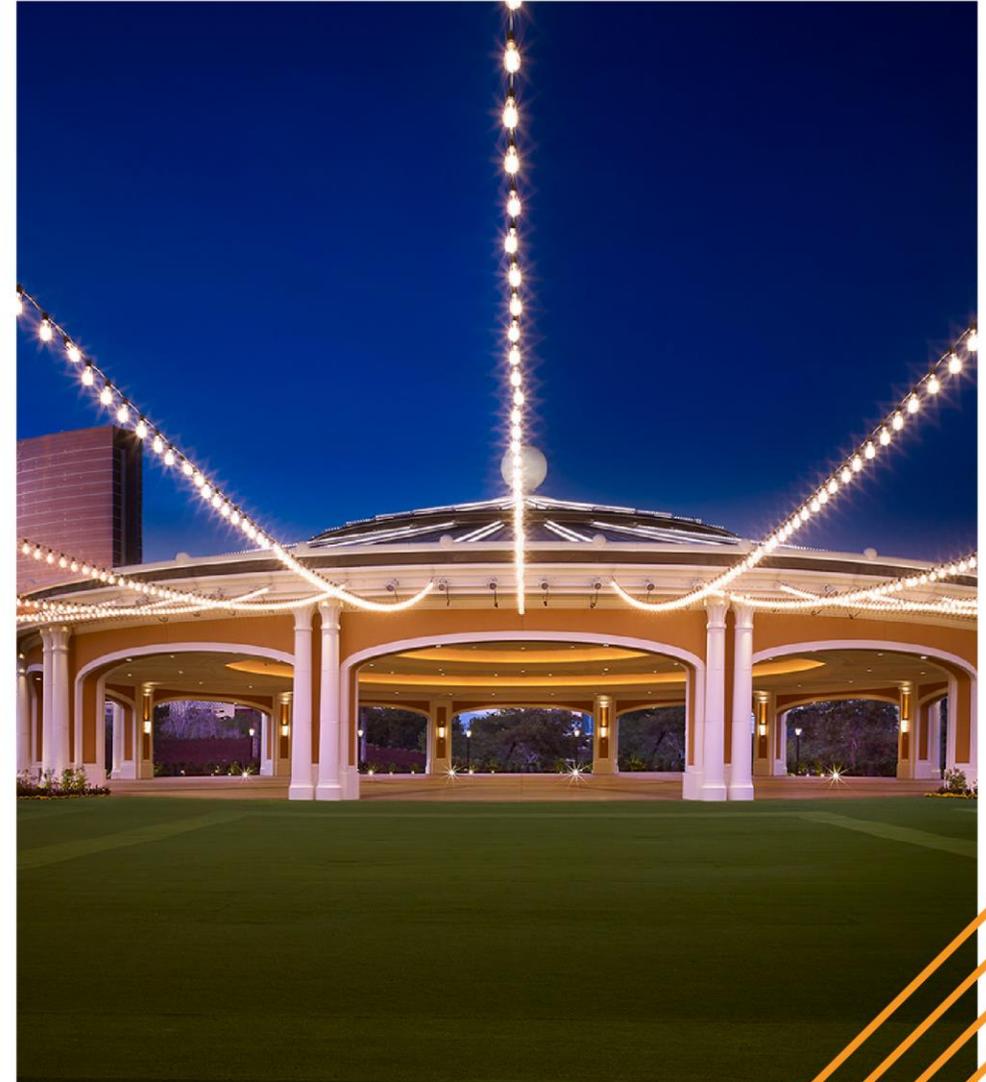


The Post Pandemic Outlook for Specialty Pharmacy

Adam J. Fein, CEO, Drug Channels Institute
Doug Long, VP, Industry Relations, IQVIA

October 27, 2021

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Agenda

- The State of Specialty Pharmacy 2021 — *Adam*
- US Specialty Pharmaceutical Trends, Issues and Outlook for Asembia — *Doug*
- Q&A

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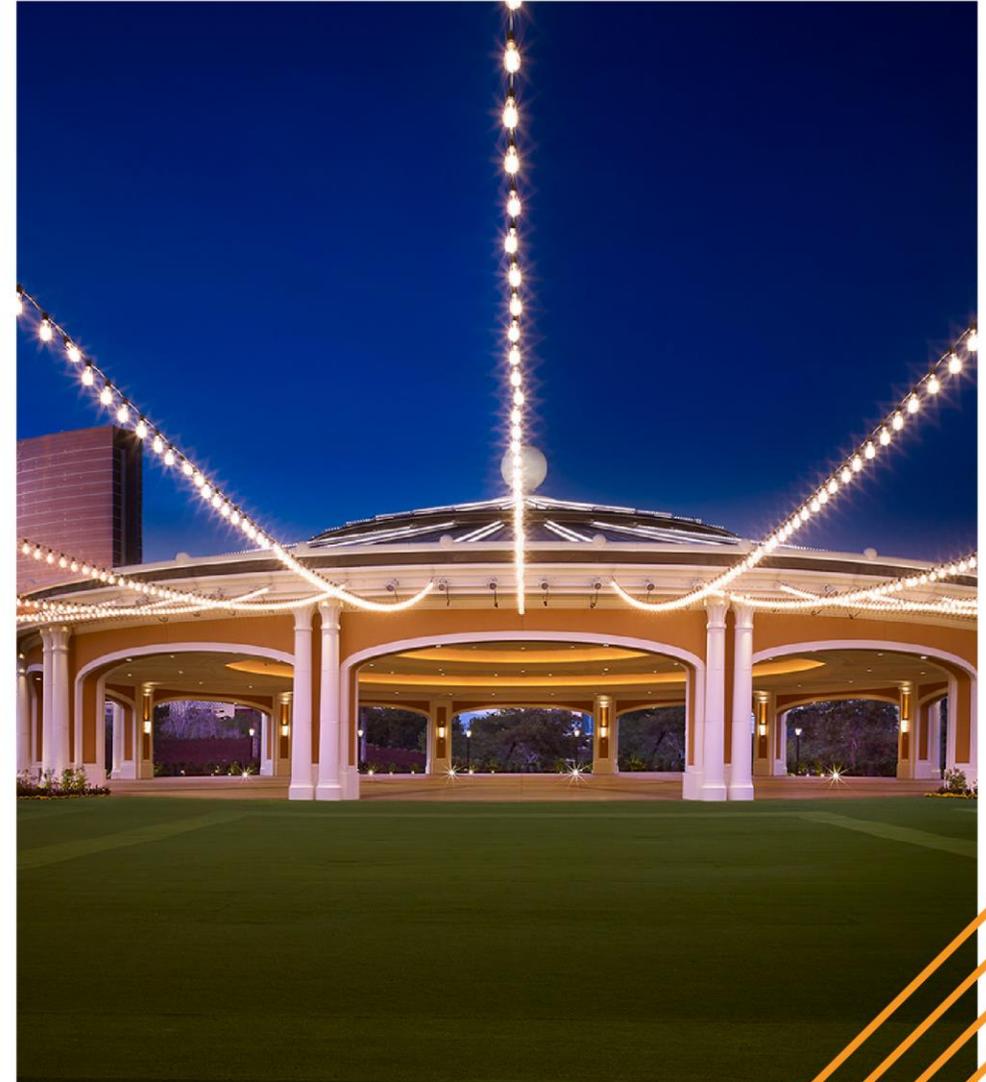
drugch.nl/asembia21

The State of Specialty Pharmacy 2021

Adam J. Fein, CEO, Drug Channels Institute

October 27, 2021

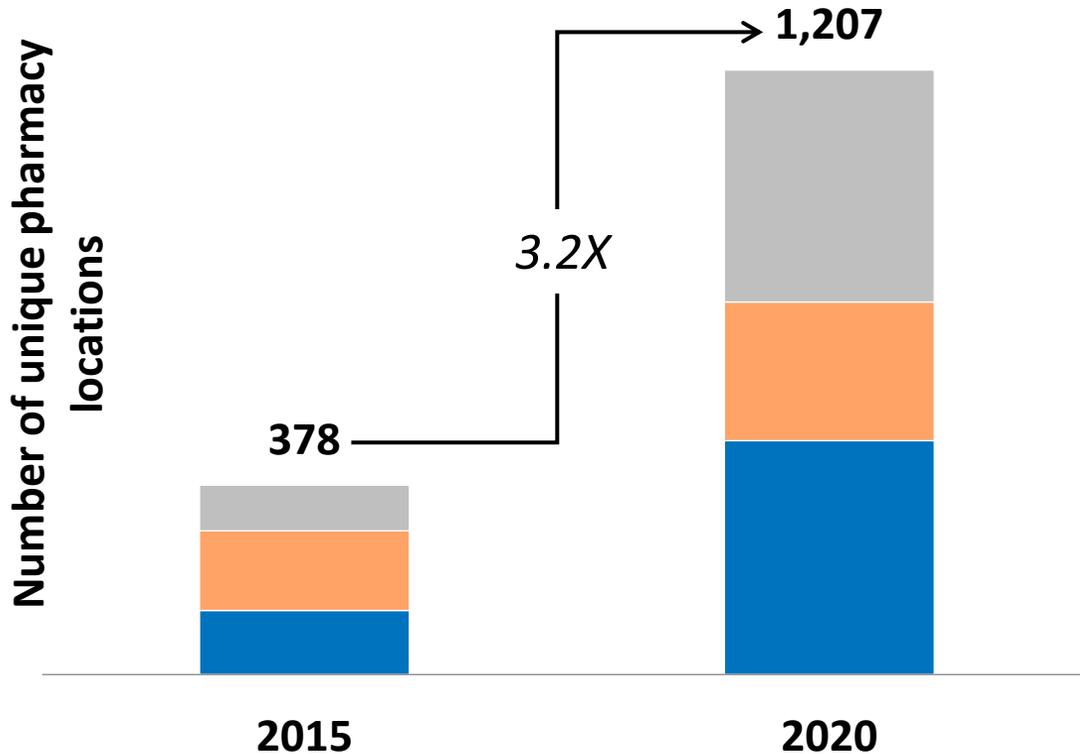
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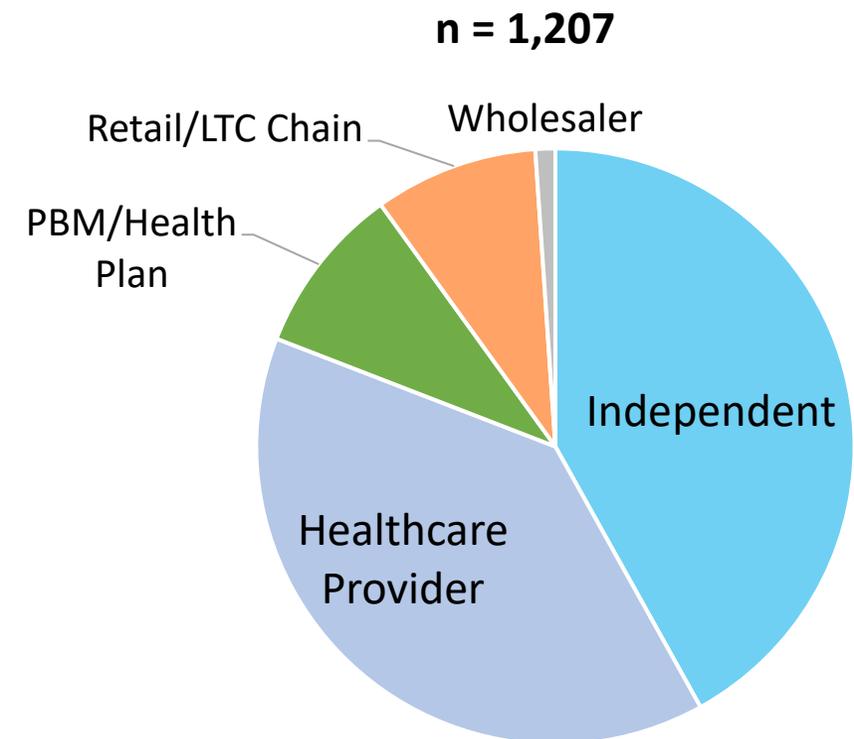
The Specialty Pharmacy Boom

NUMBER OF PHARMACY LOCATIONS WITH SPECIALTY PHARMACY ACCREDITATION, BY ORGANIZATION

■ ACHC only ■ URAC only ■ Both ACHC and URAC



SHARE OF PHARMACY LOCATIONS WITH SPECIALTY PHARMACY ACCREDITATION, BY CORPORATE OWNERSHIP, 2020



ACHC = Accreditation Commission for Health Care; URAC = Utilization Review Accreditation Commission; LTC = Long-term care; PBM = pharmacy benefit manager
 Source: [The 2021 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers](#), Exhibits 50 and 55. Figures show number of unique accredited locations at the end of the year. For comparability, data for ACHC exclude certain accredited pharmacy spoke locations within retail chains. Multiple category includes locations with accreditation from two or three of the accrediting organizations. Figures exclude locations with provisional, conditional, and expected accreditation. Independents include private independent pharmacies, pharmacies owned by private equity firms, and independently owned franchise locations. Healthcare Provider includes pharmacies owned by hospitals, health systems, physician practices, and providers' group purchasing organizations. Retail/LTC Chain includes pharmacy locations owned by chain drugstores, grocery chains, and national long-term care pharmacy chains.

Our Vertical World



1. Cigna partners with providers via its Cigna Collaborative Care program.

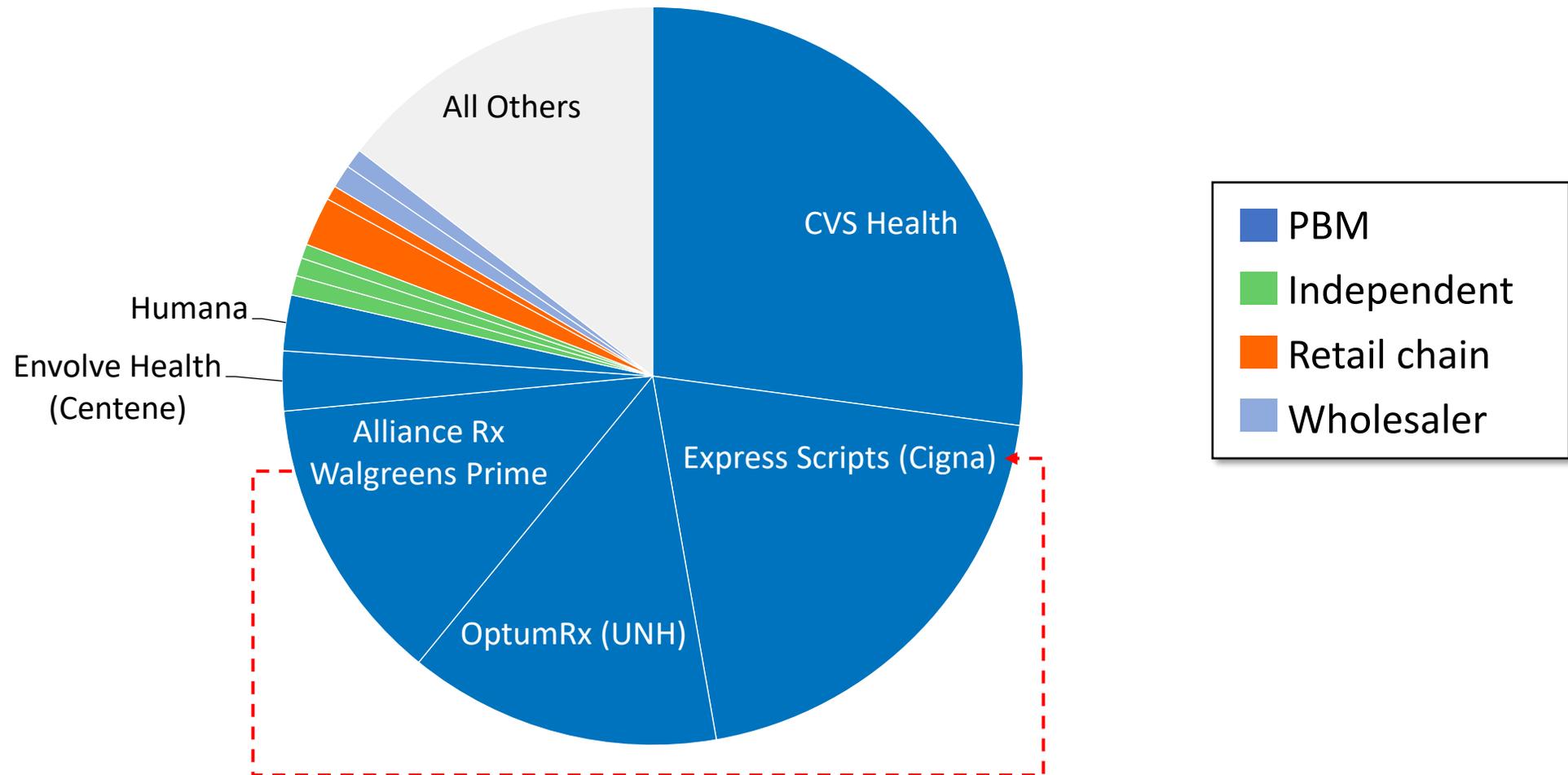
2. AllianceRx Walgreens Prime is jointly owned by Prime Therapeutics and Walgreens Boots Alliance.

3. Since 2020, Prime sources formulary rebates via Ascent Health Services. In 2021, Humana began sourcing formulary rebates via Ascent Health Services for its commercial plans.

Source: [The 2021 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers](#), Exhibit 210. Companies are listed alphabetically by insurer name.

PBMs Extend Specialty Domination

SHARE OF SPECIALTY DRUG DISPENSING REVENUES, BY COMPANY, 2020



Source: [The 2021 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers](#), Exhibit 52. Includes revenues from retail, specialty, and mail pharmacies. Excludes revenues from network pharmacies of PBM-owned specialty pharmacies and infusion services covered by medical benefit. Reflects pro-forma impact of acquisitions.

