


National Update on Drug Pricing Trends and Advocacy Efforts

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Disclosure

- Presenter has no actual or potential conflicts of interest to disclose



What keeps you up at night?

THE WALL STREET JOURNAL.

Drugmakers Raise Prices on Hundreds of Medicines

New analysis shows Allergan setting the pace with increases of nearly 10% on more than two dozen products

By David S. Reardon
 Updated Jan 1, 2019 10:45 am ET

Pharmaceutical companies are raising drug prices, with Allergan PLC setting the latest products, according to a new analysis.


The human cost of insulin in America

By Ritu Prasad
 BBC News
 © 14 March 2019


KHN

'Pharma Bro' Shkreli Is In Prison, But Daraprim's Price Is Still High

By Michael S. Rothman
 NBC News



What keeps you up at night?



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Learning Objectives for Pharmacists and Technicians

- Describe recent drug pricing trends and their impact on healthcare spending.
- Explain how drug pricing is affected by several factors, including regulations, third parties, and market environment.
- Discuss recent drug pricing legislation that has been introduced and/or passed in the United States Congress

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Agenda

- Current drug spending statistics
- Drug prices in the news
- Factors influencing drug prices
- Drug pricing policies, proposals, legislation

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Healthcare spending

- 2017 Total healthcare spending: \$3.5 trillion
 - 3.9% increase over 2016
 - Increase ranged from 5.7%-6.9% over previous three years
 - 17.9% of GDP
 - \$10,739 per person
- Retail prescription drug spending?


Schumock GT, Stubbings J, Hoffman JM, Wiest MD, Suda KJ, Rim MH, Tadrous M, Tichy EM, Cuellar S, Clark JS, Matusiak LM, Hunkler RJ, Vermeulen LC. National trends in prescription drug expenditures and projections for 2019. *Am J Health Syst Pharm*. 2019 Jul 18;76(15):1105-1121

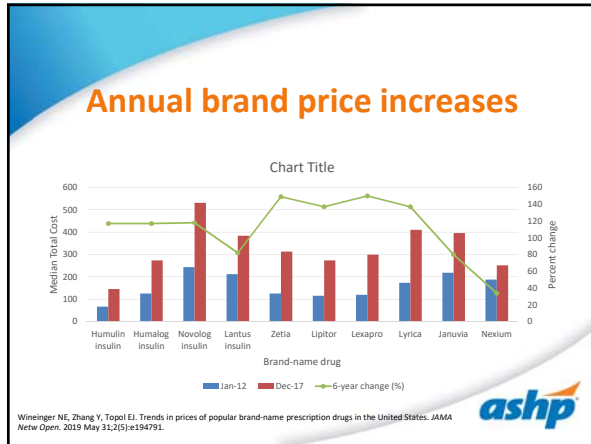


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 - 3.9% increase over 2016
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 - 17.9% of GDP
 - \$10,739 per person
- Retail prescription drug spending?
 - ~10% of total healthcare spending

Schumock GT, Stubbings J, Hoffman JM, Wiest MD, Suda KJ, Rim MH, Tadrous M, Tichy EM, Cuellar S, Clark JS, Matusiak LM, Hunkler RJ, Vermeulen LC. National trends in prescription drug expenditures and projections for 2019. *Am J Health Syst Pharm*. 2019 Jul 18;76(15):1105-1121





Top drug categories – 2018 Nonfederal hospitals

Drug Category	2018 Expenditures (\$ Thousands)	% Total 2018 Expenditures	% Change From 2017

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Top drug categories – 2018 Nonfederal hospitals

Drug Category	2018 Expenditures (\$ Thousands)	% Total 2018 Expenditures	% Change From 2017
Antineoplastic agents	7,215,055	20.2	17.1
Hemostatic modifiers	2,794,899	7.8	-8.0
Immunologic agents	2,294,635	6.4	18.0
Antiinfectives, systemic	2,078,320	5.8	-3.3
Biologicals	1,985,986	5.5	7.5
Blood factors	1,832,473	5.1	1.6
Gastrointestinal agents	1,376,293	3.8	-14.7
Antiviral drugs	1,328,391	3.7	2.3

Schumock GT, Stubbings J, Hoffman JM, Wiest MD, Suda KJ, Rim MH, Tadrous M, Tichy EM, Cuellar S, Clark JS, Matusiak LM, Hunkler RJ, Vermeulen LC. National trends in prescription drug expenditures and projections for 2019. Am J Health Syst Pharm. 2019 Jul 18;76(15):1105-1121.

