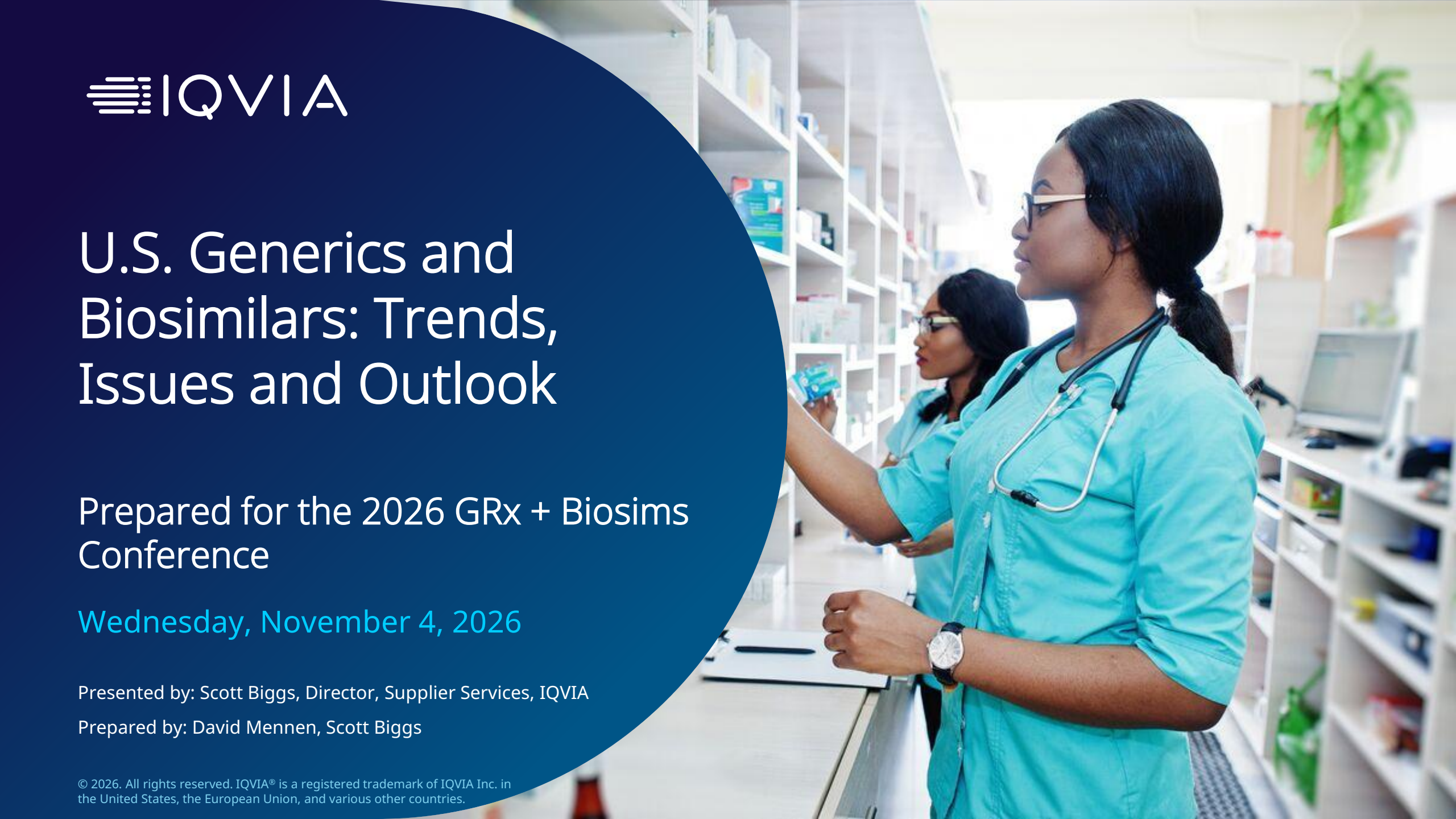
U.S. Generics and Biosimilars: Trends, Issues and Outlook

Prepared for the 2026 GRx + Biosims Conference

Wednesday, November 4, 2026

Presented by: Scott Biggs, Director, Supplier Services, IQVIA

Prepared by: David Mennen, Scott Biggs



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Agenda

- Introduction
- Current Market Performance
- Generics and Biosimilars
- Retail Pharmacy
- GLP-1s
- On the Radar
- Wrap-up



Disclaimer slide

Disclaimer

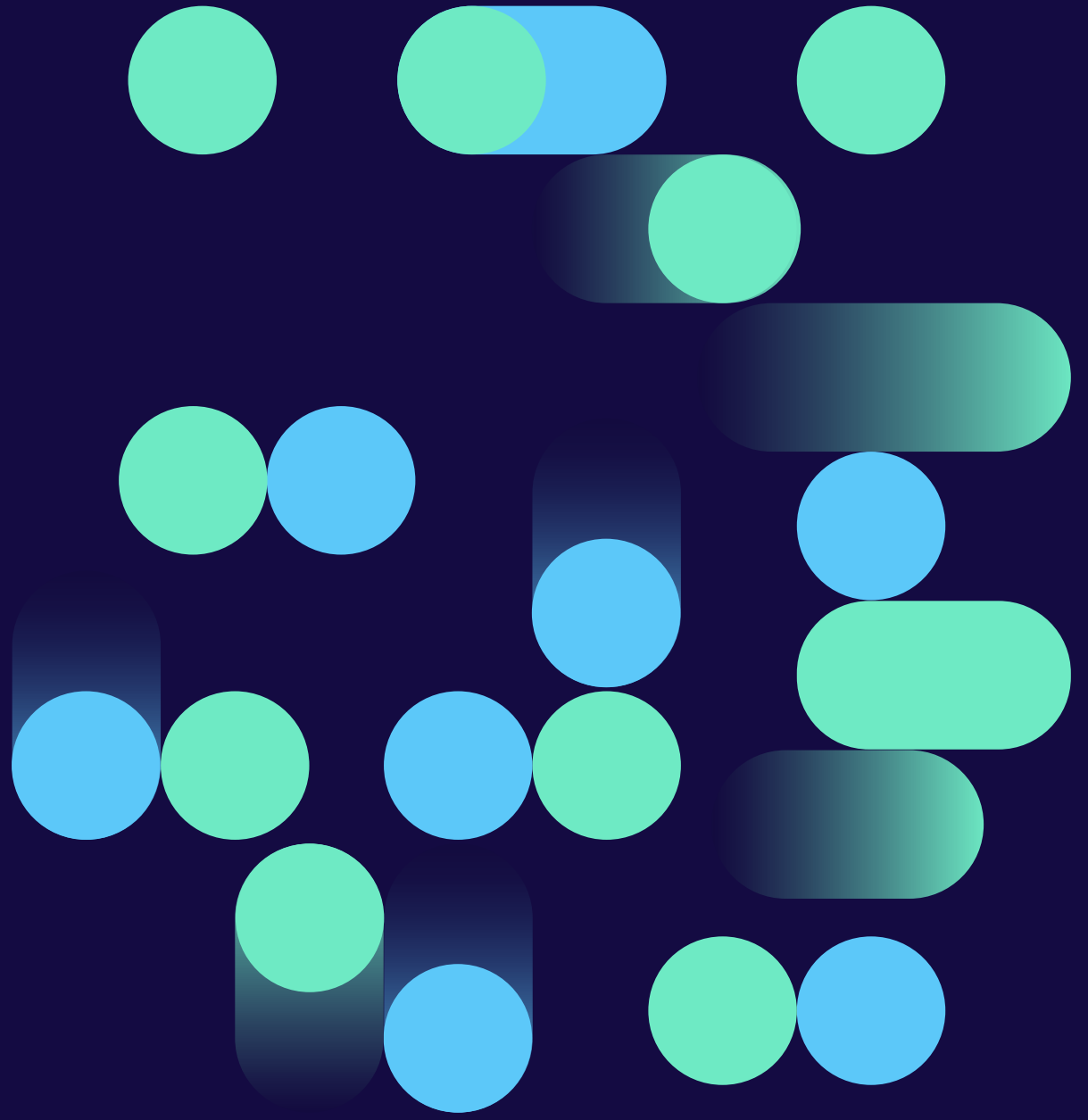
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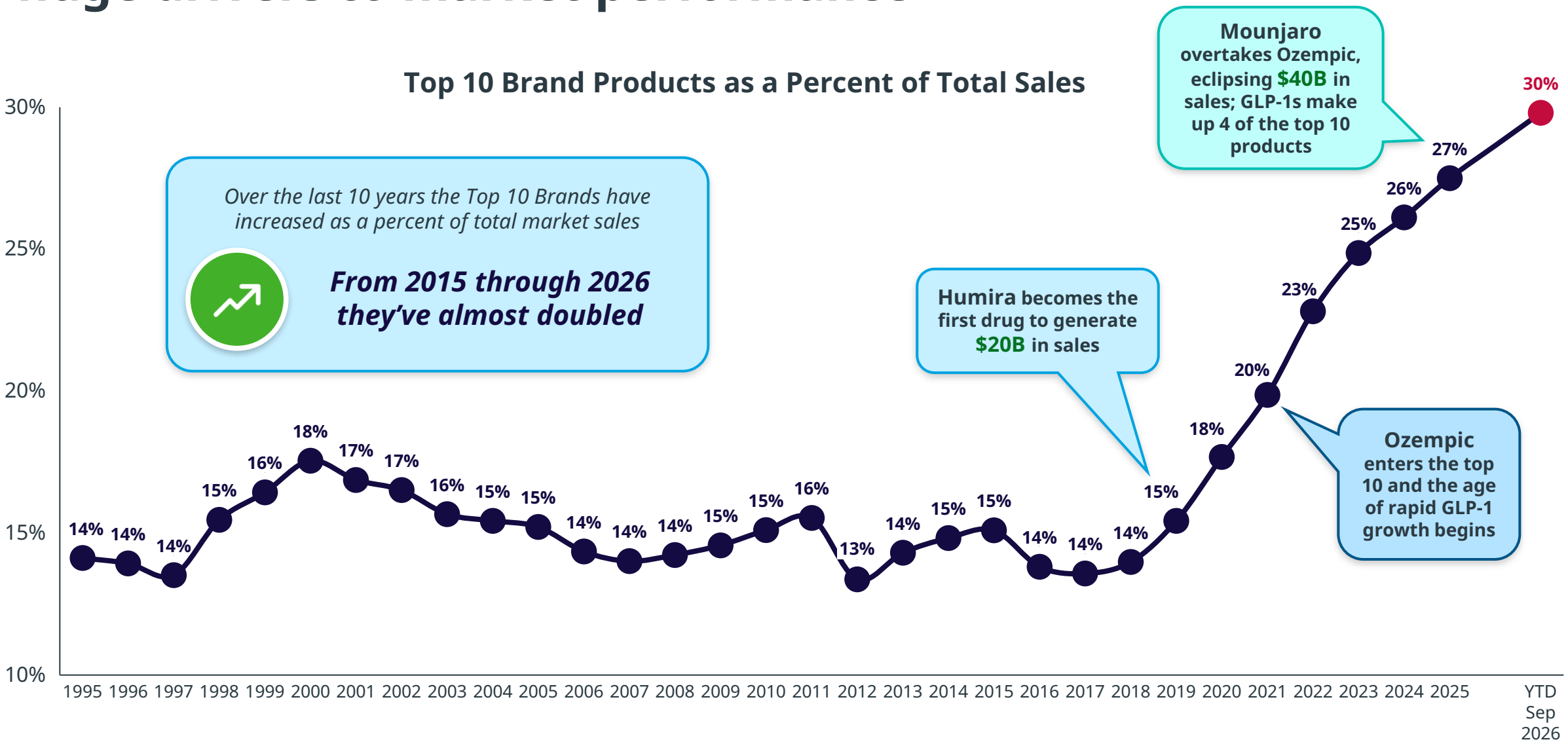
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Current Market Performance

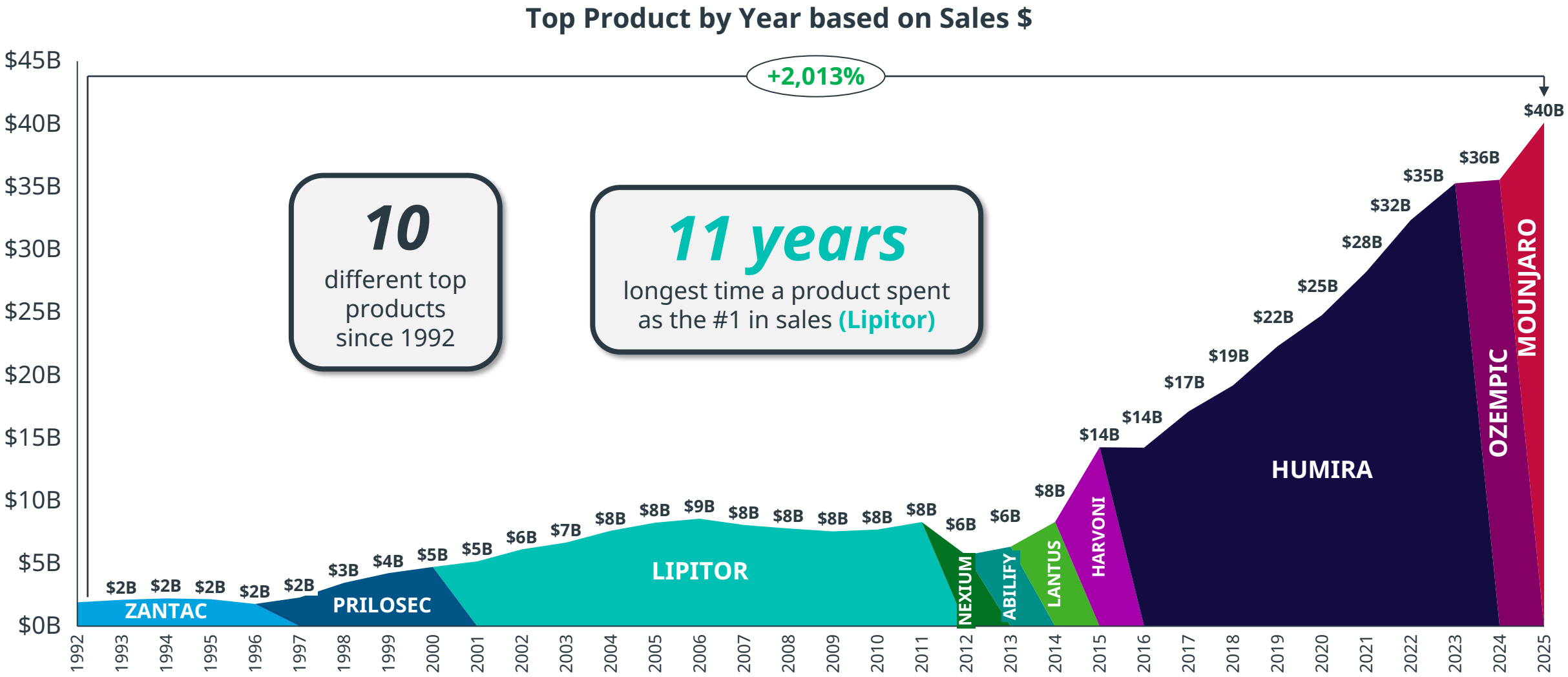


As a percent of total sales, the top 10 branded products are huge drivers to market performance



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The top product in 1992 generated $1.9B in sales; the top product today, Mounjaro, generates over 21 times that



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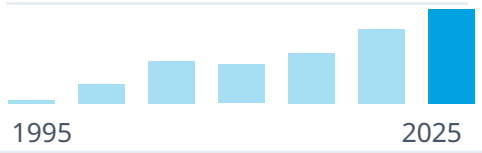
Four sales tiers, four growth stories — and an exploding $15Bn+ club

> $1Bn – $5Bn

119

PRODUCTS IN 2025

+27% vs. 2020



> $5Bn – $10Bn

12

PRODUCTS IN 2025

+9% vs. 2020

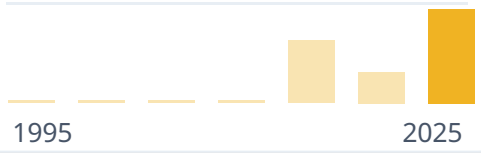


> $10Bn – $15Bn

3

PRODUCTS IN 2025

+200% vs. 2020

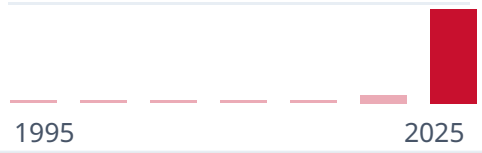


> $15Bn

11

PRODUCTS IN 2025

+1,000% vs. 2020



The era of the **mega-blockbuster is here**

145
products over $1Bn, 2025

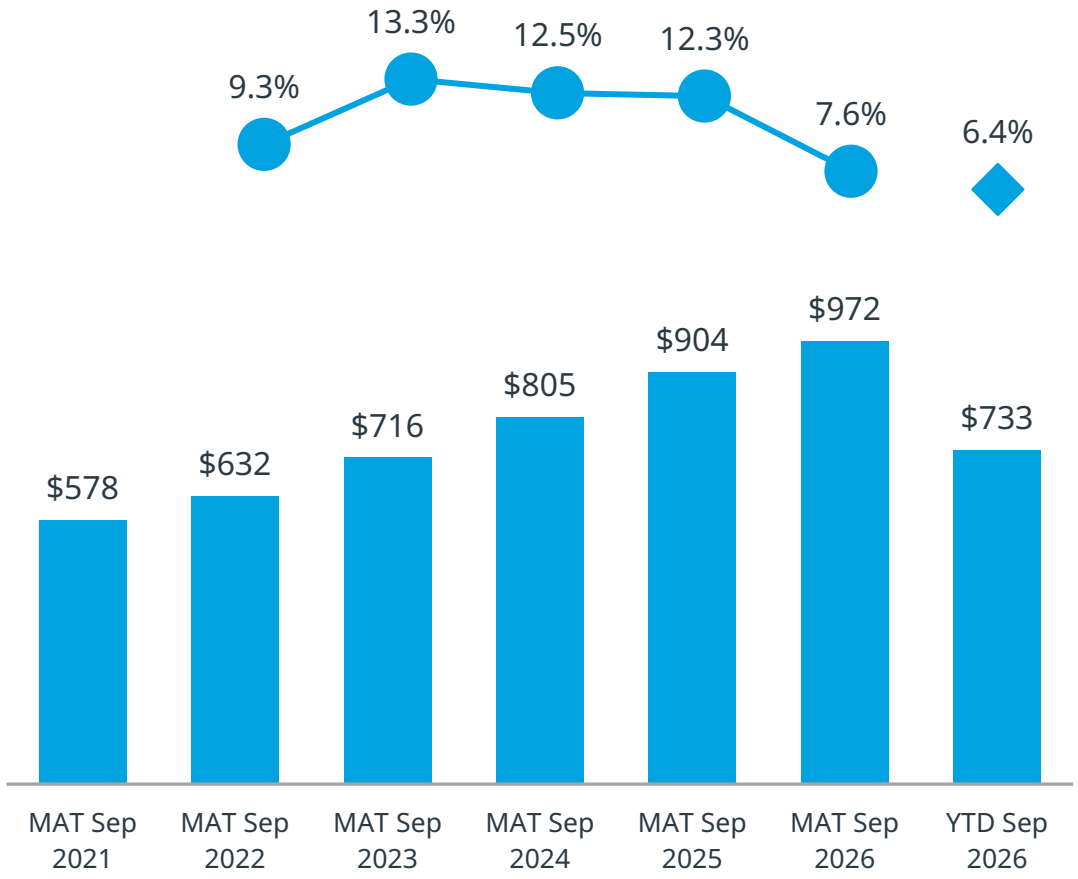
1 → 11
$15Bn+ products since 2020

36x
$1Bn+ club growth since 1995

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Market growth remains positive, but momentum has moderated in 2026

Total Market Sales $ (in Billions) and Growth

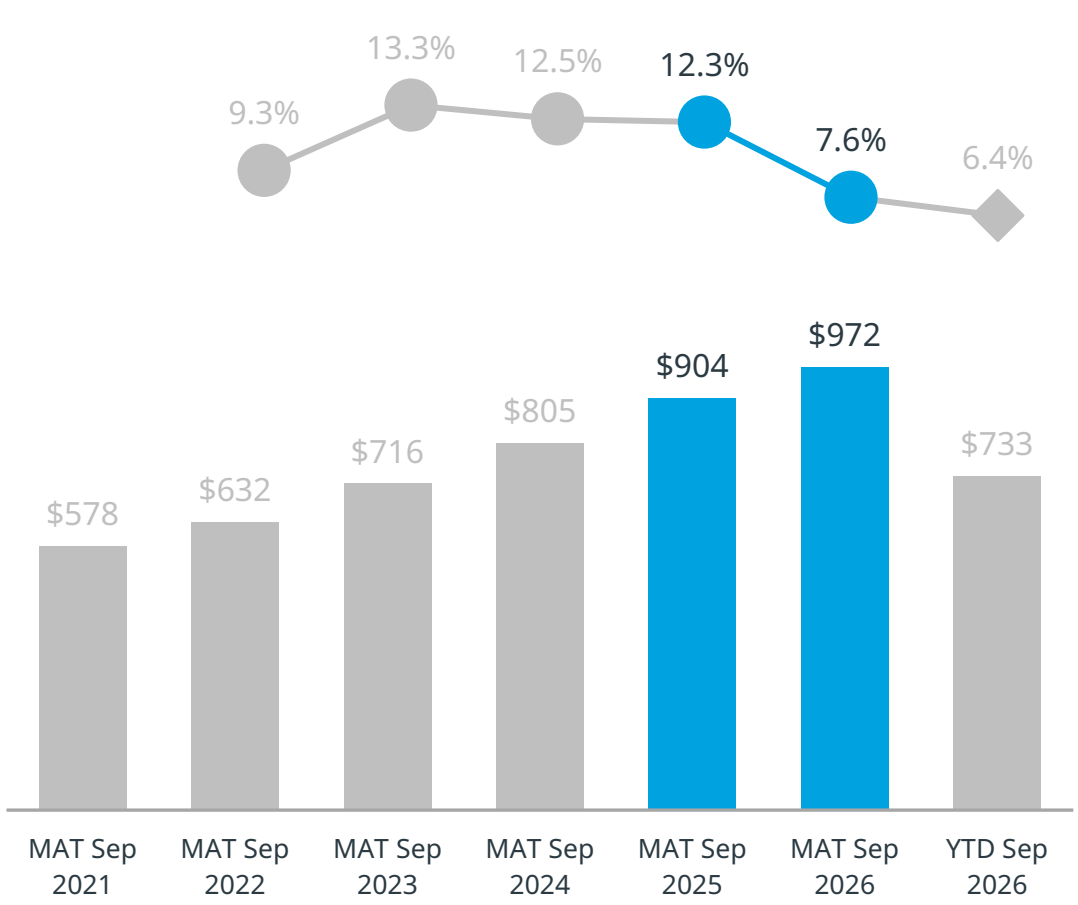


Data Source: IQVIA National Sales Perspective

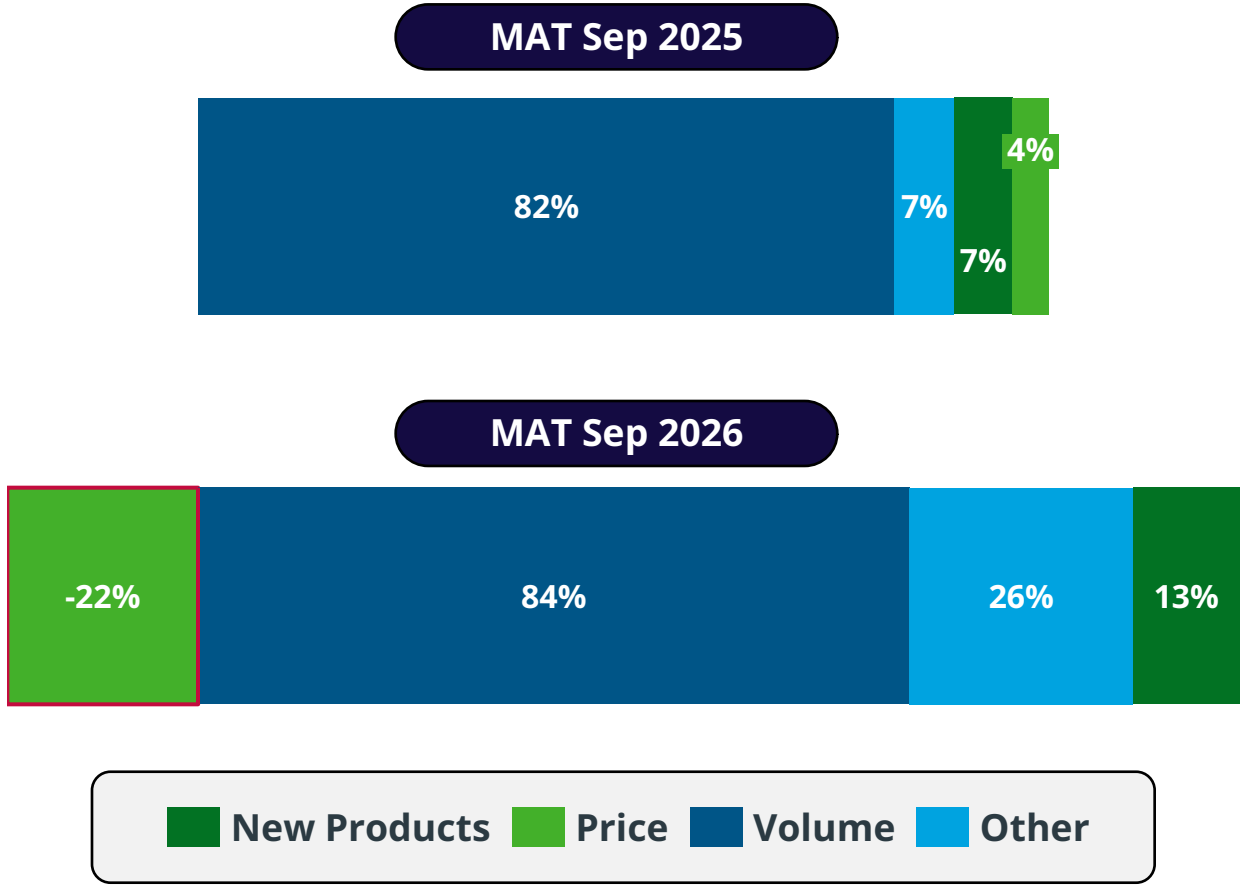
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Volume continues to drive market expansion as pricing becomes a headwind

Total Market Sales $ (in Billions) and Growth



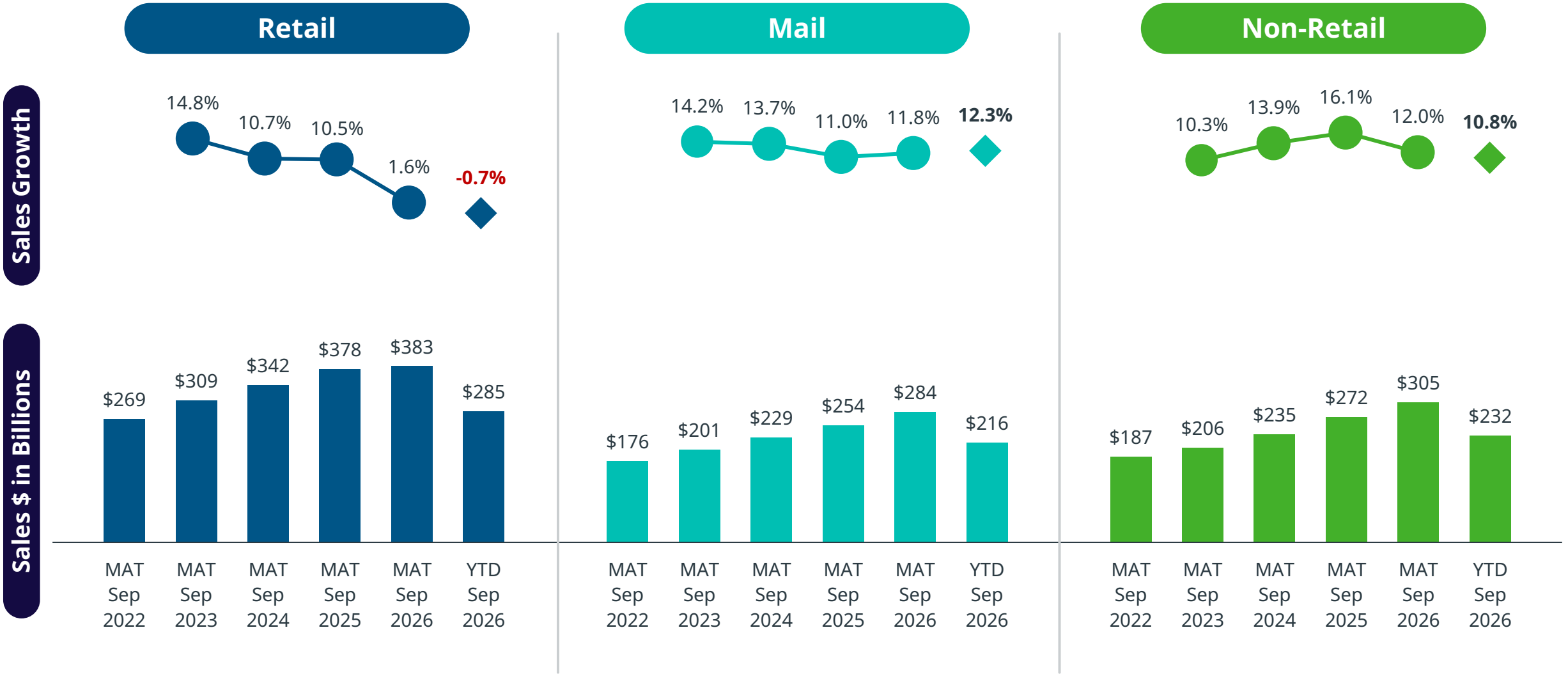
Total Market Sales $ Growth Contribution



Data Source: IQVIA National Sales Perspective

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Year-to-date growth is shifting away from Retail and towards Mail and Non-Retail channels



