

National Update on Drug Pricing Trends and Advocacy Efforts

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ICHP Annual Meeting
September 13, 2019



Disclosure

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

What keeps you up at night?

THE WALL STREET JOURNAL.

BUSINESS

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 Jared S. Hopkins

Updated Jan. 1, 2019 9:13 p.m. ET

Pharmaceutical companies are ringing in the new year with price increases on hundreds of drugs, with Allergan PLC setting the pace with increases of nearly 10% on more than two dozen products, according to a new analysis.

The human cost of insulin in America

By Ritu Prasad
BBC News

🕒 14 March 2019

KHN
KAISER HEALTH NEWS

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

By Shefali Luthra
MAY 4, 2018

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New and

Happy FRIDAY THE 13th

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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



Agenda

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

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- **Current drug spending statistics**
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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?

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 - Retail prescription drug spending?
 - ~10% of total healthcare spending

Drug spending – 2018

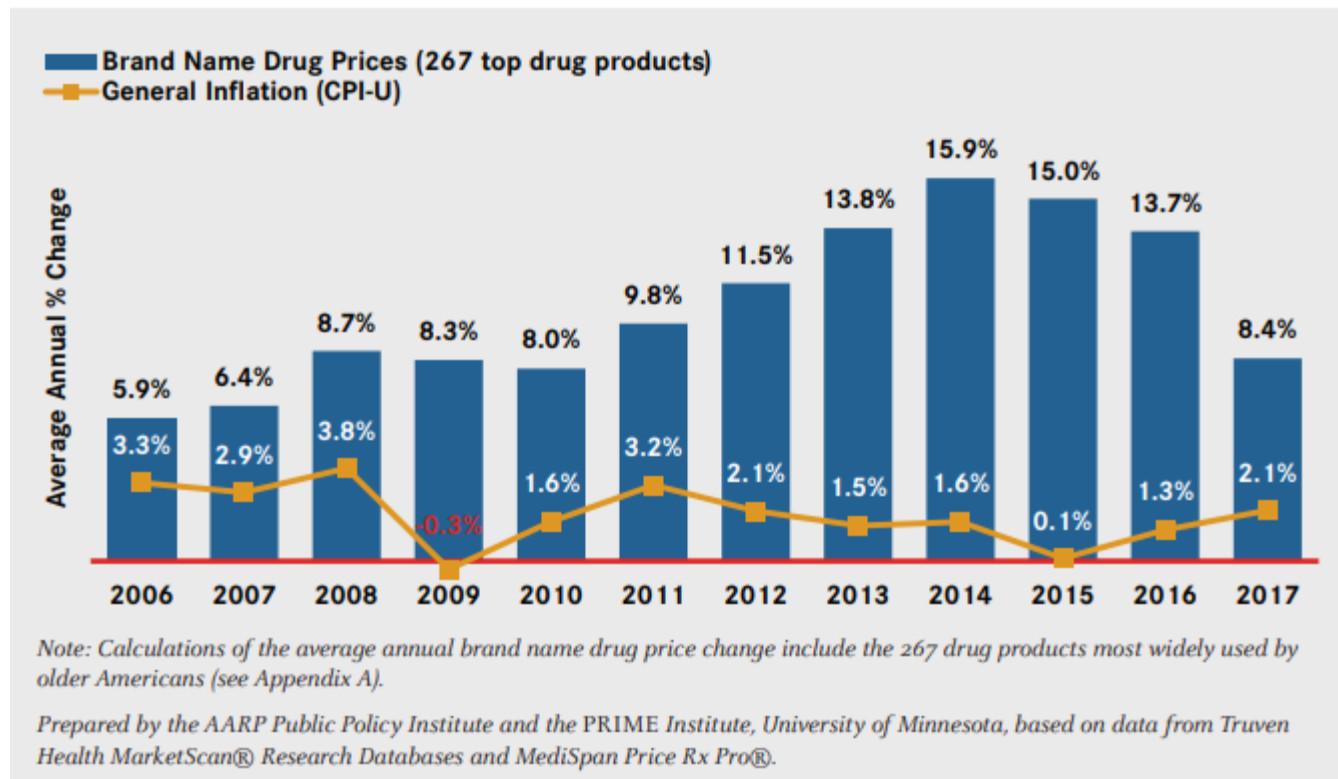
Sector	2018 Expenditures (\$ Millions)	% Total Expenditures	% Change From 2017
Retail pharmacies	214,328	45.0	2.1
Mail-order pharmacies	117,696	24.7	7.1
Clinics	80,466	16.9	13.0
Nonfederal hospitals	35,789	7.5	4.8
Long-term care	16,715	3.5	1.5
Home healthcare	5,429	1.1	30.6
Federal facilities	2,685	0.6	3.4
Staff-model HMOs	1,781	0.4	5.3
Other	1,304	0.3	-3.3
Total	476,194	100.0	5.5