Self-assessment question #1

- Which of the following best demonstrates drug spending in relation to overall healthcare spending?
 - A. Retail and mail-order prescription drugs were ~ 10% of total drug spend in 2018
 - B. Retail and mail-order prescription drugs were ~50% of total healthcare spend in 2017
 - C. Retail and mail-order prescription drugs were ~10% of total healthcare spend in 2017
 - D. Retail and mail-order prescription drugs were ~ 50% of total drug spend in 2018



Agenda

- Current drug spending statistics
- **Drug prices in the news**
- Factors influencing drug prices
- Drug pricing policies, proposals, legislation



Drug prices in the news


- Specific drugs
 - Pyrimethamine
 - Nitrofurantoin suspension
 - Insulin
 - Novel therapies
- Shortages
- Annual/semiannual price increases
- Generic manufacturer antitrust lawsuit



Drug prices in the news

The New York Times
Drug Goes From \$13.50 a Tablet to \$750, Overnight
 By Andrew Pollack
 Sept. 20, 2015

FINANCIAL TIMES
Pharma chief defends 400% drug price rise as a 'moral requirement'
 Nostrum Laboratories' Nirmal Mulye says he is right to charge as much as possible and slams FDA.
 David Crow in New York SEPTEMBER 11, 2018



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FINANCIAL TIMES
 In an interview, Nirmal Mulye, Nostrum chief executive, said he had priced the product according to market dynamics, adding: "I think it is a moral requirement to make money when you can . . . to sell the product for the highest price."
 David Crow in New York SEPTEMBER 11, 2018



Drug prices in the news

KHN Morning Briefing
 Summaries of health policy coverage from major news organizations

WEDNESDAY, AUG 7 2019
 FULL ISSUE

Insulin Pricing Crisis Takes Another Young Life: 'How Many More ... Have To Die Before Something Finally Changes?'
 News outlets report on stories related to pharmaceutical pricing.



Drug prices in the news

STAT
HEALTH

Hospitals are saving lives with CAR-T. Getting paid is another story

By IVE SWETLITZ / MARCH 12, 2019

The cost of Biogen's new drug: \$750,000 per patient

BY AIMEE PICCOLI
MARCH 21, 2019, 11:28 PM EDT

REUTERS

HEALTH NEWS | April 24, 2019 11:08 PM EDT | UPDATED 4:01

Novartis \$2 million gene therapy for rare disorder is world's most expensive drug


John Miller, Caroline Hauser



Drug prices in the news Shortages

Figure 1. Observed increases in average WACs in the 12 mo before and after the shortage began.

Hernandez I, Sampathkumar S, Good CB, Kesselheim AS, Shrank WH. Changes in drug pricing after drug shortages in the United States. *Ann Intern Med*. 2019 Jan 1;170(1):74-76.



Drug prices in the news Periodic price increases

The New York Times

Pfizer to Postpone Some Drug Price Increases, After Criticism From Trump

By Robert Pear

July 10, 2018

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Drug prices in the news
Periodic price increases

HEALTH INC.
Prescription Drug Costs Driven By
Manufacturer Price Hikes, Not Innovation
January 2, 2019 3:04 PM ET
ALISON KOSMAN npr

CBS NEWS
**Drug prices in 2019 are surging, with
hikes at 5 times inflation**
BY AIMEE PICCHI
JULY 2, 2019 7:13:24 AM / MONEYWATCH

POLITICO
HEALTH CARE
**Drug prices persistently rising despite
Trump efforts**
By SARAH OWERMOHLE | 07/01/2019 05:37 PM EDT | Updated 07/01/2019 06:56 PM EDT

Drug prices in the news
Antitrust lawsuit

Pharmacy Times
Antitrust Lawsuit Targets 20 Generic Drug Manufacturers, 15 Industry Executives Over
Medication Pricing
MAY 14, 2019
Gina Kokosky, Assistant Editor

Bloomberg
**A Massive U.S. Drug Price-Fixing
Probe Has Hit Major Roadblocks**
Authorities have called it one of the biggest cases of corporate collusion
in history, costing patients billions of dollars.
By Biley Ray Griffin, David McLaughlin and Ben Elajn
July 30, 2019

Agenda


- Current drug spending statistics
- Drug prices in the news
- **Factors influencing drug prices**
- Drug pricing policies, proposals, legislation

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Factors influencing drug prices

- Brand-name drugs
- Competition
- Regulations
- Public/Private payer policies


Kesselheim AS, Avorn J, Sarpawari A. The high cost of prescription drugs in the United States: Origins and prospects for reform. JAMA. 2016 Aug 23;316(8):858-871.