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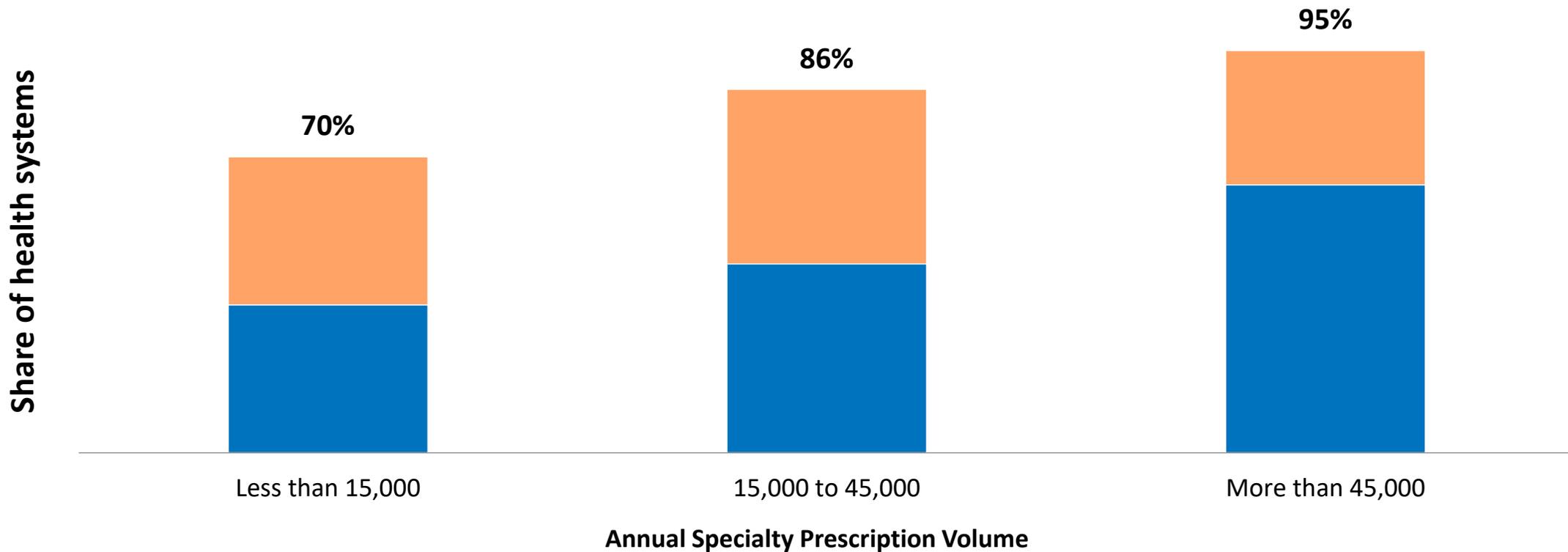
The opinions and views expressed in this presentation are those of the author and do not reflect any opinion, position, or direction of the event sponsor.

Hospitals Battle for Network Access

HEALTH SYSTEMS' REQUIREMENTS FOR EMPLOYEE USE OF INTERNAL SPECIALTY PHARMACIES, 2021

Network status of health system specialty pharmacy:

- One of the preferred specialty pharmacies in plan's network
- Exclusive specialty pharmacy in plan's network

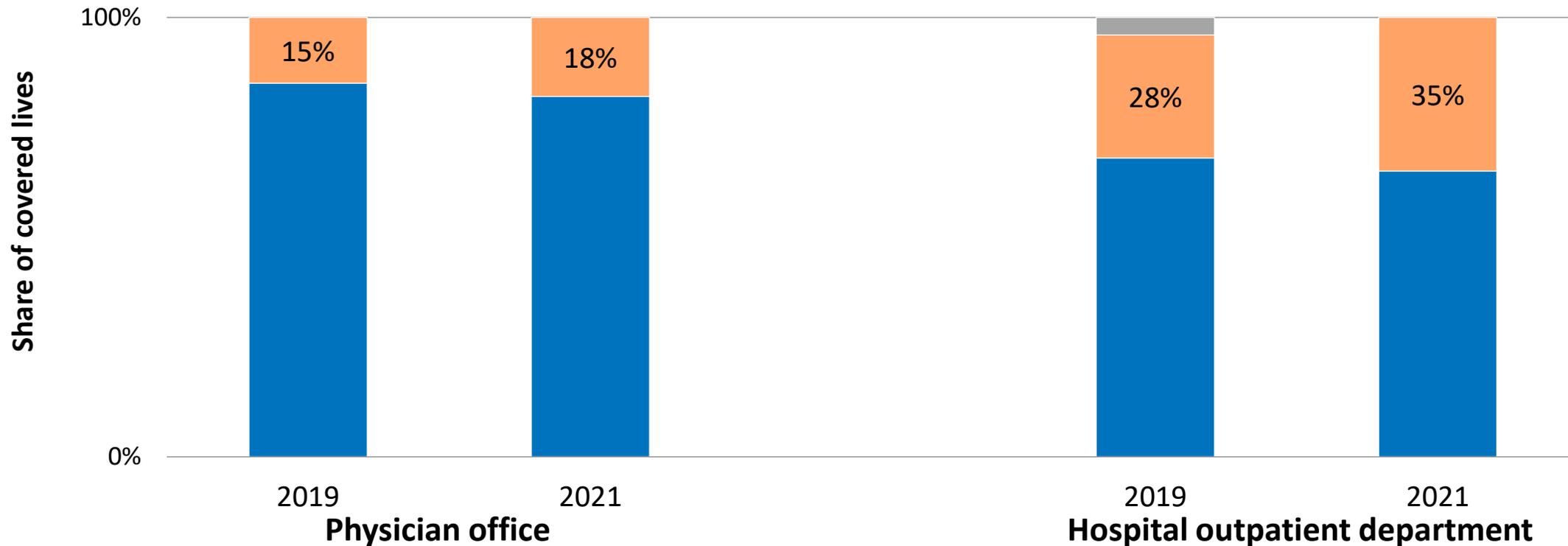


Source: Drug Channels Institute analysis of ASHP National Survey of Health-System Specialty Pharmacy Practice data. See [Fresh Evidence: How Health Systems Steer Prescriptions to Their Own Specialty Pharmacies](#), *Drug Channels*, October 2021.

Disrupting Buy-and-Bill

DRUG SOURCING FOR INFUSED ONCOLOGY THERAPIES, BY PRACTICE TYPE AND SOURCE

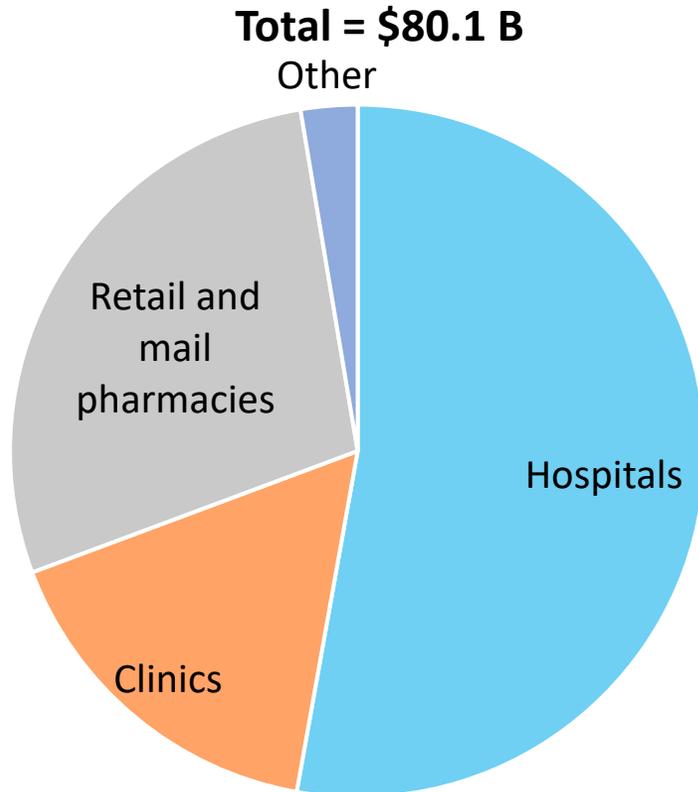
- **Buy-and-bill:** Practice purchases drug from distributor
- **White bagging:** Specialty pharmacy supplies drug to practice
- **Brown bagging:** Specialty pharmacy dispenses drug to patient, who transports it to practice



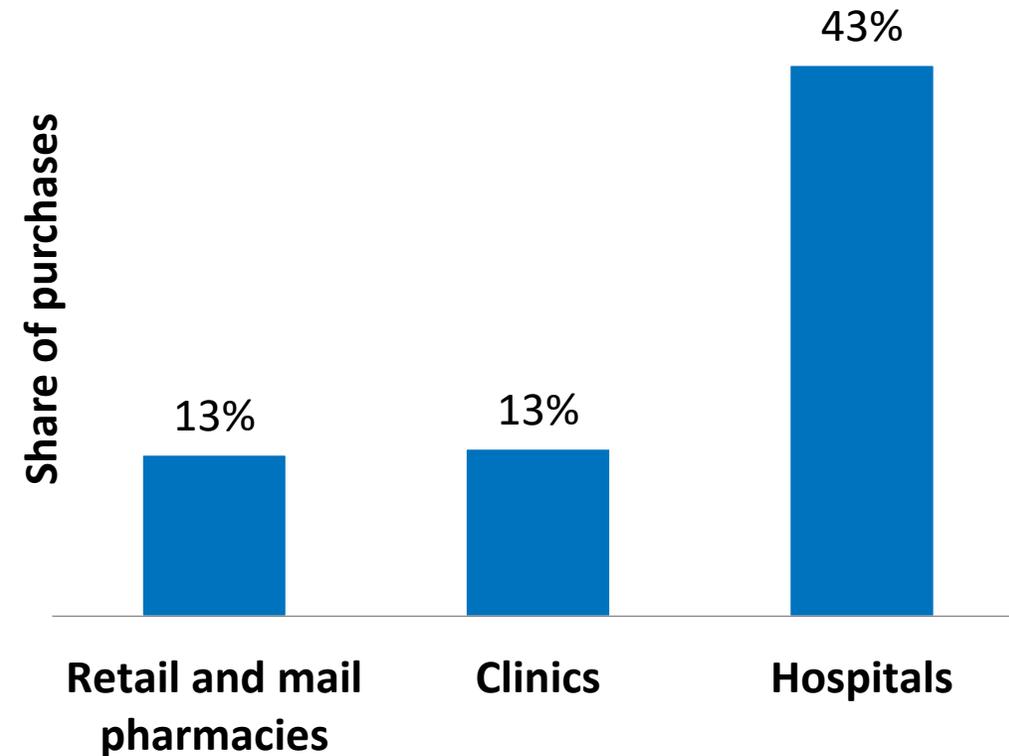
Source: [The 2021-22 Economic Report on Pharmaceutical Wholesalers and Specialty Distributors](#), Exhibit 42. Figures for 2019 based on 48 commercial plans representing 126.6 million covered lives. Figures for 2021 based on 51 commercial plans representing 124.9 million covered lives. See [White Bagging Update: PBMs' Specialty Pharmacies Keep Gaining on Buy-and-Bill Oncology Channels](#), Drug Channels, October 2021.

The 340B Drug Pricing Program

SHARE OF TOTAL 340B PURCHASES AT LIST PRICES, BY ADMINISTERING/DISPENSING CHANNEL, 2020



340B DRUG PRICING PROGRAM, SHARE OF PURCHASES AT LIST PRICES, BY ADMINISTERING/DISPENSING CHANNEL, 2020



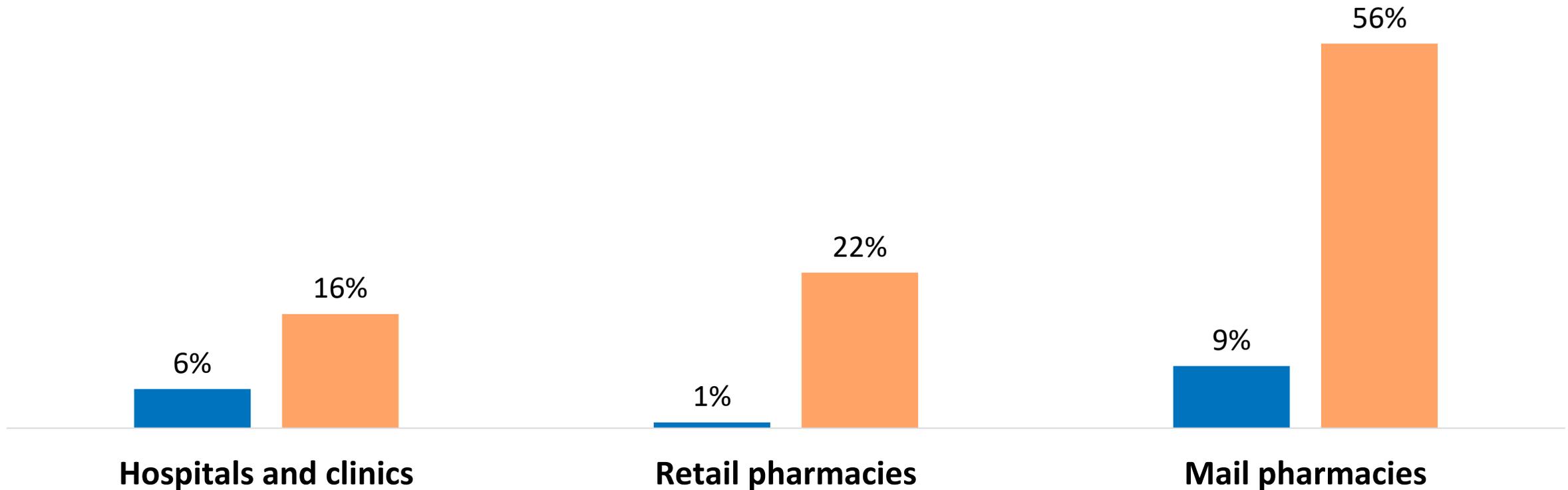
Source: Drug Channels Institute analysis of IQVIA data. See:

- [The 340B Drug Discount Program: Complexity, Challenges, and Change](#), IQVIA, 2020
- [Growth of the 340B Program Accelerates in 2020](#), IQVIA, 2021
- [The 340B Program Soared to \\$38 Billion in 2020—Up 27% vs. 2019](#), *Drug Channels*, 2021
- [Specialty Pharmacy’s Explosive 340B Growth](#), *Drug Channels*, 2021

Specialty Pharmacy: Fastest Growing 340B Channel

AVERAGE ANNUAL GROWTH RATE, 2017 TO 2020

■ Growth in value of non-340B purchases at list prices ■ Growth in value of 340B purchases at list prices



Source: Drug Channels Institute analysis of IQVIA data. See [Specialty Pharmacy's Explosive 340B Growth](#), Drug Channels, July 2021.

Final Thoughts

- Battle for control of the specialty patient continues
- Market access channels getting more organized
= new risks + potential for creative partnerships
- 340B increasingly distorts drug channel economics
- Public policy confusion persists...



Free industry updates from my *Drug Channels* blog: www.DrugChannels.net



Daily tweets about cool and intriguing stuff: twitter.com/DrugChannels



Daily posts about cool and intriguing stuff: www.linkedin.com/in/adamjfein/

The 2021 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers

Adam J. Fein, Ph.D.
Drug Channels Institute

March 2021



The 2021-22 Economic Report on Pharmaceutical Wholesalers and Specialty Distributors

Adam J. Fein, Ph.D.
Drug Channels Institute

October 2021



Adam J. Fein, Ph.D.

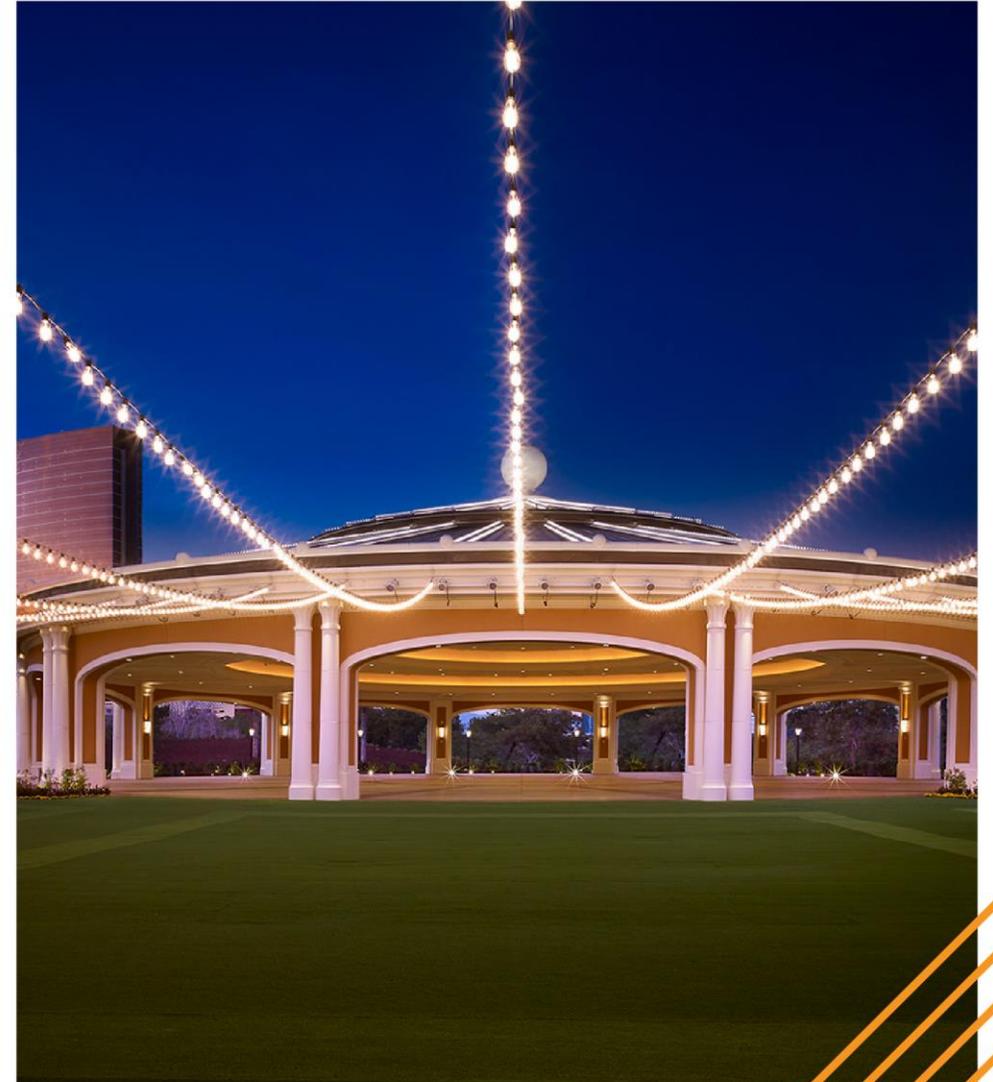
US Specialty Pharmaceutical Trends, Issues and Outlook for Asembia

Doug Long, VP, Industry Relations, IQVIA



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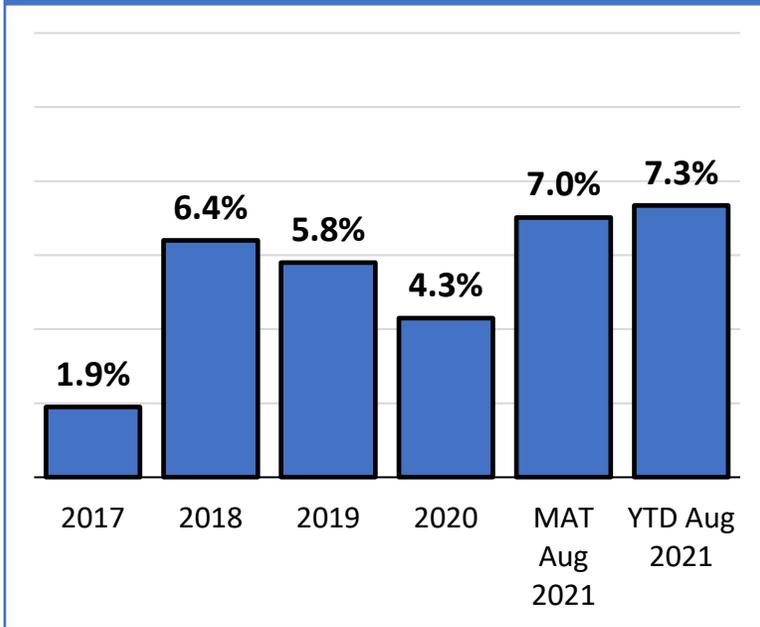


Where Are We Now?

