

# The Specialty Pharmacy Industry Update & Outlook

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

May 3, 2022



### **Agenda**

- The State of Specialty Pharmacy 2022 Adam
- US Specialty Pharmaceutical Trends, Issues and Outlook for Asembia Doug
- Q&A (Send your questions to <u>support@drugchannels.net</u>)

Download these slides:

https://drugch.nl/asembia22



### **The State of Specialty Pharmacy 2022**

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

May 3, 2022

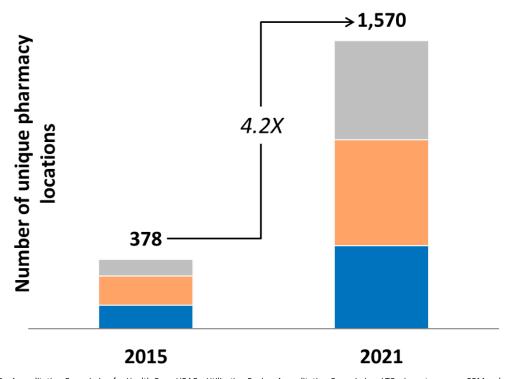




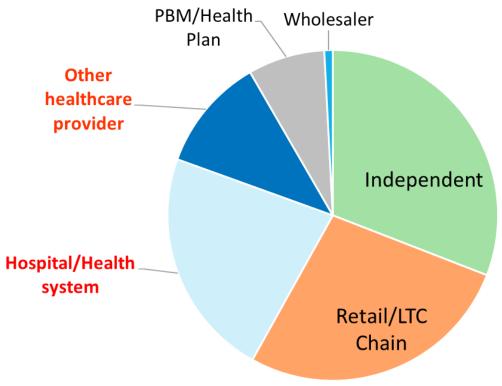
### The Specialty Pharmacy Marketplace

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, 2021
n = 1.570



ACHC = Accreditation Commission for Health Care; URAC = Utilization Review Accreditation Commission; LTC = Long-term care; PBM = pharmacy benefit manager

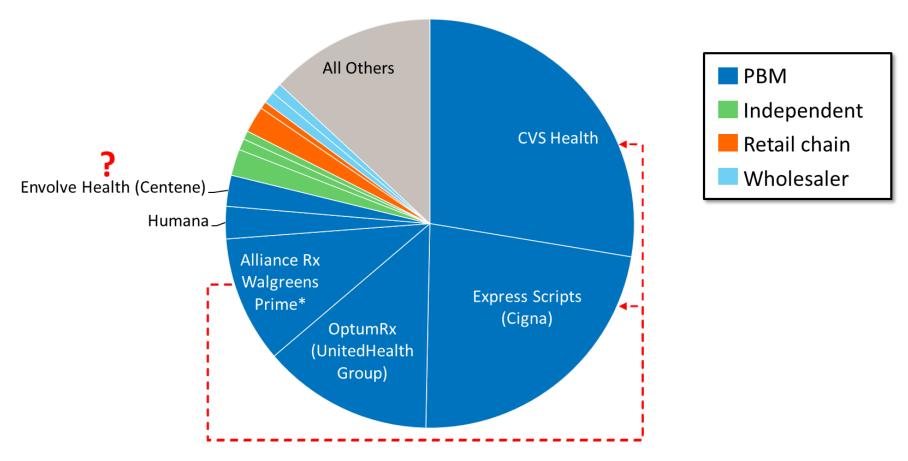
Source: The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers, Exhibits 46 and 50. Figures show number of unique accredited locations at the end of the year. For comparability, data for ACHC exclude certain accredited pharmacy spoke locations within retail chains. Figures exclude locations with provisional, conditional, and expected accreditation. Independents include private independent pharmacies, pharmacies owned by private equity firms, and independently owned franchise locations. Other healthcare provider includes pharmacy locations owned by physician practices and nonhospital providers. Retail/LTC Chain includes pharmacy locations owned by chain drugstores, grocery chains, and national long-term care pharmacy chains.





### **PBMs Still Dominate Specialty Dispensing**

SHARE OF SPECIALTY DRUG DISPENSING REVENUES, BY COMPANY, 2021



<sup>\*</sup> On Dec. 31, 2021, Walgreens purchased Prime Therapeutics' 45% ownership interest in AllianceRx Walgreens Prime, so this business has no PBM ownership in 2022. Effective June 2022, the company will be known as AllianceRx Walgreens Pharmacy.

Source: <u>The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers</u>, 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.



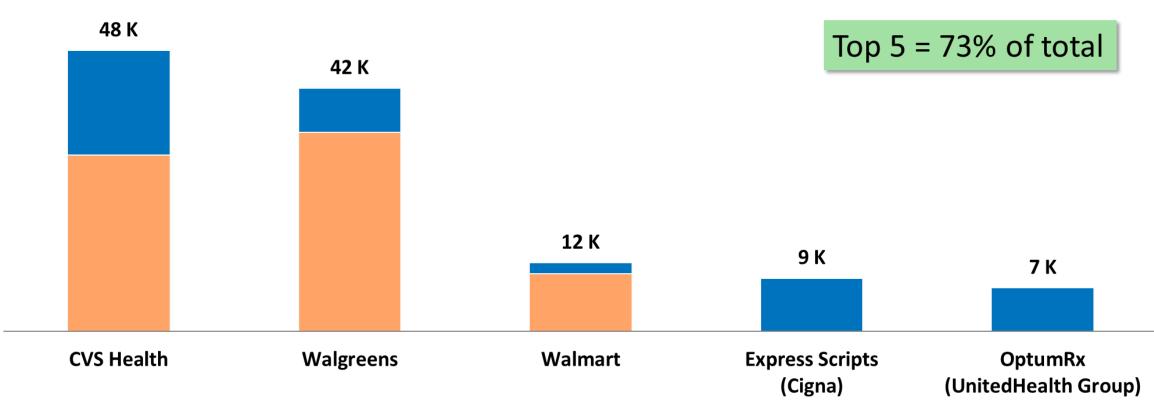


### The Top Five 340B Contract Pharmacy Players

340B CONTRACT PHARMACY RELATIONSHIPS, BY COMPANY, APRIL 2022

(U.S. Total = 161 K)





