CONGRESSIONAL HEALTH POLICY EDUCATION PROGRAM

DRUG PRICING 101

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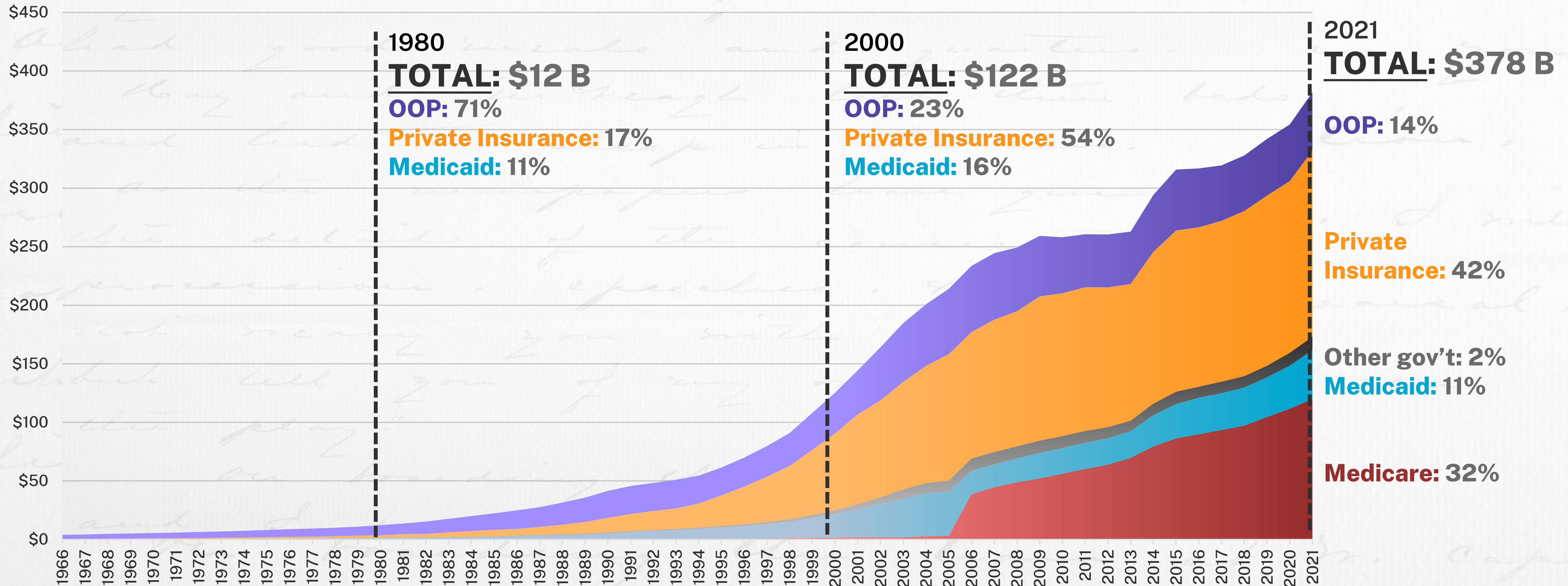
Overview

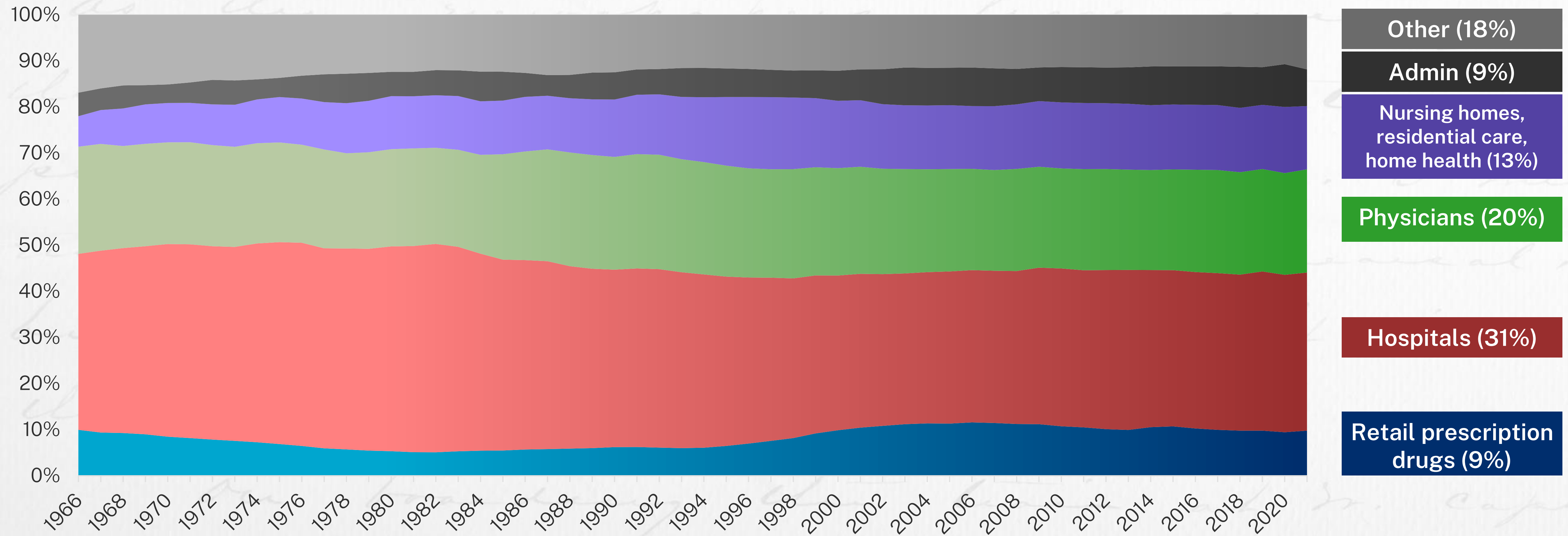
- **Context:**
  - How much do Americans spend on prescription drugs?
  - Are prescription drug prices going up?
  - Who makes money from prescription drugs?
  - Q&A
- **Demand side factors:** How does government pay for prescription drugs?
  - Medicare Part D
  - Medicare Part B
  - Medicaid "best price"
    - Lesson of unintended consequences: 340B
  - Veterans Affairs Administration
  - Q&A
- **Future briefing topics:** Supply side factors

