



# Drug Pricing Policy Solutions: Fixing an Unsustainable System

Public Sector Healthcare Roundtable

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# Out-of-Control Drug Prices:

Four themes



# Broken and Distorted Pharmaceutical Market

Government-granted monopolies via patent system and market exclusivity provisions in federal law

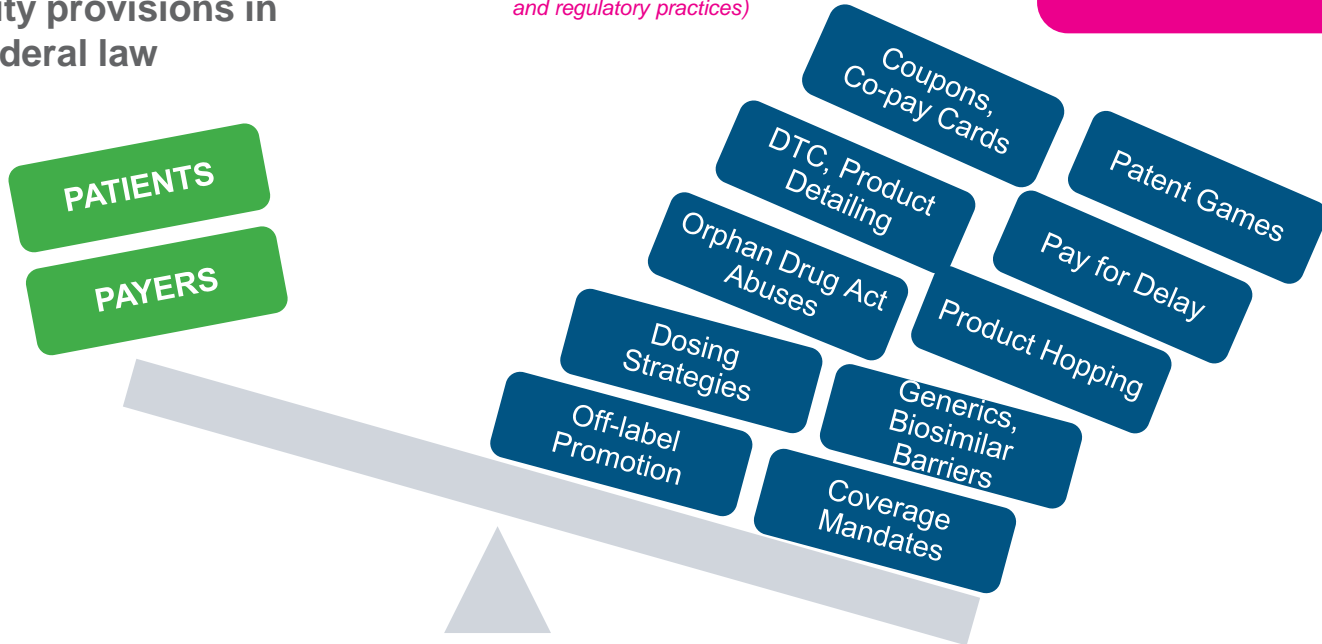


**Market Dysfunction**

*(via problematic marketing, legal, and regulatory practices)*



**HIGH PRICES  
HIGHER COSTS**



# Rx Spending Growing at Unsustainable Rates

U.S. spending on prescription medicines is projected to reach **over \$600 billion by 2022**



