

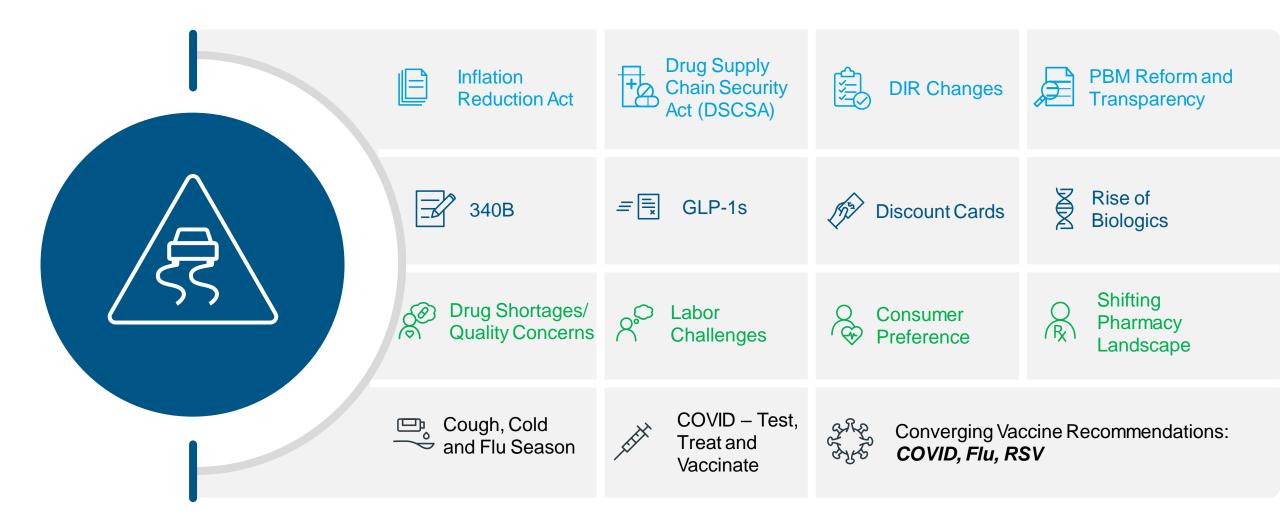
### US Generics & Biosimilars Trends, Issues & Outlook for AAM

Presented by: Doug Long, VP, Industry Relations

February 6, 2024

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#### The challenges facing our industry today are numerous







### Agenda

- + COVID, Flu, RSV, Colds, Etc.
- + Market Trends: Utilization
- + Where are we now?
- + Drug Shortage
- + Generics and Biosimilars
- + Opioids
- + Outlook

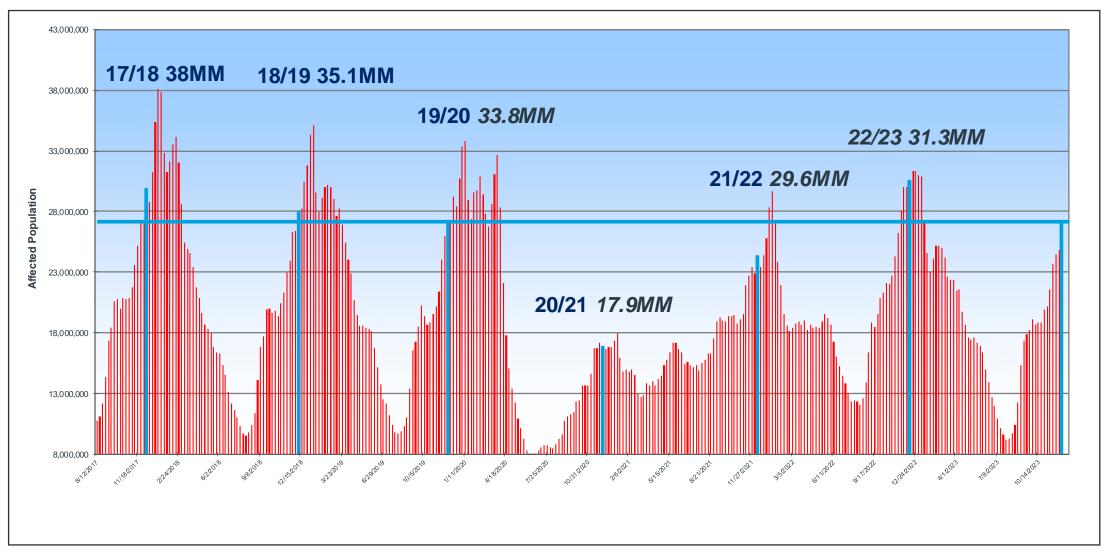




# COVID, Flu, RSV, Colds, Etc.

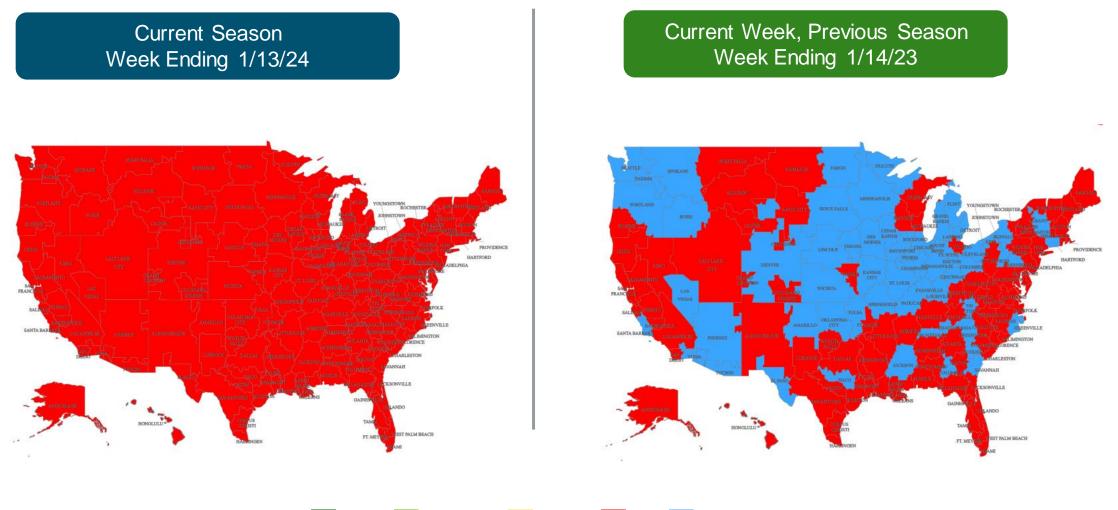
#### FAN Total Affected Population 2017/18 through 2023/24

- Current AP levels are at Q4 2018 and 2019 levels.
- Down Vs YAG -15.3%, mainly driven by flu coming in early last season by two months.



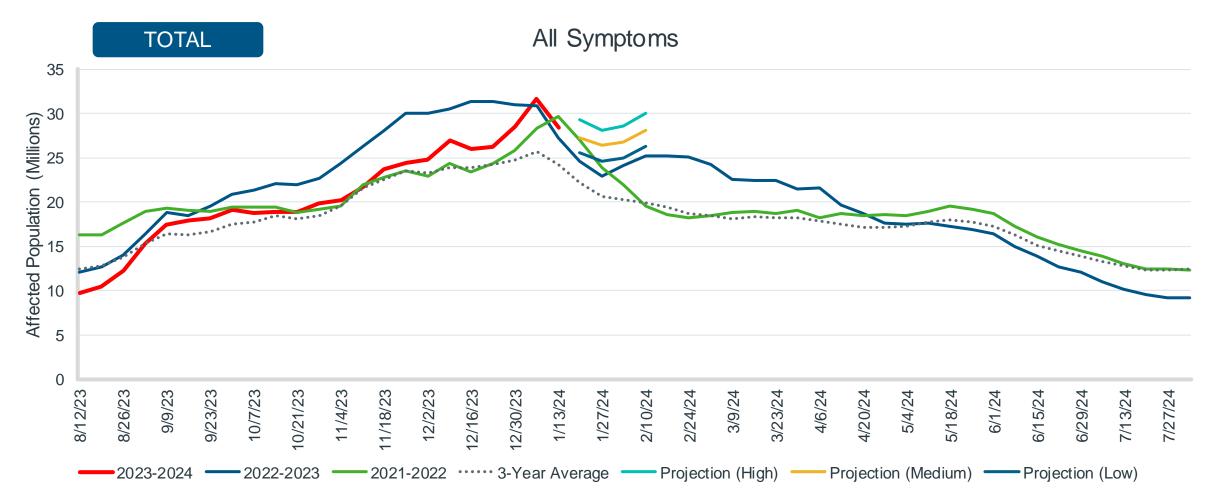


The current week in this season shows "Alert" status for the entire US while this week, previous season, show more a mixture with "Advisory Down"





## All FAN<sup>©</sup> symptoms are projected to run above prior seasons in the next four weeks



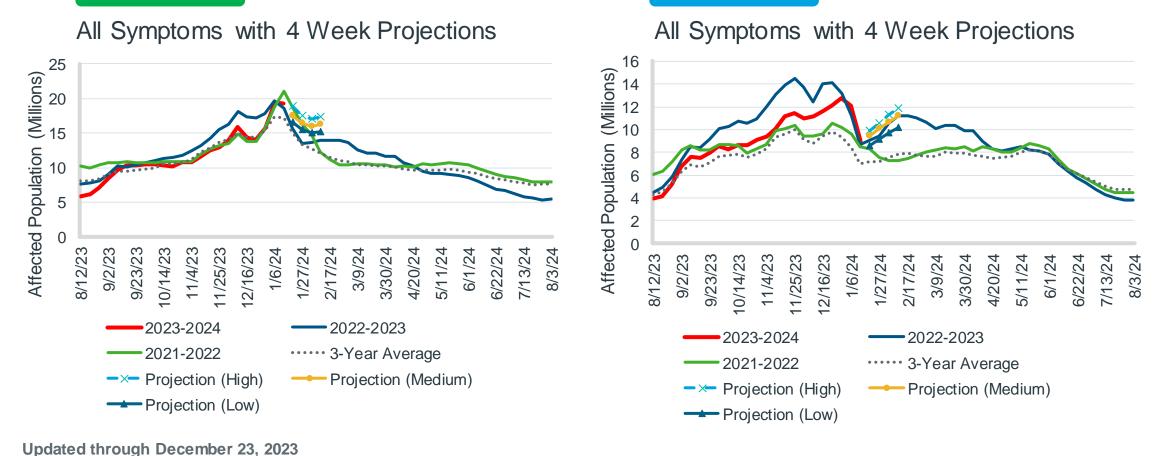
Updated through January 13, 2024



## Adult and pediatric symptoms have run below the 2022-2023 for most of the season but are now increasing

PEDIATRIC

#### ADULT



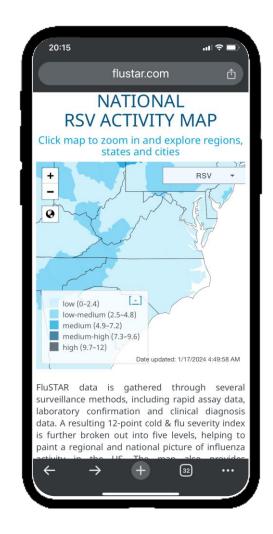
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## Flustar gathers data from surveillance methods and develops a severity index then displays it on a heat map across the U.S.

### IQVIA's Flustar website is available for all at <u>www.flustar.com</u>

FluSTAR data is gathered through several surveillance methods, including rapid assay data, laboratory confirmation and clinical diagnosis data. A resulting 12-point cold & flu severity index is further broken out into five levels, helping to paint a regional and national picture of influenza activity in the US. The map also provides breakouts for each condition on the national and local level and is updated regularly with season progress.

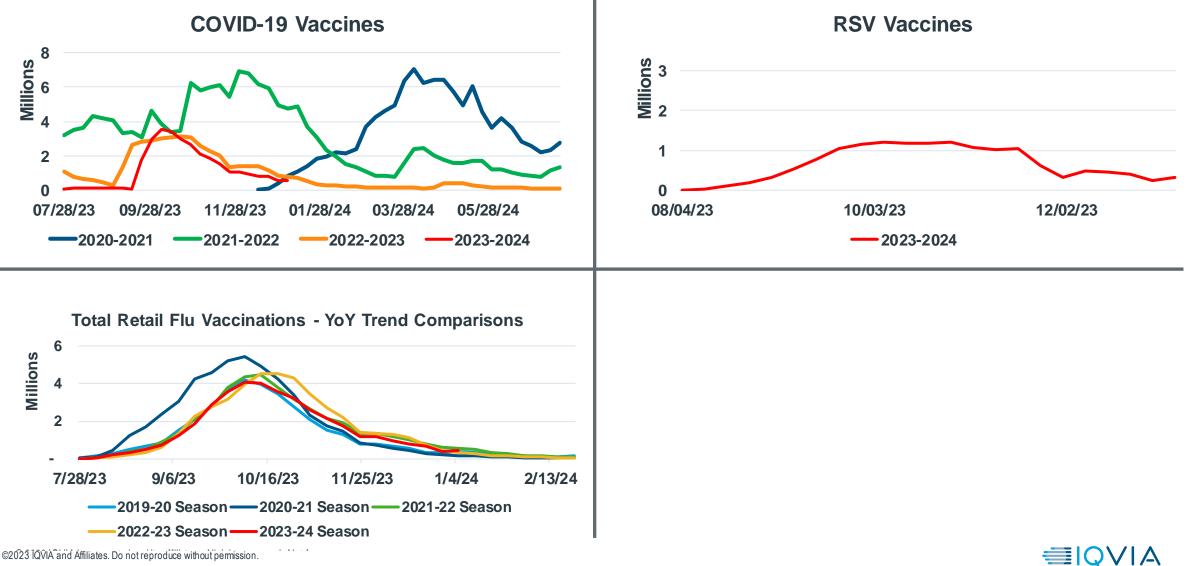


Flustar looks at activity across the U.S. and provide heat maps for the following symptoms:

- Cold & Flu
- Cough
- Strep
- Fever
- Flu
- COVID
- RSV



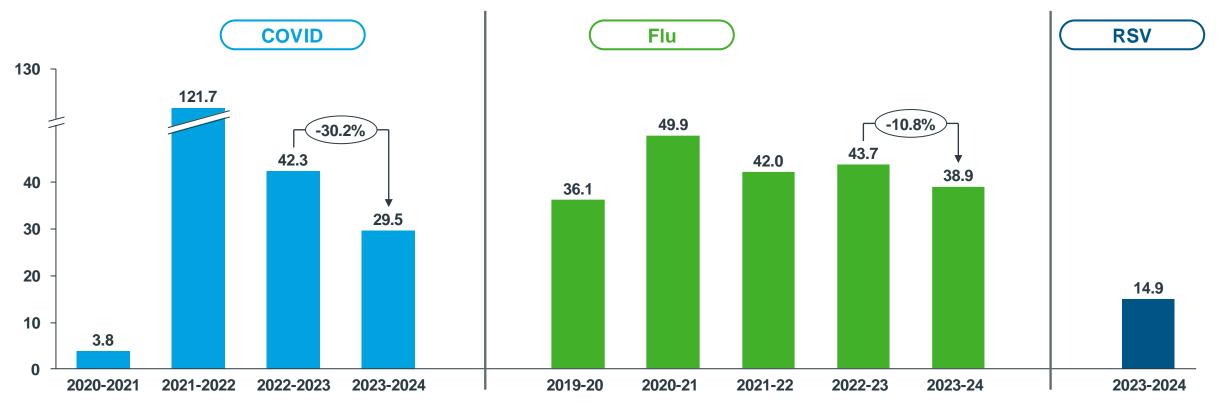
#### **COVID-19 and Flu Vaccines are lower this season than prior** seasons; RSV Vaccines are new this season





## COVID and Flu vaccines at Retail are down on a year over year basis

Season to Date Vaccine Volumes at Retail

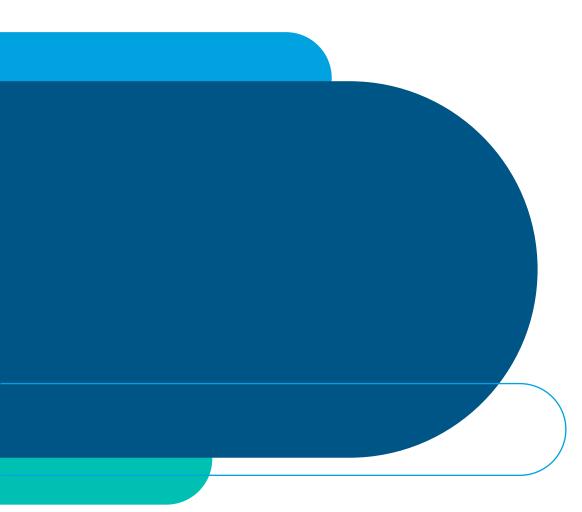


• Season to Date is defined as July 28, 2023, through January 19, 2024

• Data represents vaccinations done at retail and processed through the pharmacy's dispensing system







### Market Trends: Utilization

# The Health Services Utilization Index indicates the U.S. is operating at pre-COVID-19 levels with shifts in utilization

**Overview of Health Services Utilization Index** 



Source: IQVIA Institute; IQVIA Medical Claims Data; LAAD Prescription data, week ending 12/30/2022. The Use of Medicines in the U.S. 2023: Usage and Spending Trends and Outlook to 2027. Report by the IQVIA Institute for Human Data Science. ©2023 IQVIA and Affiliates. Do not reproduce without permission.





