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# Global / US Generics and Biosimilars: Trends, Issues and Outlook

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- + **Key Themes in Generics**
- + Market Overview
- + Biosimilars

# Key recent happenings in the US!



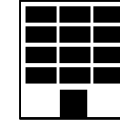
## Market Performance

- ✓ Dollar growth has improved slightly to **+5.8%** (YTD NOV 18)
- ✓ Unadjusted TRx growth YTD NOV 18 is flat while Adjusted 90-Day TRX growth is up **2.8%**
- ✓ 90 day scripts continue to grow
- ✓ Major 17-18 Flu Season
- ✓ Generic \$ sales decreases



## Mergers / Alliances

- ✓ Horizontal
- ✓ Vertical
- ✓ Amazon



## Reimbursement

- ✓ DIR fees and audits
- ✓ Patient's behavior during their deductible period
- ✓ Co-pay cards
- ✓ Accumulator programs



## Generic Space

- ✓ Record number of ANDA approvals and faster approvals, but fewer products launched
- ✓ Cialis
- ✓ Advair Diskus
- ✓ Zytiga?



## Regulation

- ✓ Opioids recognized as a national crisis
- ✓ FDA Priority list of no or limited generic entries and complex generics



## Price / Politics

- ✓ Much more public/ media scrutiny on drug prices
- ✓ Potential administrative actions
- ✓ Gross-to-net and rebates
- ✓ Generic deflation
- ✓ Less Brand price inflation
- ✓ Repeal and Replace?

# Generics and Biosimilars- Current State

## 1. FDA ANDA approvals at 2x normal rate for 4th year in a row

- a. ANDA backlog is ~50% of peak level (estimated at 4000); getting backlog to zero is unlikely
- b. Impact of higher approvals exhibited in price deflationary trends for the past few years

## 2. Low-volume single-source unprotected molecules has been FDA target—approving generics in or near these areas as a priority

- a. Much more to come re: ‘complex generics’
- b. Advair generics being approved as AB-rated in future will challenge non-substitutable generics

## 3. FDA adapting current biosimilar pathway

- a. Potential affect on the interferon-based markets (MS) but not in the near term
- b. Biosimilars face problems with litigation
  - a. Field for adalimumab biosimilars is almost set but no penetration possibly until 2023

## 4. High priced generics and branded generics

- a. Some generics and branded generics have large OOP for patients (ADHD, dermatologics, contraceptives, respiratory, etc.)



# Generic Market Update

## Customer Consolidation

- 3 GPO's control purchasing decisions for > 90% of market
- Move to bi-weekly RFP's throughout the year to reduce procurement costs
- Increased pressure on T's & C's including higher rebates & penalties impacting GTN

## Government

- Price increases have increased public & gov't scrutiny, has led to state regulations that require upfront transparency and some penalties for increasing prices
- Some ANDA backlog starting to clear, impossible to know approval sequence, approval to launch % very low
- Opioid crisis getting significant attention, regulations and tariffs on many of the states dockets for 2019

## Price Erosion

- Erosion has increased due to customer consolidation and aggressive procurement strategies
- PBM's reimbursement reductions through GER driving down prices even during exclusivity periods
- Brand aggressively defending molecules through PBM rebates during exclusivity, driving prices & volume down

## Quality & Supply

- FDA inspections creating some supply disruption, opportunities for companies with flexible supply chains
- FTS penalties increasing & exposure transferred completely to manufacturer
- Ability to supply consistently becoming paramount to maintain existing, obtain new business & minimize FTS penalties

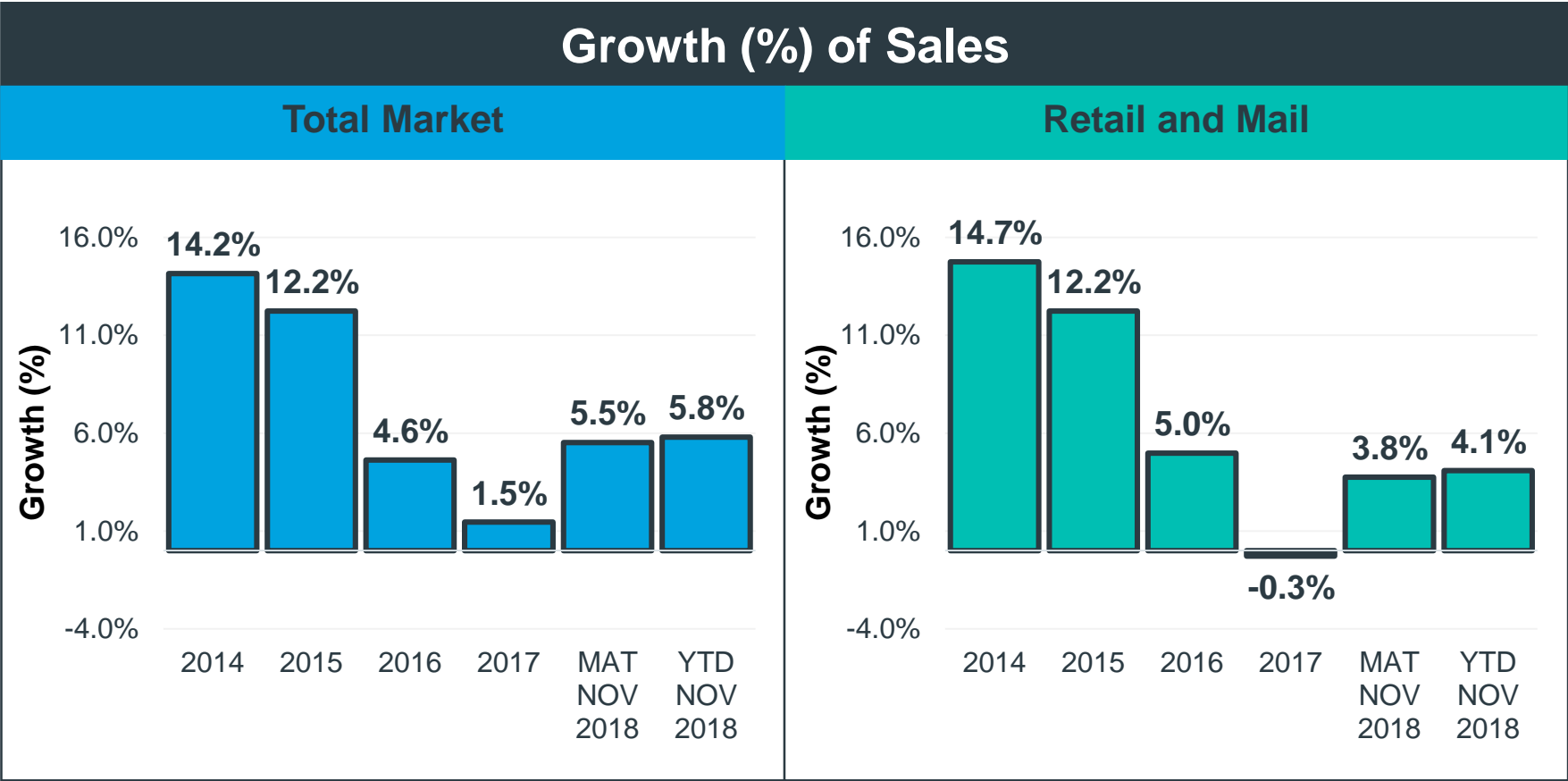
## Competitor Landscape

- Portfolio optimization by some manufacturers could improve margins and provide bid opportunities
- Smaller players accepting new volumes could lead to supply chain disruptions
- Aggressive attempt at new business to reduce price erosion impact

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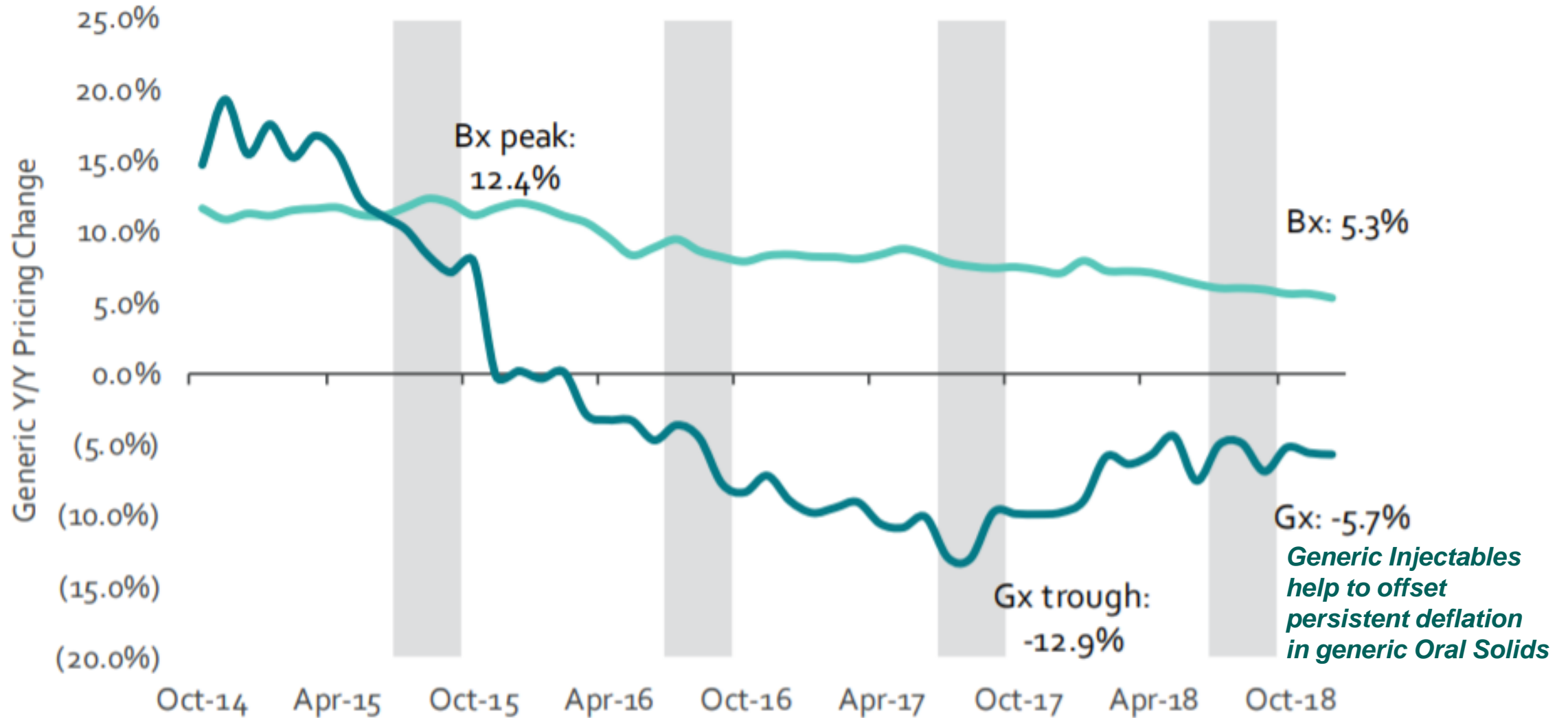
- + Key Themes in Generics
- + **Market Overview**
- + Biosimilars

# Total US market dollar sales growth is rebounding following the Hep C boom in 2014/2015



Source: IQVIA, National Sales Perspectives, January 2019

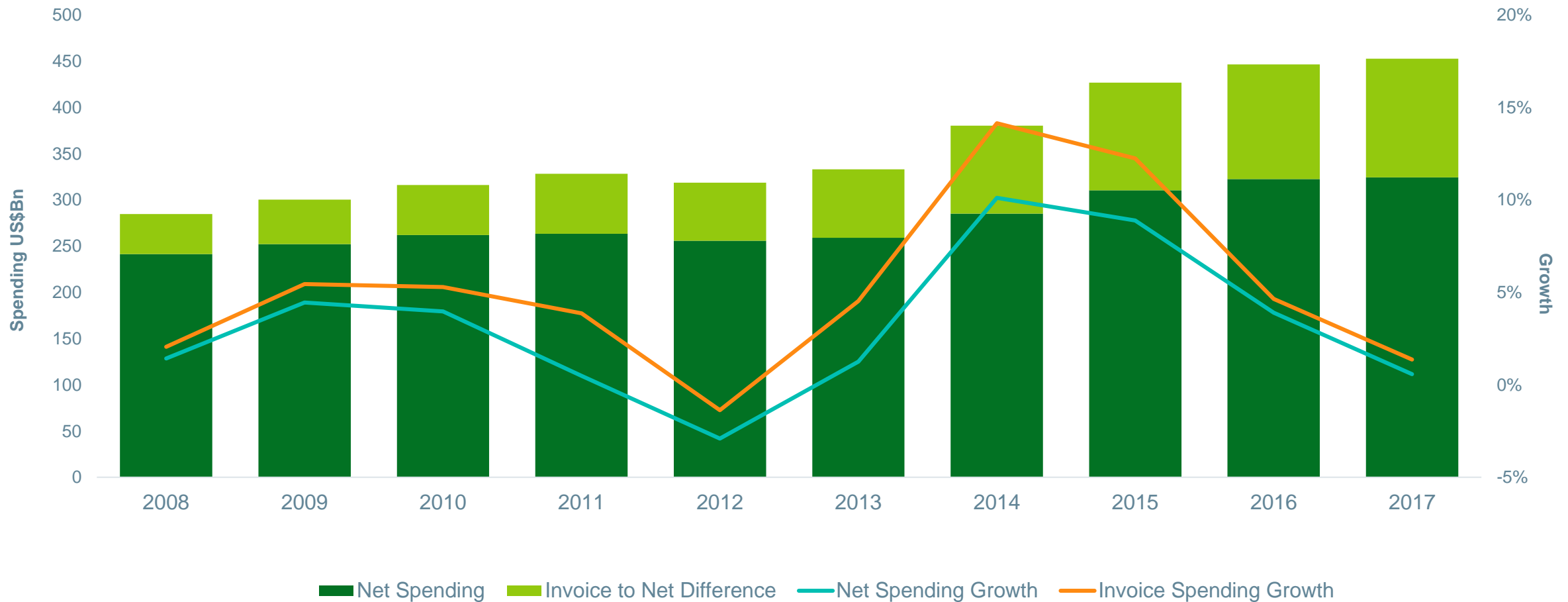
# Nephron Research estimates generic dollar deflation at -5.7% in December 2018