Prescription drug spending has grown over time...



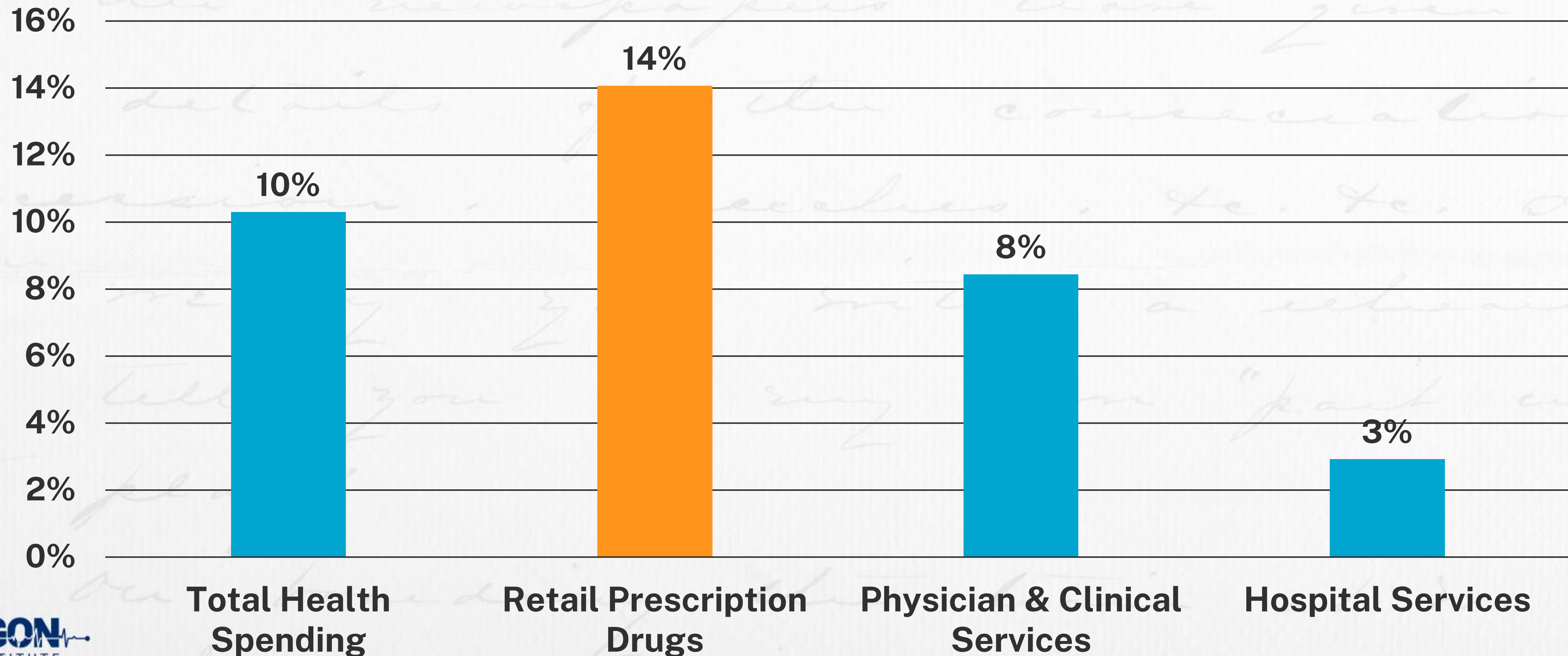
Source: NHE

...but has largely stayed consistent as a percentage of health spending



Source: NHE

Patient out-of-pocket spending as a percentage of total spending (2021)



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Source: CMS National Health Expenditure Data