Data Source: IQVIA National Sales Perspective

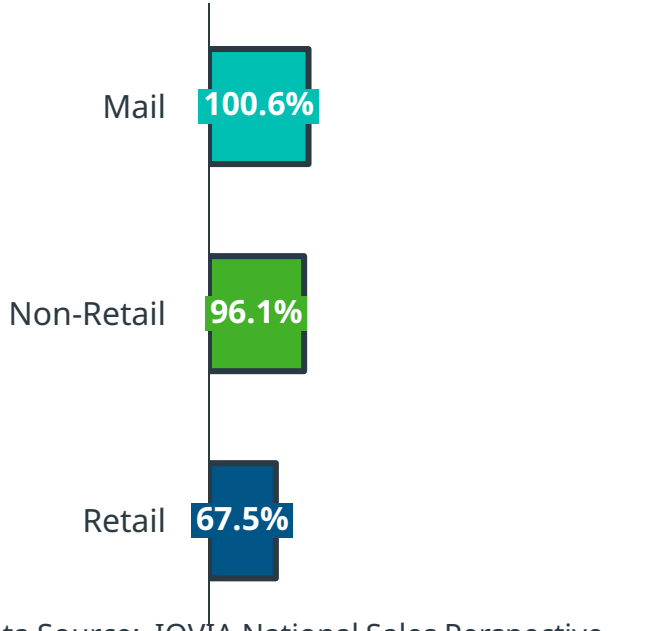
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Retail sales growth remains heavily dependent on GLP-1 demand; without them, Retail sales would be negative

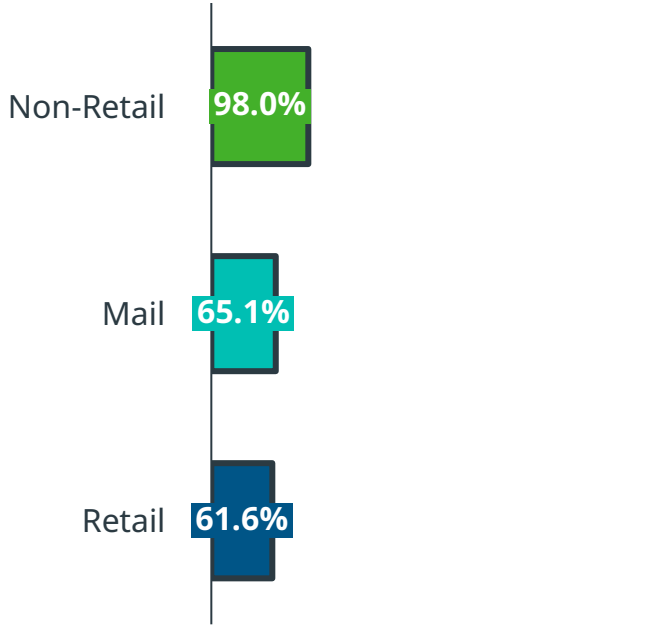
MAT Sep 2026 Sales $ Growth Contribution by Channel



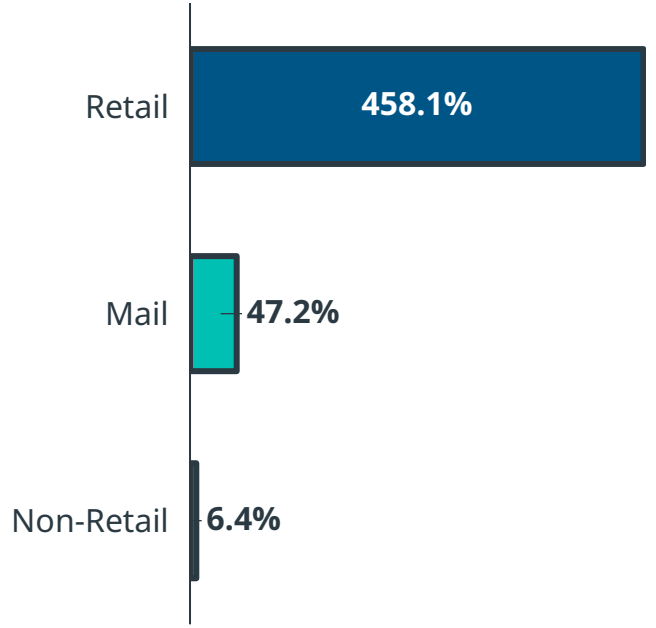
Brand contribution to Sales $ Growth



Specialty contribution to Sales $ Growth



GLP-1s contribution to Sales $ Growth



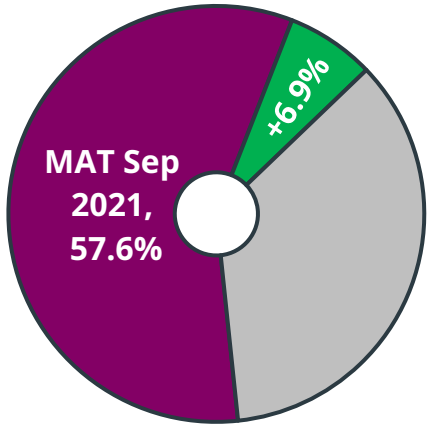
Data Source: IQVIA National Sales Perspective

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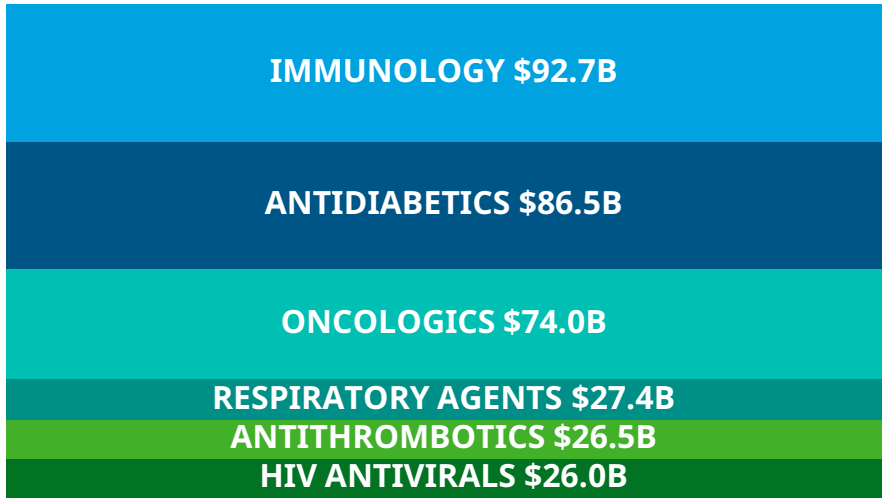
Anti-Obesity has emerged as a top-tier market segment, displacing Respiratory Agents

MAT Sep 2026 Top 6 Therapy Sales $ Share:
64.5%

Up 6.9 percentage points since MAT Sep 2021

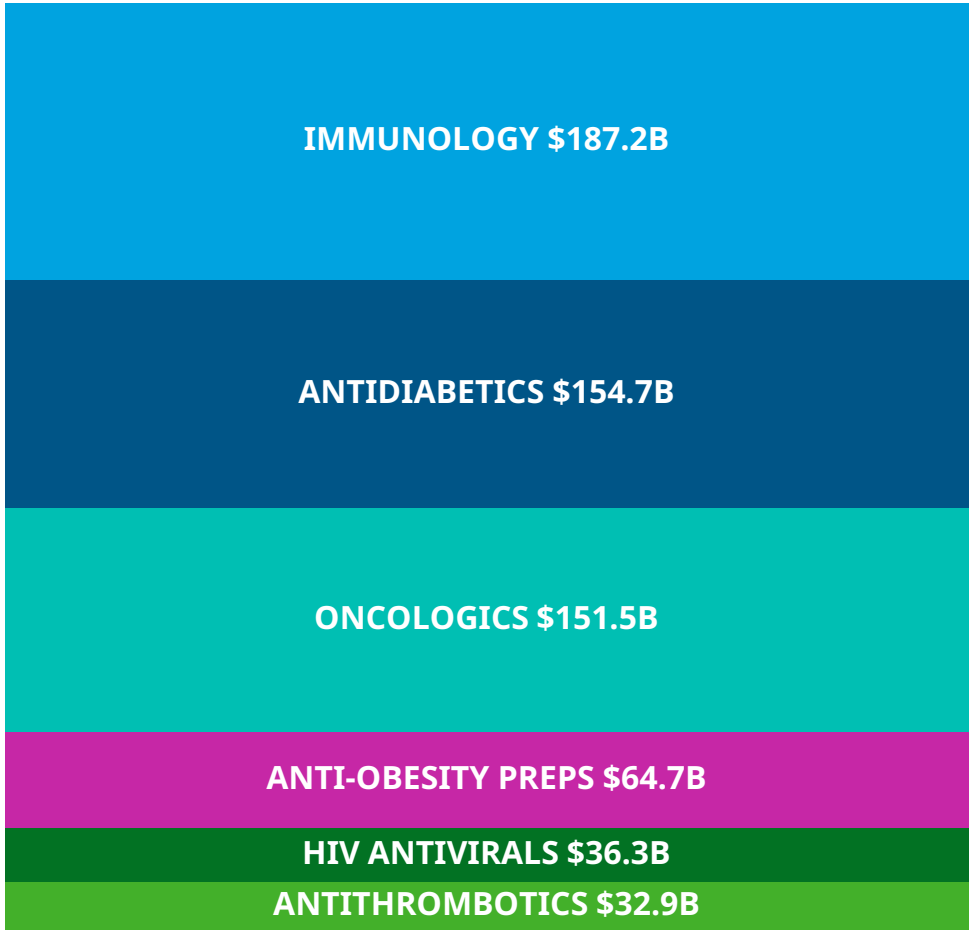


Top 6 Therapies = $333.1B



MAT Sep 2021

Top 6 Therapies = $627.4B

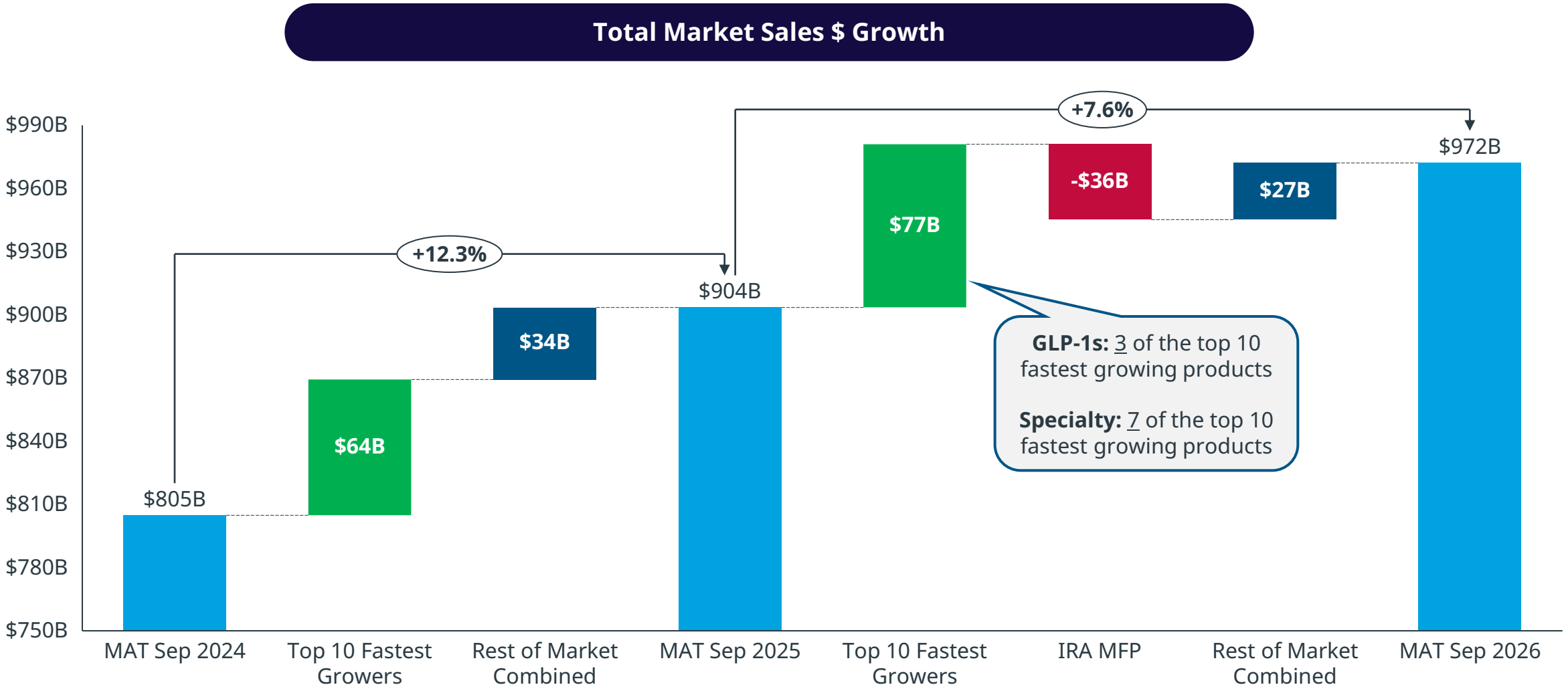


MAT Jun 2026

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Data Source: IQVIA National Sales Perspective

A small group of branded products is driving a disproportionate share of industry growth

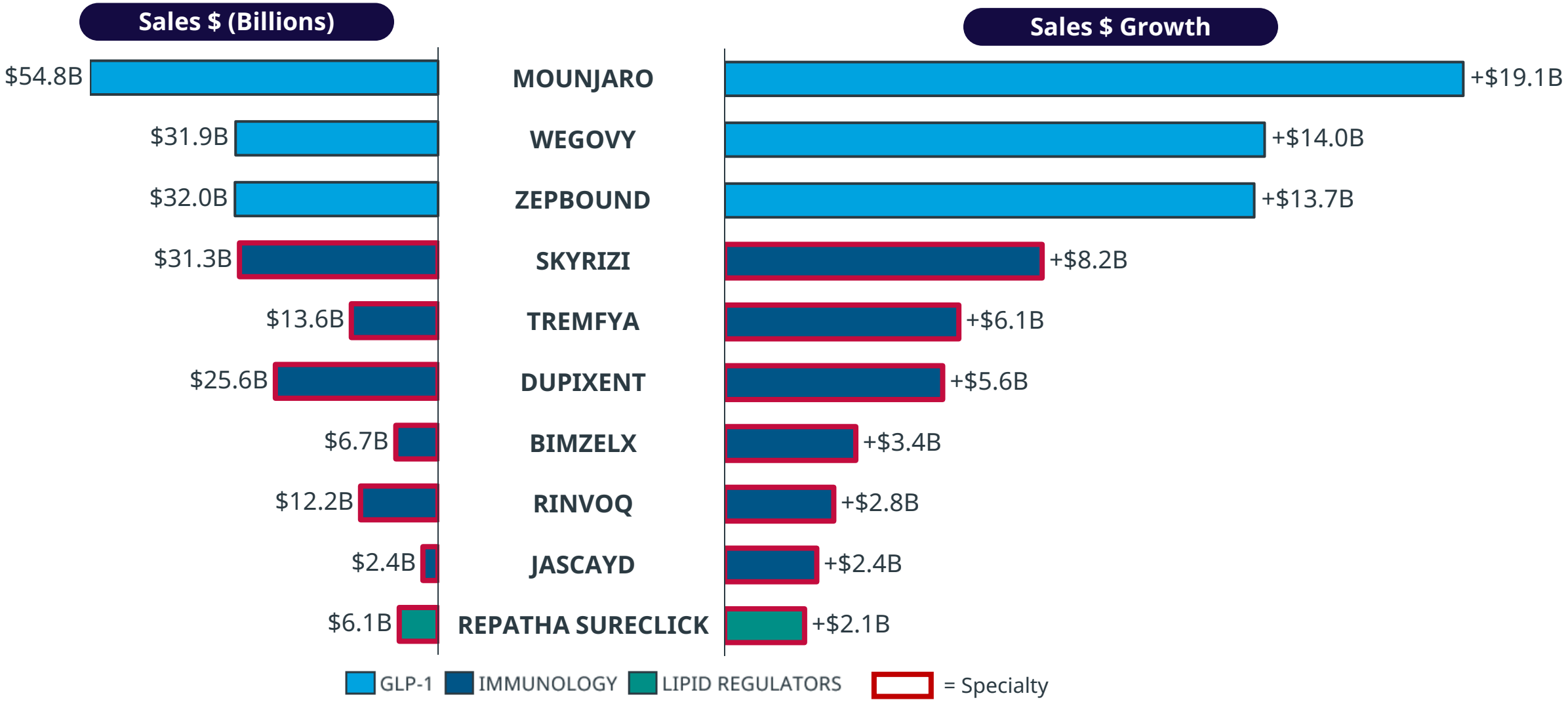


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Data Source: IQVIA National Sales Perspective

The top three fastest growing products are GLP-1s; specialty products round out the remaining top 10

Top 10 fastest growing products based on MAT September 2026 absolute sales $ growth

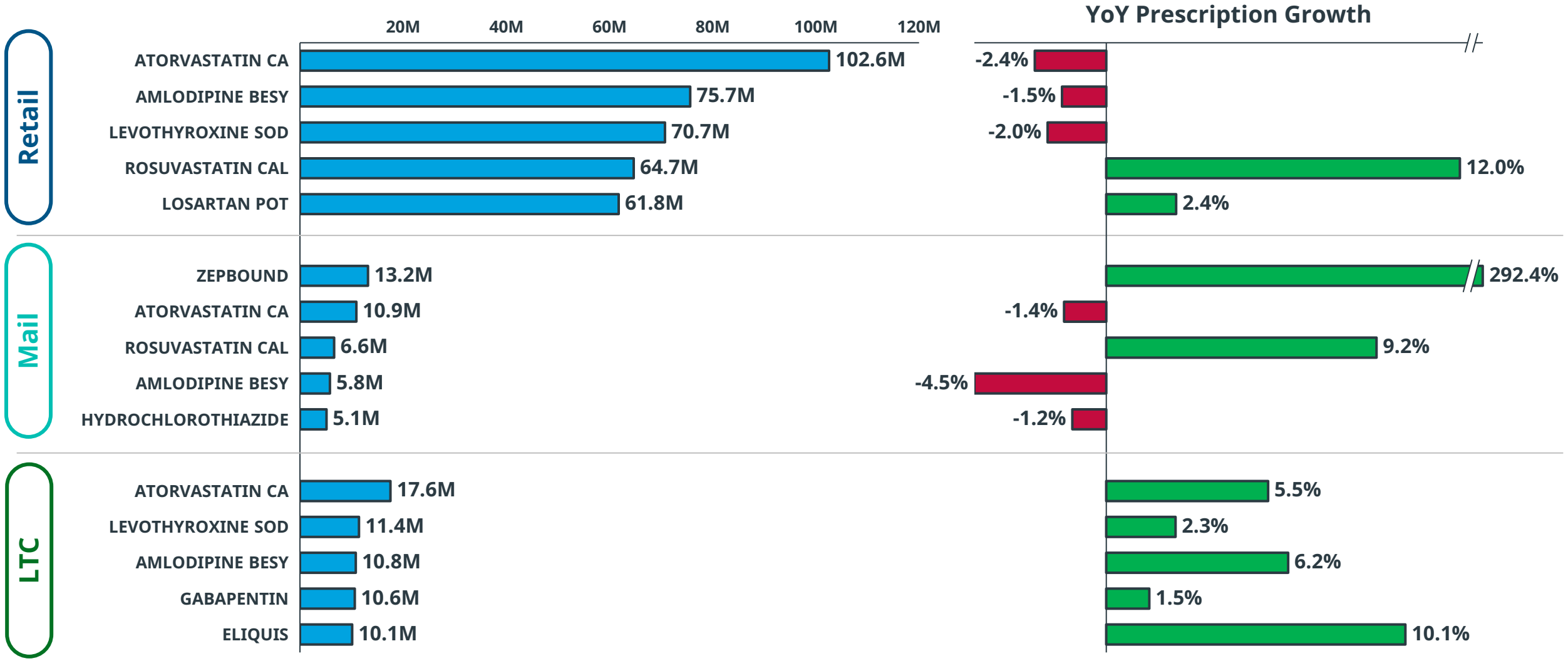


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Data Source: IQVIA National Sales Perspective

Zepbound is not the top product on Rxs in Mail

Top Five Products by Channel based on MAT September 2026 Unadjusted Rxs (in Millions)

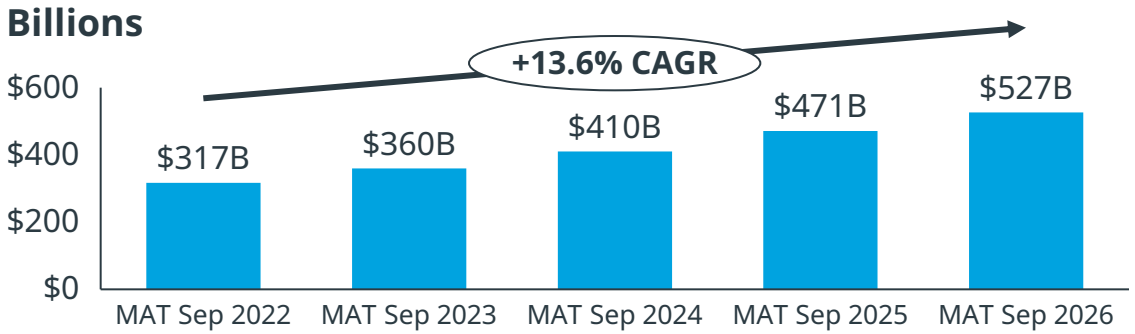


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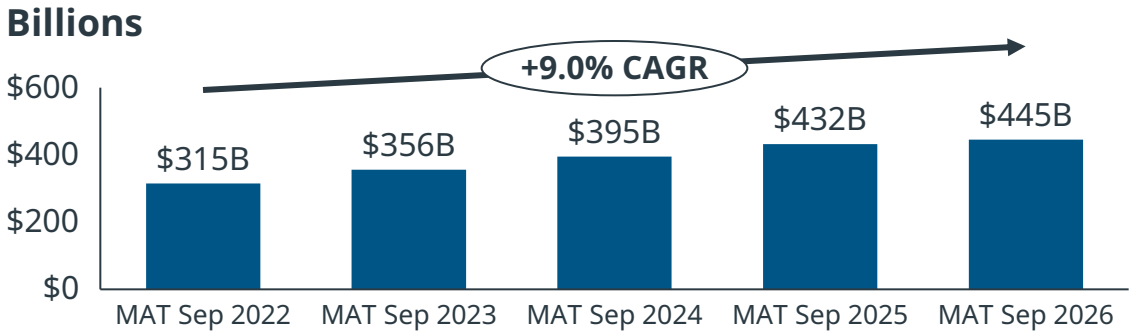
For the total market, specialty growth has consistently outpaced traditional growth and has a 54.2% share of sales

For MAT September 2026, specialty spend grew by 11.7% while traditional spend grew 3.1%

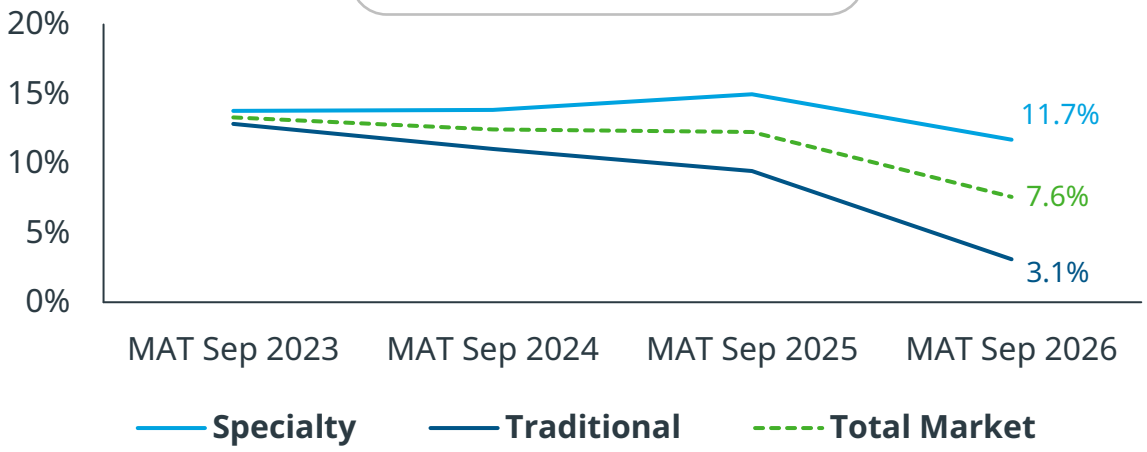
Specialty Sales $



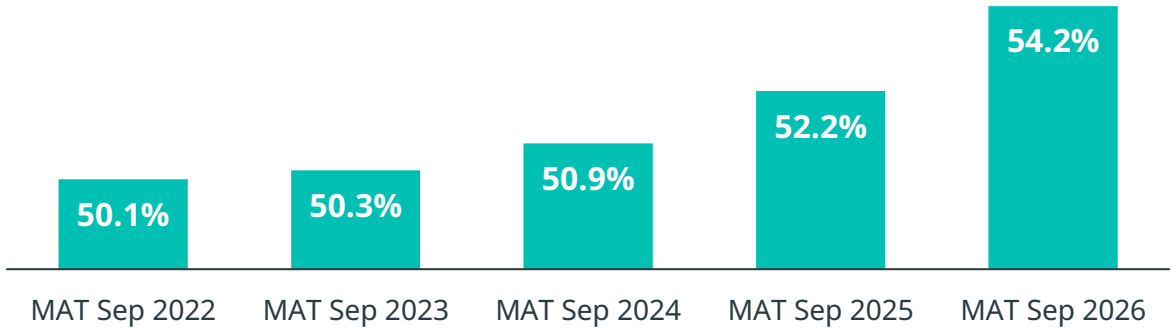
Traditional Sales $



Sales $ Growth



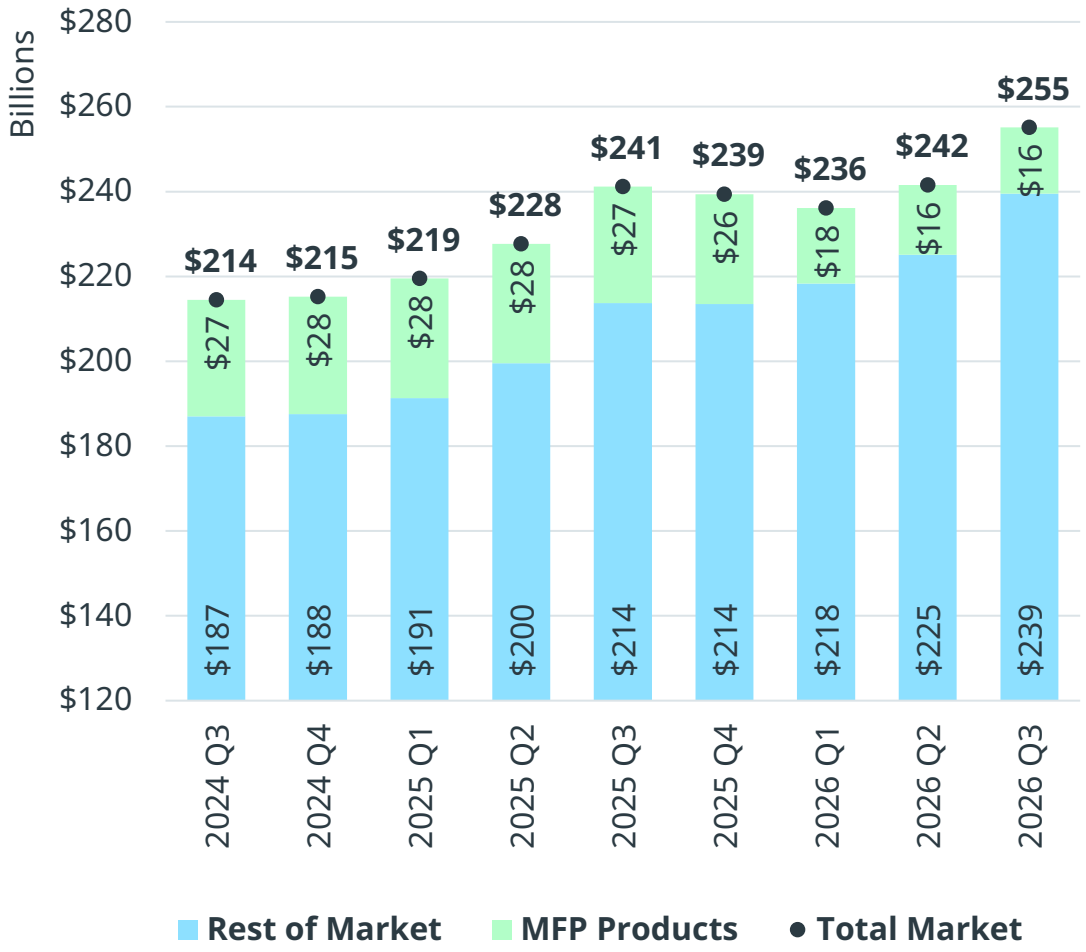
Specialty % of Sales



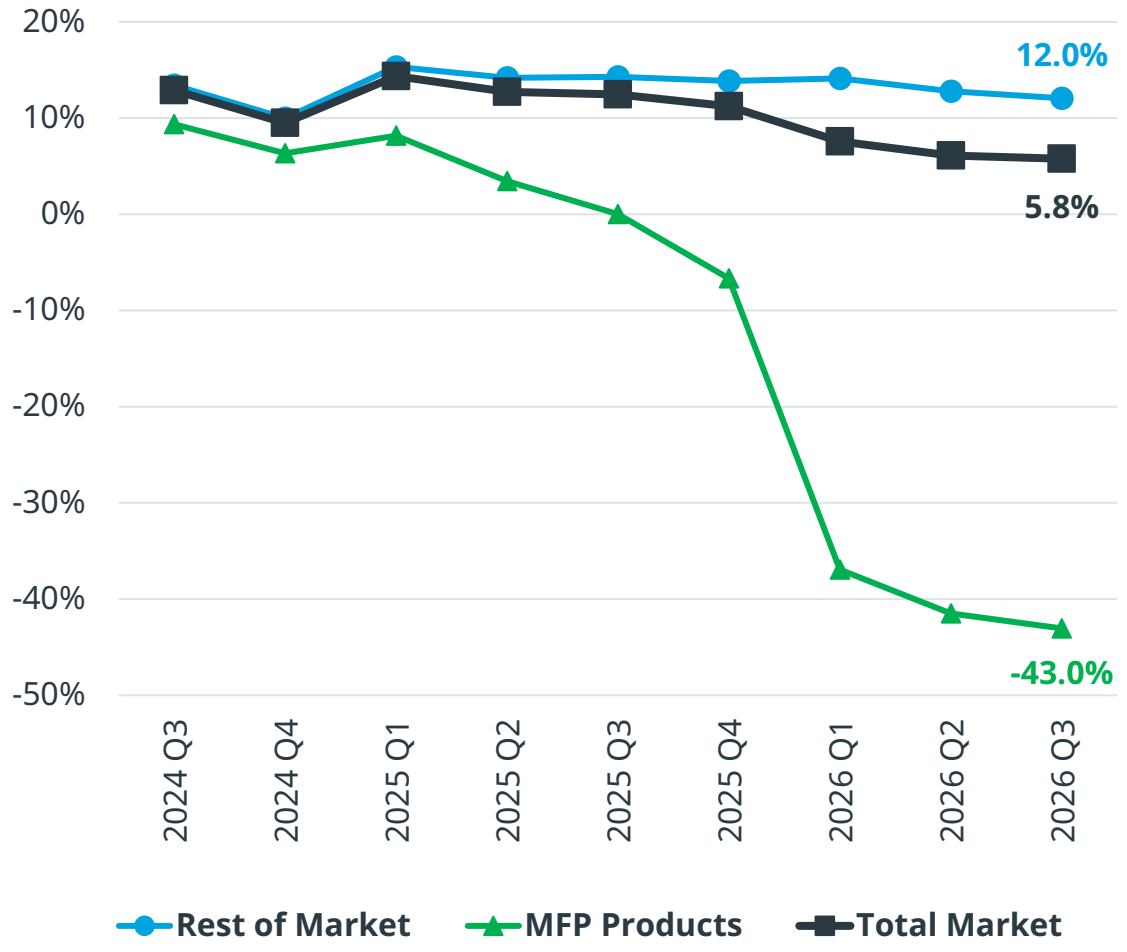
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IRA-negotiated products are creating a meaningful drag on overall market growth

