nderstanding Competitio
Prescription Drug Market
ntry and Supply Chain Dynamic

FEDERAL TRA

November 8, 2017

Introductory Remarks

Svetlana S. Gans
Chief of Staff
Federal Trade Commission

Keynote Remarks

Maureen K. Ohlhausen
Acting Chairman
Federal Trade Commission

Keynote Remarks

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

nderstanding Competitio
Prescription Drug Market
ntry and Supply Chain Dynamic

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

FEDERAL TRA

November 8, 2017

Division of
Pharmacoepidemiology & Pharmacoeconomics
partment of Medicine, Brigham & Women's Hospital, Harvard Medical Sch

omoting Timely and Effective Gene
Drug Markets

Aaron S. Kesselheim, M.D., J.D., M.P.H.
Associate Professor, Harvard Medical School
Director, Program On Regulation, Therapeutics, And Law (PORTAL
November 8, 2017
akesselheim@partners.org

PORTAL

Program On Regulation, Therapeutics, And Law

What is PORTAL?

ore faculty with expertise in medicine, business, law, epidemiology, ethics; post-docs and
umerous students

esearch on interactions among the regulatory, legal, economic, and clinical components o
harmaceutical marketplace

rgest and most prolific independent research group in the country focused on these issu

urrent research funding from Harvard Program in Therapeutic Science, Laura and John Ar
oundation, Engelberg Foundation

- Past research funding from FDA CDRH, Commonwealth Fund, Harvard Clinical and Tra
  Science Center, AHRQ, Robert Wood Johnson Foundation, CVS Caremark, FDA Office o
  Drugs, Greenwall Faculty Scholars Foundation in Bioethics

witter: @PORTAL_research; Website: www.PORTALresearch.org

PORTAL
Program On Regulation, Therapeutics, And Law

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 m did not fill a prescription due to cost
- Patients prescribed a costly branded product rather than a mor affordable generic alternative adhere less well, and have worse outcomes

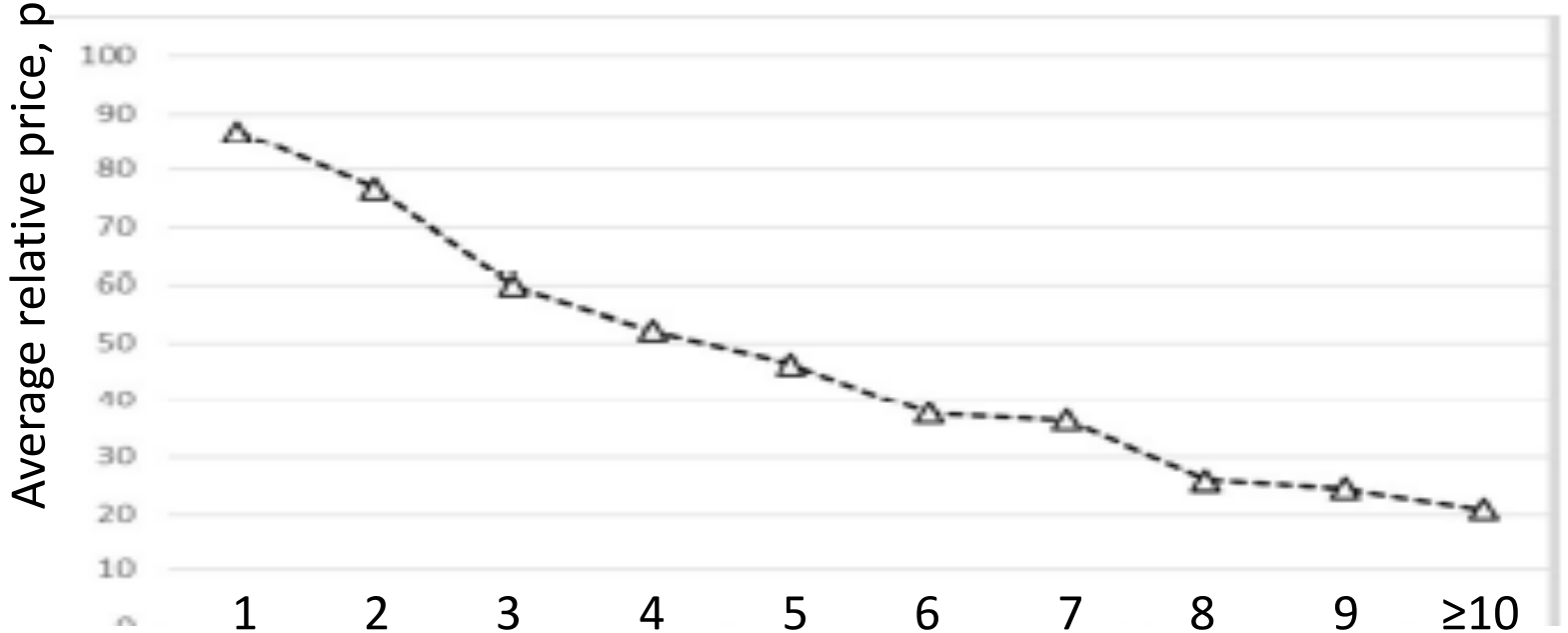
PORTAL
Program On Regulation, Therapeutics, And Law

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

Generic drugs

Generic competition consistently and substantially low
prescription drug prices

– Abbreviated FDA approval process, state Drug Product Selecti
facilitate automatic substitution

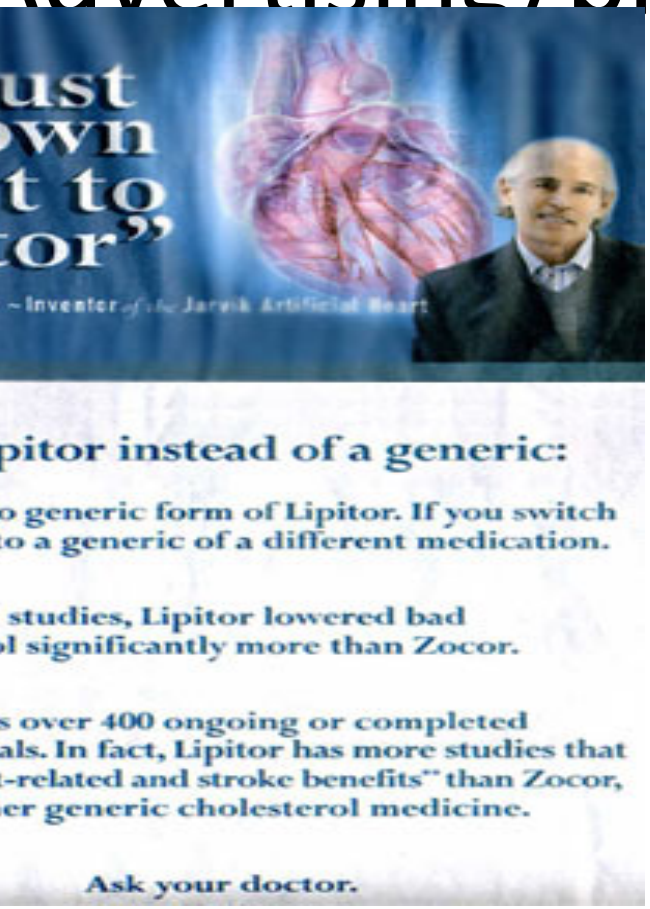


PORTAL
Program On Regulation, Therapeutics, And Law

Dave, Hartzema, Kesselheim (unpublished data)

actors affecting generic drug us

Advertising/promotion



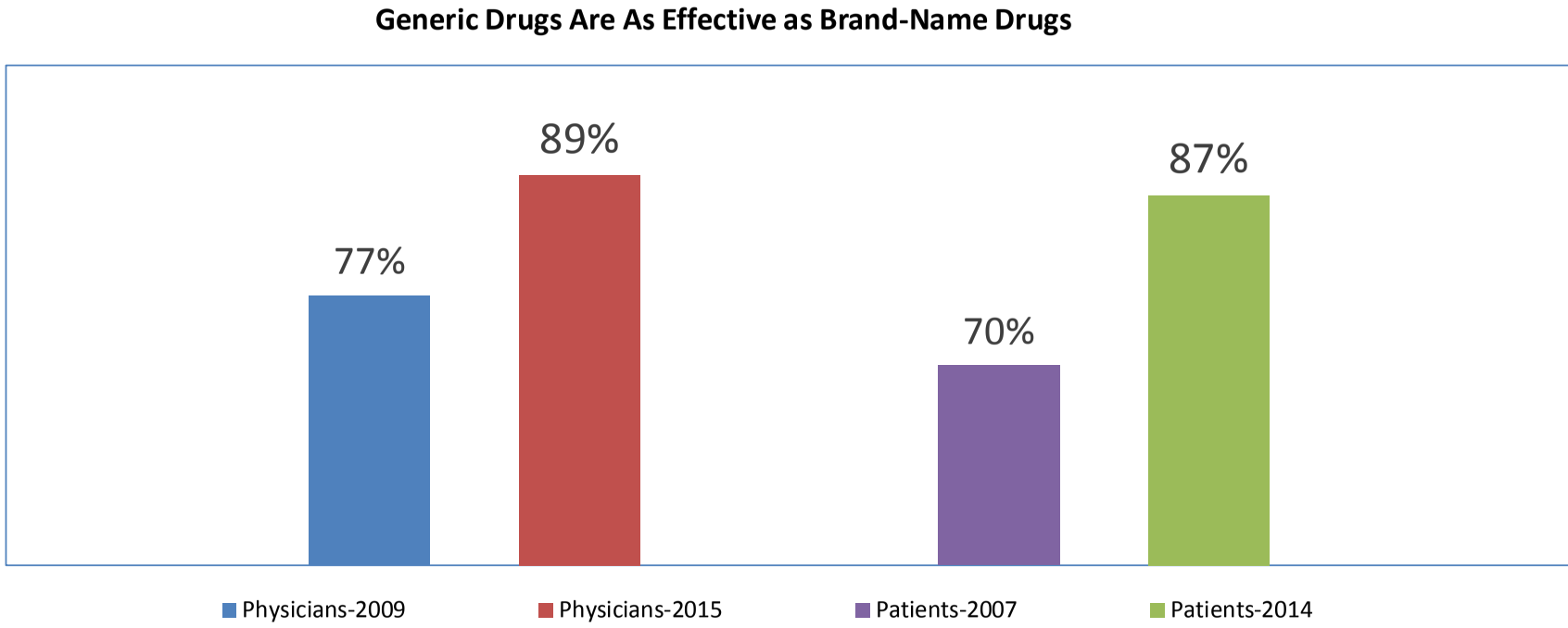
PORTAL

- *Program On Regulation, Therapeutics, And Law*

actors affecting generic drug us

Advertising/promotion

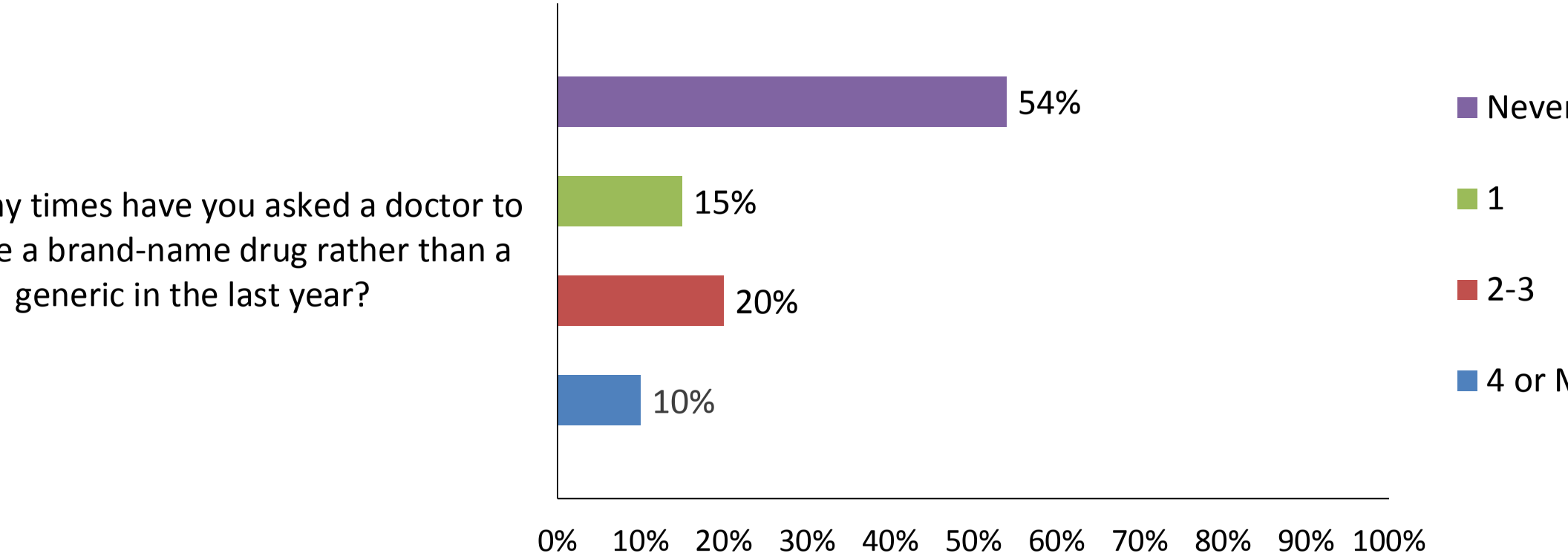
Patient/physician skepticism



PORTAL
Program On Regulation, Therapeutics, And Law

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

Patient Actions



Kesselheim et al., JGIM (2016)

actors affecting generic drug us

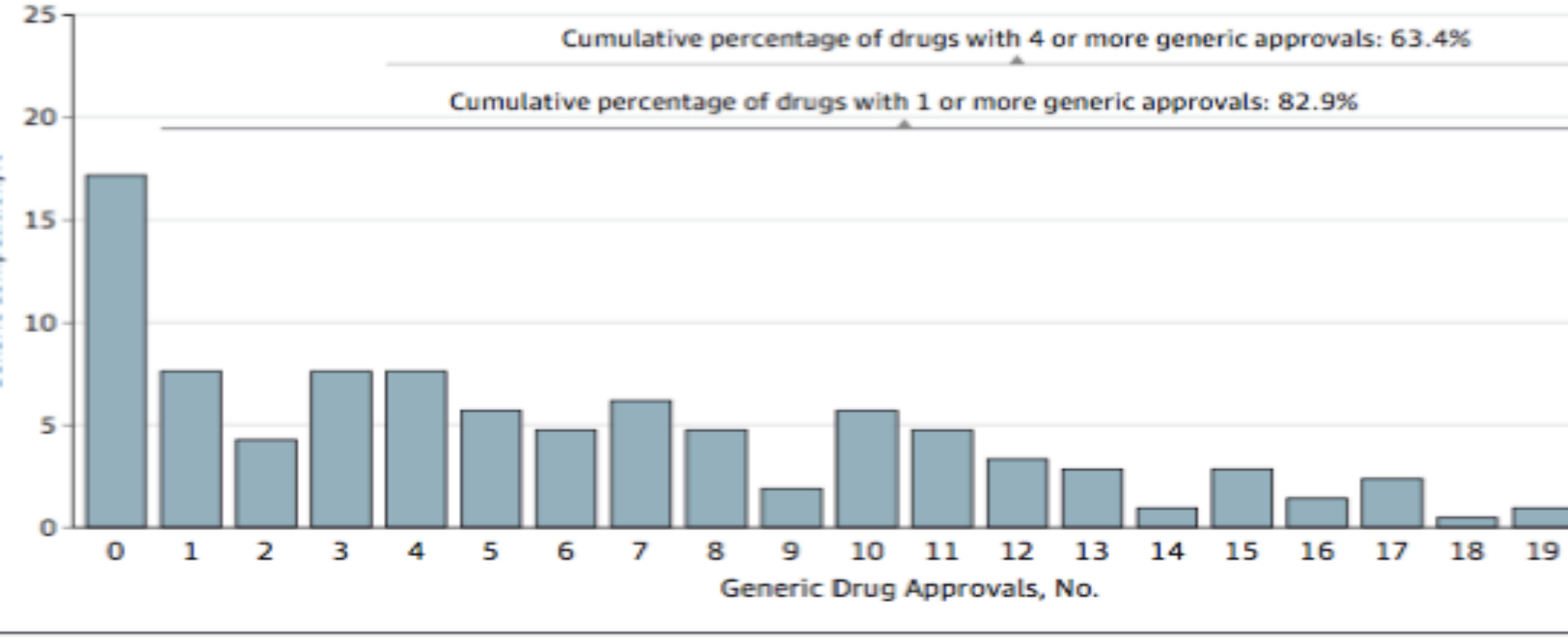
Advertising/promotion

Patient/physician skepticism

Cost/availability

Lack of vibrant competition in generic drug marke

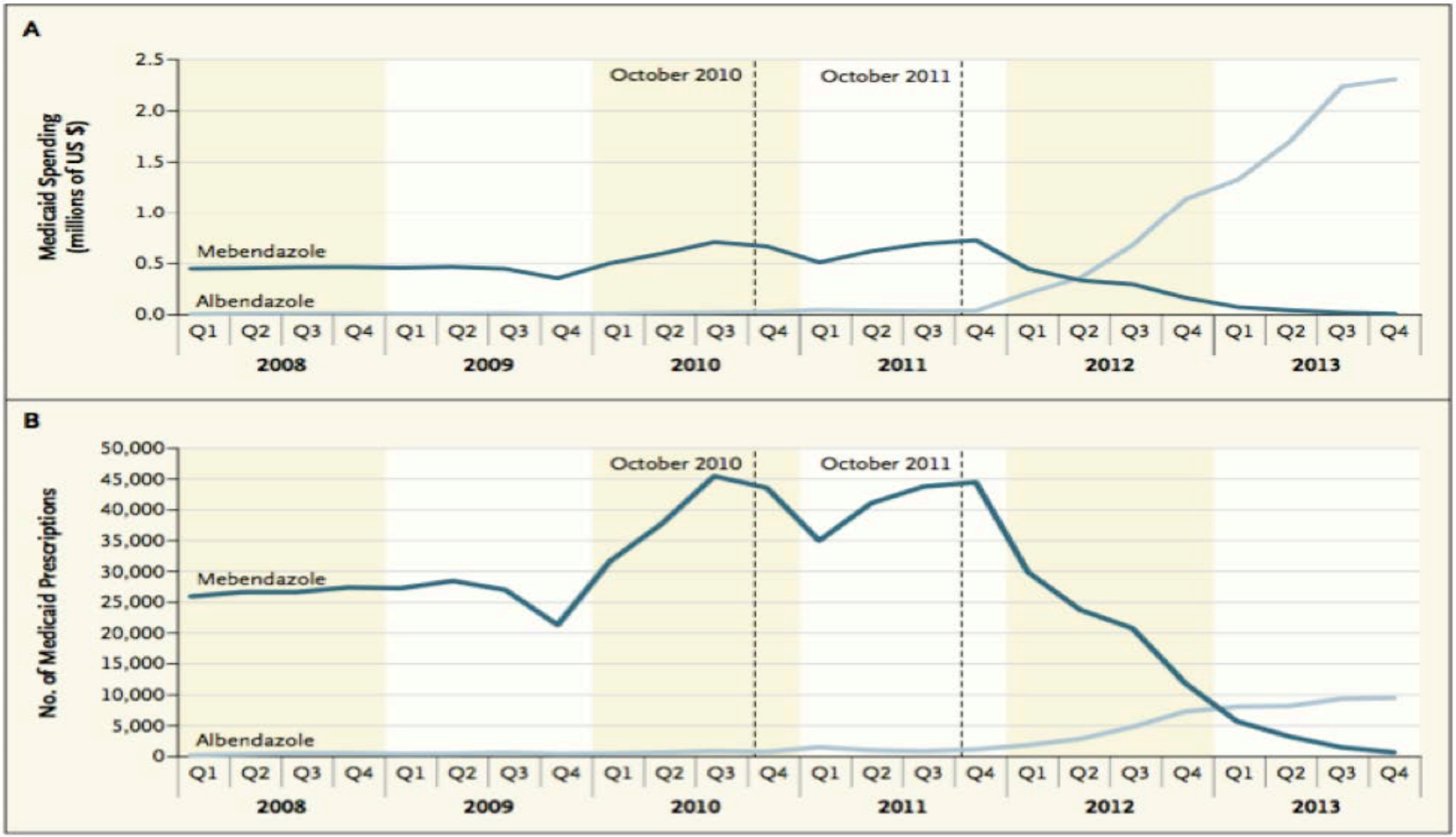
e. Generic Drug Approvals for Novel Therapeutics Approved by the US Food and Drug Administratio
le for Generic Competition.



PORTAL
Program On Regulation, Therapeutics, And Law

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

Example: Albendazole

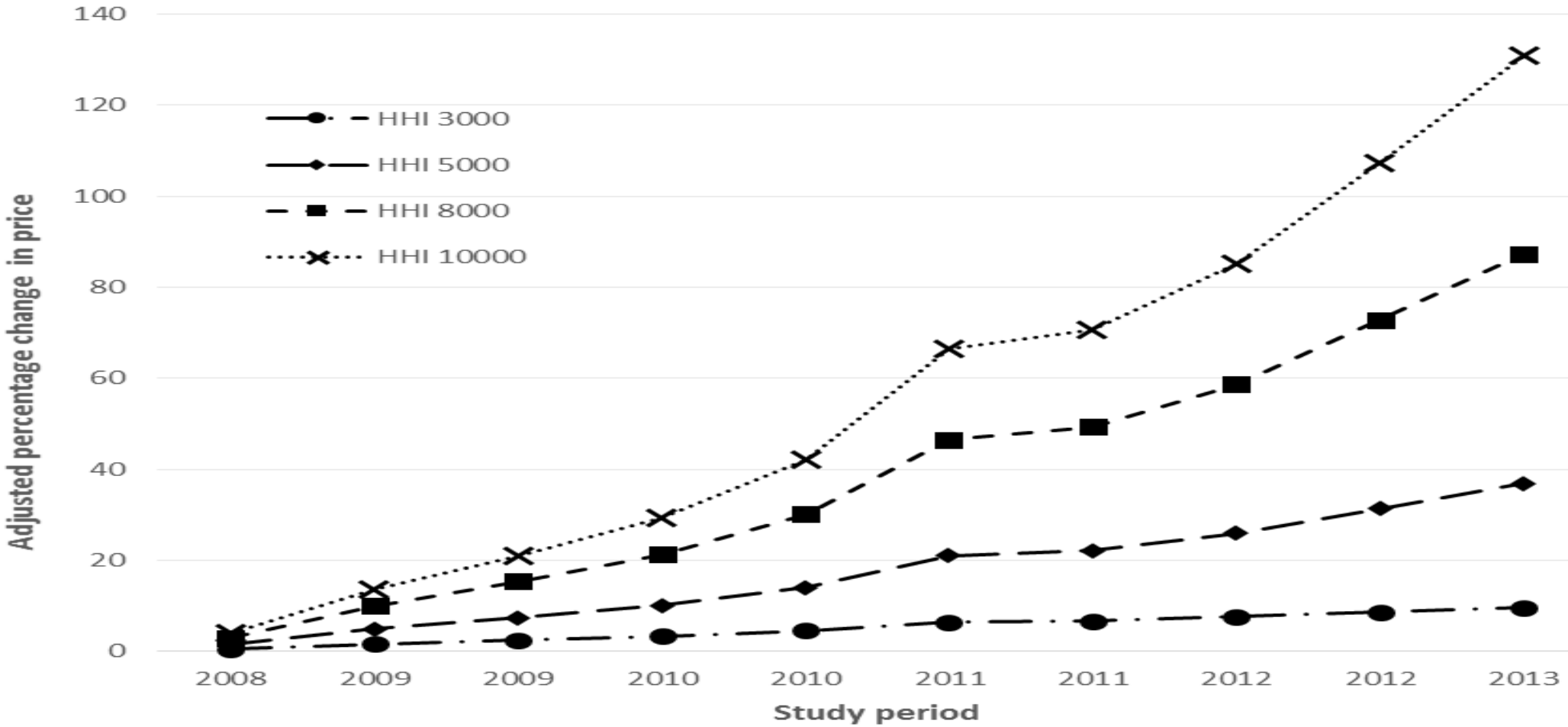


Medicaid Spending and Prescriptions for Albendazole and Mebendazole, 2008–2013.

PORTAL
Program On Regulation, Therapeutics, And Law

Alpern Stauffer Kesselheim, NEJM, 2015

sociation between generic market consolidation a generic price changes



PORTAL
Program On Regulation, Therapeutics, And Law

Dave Kesselheim Fox Hartzema, Annals of Internal Medicine, 2017

nuses of insufficiently competitive eneric 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, OI 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

Therapeutics, Anal Law.

