Understanding Competition in Prescription Drug Markets:

Entry and Supply Chain Dynamics

Introductory Remarks

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Federal Trade Commission

Keynote Remarks

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Federal Trade Commission

Keynote Remarks

Scott Gottlieb, M.D.
Commissioner
U.S. Food and Drug Administration

Understanding Competition in Prescription Drug Markets:

Entry and Supply Chain Dynamics

Panel 1: Generic Drug Competition: Understanding Demand, Price and Supply Issues

Division of
Pharmacoepidemiology & Pharmacoeconomics
Department of Medicine, Brigham & Women's Hospital, Harvard Medical School

Promoting Timely and Effective Generic Drug Markets

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November 8, 2017
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PORTAL
Program On Regulation, Therapeutics, And Law

What is PORTAL?

- Core faculty with expertise in medicine, business, law, epidemiology, ethics; post-docs and numerous students
- Research on interactions among the regulatory, legal, economic, and clinical components of the pharmaceutical marketplace
- Largest and most prolific independent research group in the country focused on these issues
- Current research funding from Harvard Program in Therapeutic Science, Laura and John Arnold Foundation, Engelberg Foundation
  - Past research funding from FDA CDRH, Commonwealth Fund, Harvard Clinical and Translational Science Center, AHRQ, Robert Wood Johnson Foundation, CVS Caremark, FDA Office of Generic Drugs, Greenwall Faculty Scholars Foundation in Bioethics
- Twitter: @PORTAL_research; Website: www.PORTALresearch.org

Prescription Drug Spending in the US

- Rose 12% in 2015, 6% in 2016 to $450 billion
  - 22% of health care spending (IMS)
  - 19% of Medicare spending (MEDPAC)
- International per capita comparisons
  - US: **$858**; avg 19 industrialized countries: **$400**
- Due to brand-name drug prices
  - 10% prescriptions, 72% of spending
- 20% of patients in 2016 reported that they or another family member did not fill a prescription due to cost
- Patients prescribed a costly branded product rather than a more affordable generic alternative adhere less well, and have worse health outcomes

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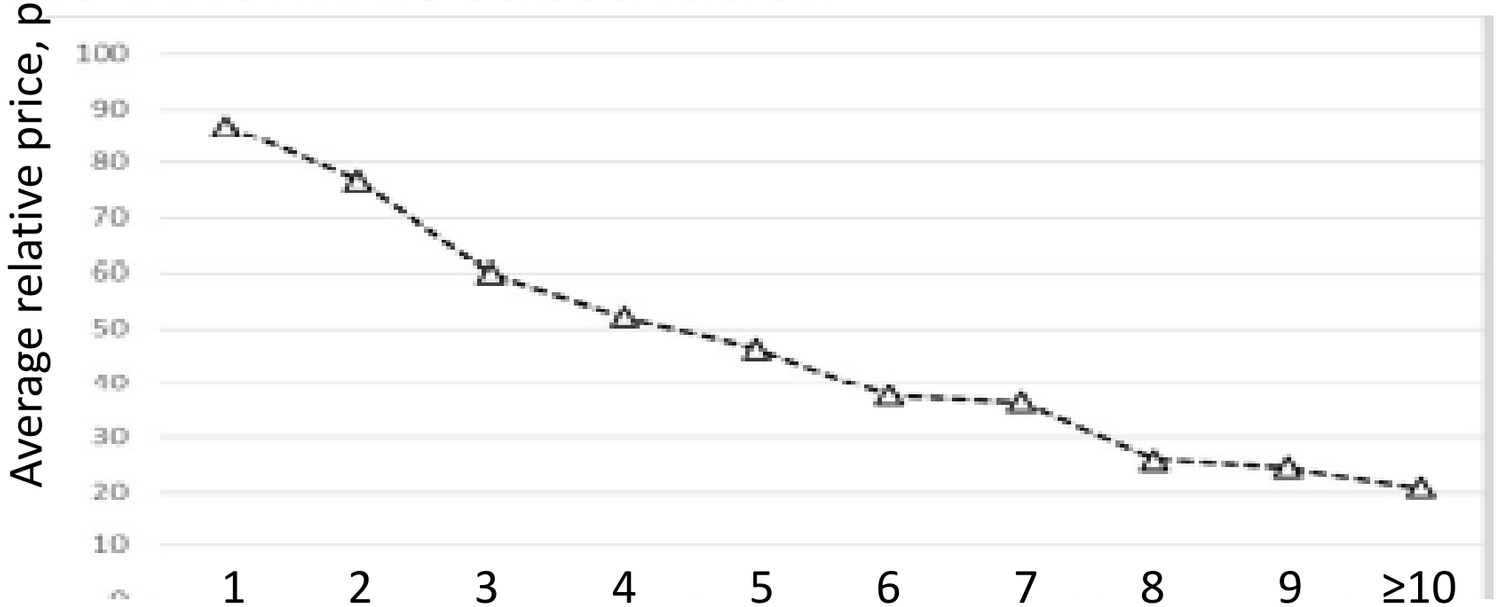
Kesselheim et al., JAMA, 2016; Shrank et al, Archives Int Med 2006; Gagne et al, Annals of Int Med, 2014; DiJulio et al., Kaiser Family Foundation

DoPE
BWH

Generic drugs

- Generic competition consistently and substantially lowers prescription drug prices
  - Abbreviated FDA approval process, state Drug Product Selection laws facilitate automatic substitution



Dave, Hartzema, Kesselheim (unpublished data)

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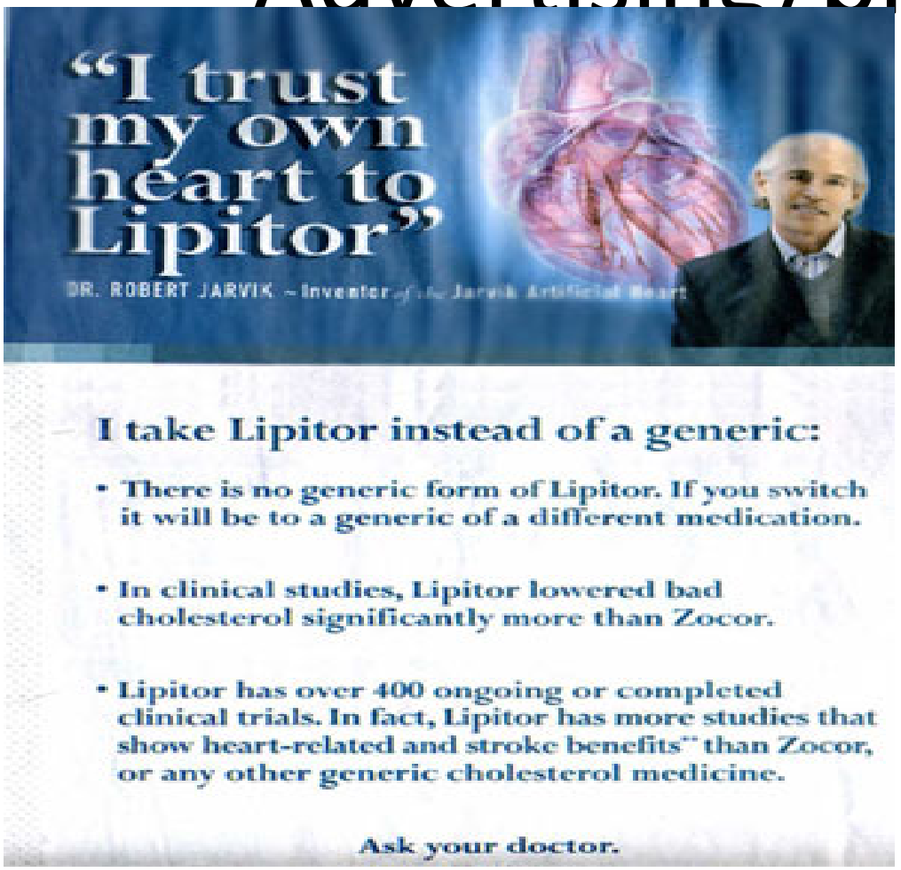
DoPE
BWH

Factors affecting generic drug use

- Advertising/promotion



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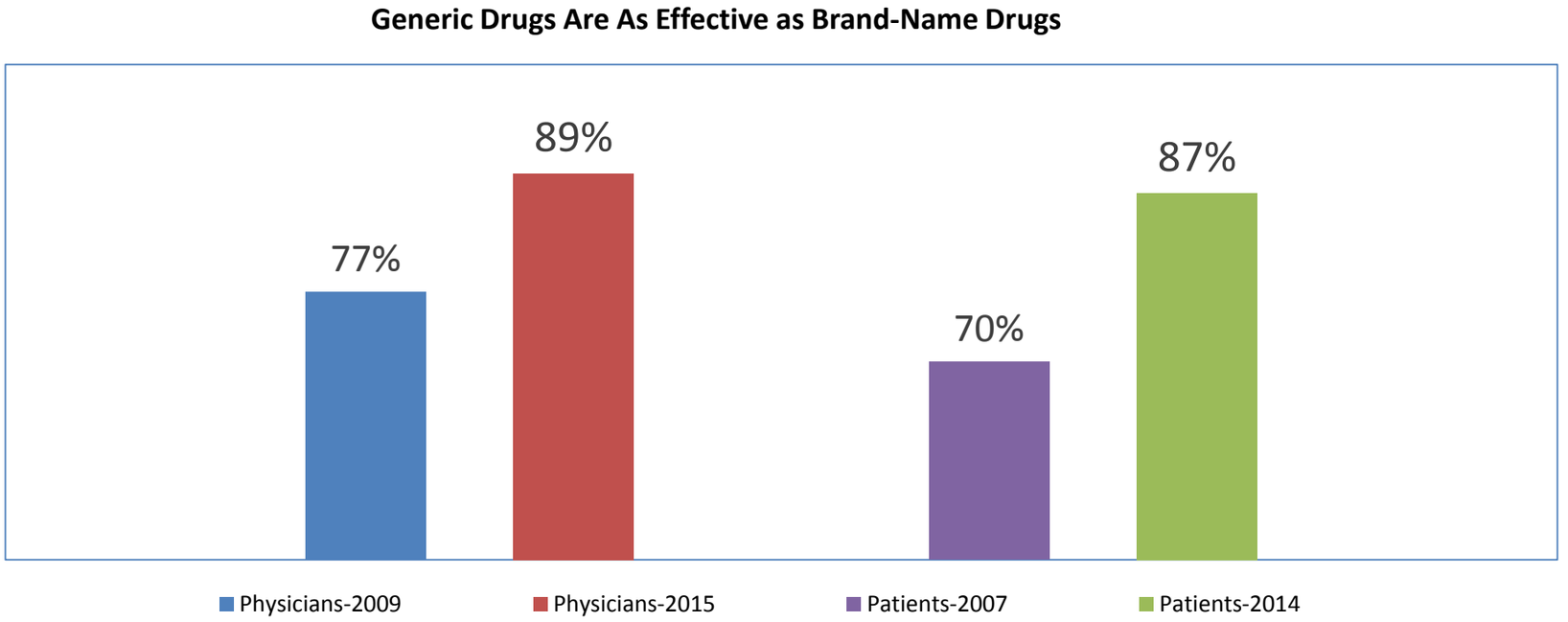
Factors affecting generic drug use

- Advertising/promotion
- Patient/physician skepticism



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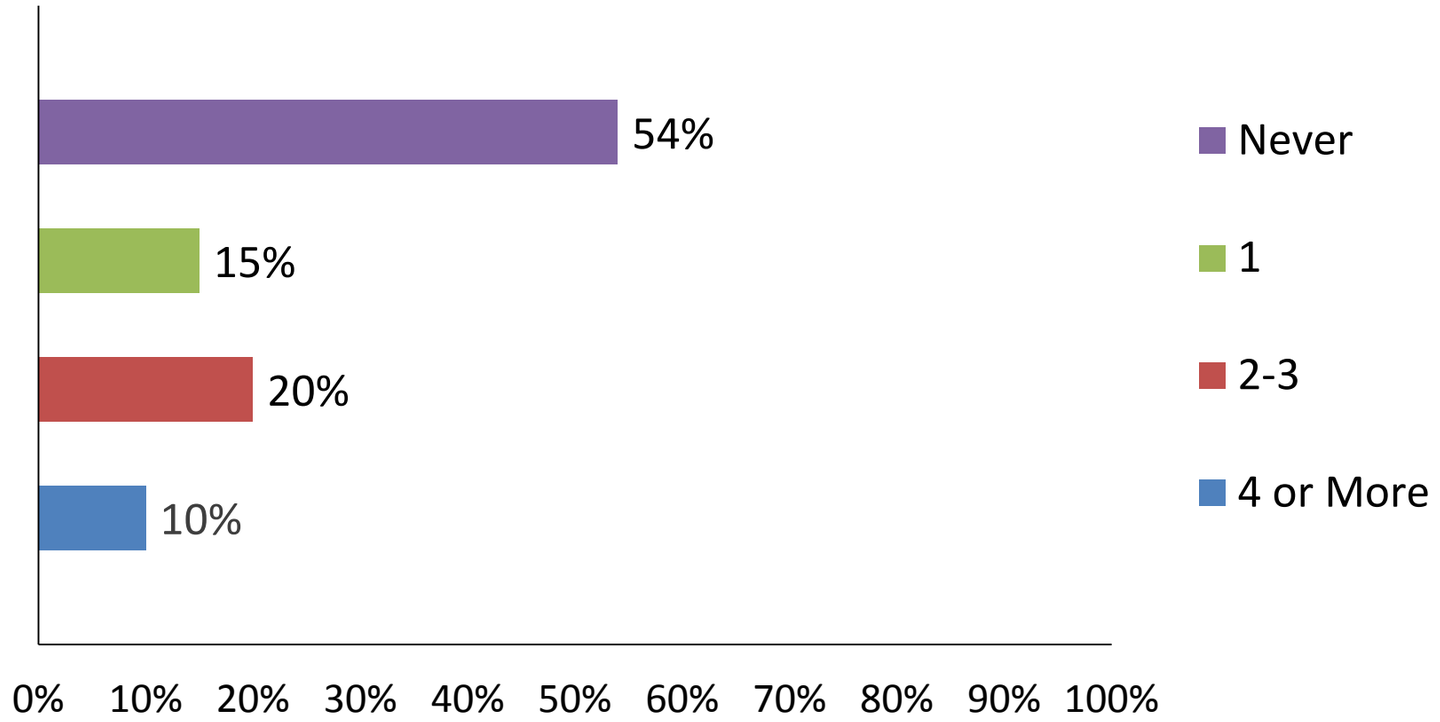
Shrank et al., Health Aff (2009); Shrank et al., Ann Pharmacotherapy (2011); Kesselheim et al., JAMA IM (2016);

Kesselheim et al., JGIM (2016)

DoPE

Patient Actions

How many times have you asked a doctor to prescribe a brand-name drug rather than a generic in the last year?



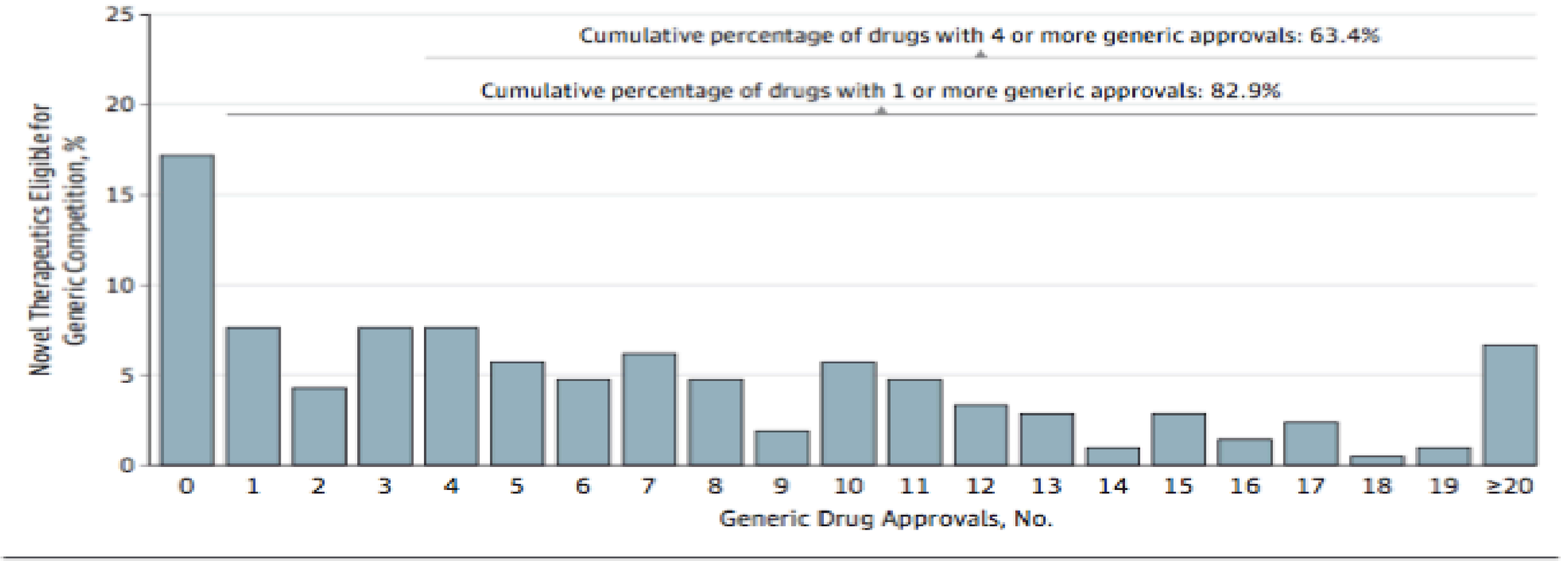
Kesselheim et al., JGIM (2016)

Factors affecting generic drug use

- Advertising/promotion
- Patient/physician skepticism
- Cost/availability

Lack of vibrant competition in generic drug market

Figure. Generic Drug Approvals for Novel Therapeutics Approved by the US Food and Drug Administration Eligible for Generic Competition.



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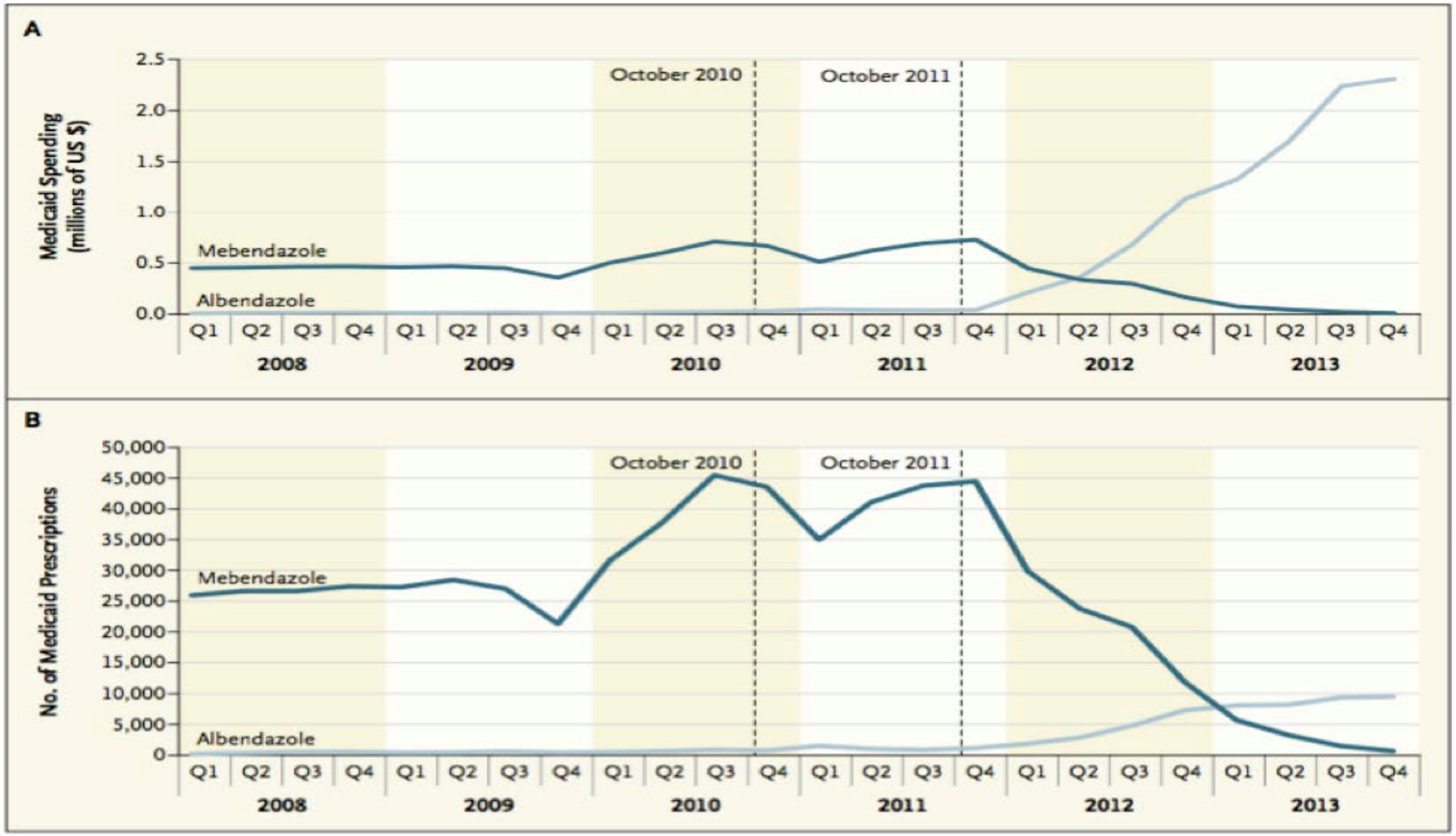
Gupta, Kesselheim, et al., JAMA IM, 2016

DoPE

Example: Albendazole



Medicaid Spending and Prescriptions for Albendazole and Mebendazole, 2008–2013.

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Alpern Stauffer Kesselheim, NEJM, 2015

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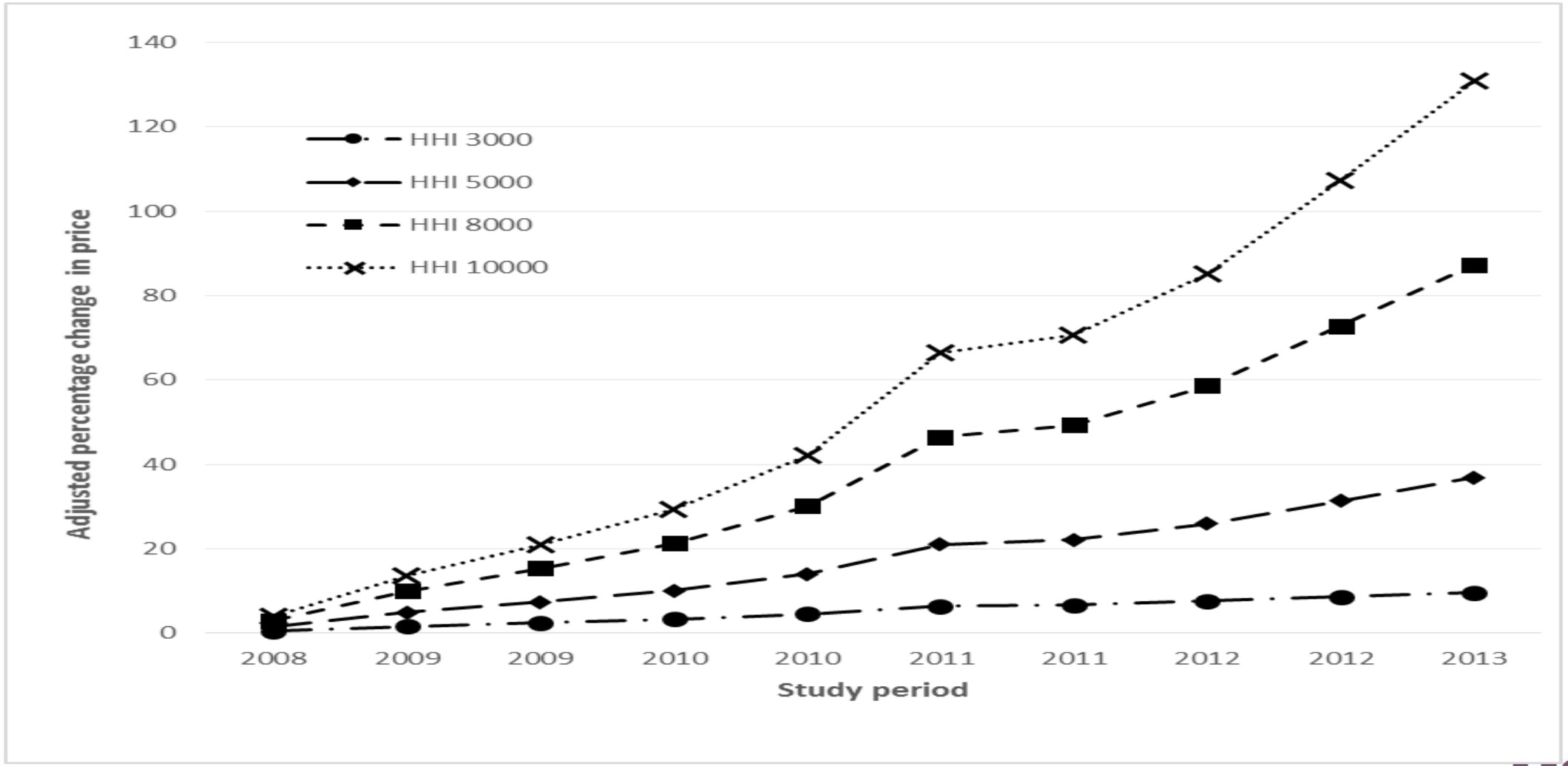
Association between generic market consolidation and generic price changes



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Dave Kesselheim Fox Hartzema, Annals of Internal Medicine, 2017

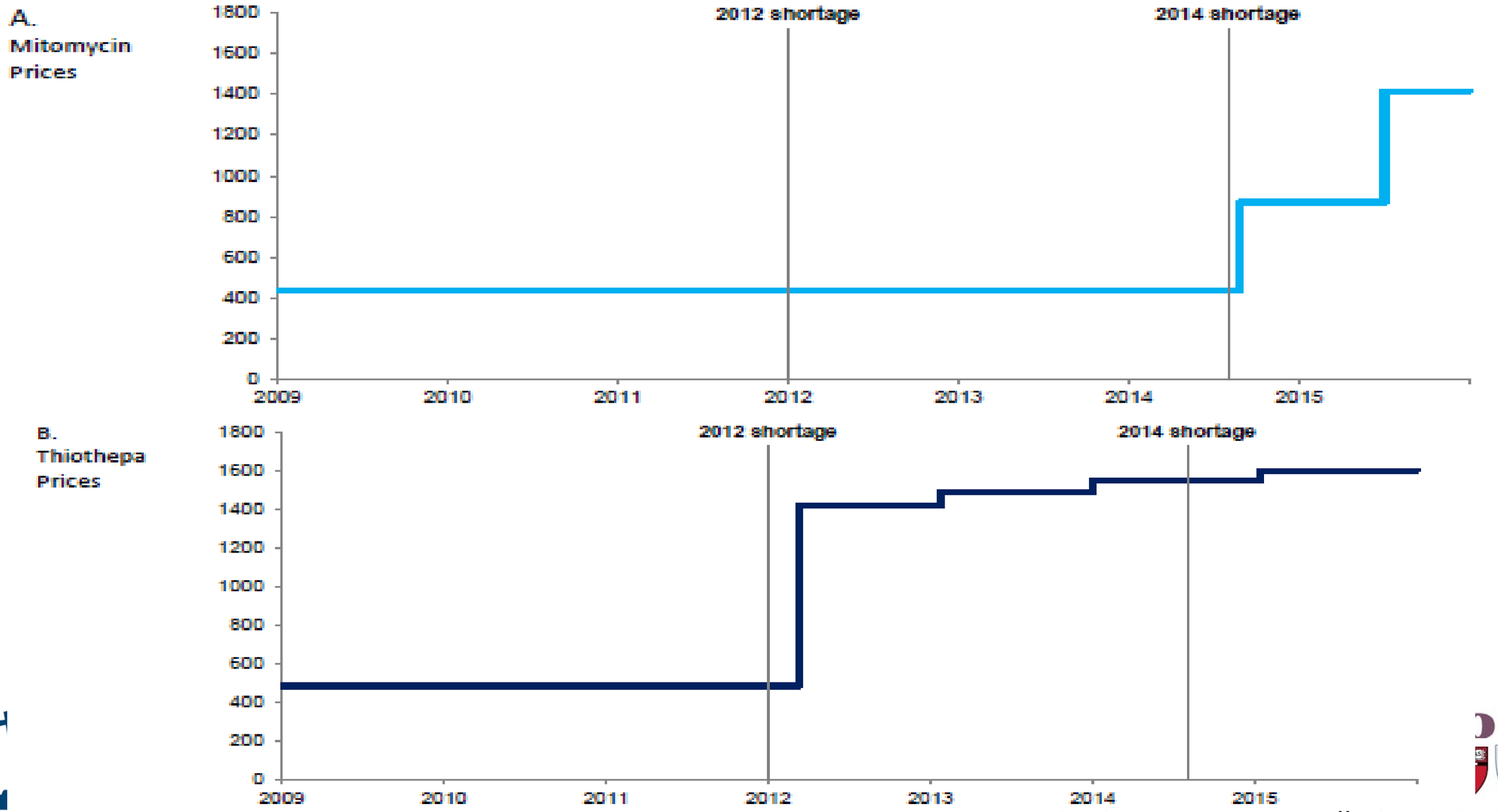
DoPE

Causes of insufficiently competitive generic markets

- Niche patient population
- Complex manufacturing process
- Consolidation
- Shortages
  - Drug prices strongly associated with shortage risk; compared to low prices, drugs with medium and high prices had a significantly lower risk of drug shortages, OR 0.64 (95% CI, 0.48-0.86) and 0.68 (95% CI, 0.50-0.93) respectively

Dave Pawar Fox Kesselheim, unpublished data

Shortages contribute to high drug prices



Davies, Hwang, Kesselheim, NEJM, 2017

Solutions

- Scrutiny of advertising practices
- Patient/physician education
- Import generics from well-regulated markets
  - When price spikes are equivalent to ‘shortages’
- Apply regulatory attention
  - Fund generic drug science and FDA Office of Generic Drugs
  - Expedite review of generic applications when three or fewer drugs in the market
- Follow-on biologics
  - Interchangeable (as science permits)
  - Naming conventions

Fralick, Avorn, Kesselheim, NEJM 2017; Bollyky and Kesselheim, 2017 Brookings Institution White Paper

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Your Generics and Biosimilars Industry

Generic Drugs – Facing Threats to Sustainable Competition & Supply

Federal Trade Commission Workshop | November 8, 2017

Overall U.S. Prescription Drug Market

Brands account for only

11% → **74%**

yet are

of prescriptions
(500 million)

of the cost.
($333.9 billion)

Generics account for

89% → **26%**

but are just

of prescriptions
(3.9 billion)

of the cost.
($116.1 billion)

Source: QuintilesIMS.

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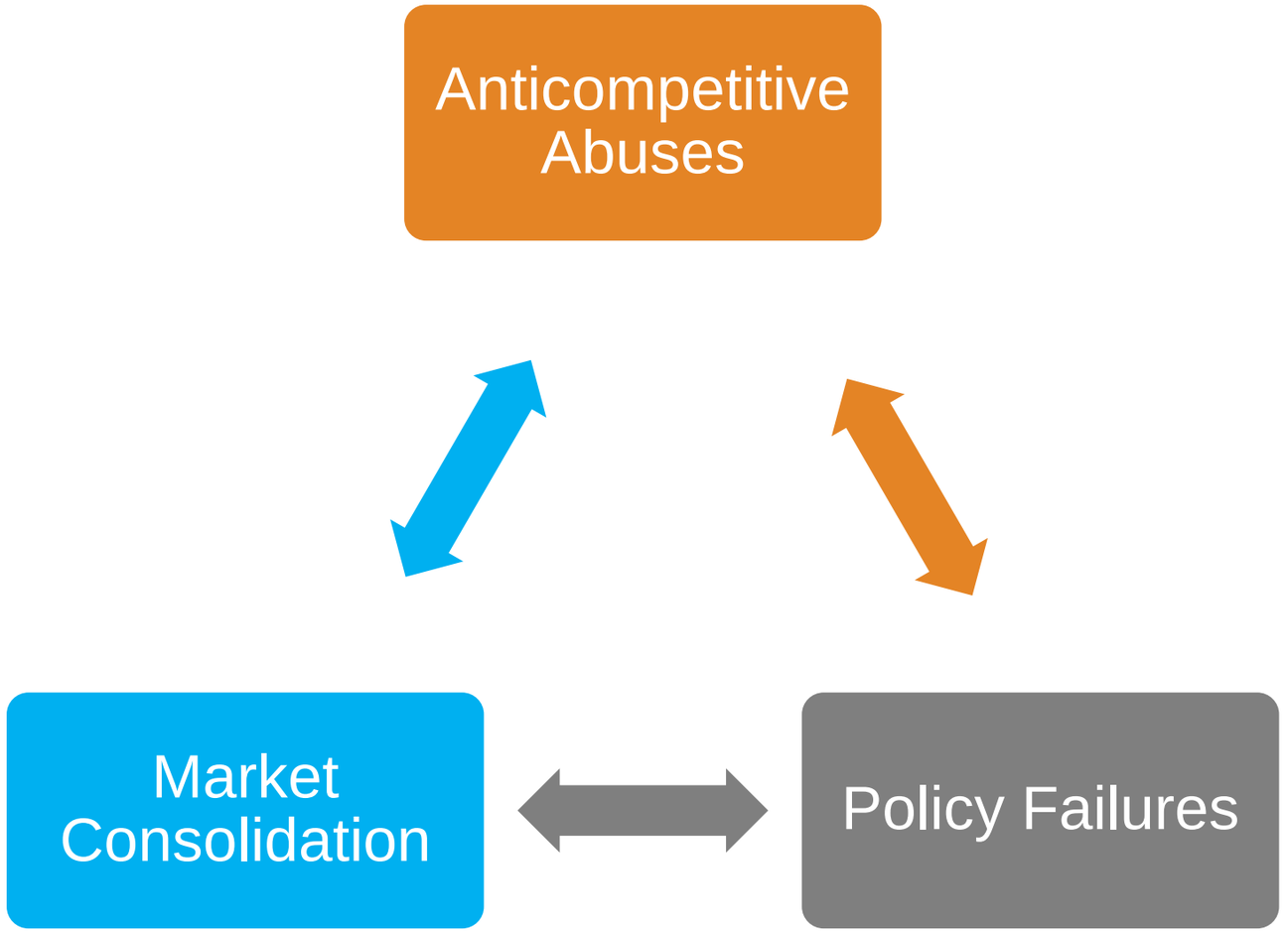
Sustainable Generic Competition Is Threatened



Anticompetitive Behavior Prevents Competition

"We know that sometimes our regulatory rules might be 'gamed' in ways that may delay generic drug approvals beyond the time frame the law intended, in order to reduce competition…

I understand that generic sponsors are willing to buy these products at fair market value; but, in some cases, branded companies may be using regulatory strategies or commercial techniques to deliberately try to block a generic company from getting access to testing samples."