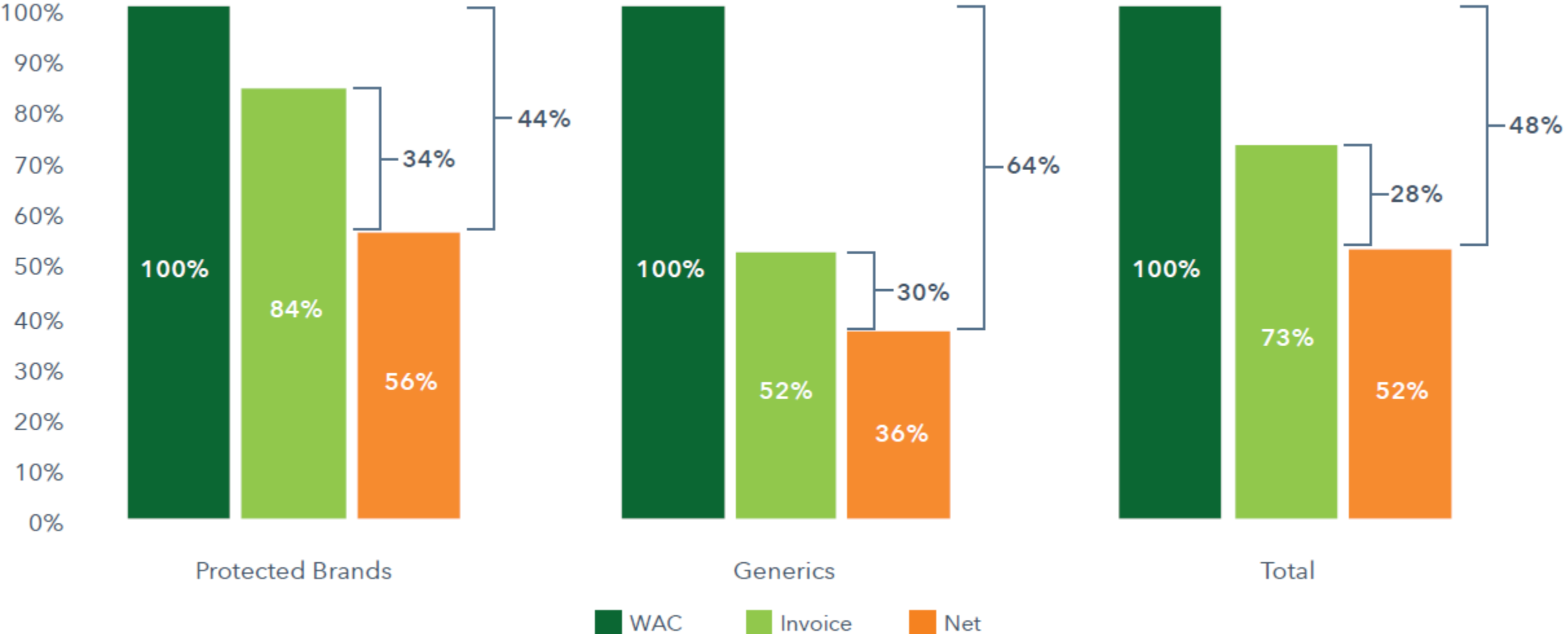
# U.S. medicines growth slowed to 0.6% in 2017 on a net basis

## Total Spending on Medicines



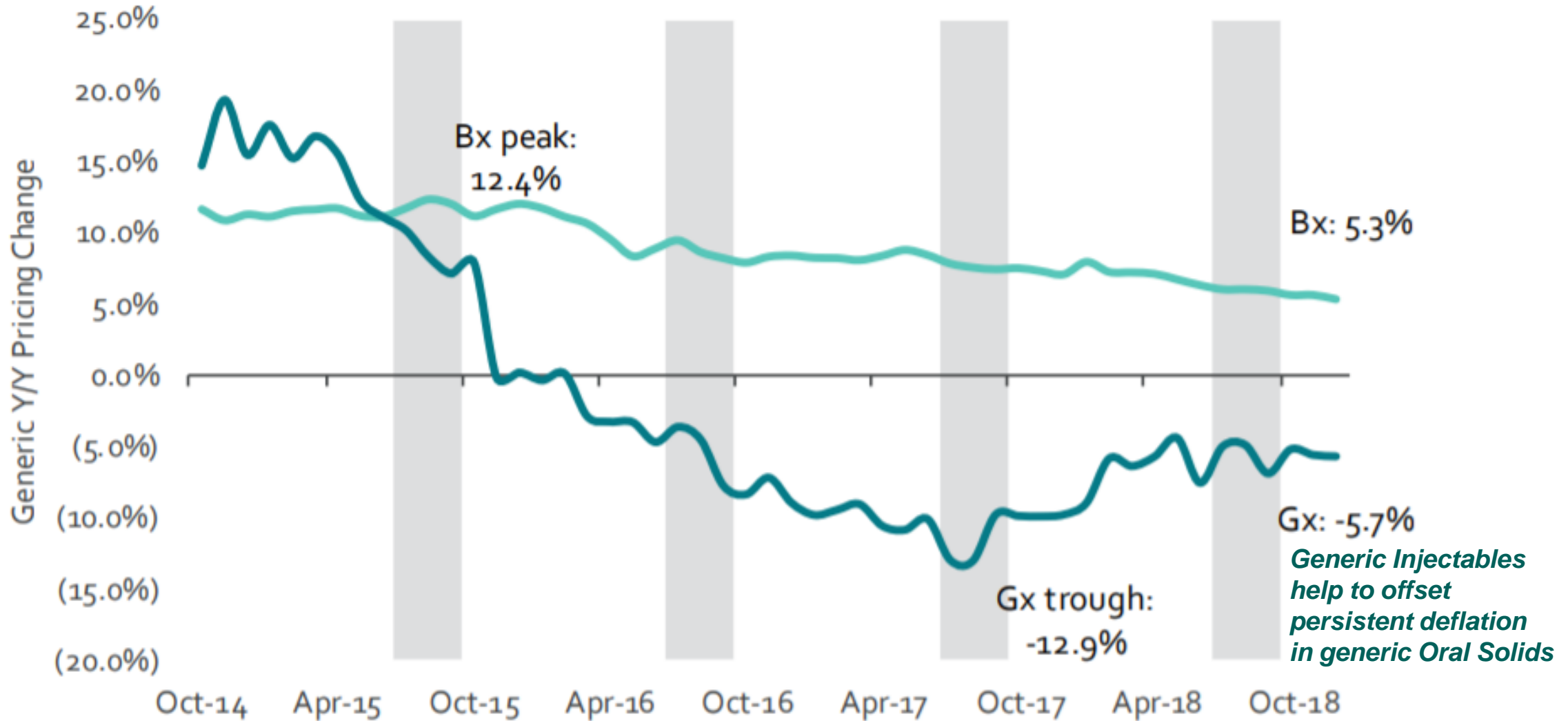
# The average gross to net discount for protected brands is 44% and generics is 64%

2017 Average Net Sales Adjustment By Product Type

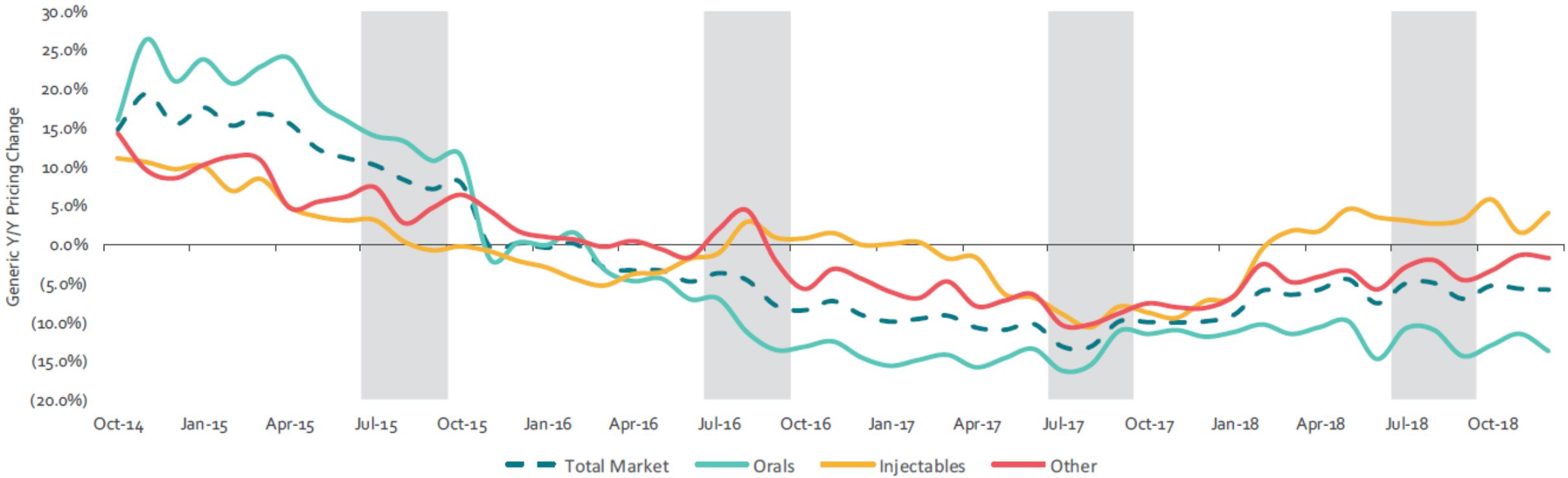


Source: IQVIA Institute; IMS MIDAS; National Sales Perspectives; Public Company SEC filings, Dec 2017