#### Antibiotic Use and Rising Antimicrobial Resistance

- 2.4Bn antibiotic days of therapy in 2022 down 7% from pre-pandemic
- use in children and older adults up
  8% in Q4 2022 from historic seasonal levels
- ADHD medicine use grew 11% over the last 5 years to over 3Bn days of therapy in 2022
- Women aged 20–64 now account for 33% of prescriptions, up from 27% in 2018

Stimulant Use and Related Shortages



*Mental Health in Young People* 

- Mental health prescriptions reached 567Mn in 2022 up 9% since 2019
- Mental health prescriptions in girls under 19 up 33% since pre-pandemic to 17Mn in 2022



Source: IQVIA Institute, Apr 2023

 Over 500k GLP-1 agonist new prescriptions across diabetes and obesity in February 2023, up 152% compared to prior year

> **Combatting the Opioid Overdose Epidemic**

Rising Use of Novel Obesity Drugs

- Per capita prescription opioid use
  down 64% since the peak in 2011
- Opioid overdose deaths up 253% since 2011

- Contraception use down 6% in 2022 with 100Mn fewer days of therapy
- Lower use of long-acting birth control, such as IUDs and injectables

*Concerning Gaps in Women's Health* 



Source: IQVIA Institute, Apr 2023



### Where are we now?

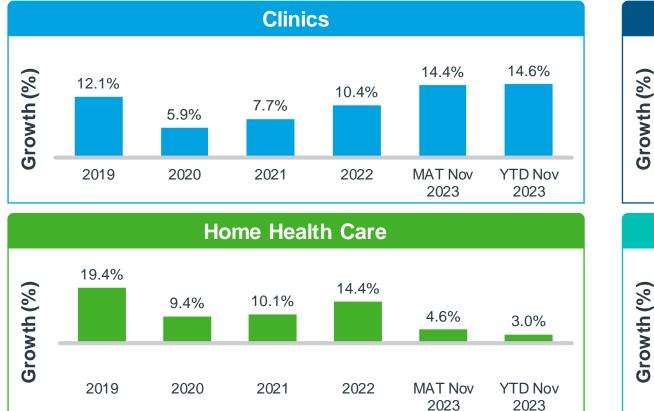
### Retail, Mail, and Non-Retail show double-digit growth

#### **Total Market Retail and Mail Non-Retail** (Retail, Non-Retail and Mail) 13.0% 13.3% 14.3% 14.5% 10.7% 10.1% 10.3% 9.4% Growth (%) Growth (%) 7.7% Growth (%) 8.0% 7.5% 7.1% 5.8% 6.5% 5.4% 5.0% 4.3% 1.8% 2019 2020 2021 2022 MAT YTD 2020 2021 2022 MAT 2019 YTD 2020 2019 2021 2022 MAT YTD Nov Nov Nov Nov Nov Nov 2023 2023 2023 2023 2023 2023

Growth (%) of Sales

Source: IQVIA, National Sales Perspectives, November 2023 Note: Limited to Rx and OTC Insulins; Includes Retail, Non-Retail and Mail

#### **COVID-19** has affected Hospital sales more than other Non-Retail



#### Growth (%) of Sales

2.0%



**Hospitals** 

7.7%

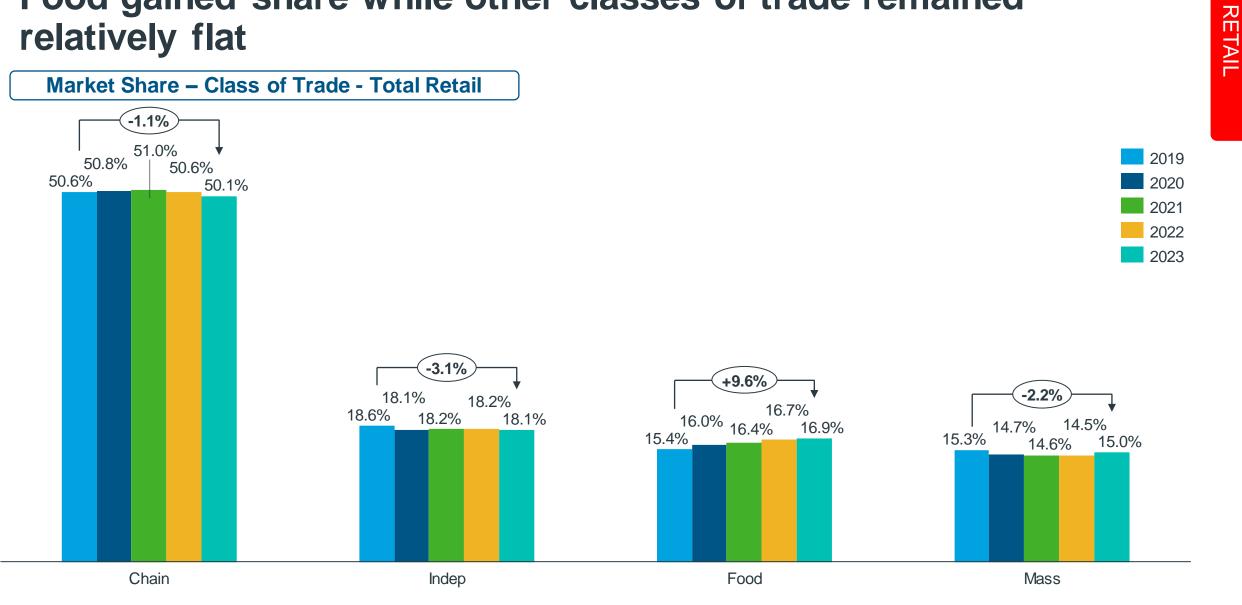
Source: IQVIA, National Sales Perspectives, November 2023 Note: Limited to Rx and OTC Insulins; Includes Retail, Non-Retail and Mail

17

-0.4%

-1.2%

#### Food gained share while other classes of trade remained relatively flat

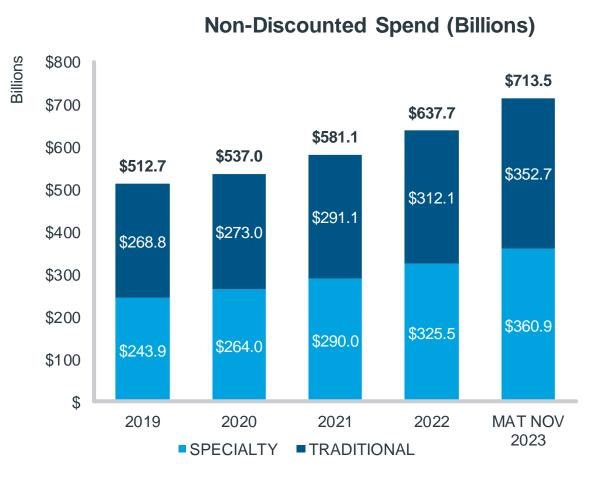


Data is based on calendar quarters, Q3 of each year Adjusted Rx's ©2023 IQVIA and Affiliates. Do not reproduce without permission.

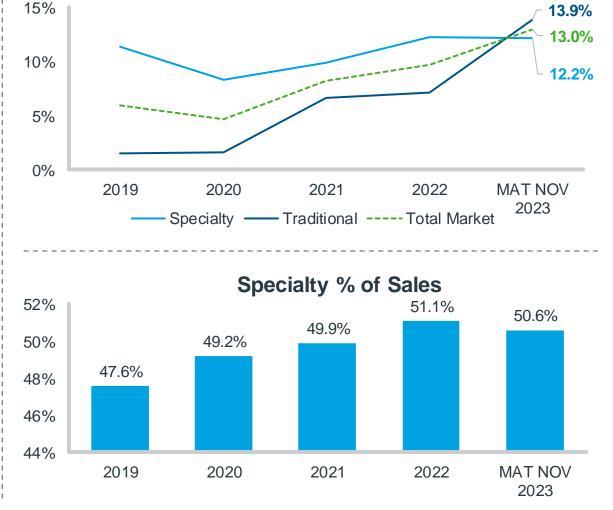


## For the total market, specialty growth at 12.2% is weaker than traditional growth at 19.9% for MAT Nov 2023

In MAT November 2023, specialty spend grew by 12.2% while traditional growth grew 13.9%



Source: IQVIA, National Sales Perspectives, November 2023



### **IQVIA** Definition of a Specialty Drug

Specialty drugs at IQVIA are classified as products that meet the following criteria



Treats chronic, rare and/or complex diseases



Expensive (USD \$6K annual cost of therapy)



Initiated and maintained by a specialist



Generally injectable and/or not self-administered



Unique distribution



Requires extensive or in-depth monitoring/patient counseling

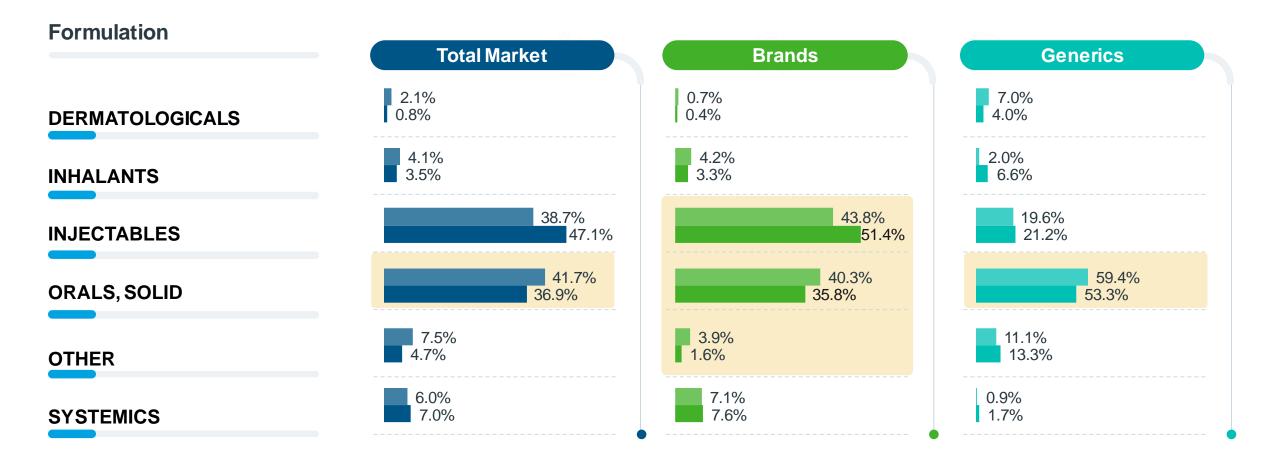


Products that require an additional level of care in their chain of custody



Requires reimbursement assistance

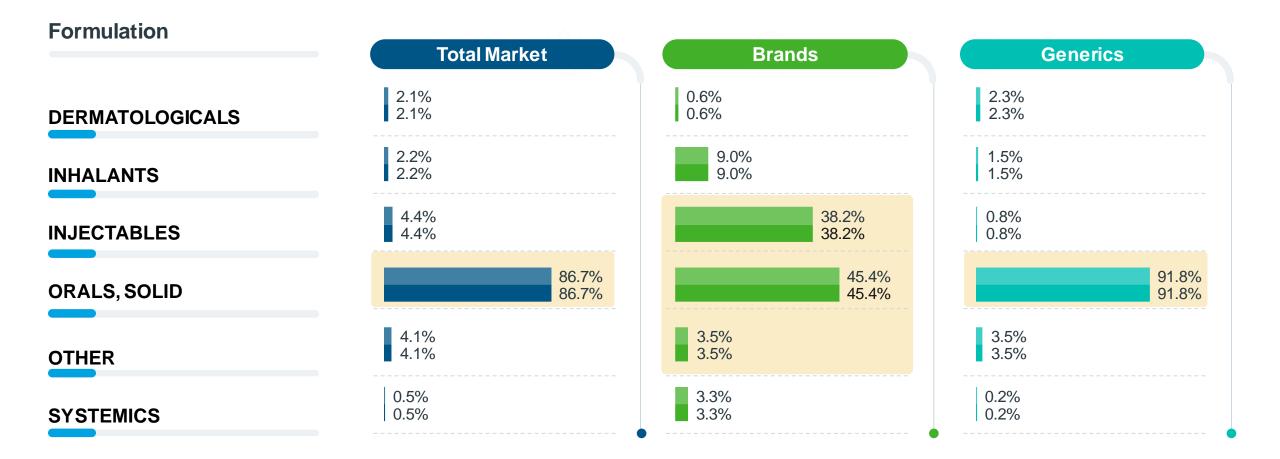
### Brand Injectables account for 47.1% of total market sales in 2023



<-1% difference



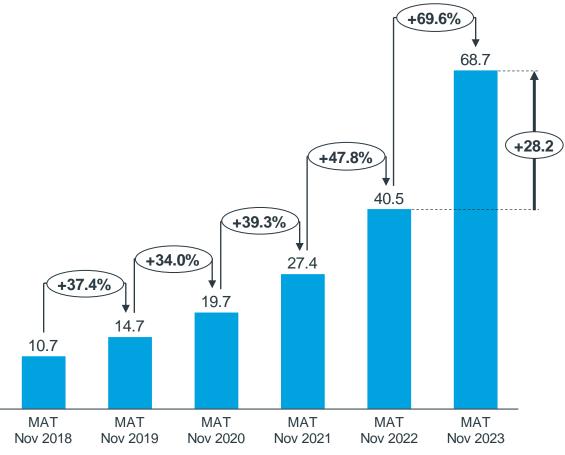
### Orals, Solid account for 86.7% of total market adjusted scripts and 91.9% of unbranded generic adjusted scripts for MAT DEC 2023





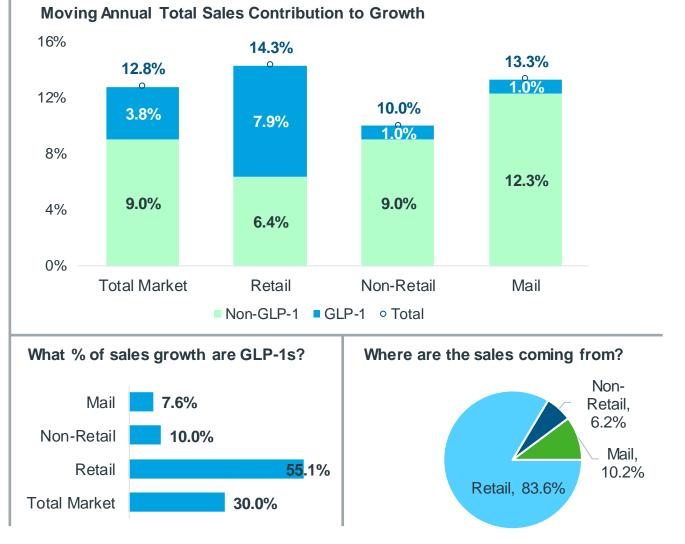
### GLP1s drugs have grown ~70% over the last 12 months and ~84% of the sales are in Retail

Moving Annual Total GLP-1 Sales Dollars (Billions)





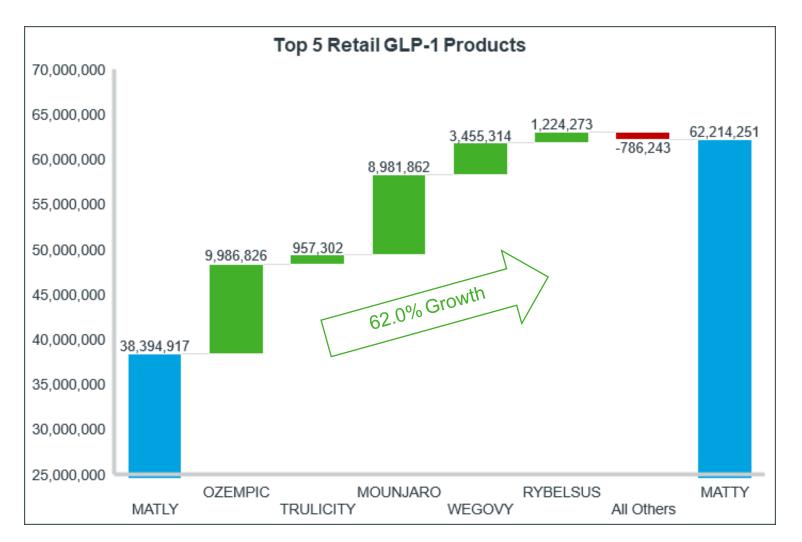
Updated with November 2023 Data



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#### **Retail Only**

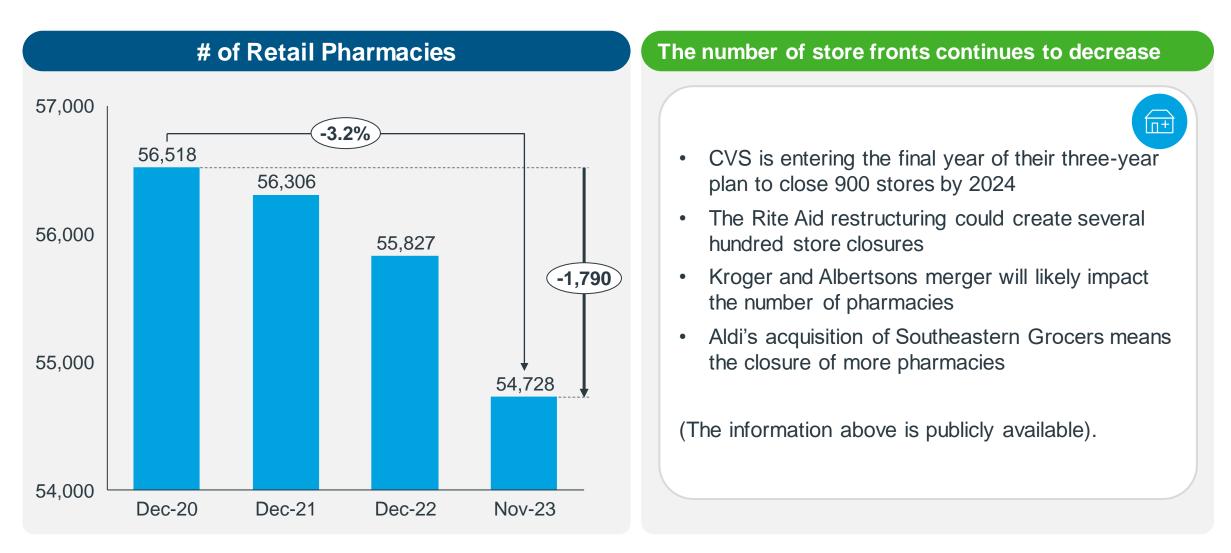
## Ozempic and Mounjaro\* drove most of the volume growth among GLP-1s



- The Retail sector grew 62.0%, over 23.8M adjusted prescriptions year over year
- All Others combined saw decline

Product	MATTY Adj. Rx's
OZEMPIC	23,969,872
TRULICITY	15,700,257
MOUNJARO	10,692,340
WEGOVY	4,391,466
RYBELSUS	3,910,841
All Others	3,549,475

