aam
Association for Accessible Medicines

2026 U.S. Generic & Biosimilar Medicines Savings Report

FORWARD FOR AMERICA

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Note: Terms in **bold and blue** are included in the Glossary.

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.

Letter From the President and CEO

Generics are a cornerstone of economic and health resilience in the U.S.

In the past decade, the generics and biosimilars industry saved U.S. patients and taxpayers a combined $3.6 trillion. These savings are astounding, and there's absolutely no denying that generic and biosimilar medicines are one of the greatest success stories of the entire U.S. healthcare ecosystem. But our job, both in Washington and throughout all 50 states, is to keep that success story alive. Because the exact market conditions that make lower-cost medicines healthcare heroes also threaten their collective ability to survive. Our 2026 Savings Report clearly spells it out: unless policymakers take purposeful, proactive steps to roll back the risks and threats to the generic and biosimilar medicines industry, America faces the potential of losing the backbone of affordable healthcare, putting the stability of the industry at risk, the resiliency of communities in limbo, and the security of our nation more prone to a devastating breach.

Affordable Prescription Options in Peril

The very forces that make generic and biosimilar medicines so affordable are now destabilizing the market. Without intervention, the U.S. is at risk for supply chain disruptions, including drug shortages, or worse, U.S. market exit.

The truth is that generic medications are the only part of the U.S. healthcare system faced with annual deflation, which has averaged 7.7% in the last 5 years. For comparison, overall medical inflation was an average of 6.2% during that same period—nearly a 14 percentage point difference. Since 2019, the value of generic sales has declined by $6.4 billion, even as volumes and launches increased. In 2016, generics represented 27% of prescription spending; today, they represent just 12%. Thirty years ago, generic prices stabilized at roughly one-third of brand costs. Today they bottom out at barely one-fifth. This is structural deflation, a silent but powerful force eroding the sustainability of the system. If paired with medical inflation, this erosion could cause the generic and biosimilar medicines industry to vanish.

Beyond Savings: Delivering Sustained Value

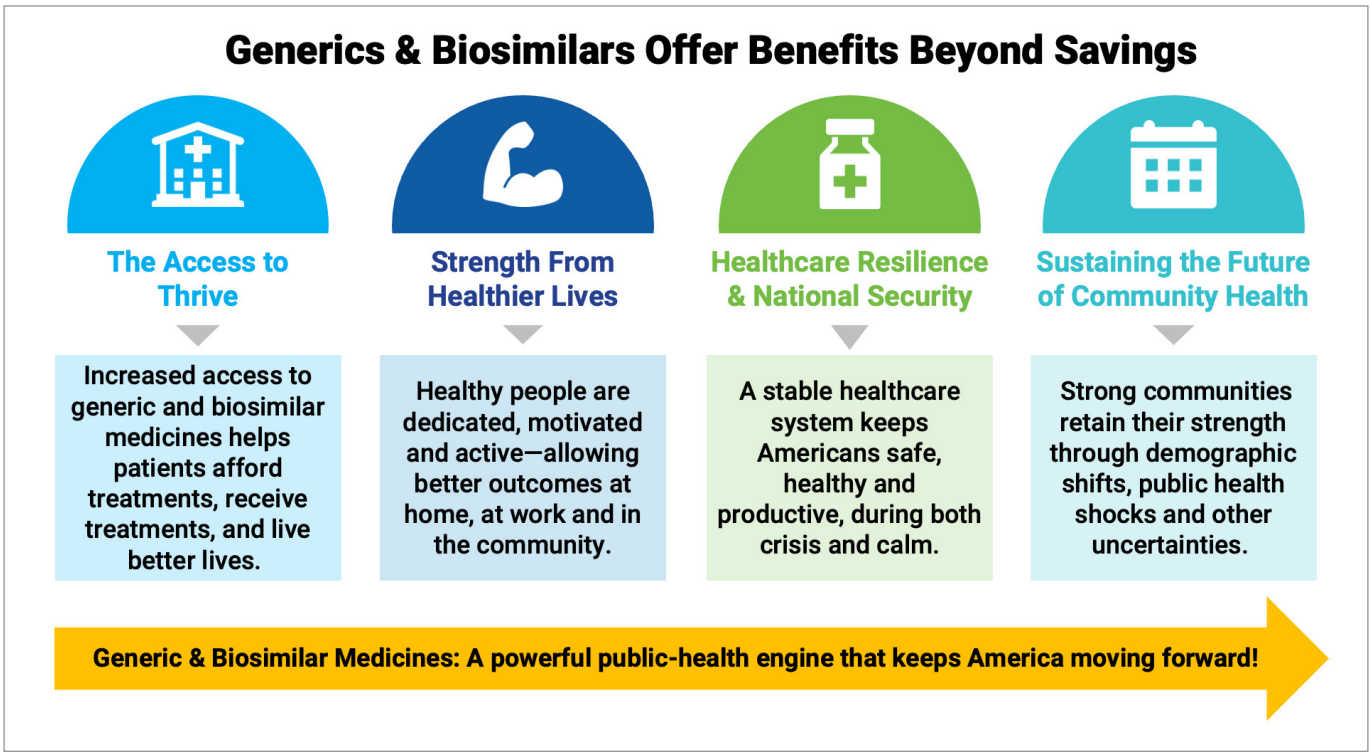
Generic and biosimilar medicines are not merely a vehicle for savings. Our industry is a public-health engine that keeps America moving forward by infusing strength and stability into communities. That strength and stability allow for greater productivity and economic resiliency—because when Americans feel well, they can work and live well, too.

As the healthcare ecosystem faces demographic shifts, there is also more potential for economic uncertainty and public health shocks. With these changes, we cannot ignore the role of generic and biosimilar medicines as a pillar of community strength. Our industry makes access to effective treatments a reality for patients; but also, through its value, supports the long-term sustainability and resilience of our healthcare system and our country at large.

Making Onshoring a Reality

Domestic manufacturing is an important component of U.S. national security and supply chain resilience. Incentivizing the **onshoring** and **friendshoring** of generic medicines' manufacturing will directly correlate to a stronger and safer America. From critical starting materials—including **active pharmaceutical ingredients** (API), **excipients**, and **key starting materials** (KSM)—to **finished dosage forms**, domestic manufacturing capacity offers significant opportunities to strengthen the U.S. pharmaceutical supply chain and support the complex ecosystem of drug production.

Alongside our member companies, I wholeheartedly welcome the opportunity to explore policies and partnerships, at both the federal and state levels, in support of expanded domestic manufacturing and U.S. job creation. Onshoring pharmaceutical manufacturing presents a significant opportunity to advance national, state, and public



health security, while reducing the risk of supply chain disruptions. This opportunity does not come without risks, however, and moving the distinct generic and biosimilar medicines industry forward and achieving full onshoring requires fair and significant investment across several key areas and coordinated, long-term support from policymakers, regulators, industry advocates, and the Administration.

Generics Forward for America

We know generic and biosimilar medicines are indispensable—the $496 billion in savings in 2025 alone underscores this point. But the market that sustains our industry is at risk. The fix for America's patients is not complicated, provided that generics and biosimilars are treated as a unique economic engine capable of driving affordable healthcare. While prices for brand drugs continue to climb along with their monopolies over patient access in many complex therapeutic areas, the total amount Americans spent on generic and biosimilar medicines in 2025 adds up to only 1.1% of all healthcare spending.

In the U.S., we must adopt a generics-and-biosimilars-first policy framework. Policymakers must streamline FDA processes, curb patent abuse, stop **pharmacy benefit managers** (PBMs) and Medicare policies from favoring higher-priced brands, and roll back harmful federal policies such as Inflation Reduction Act (IRA) price controls that impede generic and biosimilar competition.

Today, I am not calling for special treatment—though clearly our industry is distinct from the brand-drug giants. Today, I am calling on relevant stakeholders to move generic and biosimilar medicines into the future by removing the structural obstacles that prevent healthy, American competition from functioning the way it was designed to function. With the removal of these obstacles, ***we can move generic and biosimilar medicines forward***, bringing more affordable prescription options to the patients who rely on them to feel well and thrive.

John Murphy III
President and CEO, AAM

Letter from Biosimilars Council Executive Director

The road for biosimilars in America is getting less bumpy, but it isn't a smooth ride yet, especially as unfair policy and regulatory roadblocks persist. Here's the bottom line for Americans: every one of these roadblocks forces tough choices by the manufacturers of lower-cost treatment options, and these choices do more than just impact patient care. They have the dangerous potential to dictate if that care is even accessible for patients.

Progress Loading

We cannot overlook the success our industry welcomed in 2025. From July 2025 until July 2026, 15 biosimilars have launched against 9 reference products. As of July 2026, the FDA has licensed 88 biosimilars for 21 reference products, with 65 already reaching patients and contributing to more than 3.8 billion days of safe, effective therapy. Competition is expanding access—enabling 571 million additional days of treatment in 2025 that would not have been possible without biosimilars. This is positive momentum and helps real patients receive effective and affordable care.

Significant progress was seen in the review and approval of biosimilar drugs. The FDA's updated guidance on comparative efficacy studies to establish biosimilarity and other important reforms are expected to increase speed to market for lower-cost biosimilar medicines that treat cancer, rheumatoid arthritis, and a broad spectrum of other illnesses. This progress must continue.

The *Biosimilar Red Tape Elimination Act* removes the arbitrary and unscientific distinction between biosimilars and interchangeable biologics. This legislation is consistent with the FDA's recommendation on this issue, as there is no clinically meaningful difference between biosimilars and interchangeable biosimilars. In fact, the U.S. is the only country in the world with this unnecessary designation.

Despite recent wins in overall savings, streamlining, and interchangeability, the U.S. biosimilars industry continues to face challenges such as IRA price negotiation, dysfunctional pricing dynamics, and PBM distortions. And in the U.S., biosimilars manufacturers face more patent challenges than in other countries. These headwinds severely cut down the quantity of affordable treatment options for patients deciding whether to pay rent, buy groceries, or seek medical care.

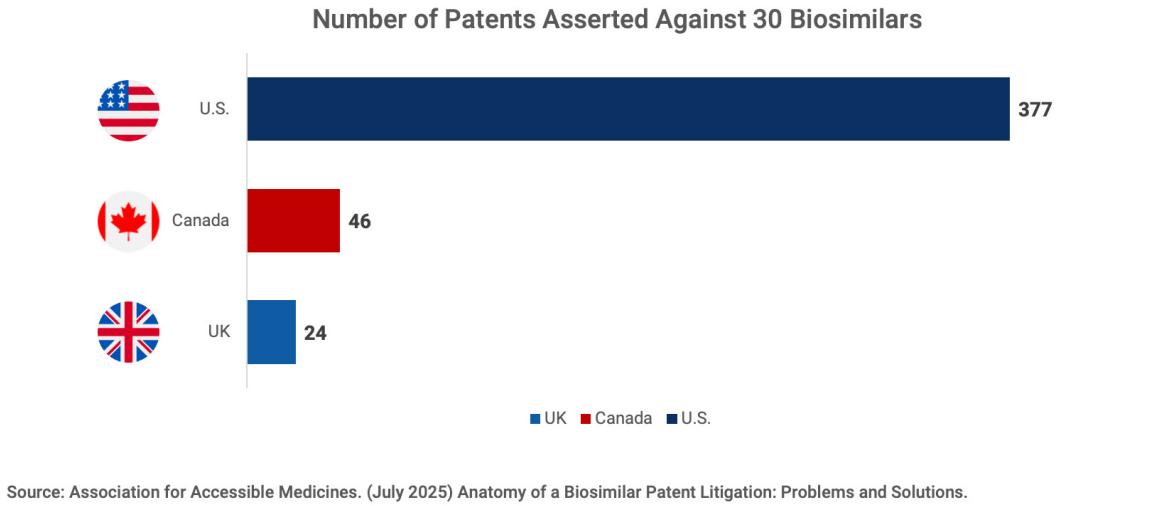
The U.S. Lags Behind

The U.S. biosimilars landscape is being held back by an unprecedented volume of patent litigation—often more than 10 times the number of patents asserted in countries like Canada and the U.K.—creating delays that directly restrict patient access and drive higher costs for families and taxpayers. Excessive patent thickets are slowing competition, inflating spending, and denying Americans timely access to lower-cost, life-changing therapies. Insulin aspart, Enbrel, Stelara, Opdivo, and Humira biosimilars launched years earlier in Europe, Canada, and India, delivering steep price reductions, rapid uptake, and billions in savings. All the while, U.S. patients waited.

Congress must stop the misuse of the patent system by limiting the number of patents brand-name manufacturers can assert, safeguarding the ability to enter into pro-competitive patent settlements, and preventing anticompetitive practices that delay access to generic and biosimilar medicines.

The Void Remains

Biosimilars often enter a marketplace where success is determined not by clinical value or lower cost, but by



Source: Association for Accessible Medicines. (July 2025) Anatomy of a Biosimilar Patent Litigation: Problems and Solutions.

opaque contracting practices, rebate-driven incentives, and formularies that favor higher-cost reference products. These dynamics undermine competition, limit patient access to lower-cost treatment options, and weaken the business cases for future biosimilars investment.

Because of this, a significant "biosimilar void" remains in our country, with 90% of brand biologics lacking a biosimilar in development for molecules losing exclusivity in the next 10 years. This void directly correlates with a substantial loss of economic potential—a $189 billion lost opportunity for total healthcare savings in just the next decade.

At this moment, biosimilar medicines represent one of the most powerful tools we have to expand access, strengthen healthcare resilience, and unlock meaningful savings—without compromising safety, efficacy, or innovation. By building on recent regulatory progress and addressing persistent barriers to market access and adoption, we can unlock the next generation of biosimilars competition and deliver even greater value for patients.

A supportive policy environment is rapid, transparent, and predictable. It reduces risk for manufacturers and encourages market entry. Ultimately, a supportive policy environment drives affordable access and frees up investments into the next wave of innovation.

I am thrilled about the progress and wins we saw in the biosimilars landscape last year. But realizing the full promise of biosimilars requires more. It demands an environment where key stakeholders, including policy and regulatory leaders, all work together to ensure the biosimilars industry can thrive, and America's patients can live healthier lives.

Alex Keeton
Executive Director, Biosimilars Council

Overall Savings Generated by Generics & Biosimilars

Key Advocacy Takeaways

Brand Drugs Drive Costs. Generics Drive Savings.

Generic Medicines

89%

Rx Drugs Filled
4B

Brand Drugs

11%

Rx Drugs Filled
485M

11.6%

Rx Drugs Spending
$106B

88.4%

Rx Drugs Spending
$804B

Total Savings from Generics & Biosimilars

- Total generic and biosimilar savings in 2025: **$496 billion**
- Total generic and biosimilar savings for the past ten years: **$3.6 trillion**
- Generic share of total U.S. prescriptions filled: **89%**
- Generic share of total U.S. prescription drug spending: **11.6%**
- Generic share of total U.S. healthcare spending: **1.1%**
- Total generic savings in Medicare in 2025: **$166 billion ($3,011 per beneficiary)**
- Total generic savings in Medicaid in 2025: $**70.2 billion ($921 per enrollee)**

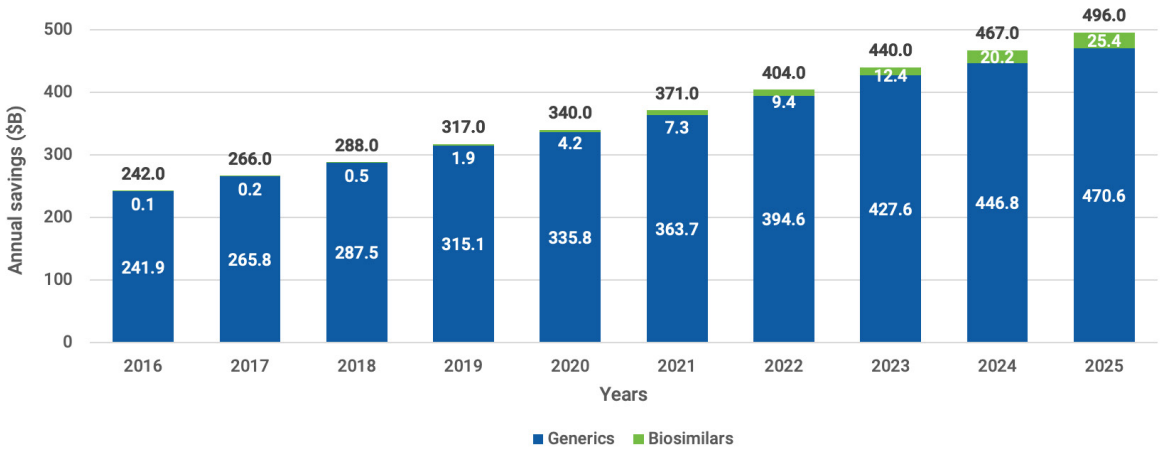
Biosimilars Savings

- Savings in 2025: **$25.4 billion**
- Total savings since first biosimilar entry in 2015: **$81.6 billion**
- Total days of patient therapy since 2015: **3.8 billion**
- Incremental days of patient therapy that would not have occurred without biosimilar competition: **571 million**

Savings From Generic & Biosimilars Totaled $496 Billion in 2025

Generic & Biosimilar Savings Increased by ~$30 Billion from Previous Year

In 2025, 89% of Prescriptions Were Dispensed as Generics or Biosimilars

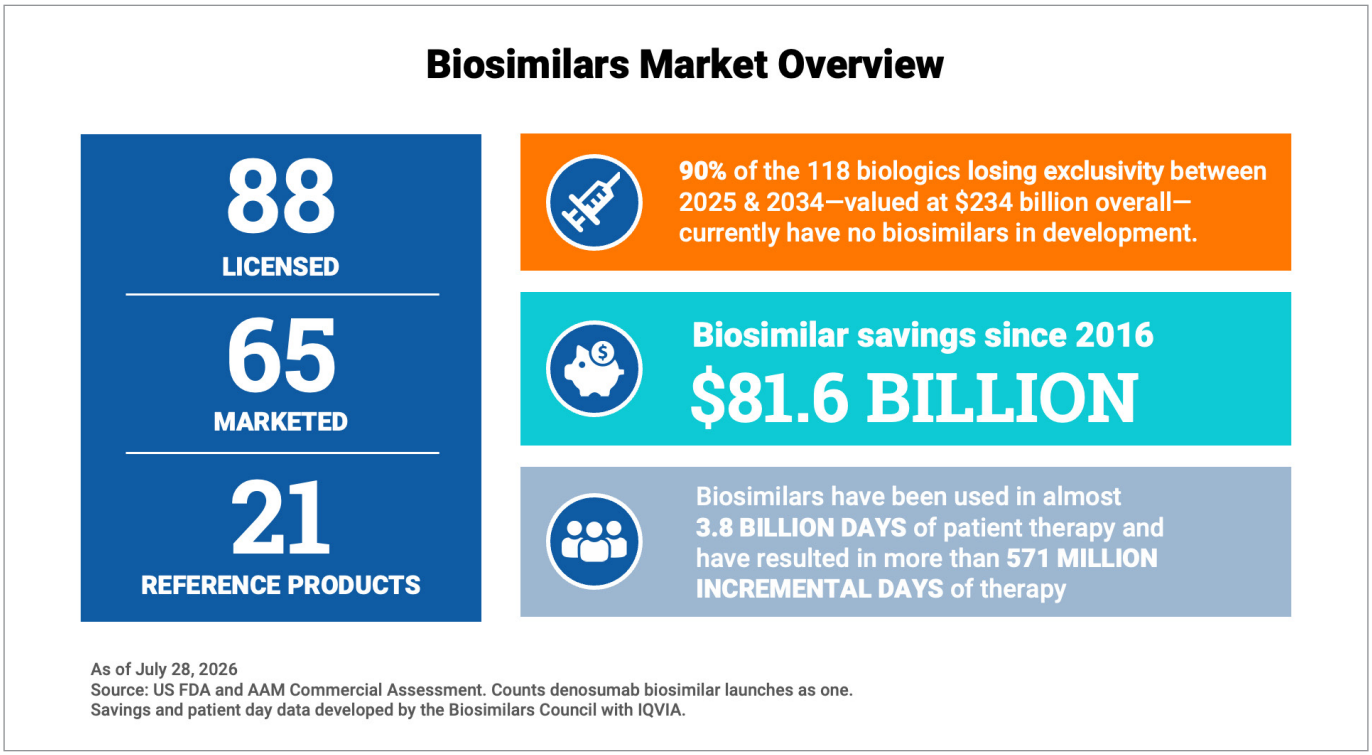


Source: IQVIA National Sales Perspectives, December 2025; IQVIA Institute, June 2026.