Quarterly Market Sales Trends



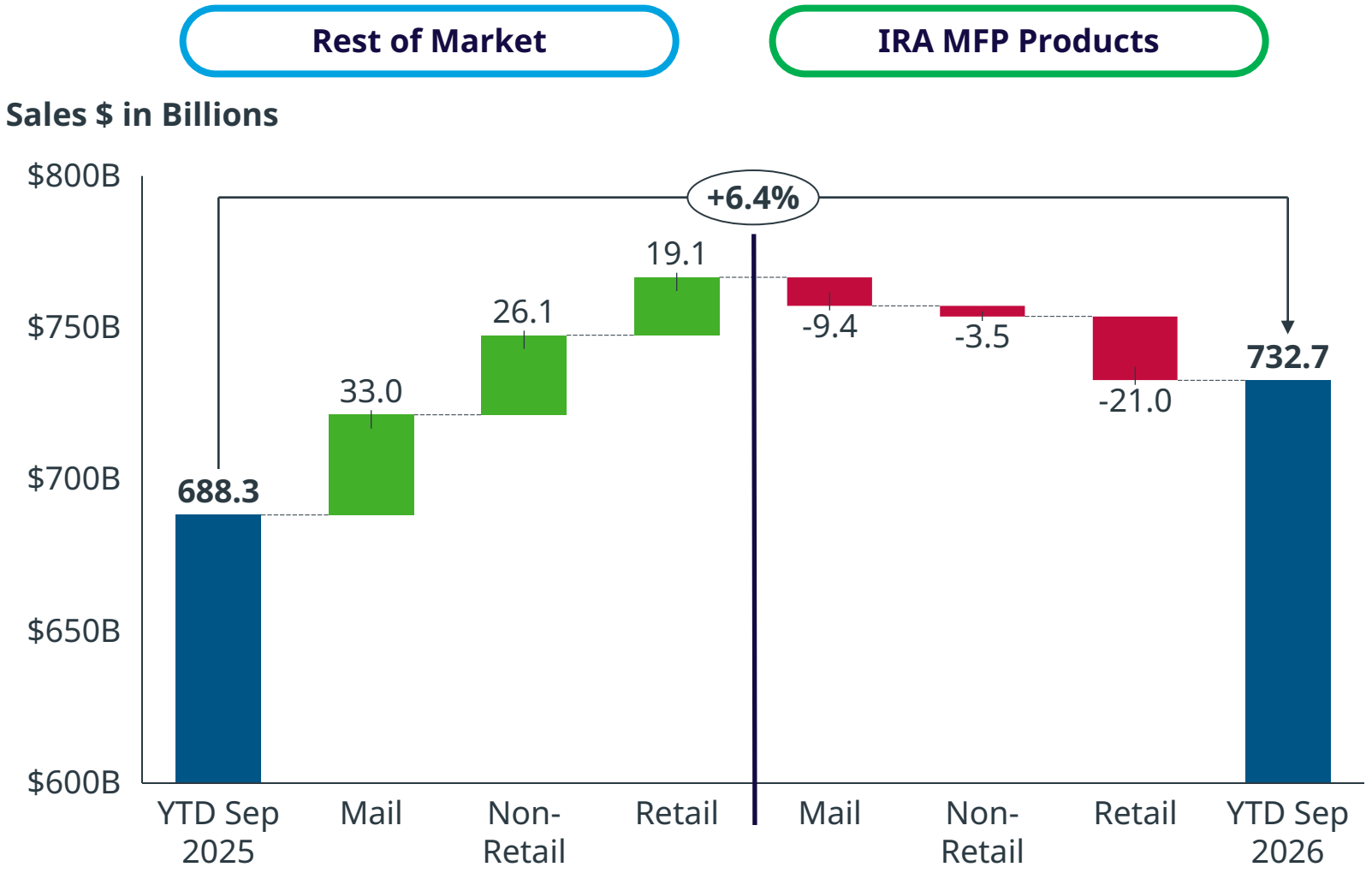
YoY Growth Trends



Data Source: IQVIA National Sales Perspective

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Retail absorbs the greatest financial impact from IRA negotiated products



Notes:

- Only the Brand molecule of the IRA MFP product was analyzed
- Other factors impacting the analysis could be loss of exclusivity

- The +6.4% market growth is made up of a contribution of:
  - ***+11.4% growth in Rest of Market***
  - ***-4.9% growth for the IRA MFP products***

Data Source: IQVIA National Sales Perspective

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A $129B savings score has become a projected deficit increase — and patients are no better off

Expected — 2022 CBO score

2022 estimate: net deficit reduction

—$129B

Negotiation	—$99B
Inflation rebates	—$63B
Part D redesign	+$30B
Implementation	+$3B

Logic: pricing savings outweigh redesign costs

Why the score changed

July 2026 revision

✕ MISS — Negotiation savings

Assumed a ~50% net-price cut; the first cycle came in 22% below 2023 net prices (revised to 25%–50%)

✕ MISS — Inflation rebates

Higher general inflation raised rebate benchmarks, cutting collections and the incentive to limit price increases

✕ BIG MISS — Part D redesign cost

The $2,000 out-of-pocket cap drove far stronger utilization than modeled; plan bids came in far above expectations

Actual — 2026

$700B

Added to projected Part D outlays, 2026–2035

$550B

Tied to new 2026 Part D plan bid information

35% vs. 5%

Plans' expected 2026 cost increase per enrollee vs. CBO

$2.1T

2026–2035 outlay projection, up from $1.5T in Jan. 2025

Redesign is the leading driver of higher 2026 bids

Access didn't improve

Negotiated prices took effect; patients still hit the same wall

23.8%
of first-fill attempts for MFP drugs were rejected in Q1 2026

Flat vs. 24.3%
2025 initial rejection rate — no measurable gain in access

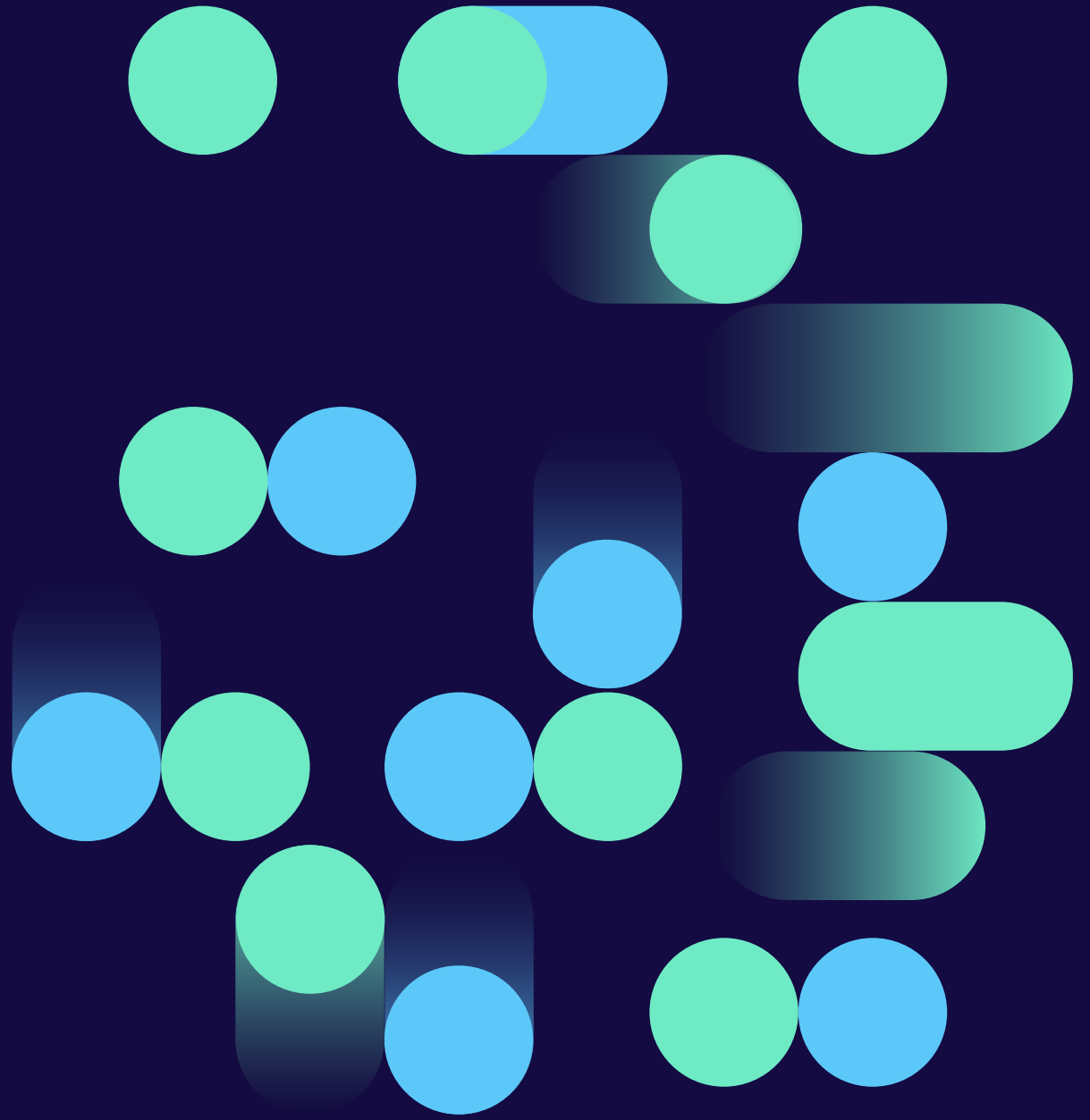
4.7%
still rejected after a 30-day look-forward in Q1 2026

Source: Congressional Budget Office, Developments in CBO's Projections for Medicare Part D, July 29, 2026; IQVIA LAAD pharmacy claims data, US Market Access Strategy Consulting analysis

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Generics & Biosimilars



Generics at a glance – *Years based on MAT September*

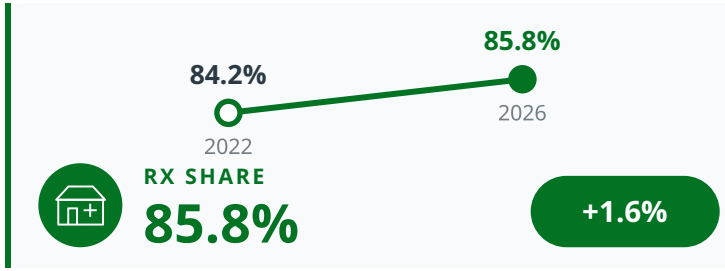
MARKET SIZE

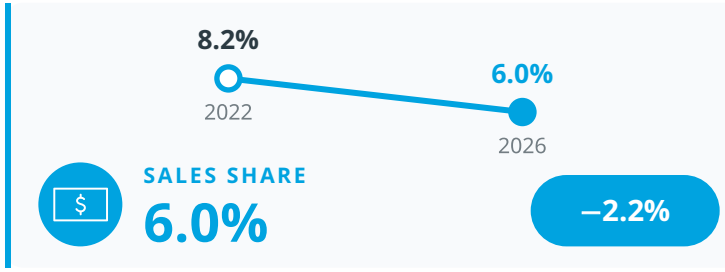
57.7B

Generic sales, MAT Sep 2026

SHARE OF MARKET

Generics keep gaining Rx share while losing sales share

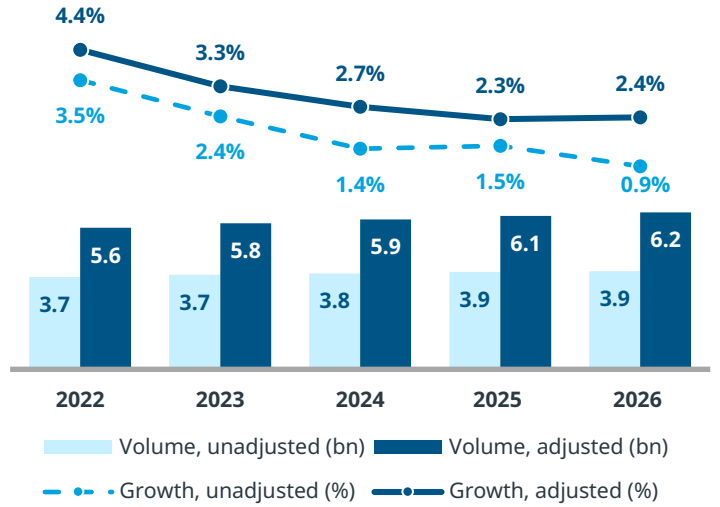




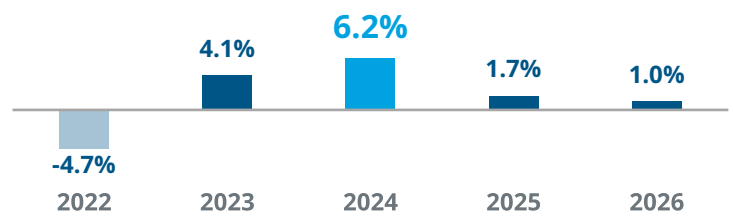
↑ **Rx share** 2022–2026 84.2 · 85.9 · 85.9 · 85.9 · **85.8**

↓ **Sales share** 2022–2026 8.2 · 7.5 · 7.1 · 6.4 · **6.0**

RX VOLUME & GROWTH



SALES GROWTH



Sales growth peaked at 6.2% in 2024, cooling to 1.0% by 2026.

VALUE & SUPPLY

-7.1% DEFLATION

YoY September generic oral deflation, up 70 bps from August

Source: September Gx Auditor, 10/19/26, Nephron Healthcare Investment Research

39% APPROVALS

of ANDAs approved since 2013 have not launched

Based on IQVIA research of FDA Orange Book, SMART NSP, SMART US Launch Edition

$496B SAVINGS

Total generic and biosimilar savings in 2025

Source: https://accessiblemeds.org/resources/reports/2025-savings-report/

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Savings fact sheet from the 2026 U.S. Generic & Biosimilar Medicines Savings Report

HEADLINE NUMBERS

2025 SAVINGS

$496B

Total generic and biosimilar savings in 2025

TEN-YEAR SAVINGS

$3.6T

Total generic and biosimilar savings for the past ten years

SHARE OF SPEND

1.1%

Generic share of total U.S. healthcare spending

GENERIC SAVINGS BY PROGRAM, 2025

MEDICARE

$166B

Total generic savings in Medicare in 2025

$3,011 per beneficiary

MEDICAID

$70.2B

Total generic savings in Medicaid in 2025

$921 per enrollee

BIOSIMILAR SAVINGS

IN 2025

$25.4B

Biosimilar savings in 2025

SINCE 2015

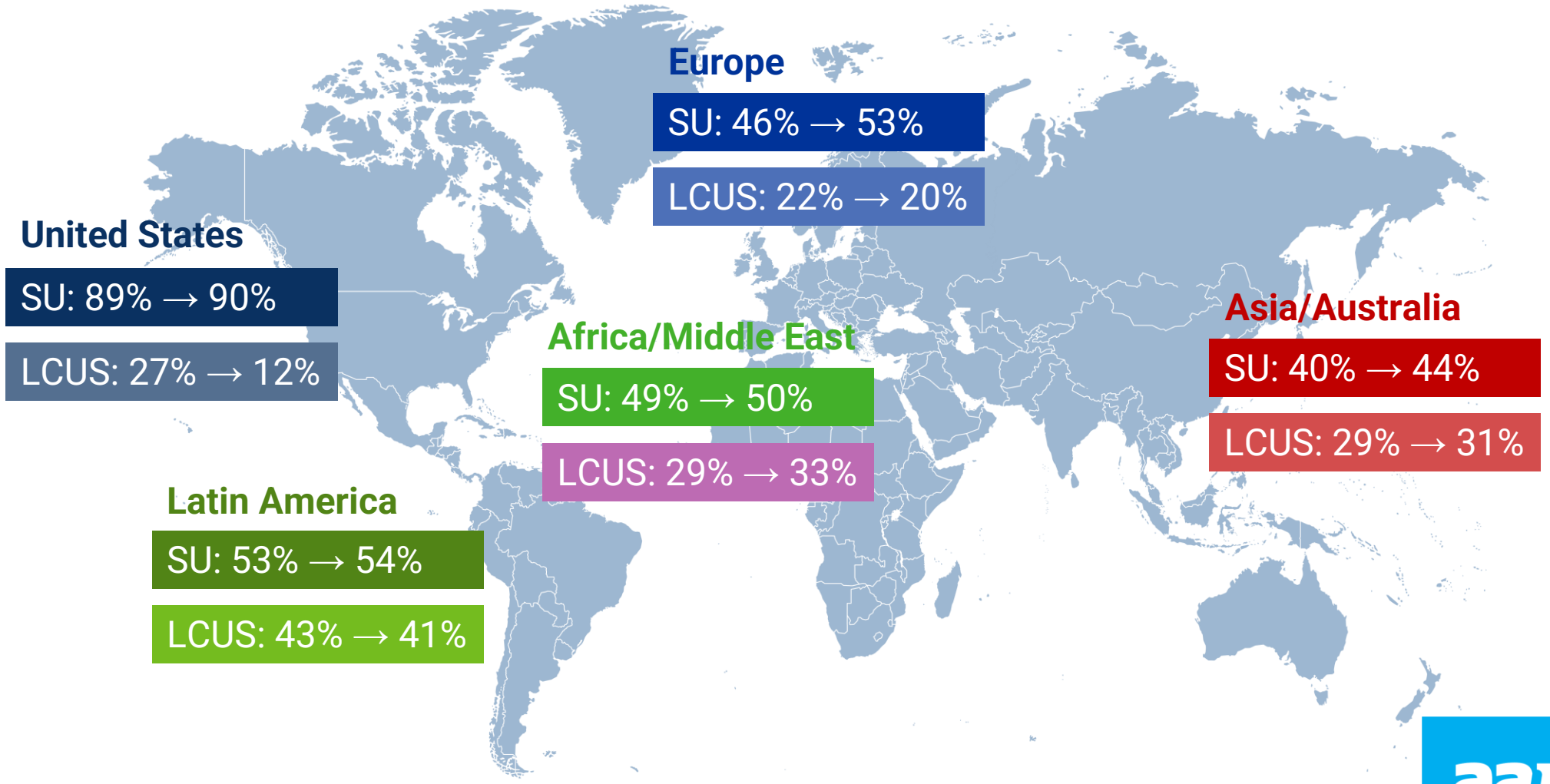
$81.6B

Total savings since first biosimilar entry in 2015

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Generics & Biosimilars Have Increased Share of Prescriptions Worldwide

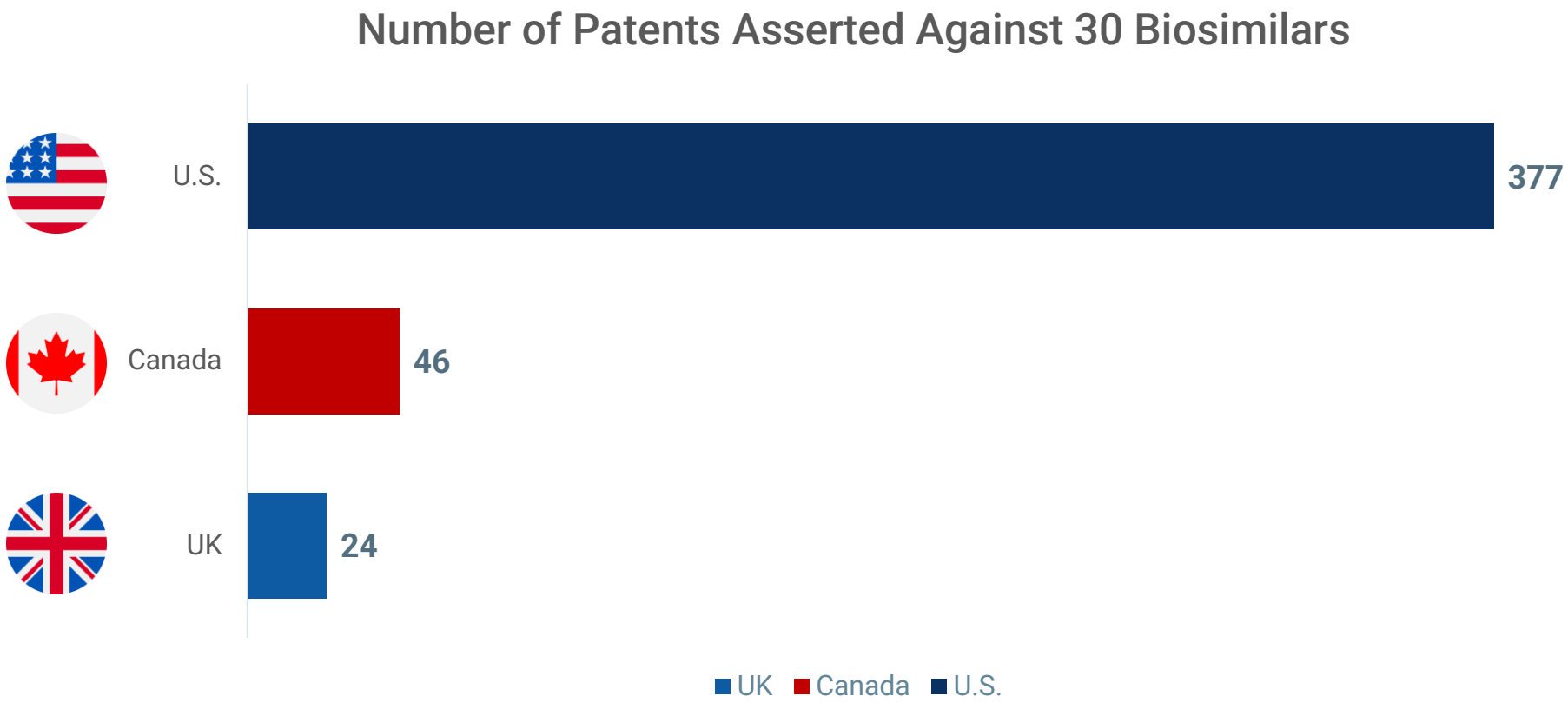
Generic and Biosimilar Market Share (LCUS, SU), 2015 → 2024



Source: IQVIA GS&AR, IQVIA, MIDAS MAT Q3 2024, Retail and Hospital, Rx and no Rx. Generics Product Class: Generics + Early Entry Generics. SU= Standard Units. Analysis includes biologics, LCUS = Spend utilizing the local currency converted to United States dollars at constant exchange rates

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Association for Accessible Medicines

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

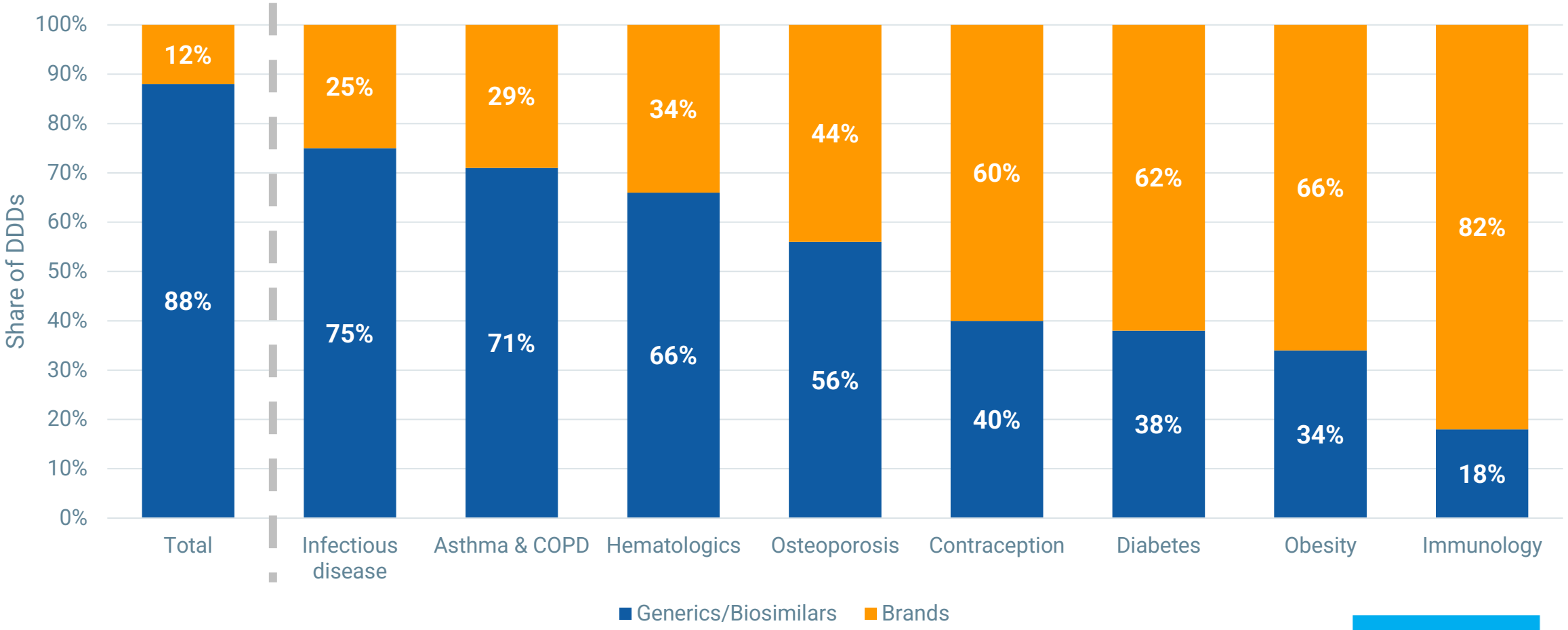


Source: Association for Accessible Medicines. (July 2025) Anatomy of a Biosimilar Patent Litigation: Problems and Solutions.

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Association for Accessible Medicines

Across All Therapy Areas, 88% of Volume Is Generics or Biosimilars

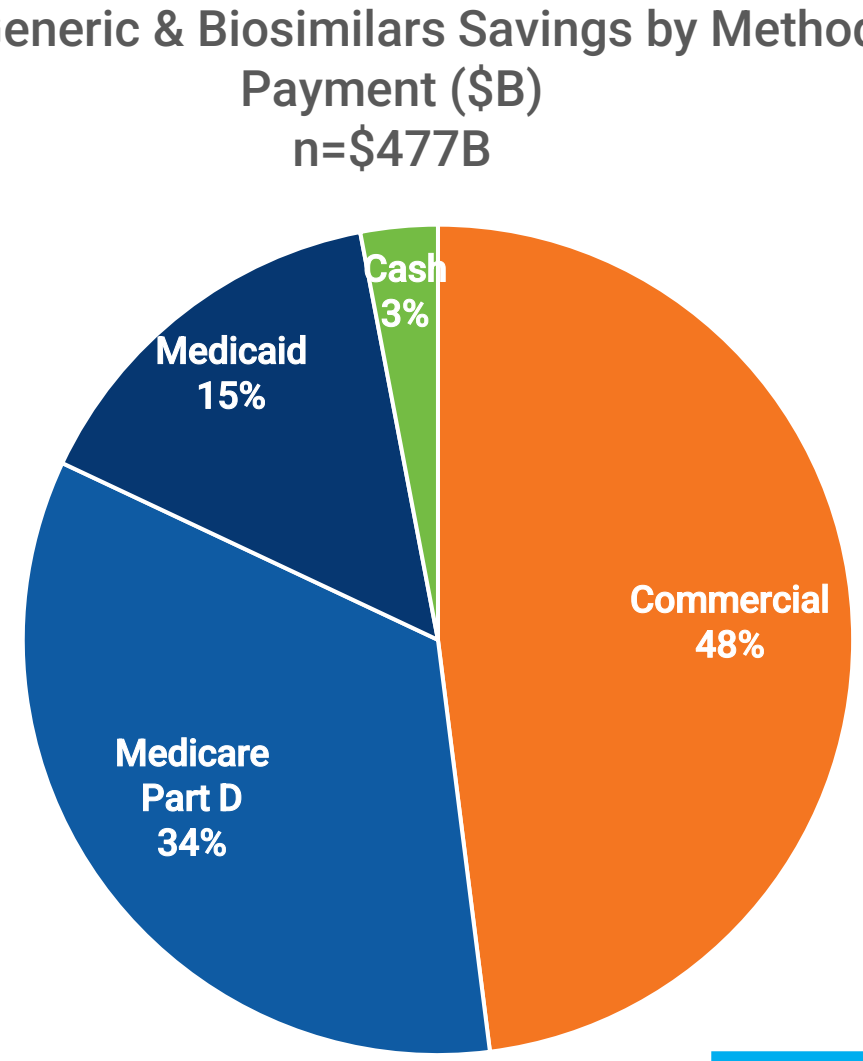
Of the Top 30 Therapy Areas, Only 8 Have Less Than 80% of the Volume, 2025



Source: IQVIA 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.