Is cost-sharing increasing? Not for most patients

Annual OOP for patients with at least one prescription			
(2018 dollars adjusted by CPI-U)	2009	2018	Change
Private (median)	$90	$48	-47%
Private (95th percentile)	$1,124	$798	-29%
Medicaid (median)	$4	$1	-75%
Medicaid (95th percentile)	$665	$416	-37%
Medicare (median)	$341	$160	-53%
Medicare (95th percentile)	$2,265	$1,490	-34%

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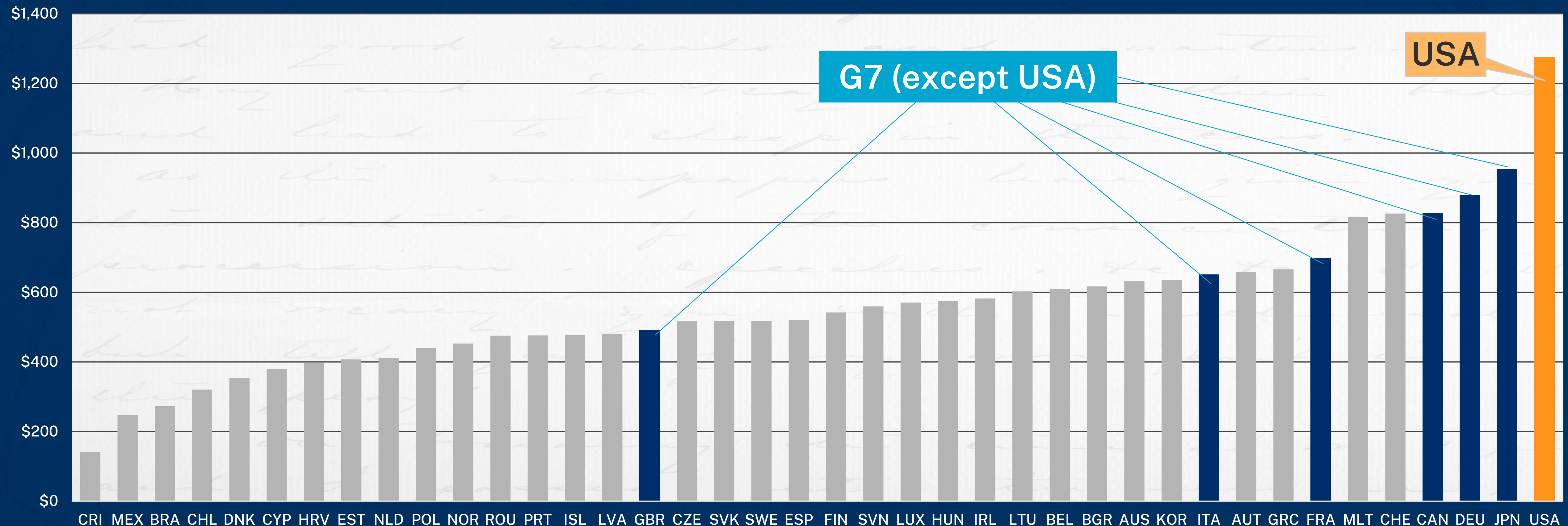
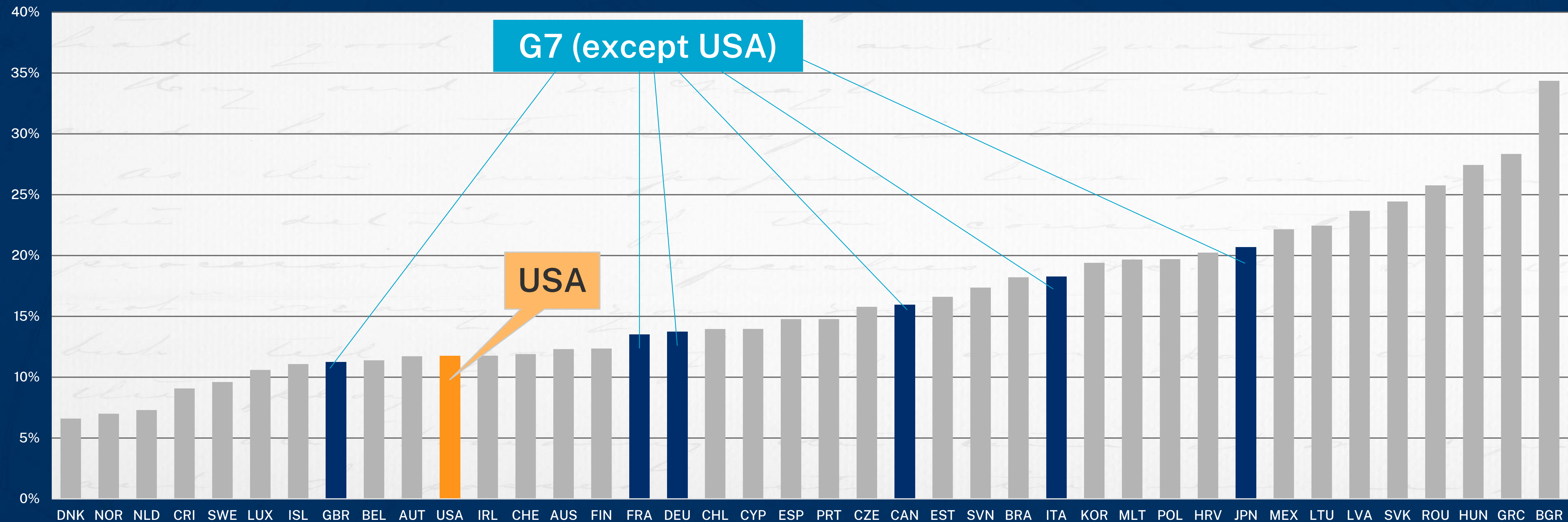
Source: AHRQ

