aam
Association for Accessible Medicines

The U.S. Generic & Biosimilar Medicines Savings Report

SEPTEMBER 2025

Accord BioPharma, Inc.
Exhibit 1065
Accord v. Janssen
IPR2026-00256, -00257, -00258, -00259
Ex. 1065-001

Letter From the President and CEO

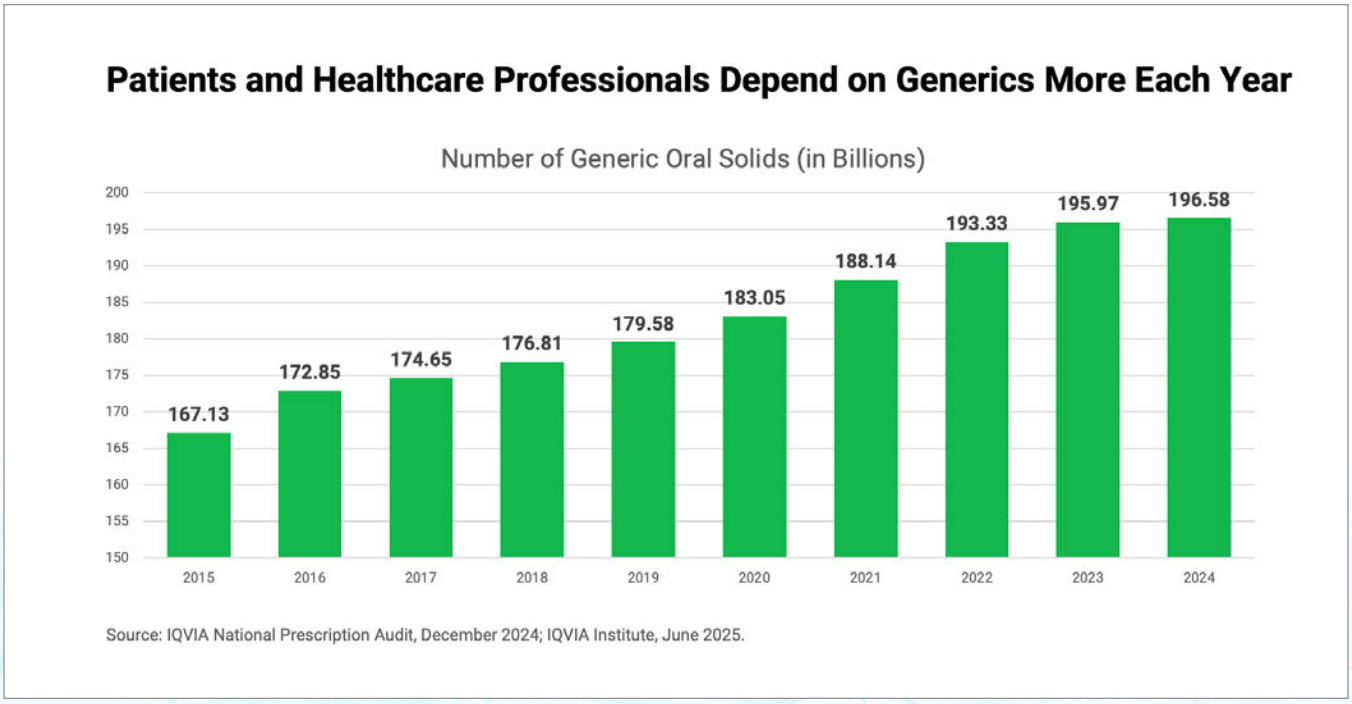
Top-line data highlights value and vulnerability across all generic markets

It is a statistic that easily rolls off the tongue: In 2024, generics encompassed approximately 90 percent of all prescriptions filled in the U.S. but can be attributed to only 12 percent of drug spending. Simply put: Generics medicines save money.

Let's take it one step further. Generics are the only sector that consistently results in **decreased** spending across the U.S. healthcare ecosystem. In fact, since 2019, the amount spent on all generic sales in the U.S. has declined by $6.4 billion, despite increased volume and new generic launches.[1]

For over a decade, AAM has partnered with The IQVIA Institute to capture relevant data and help describe the value of generic and biosimilar medicines in the U.S. Despite the hype and the discussion about drug pricing, the data shows an alarming but consistent trend. Alarmingly, it has been this way for the last decade. Since 2016, generic drugs have steadily made up nine out of every 10 prescriptions filled, all the while their overall percentage of costs has declined – from 27 percent in 2016 to only 12 percent in 2024.[2]

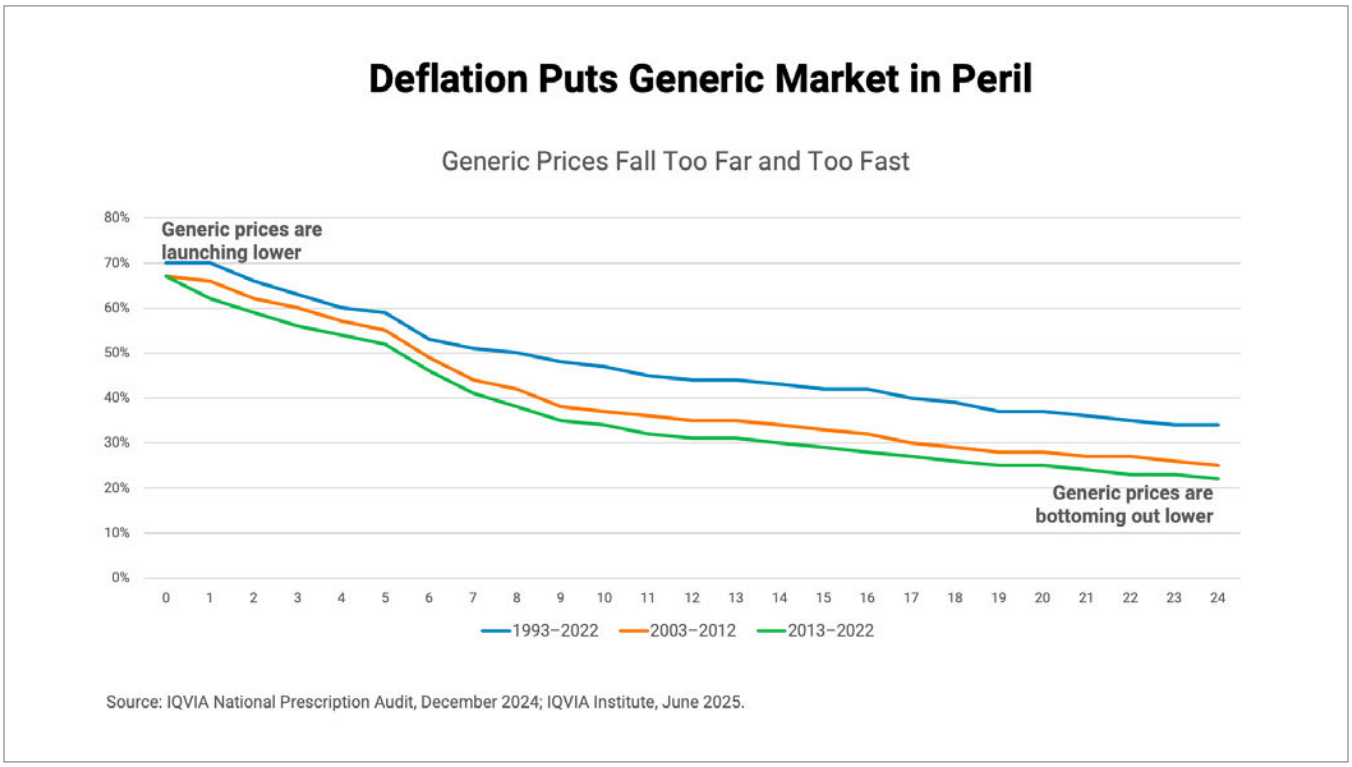
Does this mean the number of available generic drugs has decreased? NO! Americans are consuming more and more of these lower-priced, high-value medications. As noted in the graph below, with respect to generic oral solids (i.e., pills and capsules), the overall trend is an increased number of these products being prescribed and sold. In 2015, the total number of generic oral solids was approximately 167 billion. Within a decade (in 2024), that number increased to approximately 197 billion, a 15 percent increase. Over ten years, Americans were prescribed and received nearly 2 trillion generic oral solids. Keep in mind, this figure does not include a host of other products made by generic manufacturers (e.g., injectables, creams, etc.).



Ex. 1065-002

The question we must ask is clear: How then are drug prices still increasing? If the generics are lowering prices, then why are they higher overall? The answer is brand products and their increased pricing. In 2018, it took eight different brand products to equal the total U.S. spending on ALL generic products.[3] And in 2023, only two brand molecules – Ozempic and Humira – had a total cost that was greater than the cost spent on over 1,000 generic drugs combined.

Unfortunately, right now little is being done to infuse sustainability into the generic marketplace. As noted in the graph below, compared to 30 years ago, generic drugs are launching at lower prices and bottoming out at lower prices. The biggest change has been increased savings through the use of generic drugs. Thirty years ago, generic prices tended to stabilize at approximately 34 percent of the brand product's list price. In the last decade, that percentage has continued to drop – to 22 percent. This type of deflation can lead to unsustainable market conditions for generic drug manufactures and dangerously impact patient care.



While the U.S. generic market is clearly in peril, solutions are not far out of reach. Policymakers must streamline FDA processes, curb patent abuse, stop PBMs and Medicare policies from denying patient access, and rollback harmful federal policies – including IRA price controls.

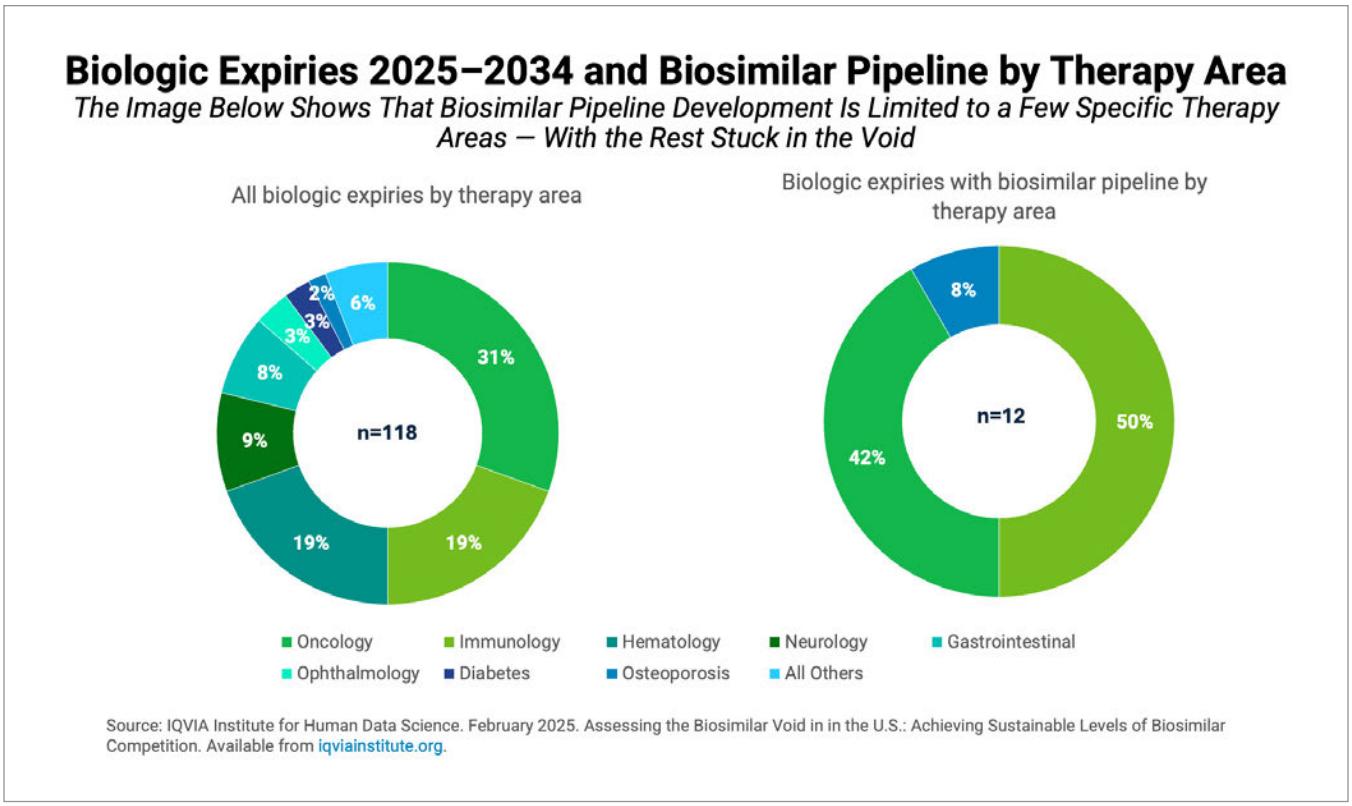
The time to act in the best interest of America's patients is now!

John Murphy III
President and CEO, AAM

Ex. 1065-003

Letter from the Biosimilars Council Executive Director

Sustainability is not guaranteed – we must double down efforts to ensure the biosimilars market reaches its full potential



This year, the biosimilars industry celebrated a decade of pathbreaking progress. This celebration was marked by many successes, including the expansion of biosimilar competition to new therapy areas (including bone and eye health), achieving $56.2 billion in savings for patients and the healthcare system, and 3.3 billion days of patient therapy.

At the same time, the biosimilars market has not yet reached its full potential. A complex web of systemic barriers, including issues related to pricing and reimbursement, patent challenges, and outdated regulatory requirements, continue to stymie the broader adoption of biosimilars. These challenges run the risk of limiting biosimilar development in the future and diminishing the patient benefits realized from biosimilar competition.

Over the next decade, 118 biologics are expected to lose patent exclusivity, presenting a $234 billion opportunity for biosimilars. But right now, of these 118 biologics, only 12 molecules have biosimilars in development. We characterize this lack of development as the 'biosimilar void.'

Ex. 1065-004

Notably, a similar analysis conducted in 2023 related to the European Union market noted that 73 percent (N=19) of high sales biologics would have a biosimilar in the pipeline. This is a sharp contrast to the 23 percent (N=11) within the United States.[4]

Closing the biosimilar void in the U.S. will take more than incremental change. It requires coordinated action across an entire ecosystem of stakeholders – manufacturers, providers, payers, and policymakers – to confront perverse, profit-driven incentives, normalize swift biosimilar adoption, and establish clear, predictable pathways to robust biosimilar competition.

I urge policymakers to wake up! Biosimilars have already provided more life-saving treatments to more patients, but additional savings and access are possible. This future is within reach if we take the bold steps needed to fill the biosimilar void.