# Nephron Research estimates generic dollar deflation at -5.7% in December 2018

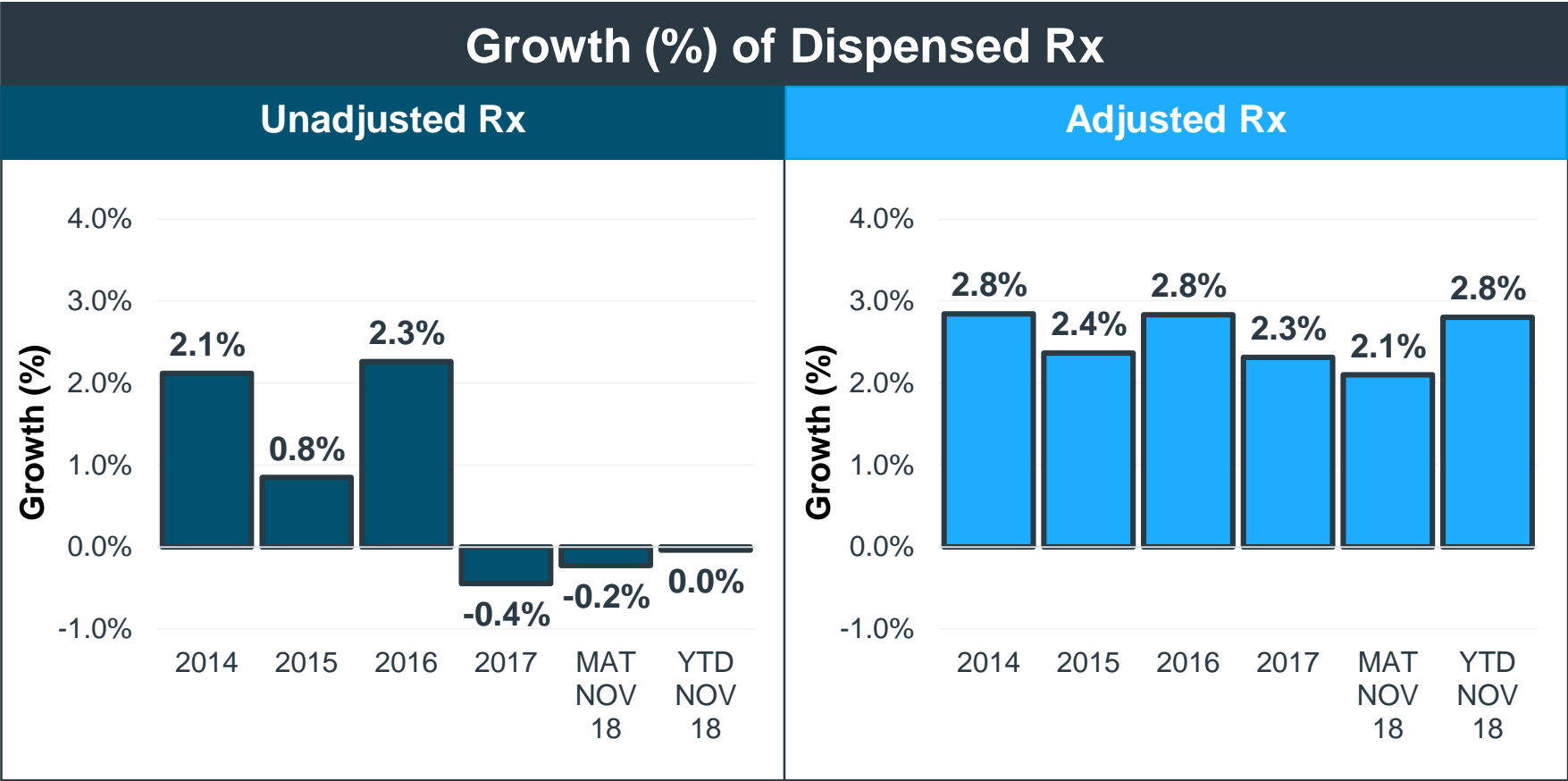


# Injectables led generic price trends in 2018



Source: Nephron Research, Glass Box Analytics, IQVIA

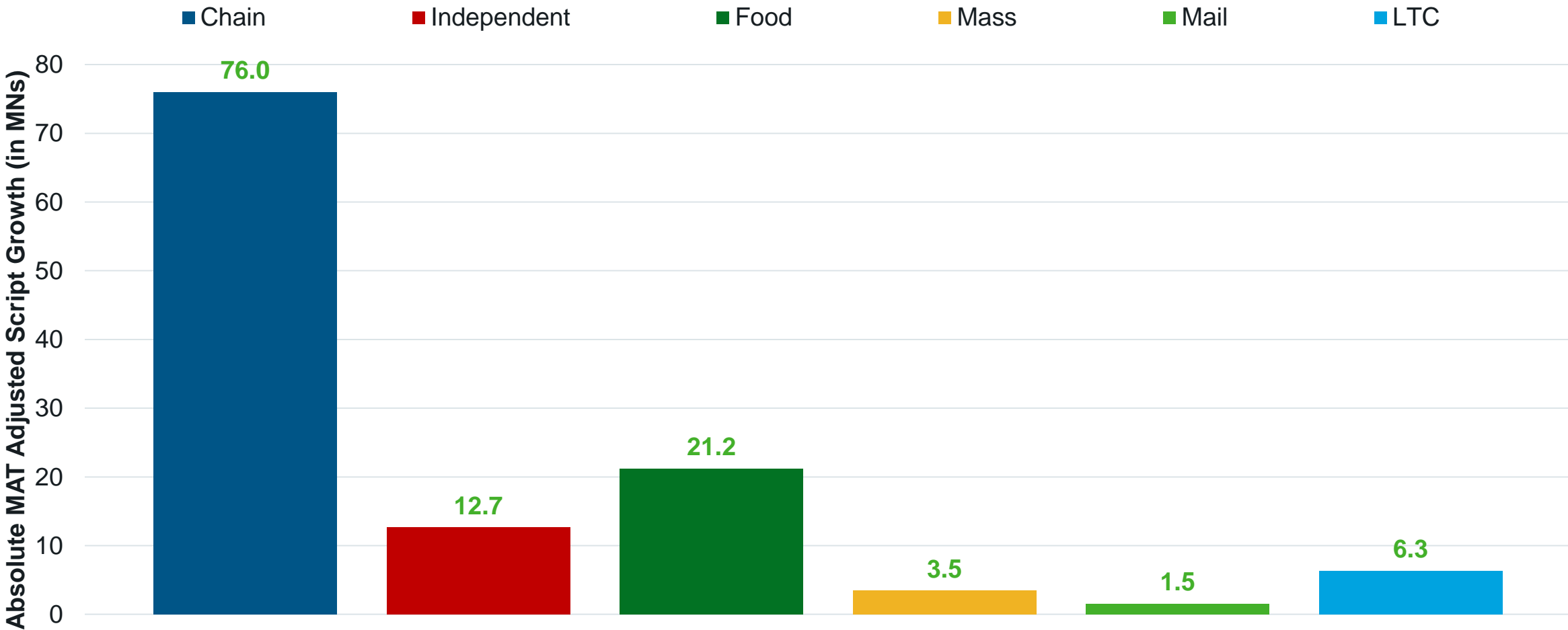
# Although unadjusted dispensed Rx growth appears to be flat, adjusted Rx growth is up 2.8% year to date



Source: IQVIA, National Prescription Audit & RxInsights, January 2019; Retail, Mail, and LTC  
 \*Note: MAT NOV 2018 and YTD NOV 2018 adjusted Rx are growth with new VRAF methodology

# Total adjusted script volume grew (+2.1%) from ~5.7BN in MAT NOV 2017 to ~5.8BN in MAT NOV 2018

## Absolute MAT (NOV 2018) Adjusted Script Growth by Channel



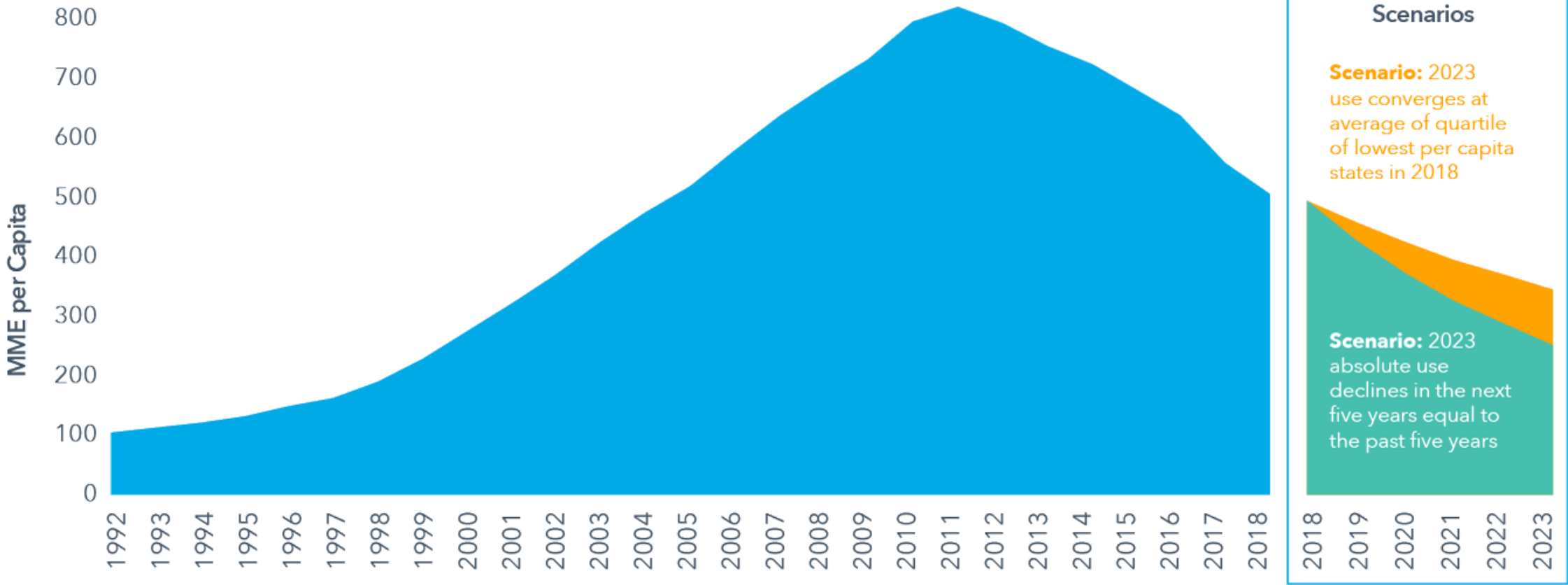
Source: IQVIA, National Sales Perspectives, January 2019



# In MAT NOV 2018, adjusted Rx growth from the top 10 therapy areas is up **2.1%** vs the decline in unadjusted Rx at **-1.0%**

Rank	Therapy Area	Adjusted				Unadjusted			
		MAT NOV 2018 RX (MNs)	Market Share	Absolute Growth (MNs)	Growth	MAT NOV 2018 RX (MNs)	Market Share	Absolute Growth (MNs)	Growth
1	ANTIHYPERTENSIVES	1,166.1	20.2%	39.5	3.5%	709.1	15.9%	-5.9	-0.8%
2	MENTAL HEALTH	514.7	8.9%	21.9	4.5%	410.3	9.2%	7.0	1.7%
3	LIPID REGULATORS	461.0	8.0%	22.1	5.0%	262.0	5.9%	-1.4	-0.5%
4	PAIN	432.2	7.5%	-24.2	-5.3%	422.0	9.4%	-23.9	-5.4%
5	DIABETES	333.4	5.8%	11.8	3.7%	227.8	5.1%	-0.2	-0.1%
6	ANTIBACTERIALS	252.4	4.4%	-9.1	-3.5%	258.0	5.8%	-8.3	-3.1%
7	NERVOUS SYSTEM DISORDERS	240.9	4.2%	6.6	2.8%	205.5	4.6%	2.5	1.2%
8	ANTI-ULCERANTS	240.8	4.2%	4.0	1.7%	170.3	3.8%	-2.8	-1.6%
9	THYROID	218.2	3.8%	4.4	2.1%	135.2	3.0%	-1.8	-1.3%
10	RESPIRATORY	206.6	3.6%	5.9	2.9%	188.7	4.2%	3.5	1.9%
<b>TOP 10</b>		<b>4,066.3</b>	<b>70.4%</b>	<b>82.9</b>	<b>2.1%</b>	<b>2,988.9</b>	<b>66.9%</b>	<b>-31.2</b>	<b>-1.0%</b>

# Prescription opioids are declining and are expected to decline through 2023



Source: IQVIA "SMART - Launch Edition", Sep 2018; IQVIA Institute, Dec 2018  
 Notes: States with MME per capita below the average of the lowest quartile do not change in the convergence scenario.  
 Report: The Global Use of Medicine in 2019 and Outlook to 2023. IQVIA Institute for Human Data Science, Jan 2019

# Total market oral solid **dollar** share is declining, while injectables and systemics is growing

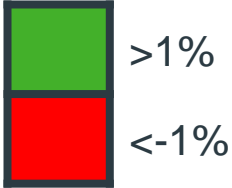
## Total Market

Formulation	2013 Share	MAT OCT 2018 Share
OTHER	10.8%	7.7%
DERMATOLOGICALS	2.8%	2.2%
INHALANTS	3.3%	4.1%
INJECTABLES	29.1%	37.5%
ORAL SOLIDS	49.7%	42.3%
SYSTEMICS	4.3%	6.2%



Formulation	2013 Share	MAT OCT 2018 Share
OTHER	7.0%	4.1%
DERMATOLOGICALS	0.9%	0.6%
INHALANTS	2.9%	4.1%
INJECTABLES	35.1%	42.2%
ORAL SOLIDS	48.7%	41.8%
SYSTEMICS	5.4%	7.2%

Formulation	2013 Share	MAT OCT 2018 Share
OTHER	8.9%	10.8%
DERMATOLOGICALS	7.0%	7.1%
INHALANTS	3.1%	2.1%
INJECTABLES	13.5%	18.8%
ORAL SOLIDS	66.8%	60.1%
SYSTEMICS	0.8%	1.0%

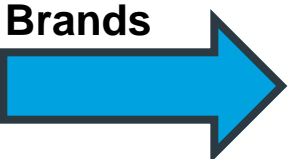


Source: IQVIA, National Sales Perspectives, December 2018

# Oral solids account for 86.7% of total market **adjusted scripts** and 91.6% of unbranded generic adjusted scripts in 2018

## Total Market

Formulation	2013 Share	2018 Share
OTHER	7.2%	6.0%
DERMATOLOGICALS	2.1%	2.1%
INHALANTS	2.0%	2.2%
INJECTABLES	2.4%	2.9%
ORAL SOLIDS	86.2%	86.7%
SYSTEMICS	0.1%	0.2%

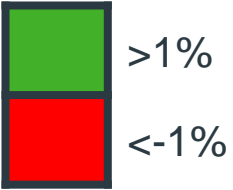


### Brands

Formulation	2013 Share	2018 Share
OTHER	12.2%	9.2%
DERMATOLOGICALS	1.3%	1.0%
INHALANTS	6.6%	13.4%
INJECTABLES	13.3%	25.0%
ORAL SOLIDS	66.0%	49.7%
SYSTEMICS	0.7%	1.8%

### Generics

Formulation	2013 Share	2018 Share
OTHER	5.5%	5.2%
DERMATOLOGICALS	2.1%	2.1%
INHALANTS	0.6%	0.5%
INJECTABLES	0.6%	0.6%
ORAL SOLIDS	91.2%	91.6%
SYSTEMICS	0.0%	0.0%



Source: IQVIA, RxInsights, February 2019

# Pain and mental health have the highest annual generic share of spend for the top 10 therapy areas

RANK*	THERAPY AREA	2013				MAT NOV 2018			
		BRAND	BRANDED GENERIC	UNBRANDED GENERIC	TOTAL \$ (BNs)	BRAND	BRANDED GENERIC	UNBRANDED GENERIC	TOTAL \$ (BNs)
1	DIABETES	93.1%	1.8%	5.1%	\$25.6	97.0%	0.8%	2.2%	\$60.0
2	ONCOLOGY	91.6%	1.2%	7.2%	\$28.2	95.7%	0.6%	3.6%	\$57.8
3	AUTOIMMUNE	99.9%	0.0%	0.1%	\$18.2	99.8%	0.1%	0.1%	\$53.5
4	RESPIRATORY	80.1%	9.1%	10.8%	\$19.9	86.0%	9.1%	4.9%	\$29.0
5	HIV ANTIVIRALS	98.5%	0.0%	1.5%	\$12.2	98.6%	0.0%	1.4%	\$22.4
6	MULTIPLE SCLEROSIS	88.3%	11.7%	0.0%	\$11.9	91.2%	7.0%	1.8%	\$18.9
7	ANTICOAGULANTS	69.6%	0.4%	29.9%	\$7.2	90.6%	0.3%	9.2%	\$16.7
8	MENTAL HEALTH	83.4%	0.7%	15.8%	\$21.2	75.9%	0.8%	23.3%	\$16.4
9	PAIN	42.1%	20.9%	37.0%	\$18.9	30.0%	34.1%	35.8%	\$16.1
10	NERVOUS SYSTEM DISORDERS	67.0%	1.8%	31.2%	\$8.2	76.4%	6.9%	16.7%	\$14.1