Davies, Hwang, Kesselheim,

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

PORTAL
Program On Regulation, Therapeutics, And Law

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

Generic Drugs – Facing Threats to Sustainable Competition & Supply

Federal Trade Commission Workshop | November 8, 2017

verall U.S. Prescription Drug Market

Brands account for only

11% → **74%**

of prescriptions
(500 million)

yet are

of the cost.
($333.9 billion)

Generics account for

89% → **26%**

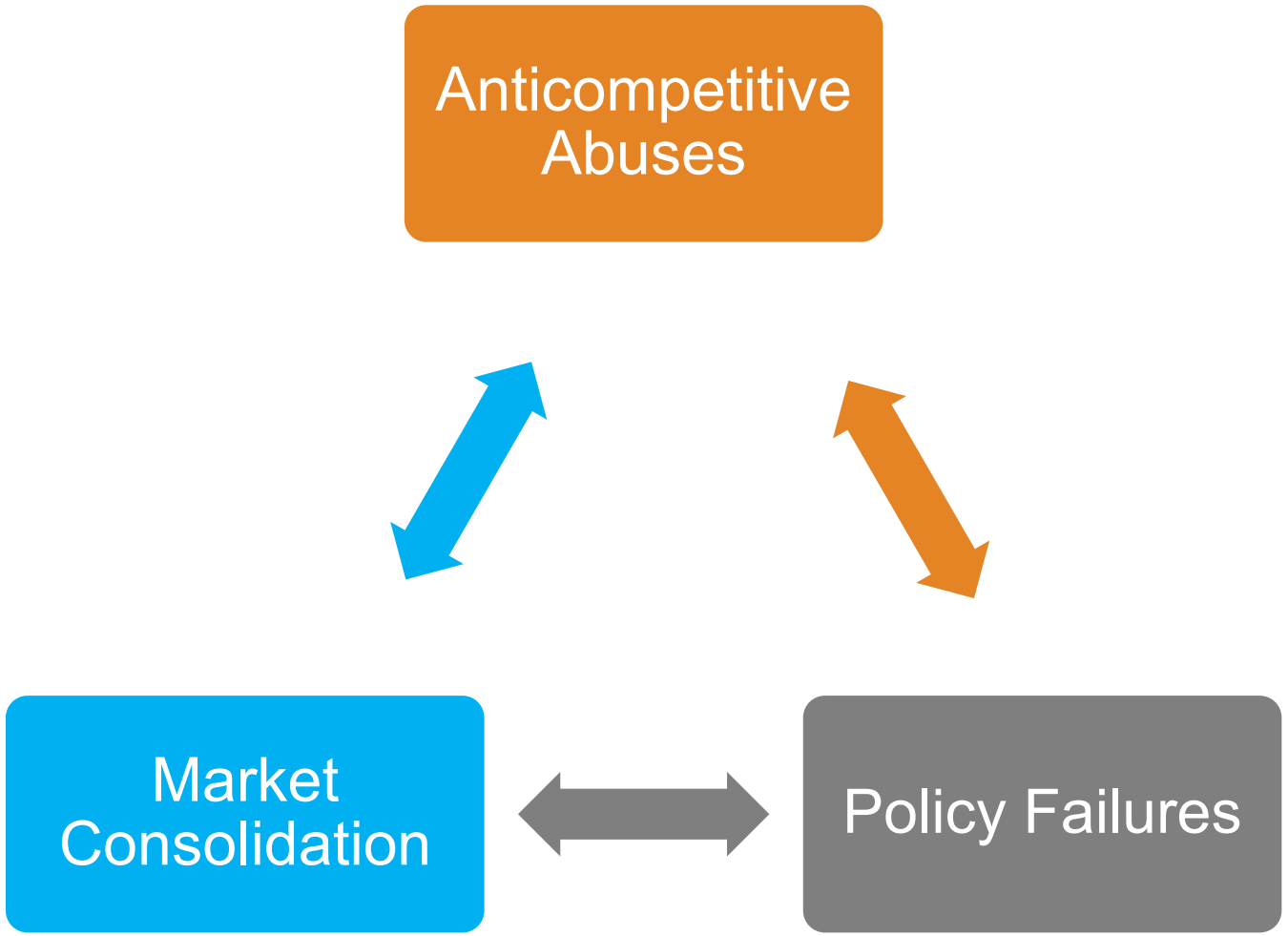
of prescriptions
(3.9 billion)

but are just

of the cost.
($116.1 billion)

Source: QuintilesIMS.

ustainable Generic Competition Is Threatened



nticompetitive Behavior Prevents Competition

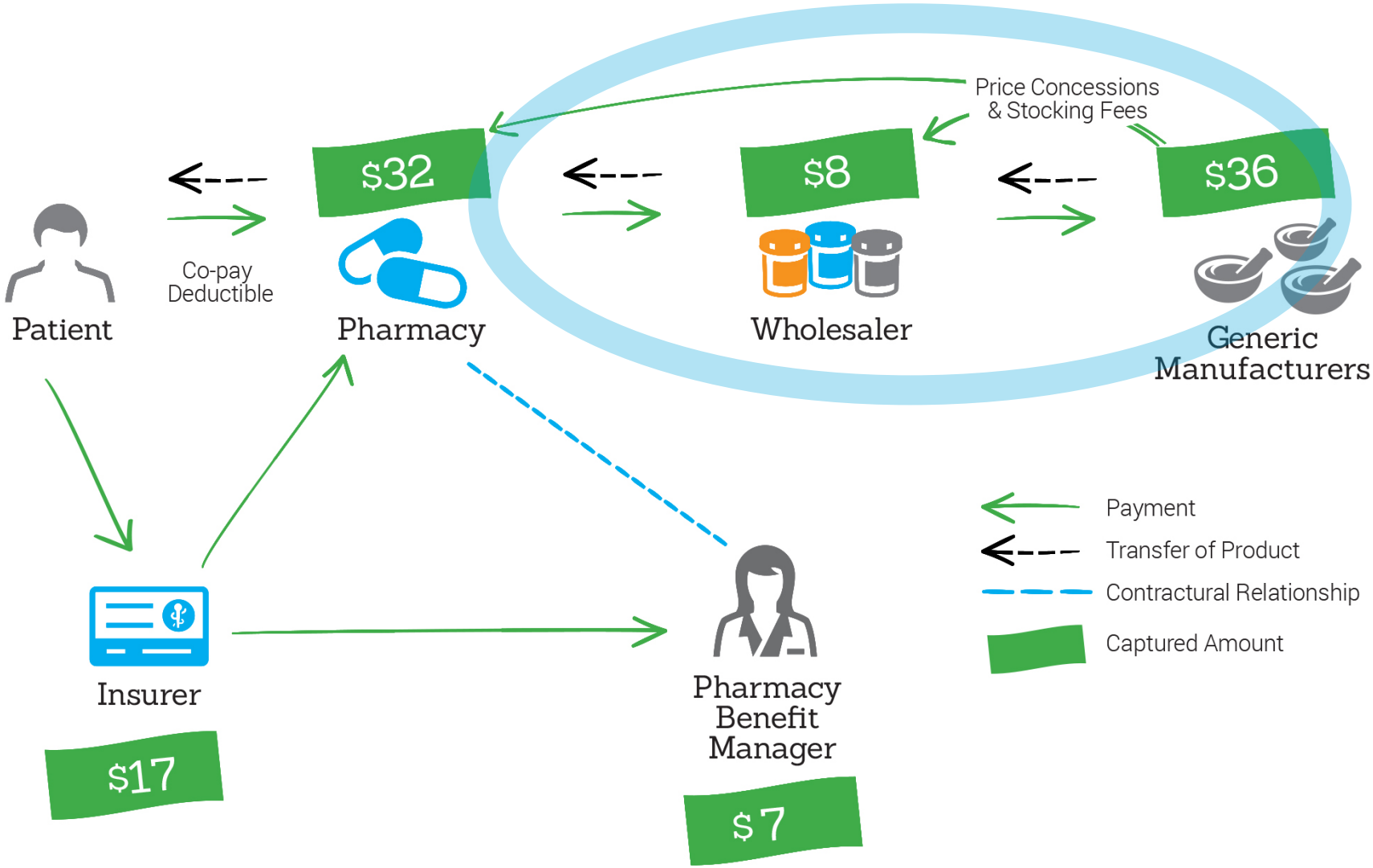
We know that sometimes our regulatory rules might be 'gamed' in ways that may delay generic drug approvals beyond the time frame the aw intended, in order to reduce competition…

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

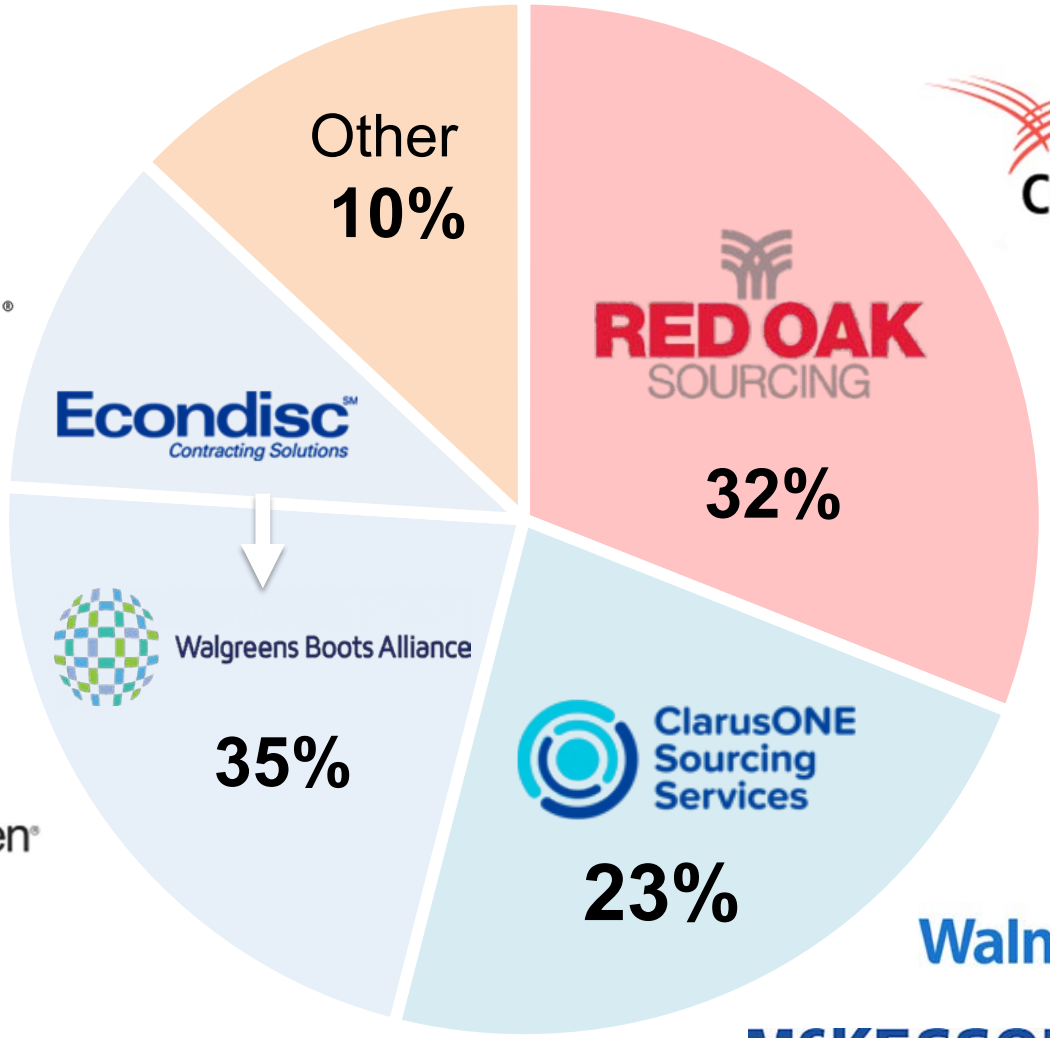
- FDA Commissioner Scott Gottlieb, M.D.
June 21, 2017

Understanding the Generic Marketplace

e Generic Drug Market Is Not the Brand Drug Ma



arge Buyers Control Almost 90% of Generics



EXPRESS SCRIPTS®

erisourceBergen

CardinalHealth

CVS caremark

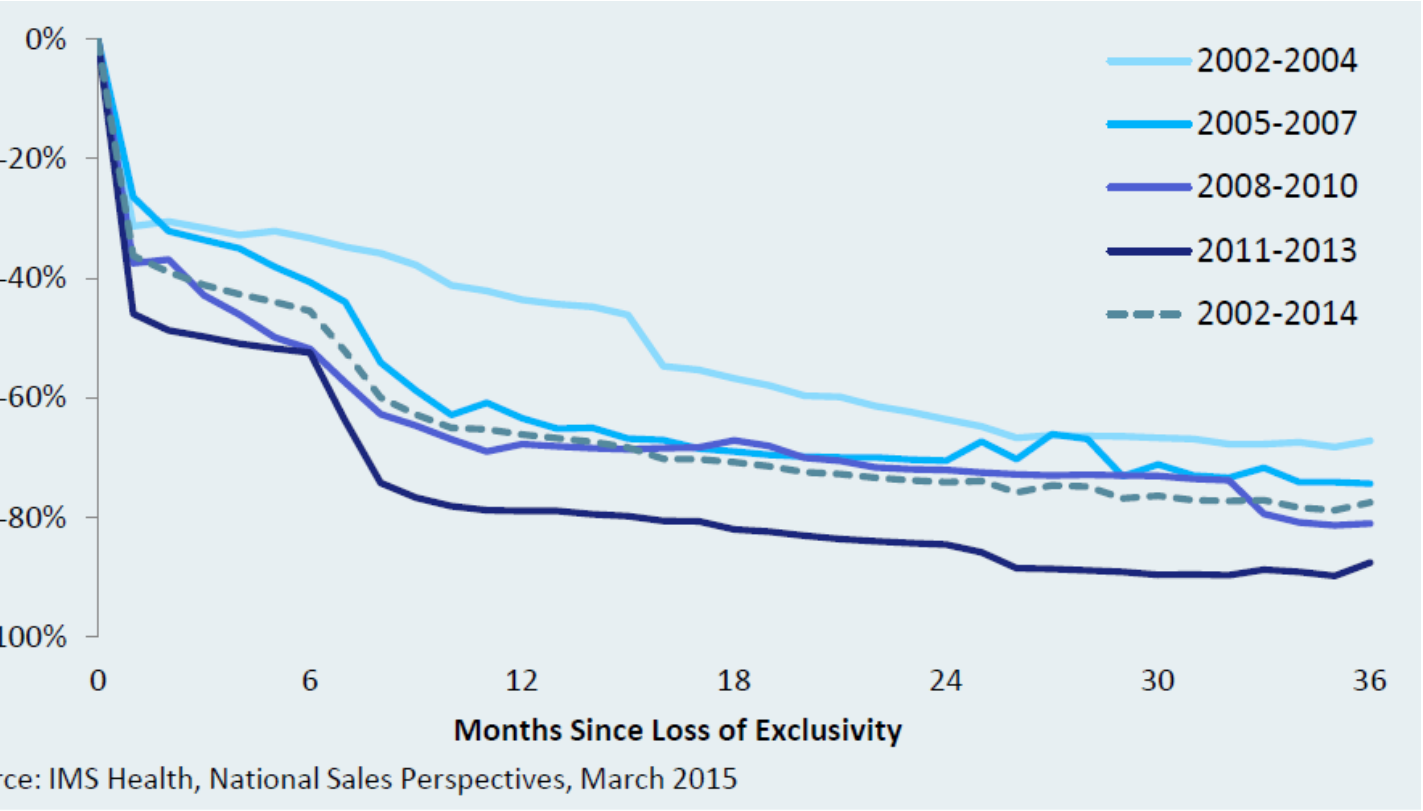
Walmart

McKESSON

Sourcing from mor
than 200 generic
manufacturers

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

Generics Drug Prices Are Falling Further, Faste



rce: IMS Health, National Sales Perspectives, March 2015

- But the market trends - decreasing prices – are sustainable.
- In the last year, total ge prescriptions are up 2 p but revenue is down 13 percent.
- Policies must safeguar generic market.
- Otherwise, manufactur be forced to exit unpro markets – harming pat through potential drug shortages.

urchasers 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 t the previously mentioned generic market pricing.

– Cardinal CFO Michael Kaufmann (May 2017)

Impact on Patient Access & Outcomes

rug 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.”

he FTC and FDA Should…

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

he continued sustainability of generic, and the promise of atient access through biosimilar, competition depends on ctive policy engagement.

Thank You

Association for Accessible Medicines

BERNSTEIN

November 8,

perspective on the competitive dynamics o eneric drugs

C/FDA Joint meeting on drug competition

n (Ronny) Gal, Ph.D. • +1-212-756-4208 • ronny.gal@bernstein.com
ew Choo, Ph.D. • Associate • +1-212-756-1856 • andrew.choo@bernstein.com
Huang • Associate • +1-212-756-4602 • betty.huang@bernstein.com
Kazlow • Associate • +1-212-823-3977 • erica.kazlow@bernstein.com

messages

generic value chain is broadly competitive; prices are low and are ctively negotiated lower

/e are getting a bit worried that there will not be sufficient profit pool to make the dustry attractive for investment

r eddy currents in the competition

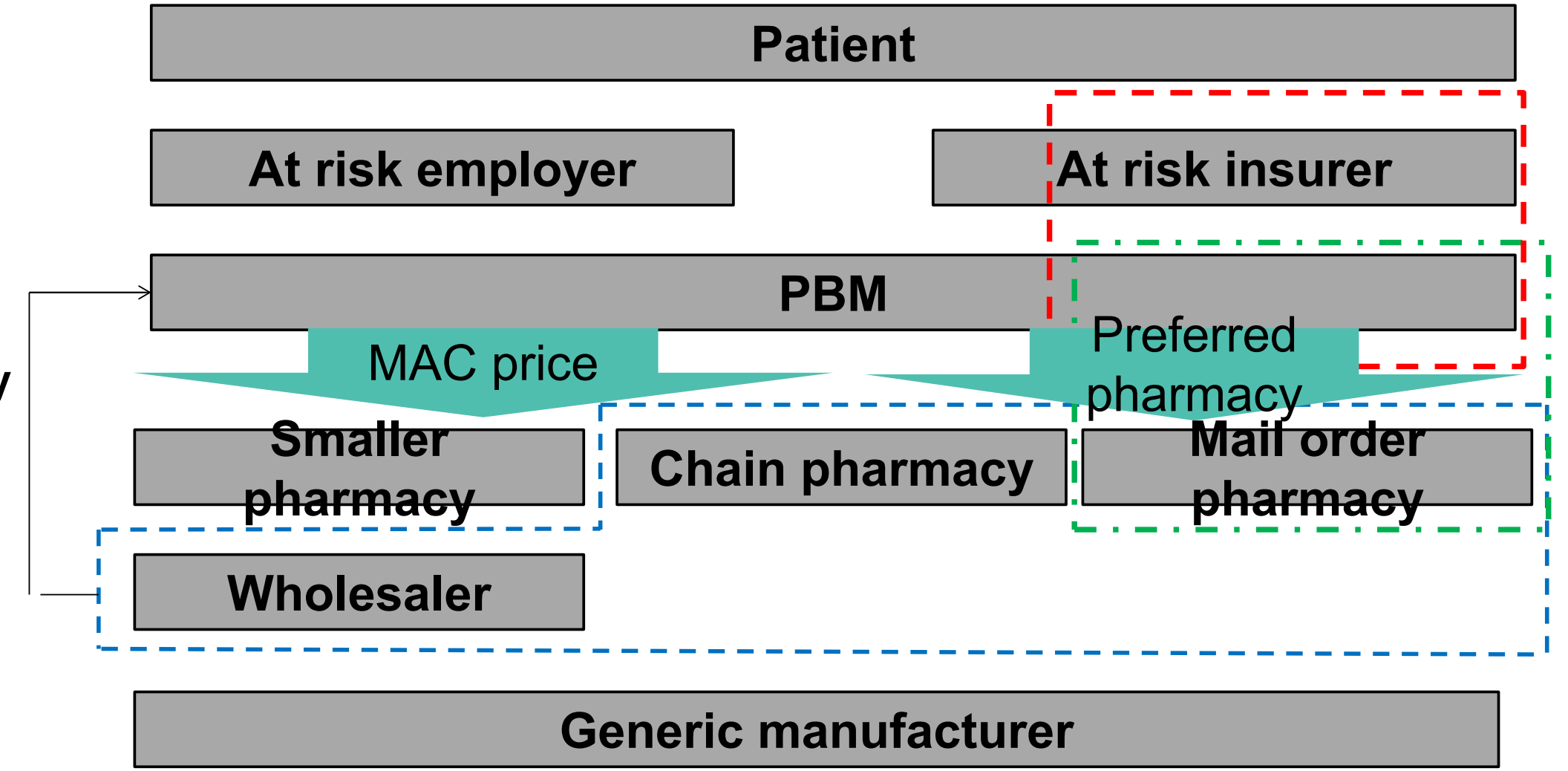
ompetition between brand and generic in limited generic markets

isruption of physician administered biosimilars by using the payer / provider spilt

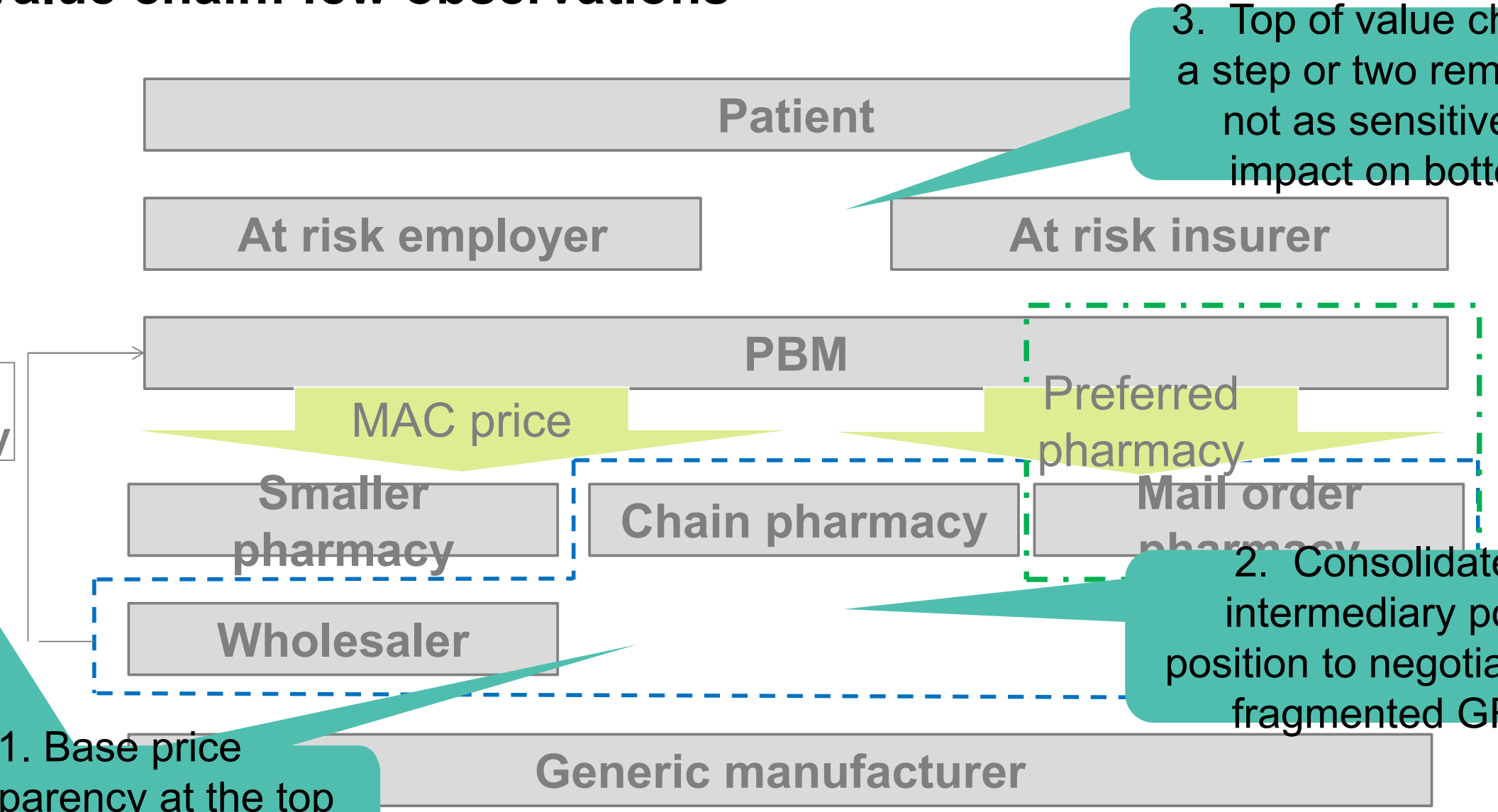
sing FDA processes to slow generic entry

