESCRIPTIONS AND SAVINGS ARE ATTRIBUTED TO COMMERCIALLY INSURED PATIENTS



- 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 2021, the use of generics and biosimilars saved:
 - » \$119 billion, about \$10 billion more than in 2020, in Medicare.
 - » \$178 billion in commercial health insurance.
- Medicines taken by older adults account for the majority (approximately 80%) of total savings.

- » Adults aged 40-64 accounted for \$160 billion in savings.
- » Seniors over age 65 accounted for \$132 billion in savings.
- Despite these savings, many seniors are paying too much for their generics as a result of increasing copays, even when the price of their generic has declined.
- In fact, in 2020, almost two-thirds of all Medicare patients were forced to pay the full cost of their generic at least once because their health plan's copay was higher than the cost of the drug.

Savings by Primary Patient Condition

GENERICS SAVE BILLIONS FOR AMERICA'S PATIENTS WITH COMMON CONDITIONS

TOP 10 GENERIC SAVINGS BY CONDITION IN 2021

CONDITION	TOTAL SAVINGS (PRIMARY CONDITION + COMORBIDITIES)
Heart Disease	\$96.7 Billion
Mental Illness	\$59.7 Billion
Diabetes	\$56.7 Billion
Epilepsy	\$37.4 Billion
Cancer	\$17.9 Billion
Allergies and Asthma	\$12.4 Billion
HIV/AIDS	\$5.8 Billion
Alzheimer's disease	\$5.5 Billion
Chronic Obstructive Pulmonary Disease (COPD)	\$5.3 Billion
Crohn's & Colitis	\$3.3 Billion

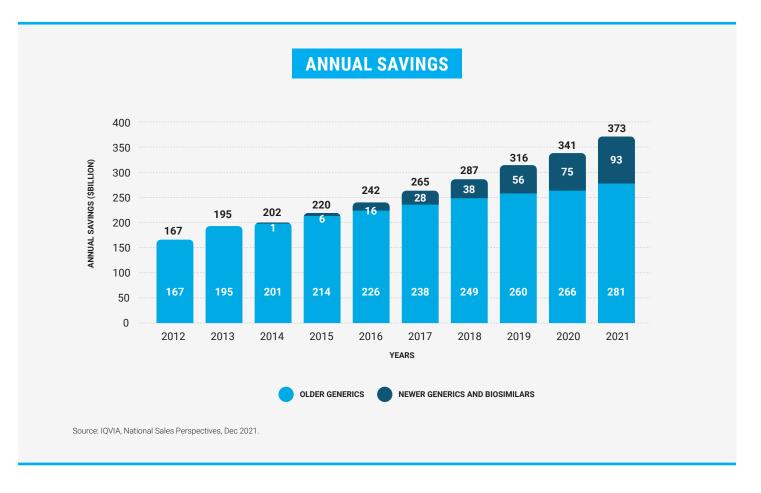
Source: IQVIA, National Sales Perspectives, Dec 2021.

- Generic drugs are used in every disease state treated with pharmaceuticals, demonstrating the tremendous value they bring year over year to individual patients.
- Savings by condition correlate with the top 10 chronic conditions affecting Americans, including hypertension, major depressive disorder, high cholesterol and coronary artery disease.
- Just as generics offer savings over brand-name drugs, biosimilars — safe, effective alternative versions of a biologic — have great potential to improve quality of life, while saving the health system billions of dollars.

New Generic Savings

New Generic and Biosimilar Competition Generated \$93 Billion in Savings in 2021

GENERICS AND BIOSIMILARS LAUNCHED SINCE 2012 HAVE \$312 BILLION IN CUMULATIVE SAVINGS



- New generics entering the market generate lower costs and greater access to care for patients.
- These include 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 also 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.
 - » For new products entering the market in 2021, the average efficiency rate (the rate at which a generic or biosimilar is used instead of the brand) was only 73%.