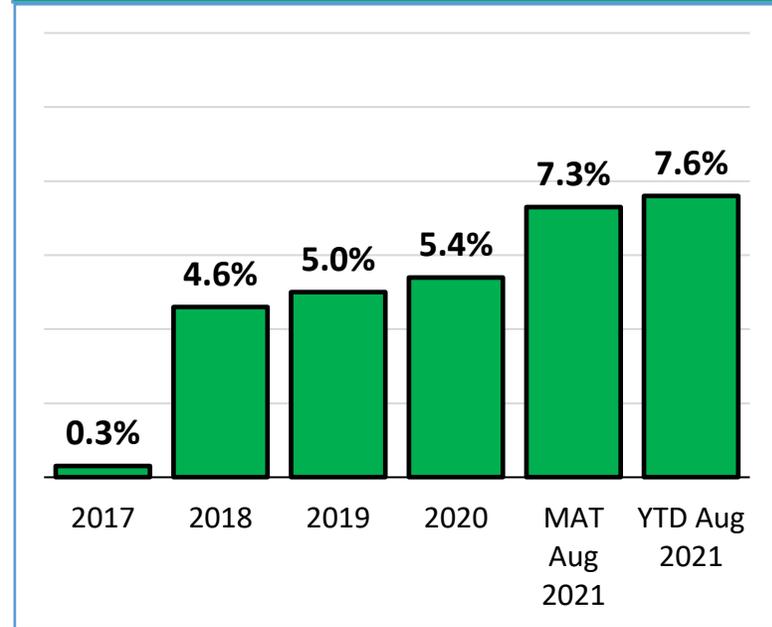
The Non-Retail channel is recovering from effects of COVID-19

Growth (%) of Sales

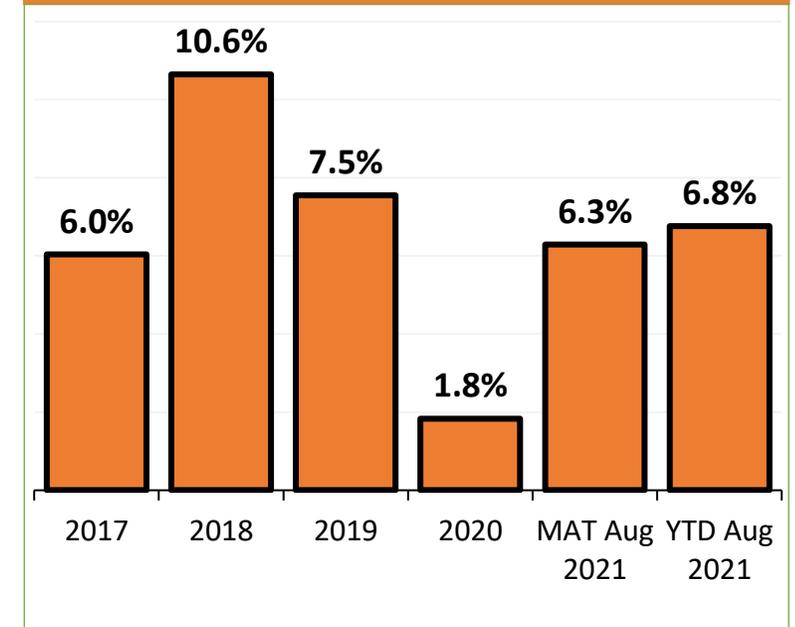
Total Market (Retail, Non-Retail and Mail)



Retail and Mail

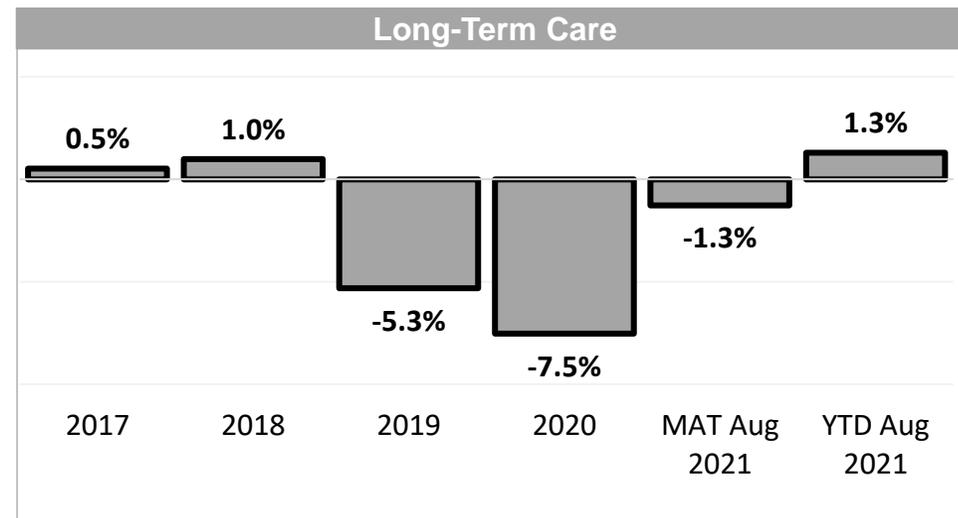
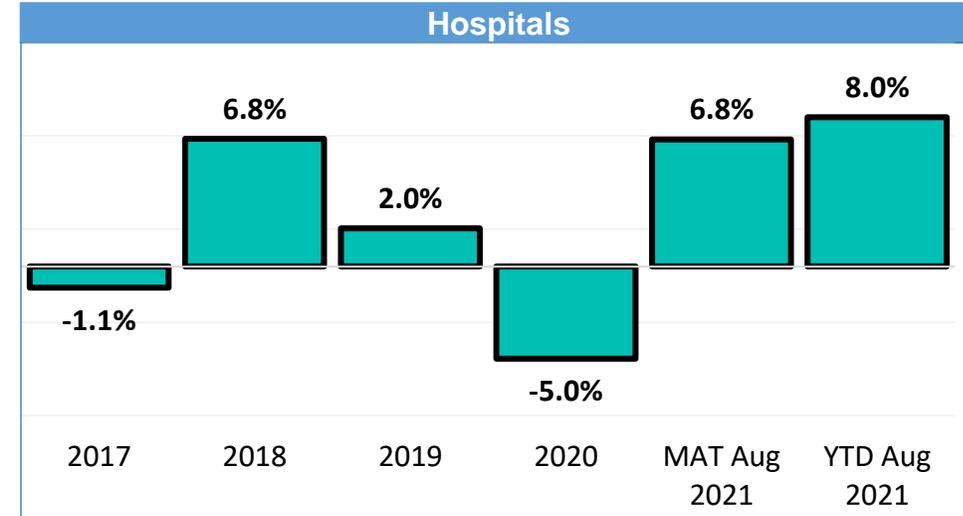
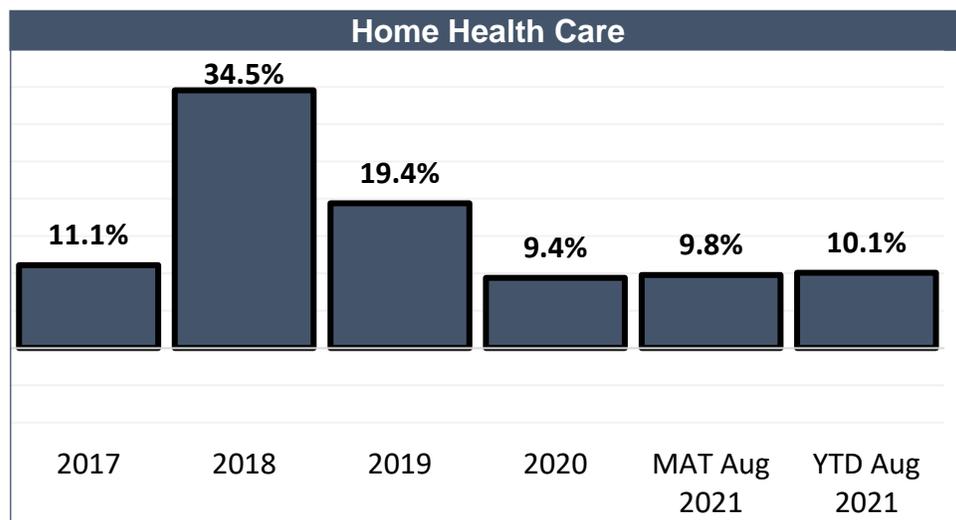
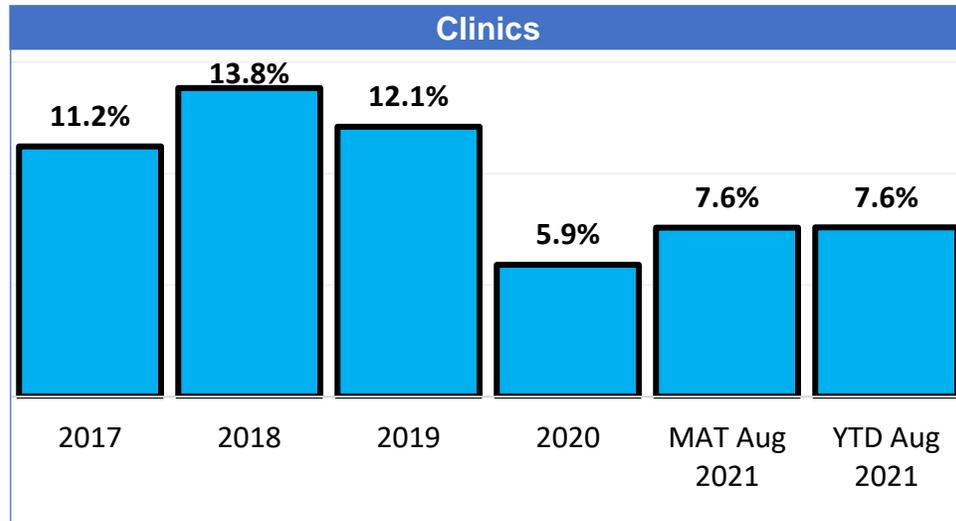


Non-Retail



Hospitals and Long-Term Care have been most affected by COVID-19 while Home Health Care is booming!

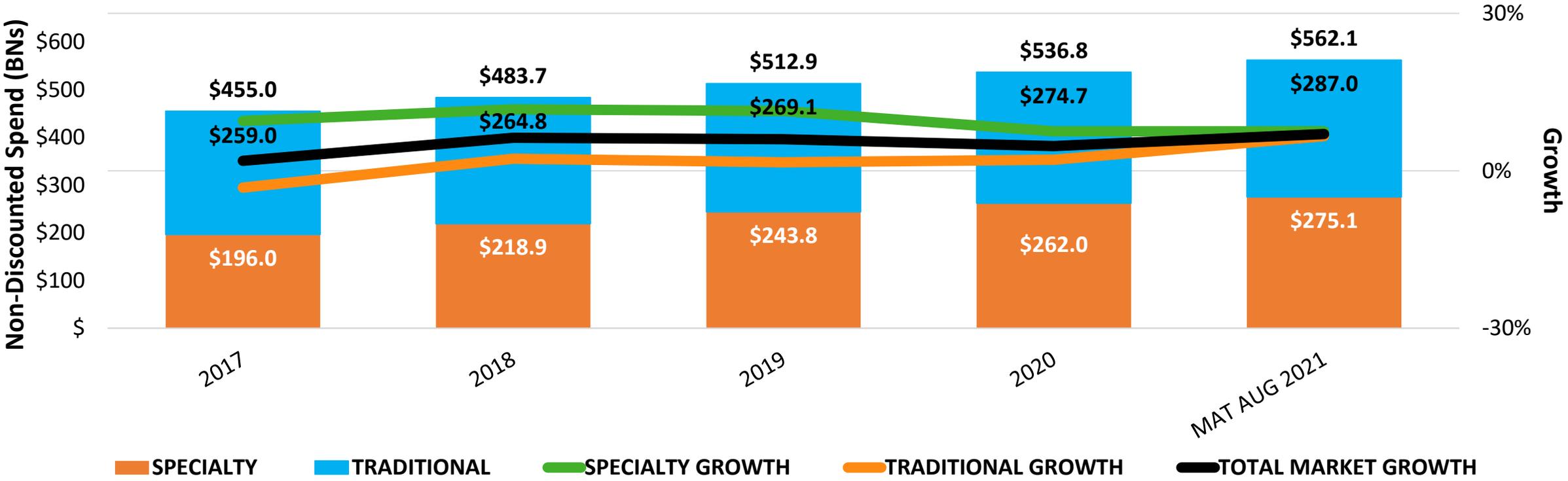
Growth (%) of Sales



Source: IQVIA, National Sales Perspectives, August 2021
 Note: Limited to Rx and OTC Insulins; Includes Retail, Non-Retail and Mail

For the total market, specialty growth is outpacing traditional growth and now has ~49% share of total non-discounted spend

In MAT August 2021, specialty spend grew by 7.5% while traditional growth grew 6.6%



Share of Sales	2017	2018	2019	2020	MAT AUG 2021
SPECIALTY	43.1%	45.3%	47.5%	48.8%	48.9%
TRADITIONAL	56.9%	54.7%	52.5%	51.2%	51.1%

Source: IQVIA, National Sales Perspectives, August 2021

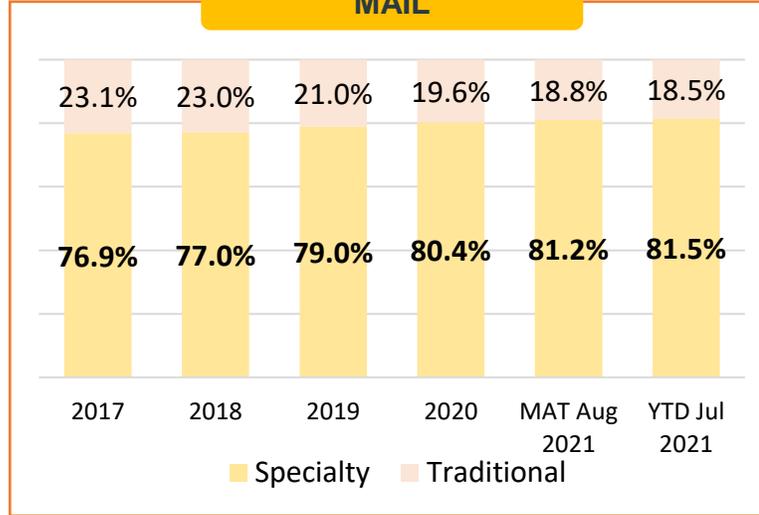
Based on sales dollars, Specialty is increasing at Mail and Non-Retail while slowing at Retail

% OF SALES \$

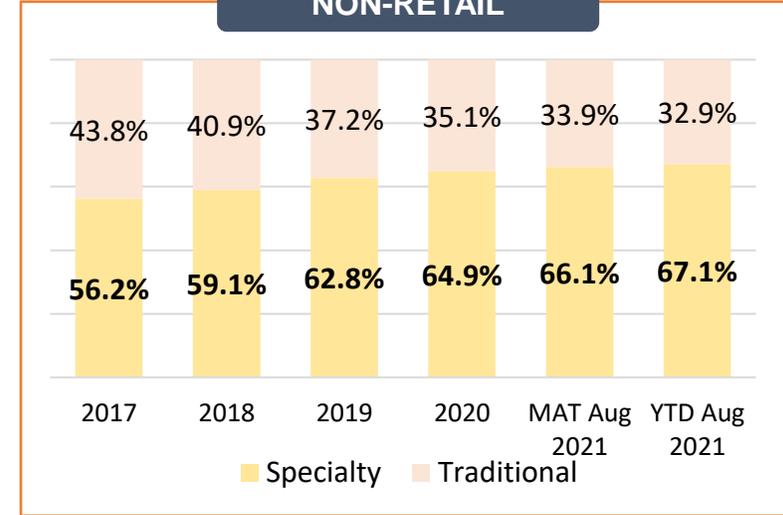
RETAIL



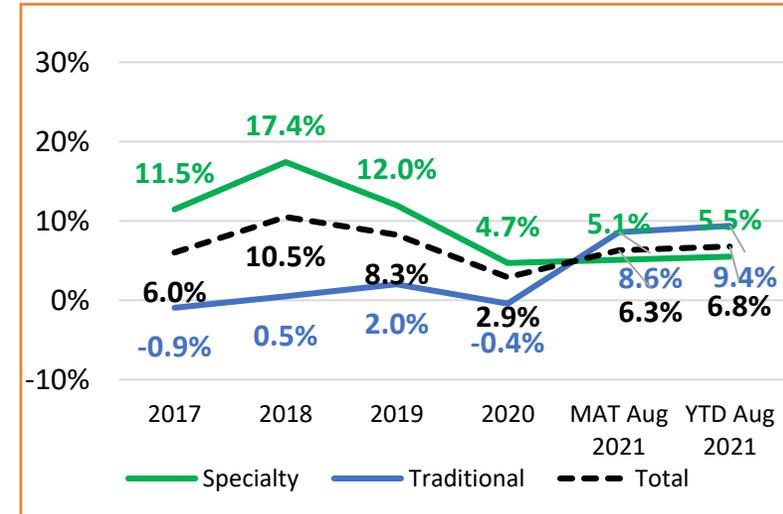
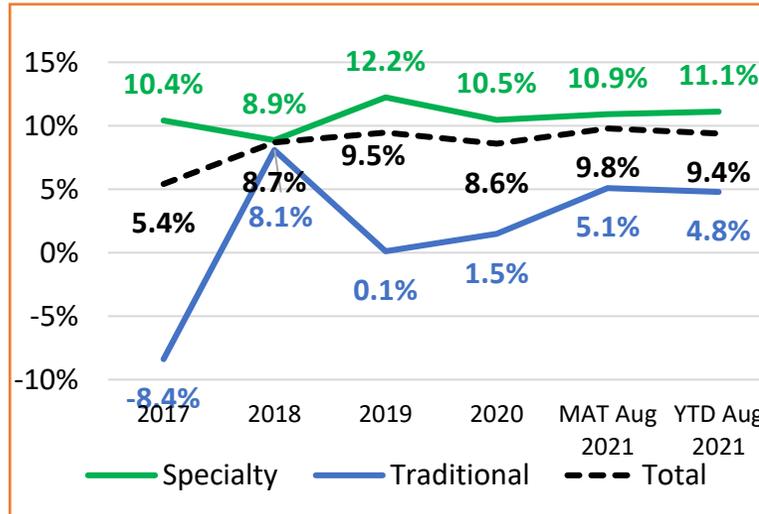
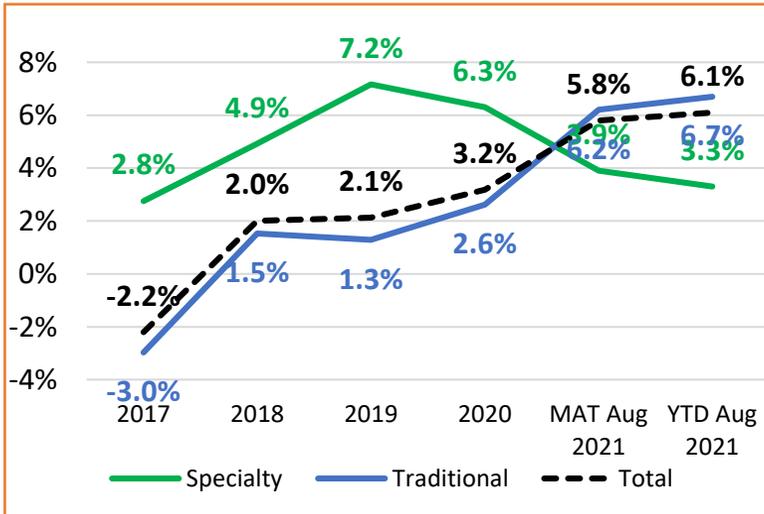
MAIL