ne regressive nature of the patient's generic costs

eric drugs: a simplistic view of the value chain

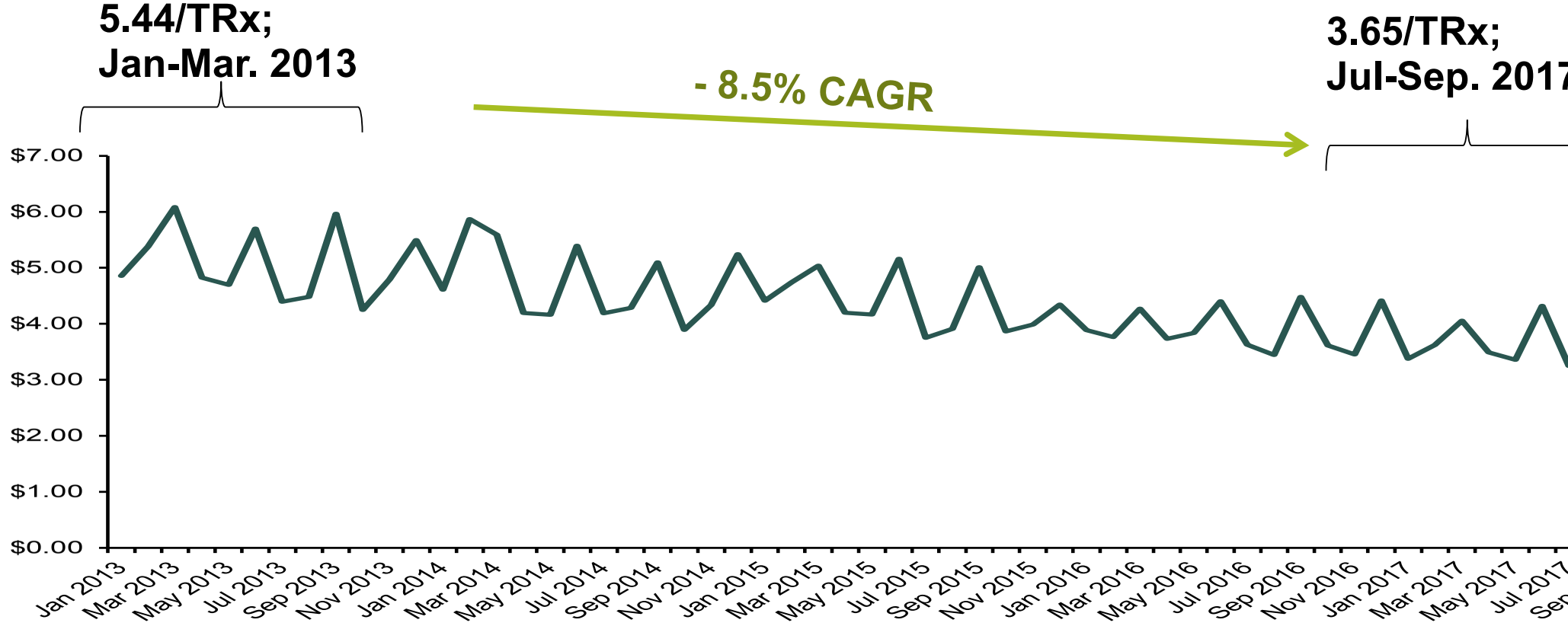


value chain: few observations



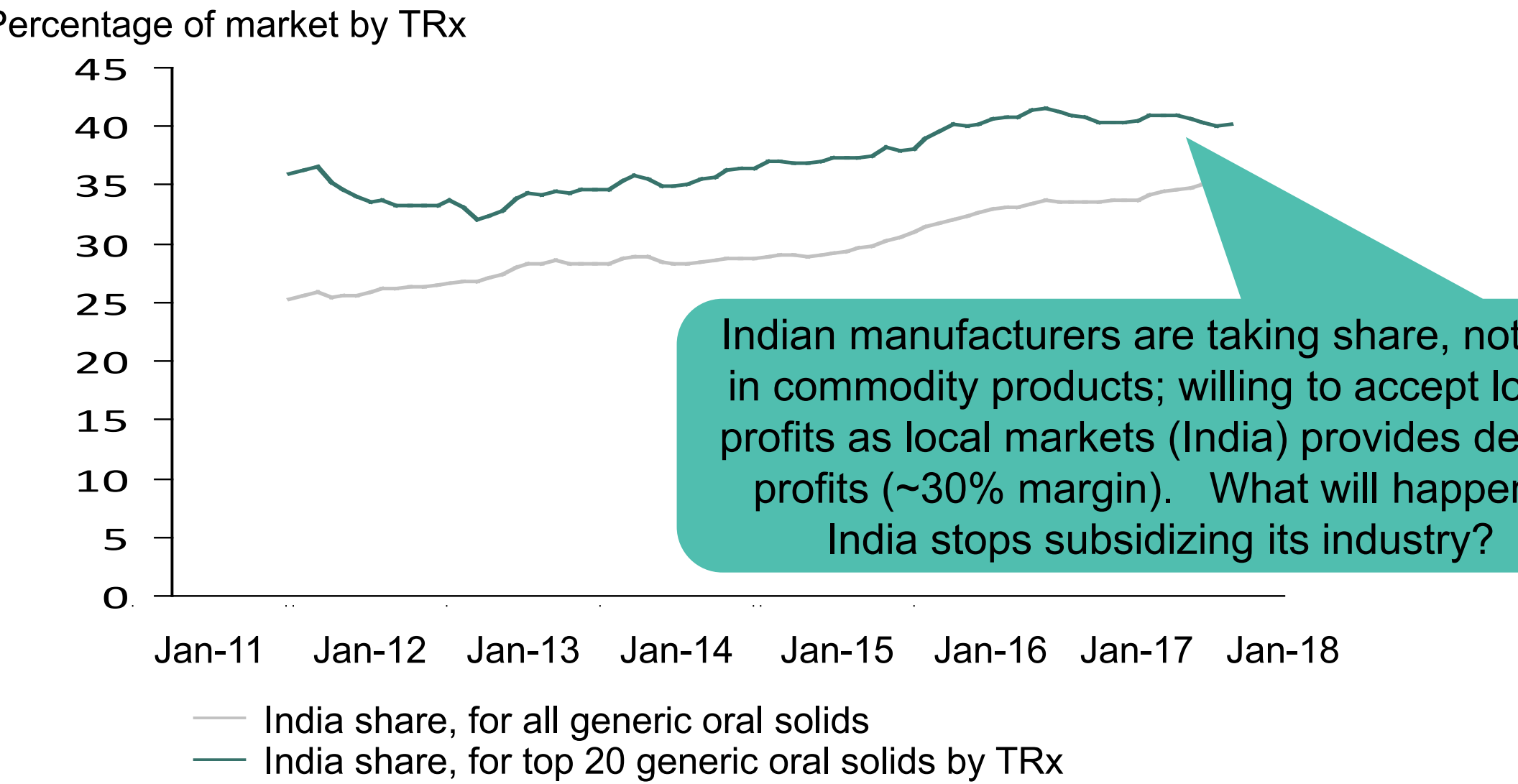
lt: US generic prices are broadly cheap at manufacturer leve
are getting cheaper; all good, but…

MS monthly sales / TRx)
generic products by TRx



ta includes top 20 US products by volume (amlodipine; atorvastatin, escitalopram; furosemid
tin, HCT, ibuprofen, levothyroxine, Lisinopril, losartan, metformin, metoprolol, montelukast,
ole, pantoprazole, prednisone, sertraline, simvastatin, amoxicillin)

re gradually driving the industry off shore; becoming more ndent on economics elsewhere



profits means less investment…

rapy areas with higher upfront costs will see lower willingness to
icipate given three buyers

lready hearing of less willingness to invest in respiratory, peptides

ver profit margin implies less value chain flexibility

ewer, larger facilities; lower excess manufacturing capacity

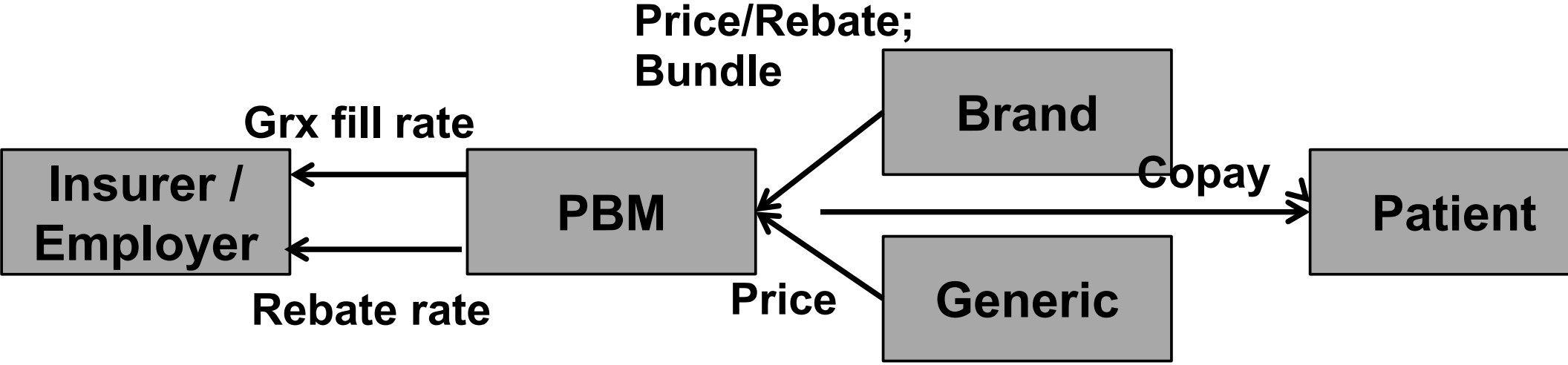
lower supply chain (defined quantities commitment)

ower ongoing Cap Ex

eterioration in expertise at local level

have seen this with generic injectables…

mpact of rebates and generic fill rate on product choice



market with 1-2 generics, brands often compete with GRx for share

eneric competes primarily in price; brand competes with price, structured rebates

BM, and may have different economics than generics; brand can also bundle adde

oducts

ost PBM contracts include targets of both GRx fill rates and branded rebate rate; l

th very high rebate may be too attractive to give up (Adderall XR)

gh discounts off price (e.g. brands where Medicaid/340B prices are a penny) may

preference of brand/AG over generic (e.g. Concerta)

itical question is isolating patients from copay differences when the branded prod

eferred

raging the split between providers and payers in physician nistered biosimilars

ysician-administered drugs have two pressure points – physician chooses produc
er can require preferring one product

ne Remicade case, incumbent contracted exclusive position vs. the biosimilar wit
nificant portion payers; thus every provider must stock innovator products

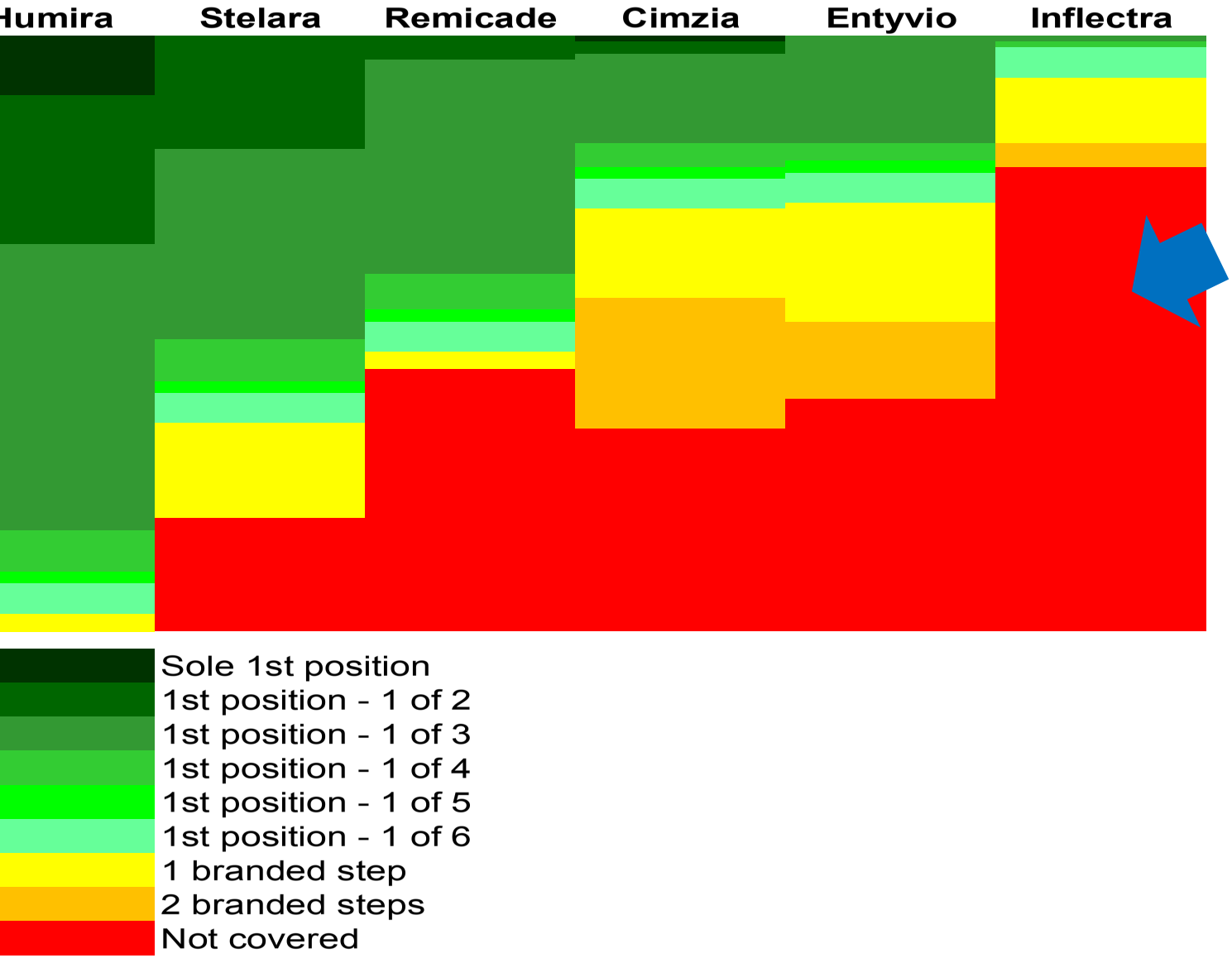
J then gave discounts to providers across a broad portfolio of products, conditione
volume of Remicade (with an understanding of demand at each provider)

ny 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
eliability – our view: true, but JNJ forced the decision and was there first to capture the volum

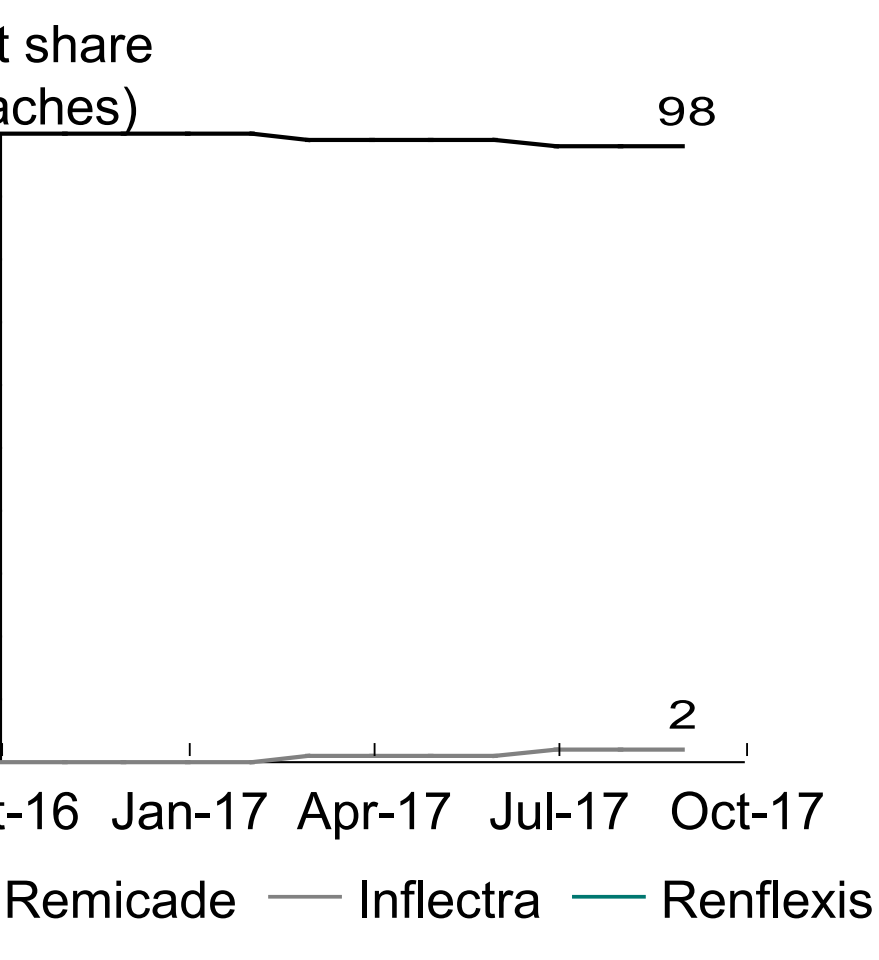
ulary coverage in Crohn's disease: Inflectra broadly blocked

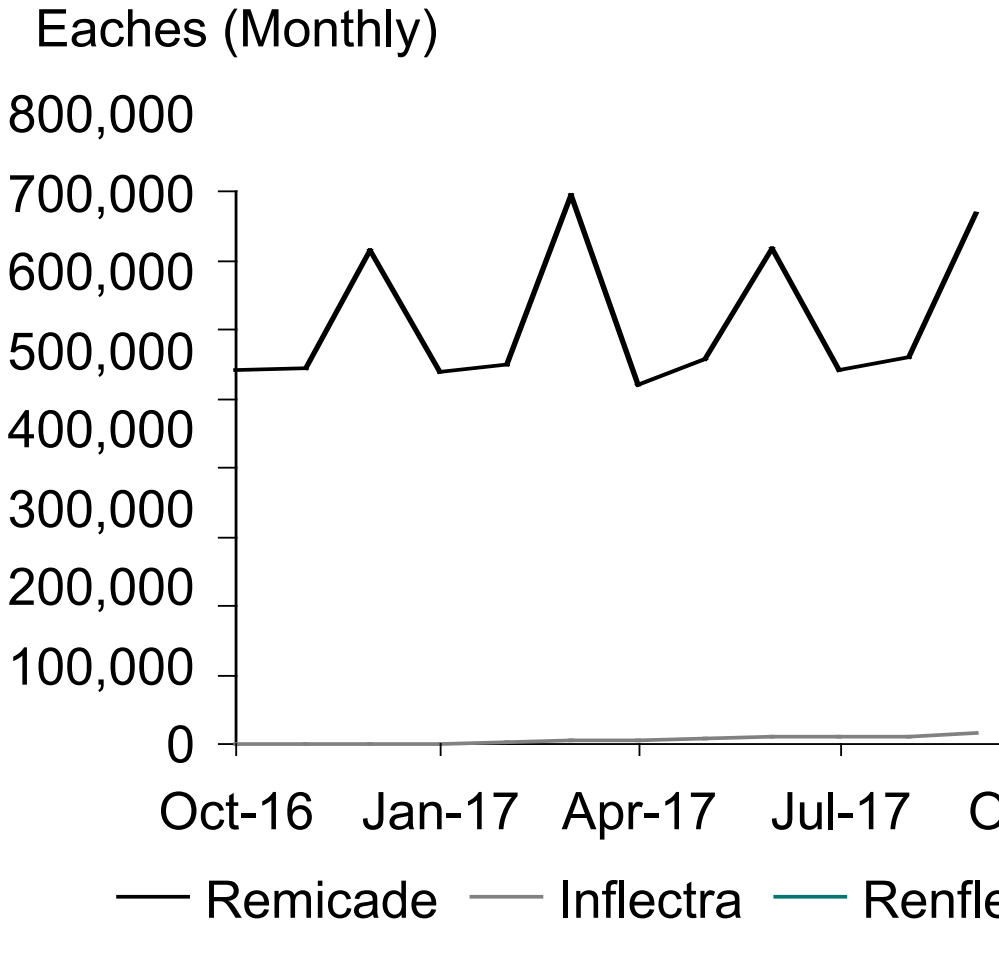


Note: data represents formulary coverage in largest formularies responsible for 50% of US commercial coverage mid 2017; source: Bernstein analysis of formulary data

imab (Remicade) US market, biosimilars did not penetrate

k's Renflexis was launched Jul-17 and just started showing up in September IMS
ches in September)



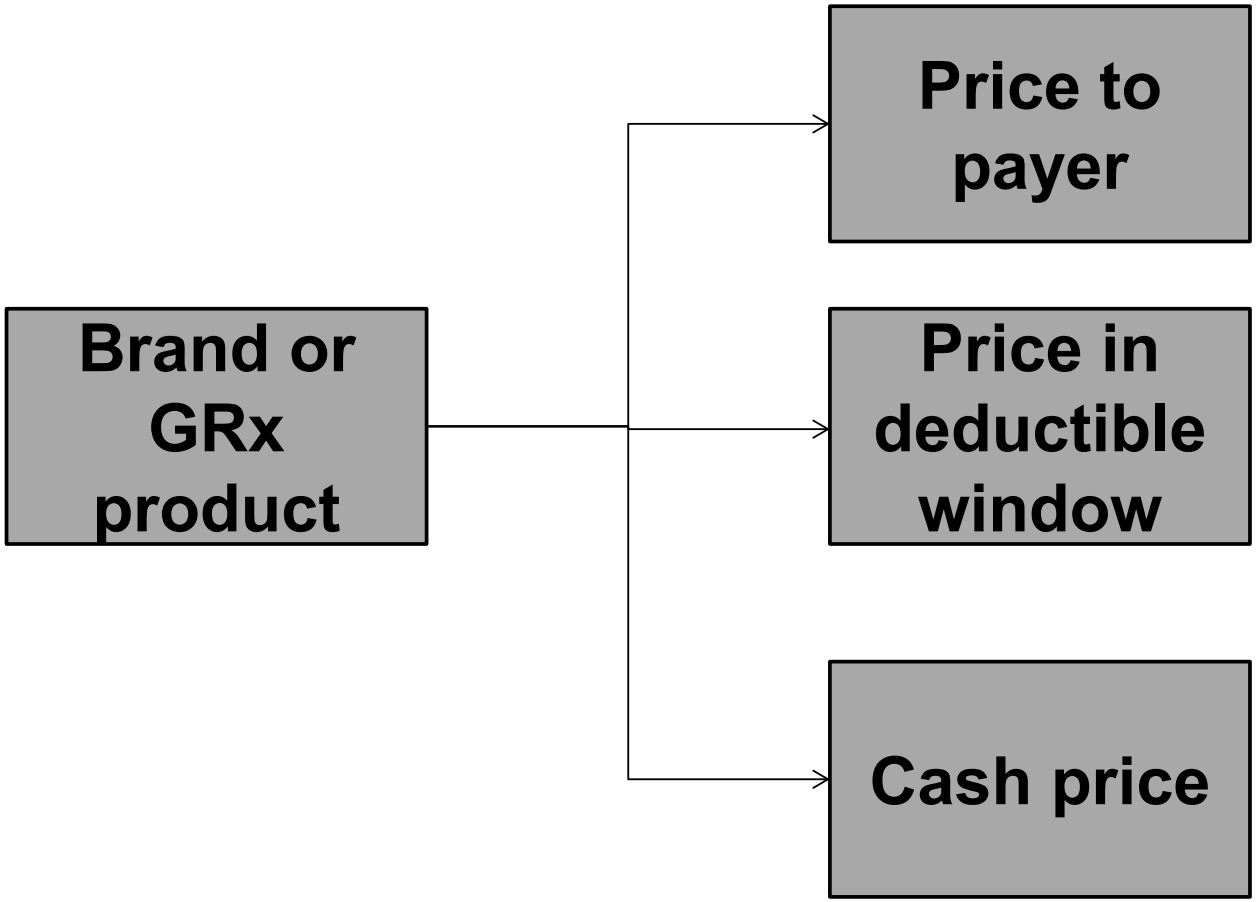


MS; Bernstein analysis

g 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
itizen titions	Multiple citizen petitions, adding information and arguments over time (e.g. Copaxone)	Require fees for CP fili corporations and use f staff response capabili
elay in cision aking	FDA refining requirements for approval after generic filing (e.g. Lialda)	Make generic product specific guidelines par NDA process

ric (and brand) prices are often regressive; most exposed nt pays the highest price



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

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

Patient pays full price; what t 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 pharmaceutic 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 af 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 expire 2016, but patent thicket of 100+ patents (indication/method of treatment (22), formulation (14), manufacturi (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 cost

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) (drug 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 en

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) 7 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

nderstanding 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 Mark

A Series of Individual Markets Defined By:

- Therapeutic Class, Drug Molecule, Dose Form &/or Stre

Patient Demand for Generics is Market Specific

- Diabetic Cannot Use Lower Cost Epileptic Drug to Treat Diab

Measures of Market Concentration by Ther. Cla

Economic Substitution vs Generic Substitution

Payer Demand Drives Low Cost Generics to 9 c

Supply of Generic Drug

Fewer Generic Firms & Industry Consolidation

- Teva acquired Actavis; Teva acquired Allergan; Teva acquired Anda

Most Generic Firms Have Broad Line of Produ

Most Brand Name Firms Have Generic Divisio

- Pfizer → Greestone & Hospira; Novartis → Sandoz; Teva → Allergan.

Authorized Generics Not Really Generics

- NDA-authorized, not ANDA; Pre-empt & may dampen 'true" generic entry o

Bundling & Tying Arrangements in Contracts

- e.g., Must buy firm's generics to access firm's discounts & rebates on b

PBMs Sometimes Add "Spread" Onto Generic

- Generic spread for mail, specialty, preferred networks, may be higher th
- Some PBMs charge full copay even when actual generic prescription co

Competition & Market Powe for Generics

of ANDAs Not Good Measure of Competitio

- Unused ANDAs;

Only 1 or 2 ANDAs in Market→ Pricing Power

API Contracts Can Limit/Manipulate Competit

- Lorazepam & Mylan in early 2000s→ exclusive dealing with API & price i
- What's up with atenolol shortage?