New Generics Face PBM Delays in Coverage

MANY PBMS AND HEALTH PLANS DELAY COVERAGE OF NEW GENERICS, DESPITE THEIR LOWER COST

PERCENT OF NEW GENERICS COVERED BY MEDICARE

PART D AND COMMERCIAL PLANS BY FORMULARY YEAR

Launch Year	2016		2017		2018		2019		2020		2021		2022	
	М	С	М	С	М	С	M	С	M	С	М	С	М	С
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)

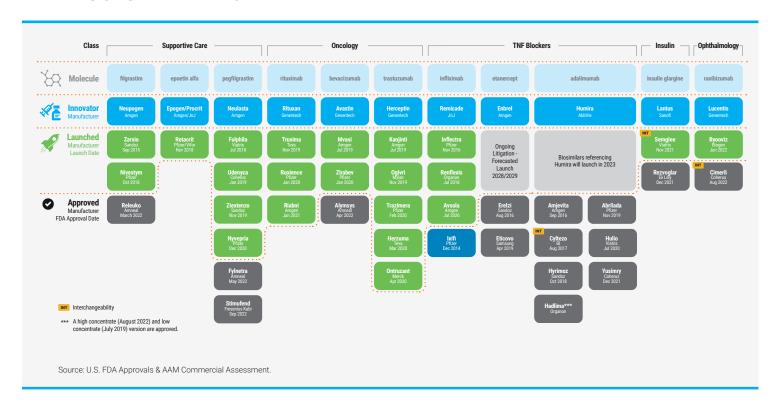
Source: Analysis of Medicare Part D formulary data from CMS and commercial market formulary data from Managed Markets Insight & Technology, LLC.

- Slower adoption and lower efficiency rates for new generics is driven in part by slower coverage decisions by both private and Medicare drug plans.
- 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 may restrict patient access to lower-cost generics.
- Although an average of 50% or more commercial plans typically cover first generics the year after launch, this coverage appears to plateau over time.
- It is critical that employers and policymakers ensure that health plan formularies cover and prioritize lower-cost generics as quickly as possible.

Biosimilars Overview

The Growing Biosimilars Market

AS OF SEPTEMBER 2022



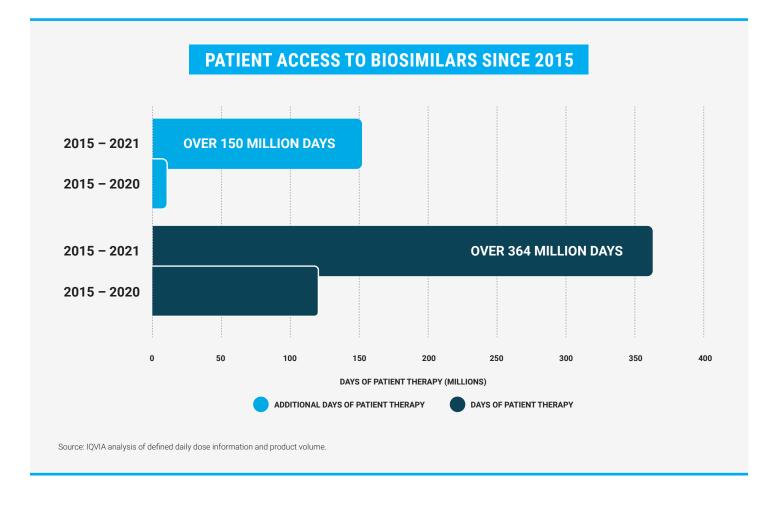
- To date, the FDA has approved 39 biosimilars across 11 molecules.
- Patients have access to 22 biosimilars, with prices that average more than 50% less than their reference brand biologic.⁴
- The biosimilar pipeline remains strong, with over 95 biosimilar development programs underway. This marks an almost 50% increase in the number of development programs over the last four years.⁵
- Competition has lowered overall costs by driving down prices for both the reference product and its biosimilars.
- Biosimilars have provided \$7 billion in savings in 2021 and more than \$13 billion in savings since 2015.

⁴ Medicare ASP data. Comparison of current biosimilar prices and reference prices at launch of first biosimilar.

⁵ FDA-TRACK: Center for Drug Evaluation & Research. Pre-Approval Safety Review. Biosimilars Dashboard. August 2022. https://www.fda.gov/about-fda/fda-track-agency-wide-program-performance/fda-track-center-drug-evaluation-research-pre-approval-safety-review-biosimilars-dashboard.