NON-RETAIL



YOY SALES \$ GROWTH



Data is based on Rx and OTC Insulins only

Immunology showed greatest Specialty growth on spend in Mail

Top 10 Specialty Therapies for Retail, Mail, and Non-Retail - MAT June 2021 (in \$ billions)

RETAIL			MAIL			NON-RETAIL		
Therapy	MAT June 2021	YoY Growth	Therapy	MAT June 2021	YoY Growth	Therapy	MAT June 2021	YoY Growth
HIV ANTIVIRALS	16.4	1.5%	IMMUNOLOGY	61.0	20.3%	ONCOLOGICS	52.8	7.0%
IMMUNOLOGY	7.7	9.5%	ONCOLOGICS	20.2	9.1%	IMMUNOLOGY	15.6	9.9%
ONCOLOGICS	2.3	-3.0%	MULTIPLE SCLEROSIS	11.3	-10.2%	MULTIPLE SCLEROSIS	5.2	4.0%
MENTAL HEALTH	2.2	6.6%	HIV ANTIVIRALS	5.1	-0.6%	POLYVAL IMMUNOGLOBULINS IV&IM	4.6	5.6%
ANTI-INFLAMMATORY AND DIGESTIVE ENZYMES AND MODULA	2.0	11.3%	ALL OTHER RESPIRATORY	3.8	21.6%	HIV ANTIVIRALS	4.5	2.0%
VIRAL HEPATITIS	1.2	-16.3%	OTHER CARDIOVASCULARS	2.3	13.1%	HEMATOPOIETIC GROWTH FACTORS	3.8	-11.6%
LIPID REGULATORS	1.0	35.9%	GROWTH HORMONES	2.2	0.2%	ERYTHROPOIETINS	2.7	-9.6%
MULTIPLE SCLEROSIS	0.7	-10.5%	RESPIRATORY AGENTS	2.2	13.4%	MENTAL HEALTH	2.1	9.3%
SEX HORMONES (ANDROGENS, OESTROGENS, PROGESTOGENS)	0.6	21.3%	VIRAL HEPATITIS	2.1	-20.9%	OCULAR ANTINEOVASCULARISATION	1.9	-9.5%
IMMUNOSUPPRESSANTS	0.5	-6.3%	BLOOD COAGULATION	1.9	0.5%	RESPIRATORY AGENTS	1.9	14.2%

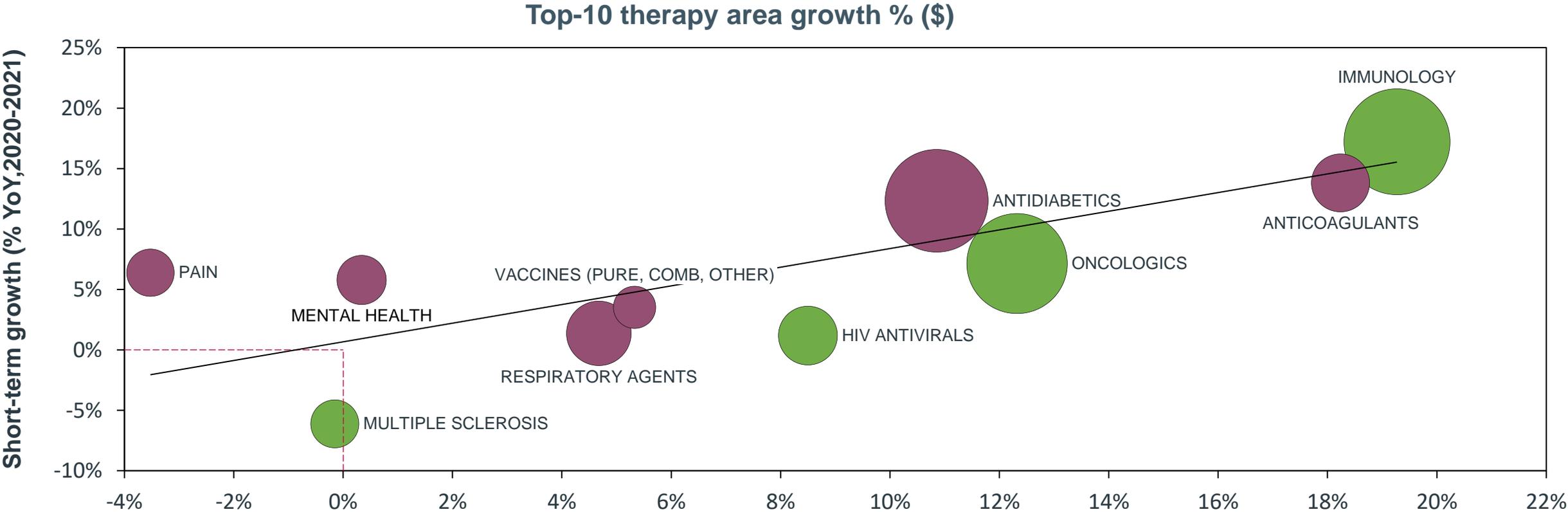
Source: IQVIA, National Sales Perspectives, June 2021

Limited to Rx and OTC Insulins

*For Client's internal use only

All therapies demonstrate short-term growth except MS; Immunology and Anticoagulants show the greatest one- and five-year growth

Slowing growth was occurring prior to COVID-19, and is not the sole contributor

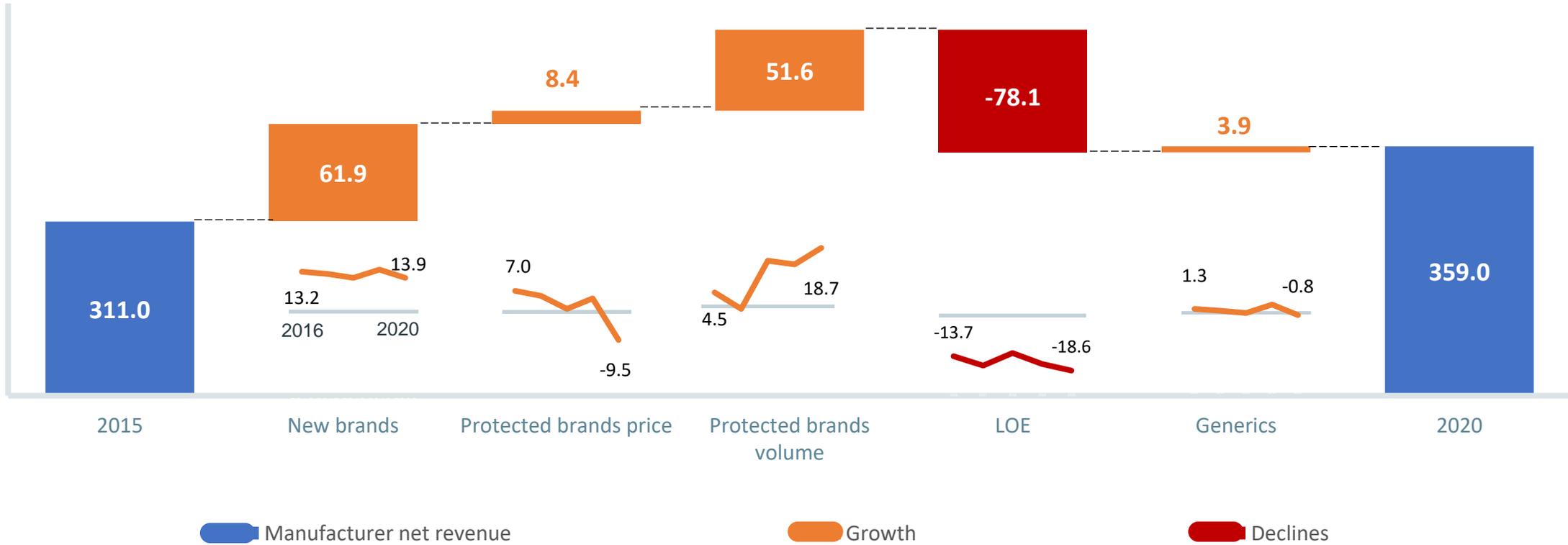


IQVIA National Sales Perspectives, June 2021, Rx's and OTC Insulins Only

● Specialty
 ● Traditional
 Jun 2021 MAT sales, Bn

Manufacturer net revenues increased by \$48 billion over the past five years primarily driven by new products and protected brand volume

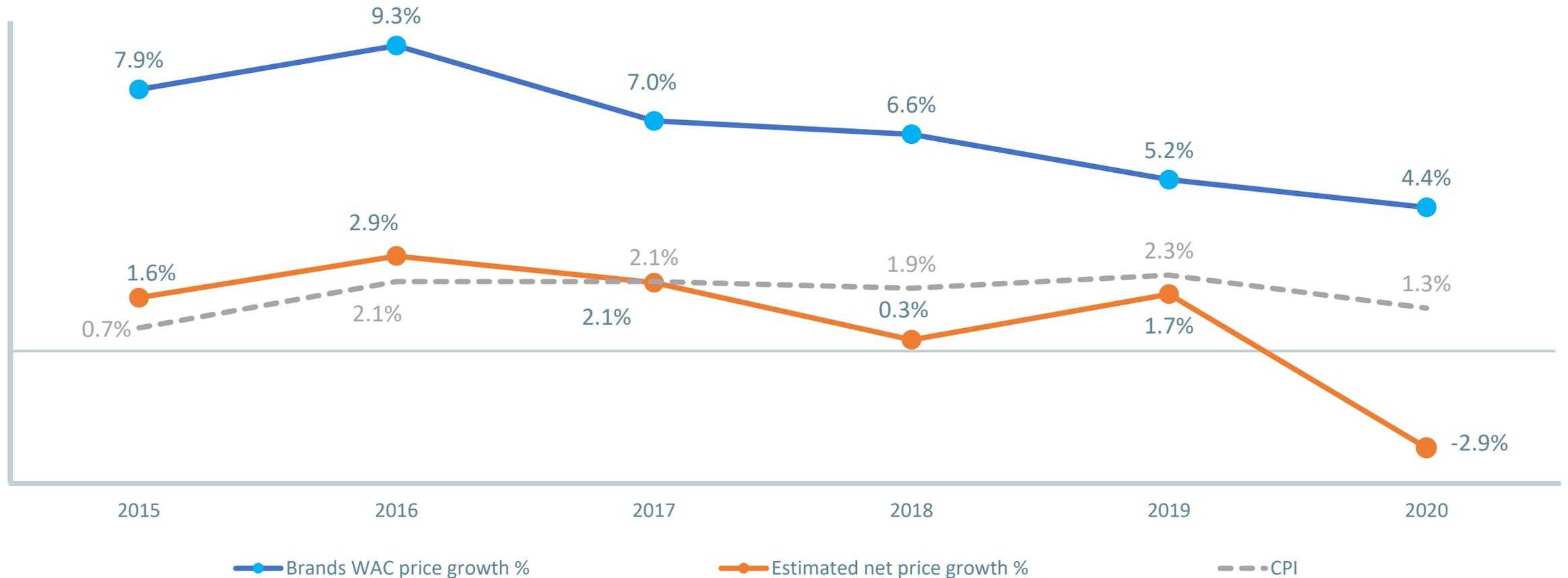
Net Manufacturer Revenues and Growth 2015–2020, All Channels, US\$Bn



Source: IQVIA Institute, May 2021

Protected brand list prices increased 4.4% in 2020, while net prices decreased -2.9% - the fourth year at or below the CPI

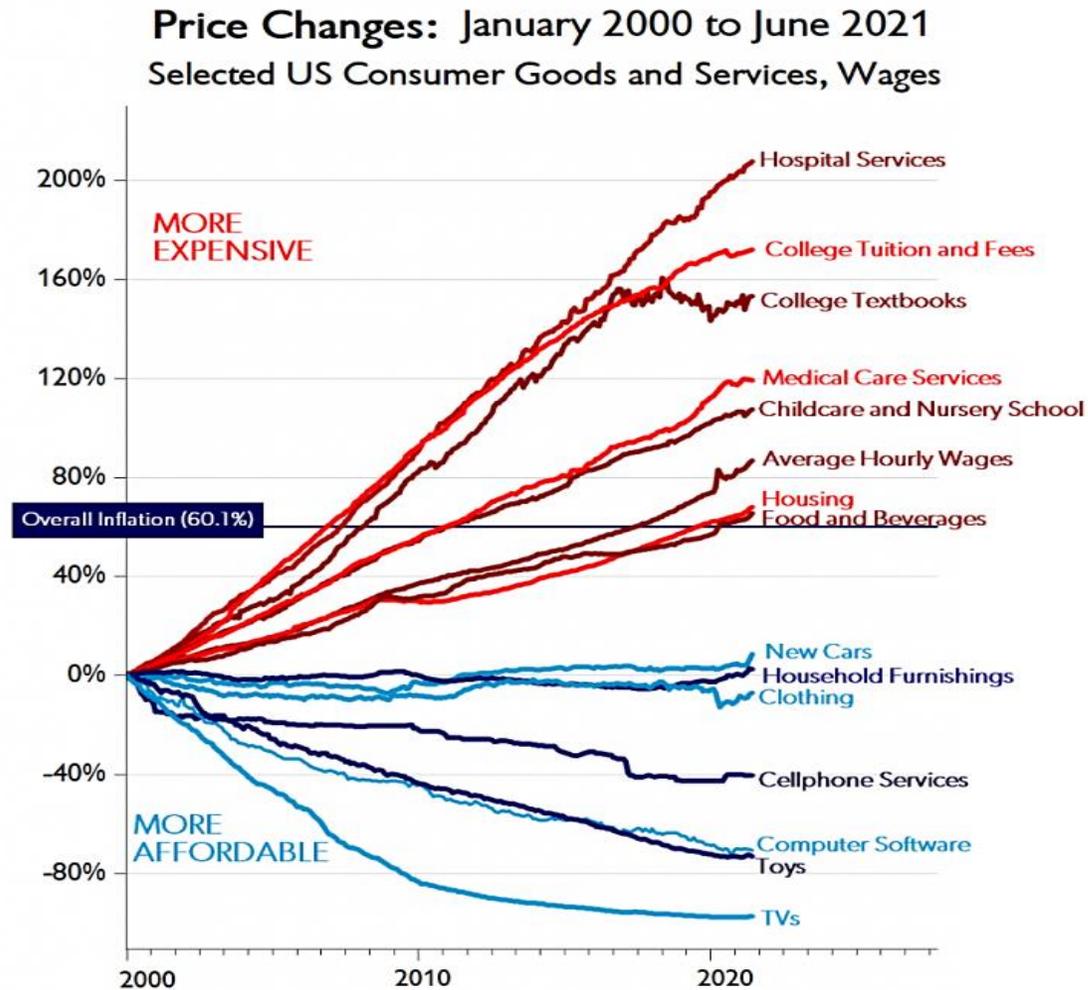
Wholesaler Acquisition Cost (WAC) Growth and Net Price Growth for Protected Brands



Source: IQVIA Institute, National Sales Perspectives, Dec 2020; Bureau of Labor Statistics, CPI Data, Dec 2015–Dec 2020