- FDA Commissioner Scott Gottlieb, M.D.
June 21, 2017

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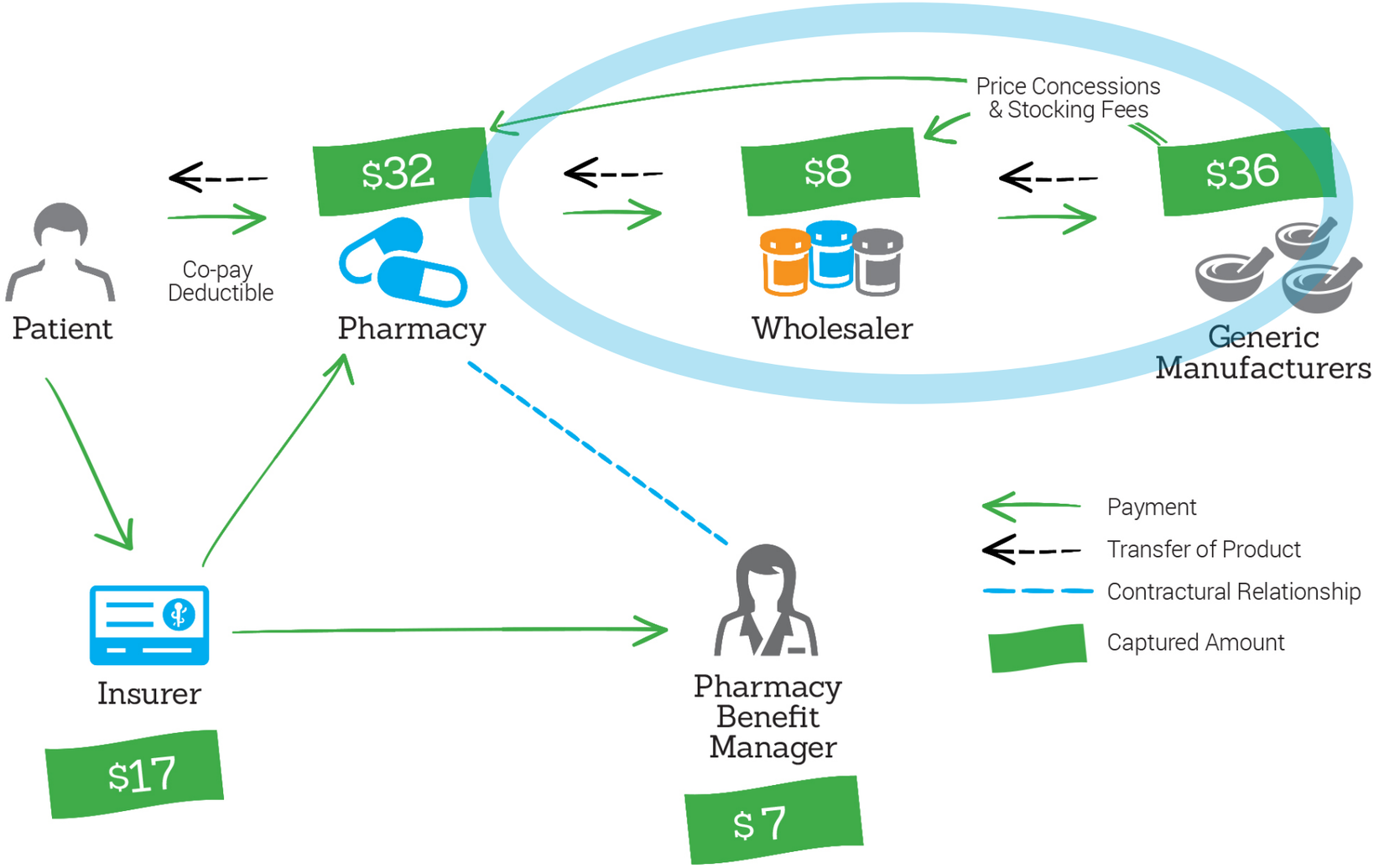
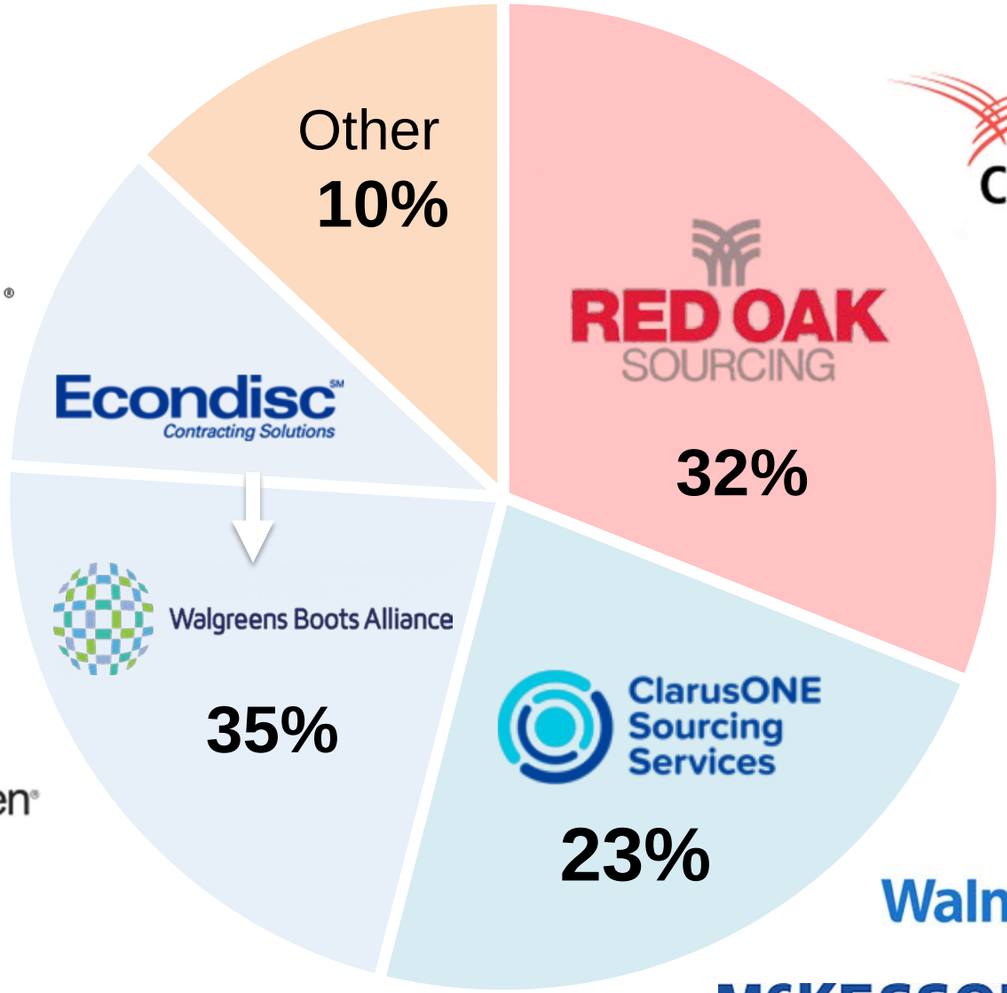
Understanding the Generic Marketplace

The Generic Drug Market Is Not the Brand Drug Market



Large Buyers Control Almost 90% of Generics



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Sourcing from more than 200 generic manufacturers

Source: Fein, Adam, "The 2017-18 Economic Report on Pharmaceutical Wholesalers and Specialty Distributors." October 2017.

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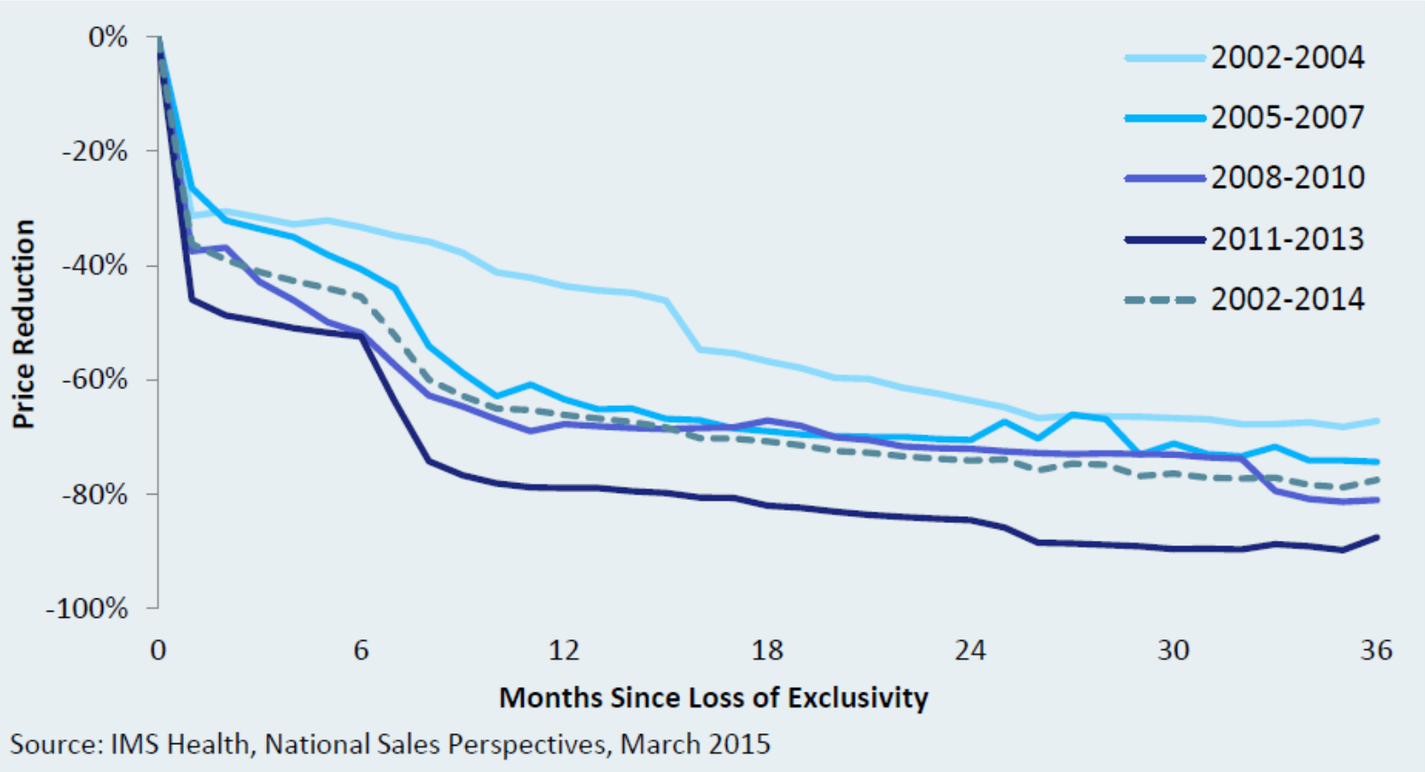
Generics Drug Prices Are Falling Further, Faster



Source: IMS Health, National Sales Perspectives, March 2015

- But the market trends – decreasing prices – are not sustainable.
- In the last year, total generic prescriptions are up 2 percent, but revenue is down 13 percent.
- Policies must safeguard the generic market.
- Otherwise, manufacturers may be forced to exit unprofitable markets – harming patients through potential drug shortages.

Purchasers Reinforce Deflationary Trends

- We have yet to see generic deflation ease from its current high single digits (-7% to -9%) where it's been for about three quarters now.
  –AmerisourceBergen CFO Tim Guttman (August 2017)
- [The] challenge and headwind we faced in the last half of the year was the rate of generic deflation.
  –McKesson CFO James Beer (May 2017)
- We now expect full year pharma segment profit to decline to low double digits versus the prior year. This is primarily due to the previously mentioned generic market pricing.
  – Cardinal CFO Michael Kaufmann (May 2017)

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Impact on Patient Access & Outcomes

Drug Shortages Threaten Patient Outcomes

- Generic drugs seem particularly susceptible to drug shortages, potentially related to existing market incentives as well as low reimbursement.
- Responding to a series of drug shortages in 2011, Dr. Scott Gottlieb testified before Congress that many such shortages were a direct result of low reimbursement for older, low-margin products and that “many hospitals are being forced to ration key medicines and patients to sit on waiting lists for vital drugs.”

The FTC and FDA Should…

- Support legislative solutions to anticompetitive, regulatory gamesmanship like REMS abuse
- Monitor IP abuses, in particular relating to sovereign immunity, that prevent generic and biosimilar competition
- Investigate whether purchaser consolidation creates anticompetitive risks

The continued sustainability of generic, and the promise of patient access through biosimilar, competition depends on active policy engagement.

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Thank You

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BERNSTEIN

November 8, 2018

A perspective on the competitive dynamics of generic drugs

FTC/FDA Joint meeting on drug competition

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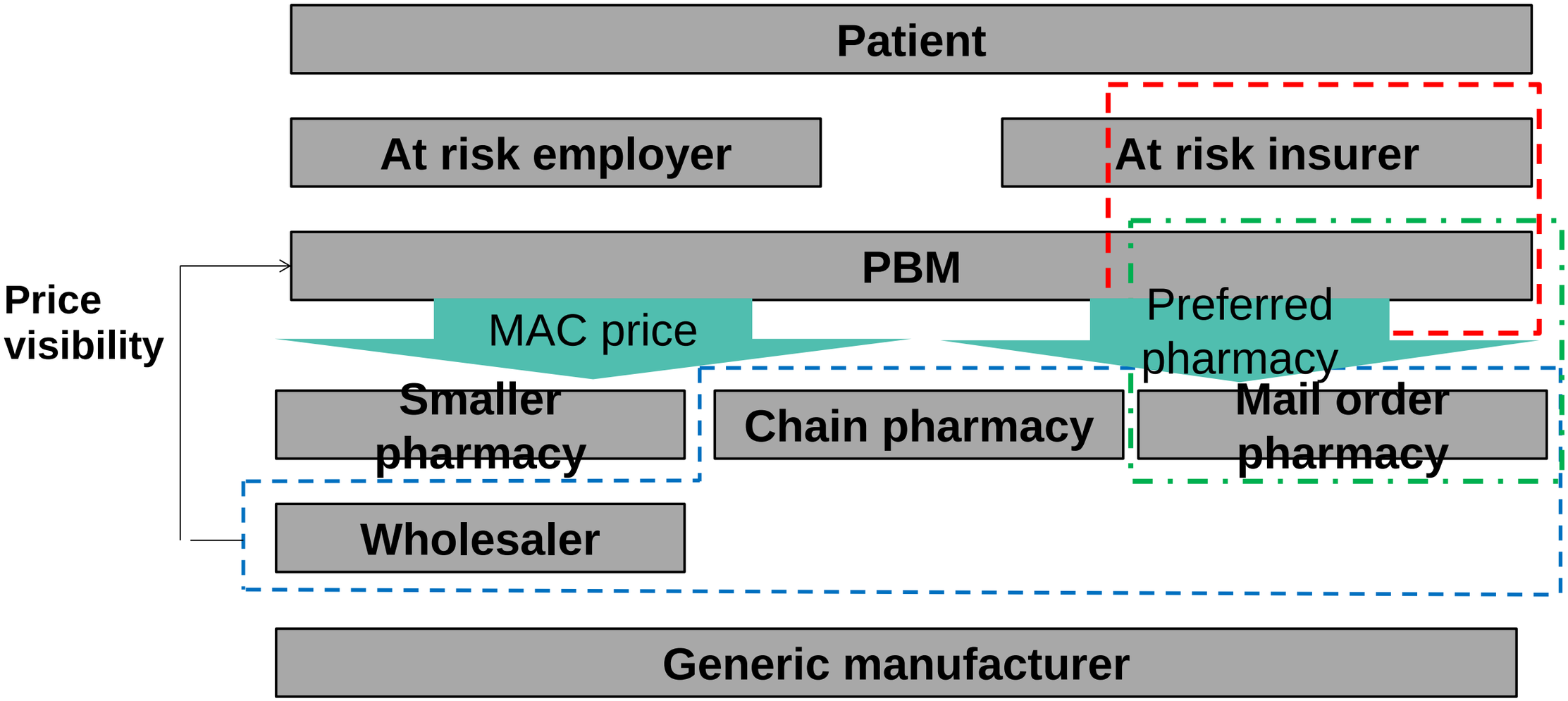
Key messages

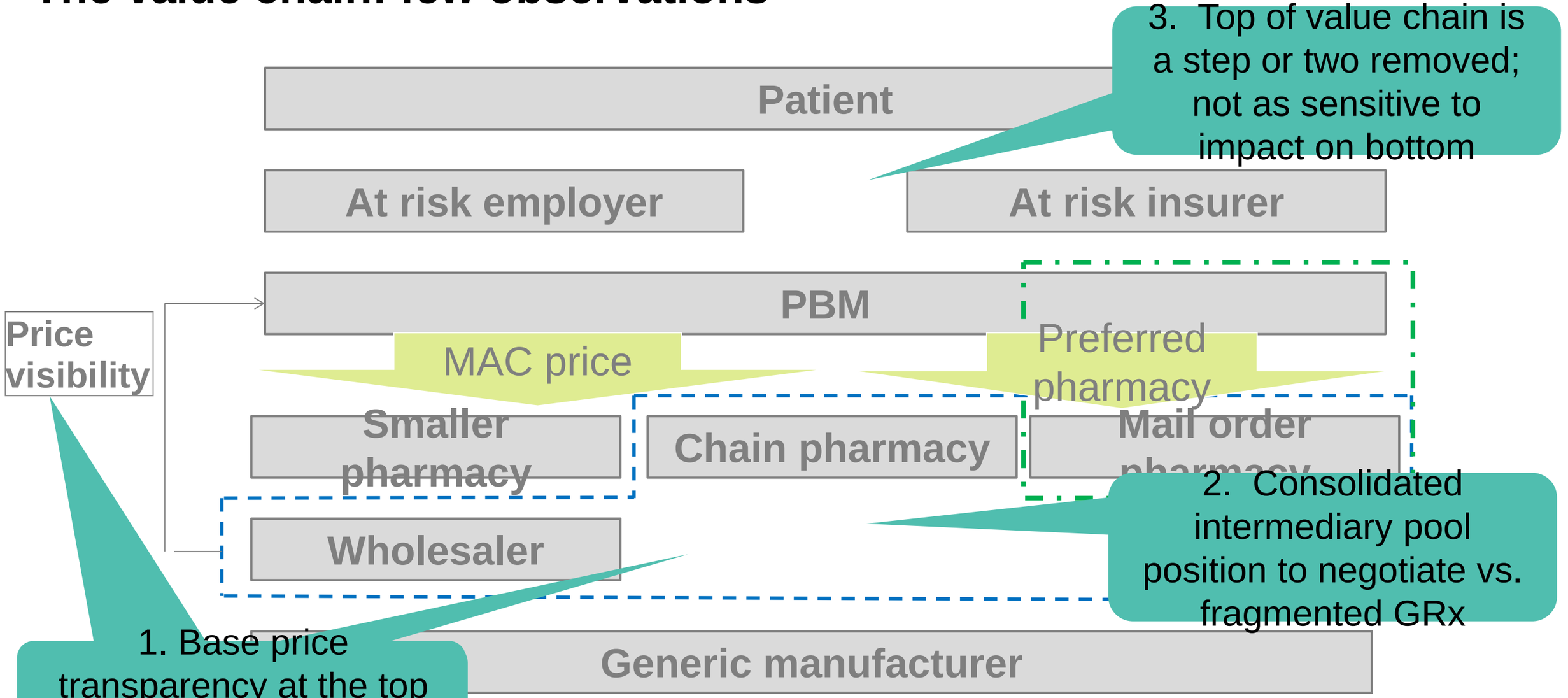
- The generic value chain is broadly competitive; prices are low and are effectively negotiated lower
  - We are getting a bit worried that there will not be sufficient profit pool to make the industry attractive for investment

- Four eddy currents in the competition
  - Competition between brand and generic in limited generic markets
  - Disruption of physician administered biosimilars by using the payer / provider spilt
  - Using FDA processes to slow generic entry
  - The regressive nature of the patient's generic costs

Generic drugs: a simplistic view of the value chain

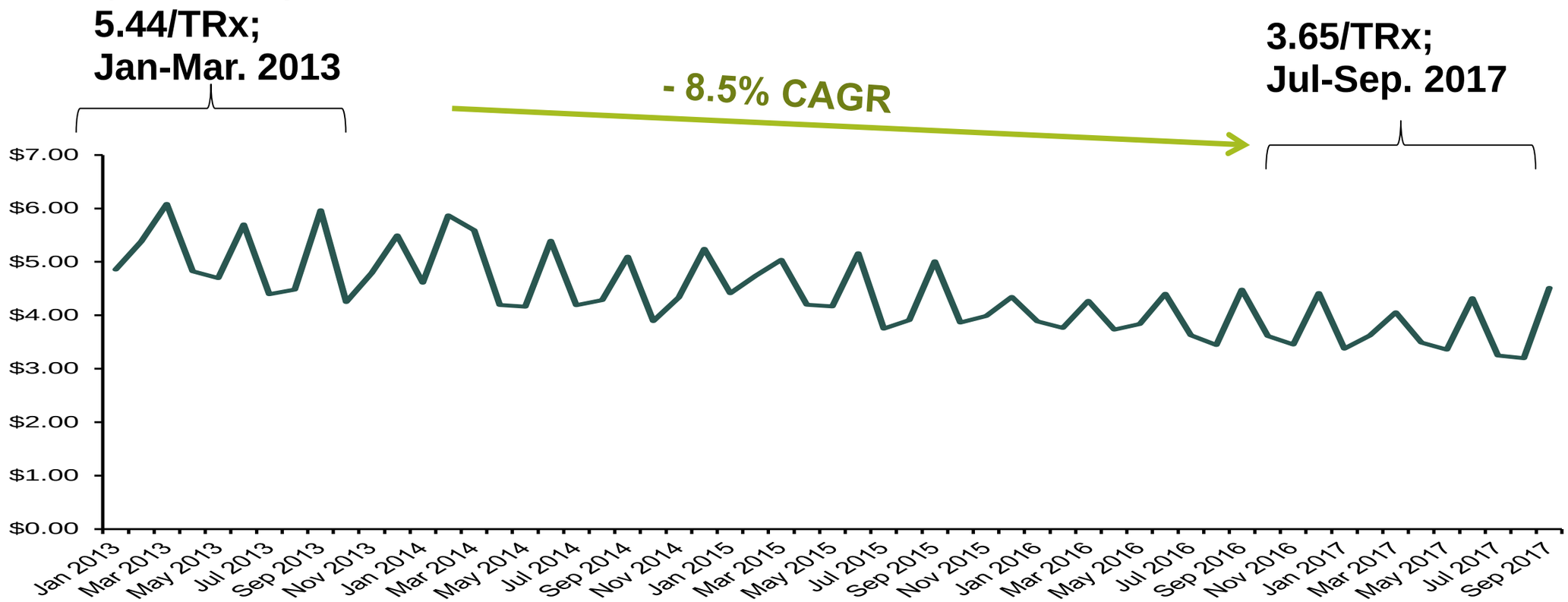


The value chain: few observations



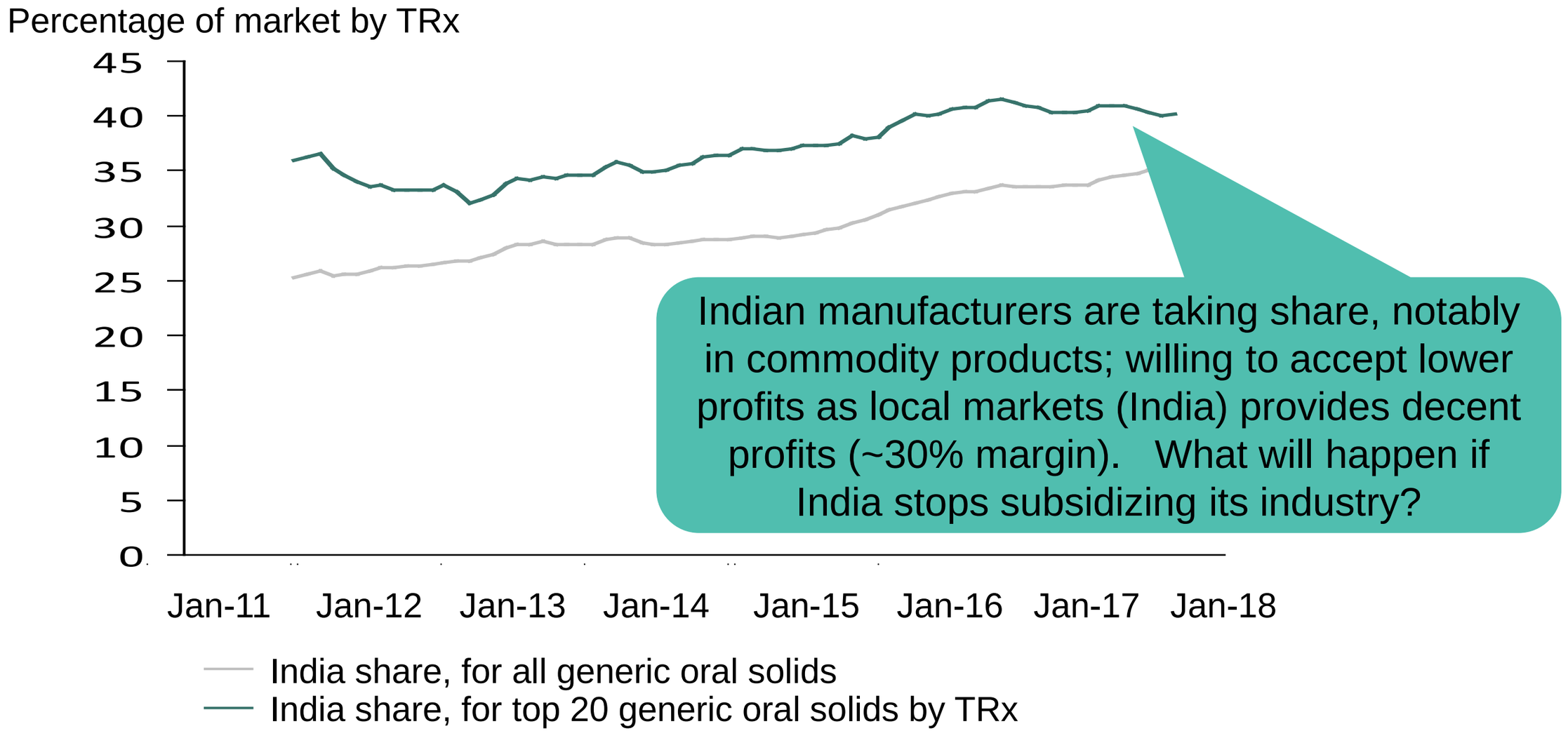
Result: US generic prices are broadly cheap at manufacturer levels and are getting cheaper; all good, but…

Price (IMS monthly sales / TRx)
for top 20 generic products by TRx



Note: data includes top 20 US products by volume (amlodipine; atorvastatin, escitalopram; furosemide, gabapentin, HCT, ibuprofen, levothyroxine, Lisinopril, losartan, metformin, metoprolol, montelukast, omeprazole, pantoprazole, prednisone, sertraline, simvastatin, amoxicillin)

We are gradually driving the industry off shore; becoming more dependent on economics elsewhere



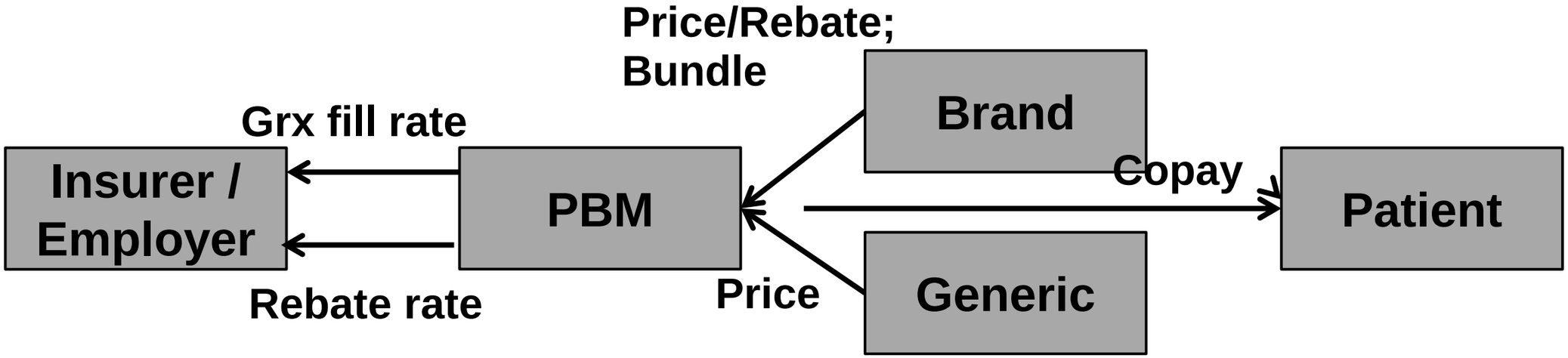
Less profits means less investment…

- Therapy areas with higher upfront costs will see lower willingness to participate given three buyers
  - Already hearing of less willingness to invest in respiratory, peptides

- Lower profit margin implies less value chain flexibility
  - Fewer, larger facilities; lower excess manufacturing capacity
  - Slower supply chain (defined quantities commitment)
  - Lower ongoing Cap Ex
  - Deterioration in expertise at local level

- We have seen this with generic injectables…

The impact of rebates and generic fill rate on product choice

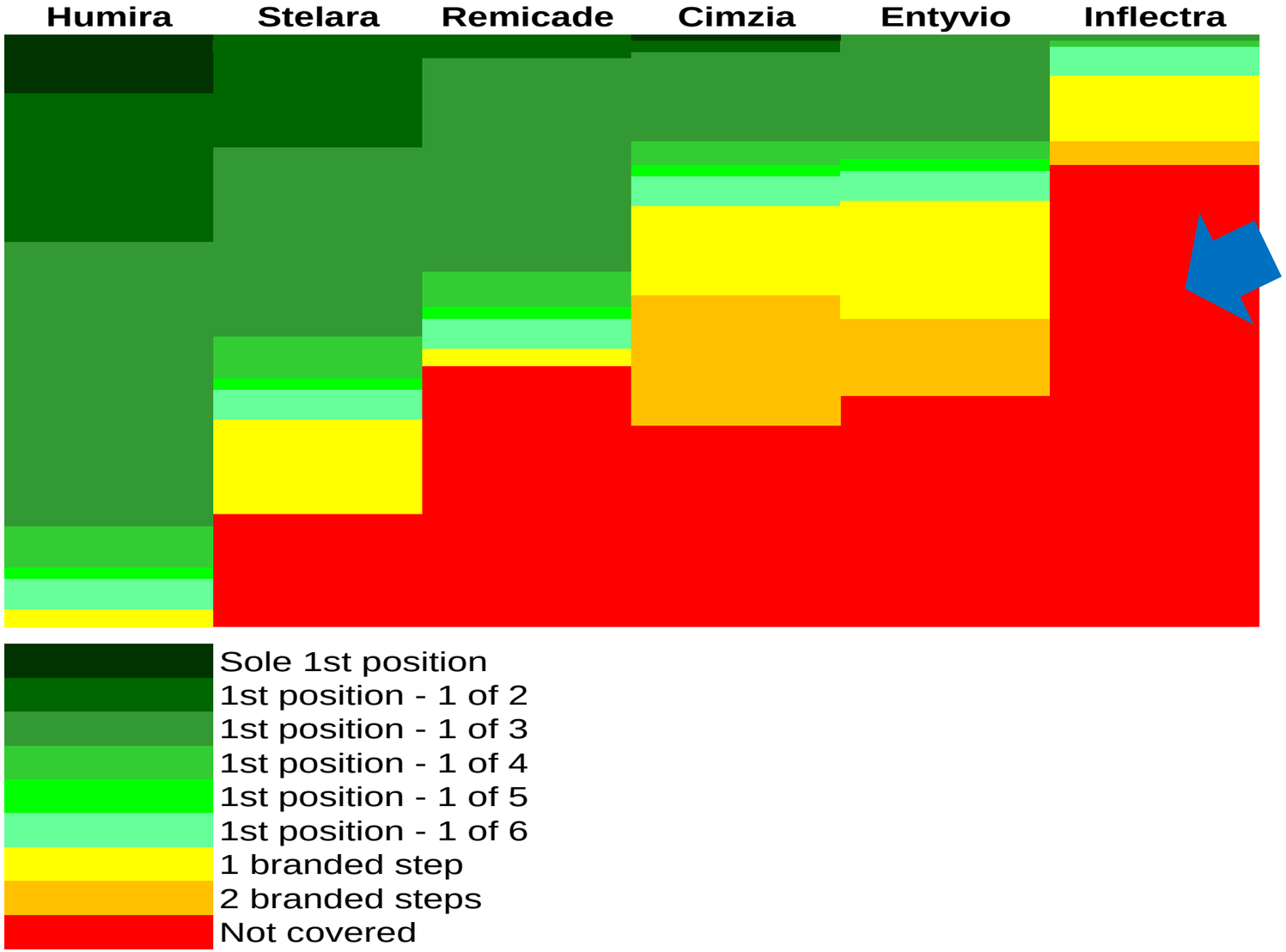


- In market with 1-2 generics, brands often compete with GRx for share
- Generic competes primarily in price; brand competes with price, structured rebates with PBM, and may have different economics than generics; brand can also bundle added products
- Most PBM contracts include targets of both GRx fill rates and branded rebate rate; brands with very high rebate may be too attractive to give up (Adderall XR)
- High discounts off price (e.g. brands where Medicaid/340B prices are a penny) may lead to preference of brand/AG over generic (e.g. Concerta)
- Critical question is isolating patients from copay differences when the branded product is preferred

Leveraging the split between providers and payers in physician administered biosimilars

- Physician-administered drugs have two pressure points – physician chooses product, payer can require preferring one product
- In the Remicade case, incumbent contracted exclusive position vs. the biosimilar with significant portion payers; thus every provider must stock innovator products
- JNJ then gave discounts to providers across a broad portfolio of products, conditioned on volume of Remicade (with an understanding of demand at each provider)
- Many providers standardized on innovator; biosimilar share negligible
  - Source of current lawsuit
  - JNJ argues market chose to standardize on innovator rather then on biosimilar given clinical reliability – our view: true, but JNJ forced the decision and was there first to capture the volume