Biosimilars Are Increasing Patient Access to Care

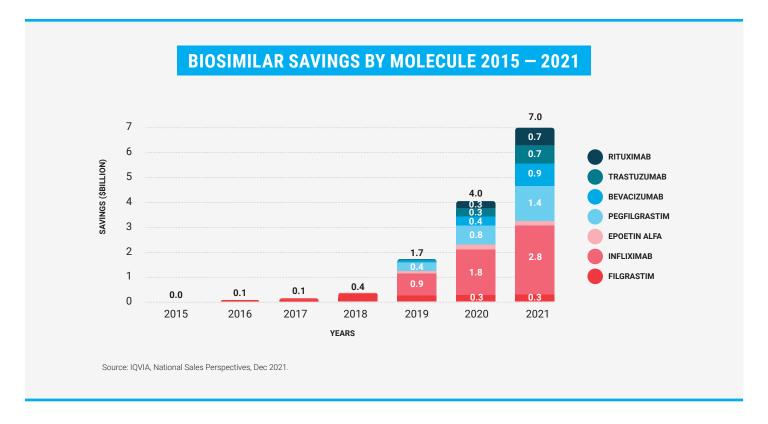
TOTAL PATIENT UTILIZATION HAS INCREASED IN EVERY MOLECULE WITH BIOSIMILAR COMPETITION



- The increasing use of biosimilars is quickly putting to rest any questions about their safety and efficacy.
- Since 2015, biosimilars have been used in more than 364 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.
- In fact, biosimilar competition has now supported more than 150 million incremental days of therapy — care that patients would not have received otherwise.
- The result: more patients suffering from cancer and other life-threatening diseases have access to pharmaceutical care.

Biosimilar Savings Totaled \$7 Billion in 2021

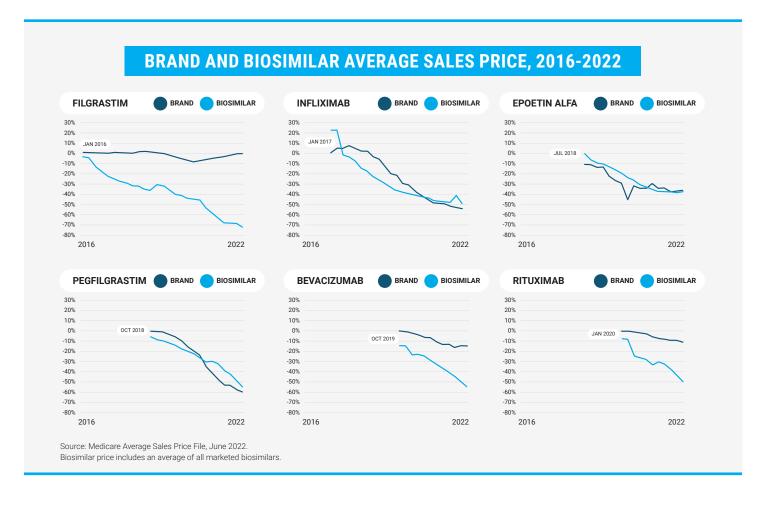
SINCE 2015, BIOSIMILARS HAVE GENERATED \$13.3 BILLION IN SAVINGS



- Savings from biosimilars continued to grow in 2021, with recently launched oncology biosimilars (bevacizumab, rituximab, and trastuzumab) continuing to build upon their market share.
- However, the biosimilars market is not homogeneous, with varying market adoption across each molecule and the resulting savings.
- Adoption can be affected by three general areas:
 - » Education and misinformation.
 - » Provider incentives
 - » Health plan formulary decisions.
- Policymakers should align programs to support broad adoption of lower-cost biosimilars, to ensure that the market functions optimally for all biosimilars and not just certain markets.