- 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 **licensed** by the Food and Drug Administration (FDA) as being highly similar to, and with **no clinically meaningful differences** from, an existing FDA-licensed biologic.
- Once the price of a biologic drug decreases due to competition between the reference product and its biosimilar, more patients can afford the drug. As such, patients have received nearly 571 million more days of therapy than if no biosimilar was available. Put simply, biosimilars are making it possible for more patients to receive care, feel well, and thrive.
- Annual savings from generics and biosimilars totaled $496 billion in 2025, more than $25 billion of which comes from biosimilar medicines. The combined savings results in nearly a $30 billion increase compared to 2024.
- Such savings are consistent with patient sentiment. In a 2025 survey, 90% of patients noted that they would be happy if their doctor switched them to a less expensive medication, while a slightly lower percentage (85.5%) wanted prescribers to default to the lowest-cost option when clinically appropriate.[1]

Biosimilars are Delivering Savings and Expanding Patient Access

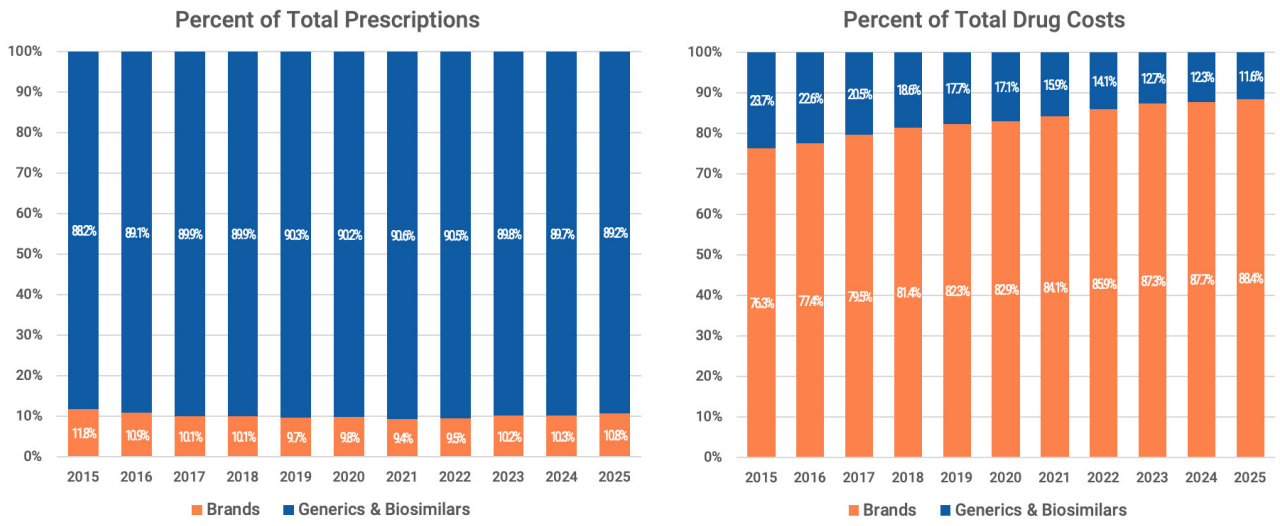
Still, a Biosimilar Void Remains, Hindering Patient Access



- The biosimilars market is rapidly growing. As of July 2026, the FDA has licensed 88 biosimilars for 21 reference products. Counting denosumab biosimilars as 1 launch, 65 biosimilar medicines are now available to patients.
- Biosimilars have been used in over 3.8 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 its biosimilar, more patients can afford the drug. As such, patients have received nearly 571 million **more days of therapy** than if no biosimilar was available. Put simply, biosimilars are making it possible for more patients to receive care, feel well, and thrive.
- More remains to be done. Biosimilar adoption has been slower than anticipated. 90% of brand biologics do not currently have a biosimilar in development, despite **losing exclusivity** (between 2025 and 2034).[2] This is often called the "**biosimilar void**."
- Policymakers must take action to reduce the cost of biosimilar development and ensure policy and regulatory conditions are in place for quicker adoption of these lower-priced medicines.

Volume & Value: 89% of All Prescriptions Filled, But Only 11.6% of Prescription Spending

Generic Prices Continue to Fall

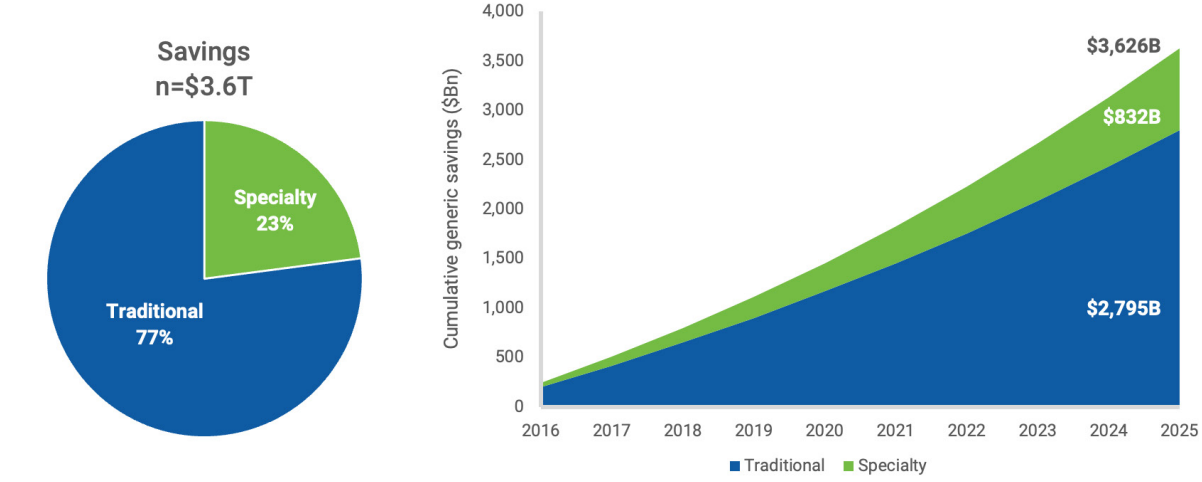


Source: IQVIA National Prescription Audit & National Sales Perspective, December 2025; IQVIA Institute, June 2026.

- In 2025, generics and biosimilars continued to demonstrate their value proposition—representing 89% of all prescriptions filled but only 11.6% of all prescription drug spending.
- Generic and biosimilar medicines are the only segment of healthcare that consistently delivers lower costs. In contrast to the broader drug market, generic prices continue to experience severe deflation. Since 2019, the overall value of all generic sales in the U.S. declined by $6.4 billion, despite increased volume and new generic launches.[3] This price deflation is a standout characteristic and expectation of the generic market.
- Generic drugs save patients money. In 2025, the average out-of-pocket cost for a generic was $6.67, while the average out-of-pocket cost for a brand drug was nearly 5 times higher at $33.58.[4]
- Similarly, biosimilars can save money for patients. 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 are decreasing across all pay types, reaching an average of $14.51 for a month's supply for all payers in 2025, compared to $28.09 in 2020.[5]

Vast Majority of the Generics & Biosimilars Savings is Attributable to Traditional Products

To Ensure Patients Receive Additional Savings, More Focus on Specialty Products (Including Biosimilars) is Necessary

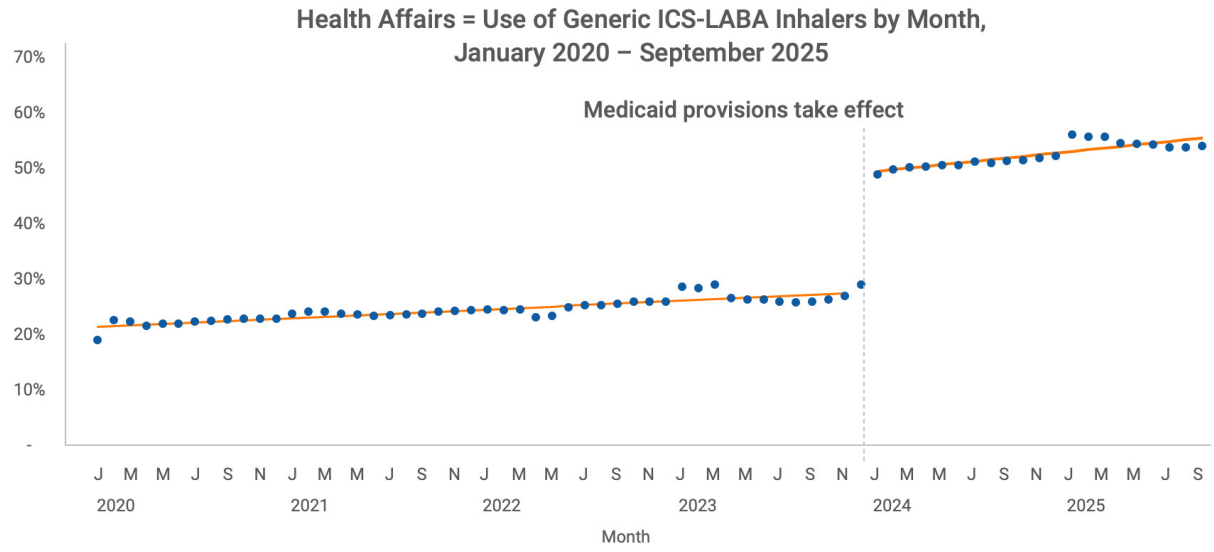


Source: IQVIA National Sales Perspective, December 2025; IQVIA Institute, July 2026.

- While generics and biosimilars have saved the healthcare system $3.6 trillion in the last decade, those savings are not uniform: the vast majority of savings are from older, **traditional generic products**, or small molecule generic products.
- While definitions of "specialty" products may vary, for this analysis, IQVIA defined a "**specialty drug**" as one that treats chronic, complex, or rare diseases and has a minimum of 4 out of 7 additional characteristics related to the distribution, care delivery, or cost of the medicine.
- As indicated above, specialty products (which often include biosimilars) are lagging in their savings potential, producing only 23% of the total savings.
- Even within the specialty category, there is a wide variation in access and utilization.
  - For 2025, specialty savings was concentrated in a particular care category — oncology (including **supportive care products**), generating $52 billion in savings, or 40% of the total.
  - Further, specialty savings in 2025 for only 2 products — ondansetron (an anti-nausea medication) and aripiprazole (an atypical antipsychotic) — generated 27% of specialty savings in 2025.

Patient Access Issues, Specific to Generics, Uncovered

Health Affairs Analysis Highlights Market Pressures Denying Patients Immediate Access to Lower-Cost Medications



Source: Han et al. (March 2026) List Price Reductions Among Brand-Name ICS-LABA Inhalers In 2024 Were Associated With Increased Generic Uptake. Health Affairs

- While definitions of "**specialty generics**" vary, the FDA notes that "**complex generics**" are products that have complex active ingredients, formulations, dosage forms, or routes of administration, or are complex drug-device combination products.[6] Unlike simple oral solids, the development costs for these products can be 10 times higher than the **traditional generic**.[7] From a payer perspective, these products are often much more expensive and, as such, patients would benefit from generic competition.

- Policymakers' efforts should not only focus on high-prevalence diseases (e.g., asthma and chronic obstructive pulmonary disease, or **COPD**) but also on low-prevalence, high patient cost products (such as those for thrombocytopenia and aplastic anemia).

- With respect to asthma and COPD, there are a variety of treatment options.[8] However, one prominent product for controlling the disease is inhaled corticosteroid–long-acting beta-agonist (ICS-LABA) inhalers. Five brand-name ICS-LABA products (e.g., Advair Diskus, Symbicort) are available, and they have faced generic competition since 2017.[9]

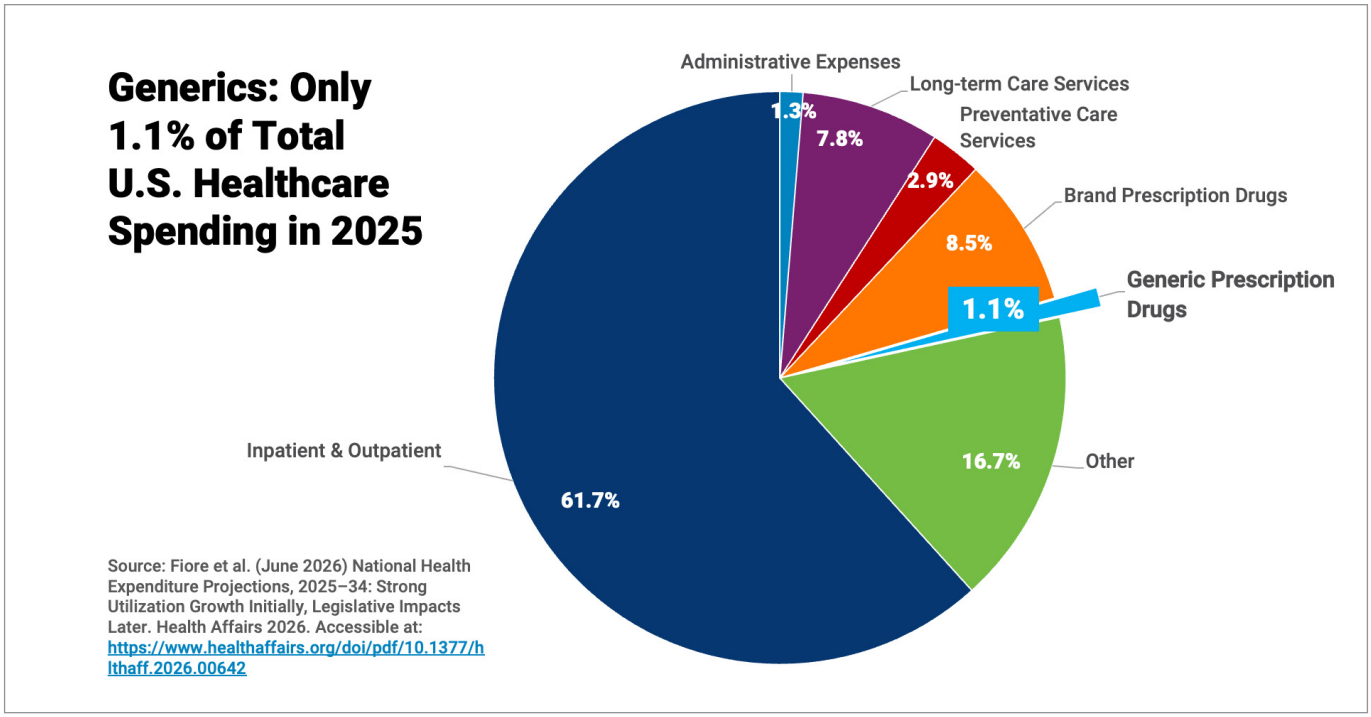
- A recent Health Affairs article examined issues with market access to generic versions of these inhalers. This analysis highlighted various market pressures, which can deny patients immediate access to lower-cost medications.
  - Prior to 2024, generic utilization was limited to about 22%, likely due to PBM practices, which favored the higher rebate brand products. Recent changes within the Medicaid Drug Rebate Program, which altered the calculations for

required discounts, resulted in several brand manufacturers decreasing their **list prices**. As a result, generic utilization increased by 23 percentage points at the start of 2024.[10] Thus, without additional market interventions, patients had delayed access to lower-cost alternatives. Even when there was access, it did not approach 90% uptake, as is common with traditional generics.

- Specialty products can cost the healthcare system thousands of dollars per month.
  - Promacta (eltrombopag) has had generic competition since May 2025. Before the launch of this generic, Promacta carried a significant cost burden, limiting its accessibility for some patients.[11] Generic competition has provided some relief. Recent AAM analysis found that the overall cost of the molecule has declined by 31% (from Q1 2025 to Q1 2026), while the generic uptake has increased to approximately 70%.
- To ensure patients have access to lower cost specialty products, policymakers should focus on big picture progress as well as product-specific guidance.

Generics & Biosimilars Account for Scarcely More than 1% of Total Spending on Healthcare

Generic & Biosimilar Medicines Provide Patient Access to Quality Care



- Within retail settings (given that some medications will also be counted within the inpatient and outpatient data), generic and biosimilar medications are a little over 1 of every 100 dollars spent on healthcare in the U.S.[12]

- The U.S. healthcare system has saved $3.6 trillion in the last 10 years due to the availability of affordable generic and biosimilar medicines. In 2025, competition from generics and biosimilars resulted in more than $496 billion in savings to the healthcare system.

- According to a recent report by IQVIA,[13] higher healthcare costs are "driven mostly by higher payments to hospitals and physicians, and administrative costs in the U.S." Moreover, 15% of healthcare spending in the U.S. is allocated to prescription medications, which is the average across similarly situated countries.[14]

- This percentage has held steady due to the existence of the generic and biosimilars market, which adds downward pressure on pricing. Other parts of the healthcare system do not typically have such downward pressure.[15]

- A recent JAMA Health Forum article examined why, despite hospitals being one of the primary cost drivers, prescription drugs were still top-of-mind for American consumers. The disconnect is due to several factors:(1) consumers are aware of retail drug prices but are confronted with opaque hospital pricing, and (2) more consumers utilize medicines compared to hospital care.[16]

Most Dispensed Generics of 2025 Saved $625 Billion from 2016–2025

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)**	**10-Year Savings ($Billion)**	**Percent Savings**	**2023 Volume Units Dispensed (Billion)**
Glucophage	2001	$0.66	$0.03	49	88%	84.4
Neurontin	2003	$1.02	$0.05	72.1	94%	75.6
Lipitor	2010	$3.29	$0.06	202.1	98%	63.1
Toprol XI	1993	$0.41	$0.05	19.1	82%	57.1
Norvasc	2006	$1.54	$0.02	73.3	99%	48.2
Zestril	1998	$0.67	$0.03	30.5	96%	45.8
Vicodin	1993	$0.27	$0.13	6.3	55%	47.6
Prilosec	2001	$3.31	$0.06	117.7	98%	36.3
Cozaar	2009	$1.51	$0.05	51.1	96%	35.3
Diprivan	1998	$0.52	$0.08	4.1	78%	28.8

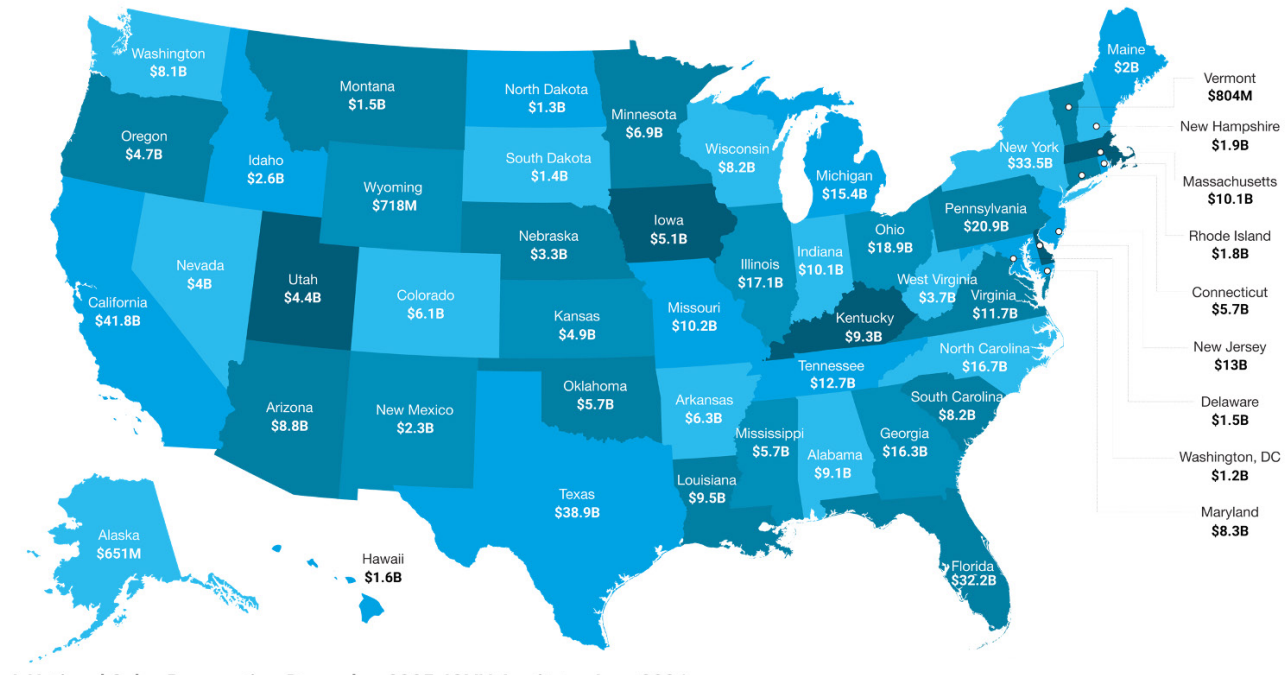
Source: IQVIA National Prescription Audit, December 2025; IQVIA Institute, June 2026.

- Many patients can realize the benefits of lower-cost generics, including people with diabetes taking metformin (Glucophage), those with high cholesterol taking atorvastatin (Lipitor), people living with gastroesophageal reflux disease (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 $625 billion in the last decade, with discounts off the brand price between 58% and 99%.
- A similar analysis examining the top 10 generics with the most savings identified $134.9 billion in savings for 2025 (29% of total savings), with discounts off the brand price between 89% and 99%.
- The generics industry is built upon a high-volume model, making these lower-cost medicines a key driving force of economic stability.