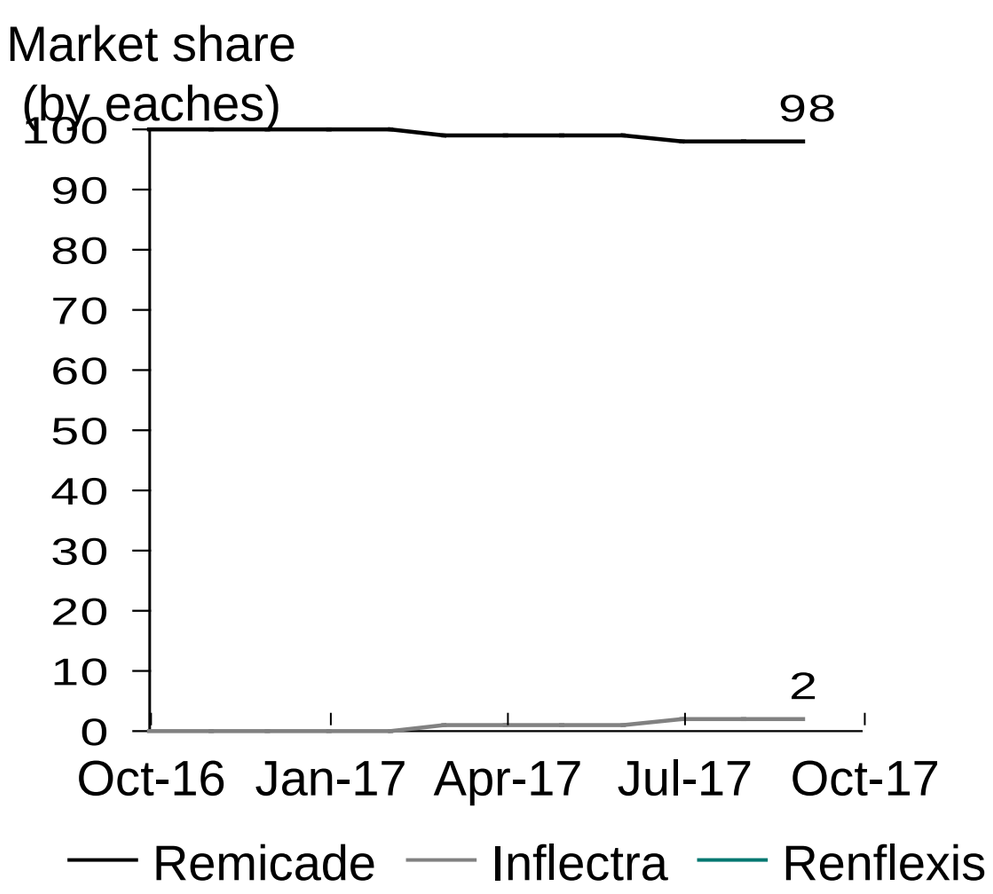
Formulary coverage in Crohn's disease: Inflectra broadly blocked

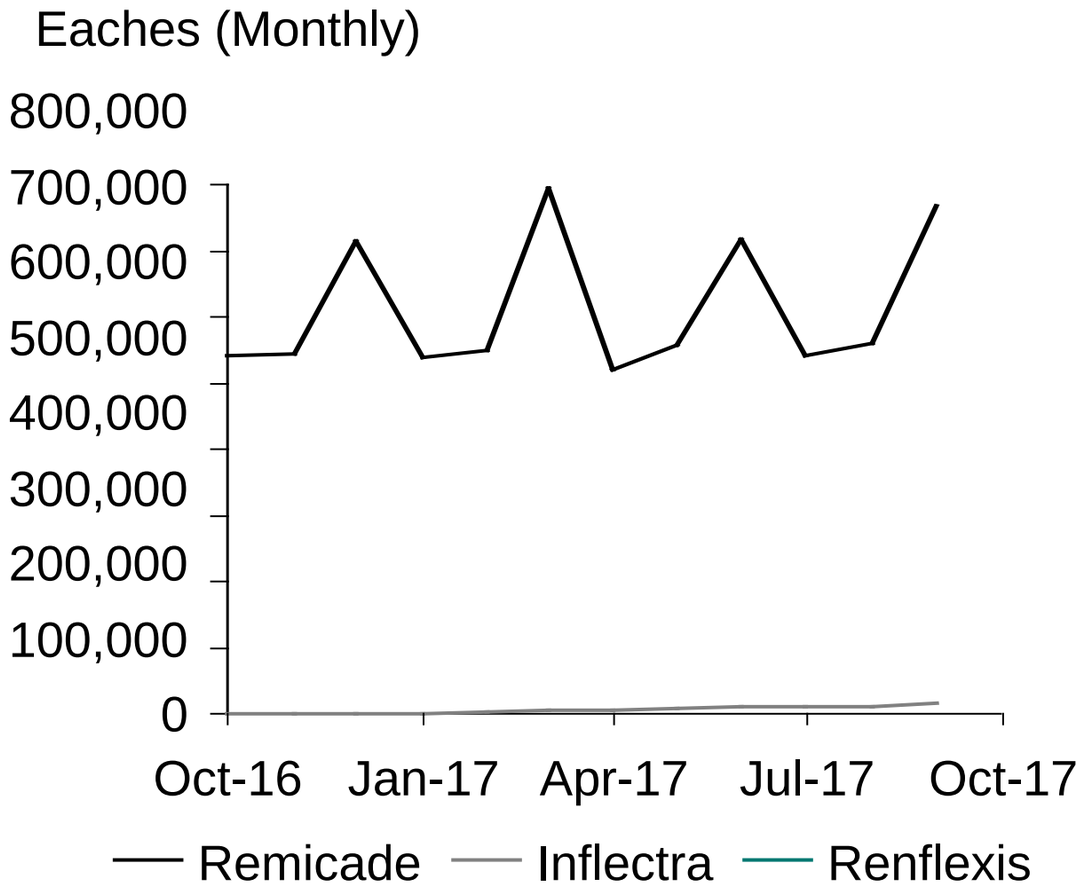


Note: data represents formulary coverage in largest formularies responsible for 50% of US commercial coverage mid 2017; source: Bernstein analysis of formulary data

Infliximab (Remicade) US market, biosimilars did not penetrate

Merck's Renflexis was launched Jul-17 and just started showing up in September IMS data (7 eaches in September)



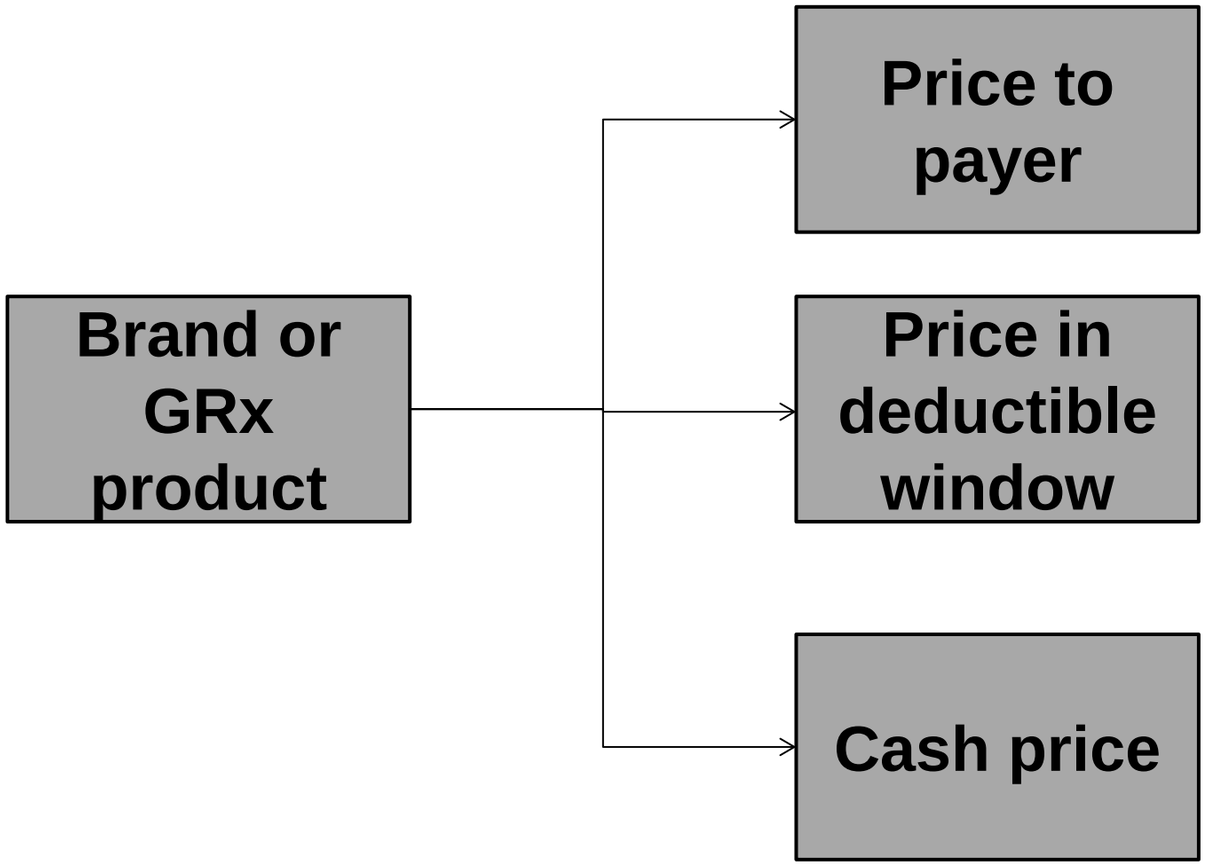


Source: IMS; Bernstein analysis

Using FDA processes to delay GRx competition

	Issue	Potential solutions
REMs	Two issues: access to reference drug (e.g. Revlimid) and participation in shared REM (e.g. Xyrem. Tracleer)	Require third party management of REMS and generic product sourcing
Citizen petitions	Multiple citizen petitions, adding information and arguments over time (e.g. Copaxone)	Require fees for CP filing by corporations and use fees to staff response capabilities
Delay in decision making	FDA refining requirements for approval after generic filing (e.g. Lialda)	Make generic product specific guidelines part of NDA process

Generic (and brand) prices are often regressive; most exposed patient pays the highest price



Price and dispensing fees negotiated between pharmacy and PBM; patient pays deductible (~$10) often covers most of cost

Patient pays price determined by pharmacy; with ‘guardrails’ provided by PBM/insurer

Patient pays full price; what the market will bear

HIGH PRICES & NO EXCUSES: 6 ANTICOMPETITIVE GAMES

MICHAEL A. CARRIER
DISTINGUISHED PROFESSOR
RUTGERS LAW SCHOOL

Crucial Topic

- Important exercise: patents get attention; post-patent entry often does not
- I have comprehensively studied patents and antitrust in pharmaceutical industry
  - Co-author of leading IP/antitrust treatise
  - Author of more than 100 articles (40 on pharmaceutical antitrust law)
  - Author of amicus curiae briefs on behalf of hundreds of professors
  - Frequently cited in media (1000+ times) and courts (including U.S. Supreme Court)

No (or Weak) Patents Delay Generics

- Brand profits from monopoly (each day = millions)
- Regulatory regime used to delay entry: FDA exclusivity, reformulation time, petition process, distribution restrictions
- This behavior and others also follows from patenting of secondary advances
- "Off-patent" not coming as quickly as it used to as brands obtain weaker patents covering developments after active-ingredient patent expires
- **Small molecule example**: Pfizer's strongest Lipitor patents expired in March 2010 & June 2011, but settlement with generics delayed entry until after these periods because of minor patents expiring in 2016
- **Biologic example**: AbbVie's composition-of-matter patent on inflammatory-disease-treating Humira expired in 2016, but patent thicket of 100+ patents (indication/method of treatment (22), formulation (14), manufacturing (24), "other" (15)) extends protection until 2034…53 patents obtained in 2015 and 2016 alone
  - *AbbVie Long-Term Strategy*, Oct. 30, 2015, http://www.biotechduediligence.com/uploads/6/3/6/7/6367956/abbvie_strategy_presentation__1_.pdf;
  - Cynthia Koons, *This Shield of Patents Protects the World's Best-Selling Drug*, BLOOMBERG BUSINESSWEEK, Sept. 7, 2017, https://www.bloomberg.com/news/articles/2017-09-07/this-shield-of-patents-protects-the-world-s-best-selling-drug.

Game 1: Pay-for-delay Settlements

- *FTC v. Actavis*: Settlements by which brands pay generics to delay entering market can have "significant anticompetitive effects" and violate antitrust law
- Parties can settle without payment: 2015 FTC Report shows number of settlements (170) increasing while "pay for delay" deals fall from 40 (FY2012) to 14 (FY2015), with only 5 above $7m litigation costs
- 89% of patents in settled litigation are secondary patents; brand less likely to win on these (32%) than on active-ingredient (92%) patents
    - C. Scott Hemphill & Bhaven Sampat, *Drug Patents at the Supreme Court*, 339 SCIENCE 1386, 1387 (2013) (drugs first eligible for challenges between 2000 and 2008)
- Most post-*Actavis* cases cover secondary patents: Actos (method of use), AndroGel (formulation), Cephalon (particle size), Effexor (extended release), K-Dur (formulation), Lidoderm (skin application), Loestrin (contraception method), Niaspan (time release), Opana (time release), Solodyn (treatment method), Wellbutrin (extended release)
    - **AndroGel**: Patent for synthetic testosterone expired in 1950s
    - **Loestrin**: FDA approved active ingredients in 1970s
    - **Niaspan**: Active ingredient niacin sold since early 20th century

Game 2: Product Hopping

- Brand firms often switch to new versions of drug products; many switches not connected to generic entry
- But some changes, with patient migration to reformulated product, have one purpose: **delay generics**
  - Prevent operation of state substitution laws and Hatch-Waxman Act
  - Aim to switch market to reformulated version before generic of original version enters market
  - Each switch results in delay from generic reformulation, FDA approval, patent litigation
- **Secondary patents** give extra protection: Prilosec to Nexium = 13 years; Suboxone tablet to film = 14 years; Namenda IR to XR = 14 years
- Even if **no patent**, delay from FDA exclusivity and time it takes to reformulate drug
  - Warner Chilcott engaged in multiple hops on acne-treating Doryx (first available in 1985 as unpatented capsule): (1) capsule to 75- and 100-mg tablets, (2) 150-mg single-scored tablet, (3) 75- and 100-mg single-scored tablets, (4) 150-mg dual-scored tablet
  - Also stopped selling capsules, removed capsules from website, worked with retailers to auto-reference tablet in filling prescriptions, informed purchasers and doctors that capsules replaced by tablets, bought back and destroyed capsules

Game 3: Citizen Petitions

- Citizen petitions are meant to raise legitimate safety concerns with FDA
- But my empirical study of all petitions filed between 2011 and 2015 against pending generics ("505(q)" petitions) found that FDA denies 92%; also 98% of late-filed petitions (within 6 months of expiration of patent or FDA exclusivity), 100% of simultaneous petitions (when FDA resolves petition on same day it approves generic)
  - Michael A. Carrier & Carl J. Minniti III, *Citizen Petitions: Long, Late-Filed, and At-Last Denied,* 66 AMERICAN UNIVERSITY LAW REVIEW 305 (2016)
- **Last-minute petition example**: Bayer's petition on IUD Mirena 1 day before patent expiration
- **Bottleneck example**: Allergan's dry-eye-treating Restasis petitions delay generics
  - Feb. 2014 petition denied Nov. 2014; Dec. 2014 petition denied Feb. 2016; Aug. 2017 petition filed
    - Each petition challenges generics' use of in vitro (as opposed to human) testing protocols
  - In 135-page opinion, Judge Bryson invalidated 6 Restasis patents, but generics Mylan, Teva, Akorn still cannot enter market because of Aug. 2017 petition

Game 4: REMS Restrictions

- REMS serve important purpose in making sure risky drugs reach market
- But brands have used REMS to deny samples generics need for bioequivalence testing
  - 2017 study: REMS restricts 41 drugs with sales exceeding $11 billion
    - Alex Brill, *REMS and Restricted Distribution Programs*, June 2017, https://www.gphaonline.org/media/cms/Alex_Brill_REMS_Study_June_2017.pdf
  - More than 150 generics have informed FDA they cannot obtain samples
- In litigated cases, brands have **denied samples** to generics willing to pay market prices and enter into indemnification agreements
  - And brands have ignored FDA letters showing REMS compliance and protections
    - E.g.: 1) Actelion "would sell" sample upon receiving FDA letter but 2) after Apotex provides FDA letter, Actelion responds: "This changes nothing" and "you don't get [the sample]"
- Brands also have not negotiated in good faith for **shared REMS** programs
  - E.g.: Suboxone allegedly turned down invitations to participate in meetings, insisted on unfavorable conditions, refused to share nonpublic information, demanded veto authority and supermajority vote, engaged in delay tactics
    - *See* Michael A. Carrier, *Sharing, Samples, and Generics: An Antitrust Framework*, CORNELL LAW REVIEW, at 37-42 (forthcoming 2017), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2979565)

Game 5: Non-REMS Distribution Restrictions

- Some companies have imposed distribution restrictions not required by FDA
- 2017 study: Non-REMS programs restrict 33 drugs with sales exceeding $11 billion
  - Alex Brill, *REMS and Restricted Distribution Programs*, June 2017, https://www.gphaonline.org/media/cms/Alex_Brill_REMS_Study_June_2017.pdf
- Martin Shkreli (aka “Pharma Bro”) switched Turing’s distribution system for infection-treating **Daraprim** from nationwide to single source: Walgreen’s Specialty Pharmacy
  - Active ingredient introduced in 1953; distribution limited 62 years later for no safety-related reason
  - Turing official: “would like to do our best to avoid generic competition”; “certainly not going to make it easier” for generics
  - 5000% price increase ($13.50 to $750)
- Retrophin (Shkreli’s prior company) also switched to closed distribution, blocking generic access on cholesterol-deficiency-treating **Chenodal** (400% increase) and kidney-stone-treating **Thiola** (1900% increase)
  - Shkreli: “We do not sell Retrophin products to generic companies. . . . The whole model that generics rely upon is turned upside down with specialty pharmacy distribution”

Game 6: Bundling/Rebates

- **Restasis**: Shire sued Allergan for blocking access to dry-eye-disease-treating Xiidra
  - Xiidra can be prescribed to "much larger population" and lacks Restasis's side effects but limited to 10% Medicare Part D market (vs 35% commercial market)
  - Challenge bundling and exclusive dealing (if include Xiidra on formularies, lose substantial discounts/rebates on other Allergan drugs)
    - Even if plan received Xiidra for free, "the numbers still wouldn't work"
- **Remicade**: J&J had only product on market 1998-2016; Pfizer sued, claiming J&J blocked access to arthritis- and Crohn's-treating rival Inflectra
  - Insurers cannot cover Inflectra; otherwise J&J deny rebates (which apply to multiple products)
  - Inflectra has less than 4% of market; J&J raise Remicade list price 9%
- **EpiPen**: Sanofi sued Mylan for offering high ("practically impossible to refuse") rebates to insurers, PBMs, and state Medicaid programs; had effect of blocking coverage of rival Auvi-Q
  - Auvi-Q market share fell roughly 50% after rebates took effect
- **Exclusive dealing law**: Percentage of market foreclosed important. Also: contract duration, industry prevalence, entry barriers, distribution alternatives
- **Rebate law**: Exclusionary effect on competitors (3rd Cir.) vs. attribution test (attribute discount to product on which plaintiff claims exclusion and see if price below cost) (9th Cir.)

Proposals

- **Antitrust enforcement**: Careful scrutiny of thickets and conduct accompanying secondary patents
- **Settlements**: Continued judicial scrutiny and FTC enforcement; consideration of legislation applying presumptive illegality or expanded 180-day exclusivity period
- **Product hopping**: Scrutiny of reformulations that cannibalize profitable drugs, making no economic sense other than by stifling generic entry (can apply to hard **and soft** switches)
  - *See* Michael A. Carrier & Steve Shadowen, *Product Hopping: A New Framework*, 92 NOTRE DAME LAW REVIEW 167 (2016)
- **REMS**: Antitrust scrutiny for sample denials and delayed negotiations on shared REMS
  - *See* Michael A. Carrier, *Sharing, Samples, and Generics: An Antitrust Framework*, CORNELL LAW REVIEW (forthcoming 2017), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2979565)
  - CREATES Act would provide bipartisan statutory fix for sample denials and blocked negotiations
- **Non-REMS distribution restrictions**: Rigorous antitrust scrutiny (apply no-economic-sense test)
- **Citizen petitions**: Antitrust scrutiny and enforcement (like FTC case against Shire ViroPharma)
  - Also consider: (1) list of 505(q) petitions and delay in annual reports to Congress; (2) determine if simultaneous generic approvals and petition resolutions caused delay; (3) make easier for FDA to summarily dispose of petitions; (4) determine money and time incurred resolving petitions; (5) certify objections filed within one year
    - *See* Michael A. Carrier, *Five Actions to Stop Citizen Petition Abuse*, 118 COLUMBIA LAW REVIEW ONLINE __ (forthcoming 2018), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3043541
- **Bundling/rebates**: Robust antitrust scrutiny of exclusive dealing and bundling

Generic Drug Competition:
Understanding Demand, Price & Supply
Market Failures, Fixes & the Future

Understanding Competition in Prescription Drug Markets:
Entry & Supply Chain Dynamics

The Federal Trade Commission
Office of Policy and Planning

Washington, D.C.
November 8, 2017

Stephen W. Schondelmeyer
Professor and Director
***PRIME* Institute**
University of Minnesota

Overview

Understanding the Generic Pharmaceutical Market:

- Demand for Generic Drugs
- Supply of Generic Drugs
- Competition & Market Power for Generics
- Regulatory & Legal Influences on Generics
- Generic Drug Price Trends
- Finding Fixes for the Future

Demand for Generics

- The Generic Drug Market is NOT a Single Market
- A Series of Individual Markets Defined By:
  - Therapeutic Class, Drug Molecule, Dose Form &/or Strength
- Patient Demand for Generics is Market Specific
  - Diabetic Cannot Use Lower Cost Epileptic Drug to Treat Diabetes
- Measures of Market Concentration by Ther. Class
- Economic Substitution vs Generic Substitution
- Payer Demand Drives Low Cost Generics to 9 of 10

Supply of Generic Drugs

- **Fewer Generic Firms & Industry Consolidation**
  - Teva acquired Actavis; Teva acquired Allergan; Teva acquired Anda
- **Most Generic Firms Have Broad Line of Products**
- **Most Brand Name Firms Have Generic Divisions**
  - Pfizer → Greestone & Hospira; Novartis → Sandoz; Teva → Allergan.
- **Authorized Generics Not Really Generics**
  - NDA-authorized, not ANDA; Pre-empt & may dampen 'true" generic entry over time
- **Bundling & Tying Arrangements in Contracts**
  - e.g., Must buy firm's generics to access firm's discounts & rebates on brands
- **PBMs Sometimes Add "Spread" Onto Generics**
  - Generic spread for mail, specialty, preferred networks, may be higher than retail
  - Some PBMs charge full copay even when actual generic prescription costs less

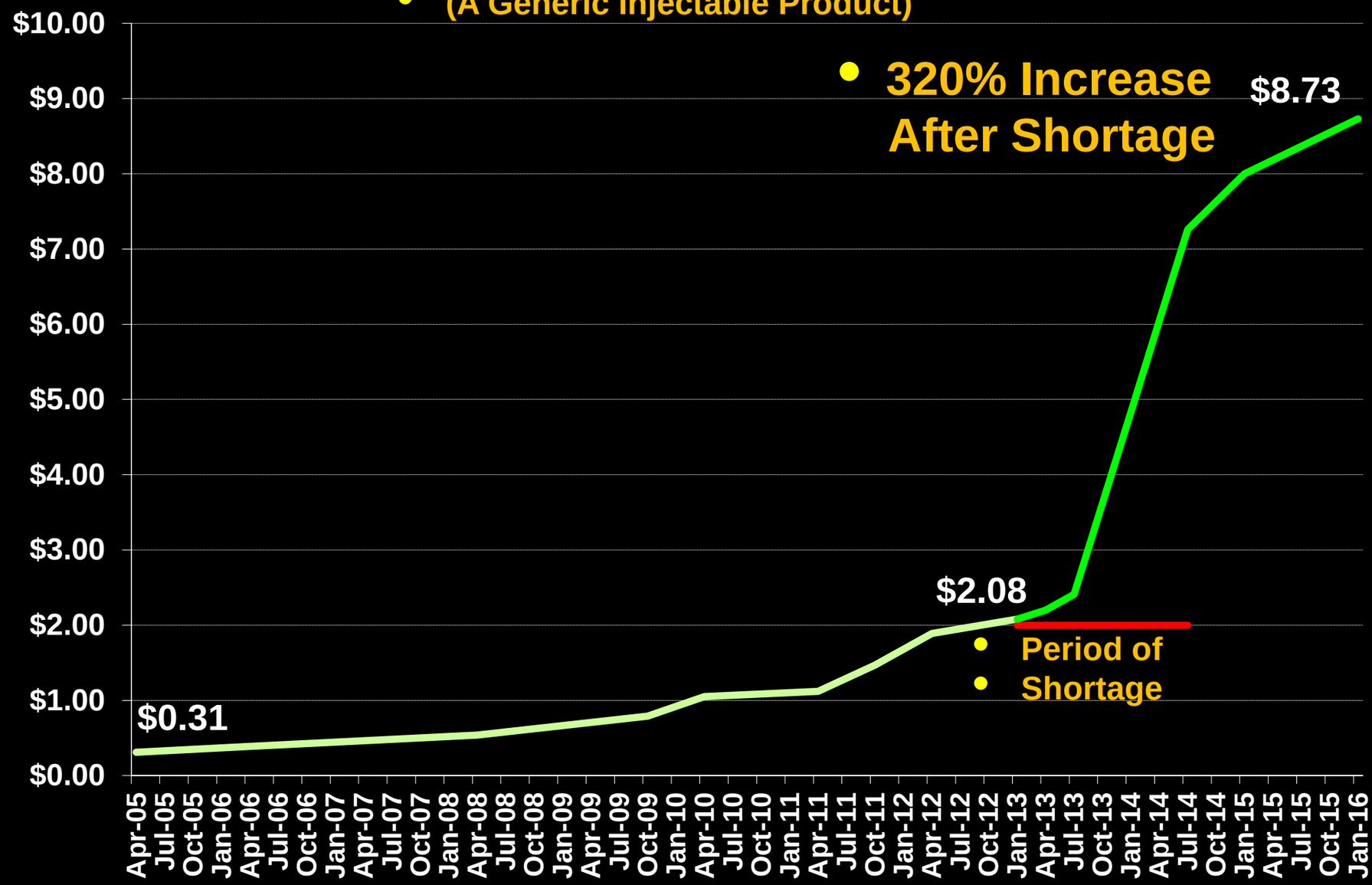
Competition & Market Power for Generics

- # of ANDAs Not Good Measure of Competition
  - Unused ANDAs;
- Only 1 or 2 ANDAs in Market→ Pricing Power
- API Contracts Can Limit/Manipulate Competition
  - Lorazepam & Mylan in early 2000s→ exclusive dealing with API & price increase
  - What's up with atenolol shortage?
- Some Generics Have Faced Over-Competition
  - GPOs have driven some generic injectable prices so low firms exit the market
  - Infrastructure for sterile injectables not keeping up→ recalls & shortages
- Some Generic Markets Too Small to be Profitable
  - Usual incentives (i.e., exclusivity) will not increase competition when market too small
- FTC Should Evaluate Shortages for Business Reasons

Verapamil Injection (Hospira)

Impact of a Drug Shortage: April 2013 to Jan. 2015

- (A Generic Injectable Product)



Based on data found in Truven's MarketScan® Commercial Claims and Encounter and Medicare Supplemental Data, 2005-2016 and other sources and *compiled by PRIME Institute, University of Minnesota.*

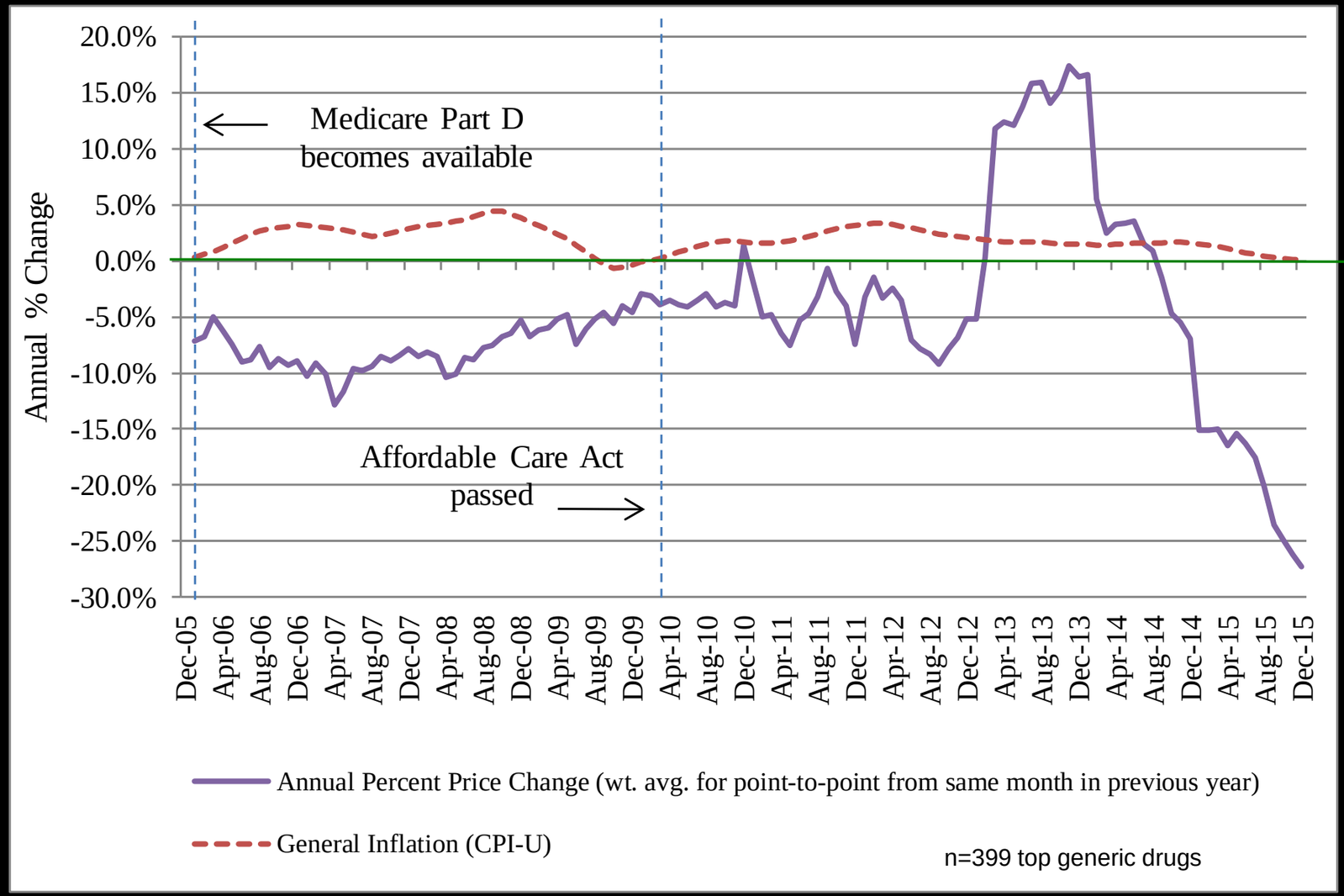
Regulatory & Legal Influences on Generics

- **FDA Review Time for ANDAs Getting Better**
  - Has been a rate-limiting step for ANDA approval & has limited competition
- **Make Sure the 'Total Time' to Market Is Managed**
  - Should not just shift ANDA review time from FDAs clock to firm's clock.
- **Unapproved Drugs Initiative → Competition Worse**
  - Colchicine (Colcrys) reduced competitors and ↑ price from $.09 to $4.85
  - Multiple unapproved drugs → 1 high-priced brand instead of more competitors
  - Cost Medicare about $1.2 billion from 2011-2015 (total national effect ~$3.7 billion)
- **Pay-for-Delay Invites Gaming & Delayed Competition**
- **Authorized Generics Confuse Consumers**
- **Trade Agreements Expand IP & Limit Generics**
  - TPP would have taken length of biologics exclusivity out of Congress' hands

Generic Drug Price Trends

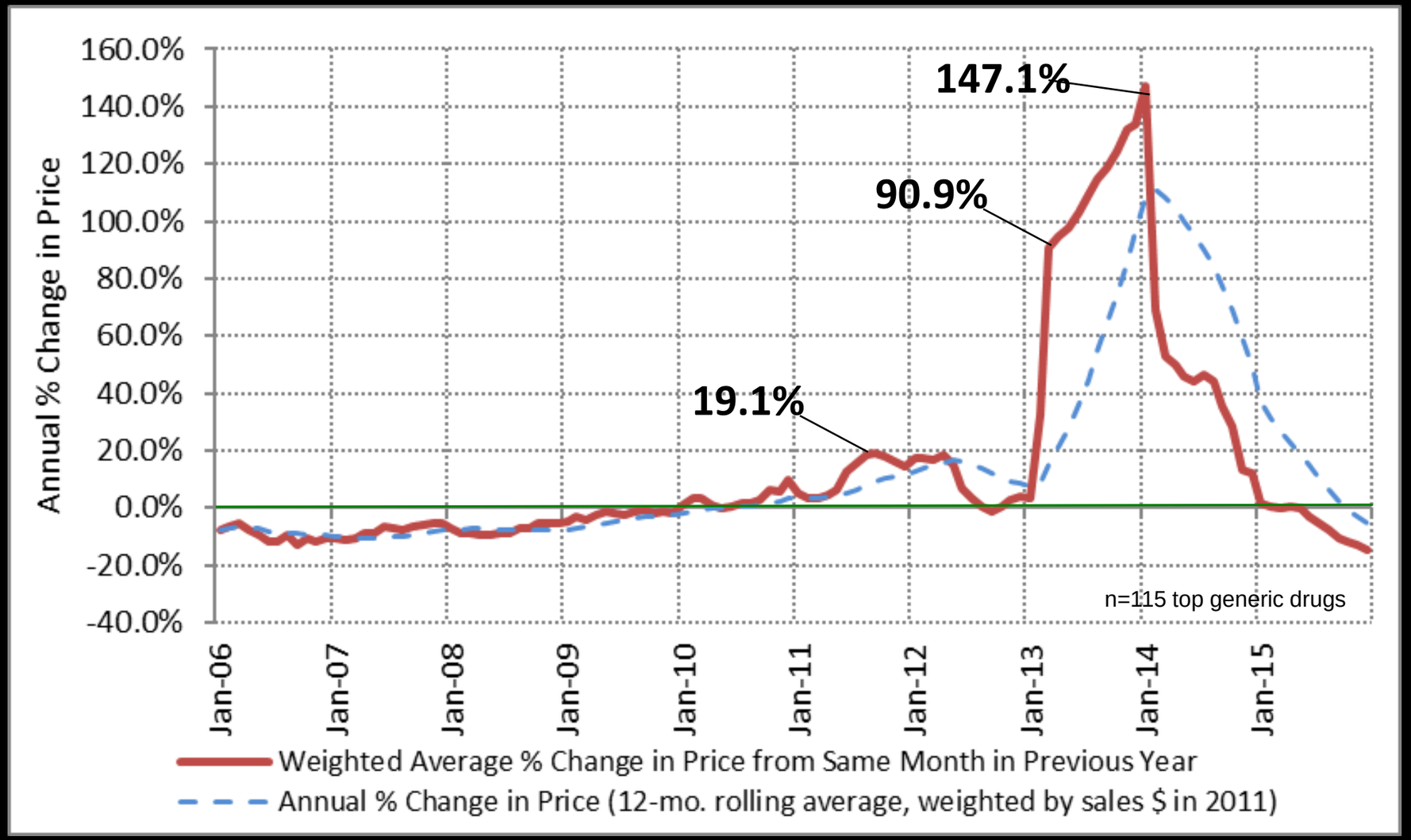
- **Generic Prices Go Down, But Not Always**
  - All but 1 of Top 399 generics had a price increase between 2011 & 2015.
- **1 in 4 Old Generics Had ≥100% Price ↑ in Last 5 Years**
- **2 in 3 Old Generics Had >25% Price ↑ in Last 5 Years**
  - These were one time price increases, not cumulative increases
- **Brand:Generic Price Gap ↑ from 3:1 to ~ 10:1**
  - Generics have doubled in price ($20/Rx to $40/Rx), brands have ↑
- **Older Generics Raise Prices to Keep Up** ($0.50 ↑ to $1.20/day)
- **New Generics Enter at Much Higher Price** (>$5/day)
  - Ondansetron (8 mg tabs) entered at $85/day (2007)
  - Enoxaparin injection entered at $98/day (2011)

Weighted Average Annual % Change in Retail Prices Paid for Most Widely Used Generic Prescription Drugs: 2006 to 2015



Schondelmeyer S, Purvis L, Trends in Retail Prices of Generic Prescription Drugs Widely Used by Older Americans 2006 to 2015. AARP Public Policy Institute, Rx Price Watch Report June 2017. Prepared by the AARP Public Policy Institute and the *PRIME* Institute, University of Minnesota, based on data from Truven Health MarketScan® Research Databases.