Biosimilar Competition Results in Lower Prices

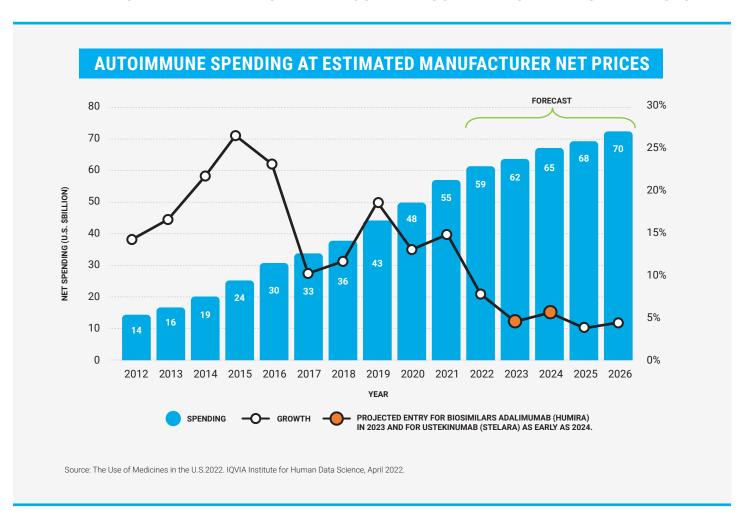
BRAND BIOLOGIC AND BIOSIMILAR PRICES DECLINE FOLLOWING BIOSIMILAR LAUNCH



- On average, biosimilar sales prices are more than 50% lower than the reference product's price was at the time of biosimilar launch.
- Similarly, the average sales price of brand biologics competing with biosimilars has fallen an average 25% since biosimilar launch.
- Lower-cost biosimilars help patients afford treatment to manage life-threatening and chronic conditions.
- These trends signal a robust level of price competition between biosimilars, their reference brand biologic and, in cases, other high-priced brands. The result is lower prices across the board.
- Additional savings can be found by addressing perverse incentives that penalize use of lowercost biosimilars in favor of higher priced brands.

Biosimilars Are Projected To Reduce Spending Growth on Medicines To Treat Autoimmune Diseases

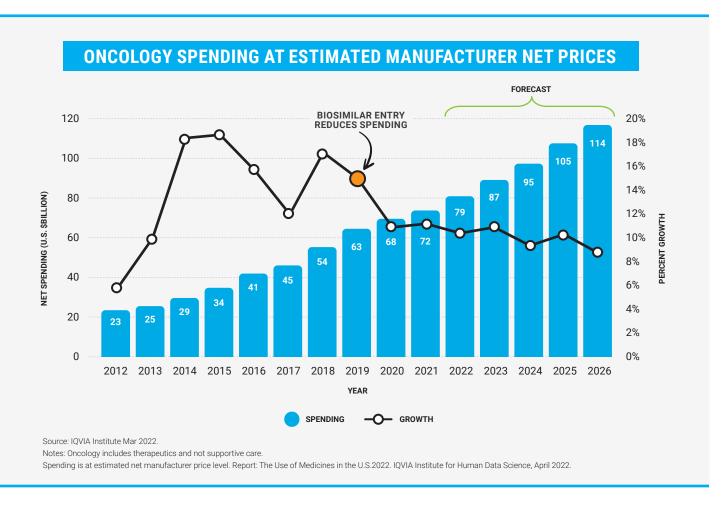
PATIENTS WILL BENEFIT FROM NEW BIOSIMILAR COMPETITION AND LOWER PRICES



- Since 2012, spending among therapies for autoimmune diseases has consistently increased by 10% - 25% each year, driving higher overall spending and patient costs.
- The entry of new biosimilar competition in 2023 and 2024 is projected to dramatically reduce this trend. Specifically, the launches of multiple biosimilars for adalimumab and ustekinumab promise important savings for patients, employers and taxpayers.
- These launches are facilitated by procompetitive patent settlements that allow the biosimilars to launch sooner. The success of these market entrants will be impacted by the degree to which health plans encourage use of the lower-cost biosimilar over the brand.