Adding Value, State by State

State Savings from Generic and Biosimilar Medicines Bring Patients Relief from Prescription Costs

2025 Generic and Biosimilar Savings by State



Source: IQVIA National Sales Perspective, PayerTrak.

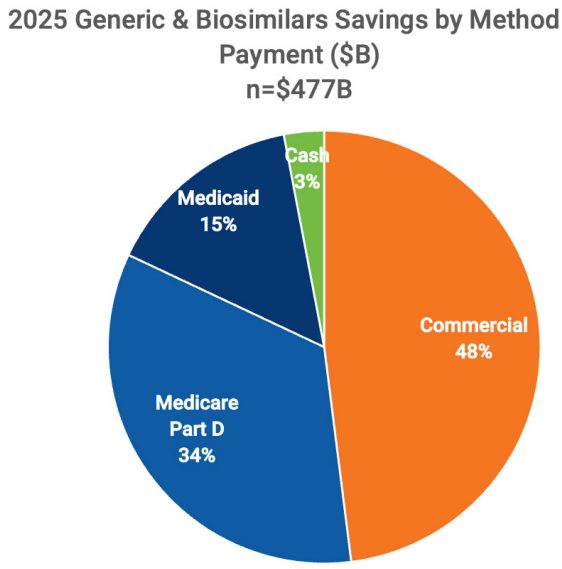
- Prioritizing the utilization of lower-cost generics and biosimilars is a way for employers and state payers to ensure access and manage spending.
- On average, the use of generics and biosimilars saved more than $9.3 billion per state in 2025, with savings ranging from $651 million in Alaska to $41.8 billion in California.
- States with large Medicare populations often realize significant savings through the use of generics and biosimilars. For example, in New York, the use of generics resulted in more than $12 billion in Medicare savings, with an average of $3,705 per enrollee.
- In 2025, generics saved the state Medicaid programs an average of $1.4 billion. Highest per capita savings occurred in Kentucky, West Virginia, North Dakota, Louisiana, and Idaho.
- State policymakers need to stay informed about the numerous benefits generic and biosimilar medicines offer payers and patients in their respective states, and they must take necessary actions that enhance plan and patient access to lower-cost prescription options.

Commercial Insurance and Medicare

Use of Generics and Biosimilars in Medicare Saved $166B in 2025

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

Share of Generic & Biosimilar Savings by Method of Payment, 2025



Source: IQVIA National Sales Perspective, December 2025; IQVIA Institute, June 2026.

- Generics and biosimilars provide critical savings throughout the healthcare system and are particularly valuable to Medicare and the patients they serve.In 2025, the use of generics saved $166 billion in Medicare.

- In 2025, the use of generics saved $166 billion in Medicare.
  - Adults aged 40-64 accounted for $194 billion in savings.
  - Seniors over age 65 accounted for $209 billion in savings.

- According to **MedPAC**, brand-name drugs with very high prices are the primary driver of **Medicare Part D** spending. Brand-name drugs and biologics without a generic or biosimilar competitor now account for over 83% of gross Medicare Part D spending, despite constituting less than 10% of prescriptions.[17]

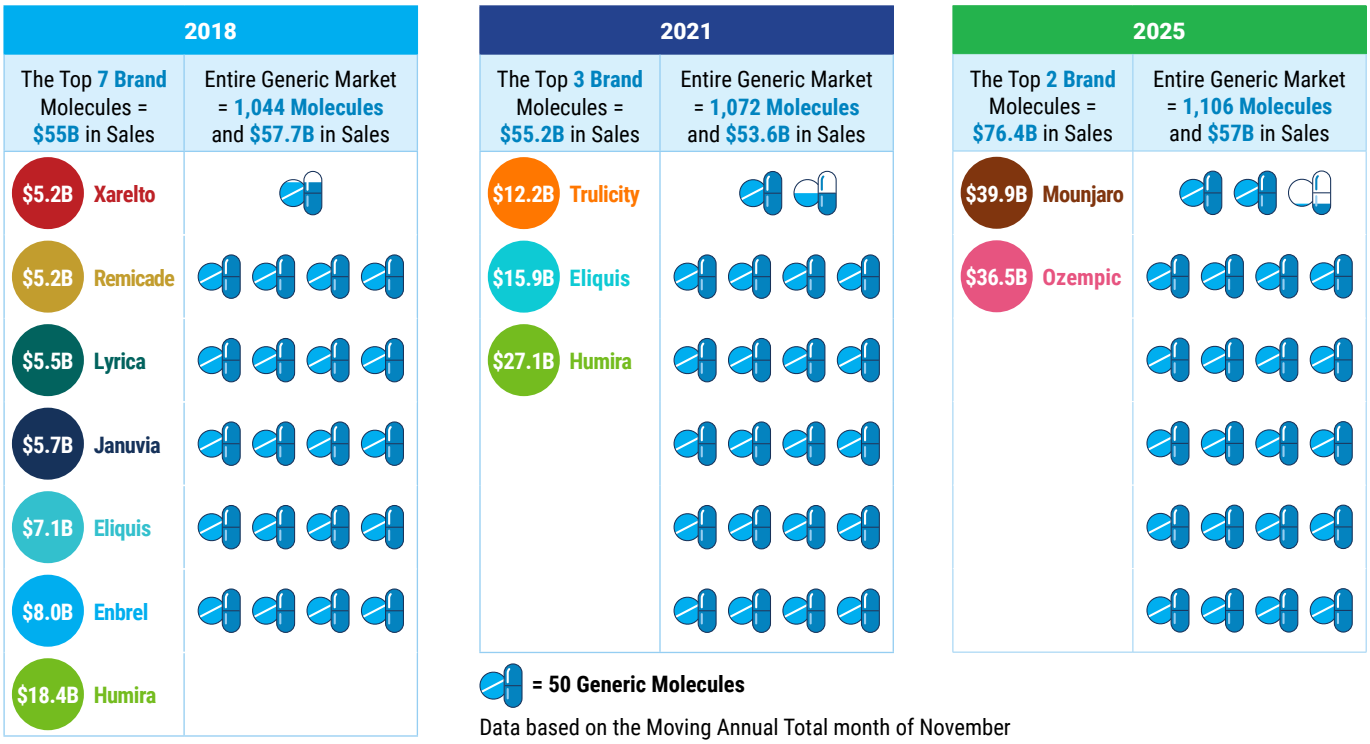
- In 2025, Medicare average prescription costs dropped to $4.57, largely due to changes to the Medicare Part D program required by the **IRA**, which decreased overall brand costs. In addition, generic drug costs also declined from an average cost of $3.50 to $2.31, a $1.19 difference, and they were utilized more frequently than brand products by Medicare beneficiaries.[18]

- Despite the value of generics to the Medicare program, Medicare reimbursement is often too low. For instance, Medicare reimbursement policies for sterile injectables create a race-to-the-bottom that drives prices below market equilibrium.[19] In many cases, this also harms generic adoption by rewarding providers for using higher-cost brand drugs.[20]

Challenges Facing Generics & Biosimilars

Economics is Defining Factor for Generics Market, Compared to Brand-Drug Giants

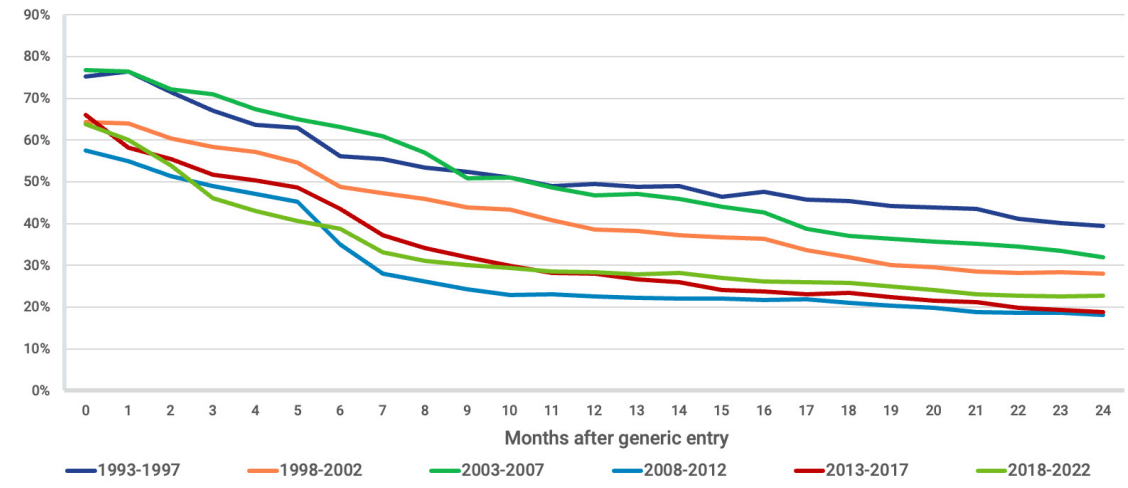
Prioritizing Generic and Biosimilar Medicines, as a Unique Market, Essential for Sustainable Patient Access



Data based on the Moving Annual Total month of November

- In the U.S., what makes generics structurally different from brand medicines is not chemistry. It's economics.
- Generics and biosimilars operate in distinct markets from their brand counterparts. Policymakers must prioritize generics and biosimilars as a way of acknowledging the difference in these markets. This prioritization is imperative to healthcare and U.S. economic resilience and national security.
- Ensuring healthy and sustainable generic and biosimilar supply-chain conditions means mitigating risks that stem from razor-thin revenue margins—a fact unique to the **off-patent medicines** industry.
- To put that into perspective, the entire generic market generated $57 billion in sales in 2025 across just 1,106 molecules. That's compared to the brand market, in which only 2 products, Mounjaro and Ozempic, captured $76.4 billion in sales, nearly 50% more.
- Generics and biosimilars cannot be directly compared to brand drugs that offer higher rebates to PBMs, for example, for more favorable formulary placement.
- If not prioritized through policy and regulatory actions, the generic and biosimilar medicines industry will continue operating in an unsustainable, race-to-the-bottom environment until products are forced out of the U.S. market entirely. This scenario can yield supply chain disruptions, drug shortages, and manufacturers exiting the U.S. market altogether, which can also create a signi icant national security threat.

Savings in Jeopardy: Unsustainable Deflation



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

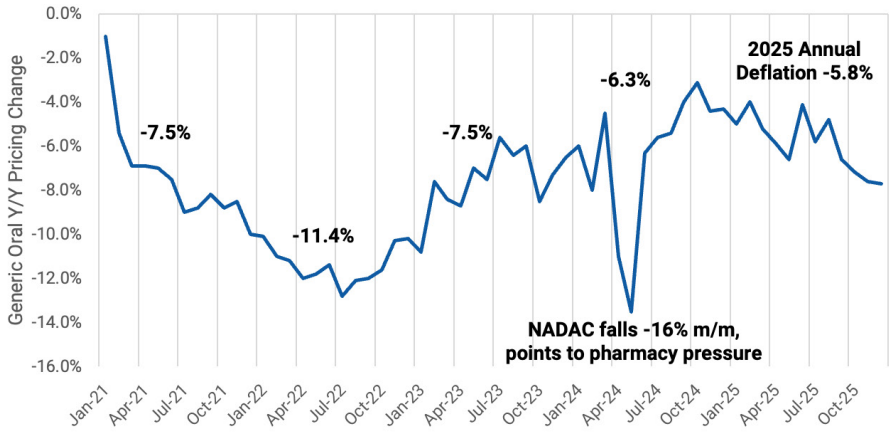
- Within the U.S., due to its highly competitive market, generic drug prices are launching at lower prices and bottoming out at lower prices. This occurrence has led to overall generic deflation.
- As indicated in the chart above, while there is some improvement in 2018-22 compared to 2008-2017, generic 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.
- The economics of generics have deteriorated to the point where sustainability of the industry is in peril. Significant price deflation of the last 30 years has created conditions in which essential products are sold below sustainable cost levels, forcing players to leave the U.S. market. This is alarming and a cause for great concern in terms of societal (health and economic) resilience and national security.
- This deflationary effect is also evident in Medicare spending. A recent **Medicare Payment Advisory Commission** (MedPAC) analysis found that between 2015 and 2024, prices of generic drugs covered under **Medicare Part D** fell to 29% of the average price observed at the beginning of 2015.[21]

Structural Deflation Eating Away at Backbone of Healthcare Ecosystem

Decades Ago Generic Prices Stabilized at One-Third Brand Costs, Now Even Less for 2025

According to Nephron Research, Generic Deflation was -5.8% in 2025

Year-over-Year deflation was consistent with Nephron Research's mid-single digits projection for 2025



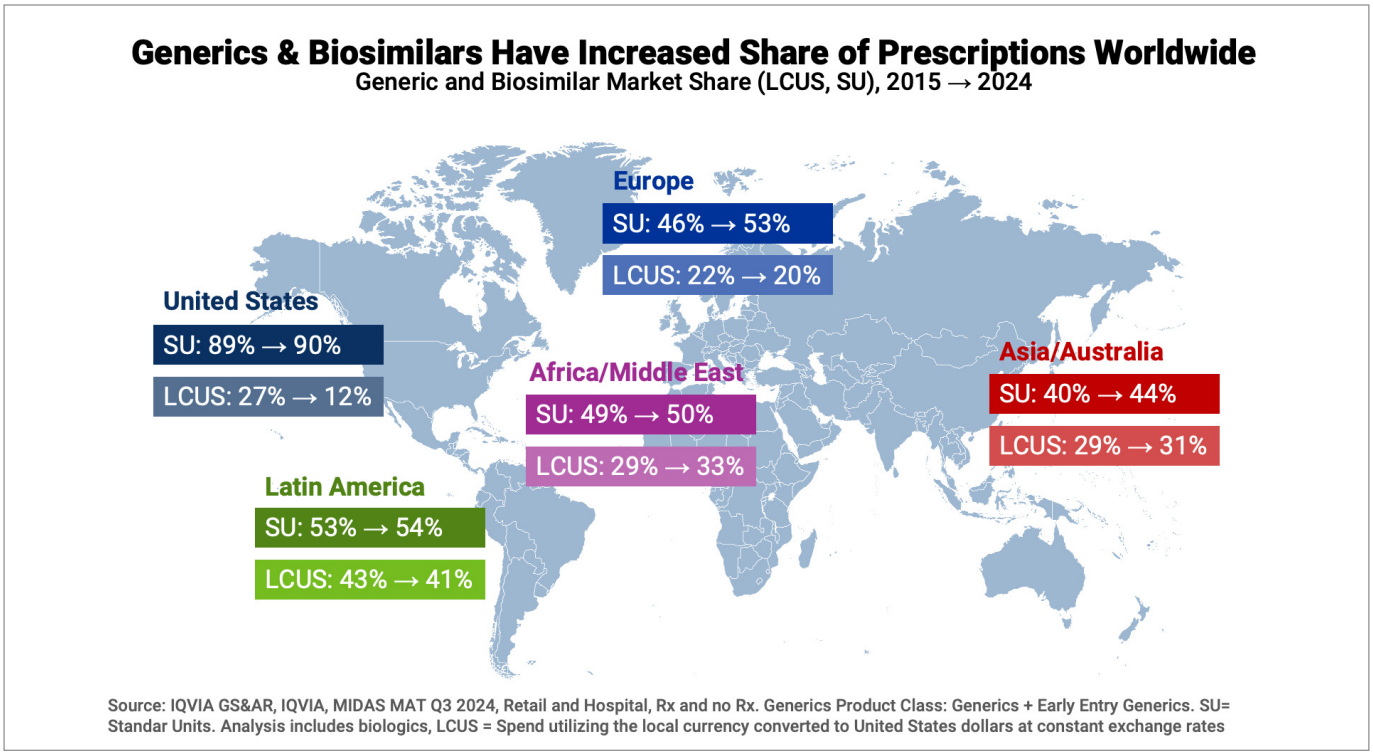
- In 2025, generic prices deflated -5.8% y/y from 2024, modestly lower deflation vs -6.3% y/y in 2024.
- Generic deflation accelerated toward the end of 2025, with the month of December down -7.6% y/y.
- As we entered 2026, tariffs moved from near-term to mid-term concern. Nephron Research expected 2026 deflation to run at the high end of the mid-single digit long-term trend.

Source: Nephron Research Generic Price Auditor, January 2025.

- Generic medications are the only part of the U.S. healthcare system faced with annual deflation, which has averaged 7.7% in the last 5 years, as indicated in the chart above by Nephron Research, a healthcare data intelligence and investment research provider. For comparison, overall medical inflation was an average of 6.2% in that same time period, nearly a 14 percentage point difference.[22] [23]
- Since 2019, the total value of all generics sold in the U.S., including a range of new generics, has fallen by $6.5 billion.[24]
- In 2016, generics represented 27% of prescription spending; today, they represent just 11.6%.[25]
- Thirty years ago, generic prices stabilized at roughly one-third of brand costs. Today, they bottom out at barely one-fifth.
- This structural deflation is eroding the sustainability of a system that functions as the backbone of healthcare in America. When paired with medical inflation, this erosion may cause the generic and biosimilar medicines industry to shrink beyond repair.

Substantially More Generics Filled at Substantially Lower Costs, Compared to Other Global Regions

Dramatic Price Decrease Upon Generic Entry the Culprit for Disproportionate Market in the U.S.



- As indicated above, a recent IQVIA analysis examined prescription drug trends from 2015 versus 2024. That analysis found that, worldwide, the overall share of the prescription drug market has increased for generics and biosimilars (utilizing a "**standard unit**" or SU).
  - For instance, within the U.S., the overall generic and biosimilar share of the market was 89% of prescriptions in 2015. In 2024, that percentage increased to 90% (before decreasing slightly to 89% for 2025).

- Unfortunately, while the overall share of the market has increased, the amount of spending on those same products within certain regions has tended to decrease.
  - Generics and biosimilars accounted for 27% of U.S. drug spending in 2015, falling to 12% in 2024 and 11.6% in 2025.

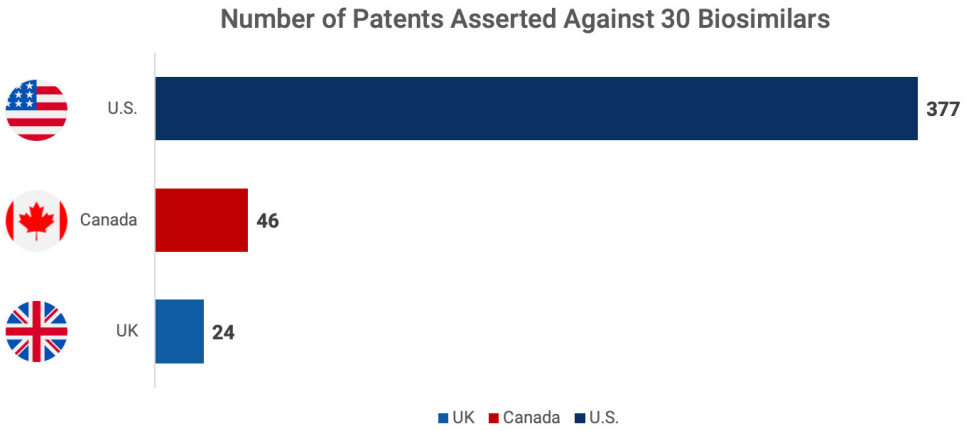
- Using local currency converted to U.S. dollars at a constant exchange rate (**LCUS**), other areas of the world did not show such dramatic price deflation. For instance, in Africa and the Middle East, while the share of the generic and biosimilar market increased (from 49% in 2015 to 50% in 2024), the overall share of the costs increased by 4 percentage points (from 29% in 2015 to 33% in 2024).

- This information is consistent with other analyses comparing U.S. spending to other countries. A recent analysis by RAND found that generic prices in the U.S. average 16% less than other countries, and between 30% to 50% less than nations such as the U.K., Mexico, France and Japan.[26] This difference is the result of a U.S. generic drug market in which prices can rapidly fall by as much as 95% upon generic entry.[27]

Patent Litigation in U.S. More Complex, Impacts Access to Biosimilars

As a Result, American Patients Have Delayed Access to Lower-Cost Biosimilars

Biosimilars in the U.S. Face More Patent Challenges Than Other Countries



Source: Association for Accessible Medicines. (July 2025) Anatomy of a Biosimilar Patent Litigation: Problems and Solutions.

- Patent litigation in the U.S. is far different—and more complex—than other countries. A critical difference between the U.S. versus Canada and the U.K., where biosimilar access is far greater, is the sheer number of patents asserted in such litigation.[28] As indicated in the chart above, the number of patents asserted in the U.S. can be more than 10 times that of other countries.[29]

- This complex litigation delays patient access to lower-cost products. As a result, patients and the taxpayer pay more for a longer period of time.