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

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

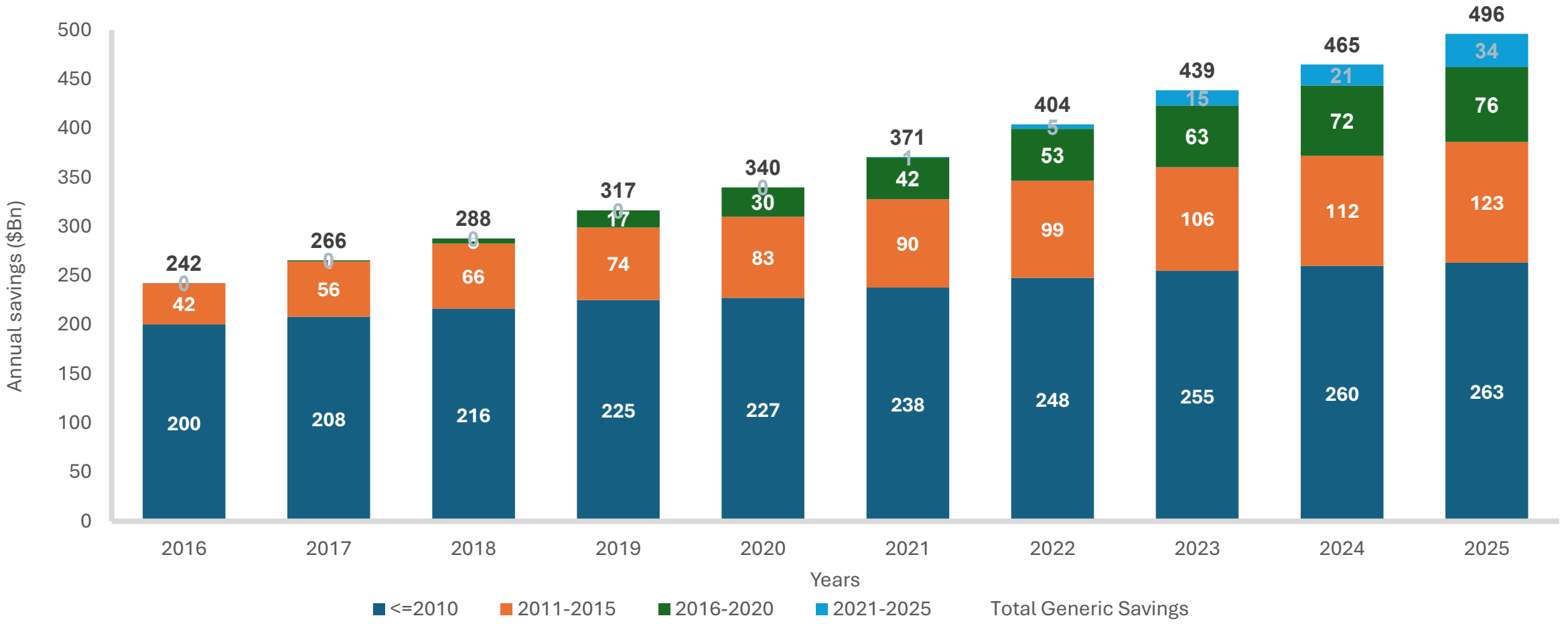


Source: IQVIA National Sales Perspective, December 2025; IQVIA Institute, June 2026.

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Association for Accessible Medicines

Annual savings from generics that entered the U.S. market in the last ten years totaled $110Bn in 2025

Annual savings from generics by year of generic entry, 2016–2025, US$Bn

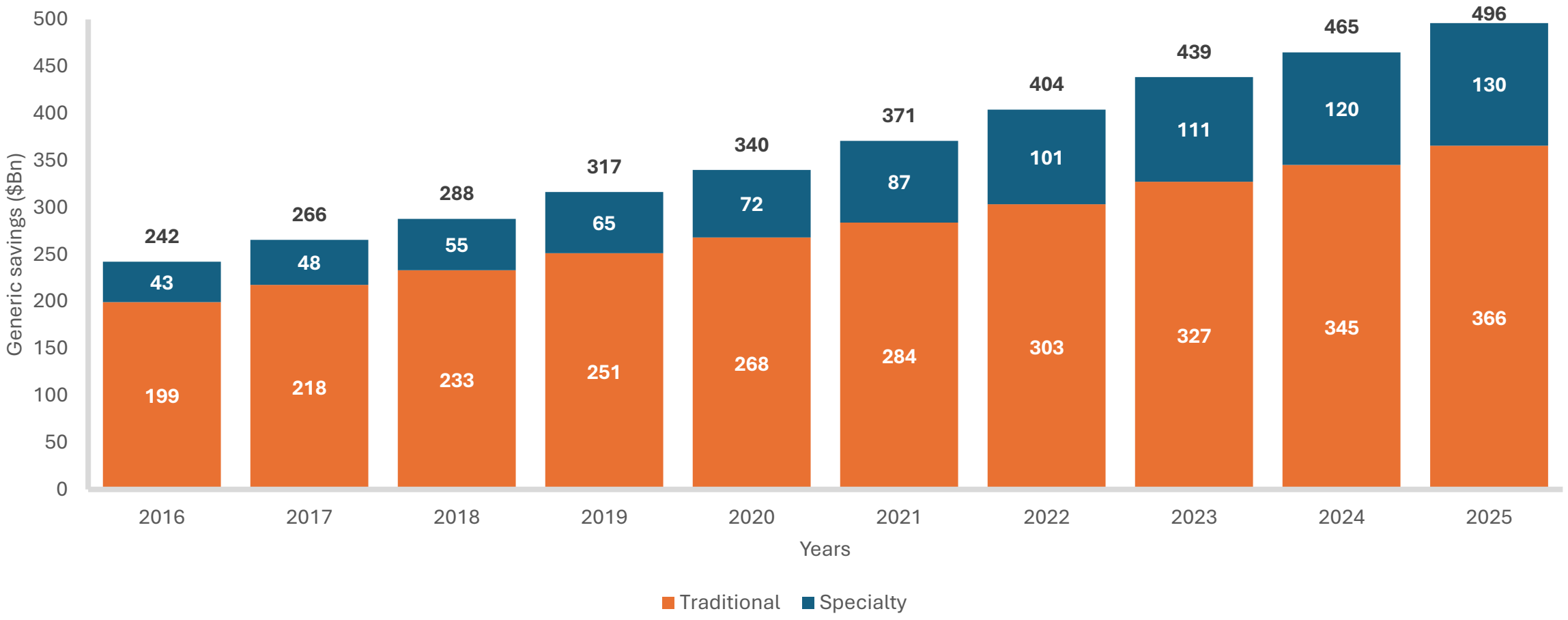


Source: IQVIA National Sales Perspectives, Dec 2025; IQVIA Institute, Jul 2026.

Generic Savings, 2016-2025

Generic savings reached $496Bn in 2025, with 74% of savings from traditional products

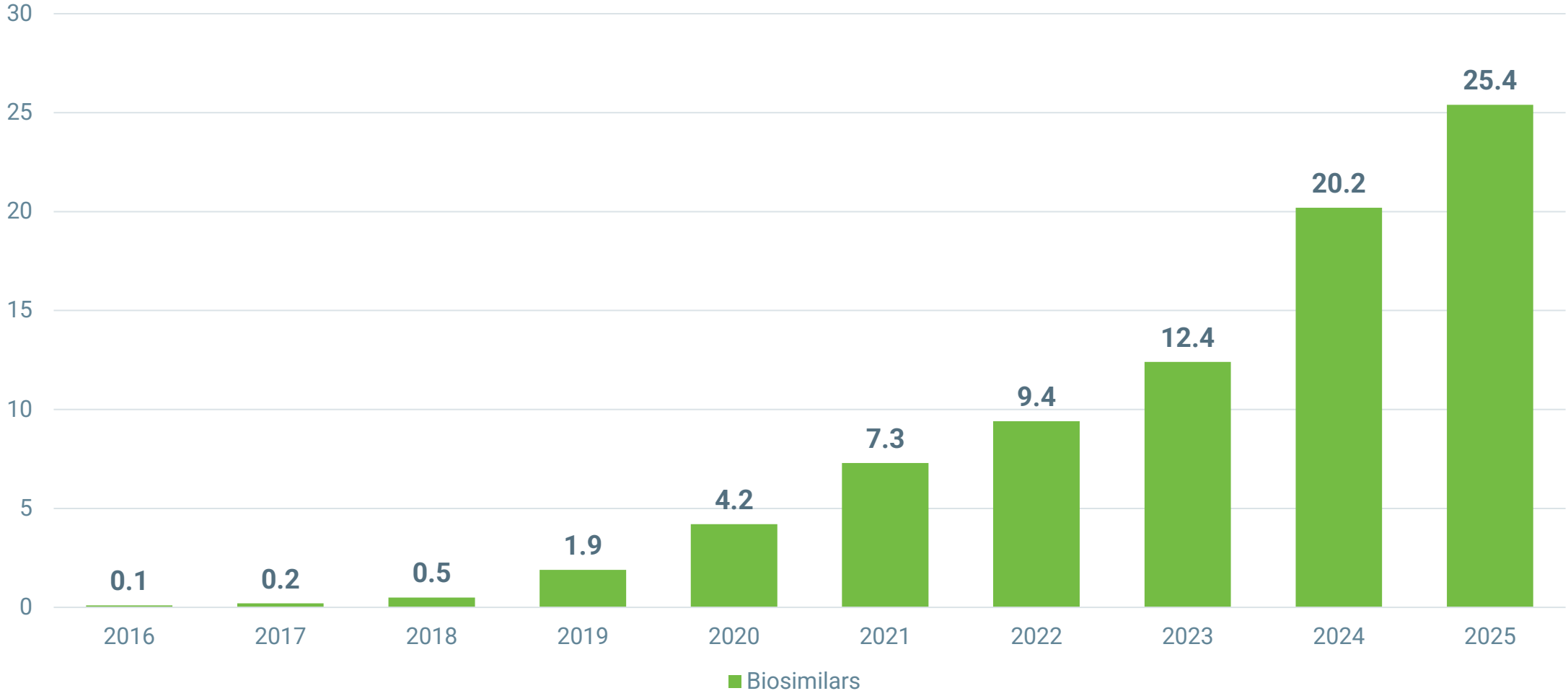
Annual savings from generics by product type, 2016–2025, US$Bn



Source: IQVIA National Sales Perspective, Dec 2025; IQVIA Institute, Jul 2026.

Generic Savings, 2016-2025

Biosimilars Generated $81.6B in Savings Since 2016



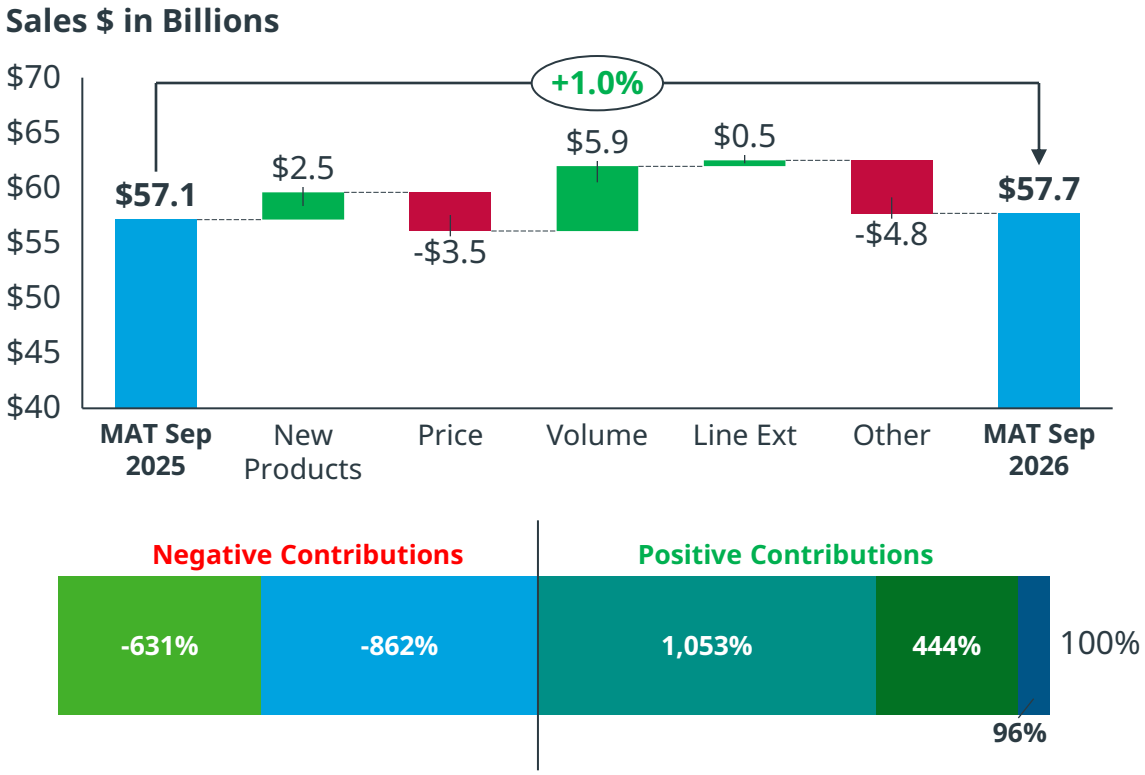
Source: IQVIA National Prescription Audit, December 2025; IQVIA Institute, June 2026.

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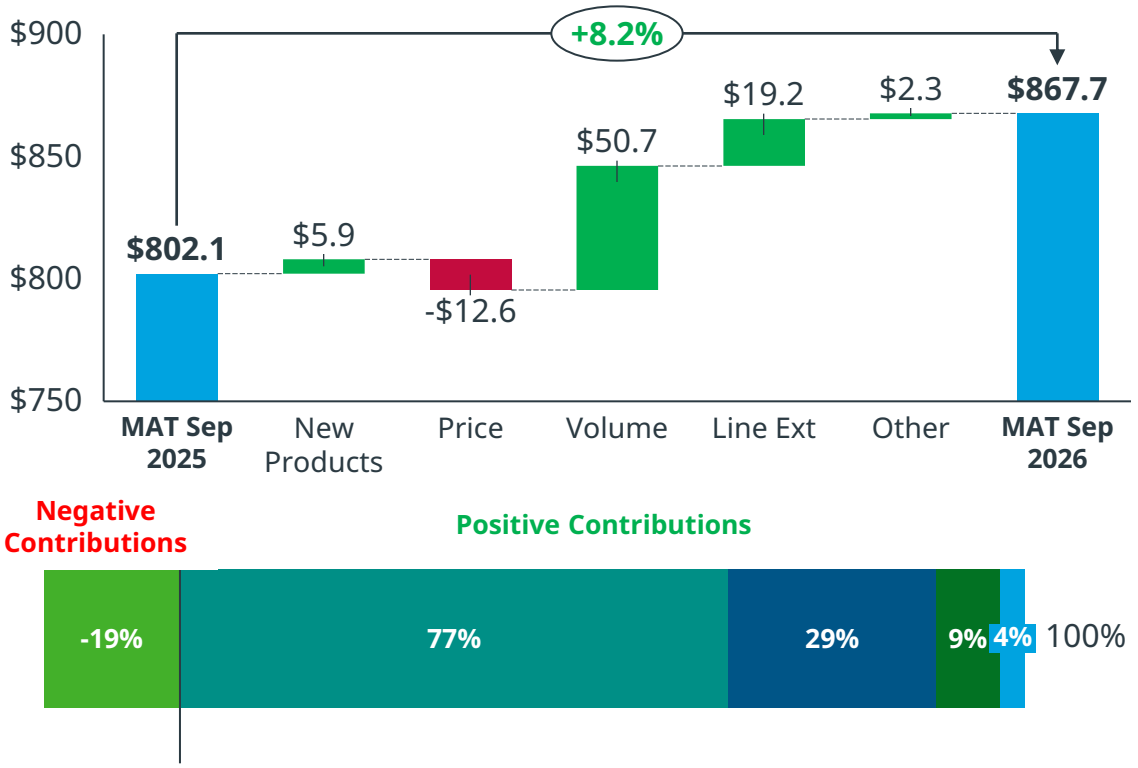
Price deflation is consuming 630%+ of generic gains while brands grow 8.2% on volume momentum

*U.S. **Total Market** Generic and Brand Sales Growth Contributions MAT September 2026*

Generics



Brands



New Products | Price | Volume | Line Ext | Other

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Price is a larger negative contributor in the Market across all three channels

*U.S. **Generic** Sales Growth Contributions (Sales $ in Billions)*



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Two blockbuster brands now generate more revenue than the entire generic market

2018

The Top **7 Brand** Products = **$55.0B** in Sales

- $5.2B Xarelto
- $5.2B Remicade
- $5.5B Lyrica
- $5.7B Januvia
- $7.1B Eliquis
- $8.0B Enbrel
- $18.4B Humira

Entire Generic Market = **1,044 Molecules** and **$55.7B** in Sales

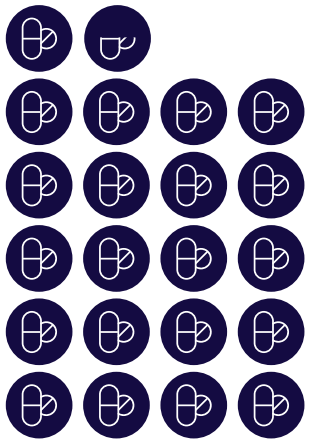


2021

The Top **3 Brand** Products = **$55.2B** in Sales

- $12.2B Trulicity
- $15.9B Eliquis
- $27.1B Humira

Entire Generic Market = **1,072 Molecules** and **$53.6B** in Sales

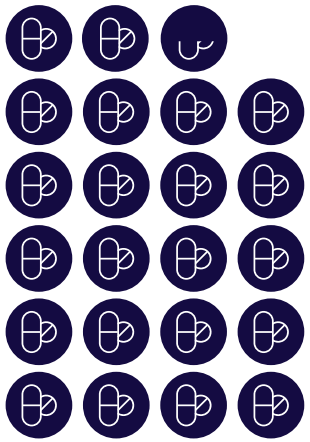


MAT September 2026

The Top **2 Brand** Products = **$91.1B** in Sales

- $36.3B Ozempic
- $54.8B Mounjaro

Entire Generic Market = **1,123 Molecules** and **$57.7B** in Sales

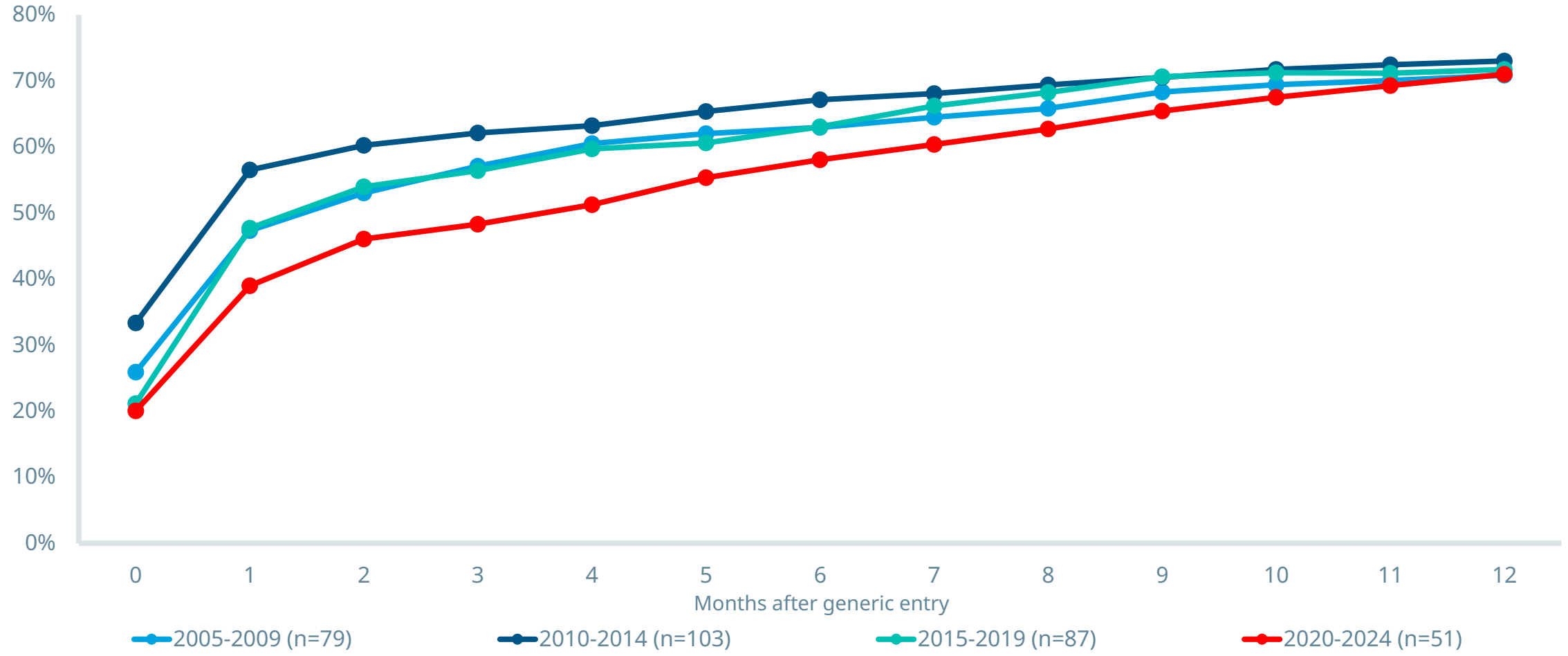


= 50 Generic Molecules

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Generic uptake is lower for generics entering in the last 5 years compared to those entering 10-20 years ago

Average generic uptake for small molecule generics by generic entry year



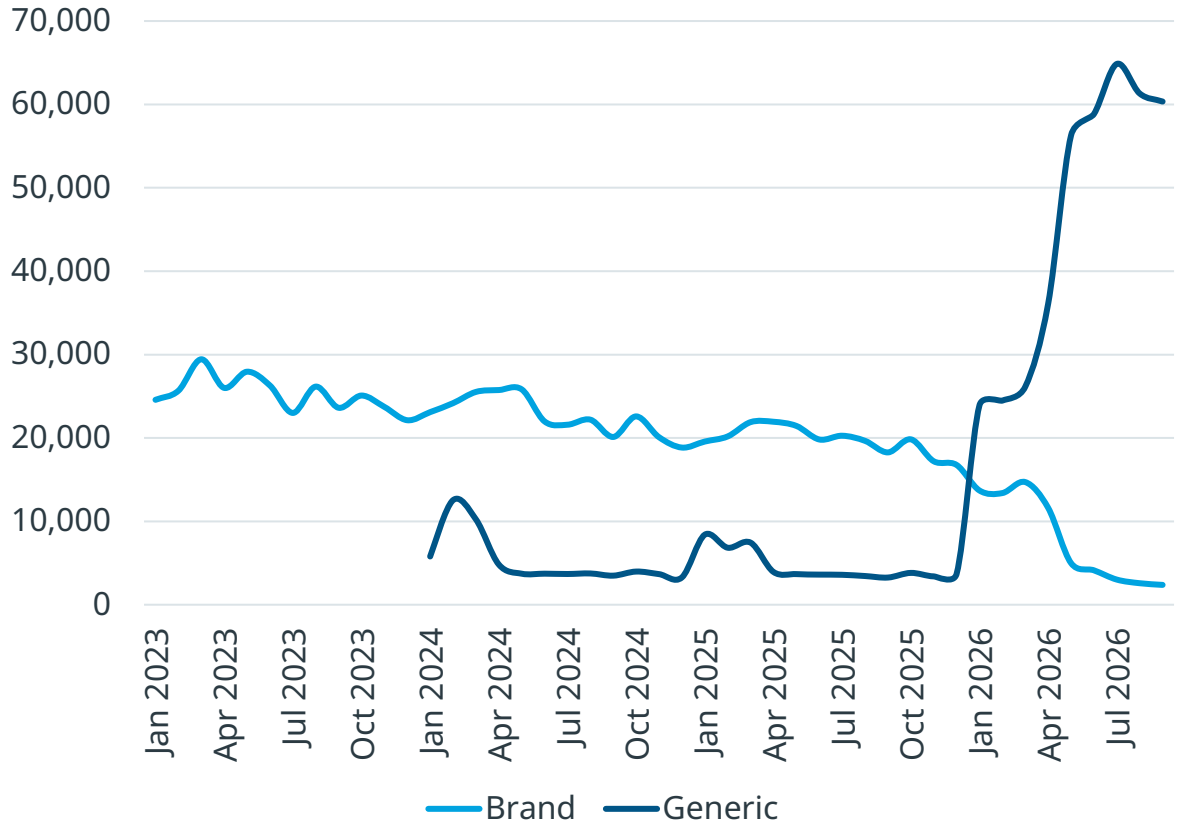
Source: IQVIA National Sales Perspective, Dec 2025; IQVIA Institute, Mar 2026.

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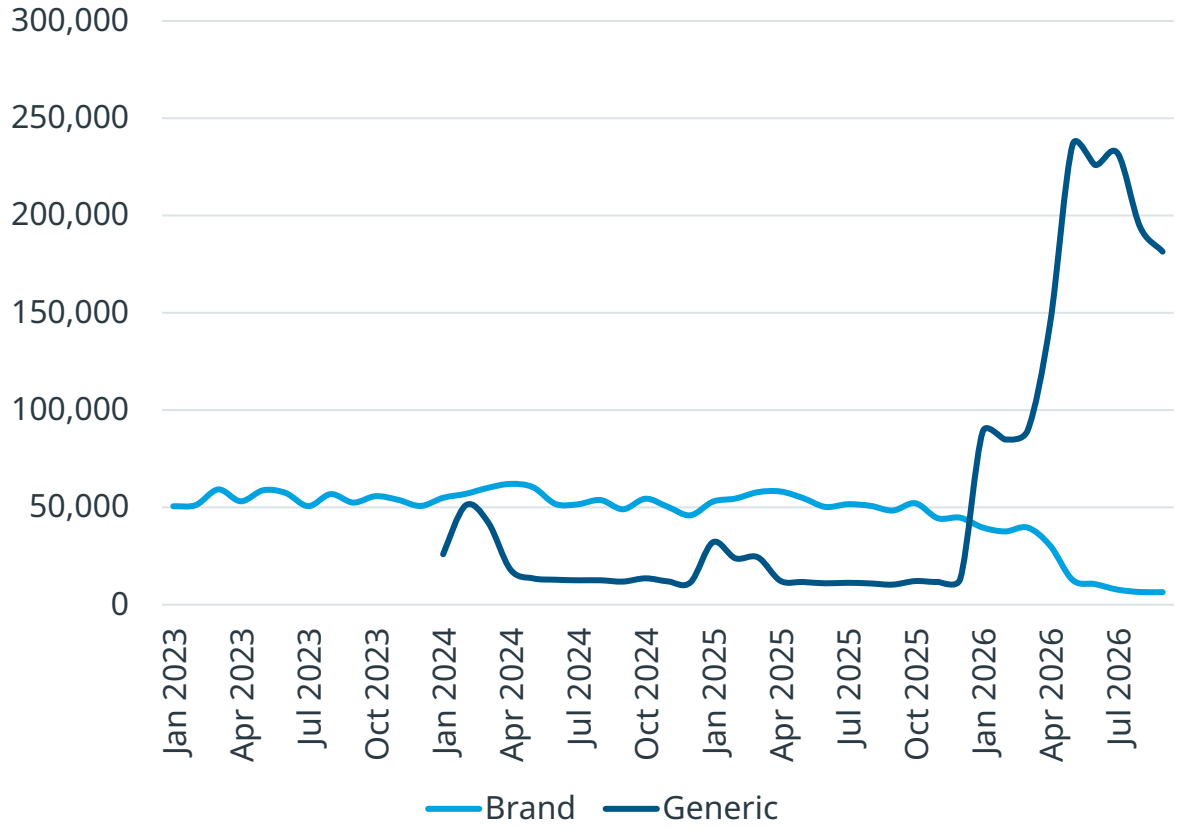
It took over 18 months for generic Dapagliflozin to overtake Farxiga

Trends of New to Brand Rxs for Brand and recently launched Generics

Dapagliflozin – 5 MG

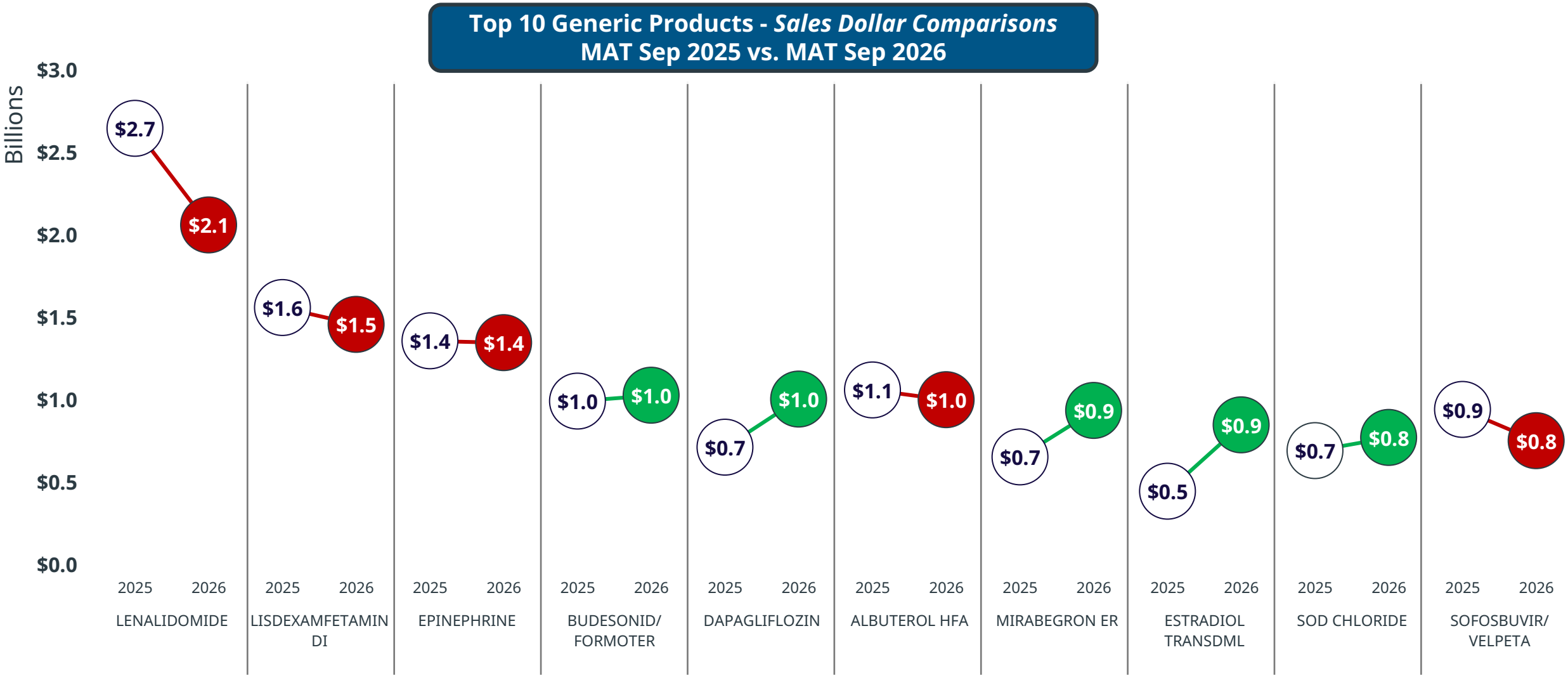


Dapagliflozin – 10 MG



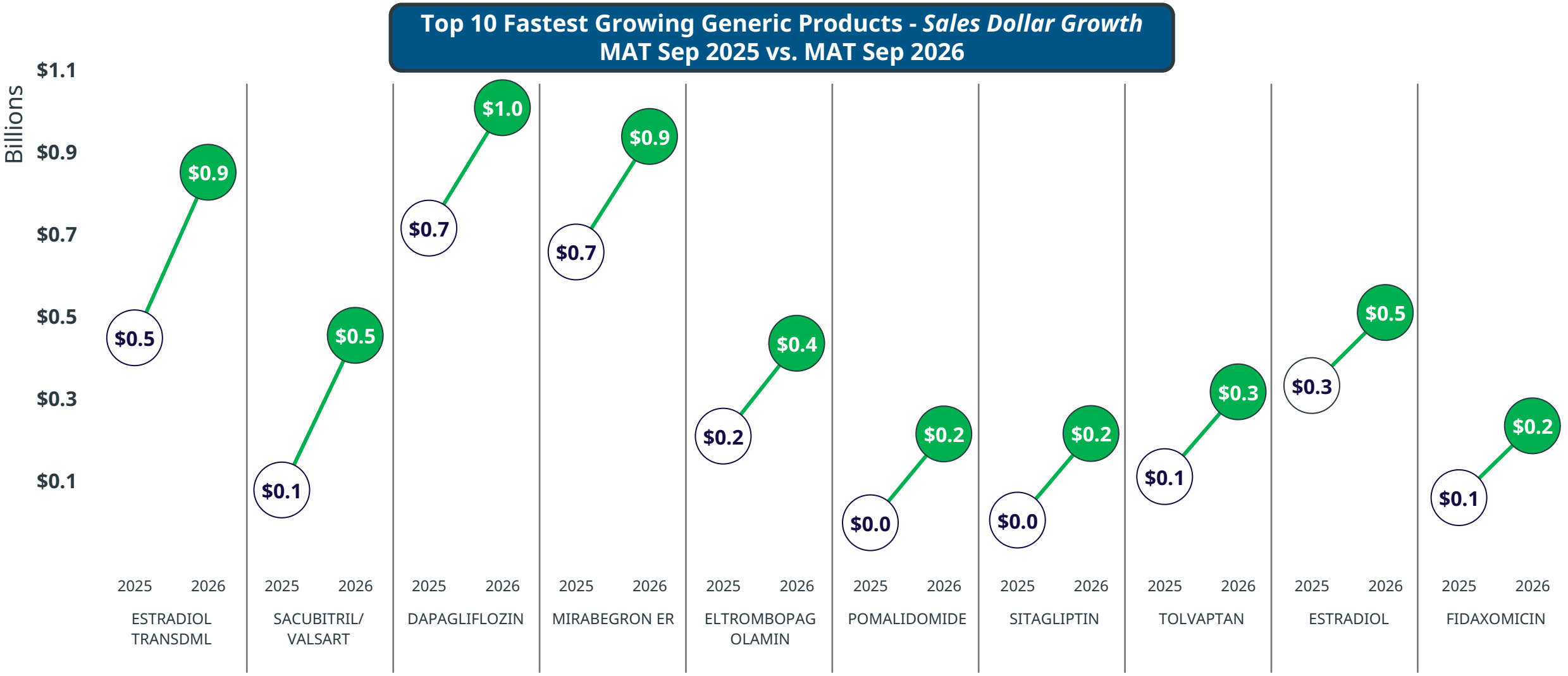
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Five of the top ten generic products have experienced a year-over-year decrease in sales