Sincerely,

Giuseppe Randazzo
Interim Executive Director, Biosimilars Council

Ex. 1065-005

About the Association for Accessible Medicines & the Biosimilars Council

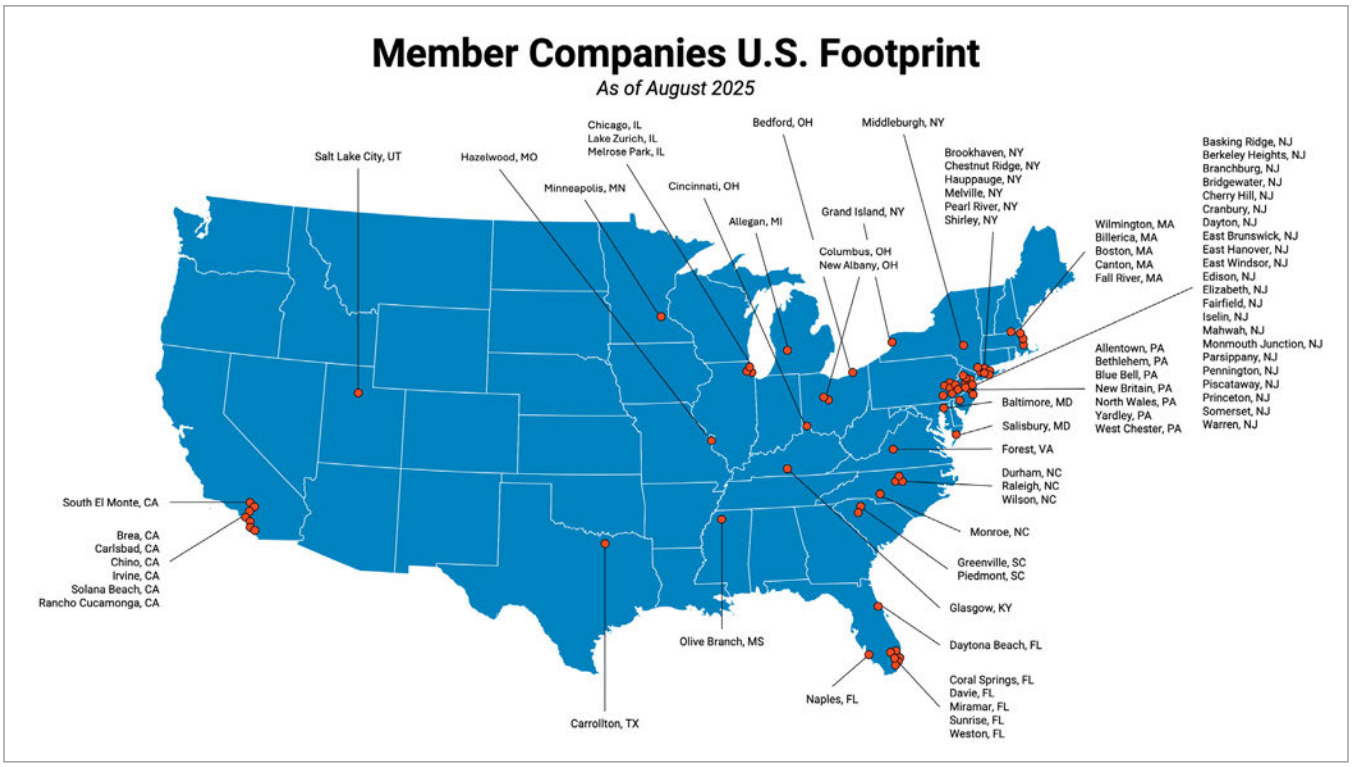
- The Association for Accessible Medicines (AAM) is the nation's trade association for manufacturers of generic and biosimilar prescription medicines. AAM's core mission is to improve the lives of patients by advancing timely access to affordable, FDA-approved generic and biosimilar medicines.

- 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 instill a healthy marketplace where manufacturers can deliver these medicines to America's patients.

Ex. 1065-006



- AAM members have a sizable footprint within the United States. In recent months, several AAM members have announced additional investment in their domestic footprints.

- In June of 2025, Hikma announced a $1 billion investment – by 2030 – to further expand its U.S. manufacturing and research and development capabilities in Columbus and Cleveland, Ohio, and Cherry Hill and Dayton, New Jersey. Hikma has invested more than $4 billion over the past 15 years to build, enhance, and expand its US-based R&D and manufacturing capabilities and now has annual domestic capacity to produce more than 12 billion finished doses of more than 800 medicines.[5]

- In July 2025, Amphastar Pharmaceuticals, Inc. announced a multi-year expansion of its U.S. manufacturing operations in California. The company plans to quadruple production capacity over the next three to five years, reinforcing its commitment to domestic pharmaceutical manufacturing and strengthening supply chain resilience.[6]

Ex. 1065-007

The U.S. Generic & Biosimilar Medicines Savings Report

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Overall Savings Generated by Generics and Biosimilars

Ex. 1065-009

Key Advocacy Takeaways

Brand Drugs Drive Costs. Generics Drive Savings.

Generic Medicines

90%

Rx Drugs Filled
3.9B

12%

Rx Drugs Spending
$98B

Brand Drugs

10%

Rx Drugs Filled
435M

88%

Rx Drugs Spending
$700B

Total Savings from Generics and Biosimilars

- Total generic and biosimilar savings in 2024: **$467 billion**
- Total generic and biosimilar savings for the past ten years: **$3.4 trillion**
- Generic share of total U.S. prescriptions filled: **90 percent**
- Generic share of total U.S. prescription drug spending: **12 percent**
- Generic share of total U.S. healthcare spending: **1.2 percent**
- Total generic savings in Medicare in 2024: **$142 billion ($2,643 per beneficiary)**
- Total generic savings in Medicaid in 2024: **$62.1 billion ($782 per enrollee)**

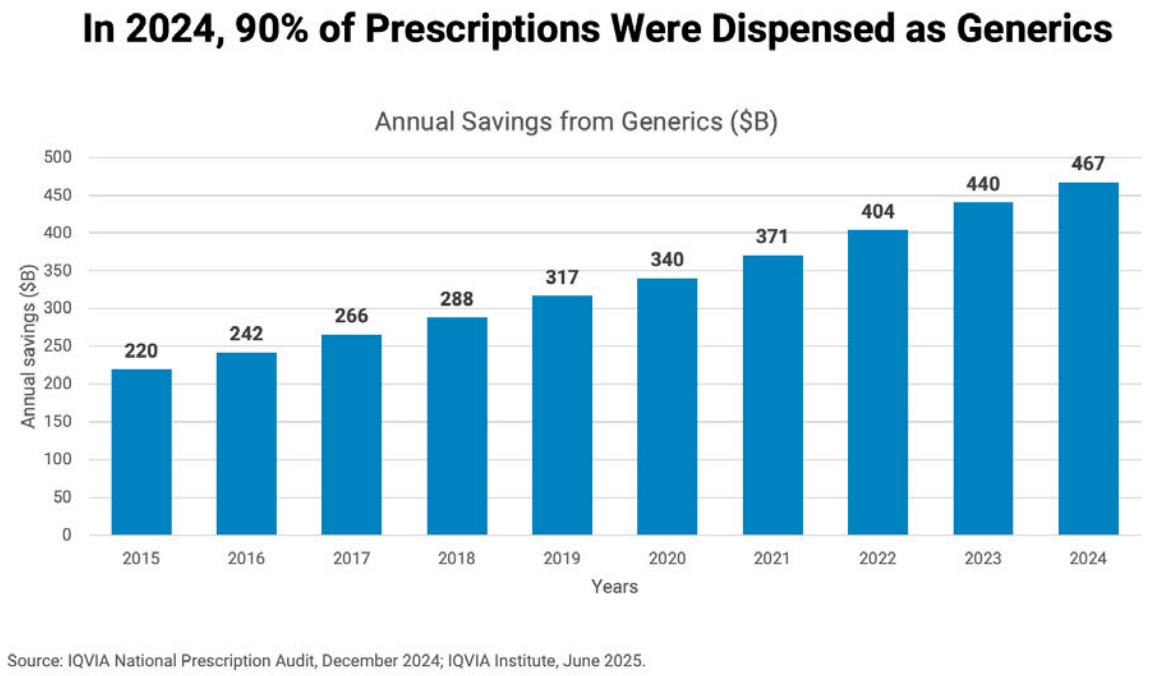
Biosimilar Savings

- Biosimilar savings in 2024: **$20.2 billion**
- Total savings since first biosimilar entry in 2015: **$56.2 billion**
- Total days of patient therapy with biosimilars since 2015: **3.3 billion**
- Incremental days of patient therapy that would not have occurred without biosimilar competition: **460 million**

Ex. 1065-010

Savings From Generic and Biosimilars Totaled $467 Billion in 2024

Generic and Biosimilar Savings Increased by $27 Billion from Previous Year



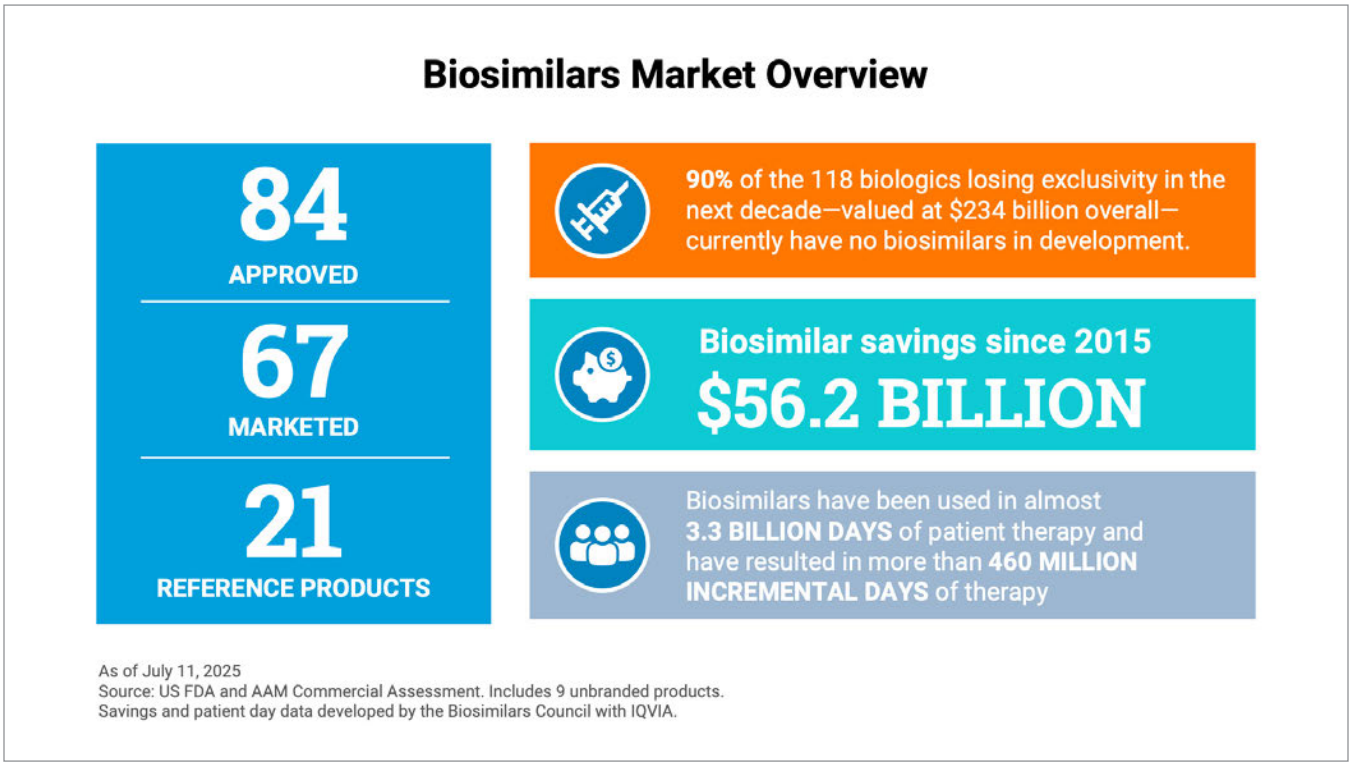
Source: IQVIA National Prescription Audit, December 2024; IQVIA Institute, June 2025.

- Generic drugs contain the same active ingredients at the same strength as their brand counterparts but are priced at a fraction of the cost.
- Biosimilars are lower-cost versions of biologic medicines. They are approved by the Food and Drug Administration (FDA) as being highly similar to, and with no clinically meaningful differences from, an existing FDA-approved biologic.
- Because of their lower costs, generics and biosimilars represent approximately nine out of 10 of all prescriptions dispensed in the U.S.
- Annual savings from generics and biosimilars exceeded $467 billion in 2024.The combined savings results in a $27 billion increase compared to 2023.
- Such savings are consistent with patient sentiment. In a recent survey, 90 percent noted that they would be happy if their doctor switched them to a less expensive medication, with 85.5 percent of patients wanting prescribers to default to the lowest-cost option when clinically appropriate.[7]

Ex. 1065-011

Biosimilars are Delivering Savings and Expanding Patient Access

Yet, a Biosimilar Void Remains, Hindering Patient Access

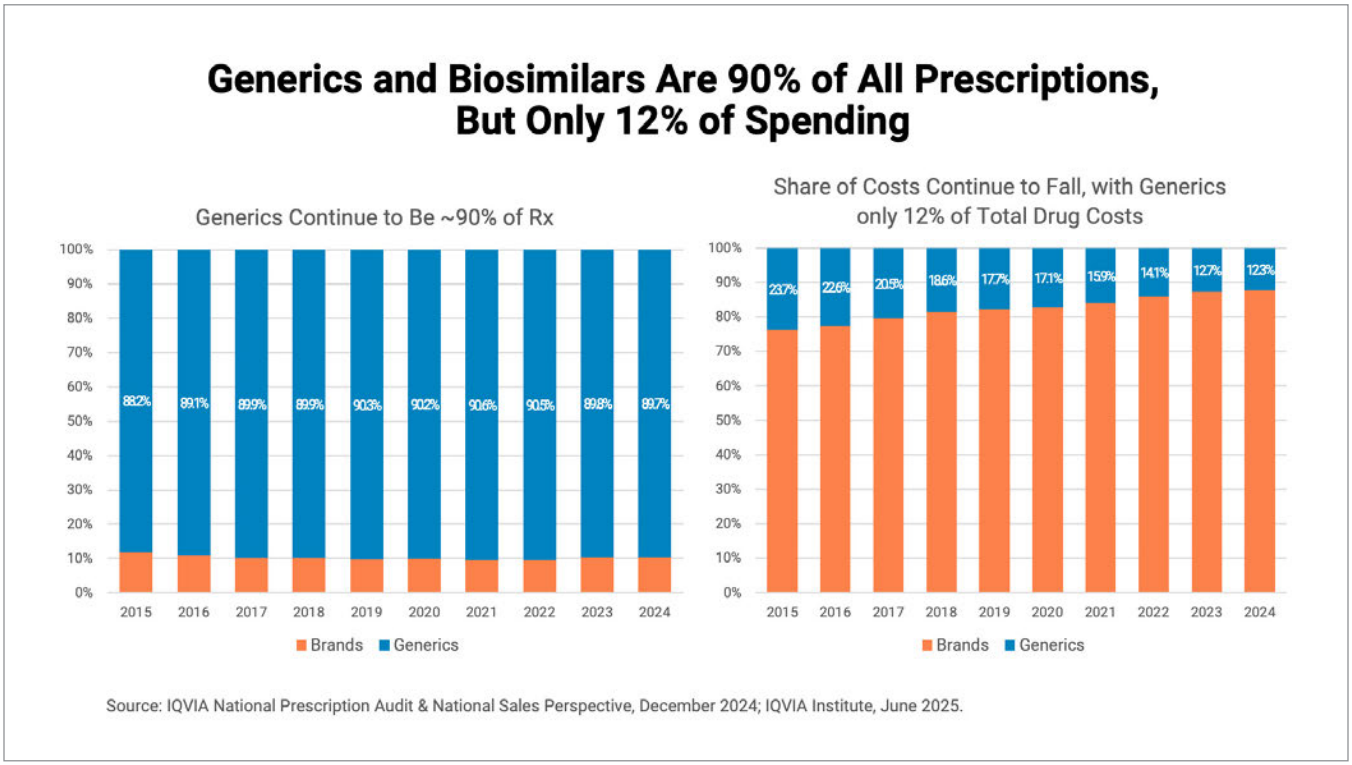


- The biosimilars market is rapidly growing. As of July 2025, the FDA has approved 84 biosimilars for 21 reference products (including nine unbranded products). And 67 biosimilar medicines are now available to patients. Of the approved products, 25 are currently designated as interchangeable.
- Biosimilars have been used in 3.3 billion days of patient therapy, with no clinically meaningful differences in safety or efficacy.
- Once the price of a biologic drug decreases due to competition between the reference product and biosimilar, more patients can afford the drug. As such, patients have received 460 million more days of therapy than if no biosimilar was available. Put simply, biosimilars are making it possible for more patients to receive care and thrive.
- More remains to be done: biosimilar adoption has been slower than anticipated due to brand biologic rebate barriers—90 percent of brand biologics with expiries in the next 10 years do not have a biosimilar in development.
- Policymakers must take action to reduce the cost of biosimilar development and ensure more rapid adoption of these lower-priced medicines.