- A biosimilar to insulin aspart (Kirsty) has been available in Europe and Canada since 2022, and yet the product did not launch in the U.S. until Q1 of 2026.[30]

- Biosimilars for Enbrel launched in Europe in Q1 of 2016.[31] To illustrate the effect of biosimilar competition in Europe, Pfizer reported its Enbrel sales outside of the U.S. and Canada peaking at $3.8 billion in 2014 before declining to $3.3 billion and $2.9 billion, respectively, in the following 2 years. By 2025 those Enbrel sales had shrunk to $690 million.[32]
  - With the launch of biosimilars to Enbrel in Europe, the price has declined by 50%, with biosimilars holding 40% of the market share.[33]

- Biosimilars to Stelara launched in Europe as early as July 2024 but did not launch in the U.S. until Q1 of 2025.[34]

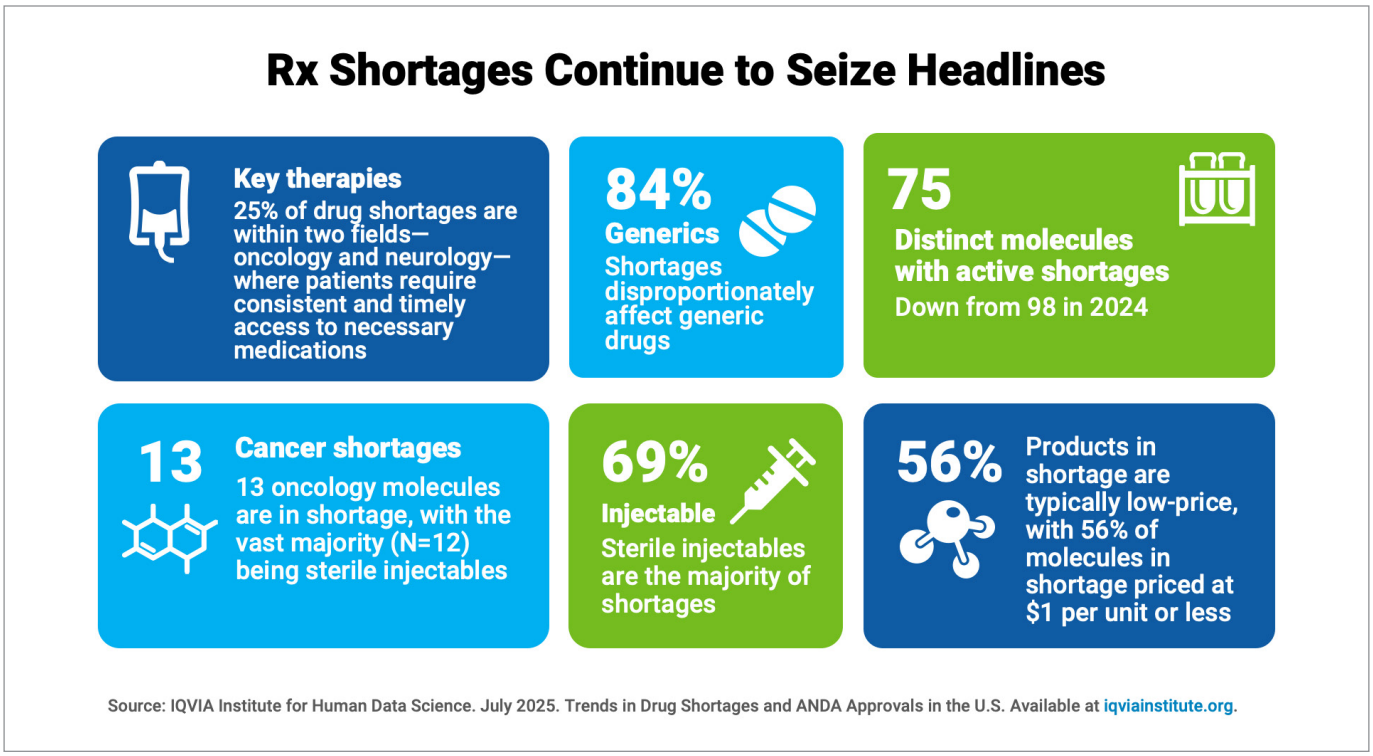
- In January 2026, Zydus launched its biosimilar to Opdivo in India.[35] Within the U.S., IQVIA has forecasted biosimilar entry to occur in late 2028.[36]

- In Europe, biosimilars that reference Humira have already been on the market since 2018.[37] Within one year of market entry, adalimumab biosimilars accounted for more than 50% of the market share in Germany. Moreover, in many European markets by the early 2020s, biosimilars had more than 85% of market share. In Denmark, adalimumab biosimilars captured 95% of market share almost immediately after the loss of **exclusivity**.[38]

- Patent abuse in the U.S. must be stopped. Policymakers must work to limit the number of patents brand-name manufacturers can assert and prevent anticompetitive practices that delay patient access to biosimilars.

Drug Shortages Continue to Hamper Patient Care

Shortages in the U.S. Are a Symptom of Challenges Facing Generic Sustainability Generic Sustainability

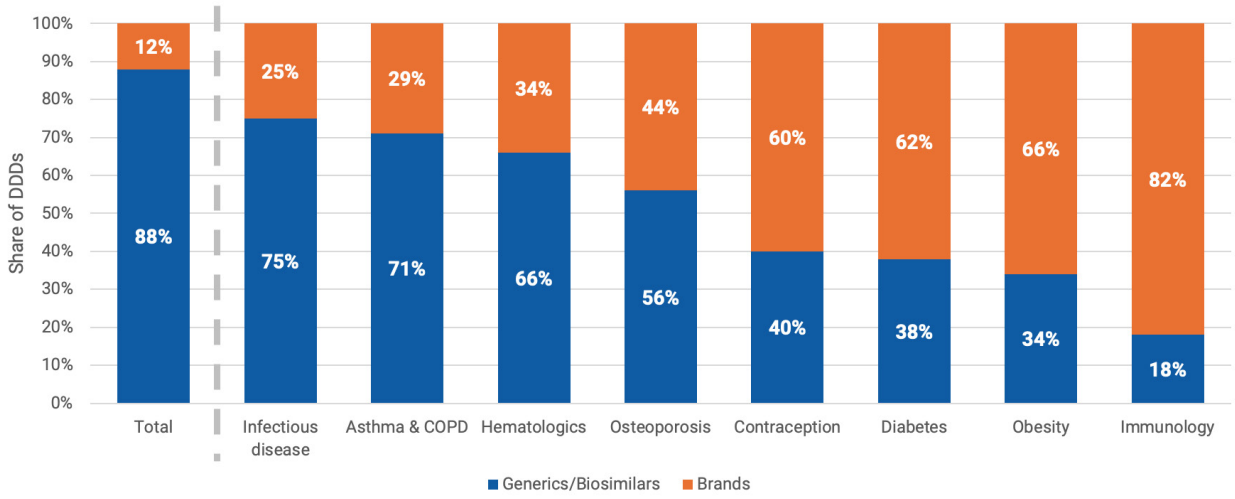


- The U.S. faces continued drug shortages, especially among lower-cost generics.[39]
- An analysis by USP found that total drug shortages declined for the second consecutive year (from 98 in 2024 to 75 in 2025), but the average length of those shortages is longer (now with an average duration of 5 years).[40]
- A recent JAMA analysis suggests that higher prices for generic medicines may help explain why Canada has 40% fewer drug shortages, despite having overlapping and similar regulatory processes.[41]
- A 2021 comparison between U.S. and Australian drug shortages noted that only 4%–7% of drug shortages were the same, despite Australia being heavily dependent on importing drugs from the U.S.[42]
- A study of 99 drug shortages across Finland, Spain, Norway, Sweden, and the U.S. showed that 41% of shortages affected only the U.S., and only 1 % affected all 5 countries.[43]
- The U.S. has a greater shortage problem, due to consolidated purchasing power[44] and lower reimbursement for generic drugs compared to other countries,[45] which results in differences in profit margins between various generic markets.[46] To curb these issues, policymakers must provide a sustainable reimbursement plan that does not focus solely on costs and addresses misaligned incentives.

Generics & Biosimilars Are Not Always Available to Patients

Lack of Access to Generic & Biosimilars is a Lost Opportunity for Savings and Enhanced Patient Access Access

Across All Therapy Areas, 88% of Volume Is Generics or Biosimilars
Of the Top 30 Therapy Areas, Only 8 Have Less Than 80% of the Volume, 2025



Source: QVIA Institute for Human Data Science. U.S. Medicine Use Trends 2026: Increased Use and Spending Amid Access and Cost Pressures, April 2026. Available from www.iqviainstitute.org

- While approximately 9 out of every 10 prescriptions are for generics and biosimilars, the volume share of prescriptions dispensed as generics and biosimilars varies significantly across therapy areas. For instance, generics account for 97% or more of the prescriptions for hypertension and mental health.[47]

- However, it is much lower for other therapy areas. This lack of patient access to lower-cost medications indicates a lost opportunity for significant savings.

- As indicated in the chart above, within the top 30 therapy areas, only 8 have less than 80% generic or biosimilar utilization: immunology (18%), obesity (34%), diabetes (38%), contraception (40%), osteoporosis (56%), hematologics (66%), asthma and **COPD** (71%), and infectious disease (75%).[48] By examining potential reasons for this lack of access, policymakers can focus on viable solutions.

- As further discussed below, certain therapeutic areas highlight the need for additional patent reforms to address lagging access to products (including addressing drug-device combinations) and payment barriers to generic and biosimilar uptake (including misaligned incentives).

- Many of the top brand manufacturers have revenue-generating immunology products. Some of which have recently experienced generic and biosimilar competition, while many others will experience it within the next 5 years.[49]

- For obesity and diabetes, the main drivers for lack of generic uptake are the GLP-1s. While some generic GLP-1s (e.g., liraglutide) are available to American patients, access to generic semaglutide in the U.S. lags behind other countries, with U.S. access anticipated in 2032.[50] [51]

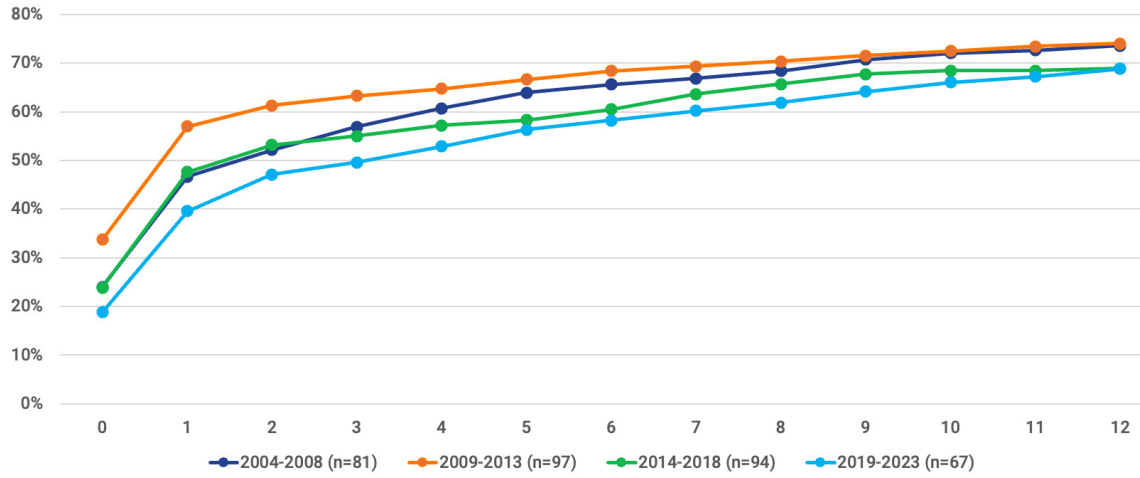
- In the last 5 years, generics have also made inroads in asthma and COPD care, with the generic share growing from 63% in 2020 to 71% in 2025. However, brand drugs still hold a sizable share of these products (29%), often due to the patented, complex devices that accompany these medications.[52]

- Clinical guidelines support 2 main drugs for the medication management of osteoporosis – bisphosphonates and denosumab (Prolia/Xgeva).[53] Unfortunately, denosumab biosimilars have had only a 20% uptake so far.[54]

- Even where generics are widely used, brand-name drugs can still dominate spending. For example, **MedPAC** found that in 2024, generics accounted for 84% of Medicare Part D cancer-drug prescriptions, while brand drugs accounted for 91% of gross spending.[55]

New Generics Bring Lower Prices, But Patients Lack Access

Generic Uptake is Lower for Generics Entering in the Last 5 Years



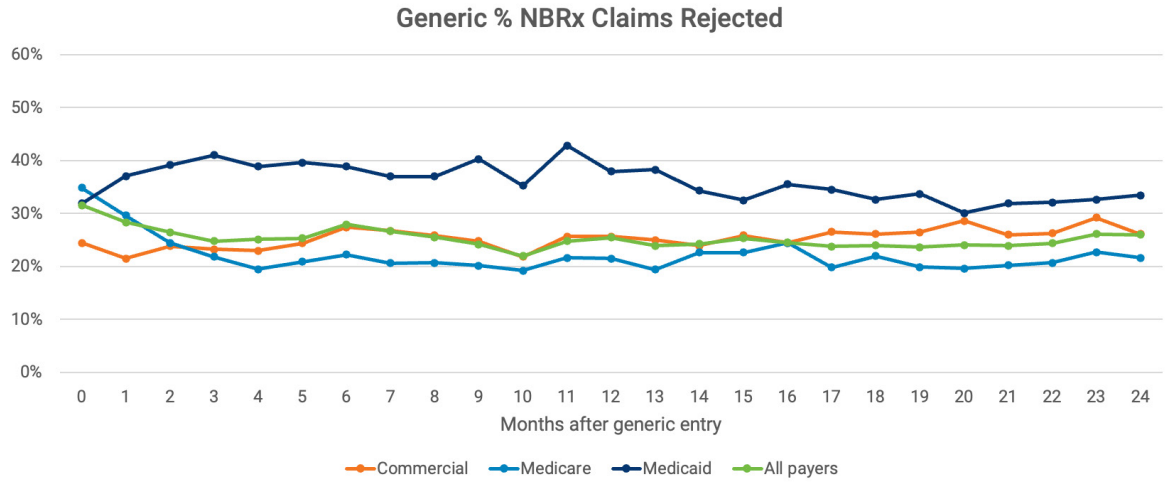
Source: IQVIA Institute for Human Data Science. April 2025. Understanding the Use of Medicines in the U.S. 2025: Evolving Standards of Care, Patient Access, and Spending. Available from iqviainstitute.org.

- Brand drug manufacturers benefit financially from years of **exclusivity** prior to a generic or biosimilar manufacturer'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 5 years, generic uptake of small molecules in the first 6 months after **loss of exclusivity** has been 5%–9% lower than the prior 5 years, and 9%–18% lower than it was during 2010–2014.[56]
- Put another way, on average, small-molecule generics reached 57% uptake within 1 month of launch from 2009–2013, compared with 6 months in the last 5 years of data (2019–2023).[57]
- A recent IQVIA analysis postulated that this erosion in rapid coverage is related to expansion of payer controls (e.g., utilization management, formulary design, and access controls), which have shifted the market to delay generic uptake until the payer economics shift.[58]

Formulary Placement, Utilization Management Practices Impact Patient Access

Policymakers Must Look Closely at Prescription Rejection Causes

While Generics Are Generally Preferred, Over 25% of New Generic Claims Are Rejected by Payers 2 Years After Generic Entry

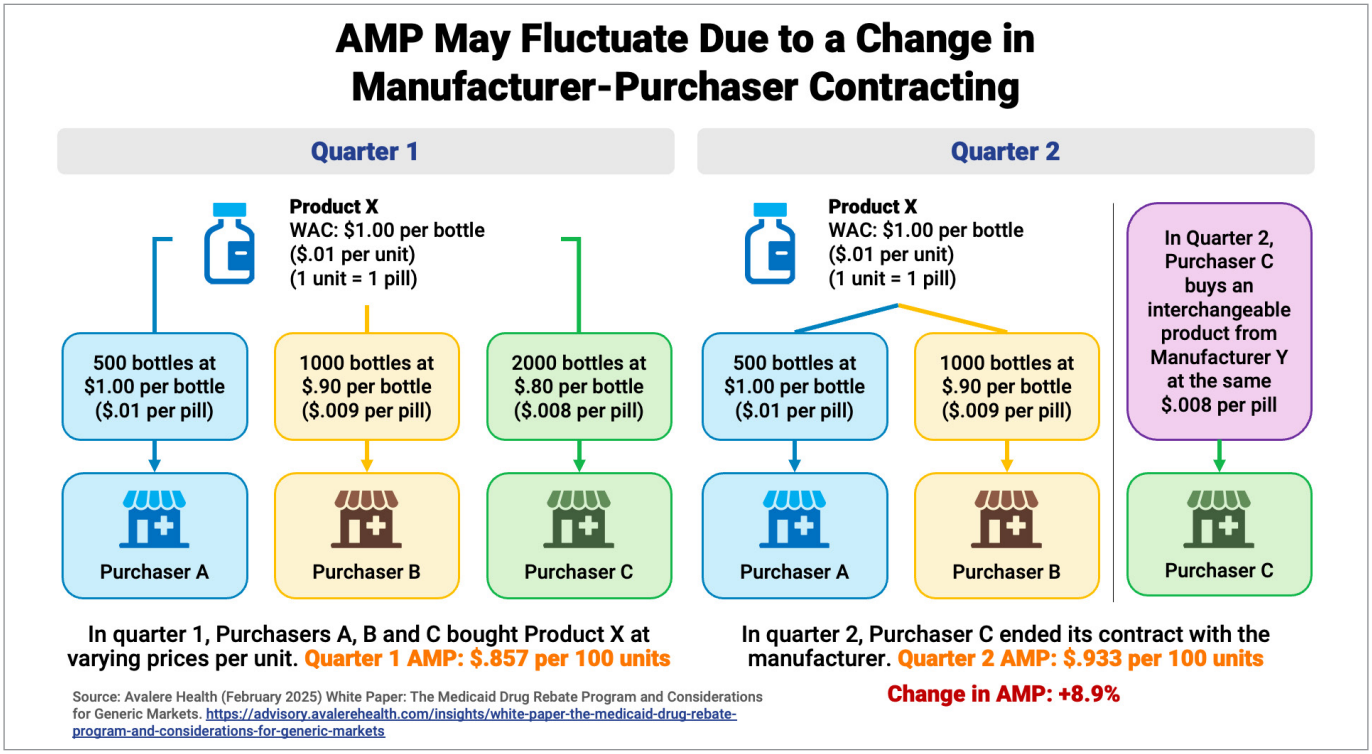


Source: IQVIA LAAD Sample Claims Data, December 2024; IQVIA Institute, April 2025.

- In determining whether American patients have access to lower-cost generics, policymakers need to examine **formulary placement** and **utilization management** practices, which can result in an initial prescription being rejected.
- As outlined in the chart above, generics are generally preferred, which means that they are placed on more favorable formulary tiers. However, over 25% of the new generic claims are still rejected by payers 2 years after generic entry. The commercial market (identified by the bright blue line) has a similar pattern.
- The Medicaid market (denoted by the light green line) has even higher rejections at 2 years—close to 35%.