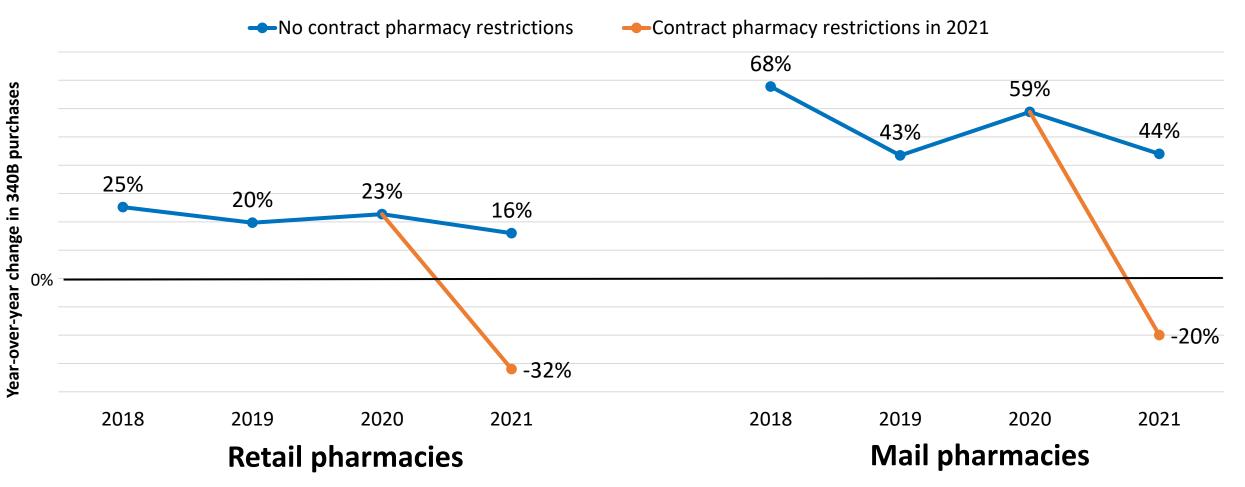
Source: Drug Channels Institute analysis of OPA Daily Contract Pharmacy Database. Data show number of unique contract pharmacy relationships as of April 5, 2022. Company totals are computed from combined banners (store and business names) and subsidiaries in the database. See: (1) The 340B Program Soared to \$38 Billion in 2020—Up 27% vs. 2019, Drug Channels, June 2021.





### Manufacturer actions = Contract pharmacy slowdown

#### **GROWTH IN VALUE OF 340B PURCHASES AT LIST PRICES**

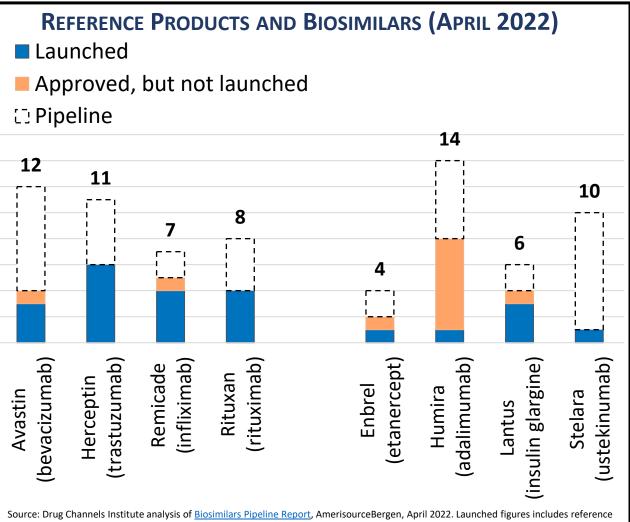


Source: Drug Channels Institute analysis of IQVIA data. See 340B Program Continues to Grow While Contract Pharmacy Restrictions Take Effect, IQVIA, April 2022. Nine manufacturers had restrictions in place for some or all of 2021.





### **Emerging Profit Drivers for Specialty Pharmacy**



Copay Maximizers

Non-biologic specialty generics

White bagging

Pharmacy benefit biosimilars

#### See:

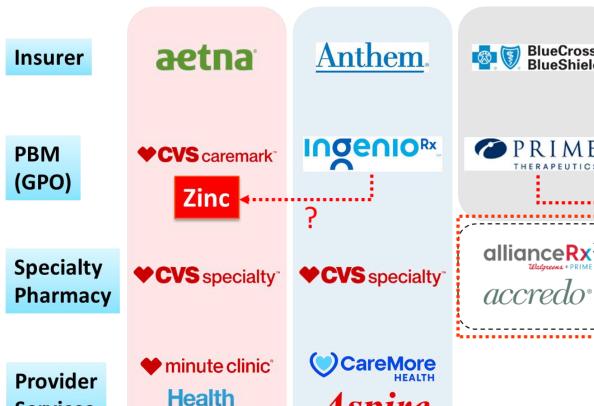
- Four Reasons Why PBMs Gain As Maximizers Overtake Copay Accumulators, Drug Channels, February 2022.
- Why PBMs and Payers Are Embracing Insulin Biosimilars with Higher Prices—And What That Means for Humira, Drug Channels, November 2021.
- The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers, Sections 7.3.2. and 12.2.

product. Lantus figures include follow-on biologics.



#### Let's Get Vertical...Or Not?















- 1. Cigna also partners with providers via its Cigna Collaborative Care program.
- 2. Since January 2021, Prime's Blue Cross and Blue Shield plans have had the option to use Express Scripts or AllianceRx Walgreens Prime for mail and specialty pharmacy services. In December 2021, Walgreens Boots Alliance purchased Prime Therapeutics' 45% ownership in AllianceRx Walgreens Prime.
- 3. In 2021, Centene has announced its intention to consolidate of all PBM operations onto a single platform and outsource its PBM operations to an external company.
- 4. In 2021, Centene sold a majority stake in its U.S. Medical Management to a group of private equity firms.
- 5. Since 2020, Prime has sourced formulary rebates via Ascent Health Services. In 2021, Humana began sourcing formulary rebates via Ascent Health Services for its commercial plans.
- 6. In April 2022, Humana announced an agreement to divest a majority interest in Kindred at Home's Hospice and Personal Care divisions to private equity firm Clayton, Dubilier & Rice.

Source: The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers, Exhibit 212. Companies are listed alphabetically by insurer name.