Much more expensive: Hospital Services and College Tuition and Fees

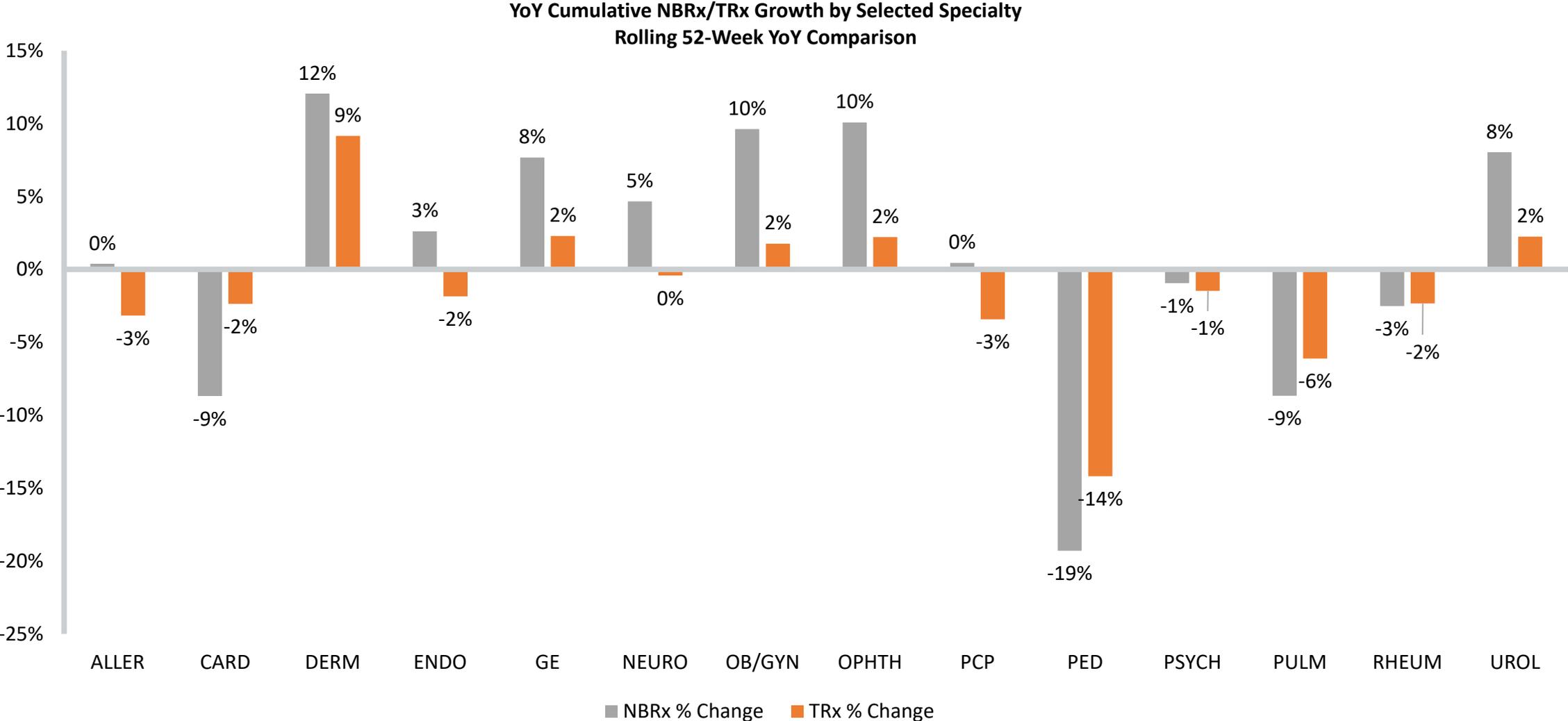
More affordable: TVs and Computers



Source: Bureau of Labor Statistics

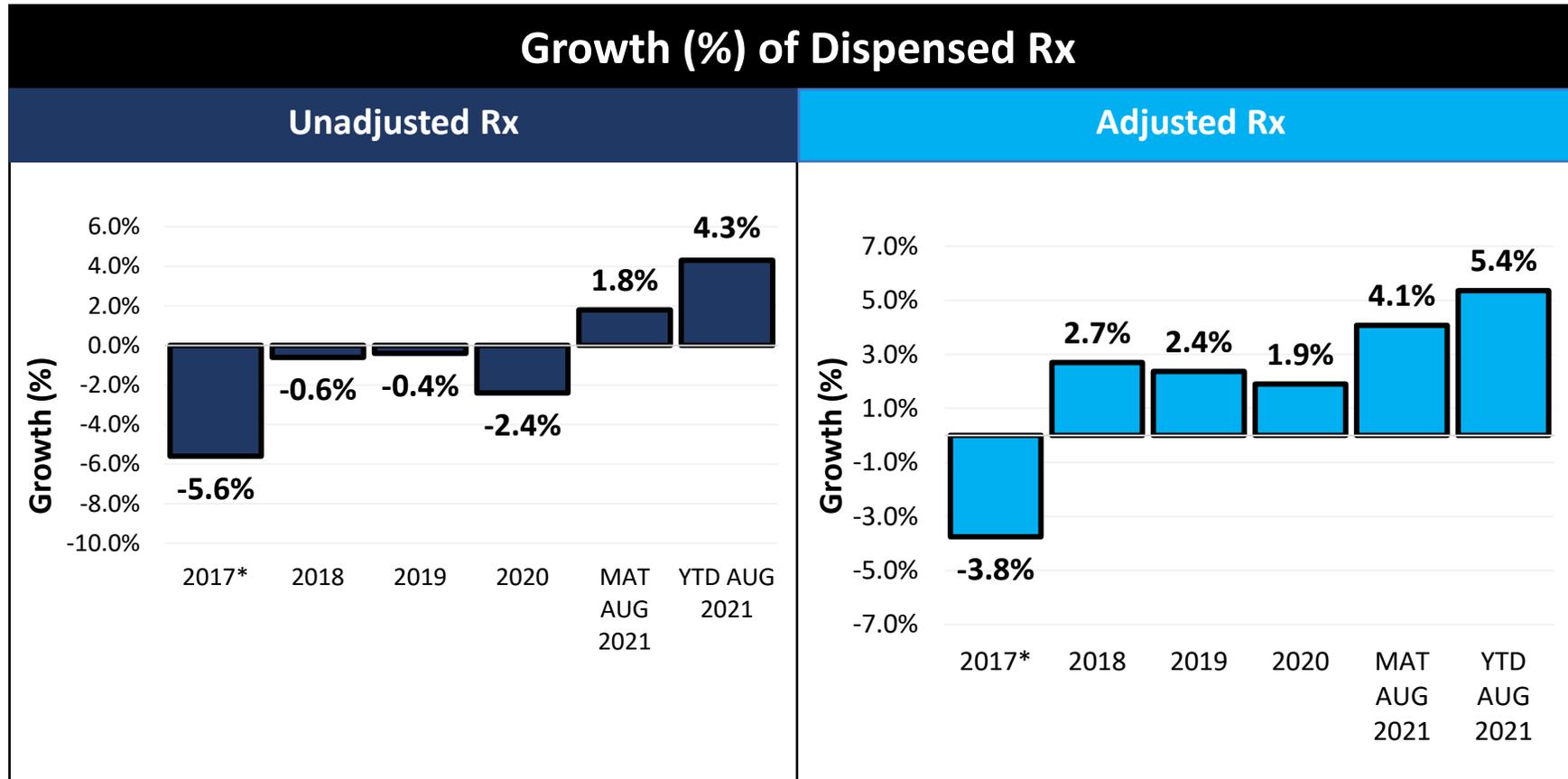
Carpe Diem **AEI**

Many specialties – especially Derm – show NBRx and TRx recovery over the past 52 weeks; pediatric volumes are slowly recovering from COVID lows

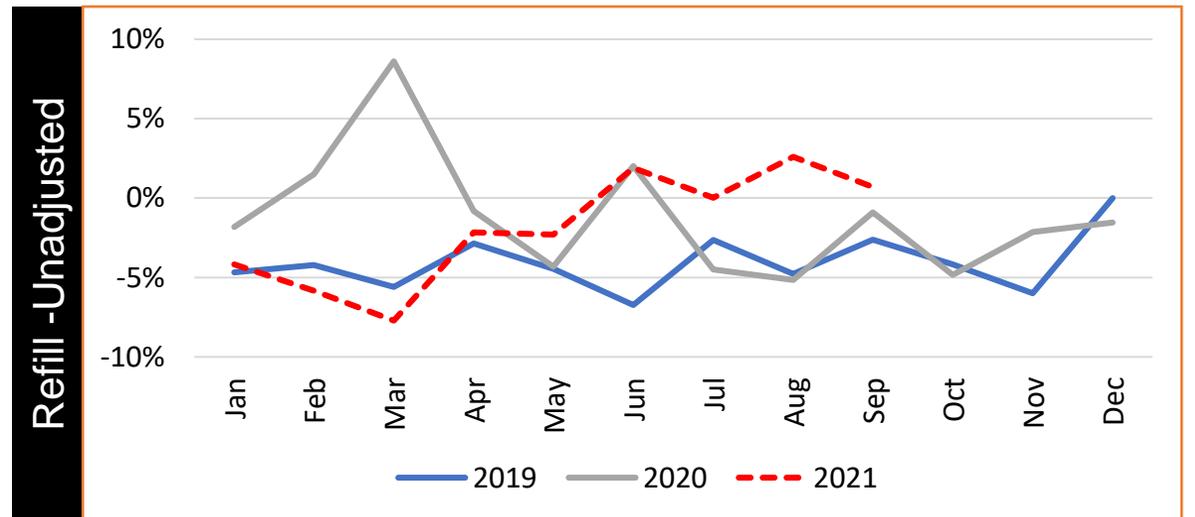
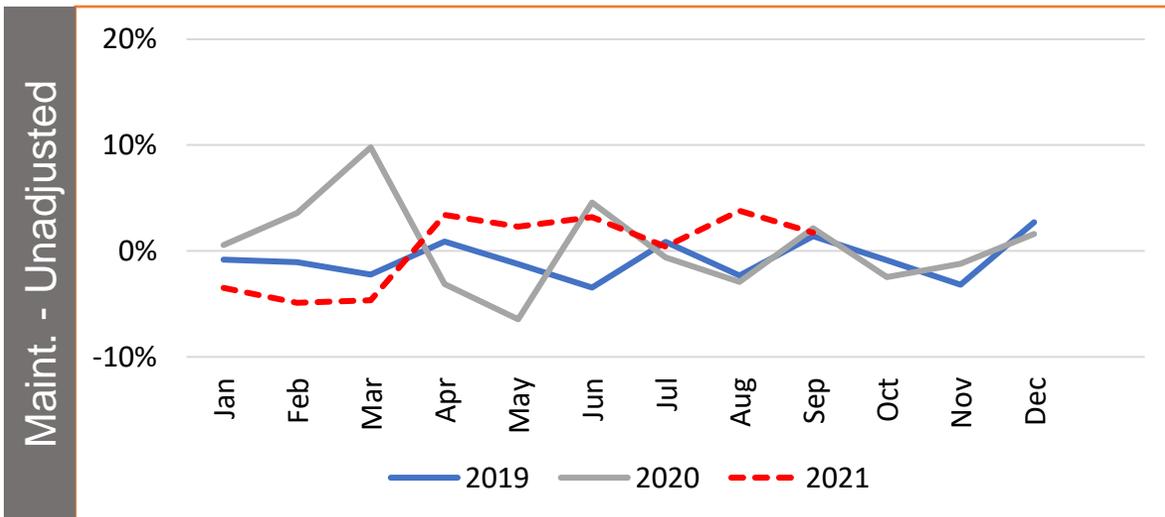
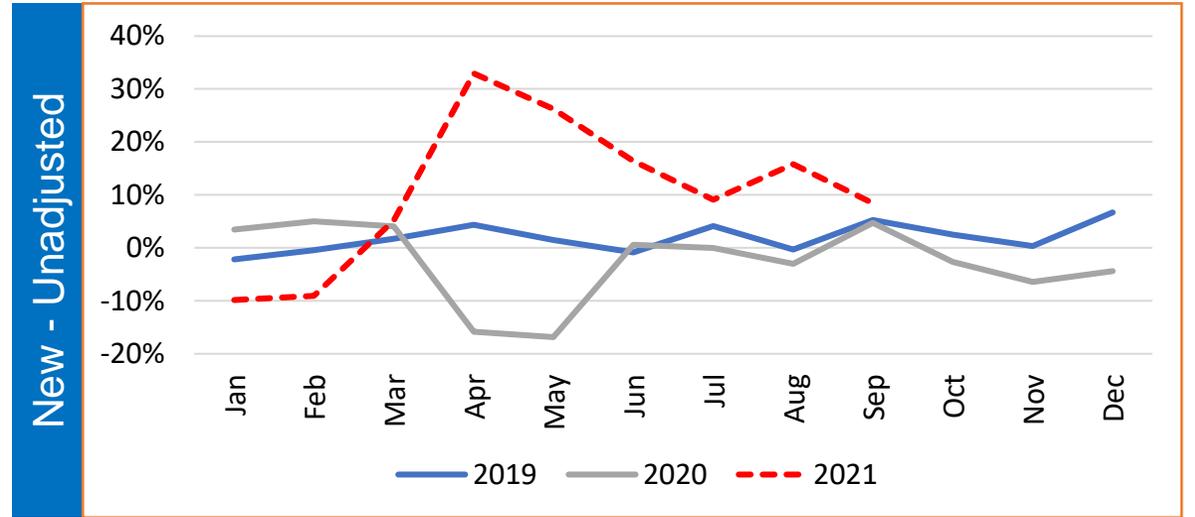
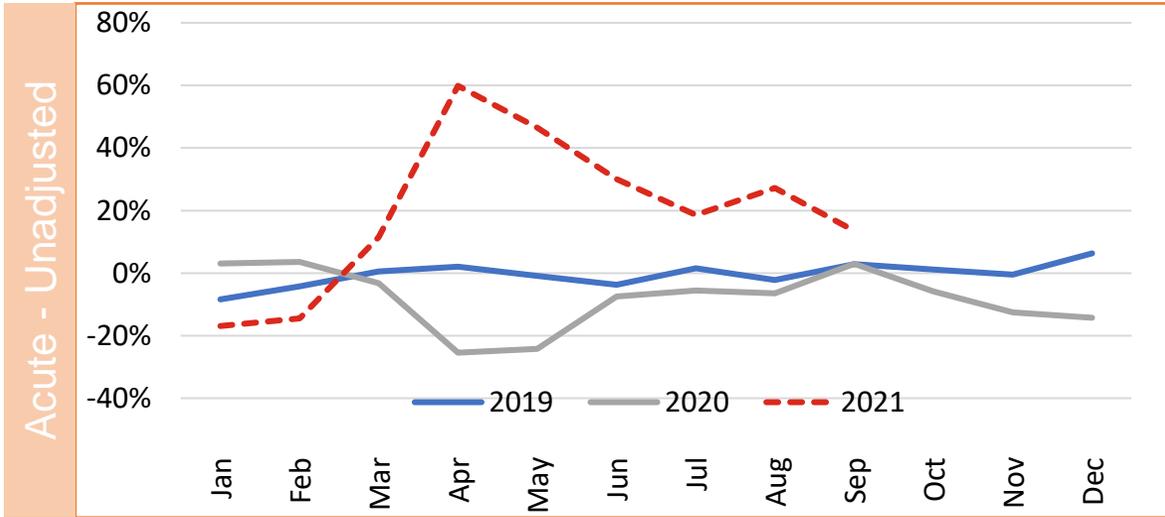


Source: IQVIA: National Prescription Audit (NPA), National Prescription Audit: New to Brand (NPA NTB); Time aligned weeks W/E 10/2/20 – 9/24/21

Unadjusted Rx growth for MAT and YTD August is positive, but Adjusted growth is higher, at 4.1% for MAT August and 5.4% year to date



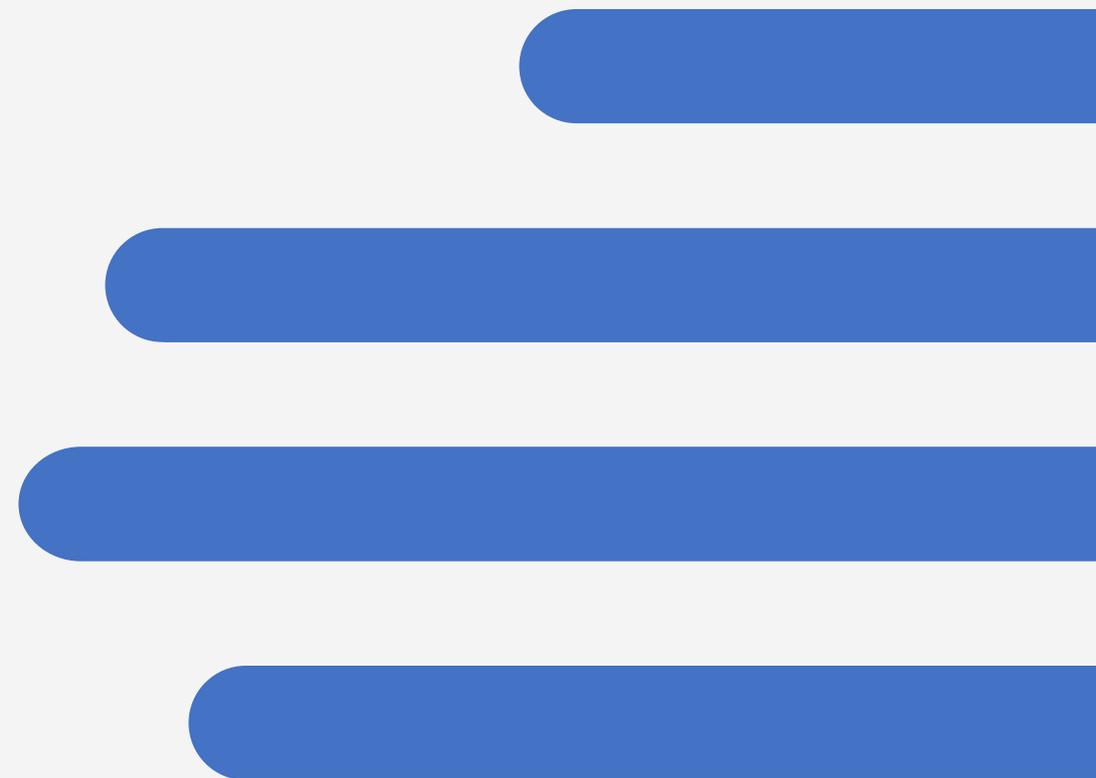
Acute and New growth slow over last three months; driven by COVID vaccines



All Rx's shown in Millions

Total Retail & Mail - Acute & Maint., New/Refill - Unadjusted Rx's

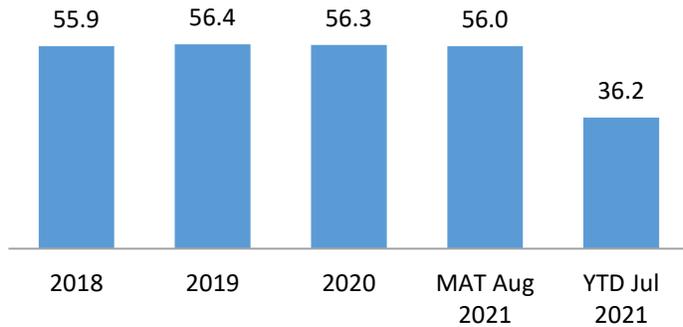
Generics & Biosimilars



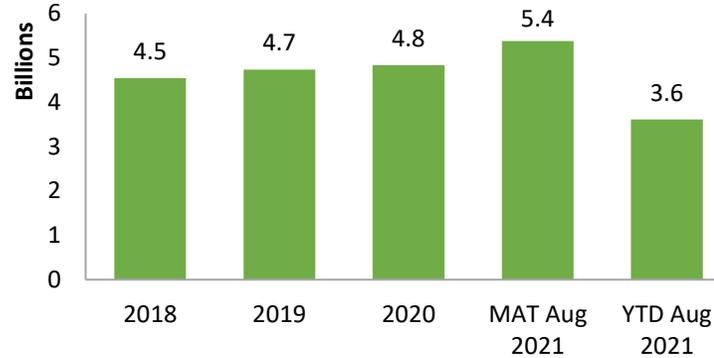
Unbranded generics show negative sales growth and unadjusted volumes