Medicaid Inflationary Rebates: A Misguided Effort to Quell Drug Costs

Razor-Thin Revenue Margins Leave Little Room to Absorb Fluctuations



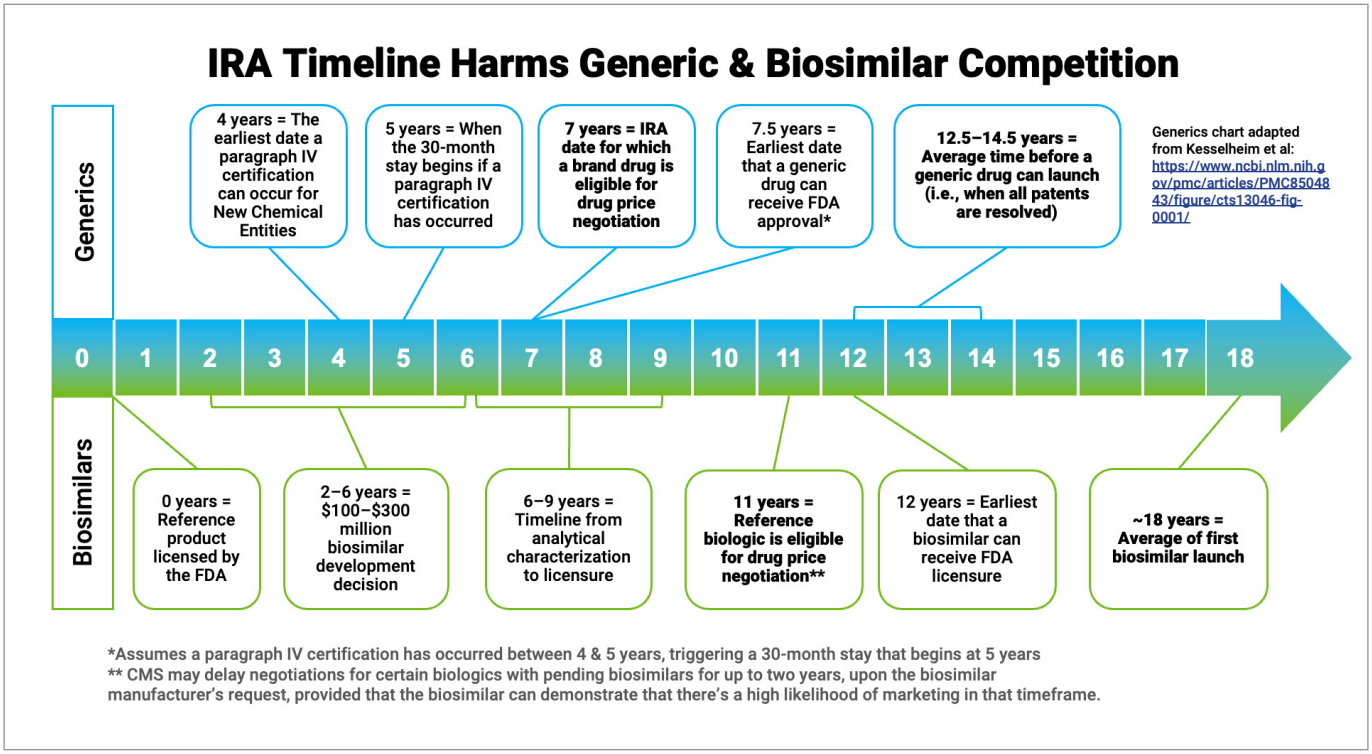
Source: Avalere Health (February 2025) White Paper: The Medicaid Drug Rebate Program and Considerations for Generic Markets. https://advisory.avalerehealth.com/insights/white-paper-the-medicaid-drug-rebate-program-and-considerations-for-generic-markets

- In 2017, a new penalty was imposed on generic manufacturers participating in the Medicaid program: The Medicaid Generics Penalty. Targeting price increases exceeding the rate of inflation, the penalty ignores important market differences between generic medicines and brand drugs.
- To better understand the impact of this penalty on generic manufacturers, an in-depth analysis was performed by Avalere Health.[59]
- 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 increase prices for reasons 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 scenario 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 with established and sustained price competition.
- 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 Impedes Competition

The Inflation Reduction Act (IRA) Impedes Healthy Competition

Timing of Negotiation Process Yields Uncertainty for Potential New Launches



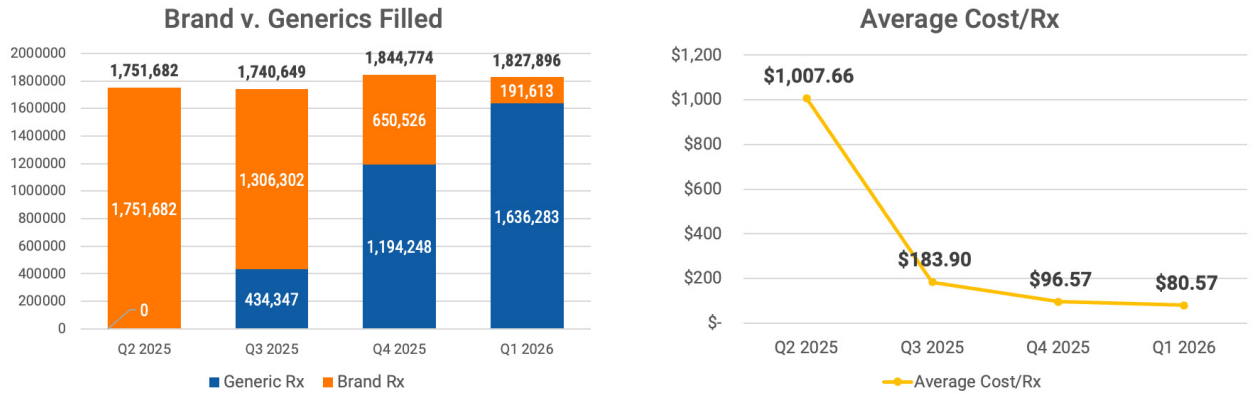
- Although the **Inflation Reduction Act (IRA)** exempted products from negotiation when a generic or biosimilar was approved and marketed, the law explicitly starts the negotiation process before generic and biosimilar competition has a chance to begin.
- The IRA does this by instituting the price control process when the brand drug has been approved for 7 years (or, if a biologic, was licensed at least 11 years ago, with the possibility of applying for a 2-year delay).
- As noted above, data showing that the average market entry of a first generic is between 12.5 and 14.5 years,[60] and approximately 18 years for a first biosimilar (with the earliest a biosimilar has ever entered as just over 13 years),[61] makes clear that preempting lower-cost competition through price controls is a design feature that inhibits generic and biosimilar market entry, not an unexpected outcome.
- Moreover, recent research suggests that while the IRA may generate near-term savings, particularly for biosimilars, those savings could be short-lived if the policy reduces long-term competition and associated savings.[62]

Healthy Competition: The Proven Approach to Lowering Drug Costs

One of the First IRA Drugs: Entresto Case Study

Entresto: Competition Beats Price Controls

Generic competition for Entresto Resulted in More Patients Receiving Drug, Decrease in Average Cost Per Prescription



Source: AAM Analysis of IQVIA National Prescription Audit & National Sales Perspective, May 2026

- The price controls established by the IRA can be removed if CMS deems that there is "bona fide" marketing of a generic or biosimilar.

- Of the first 10 drugs selected for IRA price controls, CMS has determined that 4 of them have met that standard. As such, their **maximum fair price** (MFP) will be removed in subsequent cycles.
  - For 3 of these drugs (Novartis' chronic heart failure treatment Entresto, Janssen's anti-inflammatory medicine Stelara, and Bayer and Janssen's blood clotting drug Xarelto), CMS previously announced that their MFPs will no longer be in effect, starting January 1, 2027.[63]
  - For 1 of those drugs (Novo Nordisk's rapid-acting insulin Fiasp/Novolog), CMS recently announced that its MFP will no longer be in effect, starting January 1, 2028.[64]

- As noted in the chart above, competition beats price controls. One can see this upon examining the decreased costs and increased patient uptake after generic competition for Entresto.
  - Entresto's MFP was set at $295 starting in CY 2026 for all Medicare beneficiaries.[65]
  - According to an AAM analysis of IQVIA data, the average cost of a patient prescription for all U.S. sales was a little over $1,000 in Q2 of 2025.

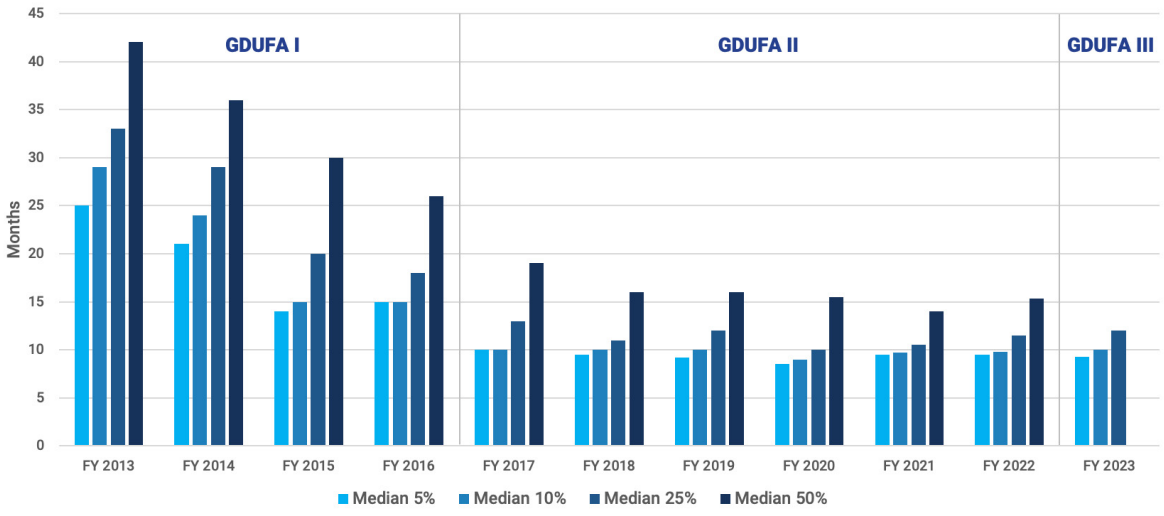
- When more than a dozen generic companies began marketing the product in Q3 of 2025, the number of Americans able to afford the drug increased over time, while the overall price of both the **reference product** and the generic competition decreased.
  - By Q1 of 2026, the average cost per prescription for the generic was $80.57, less than a tenth of the reference product price of $820.53 and well below Entresto's MFP. During that same timeframe, 80,000 more Americans received access to the drug.

- This underscores the value of competition—a proven approach to reducing drug prices.
  - According to the FDA, when there are 4 or more generics, the **average manufacturer price** falls by 75%.[66]
  - For biosimilars, a recent IQVIA analysis found that a second-to-market biosimilar launched within 3 years of the first can nearly double the **Average Sales Price** (ASP) pressure, accelerating price erosion for all treatments.[67]

Value of the User Fee Amendments (UFA) Programs

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

Swift Review Actions Help Increase Patient Access

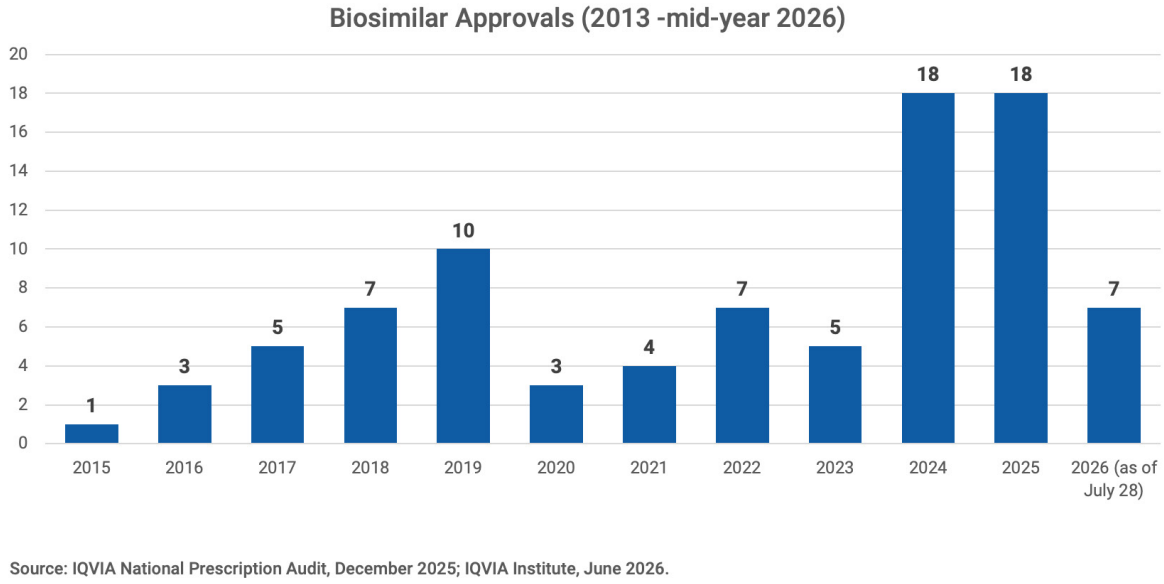


Source: Darby Kozak (April 2025), Working Together to Increase Access to Generic Drugs, Accessible at https://sbiaevents.com/gdf2025/

- Building upon the success of other user fee programs, **Congress established the Generic Drug User Fee Amendments (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 because of the long review times (i.e., 31 months to approve new generic medications). As a result of changes due to the GDUFA program[68] (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.[69]
- The improvements in review timelines helped facilitate more approvals of lower-cost generics.
- Unfortunately, FDA approval does not always mean that there is enhanced patient access to these lower-cost products. New analysis from the IQVIA Institute shows that 37% of FDA-approved generics between 2013 and Q1 2024 never launched, and it often takes more than 4 years for 70% of approved generics to reach the market. Even worse, 84% of drugs currently in shortage have at least 1 approved generic that remains unlaunched, which highlights that economics, rather than regulatory barriers, are preventing supply from reaching patients.[70]

The Biosimilar User Fee Program: Ensuring Faster Access to Lower-Cost Biologics

FDA Continues Critical Role in Biosimilar Uptake

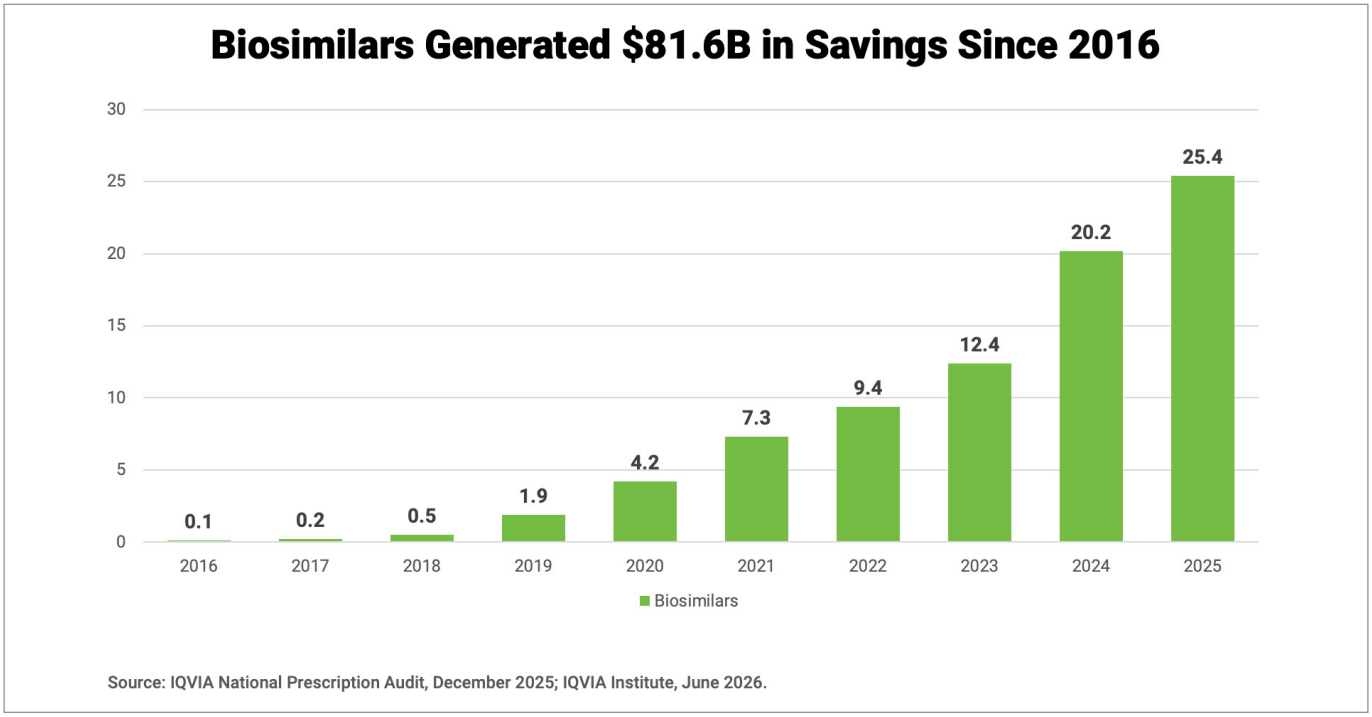


- The U.S. Food and Drug Administration (FDA) plays a critically important role in ensuring America's patients gain access to high-quality, more-affordable **biologic drugs** in the form of **biosimilars**.
- The **Biologics Price Competition and Innovation Act of 2010 (BPCIA)** created FDA's biosimilar approval pathway.
  - For a biosimilar to be marketed in the U.S., data submitted in a **biological license application (BLA)** must demonstrate the biosimilar is "highly similar" to the reference biologic product (brand product) and that there are **no clinically meaningful differences** in safety, purity, or potency.
- The first biosimilar was approved in 2015, and as of July 28, 2026, there are 88 FDA-approved biosimilars with dozens more in the queue. The **Biosimilar User Fee Amendments (BsUFA)** is a law authorizing FDA to assess and collect fees from drug manufacturers that submit BLAs for FDA's review and licensure.
- BsUFA was originally enacted in 2012 under the Food and Drug Administration Safety and Innovation Act (FDASIA) for a period of 5 years. Each subsequent reauthorization requires industry and FDA to negotiate commitments to enhance and improve the review process to facilitate timely access to biosimilars. FDA assesses and collects user fees to ensure the agency has the necessary resources to fulfill the agreed-upon commitments.
- With the current BsUFA program set to expire on October 1, 2027, Congress must provide a timely reauthorization so the FDA can continue timely reviews and other important regulatory activities.

Biosimilars: Savings & Challenges

Biosimilars Have Generated $81.6 Billion in Savings Since 2016

Savings Reflect Provider Confidence and Robust Price Competition



- **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 healthcare ecosystem billions of dollars.

- Since 2016, patients and the healthcare system have saved $81.6 billion thanks to biosimilars. Savings increase as biosimilar adoption grows. Savings in 2025 are larger than the savings in 2024—from $20.2 billion to $25.4 billion.

- 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**) as compared to the **pharmacy benefit** biosimilars (i.e., those dispensed through a retail or **specialty pharmacy**).

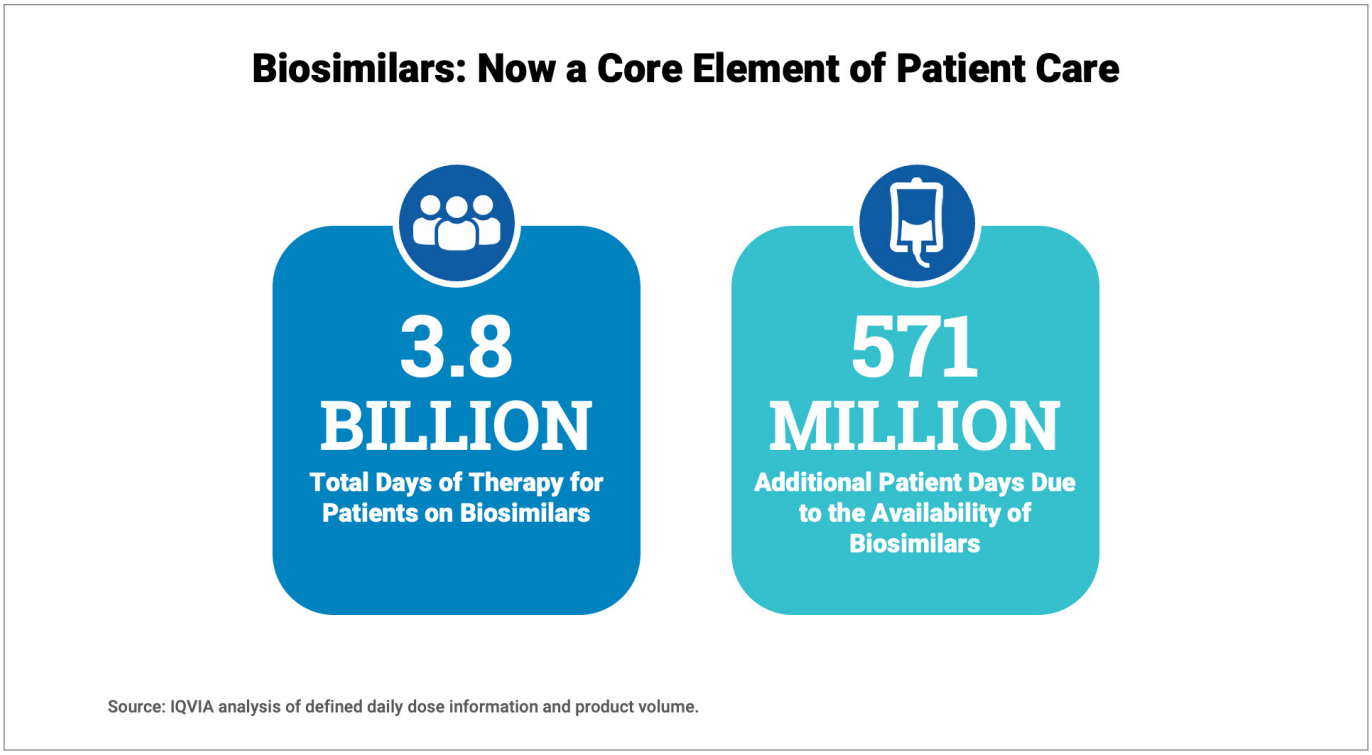
- A recent **MedPAC** analysis further highlights the value of biosimilar competition within the medical benefit. For the 9 biologics that had biosimilars on the market in 2024 (excluding Eylea due to data limitations), Medicare spending on Part B (or medical benefit) brand biologics and their biosimilars declined on a nominal basis by about 9%, from $3.7 billion in 2023 to $3.4 billion in 2024.[71]

- Uptake of biosimilars in the first 3 years after launch varies significantly by **drug channel** (whether the biosimilar is obtained as a medical benefit versus the pharmacy benefit) and brand defense strategies. Overall, biosimilars typically covered through the medical benefit have average uptake of 48% 36 months after introduction. Those covered through the pharmacy benefit have a lower average uptake of 28%.[72]

- Unfortunately, biosimilar adoption continues to trail expectations because of poor reimbursement and misaligned incentives.