**\$600 billion (2022)**

**\$453 billion (2017)**

**\$380 billion (2014)**

# Specialty Rx = Small Volume x High Prices = Big \$\$

**2.2 % of Rxs = \$237 Billion**

*(2018 specialty drug volume and spending)*

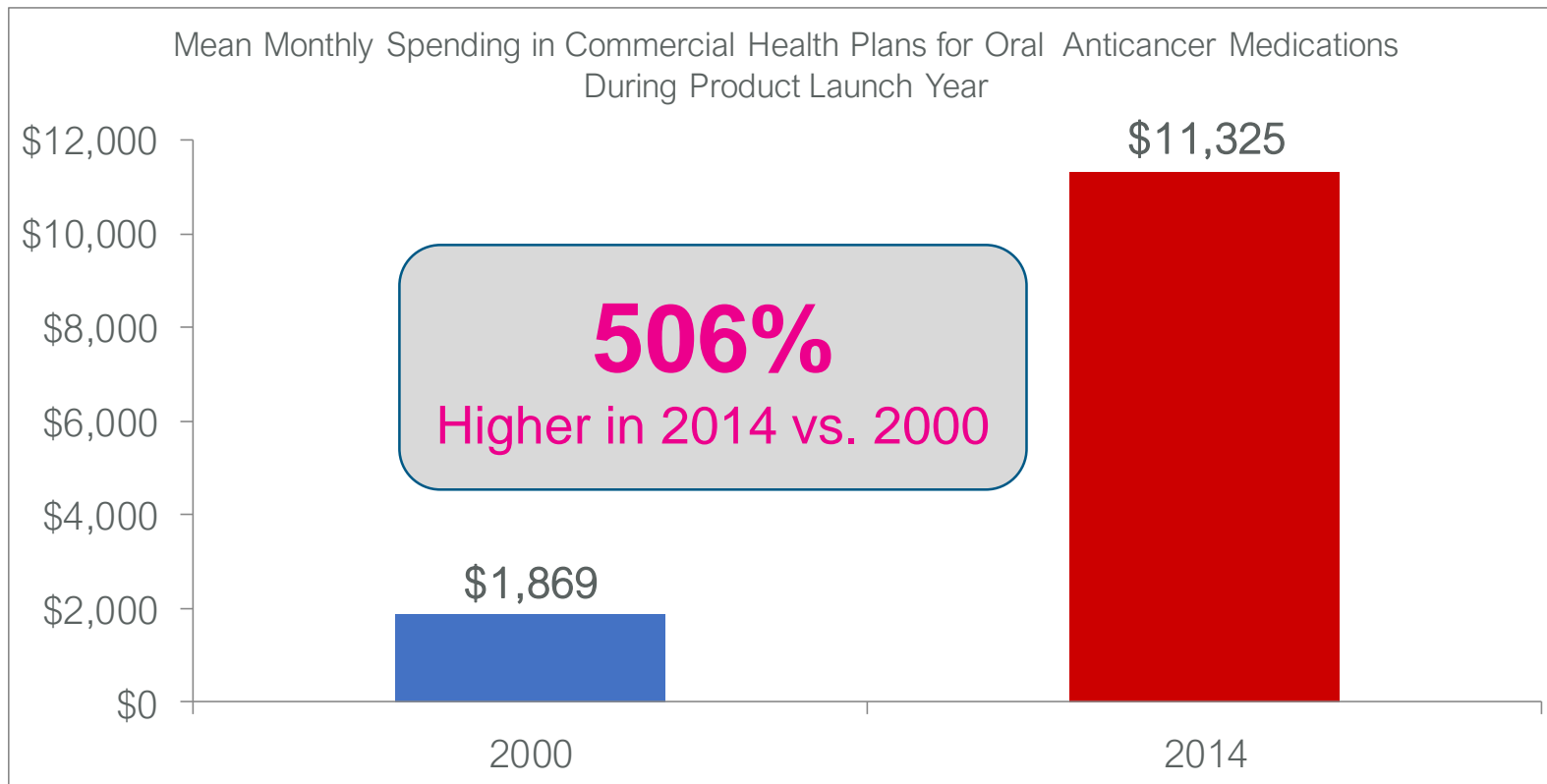
**55%**  
Autoimmune  
Treatments

**18%**  
Hep C

**19%**  
Oncology  
Therapies

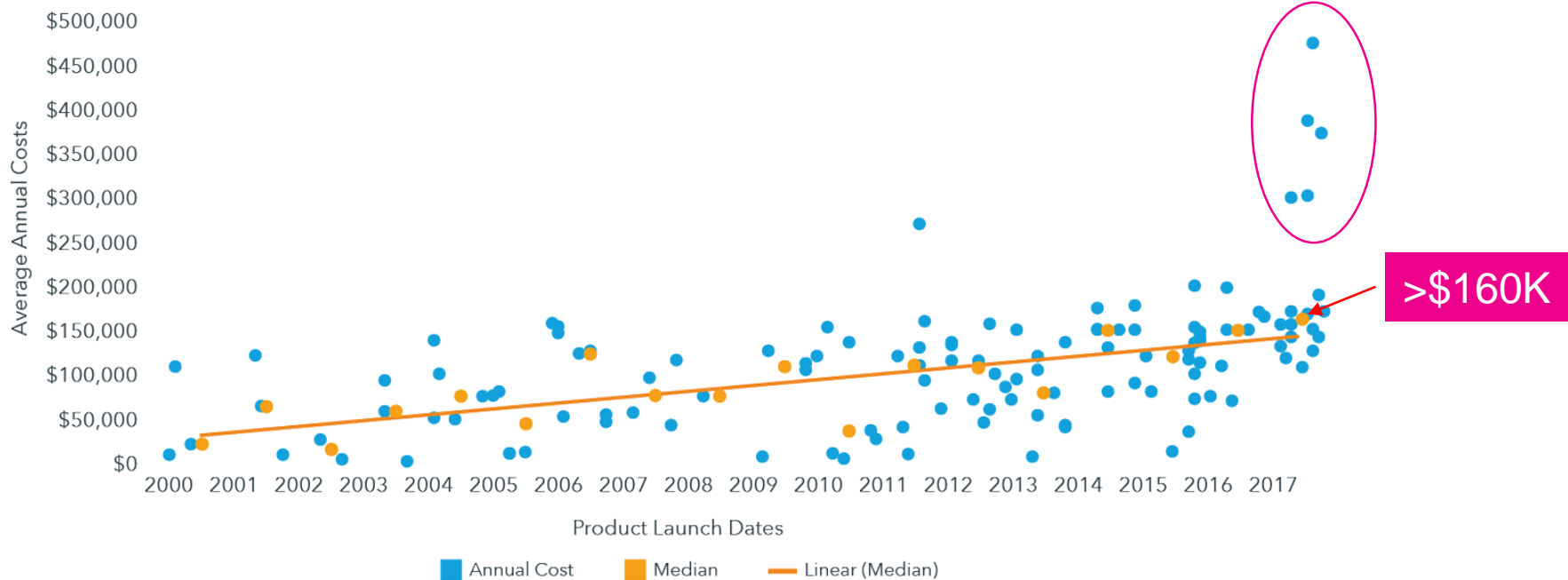
Of the 59 new drugs launched in 2018, almost **40** were specialty drugs

# New Drug Launch Prices Continue to Skyrocket



# New Drug Launch Prices Continue to Skyrocket

## Average Annual Costs For Oncology Products by Launch Year in the United States



Source: IQVIA Institute, Apr 2018

Notes: If published annual costs are available they have been included, and if not, annual costs were estimated based on IQVIA Institute interpretation of the most-common dosing in the approved label and available product unit pricing information.

Report: Global Oncology Trends 2018: Innovation, Expansion and Disruption. IQVIA Institute for Human Data Science, May 2018

# Large Price Increases on New & Older Therapies

*Multiple Sclerosis Drugs Cost Much More Today than When Introduced*

FDA Approval

(1993)



**\$8,300 - \$11,000**

Average cost in 1990s

(2004)



**30% per year**

Average price increase for some drugs over two decades

(2016)



**\$83,000+**

Average cost in 2017 for all MS therapies



# Humira: A Case Study: Humira



**+6.2%**  
**(Jan 2019)**

**+9.4%**  
**(Jan 2018)**

**+8.4%**  
**(Jan 2017)**

**+7.9%**  
**(Jun 2016)**

**+9.9%**  
**(Jan 2016)**

**#1 selling drug** in the world with  
\$19.9 billion in sales in 2018\*

\*Abbvie Financial Results 2018, reported Jan 25, 2019

**>\$50,000** in annual drug expenses per patient

**15+ years** with no biosimilar competition  
(FDA approved in 2002)

**Patent settlement blocks biosimilar**  
(until at least July 1, 2023)

# Market Distortion:

Copay Cards



Coupon usage is **18% of all branded prescriptions** in 2017

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Usage is **42% of all specialty prescriptions**

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Specialty medications for autoimmune diseases, HepC, and MS have **coupon usage rates above 50%**

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**Very little transparency** in the system when they are used