Source: IQVIA, National Sales Perspectives, January 2019  
 Note: Unbranded Generic includes "Other" category  
 \*: Ranked on MAT NOV 2018 \$

# The top 10 therapy areas have an average of 6.2% unbranded generic sales

Rank	Therapy Area	MAT NOV 2018 NON-DISCOUNTED SPEND (\$BNS)				SHARE (%)		
		TOTAL SPEND	BRAND	BRANDED GENERIC	UNBRANDED GENERIC	BRAND	BRANDED GENERIC	UNBRANDED GENERIC
1	DIABETES	\$60.0	\$58.1	\$0.5	\$1.3	97.0%	0.8%	2.2%
2	ONCOLOGY	\$57.8	\$55.3	\$0.4	\$2.1	95.7%	0.6%	3.6%
3	AUTOIMMUNE	\$53.5	\$53.4	\$0.1	\$0.1	99.8%	0.1%	0.1%
4	RESPIRATORY	\$29.0	\$25.0	\$2.6	\$1.4	86.0%	9.1%	4.9%
5	HIV ANTIVIRALS	\$22.4	\$22.1	\$0.0	\$0.3	98.6%	0.0%	1.4%
6	MULTIPLE SCLEROSIS	\$18.9	\$17.2	\$1.3	\$0.3	91.2%	7.0%	1.8%
7	ANTICOAGULANTS	\$16.7	\$15.1	\$0.0	\$1.5	90.6%	0.3%	9.2%
8	MENTAL HEALTH	\$16.4	\$12.4	\$0.1	\$3.8	75.9%	0.8%	23.3%
9	PAIN	\$16.1	\$4.8	\$5.5	\$5.8	30.0%	34.1%	35.8%
10	NERVOUS SYSTEM DISORDERS	\$14.1	\$10.8	\$1.0	\$2.4	76.4%	6.9%	16.7%
<b>TOP 10</b>		<b>\$304.9</b>	<b>\$274.3</b>	<b>\$11.6</b>	<b>\$19.0</b>	<b>90.0%</b>	<b>3.8%</b>	<b>6.2%</b>



# The top 20 therapy areas have an average of 10.2% unbranded generic sales

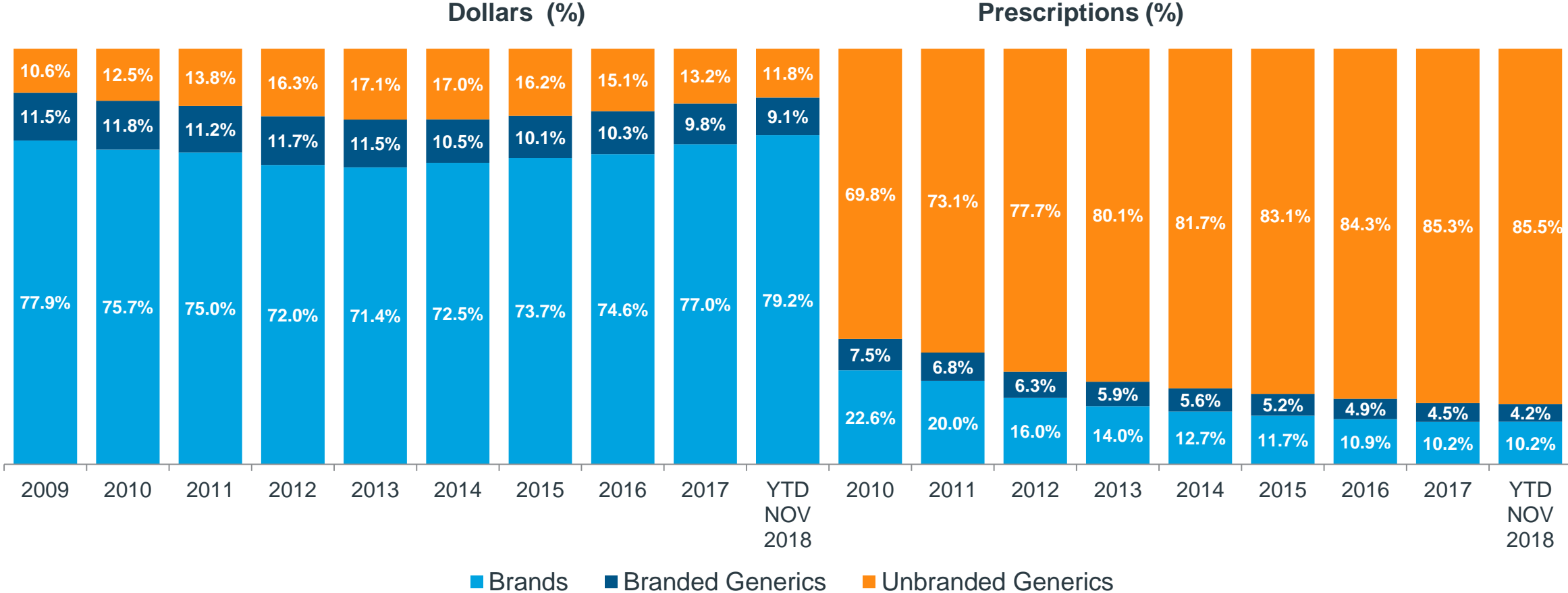
Rank	Therapy Area	MAT NOV 2018 NON-DISCOUNTED SPEND (\$BNS)				SHARE (%)		
		TOTAL SPEND	BRAND	BRANDED GENERIC	UNBRANDED GENERIC	BRAND	BRANDED GENERIC	UNBRANDED GENERIC
11	VACCINES	\$11.2	\$11.2	\$0.0	\$0.0	100.0%	0.0%	0.0%
12	ADHD	\$9.3	\$4.2	\$2.2	\$2.9	45.1%	24.0%	30.9%
13	DERMATOLOGICS	\$8.8	\$2.2	\$2.9	\$3.7	24.9%	33.3%	41.9%
14	GI PRODUCTS	\$8.6	\$4.6	\$2.2	\$1.8	53.4%	25.4%	21.1%
15	OTHER CARDIOVASCULARS	\$7.9	\$4.6	\$1.0	\$2.3	57.8%	13.2%	29.0%
16	OTHER CNS	\$7.9	\$5.6	\$0.9	\$1.4	71.2%	11.4%	17.4%
17	VIRAL HEPATITIS	\$7.8	\$7.8	\$0.0	\$0.1	99.3%	0.0%	0.7%
18	ANTIHYPERTENSIVES	\$7.1	\$3.3	\$0.2	\$3.6	46.6%	2.2%	51.3%
19	SEX HORMONES	\$6.3	\$2.3	\$2.9	\$1.2	35.8%	45.2%	19.0%
20	ANTIBACTERIALS	\$5.8	\$1.8	\$0.5	\$3.5	31.6%	8.3%	60.1%
<b>TOP 20</b>		<b>\$385.6</b>	<b>\$321.8</b>	<b>\$24.3</b>	<b>\$39.4</b>	<b>83.5%</b>	<b>6.3%</b>	<b>10.2%</b>

# 90.1% scripts for the top 10 therapy areas are dispensed as unbranded generics

Rank	Therapy Area	MAT NOV 2018 UNADJUSTED RX (MNs)				SHARE (%)		
		TOTAL SPEND	BRAND	BRANDED GENERIC	UNBRANDED GENERIC	BRAND	BRANDED GENERIC	UNBRANDED GENERIC
1	ANTIHYPERTENSIVES	709.1	10.6	4.9	693.6	1.5%	0.7%	97.8%
2	PAIN	422.0	7.3	3.6	411.1	1.7%	0.9%	97.4%
3	MENTAL HEALTH	410.3	12.1	0.2	398.0	3.0%	0.0%	97.0%
4	LIPID REGULATORS	262.0	3.5	0.3	258.2	1.3%	0.1%	98.6%
5	ANTIBACTERIALS	258.0	0.5	0.9	256.6	0.2%	0.4%	99.4%
6	DIABETES	227.8	97.1	0.9	129.8	42.6%	0.4%	57.0%
7	NERVOUS SYSTEM DISORDERS	205.5	15.3	1.5	188.7	7.4%	0.7%	91.8%
8	RESPIRATORY	188.7	87.6	31.9	69.2	46.4%	16.9%	36.7%
9	OTHER CNS	179.5	14.2	1.6	163.6	7.9%	0.9%	91.2%
10	ANTI-ULCERANTS	170.3	6.1	0.1	164.1	3.6%	0.1%	96.4%
<b>TOP 10</b>		<b>3,033.2</b>	<b>254.3</b>	<b>45.9</b>	<b>2,733.0</b>	<b>8.4%</b>	<b>1.5%</b>	<b>90.1%</b>

# 85.5% of prescriptions are dispensed as unbranded generics

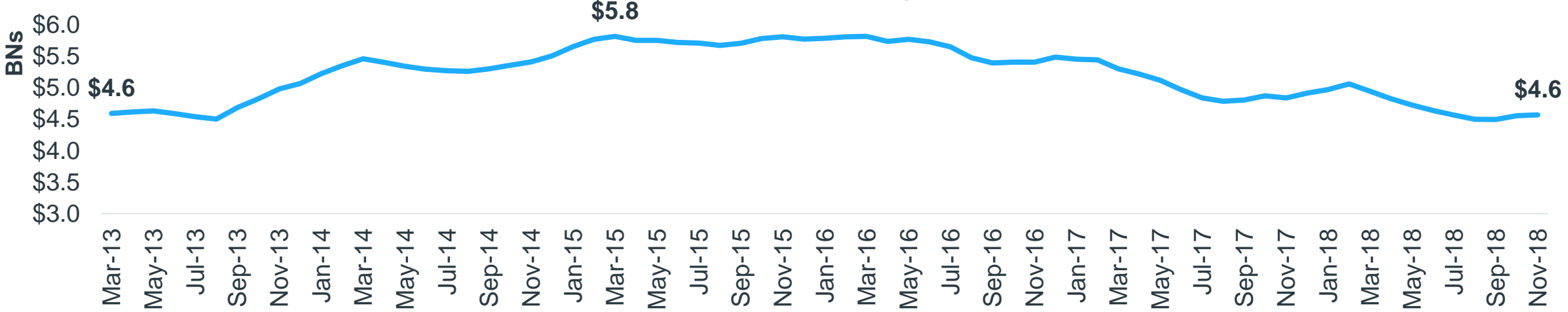
*Unbranded and branded generics account for 20.8% of spending year to date*



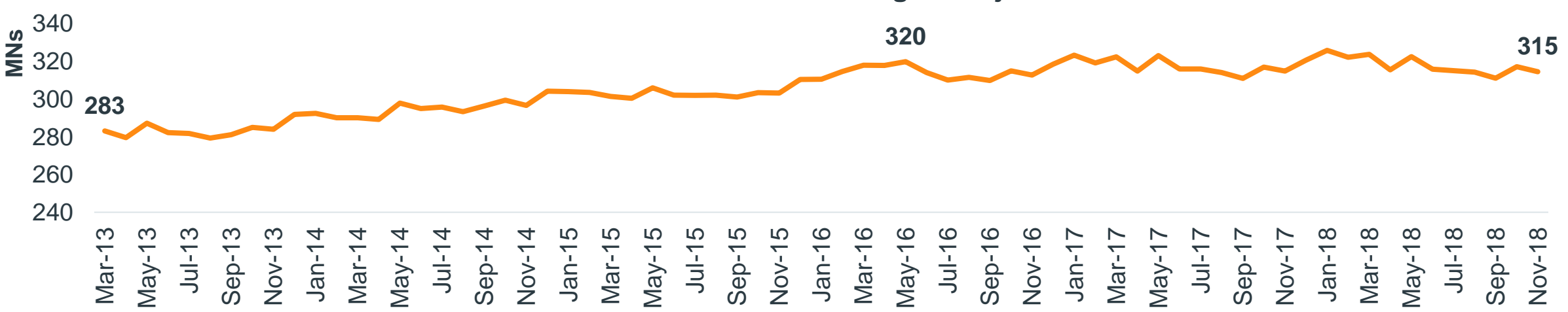
Source: IQVIA, National Sales Perspectives, National Prescription Audit, January 2019  
 Note: numbers may not add exactly to 100% due to rounding

# Unbranded generic script volume appears to continue steady demand while monthly sales have declined since deflation in 2015

Unbranded Generic 3 Mth Avg. \$ Sales



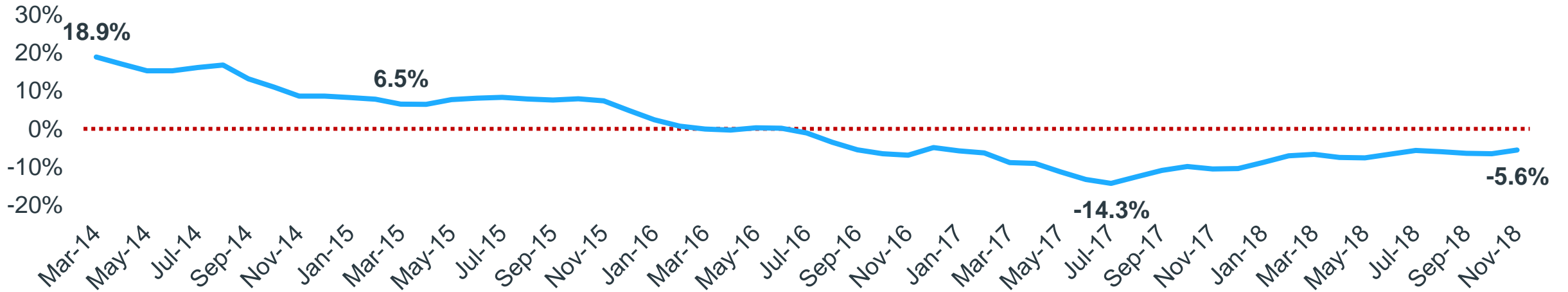
Unbranded Generic 3 Mth Avg. Unadjusted TRx