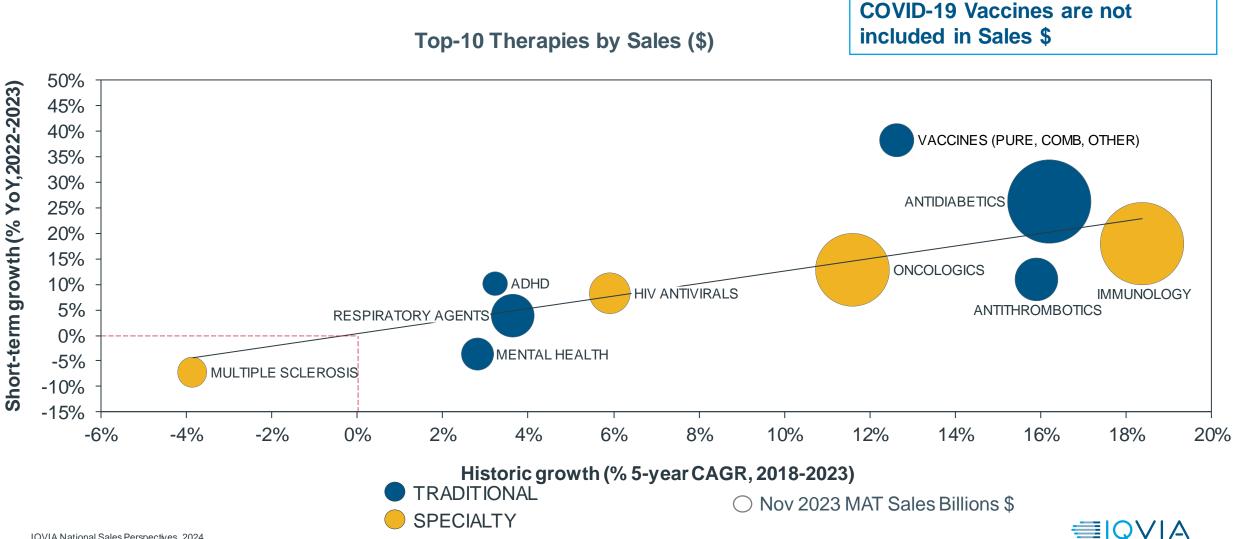
### There are ~1,800 fewer pharmacies since December 2020





#### Immunology and Antidiabetics lead long-term growth

Vaccines lead short-term growth



#### On a Units basis, Antibacterials leads short-term growth and Antidiabetics leads long-term growth

#### 20% Short-term growth (% YoY,2022-2023) 15% ANTIBACTERIALS 10% 5% **ANTIDIABETICS** ANTIHYPERTENSIVES, PLAIN & COMBO **GI PRODUCTS** 0% DERMATOLOGICS PAIN -5% MENTAL HEALTH **RESPIRATORY AGENTS** COUGH COLD, INCL FLU ANTIVIRALS -10% **BLOOD COAGULATION** -15% 2% -6% -4% -2% 0% 4% Historic growth (% 5-year CAGR, 2018-2023)

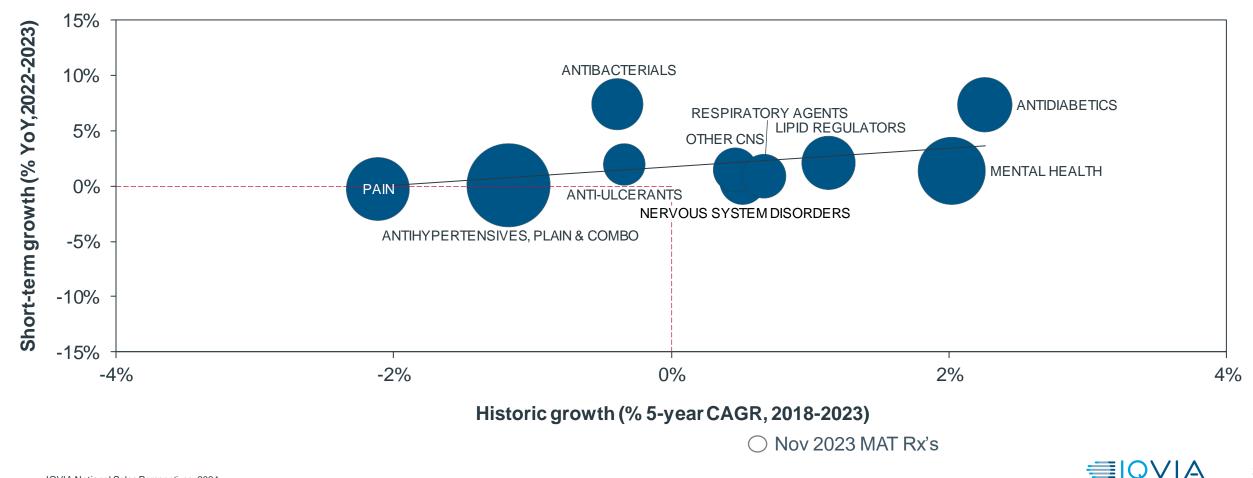
#### **Top-10 Therapies by Units**

○ Nov 2023 MAT Units

#### Antidiabetics and Mental Health lead long-term growth while Antibacterials lead short-term growth

Traditional therapies command the Top 10 therapies by prescription

#### Top-10 Therapies by Rx's





### **Drug Shortages**

#### Not all drug shortages are created equal

Drug shortages are large and increasing; fewer are being resolved Some of the impact of injectable shortages is driven by demand, where some purchasers have increased orders to buffer the expected disruptions.

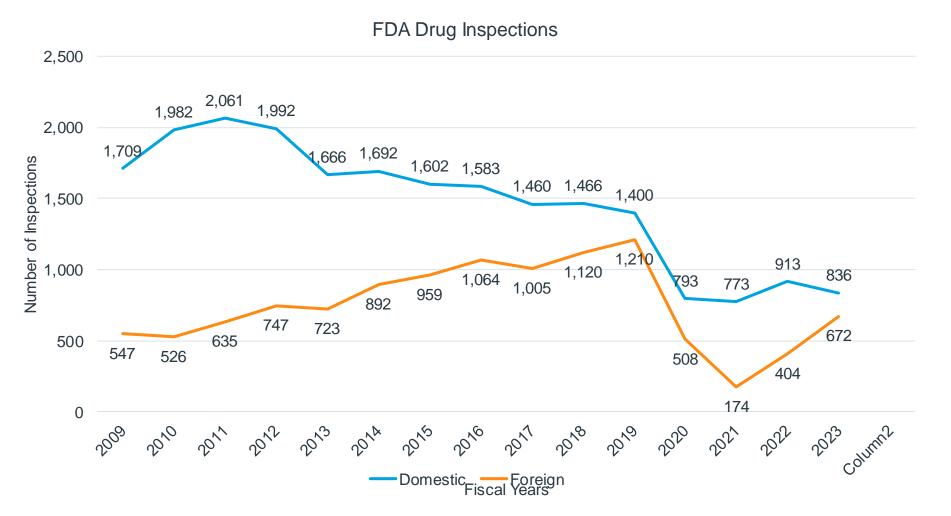
Not all purchasers are able to pursue these approaches and shortages have impacted some differently than others. There are **more shortages in generics** and **injectables; Orals** and **brand** shortages are due to demand. Key drugs in shortage include cancer medications **cisplatin** and **carboplatin**; a form of the antibiotic **amoxicillin**; **Ozempic**, **Mounjaro** and **Trulicity**; as well as **Adderall**.

**Supply issues** within the **sterile injectables** include the impacts of dynamic market shifts between manufacturers from **production disruption** (e.g., due to inspection, shortage of active ingredient, natural disasters) which have impacted oncology and antibacterials.

Sources: Michael Kleinrock, IQVIA Institute, Drug shortages shine spotlight on FDA powers! The Hill



## FDA's inspections of pharmaceutical manufacturing facilities have yet to return to pre-COVID levels

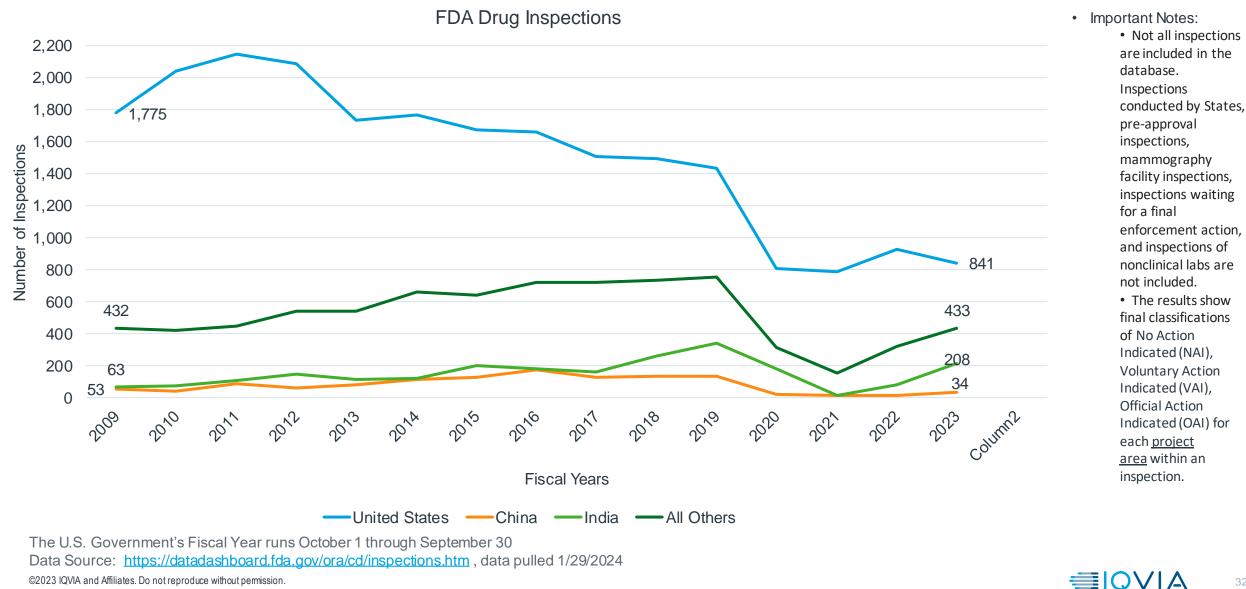


The U.S. Government's Fiscal Year runs October 1 through September 30 Data Source: <u>https://datadashboard.fda.gov/ora/cd/inspections.htm</u>, data pulled 1/29/2024

- Important Notes:
  - Not all inspections are included in the database. Inspections conducted by States, pre-approval inspections, mammography facility inspections, inspections waiting for a final enforcement action, and inspections of nonclinical labs are not included.
  - The results show final classifications of No Action Indicated (NAI), Voluntary Action Indicated (VAI), Official Action Indicated (OAI) for each <u>project area</u> within an inspection.



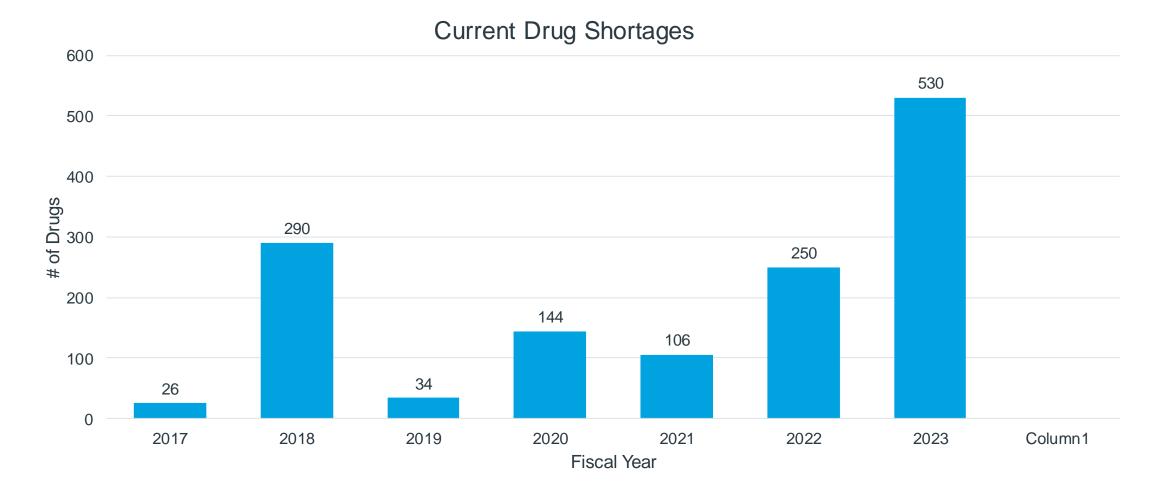
#### Inspections of pharmaceutical manufacturing facilities have increased in India and other foreign countries in the last 2 years



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## The number of drugs listed in the FDA Drug Shortages data set continues to remain high

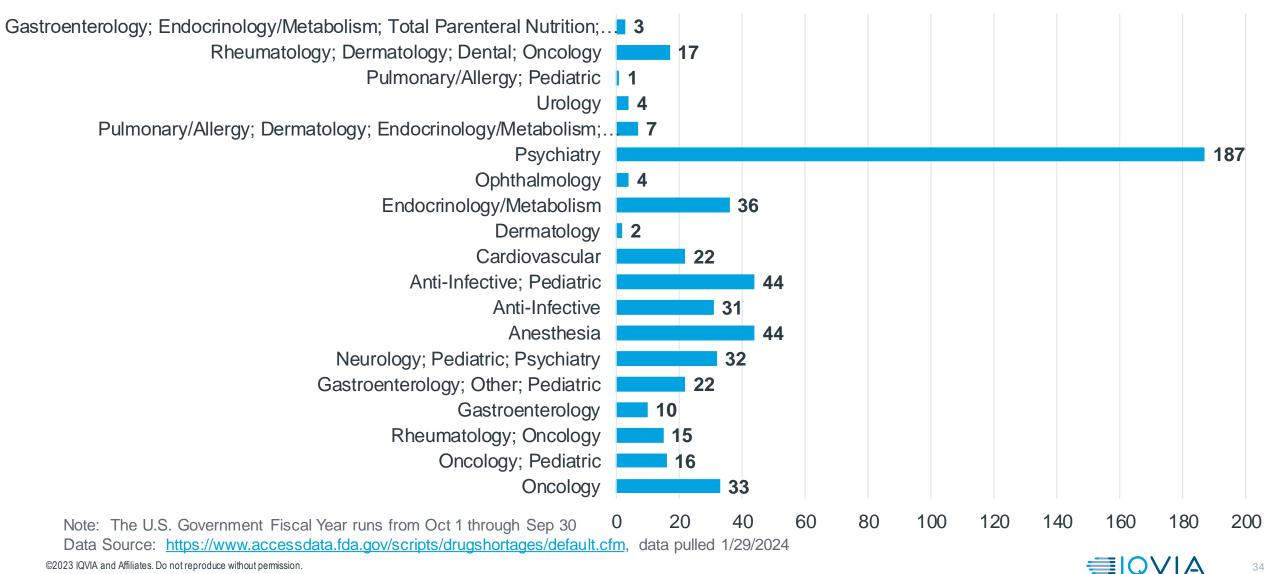


Note: The U.S. Government Fiscal Year runs from Oct 1 through Sep 30 (This slide depicts only three months of the fiscal year for 2024) Data Source: <u>https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm</u>, data pulled 1/29/2024 ©2023 IQVIA and Affiliates. Do not reproduce without pemission.

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#### Psychiatry drugs have the greatest number of shortages according to the FDA

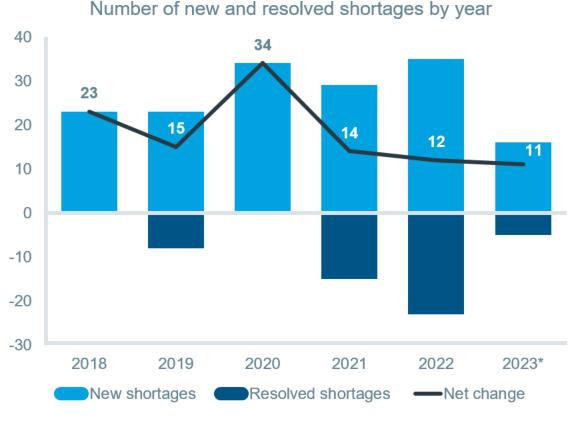
Drug Shortages by Therapy Area Fiscal Year 2023

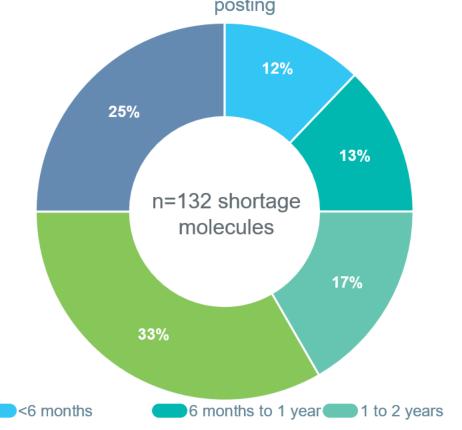


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# More shortages continue to be reported than resolved with 58% of current shortages ongoing for more than two years

Net shortage increase by year and time since first posting of current shortages





5+ years

2 to 5 years

Current shortages as of Jun 2023 by time since first posting

\*2023 is through June

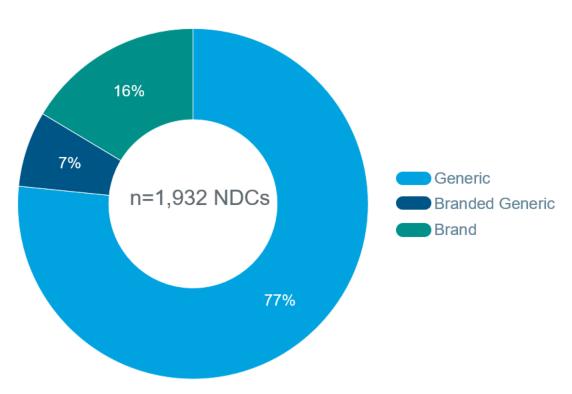
Source: FDA Drug Shortages Database, IQVIA National Sales Perspective, Jun 2023; IQVIA Institute, Oct 2023.