Weighted Average Annual Percent Change in Retail Price for Older Cohort (1980-2003) of Most Widely Used Generic Prescription Drugs, 2006 to 2015



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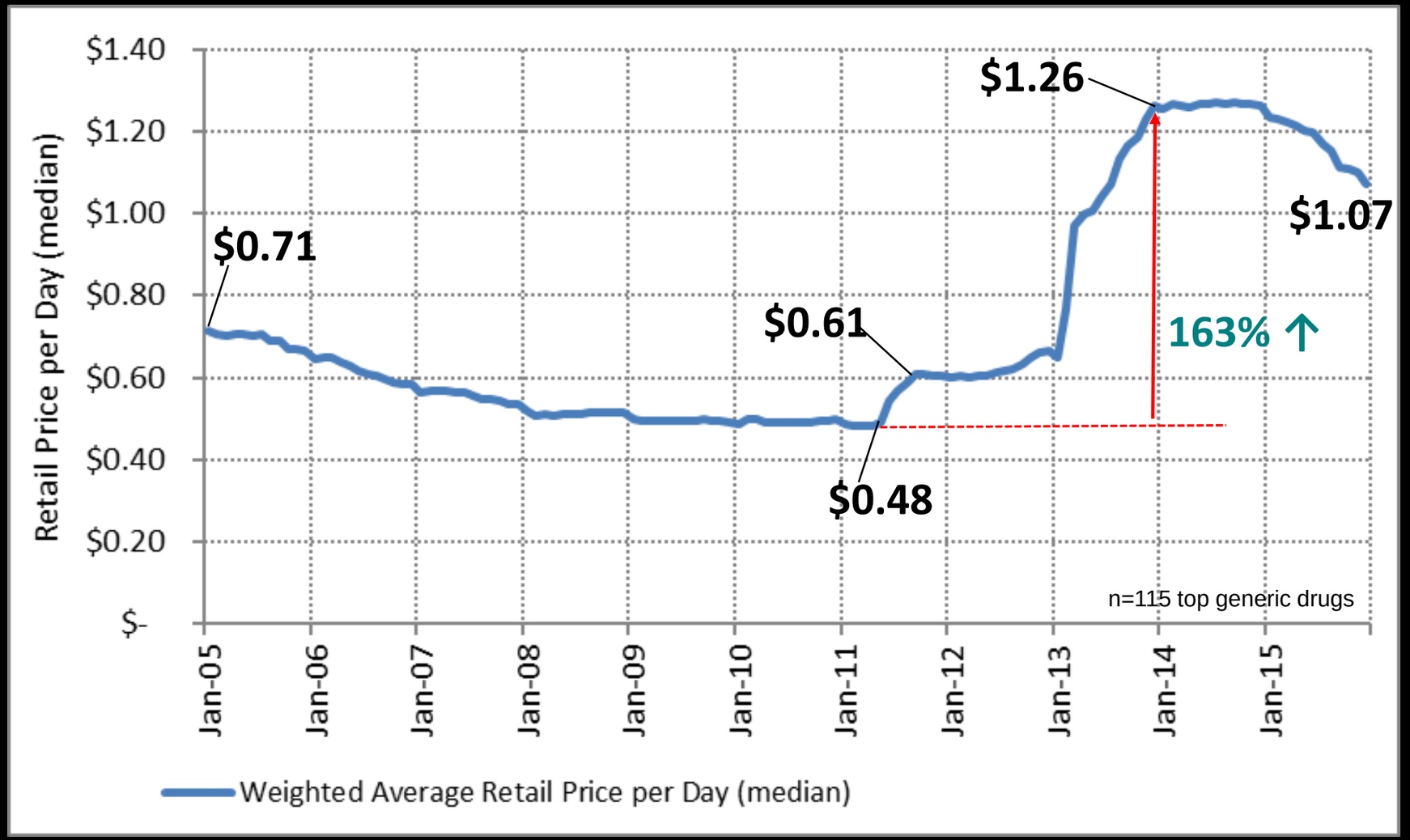
Weighted Average Retail Price Paid per Day for Older Cohort (1980-2003) of Most Widely Used Generic Prescription Drugs: 2005 to 2015



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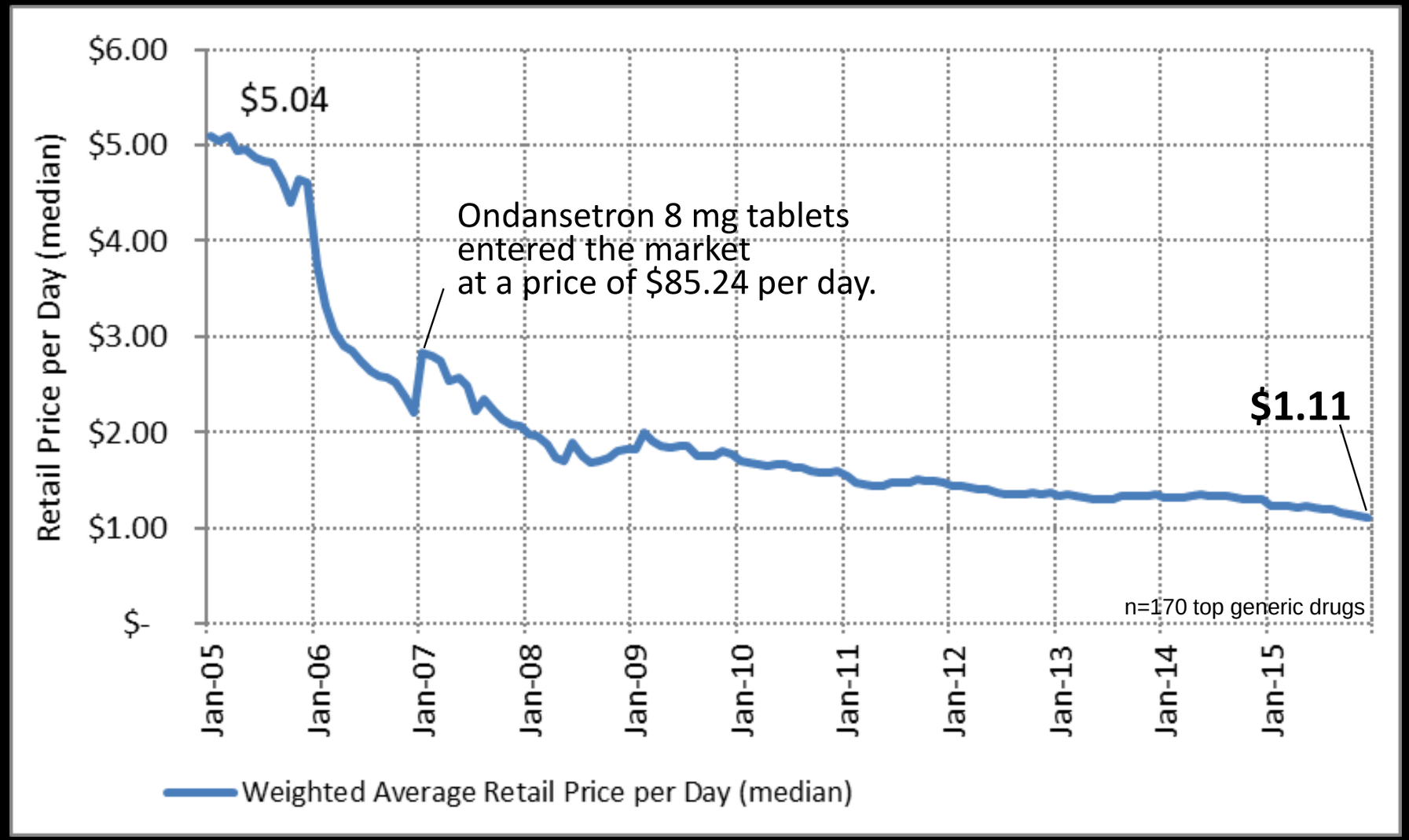
Weighted Average Retail Price Paid per Day for Newer Cohort (2004-2009) of Most Widely Used Generic Prescription Drugs: 2005 to 2015



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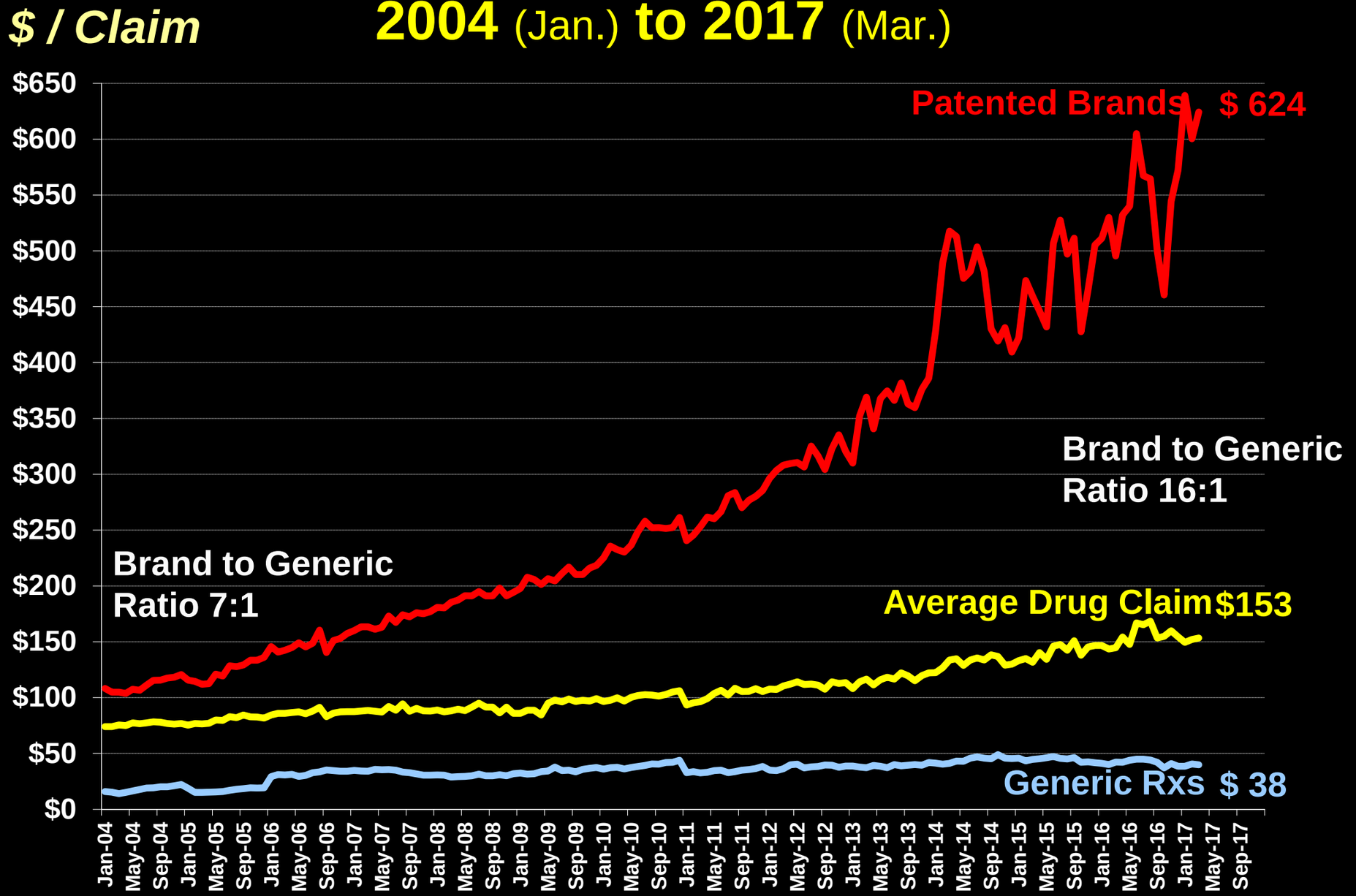
Weighted Average Retail Price per Day (median) from 2005 to 2015 For Older Generic Cohort (1980-2003) & Newer Generic Cohort (2004-2009)

Schondelmeyer S, Purvis L, Trends in Retail Prices of Generic Prescription Drugs Widely Used by Older Americans 2006 to 2015. AARP Public Policy Institute, Rx Price Watch Report June 2017. Prepared by the AARP Public Policy Institute and the *PRIME* Institute, University of Minnesota, based on data from Truven Health MarketScan® Research Databases.

Total Paid ($) per Claim by Drug Type: 2004 (Jan.) to 2017 (Mar.)



Based on data from Univ. of Minnesota self-insured drug benefit (UPlan) 2004 to 2017 & compiled by PRIME Institute, University of Minnesota.

Finding Fixes for the Future

- Make Drug Prices Transparent & Accountable
- Systematically Monitor for Extraordinary Drug Prices
  - Screen for prices & price changes that are ‘unconscionable’ & ‘unreasonable’
  - Single point price changes >10%, >25%, >50% & >100%
- Link Transparent Prices, Accountability & Coverage
  - Quasi-governmental commission reviews & evaluates prices & price changes
  - Price behavior not justified, drug not covered by Medicare, Medicaid, commercial
- Prohibit Market Distorting Behaviors
  - Copay Coupons, Undisclosed Rebates, Patents for Product Hopping & Combinations
  - HHS OIG has declared copay coupons as ‘kickbacks’ & prohibited them in govt. plans
- Recognize Economic Impact of FDA Policy & Actions
- Enable Value-Based Decisions→Requires Actual Price

Understanding Competition in Prescription Drug Markets:

Entry and Supply Chain Dynamics

Panel 1: Generic Drug Competition: Understanding Demand, Price and Supply Issues

BREAK

Understanding Competition in Prescription Drug Markets:

Entry and Supply Chain Dynamics

Panel 2: Understanding Intermediaries: Pharmacy Benefit Managers

USC Schaeffer
Leonard D. Schaeffer Center for Health Policy & Economics

USC Price
Sol Price School of Public Policy

Follow the money: The flow of funds in the pharmaceutical distribution system

Neeraj Sood
Vice Dean for Research and Professor, USC Price School of Public Policy
Faculty, USC Schaeffer Center

Disclosures

Support for the research cited in this presentation was provided by the Schaeffer Center for Health Policy & Economics and by Amgen through a contract with Precision Health Economics.

The views expressed herein are mine and do not represent the views of the funders; the sponsors had no role in the research.

Today’s talk

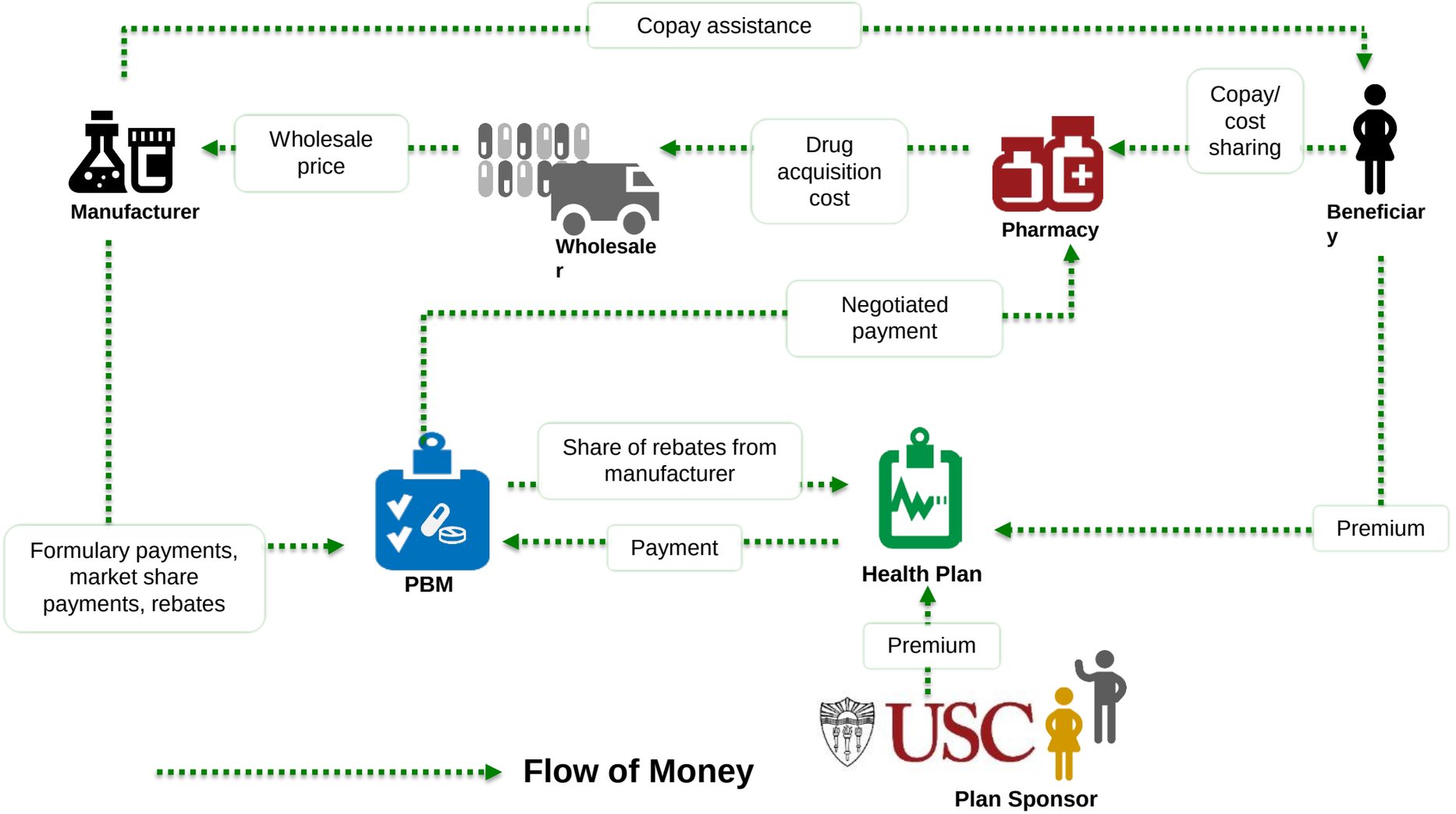
- **How do drugs reach from manufacturers to consumers?**
- **Who makes how much money?**
- **Are PBMs making too much money?**

Conceptual framework: Flow of prescription drugs

Manufacturer **Wholesaler** **Pharmacy** **Beneficiary**

Pharmacies may be mail order or retail, and may be integrated with PBM. Plan sponsors may include employers, unions, managed care orgs, among others.

Conceptual framework: Flow of money



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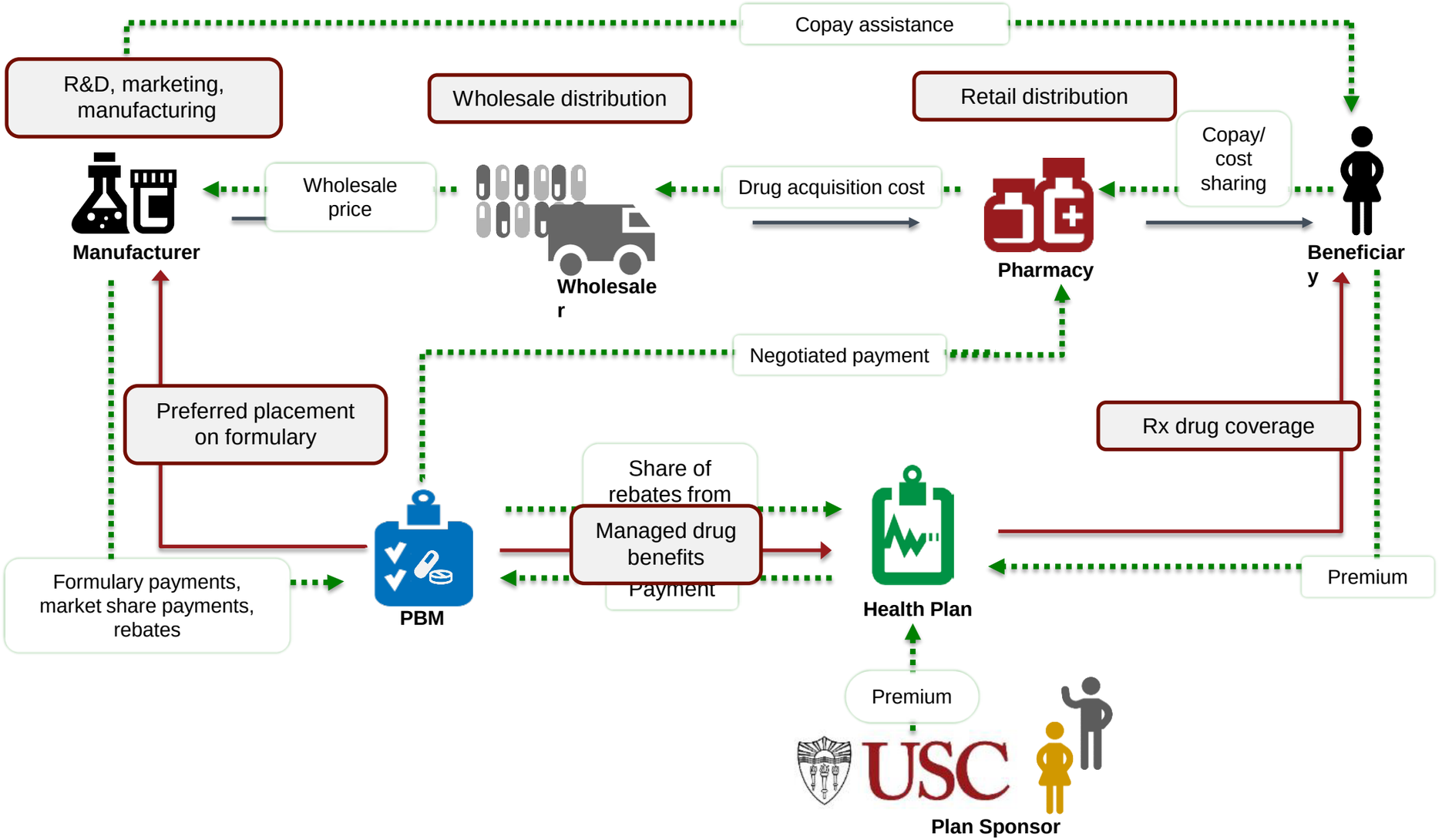
Conceptual framework

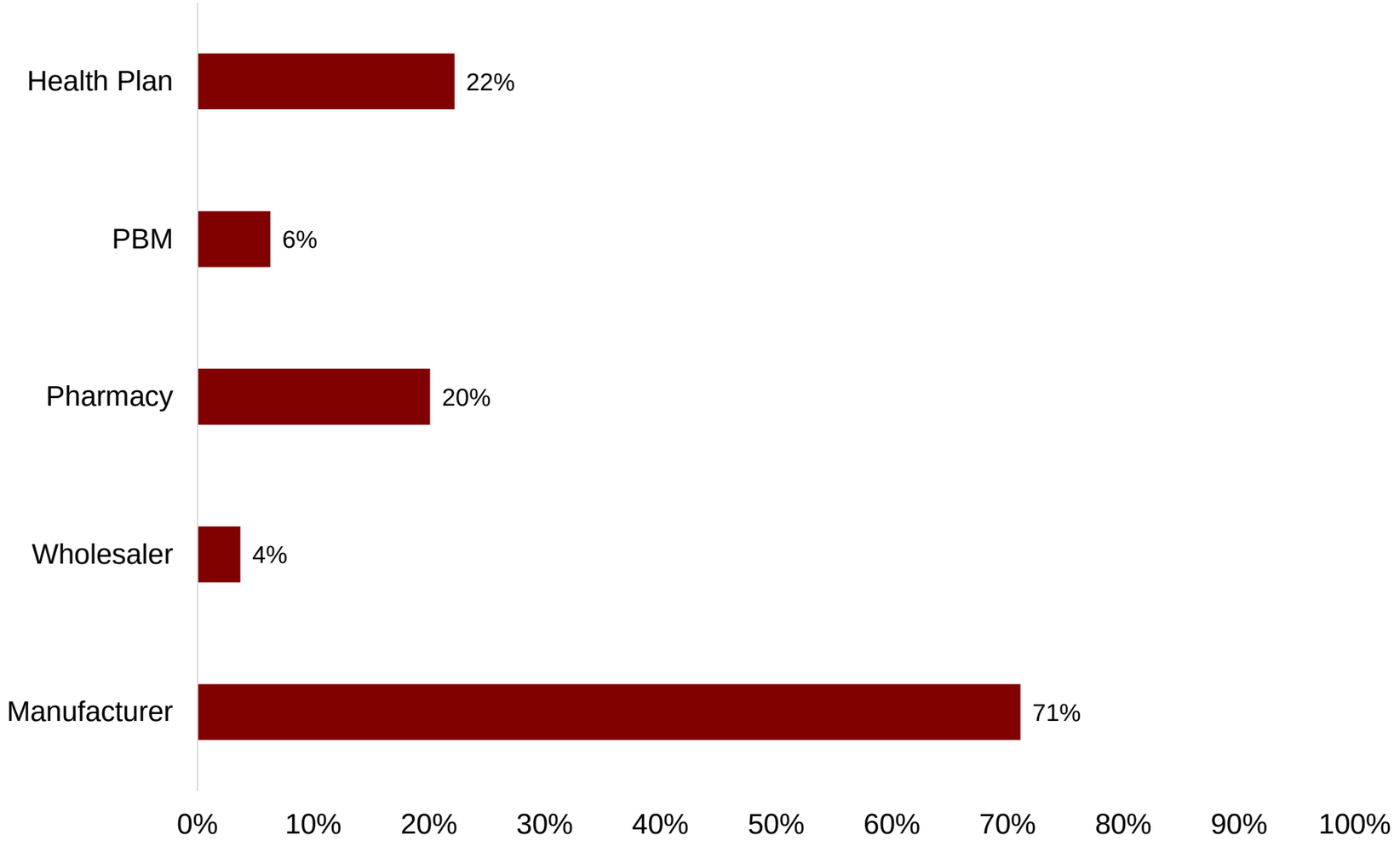


Pharmacies may be mail order or retail, and may be integrated with PBM. Plan sponsors may include employers, unions, managed care orgs, among others.

How do we estimate the flow of money?

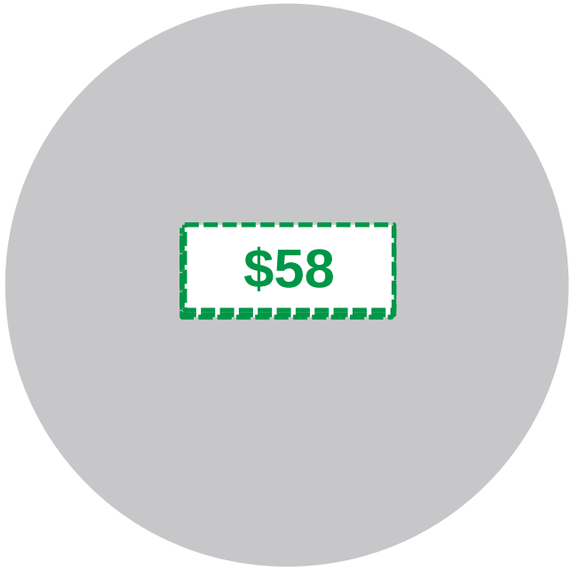
1. Identify top publicly traded firms for each market segment: manufacturers, wholesalers, retailers, pharmacy benefit managers, & health plans
2. Use SEC filings of these firms to estimate:
   - Gross profits: Revenue less cost of goods/services sold
   - Net profits: The profits returned to owners after operating expenses
3. Use the conceptual framework and financial data to illustrate the flow of funds for a drug purchased by an insured consumer at a retail pharmacy

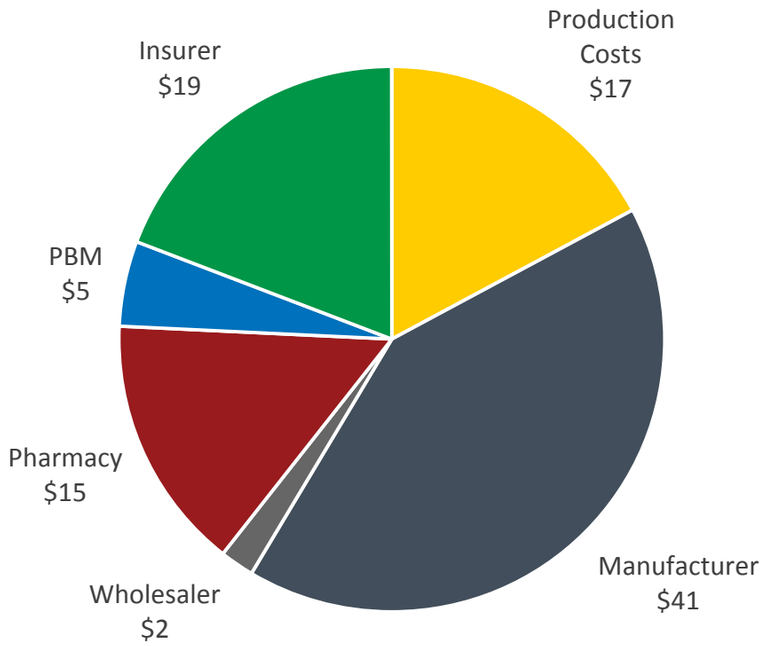
Gross profit margins



All gross margins are are US sales-weighted averages based on data from 2015 SEC 10K filings and annual reports

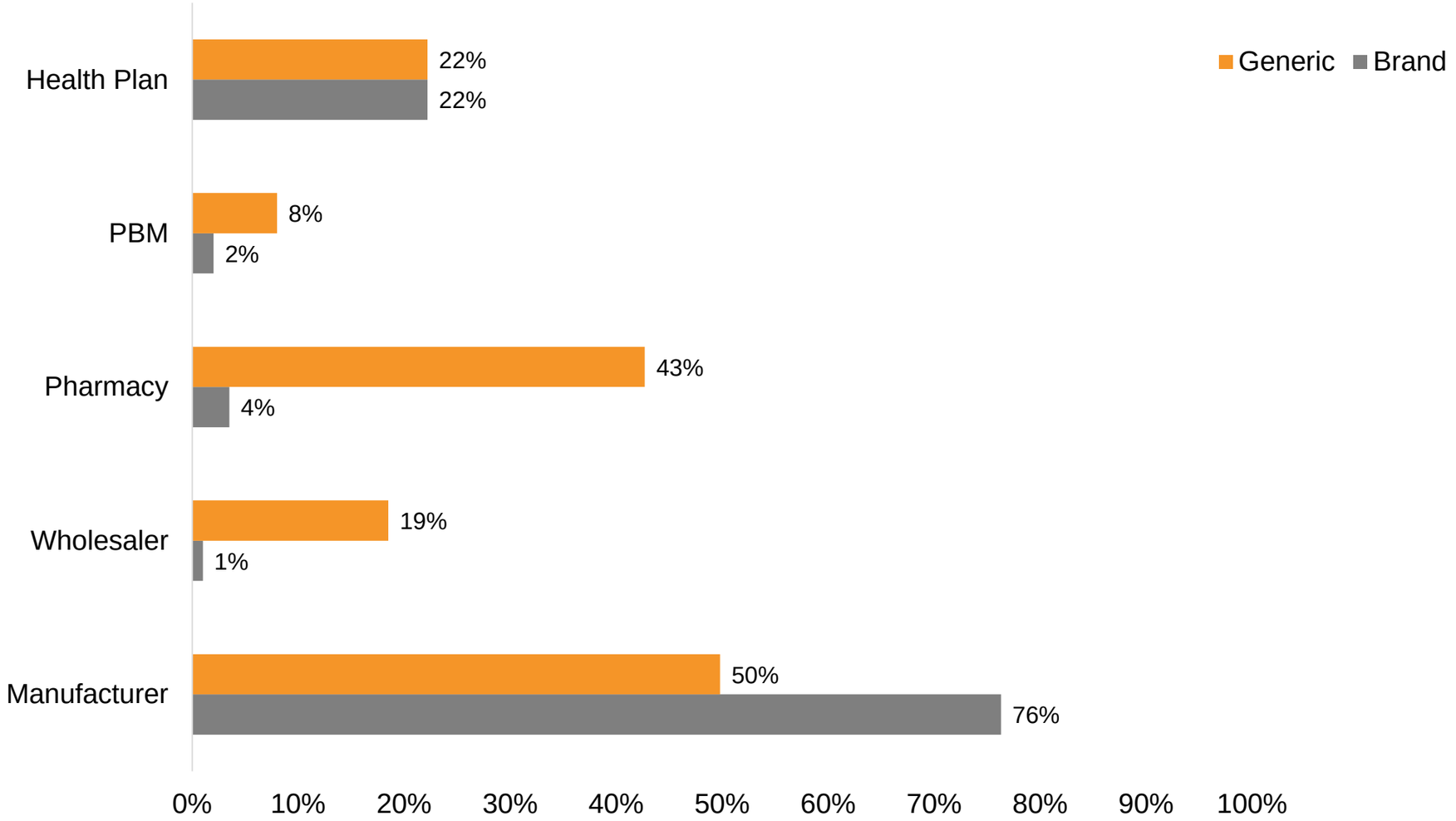
Flow of $100 spent on pharmaceutical drugs, overall industry



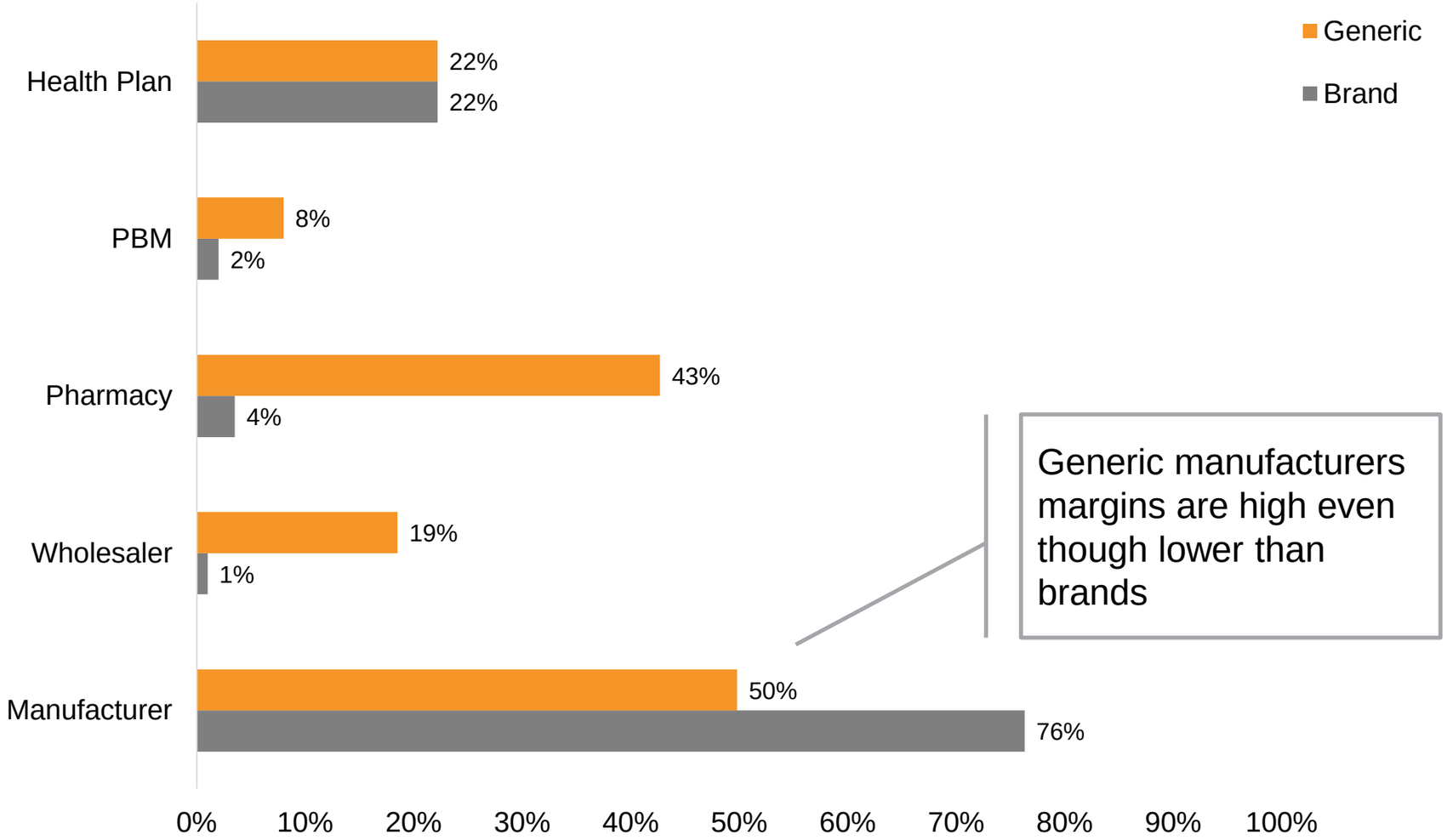


negotiate discounts and rebates with drug makers.