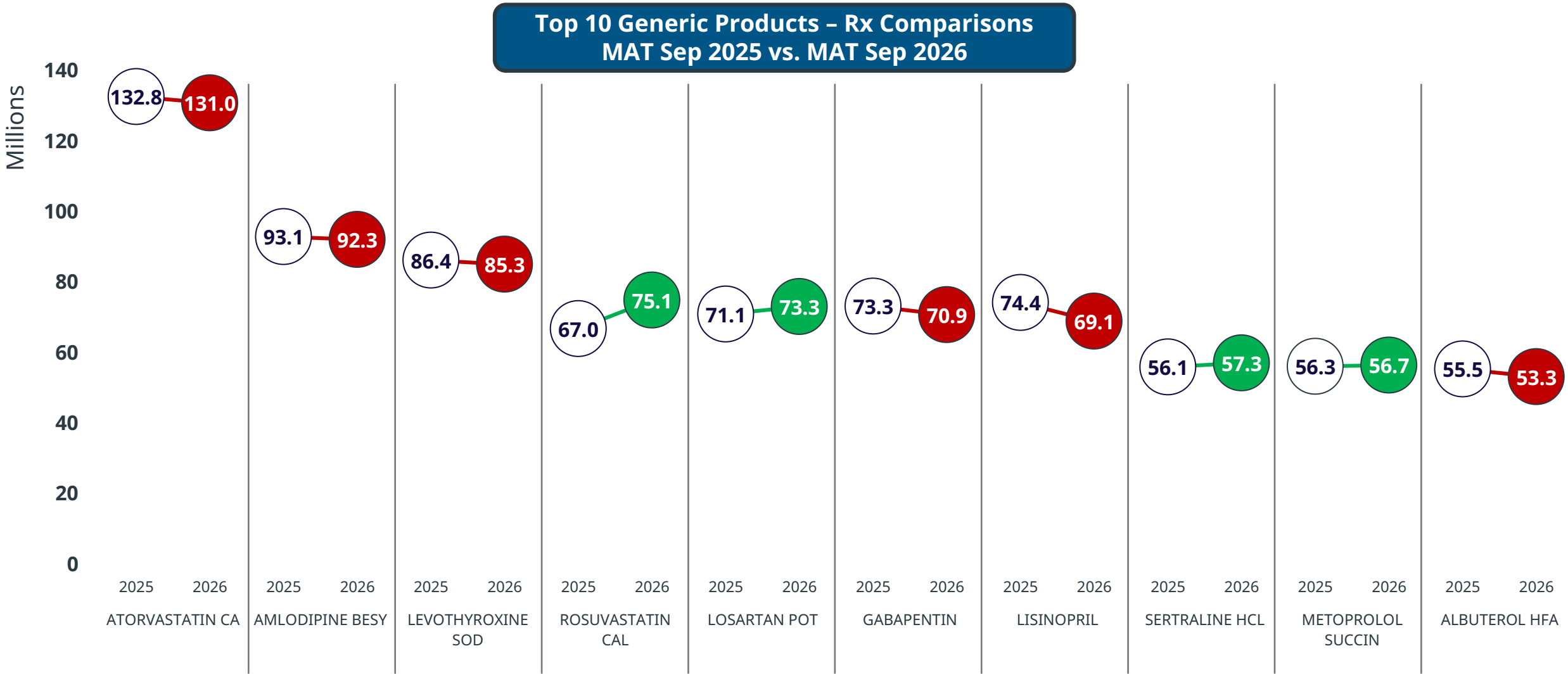
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Estradiol Transdermal is the fastest growing generic product on sales dollars year-over-year



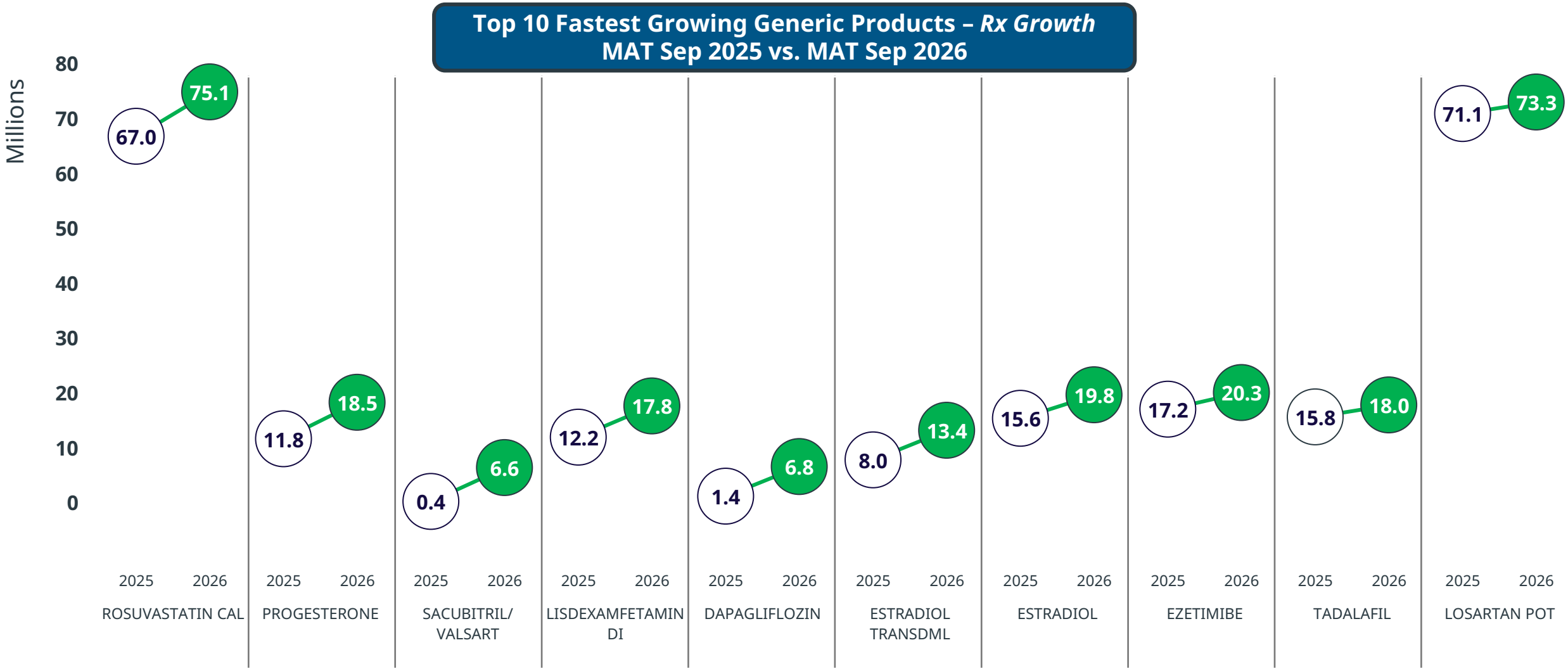
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Six of the top ten generic products have experienced a year-over-year decrease in Rxs, including each of the top three



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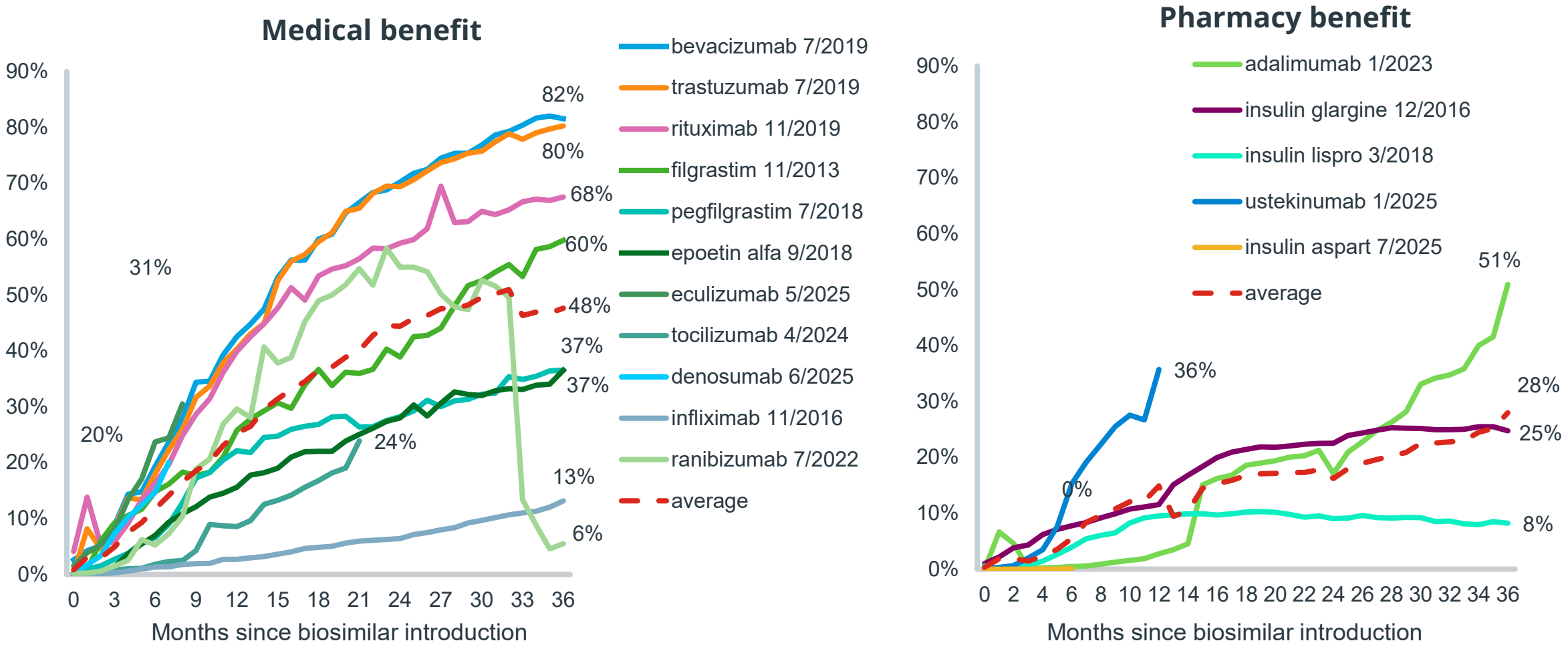
Rosuvastatin is the fastest growing product with Rxs year-over-year



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Biosimilar uptake varies across molecules, with average uptake of 48% in medical benefit and 26% in pharmacy benefit

Biosimilar uptake by molecule in defined daily doses (DDDs)



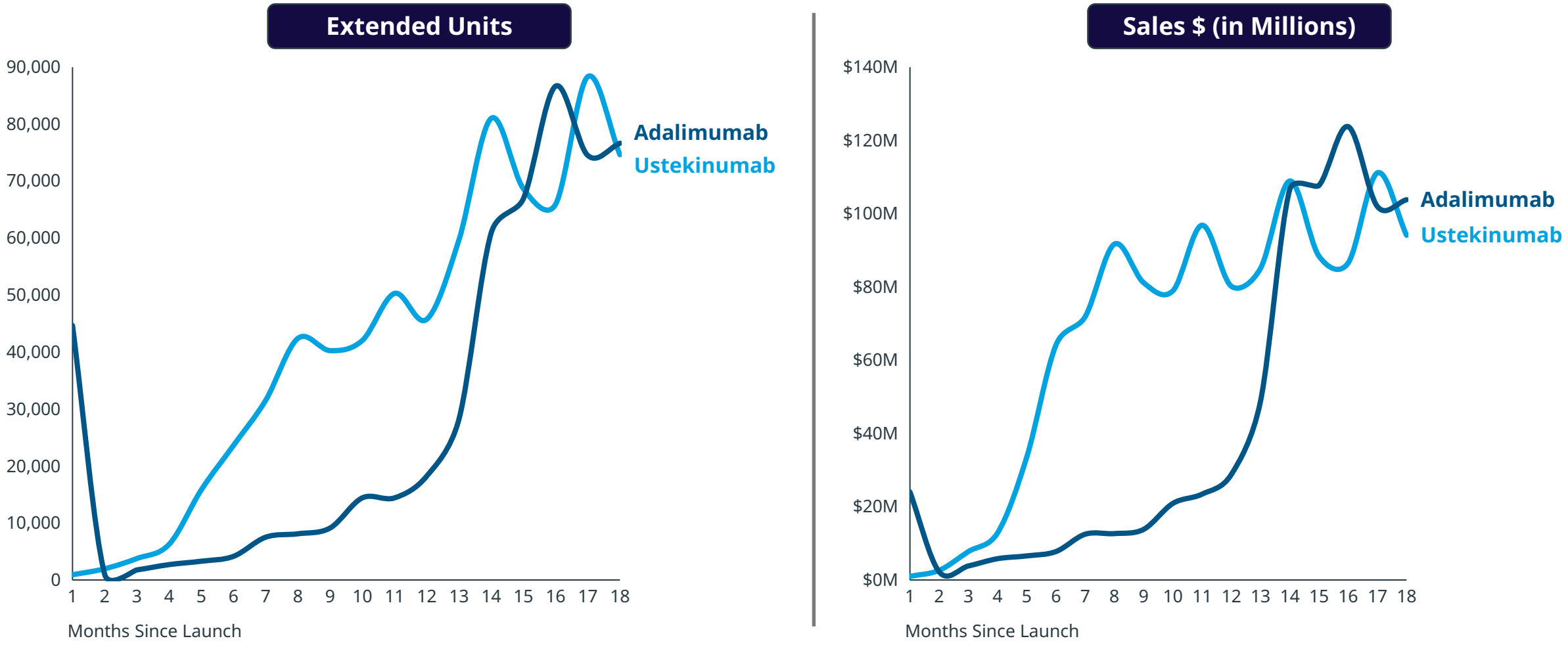
Source: IQVIA National Sales Perspective, Dec 2025; IQVIA Institute, Mar 2026.

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Ustekinumab biosimilars are now tracking similarly to where Adalimumab biosimilars were after month 18

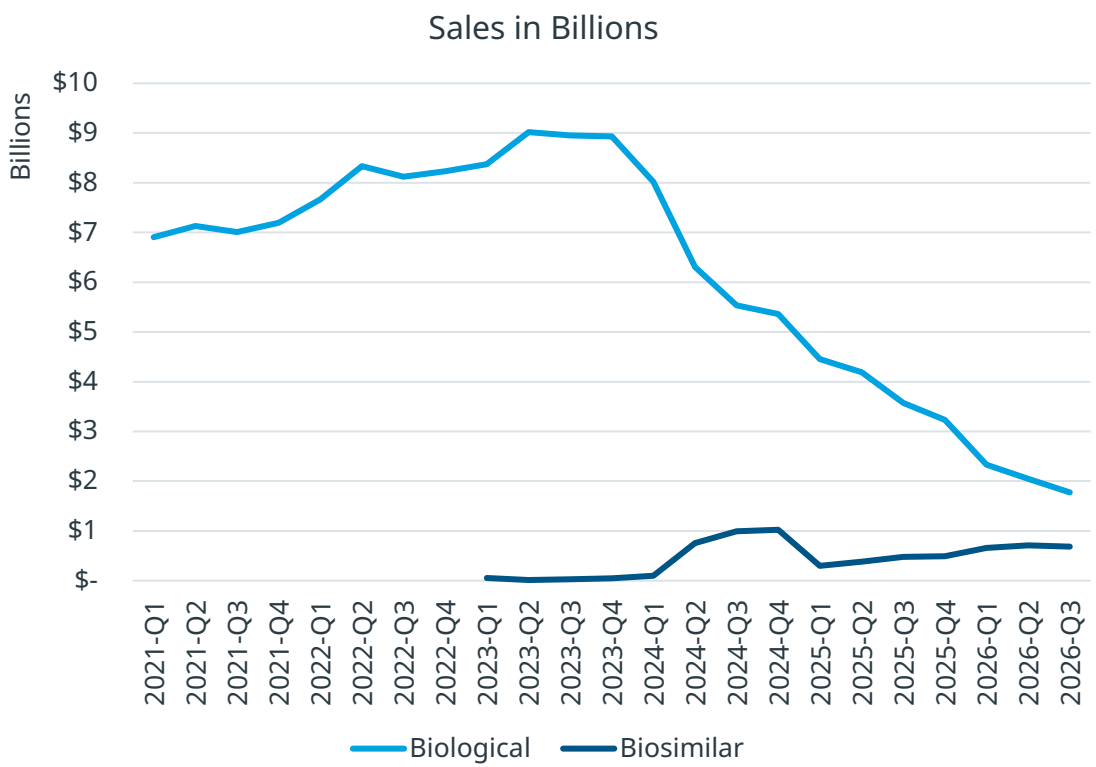
1st 18 months Units and Sales Comparisons – Ustekinumab vs. Adalimumab biosimilars

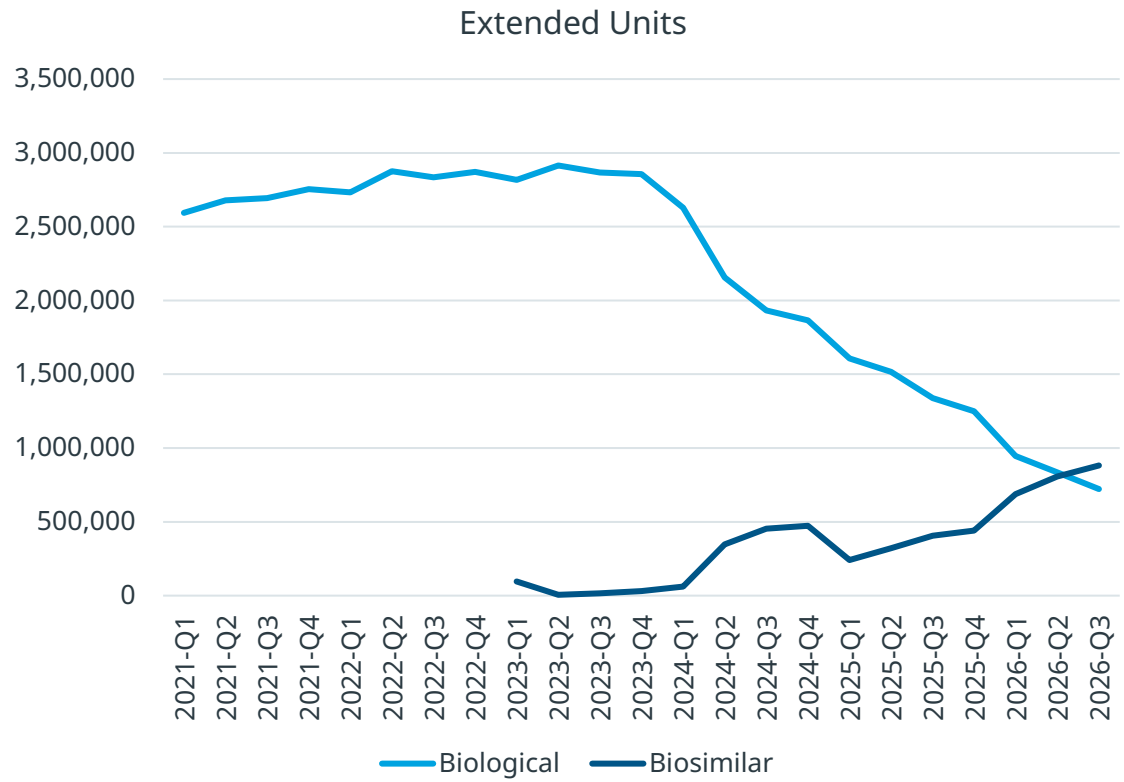


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In unit terms, Adalimumab has at last moved ahead of Humira

Adalimumab Trends

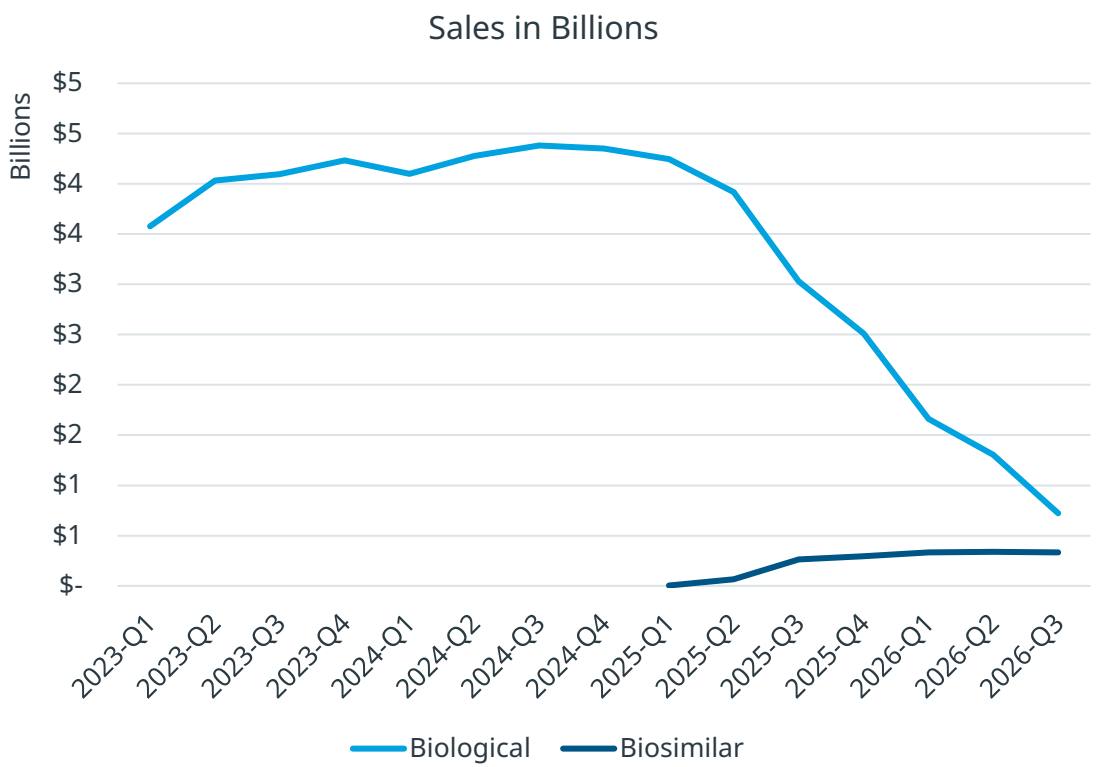


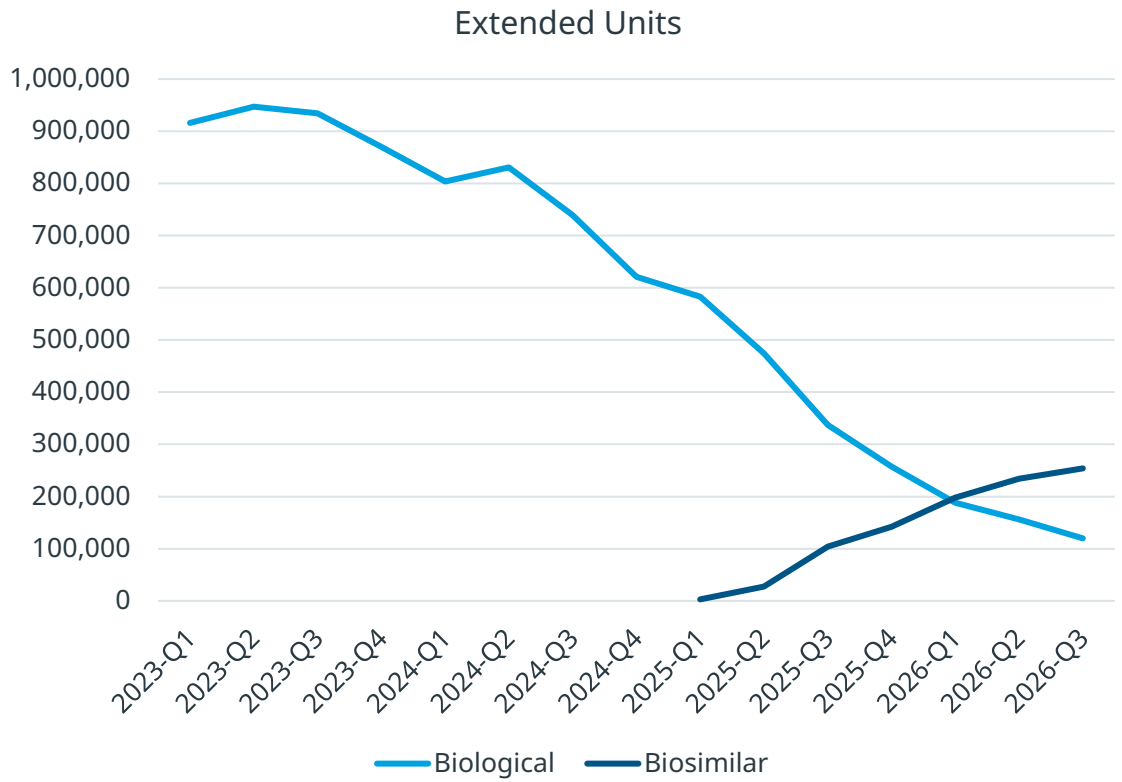


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Ustekinumab overtook Stelara much faster