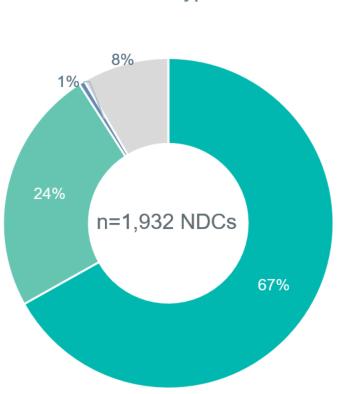


# 84% of the drugs in shortage in the last six years are generics, 67% injectables, and 24% orals

FDA shortages by product type and form, 2017–Jun 2023

#### Product type





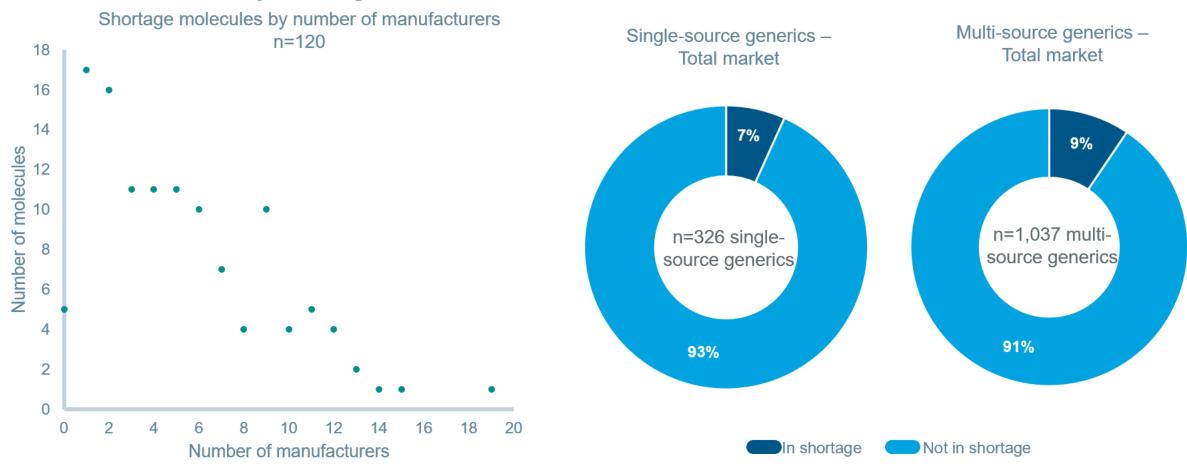
#### Form type

- Injectables
- Orals
- Dermatologicals
- Others



# Multi-source generic molecules are more likely to be in shortage than single-source molecules

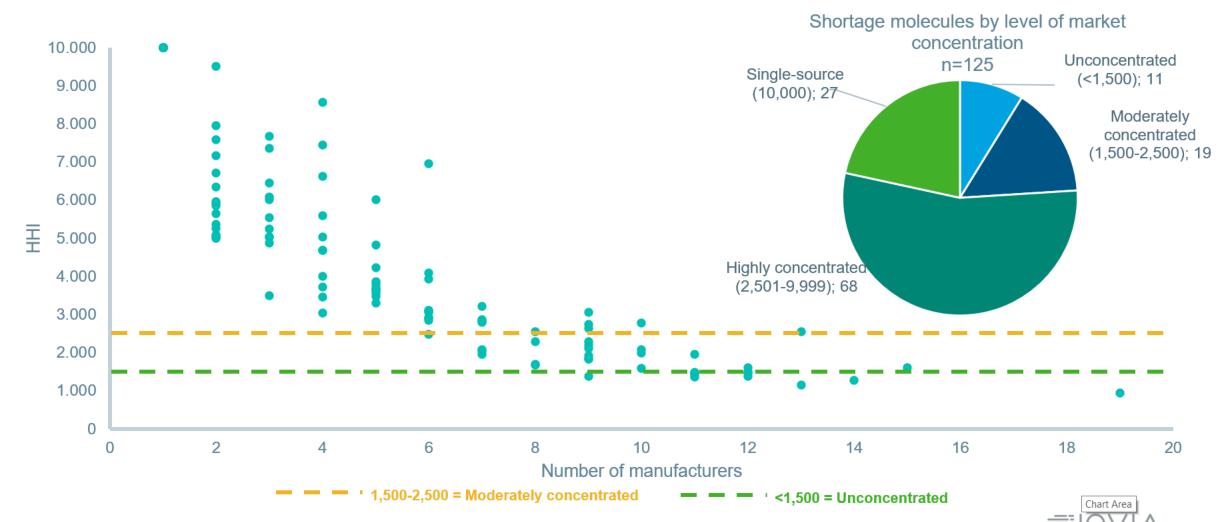
Generic molecules by shortage status and number of manufacturers, Jan–Jun 2023





# Most molecules with shortages are multi-source but remain highly concentrated, impacting resilience to shortages

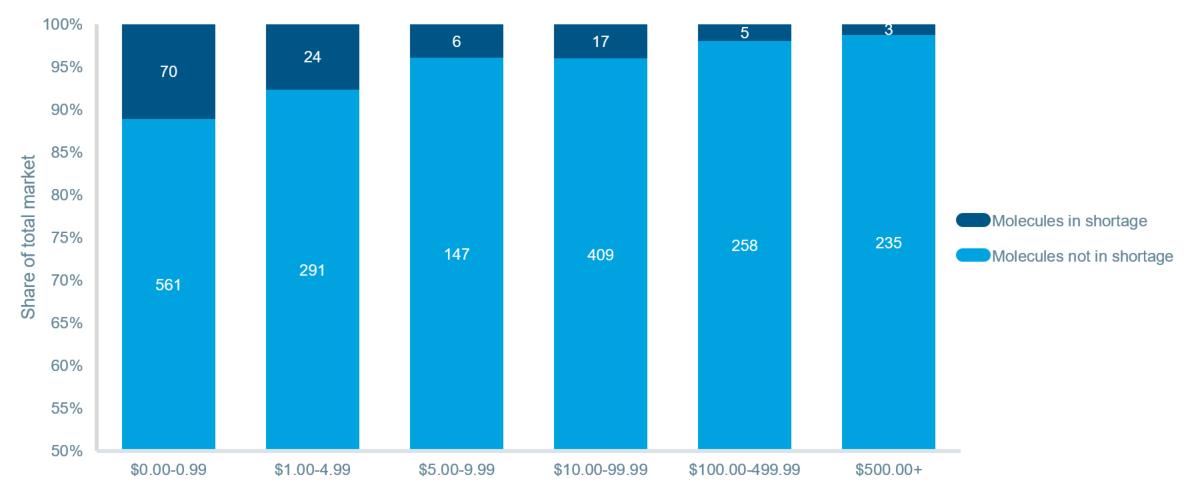
Shortage molecule Herfindahl-Hirschman Index (HHI) and number of companies, Jan–Jun 2023



Source: FDA Drug Shortages Database, Jun 2023; IQVIA National Sales Perspective, Jul 2023; IQVIA Institute, Jul 2023.

# Shortages are more common at lower prices with 56% of molecules in shortage priced less than \$1.00 per unit

Average invoice price per extended unit of molecules, Jan–Jun 2023, n=2,026

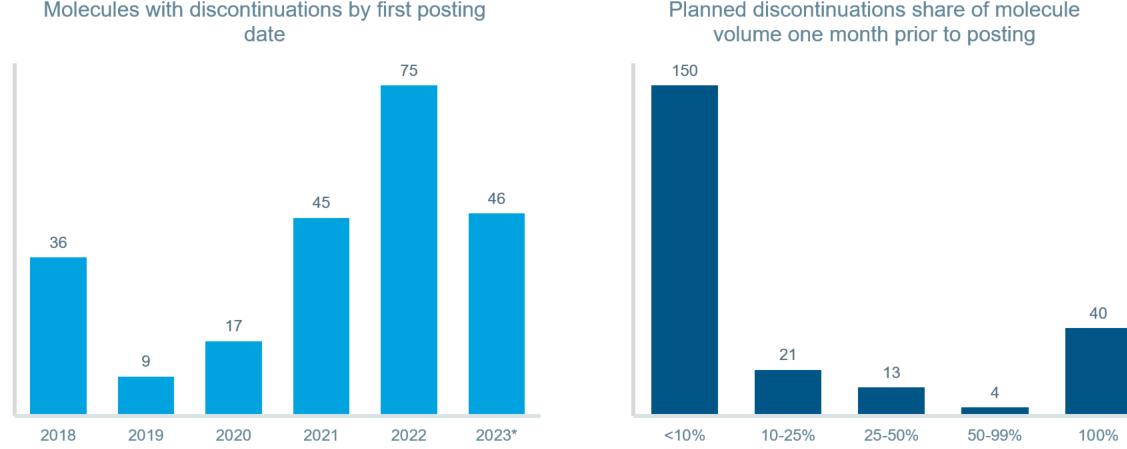


Source: FDA Drug Shortages Database, Jun 2023; IQVIA National Sales Perspective, Jul 2023; IQVIA Institute, Jul 2023.



# Planned pack discontinuations rarely lead to shortages, but market exit can disrupt other participants and affect resilience

Planned discontinuations by first posting date and volume share prior to posting



\*2023 is through June

Source: FDA Drug Shortages Database, IQVIA National Sales Perspective, Jun 2023; IQVIA Institute, Oct 2023.



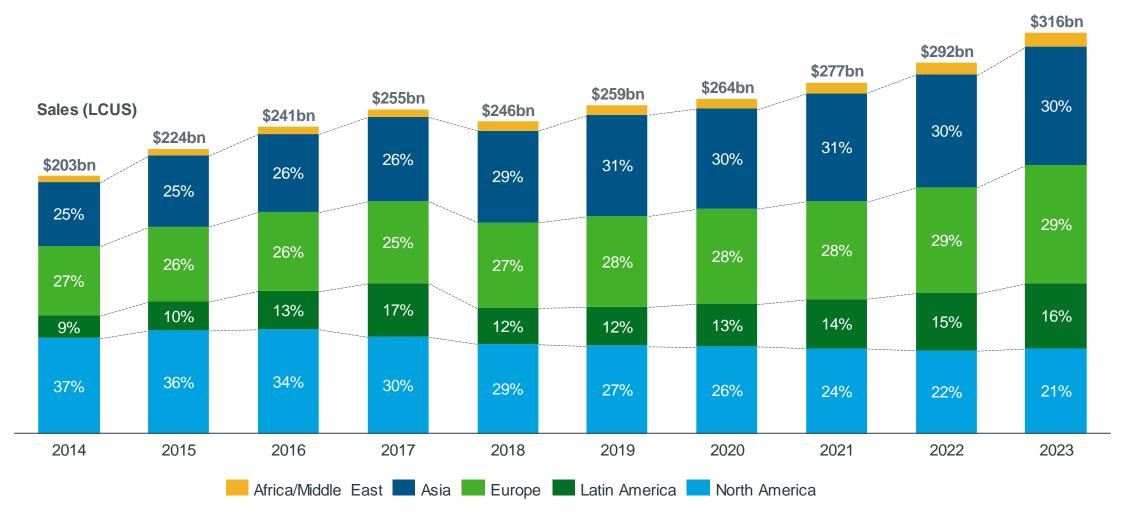


### **Generics and Biosimilars**



### Global generic sales continued to grow in 2023

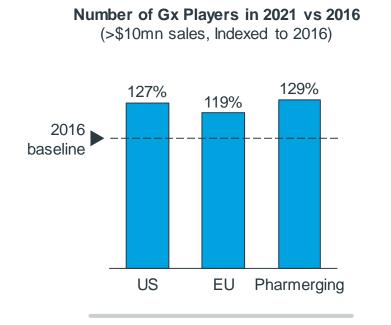
Latin America continues to record YoY growth, driving growth worldwide



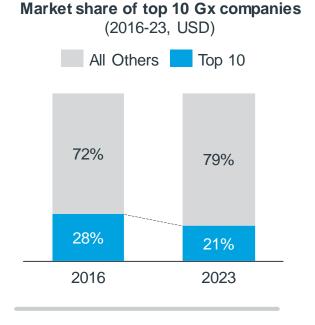


### Increasing competition has pressured the generics market

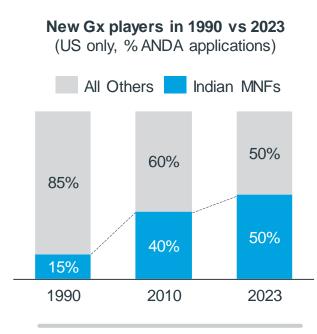
New players have reduced the top 10 companies market share (globally)



- Rapid increase in competition in the US and Europe is driving fragmentation
- Manufacturers seek growth in Pharmerging



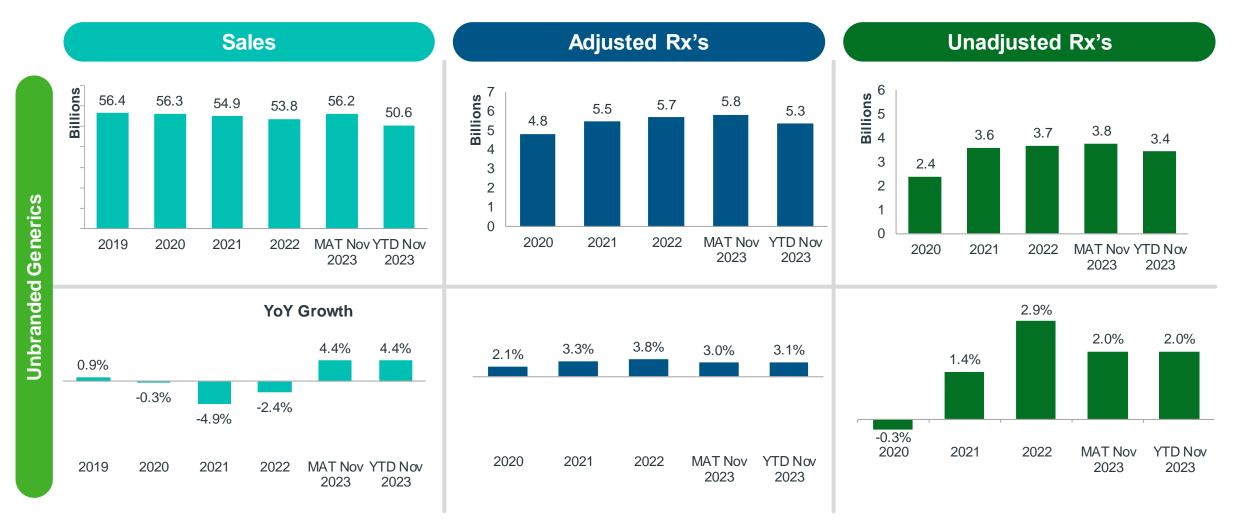
- Rapid rise of competition has eroded share from top 10
- The Gx sector is increasingly fragmented



- In 1990, ~50% of ANDAs came from U.S. firms and 15%, from India
- Indian players continue to compete for market share



### **Unbranded Generics sales and Rx's are positive**

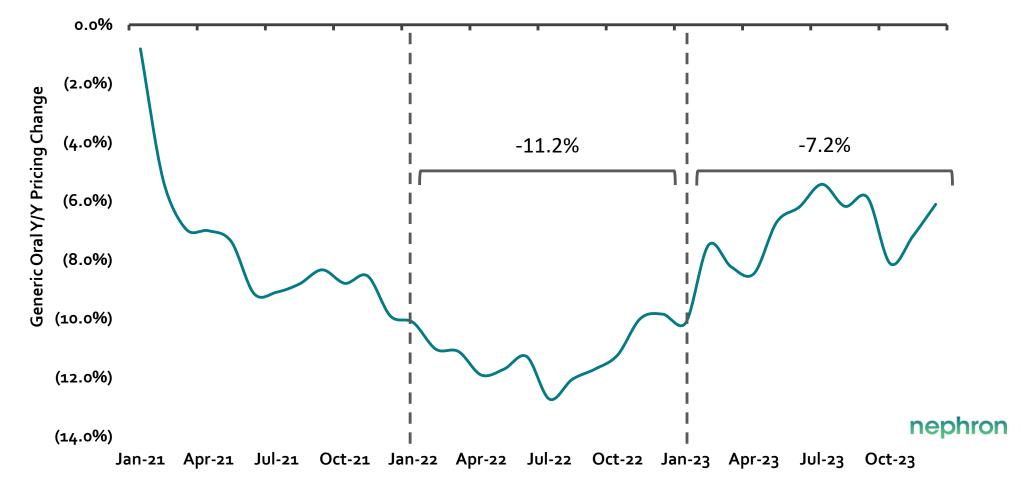


Source: IQVIA, National Sales Perspectives and RxInsights, 2023 Note: Limited to Rx and OTC Insulins; Includes Retail, Non-Retail and Mail



### **Generic price deflation is slowing**

Y/Y Mature Oral Generic Price Trend

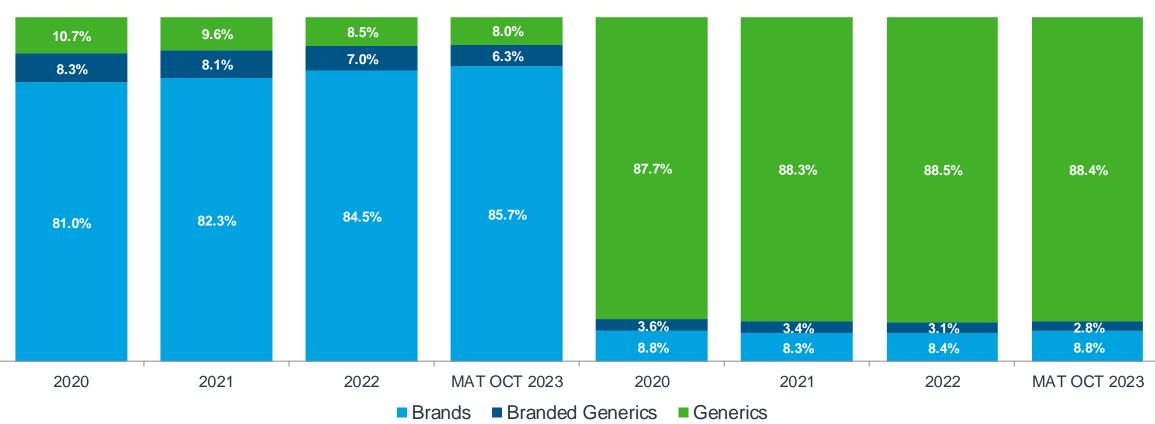


Source: Nephron Research, IQVIA, Glass Box Analytics



# 88.4% of prescriptions in the US are dispensed as generics (Adjusted)

Unbranded Generics account for 8% of spending



Dollars (%)

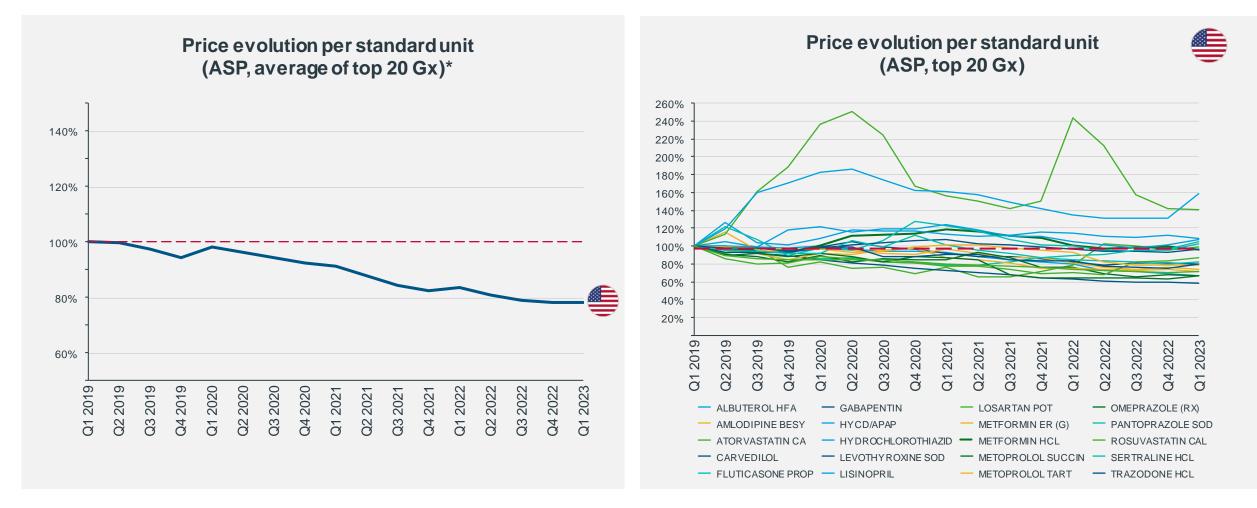
Source: IQVIA National Sales Perspectives; National Prescription Audit(Adjusted), Oct 2023.