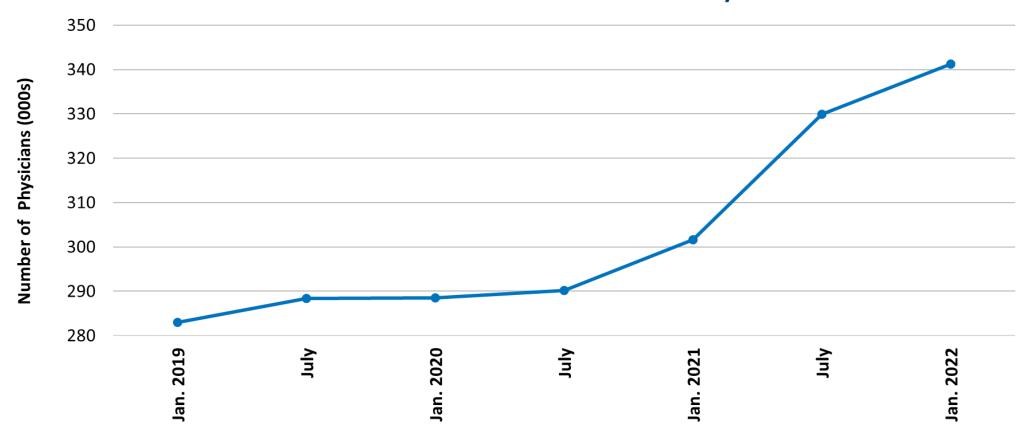


**Services** 



### **Let's Get Vertical: Hospitals + Physicians**

#### NUMBER OF U.S. PHYSICIANS EMPLOYED BY HOSPITALS/HEALTH SYSTEMS



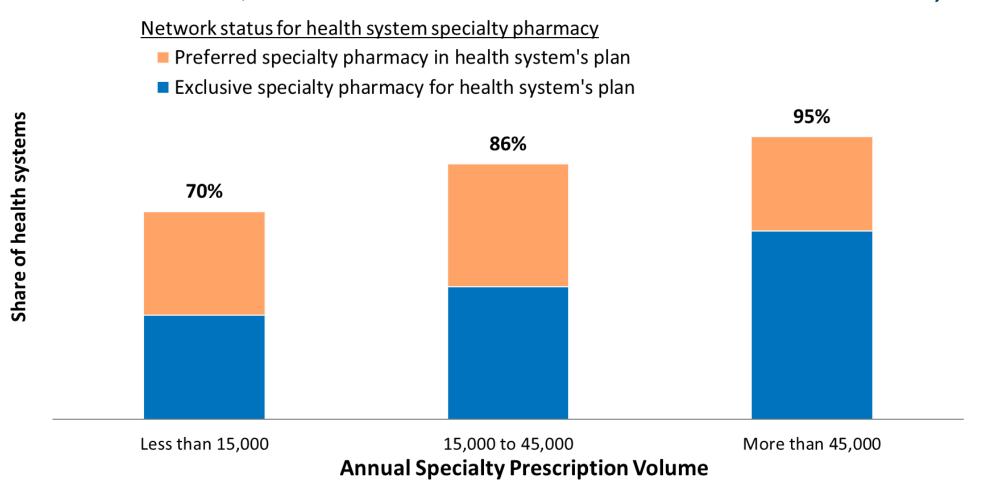
Source: Drug Channels Institute analysis of COVID-19's Impact On Acquisitions of Physician Practices and Physician Employment 2019-2021, Avalere Health, 2022.





### **Hospitals Battle for Specialty Network Access**

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



Source: The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers, Exhibit 147. See also: Fresh Evidence: How Health Systems Steer Prescriptions to Their Own Specialty Pharmacies, Drug Channels, October 2021.





### **Final Thoughts**

Battle for control of the specialty patient continues

Specialty pharmacy profit models becoming more opaque

Unwinding 340B's distortions will be costly

Vertically aligned channels pose new market access risks







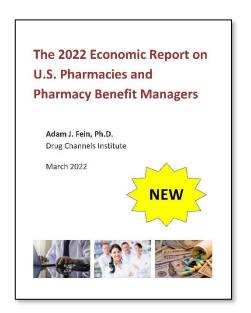
Free industry updates from my *Drug Channels* blog: <u>DrugChannels.net</u>



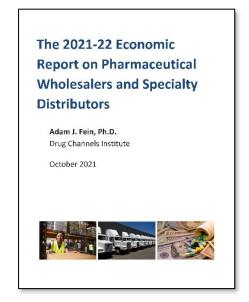
Daily posts about cool and intriguing stuff: <a href="linkedin.com/in/adamjfein/">linkedin.com/in/adamjfein/</a>



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



https://drugch.nl/pharmacy



https://drugch.nl/wholesale



Adam J. Fein, Ph.D.





# **Specialty Pharmacy Industry Update and Outlook for Asembia**

Doug Long

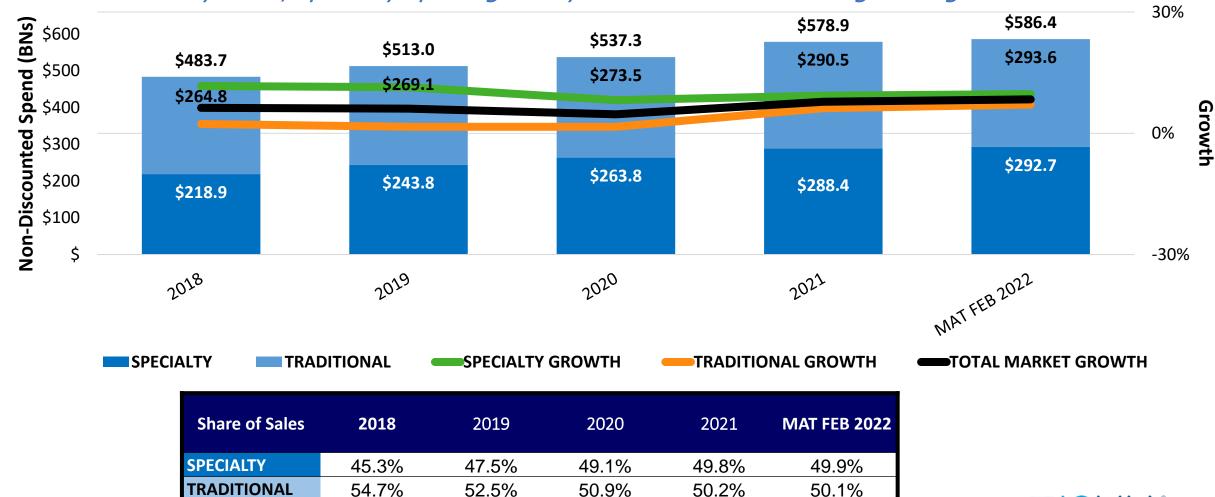
Vice President Industry Relations, IQVIA

May 3, 2022



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

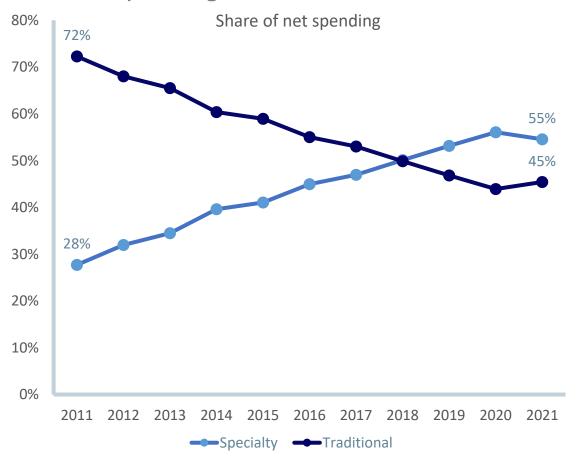
In MAT February 2022, specialty spend grew by 9.7% while traditional growth grew 7.1%