Ustekinumab Trends

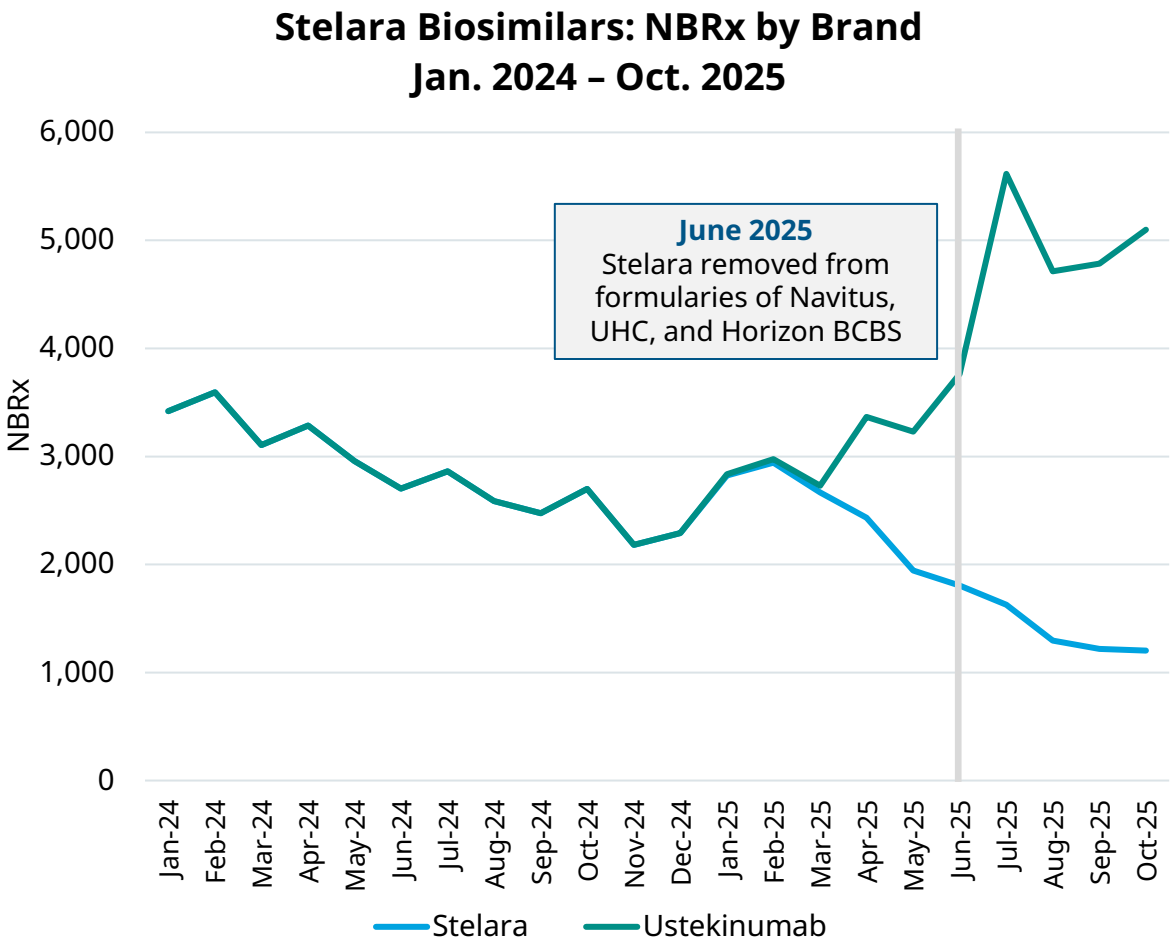


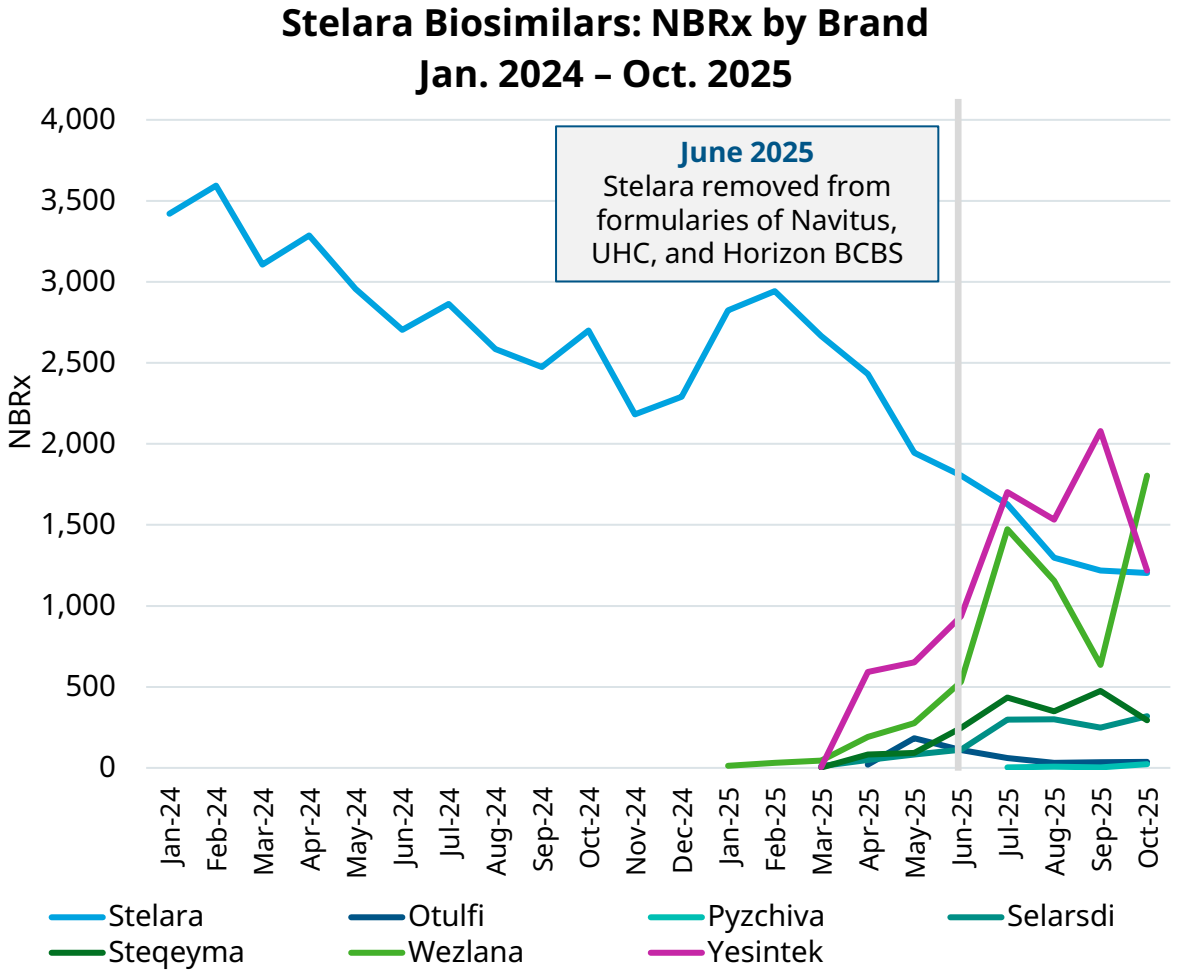


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Stelara market share erodes as biosimilars gain traction across payer channels

Aggressive discounts, coordinated launches, and payer-driven formulary shifts propel Stelara biosimilar uptake

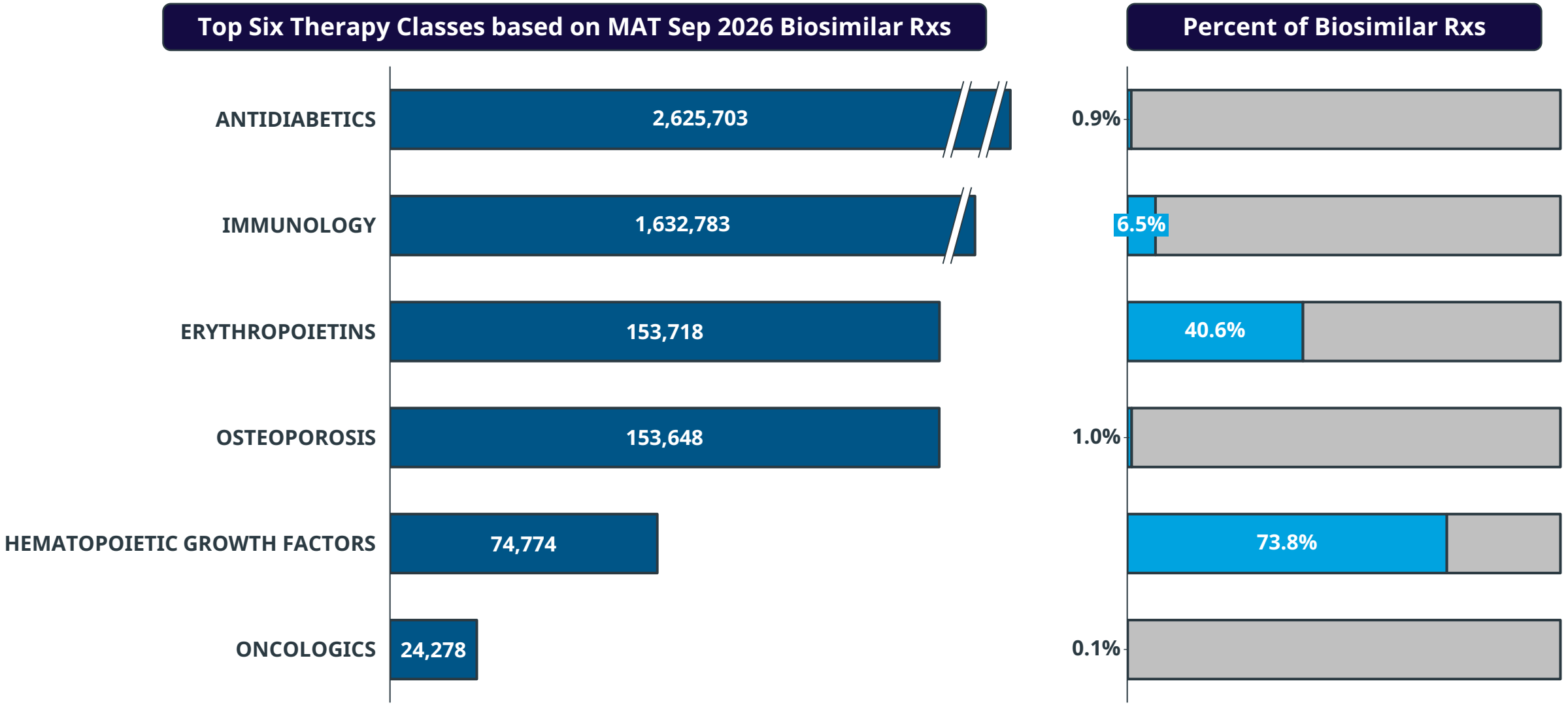




Source: National Sales Perspective; National Prescription Audit, Patient Insights; Launch Center of Excellence, IQVIA
IQVIA U.S. Launch Landscape Tracker, December 2025 Edition

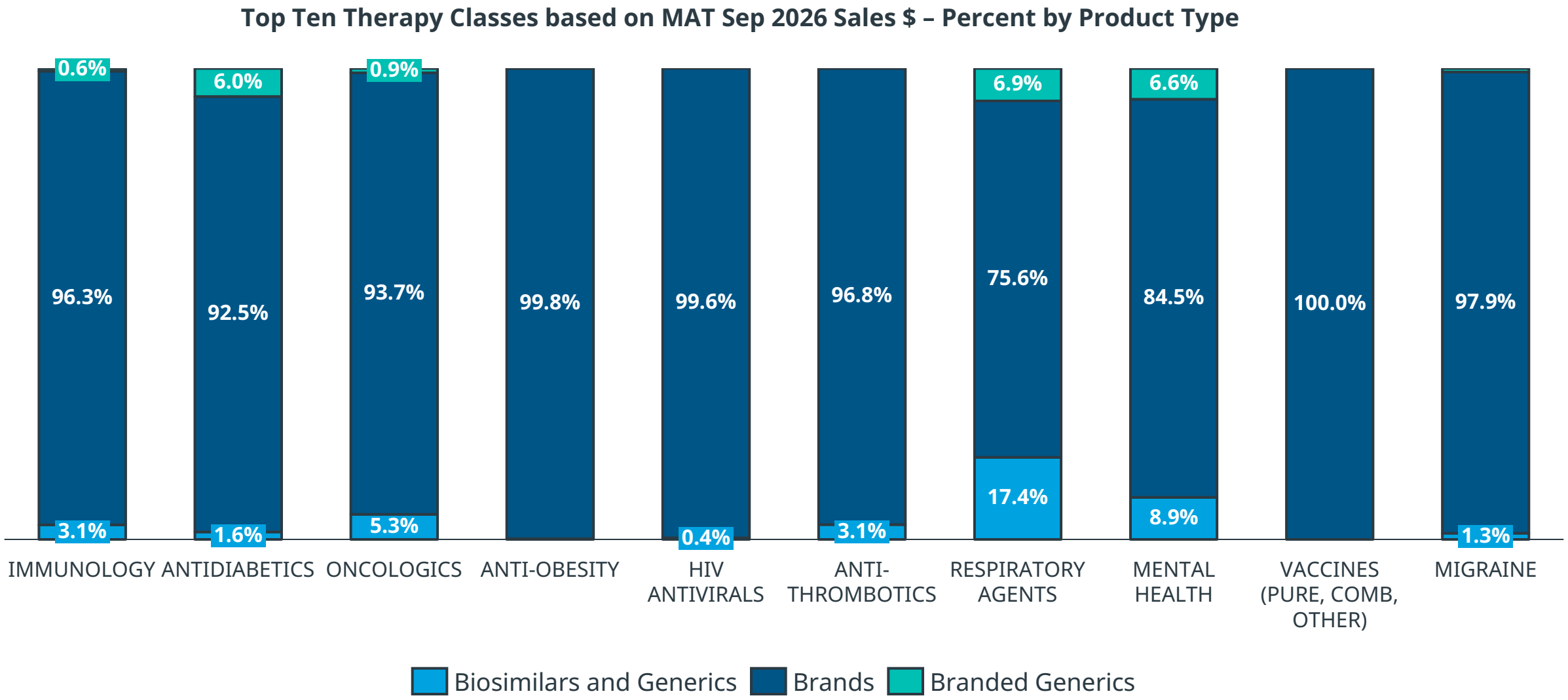
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Biosimilars make up the highest proportion of Rxs in Erythropoietins and Hematopoietic Growth Factors



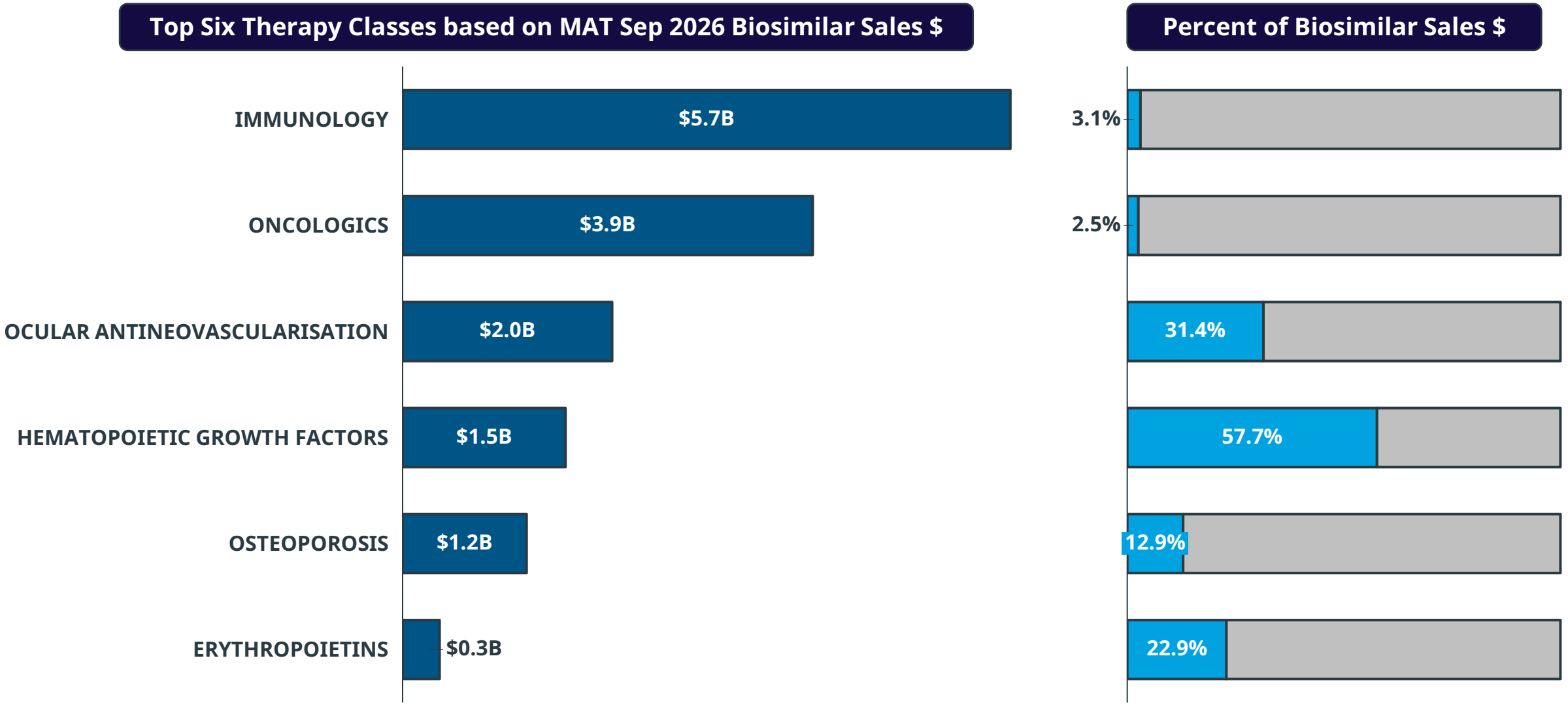
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Respiratory Agents and Mental Health have a higher percentage of Biosimilar/Generic sales $ versus the rest of the top ten



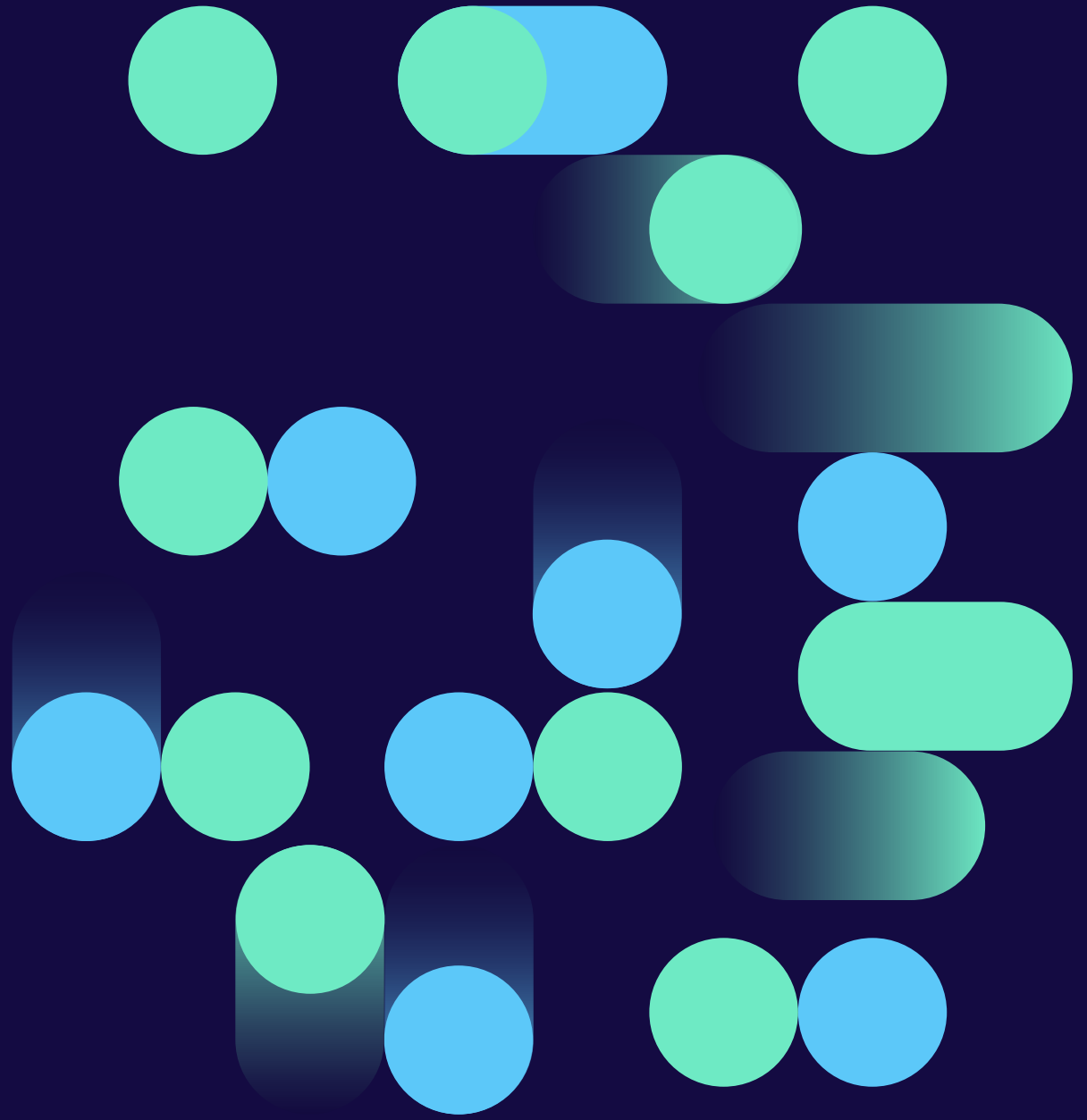
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Biosimilars make up the highest proportion of sales $ in Hematopoietic Growth Factors



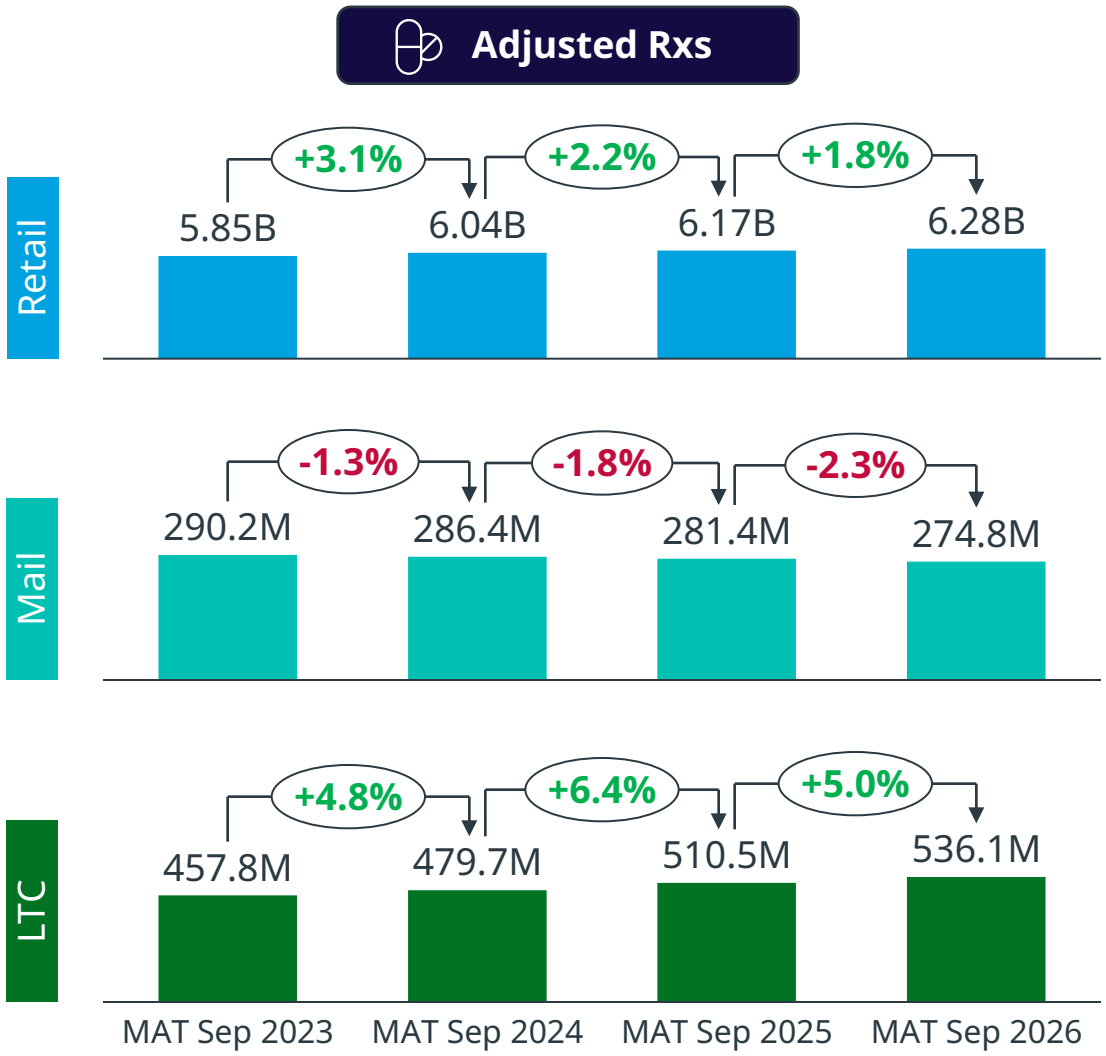
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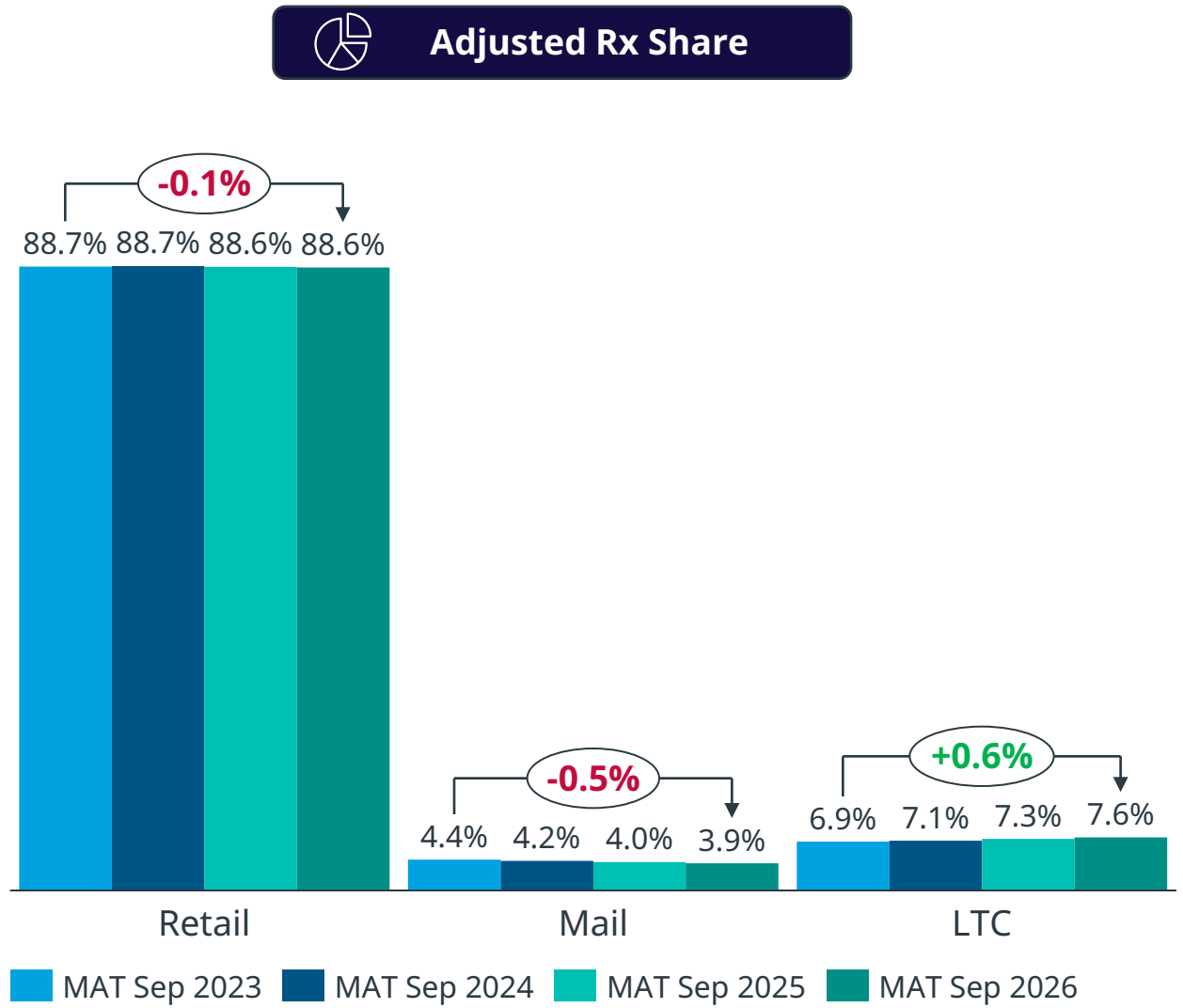
Retail Pharmacy



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Long-Term Care continues to gain adjusted Rx share as Mail declines and Retail share is flat





Source: IQVIA, RxInsights, June 2026

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Chain scripts decline as total Retail grows 1.8%

MOVING ANNUAL TOTAL
MAT September 2026

Chain

47.5%

Previously 49.0%

of retail scripts · 16,144 stores

-1.4% growth -1.5% share

Generic	88.1%
90-day	45.2%

Indep

17.8%

Previously 17.6%

of retail scripts · 18,276 stores

+2.8% growth +0.2% share

Generic	85.5%
90-day	26.7%

Food

18.4%

Previously 17.6%

of retail scripts · 9,154 stores

+6.5% growth +0.8% share

Generic	89.4%
90-day	40.5%

Mass

16.3%

Previously 15.8%

of retail scripts · 7,273 stores

+5.2% growth +0.5% share

Generic	88.1%
90-day	41.4%

RETAIL PHARMACY FOOTPRINT

7,891
fewer pharmacies than seven years ago

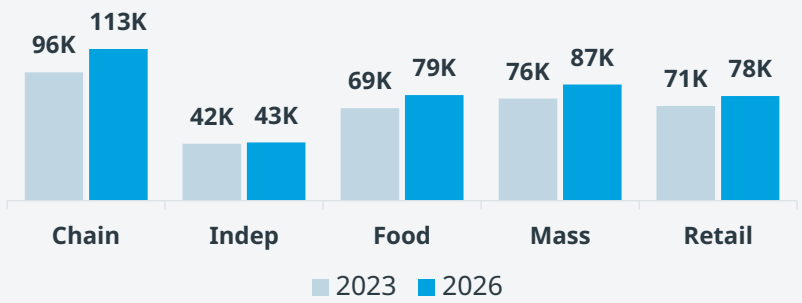
Closures are concentrated in chain stores

Net loss of 2,043 since 2025

Avg Rxs per store

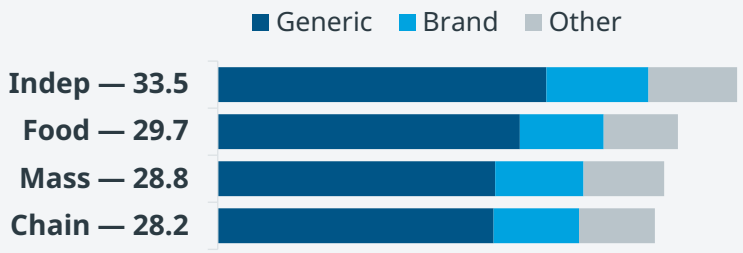
Closures push output higher

+10.5% retail avg vs 2023



Adjusted Rxs per patient

Ranked by total, split into generic, brand and other Rxs



Indep leads on every component — generic, brand and other

Source: IQVIA, RxInsights

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Insured pay types gain share as discount cards collapse

Adjusted Rx data is based on Moving Annual Total, September 2026

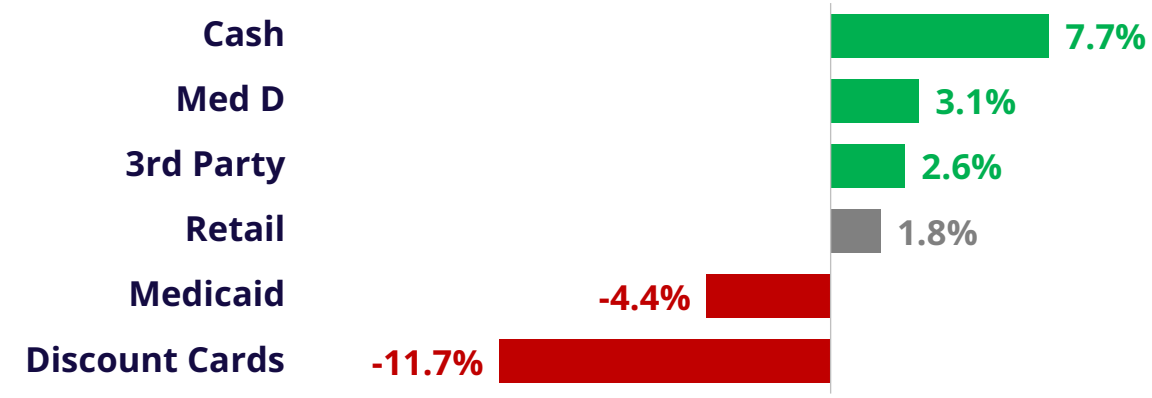
CLASS OF TRADE	LOWEST SHARE OF PAY TYPE	SHARE OF TOTAL RETAIL RX	HIGHEST SHARE OF PAY TYPE
Chain	Disc. Cards 27.4%	47.5%	3rd Party 53.2%
Indep	Disc. Cards 5.3%	17.8%	Cash 49.2%
Food	Cash 4.0%	18.4%	Disc. Cards 42.3%
Mass	Medicaid 15.0%	16.3%	Disc. Cards 24.9%

Each % = the class of trade's share within that pay type — not its internal pay-type mix.