Unbranded Generics

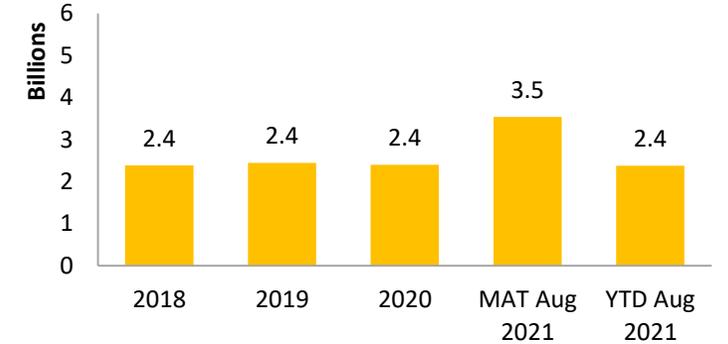
Sales



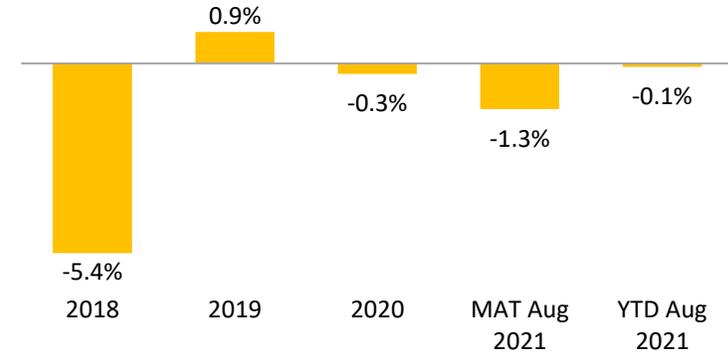
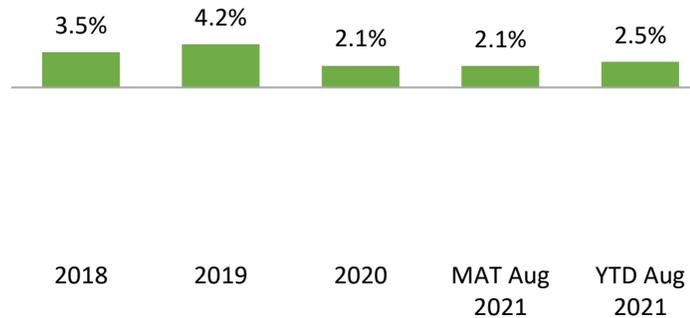
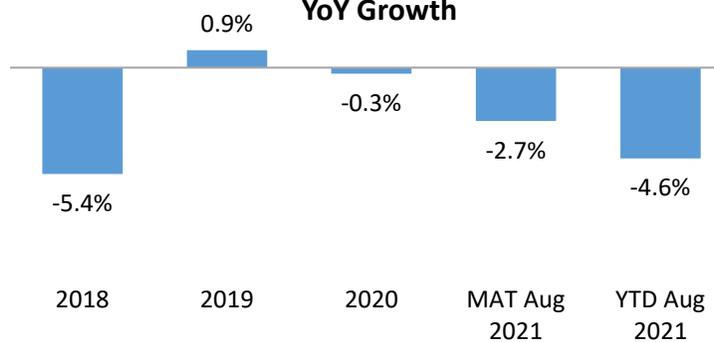
Adjusted Rx's



Unadjusted Rx's



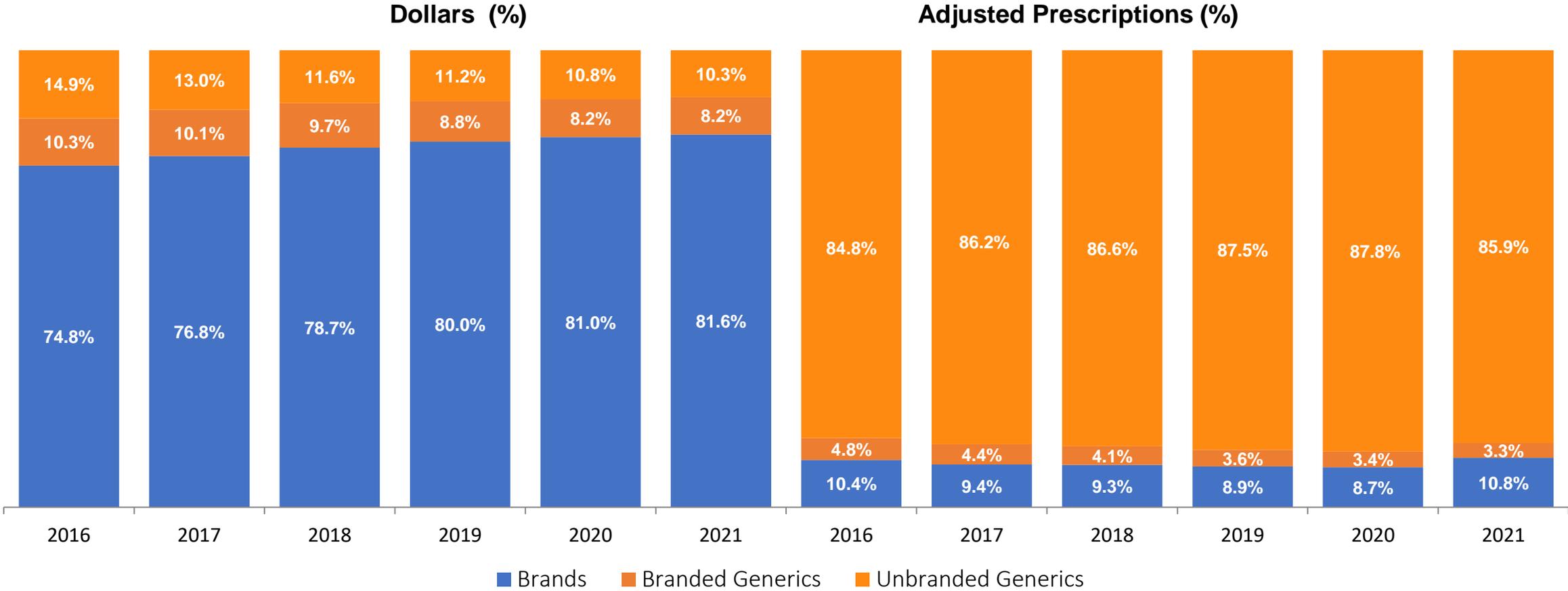
YoY Growth



Source: IQVIA, National Sales Perspectives and RxInsights, September 2021
 Note: Limited to Rx and OTC Insulins; Includes Retail, Non-Retail and Mail

85.9% of prescriptions are dispensed as unbranded generics for 2021 (adjusted)

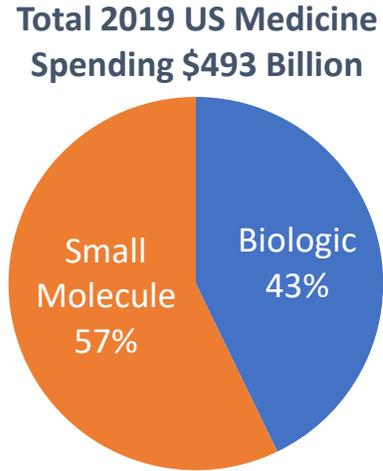
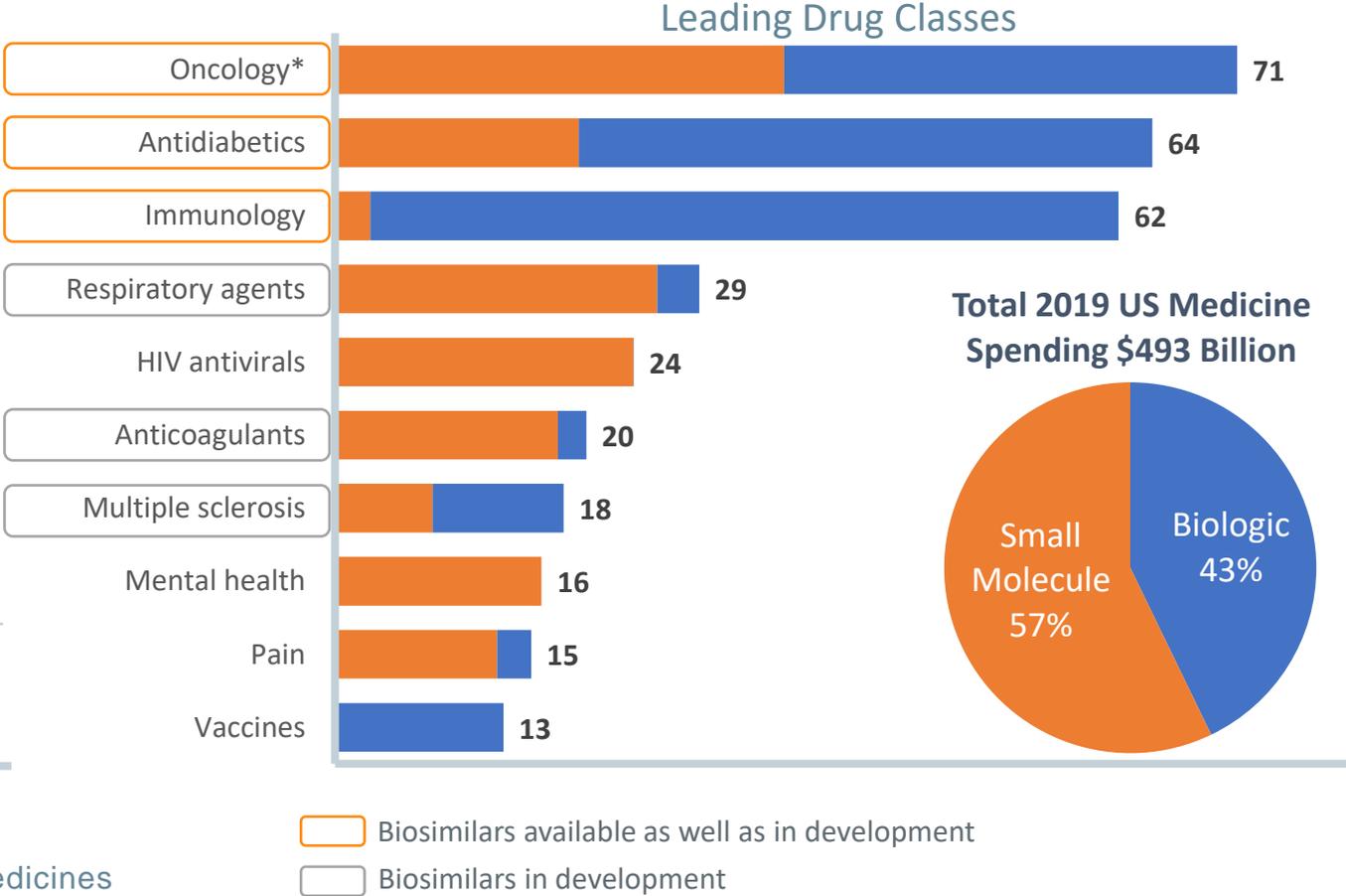
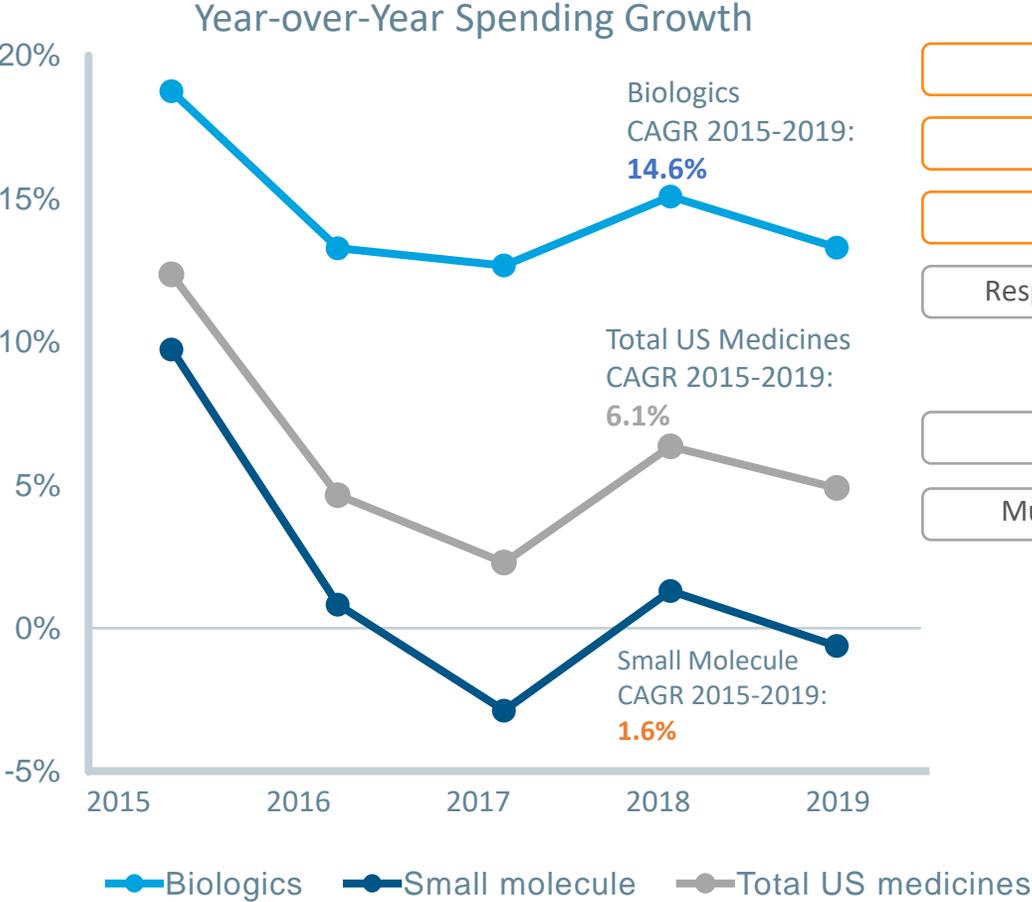
Unbranded and branded generics account for 18.4% of spending in 2021



Source: IQVIA, National Sales Perspectives, August 2021
 Note: Limited to Rx and OTC Insulins; Includes Retail, Non-Retail and Mail

The U.S. biologics market continues to grow faster than non-biologics on an invoice-basis, and now comprises 43% of spending

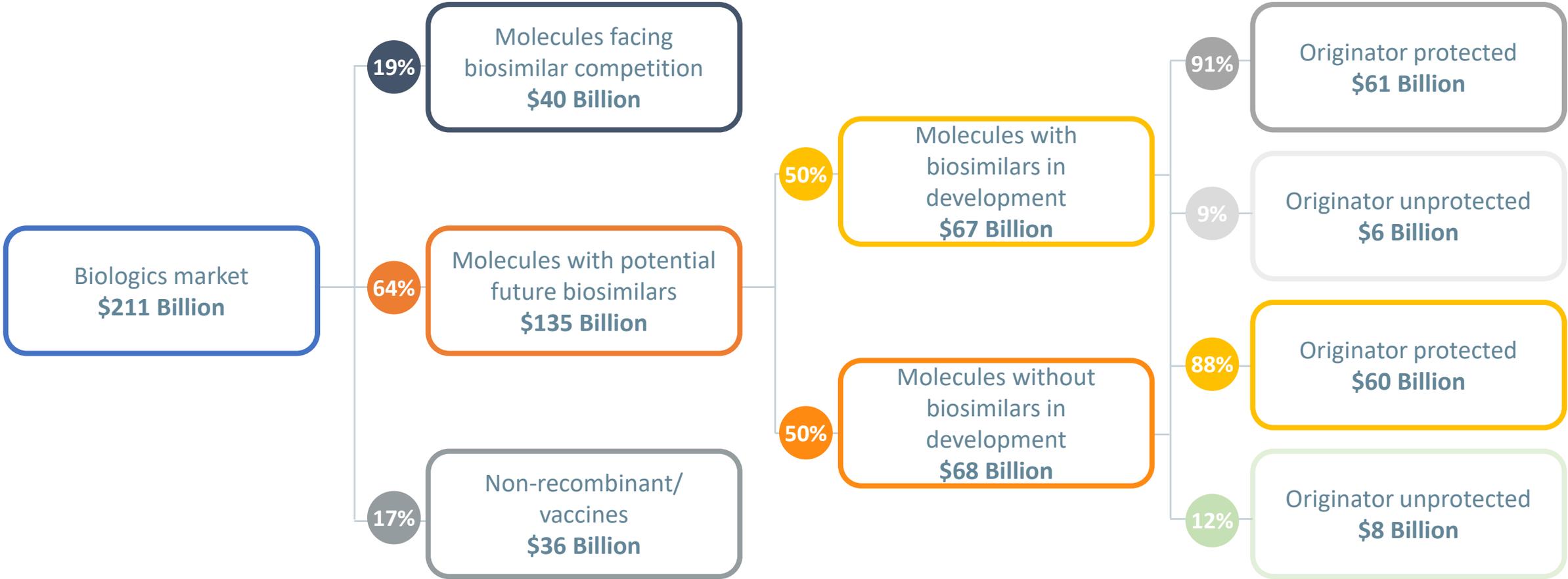
Total U.S. Invoice Spending Growth by Type and Leading Therapy Areas by 2019 Spending, US\$Bn



Source: IQVIA MIDAS®; IQVIA Institute, Jun 2020

Molecules with biosimilars total \$40 billion of invoice spending, while biosimilar development is targeting a further \$67 billion

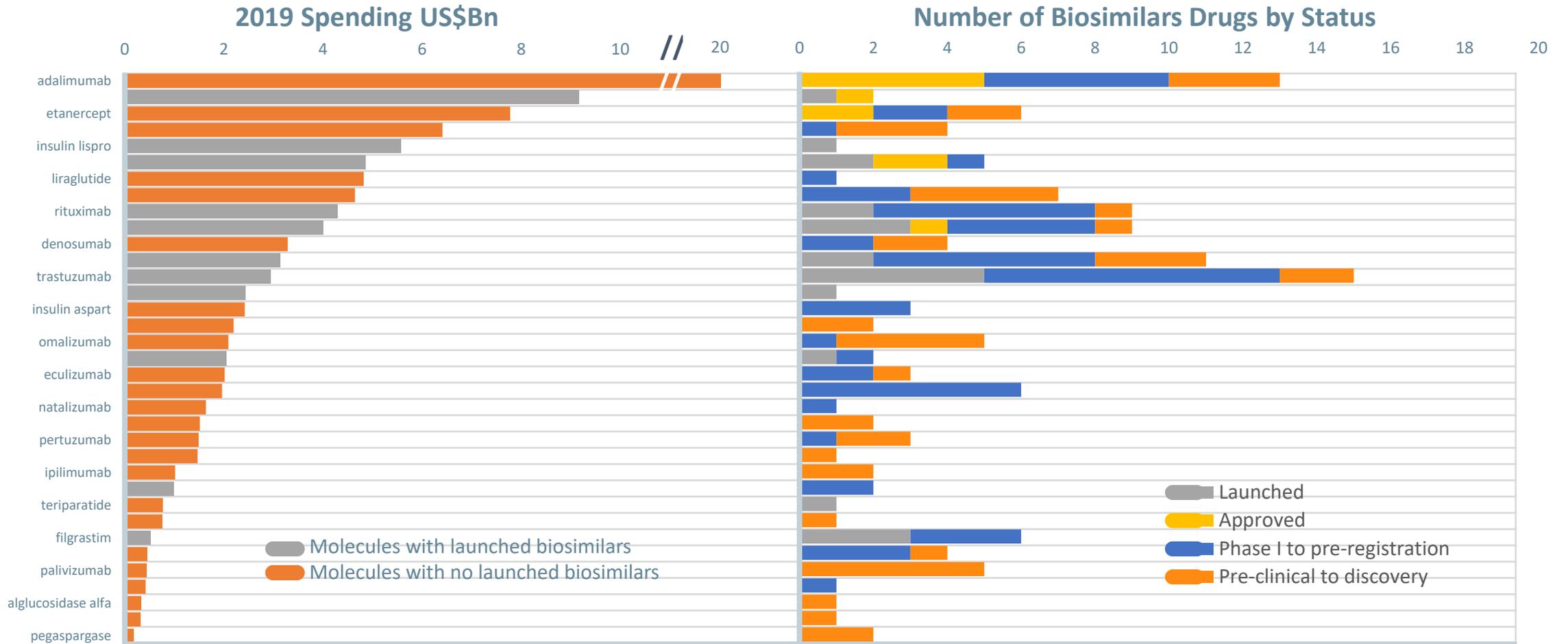
2019 Biologics Market Segmented by Status of Biosimilar Competition, Biosimilar Development and Market Exclusivity