USA spends more on prescription drugs than other OECD nations…



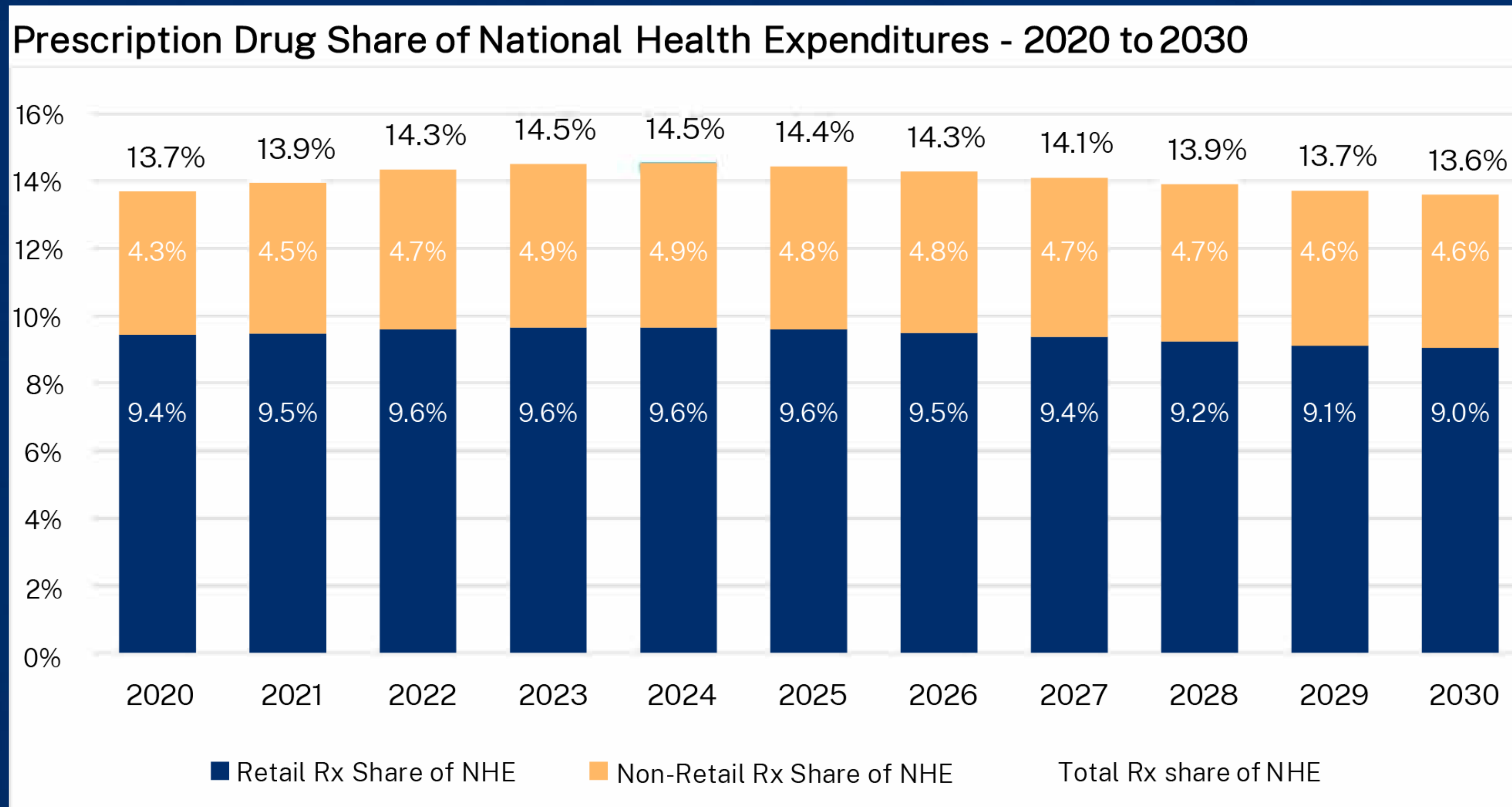
...but ranks low when measuring drug spending as a percentage of all health spending



Source: OECD

Retail prescription drug spending not the entire picture

Approximately 12% of physician spending & 3% of hospital spending is on non-retail drugs



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Source: Altarum

Are prescription drug prices going up?

It depends!