Some Generics Have Faced Over-Competition

- GPOs have driven some generic injectable prices so low firms exit the m
- Infrastructure for sterile injectables not keeping up→ recalls & shortage

Some Generic Markets Too Small to be Profita

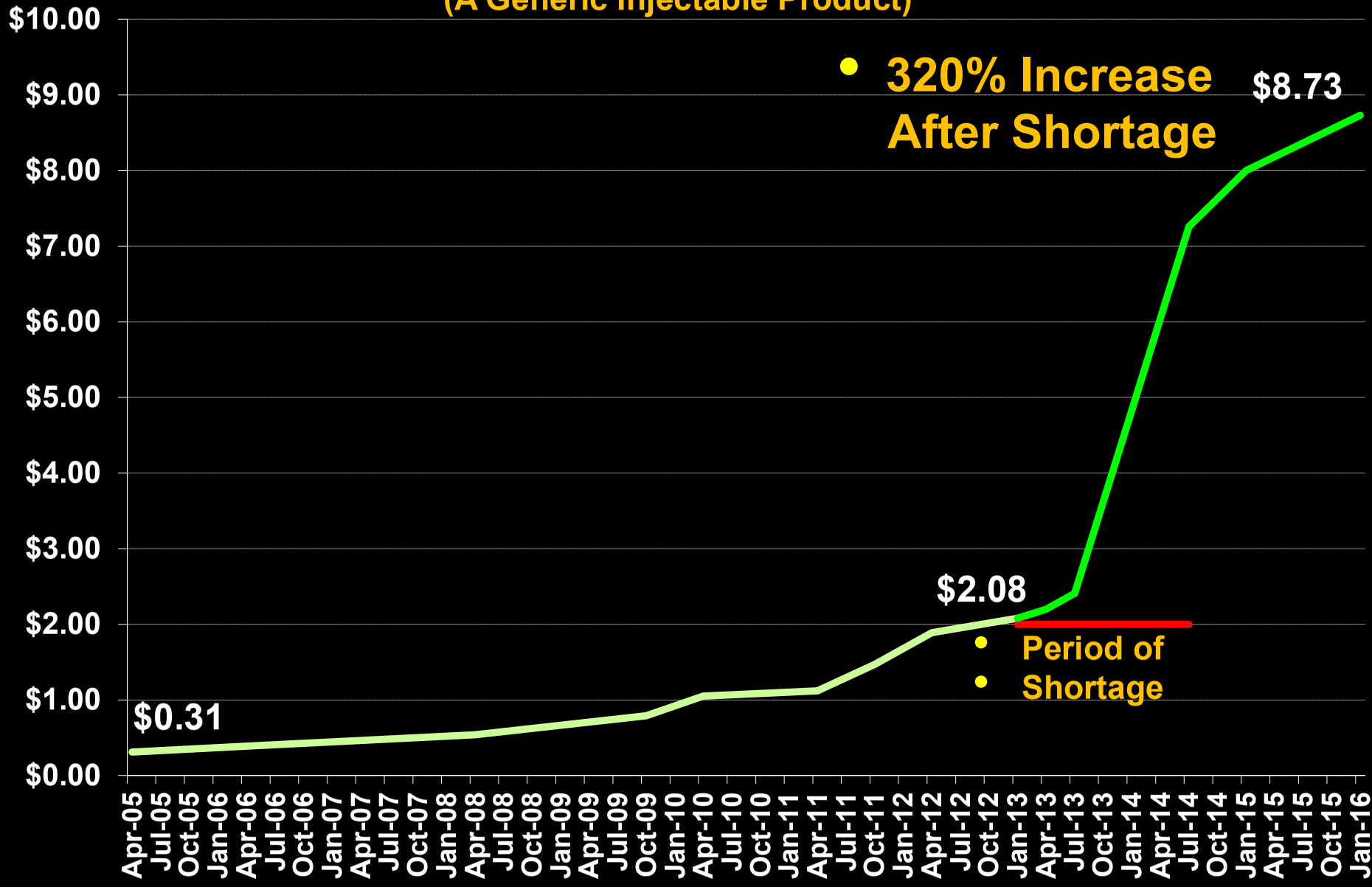
- Usual incentives (i.e., exclusivity) will not increase competition when market too

FTC Should Evaluate Shortages for Business Rea

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 competiti

Make Sure the 'Total Time' to Market Is Manag

- Should not just shift ANDA review time from FDAs clock to firm's clock.

Unapproved Drugs Initiative → Competition W

- Colchicine (Colcrys) reduced competitors and ↑ price from $.09 to $4.85
- Multiple unapproved drugs → 1 high-priced brand instead of more comp
- Cost Medicare about $1.2 billion from 2011-2015 (total national effect ~$3.7 b

Pay-for-Delay Invites Gaming & Delayed Compet

Authorized Generics Confuse Consumers

Trade Agreements Expand IP & Limit Generic

- TPP would have taken length of biologics exclusivity out of Congress' h

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 Y

2 in 3 Old Generics Had >25% Price ↑ in Last 5 Ye

- These were one time price increases, not cumulative increases

Brand:Generic Price Gap ↑ from 3:1 to ~ 10:1

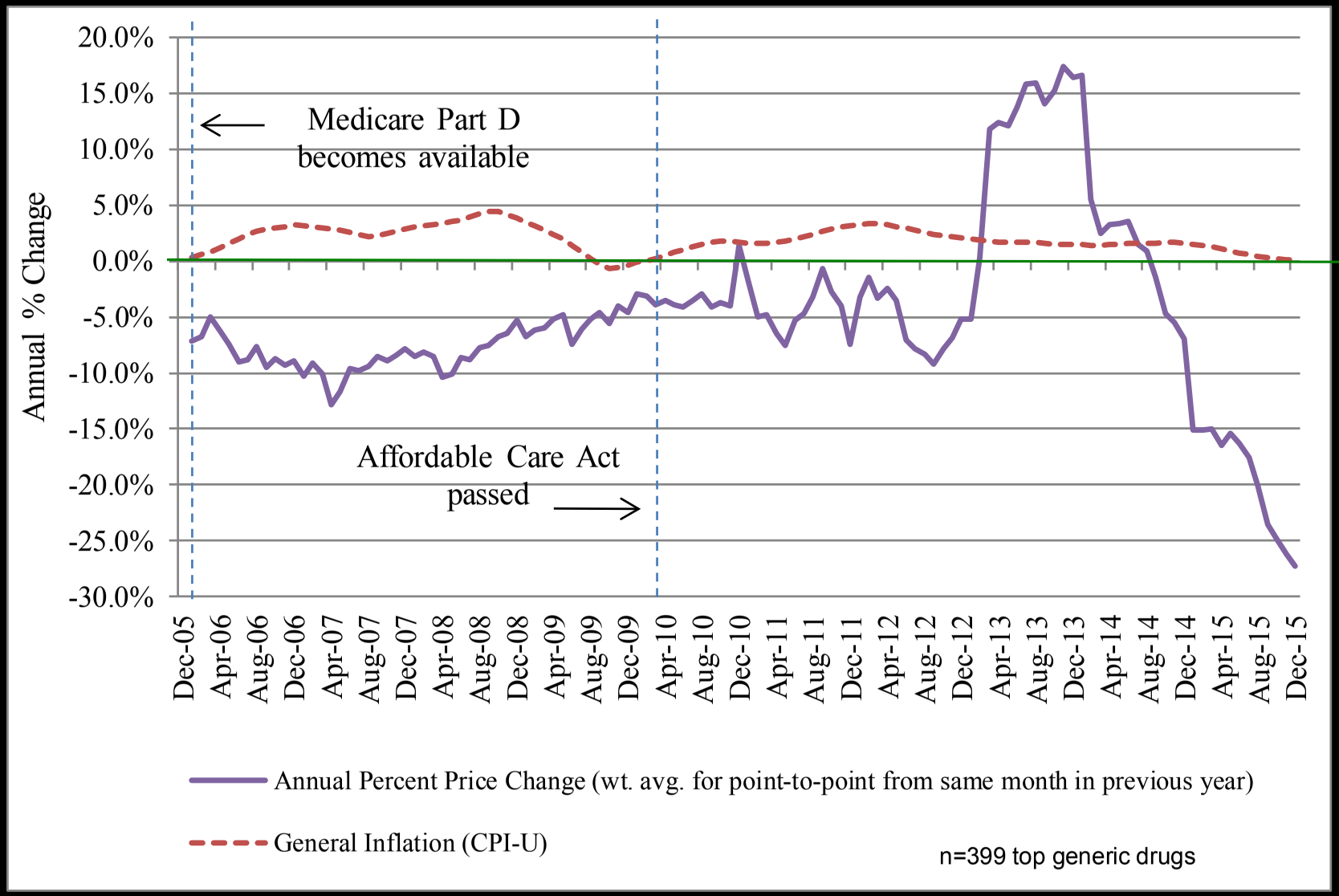
- Generics have doubled in price ($20/Rx to $40/Rx), brands have ↑

Older Generics Raise Prices to Keep Up ($0.50 ↑ to $

New Generics Enter at Much Higher Price (>$5/da

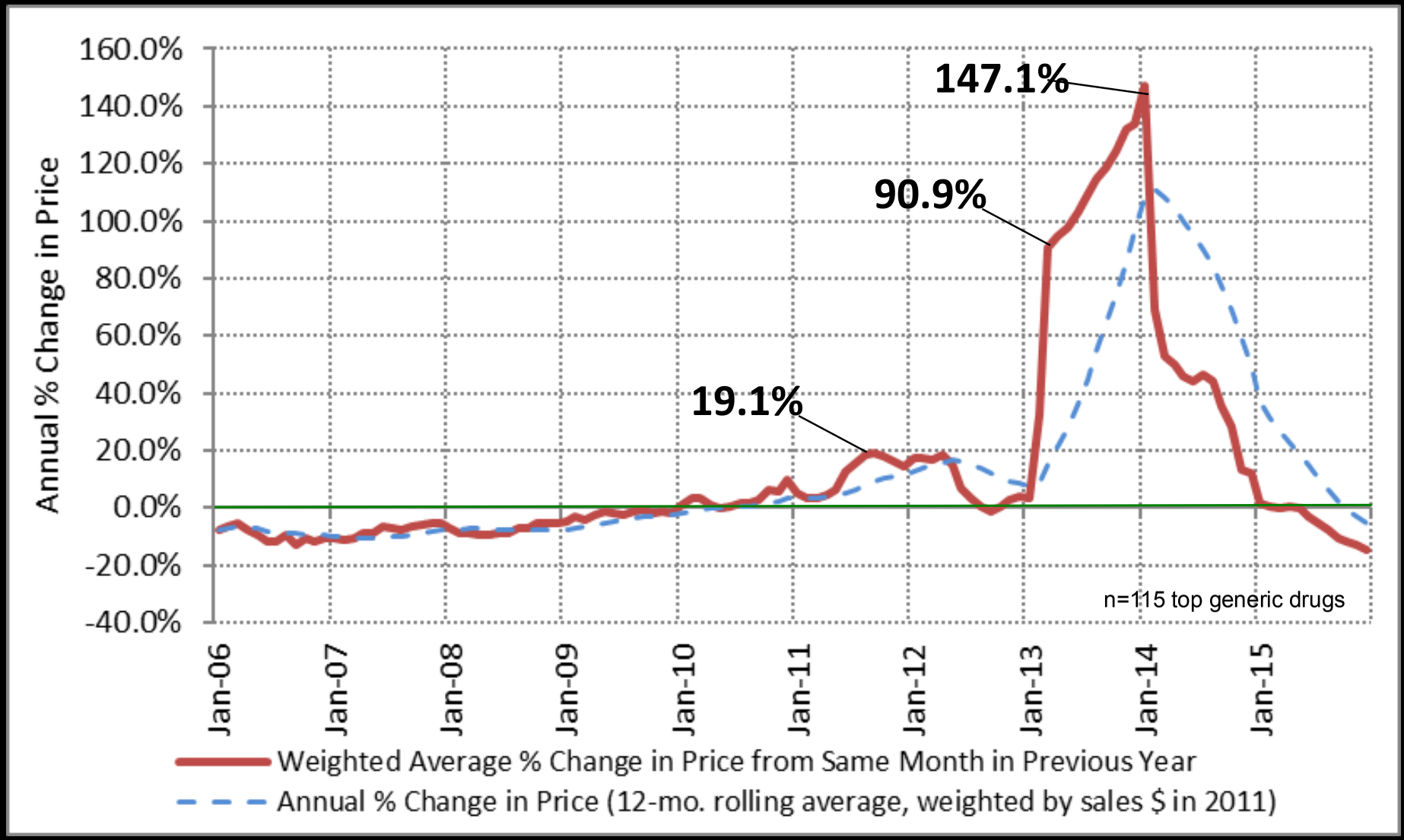
- Ondansetron (8 mg tabs) entered at $85/day (2007)
- Enoxaparin injection entered at $98/day (2011)

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



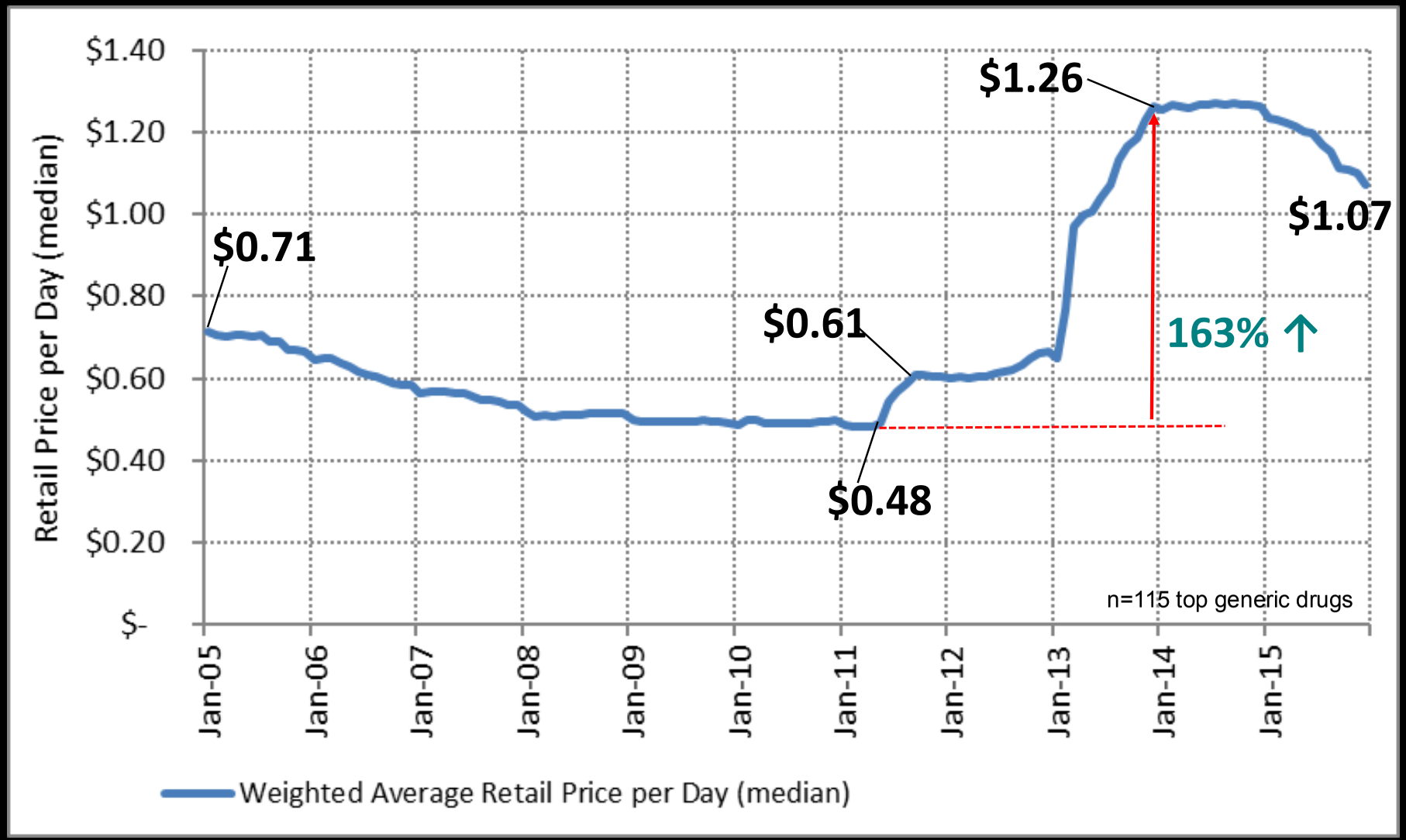
er S, Purvis L, Trends in Retail Prices of Generic Prescription Drugs Widely Used by Older Americans 2006 to 2015. AARP Public Policy Institute, Rx Price Watch Report June 2
he AARP Public Policy Institute and the *PRIME* Institute, University of Minnesota, based on data from Truven Health MarketScan® 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



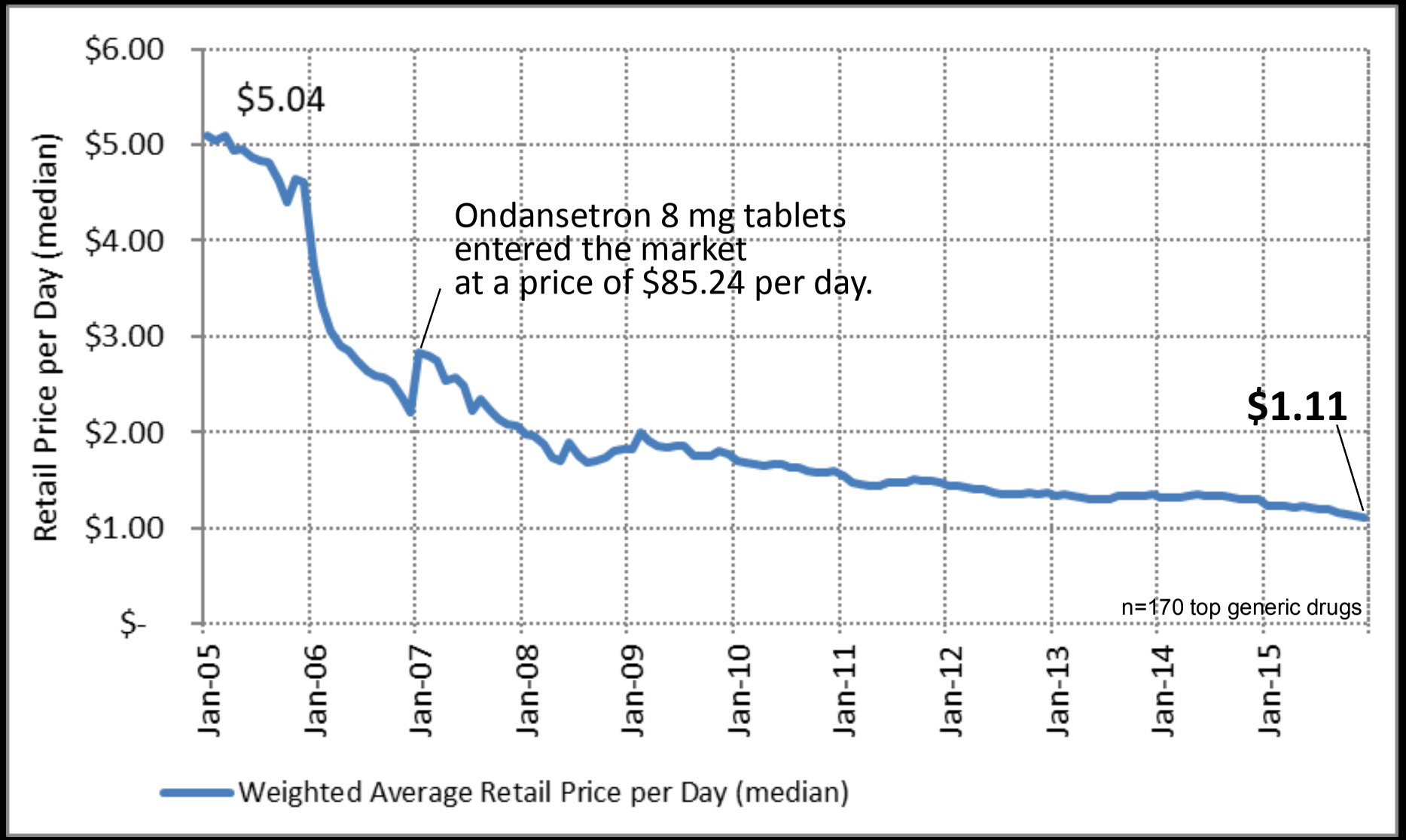
er S, Purvis L, Trends in Retail Prices of Generic Prescription Drugs Widely Used by Older Americans 2006 to 2015. AARP Public Policy Institute, Rx Price Watch Report June 2
he AARP Public Policy Institute and the *PRIME* Institute, University of Minnesota, based on data from Truven Health MarketScan® Research Databases.

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



er 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 2
he AARP Public Policy Institute and the *PRIME* Institute, University of Minnesota, based on data from Truven Health MarketScan® Research Databases.

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

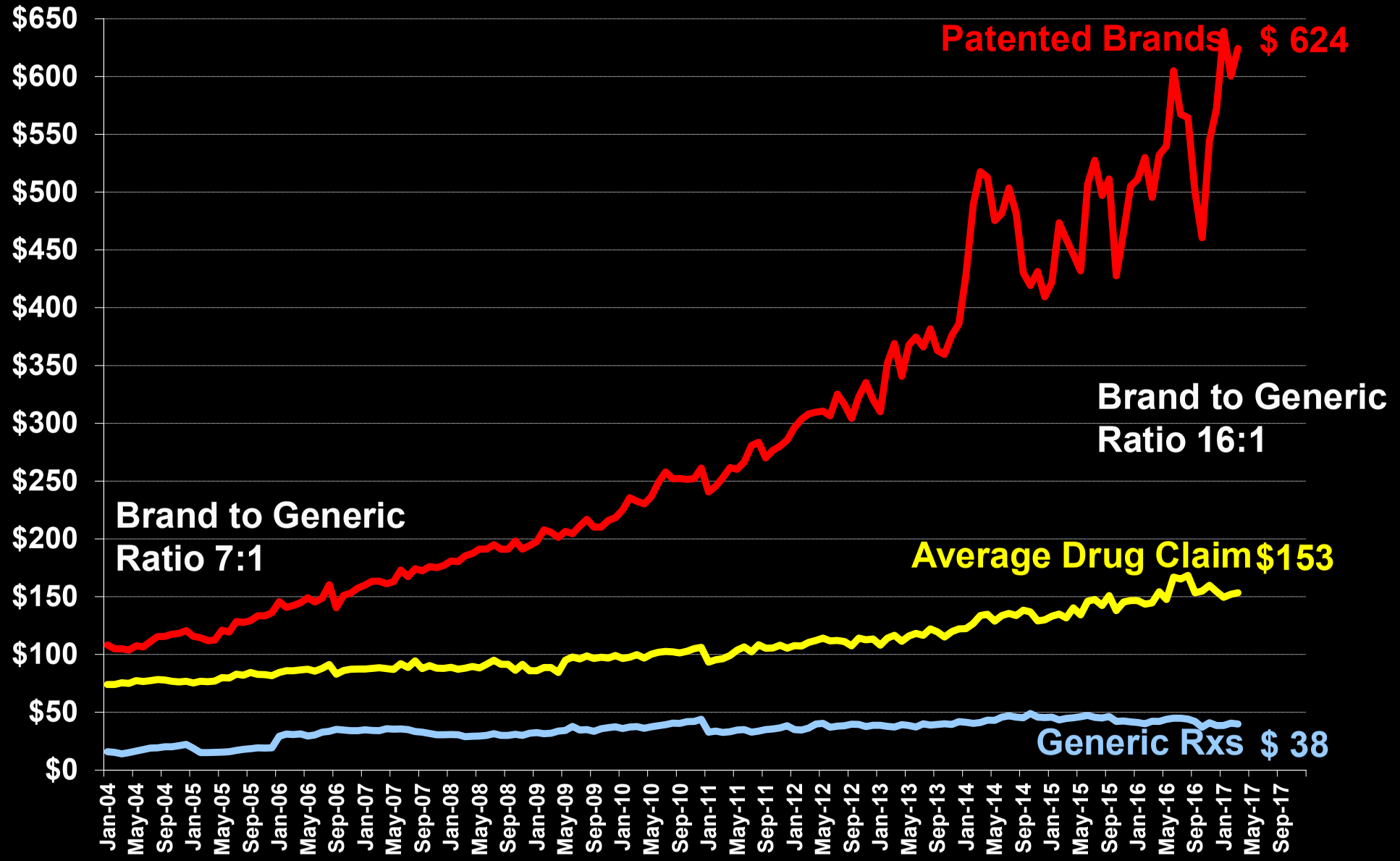


er S, Purvis L, Trends in Retail Prices of Generic Prescription Drugs Widely Used by Older Americans 2006 to 2015. AARP Public Policy Institute, Rx Price Watch Report June 2
he AARP Public Policy Institute and the *PRIME* Institute, University of Minnesota, based on data from Truven Health MarketScan® Research Databases.

Weighted Average Retail Price per Day (median) from 2005 to 201
For Older Generic Cohort (1980-2003) &
Newer Generic Cohort (2004-2009)

er 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 2
he 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 Pri

- Screen for prices & price changes that are 'unconscionable' & 'unreason
- Single point price changes >10%, >25%, >50% & >100%

Link Transparent Prices, Accountability & Covera

- Quasi-governmental commission reviews & evaluates prices & price cha
- Price behavior not justified, drug not covered by Medicare, Medicaid, com

Prohibit Market Distorting Behaviors

- Copay Coupons, Undisclosed Rebates, Patents for Product Hopping & Comb
- HHS OIG has declared copay coupons as 'kickbacks' & prohibited them in gov

Recognize Economic Impact of FDA Policy & Acti

Enable Value-Based Decisions→Requires Actual

nderstanding Competitio
Prescription Drug Market
ntry and Supply Chain Dynamic

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

FEDERAL TRA

November 8, 2017

BREAK

nderstanding Competitio
Prescription Drug Market
ntry and Supply Chain Dynamic

Panel 2: Understanding Intermediaries: Pharmacy Benefit Managers

FEDERAL TRA

November 8, 2017

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

USC Price
Sol Price School of Public

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

port for the research cited in this presentation was provided by the Scha
ter for Health Policy & Economics and by Amgen through a contract with
cision Health Economics.

