

Skyrocketing Drug Prices:

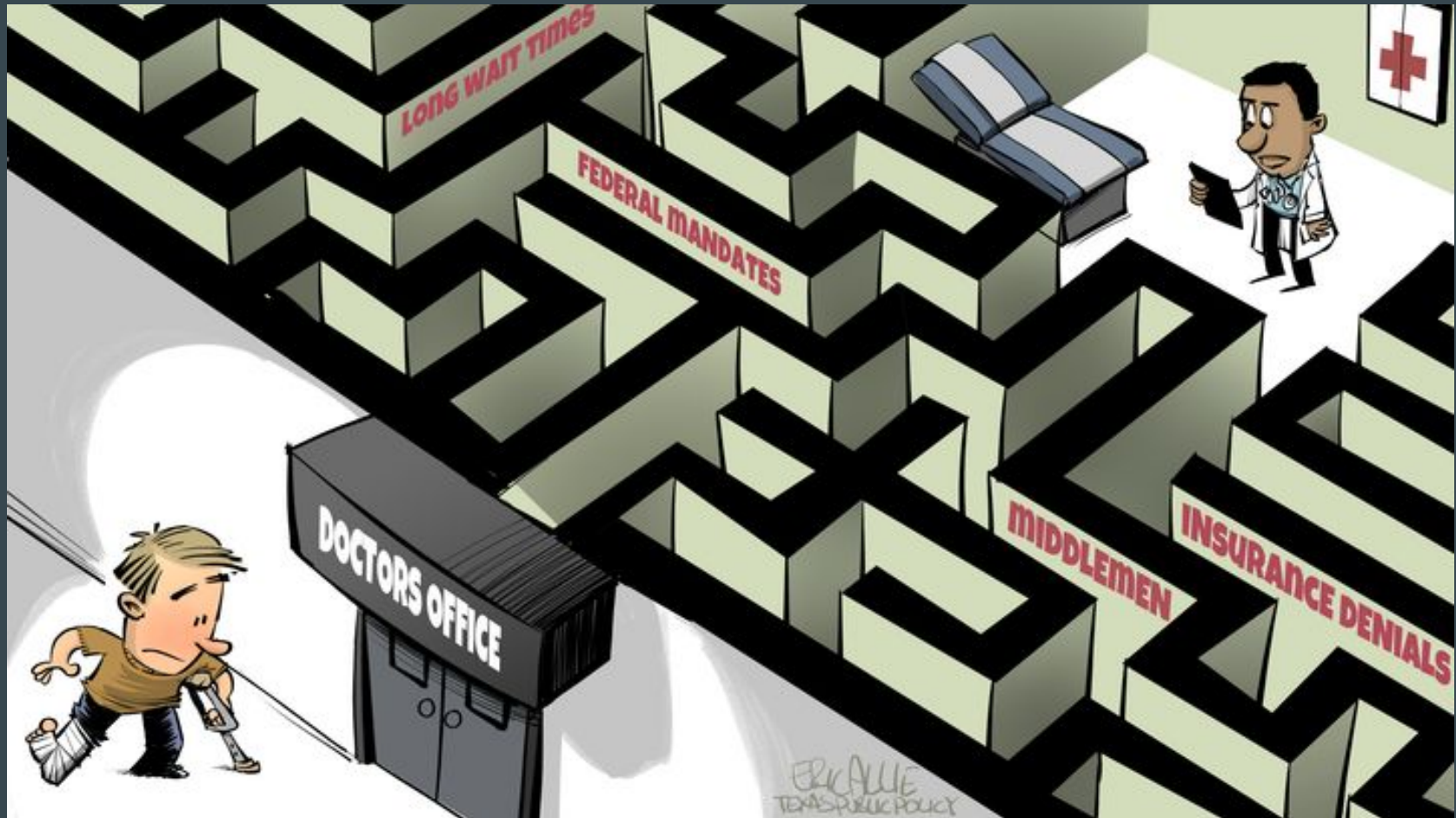
Middlemen, Monopolies and Markets

...

Mary Tipton, MD FAAP

Skyrocketing Drug Prices: Middlemen, Monopolies & Markets

- 1) Describe the scope of the problem
- 2) Why does the problem exist?
- 3) What can we do about it?



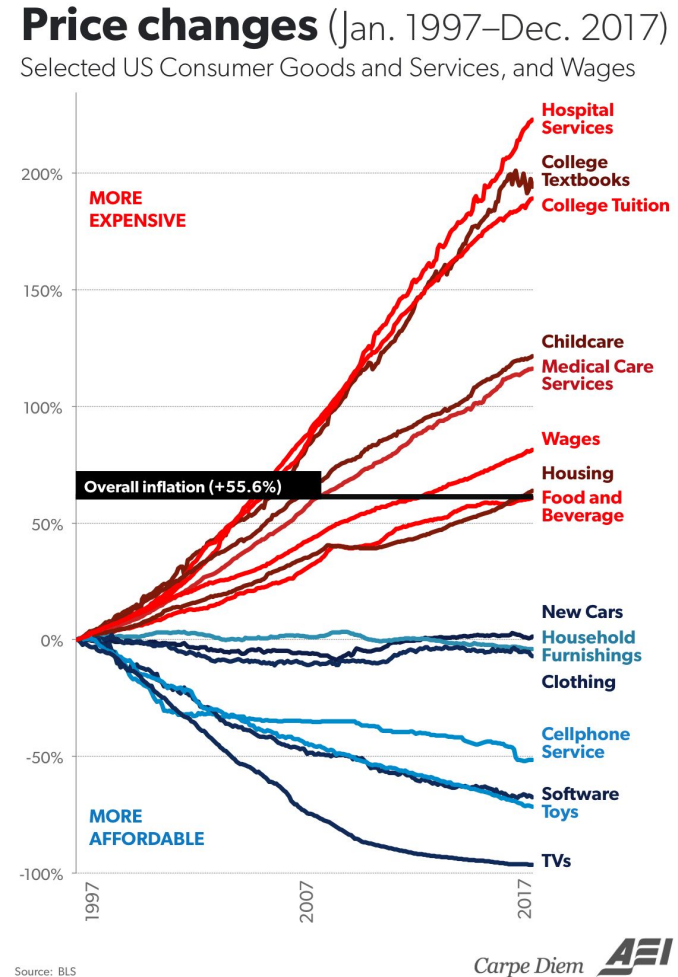
Patient Q.B. : a search for ADHD meds

- Healthy boy, one of 4 in the family, \$1000 deductible private insurance
- New diagnosis of ADD
- Methylphenidate prescribed, can't swallow pills, need to titrate dose, want once daily dosing
- 5-7 min spent in office picking rx, based on rudimentary formulary info through EMR
- 30 min spent on 4 portal messages after visit explaining drug pricing



How expensive are drugs?