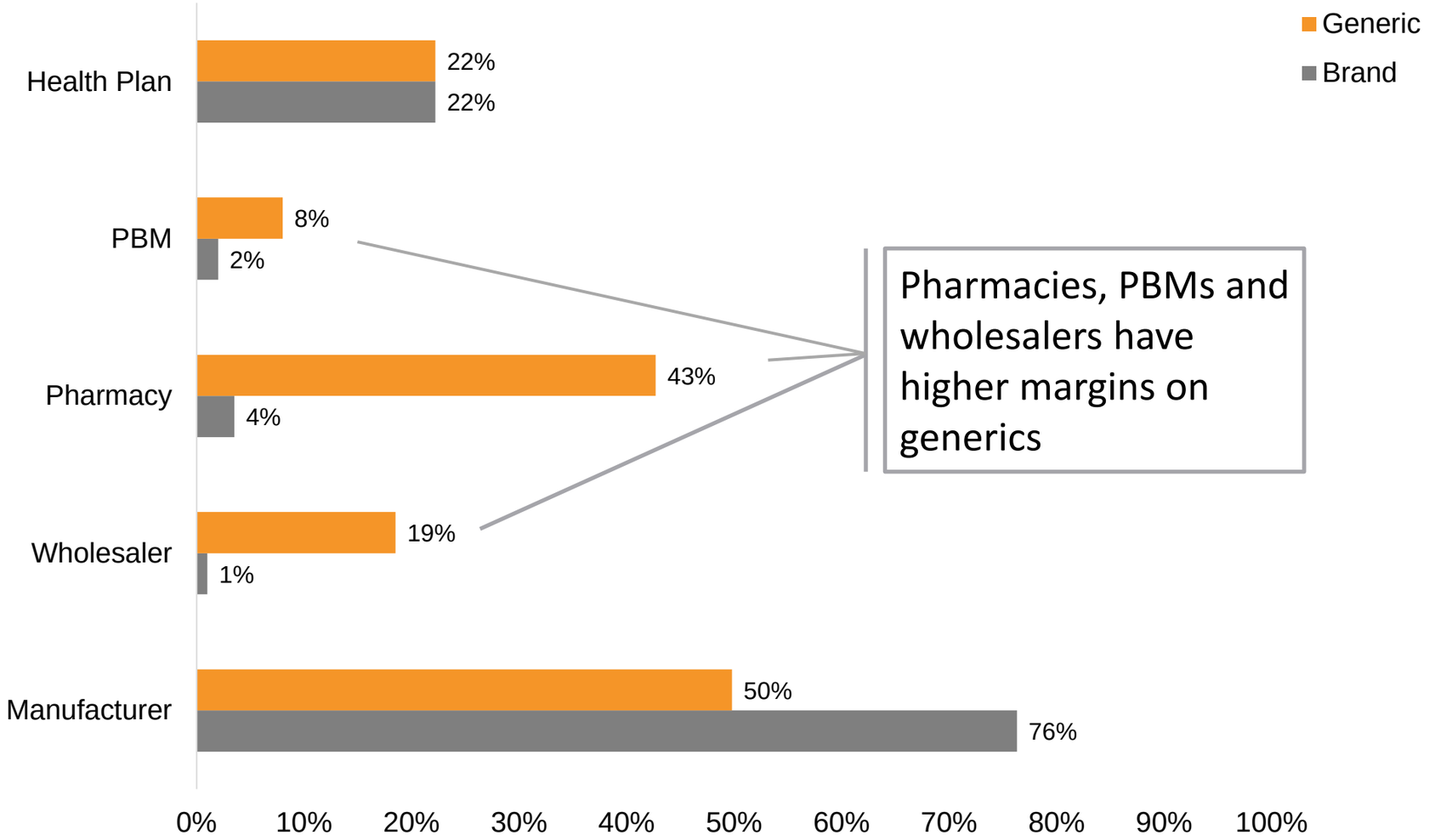
Gross profit margins: Brands versus generics



Gross profit margins: Brands versus generics



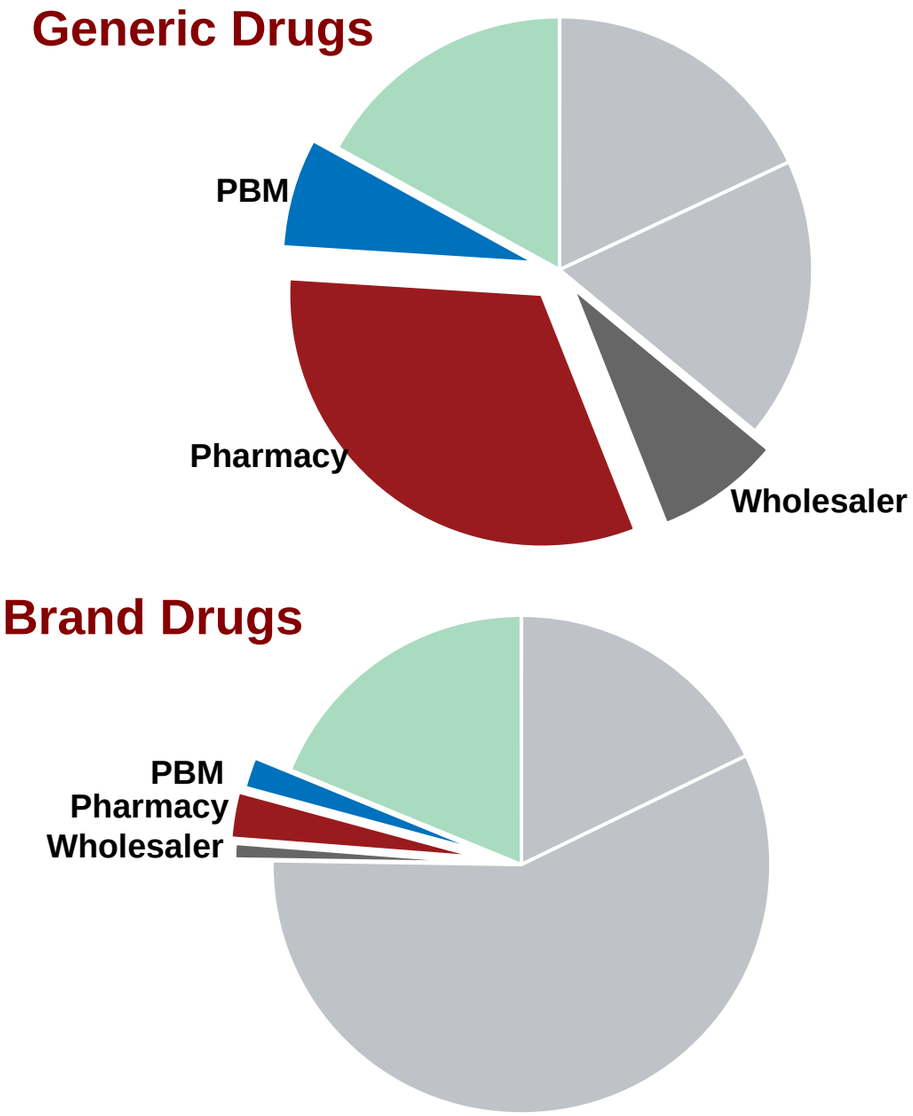
Gross profit margins: Brands versus generics



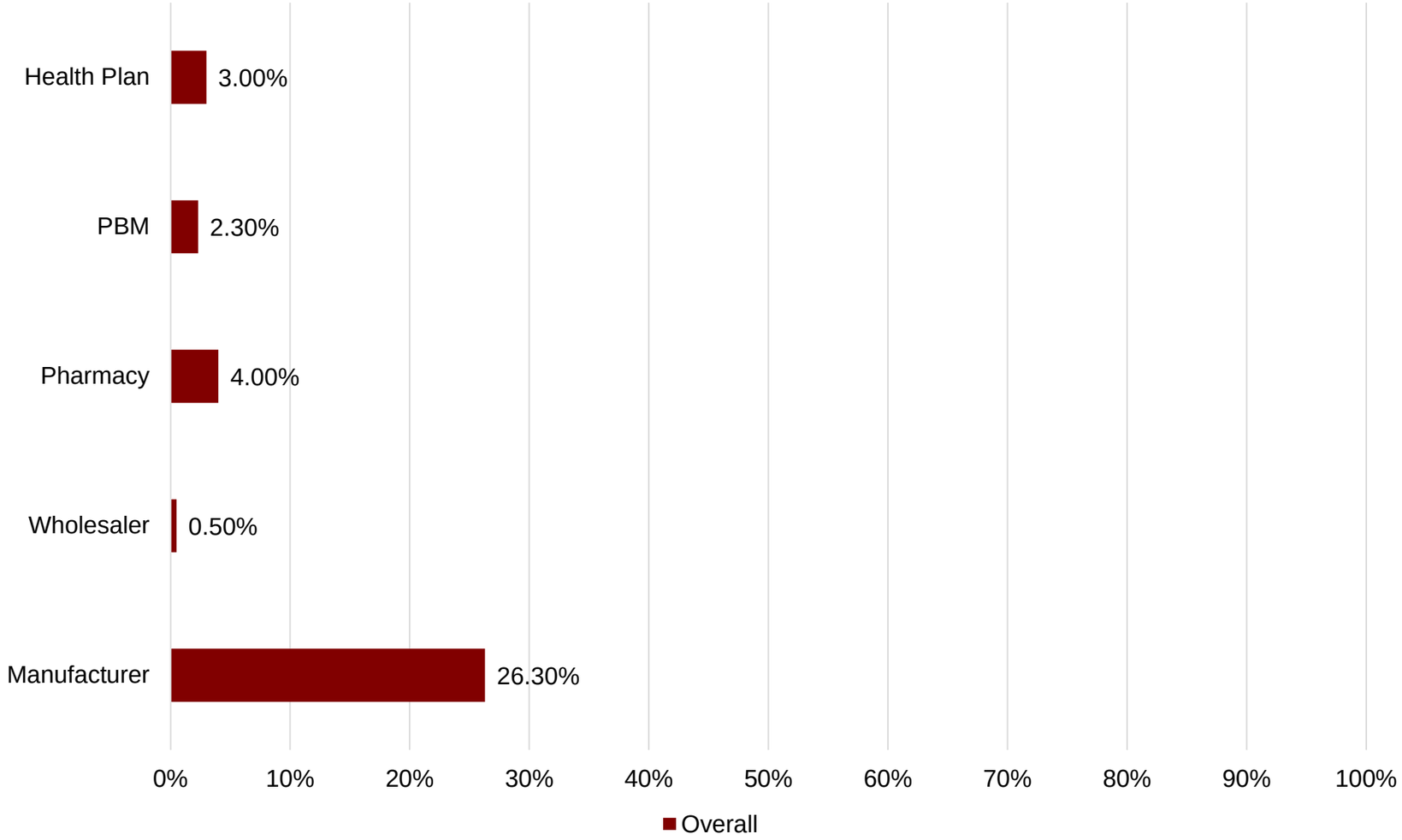
Flow of $100 spent on pharmaceutical drugs, brand and generic

In total, PBMs, Pharmacies, and Wholesalers **capture $47 for every $100 on generics**

compared to **$8 for every $100 on brands**

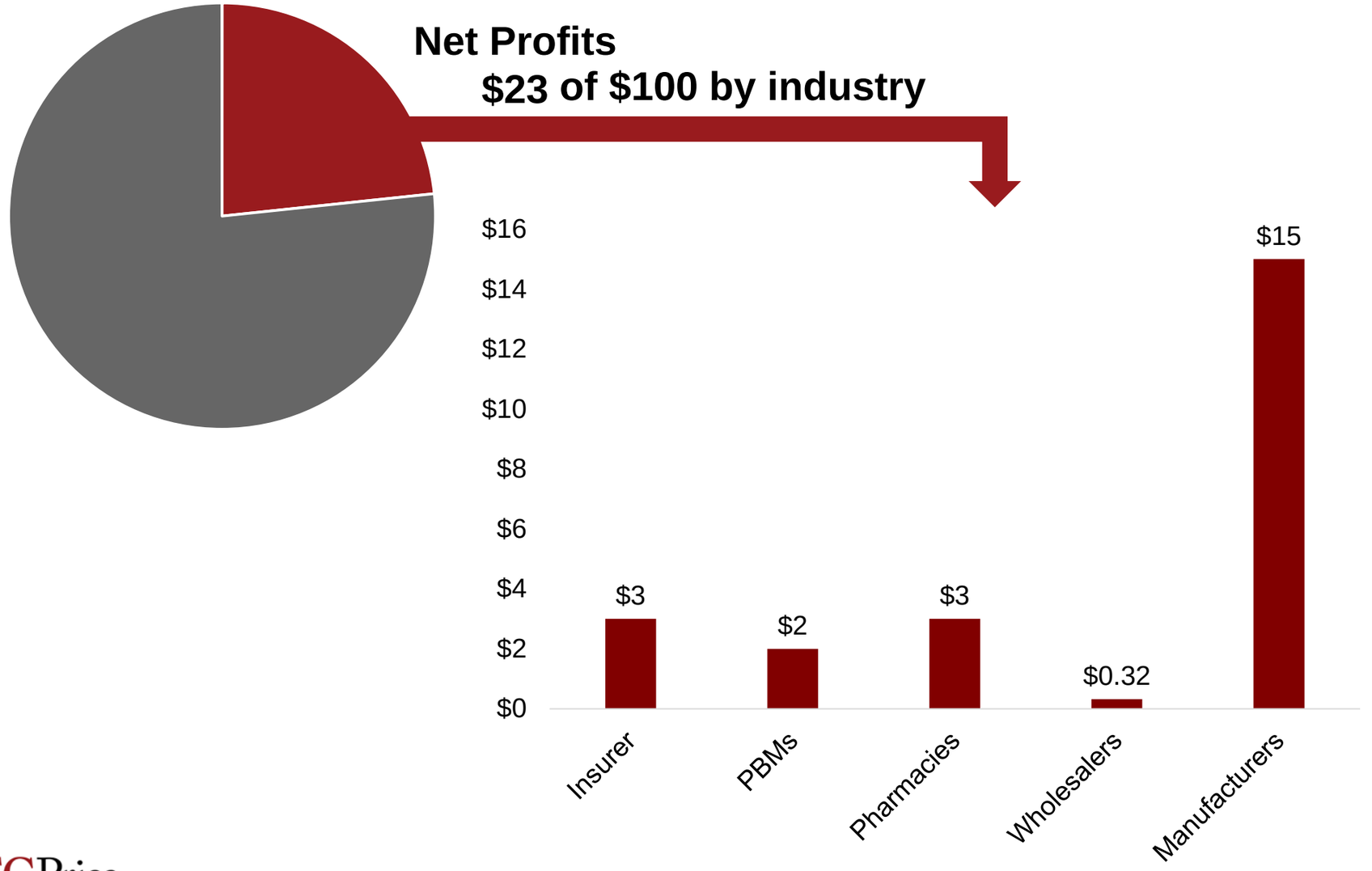


Net profit margins



All net profit margins are US sales-weighted averages based on data from 2015 SEC 10K filings and annual reports

Net profits, overall industry



Are PBMs making too much money?

1. Evaluate level of competition or concentration in these markets
2. Compare returns of PBMs to other industries
3. Compare returns of PBMs to “value” provided
4. Evaluate if PBM incentives are aligned with incentives of plans and consumers

PBM market segment is highly concentrated

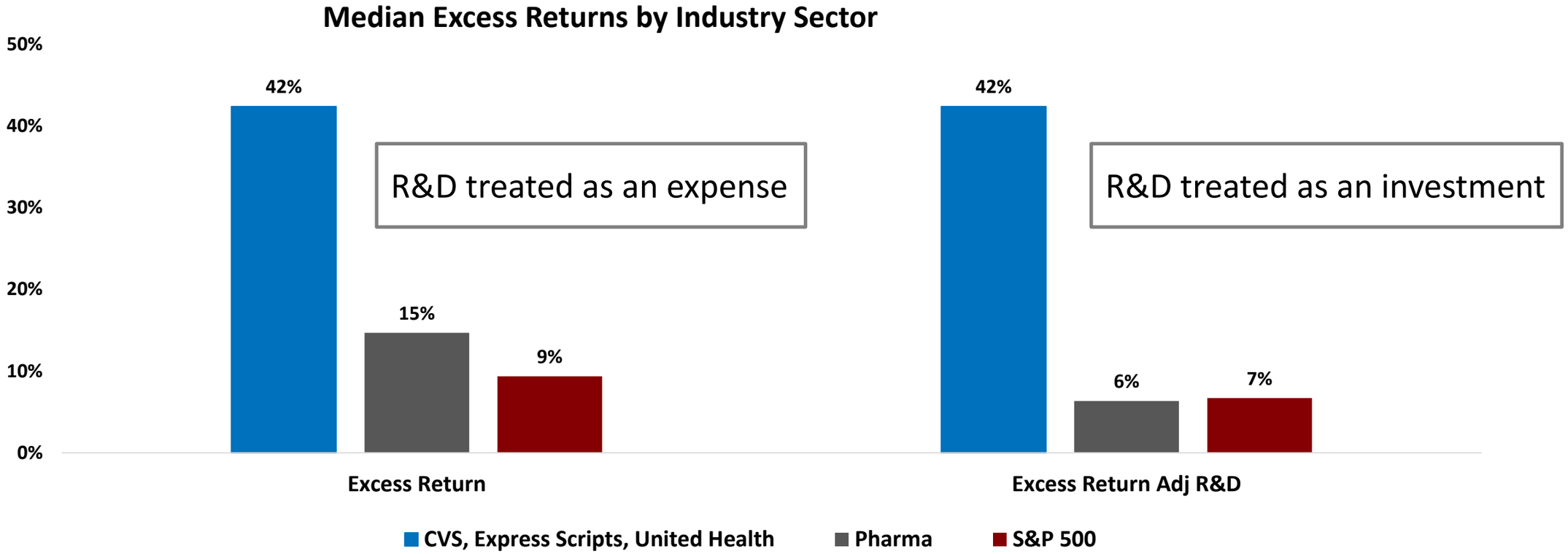
Top 3 PBMs control more than two-thirds market share

Higher concentration means:

- More bargaining power to negotiate lower prices with manufacturers and pharmacies
- More market power relative to health plans

The link between PBM market power and consumer savings is tenuous

Are PBMs making “excess” returns?



Excess Return = Return on invested capital – weight average cost of capital

Excess Return adjusted for R&D treats R&D as an investment rather than expense

The **weighted average cost of capital (WACC)** is the rate that a company is expected to pay on average to all its security holders to finance its assets. **Return on invested capital (ROIC)** is a profitability ratio. It measures the return that an investment generates for those who have provided capital, i.e. bondholders and stockholders. ROIC tells us how good a company is at turning capital into profits. (Source: http://www.htahealth.com)

Authors calculation based on most recent three years of data 2015-2017 from Damodaran Online
http://pages.stern.nyu.edu/~adamodar/

Are PBMs earning their value?

For every $100 in spent on drugs PBMs keep about $5

Without PBMs, we would save $5, but also not get the value provided:

- Lower drug prices for health plans, consumers
- Lower reimbursement to pharmacies
- Higher market share of generics
- Higher market share of lower cost brands

Is the value from PBMs worth more than $5?

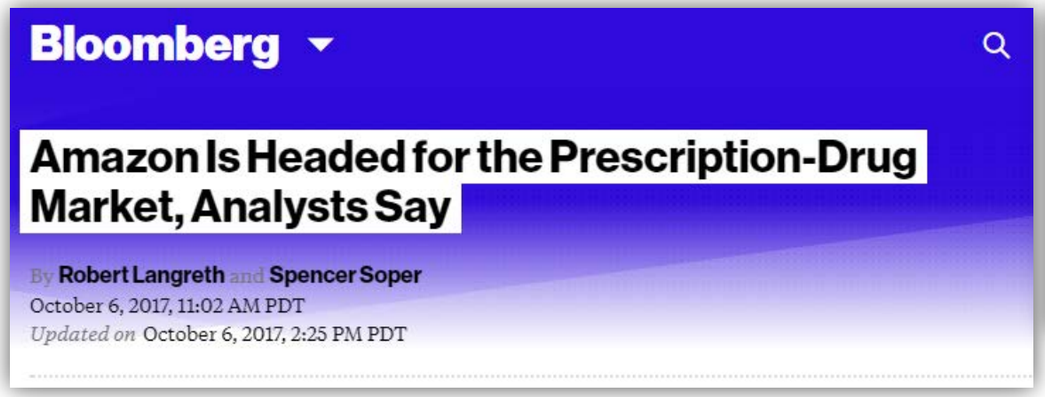
Drug A with PBM:
Price: $100
Rebate: $10

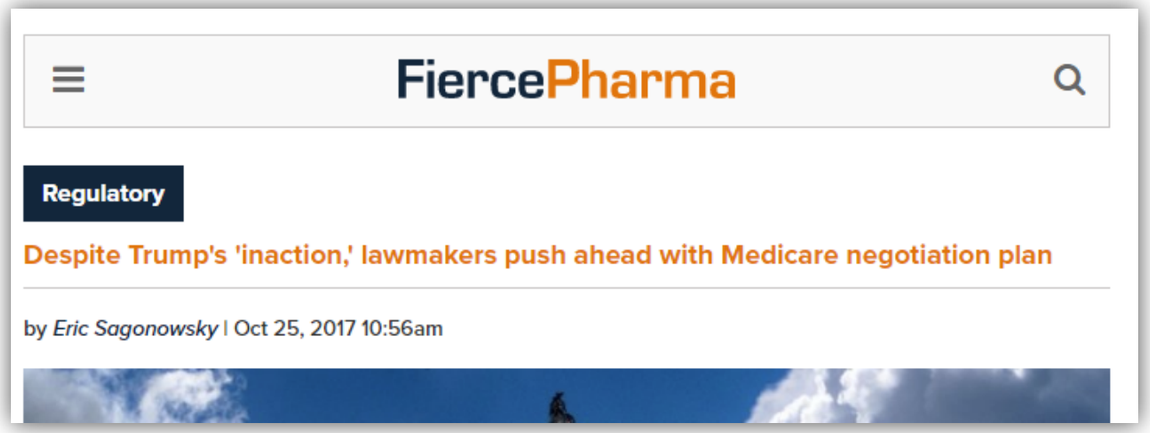
- PBM keeps $5

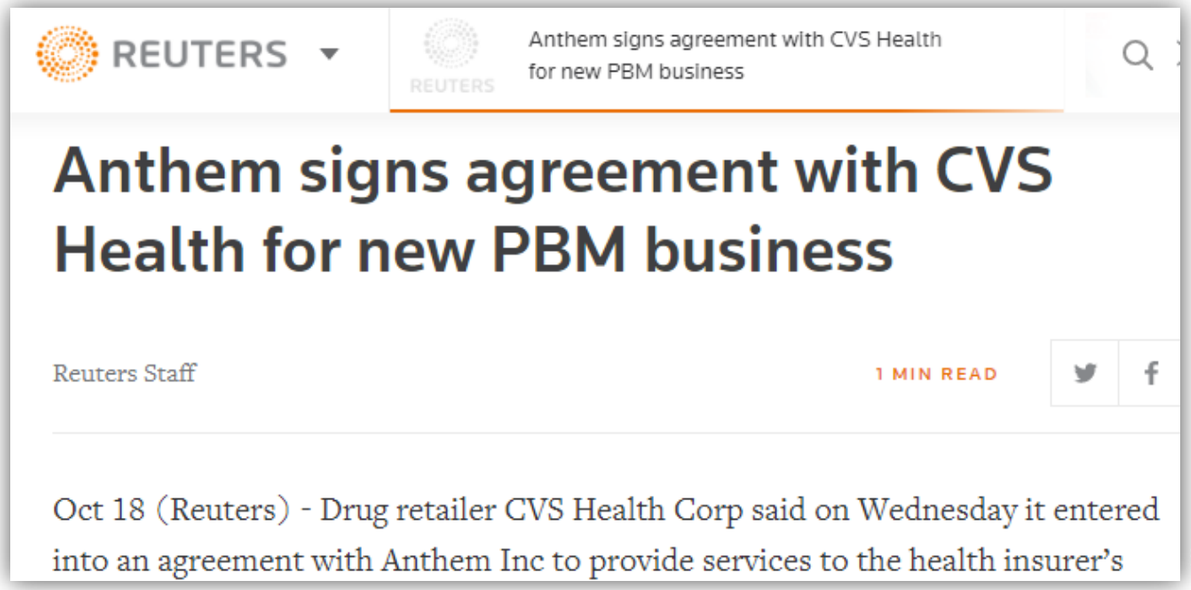
Cost to health plan: $95

Drug A without PBM:
Price: $100
Rebate: $0
Cost to health plan: $100

Are there alternatives that can do the same or better job for less?







Rebates misalign incentives: Issues of list price inflation

	PBMs keeps (=10% of rebate)	Cost to health plans (= retail price - rebate pass through)	Net revenue to manufacturers (= retail price - retail and wholesale mark-up- rebate)	cost to consumers?
Drug A (Low) List Price: $200 Retail Price: $200 • rebate of $50	$5	$155 ✓	$130 ✓	✓ **Uninsured** might pay list price ✓ **Insured consumers below deductible** might pay list price ✓ **Insured** may pay higher premiums
Drug A (High) List Price: $250 Retail Price: $210 • rebate of $60	$6 ✓	$156	$129	

USC Schaeffer | USC Price

Assume retail and wholesale mark-up is 10%; PBM keeps 10% of rebate

Rebates misalign incentives: Not choosing cheaper drug

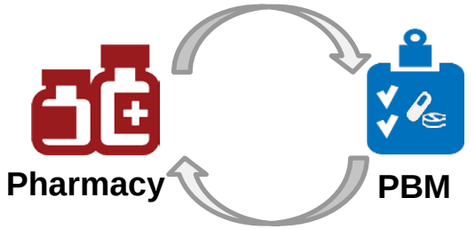
	PBMs keeps	Cost to health plans
Drug A Retail Price: $200 • rebate of $50	$5 ✓	$155
Drug B Retail Price: $100 • rebate of $30	$3	$73 ✓

Assume retail and wholesale mark-up is 10%; PBM keeps 10% of rebate

PBMs and pharmacies

PBM ownership of mail order pharmacies: Misaligned Incentives

- Might pay higher prices to PBM-owned pharmacy
- Might overuse PBM-owned pharmacy



Narrow network pharmacies combined with market power in insurance markets might hurt consumers

- Plans save money through lower pharmacy reimbursement
- Consumers get some of these savings but have restricted choice

Research Agenda for FTC

- Empirically estimate the consequences of
  - market power in PBM markets for consumers
  - list price inflation for health plans and consumers
  - narrow network pharmacies for consumers from different socio-economic neighborhoods
  - PBM ownership of pharmacies

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Top Manufacturers, by Market Share

	US Market Share		
Company	**All[a]**	**Brands[a]**	**Generics[13]**
Gilead Sciences (Brand)	6.9%	10.9%	--
J&J (Brand)	5.9%	9.4%	--
Roche (Brand)	5.7%	9.0%	--
Merck & Co (Brand)	5.7%	9.0%	--
Amgen (Brand)	5.3%	8.5%	--
Pfizer (Brand)	4.7%	7.4%	--
Fresenius Kabi (Generic)	4.6%	--	3.1%
AbbVie (Brand)	4.4%	6.9%	--
Sanofi (Brand)	4.3%	6.8%	--
Novartis (Brand)	3.3%	5.3%	--
Astrazeneca (Brand)	3.1%	4.8%	--
Allergan (Brand)	3.0%	4.7%	--
GlaxoSmith Kline (Brand)	2.6%	4.2%	--
Pfizer-Hospira (Generic)	2.3%	--	3.6%
Teva (Brand)	2.1%	3.3%	--
Mylan (Generic)	1.6%	--	8.8%
Teva (Generic)	1.5%	--	12.2%
Novartis-Sandoz (Generic)	1.1%	--	11.5%
Allergan-Actavis (Generic)	1.1%		8.9%
Aspen (Generic)	0.4%	--	4.1%
Lupin (Generic)	0.3%	--	2.7%
Total	**70%**	**90%**	**55%**

Top PBMs, by Market Share

Pharmacy Benefit Managers	
Company	**Share**[11]
Express Scripts	29%
CVS Health	24%
Optum Rx	13%
Total	**66%**

Top Wholesalers, by Market Share

Wholesalers	
Company	**Share**[10]
McKesson	32.7%
AmerisourceBergen	31.6%
Cardinal Health	20.7%
Total	**85%**

Top Pharmacies, by Market Share

Pharmacies	
Company	**Share**[12]
Walgreens	14.9%
CVS Retail	13.8%
Express Scripts Mail Order Pharmacy	11.0%
CVS Mail Order	9.0%
Walmart	5.5%
Total	**54%**

Top Insurers, by Market Share

Insurers[8]	
Company	**Share[b]**
UnitedHealth Group	11.4%
Anthem	9.2%
Aetna	4.1%
Cigna	4.5%
Humana	8.7%
Centene	3.4%
HealthNet	2.6%
WellCare	2.1%
Molina	2.0%
Magellan	0.5%
Total	**49%**

Mark Merritt

President and CEO

Pharmaceutical Care Management Association

Federal Trade Commission- PBM Workshop

Jenny Bryant- Senior Vice President
Policy & Research

November 8, 2017

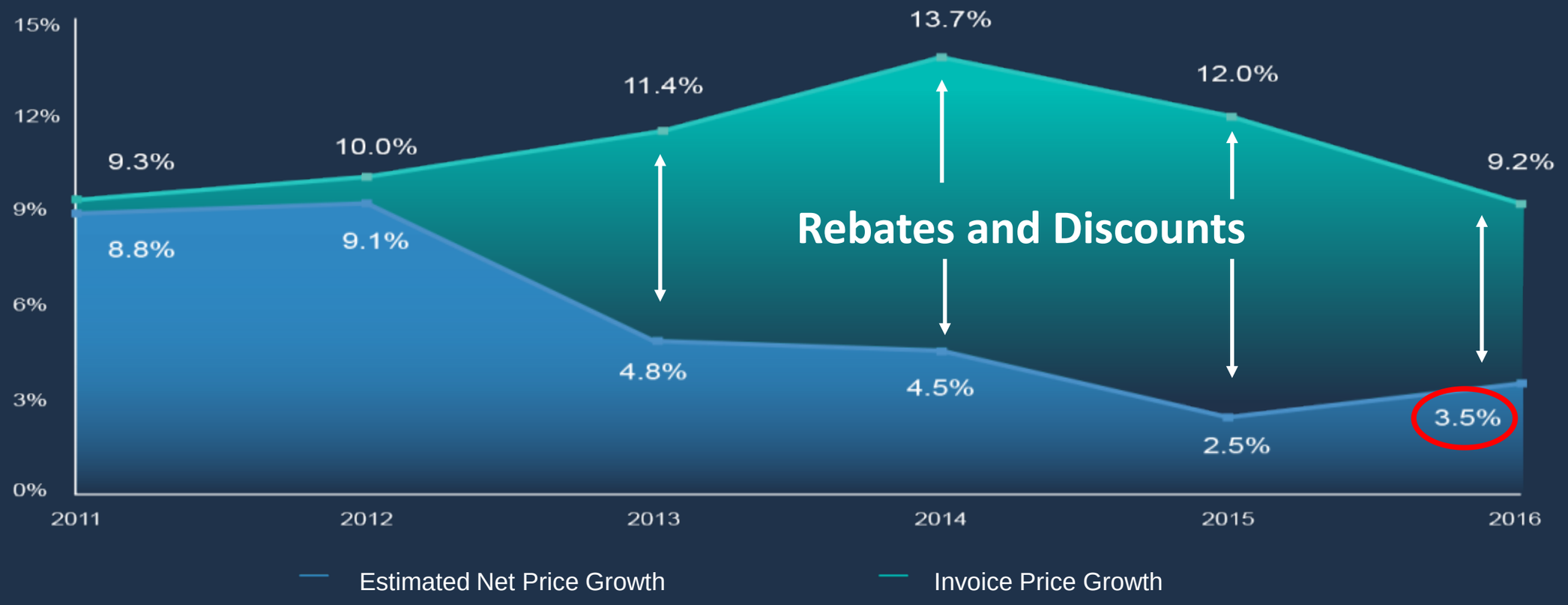
In the Midst of Great Progress, Cost Growth is Modest

Per capita spending growth.