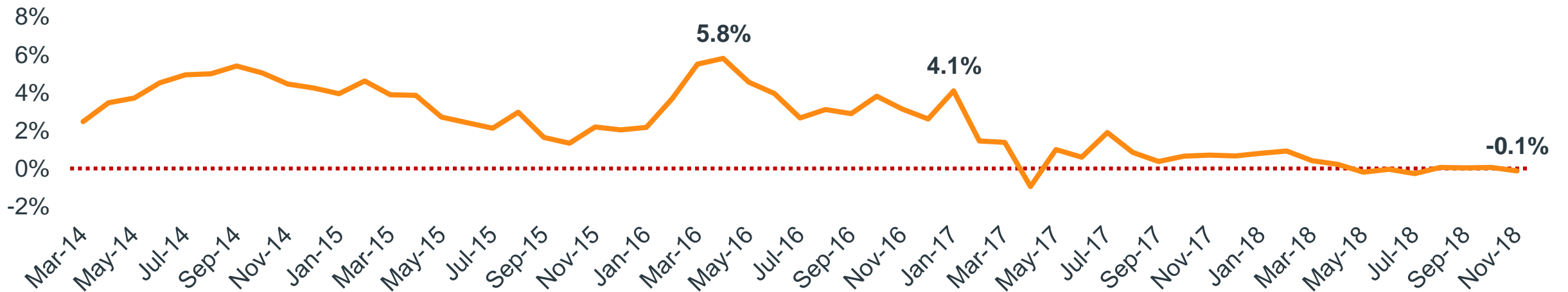
Source: IQVIA, National Sales Perspectives and National Prescription Audit, January 2019

# Unbranded Generic % change vs. a year ago is getting better

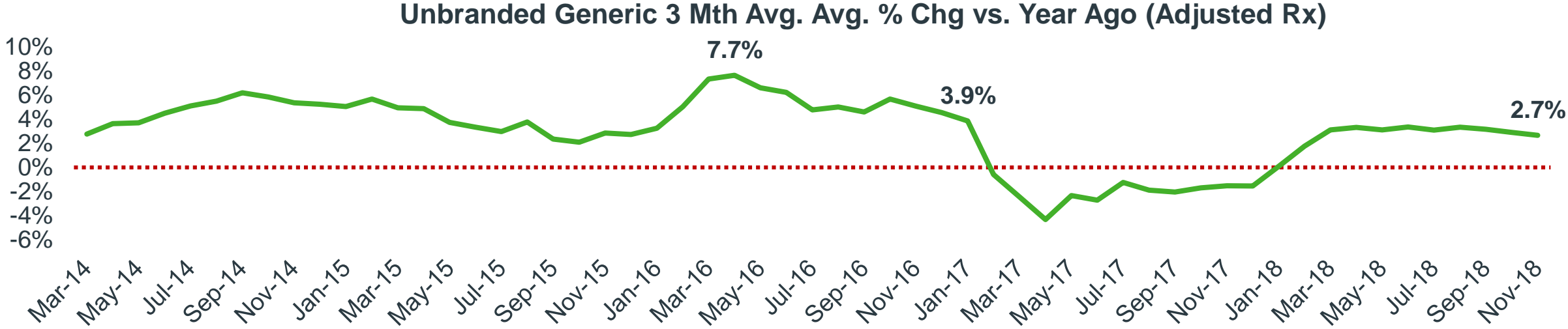
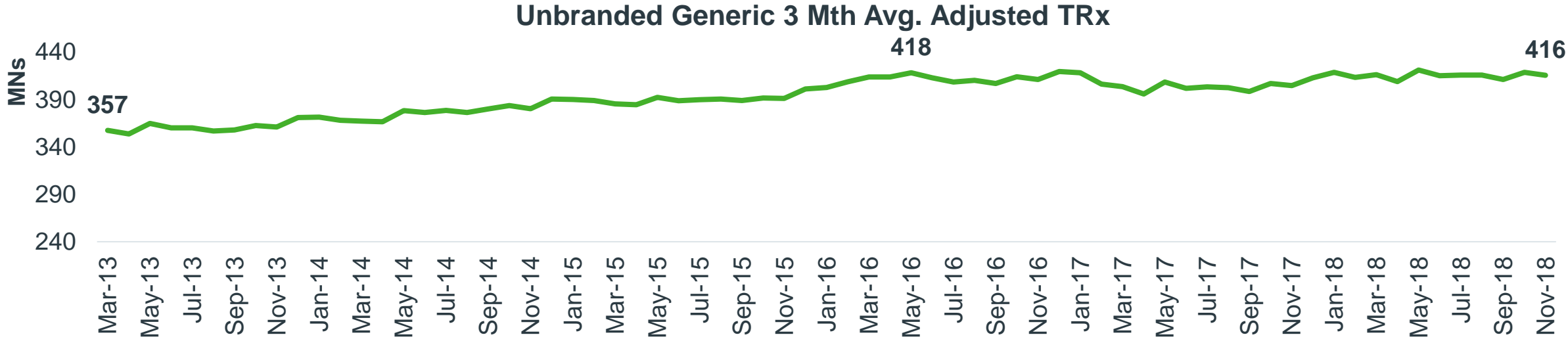
Unbranded Generic 3 Mth Avg. % Chg vs. Year Ago (\$)



Unbranded Generic 3 Mth Avg. Avg. % Chg vs. Year Ago (Rx)



# Adjusted unbranded generic scripts are growing at 2.7% in the most recent month (NOV 2018)





# US is facing price deflation, decreased dollar growth, and concentrated buying power in generics market

## Decreased sales and TRx



- Generic dollar sales have declined for **30 consecutive** months (thru November 2018)
- **12 of top 20** generic companies had **negative dollar growth** over the last 12 months, supporting the slowed generic deflation rate

## Consolidated buying power



- **Three generic purchasers** have **90%** share of generic purchases
- The **top 4 generic** companies\* have **33% dollar share** and **28% of TRX share**
- It would only take **22** generic companies to comprise **75+% dollar share** and **21** generic companies to comprise **76+% Rx share**

# Market consolidation means there are now three key drug purchasers in the US



1. WBAD = Walgreens Boots Alliance Development GbMH. Includes U.S. volume only. Includes AmerisourceBergen volume and pro forma volume from Prime Therapeutics.  
2. McKesson OneStop figures include Rite Aid and Albertsons. Excludes Celesio and other non-U.S. volume.  
3. Econdisc Contracting Solutions includes Express Scripts, Kroger, Supervalu, and other retail chains. In May 2017, Econdisc agreed to partner with WBAD to purchase generic drugs.  
Source: *The 2018 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers*, Drug Channels Institute, 2018  
Published on *Drug Channels* ([www.drugchannel.com](http://www.drugchannel.com)) on February 1, 2018.

# Top 10 Corporations by Unbranded Generic Non-Discounted Spend and Unbranded Generic Unadjusted Script Growth (MAT NOV 2018)

Rank	Corporation	Non-Discounted Spend (US\$)	
		MAT NOV 2018 Abs Growth (MNs)	Growth (YoY Δ)
1	GRIFOLS	\$510.6	110.6%
2	ZYDUS	\$370.7	36.4%
3	TRIGEN LABS	\$199.8	68.9%
4	SHIRE	\$163.3	517.9%
5	TORRENT	\$130.9	54.4%
6	ASCEND LABS	\$130.6	58.9%
7	ALVOGEN	\$126.5	14.0%
8	HIKMA	\$118.9	7.7%
9	CIPLA	\$117.9	28.7%
10	SOLCO HEALTHCARE	\$113.7	74.6%
<b>TOP 10</b>		<b>\$1,982.8</b>	<b>37.5%</b>

Rank	Corporation	Unadjusted Rx	
		MAT NOV 2018 Abs Growth (MNs)	Growth (YoY Δ)
1	SOLCO HEALTHCARE	33.0	56.0%
2	ACCORD HEALTHCARE	32.2	36.8%
3	ASCEND LABS	30.3	79.1%
4	LUPIN	27.6	14.0%
5	AUROBINDO	27.1	13.3%
6	TORRENT	23.5	46.6%
7	UNICHEM	21.9	56.8%
8	LEGACY PHARM PKG	17.3	25.4%
9	ALEMBIC	13.7	172.0%
10	LANNETT COMP	13.5	23.8%
<b>TOP 10</b>		<b>240.2</b>	<b>29.8%</b>

# Top 10 Corporations by Unbranded Generic Non-Discounted Spend

Rank	Corporation	Non-Discounted Spend (US\$)	
		MAT NOV 2018 Total (BNs)	Market Share (%)
1	TEVA	\$6.4	11.5%
2	MYLAN LABS	\$5.6	10.0%
3	SANDOZ	\$3.8	6.8%
4	AMNEAL	\$2.8	4.9%
5	ENDO	\$2.2	4.0%
6	GREENSTONE	\$2.0	3.5%
7	SUN PHARMA	\$1.7	3.0%
8	HIKMA	\$1.7	3.0%
9	LUPIN	\$1.6	2.9%
10	FRESENIUS KABI	\$1.4	2.5%
<b>TOP 10</b>		<b>\$29.2</b>	<b>52.3%</b>

# Top 11-20 Corporations by Unbranded Generic Non-Discounted Spend

Rank	Corporation	Non-Discounted Spend (US\$)	
		MAT NOV 2018 Total (BNs)	Market Share (%)
11	ZYDUS	\$1.4	2.5%
12	DR REDDY	\$1.3	2.4%
13	PERRIGO	\$1.3	2.3%
14	PRASCO LABS	\$1.3	2.3%
15	APOTEX	\$1.2	2.1%
16	AUROBINDO	\$1.1	2.0%
17	ALVOGEN	\$1.0	1.8%
18	VALEANT	\$1.0	1.8%
19	GRIFOLS	\$1.0	1.7%
20	LANNETT	\$0.8	1.5%
<b>TOP 20</b>		<b>\$40.6</b>	<b>72.7%</b>

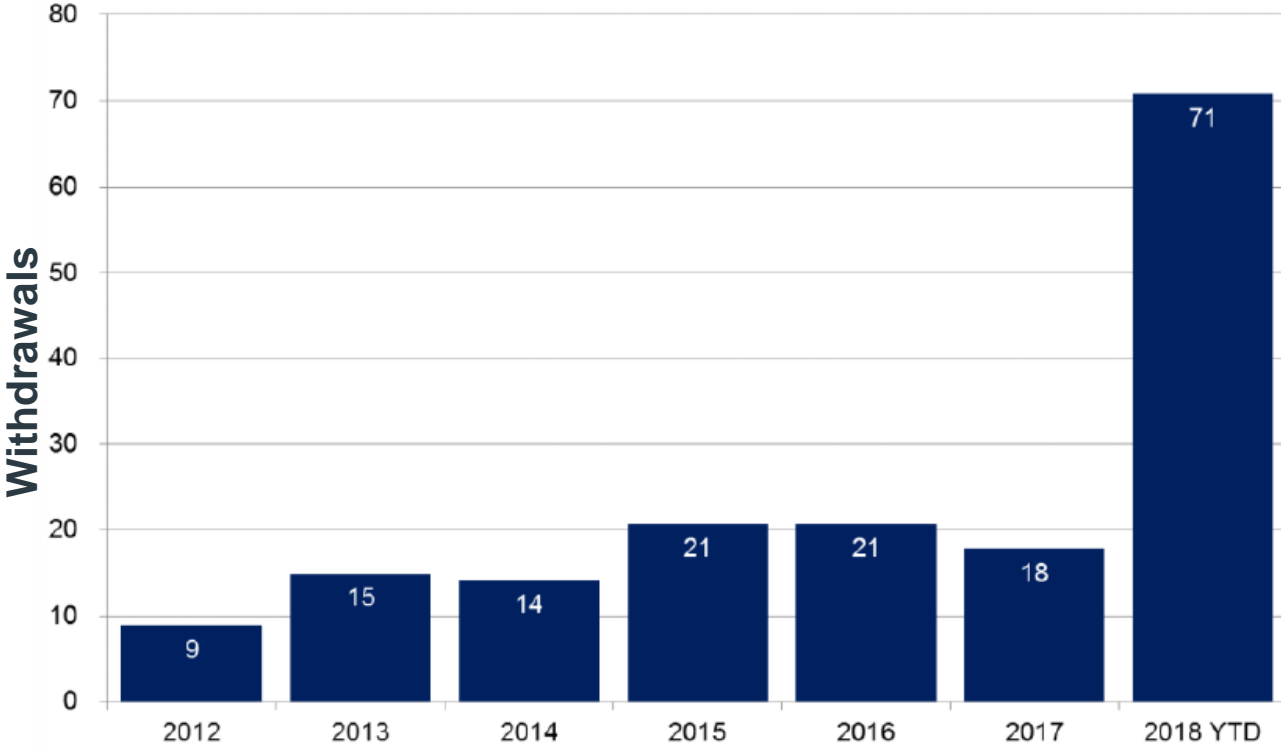
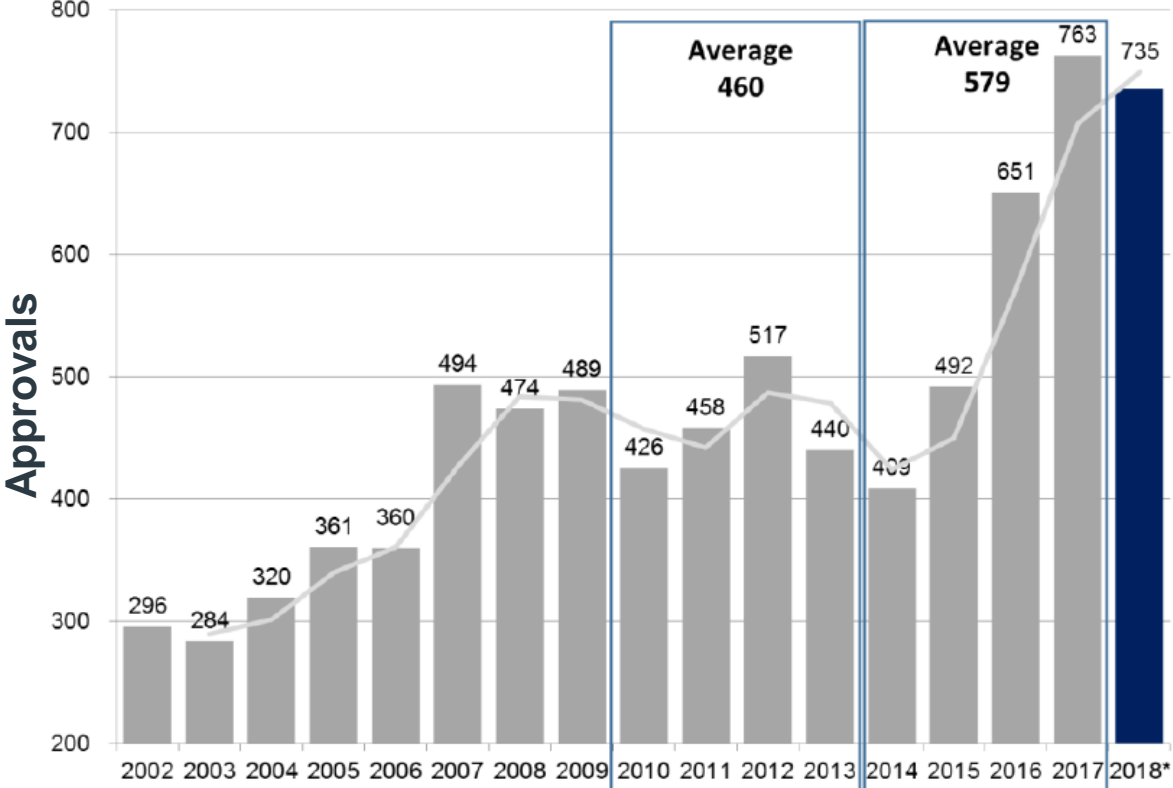
# Top 10 Corporations by Unbranded Generic Unadjusted Scripts