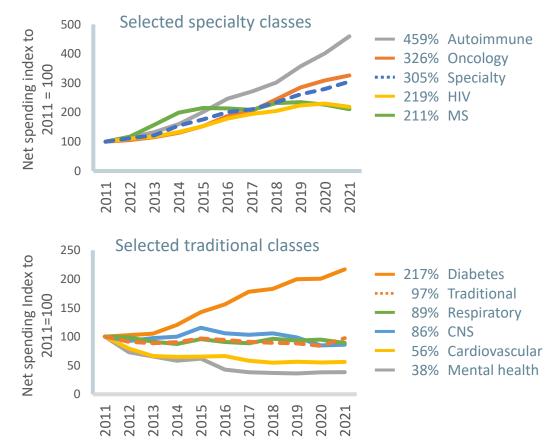




# Specialty medicines now account for 55% of spending, up from 28% in 2011, driven by growth in auto-immune and oncology

Share of spending at estimated net manufacturer prices







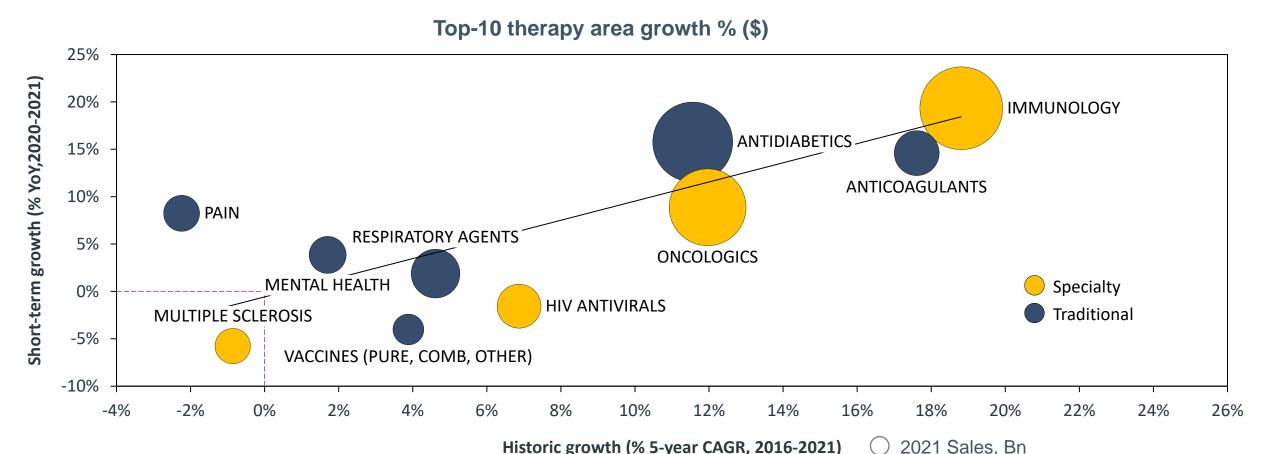






# Immunology and Anticoagulants show the greatest one- and five-year growth in the US

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

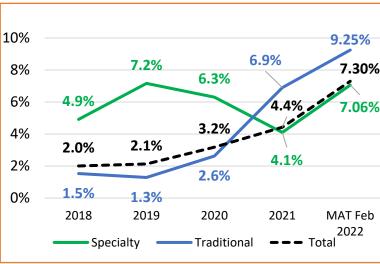


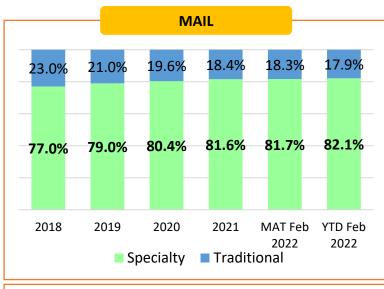
% OF SALES

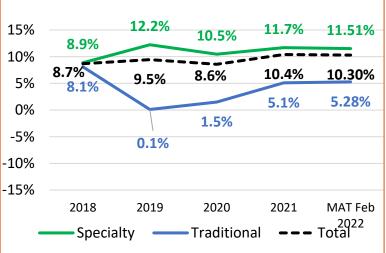
**YOY SALES \$ GROWTH** 

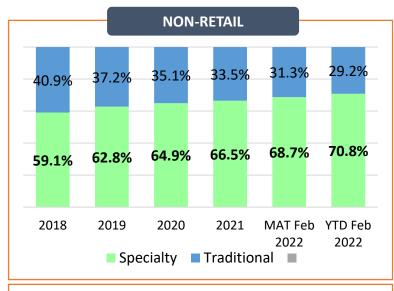
#### Based on sales dollars, Specialty is increasing in all channels

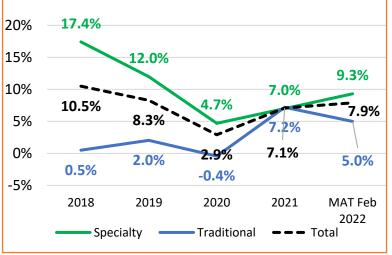
















#### **Coronavirus Antivirals showed greatest Specialty growth on spend in Non-Retail**

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

RETAIL			
Therapy	2021	YoY Growth	
HIV ANTIVIRALS	16.3	-2.1%	
IMMUNOLOGY	8.4	14.1%	
ONCOLOGICS	2.4	-0.5%	
MENTAL HEALTH	2.3	6.9%	
ANTI-INFLAMMATORY AND DIGESTIVE ENZYMES AND MODULA	2.1	13.8%	
VIRAL HEPATITIS	1.2	-1.6%	
LIPID REGULATORS	1.2	36.9%	
SEX HORMONES (ANDROGENS, OESTROGENS, PROGESTOGENS)	0.7	30.6%	
MULTIPLE SCLEROSIS	0.6	-10.7%	
OTHER CNS	0.6	18.9%	

MAIL				
Therapy	2021	YoY Growth		
IMMUNOLOGY	66.4	20.5%		
ONCOLOGICS	21.2	9.7%		
MULTIPLE SCLEROSIS	10.6	-13.4%		
HIV ANTIVIRALS	5.1	-3.5%		
ALL OTHER RESPIRATORY	4.1	11.9%		
RESPIRATORY AGENTS	2.4	16.2%		
GROWTH HORMONES	2.3	6.1%		
OTHER CARDIOVASCULARS	2.3	-1.5%		
VIRAL HEPATITIS	2.0	-5.5%		
BLOOD COAGULATION	2.0	4.7%		

NON-RETAIL			
Therapy	2021	YoY Growth	
ONCOLOGICS	55.6	9.1%	
IMMUNOLOGY	17.0	15.9%	
MULTIPLE SCLEROSIS	5.5	8.1%	
POLYVAL IMMUNOGLOBLULINS IV&IM	4.8	7.2%	
HIV ANTIVIRALS	4.7	2.8%	
CORONAVIRUS ANTIVIRALS	3.6	162.0%	
HEMATOPOIETIC GROWTH FACTORS	3.5	-13.4%	
ERYTHROPOIETINS	2.7	-4.9%	
MENTAL HEALTH	2.2	11.5%	
RESPIRATORY AGENTS	2.0	11.1%	

Source: IQVIA, National Sales Perspectives, April 2022

Limited to Rx and OTC Insulins





### On a non-discounted spend basis, the top 10 products are growing at 23.0% and account for 20.3% market share

Rank	Product	Non-Discounted Spend (US\$ BNs)			
		MAT DEC 2021	Market Share	ABS Growth	Growth
1	HUMIRA	\$27.5	4.8%	\$3.4	14.2%
2	ELIQUIS	\$15.8	2.7%	\$3.0	23.2%
3	TRULICITY	\$12.2	2.1%	\$3.5	40.2%
4	STELARA	\$10.7	1.9%	\$2.4	28.3%
5	KEYTRUDA	\$9.9	1.7%	\$1.6	18.7%
6	BIKTARVY	\$9.6	1.7%	\$1.5	19.1%
7	OZEMPIC	\$8.6	1.5%	\$3.5	68.5%
8	ENBREL	\$8.1	1.4%	\$0.3	4.2%
9	JARDIANCE	\$8.0	1.4%	\$2.3	40.8%
10	XARELTO	\$7.1	1.2%	\$0.5	7.5%
TOP 10		\$117.4	20.3%	\$22.0	23.0%