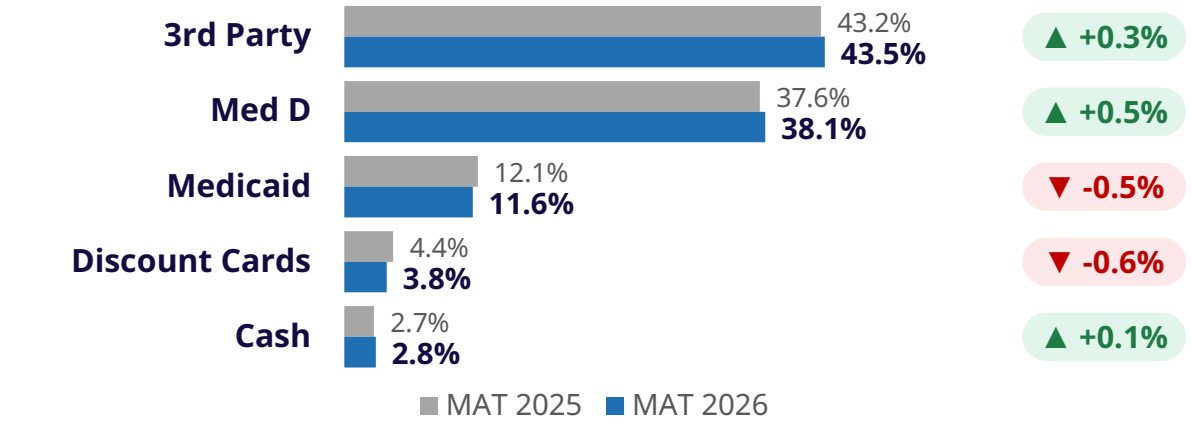
What it means

- Chain and Indep hold their lowest market share with Discount Cards, while Food (**42.3%**) and Mass (**24.9%**) hold their highest share there
- Indeps stay cash-driven at **49.2%**; Cash retail share up **+0.1%**
- Chain captures **47.5%** of all retail scripts, and **53.2%** of the 3rd Party market

YOY GROWTH, MAT SEP 2026



RETAIL SHARE SHIFT, MAT SEP 2025 VS. SEP 2026



Source: IQVIA, RxInsights, June 2026

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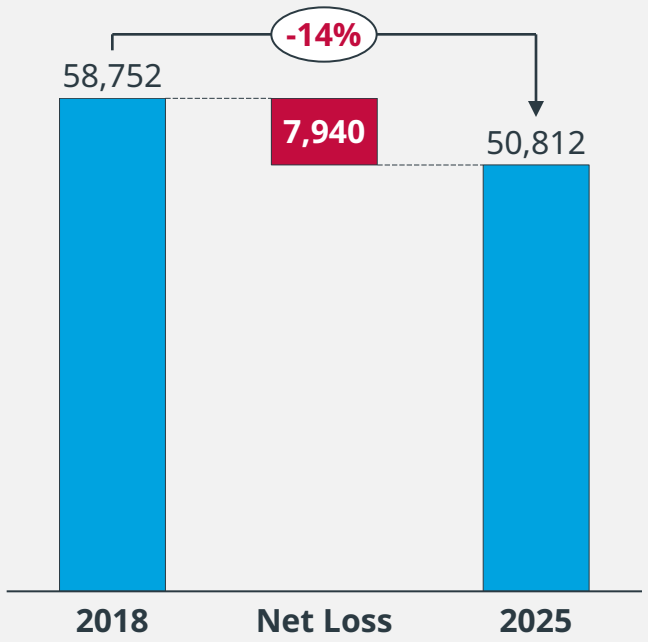
Each pharmacy closure now disrupts more than twice as many patients as in 2018

STRUCTURAL DRIVERS

Fewer Access Points

Nearly 8K fewer active retail pharmacy locations since 2018

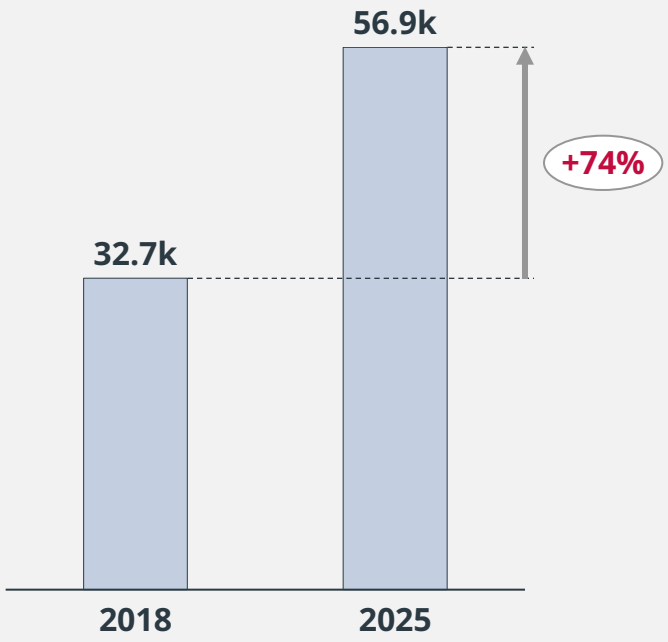
Active Retail Pharmacies by Year



More Claims per Pharmacy

Remaining pharmacies now carry more prescription volume

Average Claim Count per Pharmacy Closure
(1 Year Lookback)



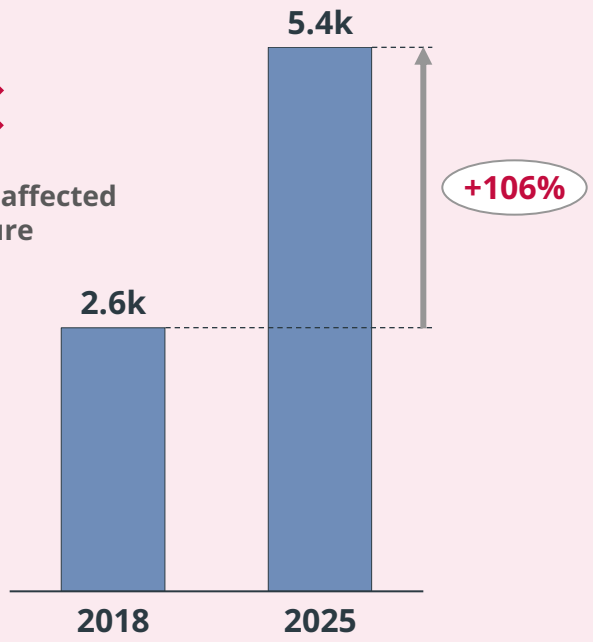
RESULTING PATIENT IMPACT

Higher Patient Disruption per Closure

Average patients affected per pharmacy closure more than doubled

Average Patient Count per Pharmacy Closure
(1 Year Lookback)

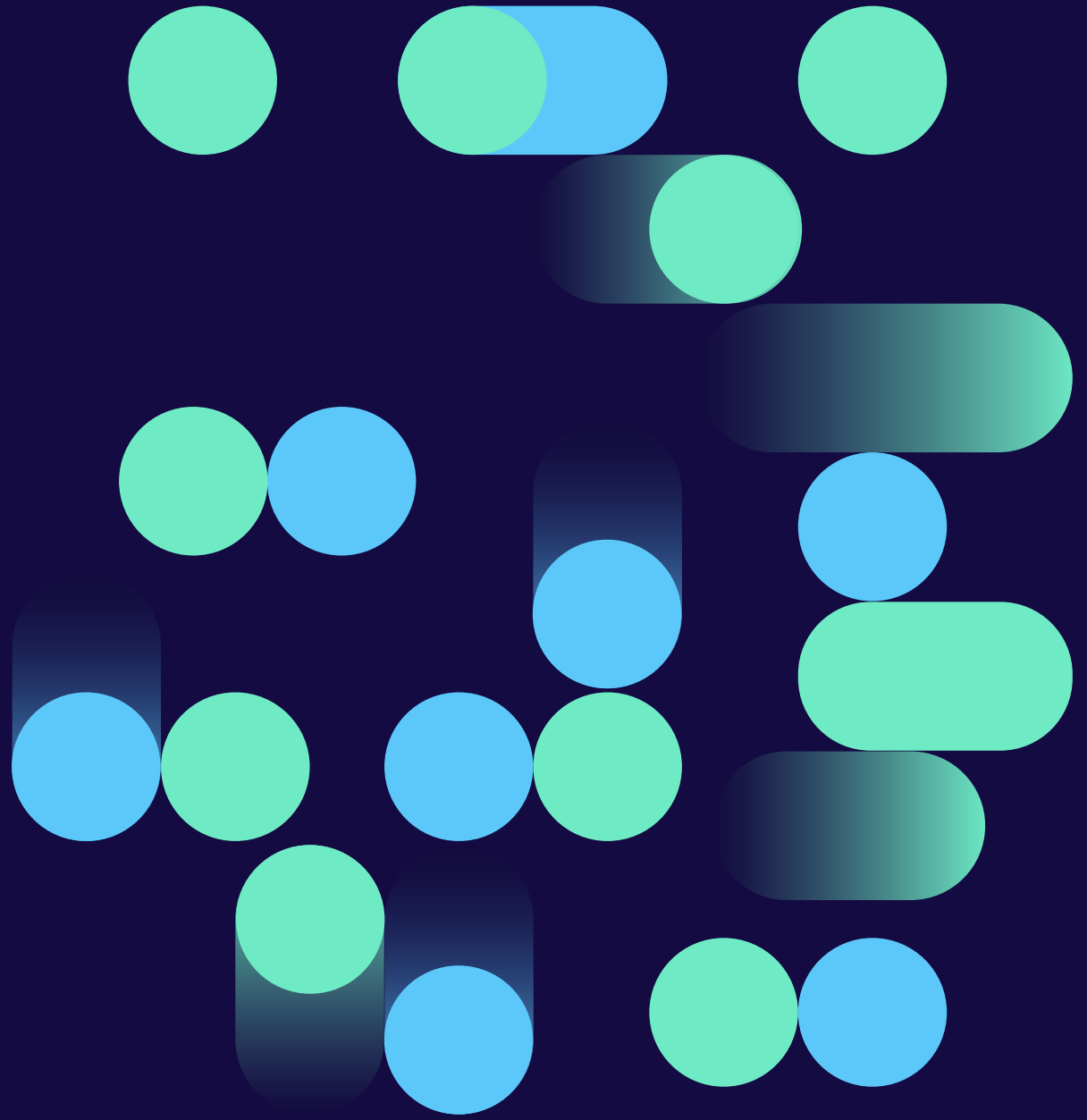
2×
patients affected per closure



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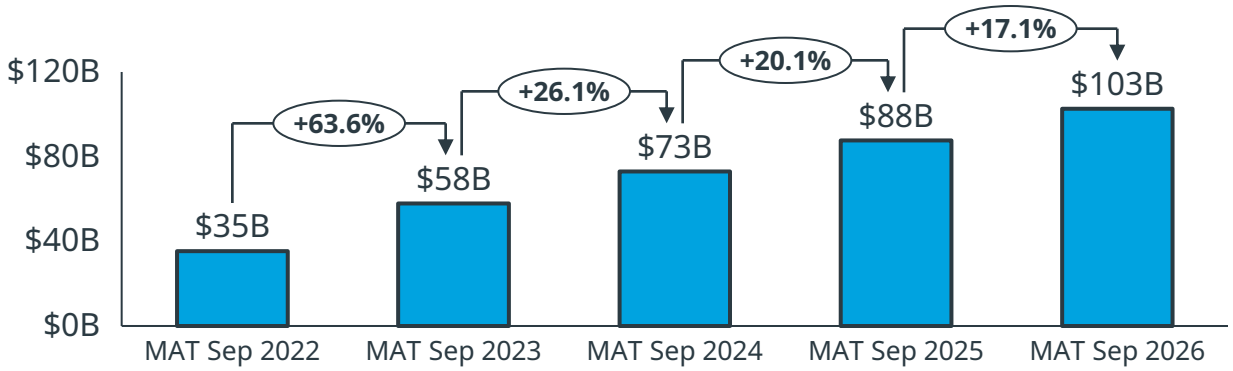
GLP-1s



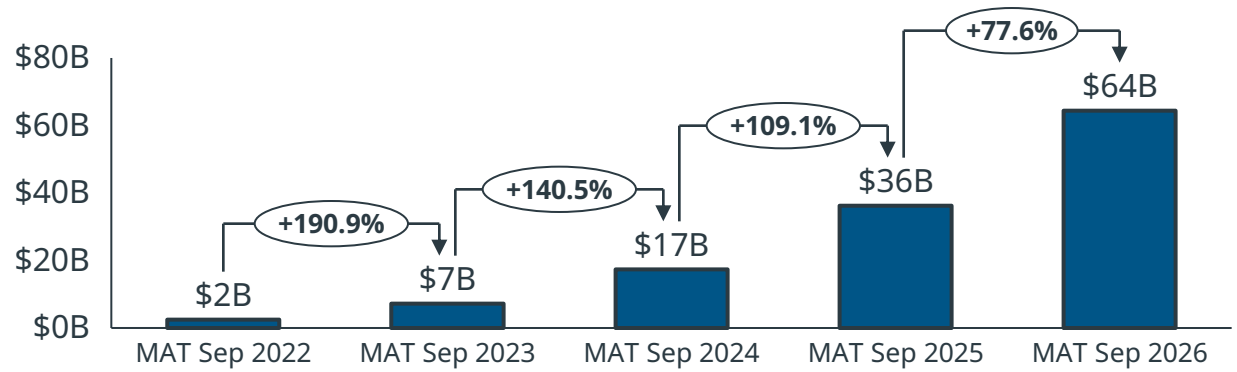
63% of all market growth is now attributable to GLP-1 products

GLP-1 Sales Impact; MAT September

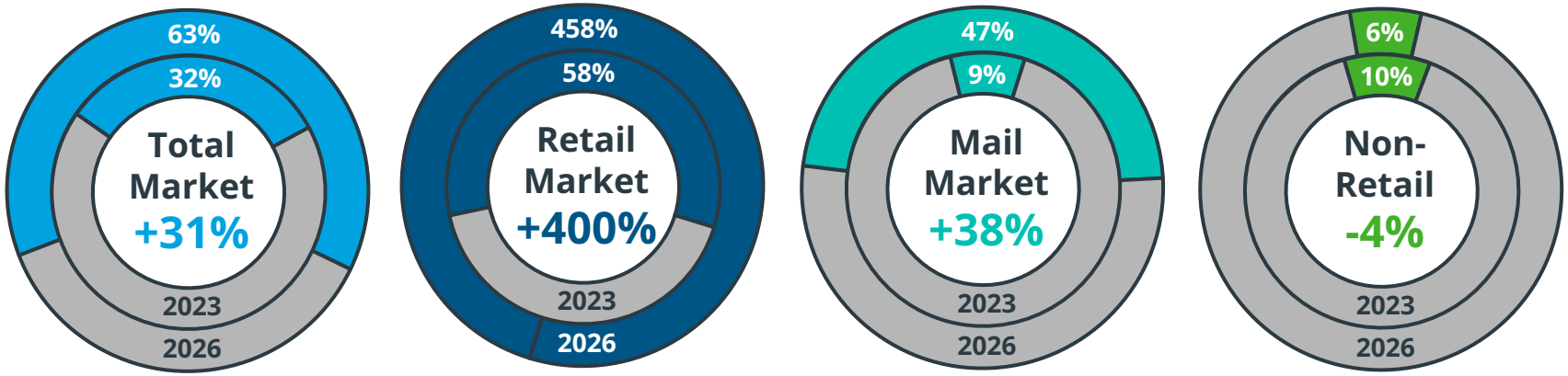
Diabetes GLP-1 Sales $



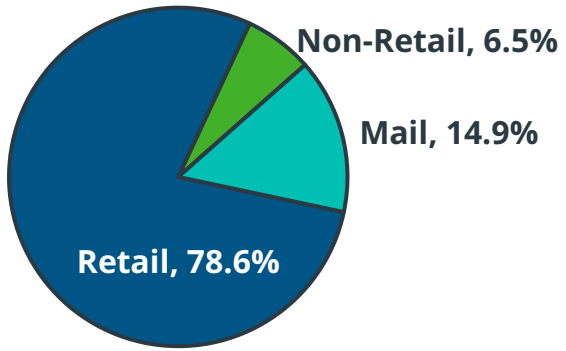
Weight Loss GLP-1 Sales $



What % of sales growth are GLP-1s?



Sales Distribution

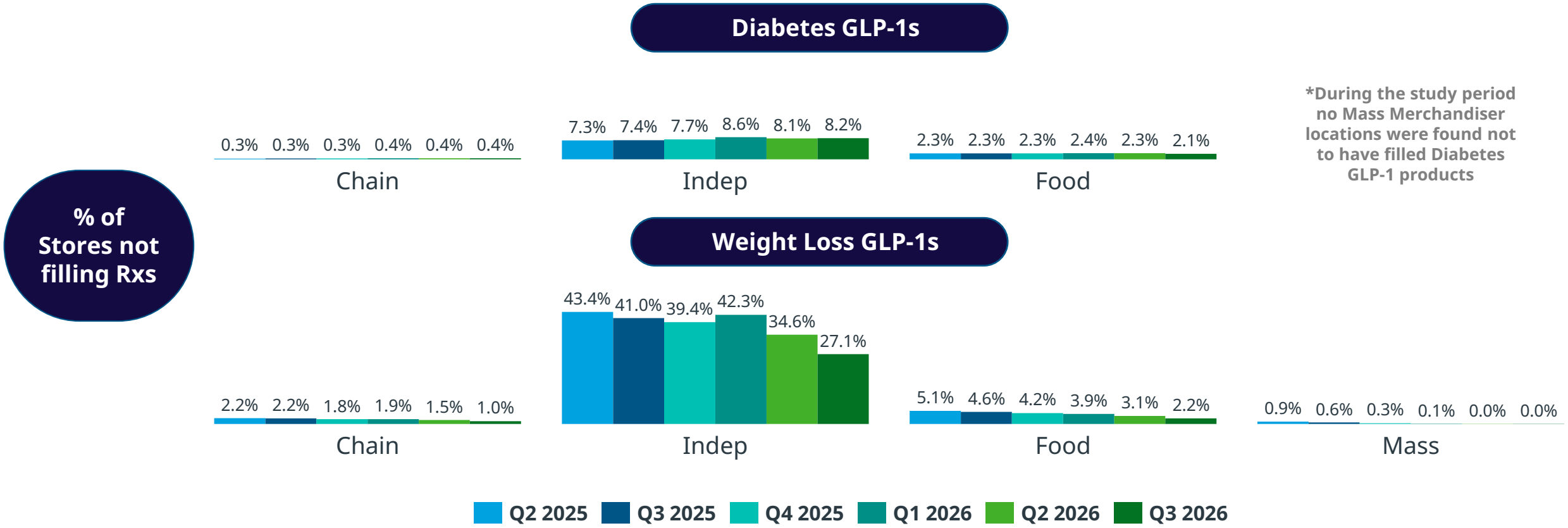


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The percentage of Independent stores that are not filling weight loss GLP-1 products continues to fall

Business Rules

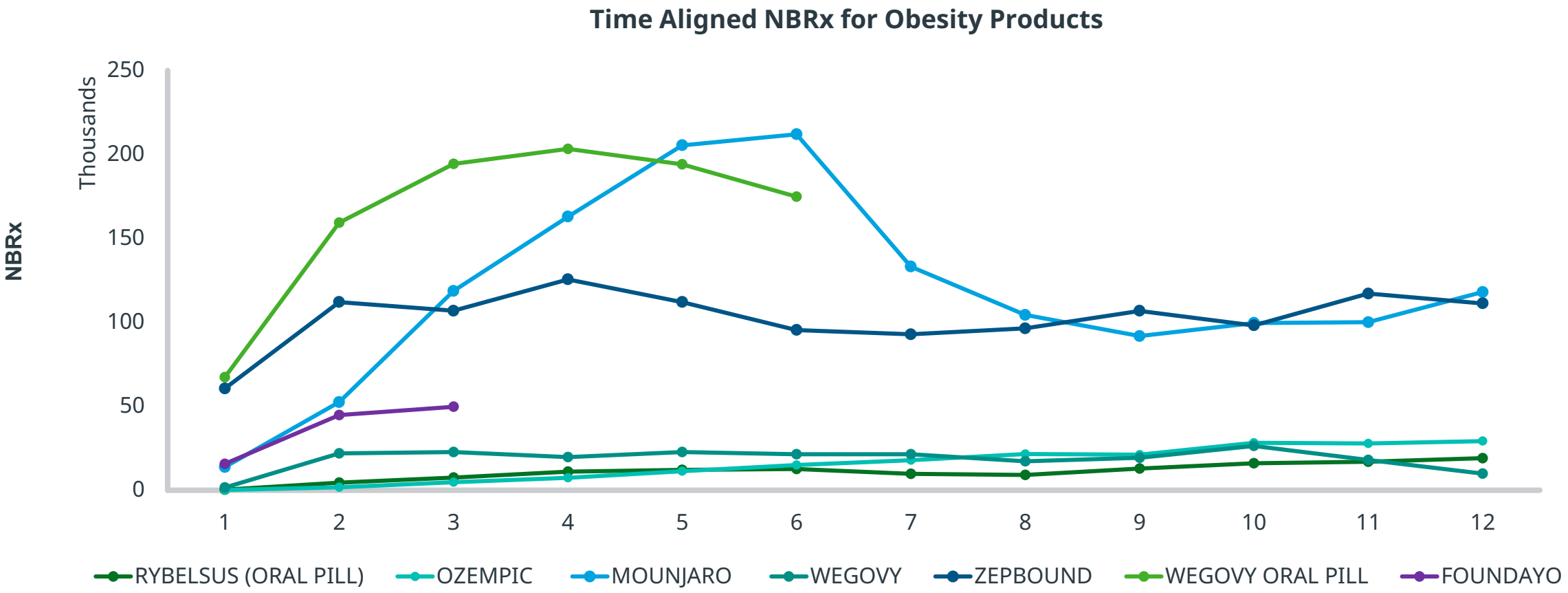
- Using IQVIA data, stores must have filled 1,000 or more Rxs in each quarter of the observation period
- Observation Period: 2025 Q2through 2026 Q3
- Each store had to have filled less than 10 Rxs for the specified category of drugs in each quarter



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Competition in the oral GLP-1 market is accelerating following the launch of Oral Wegovy and Eli Lilly's Foundayo

Oral asset approval in the GLP-1 space marks a critical inflection point for market entry and differentiation



IQVIA U.S. Launch Landscape Tracker, August 2026 Edition

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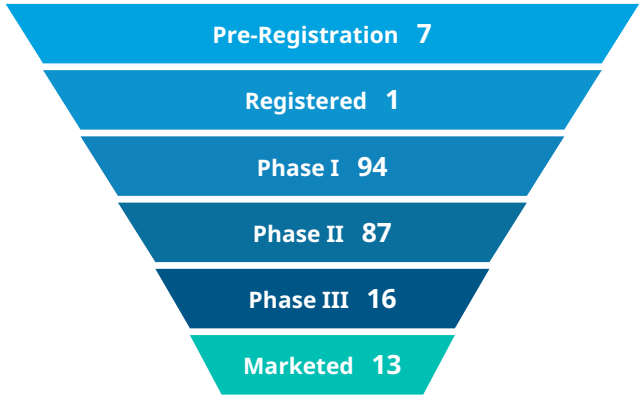
Three forces now define the obesity medicine market: pipeline depth, a new Medicare bridge, and expansion beyond weight

PIPELINE SUPPLY

218

molecules in development globally, Jul 2026

Obesity drugs by stage of development



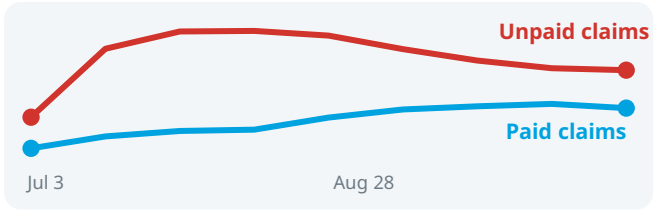
GLP-1s and combinations lead R&D — 75 oral, 111 subcutaneous, 11 other routes

ACCESS

$50

patient out-of-pocket per month ($245 net price)

Weekly claims trajectory, Jul–Aug 2026



Paid claims
+1,158%
9.3K → 116.5K per week

Unpaid claims
-32%
321K → 218K since mid-Jul

Bridge runs Jul 2026–Dec 2027; BALANCE from Jan 2028. PA required for PDP and MA-PDP; BMI ≥35, or ≥30 / ≥27 with qualifying comorbidity

EXPANSION

6

therapeutic frontiers beyond obesity

Emerging therapeutic frontiers

- Neuro-degenerative
- Mental health
- Substance use
- Respiratory
- Women's health
- Cancer

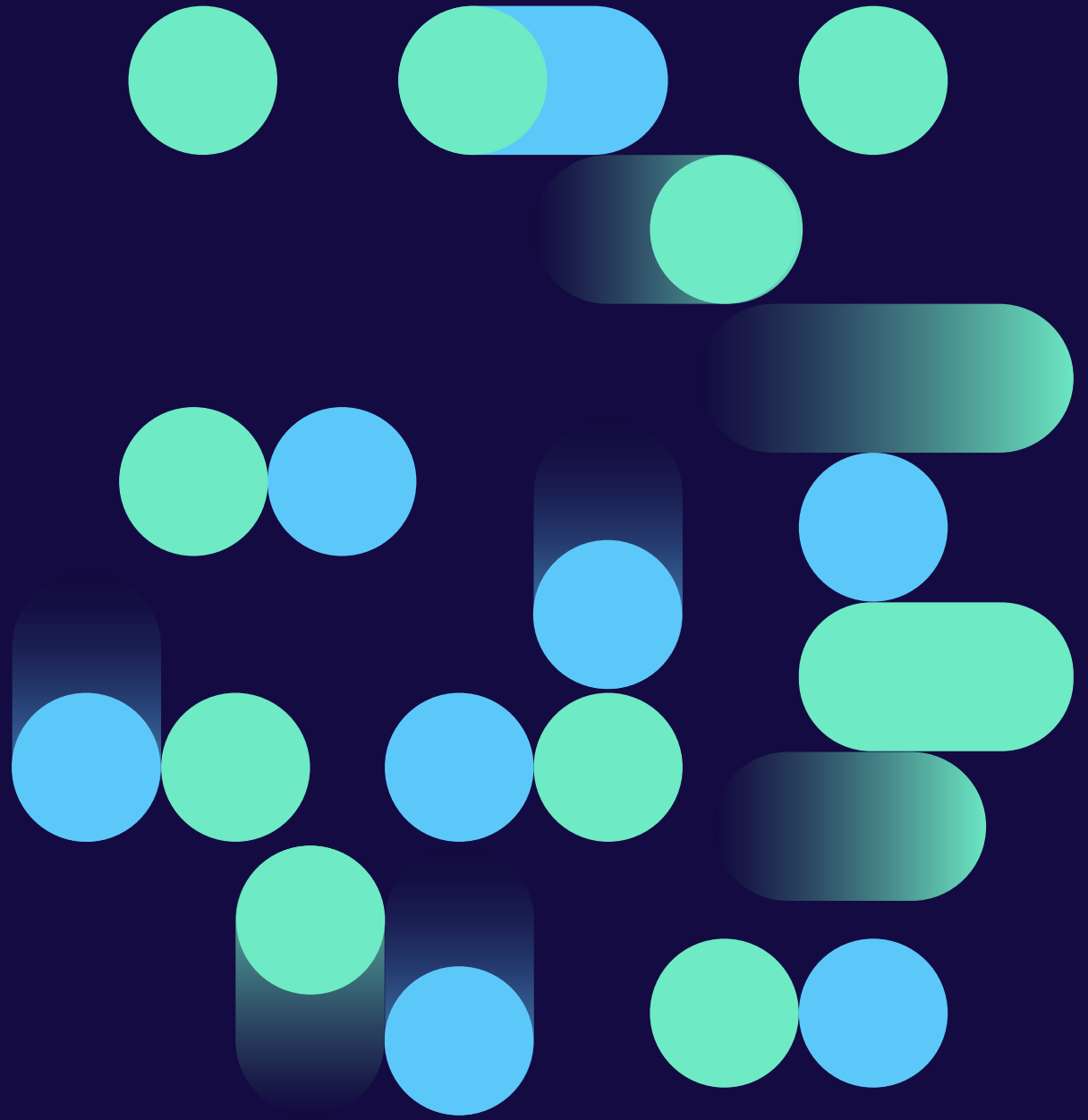
Beyond obesity, tolerability — not peak weight loss — becomes the gating factor

SO WHAT

Supply and demand arrive together in 2026–27. The open questions are how payers respond to the Bridge, how many 65+ patients initiate, and how share plays out across brands — while indication expansion shifts the win condition from peak weight loss to tolerability.