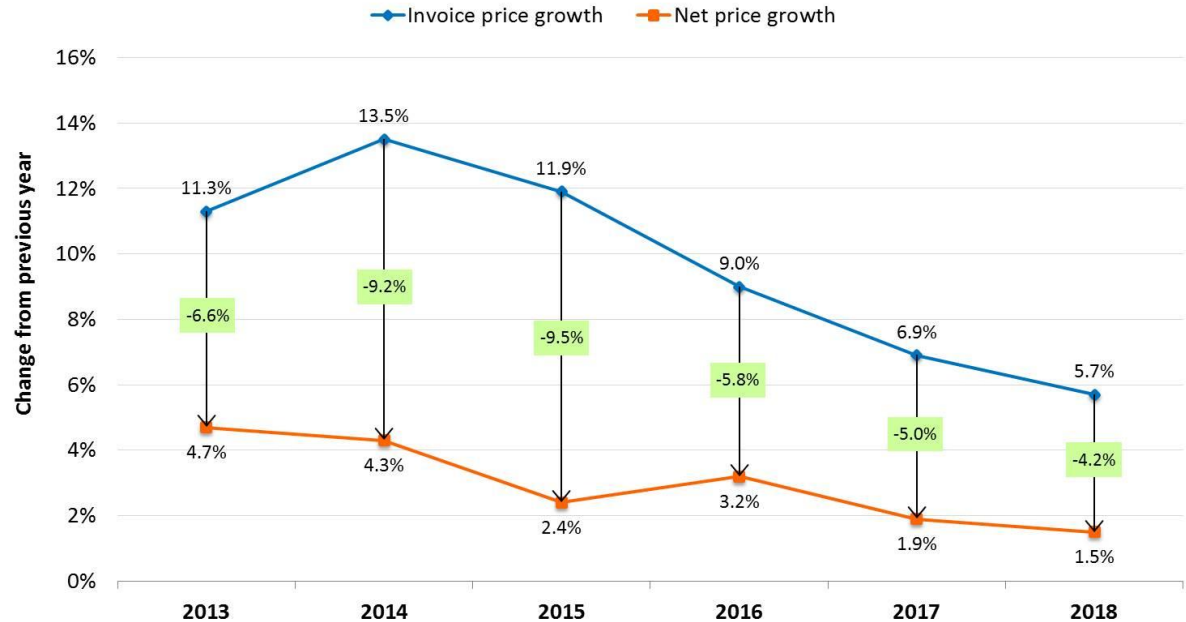
- Cost of all healthcare services are rising faster than inflation
- Note that all lines rising above inflation are all heavily government regulated industries



Are they really skyrocketing? (yes and no)

- “Drug Cost” must be clarified
 - List/Invoice vs. Net
- Overall drug spending is going up
- List price increases are actually leveling off
- Gross to Net Bubble is significant
- Out of pocket costs for patients are increasing

Price Increases for Brand-Name Drugs, Invoice vs. Net Price Growth, 2013 to 2018



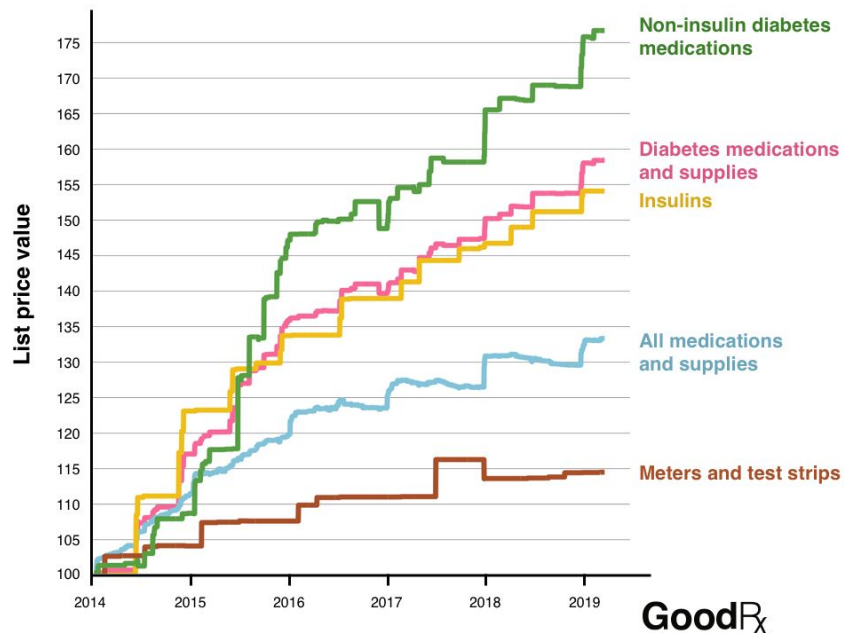
Source: Drug Channels Institute analysis of IQVIA data. Data show invoice and net price changes for brand-name products that are more than two years old and have not yet faced generic competition. Invoice prices are the amounts paid to distributors by their pharmacy or hospital customers, including prompt-payment and volume discounts. For brand-name drugs, changes in invoice and list prices are very highly correlated. Invoice price growth for 2018 based on first three calendar quarters. Net prices equal list price minus off-invoice rebates and such other reductions as distribution fees, product returns, chargeback discounts to hospitals, price reductions from the 340B Drug Pricing Program, and other purchase discounts.