Biosimilars Have Already Slowed Spending Growth for Cancer Treatments

BIOSIMILARS AND GENERICS HAVE REDUCED ONCOLOGY SPENDING GROWTH BY ROUGHLY 50%



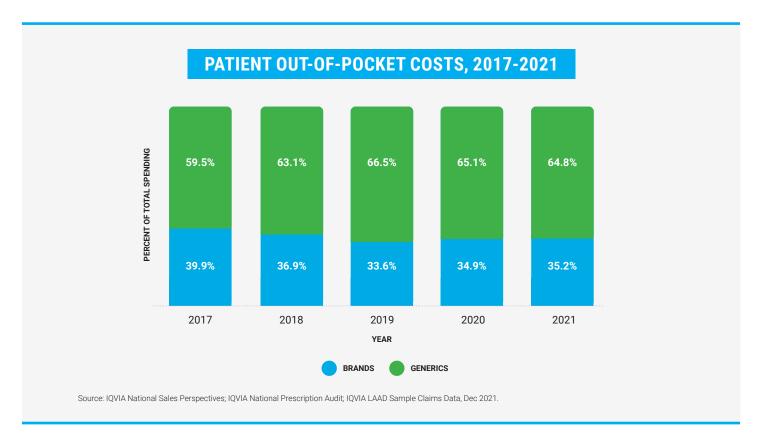
- Treatments for cancer are the leading driver of health care costs for employers, and controlling spending in this area is critical to keeping overall costs low.⁶
- Oncology biosimilars are a prime example of biosimilar competition's ability to reduce spending. Altogether, the use of new biosimilars has saved patients with cancer more than \$3.5 billion.
- In fact, new biosimilars cut the growth rate in oncology spending by nearly half, and this is projected to continue to decline over the next four years.

⁶ Business Group on Health. August 2022. "2023 Large Employers' Health Care Strategy and Plan Design Survey."

Patient Out-of-Pocket Costs

Patient Costs for Generics Do Not Reflect Generic Prices

GENERICS ARE ONLY 16% OF INVOICE-LEVEL SPENDING BUT 65% OF PATIENT OUT-OF-POCKET COSTS

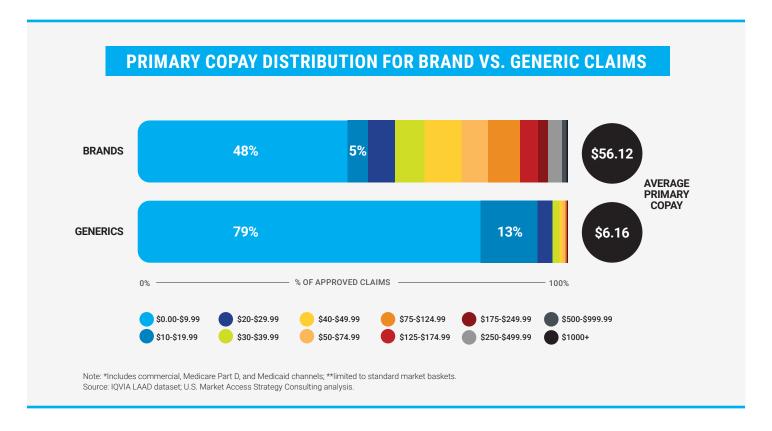


- Although generics represent only 18% of total drug spending, they account for almost two-thirds of patient out-of-pocket costs.⁷
- This means that patients are paying more for their generics — even as those generic prices have declined
- And in many cases, patients using a generic drug pay a copay that exceeds the manufacturer's price for the generic. This is caused by profit-seeking practices performed by middlemen such as pharmacy benefit managers and wholesale distributors.

⁷ Generic medicines accounted for 16% of net spending and 92% of volume when measured at invoice level, but 18% of total medicines spending and 90% of volume when measured using IQVIA's National Sales Perspective. Invoice level spending reflects supply-chain price concessions but do not include off-invoice discounts and rebates separately paid to insurers or other price concessions paid to patients or other health systems participants.