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

oday's talk

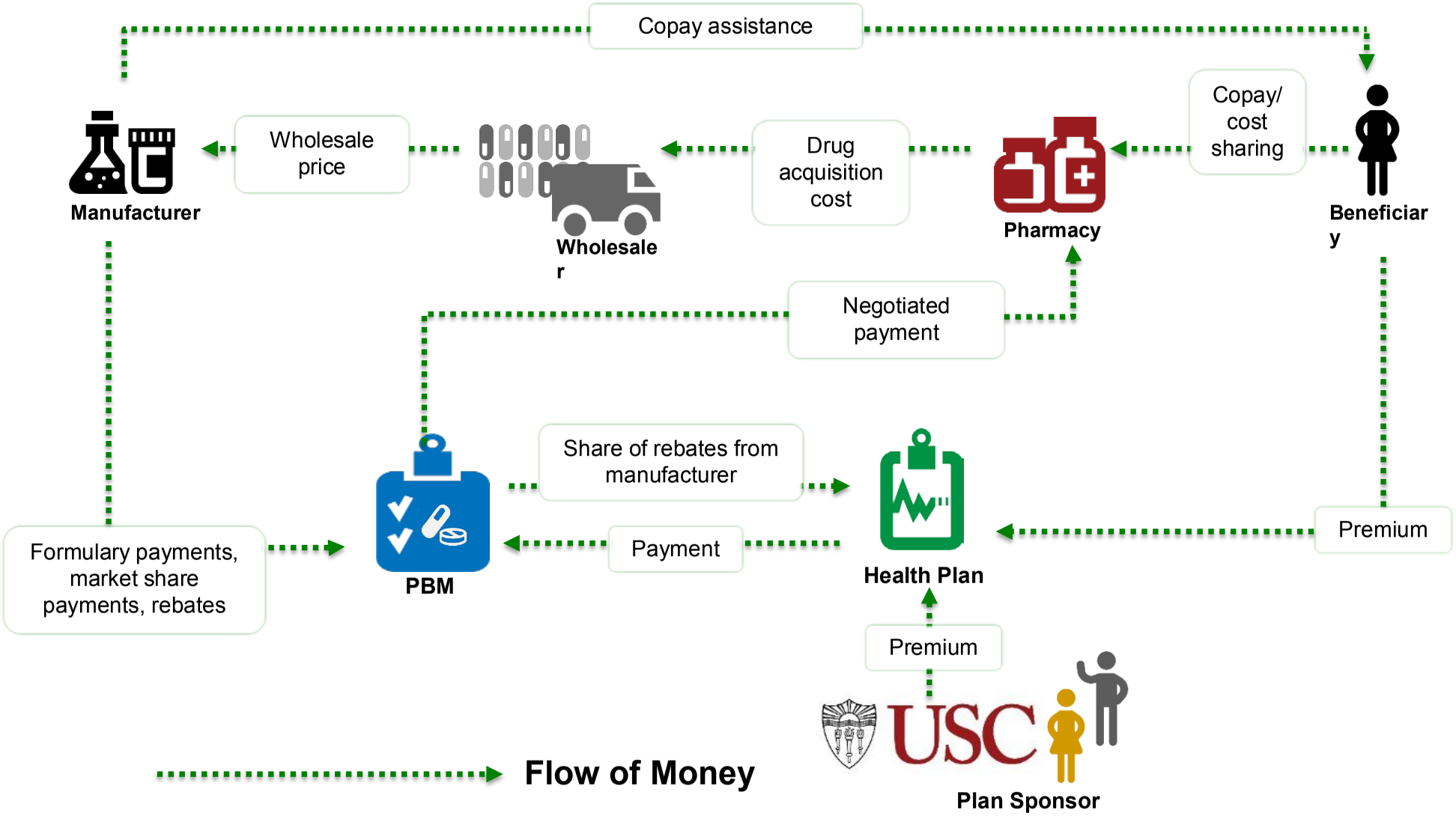
How do drugs reach from manufacturers to consumers?
Who makes how much money?
Are PBMs making too much money?

Conceptual framework: Flow of prescription drugs

Manufacturer | Wholesaler | Pharmacy | Beneficiary

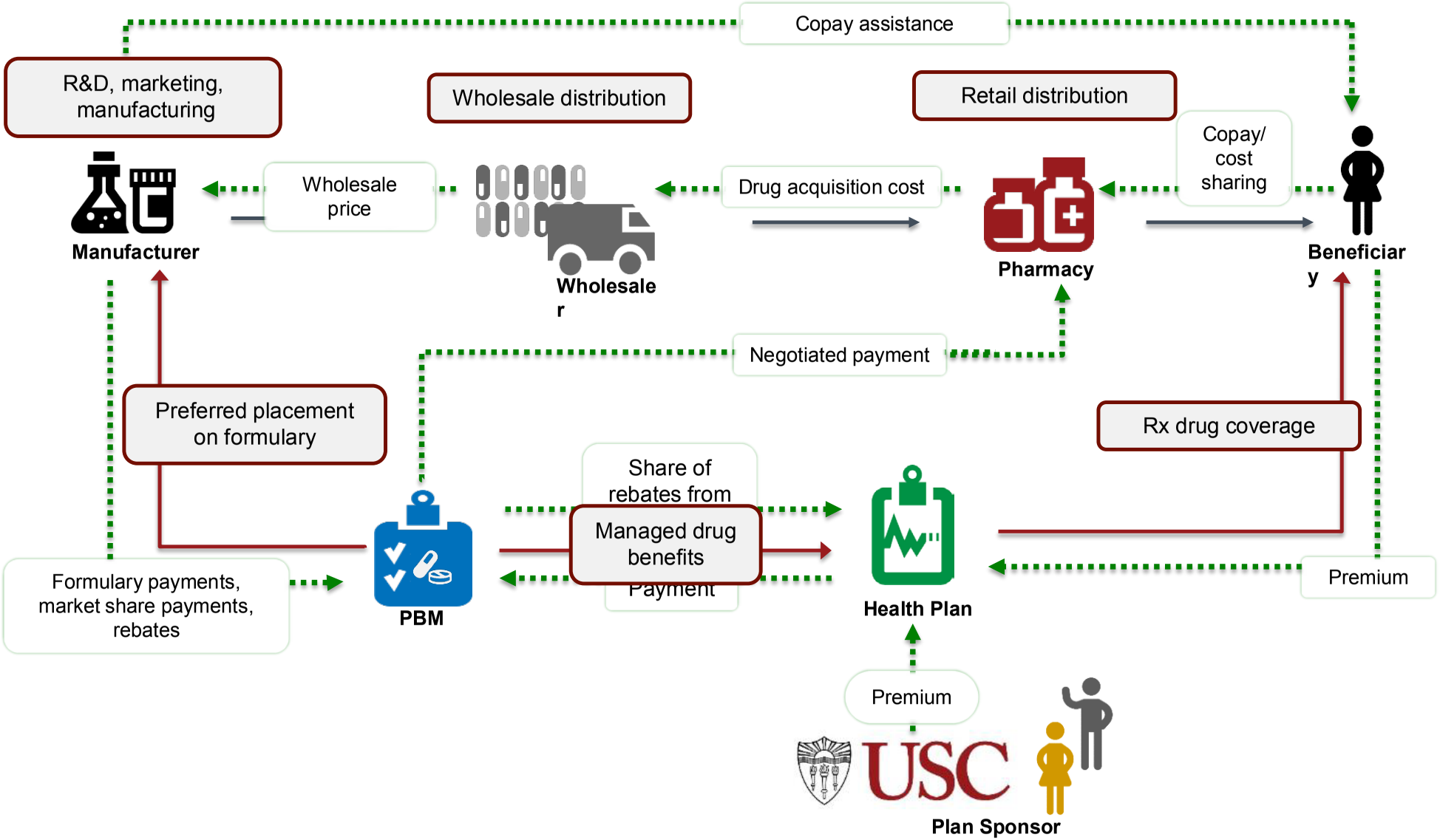
Pharmacies may be mail order or retail, and may be integrated with PBM. Plan sponsors may include employers, unions, managed care orgs, among others.

Conceptual framework: Flow of money



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



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?

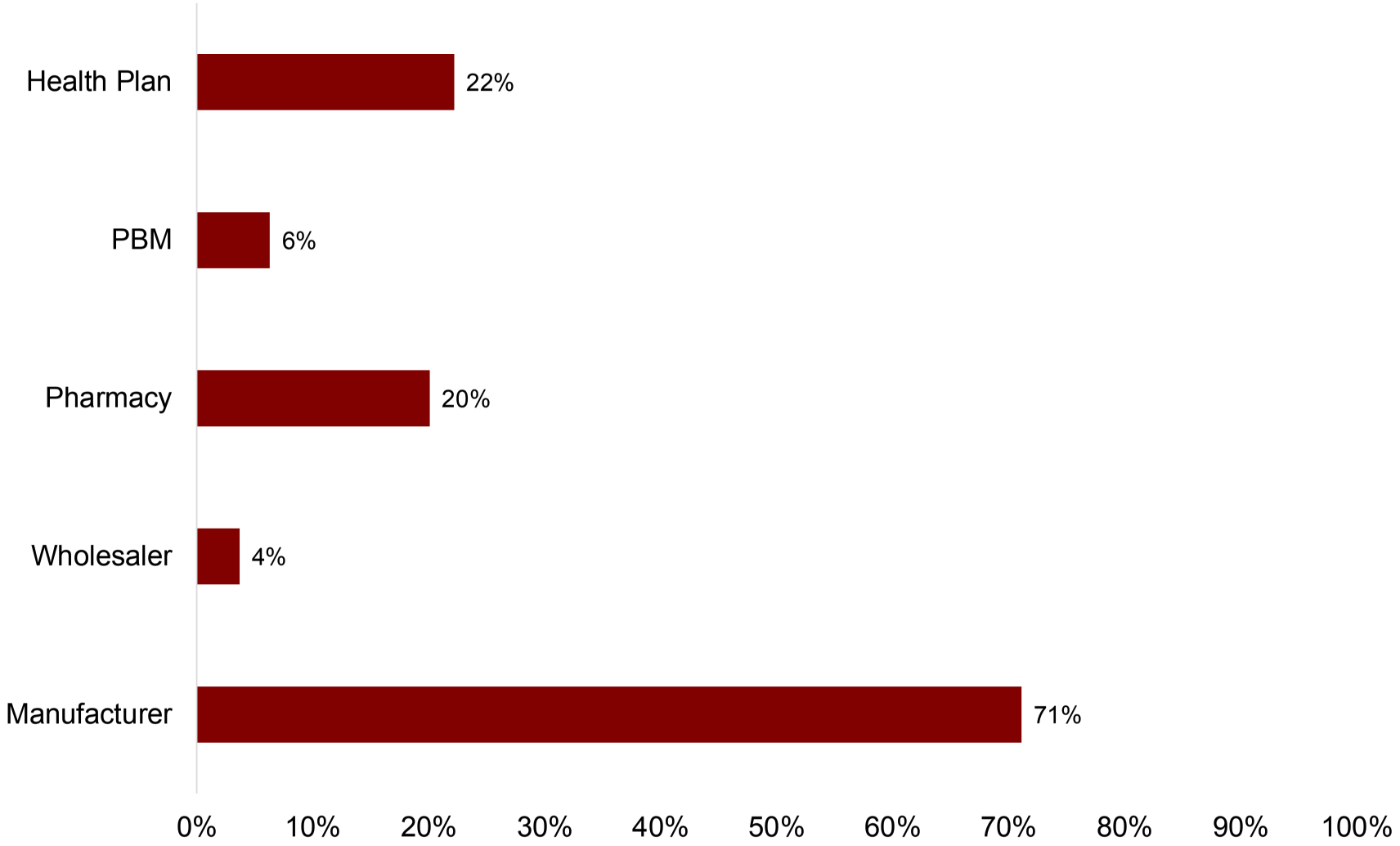
Identify top publicly traded firms for each market segment: manufacturers, wholesalers, retailers, pharmacy benefit managers, & health plans

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

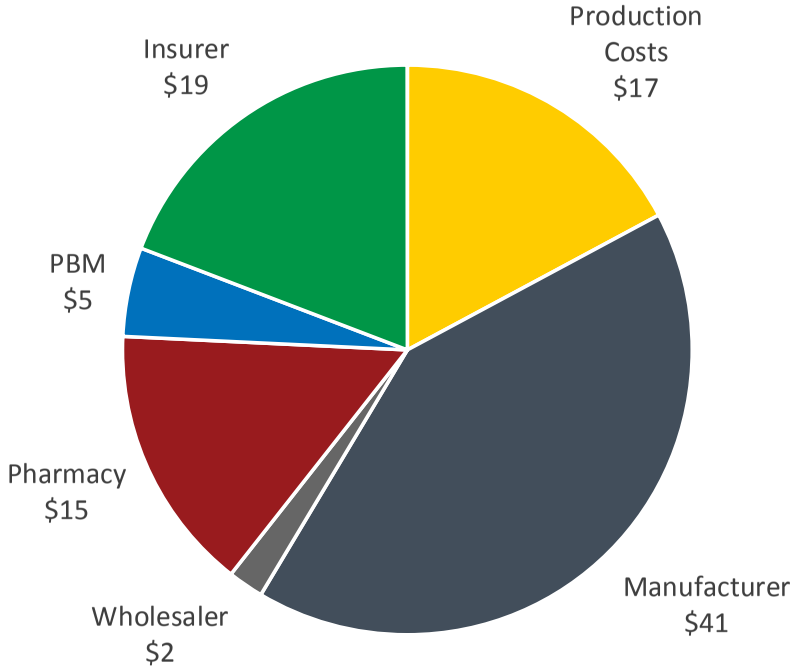
Use the conceptual framework and financial data to illustrat the flow of funds for a drug purchased by an insured consumer at a retail pharmacy

Gross profit margins



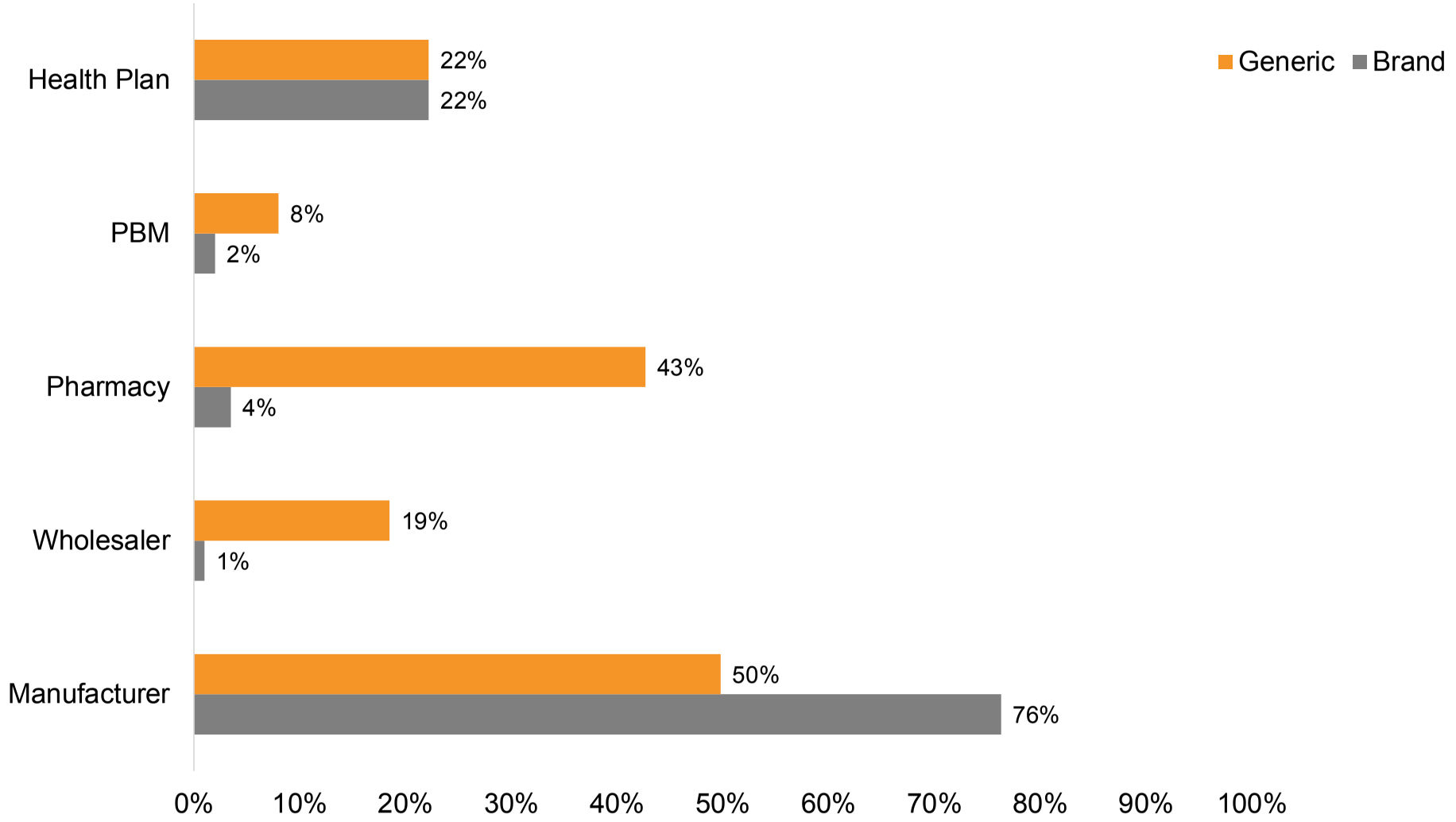
All gross margins are are US sales-weighted averages based on data from 2015 SEC 10K filings and annual reports

Flow of $100 spent on pharmaceutical drugs, overall industry

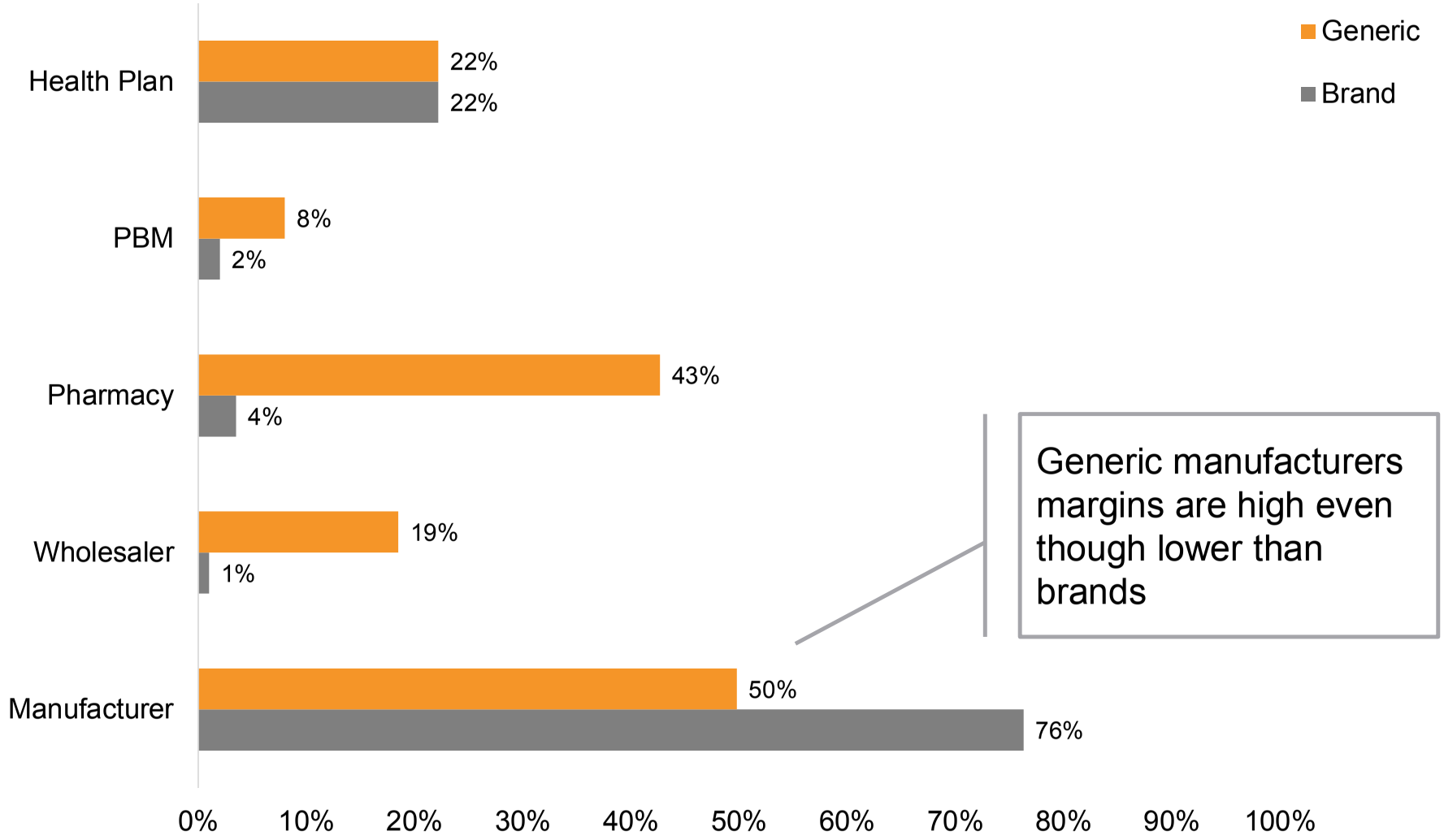


negotiate discounts and rebates with drug makers.

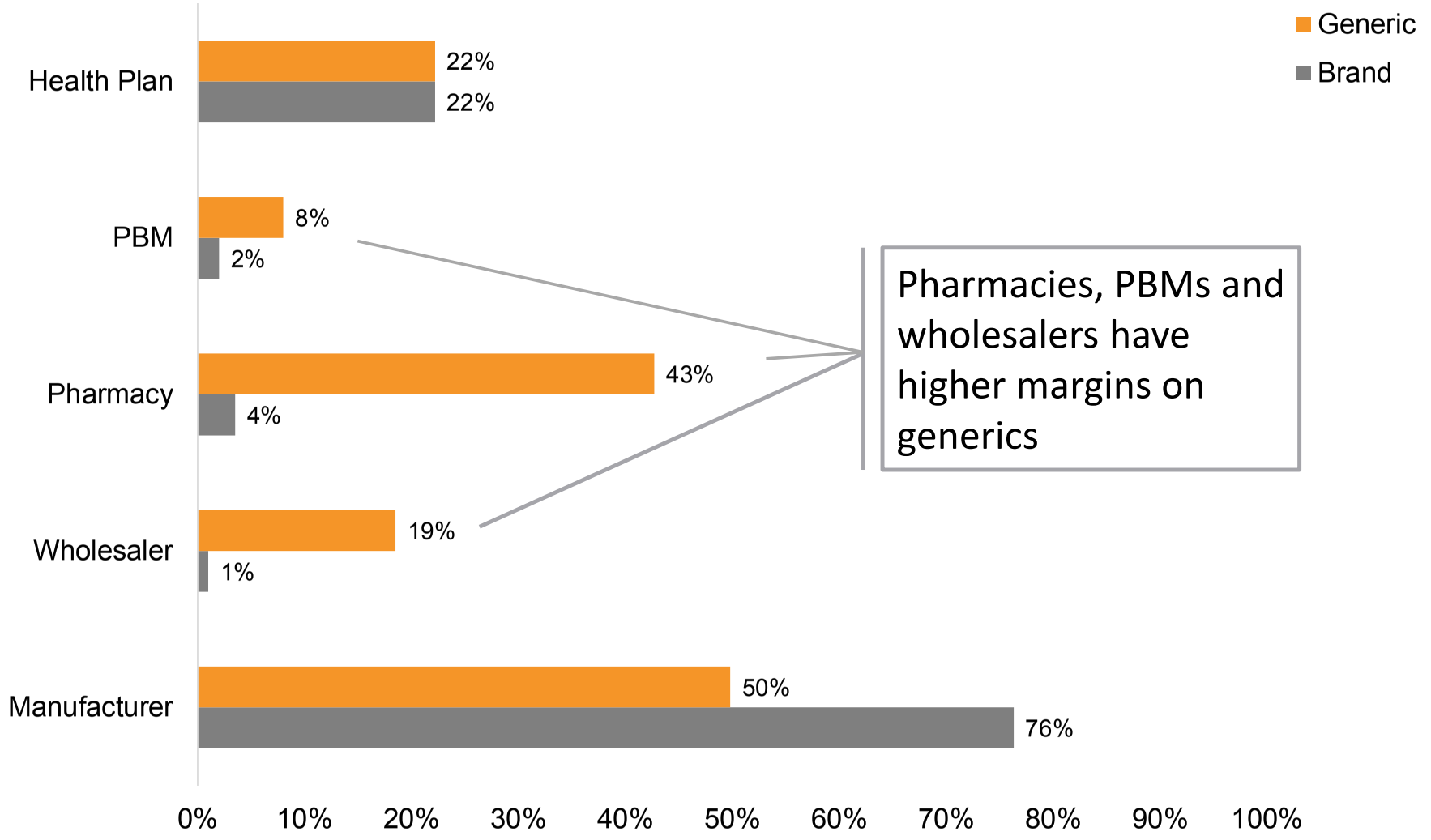
Gross profit margins: Brands versus generics



Gross profit margins: Brands versus generics



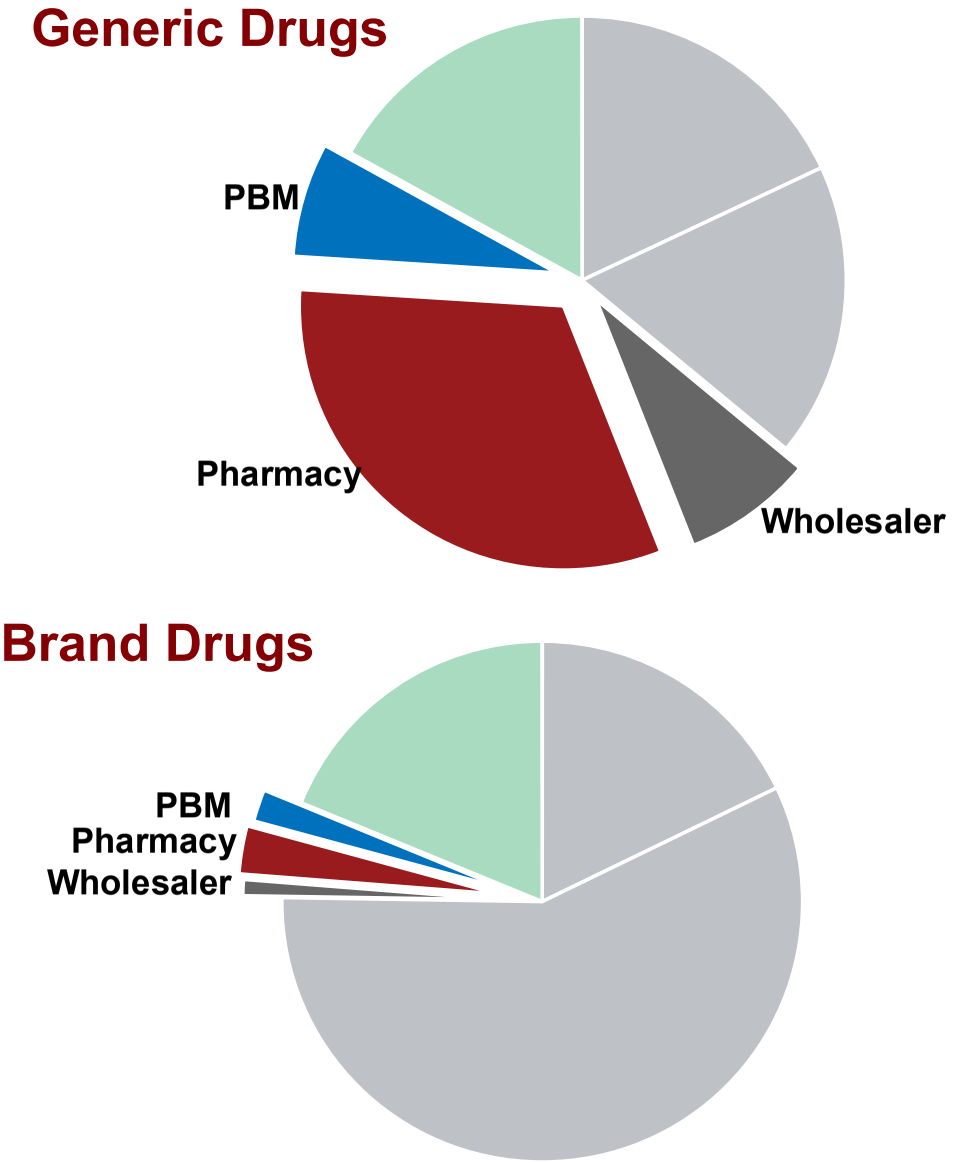
Gross profit margins: Brands versus generics