Published on Drug Channels (www.DrugChannels.net) on January 29, 2019.



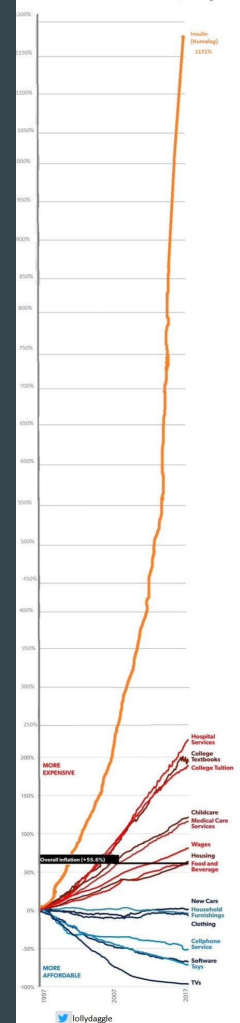
DRUG CHANNELS
INSTITUTE

List Price Trends Diabetes Medications and Supplies



Having diabetes is getting more expensive by the year

<https://www.goodrx.com/blog/goodrx-list-price-index-rising-cost-of-diabetes-treatments/>



Gross-to-Net Bubble

List (gross) price leveling off

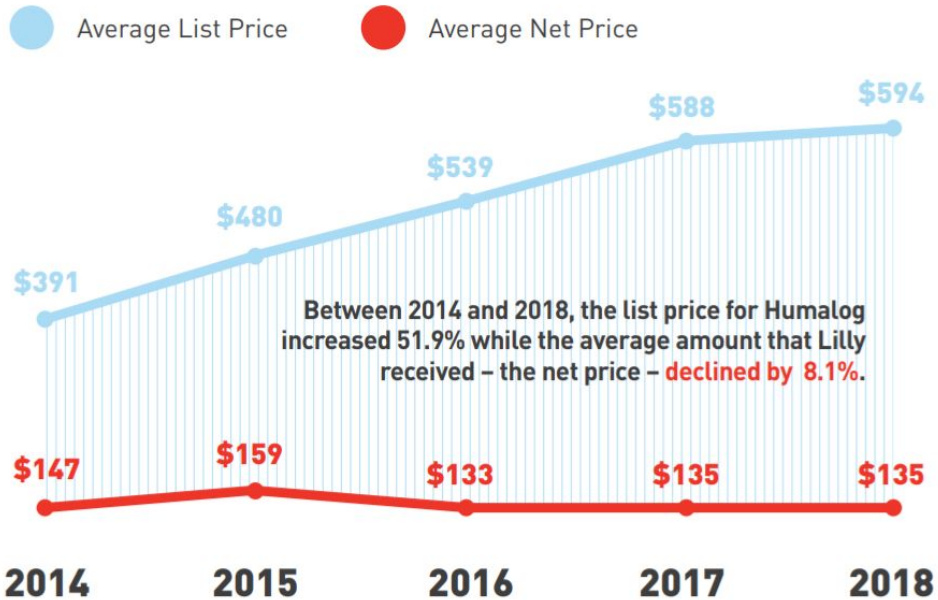
Net price from 2014 - 2018
was similar

*See how politicians can say
drug prices are coming down
and going up at the same
time?*

Rebates grew:

\$2928 -> \$5508 in 4 years

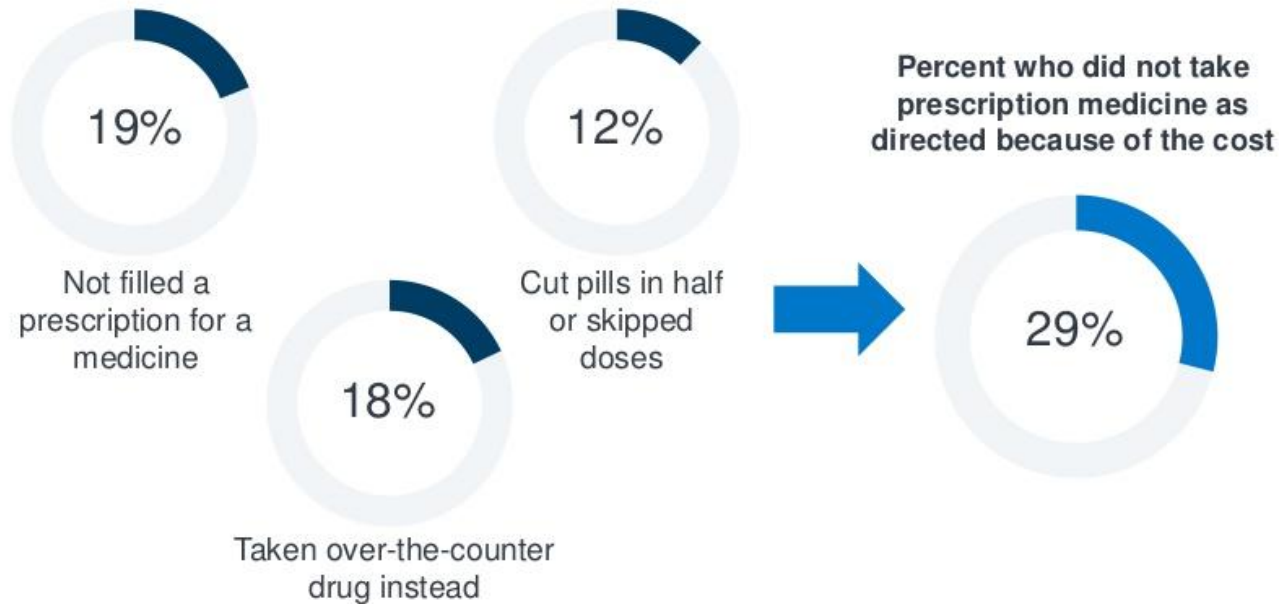
HUMALOG® (U100) AVERAGE LIST AND NET PRICE (USD) PER PATIENT PER MONTH, IF TAKEN AS PRESCRIBED²



Humalog U100 is the most broadly used Lilly insulin product. The last list price increase for Humalog U100 was May 2017. The net price in the chart represents the average revenue Lilly realized per patient per month for Humalog U100 if taken as prescribed. Because of rebates and fees Lilly provides insurers and/or PBMs, increases in list prices do not always reflect increases in net prices.