Note: 4 key GLP-1 brands Zepbound, Wegovy, Wegovy Pill, Foundayo. Pipeline counts global as of July 2026; claims weeks ending 7/3/2026–8/28/2026.
Source: Citeline Trialtrove; IQVIA Institute; LAAD Rx claims; IQVIA U.S. Thought Leadership & Innovation and Market Access Strategy Consulting Analysis

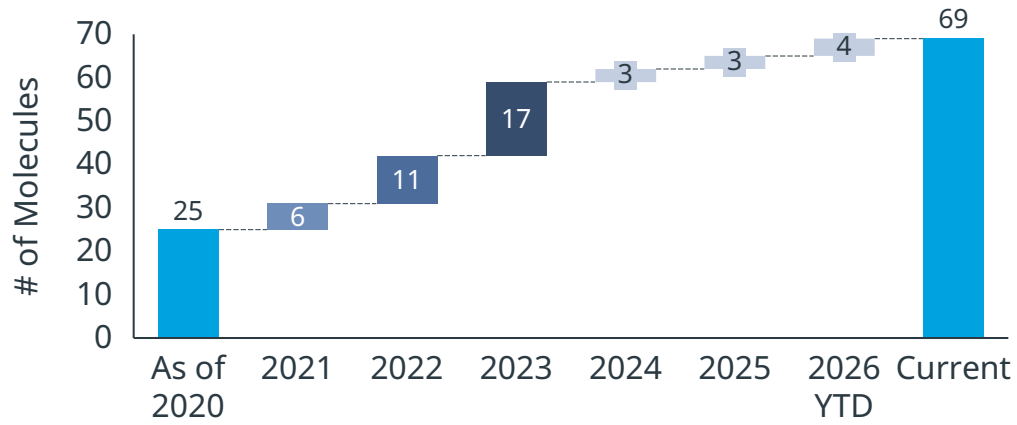
On the Radar



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Drug Shortages and Inspections

Current Drug Shortages by Year Reported

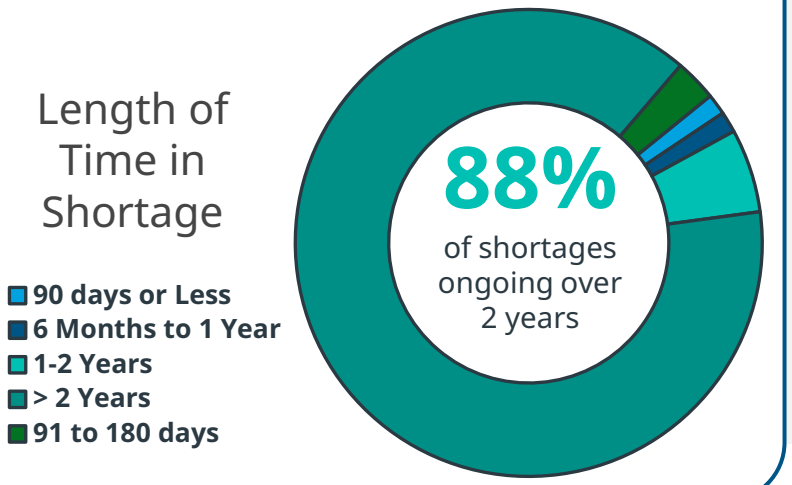


Current Drug Shortages
69

Top Therapies by # of Shortages

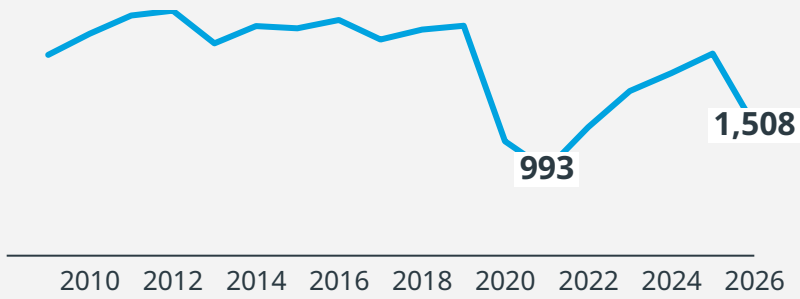
Anesthesia	10
Cardiovascular	8
Analgesia/Addiction	8
Endocrinology/Metabolism	7
Anti-Infective	7

Length of Time in Shortage



FDA Drug Inspections

1,012
in Fiscal Year 2026

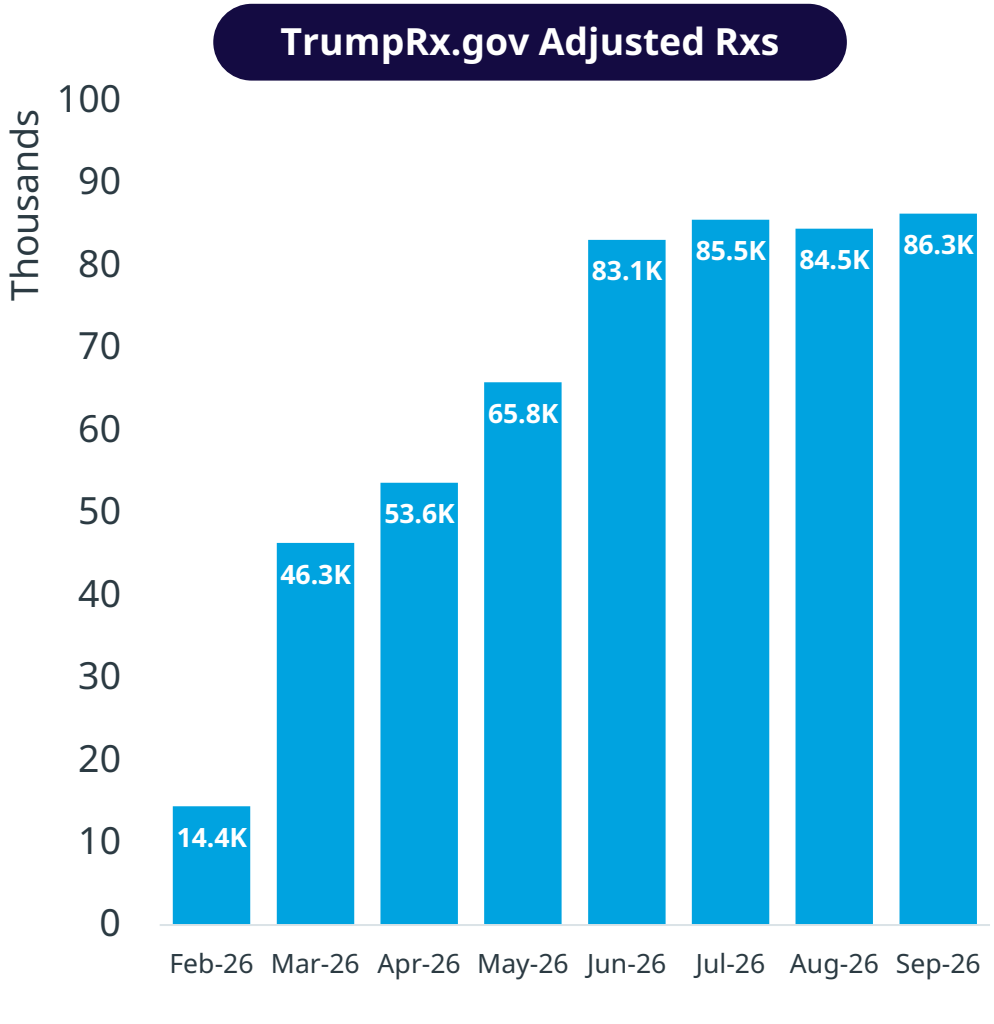


Lowest fiscal year total since 2022

Data Sources: https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm and https://datadashboard.fda.gov/ora/cd/inspections.htm, data pulled 10/29/2026

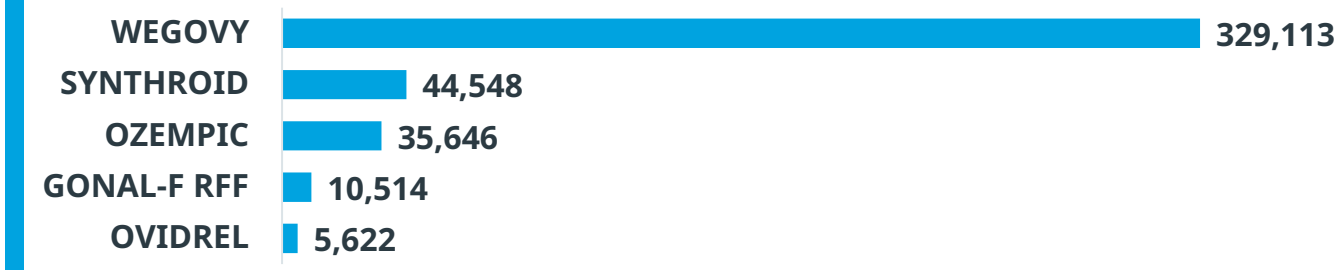
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TrumpRx.gov volume is climbing, and branded products account for nearly 86% of adjusted Rxs



86% of all scripts are processed for a branded product

TOP FIVE BRANDED PRODUCTS



TOP FIVE GENERIC PRODUCTS



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Scale today | Patient-direct access is broadening, but true DTP fulfillment remains small

Broader DTP definition includes manufacturer-sponsored direct access, cash-pay/discount pathways, home delivery, and patient access support programs

TAs with meaningful patient-direct access activity

Broader definition captures direct fulfillment, cash-pay, affordability and patient support pathways

CV/antithrombotic
Emerging activity

Respiratory
Moderate activity



Obesity/GLP-1
Highest commercialization

Diabetes/ cardiometabolic
High activity

Immunology/inflammation
Moderate-high activity

Update: DTP/patient-direct activity now spans at least 5 TAs, but high-volume direct-fill activity remains led by obesity and cardiometabolic brands

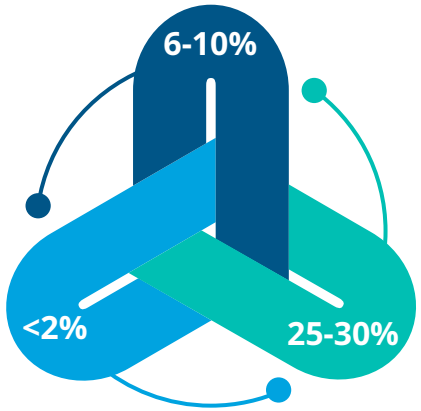
DTP penetration & program breadth

Updated stats using broader definition; fulfillment penetration remains directional

Patient-direct/DTP fulfillment as % of US branded TRx

National estimate remains below 2% despite broader program footprint

Do not include traditional copay/ PAP/support interactions unless tied to fulfillment



NovoCare as % of US Wegovy Rx

Low-single-digit directional range; no updated public share disclosed

NovoCare now supports self-pay, savings and free delivery pathways

LillyDirect as % of US Zepbound Rx

Directional range; remains the highest visible DTP penetration example

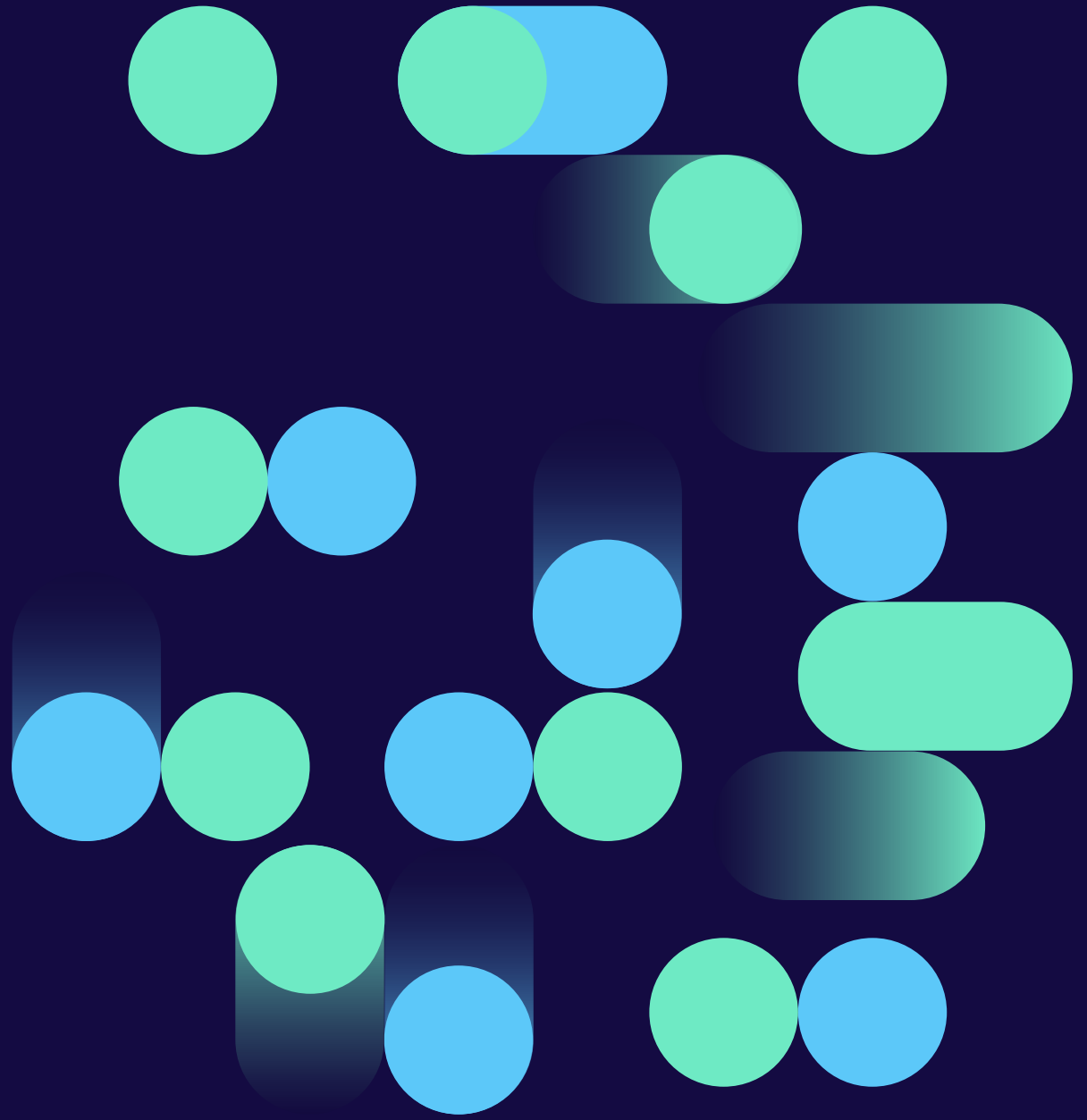
Lilly continues to cite LillyDirect as a scalable platform, but not updated share

3	True multi-brand DTP platforms
~5	Additional direct-access/ fulfillment programs

Source: IQVIA analysis of public manufacturer programs and press releases, updated July 2026. Broader DTP definition includes manufacturer-sponsored direct access, cash-pay, direct fulfillment, and patient support programs. Counts and penetration ranges are directional and should be reconciled with IQVIA channel tracking before final publication

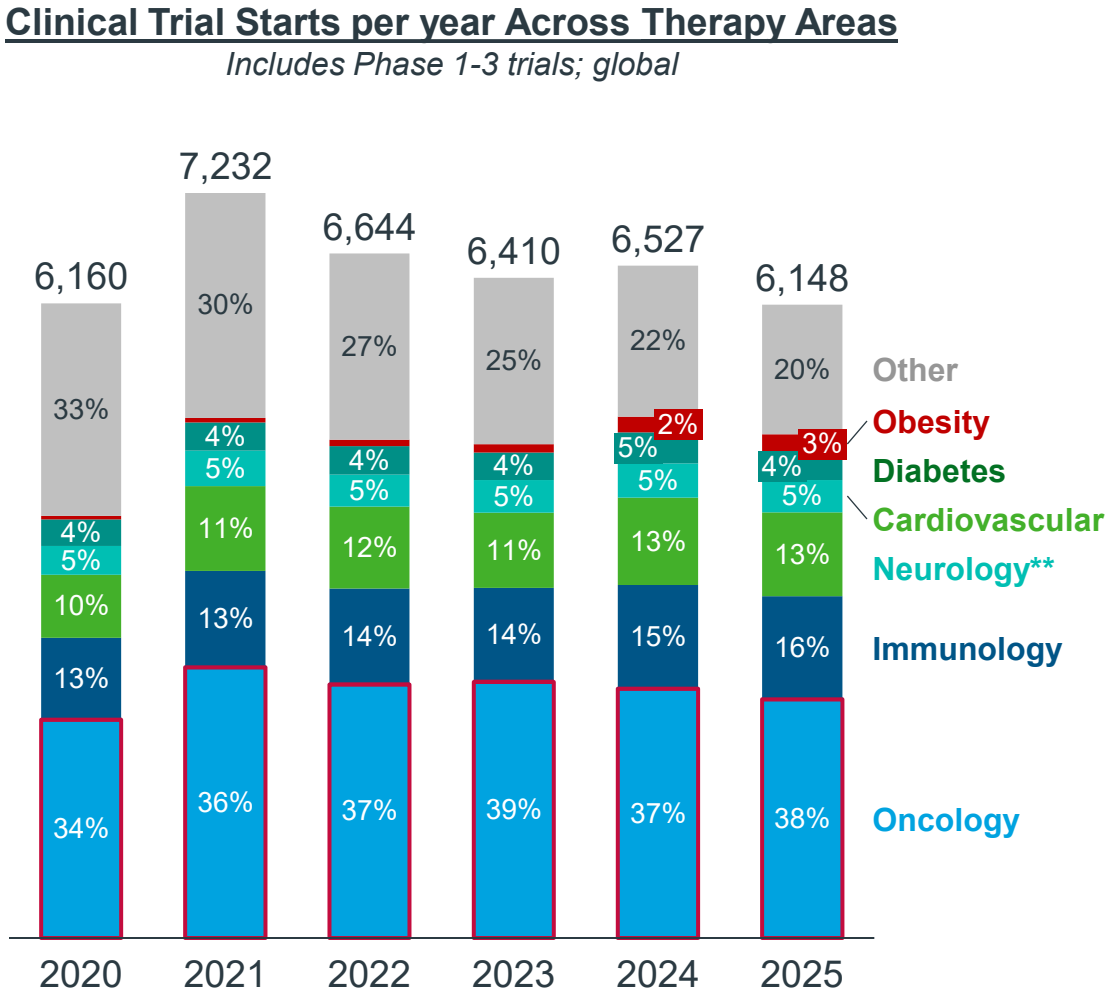
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Wrap Up



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Industry pipelines have herded into oncology, immunology, and neurology



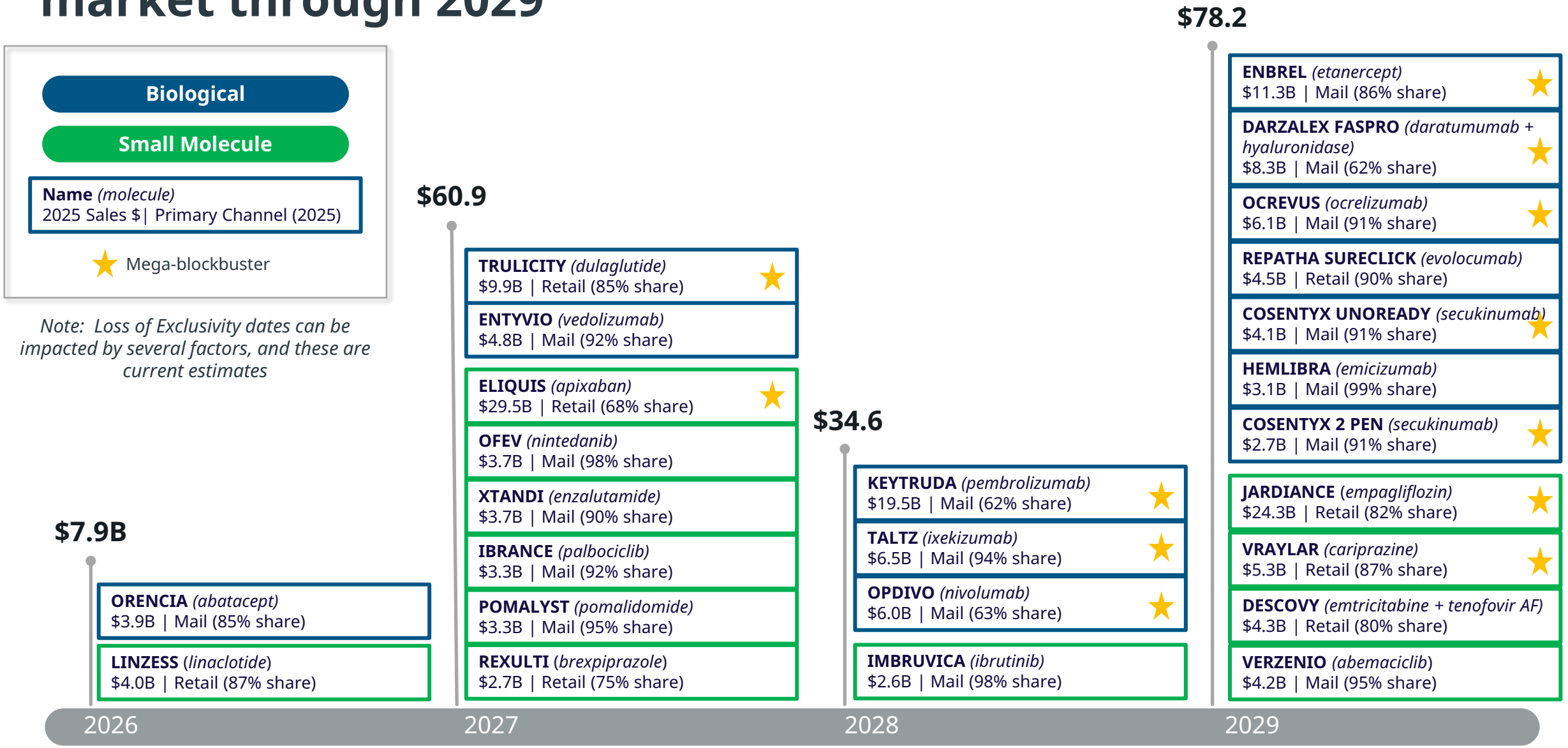
Rare & orphan drugs have made up more **than 50% of Novel Active Substance approvals** since 2020

Over the past decade, there have been **155 NAS launches in oncology with +350 follow-on indications** totaling more than 500

U.S. median annualized treatment cost of **new oncology medicines in 2024 = $411,855**

*Excludes gastrointestinal launches; **Excludes pain centered;
Source: IQVIA Institute, Mar 2026; Citeline Trialtrove; IQVIA Institute, Mar 2026;
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A major wave of exclusivity losses is poised to reshape the market through 2029

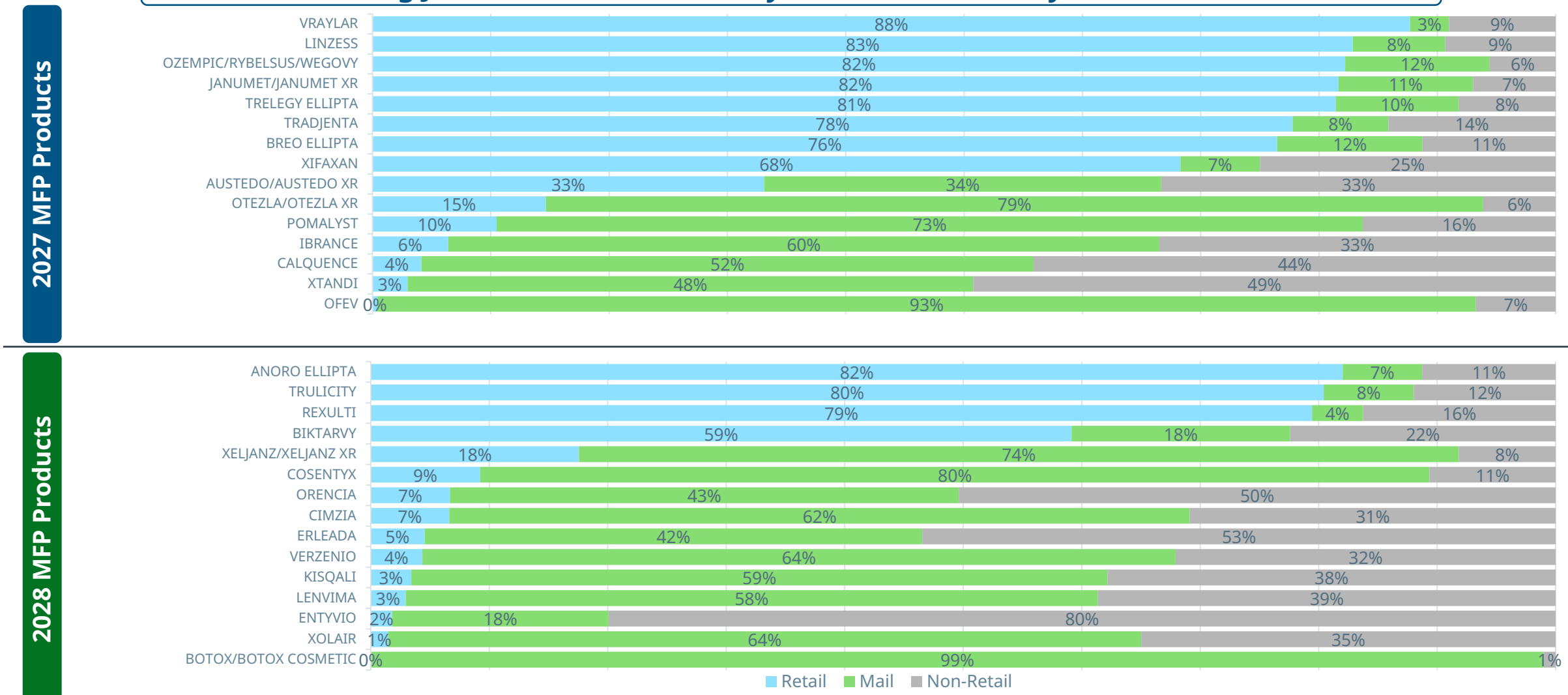


Source: IQVIA U.S. Thought Leadership & Innovation Analysis; National Sales Perspective

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The upcoming MFP products will heavily impact retail in 2027 while the 2028 will shift more toward Mail and Non-Retail

MAT Ending June 2026 Sales – Share by Channel – Sorted by % of Sales in Retail



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Outlook to 2030

1 Spending growth

U.S. medicine spending is forecast to grow 4.5–7.5% through 2030, lifted by novel drugs and offset by expiries and price cuts

2 Policy impact

U.S. policy changes affecting spending and use of medicines are beginning to have clearer impacts

3 Exclusivity losses

Impact rises to $111.7Bn over five years, driven by significant patent expiries beginning in 2028

4 Growth drivers

Oncology and obesity drive growth through 2030, while diabetes, immunology and hematology contribute to slowing

5 Immunology

Spending growth slows to 4–7% through 2030 on biosimilar impact and slowing volume growth

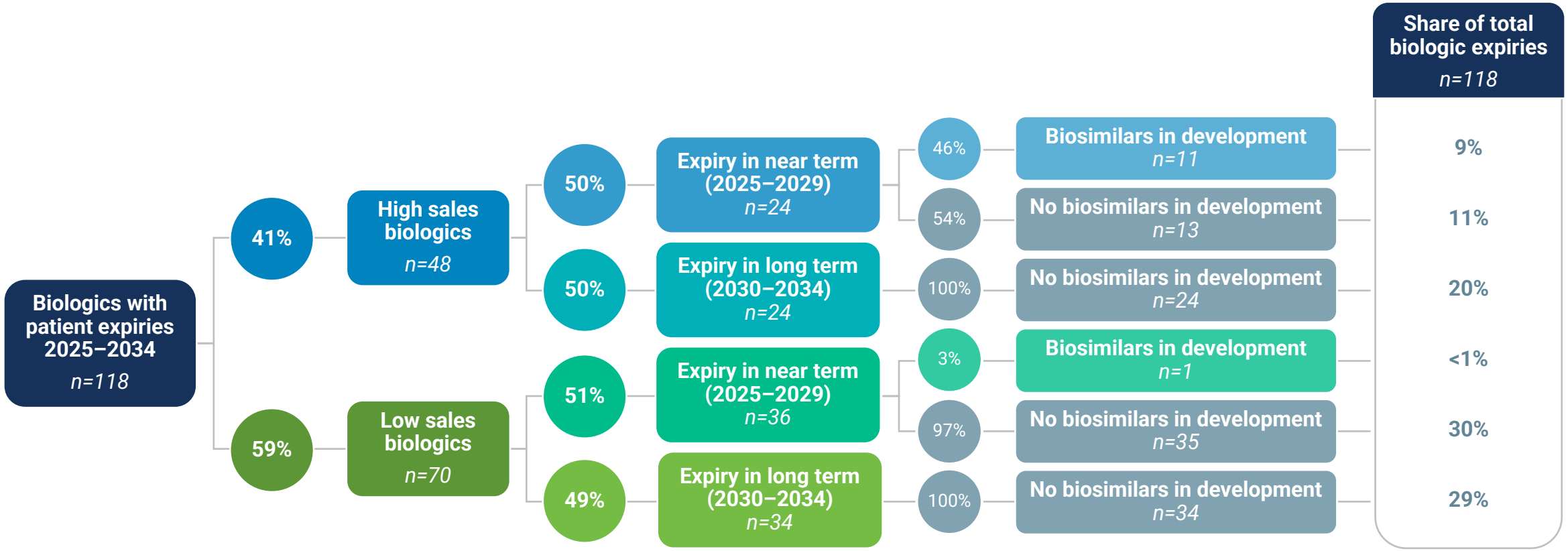
6 Cell and gene therapy

Spending is expected to reach $12.5Bn by 2030, more than double the current level

Source: https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/us-medicine-use-trends-2026

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



Source: Accessing the Biosimilar Void in the U.S.

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IQVIA INSTITUTE FOR HUMAN DATA SCIENCE

Meet the Industry Relations Team 2026



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Director, Supplier Services



David Mennen

Analyst, Supplier Services

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Scott serves as a Director in the Supplier Services Group at IQVIA, a leading global provider of advanced analytics, technology solutions, and clinical research services tailored for the life sciences and healthcare sectors. IQVIA's mission is to enhance patient outcomes by fostering healthcare innovations through its data, technology, and expertise. By integrating big data, advanced analytics, and industry knowledge, IQVIA assists clients in making informed decisions and speeding up the development of groundbreaking treatments.

He initiated his career in the pharmacy field at Rite Aid, where he undertook various roles with escalating responsibilities. Prior to joining IQVIA in 2011, he was employed by other pharmaceutical information firms like Verispan and SDI. Scott holds a BS degree in Accounting from Penn State University and has nearly three decades of experience working with pharmacy data. In his capacity at IQVIA, Scott collaborates with retailers, software vendors, and various data suppliers, helping them gain insights into their market performance through business reviews and market analysis.

Scott resides in Ludington, MI, with his wife and three children. He enjoys woodworking, honing his shooting skills, and volunteering. He actively contributes to his community through service on county boards, involvement with his church, and with the Mason County Sheriff's Office. Additionally, Scott and his wife are dedicated advocates for organizations aimed at combating human trafficking. Scott is also an Army Veteran who served in the U.S. Army Reserves and Pennsylvania Army National Guard.

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