Rank	Corporation	Unadjusted Rx	
		MAT NOV 2018 Total (MNs)	Market Share (%)
1	TEVA	484.0	12.7%
2	MYLAN LABS	240.0	6.3%
3	AUROBINDO	230.7	6.0%
4	LUPIN	223.9	5.9%
5	SANDOZ	177.9	4.7%
6	AMNEAL	151.1	4.0%
7	APOTEX	126.8	3.3%
8	ZYDUS	122.3	3.2%
9	ACCORD HEALTHCARE	119.9	3.1%
10	DR REDDY	105.5	2.8%
<b>TOP 10</b>		<b>1,982.1</b>	<b>52.0%</b>

# Top 11-20 Corporations by Unbranded Generic Unadjusted Scripts

Rank	Corporation	Unadjusted Rx	
		MAT NOV 2018 Total (MNs)	Market Share (%)
11	HIKMA	104.8	2.7%
12	SUN PHARMA	101.0	2.6%
13	CIPLA	94.3	2.5%
14	SOLCO HEALTHCARE	92.0	2.4%
15	ENDO	89.5	2.3%
16	LEGACY PHARM PKG	85.7	2.2%
17	GLENMARK	77.9	2.0%
18	TORRENT	74.1	1.9%
19	LANNETT COMP	70.0	1.8%
20	HETEROPHARMACEUTICALS	69.4	1.8%
<b>TOP 20</b>		<b>2,840.8</b>	<b>74.5%</b>

# Abbreviated New Drug Application (ANDA) approvals have continued to accelerate since 2014; at the same time, withdrawals are increasing



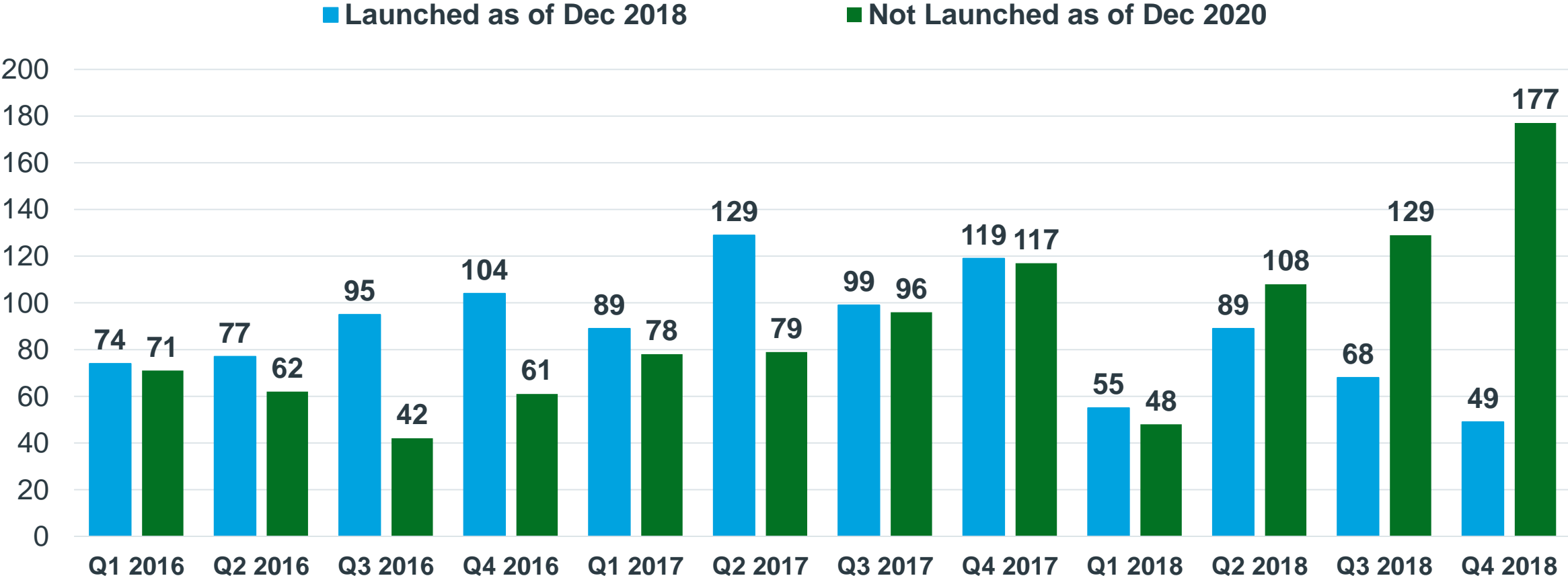
Monthly ANDA withdrawals spiked in fiscal 2018 as companies realized that “me-too” type products, which make up a portion of the FDA backlog, are unlikely to be financially viable

Source: RBC Capital Markets, FDA



# IQVIA ANDA Approvals: launched vs. non launched by quarter

*IQVIA launch data as of Dec 2018*



# Summary of findings

*IQVIA launch data as of Dec 2018*

FDA ANDA Approval Year	Total Approvals	Launched in 2016	% Launched in 2016	Launched by 2017	% Launched by 2017	Launched as of Dec 2018	% Launched as of Dec 2018
2016	586	178	30.4%	308	52.6%	350	59.7%
2017	806			257	31.9%	436	54.1%
2018	723					261	36.1%

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- + Key Themes in Generics
- + Market Overview
- + **Biosimilars**

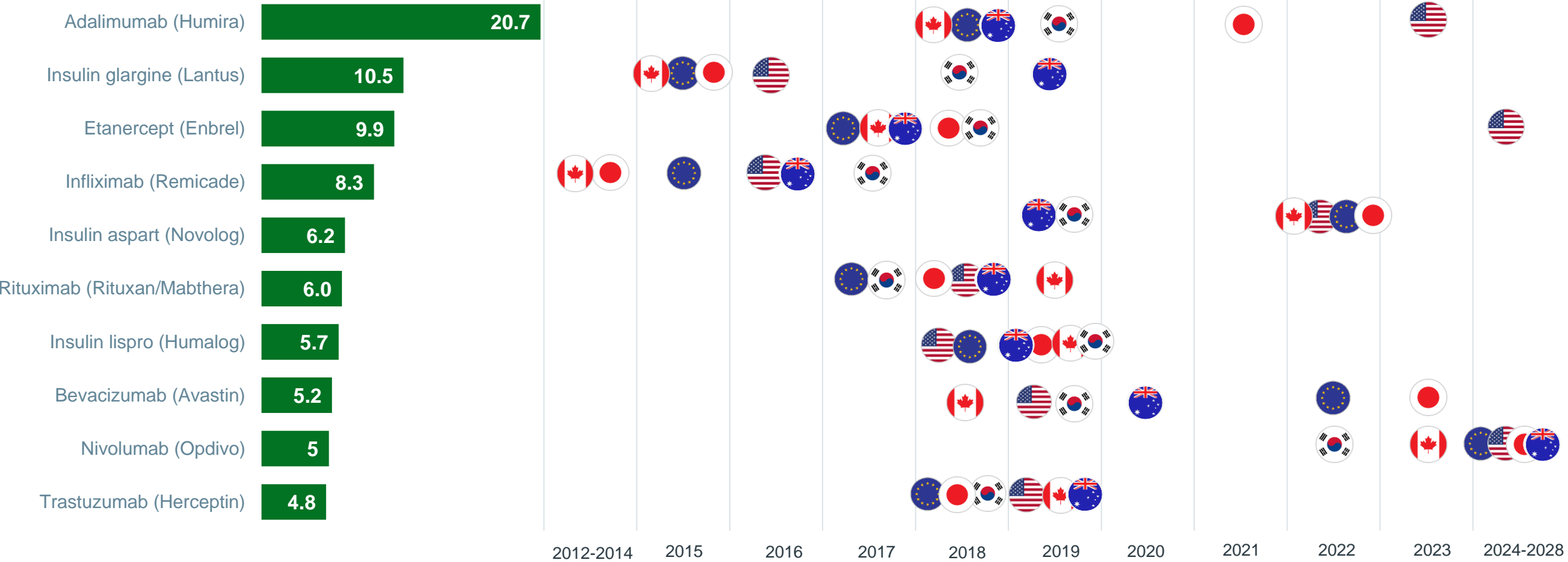
# 5 of the 17 FDA approved biosimilars have launched in the US

Approval Count	FDA Approval Date	Biosimilar	Biosimilar Manufacturer	Reference Product	Reference Manufacturer	Molecule	Launch Status
1	March 2015	<b>Zarxio</b>	Sandoz Novartis	Neupogen	Amgen	filgrastim	2015
2	April 2016	<b>Inflectra</b>	Celltrion	Remicade	Janssen (J&J)	infliximab	2016
3	August 2016	<b>Erelzi</b>	Sandoz Novartis	Enbrel	Amgen	etanercept	2018
4	September 2016	<b>Amjevita</b>	Amgen	Humira	Abbvie	adalimumab	2023
5	May 2017	<b>Renflexis</b>	Merck & Co	Remicade	Janssen (J&J)	Infliximab	2017
6	August 2017	<b>Cyltezo</b>	Boehringer Ingelheim	Humira	Abbvie	adalimumab	
7	September 2017	<b>Mvasi</b>	Amgen	Avastin	Genentech	bevacizumab	2019
8	December 2017	<b>Ogivri</b>	Mylan	Herceptin	Genentech	trastuzumab	
9	December 2017	<b>Ixifi</b>	Pfizer	Remicade	Janssen (J&J)	Infliximab	
10	May 2018	<b>Retacrit</b>	Hospira (Pfizer)	Epogen	Amgen	epoetin alfa	2018
11	June 2018	<b>Fulphila</b>	Mylan	Neulasta	Amgen	pegfilgrastim	2018
12	July 2018	<b>Nivestym</b>	Hospira (Pfizer)	Neupogen	Amgen	filgrastim	2018
13	October 2018	<b>Hyrimoz</b>	Sandoz	Humira	Abbvie	adalimumab	2023
14	November 2018	<b>Udenyca</b>	Coherus BioSciences	Neulasta	Amgen	pegfilgrastim	2019
15	November 2018	<b>Truxima</b>	Celltrion	Rituxan	Genentech	rituximab	
16	December 2018	<b>Herzuma</b>	Celltrion	Herceptin	Genentech	trastuzumab	
17	January 2019	<b>Ontruzant</b>	Samsung Bioepis (Merck)	Herceptin	Genentech	trastuzumab	