**Prescriptions(%)** 

### In the US, the price of generics has fallen by ~20% since 2019

Shortages were behind fluctuating prices for losartan and hydrochlorothiazide





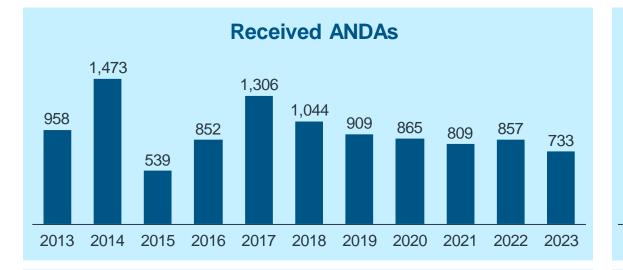
# In 2018, it took eight Brand drugs to equal the total Generic business; in 2023 it only takes two



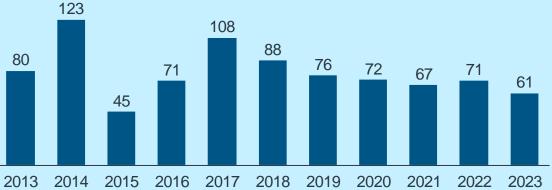


### ANDA approvals are trending up since 2021

FDA Fiscal Year Basis

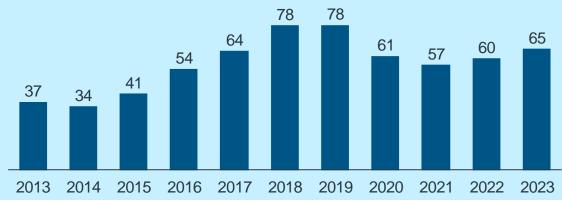






Average received ANDAs per month

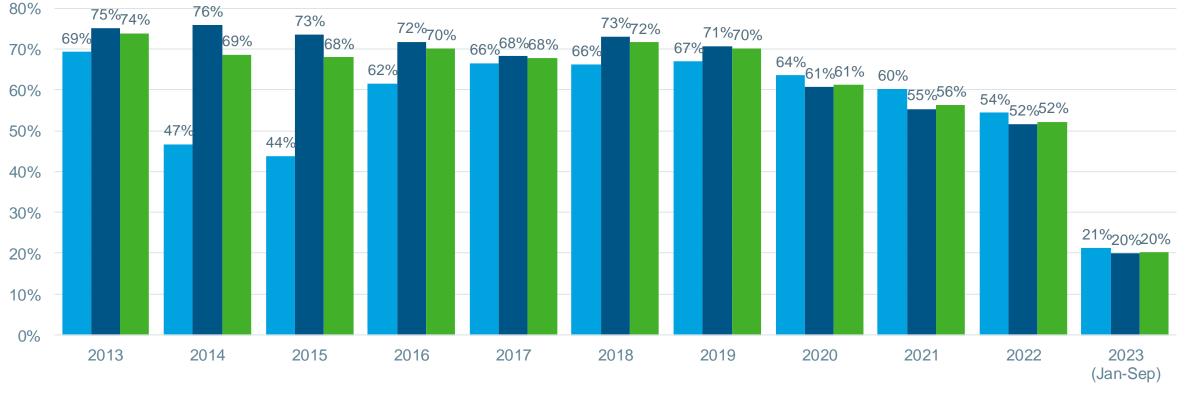
#### Average approved ANDAs per month



Source: GDUFA approvals, Jan 2023

## Unlaunched ANDAs account for 39% of approvals since 2013, 42% of injectables and 33% of other forms

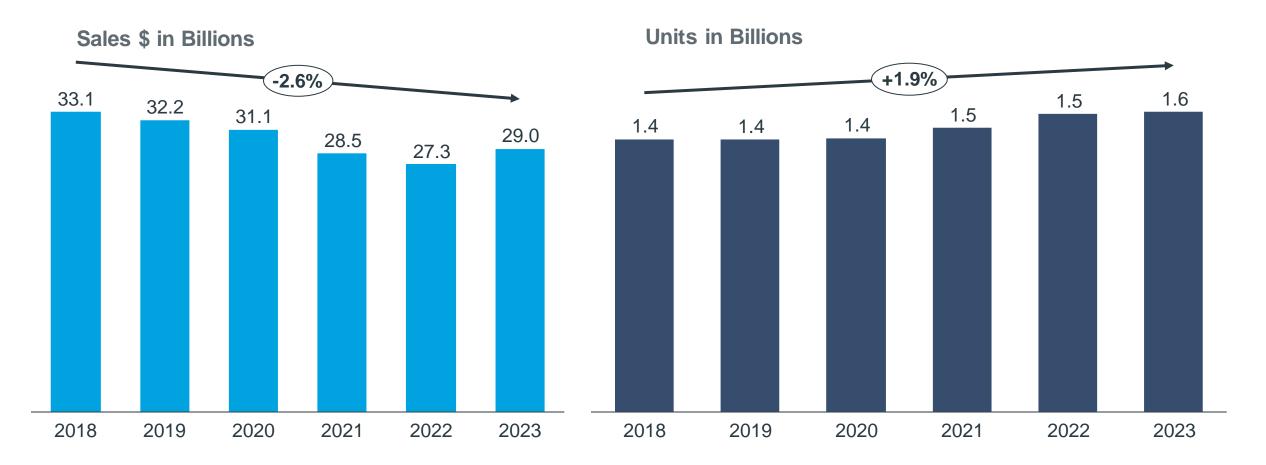
A rise in trend of the percentage of approved injectable ANDAs launched since 2020



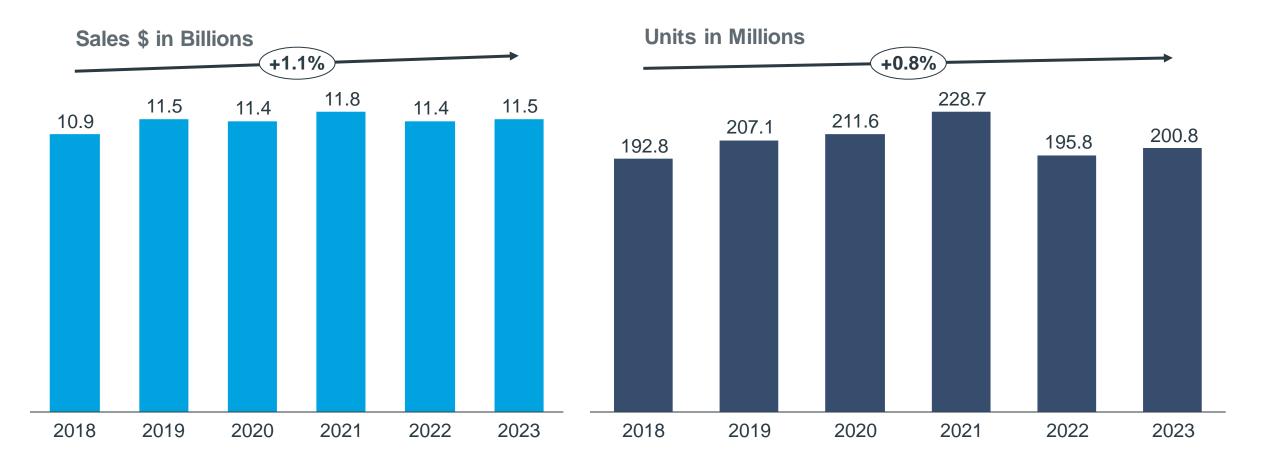
% of ANDAs launched to date by Type

Injectables Other Forms Total

# Unbranded Generic Oral Solids CAGR sales decrease while units increase

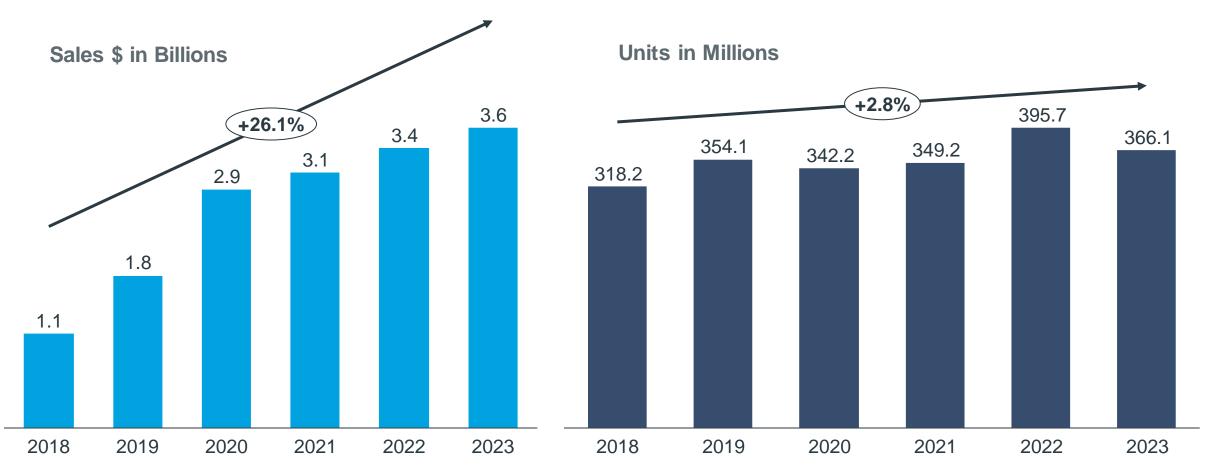


### **Unbranded Generic Injectables\* CAGR sales and units increase**



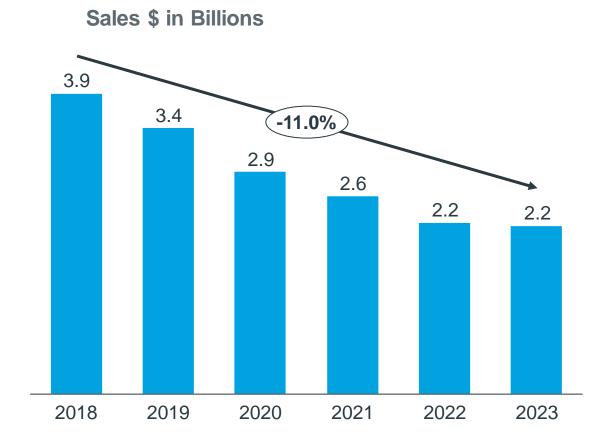


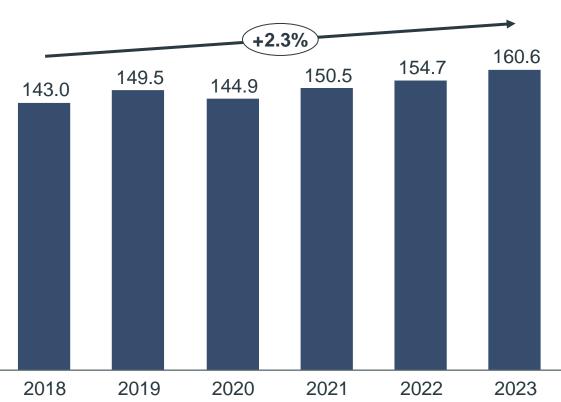
### **Unbranded Generic Inhalants CAGR sales and units increase**



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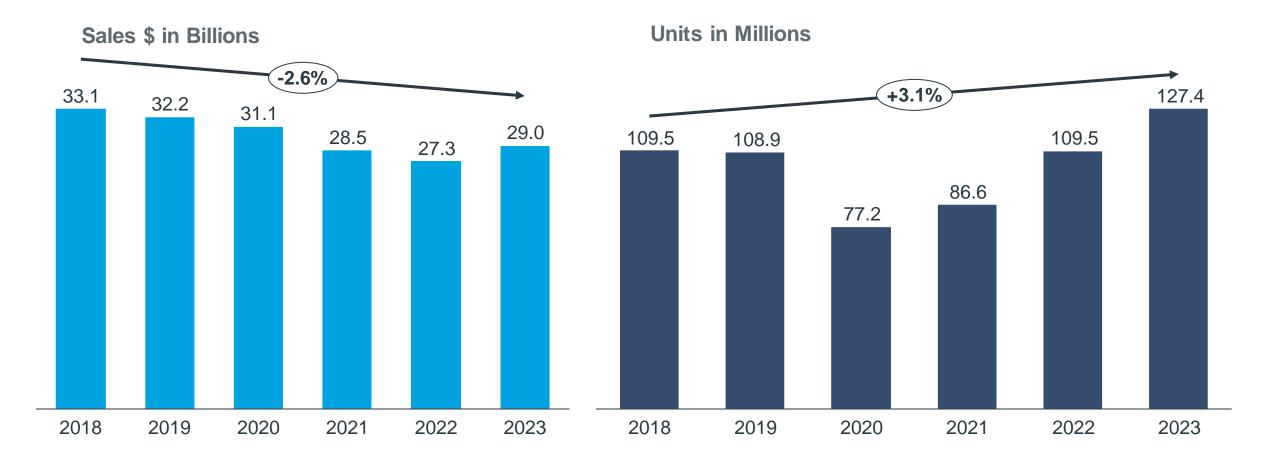
## Unbranded Generic Dermatological CAGR Sales decrease while units increase





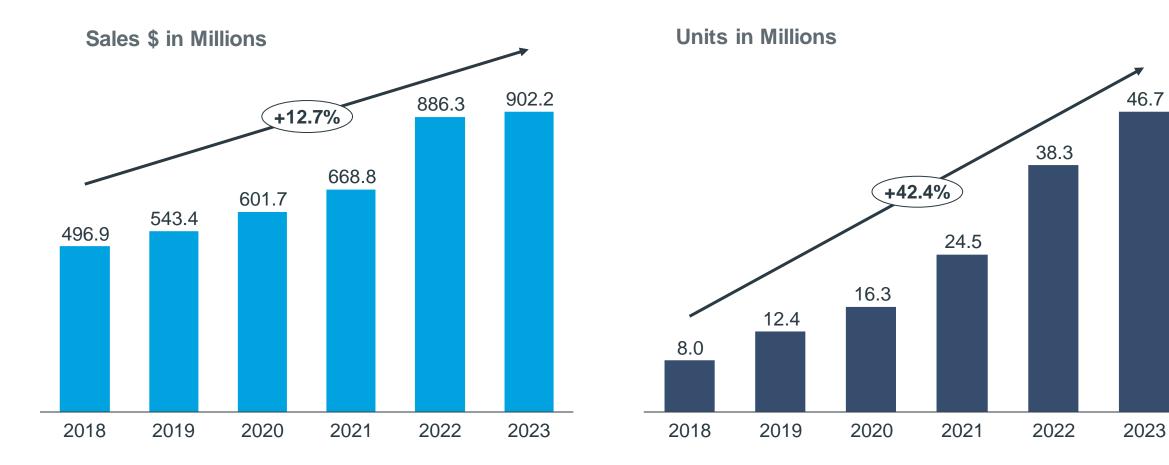
Units in Millions

## Unbranded Generic Oral Liquids CAGR sales decrease while units increase

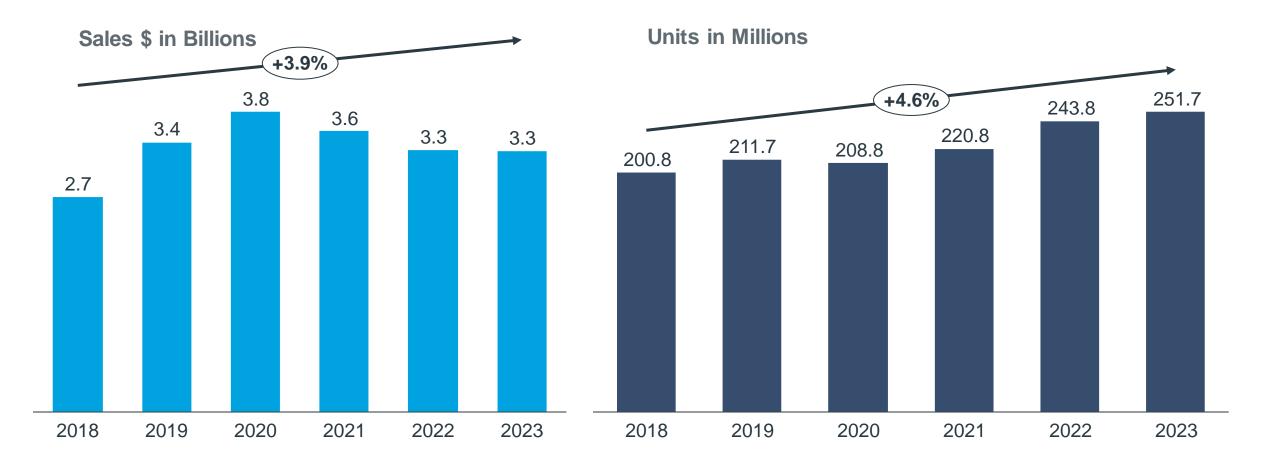


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### Systemics Generic CAGR sales and units increase