Factors: Brand name products

- Exclusivity
 - Patent protections
 - Regulatory guarantees
 - Average 12.5 years for small-molecule drugs
 - Average 14.5 years for first-in-class or highly innovative drugs
- Pay-to-delay
- Limited distribution
- Biologics and biosimilars
 - Biologics Price Competition and Innovation Act in 2010


Kesselheim AS, Avorn J, Sarpawari A. The high cost of prescription drugs in the United States: Origins and prospects for reform. JAMA. 2016 Aug 23;316(8):858-871.



Factors: Competition


- Lack of competition applies to older generic drugs, too
 - Pyrimethamine 5500% price increase
 - Nitrofurantoin 400% price increase
 - Isoproterenol 2500% price increase
 - Nitroprusside 1700% price increase
- FDA Safety and Innovation Act in 2012
 - Established generic-drug user fees that improved processing of ANDAs

Kesselheim AS, Avorn J, Sarpawari A. The high cost of prescription drugs in the United States: Origins and prospects for reform. JAMA. 2016 Aug 23;316(8):858-871.



Factors: Regulations


- Related to competition
- Unapproved drugs
- Drug efficacy study implementation (DESI) drugs
 - Drugs approved between 1938 and 1962
 - Allows exclusivity
 - Vasopressin
 - Methylene blue
 - Phenylephrine
 - Has also resulted in short-term shortages



Factors: Regulations

- 34 previously unapproved drugs examined from 2006-2015
 - For 26 with AWP data, 37% increase in price during 2 years before and after approval
 - Drugs in short supply increased from 17 (50%) to 25 (74%) during 2 years before and after approval
 - Median shortage duration increased from 31 days to 217 days


Gupta R, Dhruva S, Fox, ER, Ross JS. The FDA unapproved drugs initiative: an observational study of the consequences for drug prices and shortages in the United States. *J Manag Care Spec Pharm.* 2017 Oct;23(10):1066-1076.



Factors: Payer policies


- Negotiated contracts
 - Group purchasing organizations (GPOs)
 - Pharmacy benefit managers (PBMs)
- Medicare/Medicaid policies
 - Medicaid inflation rebates
- Site-of-care policies
 - Lower cost of care (for patients)

<https://annals.org/aim/fullarticle/2748279/medicare-part-d-spending-single-enantiomer-drugs-versus-racemic-precursors>




Self-assessment question #2

- Which of the following can be a factor in the price of a drug?
 - A. Branded product
 - B. Competition
 - C. Regulations
 - D. Payer policies
 - E. All of the above



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- **Drug pricing policies, proposals, legislation**



Policies, proposals, legislation


- International pricing
- Importation
- Pricing transparency in direct-to-consumer advertisements
- Pharmacy benefit managers (PBMs)
- Gag clauses
- Congressional activity



International pricing

- October 30, 2018 CMS advanced notice of proposed rule-making
 - International Pricing Index (IPI)
 - Private vendors procure and distribute drugs and bill Medicare
 - Medicare Part B reimbursement tied to average of international prices
- Planned to release proposed rule Spring 2019 to be effective Spring 2020

Fierce Healthcare. Verma: CMS working 'fast and furious' on IPI drug pricing model, but doesn't say when it will be released. <https://www.fiercehealthcare.com/payer/verma-cms-working-fast-and-furious-ipl-drug-pricing-model-but-doesnt-say-when-will-be>. Published August 15, 2019. Accessed August 15, 2019.



International comparisons

Image removed due to copyright. Refer to citation for information

Frakt A. Something Happened to U.S. Drug Costs in the 1990s. New York Times. November 12, 2018. <https://www.nytimes.com/2018/11/12/unshot/why-prescription-drug-spending-higher-in-the-us.html>. Accessed August 12, 2019.