Ex. 1065-012

Generics and Biosimilars Positively Impact Livelihood of America's Patients

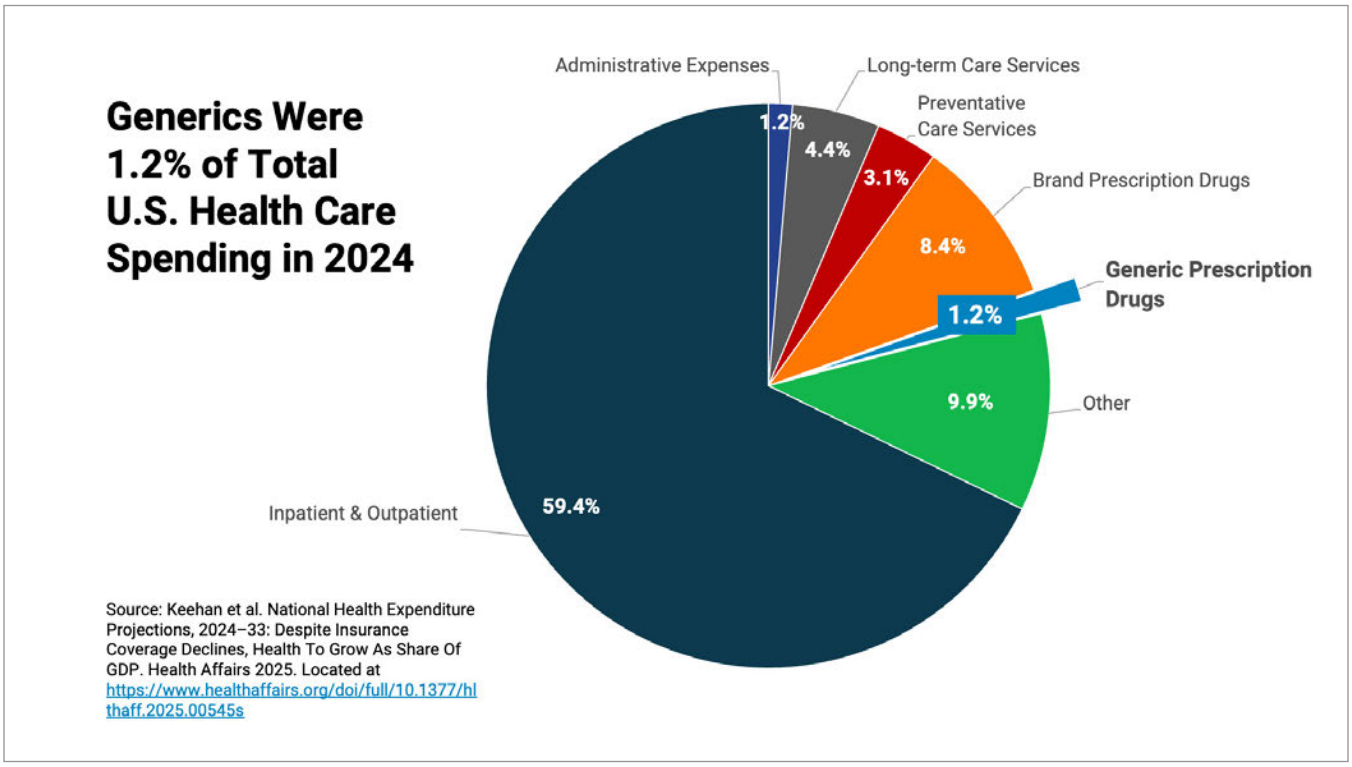
Generic Prices Continue to Fall



- In 2024, generics and biosimilars continued to demonstrate their value – representing 90 percent of all prescriptions filled but only 12 percent of all prescription drug spending.
- Across all therapy areas, in 2024, 90 percent of prescriptions are generics, while immunology, obesity, and diabetes have more brand prescriptions—showing opportunities for market penetration.[8]
- Generic and biosimilar medicines are the only segment of healthcare that consistently delivers lower costs. 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.[1]
- Generic drugs save patients money. In 2024, the average out-of-pocket cost for a generic was $6.95; while the average out-of-pocket cost for a brand drug was nearly five times higher – at $28.69.[8]
- For the uninsured population, brand out-of-pocket costs have increased, while generic out-of-pocket costs have decreased. For these patients, brand prices are up by approximately 50 percent since 2019 to $130.18, while generic prices have dropped by $2.45 per prescription (approximately 6 percent) in that same timeframe.[8]

Generics and Biosimilars Account for Less than Two Percent of Total U.S. Spending on Healthcare

Generic and Biosimilar Medicines Provide Patient Access to Quality Care

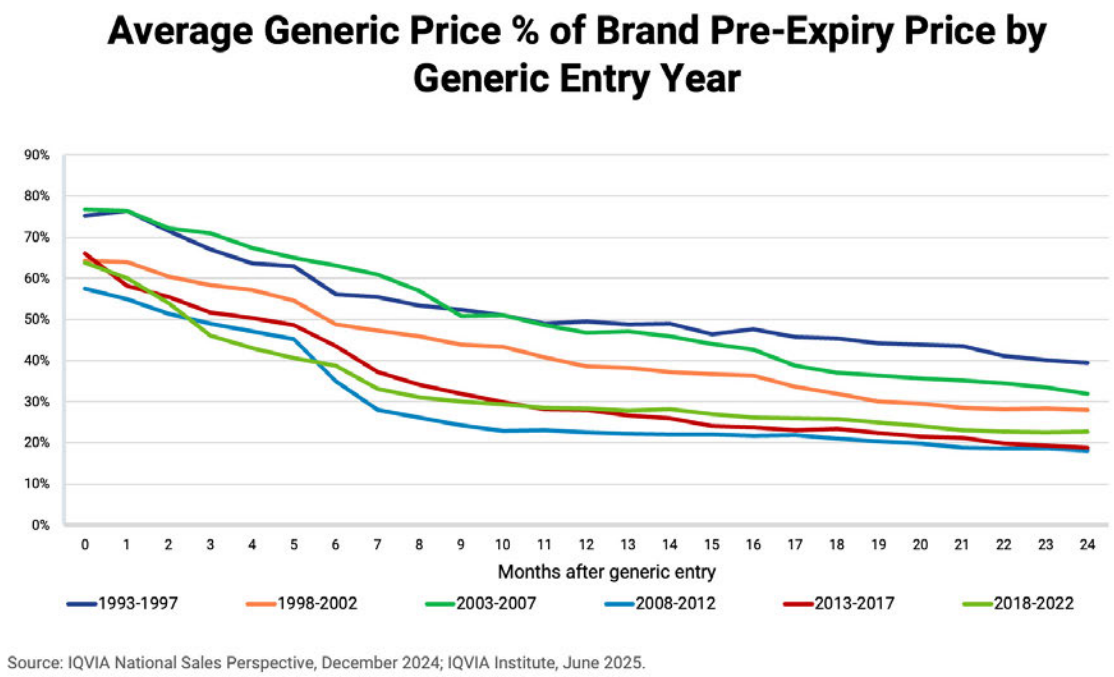


- Although patients receive a generic or biosimilar prescription approximately 90 percent of the time, these lower cost medications are less than two of every 100 dollars spent on healthcare in the U.S.
- The U.S. healthcare system has saved nearly $3.4 trillion in the last 10 years due to the availability of affordable generic and biosimilar medicines. In 2024, competition from generics and biosimilars resulted in more than $467 billion in savings to the healthcare system.

Ex. 1065-014

Savings in Jeopardy: Unsustainable Deflation

Price Deflation Is More Rapid and Prices Bottom Out Lower for More Recent Patent Expiries Compared to Nearly 30 Years Ago



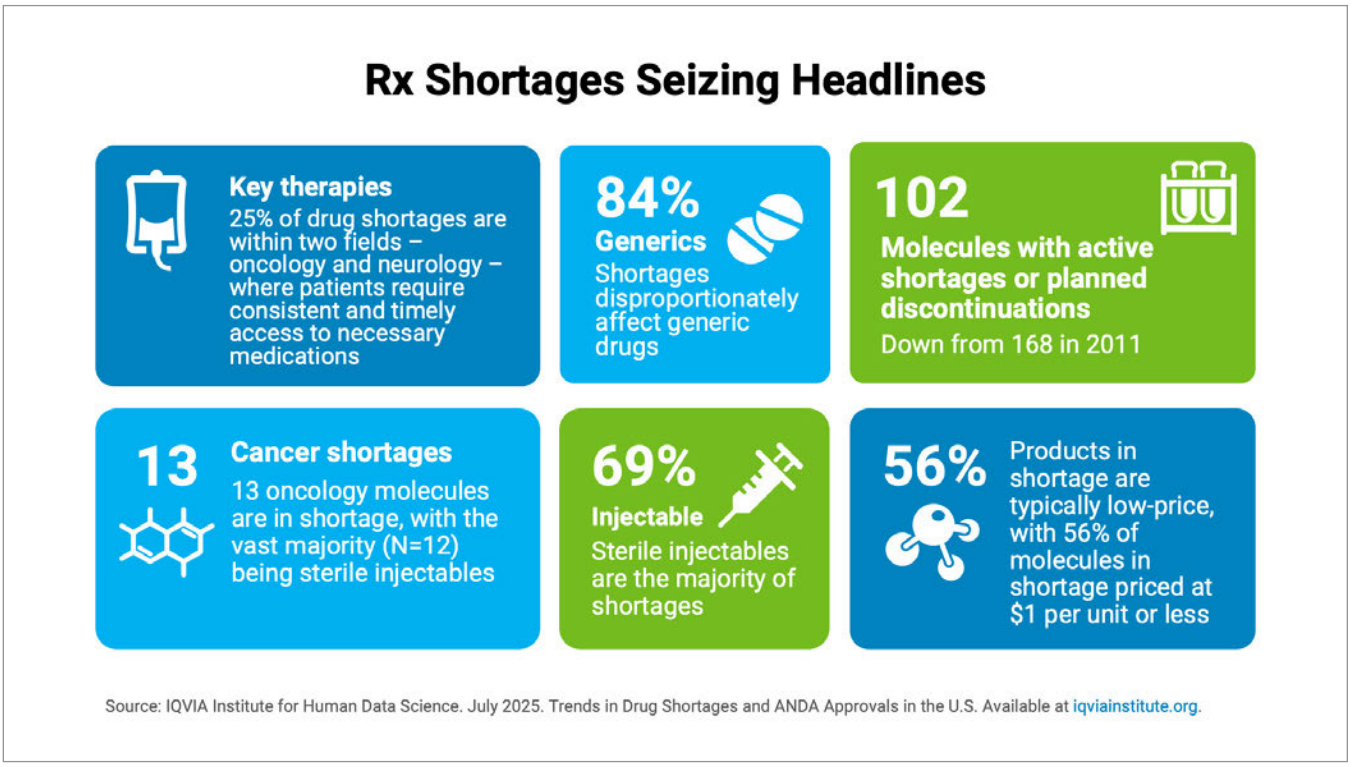
Source: IQVIA National Sales Perspective, December 2024; IQVIA Institute, June 2025.

- Within the U.S., due to its highly competitive market, generic drug prices are launching at lower prices and bottoming out at lower prices. This has led to overall generic deflation.
- As indicated in the chart above, while there is some improvement in 2018–2022 compared to 2008–2017, generic drugs continue to face rapid price deflation. Further, the overall bottoming out of the market is happening at lower percentages, as compared to 30 years ago.
- A recent analysis by RAND found that generic prices in the U.S. average 16 percent less than other countries, and between 30 to 50 percent less than nations such as the U.K., Mexico, France, and Japan.[9] This difference is the result of a hyper-competitive U.S. generic drug market in which prices can rapidly fall by 40 percent on average, and as much as 95 percent upon generic entry.[10]
- Other countries, which generally pay more for their generic drugs, do not have as many drug shortages.