Biosimilars Deliver Safe Therapy

Biosimilar Introduction Often Results in Greater Patient Access

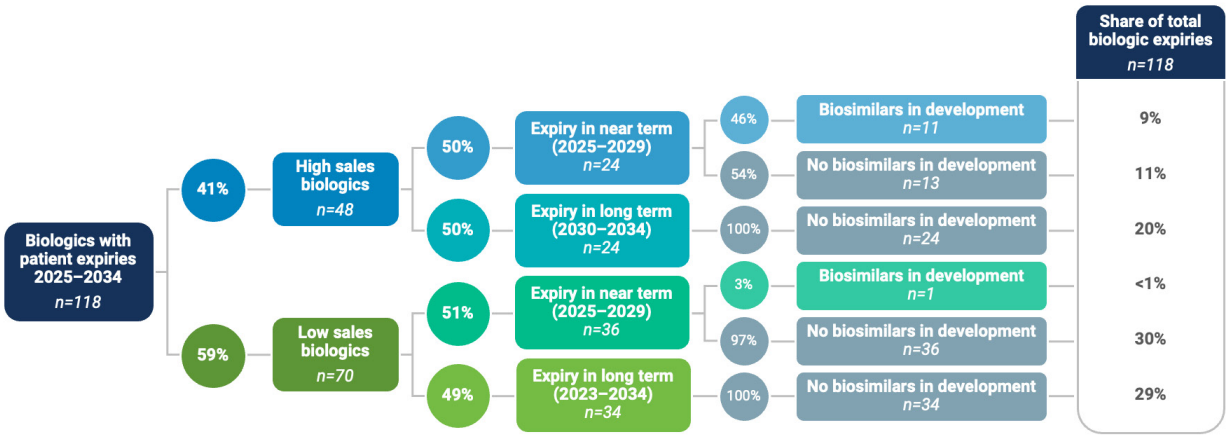


- The increasing use and proven scientific effectiveness of biosimilars should put to rest any questions about their safety and efficacy.
- Since the first biosimilar launched 10 years ago, biosimilars have been used in over 3.8 billion days of patient therapy, with **no meaningful clinical differences** in safety or therapeutic outcomes.
- Moreover, the overall use of molecules with biosimilar competition has increased. This increase means that more patients receive treatment when a biosimilar is available.
- Biosimilar competition has now supported nearly 571 million **additional days of therapy** — care that patients would not have otherwise received. For example, over 25% more doses of pegfilgrastim, used to generate new white blood cells for patients fighting cancer, have been dispensed since its biosimilar entered the market.

The Biosimilar Void Continues

Closing the Void Could Mean Additional $189 Billion in Biosimilar Savings

Biosimilar Development Is Concentrated in High-Sales Biologics with Near-Term Patent Expiries in the Next 5 Years

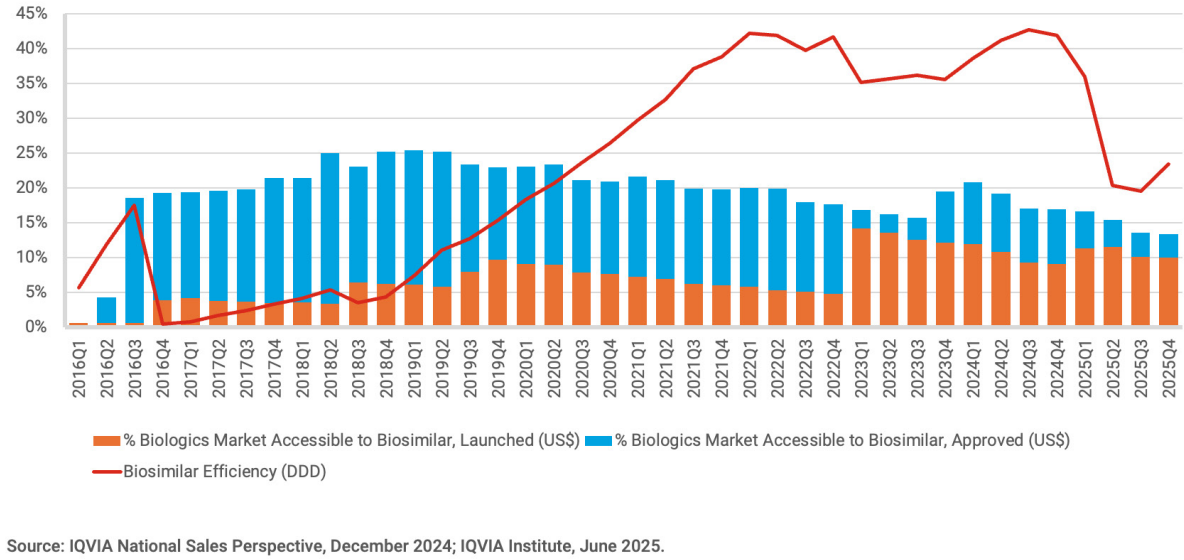


Source: Accessing the Biosimilar in the U.S.

- In examining all biological products that face patent expiration between 2025 and 2034, only 10% of the 118 products are currently staged to face biosimilar competition. The remaining products are in the "**biosimilar void**."[73]
- Biologics with patent expiries over the next decade will account for $234 billion in spending at invoice prices in the U.S. 1 year prior to patent expiry, highlighting a significant potential for savings for the U.S. healthcare ecosystem.
- Biosimilar development is concentrated in biologics with high sales potential and near-term expiries, although these do not always predict biosimilar development. The pipeline for biosimilars is most robust for products in which the pre-expiry biologic sales are over $1 billion per year.[74]
- If all products losing exclusivity over the next 10 years that currently lack a biosimilar pipeline faced biosimilar competition at expiry, the U.S. healthcare system could save an additional $189 billion, on top of savings from biosimilars already on the market or expected to enter.[75]

Biosimilar Adoption Remains Low

Current Environment Hampers Future Development and Negatively Impacts Patient Care



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

- The **biosimilar efficiency rate**, or the rate at which biosimilars are dispensed when available, is both a function of market access over time as well as a marker for new entrants, given that the efficiency rate is generally lower for new entrants. The efficiency rate in 2024 was nearly 40%, but it has declined to 23% in 2025, due to lower uptake among several of the newly launched biosimilars (e.g., insulin aspart and denosumab).

- Although the average efficiency rate provides a picture of the biosimilar market, there is wide variation in biosimilar uptake. To date, 3 years after entry, biosimilars provide 24% of the total volume in days of therapy, ranging from 8% for ranibizumab to 82% for bevacizumab.[76]
  - This data is similar to the information for the Medicare market, in which **MedPAC** recently noted that the Medicare market share ranged from 1% for eculizumab to 89% for filgrastim.[77]

- Biosimilars for adalimumab (Humira) had relatively low uptake for the first year, accounting for only 3% of volume, largely due to formulary preference for the originator product. However, changes in contracting practices boosted biosimilar uptake, resulting in 51% market share by the end of the third year.[78]

- Ustekinumab biosimilars had rapid uptake in the first year, reaching 36% volume share, a striking outlier in the **pharmacy benefit** space.[79]

- Some of the biosimilars with lower uptake in their first 3 years have seen increased adoption later, while some have had rapid early adoption.
  - The diverse range of uptake patterns reinforces the degree of uncertainty for biosimilar makers, purchasers, and policymakers in this area.[80]

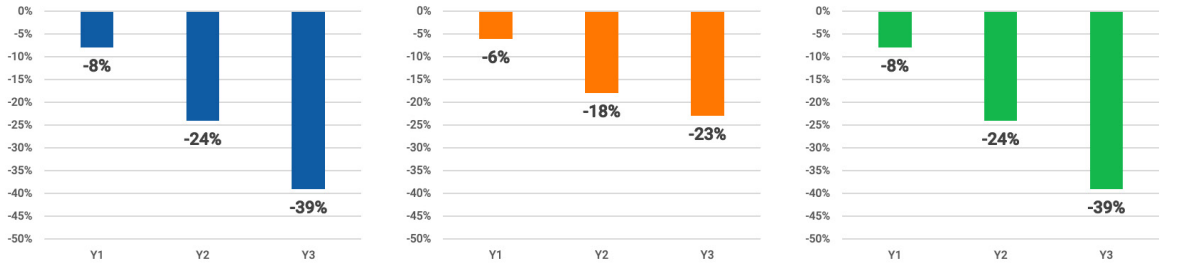
- A sustainable biosimilars market supports rapid adoption by multiple competitors. Even where biosimilars have been adopted, the majority of the market share is concentrated among 1 or 2 competitors.

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

Rewarding High Rebate Drugs Serves as Disincentive for Biosimilar Use

In First 3 Years After Biosimilar Entry, an Average Originator Brand Suffers a ~23% Drop in ASP and a Nearly Two-Fold Increase in List-to-Net Gap

Molecule-Average ASP Is Declining Faster Than Originator ASP Due to Lower Prices of Biosimilars



Molecule ASP

On average,
-39%
in first 3 years of Biosimilar Market Presence

Originator ASP

On average,
-23%
in first 3 years of Biosimilar Market Presence

Originator WAC to ASP Gap

On average,
1.8x
Increase in off-WAC discounting in first 3 years of Biosimilar Market Presence

Source: US Market Access Strategy Consulting analysis, CMS ASP Data, NSP Sales, Redbook WAC Data

- When the **ASP** reimbursement model was first enacted in 2005, biosimilars had not yet entered 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 +6% (or +8% 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.[81] This scenario is because a reference biologic with a higher ASP generates a larger add-on payment than a less expensive biosimilar, incentivizing providers to prefer high-cost brand drugs, 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 costs them to acquire the biosimilar. This leads to providers being "**underwater**," serving as a disincentive for biosimilar use altogether.[82]
- Biosimilar manufacturers may also be "underwater." As part of the rulemaking process, CMS recently highlighted that several biosimilars had a zero or negative ASP (e.g., Ziextenzo).

- According to a recent analysis by IQVIA,[83] on average, ASP is shown to decline across all products in biosimilar markets by:
  - 24% during the second-year post-biosimilar launch; and
  - 24% during the second-year post-biosimilar launch; and
  - 39% in the third-year post-biosimilar launch.

- Not only does the launch of biosimilars put pressure on the overall molecule pricing, but 3 years after the launch of a biosimilar, the brand ASP declines by an average of 23%.[84] However, despite the decrease in brand ASP once a biosimilar launches, as **MedPAC** recently noted, nearly all of these brand biologics experienced substantial price increases before biosimilar entry. With the exception of Lucentis and Eylea (which had price declines), the brand biologics' cumulative growth in payment rates over the 10 years before biosimilar entry ranged from 6% to 117%.[85]

- A recent Cardinal Health survey found that nearly three-quarters of physician practices (74%) check biosimilar ASP information at least quarterly, while 94% stated that a stable reimbursement rate was somewhat important or very important.
  - In that same survey, 82% of providers noted that they were either very concerned or somewhat concerned that the biosimilar prices would be "underwater." Those that were very concerned (26%) noted that they would consider not prescribing or administering a biosimilar that was "underwater."[86]

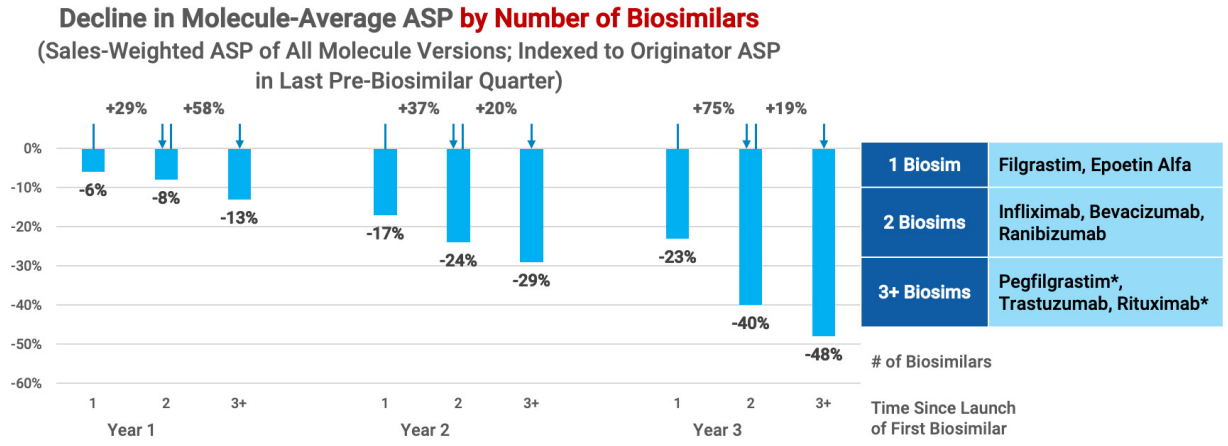
- Given these reimbursement challenges, Congress and the Administration should act to modernize the Medicare Part B reimbursement for biosimilars so that providers are not being reimbursed by CMS for less than the market price of the drug and, as such, putting the biosimilar out of reach for patients.

Biosimilar Competition Results in Savings After Only 2 Biosimilars

A Healthy Market Works for Lower Prices, But Current Reimbursement System Flawed

Second-to-Market Biosimilar Launched Within 3 Years of the First Has Potential to Nearly Double the ASP Pressure

Further Competition (Third and Later Biosimilars) Does Increase ASP Pressure, but Marginal Impact of Further Launches Is Lower Than That of the First and Second Biosimilars



Source: US Market Access Strategy Consulting analysis, CMS ASP Data, NSP Sales, Redbook WAC Data

- Biosimilar competition results in patient savings after only 2 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 3 years of the first can nearly double the ASP pressure, accelerating price erosion for all treatments
  - The first biosimilar was approved in 2015, and as of July 28, 2026, there are 88 FDA-approved biosimilars with dozens more in the queue. The Biosimilar User Fee Amendments (BsUFA) is a law authorizing FDA to assess and collect fees from drug manufacturers that submit BLAs for FDA's review and licensure.
- Policymakers must update the biosimilar reimbursement system in the U.S. to align with today's market realities.
  - A healthy system rewards providers for using lower-cost therapies, instead of punishing them with financial losses.
  - A healthy system increases transparency in pricing and **rebate** structures, particularly around **PBM** practices.
  - A healthy system encourages sustainable biosimilar development by creating predictable and logical market incentives.

PBM "Product Hopping" Suppresses Uptake of Lower-Cost Biosimilars

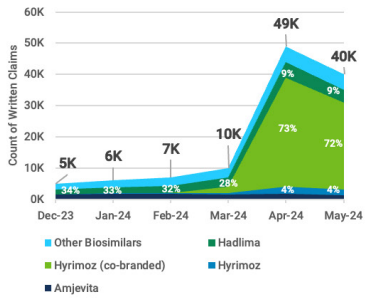
Many PBMs and Health Plans Continue Use of High-Cost Humira Instead of Lower-Cost Biosimilars

While the Launch of Co-Branded Treatments Grew Biosimilar Use in Q2 2024, PBMs Continue to Play a Large Role in Patient Access to Biosimilars

Most Biosimilar Growth Can Be Attributed to Co-Branded Hyrimoz; Volume Still Trails AbbVie's Immunology Portfolio

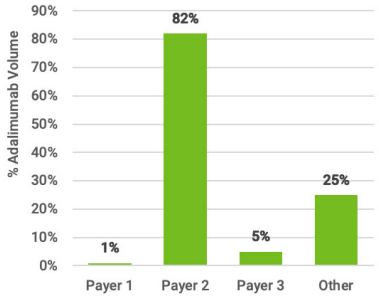
Co-Branded Hyrimoz is Driving Increased Biosimilar Utilization

Adalimumab Biosims Written Scripts by Brand *(LAAD Rx; Filled Claims; All Channels; Feb 2023 – May 2024)*



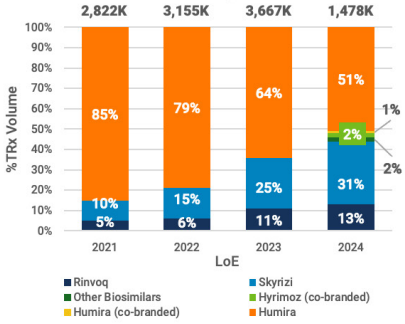
Large PBMs Continue To Favor Humira or Co-Branded Options

% of Ada. TRx from Biosimilars by Payer – May 2024 *(LAAD Rx; Filled Claims; All Channels; May 2024)*



Product Hopping Outpaces Biosimilars

Adalimumab, Skyrizi, and Rinvoq TRx by Brand *(LAAD Rx+Mx; Filled Claims; All Channels; Jan 2021 – May 2024)*



Source: IQVIA LAAD 3.0, US Market Access Strategy Consulting analysis.

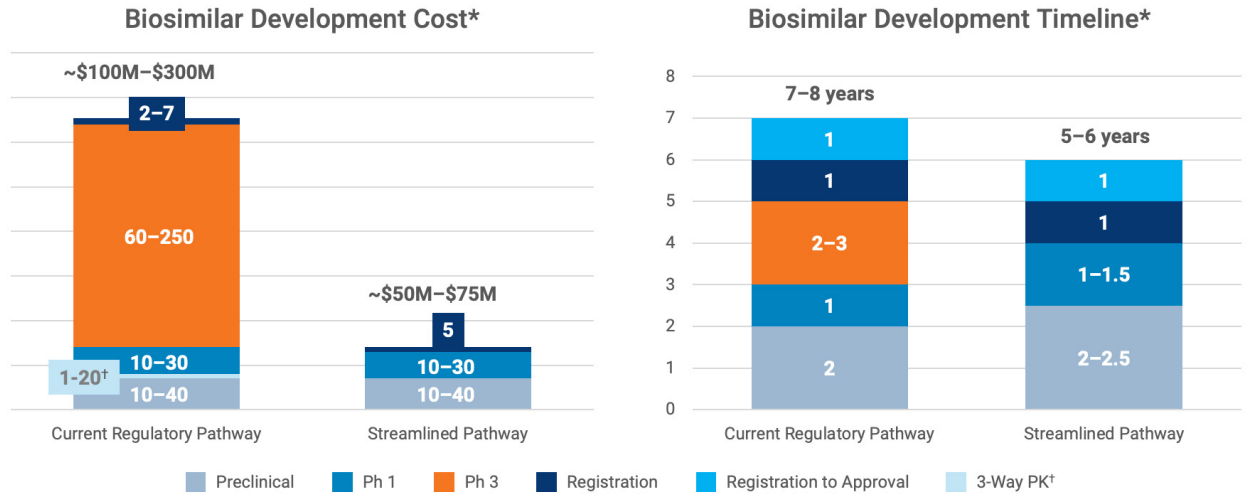
- In the U.S., brand manufacturers will often pay **rebates** to a health plan or **PBM** to ensure that a particular drug is **on formulary** and has little **utilization management**.
- The "**gross to net**" calculation examines the list price and subtracts any of those rebates. In 2024, the "gross to net" reduction for brand products totaled $356 billion.[87]
- These rebate payments create perverse incentives for PBMs and health plans to prefer brand products over generics or biosimilars. Most, if not all, of those rebates get passed on to **plan sponsors**, who then tend to use rebates to reduce premiums and offset overall healthcare costs instead of reducing the cost of prescriptions for patients.[88] Recent reports suggest that, rather than relying on rebates to drive compensation, PBMs are instead focused on various fees (including GPO fees) and **specialty pharmacy** offerings.[89]

- Despite price discounts of greater than 80%, initial adoption of biosimilars to Humira has been incredibly slow. In their first year on the market, biosimilars to Humira achieved less than 2% 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.
- Large PBMs continue to prefer the high-priced brands over biosimilars. As noted in the third chart above, major PBMs have chosen to partner 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 3 products, currently outnumbers all adalimumab biosimilar dispensing.[90]

Streamlining Reduces Investment Burden for New Biosimilars, Expands Options for Patient Care

Updated Interchangeability and CES Rules Key for Faster Access

Biosimilar Development Streamlining Reduces Costs and Time



Source: Figure adapted from Samsung Bioepis (March 2025), Biosimilar Market Report Q2 2025.
* Costs & Development Timelines are estimated ranges
† 3-way PK estimates: *see* Webster & Woollett (May 2017), A 'Global Reference' Comparator for Biosimilar Development; *see also* FDA News Release (March 2026), FDA Takes Further Steps to Streamline Biosimilar Development and Make Medicines More Affordable.