EXPRESS SCRIPTS®	CVSHealth	PRIME THERAPEUTICS®	QuintilesIMS™ formerly known as IMS Health
5.2% 2015	**5%** 2015	**2.8%** 2016	**7.8%** 2015
3.8% 2016	**3.2%** 2016	**0.8%** First Half 2017	**4.1%** 2016

3 PBMs are commercial sector.
IMS adjusted to per capita based on author's calculation.

Brand medicine prices grew just 3.5% in 2016, after rebates and discounts were removed

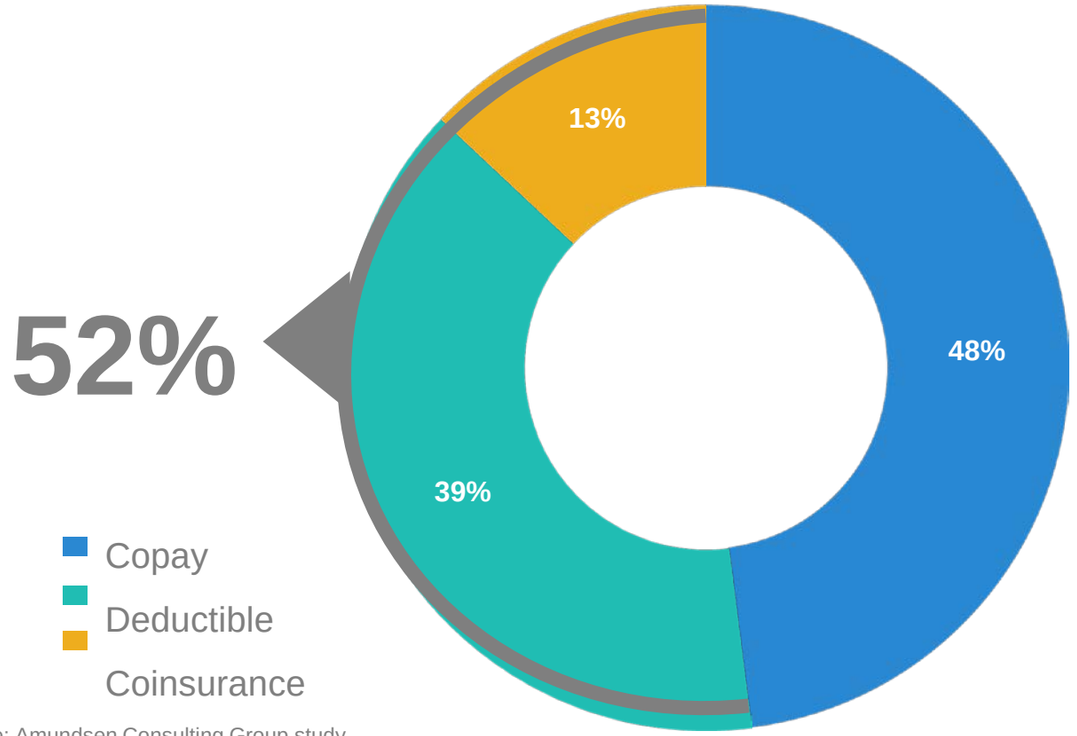


Source: Quintiles MS Institute , Medicines Use and Spending in the U.S., May 2017.

But too often negotiated savings do not make their way to patients

More than half of commercially insured patients' out-of-pocket spending for brand medicines is based on the full list price

Cost sharing for nearly 1 in 5 brand prescriptions is based on list price



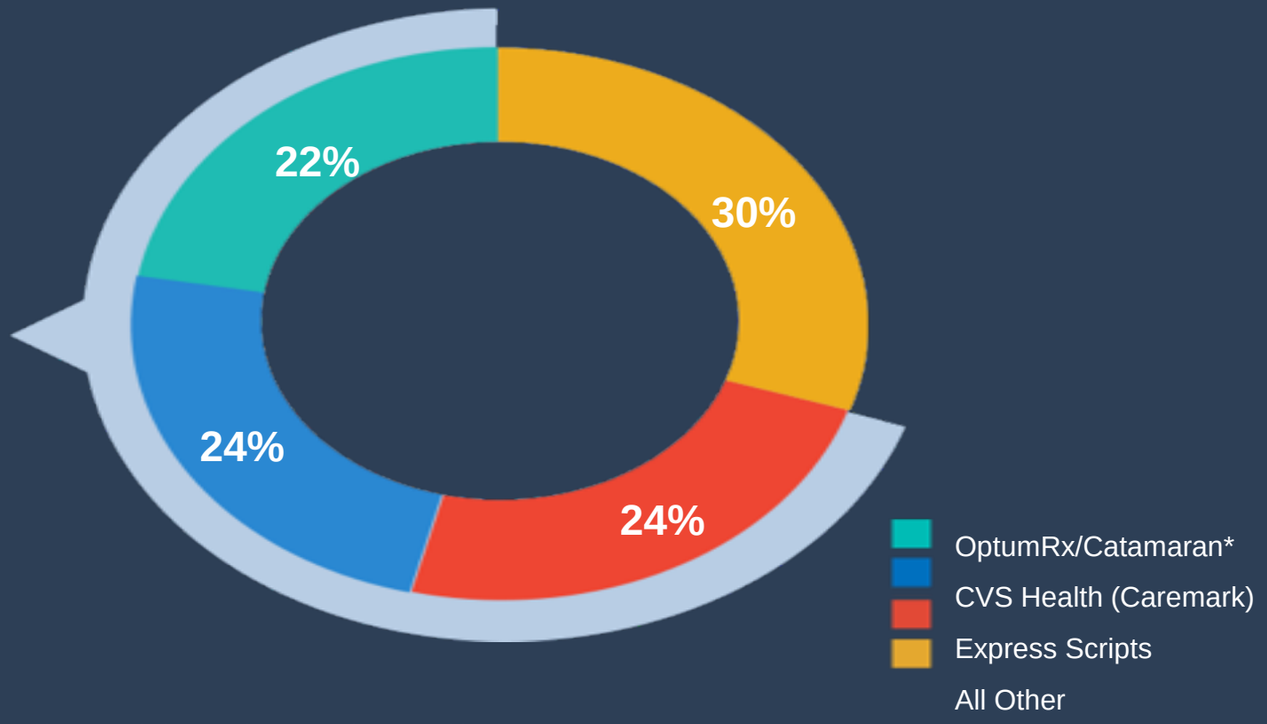
Source: Amundsen Consulting Group study.

Insurers and PBMs Have a Lot of Leverage to Hold Down Medicine Costs

Negotiating power is increasingly concentrated among fewer pharmacy benefit managers (PBMs).

Top 3 Market Share:

70%



Note: OptumRx and Catamaran merged in 2015. Their 2014 shares are shown combined.
Source: Drug Channels Institute.

Insurers determine:

FORMULARY
if a medicine is covered

TIER PLACEMENT
patient cost sharing

ACCESSIBILITY
utilization management through prior authorization or fail first

PROVIDER INCENTIVES
preferred treatment guidelines and pathways

Employers are increasingly demanding more transparency in PBM contracts

Supposedly, PBMs make their profit by charging employers administrative fees. If that was the case, theoretically, PBMs would be making nothing. But PBMs' reported profits are so high. It shows that they are making money in ways that are not disclosed.

– VP and CFO, Corporate HR Shared Services

It's hard to know if you are maximizing the value of your PBM contract. It's very conflicting and confusing. There are so many ways to contract with PBMs. There is no standard way.

– Director of Benefits

"The majority of employers are still using HR specialists to do negotiations and manage health care plans. Formularies are mostly based off of cost savings not clinical outcomes and most employers don't know how to ask the PBM the right questions. Contracts need to be reworded. What does it really say? How is it helping my business/ member? Employers should not engage in contracts they do not understand."

"As an employer, we learned that we are only getting 70% of our rebate dollars. We need to review our PBM contract language and if necessary, change it to demand more rebates get passed through."

"Our "suppliers" don't share contracts or disclose fees. Employers are starting to notice and wondering why they are paying so much. We need to ask intermediaries what they are paying each other and how they spent the money."

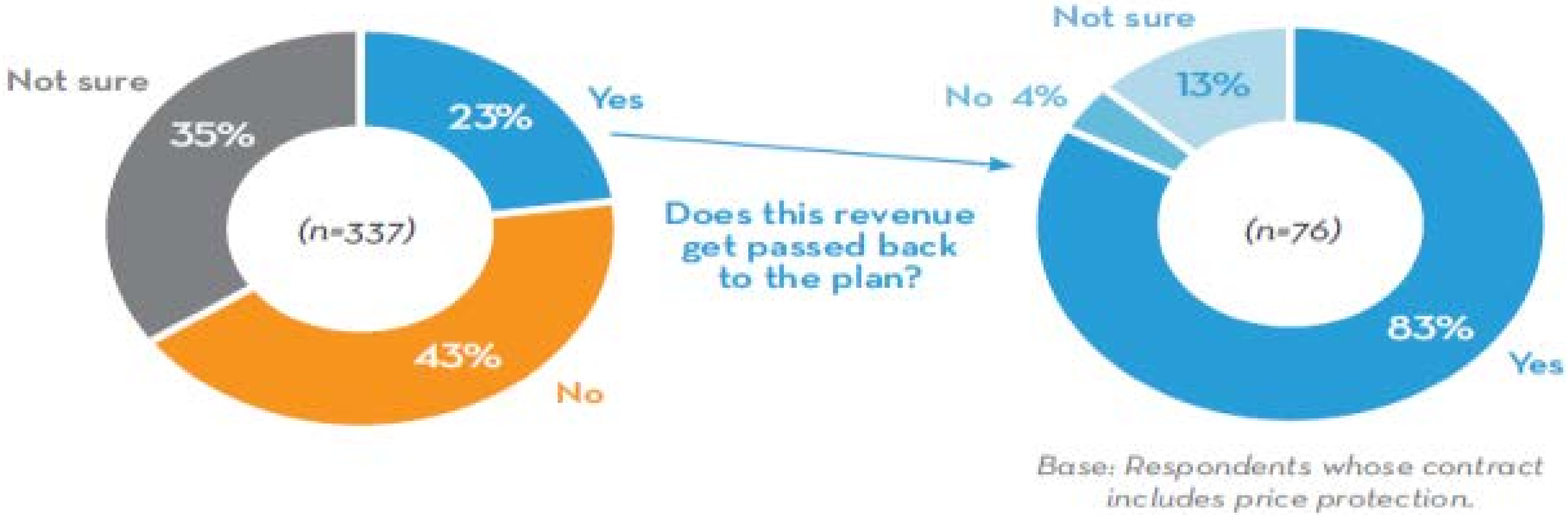
A properly designed, full pass through, transparent PBM/PBA is clean, audit-friendly and the best option for legal compliance, but most PBMs don't want to sell you a transparent contract. Traditional contracts are much more profitable.

- Mid-West Business Group on Health

Source: National Pharmaceutical Council study, Mid-West Business Group on Health white paper

Price protection is a standard feature in PBM contracts with manufacturers

Yet three fourths of employers report they do not have price protection provisions in their contracts -- or weren't sure if they did



Source: PBMI study

Drug Pricing Crisis and the Role of the Intermediary

How Did We End Up Here???

Susan Pilch, VP, Policy and Regulatory Affairs
National Community Pharmacists Association

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Contributing Factors……

- High deductible plans + high priced medications + consumer costs are driving increased demands for information
- Poorly understood drug supply chain and drug pricing systems
- Complete lack of awareness of hidden PBM revenue streams
- Plan sponsor dependence on PBMs to navigate drug pricing and supply chain coupled with lack of corresponding PBM fiduciary duty
- PBM influence on formulary and plan benefit design = tangible consequences on patient access to care and cost

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Independent Pharmacy Landscape

- Pharmacy owners, managers and employees of more than 22,000 independent community pharmacies across the U.S.
- Often located in underserved rural or urban areas (significant # of Medicaid beneficiaries)
- Independent pharmacies represent 52% of all rural pharmacies
- Over 1,800 independent community pharmacies operating as only retail pharmacy in their rural communities

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Independent Pharmacy Marketplace Realities

- Represented by PSAOs (Pharmacy Services Administrative Organizations) for contracting—attempt to gain some negotiating power
- Reality: PSAOs are no match against the Big 3 PBMs
- 2013 GAO Study (GAO 13-176): *"Over half of the PSAOs we spoke with reported little success in modifying certain contract terms as a result of negotiations. This may be due to PBMs use of standard contract terms and the dominant market share of the largest PBMs. Many PBM contracts contain standard terms and conditions that are largely nonnegotiable."*
- Big 3 PBM Size/Power only increased since 2013

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PBM Marketplace

- “Big Three” PBMs-Express Scripts, CVS Caremark and OptumRx control between 75-80 percent of the market
- All three companies are listed in top 22 of Fortune 500 and in 2013 PBM revenues were estimated at more than $250 Billion
- Significant market consolidation; CVS Caremark merger; ESI-Medco; Optum-Catamaran
- Big three PBMs are realistically the only choice for large plans
- PBMs contract with virtually every other entity in the drug supply chain—This data knowledge and sheer size = huge advantage

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PBM Influence in U.S. Supply Chain

- PBMs negotiate rebates with pharmaceutical manufacturers
- Rebate negotiations drive PBM formulary placement (ultimately determine what medications patients have access to AND at what cost share
- PBMs contract with employers and health plans to administer their prescription drug benefit and in doing so, heavily influence Rx benefit design—with no PBM fiduciary obligation
- PBMs own mail order pharmacies and mail order specialty pharmacies that directly compete with retail pharmacies (PBMs also dictate what competing retail pharmacies are reimbursed and what they may charge beneficiaries

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PBMs, Plan Benefit Design and Lack of Fiduciary Responsibility

- Employers rely on PBMs to help them navigate drug pricing and plan benefit design
- PBMs consistently take the position that they are not ERISA fiduciaries and very often contract away any fiduciary responsibility
- As a result, PBMs typically have no obligation to disclose any/all of their revenue streams OR that certain plan benefit designs may increase PBM profits perhaps at the expense of the plan sponsor
- <u>If PBMs were required to disclose these potential conflicts of interest, plan sponsors may make different economic decisions or be better equipped to drive a harder bargain</u>

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PBM Revenue Streams

- Revenue stream(s) derived from every supply chain participant
- Manufacturer rebates—what is a rebate?-access rebates vs. performance rebates—rebate “relabeling”)
- “Spread” profits—amount paid to pharmacy—different than amount charged to plan/employer on each prescription filled—not necessarily disclosed to plan
- PBM owned mail order/specialty pharmacies
- Prescriptions filled by plan members are often sold to manufacturers/data repositories. PBM may receive up to $1.00 per script

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PBM Influence and Retail Pharmacy

- PBMs contract with retail pharmacies to form pharmacy networks (network pharmacies compete with PBM mail order/specialty pharmacies)
- CVS Health-combination of PBM plus 2nd largest retail pharmacy chain. PBM side of the business has direct access to sensitive records of pharmacies in direct competition with retail chain
- PBMs determine pharmacy reimbursement amounts for Rx drugs dispensed through insurance coverage

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PBM Influence and Retail Pharmacy

- PBMs audit retail pharmacies (have access to detailed financial information and drug purchasing records)
- PBMs wield absolute control over pharmacy reimbursement for generics: Each PBM controls proprietary MAC lists—Brand name drugs have public benchmarks—These do not exist for generics…..

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MAC Pricing: PBM Proprietary Drug Pricing Standard

- Maximum Allowable Cost (MAC) lists are created by PBMs that determine the maximum amount they will reimburse a pharmacy for a generic or multi-source product
- No transparency to pharmacy or plan sponsor on methodology (different MAC lists for different plan sponsors) or how lists will be updated. Also use of one MAC list for pharmacy reimbursement (low) and one for plan sponsor (high)—PBM profit on “spread”
- Pharmacies sign contracts with virtually no information on generic pricing—only learn of reimbursement amount when claim is adjudicated (at point of sale)

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Pharmacy “DIR” Fees

- Retroactive reductions of pharmacy reimbursement often months after claim adjudication
- Part D program treats discounts (AT point of sale) and rebates (POST point of sale) differently for the purposes of the Part D bid. Financially advantageous for PBMs and plan sponsors to shift as much as possible to post point of sale
- Problem: Cost sharing obligations (patient and federal govt. are based on “negotiated price”—the amount paid by PBM to pharmacy at point of sale
- Ultimate price lowered after the point of sale—patient and government do not benefit!!

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Specialty Pharmacy

- Specialty pharmacy/specialty drugs = typically very high price medications
- Currently a PBM conflict of interest “flash point.” PBM-owned specialty pharmacies have significant incentive to capture these prescriptions
- Increasing incidence of PBMs terminating or declining network applications of independent specialty pharmacies, imposing excessive accreditation requirements and excessive audits
- Fed. Judge in ESI-Medco merger raised concerns about specialty conflicts of interest…….

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Moving Forward…….

- Current model dysfunctional with misaligned incentives
- Employers/payors searching for new models
- Direct contracting with pharmacies
- Outcomes based reimbursement
- Need for greater connectivity between Rx spend and medical spend—using Rx to stave off costly downstream medical intervention
- Renewed interest in capitalizing on expertise of pharmacists to stretch limited resources/services

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Rob Andrews

CEO

Health Transformation Alliance

Relationships and Competition in the Drug Channel System

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Federal Trade Commission
Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics
November 8, 2017

The opinions and views expressed in this report are those of the author and do not necessarily reflect the opinions or views of the organization to whom it is addressed.

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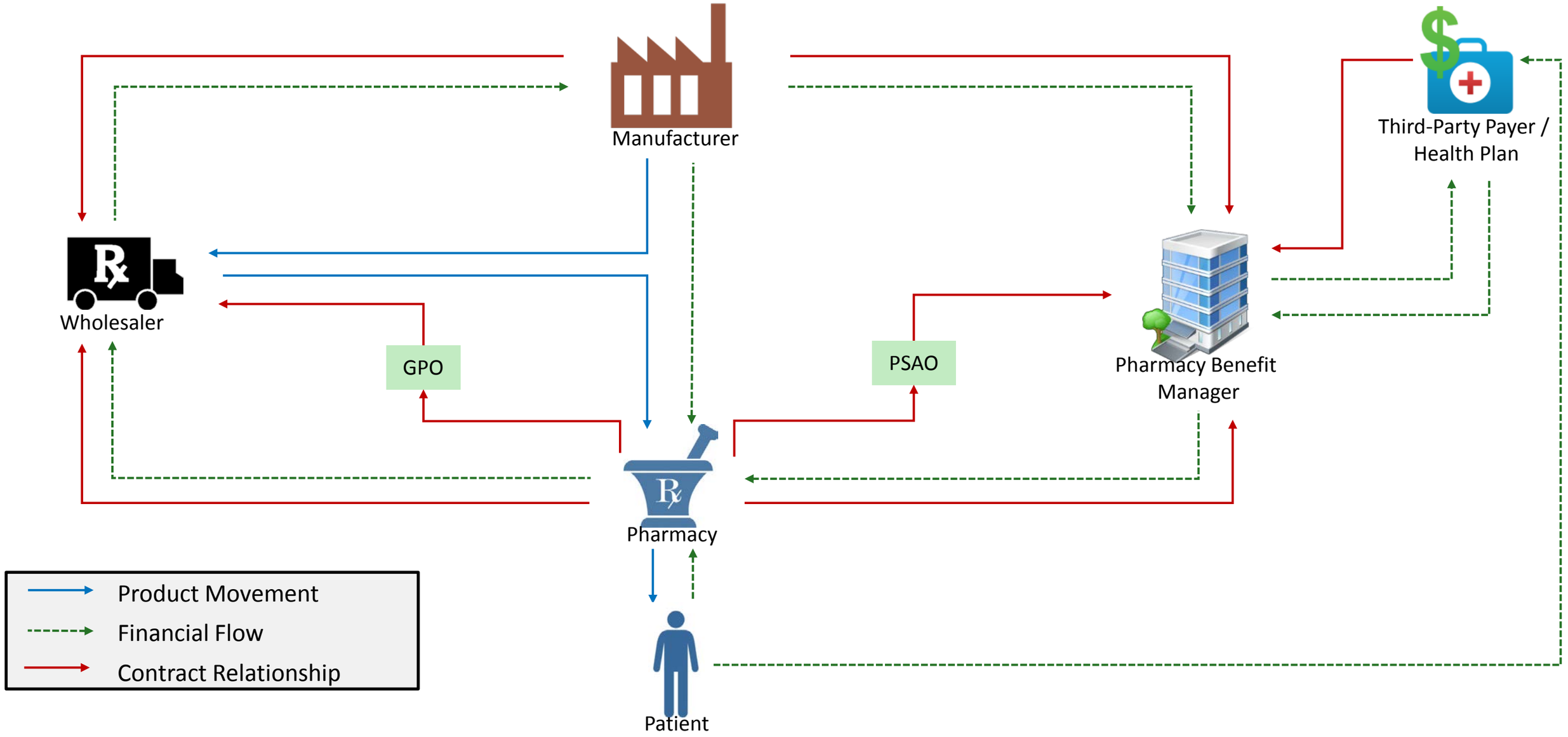
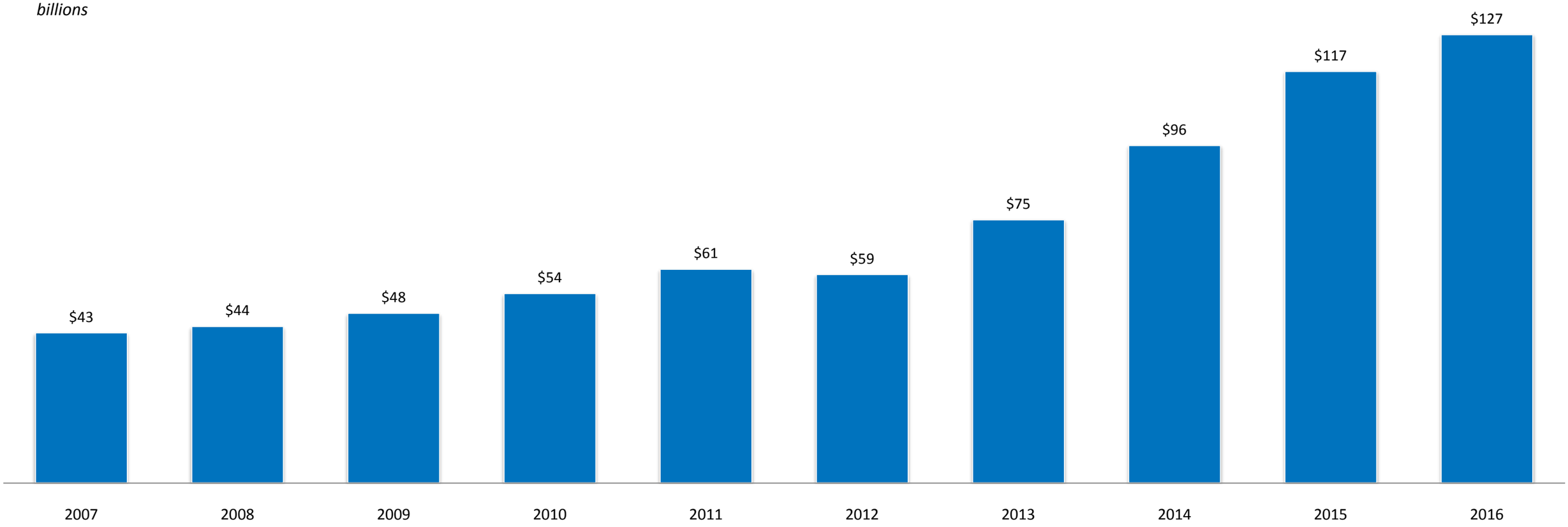
U.S. Distribution and Reimbursement System: Patient-Administered, Outpatient Drugs



GPO = Group Purchasing Organization; PSAO = Pharmacy Services Administrative Organization

Source: *The 2017 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers*, Drug Channels Institute, 2017. Chart illustrates flows for **Patient-Administered, Outpatient Brand-Name Drugs**. Please note that this chart is illustrative. It not intended to be a complete representation of every type of financial, product flow, or contractual relationship in the marketplace.

Total Value of Pharmaceutical Manufacturers' Off-Invoice Discounts, Rebates, and Price Concessions, 2007-2016



Source: Pembroke Consulting analysis of *Medicines Use and Spending in the U.S.: A Review of 2016 and Outlook to 2021*, QuintilesIMS, May 2017
See New Data Show the Gross-to-Net Rebate Bubble Growing Even Bigger, Drug Channels, June 2017

PEMBROKE CONSULTING

Understanding Competition in Prescription Drug Markets:

Entry and Supply Chain Dynamics

Panel 2: Understanding Intermediaries: Pharmacy Benefit Managers

Lunch

Understanding Competition in Prescription Drug Markets:

Entry and Supply Chain Dynamics

Panel 3: Understanding Intermediaries: Group Purchasing Organizations

Healthcare Group Purchasing Organizations (GPOs):

Reducing Costs and Increasing Competition and Innovation in the Pharmaceutical Market

Healthcare Supply Chain Association (HSCA)

Todd Ebert, R.Ph., President & CEO

November 8, 2017

HSCA
HEALTHCARE SUPPLY CHAIN ASSOCIATION

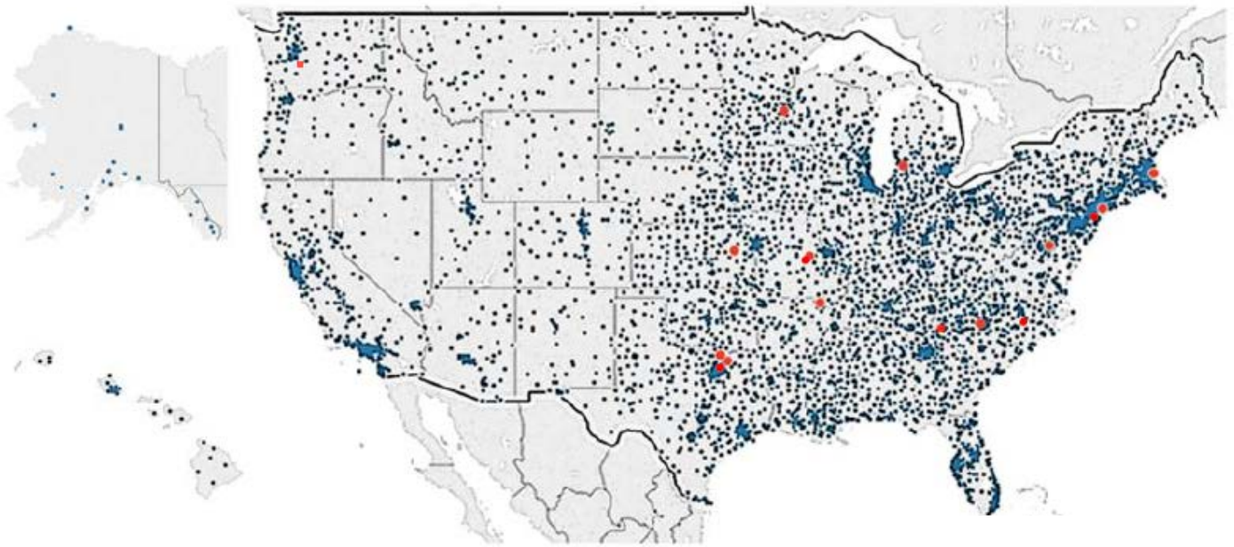
Overview: GPOs are Critical Sourcing and Cost-Savings Partners to Hospitals, Long-Term Care, Other Providers

For more than a century, healthcare group purchasing organizations (GPOs) have helped their healthcare provider partners **leverage purchasing volume to lower prices** on healthcare products and services, **which lowers costs for patients**, hospitals, payers, Medicare and Medicaid, and taxpayers:

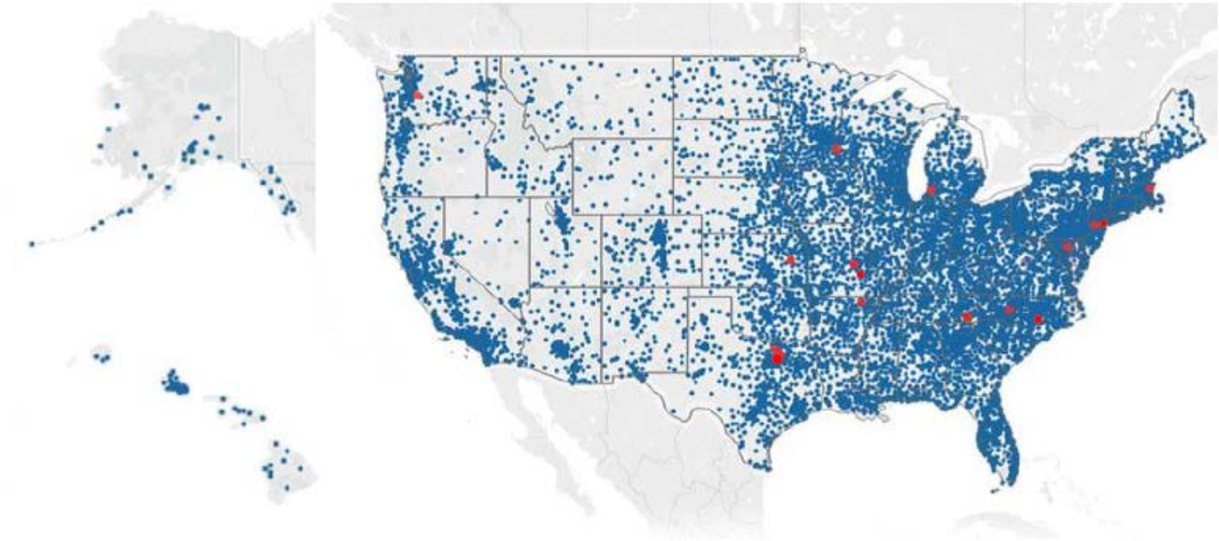
- The GPO mission is focused on **reducing healthcare costs**, **increasing competition and innovation**, **supporting transparency**, and **improving healthcare processes and outcomes**.
- Virtually **every hospital** and the vast majority of **non-acute care facilities** in the U.S. use a GPO.
- GPOs are **competitive** and GPO use is **completely voluntary** – providers can and do purchase off-contract, and GPO use is **driven by value provided**.
- Product decisions are **made at the facility level**, with member input and support groups for all disciplines.
- GPOs have processes in place to **identify innovative and breakthrough products** and help them to market.
- The average GPO contract administrative fee is **1.22% to 2.25%.** *(Source: US Government Accountability Office)*

At a Glance: Virtually All Hospitals and the Vast Majority of Non-Acute Care Facilities Use a GPO

The Healthcare Supply Chain:
Map of 7,000+ U.S. Acute Care Providers
98% of all U.S. Hospitals Utilize a GPO



The Healthcare Supply Chain:
Map of 68,000+ U.S. GPO-Member Non-Acute Care Providers
Including long-term care providers, clinics, surgery centers, home health providers, and more.



● GPO Member Providers
● HSCA Member Headquarters
Andover, MA | Asheville, NC | Brentwood, TN
Charlotte, NC | Elkridge, MD | Irving, TX (2)
Middleville, MI | Mission, KS | New York, NY (2) Plano,
TX | Seattle, WA | St. Louis, MO (2)|St. Paul, MN

Source: Definitive Healthcare

GPOs Reduce Costs for Hospitals, Healthcare Providers, Medicare and Medicaid, and Taxpayers

A broad range of empirical and academic research finds that GPOs reduce costs for healthcare providers:

- GPOs reduce healthcare costs; providers realize **savings of 10% to 18% by using GPOs**; these savings are likely to be especially **valuable to smaller, rural hospitals**; and providers **pass these savings onto patients and ultimately to taxpayers**. *(Leibowitz, O'Brien, 2017)*
- GPOs save the U.S. healthcare system up to **$55 billion annually**, up to **$864.4 billion over ten years**, and up to **$229 billion in Medicare**- and **$169 billion in Medicaid** savings over the same period. *(Dobson DaVanzo, 2014)*
- Approximately **90% of hospitals are satisfied with their GPO**, and **88% agree that GPOs reduce costs**. *(American Hospital Association, Association for Healthcare Resources & Materials Management, Wharton School, 2014)*
- GPOs save the U.S. health care industry **$36 billion dollars annually** and create an **additional $2 billion in annual savings** associated with human resources uncommitted to the purchasing process, according to a study of 400+ hospitals. *(Schneller, 2009)*
- GPO contract **administrative fees have no effect** on the total purchasing costs of any provider. *(Purdue University, Krannert School of Management, 2011)*

GPO U.S. Cost Savings:

Up to **$55 billion** annually

Up to **$864 billion** over ten years

Up to **$229 billion** in Medicare savings and **$169 billion** in Medicaid savings over 10 years

$2 billion in annual savings on human resource costs

10%-18% average savings

Former FTC Chair Jon Leibowitz and Deputy Director Dan O'Brien Affirm GPO Cost Savings, Competition

In 2017, Former FTC Chair Jon Leibowitz and former FTC Deputy Director of the Bureau of Economics Dan O'Brien conducted a comprehensive economic and legal analysis of the role, business model and impact of GPOs and found that:

- GPOs **save money** for healthcare providers, patients and taxpayers.
- GPOs operate in a **vigorously competitive** procurement market.
- The current GPO vendor funding model is **consistent with competition and cost savings**.
- Changing the GPO vendor funding model **would likely raise costs**.

"We find no empirical, economic or policy basis for forcing GPOs to shift to an alternate funding mechanism."

- Leibowitz, O'Brien, Anello, 2017.

Source: Leibowitz, O'Brien, Anello, "Group Purchasing Organizations: How GPOs Reduce Healthcare Costs and Why Changing their Funding Mechanism Would Raise Costs," 2017.
Funded by the Healthcare Supply Chain Association

GPOs Operate in a Highly Competitive Market

The 2017 Leibowitz/O'Brien study found that GPOs **operate in a highly competitive market**. Specific conclusions about the competitive nature of the GPO market included:

- **More than 100 national, regional and local GPOs and regional cooperatives compete with each other** to provide GPO services;
- The GPO market operates with a level of competition equivalent to an unconcentrated market with **more than 10 independent competitors** of equal size;
- Providers can **choose from multiple GPOs** and also can, and commonly do, **use multiple GPOs simultaneously**. On average, providers use between 2-3 GPOs;
- Providers often control their own GPO, which creates **strong incentives to offer competitive pricing**;
- Providers can **purchase from a competing GPO** or **procure supplies directly from vendors**;
- Intense competition suggests that the vendor-fee model is **more efficient than other models.**

Source: Leibowitz, O'Brien, Anello, "Group Purchasing Organizations: How GPOs Reduce Healthcare Costs and Why Changing their Funding Mechanism Would Raise Costs," 2017.
Funded by the Healthcare Supply Chain Association

GPO Safe Harbor, Model, and Oversight

Congress included the **GPO Safe Harbor** in its **Medicare and Medicaid Patient Protection Act of 1987** to protect the cost-savings and efficiencies realized through lawful GPO practices.* The provision did not initiate any new business practices, it merely clarified that existing GPO business practices were lawful:

Pursuant to the GPO Safe Harbor:

- GPOs have **written contract** with each member;
- GPOs disclose that an administrative fee is collected, and **any fee above 3% must be specifically identified in the contract agreement**;
- GPOs **report annually** to members on all administrative fees collected from GPO contract use;
- GPOs **make all fee information available** at the request of the Secretary of Health and Human Services;
- Hospitals must **report GPO fee distributions as part of Medicare cost reports** and GPOs encourage hospitals to accurately reflect fee information in these reports.