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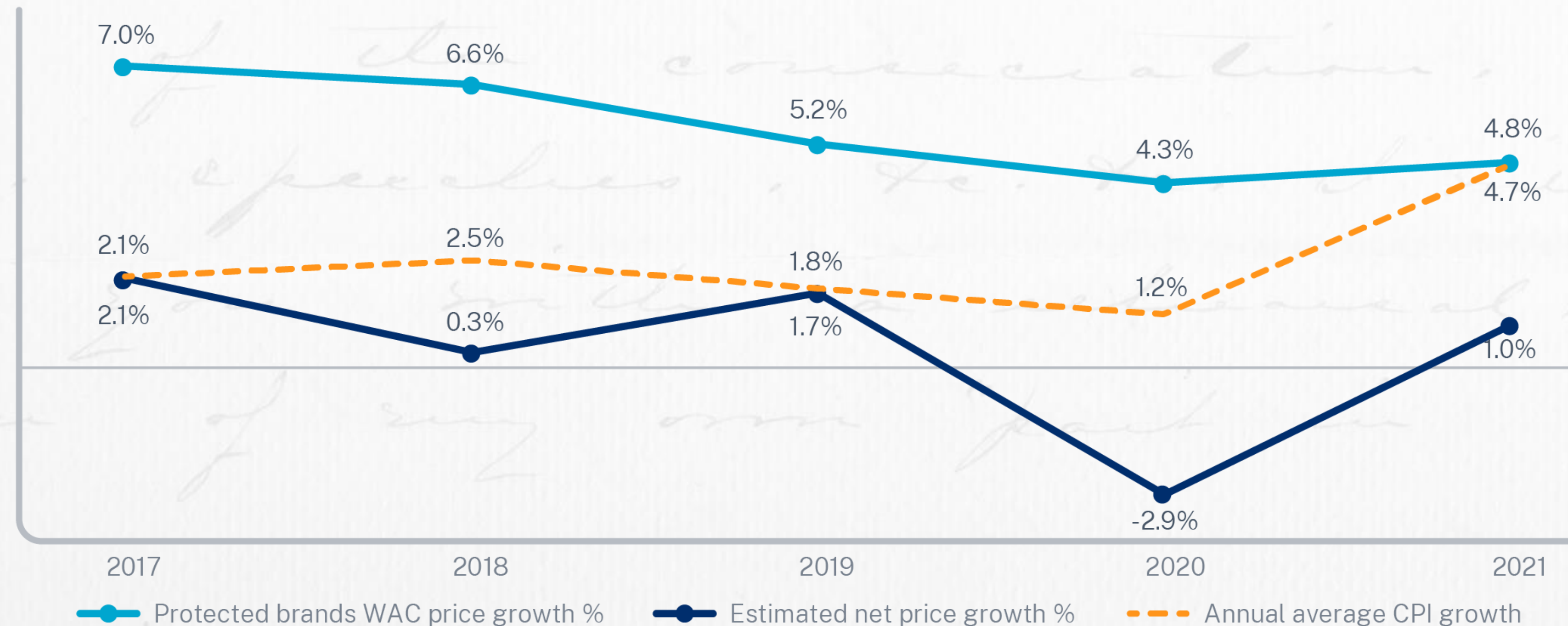
List versus net

- List prices increase almost every year; usually announced in January
- Net prices include discounts and increase much slower