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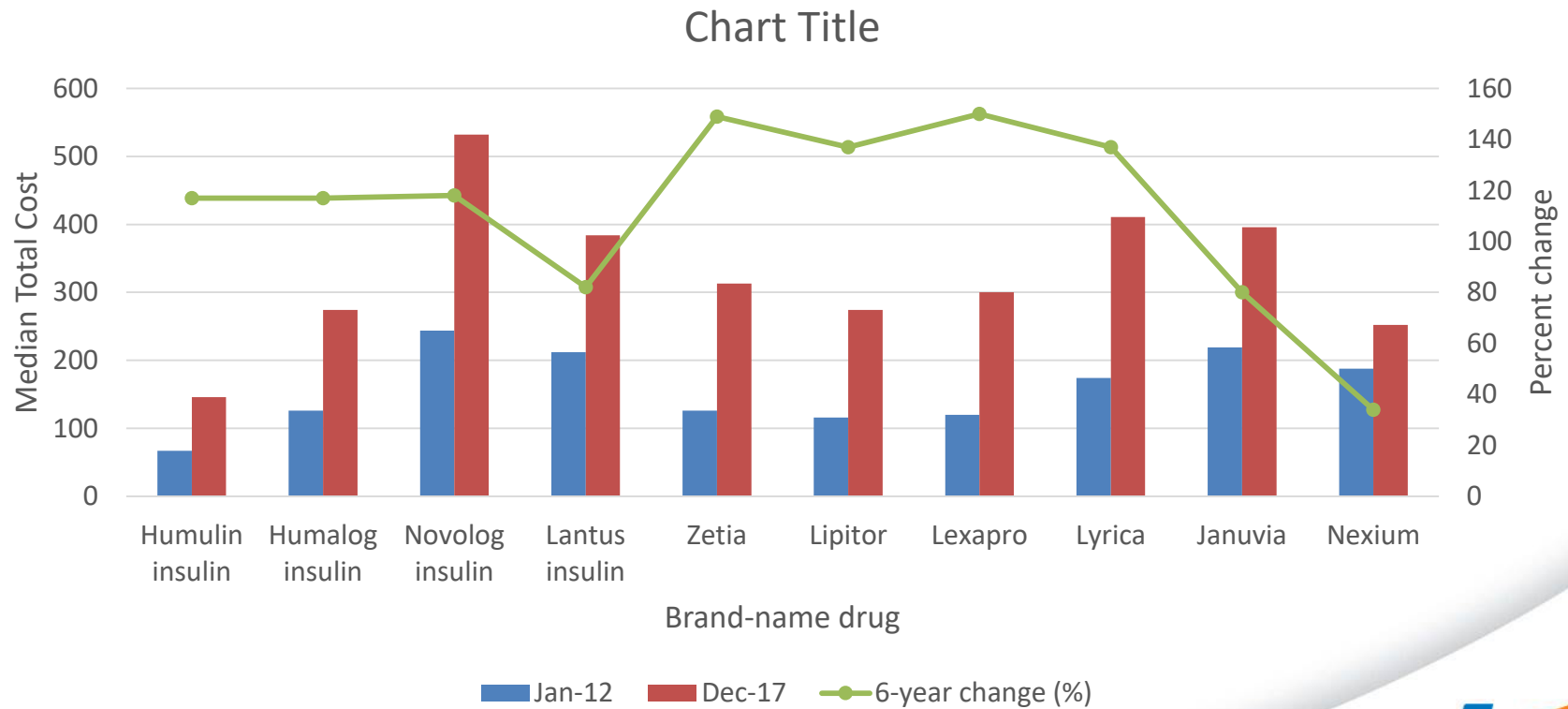
Annual brand price increases



American Association of Retired Persons. Trends in retail prices of brand name prescription drugs: 2017 year-end update. <https://www.aarp.org/content/dam/aarp/ppi/2018/09/trends-in-retail-prices-of-brand-name-prescription-drugs-year-end-update.pdf>. Published September 2018. Accessed August 15, 2019. Reprinted with permission from the AARP Public Policy Institute.