Business model and oversight:

- **GPO Safe Harbor not unusual** – 1 of 23 provisions in 1987 Act addressing a range of lawful business practices;
- **Vendor funding model likely reduces transaction costs** and neither empirical evidence nor economic theory suggests that vendor fees raise prices;
- Industries leveraging group buying/vendor fee model include **government procurement** (DOD, VA), **food service**, **online marketplaces** (Amazon, eBay, Living Social), **consumer credit**, **hospitality** and **non-profit industries**;
- GPO model and business practices thoroughly reviewed by **FTC**, **GAO**, **DOJ**, **U.S. Supreme Court**, **8th Circuit Court of Appeals**, academia, and hospitals, and all have concluded that no change is needed.

Source: Kusserow, Herrmann, "Activities and Perspectives of the Office of the Inspector General in the U.S. Department of Health and Human Services Regarding Group Purchasing Organizations (GPOs)," 2013.

GPOs are Most Transparent Sector in Healthcare

The **Healthcare Group Purchasing Industry Initiative (HGPII)** is an independent, voluntary organization founded by the chief executives of healthcare GPOs who believed industry **should collectively demonstrate a strong commitment to transparency and ethical values**. HGPII promotes the development of transparency and accountability standards and ethical business practices, and all HSCA members are also members of HGPII.

- Members submit to **annual independent review** of business practices;
- Comprehensive industry reviews conducted by former **U.S. Representative Phil English** (R-PA) and former **U.S. Senator Byron Dorgan** (D-ND);
- Participating GPOs consistently found to have **high ethical standards** and **business practices that promote innovation**, **transparency** in bidding process, and **compliance;**
- Every HGPII member actively promulgates and enforces a **code of conduct** to ban conflicts of interest;
- GPOs offer an **independent grievance process** to suppliers through the American Arbitration Association;
- All **GPO contracts are voluntary** and the product of **competitive market negotiations**.

For more: www.hgpii.com

GPOs Taking Steps to Eliminate Drug Price Spikes & Shortages

Price spikes for critical generic drugs and ongoing prescription drug shortages continue to jeopardize patient access to care. **Healthcare GPOs are working vigorously with regulators, providers, manufacturers and distributors** to ensure a safe and reliable supply of product, and are **taking a number of innovative steps to help increase competition in the market**, **avoid generic drug price spikes**, and **eliminate prescription drug shortages**, including:

- Policy advocacy to increase competition (e.g., expedited FDA review, closing REMS loophole, biosimilars, etc.)
- Supplier price adjustments to contracts to reflect market conditions (e.g., raw materials shortages)
- Data tracking to anticipate shortages
- Work with suppliers and providers to understand supply issues, and to identify alternative suppliers and products as appropriate
- Manufacturer reliability evaluation
- Increased supplier-provider communication
- Identification of additional manufacturers for products in shortage and help bringing them to market
- Migration to alternative products where available
- Failure-to-supply clauses to ensure that suppliers meet contract requirements

GPOs Evolving and Expanding Offerings to Help Providers Confront New Challenges

Because efficiently and effectively driving cost-savings required complementary services, GPOs **evolved and expanded their offerings to meet member needs**, including:

- Data analysis and benchmarking
- Market research
- Innovative technology integration
- Infection control
- Electronic product tracking
- Developing communities of knowledge to share best practices

The healthcare industry is complicated, fast-moving, and dependent on a wide range of external dynamics. GPOs are **on the front lines of helping providers successfully confront key trends and challenges**, including:

- Emergency preparedness & natural disaster response
- Patient safety and improved patient outcomes
- Energy management
- Drug utilization management
- Value-based purchasing

Role of Wholesalers/Distributors in Pharmaceutical Supply Chain

- Deliver drugs, medical supplies and durable medical equipment from pharmaceutical manufacturers to downstream purchasers such as pharmacies, hospitals, long-term care facilities and clinics

- Conduit for medicines to travel from manufacturer to patient

- Over 93% of pharmaceuticals in the U.S. flow through primary distributors

The U.S. Pharmacy Distribution and Reimbursement System for Patient-Administered, Outpatient Prescription Drugs

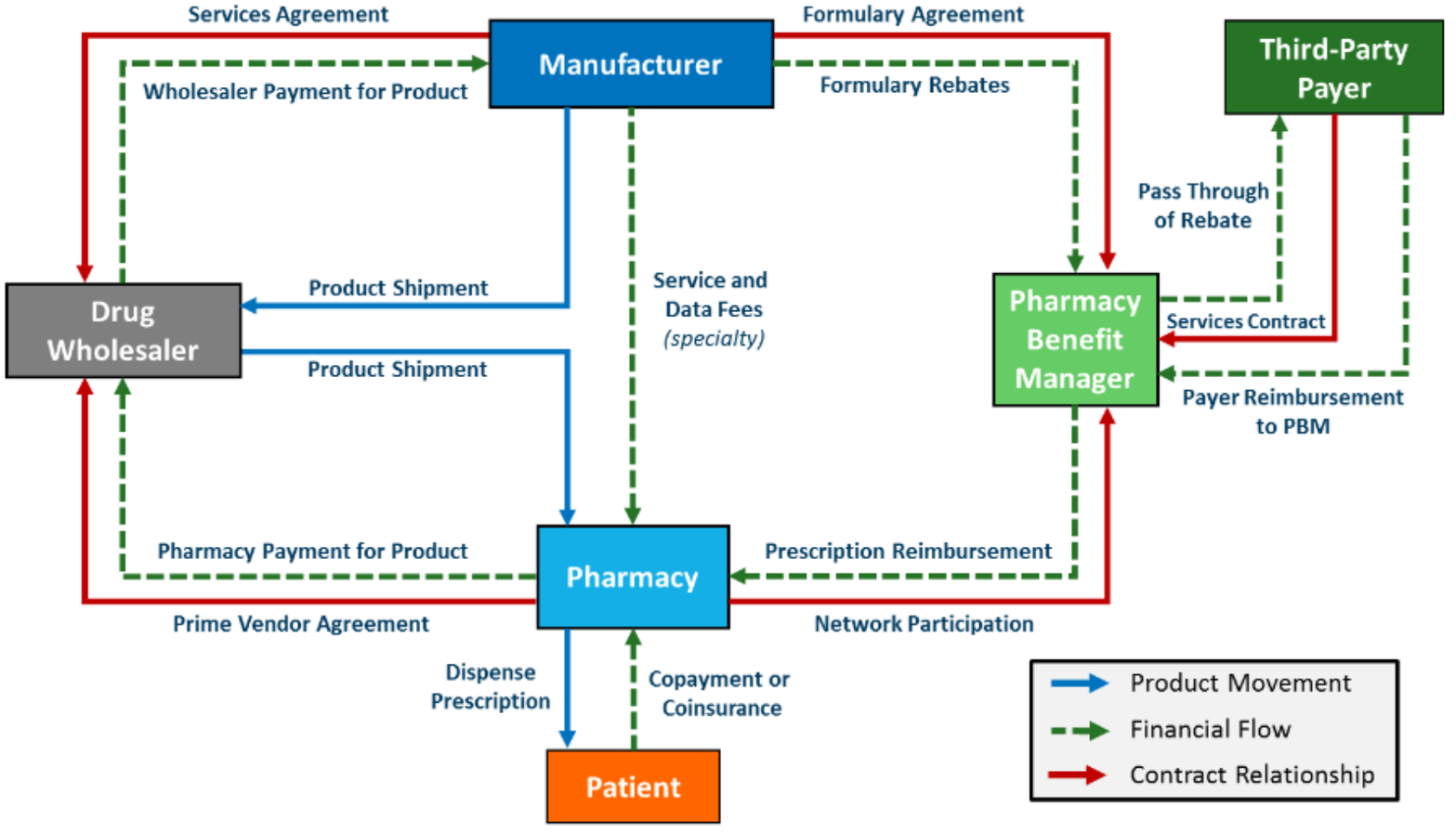


Chart illustrates flows for patient-administered, outpatient drugs. Please note that this chart is illustrative. It is not intended to be a complete representation of every type of financial, product flow, or contractual relationship in the marketplace.
Source: Fein, Adam. J., *The 2016 Economic Report on Retail, Mail and Specialty Pharmacies*, Drug Channels Institute, January 2016.
(Available at http://drugchannelsinstitute.com/products/industry_report/pharmacy/)

Role of Wholesalers/Distributors in Pharmaceutical Supply Chain

- Focus significant resources on the safety and security of the supply chain
  - Secure supply chain efforts may be most important service distributors provide to overall pharmaceutical delivery system
  - Healthcare Distribution Alliance (HDA) integral to passage of Drug Supply Chain Security Act (DSCSA)

- “One stop” ordering for all drugs/medical supply needs
- Allows providers to have “just in time” drug inventories

Distributor/Wholesaler Services & Compensation

- Distributors provide a variety of services to pharmaceutical manufacturers and their downstream customers
  - Receiving orders & shipping products is a safe and efficient manner
  - Inventory management
  - Reporting as to where manufacturer products are utilized
  - Chargeback management related to direct agreements between manufacturers and downstream customers/GPOs and for government programs like the VA/FSS program and the 340B program

Distributor/Wholesaler Services & Compensation

- Bona Fide Service Fees
  - Itemized services provided to manufacturers
  - Manufacturers would otherwise perform/contract for in the absence of the arrangement
  - Fair Market Value
  - Not passed on in whole or in part to downstream customers

- Fees tend to be itemized per service rather than one aggregated amount and percentage of Wholesale Acquisition Cost (WAC)-based

Distributor/Wholesaler Services & Compensation

- Distributors do not profit from manufacturer WAC increases for existing inventory

- Most distributor agreements with manufacturers mandate price appreciation credits be provided to the manufacturer when the manufacturer increases WAC for a product related to the distributor’s existing inventory for such product

- Service-fee model not arbitrage model of compensation/profitability

Role of Wholesalers/Distributors in Drug Pricing

- For branded products, purchase at WAC and sell to downstream customers at WAC

- Manufacturers set the WAC prices for their products; wholesalers are not privy to how such WAC pricing decisions are made
  - WAC is the “list price” and does not include rebates, discounts or adjustments from proprietary negotiations between manufacturers and distributors, GPOs or other customers
  - WAC is published in various compendia including Medi-Span and First DataBank

Role of Wholesalers/Distributors in Drug Pricing

- Generics drug pricing is more complicated; generics are commodities

- Distributors may sell generic drugs to downstream customers based on WAC or they may price generic drugs to downstream customers in response to the market considering-
  - Supply of competing generic drugs
  - WACs for the competing generic drugs

Generic Sourcing Programs

- Distributors may offer generic sourcing programs/pricing to some customers
- Negotiate with generic drug manufacturers to purchase all requirements for certain classes of generic solely from manufacturer in exchange for discounts/rebates
- May provide some or all of the discounts/rebates to downstream customers in exchange for exclusivity or volume commitments related to generics

Intersection of Distributors & GPOs

- Distributors do not typically have direct agreements with GPOs
- Manufacturers may have agreements with GPOs to sell certain drug products to GPO members at a discount; may have purchasing and volume commitments
- GPO members still acquire drugs through distributors and distributors process chargebacks to manufacturers for the difference between WAC and the Member’s discounted price of a drug under the manufacturer/GPO agreement

Intersection of Distributors & Pharmacies

- Joint Ventures/Buying Groups
  - Walgreens Alliance Boots/AmeriSourceBergen
  - McKesson/Wal-Mart
  - Cardinal/CVS

- Exclusivity/volume commitments on generic drugs and substantial discounts on generics for the purchasing pharmacies

Medication Access – Perspective from a Purchaser

Erin R. Fox, PharmD, BCPS, FASHP

HEALTH
UNIVERSITY OF UTAH

@foxerinr

DISCLOSURE

- This presentation represents my own opinions
- University of Utah Drug Information Service receives funding from Vizient (a GPO) to provide drug shortage content
- University of Utah Health is Vizient member

CHALLENGES FROM A PURCHASER'S PERSPECTIVE

- Drug shortages
- Few choices due to sole source products
- No transparency to make good choices
- What is the price?

DRUG SHORTAGES OF ESSENTIAL PRODUCTS

- Hospitals struggle to purchase basics
  - Mainly generic injectables
- Shortage definition: a supply problem that
  - Changes preparation
  - Requires prescribers to use an alternative
  - Delays therapy
  - Results in patients going without treatment

Mayo Clinic Proc. 2014.89(3):361-373

WHAT HAPPENS DURING A SHORTAGE?

- Pharmacists find alternatives
- Patients prioritized, care is rationed
- Huge labor costs to change electronic medical records, switch products in automation
- Medication errors
- Patient harm

INCREASED LABOR

- Lose entire supply with a single recall

- Switching to IV push due to minibag shortage required review and changes to 700 electronic treatment plans (for just 2 drugs)

Photo credit: Erin Fox

Kaakeh R et al. AJHP. 2011;68:1811-1819

FRAGILE SUPPLY CHAIN

- Poor quality, manufacturing problems, delays
- Few suppliers
  - More than 1/3 of products have just 1 or 2 suppliers
- Limited capacity
  - No redundancy or back up plans
  - Concentrated, just in time production (24/7)
- Business drives decisions (profits, costs to fix, prioritizing new opportunities, contracts)

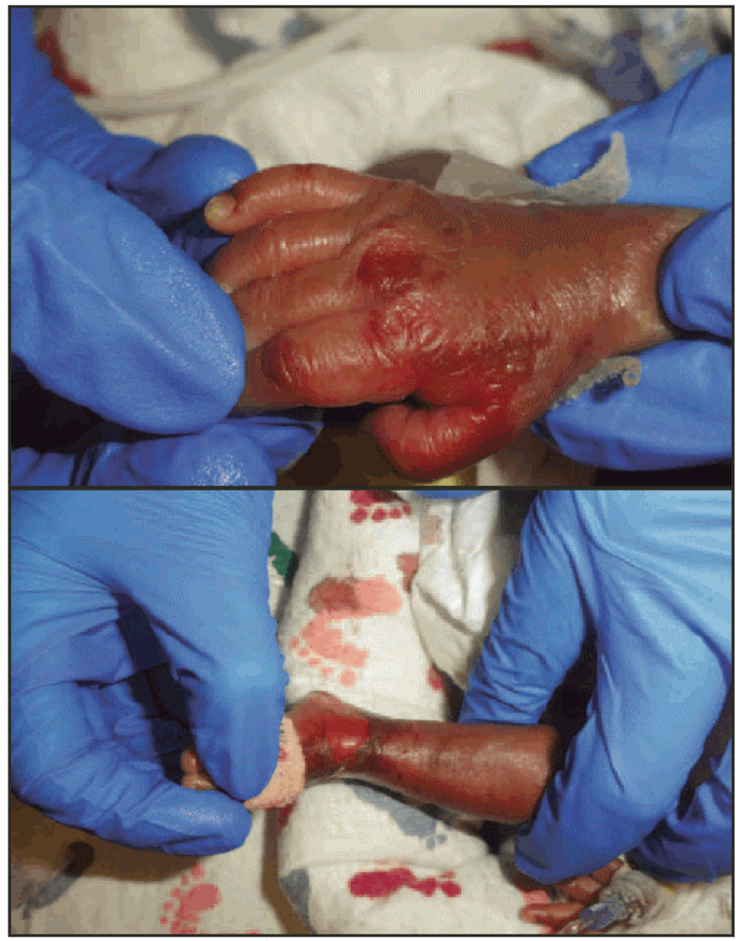
http://www.gao.gov/products/GAO-16-595

Clin Pharmacol Ther. 2013;93:170–176

POOR QUALITY LEADS TO HARM

Warning letter (2011) to key supplier of critical electrolytes outlined years of deficiencies

- Calcium
- Phosphates
- Trace elements
- **Zinc**
  - **Shortage = dermatologic adverse events for premature infants**



Zinc shortage - 2012

Photo/S.A. Norton, Children's National Medical Center

MMWR. February 22, 2013;136-137.

SOLE SOURCE / NEAR SOLE SOURCE PRODUCTS

- Single firm often produces 90% of total supply – common to have sole source raw materials
- What limits competition and new entrants?
  - Low use products
  - Practice changes
  - Approval backlog?
- Are FDA recommendations / public health considered during mergers?
- Are essential medications critical infrastructure?
  - Cancelled surgeries

https://www.blumenthal.senate.gov/imo/media/doc/Letter%20to%20FTC%20on%20Pfizer%20Drug%20Shortage.pdf

SOLE SOURCE PRODUCTS

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CAN YOU PURCHASE FOR QUALITY?

- FDA makes warning letters and 483 inspections public, but names of drugs are redacted
- No requirement to disclose which company actually makes a product, or manufacturing site
- Purchasers can't follow the data to spend their limited dollars wisely
- FDA Quality Metrics program is voluntary, not public
- Few data available for higher risk 503b compounders

https://www.fda.gov/downloads/drugs/guidances/ucm455957.pdf

WHAT IS THE PRICE?

- It depends...
  - AWP (average wholesaler price)
  - WAC (wholesale acquisition cost)
  - ASP (average sales price)
  - AMP (average manufacturer price)
  - MAC (maximum allowable cost)
  - 340B
  - GPO (group purchasing organization)
  - Contract

TAKEAWAYS

- Shortages mean hospitals don't have critical medications needed for patient care
- Purchasers have few choices due to sole suppliers and consolidation
- Quality problems are concerning, but not transparent
- Drug pricing is complicated

Conflict of Interests: Does GPO Compensation Lead to Higher Drug Prices?

Hal J. Singer

FTC Prescription Drug Market Competition Workshop

Nov. 8, 2017

Original Research

- “The Budgetary Impact of Eliminating the GPOs’ Safe Harbor,”(2006) (funded by MDMA)
- “Broken Compensation Structures and Health Care Costs,” Harv. Bus. Rev. (2010)
- “Assessing Bundling and Share-Based Loyalty Rebates: Applications in the Pharmaceutical Industry, J. Comp. L. & Econ. (2012) (with Kevin Caves)
- “An Empirical Analysis of Aftermarket Transactions by Hospitals,” 28 J. Contemp. Health L. & Pol’y 23 (2012) (with Robert Litan & Anna Birkenbach)

Relevant (and Irrelevant) Questions

- Relevant Q: Would a change in the GPO ***compensation structure*** lead to lower supply costs for member hospitals?
  - Compensation is from suppliers, not their member hospitals
  - GPOs enjoy exemption to the anti-kickback statute of the Social Security Act, which makes it illegal to receive any compensation from suppliers for items reimbursable by federal health care programs
  - Theory of harm in RTI v Becton Dickinson (E.D. Tex 2003)
- Irrelevant Q: Do GPOs reduce health care prices relative to a world without GPOs?
  - In theory (though not proven), GPOs lower prices relative to individual negotiations by hospitals due to (1) bargaining power and (2) transactions costs
- Two questions blur only if you believe there is no alternative to current compensation structure
  - GAO (2014): Hospital consolidation + use of aftermarket subscription services suggest GPOs would survive
  - GPOs survived for ~80 years without supplier-side funding

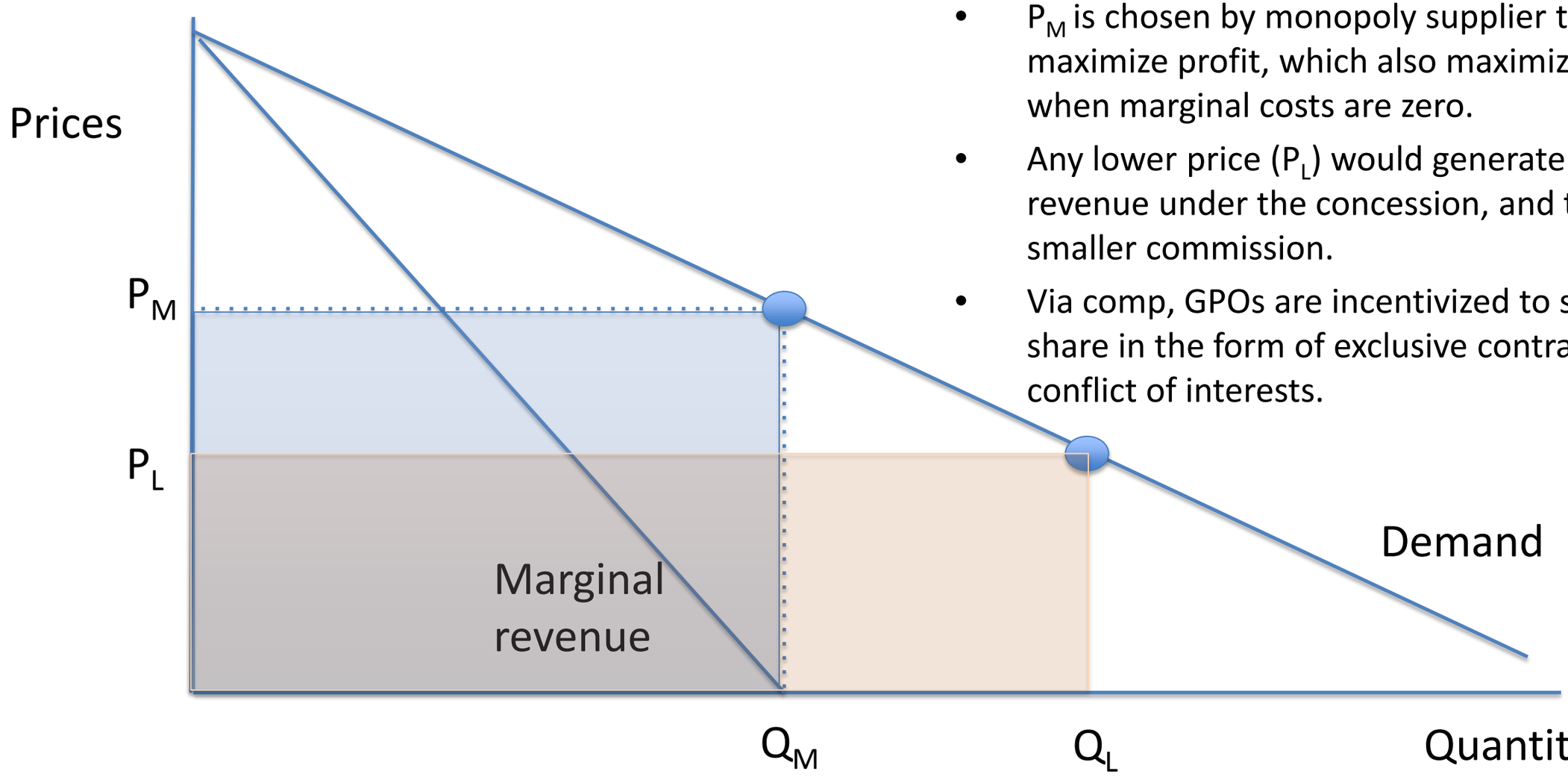
Monopoly Concessions in Other Industries

- Municipalities grant concessions to cable service providers, funded by franchise fees
  - DOJ (2007-08) recognized conflict of interests; sent *ex parte* letter to FCC, sent letters to nine states considering statewide franchising legislation, and issued a report on video competition
- Prisons grant concessions to single provider of long distance service, funded by "site commissions" (aka kickbacks)
  - Average cost of 15-minute call in states (37) that allow kickbacks: $2.40
  - Average cost of 15-minute call in states (14) that don't allow kickbacks: $1.58
    - *Source*: www.prisonphonejustice.org

Testimonials

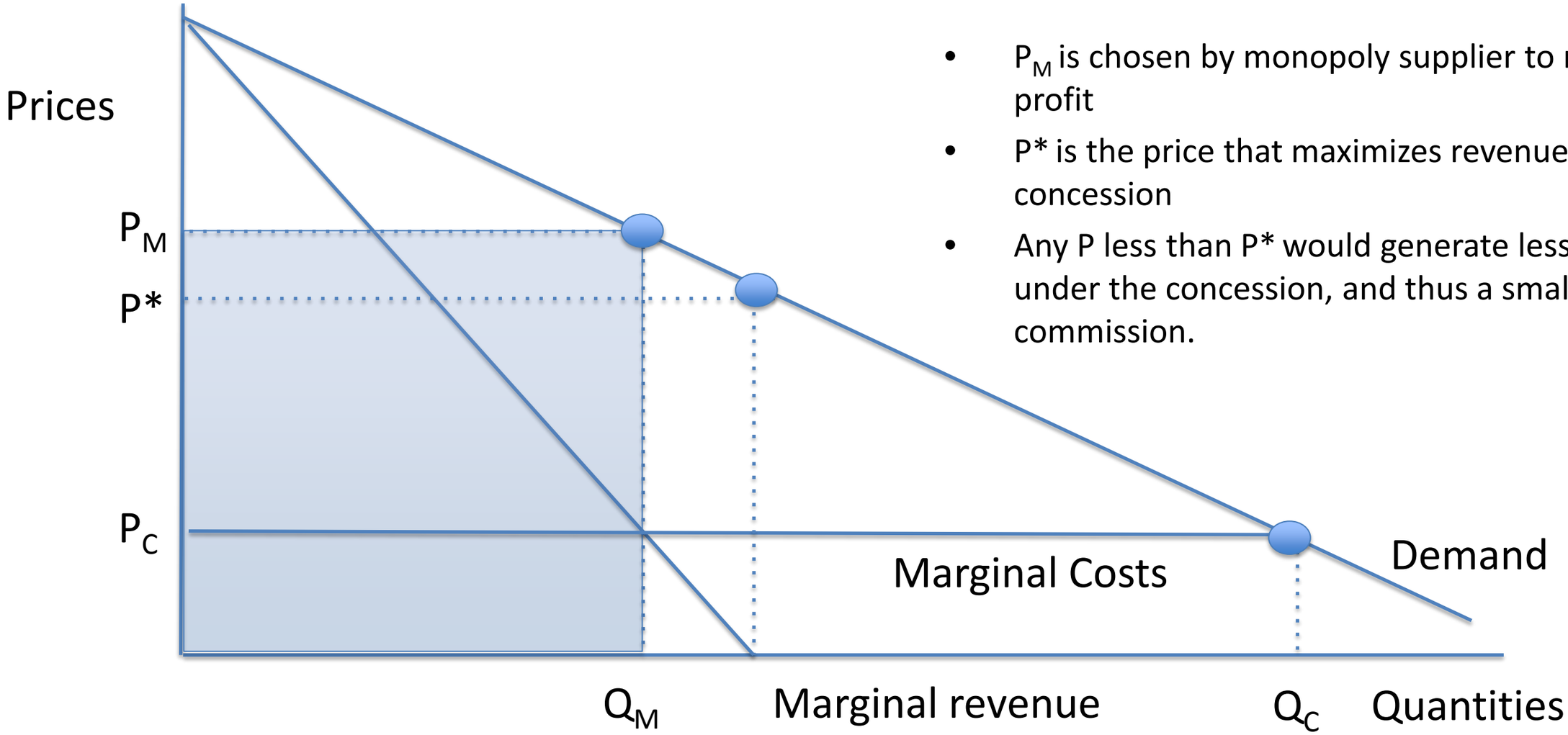
- Healthcare Matters Principal Editor Thomas Finn: “As a member-driven enterprise, it is common knowledge that Premier [the second largest GPO] and other **GPOs ‘share back’** with their members and owners. In fact, many hospital executives who are part of the Premier alliance have learned to rely on that share back as an integral part of their annual compensation.”
  - Healthcare Matters, July 22, 2013
- Asst. Secretary of HHS Koh under President Obama: “First of all, these agreements are made often through these long-term contracts and so also this whole process involves multiple stake-holders, especially and including the pharmacy benefit managers and the **group purchasing organizations**. So it complicates this environment and sort of does not make relevant the sort of standard supply and demand economic principles that we see in other businesses.”
  - Testimony before the September 23, 2011 House Energy & Commerce Committee

When Buying Agent Is Compensated by a Fixed Percent of Revenues from Supplier, and Marginal Costs Are Zero, Best to Grant a Monopoly



- P_M is chosen by monopoly supplier to maximize profit, which also maximizes revenue when marginal costs are zero.
- Any lower price (P_L) would generate less revenue under the concession, and thus a smaller commission.
- Via comp, GPOs are incentivized to sell market share in the form of exclusive contracts—a conflict of interests.

Even When Marginal Costs Are Positive, Best to Avoid Competitive Rates



- P_M is chosen by monopoly supplier to maximize profit
- P* is the price that maximizes revenue under concession
- Any P less than P* would generate less revenue under the concession, and thus a smaller commission.

Key Findings of Litan, Singer & Birkenbach (2012)

- When brokered by an agent ***not compensated by suppliers***, hospitals enjoy an average price reduction of 10-14% from 2001 through 2010
  - Each additional rival bid dropped price significantly
  - Incumbent dropping its own bid decreased auction price significantly
  - Anecdotal evidence (e.g., Masimo/pulse oximeters) where price effect from ***entry*** is much larger
- Implication: Consistent with claim that, due to incentive distortion, GPOs are not securing competitive price for their hospital members

Other Potential Harms of Funding Mechanism

- Compared to direct payment of rebates by manufacturers, lump-sum payments of rebates from GPOs is less commonly credited by hospitals to individual medical device purchases on their cost reports to government
- GAO (2014) at 21: “To the extent that administrative fee revenue is not reflected on cost reports, Medicare could be overpaying hospitals.”

Criticisms: Johnston & Rooney (2012)

- Large, high-value products are not representative of all products purchased by GPOs (at 83); aftermarket purchases are more "definite" (at 83), exhibit greater "commitment" (at 84)
  - Caveat our findings by saying that apply to these types of purchases, which account for 20% of all GPO purchase; also, 20% is not a small sample;
  - No reason that a kickback regime would inflate the cost of high-value products but not low-value products; economic incentives are to maximize revenue regardless of product type
  - While there may be uncertainty over units purchased by *single* hospital pursuant to GPO contract, purchases across *all* hospitals within GPOs are more certain
- See appendix for more rejoinders

Criticisms: O'Brien, Leibowitz & Anello (2017)

- Findings do not suggest price differential can be attributed to GPO funding model (at 6)
  - But to what other feature of GPOs could the price differential be attributed?
  - Subscription-based aftermarket services are a reasonable proxy for outcomes with an alternative funding mechanism
- Because tax incidence is neutral with respect to where tax is levied, funding source doesn't matter (at 9)
  - Not applicable because tax revenues to be collected in econ textbooks are assumed to be *exogenous*; in case of GPOs, fees collected under the concession are *endogenous*—that is, they depend on the number of suppliers, which is within the GPO's domain
  - If the funding model doesn't matter, then why do they care enough to hire consultants to keep it the same way?
- See appendix for more rejoinders

Do These "Incentive Distortions" Apply to Prescription Drugs?

- In one sense, prescription drugs are more differentiated than devices, which suggests GPOs are not needed to maintain pricing power
- But there are still ways in which a GPO could put upward pressure on drug prices
  - Brokering a bundled contract to prevent entry on "tied" product
  - Agreeing to stock only one Hep C drug in hospital pharmacy, limiting brand-to-brand competition
  - Sole-source contracts for generic drugs means major drug makers that don't get contracts may and have discontinued production; when shortages hit, the price increases have been astronomical
- A hospital might be able to get by with an inferior medical device, as long as they have one, but they can't get by without a lifesaving generic injectable drug if it is in short supply and there is no acceptable substitute

Price Effects

- Bundling brokered by Physician Buying Groups shown to inflate price of pediatric vaccines
  - To induce Sanofi purchasers to switch to Novartis' Menveo vaccine, Novartis would have to pay a negative price (i.e., compensate the physician practice) for losing the bundled discount (Caves & Singer 2012)
- Anecdotal evidence from Physicians Against Drug Shortages (PADS)
  - "One member who practices at a surgicenter that does NOT buy through GPO contracts reports that his facility currently pays $22 for a 10-vial box of propofol, compared with $55 at another member's GPO-affiliated surgicenter."
  - "Another PADS member found that she could have purchased over-the-counter supplies, such as Advil, bandages, and cotton balls, from Costco for up to 50% less than what her health system was paying through its GPO contracts, but her superiors wouldn't allow her to do so."

Output Effects

- GPO contracting practices have been blamed for drug shortages
- GPO's tax on drug makers could lead to smaller inventories or discontinued production of some drugs, particular for **low-margin generics** (Moss 2012; Kweder & Dill 2013; Schweitzer 2013; FDA 2011; House of Reps. 2012)
- After reviewing literature and interviewing industry participants, GAO identified GPOs as one of three "underlying causes" in drug shortage (GAO Feb. 2014)
    - Other causes include competition based primarily on price (interwoven with GPO), and change in Medicare Part B reimbursement policy
    - Med Part B alt hypothesis discredited by former HHS Secretary Glied (2014) (explaining that the change in the reimbursement formula has never regulated either the level of prices paid to manufacturers or the flexibility of those prices)

Conclusions

- Removing exemption to the anti-kickback provision would benefit health care consumers by:
  - Lowering drug (and medical device) prices
  - Reducing entry barriers/fostering greater innovation in medical supply industries
  - Alleviating drug shortages

Appendix

Criticisms: Johnston & Rooney (2012)

- Policy prescription would benefit the medical device industry (at 73)
  - But fixing perverse incentives would engender more competition for the GPO contract, eroding margins in upstream industries
  - Device industry not uniformly impacted: Status quo favors incumbents (Advamed), penalizes entrants (MDMA)

- Self-funding would result in higher net outlays for hospitals (at 75)
  - Only true if the requisite administrative fees exceed the hidden costs that manifest in the form of inflated supply prices

- Some or all of the fees are returned to the hospitals via distributions (at 82)
  - But fees (around 2% of price) likely do not compensate for the overcharges on the underlying products (> 10 %)
  - GPOs distribute only 70% of total revenue to members (GAO 2014)
  - And even if they did, distributions to equity members do not compensate non-equity members

- Large, high-value products are not representative of all products purchased by GPOs (at 83); aftermarket purchases are more "definite" (at 83), exhibit greater "commitment" (at 84)
  - Caveat our findings by saying that apply to these types of purchases, which account for 20% of all GPO purchase; also, 20% is not a small sample;
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  - While there may be uncertainty over units purchased by *single* hospital pursuant to GPO contract, purchases across *all* hospitals within GPOs are more certain

Criticisms: O'Brien, Leibowitz & Anello (2017)

- Member ownership ensures GPO acts in hospitals' best interest (at 6)
  - Economists recognize agency problems (small stakes, information asymmetry); they aren't eliminated by vertical integration
  - GPO administrators' compensation is funded via hospital *expenditures*, not savings

- Ability to seek lower prices outside GPO ensures GPO act in hospitals' best interests (at 6)
  - Presumes that hospitals easily observe competitive prices for similar products; yet no such transparency exists
  - Given that government reimburses hospitals for many purchases, hospital lacks strong incentive to identify savings
  - Hospital forgoes bundled or volume discounts by purchasing outside of its GPO contract
  - It would be difficult for a GPO entrant to lure hospitals by claiming that subscription fees are "better than free"
  - Some GPO contracts with member hospitals also require GPO exclusivity

- Findings do not suggest price differential can be attributed to GPO funding model (at 6)
  - Fair, but to what other feature of GPOs could the price differential be attributed?
  - Subscription-based aftermarket services are a reasonable proxy for outcomes with an alternative funding mechanism

- Because tax incidence is neutral with respect to where tax is levied, funding doesn't matter (at 9)
  - Not applicable because tax revenues to be collected are assumed to be *exogenous*; in case of GPOs, fees collected under the concession are *endogenous*—that is, they depend on the number of suppliers, which is within the GPO's domain
  - If the funding model doesn't matter, then why do they care enough to hire consultants to keep it the same way?