Ex. 1065-015

U.S. Drug Shortages Continue to Hamper Patient Care

Generic Drug Shortages Are a Symptom of Challenges Facing Generic Sustainability



- The United States faces continued drug shortages, especially among lower-cost generics.[11]
- A recent JAMA analysis suggests that higher prices for generic medicines may help explain why Canada has 40 percent fewer drug shortages, despite having overlapping and similar regulatory processes.[12]
- A 2021 comparison between U.S. and Australian drug shortages noted that only 4–7 percent of drug shortages were the same, despite Australia being heavily dependent on importing drugs from the U.S.[13]
- A recent study of 99 drug shortages across Finland, Spain, Norway, Sweden, and the U.S. showed that 41 percent of shortages affected only the U.S., and only one percent affected all five countries.[14]
- The U.S. has a greater shortage problem, due to PBM purchasing power[14] and lower reimbursement for generic drugs compared to other countries[12]— which results in differences in profit margins between various generic markets.[14]

Ex. 1065-016

Savings by Category

Ex. 1065-017

The 10 Most Dispensed Generics of 2024 Saved $635 Billion from 2015–2024

Generic Savings for the Top 10 Products by Volume 2015–2024 Is $635 Billion

Top 10 Products by Volume in Past 10 Years						
Products	Generic Entry Year	Brand Pre-Expiry Price (Per Unit)	Price of Generic Equivalent 2024 (Per Unit)	1-Year Savings ($Billion)	Percent Savings	2023 Volume Units Dispensed (Billion)
Glucophage	2001	$0.66	$0.03	46.8	85 percent	83.0
Neurontin	2023	$1.02	$0.05	69.7	93 percent	73.4
Lipitor	2010	$3.29	$0.06	190.3	97 percent	59.6
Toprol XI	1993	$0.41	$0.06	18.5	81 percent	56.7
Zestril	1998	$0.67	$0.03	30.5	96 percent	47.5
Norvasc	2006	$1.54	$0.02	69.6	99 percent	45.8
Vicodin	1993	$0.27	$0.13	6.3	55 percent	42.3
Prilosec	2001	$3.31	$0.06	117.2	98 percent	36.2
Cozaar	2009	$1.51	$0.06	46.7	96 percent	32.3
Coreg	2006	$1.48	$0.05	39.9	97 percent	27.9

- Patients can realize the benefits of lower-cost generics – from diabetics taking metformin (Glucophage) to those with high cholesterol taking atorvastatin (Lipitor), to those with GERD taking omeprazole (Prilosec), and more.
- Generic competition continues to generate billions of dollars in savings each year. By volume, as indicated in the chart above, the top 10 generics have saved $635 billion in the last decade, with discounts off the brand price between 55 percent to 97 percent.
- A similar analysis examining the top 10 generics with the most savings identified $139 billion in savings for 2024 (30 percent of total savings), with discounts off the brand price between 89 and 99 percent.

Ex. 1065-018

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	$122.2 billion
Mental Illness	$76.8 billion
Diabetes	$61.6 billion
Cancers	$26.6 billion
Allergies & Asthma	$13.9 billion
Arthritis	$6.1 billion
Multiple Sclerosis	$4 billion
Crohn's & Colitis	$2.6 billion
Bone Disease	$2.4 billion
Autoimmune Diseases	$316 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 2024, patients were protected from higher prescription medicine costs for:
  - Heart disease: Generics saved patients $122.2 billion.
  - Mental Health: Generics saved patients with anxiety and depression almost $76.8 billion.
  - Cancers: Generics and biosimilars saved patients $26.6 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 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.

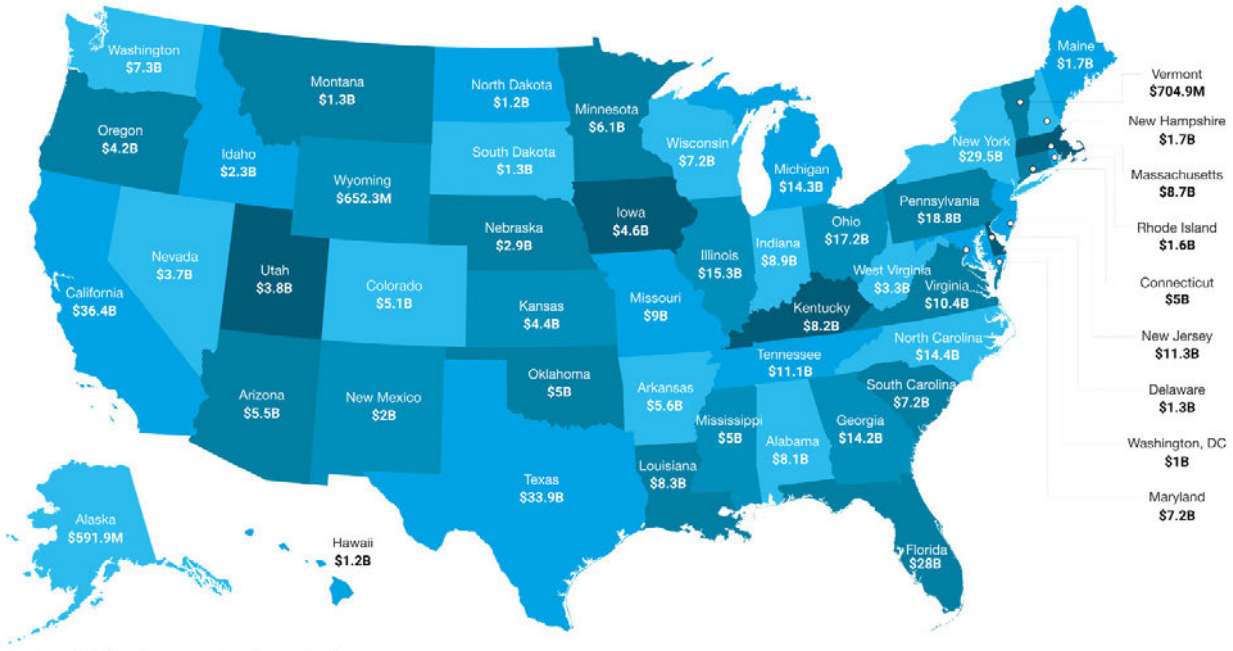
- The share of prescriptions dispensed as generics varies significantly across therapy areas, with some therapy areas almost entirely generic. For instance, generics account for 98 percent or more of prescriptions for hypertension, mental health, lipid regulators, and anti-ulcerants. In the last five years, generics have also made inroads in asthma and COPD care, with the generic share growing from 64 percent in 2019 to 77 percent in 2024. However, brand drugs still hold a sizable share of these products (23 percent) often due to the complex devices that accompany these medications.[8]

Ex. 1065-019

Savings by State

Across the U.S. Patients Find Relief from Prescription Drug Costs Through the Use of Generic and Biosimilar Medicines

2024 Generic and Biosimilar Savings by State



Source: IQVIA National Sales Perspective, PayerTrak.

- Encouraging use of lower-cost generic and biosimilars is a way for employers and states to ensure access and manage spending.
- On average, the use of generics and biosimilars saved more than $8 billion per state in 2024, with savings ranging from approximately $600 million (Alaska) to nearly $36 billion (California).
- States with large Medicare populations often realize significant savings through the use of generic and biosimilars. For example, in New York, the use of generics resulted in $10 billion in Medicare savings with an average of $3,239 per enrollee.
- In 2024, generics saved the state Medicaid programs an average of $1.2 billion. Highest per capita savings occurred in West Virginia, Kentucky, Idaho, Louisiana, and North Dakota.

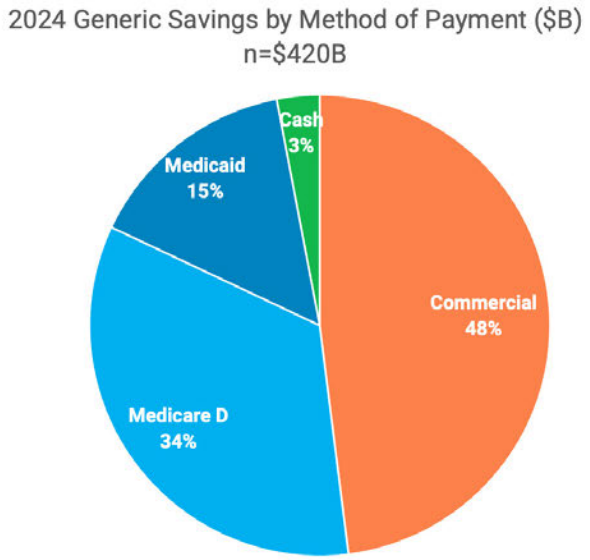
Ex. 1065-020

Generic and Biosimilar Savings Benefit Commercial Insurance and Medicare

Use of Generics and Biosimilars in Medicare Saved $142 Billion in 2024

A Majority of Prescriptions, and Thus Generic and Biosimilar Savings, Are Attributed to Commercially-Insured Patients

State-Level Savings Estimated Based on Retail Prescriptions



Source: IQVIA National Sales Perspective, PayerTrak.

- Generics and biosimilars provide critical savings throughout the healthcare system and are particularly valuable to Medicare and the patients they serve.
- In 2024, the use of generics saved $142 billion in Medicare and $62 billion in Medicaid.
- Medicines taken by older adults account for the majority (81 percent) of total savings:
  - Adults aged 40–64 accounted for $188 billion in savings.
  - Seniors over age 65 accounted for $190 billion in savings.
- In 2024, Medicare average prescription costs dropped by approximately 15 percent (from $6.19 to $5.28), as brand costs increased $1.51 and generic costs declined $1.31.[8]
- Further, Medicare patients can benefit from $0 copays on many generic drugs. For instance, Medicare has seen the largest growth in the share of $0 prescriptions, growing from 31 percent in 2019 to 56 percent in 2024, primarily driven by increased utilization of generic hypertension and cholesterol medicines, which frequently have no patient costs.[8]

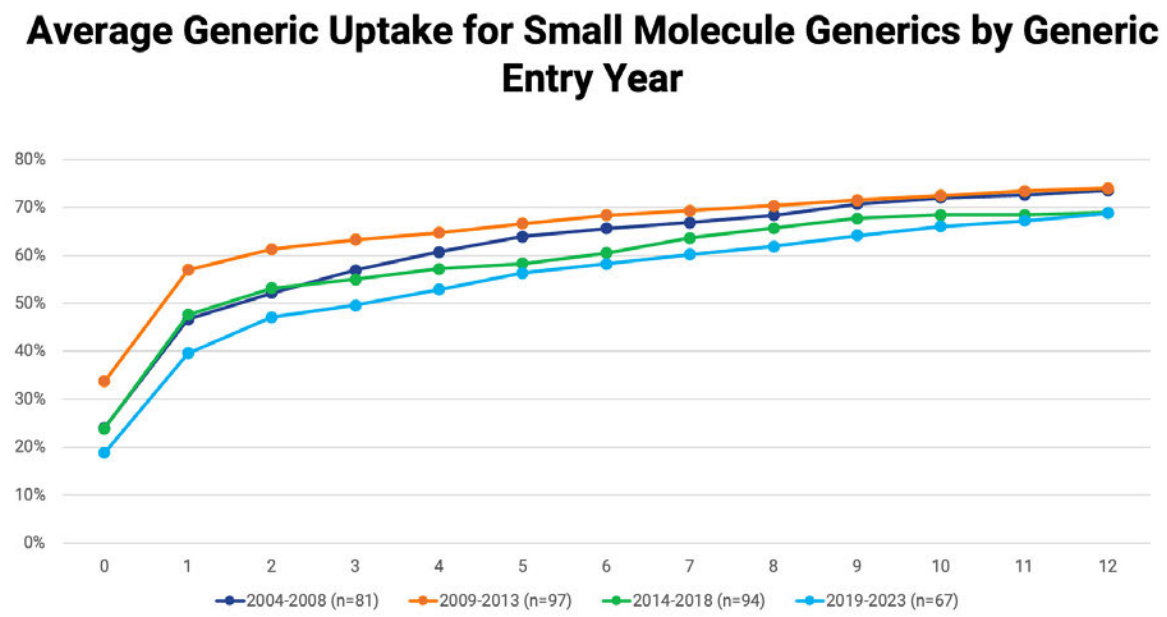
Ex. 1065-021

Generic Savings at Risk

Ex. 1065-022

New Generics Bring Lower Prices, Many Patients Lack Access

Generic Uptake is Lower for Generics Entering in the Last Five Years



Source: IQVIA Institute for Human Data Science. April 2025. Understanding the Use of Medicines in the U.S. 2025: Evolving Standards of Care, Patient Access, and Spending. Available from iqviainstitute.org.

- 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.

- Patients are paying more than necessary for prescription medicines. Previously, most patients would benefit from the entry of new generics. However, in the past five years, generic uptake of small molecules in the first six months after patent expiration has been two to five percent lower than the prior five years and 10–15 percent lower than the 2009–2013 timeframe.[8]

- Further, recent analysis has highlighted that over 25 percent of new generic claims are rejected by payers two years after generic entry, highlighting slower uptake than in previous years.[8]

Ex. 1065-023

New Generics Face Delays in Coverage

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

Summary: Across All First Generics Launched in 2024, an Average of 24 percent of Medicare and 78 percent of Commercial Plans Provide Coverage in FY 2025

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

Launch year	2016		2017		2018		2019		2020		2021		2022		2023		2024		2025	
	M	C	M	C	M	C	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%	55%	87%	56%	88%	54%	86%
2017			12%	58%	25%	73%	58%	73%	65%	76%	65%	76%	64%	89%	61%	95%	65%	95%	62%	93%
2018					17%	39%	27%	49%	51%	59%	54%	60%	54%	84%	53%	91%	54%	89%	54%	86%
2019							31%	44%	59%	60%	72%	61%	72%	88%	70%	90%	71%	90%	70%	88%
2020									21%	55%	41%	66%	60%	90%	58%	91%	58%	87%	59%	85%
2021											23%	86%	46%	89%	45%	84%	44%	81%	42%	81%
2022													39%	76%	44%	76%	45%	81%	58%	80%
2023															39%	72%	45%	88%	34%	86%
2024																	23%	84%	24%	78%

*Note: New commercial analyses were conducted using Clarivate data; previous analyses were conducted using MMIT data

*New analysis

Medicare Part D (M)

Commercial (C)

Source: Association for Accessible Medicines (June 2025) Breaking Barriers: Harnessing the Potential of Generics in Medicare and Commercial Market Drug Spending. https://accessiblemeds.org/wp-content/uploads/2025/06/harnessing-the-potential-of-generics.pdf

- First generics, or medicines approved by FDA as the first competitor to the brand drug, often face challenges in adoption. Slower adoption for first 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 and biosimilars.