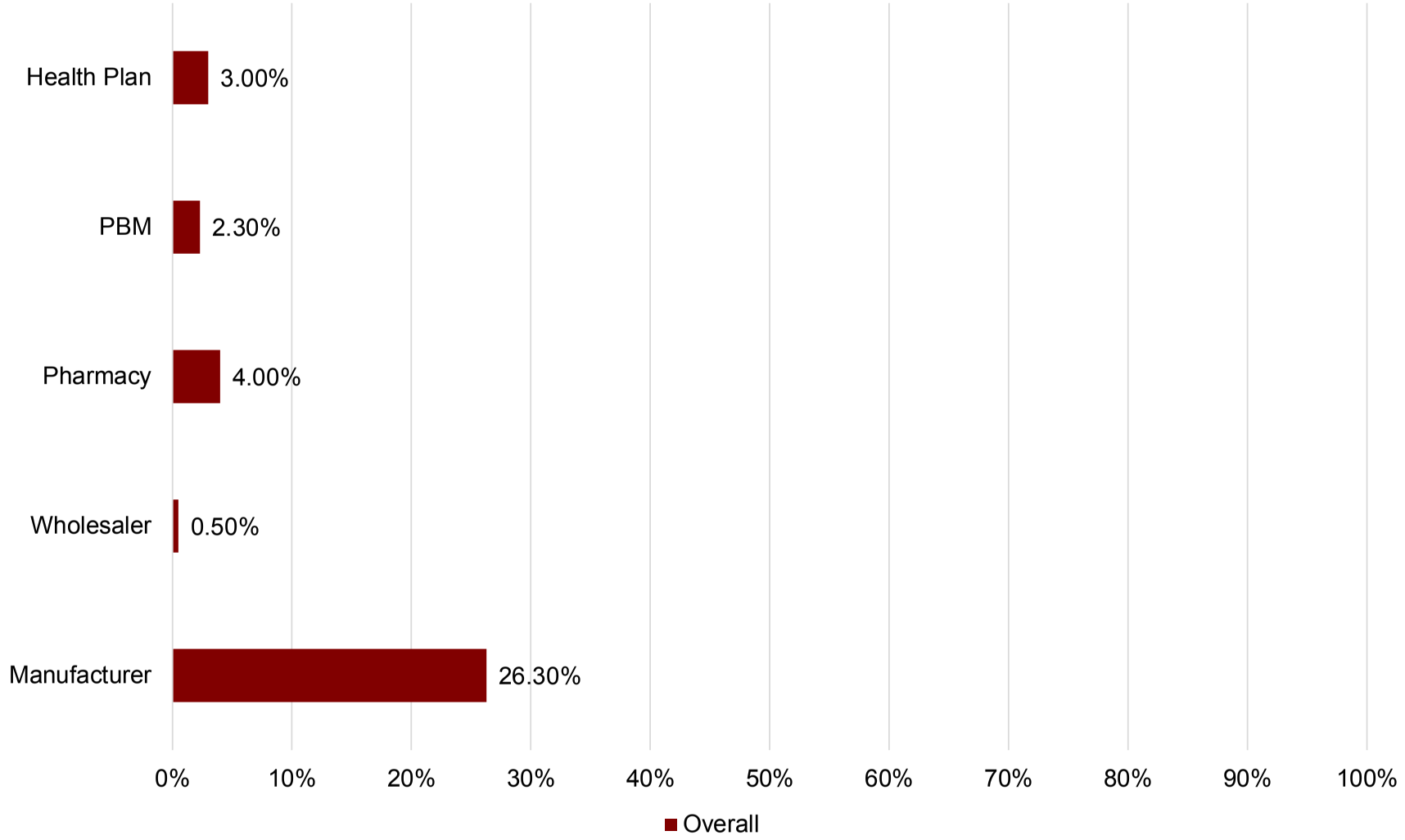
Flow of $100 spent on pharmaceutical drugs, brand and generic

al, PBMs, Pharmacies, and
esalers **capture $47 for**
$100 on generics

ared to **$8 for every $100**
ands

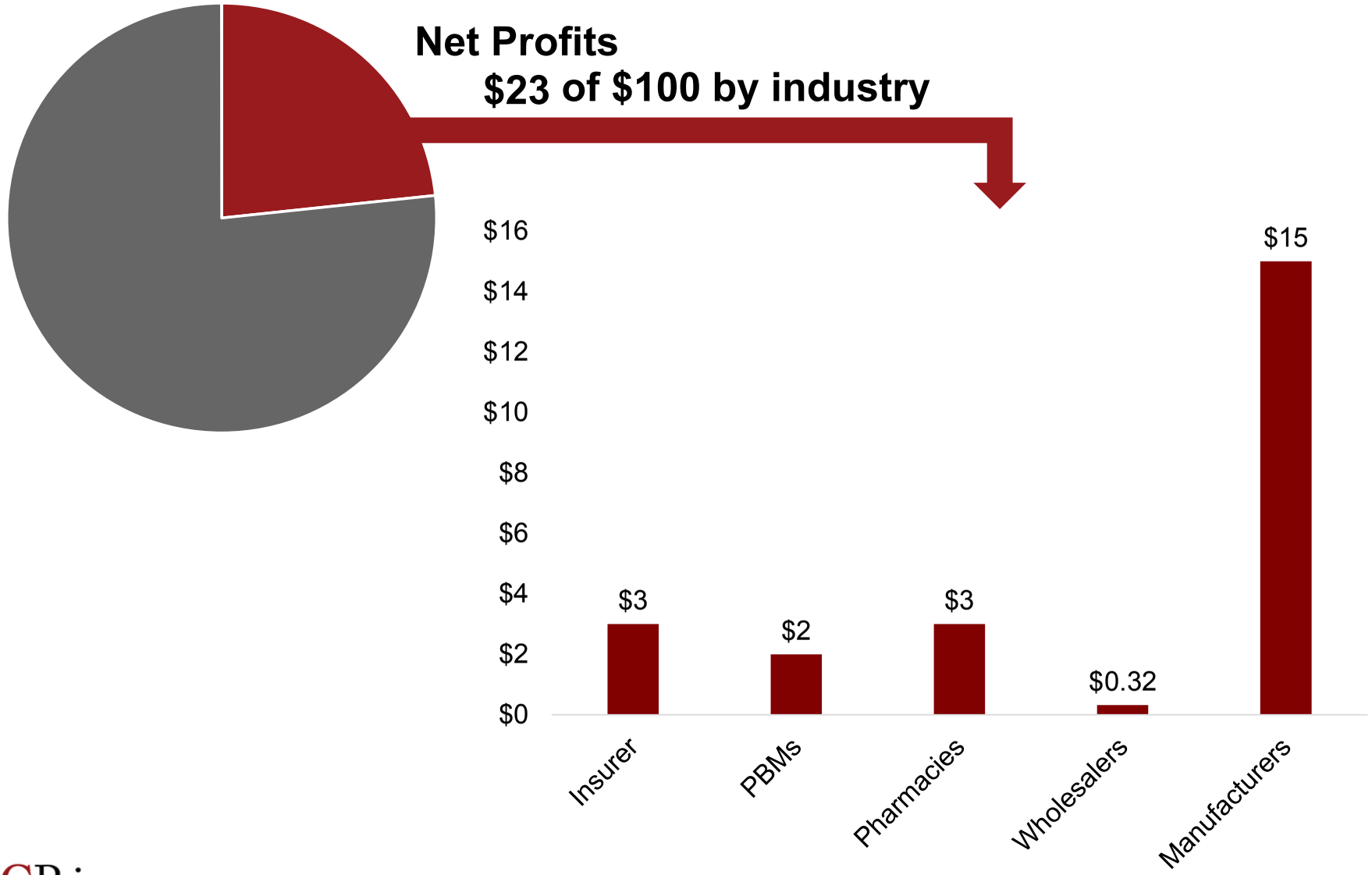


Net profit margins



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

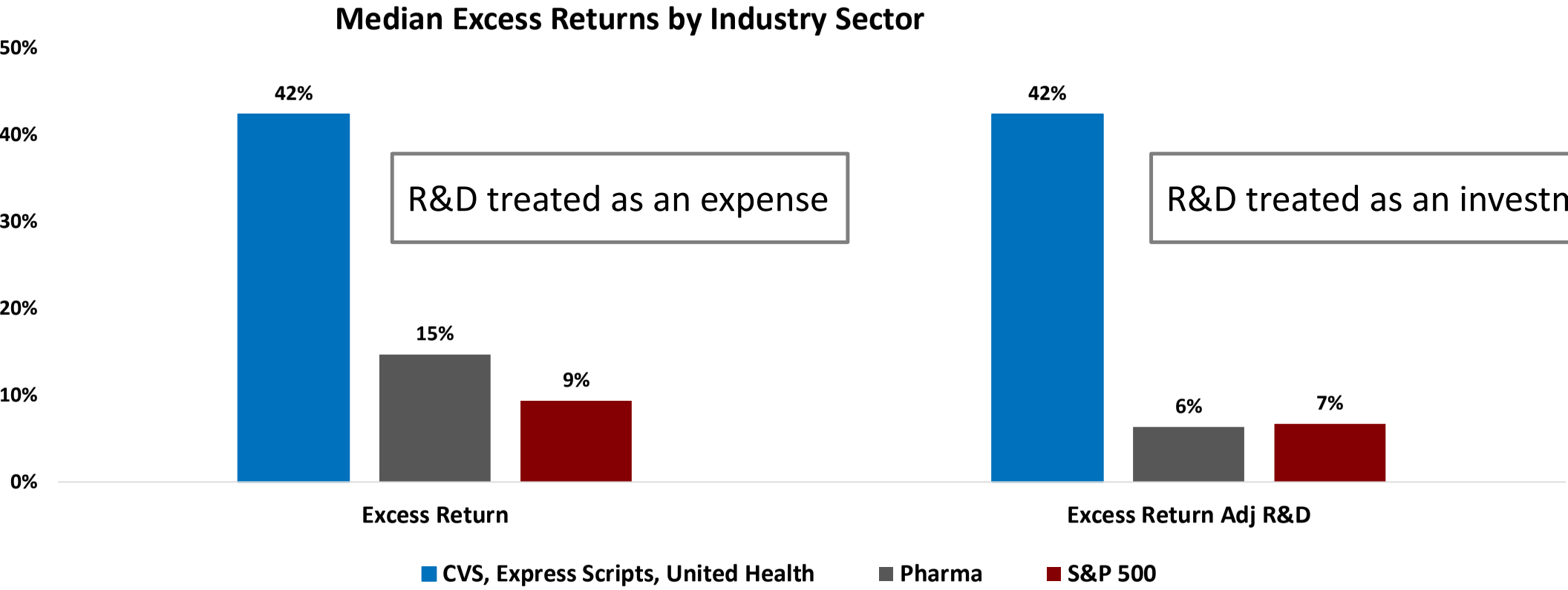
p 3 PBMs control more than o-thirds market share

Higher concentration means:

- More bargaining power to negotiate lo prices with manufacturers and pharma
- More market power relative to health p

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 asse
Return on invested capital (ROIC) is a profitability ratio. It measures the return that an investment generates for those who have provided capital, bondholders and stockholders. ROIC tells us how good a company is at turning capital into profits. (Source: http://www.htahealth.com)

ffer | USCPrice

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?

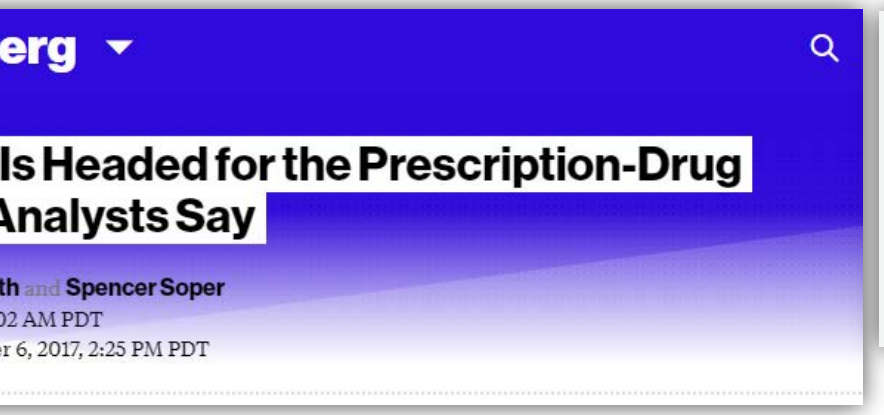
Drug A with PBM:
Price: $100
Rebate: $10

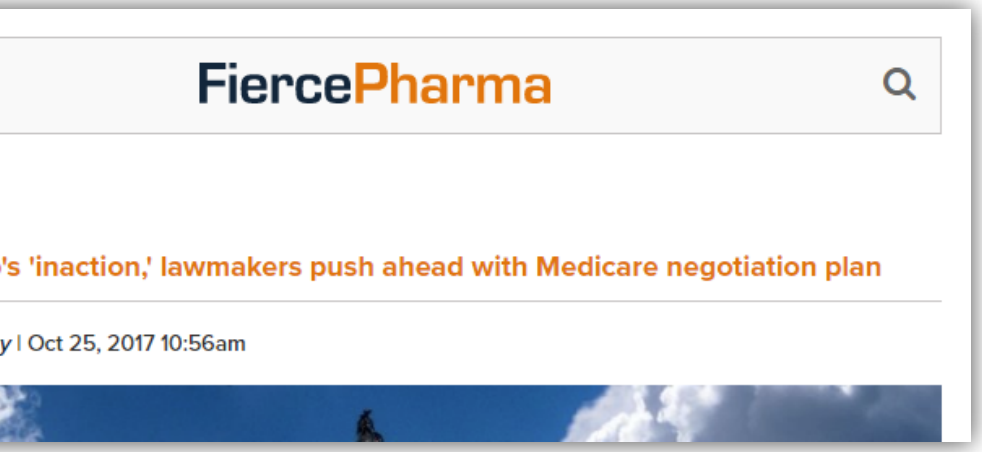
- PBM keeps $5

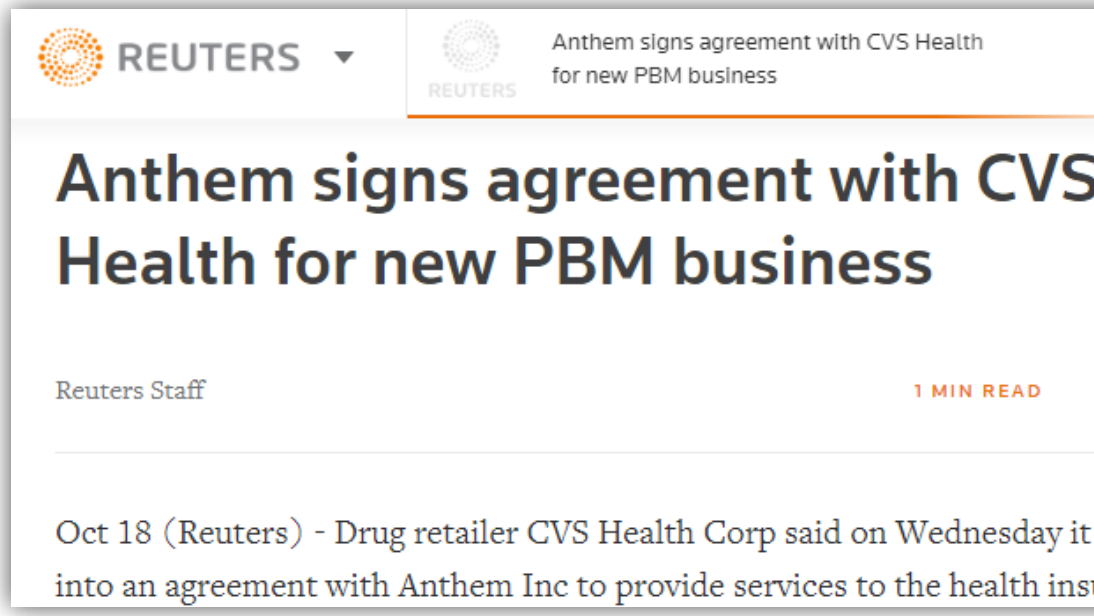
Cost to health plan: $95

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?







ffer | USCPrice

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?
(Low) e: $200 ice: $200 e of $50	$5	$155 ✓	$130 ✓	✓ **Uninsured** might p price ✓ **Insured consumer deductible** might p price ✓ **Insured** may pay h premiums
(High) e: $250 Price: $210 te of $60	$6 ✓	$156	$129	

ffer | USCPrice

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 ✓

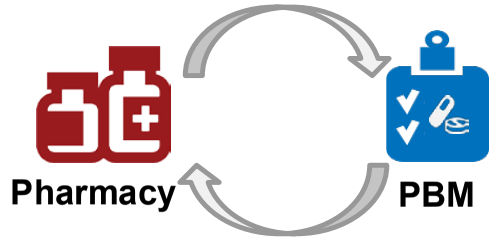
ffer | USCPrice

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

PBMs and pharmacies

BM ownership of mail order pharmacies: Misaligned Incentives

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



arrow network pharmacies combined with market power in nsurance 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

j Sood
@healthpolicy.usc.edu

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

healthpolicy.usc.edu
k.com/SchaefferCenter
@SchaefferCenter

USC Price
Sol Price School of Publi

priceschool.us
facebook.com/USC
@USC

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%**

Back to presentation

Top PBMs, by Market Share

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

Back to presentation

Top Wholesalers, by Market Share

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

Back to presentation

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

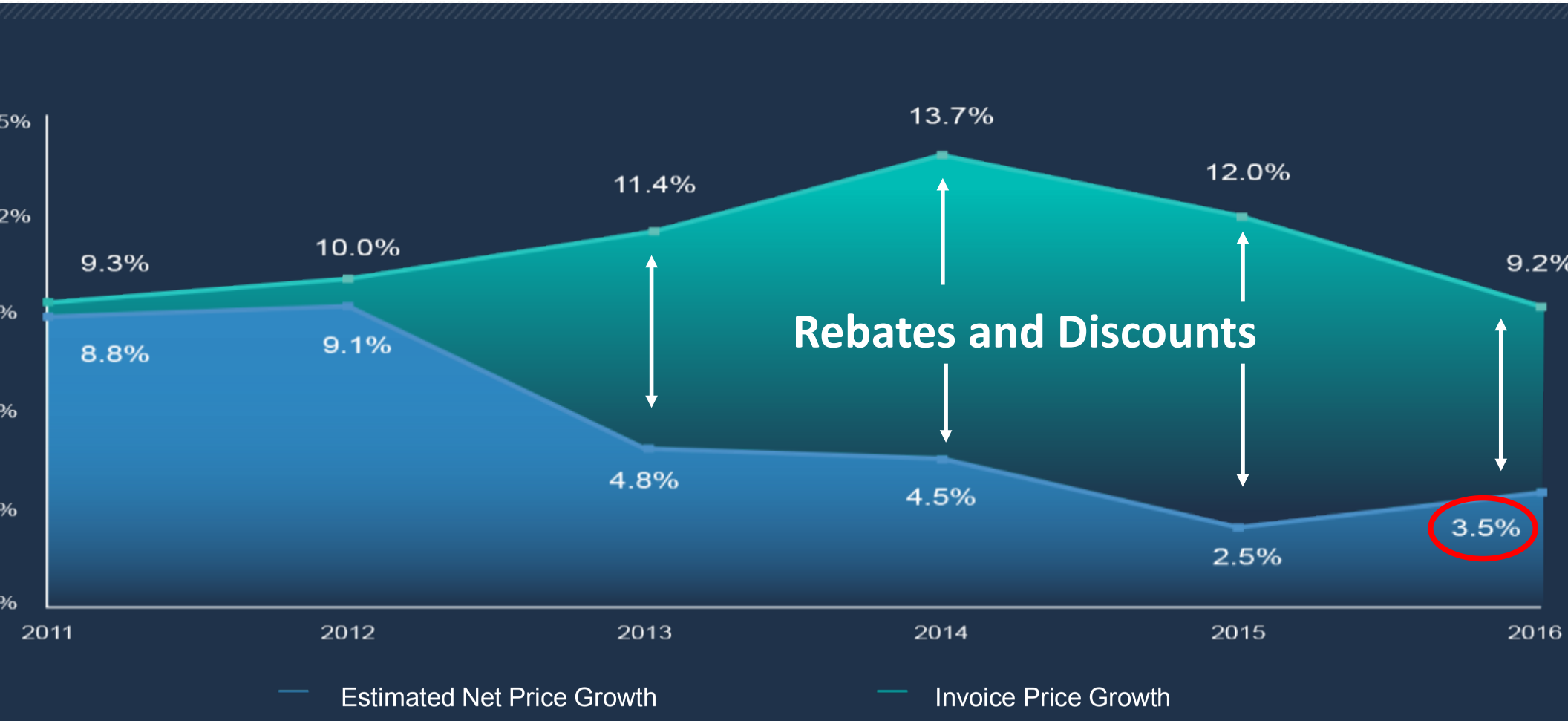
e Midst of Great Progress, Cost Growth is Modest

Per capita spending growth.

PRESS SCRIPTS®	CVSHealth	PRIME THERAPEUTICS®	Quintil formerly know
.2% 2015	5% 2015	2.8% 2016	7.8 2015
.8% 2016	3.2% 2016	0.8% First Half 2017	4.1 2016

al sector.
apita based on author's calculation.

nd medicine prices grew just 3.5% in 2016, aft
ates and discounts were removed

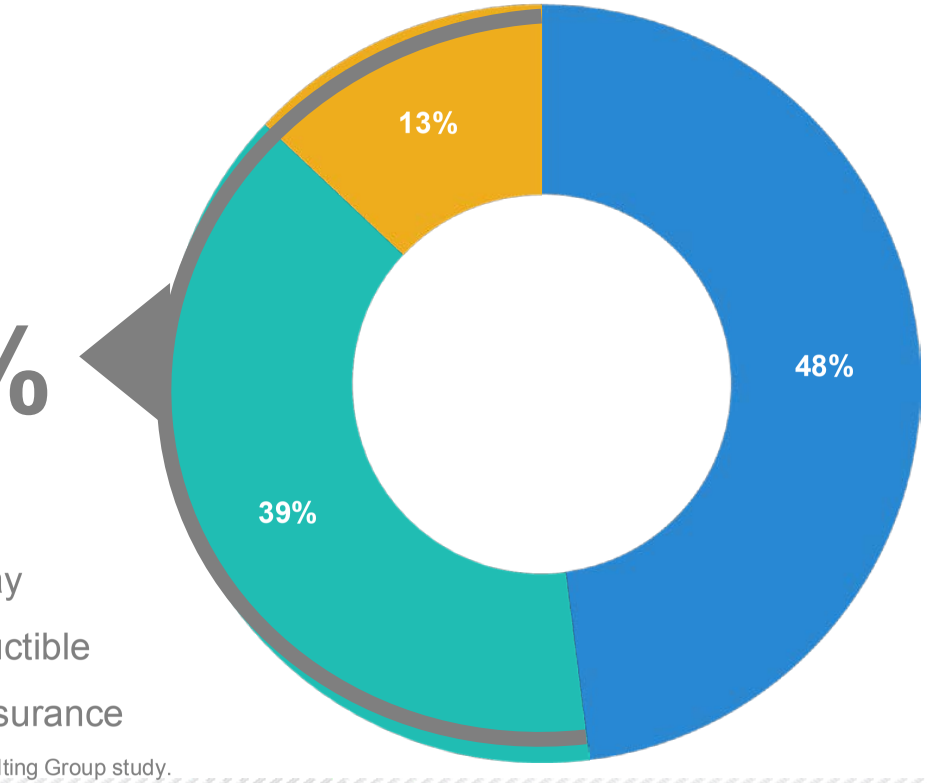


iles MS Institute , Medicines Use and Spending in the U.S., May 2017.

too often negotiated savings do not make r way to patients

than half of commercially insured nts' out-of-pocket spending for brand cines is based on the full list price

Cost sharing for nearly 1 in 5 bra prescriptions is based on list pric

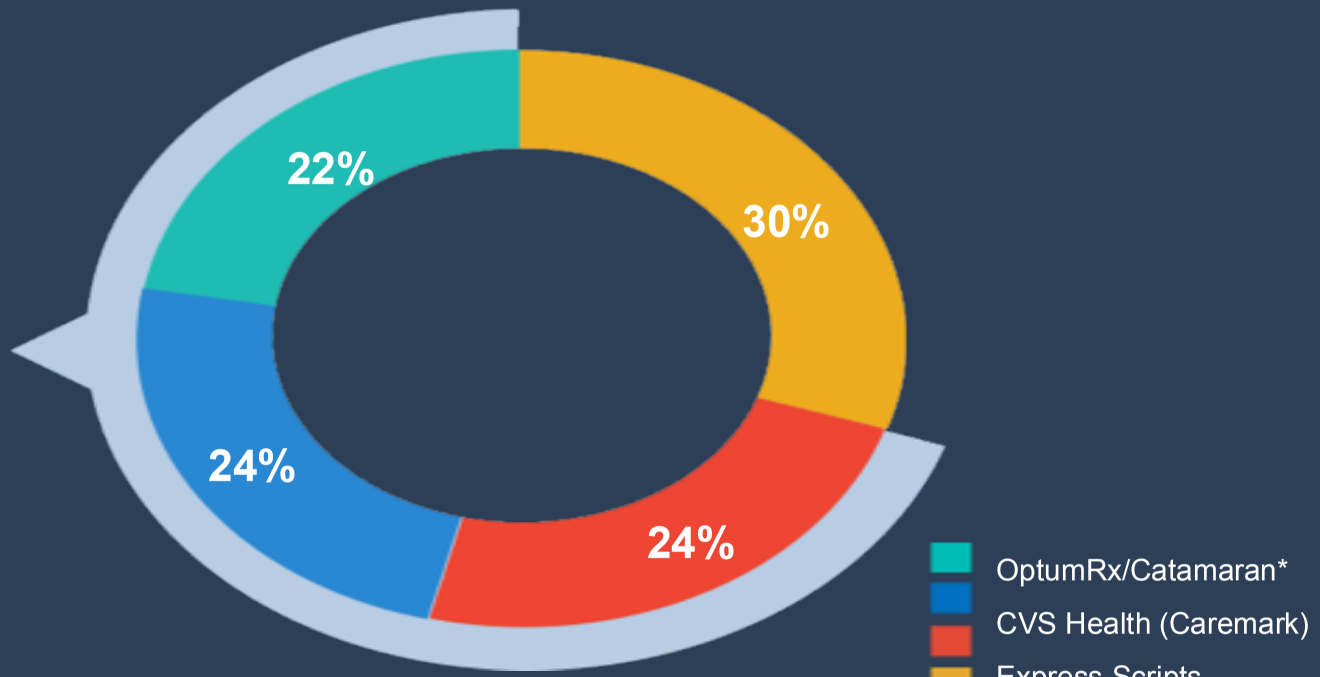


lting Group study.

rers and PBMs Have a Lot of Leverage to Hold
n Medicine Costs

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

hare:
%



Catamaran merged in 2015. Their 2014 shares are shown combined.
nels Institute.