92% of Generics Had a Copay of Less Than \$20, Compared to Just 53% of Brands

THE AVERAGE BRAND PRESCRIPTION IS ABOUT 8.5X MORE THAN THE GENERIC

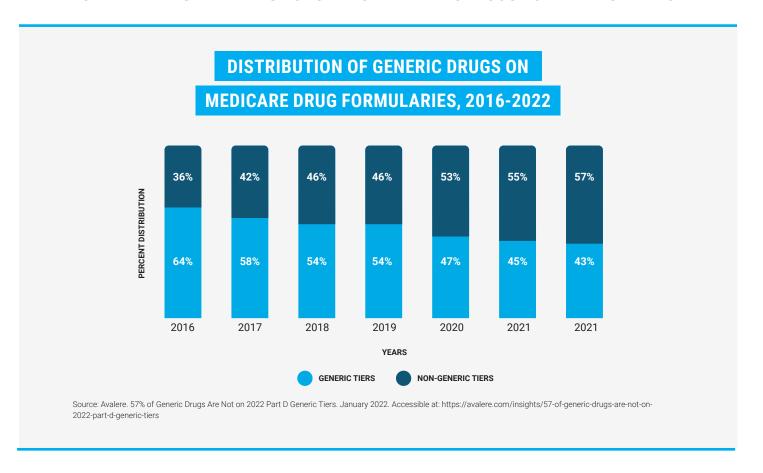


- Use of generic medicines is driven by their low costs. This allows each part of the supply chain to profit from their use.
- And even after markups driven by middlemen, patients still pay less in absolute terms (although more in percentage terms) for generic drugs.
- The average patient copay for a generic is \$6.16.
- In 2021, 93% of claims for generic products had a primary copay under \$20. In contrast, 53% of brand claims had a copay of less than \$20.

- Nonetheless, there are many instances when patients are forced to pay too much for a generic.
- In 2020, nearly two-thirds of patients in Medicare were forced to pay the full cost of at least one generic medicine because the plan-imposed copay was higher than the cost of the medicine.⁸
- As a result, many patients turn to pharmacy discount cards and pay cash for their generic to avoid high copays.⁹
- 8 Avalere. Some Medicare Part D Beneficiaries Pay Full Price for Generic Drugs. July 2022. Accessible at: https://avalere.com/insights/some-medicare-part-d-beneficiaries-pay-full-price-for-generic-drugs#:~:text=Avalere%20identified%20patients%20in%20the%20initial%20coverage%20 phase,total%20number%20of%20patients%20who%20received%20the%20generic.
- 9 IQVIA. Pharmacy Discount Card Utilization and Impact. U.S. Market Access Strategy Consulting. August 2022. Accessible at: https://www.iqvia.com/locations/united-states/library/white-papers/pharmacy-discount-card-utilization-and-impact.

Plans Continue to Shift Generics Onto Non-Generic Tiers With Higher Copay Requirements

MORE PATIENTS ARE BEING FORCED TO PAY THE FULL COST OF THEIR GENERIC

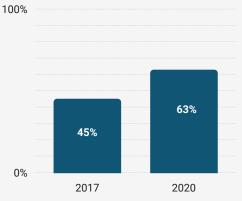


- As a result of formularies that placed generics on non-generic tiers, many patients face unnecessarily high costs.
- In recent years, even as the cost of generics continues to decrease, many Medicare Part D plans have chosen to place generics on higher tiers with higher copays.
- This is the third year in a row in which more generics have been placed on non-generic tiers than on generic tiers, this typically results in higher out-of-pocket costs for seniors.

Improper Formulary Placement Increases Patient Outof-Pocket Costs

IN 2020, 63% OF MEDICARE PATIENTS PAID THE FULL COST OF A GENERIC AT LEAST ONCE







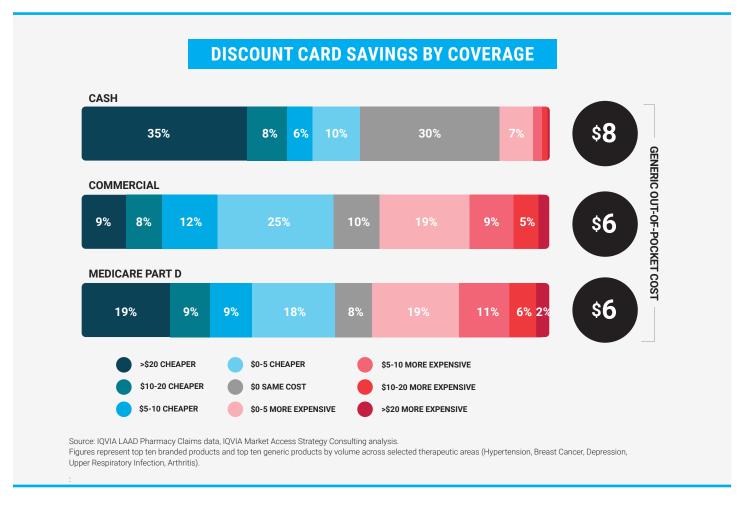
Source: https://avalere.com/insights/some-medicare-part-d-beneficiaries-pay-full-price-for-generic-drugs

Note: All findings are based on a 20% sample of the Medicare Part D population. Findings represent the percent of patients in the initial coverage phase of their benefit taking a generic prescription drug on the preferred brand tier who paid the full cost of the prescription at least once in the benefit year.