### **Generic Other\* CAGR sales and units increase**





# On a script basis, the top 10 therapy areas are growing at 2.9% adjusted and at 1.8% unadjusted

		Adjusted Scripts (MNs)			Unadjusted Scripts (MNs)				
Rank	Therapy Area	MAT DEC 2023	Market Share	ABS Growth	Growth	MAT DEC 2023	Market Share	ABS Growth	Growth
1	ANTIHYPERTENSIVES, PLAIN & COMBO	1,314.1	19.8%	24.5	1.9%	635.3	14.5%	0.5	0.1%
2	MENTAL HEALTH	654.6	9.8%	20.8	<mark>3</mark> .3%	426.3	9.8%	5.5	1.3%
3	LIPID REGULATORS	579.0	8.6%	22.4	4.0%	263.0	6.0%	5.3	2.1%
4	ANTIDIABETICS	434.9	6.3%	30.6	<mark>7.6</mark> %	251.8	5.8%	21.1	9.1%
5	PAIN	377.3	5.7%	-1.0	-0.3%	341.7	7.8%	-2.1	-0.6%
6	ANTI-ULCERANTS	284.0	4.3%	10.6	<mark>3</mark> .9%	158.1	3.6%	3.0	1.9%
7	NERVOUS SYSTEM DISORDERS	269.8	4.1%	3.7	1.4%	200.2	4.6%	0.8	0.4%
8	ANTIBACTERIALS	248.9	3.7%	15.4	<mark>6.6</mark> %	245.0	5.6%	15.2	6.6%
9	THYROID ANTI-THYROID AND IODINE PREPS	234.1	3.5%	2.2	0.9%	114.2	2.6%	-1.3	-1.1%
10	RESPIRATORY AGENTS	228.1	3.4%	2.1	0.9%	178.3	4.1%	1.0	0.6%
<b>TOP 10</b>		4624.6	<mark>69.</mark> 5%	131.4	2.9%	2813.8	<mark>6</mark> 4.4%	49.0	1.8%

Source: IQVIA, RxInsight, December 2023 Limited to Rx and OTC Insulins \*For Client's internal use only

# On a script basis, the top 20 therapy areas are growing at 1.8% adjusted and unadjusted at 0.3%

		Adjusted Scripts (MNs)				Unadjusted Scripts (MNs)			
Rank	Therapy Area	MAT DEC 2023	Market Share	ABS Growth	Growth	MAT DEC 2023	Market Share	ABS Growth	Growth
11	OTHER CNS	198.4	3.0%	3.9	2.0%	176.5	4.0%	2.2	1.3%
12	DERMATOLOGICS	135.6	2.0%	8.1	6.3%	129.3	3.0%	7.5	6.2%
13	ANTITHROMBOTICS	126.3	1.9%	2.7	2.1%	74.2	1.7%	1.1	1.5%
14	ADHD	123.7	1.9%	3.5	2.9%	112.0	2.6%	3.2	3.0%
15	HORMONAL CONTRACEPTION, SYSTEMIC&TOPICAL	109.3	1.6%	-8.0	-6.8%	55.1	1.3%	-6.3	-10.3%
16	VITAMINS & MINERALS	106.1	1.6%	0.1	0.1%	62.1	1.4%	-0.5	-0.8%
17	VACCINES (PURE, COMB, OTHER)	103.2	1.6%	-52.4	-3 <mark>3.7%</mark>	103.1	2.4%	-52.2	-33. <mark>6%</mark>
18	BPH (BENIGN PROSTATIC HYPERTROPHY)	96.6	1.5%	3.1	3.4%	47.0	1.1%	1.0	2.2%
19	CORTICOSTEROIDS, PLAIN & COMBO	85.0	1.3%	1.1	1.3%	79.4	1.8%	1.0	1.3%
20	SEX HORMONES (ANDROGENS, OESTROGENS, PROGESTOGENS,	72.4	1.1%	6.8	10.4%	44.4	1.0%	3.6	8.9%
<b>TOP 20</b>		5781.2	<mark>8</mark> 6.9%	100.3	1.8%	3696.8	84.6%	9.7	0.3%

Source: IQVIA, RxInsights, December 2023 Limited to Rx and OTC Insulins

# On a script basis, the top 10 products are growing at 3.8% adjusted and growing at 1.6% unadjusted

		Adjusted Scripts (MNs)				Unadjusted Scripts (MNs)			
Rank	Product	MAT DEC 2023	Market Share	ABS Growth	Growth	MAT DEC 2023	Market Share	ABS Growth	Growth
1	ATORVASTATIN CA	284.4	4.3%	9.4	3.4%	130.5	3.0%	1.4	1.1%
2	AMLODIPINE BESY	194.9	2.9%	5.7	3.0%	92.0	2.1%	0.8	0.9%
3	LEVOTHYROXINE SOD	179.5	2.7%	12.6	7.6%	87.6	2.0%	4.3	5.2%
4	LISINOPRIL	174.2	2.6%	-2.7	-1.5%	81.5	1.9%	-3.1	-3.7%
5	LOSARTAN POT	142.4	2.1%	9.9	7.5%	65.5	1.5%	3.0	4.8%
6	ROSUVASTATIN CAL	122.9	1.8%	18.6	<mark>17</mark> .8%	54.3	1.2%	7.3	15.7%
7	METOPROLOL SUCCIN	115.4	1.7%	5.0	4.6%	53.9	1.2%	1.5	2.8%
8	METFORMIN HCL	111.4	1.7%	-3.0	-2.6%	54.0	1.2%	-2.6	-4.6%
9	GABAPENTIN	98.1	1.5%	0.8	0.9%	72.3	1.7%	-0.1	-0.1%
10	HYDROCHLOROTHIAZIDE	94.7	1.4%	-0.4	-0.5%	42.9	1.0%	-1.2	-2.8%
<b>TOP 10</b>		1,517.9	22.8%	55.9	3.8%	734.5	16.8%	11.4	1.6%

Source: IQVIA, RxInsights, December 2023 Limited to Rx and OTC Insulins \*For Client's internal use only Top 10 - Prods Rx's



# On a script basis, the top 20 products is at 3.3% adjusted and declining at 1.6% unadjusted

		Adjusted Scripts (MNs)				Unadjusted Scripts (MNs)			
Rank	Product	MAT DEC 2023	Market Share	ABS Growth	Growth	MAT DEC 2023	Market Share	ABS Growth	Growth
11	SERTRALINE HCL	90.3	1.4%	2.6	2.9%	55.2	1.3%	0.2	0.3%
12	PANTOPRAZOLE SOD	89.4	1.3%	5.4	6.5%	49.3	1.1%	2.0	4.3%
13	OMEPRAZOLE (RX)	83.4	1.3%	-2.4	-2.7%	45.4	1.0%	-1.6	-3.3%
14	ESCITALOPRAM OXAL	80.2	1.2%	3.6	4.8%	47.8	1.1%	0.9	1.9%
15	MONTELUKAST SOD	65.6	1.0%	0.3	0.4%	35.1	0.8%	-0.9	-2.6%
16	TRAZODONE HCL	64.0	1.0%	3.4	5.7%	42.1	1.0%	1.5	3.7%
17	TAMSULOSIN HCL	63.3	1.0%	2.6	4.2%	31.7	0.7%	0.9	2.8%
18	FUROSEMIDE	62.8	0.9%	0.1	0.1%	35.9	0.8%	-0.2	-0.6%
19	AMOXICILLIN	58.1	0.9%	7.5	<mark>14</mark> .7%	58.0	1.3%	7.5	14.8%
20	SIMVASTATIN	56.9	0.9%	-6.9	-10.9 <mark>%</mark>	24.5	0.6%	-3.4	-12.3%
<b>TOP 20</b>		2,231.9	<b>33</b> .6%	72.1	3.3%	1,159.7	<mark>26</mark> .6%	18.1	1.6%

Source: IQVIA, RxInsights, December 2023 Limited to Rx and OTC Insulins \*For Client's internal use only

# On an unadjusted script basis, the top 10 generic corporations\* growth is at 1.7% and account for 39.9% market share

			U	nadjusted Scripts (MN	s)	
Rank	Corporation	MAT DEC 2023	Market Share	Generic Market Share	ABS Growth	Growth
1	AUROBINDO PHARM	338.2	7.7%	8.7%		
2	TEVA PHARM USA	321.4	7.4%	8.3%		
3	LUPIN	205.5	4.7%	5.3%		
4	AMNEAL INC	162.5	3.7%	4.2%		
5	ZYDUS PHARM	152.5	3.5%	3.9%		
6	VIATRIS INC.	128.6	2.9%	3.3%		
7	ASCEND LABS	113.6	2.6%	2.9%		
8	CAMBER	107.8	2.5%	2.8%		
9	RISING PHARM INC.	107.1	2.5%	2.8%		
10	DR REDDY INC	106.6	2.4%	2.7%		
<b>TOP 10</b>		1743.7	39.9%	<b>44.9%</b>	29.0	

Source: IQVIA, National Prescription Audit, December 2023; \*note: ranked on generic unadjusted script volume Limited to Rx and OTC Insulins



# On an unadjusted script basis, the top 20 generic corporations\* growth is at 2.5% and account for 60.0% market share

		Unadjusted Scripts (MNs)					
Rank	Corporation	MAT DEC 2023	Market Share	Generic Market Share	ABS Growth	Growth	
11	SOLCO HEALTHCARE	105.3	2.4%	2.7%			
12	SANDOZ	94.6	2.2%	2.4%			
13	UNICHEM PHARM USA	93.1	2.1%	2.4%			
14	APOTEX CORP	91.7	2.1%	2.4%			
15	NORTHSTAR RX	91.0	2.1%	2.3%			
16	CIPLA USA, INC.	87.0	2.0%	2.2%			
17	GLENMARK PHARMA	86.8	2.0%	2.2%			
18	HIKMAPHARM	82.4	1.9%	2.1%			
19	SUN PHARMA	73.8	1.7%	1.9%			
20	MALLINCKRODT	72.1	1.7%	1.9%			
<b>TOP 20</b>		2621.7	60.0%	67.5%	63.4		

Source: IQVIA, National Prescription Audit, December 2023; \*note: ranked on generic unadjusted script volume Limited to Rx and OTC Insulins



# The top 10 generic corporations\* are growing at 2.1% and account for 40.1% generic market share

		Non-Discounted Spend (US\$ BNs)					
Rank	Corporation	MAT DEC 2023	Market Share	Generic Market Share	ABS Growth	Growth	
1	TEVA PHARM USA	\$4.2	0.6%	7.8%			
2	VIATRIS INC.	\$3.3	0.5%	6.1%			
3	PRASCO LABS	\$2.3	0.3%	4.2%			
4	AMNEAL INC	\$2.1	0.3%	4.0%			
5	ZYDUS PHARM	\$1.8	0.3%	3.3%			
6	HIKMA PHARM	\$1.8	0.2%	3.3%			
7	SANDOZ	\$1.7	0.2%	3.1%			
8	DR REDDY INC	\$1.6	0.2%	2.9%			
9	APOTEX CORP	\$1.6	0.2%	2.9%			
10	AUROBINDO PHARM	\$1.4	0.2%	2.6%			
<b>TOP 10</b>		\$21.8	3.0%	40.1%	\$0.5		

Source: IQVIA, National Sales Perspectives, December 2023; \*note: ranked on generic non-discounted spend Limited to Rx and OTC Insulins



### The top 20 generic corporations\* are growing at 1.0% and account for 60.7% generic market share

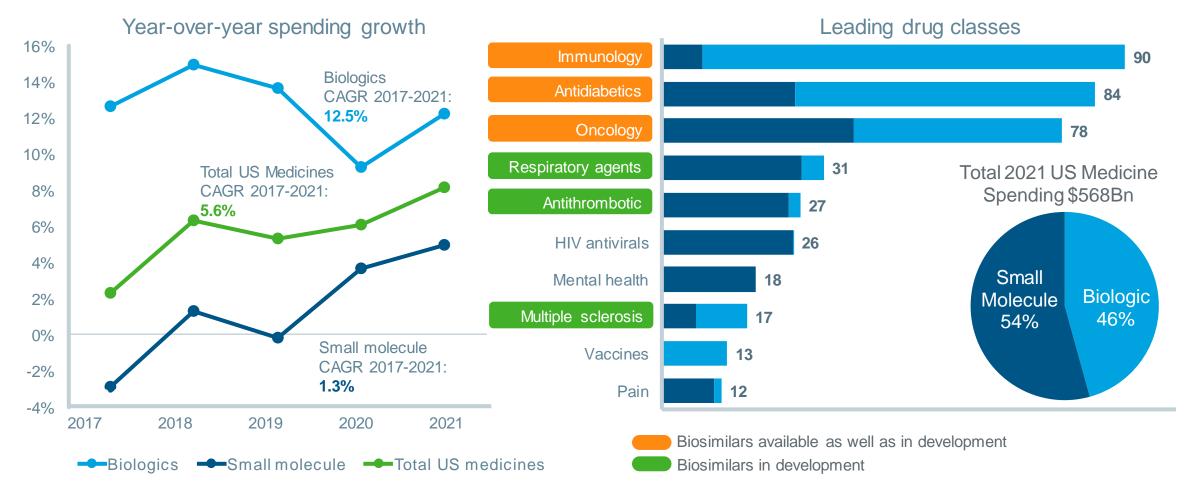
		Non-Discounted Spend (US\$ BNs)					
Rank	Corporation	MAT DEC 2023	Market Share	Generic Market Share	ABS Growth	Growth	
11	ENDO PHARM INC.	\$1.4	0.2%	2.5%			
12	FRESENIUS KABI	\$1.3	0.2%	2.4%			
13	LUPIN	\$1.3	0.2%	2.4%			
14	SUN PHARMA	\$1.3	0.2%	2.3%			
15	GRIFOLS	\$1.2	0.2%	2.1%			
16	CIPLA USA, INC.	\$1.0	0.1%	1.9%			
17	PFIZER	\$1.0	0.1%	1.9%			
18	PADAGIS LLC	\$1.0	0.1%	1.8%			
19	NORTHSTAR RX	\$0.9	0.1%	1.7%			
20	GILEAD SCIENCES,IN	\$0.9	0.1%	1.6%			
<b>TOP 20</b>		\$33.0	4.6	% 60.7%	\$0.3		

Source: IQVIA, National Sales Perspectives, December 2023; \*note: ranked on generic non-discounted spend Limited to Rx and OTC Insulins

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### The U.S. biologics market continues to grow faster than nonbiologics on an invoice-basis, and now comprises 46% of spending

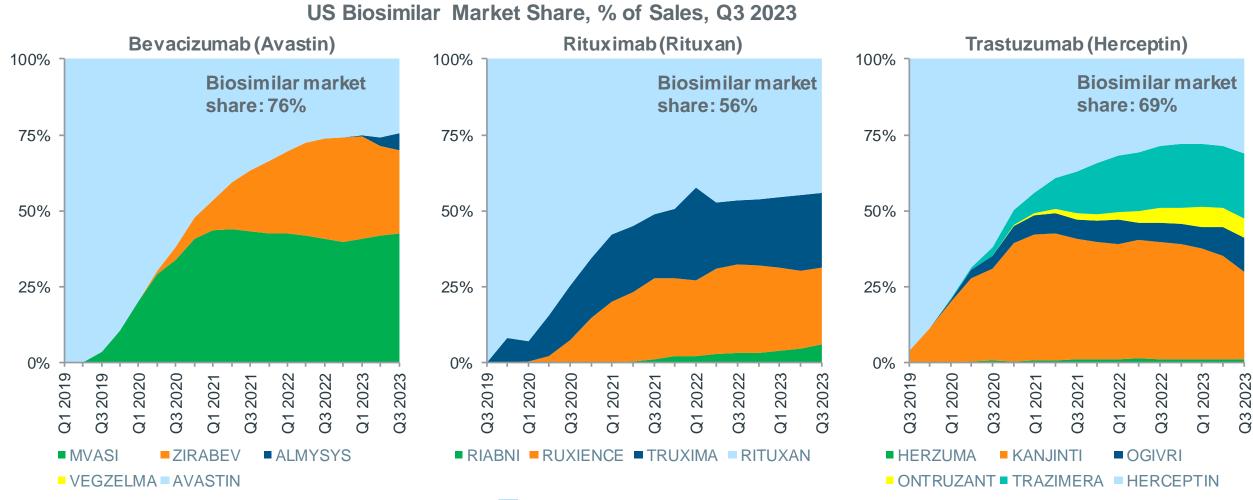
Total U.S. invoice spending growth by type and leading therapy areas by 2021 spending, US\$Bn



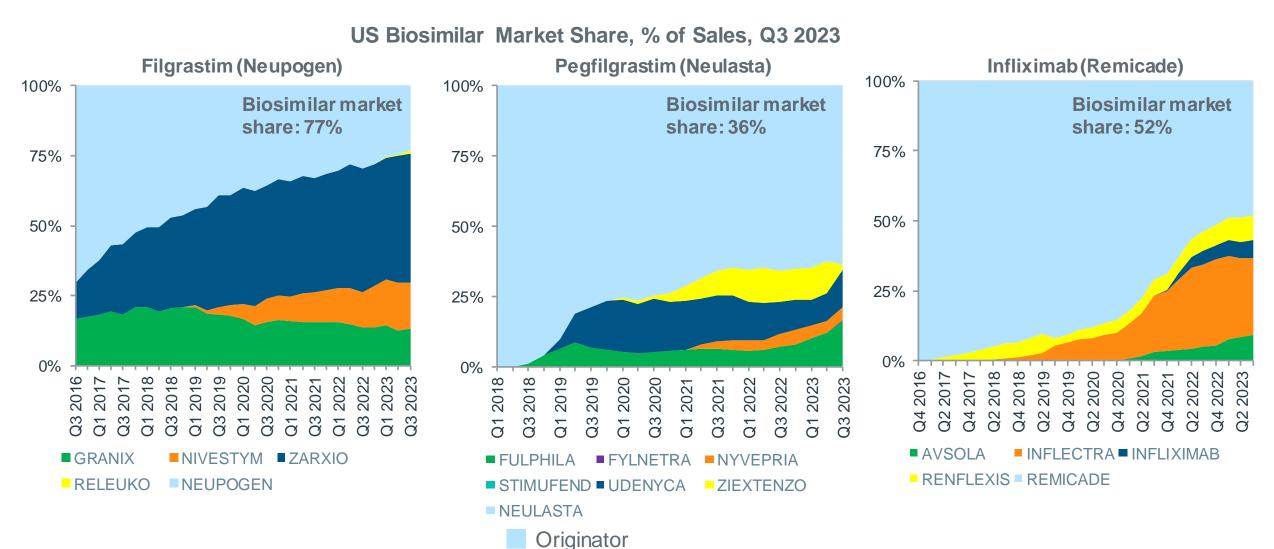
Source: IQVIA MIDAS, Dec 2021; IQVIA Institute, Nov 2022. Biosimilars in the United States 2023-2027 – Competition, Savings and Sustainability. Report by the IQVIA Institute for Human Data Science.