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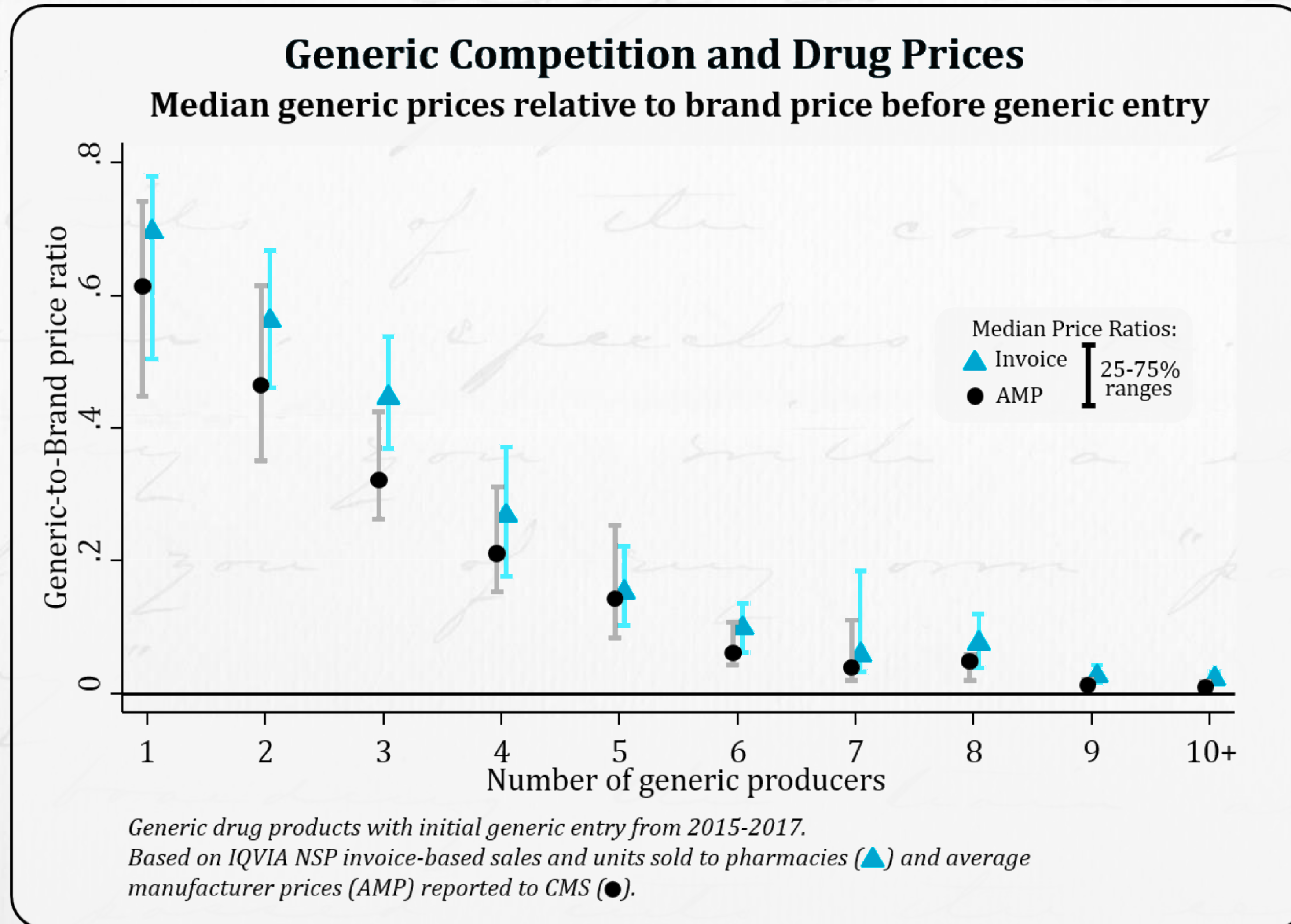
Source: IQVIA Institute, National Sales Perspectives, Dec 2021; Bureau of Labor Statistics, Annual Average Monthly CPI Growth, Dec 2021.

Brand or generic; biologic or biosimilar

- When first on the market, brands and biologics are protected from generic/biosimilar competition by patents and/or market exclusivity
- During patent protection/exclusivity, ability to increase prices less constrained, especially if no brand-named competitors on market
- Once generic or biosimilar launched, competition often fierce and prices often dramatically decline (a strength of system in USA)

Generic competition is very effective at lowering net prices



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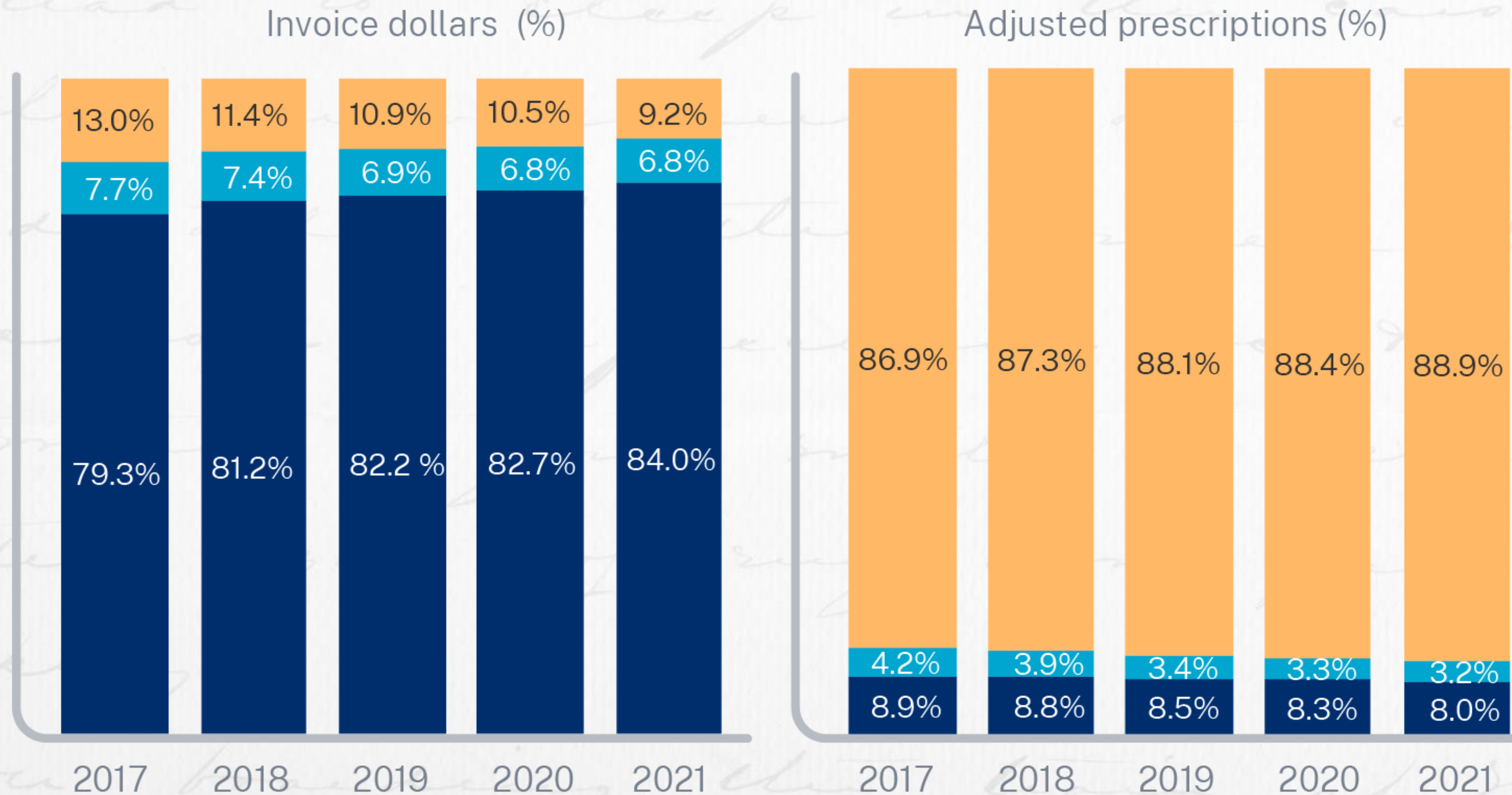
Spending and utilization of brand and generic drugs in the USA