### On a non-discounted spend basis, the top 20 products are growing at 21.7% and account for 28.1% market share

Rank	Product	Non-Discounted Spend (US\$ BNs)			
		MAT DEC 2021	Market Share	ABS Growth	Growth
11	JANUVIA	\$6.4	1.1%	\$0.1	2.4%
12	DUPIXENT	\$5.6	1.0%	\$2.0	55.2%
13	LANTUS SOLOSTAR	\$5.1	0.9%	\$0.5	9.9%
14	OPDIVO	\$4.2	0.7%	\$0.3	6.9%
15	IMBRUVICA	\$4.2	0.7%	\$0.3	8.1%
16	OCREVUS	\$4.1	0.7%	\$0.6	16.7%
17	VYVANSE	\$4.1	0.7%	\$0.3	8.9%
18	LATUDA	\$4.0	0.7%	\$0.3	7.4%
19	TALTZ	\$4.0	0.7%	\$1.3	47.3%
20	FARXIGA	\$3.7	0.6%	\$1.4	62.0%
<b>TOP 20</b>		\$162.7	28.1%	\$29.0	21.7%





# Spending increased by \$82Bn over the past five years driven by new products and brand volume, offset by expiries

Spending and growth at estimated net manufacturer prices 2015-2020, all channels, US\$Bn

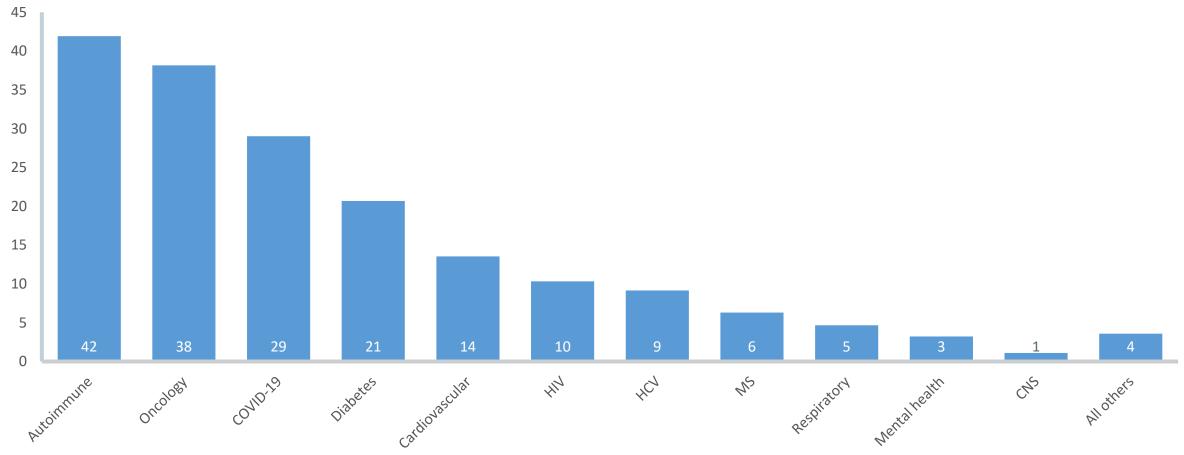






# New and existing medicines drove \$184Bn in spending growth over five years excluding impact of expiries and prices

Medicine net spending growth 2017-2021 for new brands and protected brands volume

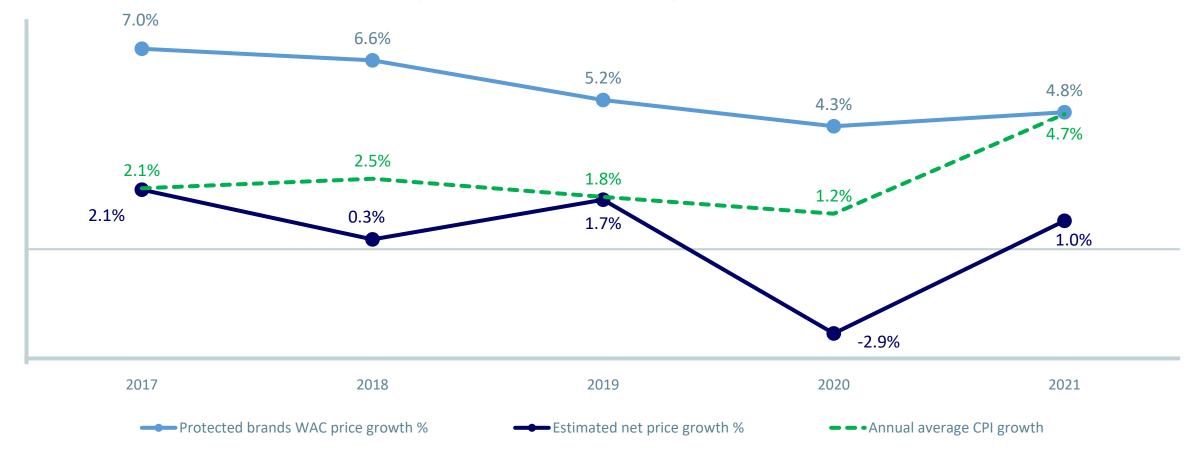






# Protected brand list prices increased 4.8% in 2021, while net prices increased 1% - the fifth year at or below the CPI

Wholesaler Acquisition Cost (WAC) growth and net price growth for protected brands

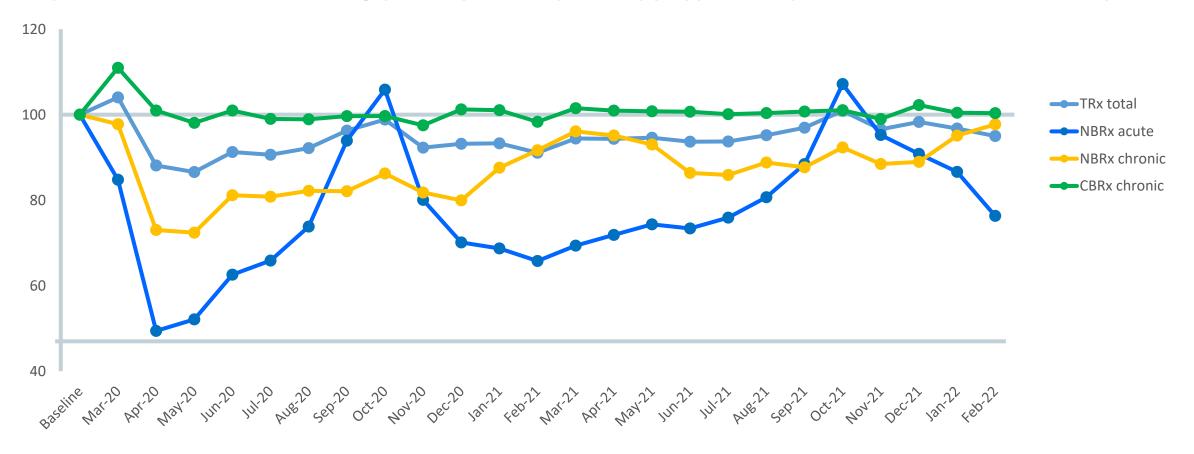






### New prescriptions for acute and chronic therapies were disrupted in the pandemic while chronic continuing remained stable

Dispensed new and continuing prescriptions by therapy type as a percent of 2020 baseline by month