Insurers determ

FORMULARY
if a medicine is covered

TIER PLACEMENT
patient cost sharing

ACCESSIBILITY
utilization management t
prior authorization or fail

PROVIDER INCENTI
preferred treatment guid
and pathways

ployers are increasingly demanding more sparency in PBM contracts

BMs make their profit by charging employers administrative fees. case, theoretically, PBMs would be making nothing. But PBMs' ts are so high. It shows that they are making money in ways that are

– VP and CFO, Corporate HR Shared Services

ow if you are maximizing the value of your PBM contract. It's very l confusing. There are so many ways to contract with PBMs. There is no

– Director of Benefits

"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 ge through."

"Our "suppliers" don't share contracts or disclos Employers are starting to notice and wondering v are paying so much. We need to ask intermediari they are paying each other and how they spent th

"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 What does it really say? How is it helping my business/ Employers should not engage in contracts they do tand."

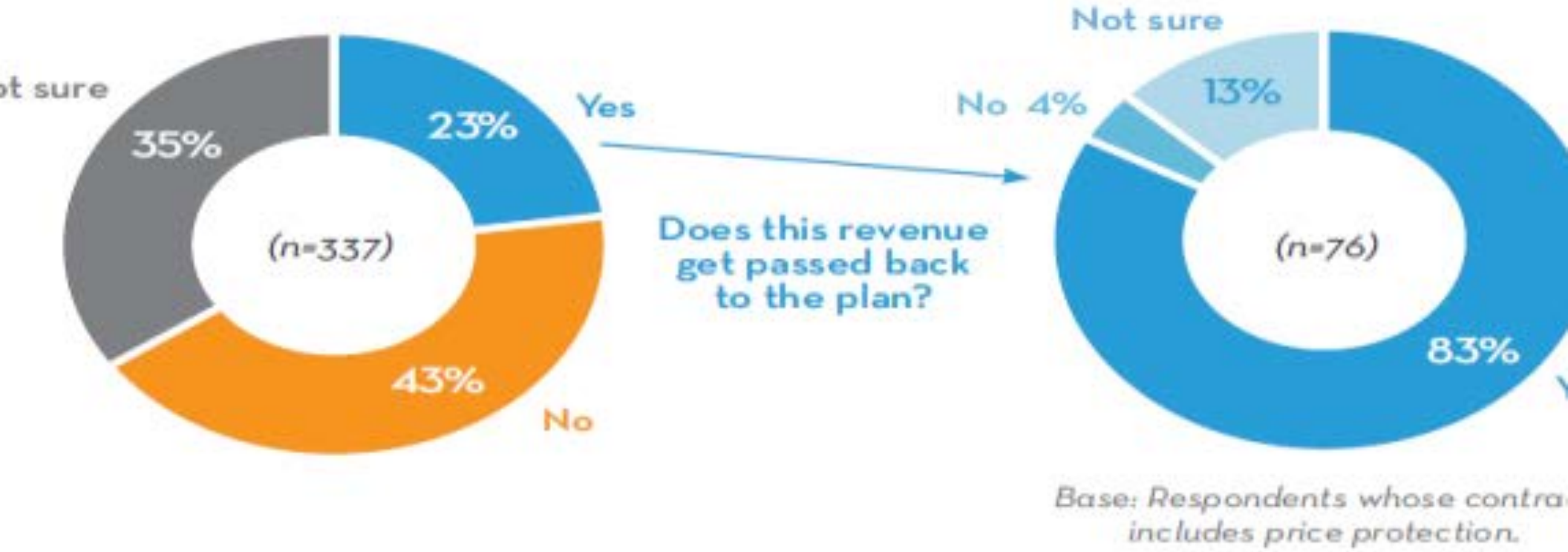
A properly designed, full pass through, transparent PB clean, audit-friendly and the best option for legal com but most PBMs don't want to sell you a transparent c Traditional contracts are much more profitable

- Mid-West Business Group

eutical Council study, Mid-West Business Group on Health white paper

ce protection is a standard feature in PBM tracts with manufacturers

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



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

NCP
NATIONAL COM
PHARMACISTS A

ntributing Factors……

- gh deductible plans + high priced medications + nsumer costs are driving increased demands for formation
- orly understood drug supply chain and drug pricing stems
- mplete lack of awareness of hidden PBM revenue reams
- an sponsor dependence on PBMs to navigate drug pricing d supply chain coupled with lack of corresponding PBM uciary duty
- M influence on formulary and plan benefit design = ngible consequences on patient access to care and cost

NCP
NATIONAL COM
PHARMACISTS A

dependent Pharmacy Landscape

armacy owners, managers and employees of more an 22,000 independent community pharmacies across e U.S.

ten located in underserved rural or urban areas gnificant # of Medicaid beneficiaries)

dependent pharmacies represent 52% of all rural armacies

ver 1,800 independent community pharmacies erating as only retail pharmacy in their rural mmunities

NCP
NATIONAL COM
PHARMACISTS A

dependent Pharmacy Marketplace Realitie

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

NCP
NATIONAL COM
PHARMACISTS A

M Marketplace

- ig Three" PBMs-Express Scripts, CVS Caremark and OptumRx ntrol between 75-80 percent of the market
- three companies are listed in top 22 of Fortune 500 and in 13 PBM revenues were estimated at more than $250 Billion
- gnificant market consolidation; CVS Caremark merger; ESI-edco; Optum-Catamaran
- g three PBMs are realistically the only choice for large plans
- Ms contract with virtually every other entity in the drug pply chain—This data knowledge and sheer size = huge vantage

NCP
NATIONAL COMI
PHARMACISTS A

M Influence in U.S. Supply Chain

Ms negotiate rebates with pharmaceutical manufacturers

bate negotiations drive PBM formulary placement (ultimately termine what medications patients have access to AND at what st share

Ms contract with employers and health plans to administer their escription drug benefit and in doing so, heavily influence Rx nefit design—with no PBM fiduciary obligation

Ms own mail order pharmacies and mail order specialty armacies that directly compete with retail pharmacies (PBMs also tate what competing retail pharmacies are reimbursed and what ey may charge beneficiaries

NCP
NATIONAL COMI
PHARMACISTS A

-Ms, Plan Benefit Design and ck of Fiduciary Responsibility

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

NCP
NATIONAL COMI
PHARMACISTS A

M Revenue Streams

- venue stream(s) derived from every supply chain rticipant
- anufacturer rebates—what is a rebate?-access rebates vs. rformance rebates—rebate “relabeling”)
- pread” profits—amount paid to pharmacy—different than nount charged to plan/employer on each prescription ed—not necessarily disclosed to plan
- M owned mail order/specialty pharmacies
- escriptions filled by plan members are often sold to anufacturers/data repositories. PBM may receive up to .00 per script

NCP
NATIONAL COM
PHARMACISTS A

M Influence and Retail Pharmacy

Ms contract with retail pharmacies to form pharmacy tworks (network pharmacies compete with PBM mail der/specialty pharmacies)

'S Health-combination of PBM plus 2nd largest retail armacy chain. PBM side of the business has direct cess to sensitive records of pharmacies in direct mpetition with retail chain

Ms determine pharmacy reimbursement amounts for drugs dispensed through insurance coverage

NCP
NATIONAL COM
PHARMACISTS A

M Influence and Retail Pharmacy

Ms audit retail pharmacies (have access to detailed ancial information and drug purchasing records)

Ms wield absolute control over pharmacy mbursement for generics: Each PBM controls oprietary MAC lists—Brand name drugs have public nchmarks—These do not exist for generics…..

NCP
NATIONAL COMM
PHARMACISTS A

AC Pricing: PBM Proprietary ug Pricing Standard

- aximum Allowable Cost (MAC) lists are created by PBMs at determine the maximum amount they will reimburse a armacy for a generic or multi-source product
- o transparency to pharmacy or plan sponsor on ethodology (different MAC lists for different plan onsors) or how lists will be updated. Also use of one AC list for pharmacy reimbursement (low) and one for an sponsor (high)—PBM profit on "spread"
- armacies sign contracts with virtually no information on neric pricing—only learn of reimbursement amount hen claim is adjudicated (at point of sale)

NCP
NATIONAL COMI
PHARMACISTS A

armacy "DIR" Fees

troactive reductions of pharmacy reimbursement often onths after claim adjudication

rt D program treats discounts (AT point of sale) and bates (POST point of sale) differently for the purposes of e Part D bid. Financially advantageous for PBMs and plan onsors to shift as much as possible to post point of sale

oblem: Cost sharing obligations (patient and federal govt. e based on "negotiated price"—the amount paid by PBM pharmacy at point of sale

timate price lowered after the point of sale—patient and vernment do not benefit!!

NCP
NATIONAL COM
PHARMACISTS A

ecialty Pharmacy

ecialty pharmacy/specialty drugs = typically very high price edications

rrently a PBM conflict of interest “flash point.”
M-owned specialty pharmacies have significant incentive capture these prescriptions

creasing incidence of PBMs terminating or declining twork applications of independent specialty pharmacies, posing excessive accreditation requirements and excessive dits

d. Judge in ESI-Medco merger raised concerns about ecialty conflicts of interest…….

NCP
NATIONAL COM
PHARMACISTS A

oving Forward…….

- rrent model dysfunctional with misaligned incentives
- nployers/payors searching for new models
- rect contracting with pharmacies
- utcomes based reimbursement
- eed for greater connectivity between Rx spend and edical spend—using Rx to stave off costly downstream edical intervention
- newed interest in capitalizing on expertise of armacists to stretch limited resources/services

NCP
NATIONAL COM
PHARMACISTS A

Rob Andrews

CEO

Health Transformation Alliance

Relationships and Competition in the Drug Channel System

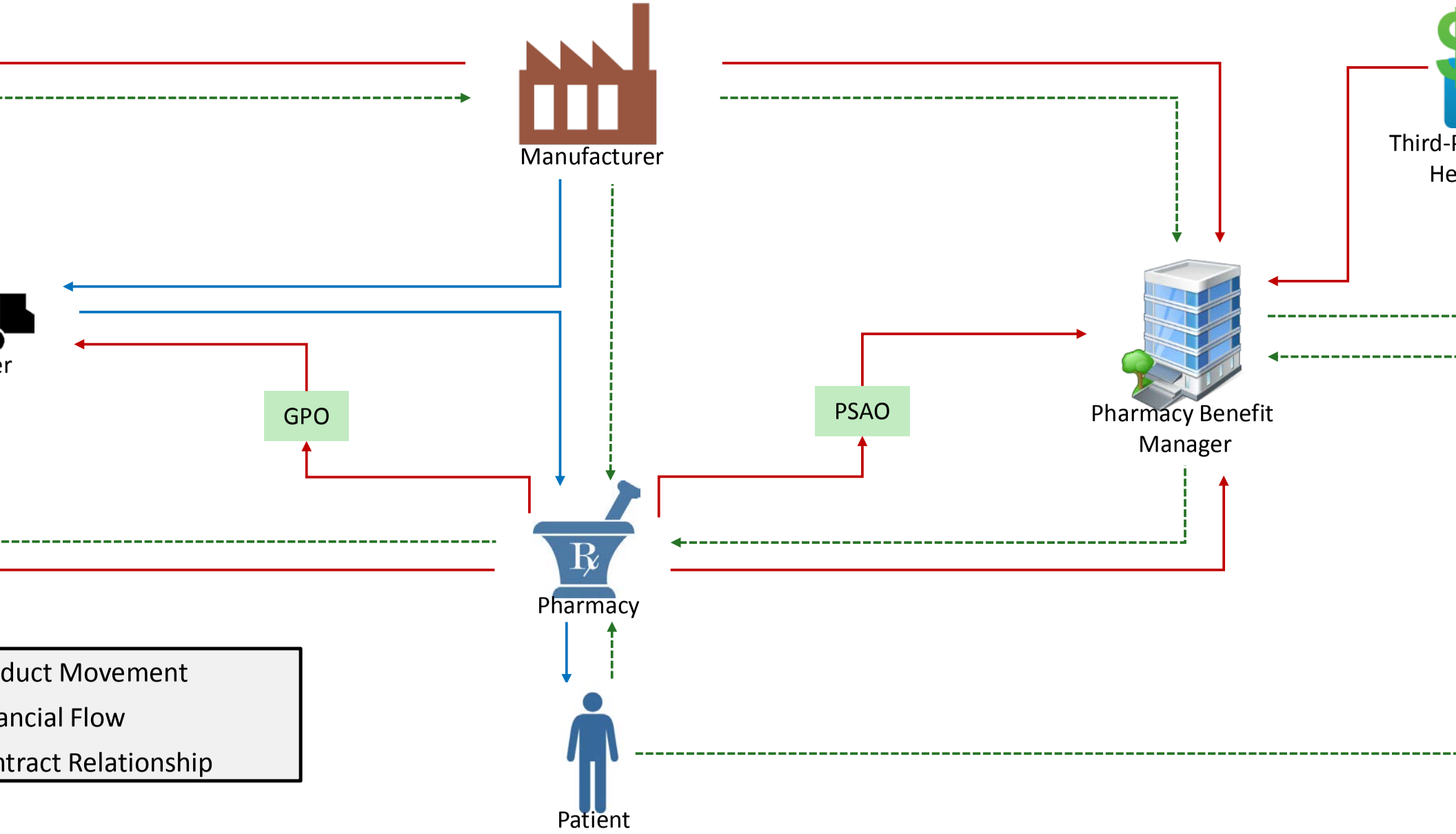
Adam J. Fein, Ph.D.
Pembroke Consulting, Inc.
www.DrugChannels.net
@DrugChannels

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.

ROKE
TING

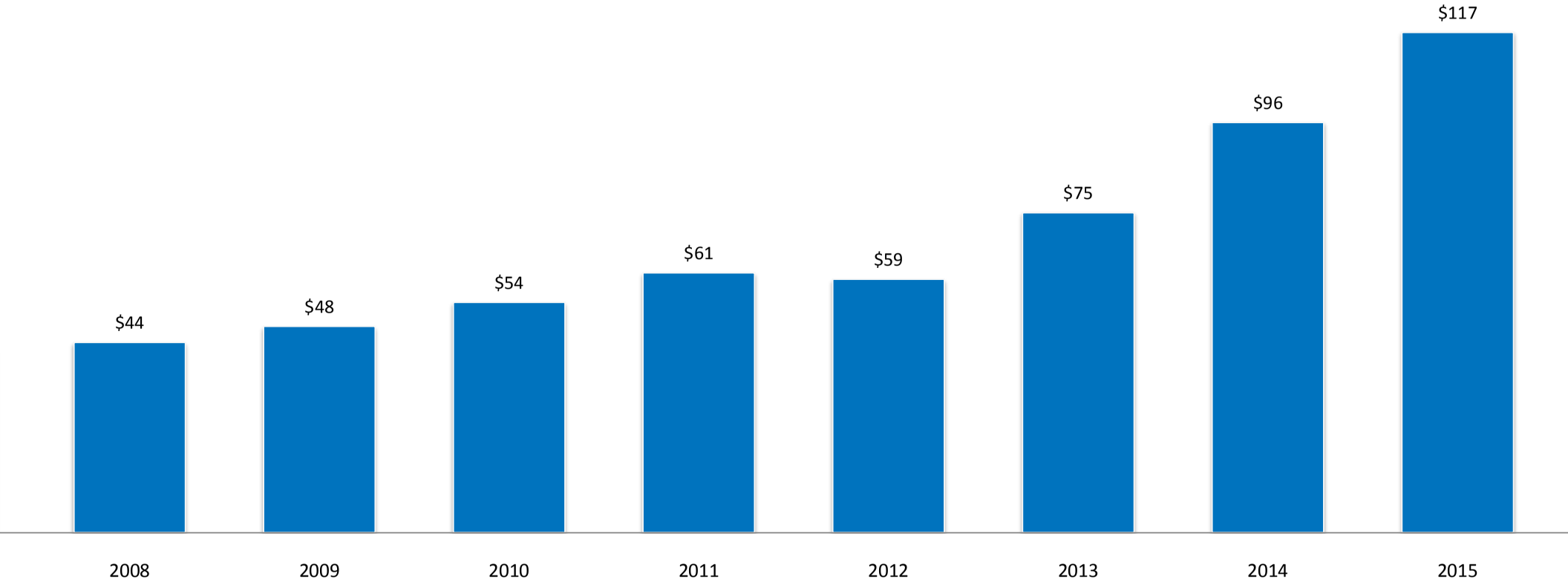
tribution and Reimbursement System: Patient-Administered, Outpatien



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, Outp**
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 th
marketplace.

lue of Pharmaceutical Manufacturers' Off-Invoice Discounts, Rebates, a oncessions, 2007-2016



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

ROKE
TING

nderstanding Competitio
Prescription Drug Market
ntry and Supply Chain Dynamic

Panel 2: Understanding Intermediaries: Pharmacy Benefit Managers

FEDERAL TRA

November 8, 2017

Lunch

nderstanding Competitio
Prescription Drug Market
ntry and Supply Chain Dynamic

anel 3: Understanding Intermediaries: Group Purchasing Organizatio

ealthcare Group Purchasing Organizations (GPO

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

HEALTHCARE SUPPL

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

ore than a century, healthcare group purchasing organizations (GPOs) have helped their ncare provider partners **leverage purchasing volume to lower prices** on healthcare products es, **which lowers costs for patients**, hospitals, payers, Medicare and Medicaid, and taxpayer

GPO mission is focused on **reducing healthcare costs**, **increasing competition and innovatio orting transparency**, and **improving healthcare processes and outcomes**.

ally **every hospital** and the vast majority of **non-acute care facilities** in the U.S. use a GPO.

are **competitive** and GPO use is **completely voluntary** – providers can and do purchase off- GPO use is **driven by value provided**.

uct decisions are **made at the facility level**, with member input and support groups for all di

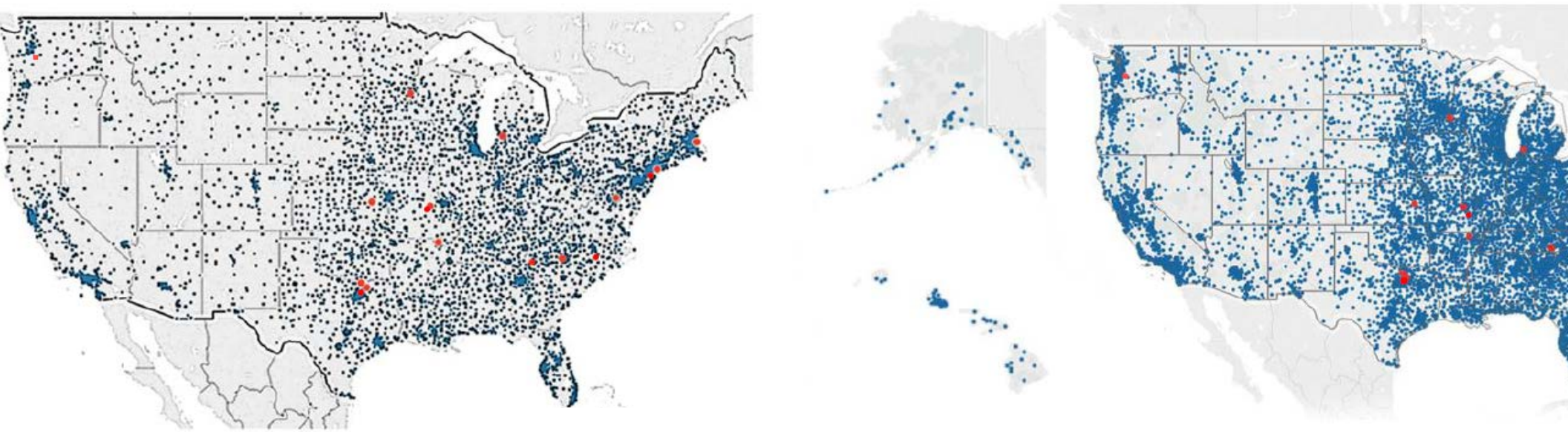
have processes in place to **identify innovative and breakthrough products** and help them t

verage GPO contract administrative fee is **1.22% to 2.25%.** *(Source: US Government Accountability Of*

a Glance: Virtually All Hospitals and the Vast Majorit
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 Pr
Including long-term care providers, clinics, surgery centers, home health prov



● 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

Os Reduce Costs for Hospitals, Healthcare Providers, dicare and Medicaid, and Taxpayers

ad range of empirical and academic research finds that GPOs e costs for healthcare providers:

educe healthcare costs; providers realize **savings of 10% to 18% by using** these savings are likely to be especially **valuable to smaller, rural hospitals**; oviders **pass these savings onto patients and ultimately to taxpayers**. *vitz, O'Brien, 2017)*

ave the U.S. healthcare system up to **$55 billion annually**, up to **$864.4 billion en years**, and up to **$229 billion in Medicare**- and **$169 billion in Medicaid** s over the same period. *(Dobson DaVanzo, 2014)*

ximately **90% of hospitals are satisfied with their GPO**, and **88% agree that educe costs**. *(American Hospital Association, Association for Healthcare Resources erials Management, Wharton School, 2014)*

ave the U.S. health care industry **$36 billion dollars annually** and create an onal **$2 billion in annual savings** associated with human resources mitted to the purchasing process, according to a study of 400+ hospitals. *ler, 2009)*

ontract **administrative fees have no effect** on the total purchasing costs of any er. *(Purdue University, Krannert School of Management, 2011)*

GPO U.S. Cost Savi

Up to **$55 billion** ann

Up to **$864 billion** over t

Up to **$229 billion** in M savings and **$169 billi** Medicaid savings over 1

$2 billion in annual sav human resource cos

10%-18% average sa

mer FTC Chair Jon Leibowitz and Deputy Director Da
Brien Affirm GPO Cost Savings, Competition

17, Former FTC Chair Jon Leibowitz and former FTC Deputy Director of the Bureau of Econom
O'Brien conducted a comprehensive economic and legal analysis of the role, business model
ct of GPOs and found that:

- Os **save money** for healthcare providers, patients
d taxpayers.
- Os operate in a **vigorously competitive**
ocurement market.
- e current GPO vendor funding model is **consistent**
th competition and cost savings.
- anging the GPO vendor funding model **would likely**
se costs.

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

- Leibowitz, O'Brien, Anello, 2017.

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

Os Operate in a Highly Competitive Market

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

e than 100 national, regional and local GPOs and regional cooperatives compete each other to provide GPO services;

GPO market operates with a level of competition equivalent to an unconcentrated ket with **more than 10 independent competitors** of equal size;

iders can **choose from multiple GPOs** and also can, and commonly do, **use multip s simultaneously**. On average, providers use between 2-3 GPOs;

iders often control their own GPO, which creates **strong incentives to offer petitive pricing**;

iders can **purchase from a competing GPO** or **procure supplies directly from dors**;

nse competition suggests that the vendor-fee model is **more efficient than other lels.**

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

O Safe Harbor, Model, and Oversight

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

t to the GPO Safe Harbor:

ave **written contract** with each member;

disclose that an administrative fee is collected, and **any ove 3% must be specifically identified in the contract nent**;

eport annually to members on all administrative fees ed from GPO contract use;

make all fee information available at the request of the ary of Health and Human Services;

als must **report GPO fee distributions as part of are cost reports** and GPOs encourage hospitals to tely reflect fee information in these reports.

Business model and oversight:

- **GPO Safe Harbor not unusual** – 1 of 23 provisions in 198 addressing a range of lawful business practices;
- **Vendor funding model likely reduces transaction costs** a neither empirical evidence nor economic theory suggest vendor fees raise prices;
- Industries leveraging group buying/vendor fee model inc **government procurement** (DOD, VA), **food service**, **onlin marketplaces** (Amazon, eBay, Living Social), **consumer cr hospitality** and **non-profit industries**;
- GPO model and business practices thoroughly reviewed **GAO**, **DOJ**, **U.S. Supreme Court**, **8th Circuit Court of App** academia, and hospitals, and all have concluded that no is needed.

erow, Herrmann, "Activities and Perspectives of the Office of the Inspector General in the rtment of Health and Human Services Regarding Group Purchasing Organizations (GPOs)," 2013.

