Skyrocketing Drug Prices: Middlemen, Monopolies and Markets

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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

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.
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
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:

- Not filled a prescription for a medicine: 19%
- Cut pills in half or skipped doses: 12%
- Taken over-the-counter drug instead: 18%
- Percent who did not take prescription medicine as directed because of the cost: 29%

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 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)
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.

<table>
<thead>
<tr>
<th>Year</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb 22, 2007</td>
<td>$93.88</td>
</tr>
<tr>
<td>May 16, 2016</td>
<td>$608.61</td>
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</tbody>
</table>

$18,931,068

2015 Executive Compensation

$2,453,456

2007 Executive Compensation

Source: Truven Health Analytics

THE WALL STREET JOURNAL.
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

**Monopsony** = single (or dominant) buyer in system.

- NHS or Medicare, also GPO (group purchasing organizations)
  - supply shortages
  - fewer new products

**Oligopoly** = market control by a few players

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

www.statnews.com “Patent abuse is driving up drug prices. Just look at Lantus” By Tahir Amin 7 Dec 2018
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

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

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

- **Manufacturer**: Retains $88
  - $18 fee
  - $400 purchase price

- **Wholesaler**: Retains $2
  - $384 purchase price

- **Pharmacy**: Retains $25.25
  - $1,50 dispensing fee
  - $408 pays above full price

- **PBM**: Retains $53.75
  - $240 rebates and fees
  - $1 admin fee

- **Health Plan/Plan Sponsor**: Retains $239
  - $408 spends

*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
Dispatch analysis shows "cost cutting" middlemen reap millions

Ohio firing pharmacy middlemen that cost taxpayers millions

Pharmacy middlemen come between cancer patients and their drugs

Ohio experience raises questions about CVS-Aetna merger

Amid PBM inquiry, officials' ties to CVS questioned

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)

Medicare Part D Standard Benefit Parameters Will Increase in 2020

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

Catastrophic coverage $9,719
5% 15% 80%

Coverage gap phase $3,820 $4,020
25% 70%

Initial coverage phase $415 $435
25% 75%

Deductible


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

https://www.drugchannels.net/2020/01/why-part-d-plans-prefer-high-list-price.html
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.


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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

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<th>Duloxetine (Cymbalta)</th>
<th>Atorvastatin (Lipitor)</th>
<th>Clopidogrel (Plavix)</th>
<th>TOTAL PRICE</th>
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