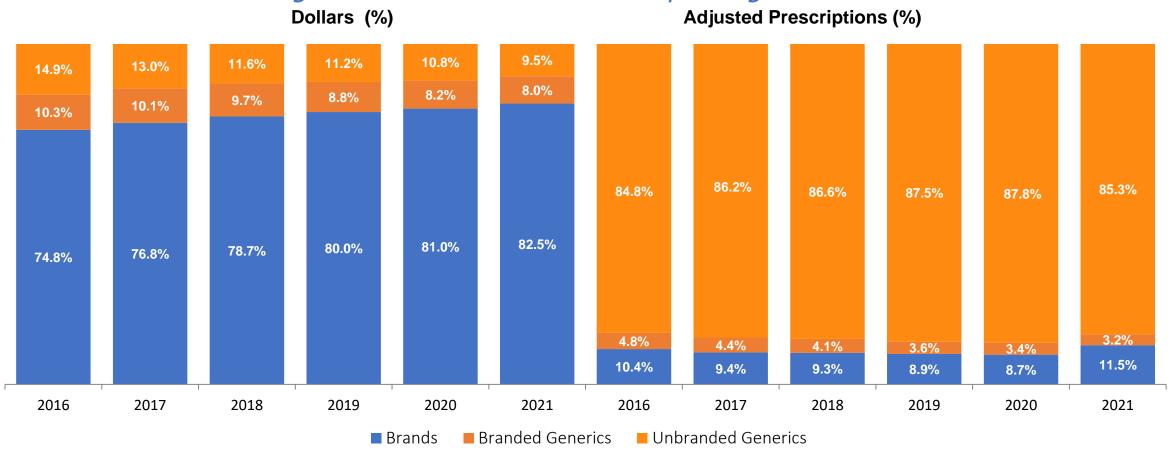






# 85.3% of prescriptions are dispensed as unbranded generics for 2021 (adjusted)

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



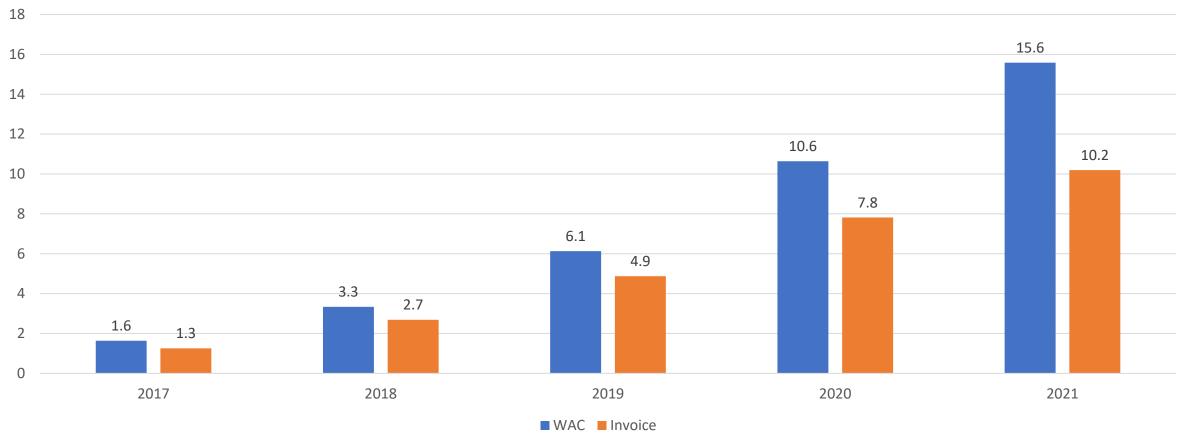
Source: IQVIA, National Sales Perspectives, December 2021

Note: Limited to Rx and OTC Insulins; Includes Retail, Non-Retail and Mail



### U.S. biosimilars have increased dramatically driven by new oncology entrants from 2019

U.S. Biosimilar Sales @ WAC and @ Invoice levels US\$Bn

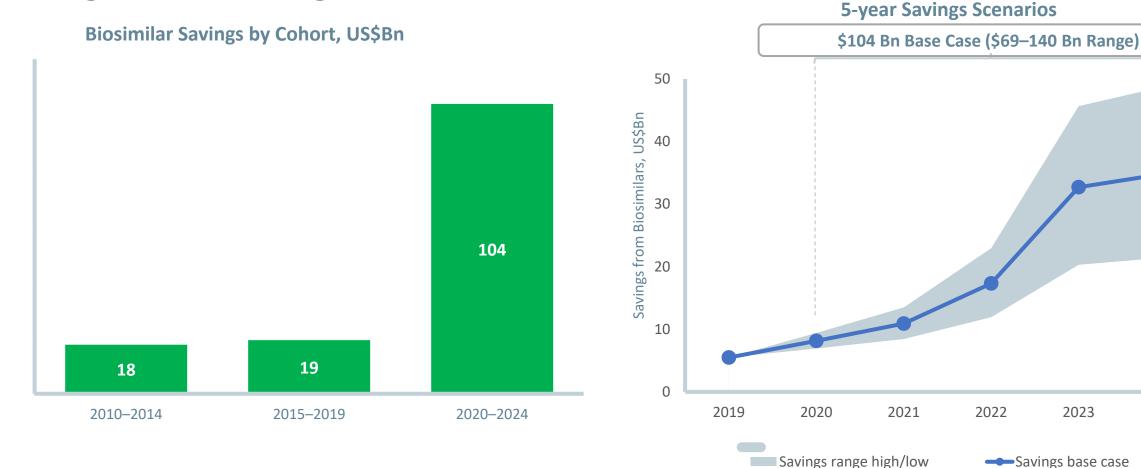


Source: IQVIA NSP Dec 2021



#### 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





2024

2023





Market dynamics have accelerated and are compounding to increase overall complexity while narrowing the path to success



How complex will the market be in 2022 or 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

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

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

Abandonment in specialty:

25%

among Part D patients

9%

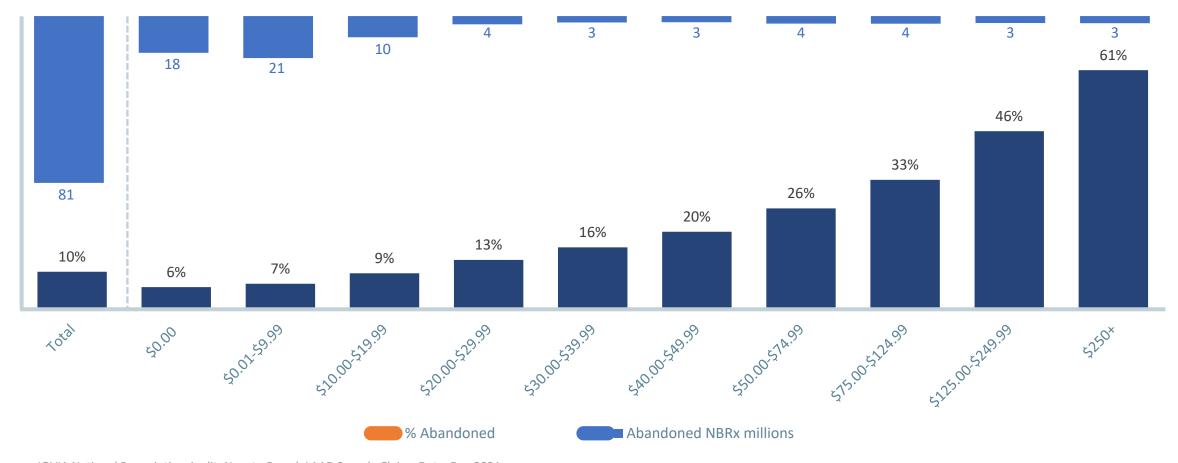
among Commercial patients (co-pay cards permissible)