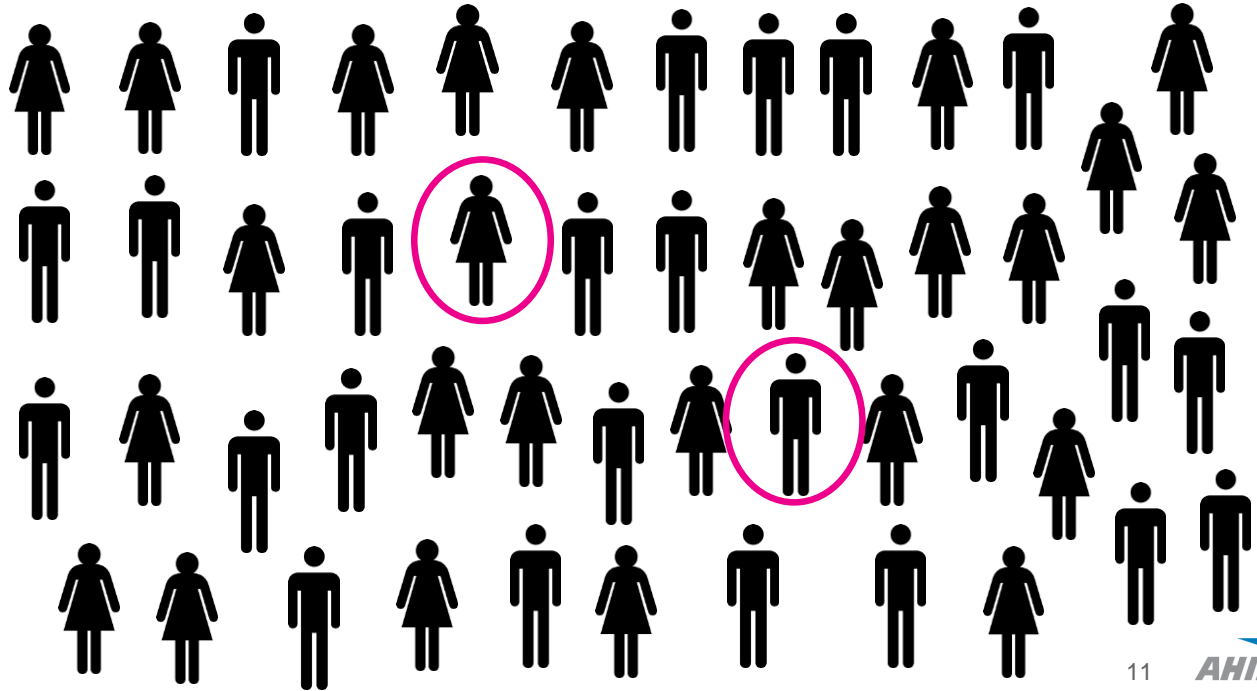
# If Rebate Savings Shared at Point of Sale....

Few Consumers Benefit, Premiums Rise for Everyone

Insurance  
Provider/ PBM

Negotiated  
savings passed  
on at point of  
sale to those  
taking particular  
drugs while still  
in deductible  
and/or who pay  
co-insurance

Pharma



# Multiple Analyses: Part D By the Numbers

<b>MedPAC</b>	<p><b>195%</b></p> <p>List price increases between 2007-2017 for small number of single-source drugs lacking alternatives</p>	<p><b>13%</b></p> <p>These same drugs comprised 13% of Rx's filled in 2016 and spending overwhelmed savings from high Part D generic utilization</p>	
<b>CMS</b>	<p><b>1.7% volume = 42% spend</b></p> <p>Top 50 highest cost Part D drugs in 2017</p>	<p><b>40% and 22%</b></p> <p>40% of these top 50 high cost drugs would alone drive enrollee into catastrophic and 22% would do so with just one prescription fill</p>	
<b>CBO</b>	<p><b>1% volume = 30%</b></p> <p>Brand specialty drugs in 2015 accounted for 1% of Part D volume but 30% of spending net of rebates</p>	<p><b>\$8,680 vs. \$2,570</b></p> <p>Average net price per Rx of new branded specialty drugs in 2015 vs. those on market prior to 2010</p>	
<b>Milliman</b>	<p><b>\$1,367 and 35%</b></p> <p>“Regular” brands (2016) Avg. annual cost and avg. rebate</p>	<p><b>\$8,476 and 24%</b></p> <p>“Specialty” brands Avg. annual cost and avg. rebate</p>	<p><b>\$4,200 and 14%</b></p> <p>“Protected Class” brands Avg. annual cost and avg. rebate</p>

[See AHIP Comment Letter of April 8, 2019 – Key Data](#)