- Biosimilars are about 10–20 times more costly to develop than small molecule generic drugs (about $100–300 million for a biosimilar compared to roughly $2–10 million for a generic).[91] [92]

- While generic drug development does not require data from a clinical comparative efficacy study (CES), initial biosimilar requirements do.

- To enable pharmacy-level substitution (subject to state law), an additional legal distinction of **interchangeability** was added by the **BPCIA**. For a biosimilar to be designated as "interchangeable", the manufacturer would need to perform additional time-consuming and expensive switching studies.

- With time and experience, the FDA began to shift its thinking regarding the various biosimilar requirements.

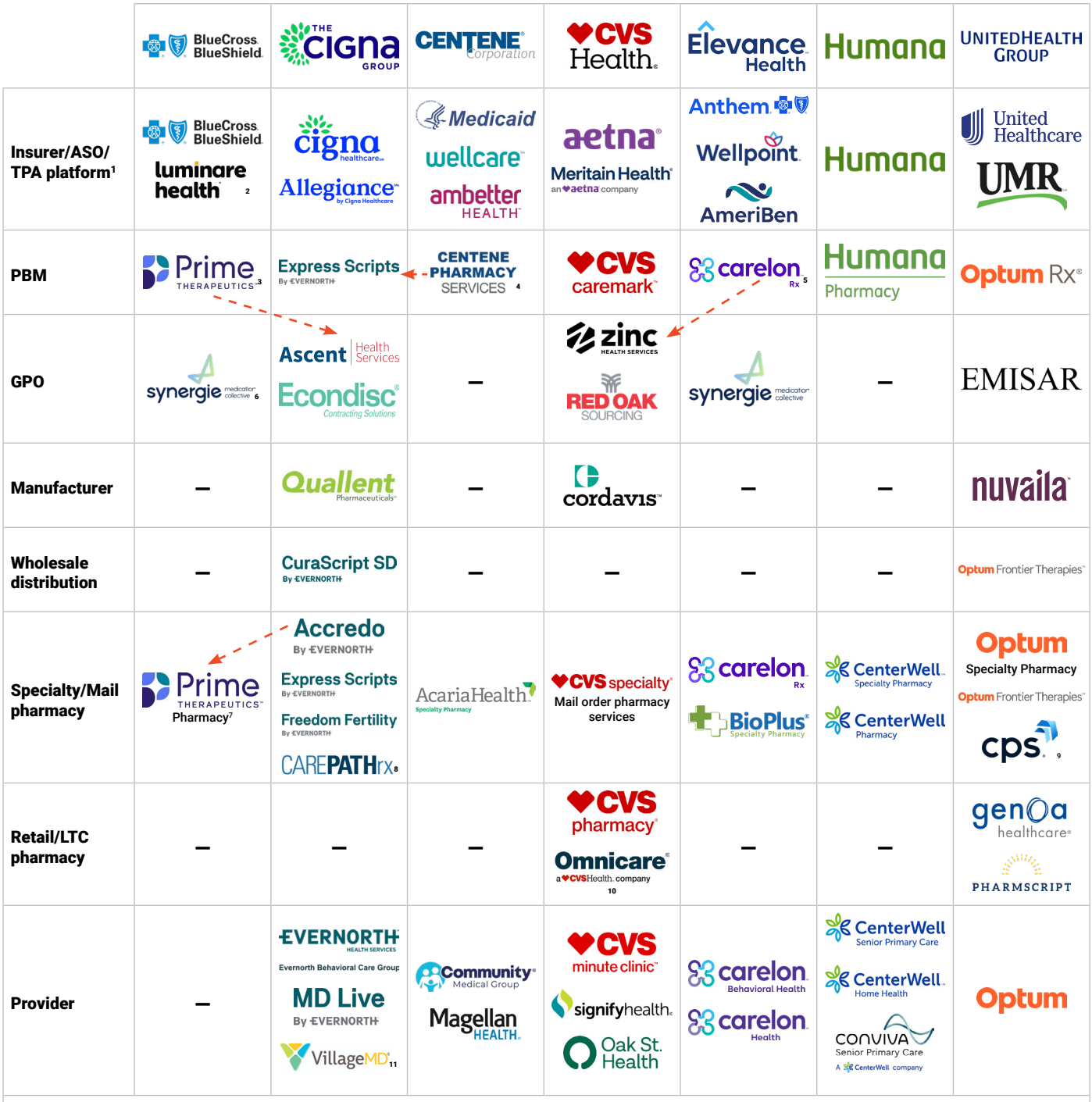
  Initially, the FDA focused on interchangeability.
  - A systematic review by FDA scientists in 2023 showed that switching between reference biologics and their biosimilars showed no difference in safety or immunogenicity in patients who switched.[93]
  - Similarly, in June 2024, the FDA updated its interchangeability guidance enabling biosimilar applicants to assess whether the evidentiary standard has been met through comparative analytical and clinical data in a standard application.[94]

- Subsequently, the FDA focused on CES. In October 2025, through guidance, FDA updated its evidentiary framework to recognize the adequacy of a Comparative Analytical Assessment, eliminating the need for CES.[95]

- Finally, in March 2026, FDA took an additional step to streamline biosimilar development by revising guidance to be more permissive with respect to sponsor use of data from a non-U.S.-licensed comparator reference product, with appropriate caveats (i.e., **global harmonization**).[96]
- These evolutions in streamlining, taken together, could reduce the investment burden of biosimilar development by approximately 50%, freeing up manufacturer resources to pursue additional biosimilar candidates, expand pipelines, and bring more of these important products to market more efficiently *without compromising the evidentiary gold standard*.

Reimbursement Challenges for Generics & Biosimilars

Vertical Business Relationships Within the U.S. Drug Channel, 2026



PBM = pharmacy benefit manager; GPO = group purchasing organization; LTC = long-term care; TPA = third-party administrator; ASO = administrative services only

[1] Many large employers self-fund their health benefits and contract with ASO/TPA platforms for claims administration and network access.
[2] Luminare Health (formerly known as Trustmark Health Benefits) was acquired by Health Care Service Corporation (HCSC) in October 2022 and now operates as an HCSC-owned third-party administrator. HCSC also holds an ownership stake in Prime Therapeutics.
[3] Prime Therapeutics sources formulary rebates from—and has a 10% ownership interest in-Ascent Health Services, which is part of Cigna's Evernorth segment.
[4] In 2022, Cigna invested $2.7 billion for an estimated 14% ownership stake in VillageMD. Following Sycamore Partners' 2025 acquisition of Walgreens Boots Alliance, VillageMD is now a standalone private company. In 2024, Cigna determined that its investment in VillageMD was fully impaired and recorded a $2.7 billion loss
[5] CarelonRx sources formulary rebates from—and has an undisclosed minority interest in —Zinc Health Services, which is a subsidiary of CVS Health.
[6] Synergie is a buying group focused on medical benefit drugs. Its primary owners are: Prime Therapeutics (40%); Elevance Health's CarelonR (26.7%); and Evio Pharmacy Solutions (17.2%), which is itself owned by six Blue Cross Blue Shield health plans.
[7] Synergie is a buying group focused on medical benefit drugs. Its primary owners are: Prime Therapeutics (40%); Elevance Health's CarelonR (26.7%); and Evio Pharmacy Solutions (17.2%), which is itself owned by six Blue Cross Blue Shield health plans.
[8] In 2023, Cigna's Evernorth Health Services acquired a 49% ownership interest in CarepathRx Health System Solutions, which assists hospitals and health systems with specialty pharmacy operations. In 2025, it acquired the remaining 51%, giving it full ownership of CarepathRx. in 2025, Evernorth also invested $3.5 billion for an undisclosed stake in Shields Health Solutions, the former Walgreens Boots Alliance subsidiary with a similar hospital-focused specialty pharmacy model.
[9] In 2024, UnitedHealth Group acquired CPS Solutions, which provides specialty pharmacy services to hospital and health systems.
[10] In May 2026, the U.S. Bankruptcy Court for the Northern District of Texas approved the sale of Omnicare to GenieR Holdings LLC.
[11] In 2022, Cigna invested $2.7 billion for an estimated 14% ownership stake in VillageMD. Following Sycamore Partners' 2025 acquisition of Walgreens Boots Alliance, VillageMD is now a standalone private company. In 2024, Cigna determined that its investment in VillageMD was fully impaired and recorded a $2.7 billion loss

- While **vertical integration** can provide some cost efficiencies, in the opaque prescription drug pricing markets, such integration generally poses problems for policymakers.

- According to a recent report by the HHS Office of Inspector General (OIG), stakeholders have raised concerns about the potential effects of vertical integration, including higher drug costs and anticompetitive behavior that negatively affects independent pharmacies.[97]

- The **Medicare Part D** market is heavily concentrated among a small number of vertically integrated organizations and their associated sponsors. In 2023, 6 of 11 vertically integrated organizations accounted for about 82% of the $275.9 billion in Medicare Part D spending that year. In examining broad market trends, the OIG found that enrollees in plans offered by vertically integrated Medicare Part D sponsors paid lower monthly premiums but substantially higher drug out-of-pocket costs.[98] This cost differential is likely attributed to **rebate walls**.

- In addition, **PBM** practices can inflate patient costs for generics. The Federal Trade Commission 2025 interim report found that the "Big 3" PBMs—CVS Caremark, Express Scripts, and OptumRx—marked up **specialty generic drugs** by hundreds or thousands of percent, allowing them to generate more than $7.3 billion in excess revenue from 2017–2022.[99]
  - These markups, which often apply to cancer and chronic disease drugs, undermine the affordability promise of generics. PBMs have steered patients to affiliated pharmacies where markups are highest, and this has contributed to higher patient out-of-pocket spending.[100]

- Further, vertical integration has a particular impact on **specialty pharmacies**. As outlined in a recent Drug Channels blog, the market share for the dispensing of specialty drugs remains highly concentrated. The top 3 companies accounted for two-thirds of prescription revenues from **pharmacy-dispensed** specialty drugs.[101] These same companies are all part of vertically integrated organizations that also own a PBM.[102] Specialty dispensing accounted for more than one-third of PBMs' total gross profits in 2025.[103]

- Finally, vertical integration may affect the **340B program**. A recent STAT analysis of the Cigna Group's Evernorth Health Services now owns 100% of CarepathRx, a company that helps hospitals and health systems build and operate in-house specialty pharmacies. By expanding deeper into hospital-owned specialty pharmacies, Cigna is executing a novel vertical integration play that helps preserve access to 340B-driven profits through a different channel.[104]

Source: The 2026 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers, Exhibit 267. The exhibit does not illustrate every subsidiary business operated by each company.

Problems With Rebate Walls Exposed in Several Key Studies

Despite Efforts to Increase Flow of Funds, Rebate Walls Increase Costs to Patients

Rebate Walls Increase Costs to Patients

Metric	Formular	Drug A (rebate)	Drug B (no rebate)
WAC	A	$5,000	$1,875
AWP	B = A × 1.2	$6,000	$2,250
AWP Discount	C	20%	20%
Ingredient Cost	D = B × (1 − C)	$4,800	$1,800
Rebate (%)	E	60%	0%
Rebate ($)	F = A × E	$3,000	$0
Net Cost	G = D − F	**$1,800**	**$1,800**
Patient Coinsurance	H = D × 20%	$960	$360
Plan Liability	I = G − H	$840	$1,440

Source: Drug Channels Institute

- The presence of **rebate walls** persists because they are generally beneficial to the health plan, brand manufacturer, and (sometimes) the **PBM**. Health plans want **rebate** dollars because they provide a flow of funds, which can be utilized to offset premium increases (either for the health plan or for the beneficiary). Brand manufacturers pay rebates to ensure the branded product retains its place on the formulary (essential to retain market share).[105] To create headroom to pay rebates, brand manufacturers will often **increase list prices** (also known as the "wholesale acquisition cost" or WAC) and then provide a rebate amount under that. The final price offered to the health plan or PBM is often described as the "net cost."

- Patients, however, generally do not benefit from rebate walls: (1) they pay more for their drugs at the pharmacy counter; and (2) they receive little of the rebate dollars for offsetting their premium costs. As illustrated above, the patient copayment is more closely tied to the WAC, not the net cost.[106] Thus, for a drug that has the same net cost, for a product with a large rebate, the patient would have an additional $630 coinsurance obligation. Health plans benefit by retaining the rebate dollars for the higher priced product, while plan liability is reduced by the additional amount paid by the patient.

- Several authors have documented the problem with rebate walls, Drug Channels analysis related to hepatitis C,[107] while a Health Affairs article details potential rebate challenges for ICS-LABA Inhalers (e.g., Advair).[108] The IRA's Part D redesign may be shifting the dynamics a little, as indicated by new research in JAMA Health Forum (and further discussed by Drug Channels),[109] which reveals a significant reversal in Medicare Part D formulary coverage for multiple sclerosis drugs.[110]

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Concentrated Buying Power Creates Peril for Generic and Biosimilar Manufacturers

Unsustainable Conditions Translate to Increased Potential for Drug Shortages and Market Exit, Resulting in Fewer Options for Patients

Generics			
Product Type	**Where Product Reaches Patient**	**Purchaser or Decision-Maker**	**Entities & Market Share**
Traditional Generic	Local Pharmacy	Generic Buying Consortia	Three entities control 90% of the market: • Red Oak Sourcing • Walgreens Boot Alliance with AmerisourceBergen coupled with Econdisc Contracting Solutions • McKesson OneStop + ClarusOne (Walmart)
Specialty Generic	Specialty Pharmacy	Specialty Pharmacy	Three entities control 2/3 of the prescription drug revenue: • CVS Specialty • Accredo/Freedom Fertility • Optum Specialty Pharmacy

Biosimilars			
Product Type	**Where Product Reaches Patient**	**Purchaser or Decision-Maker**	**Entities & Market Share**
Traditional Generic	Local Pharmacy	Generic Buying Consortia	Three entities control 90% of the market: • Red Oak Sourcing • Walgreens Boot Alliance with AmerisourceBergen coupled with Econdisc Contracting Solutions • McKesson OneStop + ClarusOne (Walmart)
Specialty Generic	Specialty Pharmacy	Specialty Pharmacy	Three entities control 2/3 of the prescription drug revenue: • CVS Specialty • Accredo/Freedom Fertility • Optum Specialty Pharmacy

- For generic and biosimilar manufacturers, **horizontal consolidation** within the pharmaceutical supply chain has created additional pricing pressure. Moreover, depending on the particular **drug channel** (i.e., how the patient receives the medication), the consolidated decision-makers may differ.

- For **traditional generics**, 3 generic buying consortia comprise about 90% of the generic drug purchases.[111]

- For **specialty generics**, the top 3 companies accounted for two-thirds of prescription revenues from pharmacy-dispensed specialty drugs.[112] These businesses are all part of **vertically integrated** organizations that also own a PBM.[113]

- With respect to PBMs, which are highly influential in the biosimilars market, 3 entities processed 80% of all equivalent prescription claims.[114]

- Fewer decision-makers means fewer access points for the more than 200 generic and biosimilar manufacturers in the U.S. The constant downward contractual pressure used by the supply chain purchasers can result in unsustainably low prices.

- In addition, given the greater bargaining power of the various decision-makers, generic and biosimilar manufacturers may be subject to one-sided contract terms, including:
  - **Failure to supply clauses**, which require drug manufacturers to pay a fee if they are unable to supply a particular drug to cover the cost of receiving the drug from another supplier;[115]
  - **Low-price clauses**, which allow a buyer to terminate the contract if a lower priced product is available;[116]
  - **Most favored nations clauses**, which guarantee health plans the same or more favorable rates for services given to other health plans;[117] or
  - **Reverse distribution arrangements**, which allow the hospital pharmacy to return expired, adulterated, or discarded pharmaceuticals in return for a credit.[118]

AAM Policy Priorities: Moving Generics & Biosimilars Forward in 2026

Regulatory, Policy, and Legal Environments that Prioritize the Generic and Biosimilar Industry as a Force for Health and Economic Resilience and National Security Help to Safeguard the Health of America and its Citizens

America's patients are facing an urgent challenge that could jeopardize their 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 a lower cost. Yet, a perfect storm of regulatory hurdles, patent abuses, and flawed policies now threatens the very foundation of this system, putting the industry in peril and the health and financial stability of patients at risk.

Generics and biosimilars are essential to the U.S. healthcare infrastructure. In 2025, these medicines accounted for 89% of prescriptions dispensed in the U.S. but only 11.6% of total drug spending. Over the past decade, their widespread adoption has saved the healthcare ecosystem an astounding $3.6 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 right now, this success story is 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 the industry.

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.

- **Patent Abuse:** Brand-name 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:** 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-name 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 could face dangerous interruptions in their 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 be forced to endure the burden of soaring healthcare costs, and the very principles of competition and innovation that have driven the success story of generics and biosimilars will be eroded.

Protecting Access: A Call to Action

If policymakers are serious about health and economic resilience, national security, and protecting patients through sustainable access to affordable medicines, they must act decisively to address these systemic threats. With gratitude for recent progress around current priorities, we urge additional action, 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 to remove redundant clinical studies;
  - Updating the **Biologics Price Competition and Innovation Act of 2010 (BPCIA)** to deem all biosimilars interchangeable and eliminate the requirement for **comparative efficacy studies**; and
  - Restoring the safe harbor for "**skinny labeling**" providing timely entry of generic and biosimilar medicines by allowing manufacturers to carve out patented indications from label information.

- **Curb Patent Abuse:** Congress must stop the misuse of the patent system by limiting the number of patents brand-name manufacturers can assert, safeguarding the ability to enter into procompetitive patent settlements, and preventing anticompetitive practices that delay access to generics and biosimilars.

- **Stop Misguided State Proposals:** State legislatures should refrain from introducing proposals to regulate the price of generic medicines and proposals to ban patent settlements. Several recently enacted state statutes have been promptly challenged in court and found to be unconstitutional.

- **Stop PBMs and Medicare policies from denying patients access to new generics and biosimilars:** Plans and PBMs must stop prioritizing higher-priced brand-name drugs over generics and biosimilars. Reforms passed in early 2026 were an important first step toward reining in PBM practices that drive up costs for our healthcare system. Congress and the Administration should build on these reforms and go further to ensure patient access to new generic and biosimilar medicines is not blocked by middlemen tactics. Policymakers can take meaningful steps to realign incentives and ensure rebates and fees that drive formulary design and product placement result in lower patient and plan costs. Medicare can also address coverage disparity of generics and biosimilars by modifying its formulary review and approval criteria.

- **Ensure Adequate Reimbursement:** Given the "**biosimilar void**", Congress and the Administration should act to modernize the Medicare Part B reimbursement for biosimilars so that providers are not "**underwater**"—being reimbursed by CMS for less than the market price of the drug and, as such, putting the biosimilar out of the reach for patients.

- **Promote Effective State Policies:** States can take steps 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 biosimilar competition by refining and extending the biosimilar delay request, ending the unfounded and unclear "bona fide marketing" standard, updating the eligibility timeline so that it reflects the average time for a generic or biosimilar to come to market, and ensure that all provisions of the IRA support generic and biosimilar competition.

Conclusion

Without a doubt, generic and biosimilar medicines provide value to patients, taxpayers, employers, and the U.S. healthcare system through savings and high-quality treatments. As such, the generic and biosimilar industry is more than the backbone of healthcare in America—it is a driving force of strength, stability, and security in the U.S.

The current global nature of the generic and biosimilar medicines industry has already been established as foundational to infusing affordability into the U.S. healthcare system. However, the industry responsible for 89% of all prescriptions filled by Americans has extreme potential to bolster domestic job creation and foster national security and economic resilience. With more than $496 billion in savings generated in 2025 alone at risk, and value compression across the U.S. market, now is the time for the Administration, policymakers, regulators, and industry advocates to take purposeful steps to mitigate these risks.

Failing to act will mean higher costs, less access, and fewer options for patients. Generic and biosimilar medicines are more than a healthcare imperative. They are a means of survival for nearly every American, from both a health and financial perspective. AAM and its Biosimilars Council urge policymakers to move swiftly to protect this system and ensure patients are not forced to choose between their health and financial security, their medicines and their homes, their treatments and their livelihoods. Sustainable access to lower-cost, lifesaving prescription options is not about dollars and cents—it's about safety, resilience and lives.

The fix is simple, but not easy. Across federal and state jurisdictions, sustained and focused actions are necessary for long-term change. With patience, substantial and consistent investments, and a commitment to transformational growth, the current challenges and risks faced by generic and biosimilar manufacturers can be eliminated—moving the industry *forward* as a dynamic vehicle for economic viability, national security, and an overall healthier America.

Glossary of Terms

- **340B program:** Program requires drug manufacturers participating in Medicaid to provide outpatient drugs to covered entities at significantly reduced prices. To participate in the 340B Program, covered entities must register and be enrolled with the 340B program and comply with all 340B Program requirements administered by the Health Resources and Services Administration.[119]

- **Abbreviated New Drug Application or ANDA:** An abbreviated new drug application contains data that is submitted to the FDA for the review and potential approval of a generic drug product. Once approved, an applicant may manufacture and market the generic drug product to provide a safe, effective, lower-cost alternative to the brand-name drug it references.[120]

- **Acquisition cost:** The cost of obtaining a drug.