# Patients starting new therapy abandoned 81Mn prescriptions at pharmacies in 2021 with increasing frequency as costs rise

14-day abandonment share of new-to-product prescriptions by final out-of-pocket cost in 2021, all payers, all products









### In the past decade of launches, did you know that...

#### Launch success is becoming more difficult

In 2021, only 1 in 4 new to brand patients who attempted to fill a launch brand was successful due to payer controls More than half of brands miss their first-year forecast, and among those that miss, only 20% are able to get back on track Recent launch brands have as much as a 40% chance of not reaching \$10M in Year One; <10% reach \$100M in Year One



As many as 70%
of patients on
newly launched
brands are
supported by
patient assistance
programs, at very
high cost to the
manufacturer



Time to positive investment is delayed

MARKET COMPLEXITY
IS COMPOUNDING &
ACCELERATING



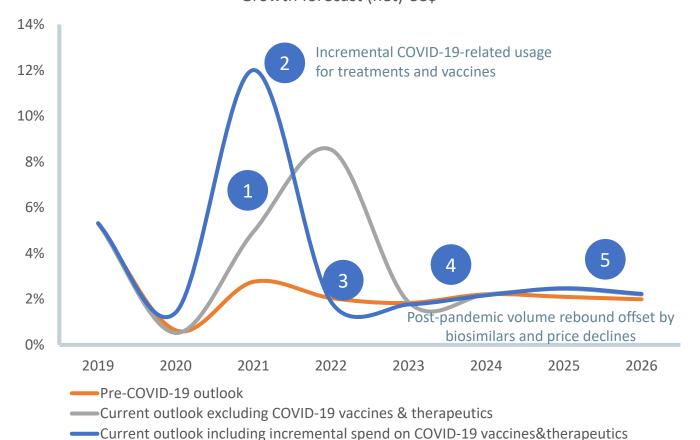
Readiness is KEY—regardless of drug profile, these forces complicate launch success





### U.S. market growth will return to pre-pandemic projections by 2023 despite year-to-year fluctuations

Comparison of current outlook to pre-COVID-19 outlook
Growth forecast (net) US\$



#### **Key changes in the outlook**

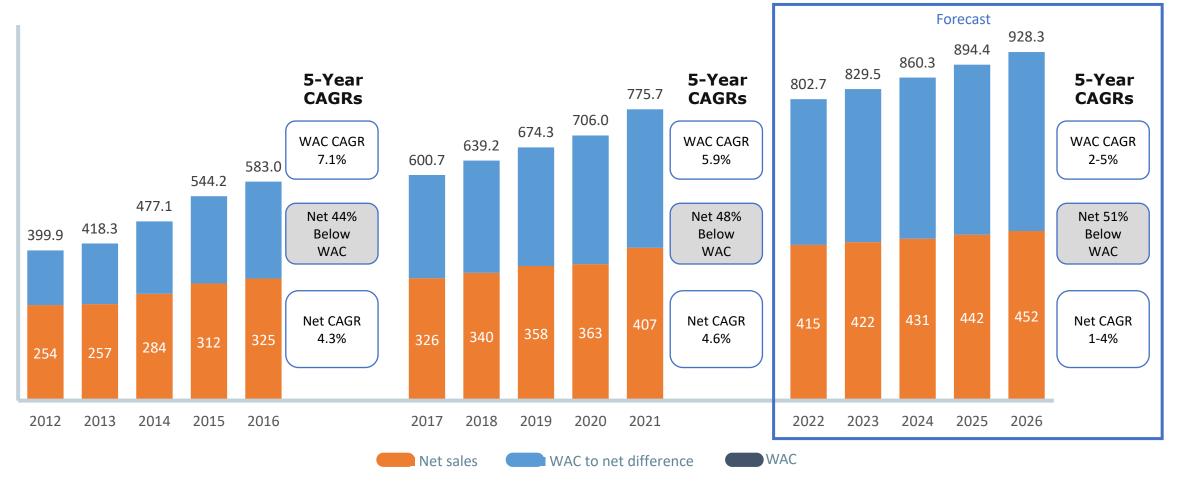
- 2021: 2.1% above pre-COVID-19 growth; 4.4% above 2020 growth as volume returns
- 2 2021 including COVID-19 vaccines and therapeutics +12% growth, higher than the 4.9% excluding vaccines and therapeutics due to ~\$29 billion of vaccine and therapeutic spending
- 3 Vaccine and therapeutic spending declines in 2022 as only boosters and limited numbers of infections drive usage
- 4 COVID-19 vaccine boosters and use of therapeutics represent \$4-5 billion per year 2023 to 2026.
- Rates of infection decline in the endemic phase, followed by overall growth returning to expected levels





# The U.S. spending forecast reflects an increasing gap between invoice level spending and manufacturer net revenues

U.S. medicine spending and growth at WAC and estimated net 2012-2026







### Net price growth for protected brands is forecast to be 0 to -3% through 2026

Protected brand invoice and net price growth



Estimated brand net price growth %

Brands WAC price growth %





# The impact of exclusivity losses will drop to \$56Bn over five years including significant biosimilars impact through the period