# Range of Impacts from Eliminating Part D Rebates

## Alternative Scenarios: 2020-2029 (\$ in billions)

	OACT Estimates	Projections Based on OACT Estimates	
<b>Rebate Share Kept by Manufacturers</b>	<b>15%</b>	<b>30%</b>	<b>50%</b>
<b>Beneficiary Costs</b>	<b>(\$25.2)</b>	<b>\$1.0</b>	<b>\$36.5</b>
Cost Sharing	(\$83.2)	(\$69.6)	(\$49.2)
Premium	\$58.0	\$70.5	\$85.7
<b>Government Costs</b>	<b>\$196.1</b>	<b>\$291.6</b>	<b>\$410.2</b>
Direct subsidy, reinsurance, low-income cost sharing and subsidy			
<b>Manufacturer Gap Discounts</b>	<b>(\$39.8)</b>	<b>(\$33.2)</b>	<b>(\$23.5)</b>

[Avalere Health analysis](#) of the 2015 Medicare Current Beneficiary Survey, the 2018 Medicare Trustees Report, and data from the Centers for Medicare & Medicaid Services (CMS) Office of the Actuary (OACT) – does not account for impact of April 5 CMS guidance on new demonstration program involving Part D risk corridors for 2020 and 2021

# Behaving Badly:

Profiting from a Crisis

*“A decade ago, a lifesaving dose of naloxone cost \$1. Today, that same dose costs \$150 for the nasal spray, a **150-fold increase**. A naloxone auto-injector, approved in 2016, costs \$4,500.”*

*—STAT, November 2018*

 **NARCAN<sup>®</sup>** (naloxone HCl)  
**NASAL SPRAY 4mg**

**Evzio<sup>®</sup>**  
(naloxone HCl injection)  
0.4 mg auto-injector

# Drug Pricing: Strong Bipartisan Legislative Interest

## House Committee Markups

<b>Energy &amp; Commerce:</b> H.R. 1781, H.R. 938, H.R. 1520, H.R. 1503, H.R.1499, H.R. 965 (CREATES Act)	<b>Ways &amp; Means:</b> H.R. 2113 (STAR Act)	<b>Judiciary:</b> H.R. 965 (CREATES Act), H.R. 2374, H.R. 2375, H.R. 2376
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## House Passed: May 8

H.R. 1503 Orange Book Transparency Act <i>Rep. Kelly (D-IL)</i>	H.R. 1520 Purple Book Continuity Book <i>Rep. Eshoo (D-CA) &amp; Burgess (R-TX)</i>
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## House Passed: May 15

### H.R. 987, the Strengthening Health Care and Lowering Prescription Drug Costs Act *(additional ACA bills also included)*

- H.R. 965 The CREATES Act (Rep. Cicilline D-RI);
- H.R. 1499 The Protecting Consumer Access to Generic Drugs Act (Rep. Rush (D-IL)); and
- H.R. 938 The BLOCKING Act (Rep. Schrader D-OR)

## Senate Finance Committee Hearings

Drug Pricing in America: A Prescription for Change Part II (Pharma)  
Drug Pricing in America: A Prescription for Change Part III (PBMs)

## Senate HELP Committee Health Care Package (Rx Provisions)

- Purple and Orange Book Transparency Bills (passed house 5/8)
- Citizen petitions/ sham petitions. (H.R. 2374 – STOP Stalling Act)
- Prevents new/extended biologic market exclusivities (starting in 3/2020)
- Preventing blocking of generics (H.R. 938 BLOCKING Act – passed house 5/16)
- Educational tools for biological product stakeholders
- Prevents delays related to USP compliance standards in the licensure of biosimilar and interchangeable products
- Clarifies the meaning of a new chemical entity (NCE)
- Streamlines March 2020 transition of biological products (e.g. insulin) from drug pathway to biologics pathway

## Senate Judiciary

Intellectual Property and Price of Prescription Drugs: Balancing Innovation and Competition

# Regulatory Action on President's Blueprint

DTC Advertising  
Final Rule

Interchangeable  
Biologics Final  
Rule

Proposed  
Rebate Rule  
(at OMB)

International  
Pricing Index  
(at OMB)



# Our Industry's Market-Oriented Solutions

## Real Competition

- Create a robust biosimilars market
- Reduce red tape and abuses to limit generic and biosimilar entry
- Revisit orphan drug incentives
- Revisit guaranteed periods of market exclusivity

## Open & Honest Price Setting

- Publish Rx prices, true R&D costs, and price increases
- Limit third-party schemes
- Evaluate DTC impact
- Extend manufacturer liability into Part D catastrophic benefit

## Delivering Value to Patients

- Inform patients on effectiveness and value
- Expand value-based formulary programs
- Reduce regulatory barriers to value-based pricing