- In 2025, Medicare Part D coverage of first generics remained similar to previous years, with an average of only 24 percent of plans covering generics first launched in 2024. Part D plans continue to have a multi-year "phase-in" period before first generics are covered. This delay restricts patient access to lower-cost generics, whereas an average of 50 percent or more of commercial plans typically cover first generics the year after launch.[15]

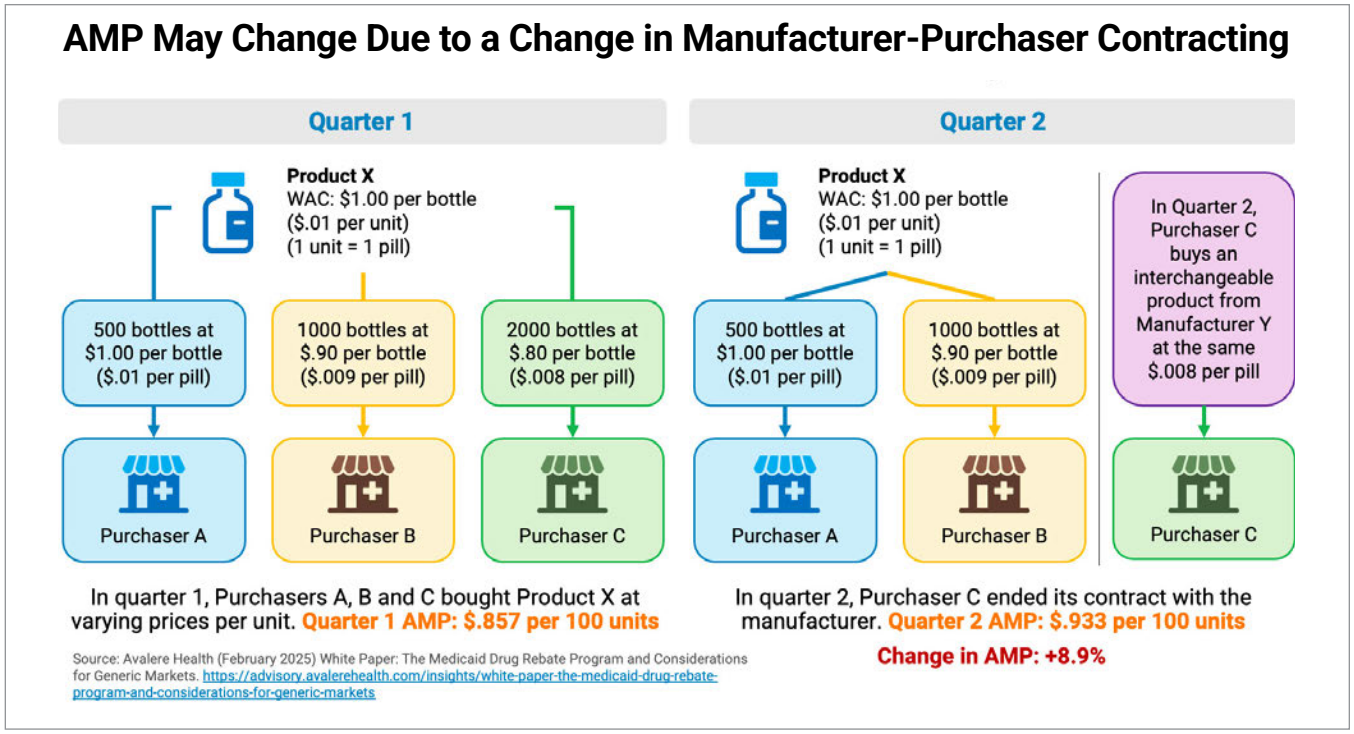
- While commercial coverage rates were higher, with an average of 78 percent of plans providing coverage in 2025 for first generics launched the previous year, the brand to generic coverage gap across commercial payers remains a challenge for new generic formulary placement.[15]

- The result is higher costs for America's patients and taxpayers, due to a continuing slowdown in the rate of generic adoption.

Ex. 1065-024

Medicaid Inflationary Rebates Are a Misguided Effort to Quell Drug Costs

AMP May Change Due to a Change in Manufacturer-Purchaser Contracting

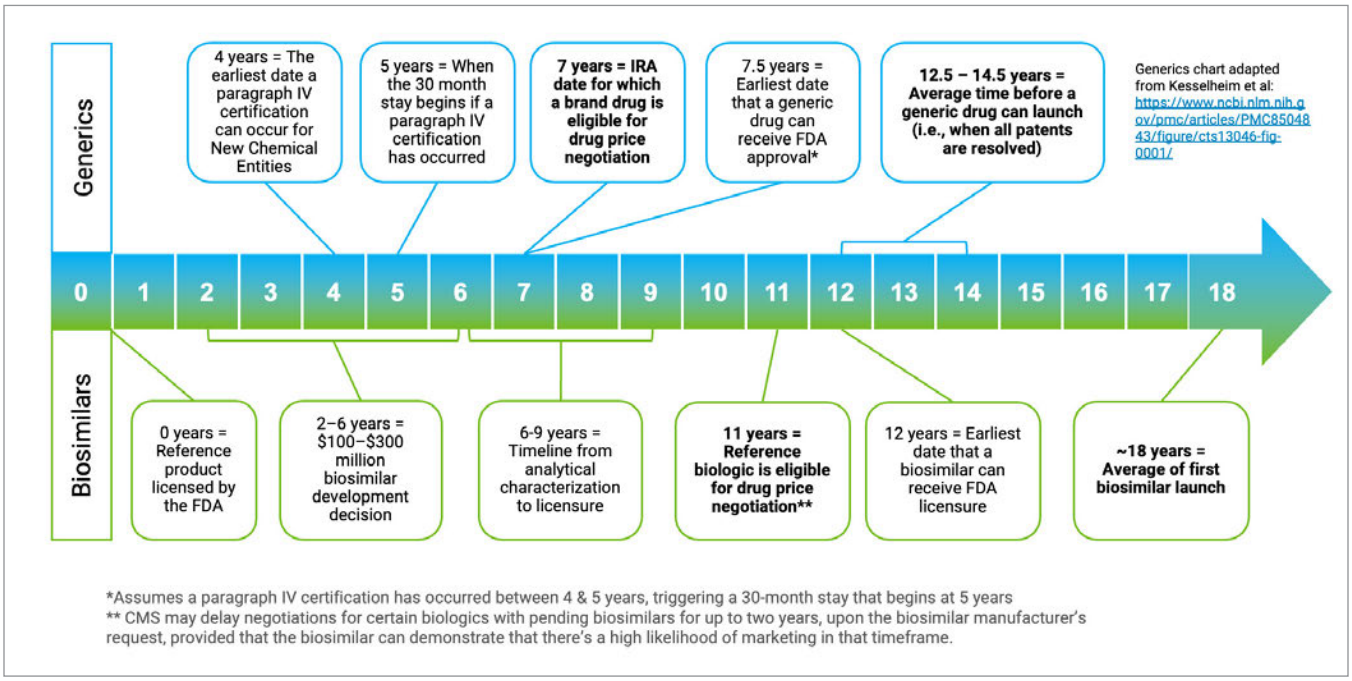


- In 2017, a new penalty was imposed on generic manufacturers participating in the Medicaid program. Targeting price increases exceeding the rate of inflation, the Medicaid Generics Penalty ignores important market differences between generics and brand drugs.
- To better understand the impact of this penalty on generic manufacturers, AAM requested an in-depth analysis by Avalere Health, and the following includes their findings.[16]
- According to Avalere Health, the rule unfairly penalizes manufacturers for price fluctuations outside of their control, increases the risk of drug shortages, and threatens the continued availability of low-cost generics to patients.
- Generic manufacturers may have price increases for items outside the manufacturer's control (e.g., purchasing pattern fluctuations, including changes in customer base and seasonal changes in product usage). Further, pricing for generic drugs is highly affected by the commoditized nature of the multi-source generic market.
- Price competition in many generic markets has driven prices down to just above production costs, with minimal margins to absorb any fluctuations (e.g., increases in manufacturing or ingredient costs). This downward pressure may result in price increases for generic manufacturers when input costs increase or when there is a shortage. This is particularly likely when the benchmark is low, which occurs when a manufacturer enters the market after others or if it is an older generic drug (where there has been sustained price competition).
- Given these problems, Congress should refine the Medicaid drug inflationary penalty and model it after the Medicare inflationary penalty, which takes into account the multi-source nature of the generic drug market.

Inflation Reduction Act

Ex. 1065-026

The Inflation Reduction Act Harms Generic and Biosimilar Competition



- One of the last acts of the outgoing Biden Administration was to announce the selection of the next 15 drugs for price negotiation. Although framed as the next step in reducing costs for patients, the vast majority of selected drugs (13 of the 15) have generic competitors already approved or seeking approval by FDA—152 approved or tentatively approved ANDAs for those 13 products.[17]

- Although the IRA exempted products from negotiation when a generic or biosimilar was approved and marketed, the law explicitly starts the negotiation process *before* generic and biosimilar competition has a chance to begin.

- The IRA does this by instituting the price control process when the brand drug has been approved for seven years (or, if a biologic, it was licensed at least 11 years ago).

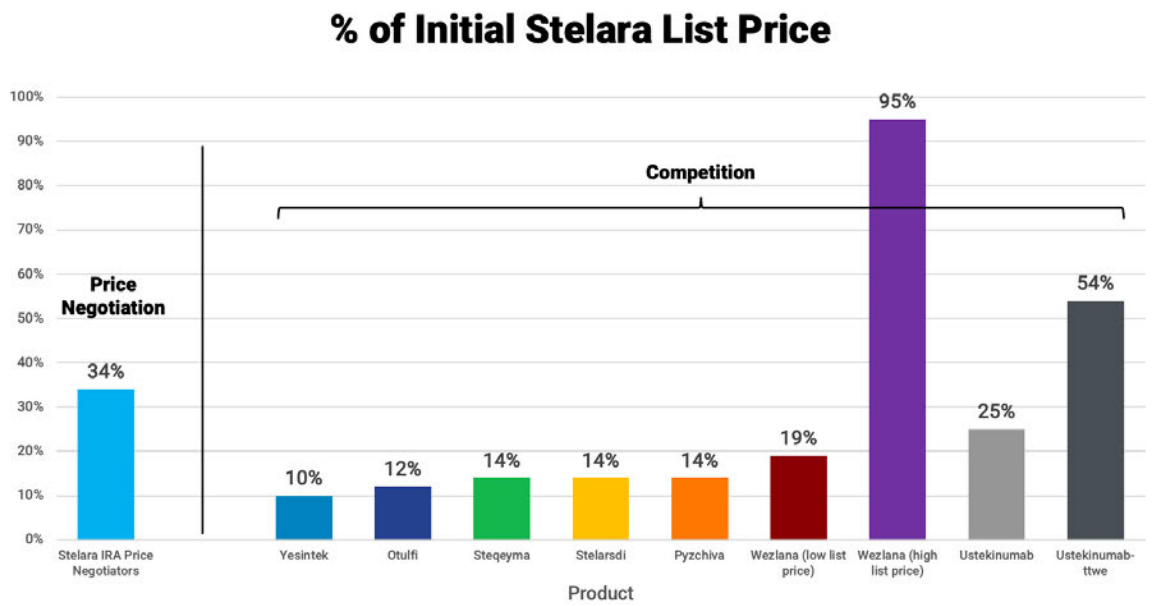
- As noted above, data showing that the average market entry of a first generic is between 12 and 14 years,[18] and approximately 18 years for a first biosimilar (the earliest a biosimilar has ever entered is just over 13 years),[17] makes clear that preempting lower-cost competition through price controls is a feature, not a bug, of the IRA.

Closer Look:

Ex. 1065-027

Stelara

Competition Beats IRA Price Negotiation



Source: Drug Channels. Drug Channels Institute Research. April 2025.

- For the first round of drugs selected for drug price negotiation under the IRA, as of March 2025, already two – Stelara and Xarleto – face generic or biosimilar competition.

- Used to treat inflammatory conditions like Crohn's disease, ulcerative colitis, and plaque psoriasis, Stelara cost the Medicare program $2.6 billion in 2023.[19]

- In August 2024, CMS announced the "maximum fair price" (MFP) for Stelara – a 66 percent discount compared to the list price of the drug.[20] Stelara's MFP will go into effect on January 1, 2026, and Medicare plans will be required to cover the drug.

- But only months after the CMS announcement, the first biosimilar version of Stelara launched with a price more than 80 percent less than the brand. As of July 2025, there are nine biosimilar products on the market, with prices as much as 90 percent less than Stelara's initial list price.[21]

- This, again, highlights the value of competition – a proven approach to reducing drug prices.
  - According to the FDA, when there are four or more generics, the average manufacturer price falls by 75 percent.[10]
  - For biosimilars, a recent IQVIA analysis found that a second-to-market biosimilar launched within three years of the first can nearly double the Average Sales Price (ASP) pressure, accelerating price erosion for all treatments.[22]

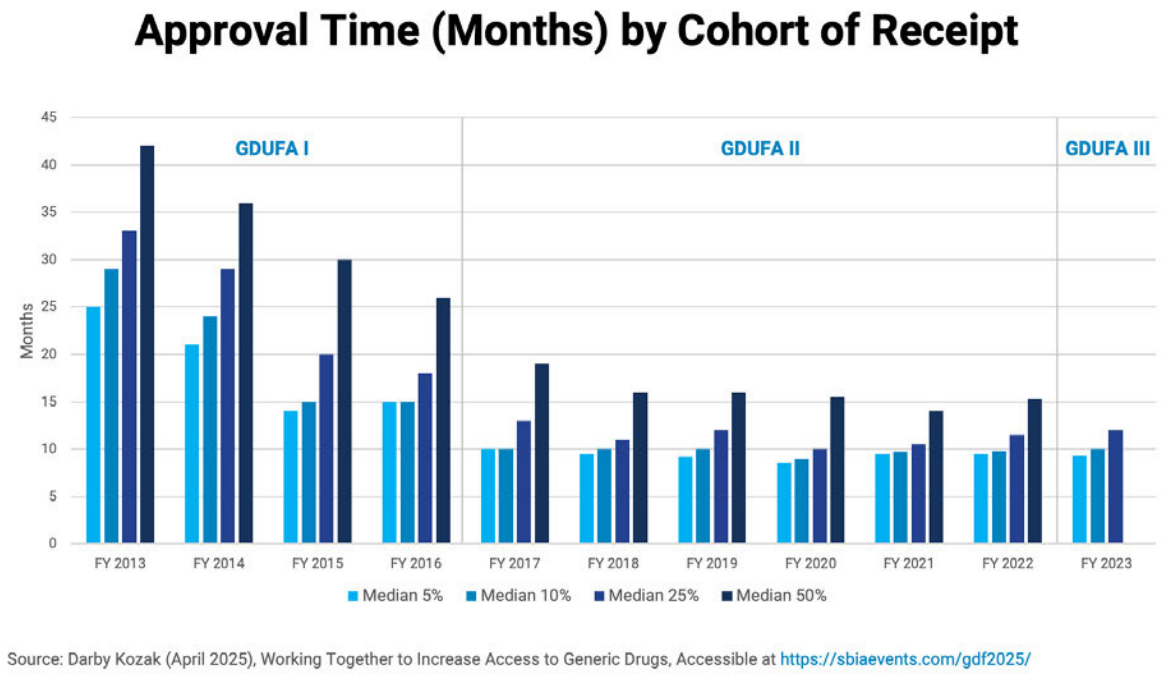
Ex. 1065-028

Value of the User Fee Programs

Ex. 1065-029

The Generic Drug User Fee Program: Ensuring Faster Access to Lower-Cost Generics

GDUFA Accelerates Access to Generic Drugs



Source: Darby Kozak (April 2025), Working Together to Increase Access to Generic Drugs, Accessible at https://sbiaevents.com/gdf2025/

- Building upon the success of other user fee programs, Congress established the Generic Drug User Fee Program (GDUFA) in 2012.
- The goal of the new generic user fee program was simple: expedite the review and approval of abbreviated new drug applications (ANDAs) – to help ensure quicker access to lower-cost medications, encourage competition, expand access to critical medications, and lower America's drug costs.
- Before the creation of GDUFA, the FDA had a backlog of more than 2,500 generic drug applications, largely due to the long review times (i.e., 31 months to approve new generic medications).[23] As a result of changes due to the GDUFA program (and its successor GDUFA II), between 2017 and 2021, the FDA approved more than 3,000 generic drugs and issued more than 50,000 individual communications to the pharmaceutical industry.[24]
- These prompt review actions have helped ensure greater and quicker access to lower-cost generics.