Three In Ten Americans Say They Haven't Taken Their Medicine As Prescribed Due to Costs

Percent who say they have done the following in the past 12 months because of the cost:



SOURCE: KFF Health Tracking Poll (conducted February 14-24, 2019)

What's Pharma's arguments for high prices?

- High cost of development
- It's a free market and the “market will decide the price”
- High costs are needed to continue innovation
- Manufacturers: “It's the PBM”

PBM: “It's the Manufacturers”



Are high costs are needed for drug development?

NO... because:

- Costs of existing medications keep rising

- There is no correlation of cost to benefit

- Why are prices so different worldwide?

- Cost of even very old medications have been suddenly marked up

Epipen, Acthar (\$40 -> \$39,000)



Diabetes

A month's supply of **LANTUS**, an insulin drug, has gone up **24 PERCENT** over the past six years.

2014



2019



Blood Clots

A month's supply of **XARELTO**, a widely advertised drug, has gone up **54 PERCENT** over the past six years.

2014



2019



Allergies

A two-pack of **EPIPEN JR**, used to treat life-threatening allergic reactions, increased **52 PERCENT** over the past six years.

2014



2019



Epipen Pricing Scandal: a demo of ALL the problems

Steep Climb

The list price for a two-pack of the EpiPen has gone up steadily.



Source: Truven Health Analytics
THE WALL STREET JOURNAL.



\$18,931,068
2015 Executive Compensation



\$2,453,456
2007 Executive Compensation



WHY do we have this Drug Cost Problem? (part 2)

Demand and Desperation

- Insulin
 - Serves a vulnerable population
 - Needed for survival
- Chemotherapeutics
 - Patient/Family will pay “anything” to save their loved one
 - Improve survival at any cost.



Monopoly / Monopsony / Oligopoly

Our “FREE MARKET” has them all!

Monopoly = a company or group having exclusive control over a commodity or service.

- Mylan epipen
- saline plant in Puerto Rico
- Insulin, 99% made by 3 companies

Oligopoly = market control by a few players

- (Big 3 PBM) Express Scripts, CVS/Caremark, Optum
- Control 90% of all prescriptions in USA

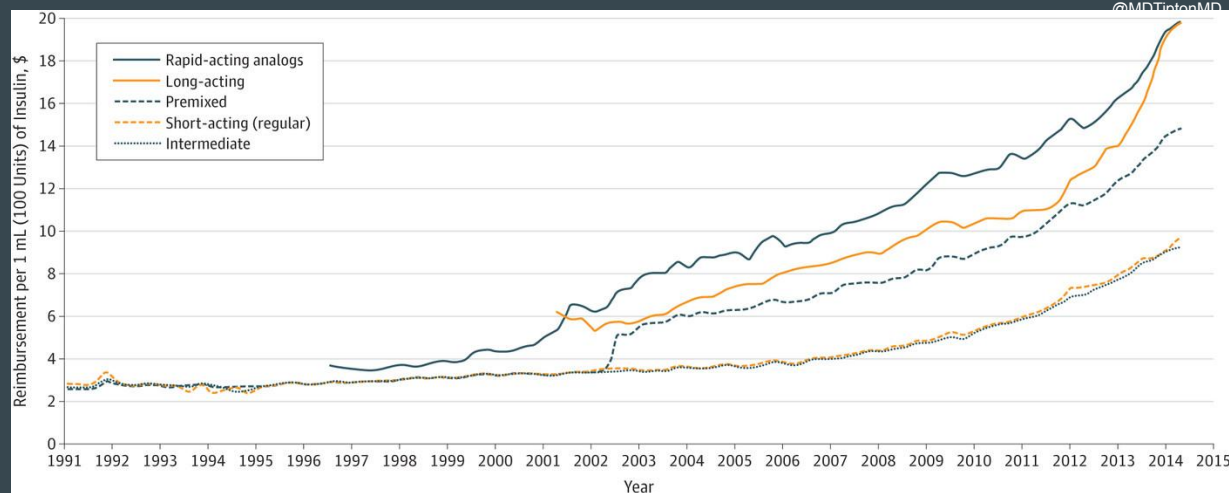


Monopsony = single (or dominant) buyer in system.

NHS or Medicare, also GPO (group purchasing organizations)

- supply shortages
- fewer new products

Patent Evergreening



- Sanofi makes \$50 million every DAY selling Lantus
- Lantus Patent (original) expired 2015 (right when Toujeo came out)
- 70 secondary patents have been filed by Sanofi
- Patents keep prices high and competition at bay

More Barriers for Competition (biosimilars & generics)

- Pay for delay of generic to market
- Withhold ingredients needed to make generics
- At least 2-3 generics are needed in market to decrease prices
- Manufacturers sue those trying to create insulin generics (“patent violation”)
- FDA laws protect biologics (different in other countries)
- Pay for position on formulary
- FDA allows “authorized” generics (fake competition, more profitable)

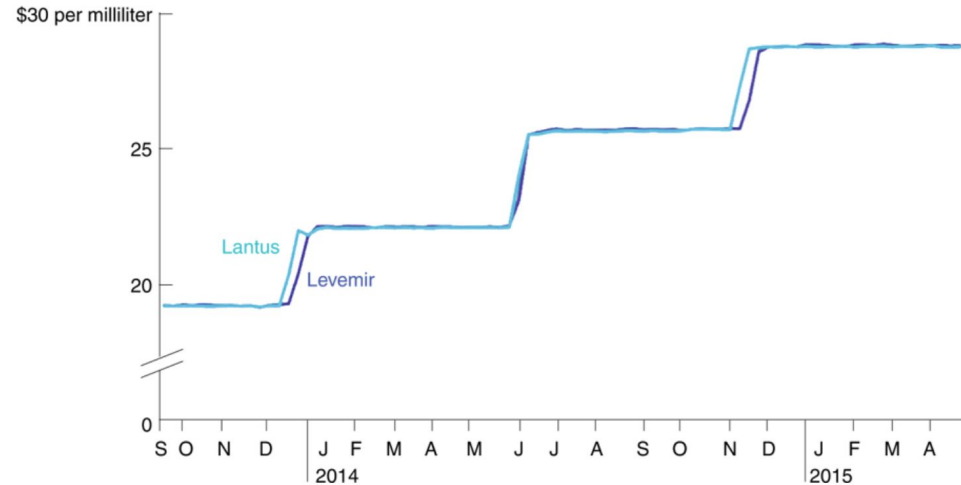
Shadow Pricing: Proof of Collusion?