- An Avalere analysis found that 63% of Medicare Part D beneficiaries paid the full cost of their generic medications during their initial coverage phase in 2020. This primarily occurred when generics were on the preferred brand tier.
- As plans continue to move generics to highercost Part D formulary tiers, more patients are liable for the full costs of their medications each year.
- When this occurs, plans are charging patients premiums for membership in a Part D prescription drug plan while also requiring patients to pay the full net cost of the drug out of pocket.
- For example, even though the manufacturer price is half of the negotiated price paid by a plan in Medicare, 99% of patients with asthma paid the full cost of their generic asthma medicine.

Many Patients Save by Paying Cash for Their Generic

EVEN PATIENTS WITH INSURANCE SOMETIMES SAVE BY PAYING CASH

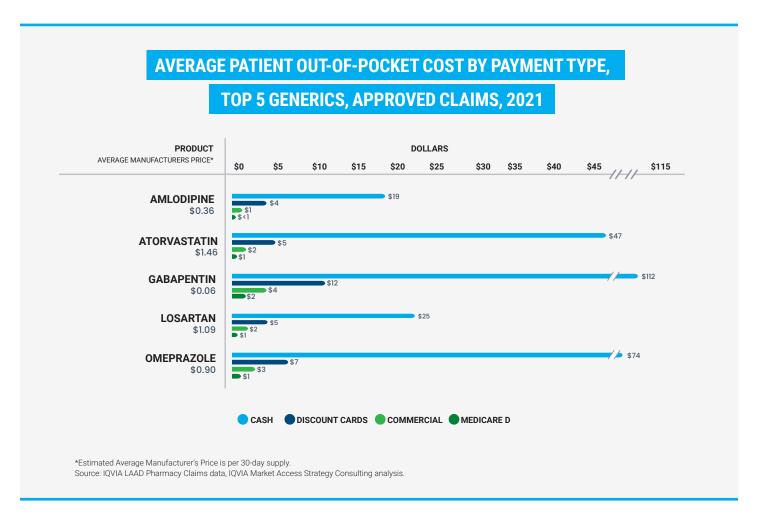


- The increasing use of pharmacy discount cards is a byproduct of formulary design that requires patients pay too much for generics. Such cards are typically used by patients with existing health coverage and are overwhelmingly used to purchase generic medicines.
- Nearly a third of all Medicare patients with prescription drug coverage have utilized a discount card to lower their costs.
- Across payer channels, 39-54% of pharmacy discount card users fill their prescribed drug following a payer rejecting coverage for the medicine.

- 55% of commercial and Medicare Part D patients could reduce out-of-pocket costs by 20% or more when they use a discount card after a previous abandonment.
- In dollar terms, nearly half of all seniors who used a discount card saved more than \$5 per prescription over what they would have spent using their Medicare drug plan. For seniors with fixed incomes and multiple prescriptions, this can add up.

Patient Costs for Common Generics Far Exceed the Manufacturer Price

PBM MARKUPS CAN INFLATE THE COST OF GENERICS FOR PATIENTS



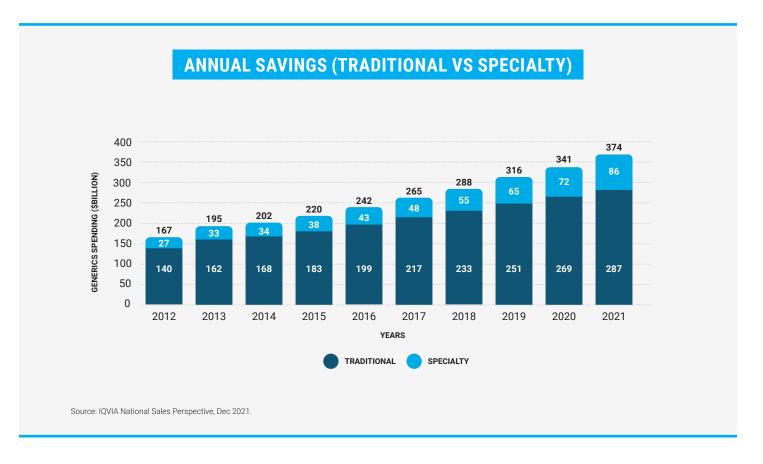
- Low-cost generic medicines account for 91% of all pharmacy discount card claims. Generic drugs are more than twice as likely to be filled using a discount card than brands.
- Patients most often utilize discount cards during the deductible and initial coverage phase of their insurance benefit. Due to improper tier placement, patients experience unnecessarily high cost sharing for generic drugs.
- Cash-paying patients can find significant savings through discount cards instead of paying the pharmacy cash price.