# The US is slow to commercialize versus other developed countries for the first biosimilar availability

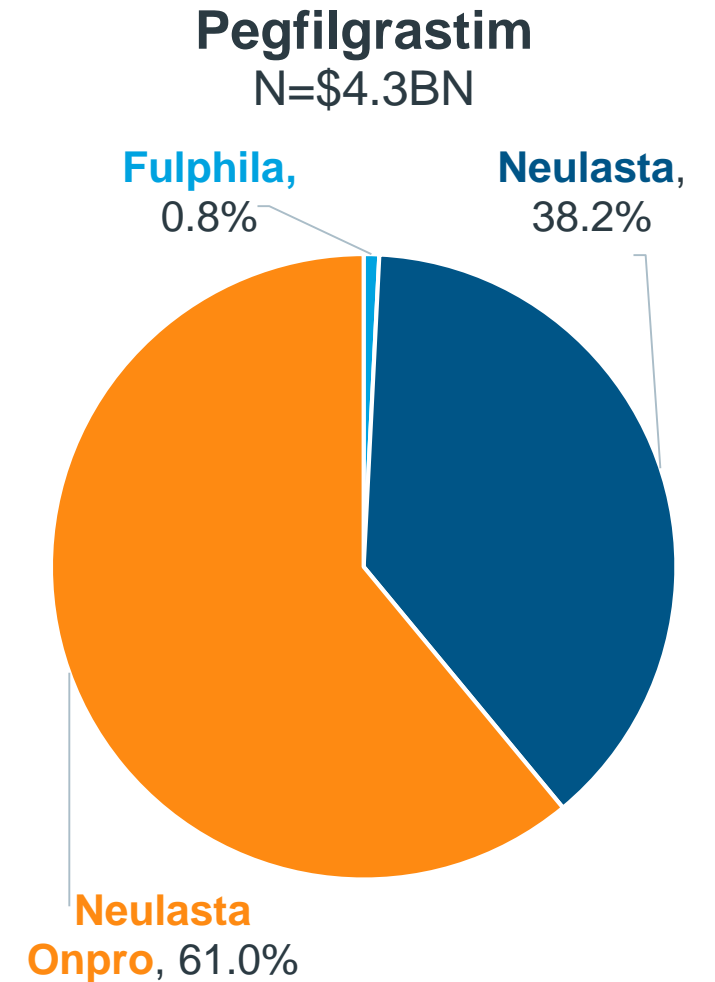
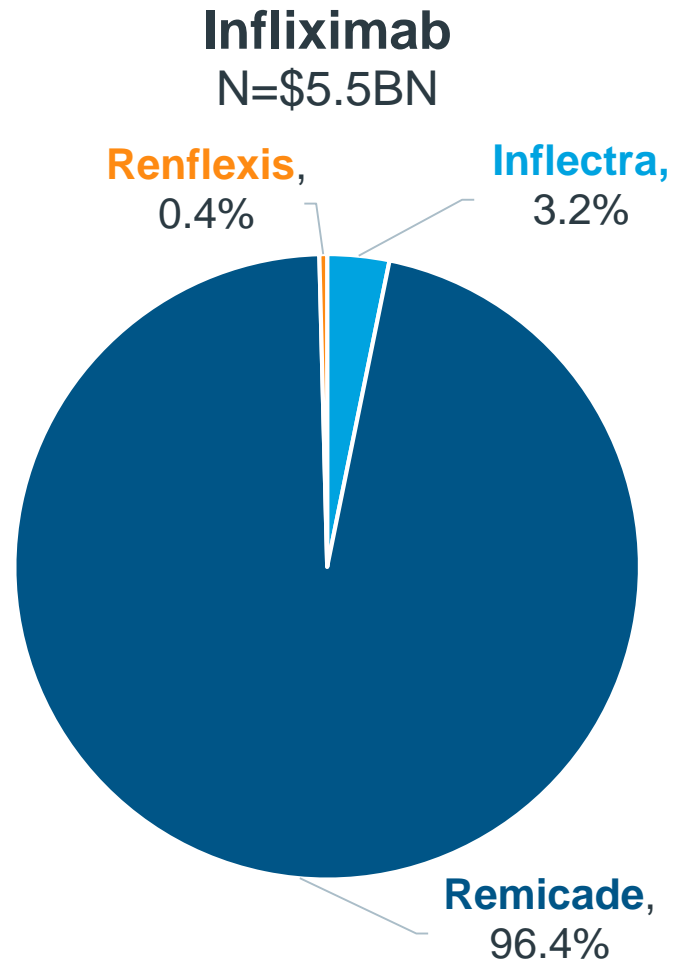
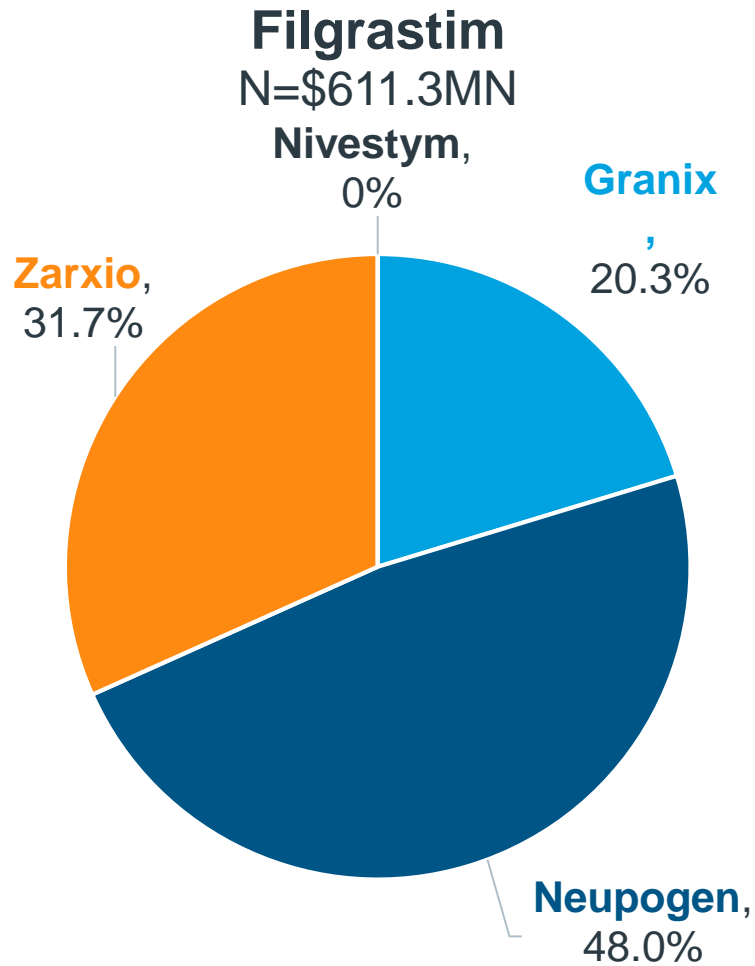
2017 Spending US\$Bn

First Biosimilar Availability by Country



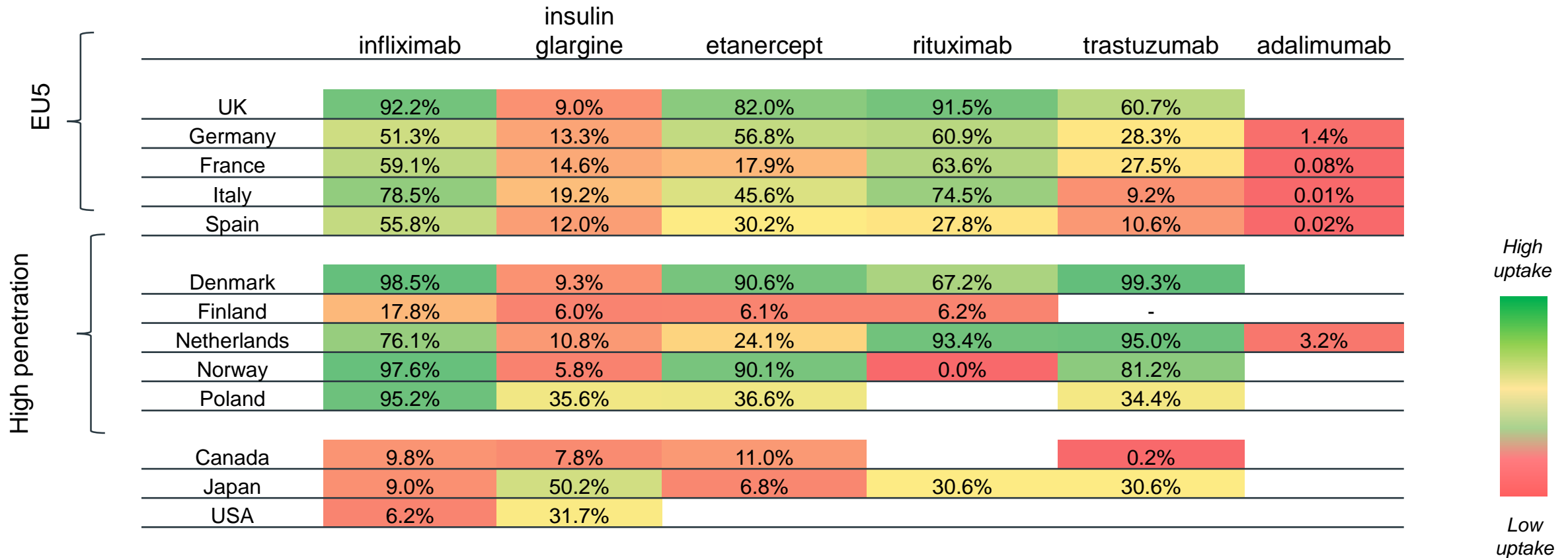
Source: IQVIA MIDAS, MAT June 2018; ARK Patent Intelligence, IQVIA Institute Dec 2018  
 Note: Developed markets include: U.S., Japan, Germany, France, Italy, U.K, Spain, Canada, S. Korea, Australia

# Biosimilar dollar share is minimal to date (MAT NOV 2018) in the US



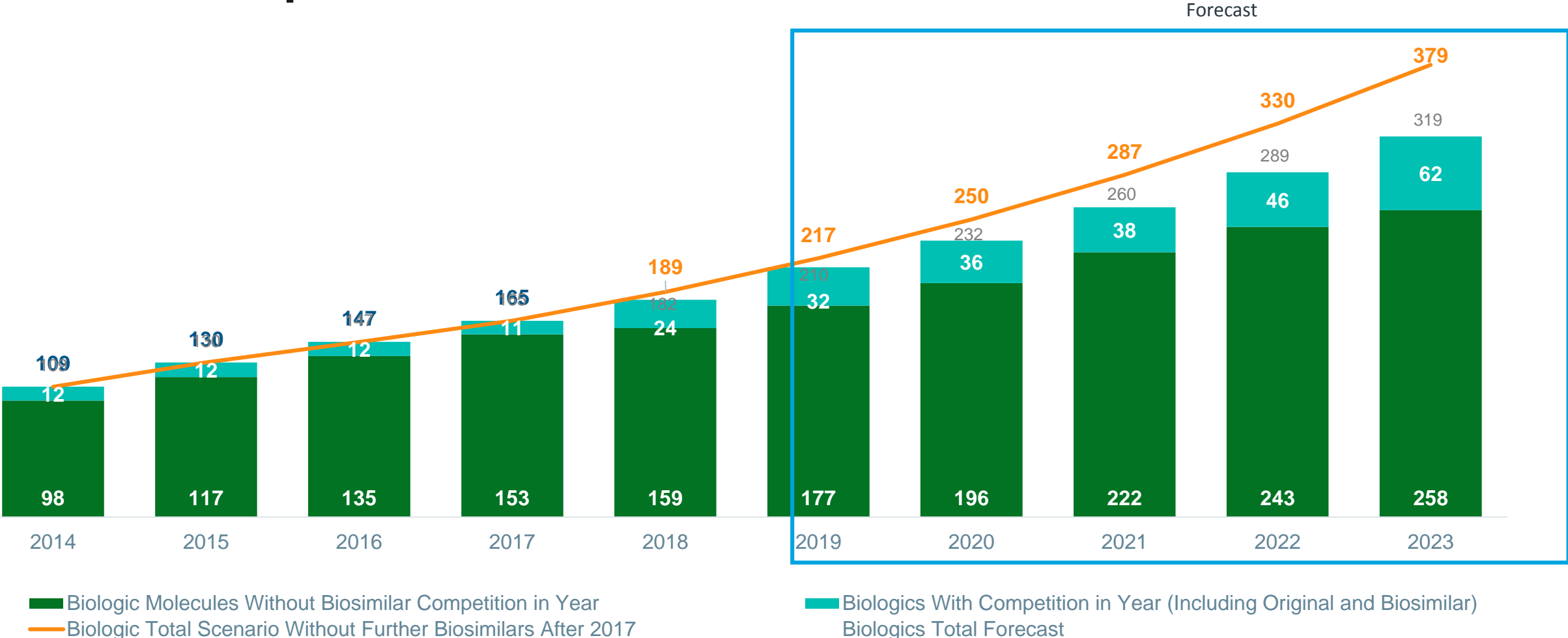
# Denmark shows the highest uptake in high penetration countries, US lags in biosimilar uptake due to late launches

Biosimilar penetration – October 2018



Notes: trastuzumab and rituximab subcutaneous form excluded from calculations  
Source: IQVIA MIDAS Restricted MTH October 2018