Source: IQVIA MIDAS®; IQVIA Pipeline Intelligence, IQVIA Institute, Jun 2020

There are biosimilars launched, approved, or in development for 35 molecules

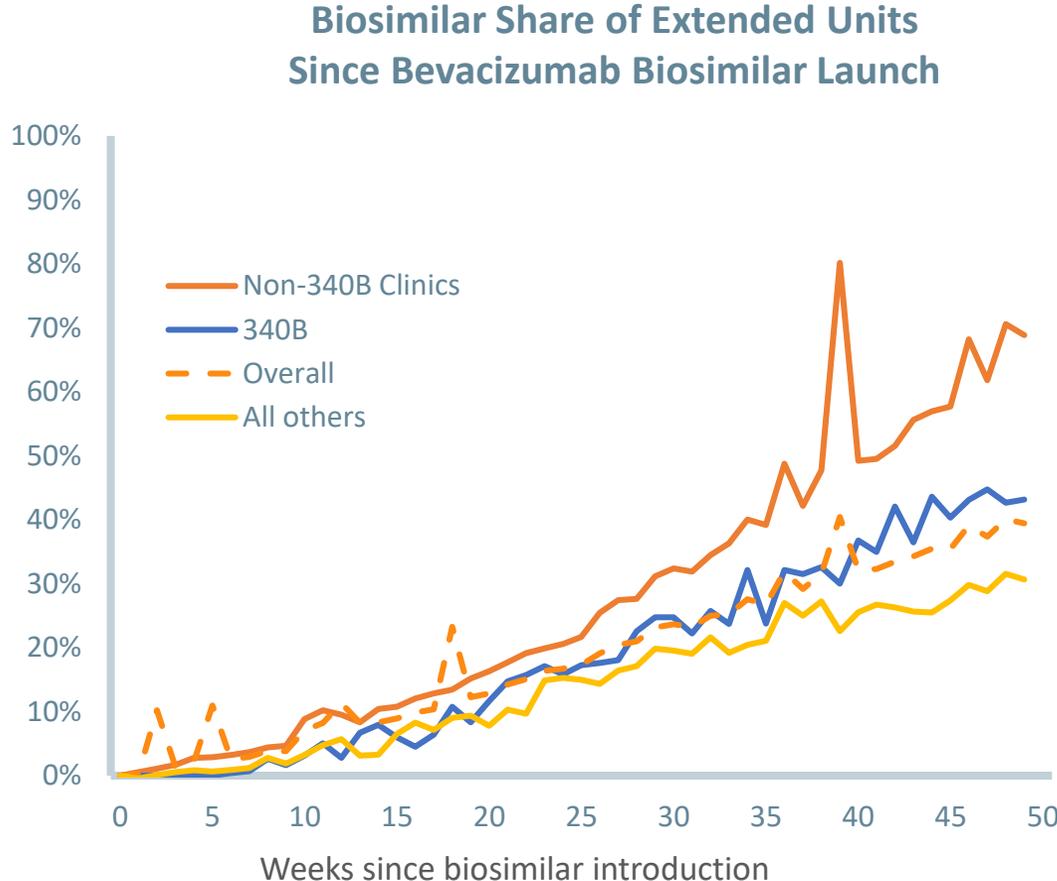
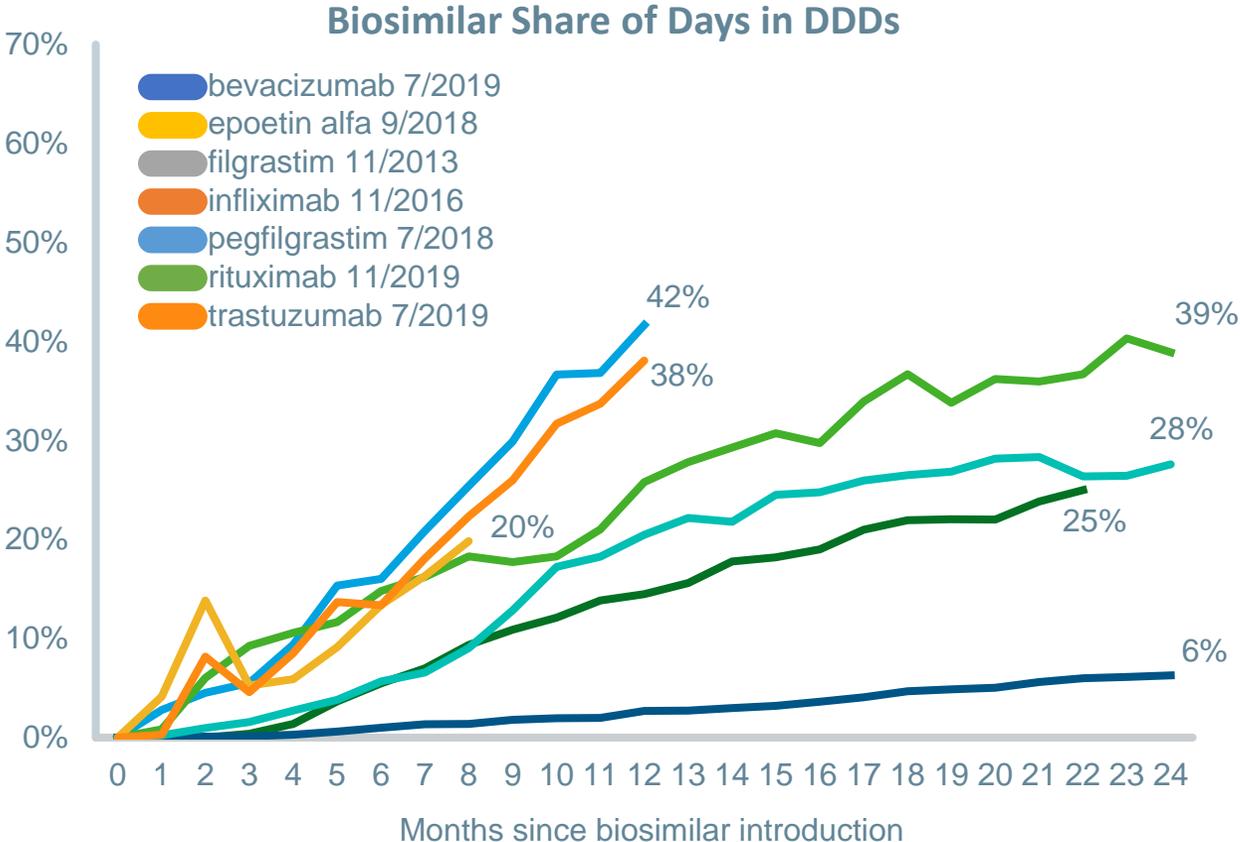
Current Total Molecule Spending and Approved, Launched and Pipeline Biosimilar Products for the Molecule



Source: IQVIA Institute, Sep 2020; IQVIA Biosimilar Database, Jun 2020

Recent biosimilars have achieved high volume shares, projected to reach more than 50% within the first two years, varying by channel

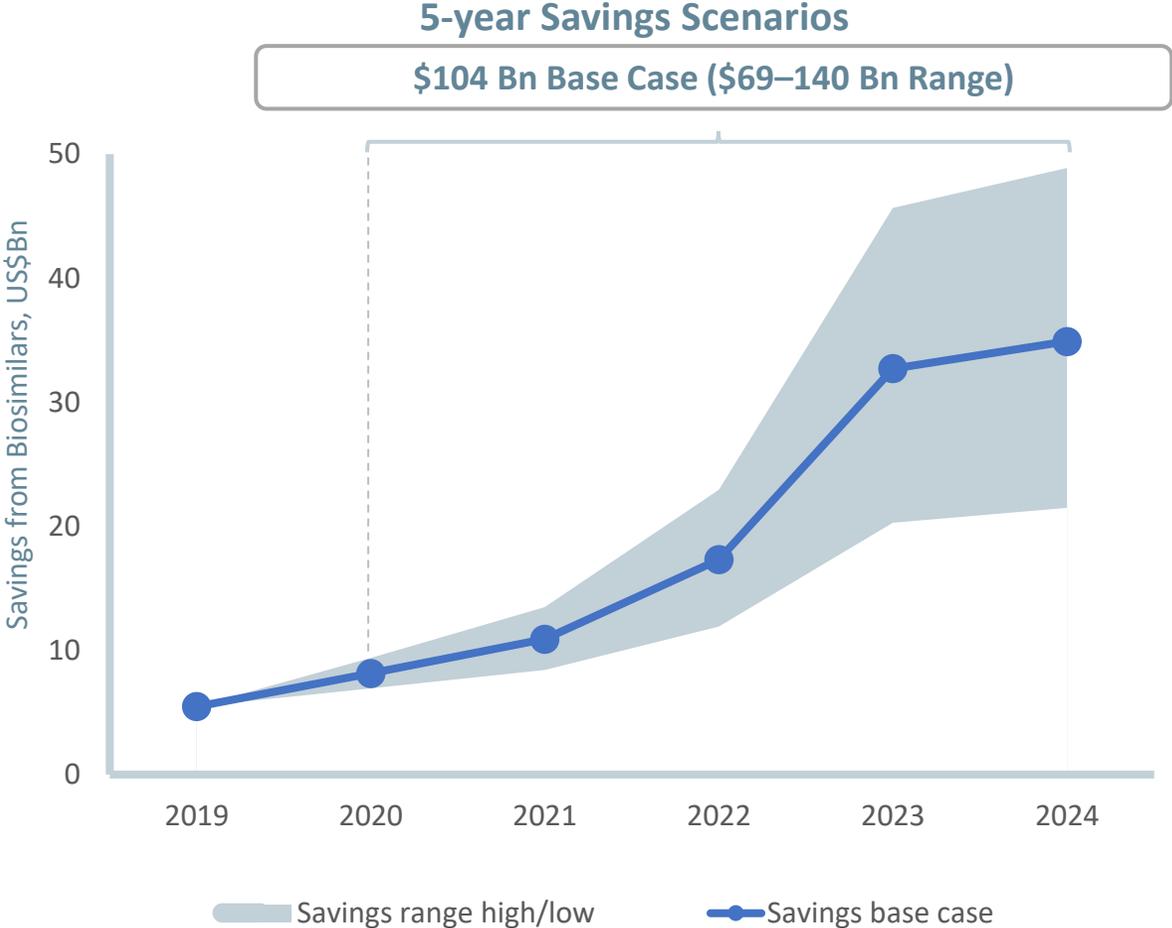
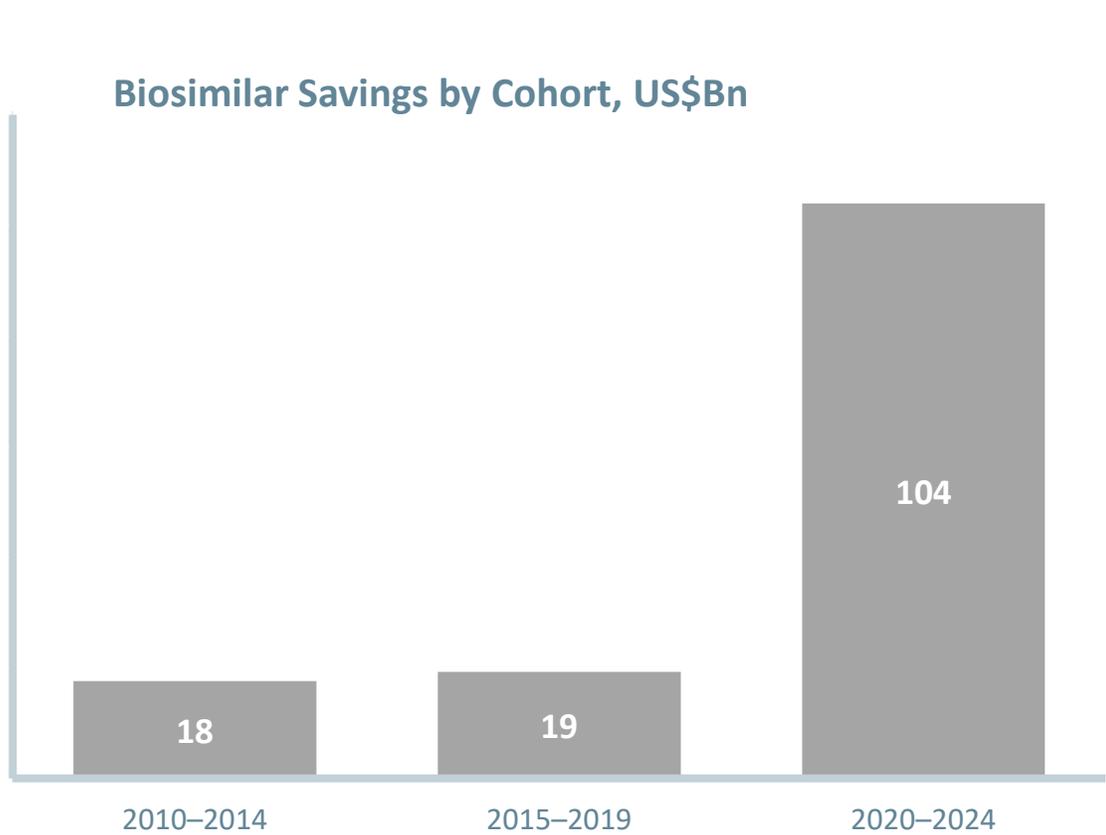
Biosimilar Share of Volume Since Biosimilar Launch



Source: IQVIA MIDAS®, Jun 2020

Savings over the next five years as a result of biosimilars are projected to exceed \$100 billion, though uncertainties remain

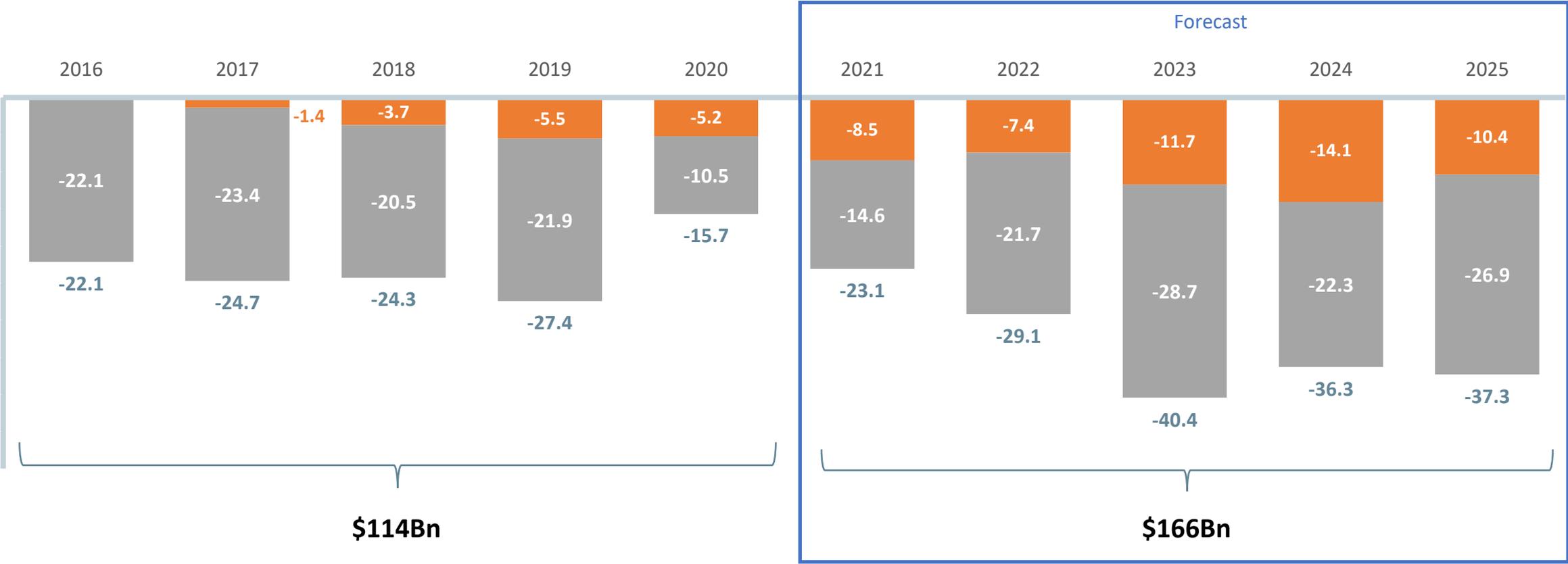
Biologic Estimated Savings from Biosimilars at Invoice Prices



Source: IQVIA National Sales Perspectives, Jun 2020; IQVIA Institute, Sep 2020

The impact of exclusivity losses will increase to \$166 billion over the next 5 years mostly due to the availability of biosimilars