Prices for Lantus / Levemir
went up in tandem in US on
13 occasions since 2009

Same graphs exist for
Humalog / Novolog

Fig. 1: 'Shadow pricing' between Lantus and Levemir from 2015 to 2016.

From: Shadow pricing and the art of profiteering from outdated therapies



Bloomberg Intelligence Analysis of Data retrieved from Symphony Health Solutions.

The prices of Sanofi's Lantus and Novo Nordisk's Levemir, which together dominate the global market for long-acting injectable insulin, have gone up in tandem in the United States on 13 occasions since 2009, according to consultants SSR Health.

Middlemen: PBM (Pharmacy Benefit Managers)

Manufacturer takes risk, develops product, tests product, produces it

Wholesaler packages product, delivers product

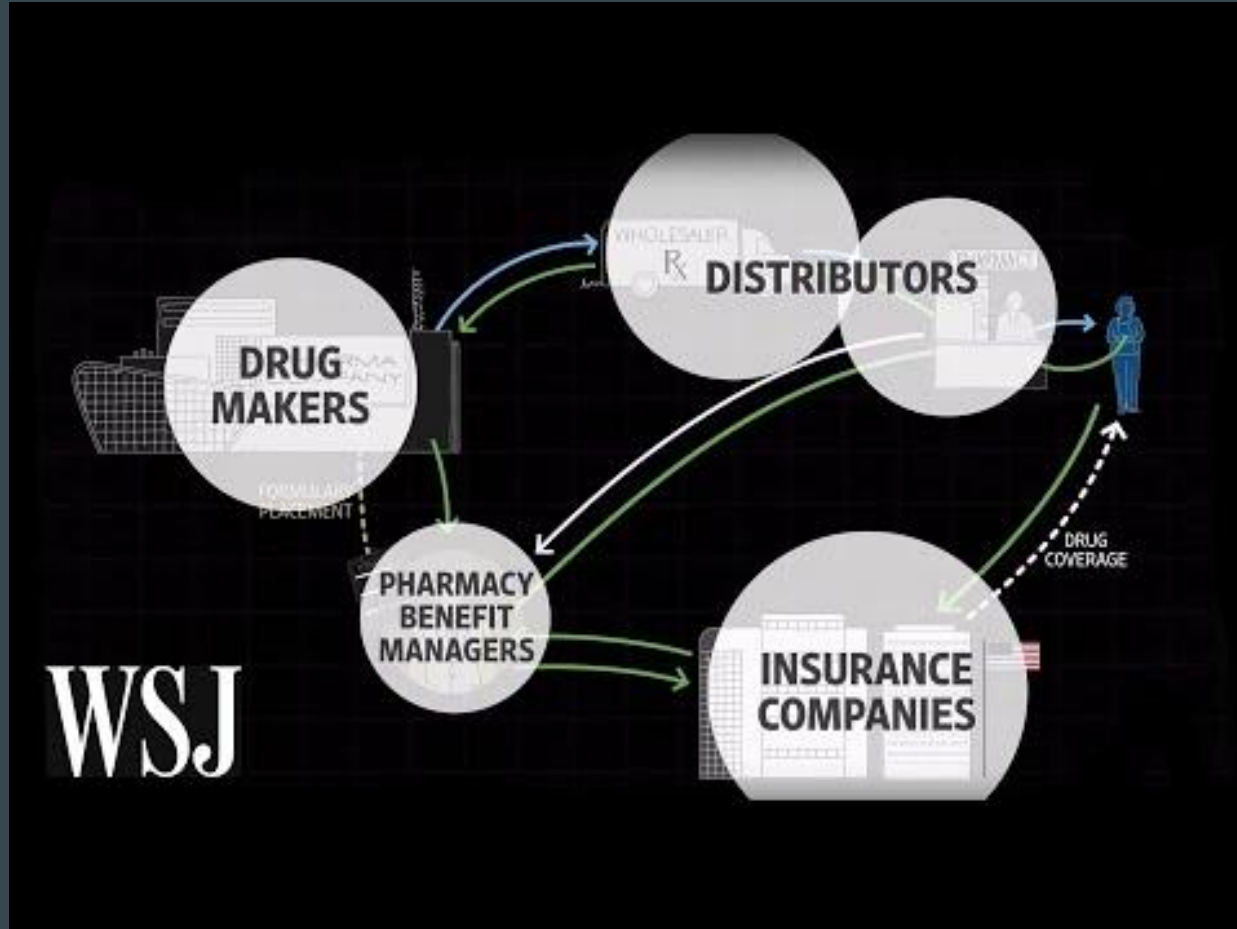
Pharmacy maintains inventory, labels product for patient, processes claim