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Measurement

- BLS CPI-Rx probably best
- Uses net prices
- Includes generic substitution
- But still needs caveats (does not include non-retail)

Source: U.S. Bureau of Labor Statistics

Who makes money from prescription drugs?

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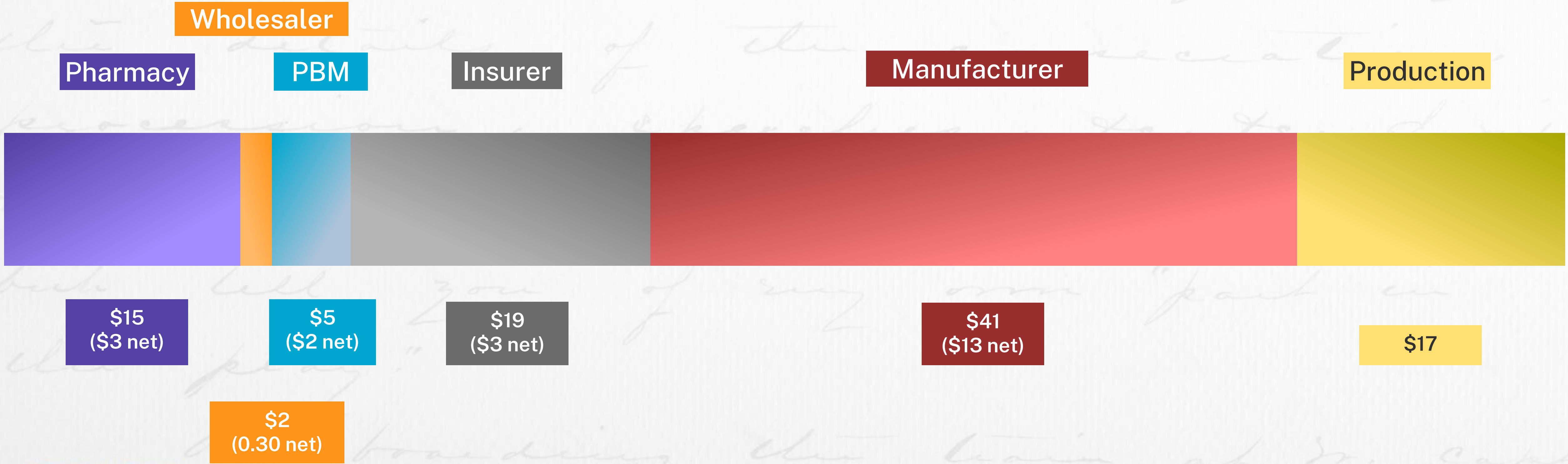
Source: Yu, Atteberry, Bach (2018)

Who makes money from prescription drugs?