Annual brand price increases



Top drug categories – 2018

Nonfederal hospitals

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

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

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

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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

227 

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

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

227

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 IKE SWETLITZ / MARCH 12, 2019

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

CBS
NEWS

BY AIMEE PICCHI

DECEMBER 29, 2016 / 2:00 PM / MONEYWATCH

 REUTERS

HEALTH NEWS MAY 24, 2019 / 12:58 PM / 3 MONTHS AGO

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

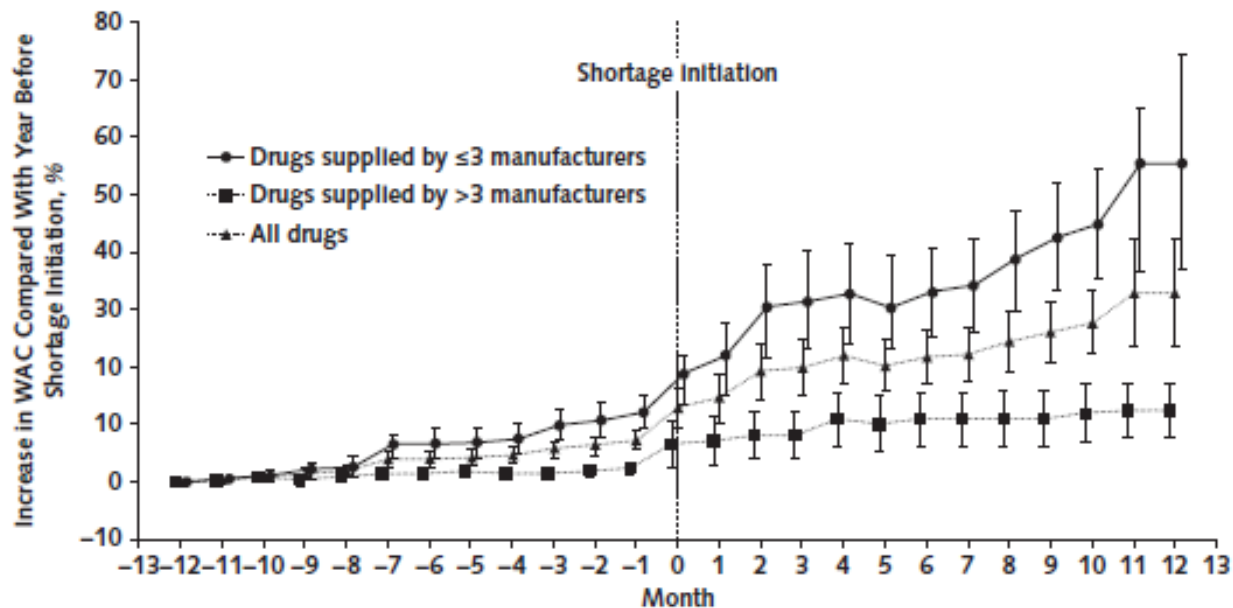
John Miller, Caroline Humer

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Drug prices in the news

Shortages

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



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



Drug prices in the news

Periodic price increases

HEALTH INC.

Prescription Drug Costs Driven By Manufacturer Price Hikes, Not Innovation

January 7, 2019 - 5:04 PM ET



ALISON KODJAK



CBS
NEWS

Drug prices in 2019 are surging, with hikes at 5 times inflation

BY AIMEE PICCHI

JULY 1, 2019 / 11:34 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

PHARMACEUTICAL INFORMATION FOR TODAY'S PHARMACEUTIST
**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 [Riley Ray Griffin](#), [David McLaughlin](#) and [Ben Elgin](#)
July 30, 2019

Agenda

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

Factors influencing drug prices

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

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

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

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

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

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/upshot/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/2019/08/12/canadians-are-hopping-mad-about-trumps-drug-importation-plan-some-of-them-are-trying-to-stop-it/>. August 12, 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

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

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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

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