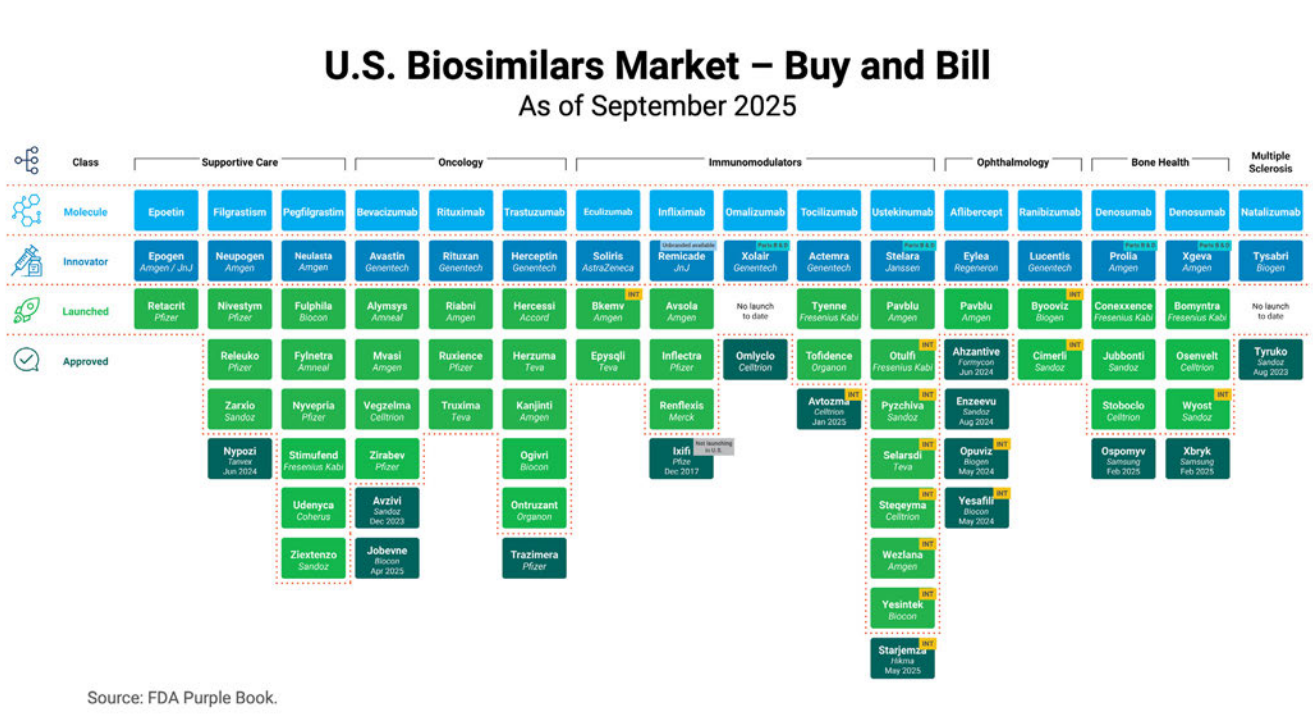
Ex. 1065-030

10 Years of Biosimilars

Ex. 1065-031

The U.S. Biosimilars Market

Ten Years Later, the Biosimilars Market Continues to Grow

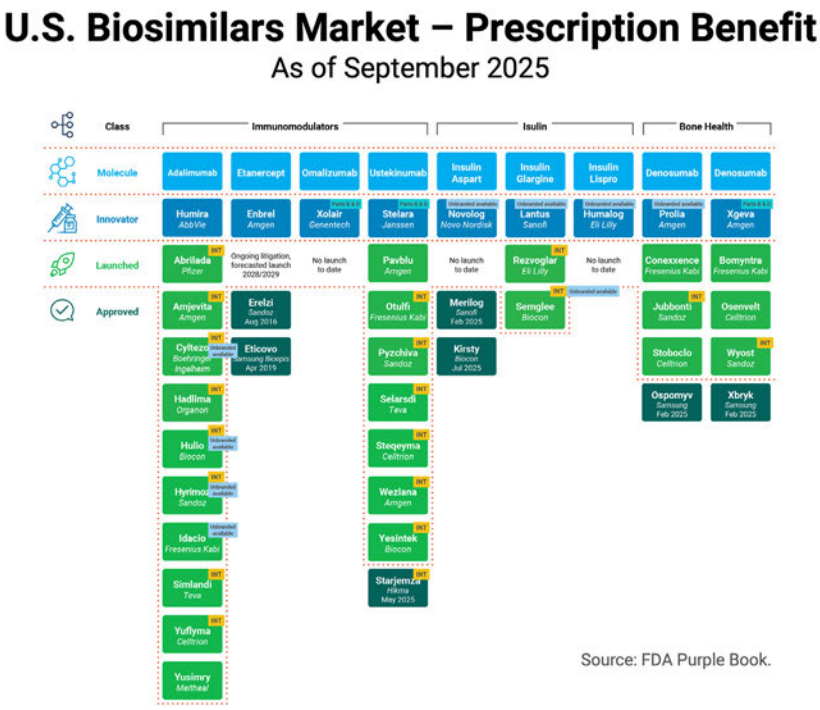


- As of July 2025, over a decade since the first FDA approval of a biosimilar, the FDA has approved 84 biosimilars across 21 molecules.
- Sixty-seven biosimilars are on the market with an average sales price of 39 percent lower than the reference product at three years post-launch.[22]
- Of the 118 biologic patent expiries over the next 10 years, only 10 percent currently have biosimilars in development, leaving 90 percent with no pipeline. This is a direct result of the cost of development and the uncertainty regarding the future of the biosimilar market in the U.S.[25]
- ***Note:*** Compared to last year's edition, the U.S. biosimilars market overview has been updated in three major ways:
  - we have indicated when an unbranded biosimilar is available and included those products in the overall count;
  - we have indicated when a biosimilar is reimbursed under both the buy-and-bill and the prescription benefit; and
  - we have changed the therapy classes (e.g., some classes have been reorganized and consolidated, while other classes – such as bone health and ophthalmology – have been added).

Ex. 1065-032

The U.S. Biosimilars Market

The Biosimilars Market Has Continued to Expand in the Prescription Benefit Space



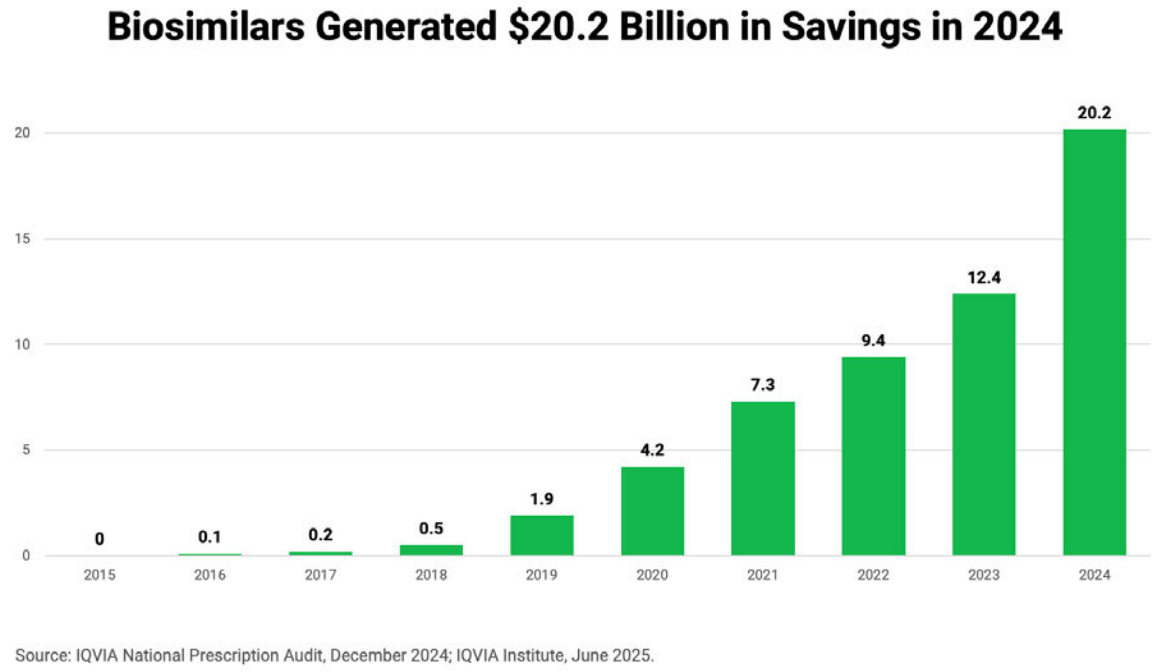
- To date, the bulk of biosimilar competition involves products that are directly purchased and administered by healthcare providers (i.e., medical benefit or buy-and-bill). New biosimilar launches in insulin and adalimumab represent the first entry of pharmacy-dispensed biosimilars.

- Many pharmacy-dispensed biosimilars also have formulations also administered to patients by a healthcare provider (i.e., medical benefit products).

- The insulin market continues to present challenges for biosimilars.[26] While policymakers continue to raise concerns about the insulin market, patients are paying less for those prescriptions. A recent IQVIA analysis suggests that the out-of-pocket costs for these drugs is decreasing across all pay types, reaching $18.64 for all payers in 2023, compared to $25.79 in 2019.[27]

Biosimilars Have Generated $56.2 Billion in Savings Since 2015

Savings Reflect Provider Confidence and Robust Price Competition



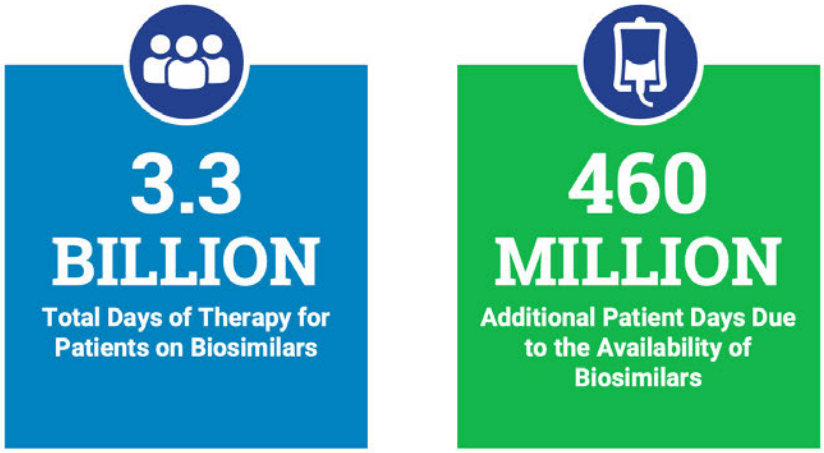
- A decade after the first biosimilar launch in 2015, patients and the healthcare system have saved over $56 billion.
- Savings increase as biosimilar adoption grows. Savings in 2024 nearly double that for 2023—from $12.4 billion to $20.2 billion. Further, approximately 60 percent of total savings from biosimilar entrants occurred in the past two years.
- Although biosimilar adoption has been higher among medical benefit biosimilars (especially bevacizumab, trastuzumab, and rituximab), in many instances it remains too low.
- Unfortunately, biosimilar adoption continues to trail expectations because of misaligned incentives and PBM practices that slow adoption.

Ex. 1065-034

Biosimilars are Delivering Safe Therapy

Biosimilar Introduction Often Results in Greater Patient Access

Biosimilars Are Now a Core Element of Patient Care



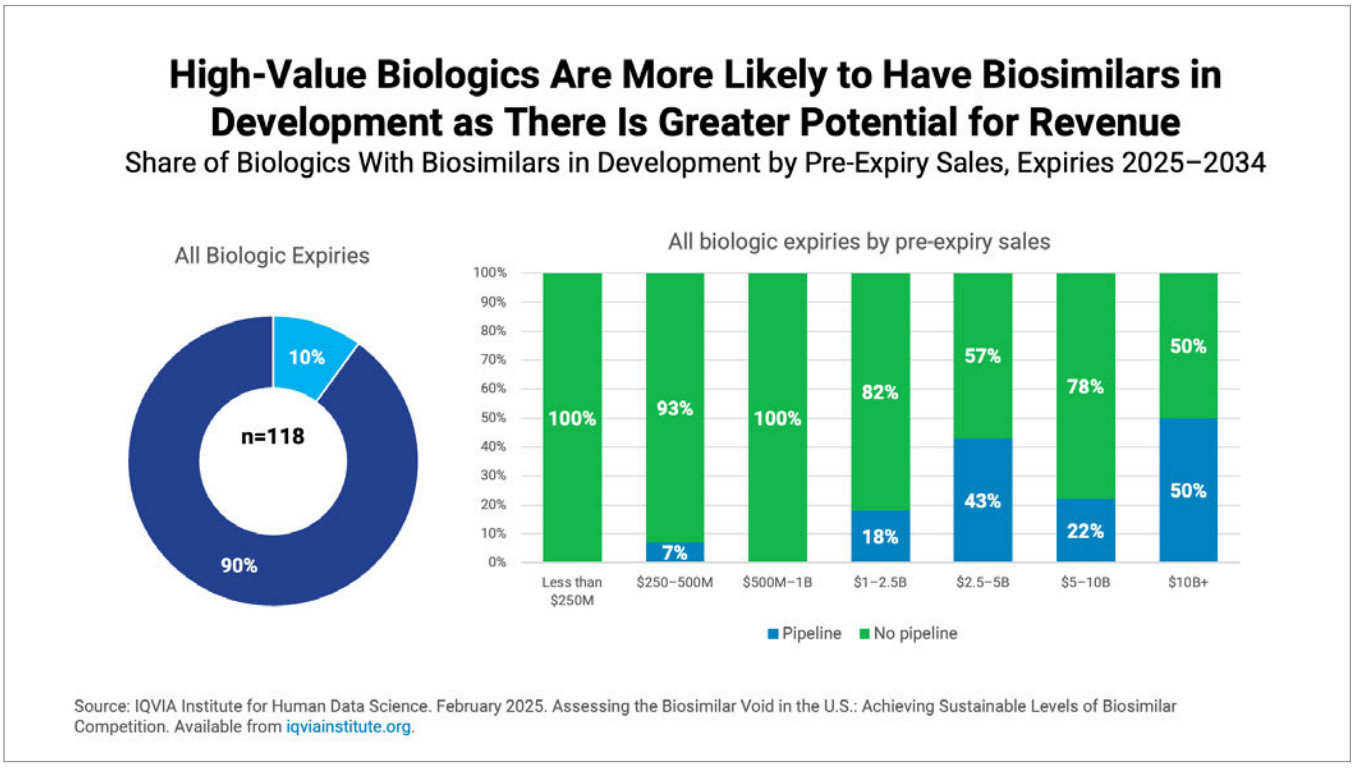
Source: IQVIA analysis of defined daily dose information and product volume.