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Source: Sood, Shih, Nuys, Goldman (2017)

Medicare Part D

Overview

- Created by Medicare Modernization Act of 2003
- Covers retail prescription drugs for eligible beneficiaries
- For most beneficiaries, government subsidy covers 74.5% of cost with rest coming from beneficiary

Harnessing competition

- Created during Republican trifecta, Part D utilizes market forces to keep prices down
- Benefit is provided through private-sector insurance plans
- Plans bid on cost to provide benefit, and government subsidy set at 74.5% of the nationwide average bid
- Private plans negotiate with drug manufacturers on price
- 28% of low-income beneficiaries have cost-sharing dramatically reduced

Medicare Part D (cont'd)

Important points

- Rare government program underbudget: outlays 45% less than CBO originally projected
- Highly effective at promoting generic utilization (90% dispense rate)
  - Low-income subsidy population 85% rate
- Since passage in 2003, Congress has modified multiple times, most significantly in 2010 (Obamacare) and 2021 (Inflation Reduction Act)

Inflation Reduction Act

- Capped beneficiary out-of-pocket liability at $2,000
- Caps list price increases at inflation
- Requires Secretary to set "maximum fair price" for certain drugs

Medicare Part B

Overview

- Since creation, Medicare has covered prescription drugs administered in hospital or doctor's office under Part B
- Payment for most Part B drugs set by statute at average sales price (ASP) + 6%
  - ASP is average that includes discounts in commercial market
  - Medicare also makes a separate payment to physician for administration under the OPPS fee schedule
- Beneficiary cost-sharing same as for all Part B services (annual deductible plus 20% co-insurance for traditional Medicare)

Medicare Part B (cont'd)

Important points

- Spending on Part B drugs has been increasing rapidly (approx. 9% annually for past decade)
- Significant variation in cost among drug types
- Top 10 drugs, focused on oncology, ophthalmology, and rheumatology, account for 38% of spending
- Approximately 900 drug codes account for other 62%
- ASP+6% methodology has been criticized for creating a financial incentive for physicians to prescribe more expensive medications

Inflation Reduction Act

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Medicaid Drug Rebate Program

Overview

- Created by the Omnibus Reconciliation Act of 1990
- If a drug manufacturer wants to participate in Medicaid, must provide "best price" they offer in commercial market
- Floor set at rebate of 15% of Average Manufacturer Price (AMP)
- Obamacare increased minimum rebate to 23% and indexed rebate to any list price increase beyond inflation (up to 100% of AMP)
- American Rescue Plan lifted "AMP cap" (now rebates can be >100%)

Important points

- Net of rebates, Medicaid spending on prescription drugs relatively low (only 5.4% of total spending in 2021)
- Unintended consequences…

Lessons of unintended consequences: 340B

- Impact of Medicaid best price reverberated across other payers
- Manufacturers were no longer willing to give large discounts if required to do so for every state's Medicaid program

GAO: Median discounts on drugs decreased following OBRA '90		
Year	HMOs (insurance)	GPOs (hospitals)
1991	24.4%	27.8%
1992	18.4%	22.1%
1993	14.2%	15.3%

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Lessons of unintended consequences: 340B (cont'd)

- In 1992, Congress stepped in to mandate similar rebates for sympathetic providers through Section 340B of PHS
- Creates a financial incentive for other providers to purchase 340B eligible entities leading to consolidation
- Obamacare exacerbated by massively expanding 340B eligibility
  - Hospital participation has doubled; overall participation has tripled
- Discounted purchases rose from estimated $30 B in 2018 to $46 B in 2021
- Hospitals account for 85-90% of all 340B purchases

Department of Veterans Affairs

Overview

- Price ceiling set by statute at Medicaid rate, BUT
- VA negotiates even lower prices by using an exclusionary formulary
- Additional discounts exempt from Medicaid best price

Important points

- Successful at negotiating low prices but at cost of restricting access to option
  - VA does not cover 1/5 of 200 most popular drugs in Part D
  - 80% of VA beneficiaries rely on multiple sources of coverage
- VA represents only 1.3% of retail prescription drug sales
- If VA discounts were applied more widely, manufacturers may not provide such large discounts

Inflation Reduction Act (P.L. 117-169)

Inflation Rebates	• Manufacturers will pay rebates to the federal government for price increases above inflation • Starting point for calculation is 2021
Part D Redesign	• First major overhaul to Medicare Part D since inception • Changes include a $2,000 out-of-pocket cap for patients, shift in liability towards plans, and $35 insulin coverage
Drug Price "Negotiation"	• Part D Drugs are eligible 9 years post approval; Part B drugs after 13 years • CMS will select 10 Part D drugs for negotiation in 2023; prices effective for 2026; after that CMS will select 15 and eventually 20 drugs per year • There is a ceiling price, but no floor, and CMS has discretion to set price

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BONUS: Pharmaceutical Benefit Managers (PBMs)

What do they do?

- PBMs pool the purchasing volume of health plans (and employers) and enter market-share based contracts with manufacturers for discounts off list price
- Manage formulary
- Manage pharmacy networks

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BONUS: Pharmaceutical Benefit Managers (PBMs)

How are the compensated?

- Mixture of fees, percentage of discount/rebate they obtain, spread between what they are reimbursed by plan and charge the pharmacy

Why are they controversial?

- They say no – PBMs limit access to drugs and pharmacies in exchange for discounts on the drugs and services they do grant access to
- Consolidated – Big three represent approximately 80% of retail drug sales
- Opaque – Conditional compensation & private contracts make it hard to know how much a PBM is making from any given transaction