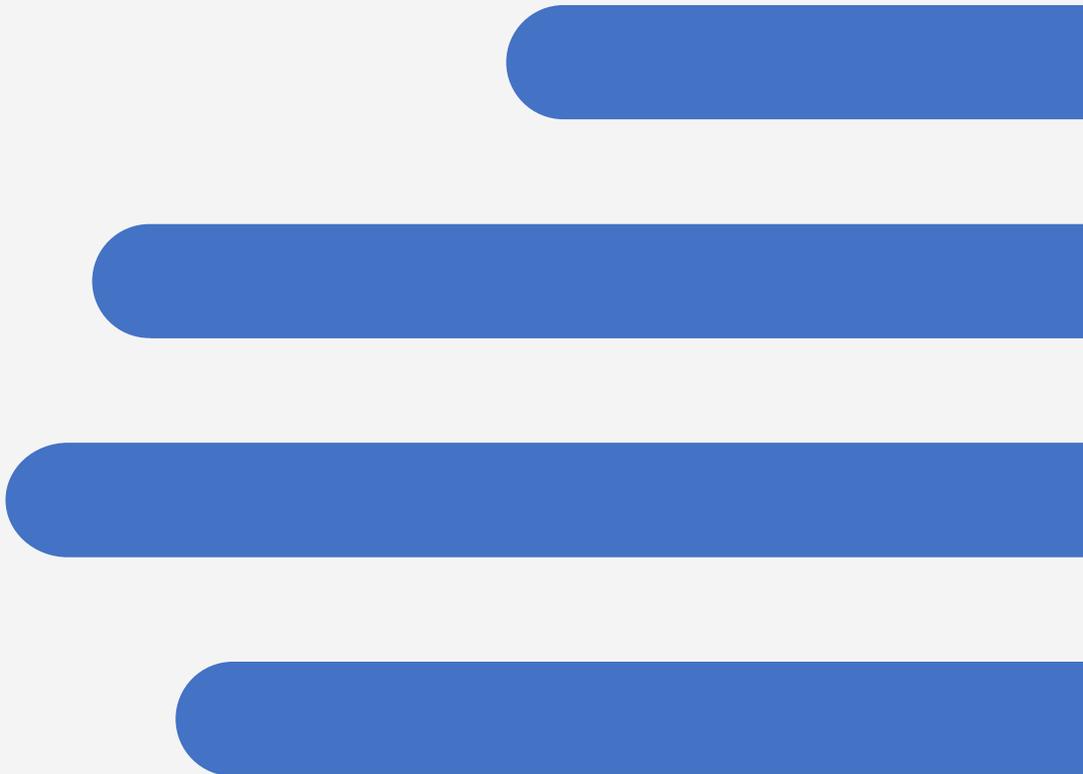
Developed Markets Impact of Brand Losses of Exclusivity 2016–2025, US\$Bn



■ Biologic
 ■ Small
 ■ Total brand loss due to LOE

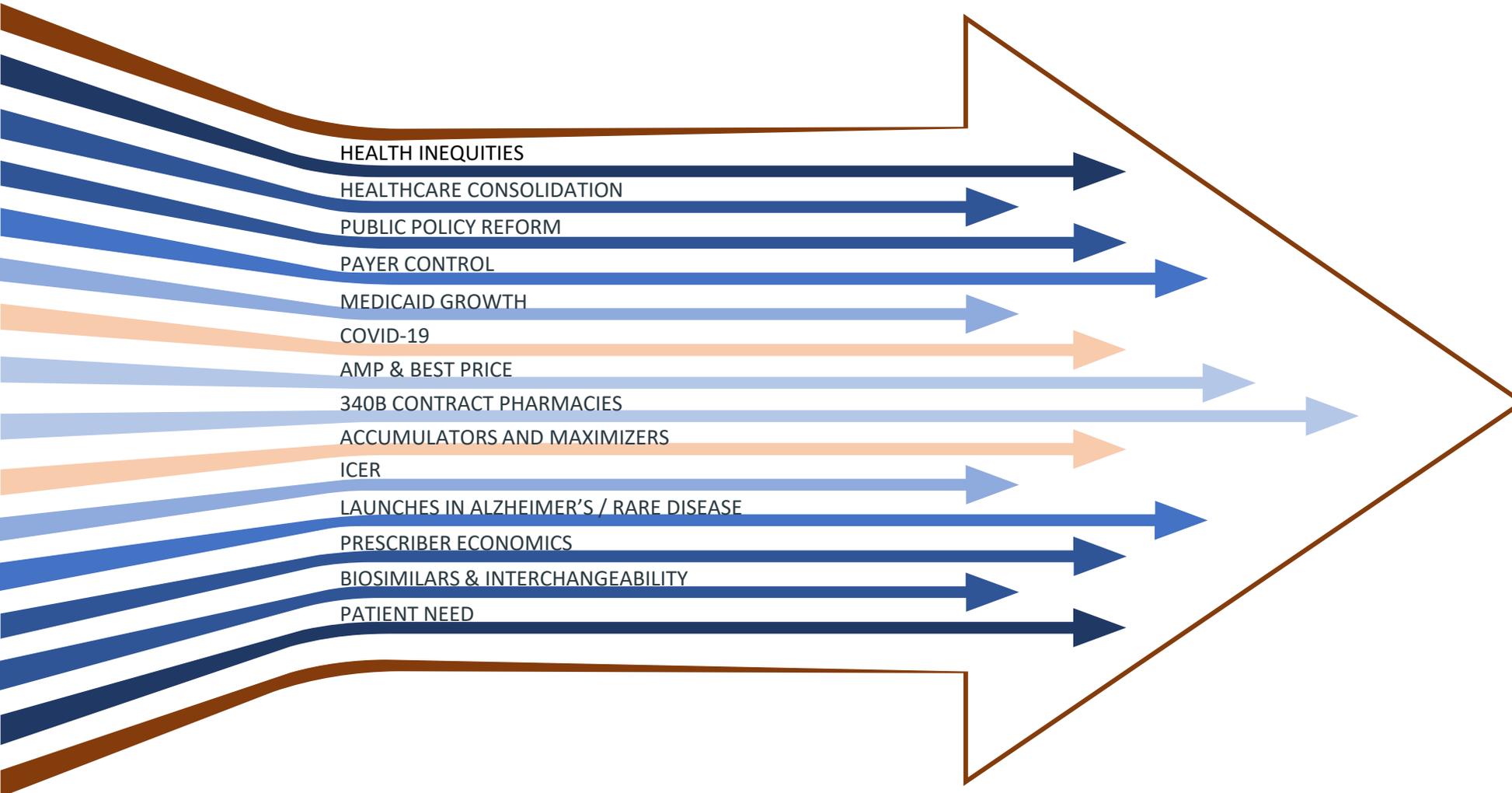
Source: IQVIA Market Prognosis, Sep 2020; IQVIA Institute, Feb 2021

Market Access



Market complexity is accelerating and compounding while narrowing the path to success

How will biopharma untangle these challenges to margin and access, prepare for the future



As margin pressure and uncertainty grows, margins are becoming smaller and smaller.

How will things continue to evolve in 2022 and 2023?

The Biden administration remains focused on several healthcare initiatives, though legislation is still pending

Manufacturers should prepare by scenario planning and strategy preparation

Expanded Access to Healthcare



Broader Access to Healthcare

- Lower age of eligibility for Medicare
- Expanded exchange subsidies
- Possible Medicaid expansion

Price Leverage



Government Leverage on Price

- Government empowerment
- Expanded CPI penalties
- International & clinical benchmarks

Reimbursement & Rebate Reform



Shifting Stakeholder Incentives

- Safe harbor removal
- Rebate pass-through in 340B
- Part D benefit design

- Early focus has been on COVID-19, but policymakers are also tasked with addressing drug costs
- COVID-19's economic impact will increase the popularity of expanding coverage... with restrictive formularies
- Large reforms requiring legislation will likely be contested if with a divided legislature

Growing payer control continues to challenge patient access

Payer control is highest in specialty medicine

*Specialty patients are **20%** more likely to not fill a prescription today as they were in 2013*

450+
blocked products

across dozens of classes in Caremark's 2021 NDC exclusions

United/Optum, Caremark, and Express Scripts place controls on more than 75% of specialty meds

79% of specialty patients with an **NDC BLOCK**

60% of specialty patients with a **STEP EDIT**

are not able to overcome the restriction within 30 days

Abandonment in specialty:

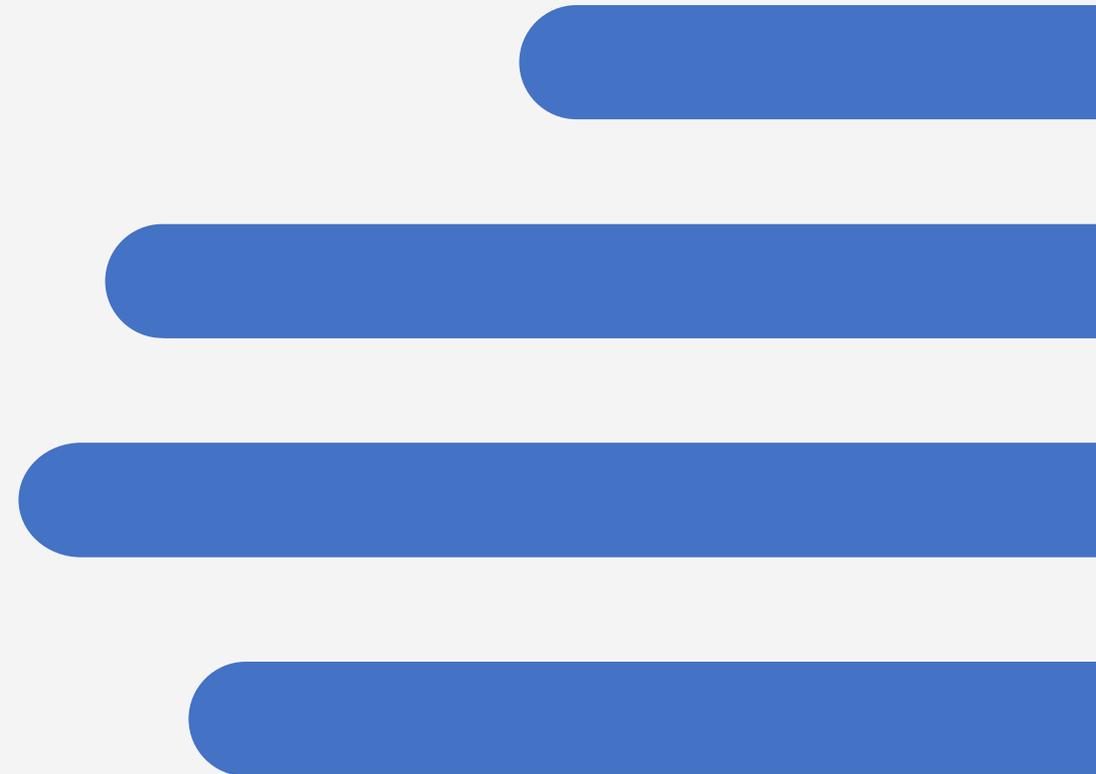
25%

among Part D patients

9%

among Commercial patients (co-pay cards permissible)

Outlook for 2021



There have been a series of legacy considerations recognized across stakeholders

Pharmacies

- Reimbursement
- Controlled Substances
- Access to Specialty Drugs
- Purchasing Alliances
- Track and Trace
- Amazon, Digital pharmacies and cash customers

Generic Manufacturers

- Purchasing Alliances
- Portfolio Optimization (“Shrink to Grow”) / Market Saturation
- Brand /niche drugs (complex generics)
- Generic Price Deflation
- Which approvals to launch?

Wholesalers

- Contract Negotiations
- Controlled Substances
- Generic Price Deflation / Slow Brand Inflation
- Track and Trace
- Purchasing Alliances

Brand/Specialty Manufacturers

- Price increase backlash
- Becoming more specialized / Oral Specialty
- Declining Hep C and Pain Dollars
- Orphan Drugs
- Copay accumulators

Payers

- Managing Specialty Drug Costs
- Rising Oncology costs
- Formularies blocks and exclusive launches

Consumers

- Rising costs: high out-of-pocket costs / coinsurance / accumulators
- Quality of Insurance Coverage
- Specialty Tiers

Trends that emerged in early 2021 remain key areas of focus

1

Unemployment, healthcare economic impact of COVID-19, and pace of recovery

2

Vaccine rollout, distribution, reimbursement, and administration

3

Healthcare reform under the Biden administration

- What is in? What is likely? What is out?
- Which Trump Admin Midnight Reforms stay?

4

Expanding payer control in pharmacy *and medical* reimbursed products

5

Growing net price pressure in immunology and other specialty markets

6

Accumulator Adjuster Programs impacting government price calculations reshape copay and hub industry

7

Explosive growth and increased controversy in 340B utilization

8

Permanent shifts in patient site of care and reimbursement rates

9

New Era for Value-Based Pricing agreements following CMS regulations

10

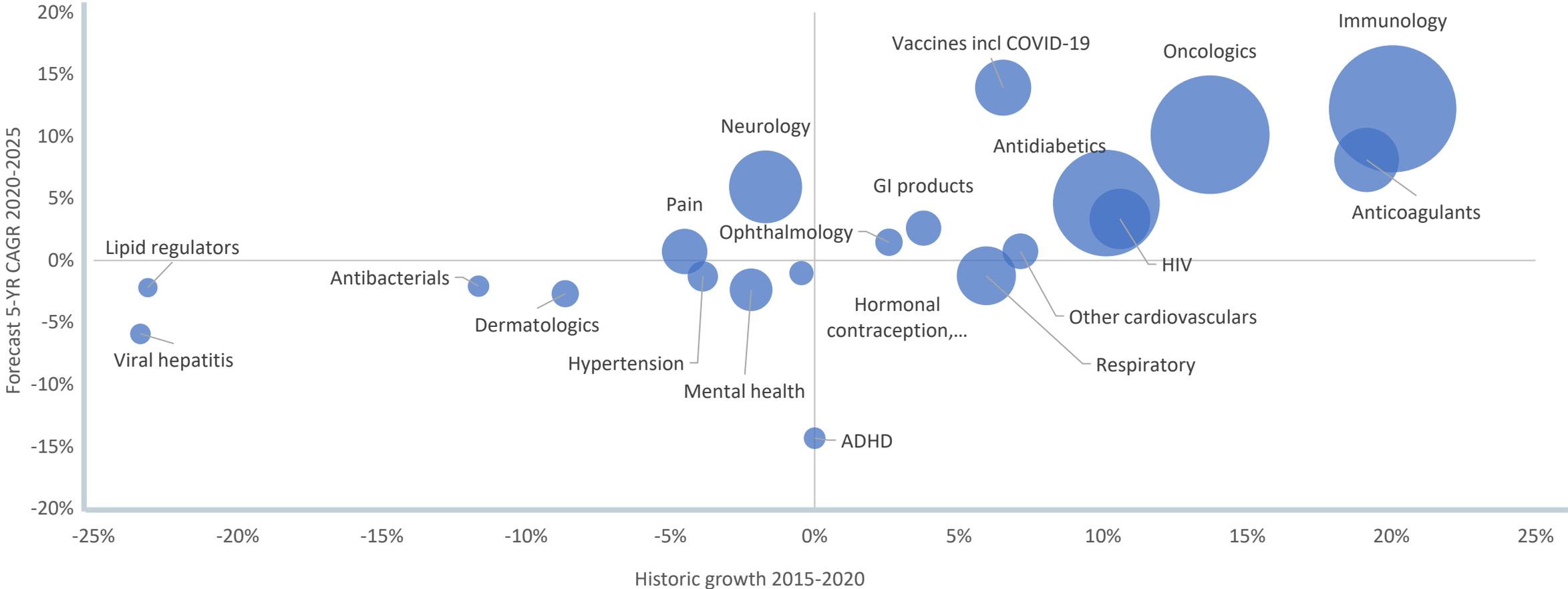
Awareness of the impact of disproportionate access and affordability for minority and underserved populations

Outlook to 2025

- **U.S. market growth will return to pre-pandemic projections by 2025 despite year-to-year fluctuations.**
- **Policy changes impacting the use of medicines are likely to be phased in over the next five years.**
- **The U.S. spending forecast reflects an increasing gap between invoice level spending and manufacturer net revenues.**
- **New brand spending in the U.S. is projected to be higher than the last five years but a smaller share of spending.**
- **Net price growth for protected brands is forecast to be 0 to -3% through 2025**
- **Losses of exclusivity expected to result in \$128 billion of lower brand spending through 2025 with \$39 billion from branded biologics.**
- **Biosimilars mature, and the impact of medicines facing new biosimilar competition in 2023 and 2024 will have a large impact.**
- **Immunology, oncology, and neurology drive growth.**
- **U.S. oncology spending to exceed \$110 billion by 2025, with growth slowing to 10% from biosimilar savings.**
- **Diabetes spending to decline 2-5% through 2025 as off-invoice discounts and rebates continue to offset list prices.**
- **Treatments for autoimmune disorders to exceed \$130 billion in the U.S. by 2025, slowing after 2023 due to key biosimilars.**

Immunology, oncology, neurology drive growth through 2025 along with COVID-19 vaccines

Historic and Forecast Growth for Top 20 Therapy Areas



Source: IQVIA Institute, Feb 2021

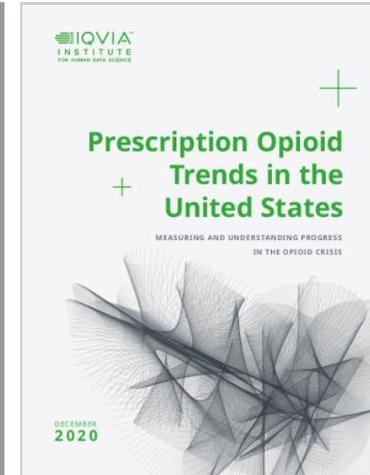
The IQVIA Institute produces a number of reports on a regular basis that you might find useful, check them out



Despite the COVID-19 pandemic having a substantial impact on patient care during 2020, the scientific advances in clinical trial activity, the pipeline of new treatments, and the increased use of available therapeutics, continued largely unaffected and reflect the commitment to advancing care for patients by oncologists, other care providers, governments and payers, and life sciences companies.



This report examines the trends in pharmaceutical research and development through the end of 2020. It provides an analysis of initiated clinical trials, including the impact of the pandemic and COVID-19-specific research. Research on clinical development productivity is also presented, as well as profiles of the R&D pipeline, R&D funding trends, and characteristics of new drug approvals and launches.



The opioid epidemic has captivated the country for a decade, although it lost attention this year in the face of the COVID-19 pandemic, which affected the life and healthcare of patients with chronic pain and addiction and so many others.



The future level of global spending on medicines has implications for healthcare systems and policymakers across developed and emerging economies, and these issues are even more important in light of the ongoing global COVID-19 pandemic.



The U.S. health system demonstrated resilience and flexibility during 2020, recovering toward its pre-pandemic levels of activity and progressing into 2021, even as the backlog of missed or delayed activity remains substantial. Medicine supply was largely maintained and spending on medicines increased by less than 1% on a net price basis.



Innovation in digital health tools, including mobile health apps and wearable sensors, bring new approaches to the management of health conditions. Digital therapeutics to treat human disease are being approved by regulatory agencies around the world and routes to reimbursement are being established as developers generate and submit high-quality data on effectiveness to payers and employers.

All these reports and others can be found at: <https://www.iqvia.com/insights/the-iqvia-institute/reports>

Thank you

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His fundamental task is to help secure data for all existing and new databases supported by IQVIA, manage supplier, manufacturer & association relationships, and develop information for data partners. As direct consequence of his involvement in these areas, Doug has considerable experience with, and a unique perspective on, the changing U.S. and global healthcare marketplace and pharmaceutical distribution.

Doug is a frequent industry speaker and the recipient of many awards from trade groups. Before joining IQVIA Doug held positions at Nielsen Market Research for 16 years in various sales and marketing capacities. A native of Illinois, Doug received a BA from DePauw University and holds an MBA in management from Fairleigh Dickinson University.

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