***** What's left? *****

Middlemen

All they do is collect money, write up secret contracts and control the market

How Drug Prices Work: Wall Street Journal 30 May 2019



High List Prices

WINNERS

Higher rebates for entire supply chain

Higher rebate for physician if selling

LOSERS

Self pay patients

High deductible patients

Higher premiums for patients

Pharmacies, especially community pharmacies

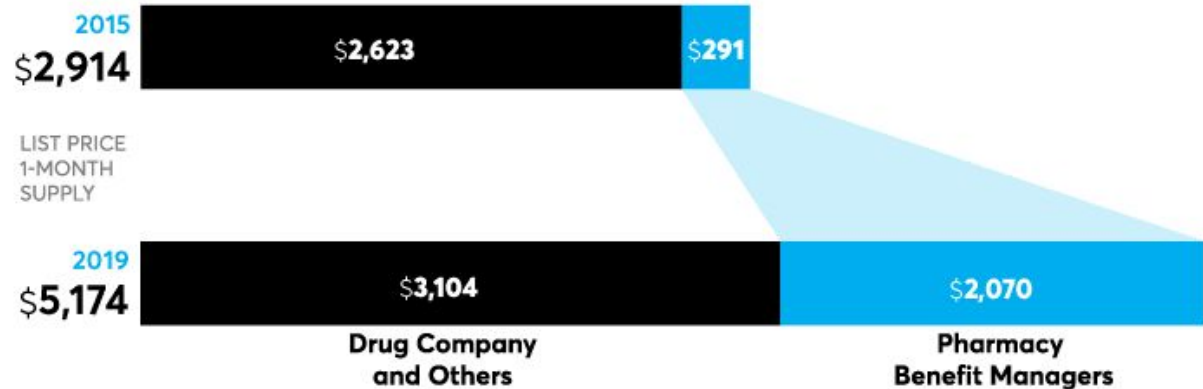
Medicare patients

Sicker patients

Follow the money

Anatomy of a Drug Price: Humira

In recent years, the full list price for Humira—an arthritis drug—has jumped, in part as middlemen in the drug supply chain called pharmacy benefit managers have taken a bigger cut. As a result, the cost to consumers—who often have to pay 30 percent of the drug's list price as coinsurance—has also risen sharply, from \$874 in 2014 to \$1,552 in 2019.

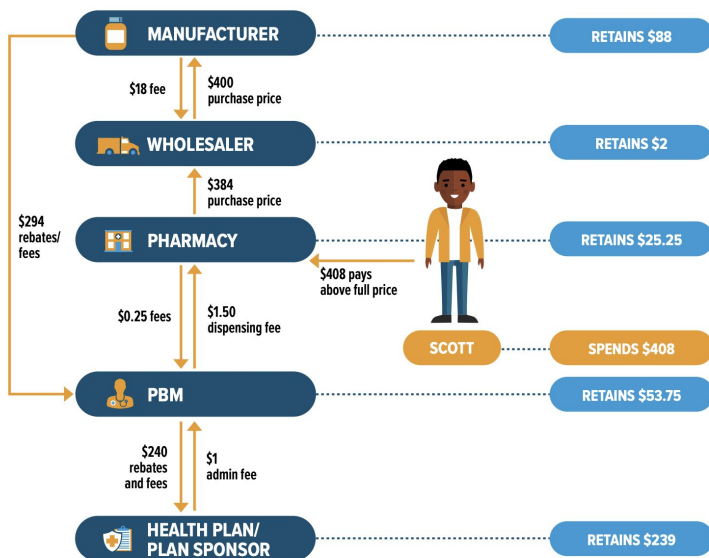


Sources: GoodRx (Humira list prices). Other figures estimated based on Credit Suisse 2015 Global Pharma Report; Feb. 26, 2019, testimony to U.S. Senate Committee on Finance; and drug pricing experts.

Follow the money

FOLLOW THE DOLLAR

Flow of Payment for a \$400 Insulin (Patient is in Deductible Phase)



*This graphic is illustrative of a hypothetical product with a WAC of \$400 and an AWP of \$480. It is not intended to represent every financial relationship in the marketplace.

**The amount of payments does not add up to \$400 due to markups and discounts as medicines are distributed.

PBM in MEDICAID (it's not just in the private market)

- Medicaid drug budgets are bursting: what to do?
 - Preferred drug lists, prior auth, cost sharing, prescription limits
 - Change from fee for service (FFS) to managed care organizations (MCO)
 - Limit high cost and specialty drugs (?closed formulary)
- Managed care and their PBM took over many states in last ten years
 - 25% of **Utah** is FFS Medicaid, 75% is MCO (split between 5, all have PBM)
 - PBM may not be saving states money

Side Effects: The Columbus Dispatch

THE COLUMBUS DISPATCH HOME SUBMIT A NEWS TIP DRUG PRICE DATABASE

Dispatch analysis shows
"cost cutting"
middlemen reap millions

>> [READ THE STORY](#)



Ohio experience
raises questions about
CVS-Aetna merger

Ohio firing pharmacy
middlemen that cost
taxpayers millions

>> [READ THE STORY](#)



Amid PBM inquiry,
officials' ties to
CVS questioned

Pharmacy middlemen
come between cancer
patients and their drugs

>> [READ THE STORY](#)



CVS accused of using
Medicaid business to drive
out retail competition

Utah Medicaid

- Preferred Drug List (PDL) changes monthly
- Only applies to Utah Medicaid, MCO have their own PDL
- Psychotropic meds are excluded
- 90 day supplies are now mandatory for many drugs
- Brand is preferred over generics in many cases

<https://medicaid.utah.gov/pharmacy/preferred-drug-list/>

PBM in Medicare

- Medicare Part D established 2003
- Bill “dropped” after midnight before holiday
- Barely passed at 6 am after heavy lobbying
- Author took a 2 million/yr job with Pharma

- Bush administration opened the door for Pharma / PBM to get Medicare \$\$
- Affordable Care Act (Obama) doubled down to boost profits (closed donut hole)

MONEY & POLITICS

The Lobbyist Who Made You Pay More at the Drugstore

Here's how the pharmaceutical industry keeps America's drug prices among the highest in the world.