- As an example, even though generic amlodipine is sold for \$0.90, its cash price is \$19. Discount cards reduced the patient's amount owed by 78%.
- For selected top generics, discount card savings to patient out-of-pocket costs when paying by cash range from \$24 (lactulose) to \$74 (omeprazole) when compared to cash costs.
- But even these costs are still significantly higher than the actual price of the generic, meaning that PBM middlemen continue to make money on the backs of patients.

Specialty Medicines

Savings From Specialty Generics and Biosimilars Continue To Increase

SPECIALTY GENERICS AND BIOSIMILARS GENERATE MUCH NEEDED SAVINGS AMID RAPIDLY GROWING SPENDING



- Specialty medicines are therapies used to treat chronic, complex or rare diseases such as cancer, rheumatoid arthritis or psoriasis.
 They may also possess additional distribution, care delivery or cost characteristics which require special management.
- New brand specialty medicines are becoming increasingly responsible for overall drug spending. While specialty medicines are only 3% of annual prescriptions, they are more than 55% of total drug spending.
- It is therefore important that the share of savings from specialty generics and biosimilars continues to increase.
- For instance, biosimilar competition has reduced the spending growth rate in oncology and is projected to slow spending to treat autoimmune diseases.
- Increasing adoption of specialty generic and biosimilar medicines is critical to controlling total drug spending in the future.

Conclusion

Conclusion



There are many large numbers in this report, savings in the "billions" and "trillions" of dollars. While those figures show the significant impact on our nation, what must be remembered is that those enormous values are created by millions of individuals — you, your family, your neighbors, your constituents — saving \$5, \$50, or \$500 by filling a prescription with a generic or biosimilar medicine instead of an expensive brand name drug.

These medicines maintain and save lives not just because they are safe and effective medicines, but because they are affordable. Despite the ongoing advances in modern medicine, if a patient can't afford to fill their prescription at the dose and interval prescribed by their doctor, the patient's health will suffer.

Collectively, these attributes lead to increased adherence which culminates in the health system's shared goal: successful patient outcomes, and fewer expensive and invasive medical interventions.

Methodology

Methodology

GENERIC DRUG SAVINGS IN THE UNITED STATES: TWELFTH EDITION

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 1,243 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 1,243 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 2021, focusing on the 10-year savings for the period 2012 to 2021. Savings from generics launched in the 1993 to 2021 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. $^{\text{TM}}$ 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.

Methodology

GENERIC DRUG SAVINGS IN THE UNITED STATES: TWELFTH EDITION

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 2015, the 10-year savings 2005-2014 were \$1.68 trillion. Using the method from the new study, the 2005-2014 savings would have been \$1.26 trillion, with the majority of the difference from older generics, due to more complete and accurate availability of pre-expiry brand prices. Offsetting these reduced savings modestly were the inclusion of some medicines where brands ceased marketing between 1992-2003, leaving only generics available for those medicines. These medicines were excluded previously due to the absence of a brand price for calculations of savings, but can now be included.

Invoice-based pricing or list prices are derived from proprietary information gathered from wholesalers and company direct sales. While invoice prices reflect supply-chain price concessions, they do not reflect the off-invoice discounts and rebates separately paid to insurers, or other price concessions paid to patients or other health system participants. Net prices are calculated by dividing publicly reported net sales values by volumes for the same products.

Due to corrections in standard dosing factors for oncology monoclonal antibodies, historic savings numbers have been adjusted from previous editions. These molecules do not have WHO assigned defined daily doses and the IQVIA Institute has calculated defined daily dose factors using the standard dosing provided on the product label for the most common indication and standard bodyweight and surface area.

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