# Biologic spending could grow more dramatically without future biosimilar penetration

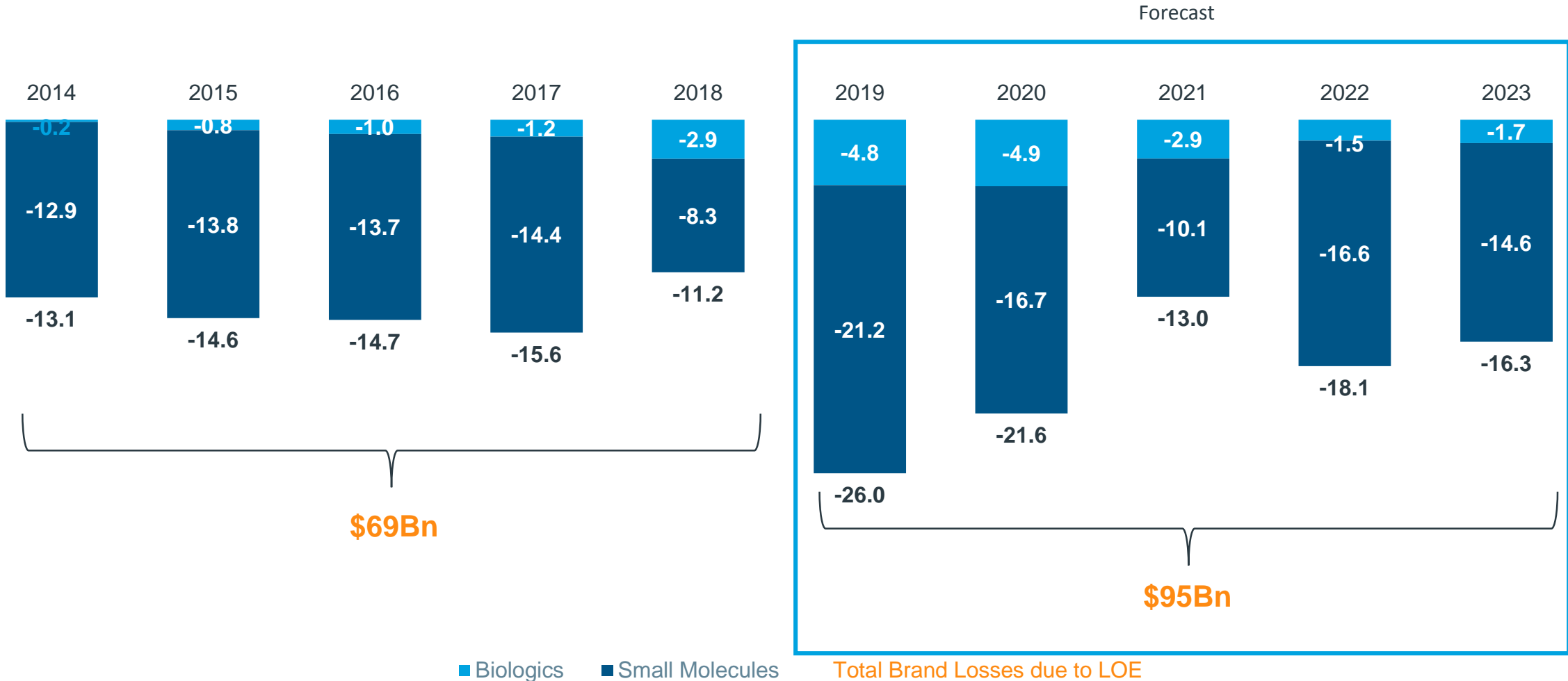


Source: IQVIA MIDAS, Jun 2018; Institute Dec 2018

Notes: Line on chart represents biologic spending using average growth of molecules not facing competition in 2017 continued to 2023 to represent what spending would have been without new molecules facing biosimilar competitors. Segments for biologics with and without competition are modeled using the average historic growth rates and expected entrance of biosimilars and price and volume changes associated with biosimilar entry.



# The U.S. Impact of brand LOE is expected to be ~\$95Bn from 2019 to 2023



Source: IQVIA Market Prognosis, Oct 2018; Institute, Dec 2018

# Top anticipated US LOE products from 2019 to 2021

Expiry Year	Product	Biologic vs Small Mol	MAT NOV 2018 \$ (in BNs)*
2019	LATUDA	Small Mol	\$3.3
2019	HERCEPTIN	Biologic	\$3.1
2019	GILENYA	Small Mol	\$2.2
2019	INVEGA SUSTENNA	Small Mol	\$2.0
2019	XIFAXAN	Small Mol	\$1.6
2019	EPOGEN	Biologic	\$1.5
2019	MYRBETRIQ	Small Mol	\$1.4
2020	AVASTIN	Biologic	\$3.0
2020	REVLIMID	Small Mol	\$1.9
2020	LUCENTIS	Biologic	\$1.8
2020	TYSABRI	Biologic	\$1.7
2020	SPRYCEL	Small Mol	\$1.2
2020	CHANTIX	Small Mol	\$1.1
2021	SYMBICORT	Small Mol	\$3.4
2021	SPIRIVA HANDIHALER	Small Mol	\$2.1
2021	ANDROGEL	Small Mol	\$1.0
2021	BYSTOLIC	Small Mol	\$1.0

Expiry Year	Product	Biologic vs Small Mol	MAT NOV 2018 \$ (in BNs)*
2017	ADVAIR	Small Mol	\$4.2
2018	ZYTIGA	Small Mol	\$1.8

Source: IQVIA, National Sales Perspectives, January 2019  
 \*Top LOE products had more than \$1BN total dollars in MAT NOV 2018

# Most significant upcoming events in 2019 for Generics/Biosimilars

## • Wholesaler

- 1. CivicaRx model trying to address injectable shortages
- 2. State regulations - opioid taxes, price increase reporting, etc.
- 3. Trump administration

## • Chain Exec

- We have started to see **the return of M&A activity** among suppliers at the tail end of 2018 and expect this trend to continue into 2019. Deals announced include the acquisition of mid-tier suppliers (Strides acquired Vensun), product divestitures, and divisional spin-offs (Novartis/Sandoz/Alcon).
- We expect **FDA scrutiny to remain high in light of the valsartan recall** event.
- Potential for further disruption in the healthcare space coming on the heels of **Amazon's acquisition of PillPack** and their acquisition of state pharmacy distribution licenses. In addition, continued pressure from the US government to manage rising healthcare costs may lead to further regulatory focus on drug pricing
- Additional focus and potential **approvals on complex generics** in 2019 e.g. Advair has finally been approved, Restasis
- I suspect you will see more adoption of Biosimilar's in 2019

## • Generic Exec 1

- At what point will manufacturer portfolio rationalization result in drug shortages?
- 2. What will the manufacturer landscape look like at the end of 2019? (e.g. Apotex, Perrigo, etc. are for sale; will companies with significant debt survive?)
- 3. Will biosimilars ever become interchangeable

# Most significant upcoming events in 2019 for Generics/Biosimilars

## • Generic CEO 2

- I'd say potential for a couple of significant moves - with a lot of the outcome determined by policy makers.
- First is biologics. We are seeing approvals in US - but not the tipping point on launched and share gain. I think something is on cusp of happening from HHS and/or PBMs.
- When you look at progress in Europe - it's embarrassing. Maybe all the PBM pressures and rebate flack will changes things.
- On core GRx side - continued move into complex and new approvals, driven by FDA commissioner. Opportunity for those companies which can execute
- M&A/valuations - what becomes of PRGO GRx and Apotex. Valuations?
- Last - Amazon .... been a little quiet, makes me think something big is coming. Perhaps a greater threat to the big 3 than to the manufacturers?
- Less nuts and bolts items this year.

## • Generic Purchasers

- Expect supply disruptions to continue
- CivicaRX the acute care provider backed generic inj mfg
- CMS action on rebates, will the PBMs have enough political clout to delay the change
- Continued generic consolidation
- How the big 3 wholesalers will manage the changing landscape and if they will attempt to move more toward a fee for service financial platform with less reliance on generic subsidization of brand
- Supply chain issues resulting from regulatory actions, controls & pricing legislative activity, margin pressures on finished dose suppliers are the 2018/19 key themes.

## • Old Industry Hand

- 1. Three main events in 2019 will be: drug pricing; drug pricing; and drug pricing.
- 2. The U.S. Congress stalemate
- 3. Continued DOJ probe into grx price collusion
- 4. Will grx price erosion stabilize?
- 5. Will the lower court's ruling that NY's Opioid Stewardship Act is unconstitutional be overturned. (HDA, AAM and Mallinckrodt all sued to block the law.)
- 6. What will happen with inter partes review in SCOTUS, both in general and specific to the Allergan-St. Regis Mohawk Tribe deal
- 7. Will 2019 be the year that CREATES finally passes?
- 8. There are four very important biosimilar cases to be decided in the courts in 2019 – will impact future development and approval.

# Most significant upcoming events in 2019 for Generics/Biosimilars

## • Industry Consultant

- In the generic space, while the rate of approvals has increased and is expected to continue its upward trend, as OGD and OPQ obtains the desired information for approval from applicants, there is potentially becoming a crisis of confidence relative to generic drug quality.
- Continued downward pricing pressures could also exacerbate the problem.
- 
- In the biosimilar space, as more and more products come to market, and the products are in wider distribution and there are no identified problems then perhaps the uptake in the market may improve

## • Generic Exec

- Pricing will continue to be a challenge.
- The quickly expanding state takeback laws are impacting expenses. We more than doubled the amounts we project to pay on these programs.
- Serialization may have an impact on the supply chain. From what we've experienced, many of our CMO partners in India and China are not prepared for the rollout of DQSA later in 2019.
- Consolidation may gain momentum in 2019.

## • Generic Exec

- I think the most significant events in both years is Dr Gottlieb's pragmatic approach to decreasing the cost of health care in the US by coming up with innovative approaches to bring more generic products to the US market

# Globally, non-original brands and unbranded generics will account for 29% of spend

SPENDING 2023 US\$	ORIGINAL BRANDS	NON-ORIGINAL BRANDS	OTC	OTHER PRODUCTS	UNBRANDED	TOTAL US\$BN
<b>Global</b>	61%	20%	6%	4%	9%	1,505-1,535
Developed	76%	10%	3%	2%	8%	90-1,020
Pharmerging	27%	40%	11%	9%	13%	355-385
Rest of World	56%	26%	7%	3%	8%	130-160

2019-2023 CAGR CONSTANT US\$	ORIGINAL BRANDS	NON-ORIGINAL BRANDS	OTC	OTHER PRODUCTS	UNBRANDED	TOTAL GROWTH
<b>Global</b>	4-7%	5-8%	3-6%	0-3%	(-1)-2%	3-6%
Developed	4-7%	5-8%	0-3%	0-3%	(-5)-(-2)%	3-6%
Pharmerging	6-9%	5-8%	5-8%	0-3%	7-10%	5-8%
Rest of World	2-5%	3-6%	2-5%	2-5%	0-3%	2-5%

Source: IQVIA Market Prognosis, Sep 2018; IQVIA Institute, Dec 2018

Notes: CAGR = Compound Annual Growth Rate; OTC = over-the-counter

Report: The Global Use of Medicine in 2019 and Outlook to 2023. IQVIA Institute for Human Data Science, Jan 2019

# Thank you

## Disclaimer:

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## **Doug Long, *Vice President, Industry Relations***

Doug Long is Vice President of Industry Relations at IQVIA (formerly QuintilesIMS), 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.

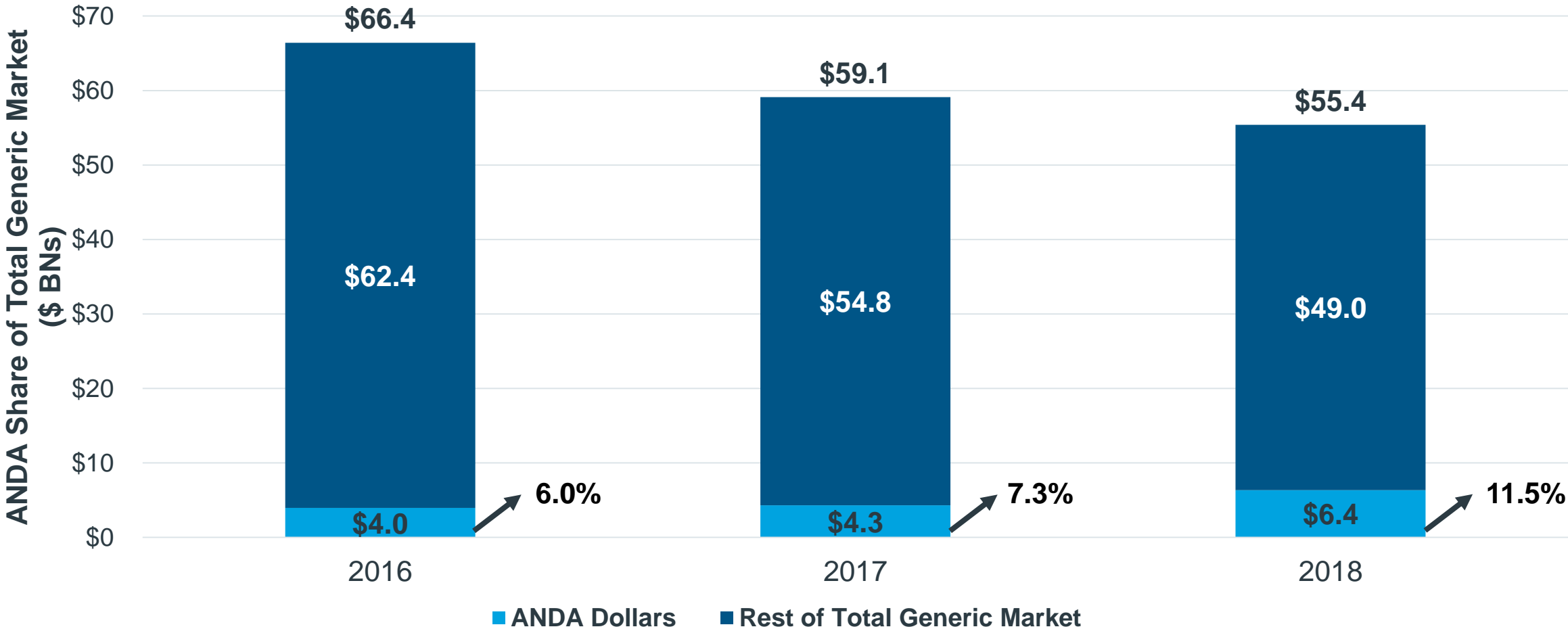
Doug is a frequent industry speaker and the recipient of many awards from trade groups. Before joining IQVIA Doug held positions at Nielsen Market Research for 16 years in various sales and marketing capacities. A native of Illinois, Doug received a BA from DePauw University and holds an MBA in management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



# Appendix

# ANDA generic dollars and share of total generic market is rising year over year

ANDA (2016 to 2018 Approvals) Share of Total Market Generic Dollars



Source: FDA, IQVIA