Criticisms: O'Brien, Leibowitz & Anello (2017)

- Collecting fees from 2,500 vendors is more efficient than doing so from 103,000 hospitals (at 10)
  - Incremental costs of accommodating your 2,501st client is effectively zero; that is, same system that could accommodate 2,500 clients could likely accommodate 103,000 clients

- If vendor fees were barred, GPOs would replace with sales-based fees from hospitals (at 11)
  - No basis to assume sales-based fees, when flat-price subscription fees for aftermarket auctions already exist in the market

- Vendor-paid fees are common; used by Amazon, eBay and credit cards (at 11)
  - But you don't have the same principal-agent problem. And Amazon users are shopping with better information, myriad choices.
  - Credit card example is inapposite. Amex receives a % of revenue paid to merchants, but it is not involved in negotiating prices on behalf of the merchants in its network.

- Econ literature doesn't support idea that sales-based payments are conducive to exclusion (at 12)
  - Literature shows that buyers do not need payments to abide by exclusivity provisions, so long as the "penalty price" for non-compliance is set sufficiently high. Thus, the form of the payments (flat or proportional to sales) is irrelevant.
  - Payment in this case is to an agent (GPO), not to the buyer (hospital), which can facilitate the exclusion.

- Direct rebates from vendors raise same concern because buyer may fail to those report too (at 12)
  - False. Rebate from a supplier would be easier to trace back to a particular purchase (for reporting purposes) than would a profit distribution from a GPO.

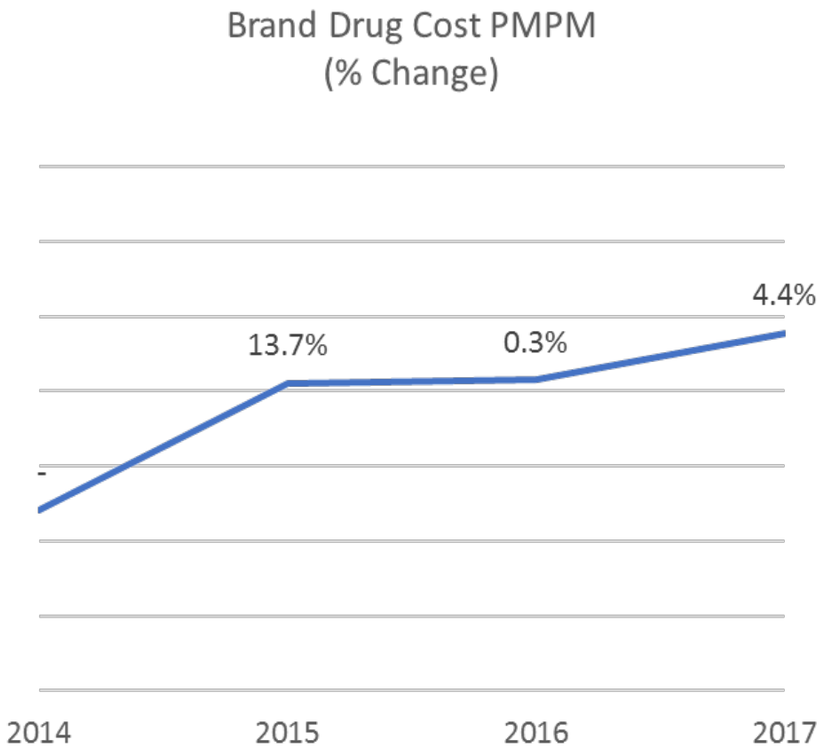
Drug Trend

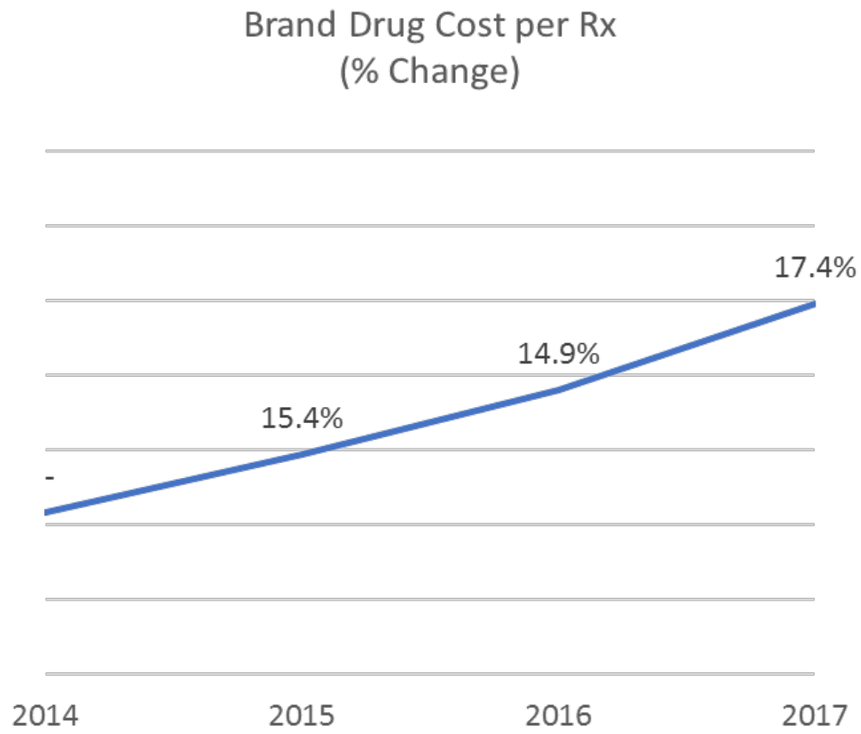
National Pharmacy Programs & Services

October 2017

KAISER PERMANENTE®

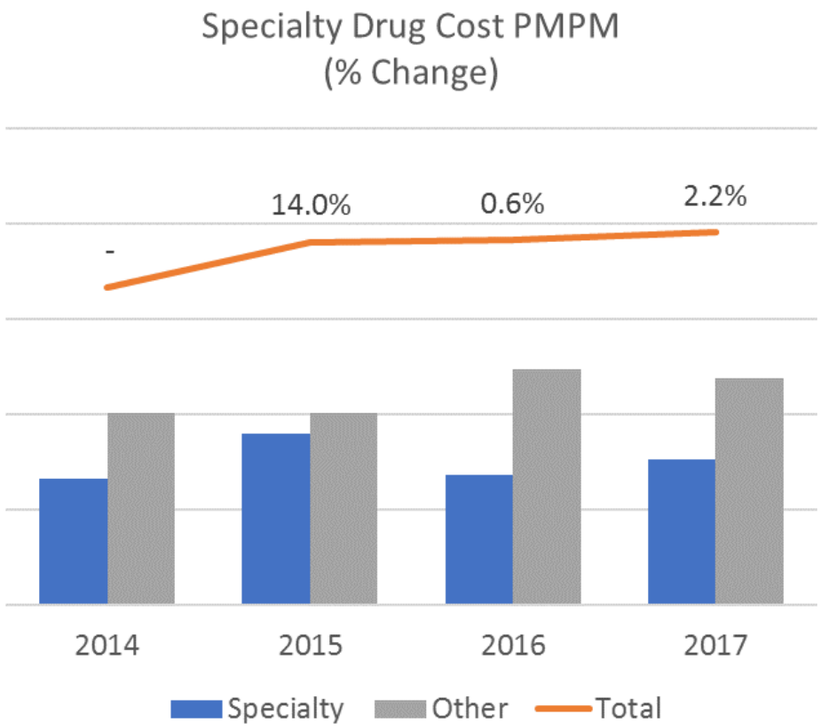
Outpatient Brand Drug Cost Trend

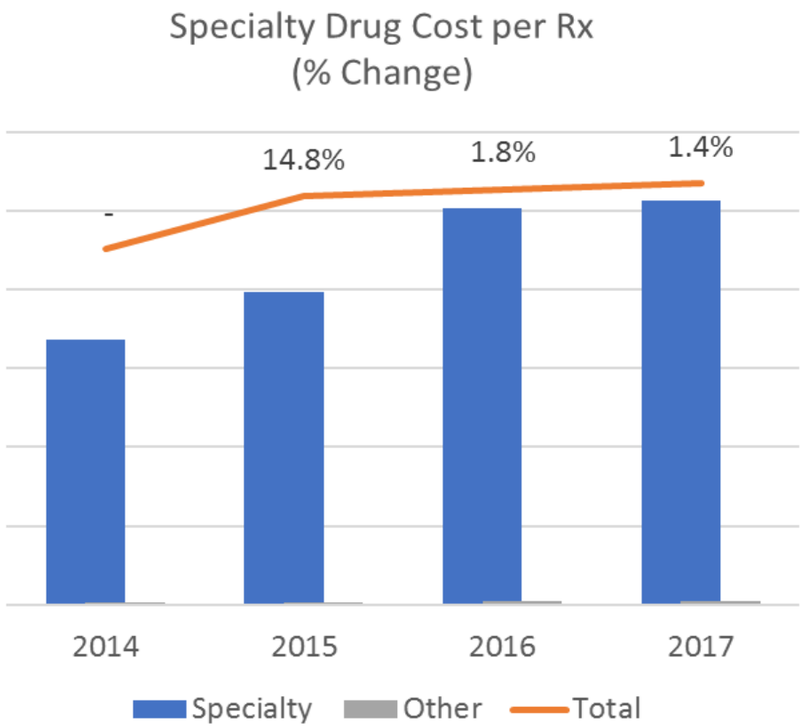




- Outpatient drug spend on brand medications has increased steadily over the last four years, averaging 16% in annual growth on a cost per prescription (RX) basis. On a PMPM basis, brand drug cost growth plateaus in 2016 due largely to lower hepatitis C utilization.

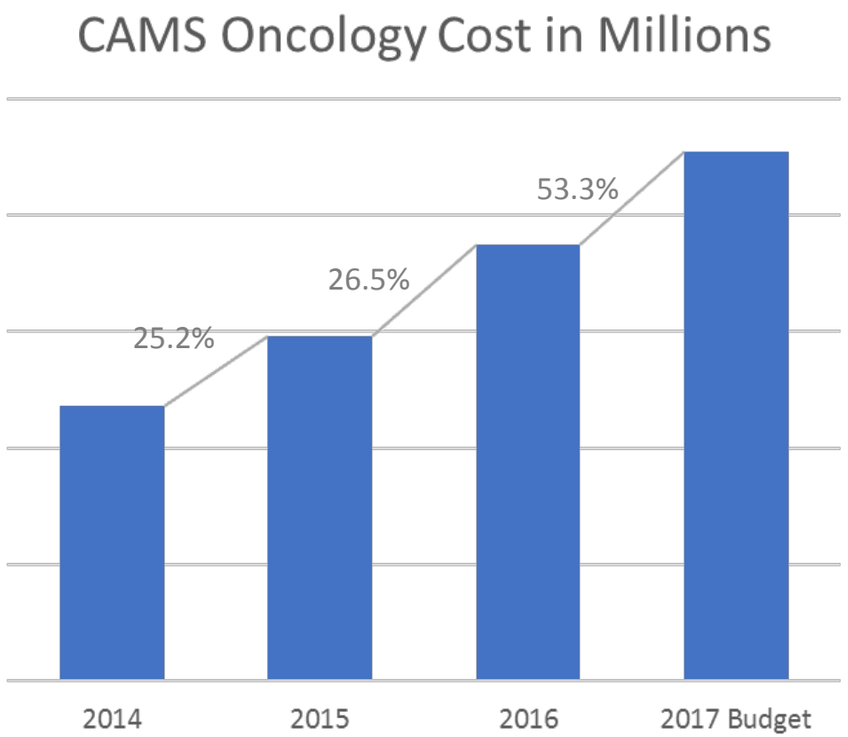
Outpatient Specialty Drug Cost Trend

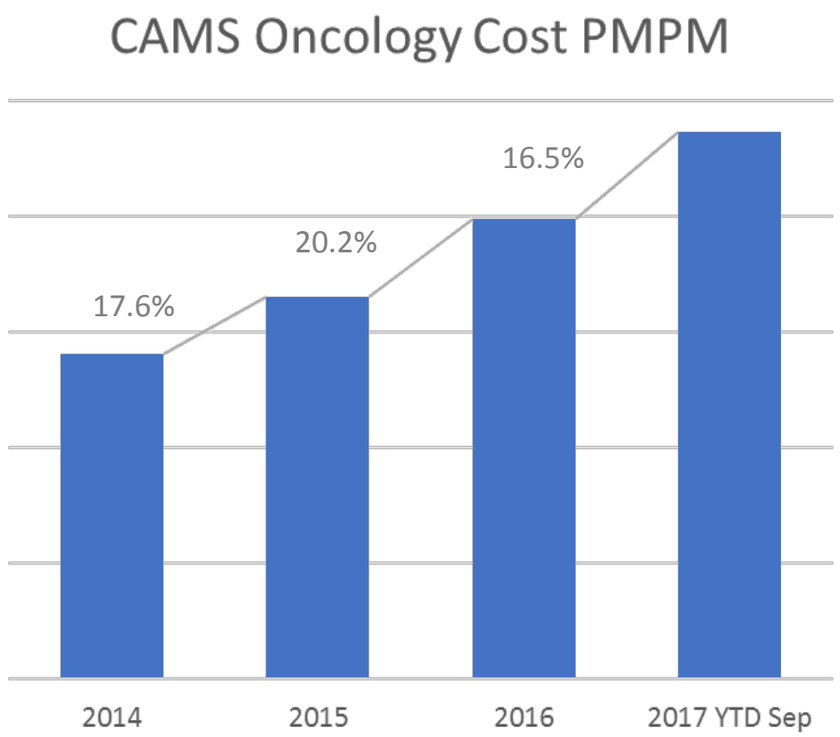




- Specialty drug is defined as cost of $600 or more for a 30 day prescription. As of YTD Sep 2017, specialty drugs represented 39% of the total outpatient drug spend but only 1% of the total outpatient prescription volume.
- Specialty drug cost on a PMPM basis has increased steadily with the exception of 2016, driven by the decline in hepatitis C utilization. Specialty drug cost on a cost per prescription basis has increased steadily, slowing in 2017 as a result of lower hepatitis C spend.

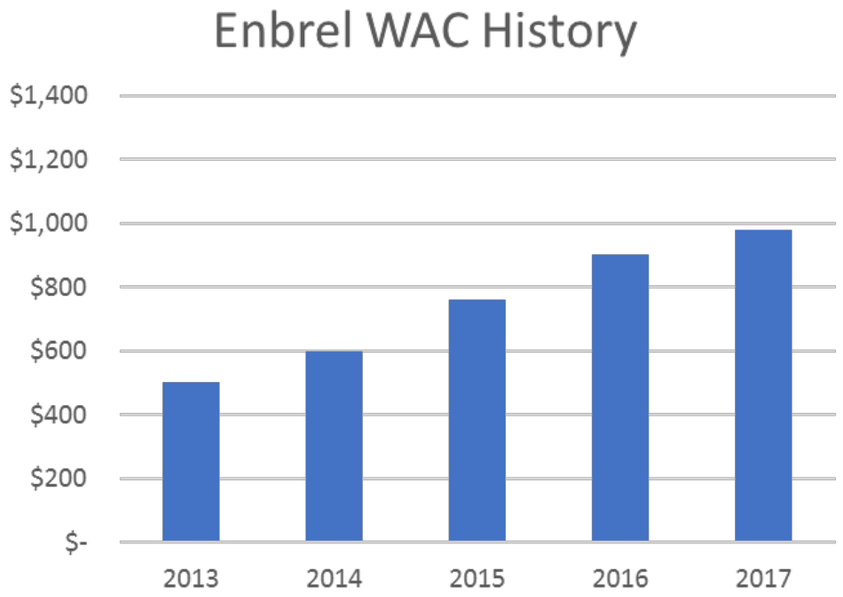
Clinic Administered Medications (CAMS) for Oncology

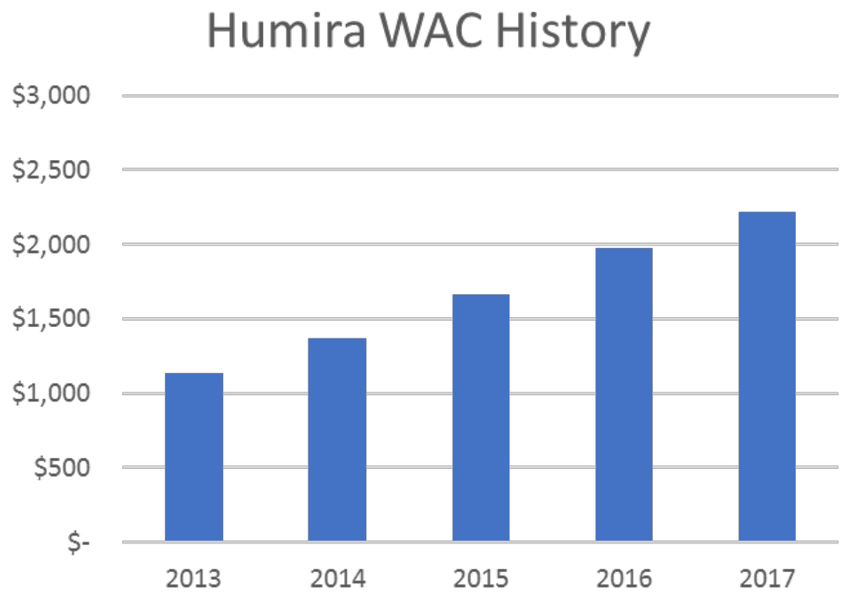




- Clinic pharmacy drug spend for oncology have increased by double digit percentages annually on a dollar and dollar PMPM basis.
- The increase in spend is driven by increases in both utilization from expanded FDA indication approvals and by unit cost increases.

Wholesale Acquisition Cost (WAC) Example





- Significant growth has been experienced for Enbrel and Humira demonstrate the increasing cost to treat patients with rheumatoid arthritis. This is one example of the rising cost of specialty drugs.

- Enbrel WAC increased by a compounded average growth rate or CAGR of 14.2% between 2013 to 2017
    - Price changes include various dosage forms of the injection and Sureclick® injection.

- Humira WAC increased by a CAGR of 14.4% between the same time period
    - Price changes include various dosage forms of the pen injection and kit injection.

Understanding Competition in Prescription Drug Markets:
Entry and Supply Chain Dynamics

Panel 3: Understanding Intermediaries: Group Purchasing Organizations

BREAK

Understanding Competition in Prescription Drug Markets:
Entry and Supply Chain Dynamics

Discussion: Potential Next Steps to Encourage Entry and Expand Access through Lower Prices

High prescription drug prices: Balancing access and affordability

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THE UNIVERSITY OF CHICAGO
BIOLOGICAL SCIENCES

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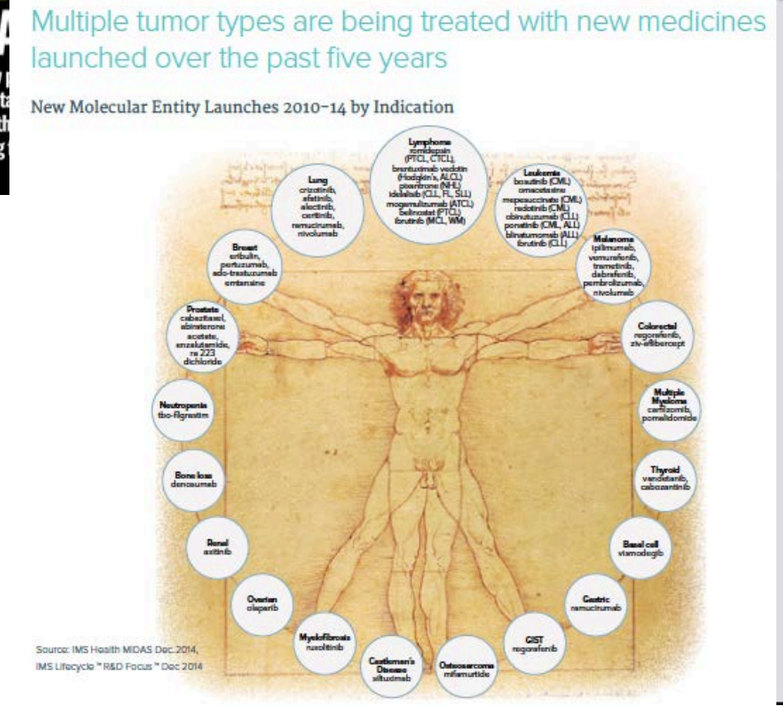
- We are grateful for the support of the NCI, the Commonwealth Fund and the American Cancer Society.

- Opinions expressed are mine alone and publicly available in a series of peer reviewed publications.

We stand in the midst of incredible scientific breakthroughs



A paradox: access to cures limited, high out of pocket costs

The National Academies of
SCIENCES · ENGINEERING · MEDICINE

A National Strategy
for the Elimination of
Hepatitis B and C

Brian Strom, Chair

BOARD ON POPULATION HEALTH AND PUBLIC HEALTH PRACTICE

The National Academies of
SCIENCES · ENGINEERING · MEDICINE

HOME BUSINESS MARKETS WORLD POLITICS TECH OPINION BREAKI

Exclusive: Costs to public of $84,000 hep C drug 'outrageous' - Kaiser

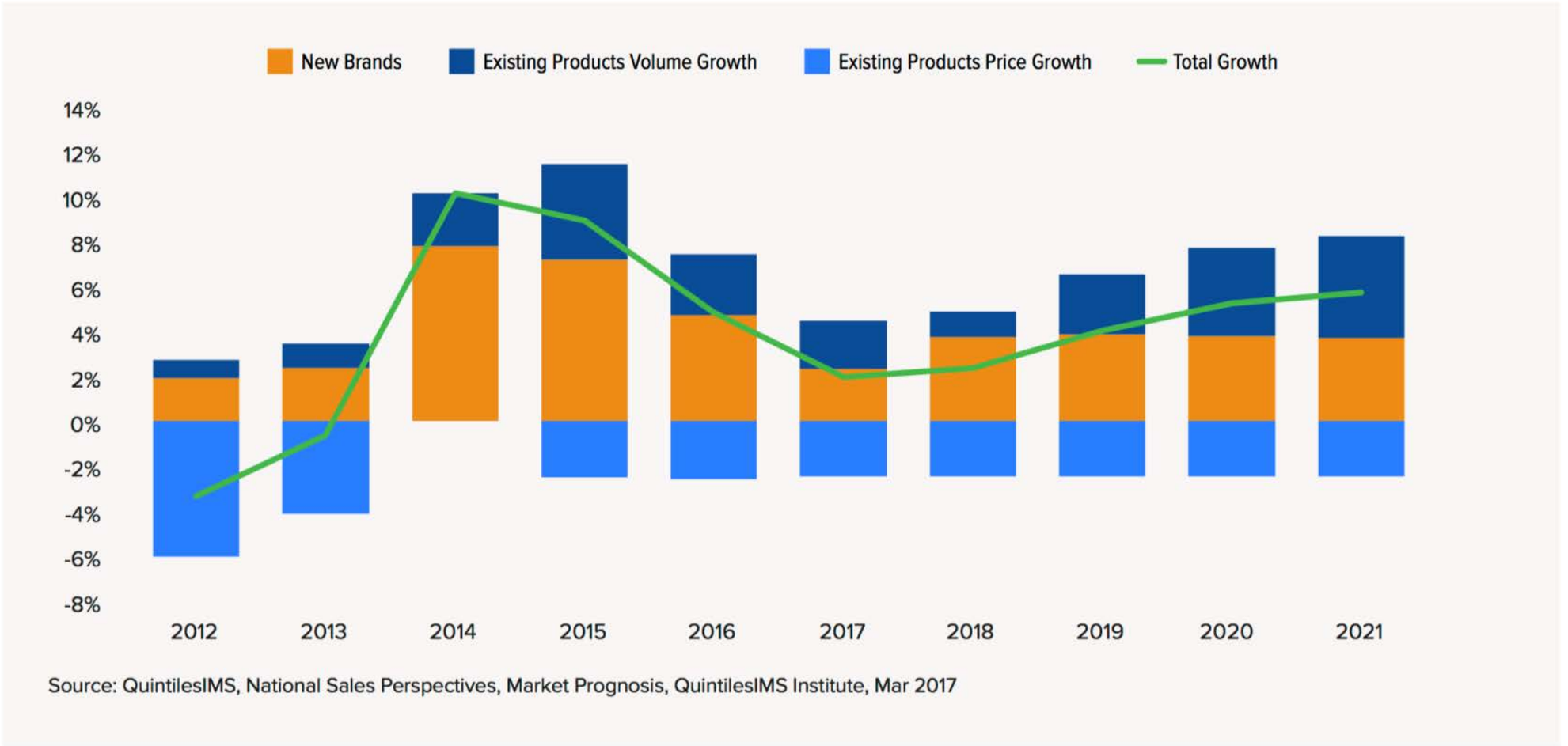
BY DEENA BEASLEY
LOS ANGELES | Wed Apr 2, 2014 3:41pm EDT

Hepatitis C Treatments
- High cure rates
- Initial prices >$80K a course
- Significant access restrictions in both public and private sector
- Market failure: Fragmented insurance; incentives to cure are misaligned.

High morbidity, mortality
Increased transmission

Spending growth: a mix of price and volume growth

Chart 8: Net Medicines Revenue Growth and Contribution by Type



Source: QuintilesIMS, National Sales Perspectives, Market Prognosis, QuintilesIMS Institute, Mar 2017

Understanding the Drivers of Drug Expenditure in the U.S. Report by the QuintilesIMS Institute

Why are prescription drug prices high and growing?

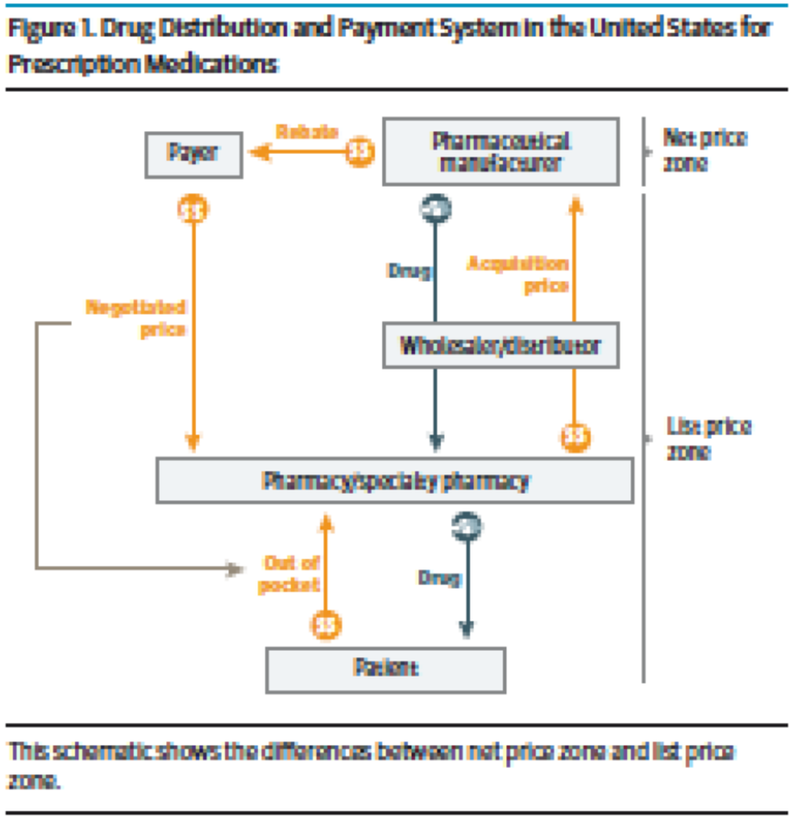
A closer look at current market incentives.

Manufacturers practice monopoly “by design” pricing

- Patent system: encourages innovative activity, private flow of capital into risky, time intensive, uncertain investment.
- Does that mean that increasing prices reflect increased value?
  - No! Newer cancer drugs are not associated with greater survival compared to older drugs.
  - The single biggest predictor of cancer drug launch price trend is time.

Howard D, PB Bach, ER Berndt, **RM CONTI**. “Pricing in the Market for Anticancer Drugs,” *Journal of Economic Perspectives*. 2015;29 (1,Winter):139–162.

Profit capturing “value” chain impacts prices, spending



- Middleman make money off difference between acquisition costs and reimbursement:
  - Manufacturers give discounts/rebates to PBMs/GPOs/hospitals/MDs.
  - Some discounts/rebates passed through to payers/patients, not all.
- Manufacturers build in discounts/rebates into launch prices, price setting over time.

Dusetzina SB, **CONTI RM**, Yu NL, Bach PB. “Association of Prescription Drug Price Rebates in Medicare Part D with Patient Out-of-Pocket and Federal Spending,” *JAMA Intern Med*. 2017 Aug 1;177(8):1185-1188.

Generics part of a “virtuous circle”, yet worry promise is fading

Three Sleazy Moves Pharmaceutical Companies Use to Extend Patents

Keith Veronese
12/06/11 5:57pm • Filed to: DRUGS

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How to Protect a Drug Patent? Give it to a Native American Tribe

By KATIE THOMAS SEPT. 8, 2017

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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

PFIZER INC.,

Plaintiff,

v.

JOHNSON & JOHNSON and JANSSEN BIOTECH, INC.,

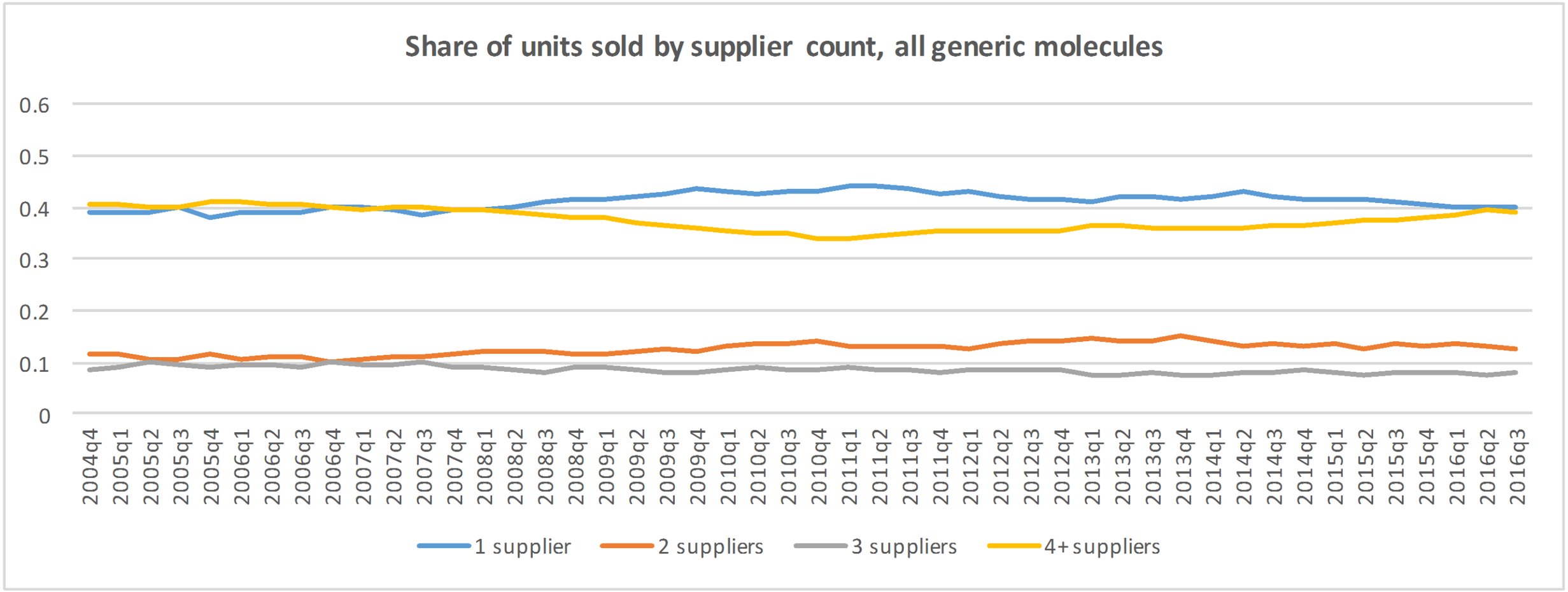
Defendants.

Case No.

JURY TRIAL DEMANDED

COMPLAINT

Suppliers of generic drugs are concentrated



Berndt ER, **RM CONTI**, SJ Murphy. "The Landscape of US Generic Prescription Drug Markets, 2004-2016." NBER working paper #w23640. July 2017. Available at: http://www.nber.org/papers/w23640.

Public concern regarding the access/affordability paradox creates an opportunity for reform.

In such a complex system, there are no “silver bullets”.

Promising reform efforts balance access & affordability

- Improve generic supply competition.
- Enhance transparency/reduce profit seeking in the value chain.

Improve generic supply competition

- FTC has critical role to play:
  - Reduce Scott-Hart-Rodino thresholds on merger revenue scrutiny.
  - Vigorously pursue pay for delay, product hop, other evergreening activities.
- FDA has critical role to play:
  - Lower barriers to entry through GDUFA fee revisions.
  - Preserve ability to reenter molecule markets after temporary supply disruptions/exits.
  - Identify alternative suppliers meeting quality manufacturing metrics.
  - Ensure quality manufacturing, redundant supply through other activities.

Enhance transparency/reduce profit seeking in the value chain

- Reduce physicians/hospitals/pharmacies ability to profit off high priced drugs.
- DOJ has critical a role to play:
  - Enforcement of anti-kickback & RICO statutes.
  - Greater scrutiny of proposed merger, acquisitions between value chain actors.

I’m happy to discuss, debate and provide more detail.

rconti@uchicago.edu

Thank you.

THE UNIVERSITY OF CHICAGO
BIOLOGICAL SCIENCES

PATIENTS FOR AFFORDABLE DRUGS™

David Mitchell

Founder & President

November 8, 2017

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High cost drugs keeping me alive

But drugs don’t work if people can’t afford them

A Patient Perspective

Key Points Made Today

Key Points Not Made Today

Contact and Resources:

David@patientsforaffordabledrugs.org

@DavidP4AD & @P4AD_

Patients For Affordable Drugs

Understanding Competition in Prescription Drug Markets:
Entry and Supply Chain Dynamics

Discussion: Potential Next Steps to Encourage Entry and Expand Access through Lower Prices

Understanding Competition in Prescription Drug Markets:
Entry and Supply Chain Dynamics

Closing Remarks