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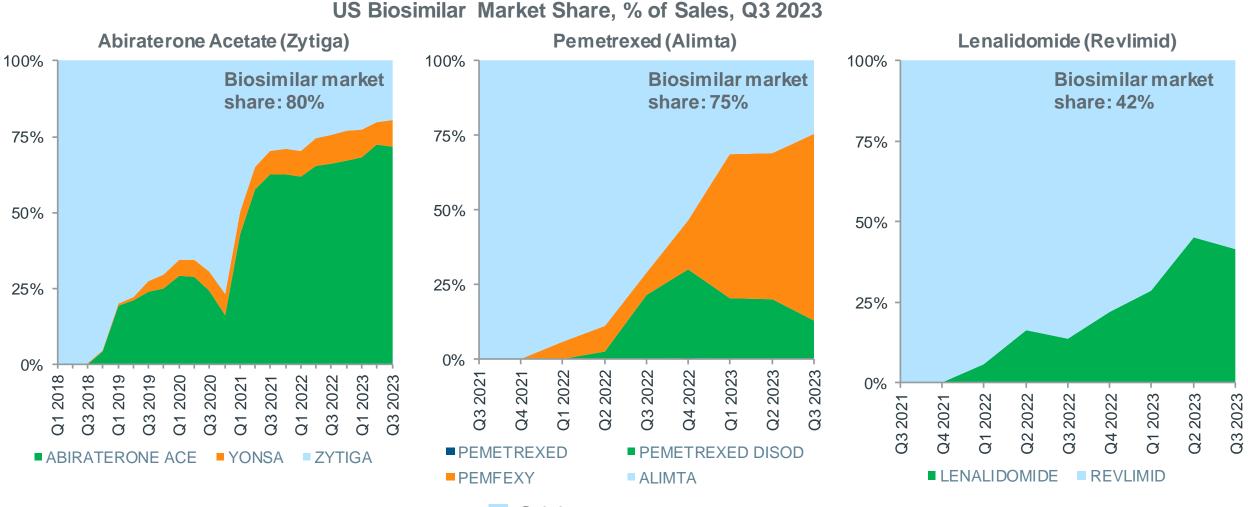
### In Oncology biosimilars market share ranges from 56% - 76%



### Filgrastim's biosimilar has 77% market share

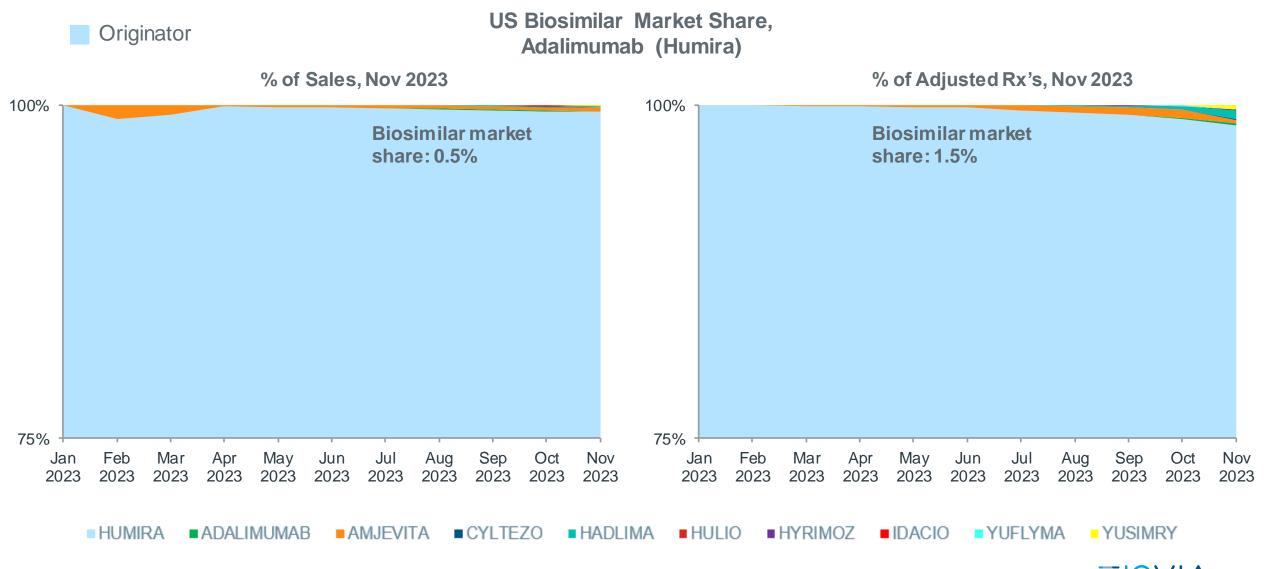


### Zytiga's biosimilar has 80% market share



Originator

### **Biosimilar sales are just beginning for Adalimumab (Humira)**

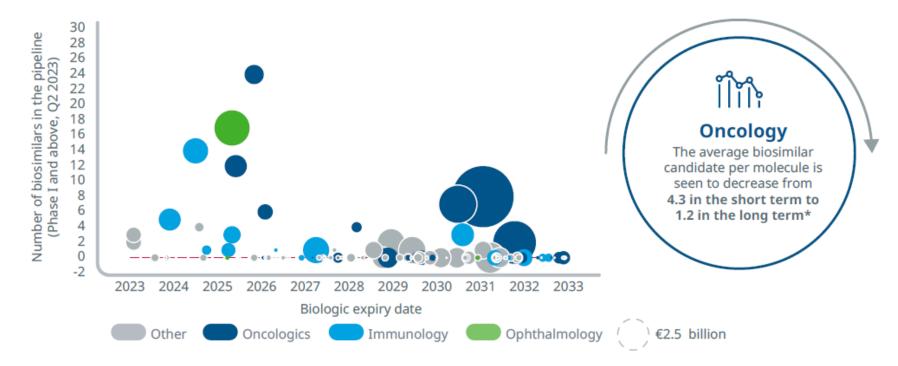


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### Three therapeutic areas have attracted 91% of pipeline

However, challenges are starting to emerge in oncology

Exhibit 4: Top 3 therapeutic areas by number of biosimilars in the pipeline



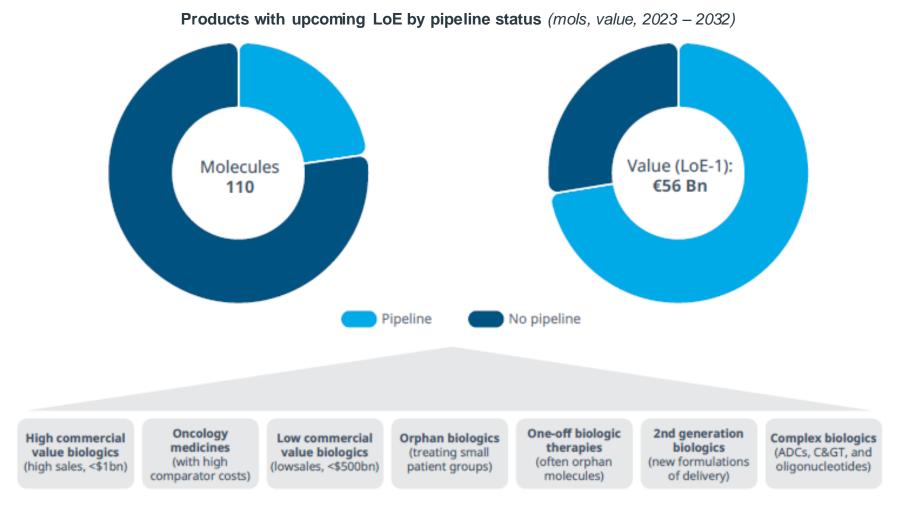
Source: IQVIA MIDAS; IQVIA Forecast Link; IQVIA Ark Intelligence; IQVIA Forecast Link.

Notes: Pipeline data only includes biosimilars in development (Phase I to Phase III, including pre-registration). No approved biosimilar is included in the analysis. Caveat: biosimilar pipeline data is based on publicly available information only. \*Short term defined as 2023 to 2027 and long term defined as 2028 to 2032.



### Significant numbers of biologics currently do not have a pipeline

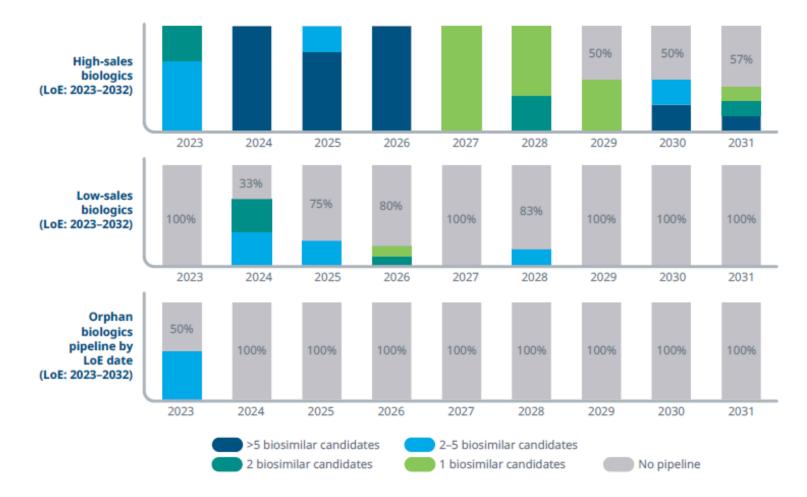
The number of biologics is high, but tend to be lower value molecules and should not be overlooked





### Segments of the biologics market are subject to a 'void'

Biosimilar pipeline for high-sales biologics by LoE date



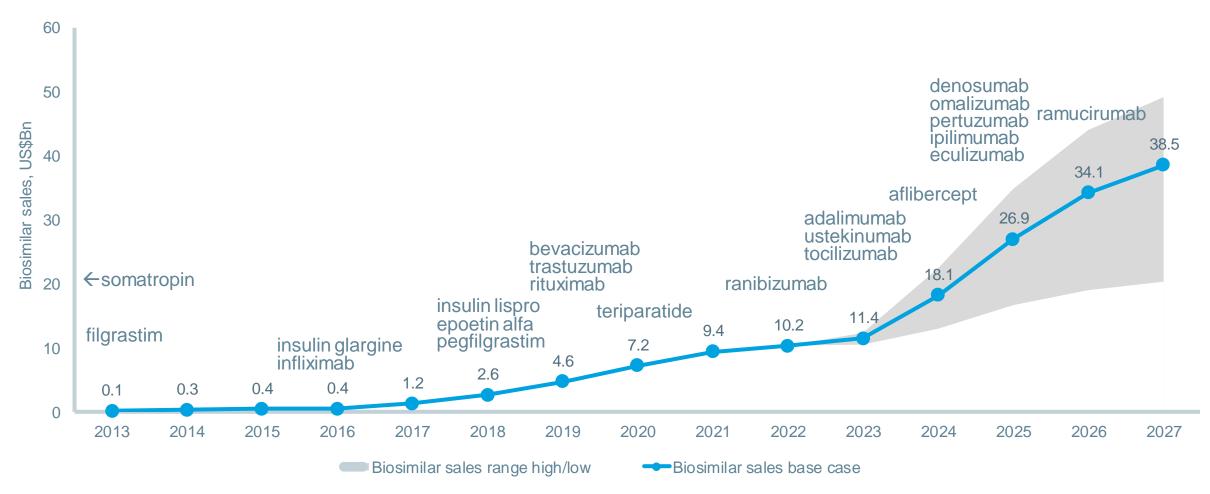
Source: IQVIA MIDAS; IQVIA Ark Intelligence; IQVIA Forecast Link; IQVIA Global Biosimilar Database. Notes: Pipeline data only includes biosimilars in development (phase I to phase III, including pre-registration). No approved biosimilar is included in the analysis. Caveat: biosimilar pipeline data is based on publicly available information only. High sales= biologics with over €500 in European sales before LoE (LoE-1). No high-sales biologic medicine is expected to lose exclusivity in 2032 (data not shown).

The Impact of Biosimilar Competition in Europe 2023



## Expected launches and uptake are likely to increase overall spending on biosimilars significantly to \$20–49 billion in 2027

Biosimilar historical sales 2013–2022 and outlook scenarios 2023–2027, US\$Bn



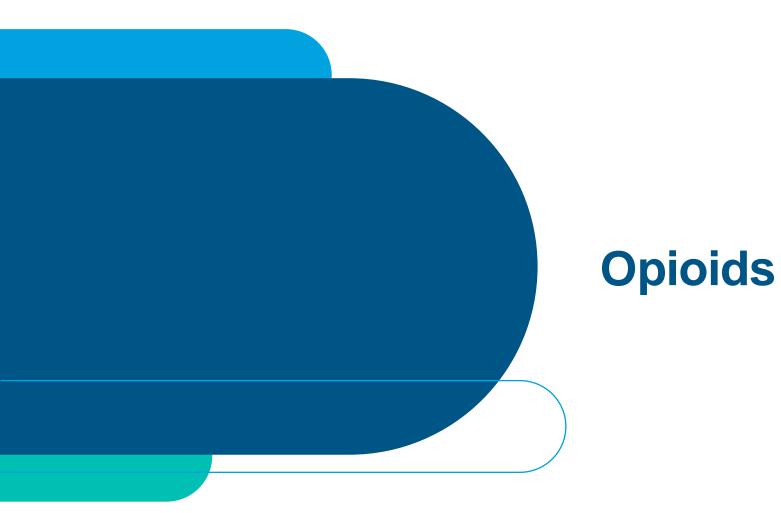
Source: IQVIA MIDAS, Jun 2022; IQVIA Institute, Nov 2022.

Biosimilars in the United States 2023-2027 - Competition, Savings and Sustainability. Report by the IQVIA Institute for Human Data Science.

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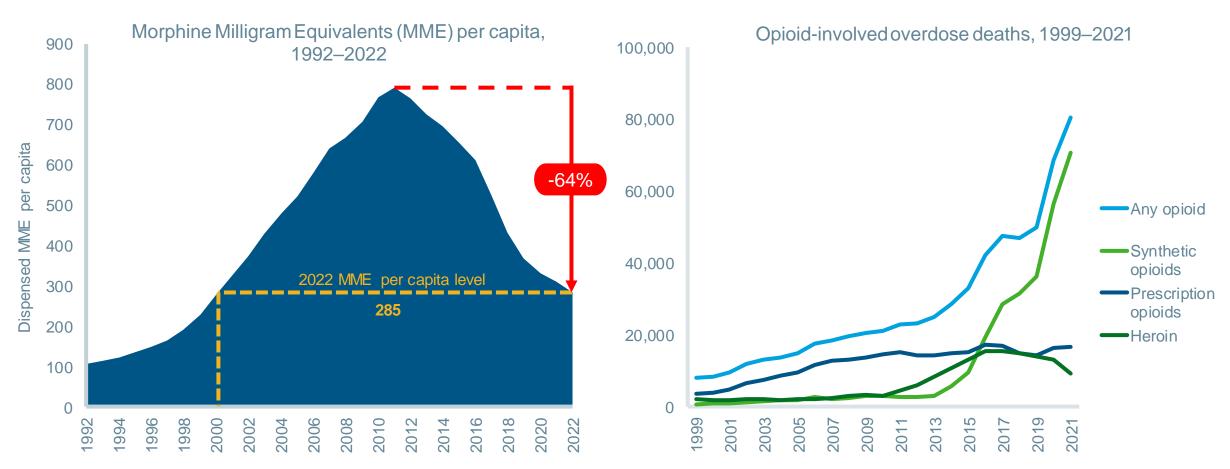
74





## Per capita prescription opioid use continues to decline to levels seen in 2000, however overdose deaths continue to rise

Prescription opioid use overall and opioid-involved overdose deaths

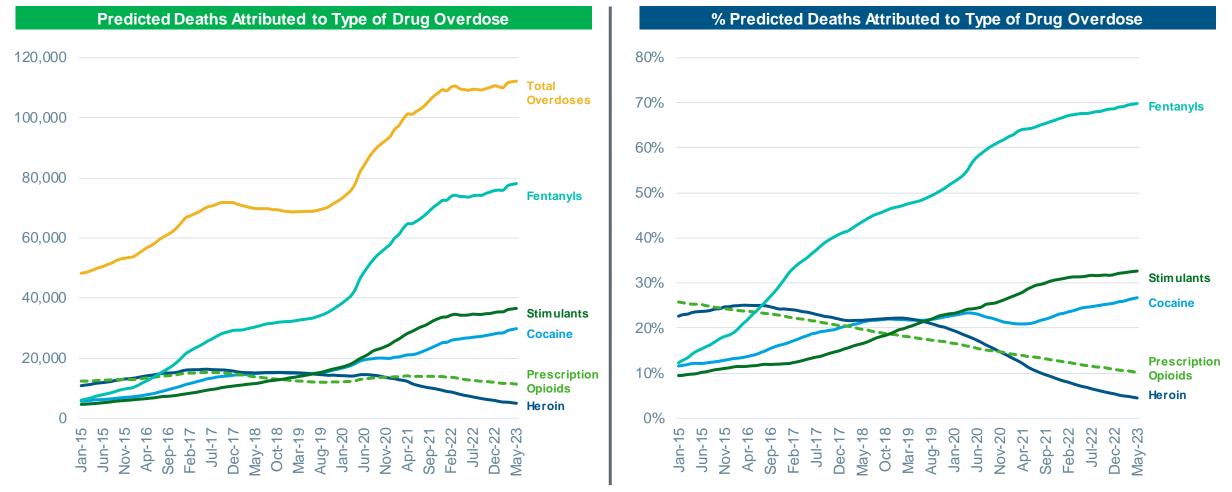


Source: IQVIA Xponent, IQVIA National Prescription Audit, Sep 2022; IQVIA Institute, Mar 2023; National Institute on Drug Abuse, Feb 2023. The Use of Medicines in the U.S. 2023: Usage and Spending Trends and Outlook to 2027. Report by the IQVIA Institute for Human Data Science.