- **Active pharmaceutical ingredient or API:** Under 21 CFR 207.1, the FDA defines an active pharmaceutical ingredient as "any substance that is intended for incorporation into a finished drug product and is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body. Active pharmaceutical ingredient does not include intermediates used in the synthesis of the substance."

- **Additional days of therapy:** The number of defined daily doses above the expected number had biosimilars not entered the market based on the growth of the brand molecule 3 years prior to first biosimilar product entry.

- **Affiliated pharmacies:** A network pharmacy that directly, or indirectly through 1 or more intermediaries, controls, is controlled by, or is under common control with, a pharmacy benefit manager or where the pharmacy benefit manager has financial interest in the pharmacy.[121]

- **Approved:** "FDA approved" means the U.S. Food and Drug Administration has reviewed scientific evidence showing a product is safe and effective for its intended use before it can be sold.[122] Approved drug products have been determined by the FDA to be safe and effective. Approved drugs (regulated by the Center for Drug Evaluation and Research [CDER]) have been evaluated and reviewed by CDER for safety and effectiveness and may be marketed in the U.S. Approved drugs are subject to the following types of drug applications: NDA (new drug application) and ANDA (abbreviated new drug application).[123]

- **Average sale price or AMP:** As defined under 42 CFR 447.504, means, for a covered outpatient drug of a manufacturer (including those sold under an NDA approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act), the average price paid to the manufacturer for the drug in the U.S. by wholesalers for drugs distributed to retail community pharmacies and retail community pharmacies that purchase drugs directly from the manufacturer.[124]

- **Average sale price or ASP:** Statutorily regulated price reported by manufacturers to CMS on a quarterly basis. ASP is used as a basis to reimburse providers for provider-administered drugs under the Medicare Part B program but may also be used by other payers, such as commercial insurers, as well.[125]

- **Biologic license application or BLA:** Submission that contains specific information on the manufacturing processes, chemistry, pharmacology, clinical pharmacology, and the medical effects of the biologic product. If the information provided meets FDA requirements, the application is approved, and a license is issued allowing the firm to market the product.[126] Both biologic medicines, brand and biosimilars, submit BLAs.

- **Biologic medicines (brand):** Biological products are approved for marketing uBiological products are approved for marketing under the provisions of the Public Health Service Act. The Act requires a firm that manufactures a biologic for sale in interstate commerce to hold a license for the product.[127] In

this report, the term "biologic medicine" sometimes refers to the brand product.

- **Biologics Price Competition and Innovation Act of 2010:** The BPCIA established an abbreviated FDA approval pathway for biosimilar and interchangeable biological products, similar to the pathway for generic drugs. The law was enacted to increase competition in the biologics market while preserving incentives for innovation through a period of exclusivity for reference biologic products. It also created a framework for resolving patent disputes between biosimilar applicants and reference product sponsors. 42 U.S.C. § 262

- **Biosimilar:** A biosimilar is a biologic medication. It is highly similar to a biologic medication already approved by the FDA—the original biologic (also called the reference product). Biosimilars also have no clinically meaningful differences from the reference product. This lack of clinical difference means you can expect the same safety and effectiveness from the biosimilar over the course of treatment as you would the reference product. Biosimilars are made from the same types of sources (e.g., living cells or microorganisms) and are just as safe and effective as their reference products.[128]

- **Biosimilar efficiency rate:** The rate at which biosimilars are dispensed when available is both a function of market access over time and a marker for new entrants, given that the efficiency rate is generally lower for new entrants.

- **Biosimilar void:** A biosimilar void occurs when biologic medicines approaching loss of exclusivity have no biosimilar competitors in development, despite the potential for cost savings and increased patient access.[129]

- **Brand drug /Brand medicine:** A brand drug or medicine is the original version of a medication that's FDA-approved to treat a specific condition.[130]

- **"Buy and bill" or Medical benefit:** Process where physician offices receive medications for in-office administration. Providers order the medication (the "buy" part) and receive reimbursements from third-party payers (the "bill" part). This process is commonly used for outpatient drugs administered by providers, with the cost of the drugs typically reimbursed by Medicare Part B.[131]

- **Clinical comparative efficacy studies (CES):** Studies conducted in patients that compare the biosimilar and reference product using an efficacy endpoint, which is a measurable outcome intended to reflect whether a treatment is working. Such endpoints can take different forms. Some are pharmacodynamic endpoints, which measure the biological effect of a drug in the body. Others are traditional clinical endpoints, such as symptom improvement or disease progression. While these studies may seem intuitive, they are the least sensitive tool for detecting clinically meaningful differences between a biosimilar and its reference product. Structural differences between 2 biological products do not necessarily translate into observable differences in clinical efficacy, and patient variability and confounding factors can obscure meaningful signals.[132]

- **Complex generics:** FDA notes that "complex generics" are products that have complex active ingredients, formulations, dosage forms, or routes of administration, or are complex drug-device combination products.[133]

- **COPD or chronic obstructive pulmonary disease:** Ongoing lung condition caused by damage to the lungs. The damage results in swelling and irritation, also called inflammation, inside the airways that limit airflow into and out of the lungs. This limited airflow is known as obstruction. Symptoms include trouble breathing, a daily cough that brings up mucus, and a tight, whistling sound in the lungs called wheezing.[134]

- **Defined daily doses:** Total days of therapy based on dosing outlined in the FDA-approved drug label, which assumes chronic and maintenance dosing.

- **Drug channel:** Process, including all intermediaries, through which a drug is delivered from the

manufacturer to the patient. Depending on the drug product, the flow of the actual product (e.g., traditional generic, specialty generic, or biosimilar), as well as payment for the product, can vary.

- **Excipient:** According to 21 CFR 210.3(b)(8), an inactive ingredient, more commonly known as an excipient, is any component of a drug product other than the active ingredient. To aid manufacturers with determining appropriate inactive ingredients, the FDA maintains an inactive ingredient database. However, only inactive ingredients in the final dosage forms of approved drug products are in this database, and the database does not include a listing of any potential contaminants or byproducts included within the finished drug form.

- **Exclusivity:** Refers to certain delays and prohibitions on approval of competitor drugs available under the statute that attach upon approval of a drug or of certain supplements. An NDA or ANDA holder is eligible for exclusivity if statutory requirements are met.[135] See also "loss of exclusivity."

- **Failure to supply clauses:** Contract requirement which requires drug manufacturers to pay a fee if they are unable to supply a particular drug to cover the cost of receiving the drug from another supplier.[136]

- **Finished drug product or finished dosage form:** Under 21 CFR 207.1, the FDA notes that a finished drug form is "a finished dosage form (e.g., tablet, capsule, or solution) that contains at least 1 active pharmaceutical ingredient, generally, but not necessarily, in association with other ingredients in finished package form suitable for distribution to pharmacies, hospitals, or other sellers or dispensers of the drug product to patients or consumers."

- **Formulary placement:** Drug tiering is the formulary placement of a drug product for coverage determinations by a **Pharmacy Benefit Manager**. This placement determines how accessible a drug will be in the market, which directly influences how many patients can access the medication. Drug tiering can be simple—such as distinguishing between preferred vs. non-preferred drugs—but it can also be quite complex. Formularies often use 3 or 4 tiers, though some may have up to 6 or more distinct tiers. Tier 1 is typically reserved for the most preferred drugs, and as the tier number increases, drugs become less affordable with higher cost-sharing for the patient.[137]

- **Friendshoring:** Growing trade practice where supply chain networks are focused on countries regarded as political and economic allies. Other trade buzzwords around global supply chains include 'nearshoring,' 'reshoring,' and 'onshoring.'[138]

- **Generic or generic drug:** A generic drug is the same as a brand drug in dosage, safety, strength, how it is taken, quality, performance, and intended use. Before approving a generic drug product, the FDA requires many rigorous tests and procedures to assure that the generic drug can be substituted for the brand drug. The FDA bases evaluations of substitutability, or "**therapeutic equivalence**," of generic drugs on scientific evaluations. By law, a generic drug product must contain the identical amounts of the same active ingredient(s) as the brand product. Drug products evaluated as "therapeutically equivalent" can be expected to have equal effect and no difference when substituted for the brand product.[139]

- **Generic Drug User Fee Act or GDUFA:** Congress enacted GDUFA to ensure patients have access to safe, high-quality, and affordable **generic drugs**. GDUFA enables FDA to assess industry user fees to bring greater predictability and timeliness to the review of generic drug applications.[140]

- **Global comparator or global comparability principles:** Major drug regulators have indicated in guidance their flexibility to accept some development data for biosimilars generated with reference product versions licensed outside their own jurisdictions, but most authorities require new bridging studies between these versions and the versions of them licensed locally. The costs of these studies are not trivial in absolute terms and, due to the multiplier effect of required repetition by each biosimilar sponsor, their collective costs

are substantial. Yet versions of biologics licensed in different jurisdictions usually share the same development data, and any manufacturing changes between versions have been justified by a rigorous comparability process. The fact that a biosimilar is usually expected to be licensed in multiple jurisdictions, in each case as similar to the local reference product, confirms that minor analytical differences between versions of reference biologics are typically inconsequential for clinical outcomes and licensing. A greatly simplified basis for selecting a reference comparator that does not require conducting new bridging studies is proposed and justified based on the shared data of the reference product versions and the proof offered where biosimilars have already been approved.[141]

- **GLP-1s or glucagon-like peptide-1 agonists:** Class of medications that mainly help manage blood sugar (glucose) levels in people with Type 2 diabetes. Some GLP-1 agonists can also help treat obesity.[142]

- **"Gross to net":** The manufacturer establishes the drug's **list (gross) price**, called the **Wholesale Acquisition Cost (WAC)**. A manufacturer's gross revenues equal its revenues from sales at a drug's WAC list price. A drug's net price equals the actual revenues that a manufacturer earns from a drug after **rebates**, discounts, and other reductions. A drug's net revenues equal its revenues from sales at the drug's net price. Drug channel intermediaries—pharmacies, **PBMs**, wholesalers, and payers—do not have access to manufacturers' net prices. The largest components of gross-to-net price reductions for brand-name drugs include: (1) Rebates, discounts, and fees to commercial payers and plans; (2) Rebates and discounts in **Medicare Part D**; (3) Rebates to the Medicaid program; Discounts under **the 340B Drug Pricing Program**; (4) Manufacturers' payments to drug channel participants, including administrative and other fees to PBMs as well as fees and discounts to pharmacies, wholesalers, and other purchasers; and (5) Patient assistance and copayment support funds.[143]

- **Horizontal consolidation:** Occurs when organizations consolidate with others operating at the same stage of the supply chain, such as hospital systems merging with other hospitals or insurers merging with other insurers.[144]

- **Inflation Reduction Act of 2022 (IRA):** Federal law that significantly reforms Medicare prescription drug pricing by authorizing the Secretary of Health and Human Services to negotiate prices for certain high-expenditure Medicare drugs, requiring drug manufacturers to pay **rebates** when prices increase faster than inflation, and redesigning the **Medicare Part D** benefit regarding out-of-pocket costs. 42 U.S.C. § 1320f et seq.

- **Interchangeable / interchangeability:** An interchangeable product is a biosimilar product that meets additional requirements outlined by the **Biologics Price Competition and Innovation Act**. As part of fulfilling these additional requirements, information is needed to show that an interchangeable product is expected to produce the same clinical result as the reference product in any given patient. Also, for products administered to a patient more than once, the risk in terms of safety and reduced efficacy of switching back and forth between an interchangeable product and a reference product will have been evaluated. An interchangeable product may be substituted for the reference product without the involvement of the prescriber. FDA's high standards for approval should assure healthcare providers that they can be confident in the safety and effectiveness of an interchangeable product, just as they would be for an FDA-approved reference product.[145]

- **Key starting materials or KSM:** Not defined by regulation and likely includes a variety of products, including inactive ingredients and other intermediate ingredients (e.g., acids, bases, etc.).

- **Licensed:** Licensed products are biological products that have been determined by FDA to be safe, pure, and potent. Biological products, once licensed, may be marketed in the U.S. Some biological products are regulated by CDER, while others are regulated by the Center for Biologics Evaluation and Research (CBER). Licensed biological products are subject to BLAs (biologic license applications).[146]

- **List price or WAC:** Also known as the list price, manufacturer's price for a drug to wholesalers or direct purchasers, before any discounts or **rebates**.[147]

- **Local currency converted to U.S. dollars or LCUS:** As used by IQVIA, a measure of the total percentage of costs of pharmaceuticals, with the local currency converted to U.S. dollars at a constant exchange rate to allow for international comparisons.

- **Losing exclusivity, loss of exclusivity, or LOE:** The point at which a brand-name drug loses the legal protections that prevent competitors from selling cheaper versions (i.e., generics and biosimilars).[148]

- **Low-price clauses:** Contract requirement, which allows a buyer to terminate the contract if a lower-priced product is available.[149]

- **Medicare Part D:** Voluntary outpatient prescription drug benefit for people with Medicare provided through private plans that contract with the federal government. Beneficiaries can choose to enroll in either a stand-alone prescription drug plan (PDP) to supplement traditional Medicare or a Medicare Advantage drug plan (MA-PD) that includes drug coverage and all other Medicare-covered benefits.[150]

- **Most favored nations clauses:** Contract requirement which guarantees health plans the same or more favorable rates for services given to other health plans.[151]

- **No clinically meaningful differences:** Statutory requirement for **biosimilars**. Requires a biosimilar licensed in the U.S. to have no clinically meaningful differences "in terms of safety, purity, and potency."[152]

- **On formulary:** Drug tiering is the formulary placement of a drug product for coverage determinations by a Pharmacy Benefit Manager. This placement determines how accessible a drug will be in the market, which directly influences how many patients can access the medication. Drug tiering can be simple—such as distinguishing between preferred vs. non-preferred drugs—but it can also be quite complex. Formularies often use 3 or 4 tiers, though some may have up to 6 or more distinct tiers. Tier 1 is typically reserved for the most preferred drugs, and as the tier number increases, drugs become less affordable with higher cost-sharing for the patient.[153]

- **Maximum fair price or MFP:** Maximum per-unit price that a manufacturer may charge Medicare for drugs selected under the Medicare Drug Price Negotiation Program created by the **Inflation Reduction Act**. The MFP is bounded by 40%–75% of the drug's nonfederal **AMP**, depending on the type of drug and how long it has been on the market.[154]

- **Medical benefit:** See **"Buy and bill."**

- **Medicare Payment Advisory Committee or MedPAC:** Nonpartisan independent legislative branch agency that provides the U.S. Congress with analysis and policy advice on the Medicare program.[155]

- **Off-patent medicine:** A pharmaceutical product experiencing a loss of exclusivity. In addition to generics and biosimilars, off-patent medicines include generics and biosimilars as well as older brand drugs whose patents have expired but are still sold under their original brand names.

- **Patent thicket:** Dense webs of often overlapping patents. These patents often cover the same or very similar subject matter, and overcoming these thickets can be costly and delay less expensive competition (i.e., generics and biosimilars).[156]

- **Patient therapy days:** Total days of therapy based on dosing outlined in the FDA-approved drug label; assumes chronic and maintenance dosing. IQVIA utilizes the term **"defined daily doses**."

- **Pharmacy benefit or pharmacy dispensed:** A drug provided to a patient via a pharmacy (not as part of a physician office visit). May be referred to as a Medicare Part D drug.

- **Pharmacy benefit managers or PBMs:** Pharmacy benefit managers manage prescription drug plan benefits for insurers or employers. PBMs are "middlemen" in the prescription drug supply chain.

PBMs were established in the 1960s to help insurers control prescription drug spending and manage benefits. Consolidation and vertical integration in the PBM market have raised concerns about the potential for reduced competition and higher prescription drug prices.[157]

- **Plan sponsor:** Entity responsible for establishing or maintaining an employee benefit plan. This term can refer to as: (1) The employer in the case of a plan set up by a single employer; (2) The employee organization if the plan is created or maintained by that organization; (3) A group of representatives, such as an association or a joint board of trustees, when the plan is established by multiple employers or jointly by employers and employee organizations.[158]

- **Pre-Expiry:** Time before the loss of exclusivity or LOE.

- **Rebates:** Discount on the medication that a pharmaceutical manufacturer gives a PBM in return for agreeing to include their drug on the formulary for a pharmacy benefit plan.

- **Rebate walls:** Rebate walls refer to a situation in which a dominant pharmaceutical manufacturer uses **rebate** strategies in its contracts with third party payors to maintain market power, by giving its products preferred status in drug formularies, and to prevent sales of competing products.[159]

- **Reference listed drug:** An approved drug product to which new generic versions are compared to show that they are bioequivalent. A drug company seeking approval to market a generic equivalent must refer to the Reference Listed Drug in its ANDA. By designating a single reference listed drug as the standard to which all generic versions must be shown to be bioequivalent, FDA hopes to avoid possible significant variations among generic drugs and their brand drug counterpart.[160]

- **Reference product:** A reference product is the single biological product, already approved by FDA, against which a proposed biosimilar product is compared. A reference product is approved based on, among other things, a full complement of safety and effectiveness data. A proposed biosimilar product is compared to and evaluated against a reference product to ensure that the product is highly similar and has no clinically meaningful differences.[161]

- **Reverse distribution arrangements:** Contract requirement which allows the hospital pharmacy to return expired, adulterated, or discarded pharmaceuticals in return for a credit.[162]

- **Skinny labeling:** Mechanism that allows a generic drug maker to obtain FDA approval for only the non-patented uses of a branded drug by carving out patented indications from its product labeling.[163]

- **Specialty drug:** While definitions of "specialty" products may vary, for this analysis, IQVIA defined a "specialty drug" as one that treats chronic, complex, or rare diseases and has a minimum of 4 out of 7 dditional characteristics related to the distribution, care delivery, or cost of the medicine.

- **Specialty generic product:** The term 'specialty generic' covers ground that the standard ANDA definition does not. A conventional generic replicates a small-molecule oral solid with a straightforward pharmacokinetic profile. A specialty generic replicates—or closely approximates—a drug that is complex by formulation, delivery system, active substance, or manufacturing process.[164]

- **Specialty pharmacy:** Specialty pharmacies help patients manage complex, chronic, or rare conditions that often require expensive medications, special handling, ongoing monitoring, or personalized support. These pharmacies provide more than prescription delivery. They also help with insurance approvals, patient education, side effect management, refill coordination, and financial assistance programs.[165]

- **Standard unit:** In the context of the IQVIA analysis, this is a measure of volume to compare market dynamics between different countries as it relates to generics and biosimilars compared to brands.

- **Supportive care products:** Refers to drugs or products primarily used for the treatment of adverse effects associated with cancer therapy, as well as to treat signs and symptoms of cancer, such as low blood counts, hair loss, vomiting, and nausea, among others. Cancer supportive care products, such as supportive drugs, are sometimes used to reduce the side effects of cancer treatment by protecting certain cells or organs.[166]

- **Traditional generic products: ANDA applications**, typically focused on oral solids.

- **Underwater:** Term used for certain physician-administered or medical benefit biosimilars in which the acquisition costs exceed reimbursement levels.[167]

- **Utilization management:** Set of techniques that health insurers and other payers use to control healthcare costs by evaluating whether a specific medical service is appropriate before, during, or after it's provided. In practical terms, it's the reason an insurance company sometimes requires approval before a surgery, an MRI, or a particular medication. The goal is to ensure that the care is medically necessary, delivered in the right setting, and not more extensive than necessary.[168]

- **Vertical integration:** Typically refers to common ownership of entities at different stages of a supply chain. In the healthcare industry, this would include hospitals acquiring independent physician offices, and corporations owning entities with different functions. For example, CVS Health owns Aetna (insurer), CVS Caremark (pharmacy benefit manager), and Oak Street Health (primary care provider group).[169]

- **Wholesale acquisition cost or WAC:** Also known as the **list price**, manufacturer's price for a drug to wholesalers or direct purchasers, before any discounts or rebates.[170]

Methodology

Generic drug savings in the U.S.: Fifteenth 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 1,092 generic molecules. The value of each generic molecule was determined by multiplying its pre-expiry brand price by the generic volume sold in each of the last ten years. This value represents what would have been spent on brand medicines in the absence of generic competition.

The savings attributed to each of the 1,092 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 U.S. between 1993 and 2025, focusing on the 10-year savings for the period 2016 to 2025. Savings from generics launched in the 1994 to 2025 study period are based on the most current knowledge of their pre-expiry prices. Savings from generics launched prior to 1994 were calculated using brand prices from 1993, 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 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 2 assumptions: first, that prices are uniform across the country, and second, that retail prescription activity mirrors prescription activity in other channels, notably mail order.

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

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

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

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Contact Us

Association for Accessible Medicines

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

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