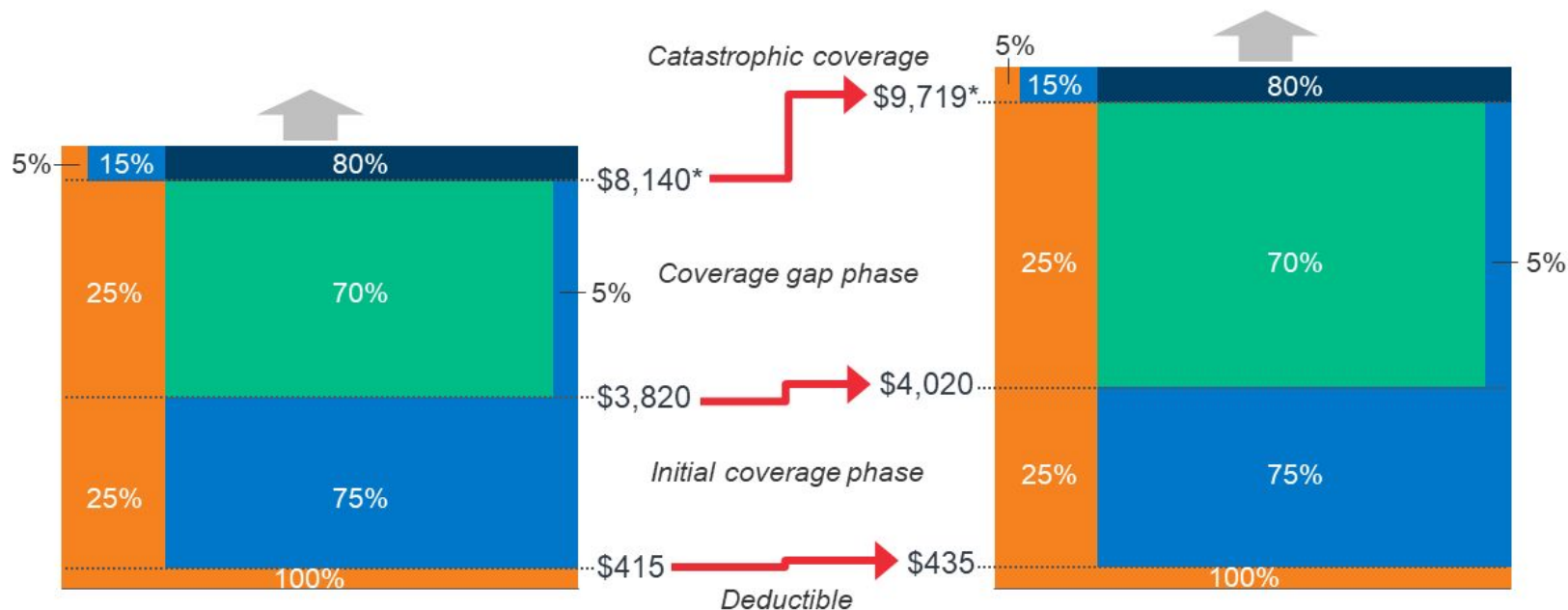
BY WENDELL POTTER AND NICK PENNIMAN | MARCH 18, 2016



Figure 4

Medicare Part D Standard Benefit Parameters Will Increase in 2020

Share of costs paid by: ■ Plans ■ Enrollees ■ Manufacturers ■ Medicare



NOTES: Some amounts rounded to nearest dollar. Share of costs in coverage gap reflect costs for brand-name drugs in 2019, and both brands and generics in 2020. *Corresponds to an out-of-pocket threshold for catastrophic coverage of \$5,100 in 2019 and \$6,350 in 2020.

SOURCE: KFF, based on 2019 and 2020 Part D benefit parameters.

How does Part D / PBM drive up costs?

Medicare 2003 law prohibits negotiation with drug companies for prices

Medicare covers 80% part D costs in catastrophic phase

PBM use same tactics as Medicaid (anti-competitive market, spread pricing)

No incentive to control drug costs by plan sponsors (PBM/Insurer mergers)