- The increasing use and proven effectiveness of biosimilars should put to rest any questions about their safety and efficacy.
- Since the first biosimilar launched 10 years ago, biosimilars have been used in almost 3.3 billion days of patient therapy, with no meaningful differences in safety or clinical outcomes.
- Moreover, the overall use of molecules with biosimilar competition has increased. This means that more patients receive treatment when a biosimilar is available. Biosimilar competition has now supported more than 460 million incremental days of therapy – care that patients would not have otherwise received.
- 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.

Ex. 1065-035

Biosimilar Void

Few Brand Biologics Losing Patent Protection in the Next 10 Years Have Biosimilar Competition in Development

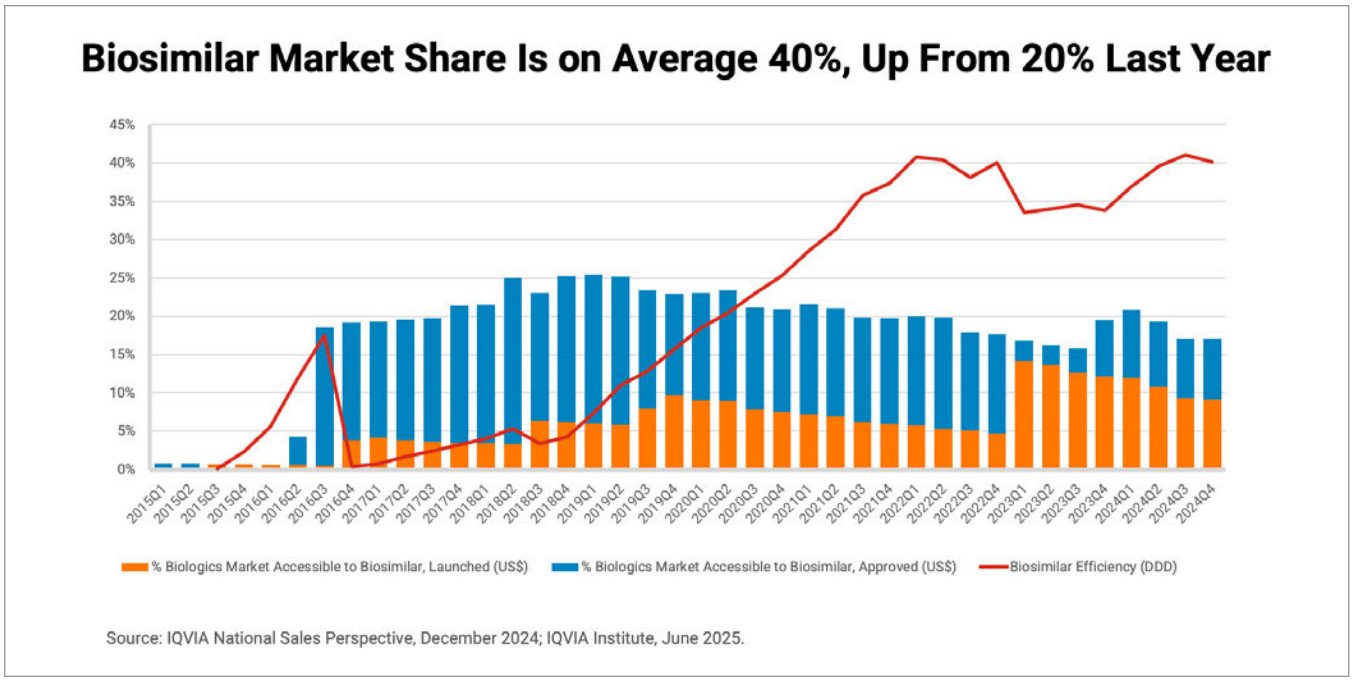


- The information above related to the U.S. biosimilar pipeline includes biosimilars in clinical development or approved but not yet launched.
- In examining all biological products that face patent expiration (between 2025 and 2034), only 10 percent of the 118 products are currently staged to face biosimilar competition.[25]
- The pipeline for biosimilars is most robust for products in which the pre-expiry biologic sales are over $1 billion per year.[25]

Ex. 1065-036

Although Improving, Biosimilar Adoption Remains Low

Although Improving, Biosimilar Market Share Remains Low

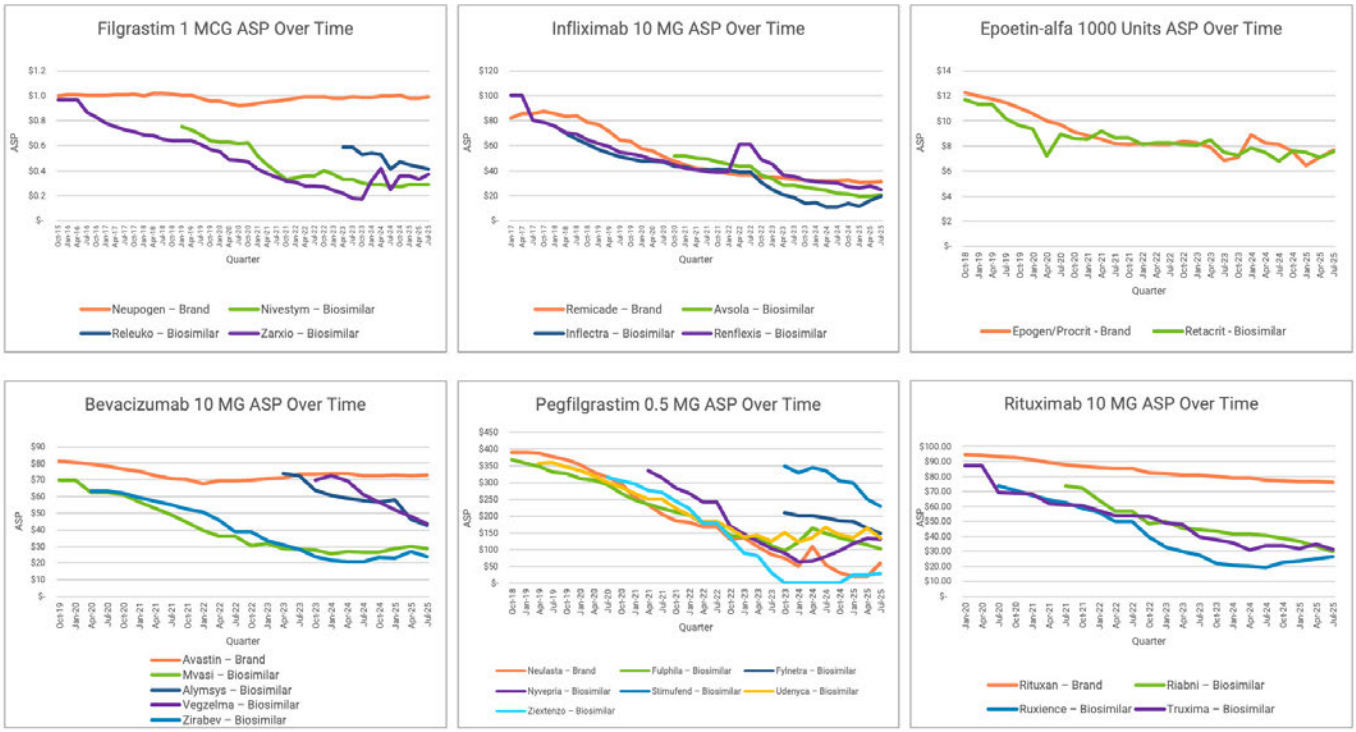


- The biosimilar efficiency rate, or the rate at which biosimilars are dispensed when available, is growing but remains too low. While biosimilars have gained a market share of over 80 percent in two therapeutic areas, the average market share for all biosimilars is approximately 40 percent.
- However, there is wide variation in biosimilar uptake, depending on the molecule. To date, three years after biosimilar entry, biosimilars have 24 percent of the volume in days of therapy for molecules, ranging from 8 percent for insulin lispro to 82 percent for bevacizumab.[8]
- Biosimilars for adalimumab (Humira) have achieved 21 percent of volume as of the end of 2024, up from 2 percent at the end of 2023, as insurer and pharmacy contracts with biosimilar makers have encouraged greater uptake.[8]
- The biosimilars for ranibizumab (Lucentis) accelerated after a slow start to 59 percent by 22 months but have slowed to 46 percent as of the end of 2024 as overall molecule usage has declined.[8]
- Some of the biosimilars with lower uptake in their first three years have seen increased adoption later, while some have had rapid early adoption. The range of uptake patterns reinforces the degree of uncertainty for biosimilar makers, purchasers and policymakers in this area.[8]
- A sustainable biosimilars market is one that supports rapid adoption by multiple competitors. 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 hamper future development.

Ex. 1065-037

Biosimilars Launch at a Discount and Continue to Decrease Their Prices

Biosimilars Also Drive Down Brand Drug Prices



- Robust biosimilar price competition results in lower prices. Today, the average sales price (ASP) of a biosimilar is approximately 40 percent lower than the brand biologic price (within three years of launch).[22]

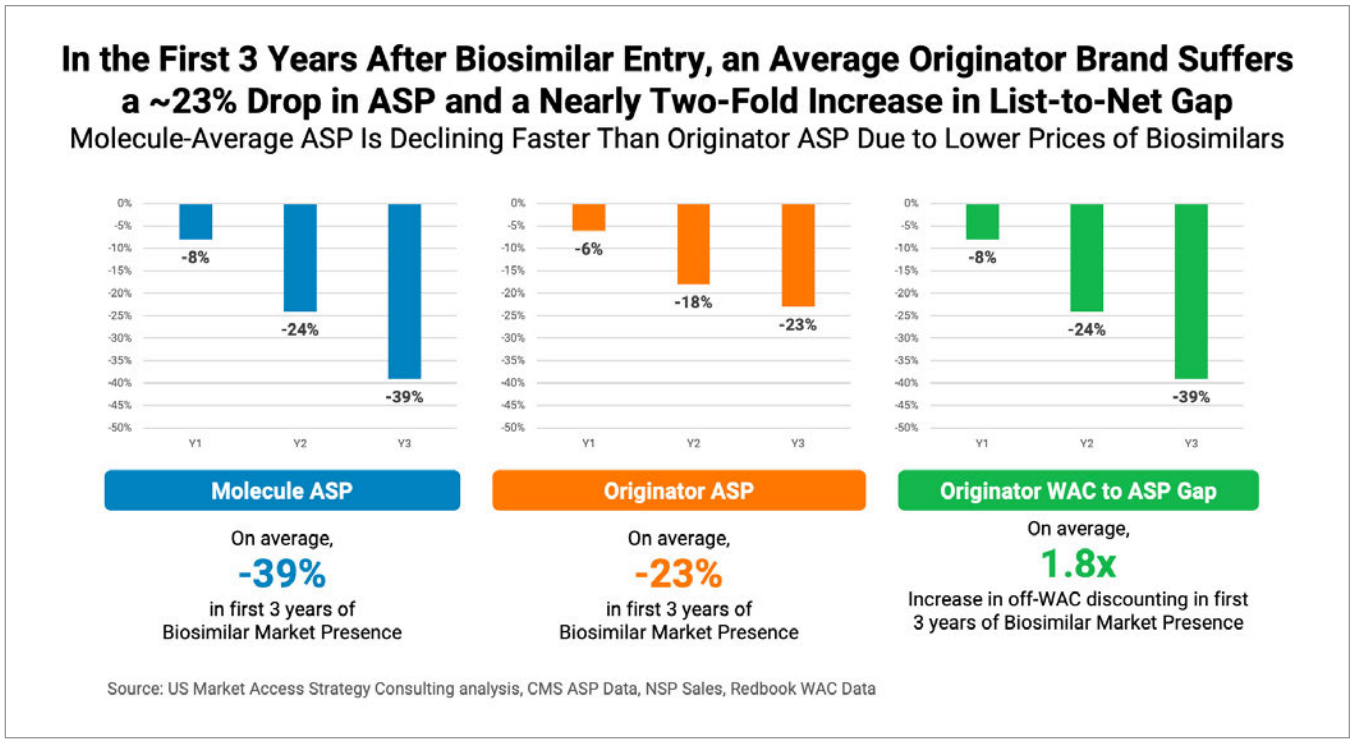
- Biosimilar competition also lowers the ASP on brand biologics – on average, three years after biosimilar market entry, the ASP decreases 23 percent.[22]

- Declines are driven by two key factors: reductions in provider acquisition costs and rebates to payers. Thus, despite not receiving any payer rebates, providers are paid based on an ASP that takes into account rebates the manufacturer provides to the payer. This has led to providers being "underwater" – being paid by Medicare less than the acquisition cost of the biosimilar.

- Similarly, biosimilar manufacturers may be "underwater." Recently, as part of the rulemaking process, CMS highlighted that several biosimilars had a zero or negative ASP (e.g., Ziextenzo).