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### Fentanyls continue to be the largest cause of drug overdose deaths



Notes: Data is based on 12 months ending February 2023, Cocaine = Cocaine (T40.5), Heroin = Heroin (T40.1), Prescription Opioids = Natural & Semi-synthetic Opioids (T40.2), Stimulants = Psychostimulants with abuse potential (T43.6) and Fentanyls = Synthetic Opioids, Excl. Methadone (T40.4)

• - Drug overdose deaths may involve multiple drugs; therefore, a single death might be included in more than one category when describing the number of drug overdose deaths involving specific drugs

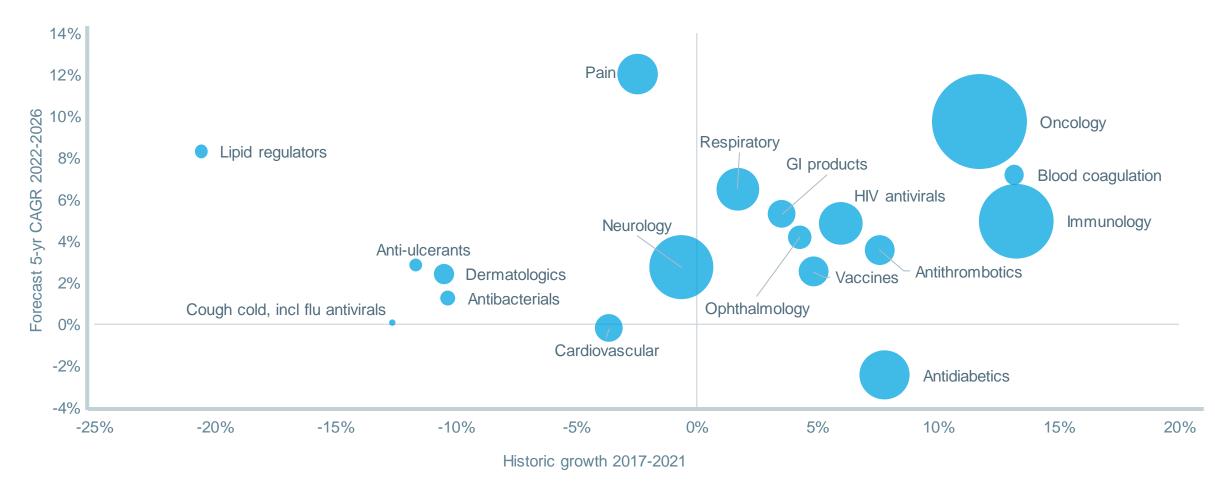






## Immunology, oncology, neurology drive growth through 2026 along with COVID-19 vaccines

Historic and forecast net spending growth for leading therapy areas



Source: IQVIA Institute, Mar 2022.

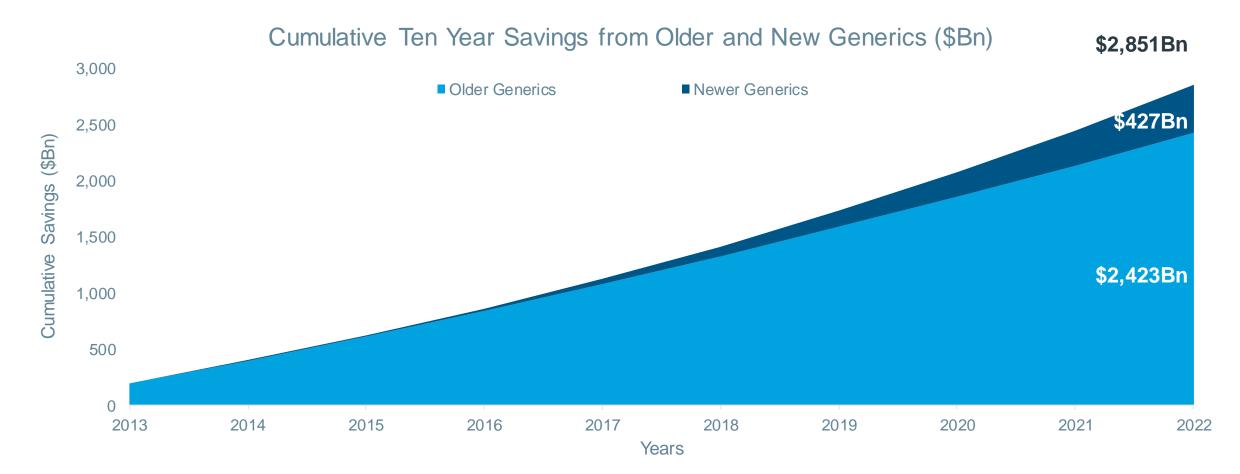
The Use of Medicines in the U.S.: Usage and Spending Trends and Outlook to 2026. Report by the IQVIA Institute for Human Data Science.

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### The U.S. healthcare system has saved nearly \$2.9 trillion in the last ten years due to the availability of low-cost generics

Older generics generated \$2,423 billion in cumulative savings in the last ten years

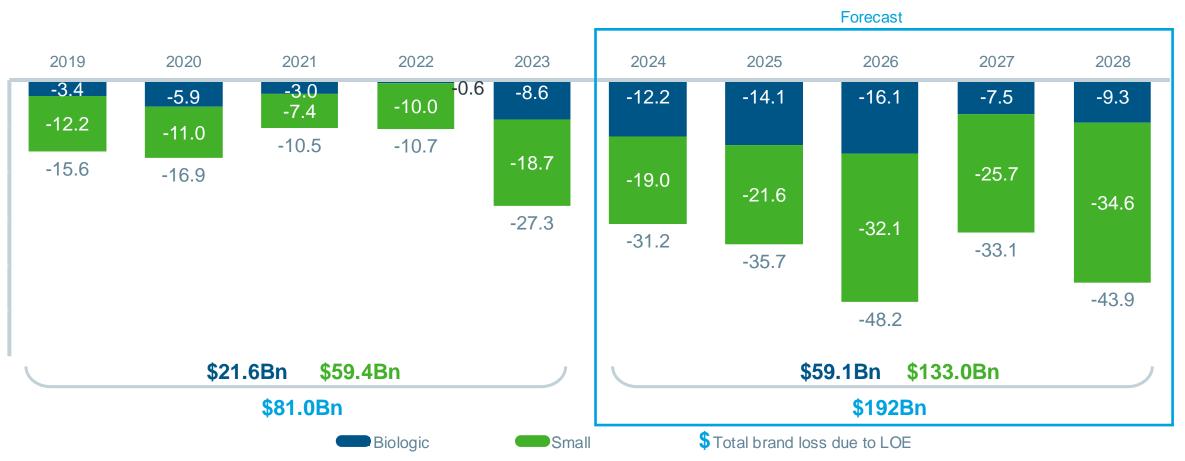


Source: IQVIA National Sales Perspectives, Dec 2022

Generic Savings, 2013-2022

# The impact of exclusivity losses will reach \$192Bn over the next 5 years, with around 30% due to the availability of biosimilars

10 developed countries impact of brand losses of exclusivity 2019–2028, US\$Bn

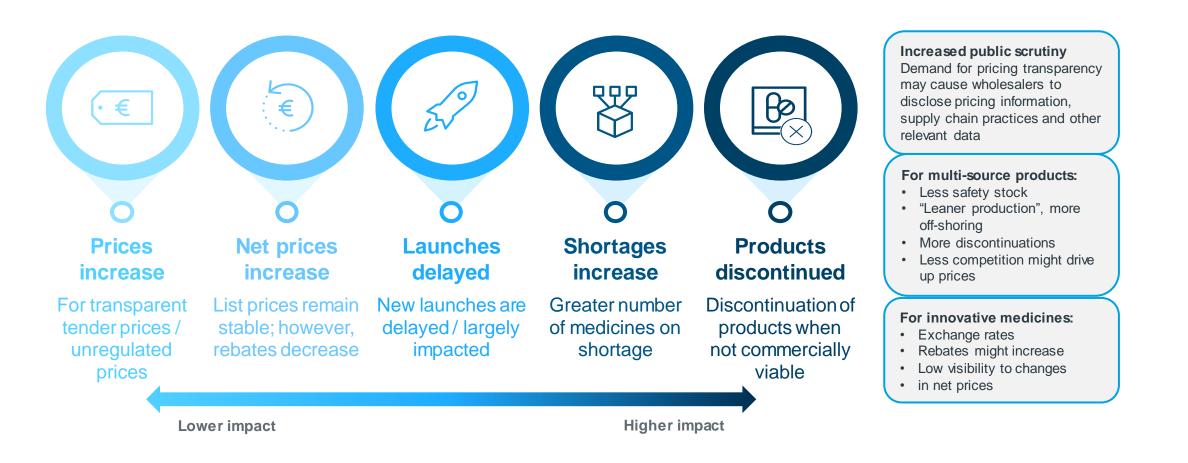


Source: IQVIA Market Prognosis, Sep 2023; IQVIA Institute, Nov 2023. Global Use of Medicines 2024: Outlook to 2028. Report by the IQVIA Institute for Human Data Science.



## Impact of the changing macroeconomic environment is significant on generic medicines, but focuses on risks

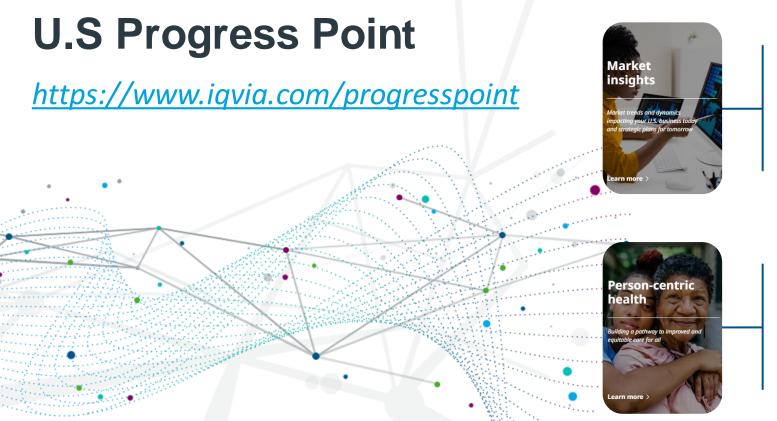
Outcomes are dependent on multiple factors, cumulative effect concerns are broad



### A quick recap

- COVID deaths and RSV, Cough, Cold Flu are on the decline
- Elective procedures are still week and screenings even weaker
- Non-retail and particularly hospitals and LTC bore the brunt of COVID
- Specialty is now 51% of the total market sales but GLP1s (non specialty) growth is spectacular
- Unbranded generics are growing on prescriptions but now have modest growth on Dollars
- Unbranded generic injectables have grown nicely until recently
- The Pharmaceutical benefit Biosimilar wave is upon us with Humira now facing many competitors
- There are plenty of LOE opportunities going forward both in Small molecules and Biologics
- There are many Biologics that have no competition
- Drug shortages continue to be a real issue
- Opioid usage is back to 2000 levels





#### Market insights

- The IQVIA U.S. Launch Quarterly
- The IQVIA Monthly Launch Tracker
- Pharmaceutical Market and MedTech Trends
- Next Generation Payor Segmentation

#### **Person-centric health**

- Impact of Medicare Part D Cost Sharing
- Health Equity in the Time of COVID-19
- Advancing Outcomes with Home Healthcare

A curation of **IQVIA's best thinking** on **topics** and **trends** driving change, disruption, and **progress** in the United States healthcare market.



#### **Engagement innovation**

- HCP Consent at Scale
- Hidden Peer-to-Peer Learning Communities
- Importance of End-to-End Data in Physician Marketing



#### Thank you

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#### **Doug Long**

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IQVIA is the world's largest pharmaceutical information company. IQVIA offers services to the pharmaceutical industry in over 100 countries around the globe. Doug has been with IQVIA since 1989.

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.





### APPENDIX

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- Total generic and biosimilar savings for 2021: \$373 billion
  - Total generic and biosimilar savings for past 10 years: more than \$2.6 trillion
    - Total generic and biosimilar savings in Medicare for 2021: \$119 billion

Total generic and biosimilar savings in commercial plans for 2021: \$178 billion

Generics represent 91% of prescriptions filled, yet account for only 18.2% of prescription drug spending

Of nearly 6.4 billion generic and biosimilar prescriptions dispensed, generics represent only 3% of all healthcare spending

- 93 percent of generic drugs have copays under \$20 as compared to 59% of brandname drugs
- Generics average copay is \$6.16 compared to an average out-of-pocket cost of \$56.12 for their brand counterparts
- The market for biosimilar drugs continues to expand, and they are nearly 30% of the overall biologics market

Competition from biosimilars has reduced the average sales price of their corresponding reference biologic by an average of 25%

1

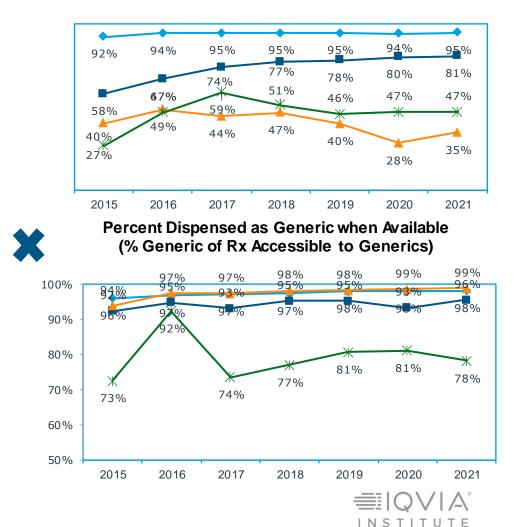


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## Generic efficiency rate broken down: traditional, specialty, inhalable/injectable, specialty injectable

Generic shares of dispensed prescriptions

Percent of Market Accessible to Generics, % of Total Rx by Segment

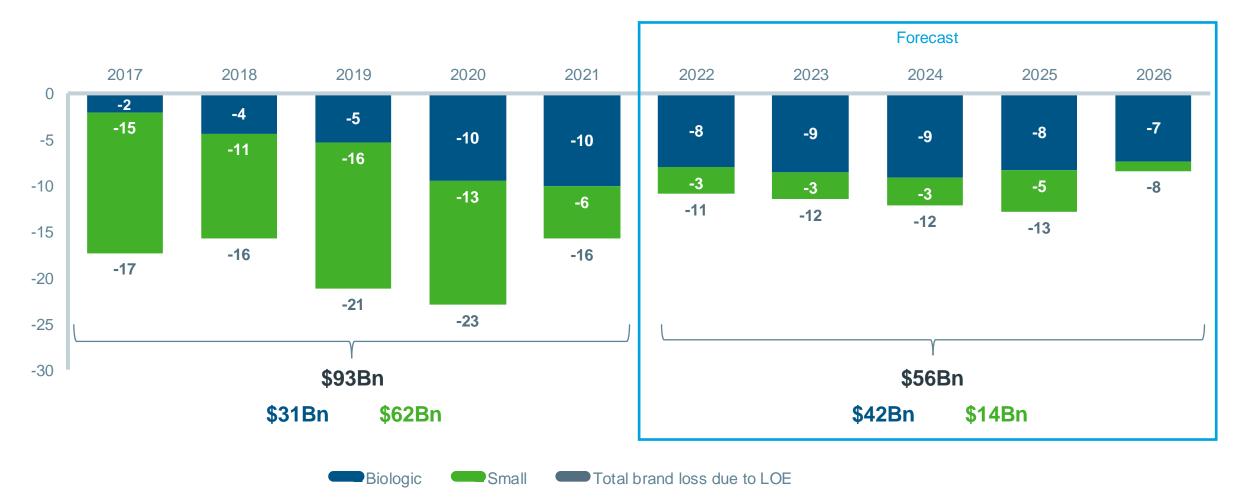


Generic (Branded and Unbranded) Market Share, % of Total Rx 100% 93% 9.3% 92% 91% 89% 90% 80% 70% 77% 75% 74% 73% 60% 69% 63% 46% 50% 43% 39% 58% 38% 34% 40% 43% 43% 39% 30% 37% 37% 20% 28% 19% 10% 0% 2015 2017 2018 2019 2020 2021 2016 Gx share of Traditional -----Gx Share of Specialty Gx Share of Traditional Inhalable/injectable 

Source: IQVIA, National Sales Perspectives, Dec 2021

# 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



Source: IQVIA Market Prognosis, Sep 2021; IQVIA Institute, Mar 2022.

The Use of Medicines in the U.S.: Usage and Spending Trends and Outlook to 2026. Report by the IQVIA Institute for Human Data Science.

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