U.S. impact of brand losses of exclusivity 2017-2026, US\$Bn

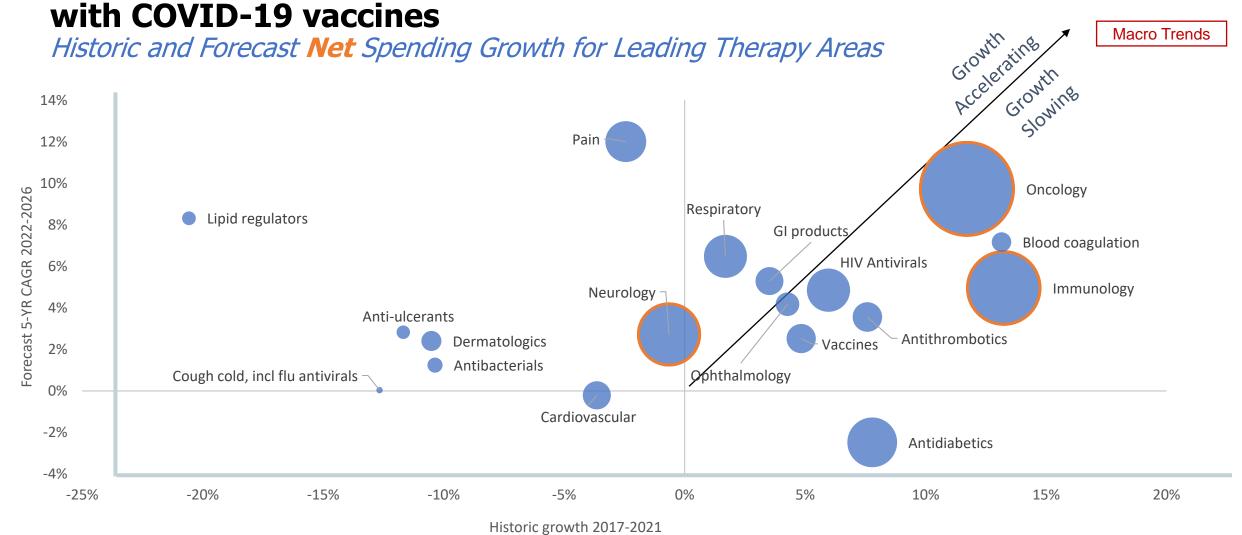








Immunology, oncology, neurology drive growth through 2026 along

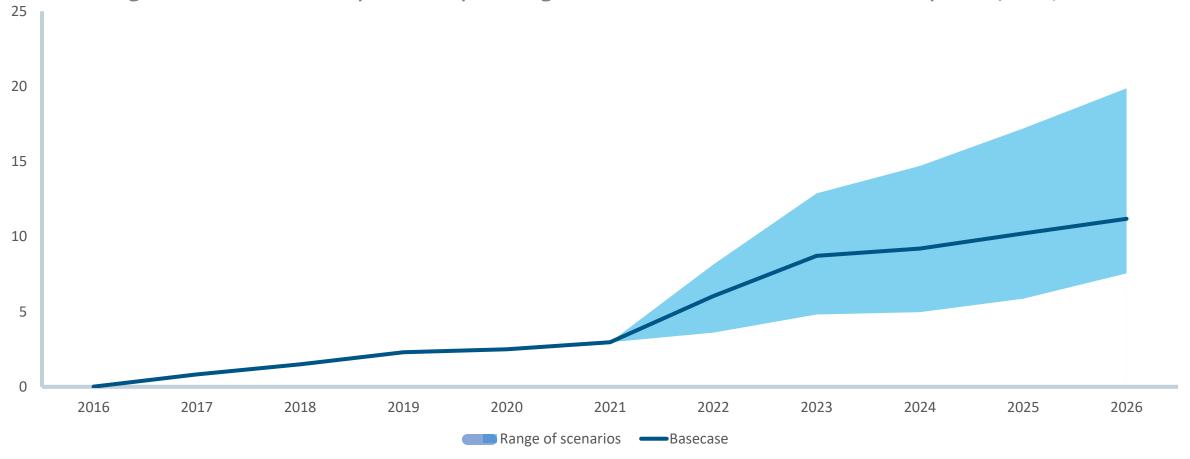


Source: IQVIA Institute, Mar 2022



# Next-generation biotherapeutics to reach \$11Bn by 2026 up from \$3Bn in 2021, with a wide range of potential scenarios

U.S. next-generation biotherapeutics spending at estimated net manufacturer prices, US\$Bn







insight

Data

Cleaning

#### **IQVIA** is Enabling the Healthcare Ecosystem to Advance Health

Convening stakeholders to connect intelligence and to change healthcare

Situation Healthcare Ranked 5 out of **10 Industry adoption of Al** Reason for lack of adoption workflow disruption Current effort and spend is **upside down** Analysis, 20%

80%

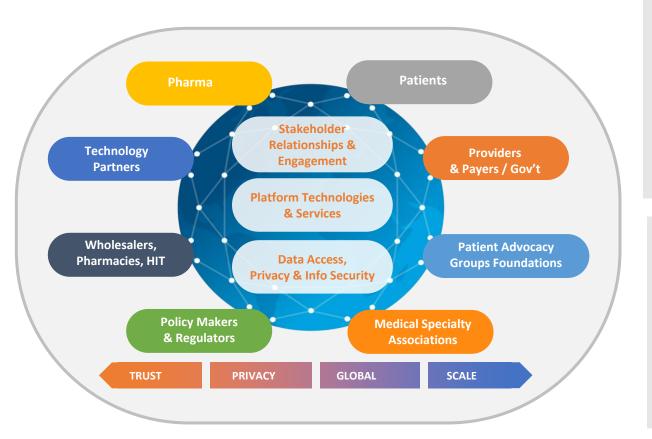
Effort

80%

20%

Value





Enabling the Advancement of Health

Improve health outcomes for patients and disease populations

health and economic sustainability of healthcare systems





#### **Improving Health Outcomes for Patients and Populations**



Accelerating patient access to research and developing treatments through novel patient outreach

- Increasing patient and physician access to research as a care option
- Expanding direct access to patients to improve trial recruitment
- Leveraging technology for data collection and patient engagement



Leveraging technology and AI for novel patient insights, early disease detection and event prediction

- Using novel technology and connected devices to capture patient insights
- Extending data and insights to proactively direct early care interventions and predict patient response.
- Leveraging technology to understand and predict disease progression and enable disease detection



Expanding patient access to novel therapeutics & scientific advances

- Administering patient financial assistance programs to ensure access and affordability of treatments
- Designing instruments to measure patient endpoints required to target appropriate treatment choices and demonstrate their value



Improving care delivery through support to patients, caregivers and communities

- Delivering patient support programs to improve quality, and adherence to care options
- Educating patients and HCPs with specialist nurse educators
- Managing safety reporting to support the appropriate use of medicines





### **Ensuring Population Health and Economic Sustainability of Healthcare Systems**



### Identifying and increasing the use of high-value medical interventions

- Benchmarking to measure and improve quality of care
- Supporting targeted disease management programs for high risk and chronic care patients
- Validating the impact of devices and diagnostics in identifying and directing optimal treatment options



# Harnessing digital and tech capabilities to increase operational efficiency and improve decision making

- Implementing technology to track healthcare provision, to improve monitoring, and delivery effectiveness
- Increasing connectivity across providers and payers to ensure high quality and timely reimbursement



#### Reallocating healthcare resources based on evidence

- Analyzing population care needs to improve service distribution
- Monitoring and informing changes in care practices to track patients' pathway and resource use



#### Supporting governments to improve public health

- Creating national programs and measures to understand and improve population health
- Developing strategies to support capacity building, new care models, gaps in care and resourcing
- Assisting governments with design and roll out of new care and reimbursement policies





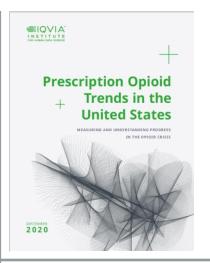
#### The IQVIA Institute produces a number of reports on a regular basis that you might find useful, check them out



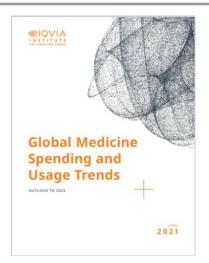
Despite the COVID-19 pandemic having a substantial impact on patient care during 2020, the scientific advances in clinical trial activity, the pipeline of new treatments, and the increased use of available therapeutics, continued largely unaffected and reflect the commitment to advancing care for patients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



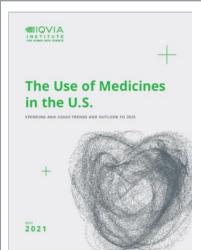
This report examines the trends in pharmaceutical research and development through the end of 2020. It provides an analysis of initiated clinical trials, including the impact of the pandemic and COVID-19-specific research. Research on clinical development productivity is also presented, as well as profiles 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 prepandemic 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: <a href="https://www.iqvia.com/insights/the-iqvia-institute/reports">https://www.iqvia.com/insights/the-iqvia-institute/reports</a>





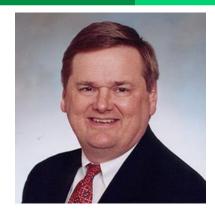
#### Thank you

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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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