Ex. 1065-038

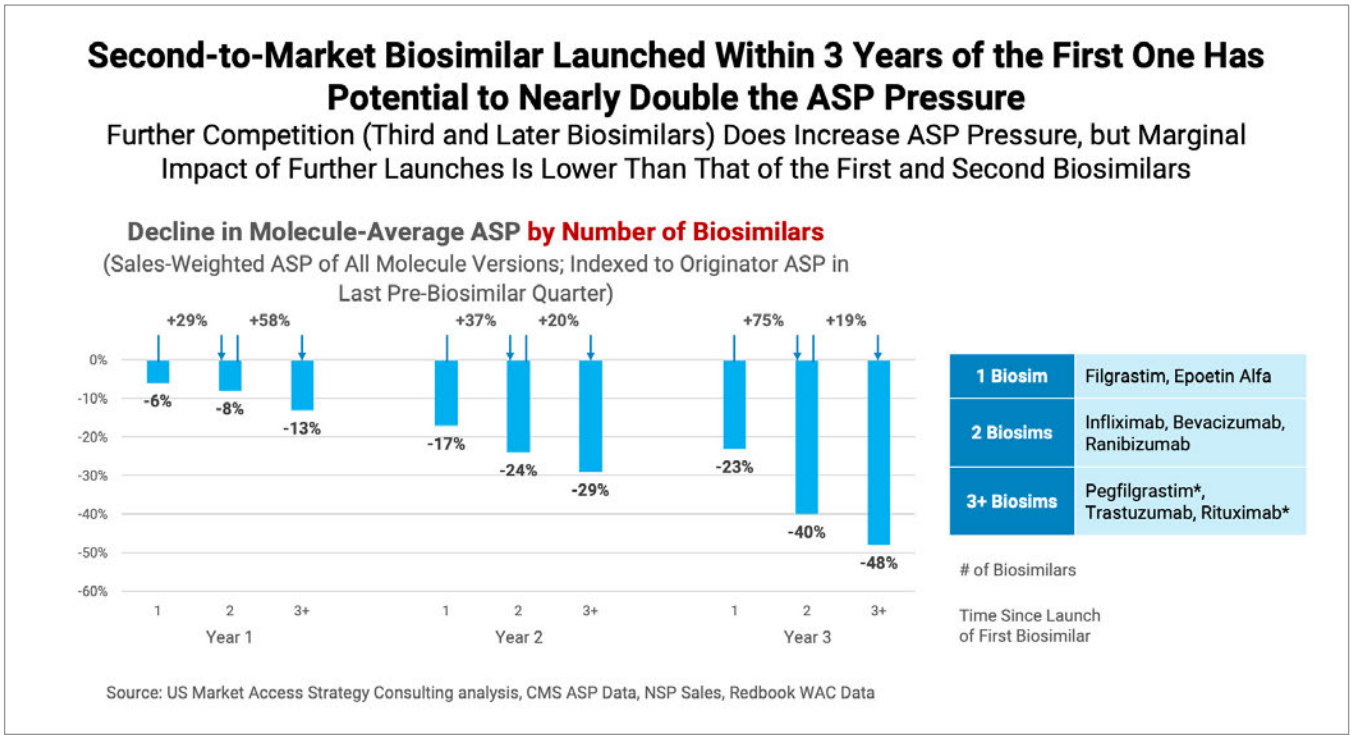
Biosimilar Competition Can Lead to a "Race to the Bottom"



- When the ASP reimbursement model was first enacted in 2005, there were no biosimilars on the U.S. market. Since biosimilars launched in 2015, it has become clear that ASP-based reimbursement was not designed for markets where there is price deflation. Under ASP + six percent (or + eight percent for certain biosimilars), providers are reimbursed based on a drug's reported average sales price, plus a fixed percentage of the reference product. The current system rewards drugs with higher reimbursement rates, regardless of cost-effectiveness.[28] This is because a reference biologic with a higher ASP generates a larger add-on payment than a cheaper biosimilar, incentivizing providers to prefer high-cost brands, even if biosimilars are available.
- Adding to this dysfunction, biosimilar manufacturers are often forced to offer substantial rebates to gain favorable formulary placement for their products. These rebates are factored into the sales price of the medication, driving ASPs downward. However, the acquisition cost for the drug does not always reflect these reductions, resulting in physicians being reimbursed far less than it cost them to acquire the biosimilar. This leads to providers being "underwater," serving as a disincentive for biosimilar use altogether.[29]
- According to a recent analysis by IQVIA,[22] on average, across all products in biosimilar markets, ASP is shown to decline by:
  - eight percent during the first-year post-biosimilar launch;
  - 24 percent during the second-year post-biosimilar launch; and
  - 39 percent in the third-year post-biosimilar launch.
- Not only does the launch of biosimilars put pressure on the overall molecule pricing, but three years after the launch of a biosimilar, the originator ASP declines by an average of 23 percent.

Biosimilar Competition Results in Savings After Only Two Biosimilars

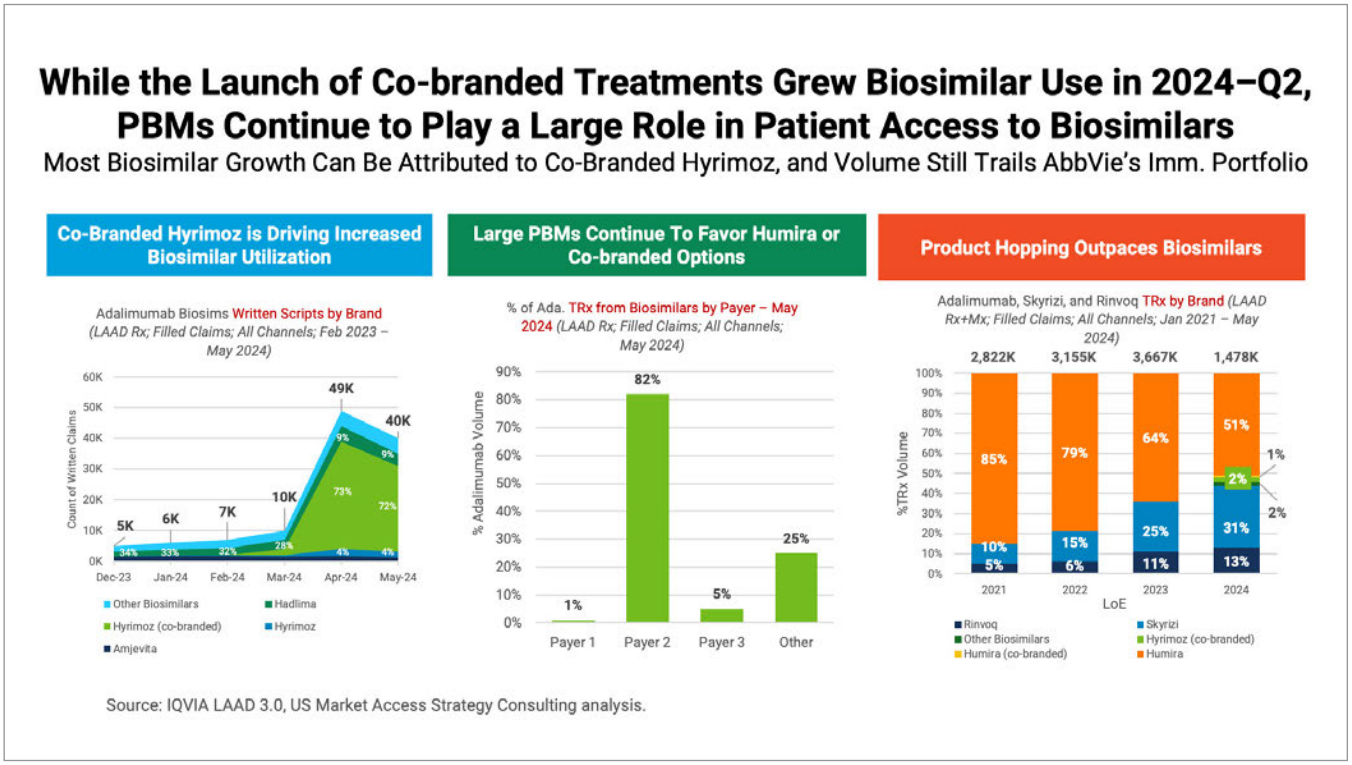
Biosimilar Competition Can Lead to a "Race to the Bottom"Second-to-market biosimilar launched within 3 years of the first one has potential to nearly double the ASP pressure



- Biosimilar competition results in patient savings after only two biosimilars enter the market. A recent IQVIA analysis found that more biosimilar competition equals lower ASP, or more savings, across the market. A second-to-market biosimilar launched within three years of the first can nearly double the ASP pressure, accelerating price erosion for all treatments.[22]
- Finally, IQVIA found that newer biosimilars are driving steeper ASP declines – markets where biosimilars launched in 2018 or later saw a 45 percent ASP drop by year three, compared to just 22 percent for those launched from 2016 - 2017. (Data not shown.)
- What does this mean? The more biosimilars in a therapeutic class – and the sooner they arrive – the faster prices fall. But while the market is doing its job, the reimbursement system is not. Instead of encouraging price competition, the current ASP-based model penalizes it, creating barriers to biosimilar uptake for both manufacturers and providers.
- It's time for policymakers to update our biosimilar reimbursement system to align with today's market realities. A healthy system rewards providers for using lower-cost therapies, instead of punishing them with financial losses. It also increases transparency in pricing and rebate structures, particularly around PBM practices. And further, it should encourage sustainable biosimilar development by creating predictable and logical market incentives.

Ex. 1065-040

PBM Strategy, "Product Hopping," Suppressing Uptake of Lower-Cost Biosimilars



- Despite price discounts of greater than 80 percent, initial adoption of biosimilars to Humira has been incredibly slow.
- In their first year on the market, biosimilars to Humira 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 the biosimilar.
- Nonetheless, large PBMs continue to prefer the high-priced brands over biosimilars.
- As noted in the third chart above, major PBMs have partnered with a brand company to shift more patients to newer, higher-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 one.

Ex. 1065-041

AAM Priorities

Ex. 1065-042

Helping America's Patients Thrive

The Advocacy Plan to Safeguard Affordable Generic and Biosimilar Medicines

America's patients are facing an urgent challenge that could jeopardize access to life-saving, affordable medicines. Generics and biosimilars—cornerstones of the U.S. healthcare system—have provided a reliable safety net for millions of Americans, ensuring access to vital therapies at the lowest possible cost. Yet, a perfect storm of regulatory hurdles, patent abuses, and flawed policies threatens the very foundation of this system, putting patients' health and financial stability at risk.

Generics and biosimilars are essential to the healthcare infrastructure. These medicines account for 90 percent of prescriptions dispensed in the U.S. but only 12 percent of total drug spending. Over the past decade, their widespread adoption has saved the healthcare system an astounding $3.4 trillion. This success is not just an economic achievement; it is a lifeline for patients who depend on affordable medicines to manage chronic conditions, treat serious illnesses, and maintain their quality of life.

But this success story is now in jeopardy. The overall value of generic sales in the U.S. has declined by $6.4 billion since 2019, despite increased utilization and new product launches. This decline isn't due to a lack of need—patients continue to rely on lower-cost medicines in greater numbers—but rather to systemic barriers that threaten the long-term sustainability of affordable access.

At the root of this crisis are a series of obstacles:

- **Regulatory Barriers:** Outdated and unnecessary FDA requirements delay the development and approval of lower-cost generics and biosimilars. For example, current biosimilar application requirements, including redundant clinical efficacy studies, impose excessive burdens that discourage competition and innovation.

- **Patent Abuse:** Brand drug manufacturers exploit the patent system to extend monopolies well beyond the original patent term, creating "patent thickets" that block generic and biosimilar competition. These anticompetitive tactics keep drug prices high and delay patient access to affordable alternatives.

- **Flawed Policies:** Flawed policies distort the market and directly harm patients, forcing them to pay more for the medicines they need.
  - Medicare policies and practices by pharmacy benefit managers (PBMs) often reward the use of higher-priced brand drugs over lower-cost generics and biosimilars.
  - Medicaid policies penalize generic products with unpredictable rebates even when there are no price increases.
  - IRA price controls remove predictability needed to support investment in developing new generic and biosimilar products.

- **Overall Sustainability:** Due to a lack of adequate reimbursement, generic medicines are increasingly at risk of shortages. Without systemic reforms to stabilize and incentivize the generic drug supply chain, patients may go without treatment.

If these challenges are not addressed, the consequences will be devastating. America's patients will lose access to reliable, low-cost therapies. Taxpayers will bear a greater burden, as healthcare costs soar. The very principles of

Ex. 1065-043

competition and innovation that have driven the success of generics and biosimilars will be eroded.

Protecting Access: A Call to Action

If policymakers are serious about protecting patients and ensuring sustainable access to affordable medicines, they must act decisively to address these systemic threats. This requires a comprehensive plan, including:

- **Streamline FDA Processes:** Ensuring quicker approvals, while maintaining FDA's high standard of safety, efficacy, and quality, will increase competition and lower prices. Policymakers should eliminate unnecessary FDA regulatory barriers that delay the approval of generic and biosimilar medicines, including through:
  - Streamlining FDA's approval process including the ability to utilize a global comparator, and removing redundant clinical studies;
  - Passing legislation directing disclosure of the qualitative and quantitative differences (Q1/Q2) between generics and brands;
  - Updating the Biologics Price Innovation and Competition Act (BPCIA) to deem all biosimilars interchangeable; and,
  - Restoring the Hatch-Waxman safe harbor for "skinny labeling."
- **Curb Patent Abuse:** Congress must stop the misuse of the patent system by limiting the number of patents brand manufacturers can assert, safeguarding the ability to enter into procompetitive patent settlements, and preventing anticompetitive practices that delay patient access to generics and biosimilars.
- **Stop PBMs and Medicare Policies from denying patients access to new generics and biosimilars:** Medicare and PBMs must stop prioritizing higher-priced brand drugs over generics and biosimilars. Congress and the Administration should ensure patient access to new generic and biosimilar medicines and reform PBM practices by encouraging PBM transparency and eliminating PBM profits from linking their fees to the drug list price (i.e., delinking).
- **Promote State Policies to Ensure Coverage and Use of Generics and Biosimilars:** Despite years of demonstrated savings and price deflation, PBMs continue to make coverage, formulary, and utilization management decisions that require patients to pay more for their medications, even as the prices of a vast number of generic drugs and biosimilars have fallen.
  - States should address PBM coverage practices that increase patient costs for lower-cost medicines. Simple formulary reforms that place lower-cost generic drugs and biosimilars on existing generic and preferred product tiers can level the playing field by prioritizing coverage decisions and nudging health plans and PBMs toward patient-centric choices.
  - Legislation aimed at changing formulary plans and design should not make a distinction between biosimilars based on an interchangeable designation. Like generic drugs, all biosimilars should be exempted from legislation limiting mid-year switching and step therapy.
- **Rollback Harmful Federal Policies:** Too many federal policies actively harm generic and biosimilar competition.
  - Congress should remove the Medicaid Generics Penalty and update Medicaid Inflation Penalties on generics to align with those included in the IRA.
  - Because generics and biosimilars save far more than arbitrary price controls, policymakers should ensure that the IRA price controls do not harm generic and

Ex. 1065-044

biosimilar competition by refining and extending the biosimilar delay request, ending the unfounded and unclear "bona fide marketing" standard, and addressing the IRA biosimilar and generic "valley of death."

The stakes are high, and the solutions are clear: failing to act will mean higher costs, less access, and fewer options for America's patients. Generic and biosimilar medicines are more than a healthcare innovation; they are a means for millions of Americans to thrive – physically, mentally and financially. Policymakers must move swiftly to protect this system and ensure patients are not forced to choose between their health and financial security.

This is not just about dollars and cents—it is about survival. Let's ensure the promise of affordable, life-saving medicines remains a reality for all Americans.

Ex. 1065-045

Conclusion

Generic medicines continue to provide value to patients, taxpayers, employers, and the U.S. healthcare system.

At the same time, biosimilars are increasingly delivering on their promise of lower prices and additional therapy days for patients.

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

Unfortunately, the continued savings achieved through the use of lower-cost generics and biosimilars is not guaranteed – and the threats to these fragile industries should not be overlooked. The long-term outlook for generic and biosimilar competition hinges on addressing the barriers to development and adoption and, ultimately, the sustainability of this vital industry. Without action to strengthen the generic and biosimilars markets, many of these lower-cost medicines may disappear, and the livelihood of patients across the U.S. will suffer.

Ex. 1065-046

Methodology

Generic drug savings in the United States: Fourteenth 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 1,319 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 1,319 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 2024, focusing on the 10-year savings for the period 2015 to 2024. Savings from generics launched in the 1992 to 2024 study period are based on the most current knowledge of their pre-expiry prices. Savings from generics launched prior to 1992 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. Generic savings includes all non-original product savings and is inclusive of biosimilar savings.

Slide 3–57 include all the non-original product savings i.e. inclusive of any biosimilar savings.

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

Ex. 1065-047

based on the number of prescriptions filled by patients of each pay type.

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. 60 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.

Ex. 1065-048

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