Importation

- Several states have introduced legislation to import drugs
- Supported by Trump administration
 - Technically allowed under current law but requires approval of HHS secretary
 - Framework being developed by HHS
 - Applies to states, pharmacies, and wholesalers
 - Not individual patients



Importation

- Problems with importation
 - Potential for counterfeit supplies
 - Potential for compromised quality
 - Potential for new or worsened drug shortages
 - Canadians response
 - Export control list
 - Tariffs
 - Law preventing export

Stat. Everything (or almost everything) you need to know about importing drugs from Canada. <https://www.statnews.com/2019/07/31/everything-about-importing-drugs-from-canada/>, July 31, 2019. Accessed August 15, 2019.


Stat. Canadians are hopping mad about Trump's drug importation plan. Some of them are trying to stop it. <https://www.statnews.com/2019/08/13/canadians-are-hopping-mad-about-trumps-drug-importation-plan-some-of-them-are-trying-to-stop-it/>, August 13, 2019. Accessed August 15, 2019.



Pricing transparency

- HHS final rule issued early May, 2019
 - Requires manufacturers to disclose price in TV ads
 - Drugs covered by Medicare/Medicaid
 - WAC > \$35/month
- Rule blocked by judge in early July
 - Lawsuit filed by Merck, Amgen, Pfizer
 - Violated First Amendment rights


Kaiser Health News. Summer setbacks: The long road to lower drug prices hits some potholes. July 24, 2019. <https://khn.org/news/summer-setbacks-the-long-road-to-lower-drug-prices-hits-some-potholes/>, Accessed August 15, 2019.



PBMs and rebates

- Middlemen negotiating between manufacturer and insurer
 - Profit from direct fee and rebates
 - Safe harbor law protects rebates
- HHS proposed a rule to eliminate safe harbor protections on specific fees
 - Actuarial analysis did not guarantee reduced healthcare costs
 - Cited possible 20% increase in premiums
 - ASHP submitted comments opposing the rule
- Direct and indirect remuneration (DIR) fees


ASHP. ASHP comments on rebates safe harbor proposed rule. <https://www.ashp.org/Advocacy-and-Issues/Key-Issues/Drug-Pricing/ASHP-Comments-on-Rebates-Safe-Harbor-Proposed-Rule>, April 8, 2019. Accessed August 15, 2019.



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Gag clauses


- Formerly part of PBM contracts
 - Pharmacists could not tell patients about more affordable options
 - Two laws signed on October 2018
 - Patient Right to Know Drug Prices Act
 - Prohibits gag clauses in PBM contracts
 - Know the Lowest Price Act
 - Prohibits gag clauses in patients covered by Medicare Advantage and Medicare Part D programs

Pharmacy Times. Legislation signed into law prohibiting 'gag clauses' for pharmacies. <https://www.pharmacytimes.com/conferences/npsa-2018/legislation-signed-into-law-prohibiting-gag-clauses-for-pharmacies>. October 10, 2018. Accessed August 15, 2019.




Congressional activity

- On May 9, 2019, the House passed H.R. 987 by a vote of 234-183, which included a series of drug pricing bills
 - CREATES
 - Pay-for delay
 - 180-day exclusivity
- Senate has remained silent on the bill and is not expected to take it up




Congressional activity

- Senate: Prescription Drug Pricing Reduction Act of 2019
 - ~30 provisions targeted at reducing drug expenditures
 - ASHP supports key provisions
 - Refunds to Medicare for single-use vial waste
 - Maximum out-of-pocket amounts for Medicare Part D
 - Rebates to Medicare for drug-price increase above inflation
 - Price transparency for large increases
 - ASHP concerned with other provisions
 - Reduced payment to off-campus hospital outpatient departments
 - Maximum add-on payment for drugs, biologics, and biosimilars




Self-assessment question #3

- ASHP did not support Rebates Safe Harbor proposed rule because:
 - A. Too much uncertainty: Analysis estimated range from \$78.9 billion in decreased costs to \$196 billion in increased costs over 10 years
 - B. Did not address transparency in treating rebates as proprietary information
 - C. Potential to increase premiums by 20% and increase out-of-pocket costs for patients
 - D. All of the above



Conclusions

- Drug spending in 2018 reached \$476.2 billion
 - 5.5% increase from 2017
 - Inflation was 1.9% in 2018
- Multiple factors affect drug pricing
 - Competition
 - Contracts
 - Regulations
 - Third parties
- U.S. Congress is considering legislation to address drug pricing




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QUESTIONS



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