Manufacturer “discounts” for patients are really “kickbacks” to the PBM

Example of Part D plan favoring a high priced drug

Market Share for Hepatitis C Therapies, New-to-Class Patients, 2019

74K

24K

94K

24K

26K

EPCLUSA-BRANDED

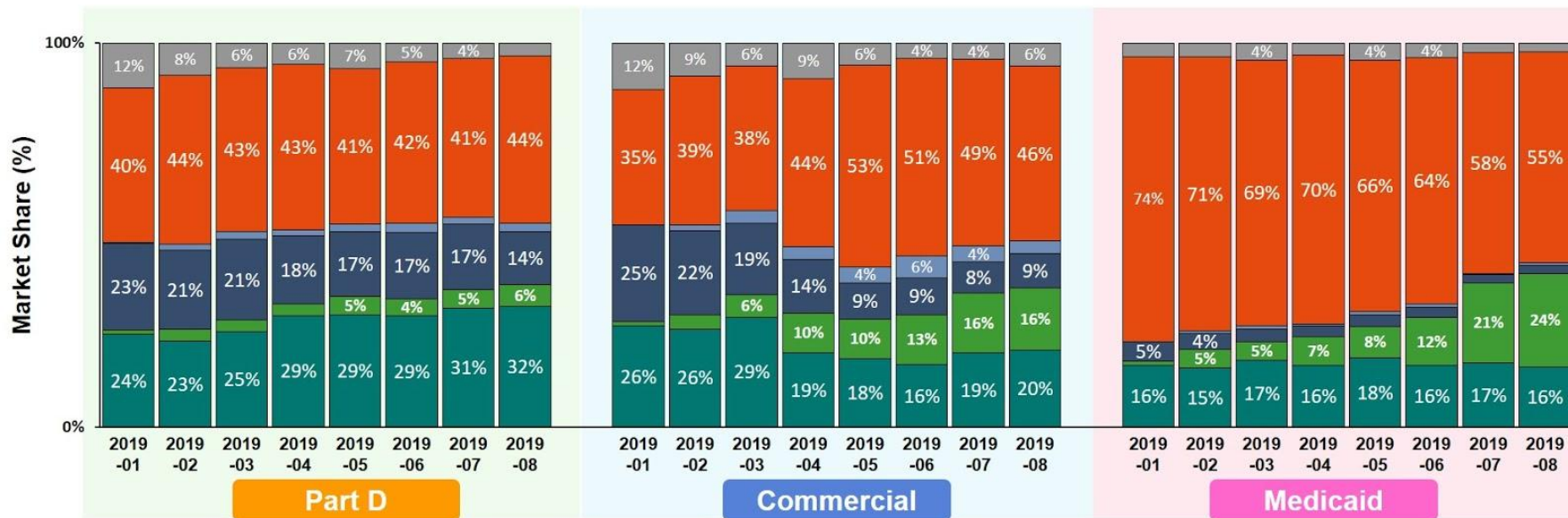
EPCLUSA-AG

HARVONI-BRANDED

HARVONI-AG

MAVYRET

OTHER



AG = authorized generic

Source: IQVIA US Market Access Strategy Consulting analysis. New-to-Class patients have not previously initiated therapy on any HEP-C product in the prior year. Data show paid claims.



Vertical Integration : Mega Mergers

Let's Get Vertical: Insurer + PBM + Specialty Pharmacy + Provider



1. Cigna partners with providers via its [Cigna Collaborative Care](#) program. However, Cigna does not directly own healthcare providers.

2. AllianceRx Walgreens Prime is jointly owned by Prime Therapeutics and Walgreens Boots Alliance.

Source: Drug Channels Institute research; [The 2019 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers](#), Chapter 5.

Where is the OUTRAGE???

Physicians - employed, salaried, no transparency/education

Physician organizations - funded by Pharma, conflicted interests

Politicians - held hostage by lobbyists and campaign donations

Patients - shielded from costs, copay cards kick in, no knowledge of true cost

Pharmacists - now owned mostly by PBM (independent are being forced out). Gag clauses, copay clawbacks

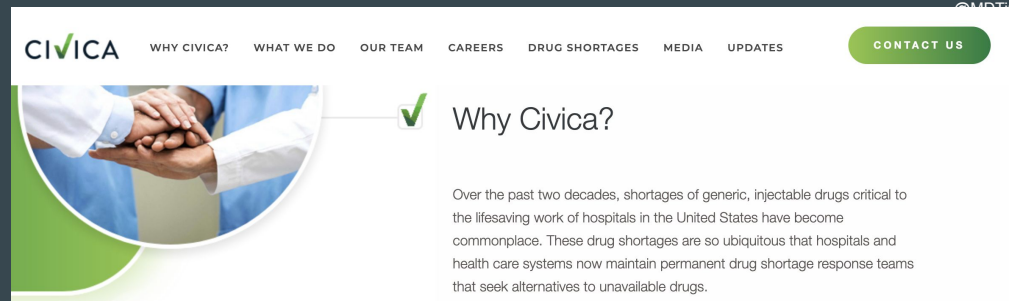


What can we do? (part 3)

- Prevent product monopolies
 - Value based pricing (PSK9 inhibitors, HCV drugs)
 - Cap price increases to inflation? OR enable true market forces without caps?
 - Remove barriers for competition products (insulin, SGLT2)
 - Reference pricing system for insulin and other lifesaving drugs?
- Remove barriers for biosimilars and generics
 - Prohibit “Authorized generics” from same manufacturers
 - Reciprocal approval for biosimilars in other countries?
 - Lawsuits to block biosimilars should not be allowed
 - Large molecules vs small molecules (same rules should apply)

What can we do? (part 3)

- Reform patent system
 - Stop patent abuse and evergreening
 - Hard limit on initial patent years?
- Reform FDA rules allowing monopoly of
 - off-patent orphan drugs (Daraprim)
 - Off-patent pre FDA drugs (colchicine)
 - Off-patent drug with special delivery device (epipen, nasal naloxone)



- Nonprofit generic manufacturers
 - Civica RX created by IHC, Mayo, VA in 2018
 - Currently making 18 medications
 - Aim to reduce drug shortages and cost
- Allow Medicare part D to negotiate with drug companies
- Stop vertical integration in market

Rebate Transparency - **REPEAL SAFE HARBOR for PBM**

- Demand transparency for every transaction in supply chain
- Potential savings of at least **135 billion per year**
- Estimated 30-60% of list price is rebates
- Utah HB 272 (Rep Paul Ray) PBM Transparency (passed House 3/5/2020)

Repeal would be revolutionary



Restore market competition, prevent shortages and price gouging

#Sunshine4All @MDTiptonMD

Talk to your patients about drug prices

Encourage price disruptors

Introduce comparison shopping

Recommend store brand meters/strips

Support independent pharmacists

Direct Primary Care

<http://www.greenhillsdirectfamilycare.com/pricing-fees/>

Avoid copay cards if possible

RETAILER	PRICE					TOTAL PRICE
	Pioglitazone (Actos)	Celecoxib (Celebrex)	Duloxetine (Cymbalta)	Atorvastatin (Lipitor)	Clopidogrel (Plavix)	
HealthWarehouse.com	\$12	\$22	\$13	\$10	\$10	\$66
Costco [1]	\$16	\$26	\$35	\$13	\$16	\$105
Independents [2]	\$19 (\$10-\$493)	\$34 (\$11-\$295)	\$31 (\$20-\$267)	\$15 (\$8-\$197)	\$15 (\$8-\$260)	\$107 (\$69-\$1,351)
Sam's Club [1]	\$20	\$38	\$31	\$20	\$45	\$153
Walmart	\$132	\$203	\$123	\$30	\$30	\$518
Kmart	\$160	\$185	\$120	\$35	\$35	\$535
Grocery Stores [3]	\$113 (\$10-\$349)	\$189 (\$46-\$250)	\$170 (\$13-\$223)	\$32 (\$11-\$71)	\$36 (\$7-\$224)	\$565 (\$88-\$1,117)
Walgreens	\$167	\$204	\$251	\$65	\$65	\$752
Rite Aid	\$255	\$194	\$170	\$128	\$119	\$866
CVS/Target	\$270	\$187	\$195	\$135	\$141	\$928

Copperview Medical Center



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