Os are Most Transparent Sector in Healthcare

ealthcare Group Purchasing Industry Initiative (HGPII) is an independent, voluntary organiz
ed by the chief executives of healthcare GPOs who believed industry **should collectively
nstrate a strong commitment to transparency and ethical values**. HGPII promotes the
opment of transparency and accountability standards and ethical business practices, and all
members are also members of HGPII.

mbers submit to **annual independent
ew** of business practices;

nprehensive industry reviews conducted by
mer **U.S. Representative Phil English** (R-PA)
former **U.S. Senator Byron Dorgan** (D-ND);

ticipating GPOs consistently found to have
n ethical standards and **business practices
t promote innovation**, **transparency** in
ding process, and **compliance;**

- Every HGPII member actively promulgates a
enforces a **code of conduct** to ban conflicts
interest;
- GPOs offer an **independent grievance proc**
to suppliers through the American Arbitrati
Association;
- All **GPO contracts are voluntary** and the pr
of **competitive market negotiations**.

For more: www.hgpii.com

s Taking Steps to Eliminate Drug Price Spikes & tages

spikes for critical generic drugs and ongoing prescription drug shortages continue to jeopar
nt access to care. **Healthcare GPOs are working vigorously with regulators, providers, ufacturers and distributors** to ensure a safe and reliable supply of product, and are **taking a ber of innovative steps to help increase competition in the market**, **avoid generic drug pric s**, and **eliminate prescription drug shortages**, including:

licy advocacy to increase competition (e.g., pedited FDA review, closing REMS loophole, osimilars, etc.)

pplier price adjustments to contracts to flect market conditions (e.g., raw materials ortages)

ta tracking to anticipate shortages

ork with suppliers and providers to derstand supply issues, and to identify ernative suppliers and products as propriate

- Manufacturer reliability evaluation
- Increased supplier-provider communicatio
- Identification of additional manufacturers f products in shortage and help bringing the market
- Migration to alternative products where available
- Failure-to-supply clauses to ensure that suppliers meet contract requirements

Os Evolving and Expanding Offerings to Help Provide
nfront New Challenges

use efficiently and effectively driving cost-
gs required complementary services,
s **evolved and expanded their offerings**
eet member needs, including:

ta analysis and benchmarking

rket research

ovative technology integration

ection control

ctronic product tracking

veloping communities of knowledge to
re best practices

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

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

ole of Wholesalers/Distributors in Pharmaceutic upply Chain

Deliver drugs, medical supplies and durable medical equipment fro 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

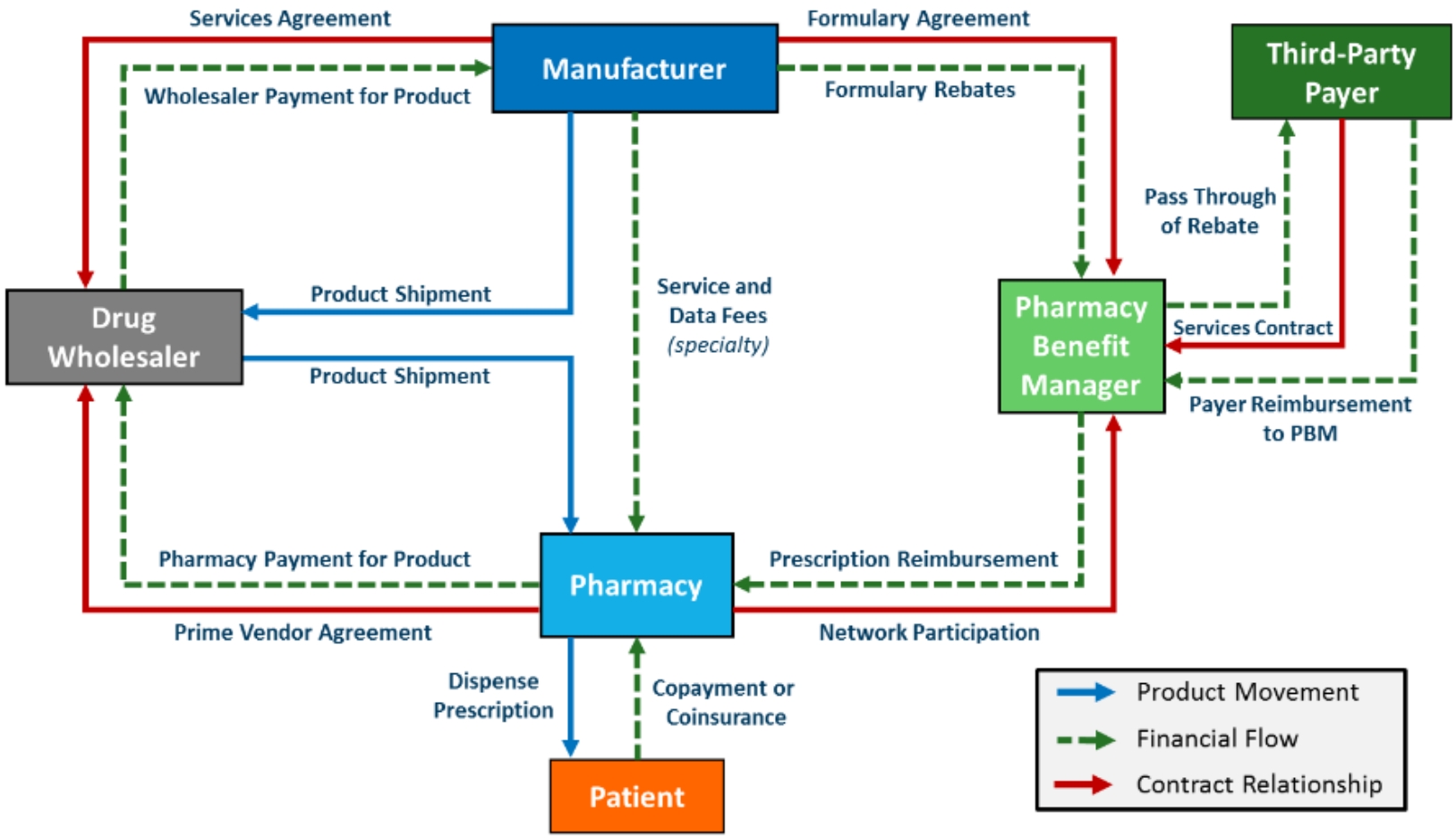


Chart illustrates flows for patient-administered, outpatient drugs. Please note that this chart is illustrative. It is not intended to be a complete representation of every type of financial, product flow, or contractual relationship in the marketplace.

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/)

ole of Wholesalers/Distributors in Pharmaceutic upply 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

istributor/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

istributor/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
mount and percentage of Wholesale Acquisition Cost (WAC)-base

istributor/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/profitabili

ole 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 adjustmer from proprietary negotiations between manufacturers and distributors, GPO or other customers
- WAC is published in various compendia including Medi-Span and First DataBank

ole of Wholesalers/Distributors in Drug Pricing

Generics drug pricing is more complicated; generics are commoditi

Distributors may sell generic drugs to downstream customers base
on WAC or they may price generic drugs to downstream customers
n response to the market considering-

- Supply of competing generic drugs
- WACs for the competing generic drugs

eneric Sourcing Programs

Distributors may offer generic sourcing programs/pricing to some customers

Negotiate with generic drug manufacturers to purchase all equirements for certain classes of generic solely from manufacture n exchange for discounts/rebates

May provide some or all of the discounts/rebates to downstream customers in exchange for exclusivity or volume commitments elated to generics

ntersection 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 differenc between WAC and the Member's discounted price of a drug under the manufacturer/GPO agreement

ntersection of Distributors & Pharmacies

oint 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

ISCLOSURE

- 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 membe

ALLENGES FROM A PURCHASER'S PERSPEC

Drug shortages

Few choices due to sole source products

No transparency to make good choices

What is the price?

RUG SHORTAGES OF ESSENTIAL PRODUCTS

- Hospitals struggle to purchase basics
  - Mainly generic injectables
- Shortage definition: a supply problem tha
  - 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 medic records, switch products in automation
- Medication errors
- Patient harm

NCREASED 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:

RAGILE 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)

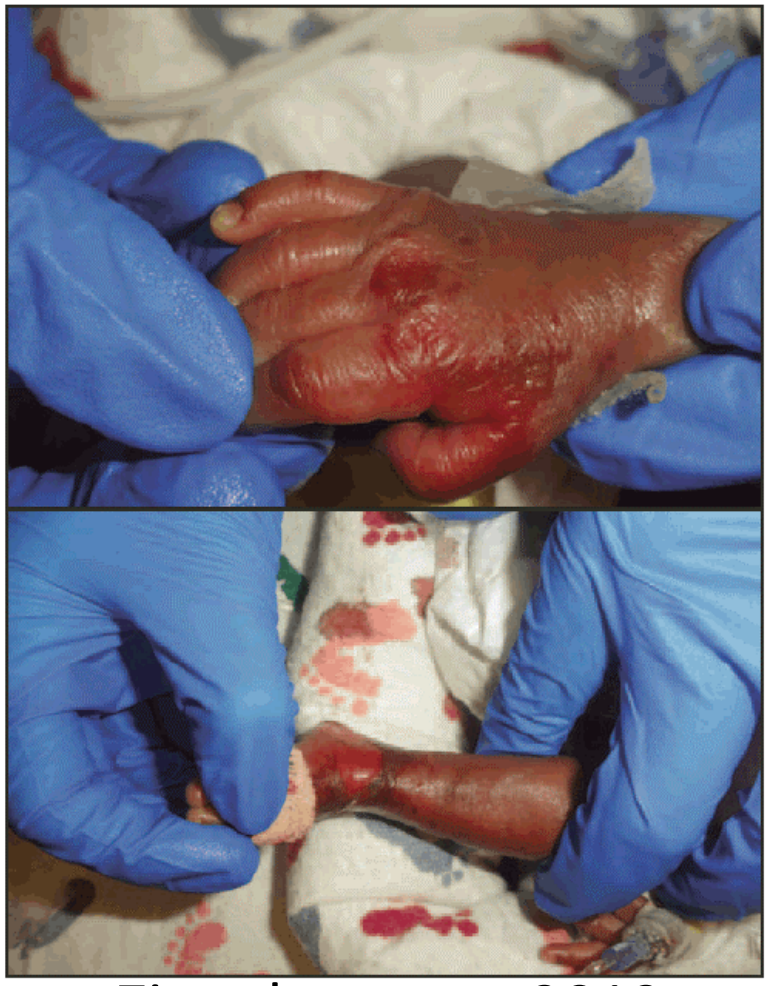
http://www.gao.gov/products/GAO-16-

Clin Pharmacol Ther. 2013;93:170–176

OOR QUALITY LEADS TO HARM

'arning letter (2011) to key
upplier of critical electrolytes
utlined years of deficiencies

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



Zinc shortage - 2012

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

MMWR. February 22, 2013;136-

LE SOURCE / NEAR SOLE SOURCE PRODUCT

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

w.blumenthal.senate.gov/imo/media/doc/Letter%20to%20FTC%20on%20Pfizer%20Drug%

OLE 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

ps://www.blumenthal.senate.gov/imo/media/doc/Letter%20to%20FTC%20on%20Pfizer%20Drug%20Short

AN YOU PURCHASE FOR QUALITY?

- FDA makes warning letters and 483 inspections public, but names of drugs are redacted
- No requirement to disclose which company actu 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 pub
- Few data available for higher risk 503b compounders

https://www.fda.gov/downloads/drugs/guidances/ucr

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

AKEAWAYS

- 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

onflict of Interests: Does GPO Compensatio 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) (wit Robert Litan & Anna Birkenbach)

elevant (and Irrelevant) Questio

elevant Q: Would a change in the GPO ***compensation structure*** lead to lower supply cos
nember 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 illeg receive any compensation from suppliers for items reimbursable by federal health care program
- Theory of harm in RTI v Becton Dickinson (E.D. Tex 2003)

rrelevant 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 to (1) bargaining power and (2) transactions costs

wo questions blur only if you believe there is no alternative to current compensation tructure

- GAO (2014): Hospital consolidation + use of aftermarket subscription services suggest GPOs wou survive
- GPOs survived for ~80 years without supplier-side funding

Monopoly Concessions in Other Industrie

- 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

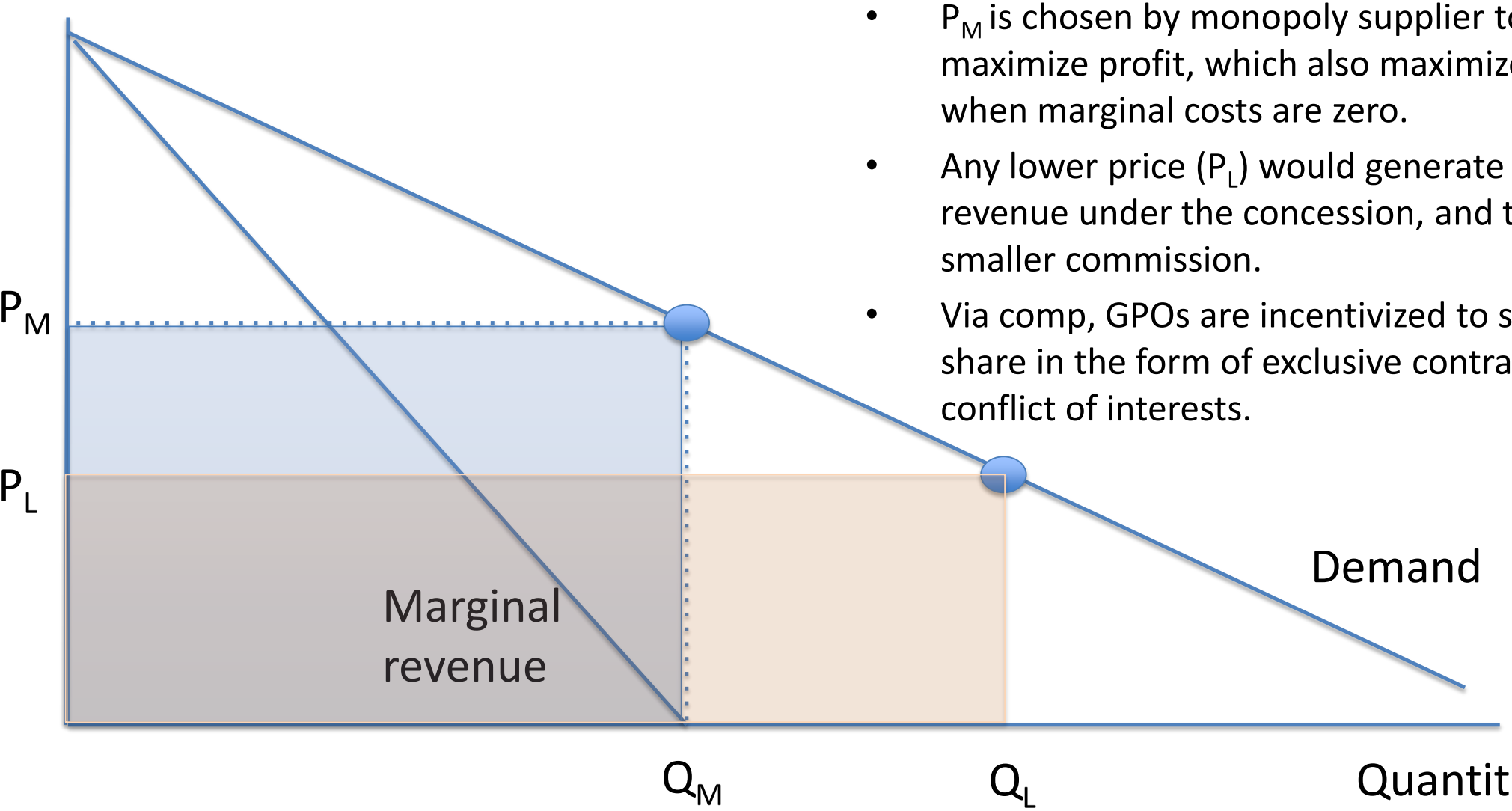
Healthcare Matters Principal Editor Thomas Finn: “As a member-driven enterpri
s common knowledge that Premier [the second largest GPO] and other **GPOs ‘s
back’ with their members and owners. In fact, many hospital executives who ar
part of the Premier alliance have learned to rely on that share back as an integr
part of their annual compensation.”

– Healthcare Matters, July 22, 2013

Asst. Secretary of HHS Koh under President Obama: “First of all, these agreeme
re made often through these long-term contracts and so also this whole proce
nvolves 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 an
demand economic principles that we see in other businesses.”

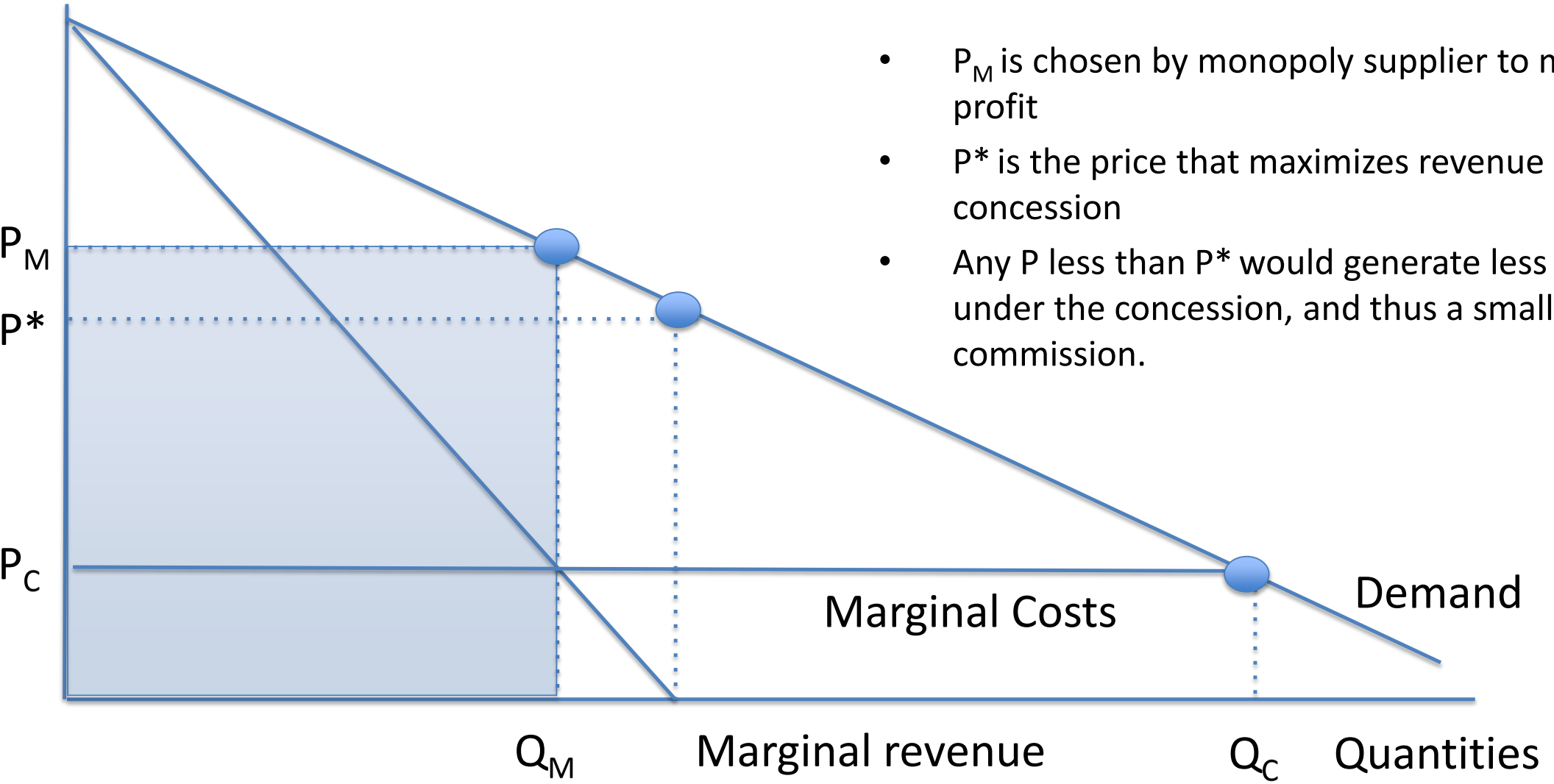
– Testimony before the September 23, 2011 House Energy & Commerce Committee

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



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

ven When Marginal Costs Are Positive, Best to Avo Competitive Rates



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

y Findings of Litan, Singer & Birkenbach (201

- When brokered by an agent ***not compensated by suppliers***, hospitals enjoy an average price reduction of 10-14% from 200 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
- mplication: 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 administrativ fee revenue is not reflected on cost reports, Medica could be overpaying hospitals.”

Criticisms: Johnston & Rooney (2012

rge, high-value products are not representative of all produ
rchased by GPOs (at 83); aftermarket purchases are more
efinite" (at 83), exhibit greater "commitment" (at 84)

- Caveat our findings by saying that apply to these types of purchases, which ac
  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 product
  not low-value products; economic incentives are to maximize revenue regardl
  product type
- While there may be uncertainty over units purchased by *single* hospital pursu
  GPO contract, purchases across *all* hospitals within GPOs are more certain

e appendix for more rejoinders

Criticisms: O’Brien, Leibowitz & Anello (2017

- dings do not suggest price differential can be attributed to GPO fundin
  odel (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
- cause tax incidence is neutral with respect to where tax is levied, fundi
  urce doesn’t matter (at 9)
  - Not applicable because tax revenues to be collected in econ textbooks are assumed to *exogenous*; in case of GPOs, fees collected under the concession are *endogenous*—that 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 it the same way?
- e appendix for more rejoinders

Do These "Incentive Distortions" Apply to Prescription Drugs?

n one sense, prescription drugs are more differentiated than devices, which sugge
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 contrac may and have discontinued production; when shortages hit, the price increases have be astronomical

A hospital might be able to get by with an inferior medical device, as long as they h one, but they can't get by without a lifesaving generic injectable drug if it is in shor 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 h to pay a negative price (i.e., compensate the physician practice) for losing the bundle 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 contra reports that his facility currently pays $22 for a 10-vial box of propofol, compared wi $55 at another member's GPO-affiliated surgicenter."
  - "Another PADS member found that she could have purchased over-the-counter supp such as Advil, bandages, and cotton balls, from Costco for up to 50% less than what h health system was paying through its GPO contracts, but her superiors wouldn't allo 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 discontin production of some drugs, particular for **low-margin generics** (Moss 20 Kweder & Dill 2013; Schweitzer 2013; FDA 2011; House of Reps. 2012)

After reviewing literature and interviewing industry participants, GAO dentified GPOs as one of three "underlying causes" in drug shortage (G Feb. 2014)

- Other causes include competition based primarily on price (interwoven with GP 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 consume 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

y 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 industri
- Device industry not uniformly impacted: Status quo favors incumbents (Advamed), penalizes entrants (MDMA)

unding 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

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

, high-value products are not representative of all products purchased by GPOs (at 83); aftermarket p
ore "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 sample;
- No reason that a kickback regime would inflate the cost of high-value products but not low-value products; economic incent maximize revenue regardless of product type
- While there may be uncertainty over units purchased by *single* hospital pursuant to GPO contract, purchases across *all* hospi GPOs are more certain

Criticisms: O'Brien, Leibowitz & Anello (2017

nber ownership ensures GPO acts in hospitals' best interest (at 6)

- Economists recognize agency problems (small stakes, information asymmetry); they aren't eliminated by vertical integratio
- GPO administrators' compensation is funded via hospital *expenditures*, not savings

ty 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

ings 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

use 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 th 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

ecting 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, clients could likely accommodate 103,000 clients

ndor 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

dor-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 cho
- Credit card example is inapposite. Amex receives a % of revenue paid to merchants, but it is not involved in negotiating pric behalf of the merchants in its network.

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.

ct 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 p distribution from a GPO.

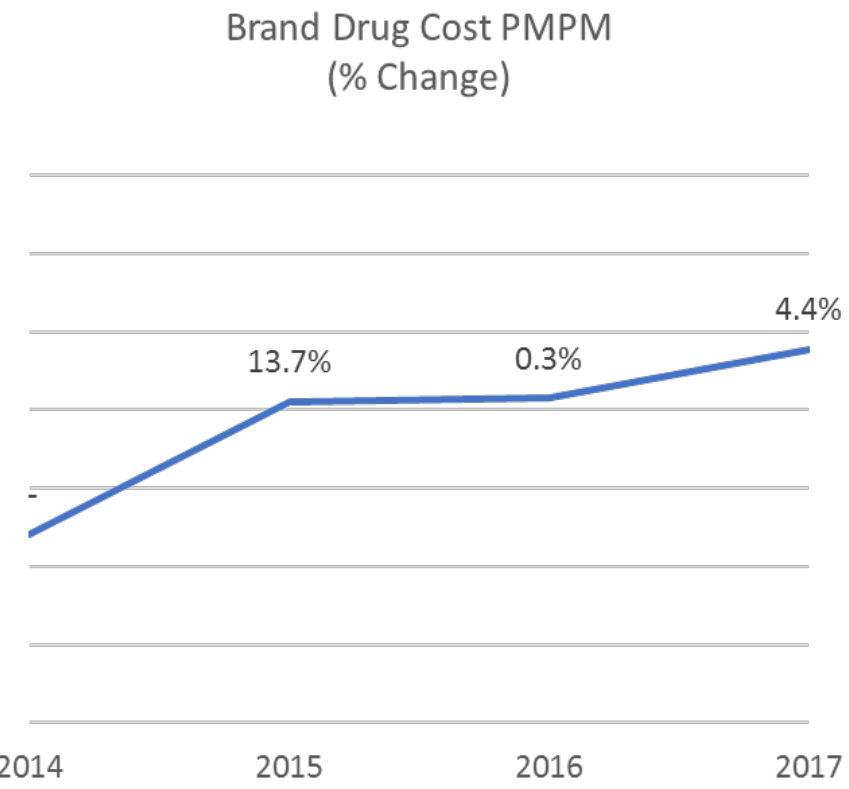
Trend

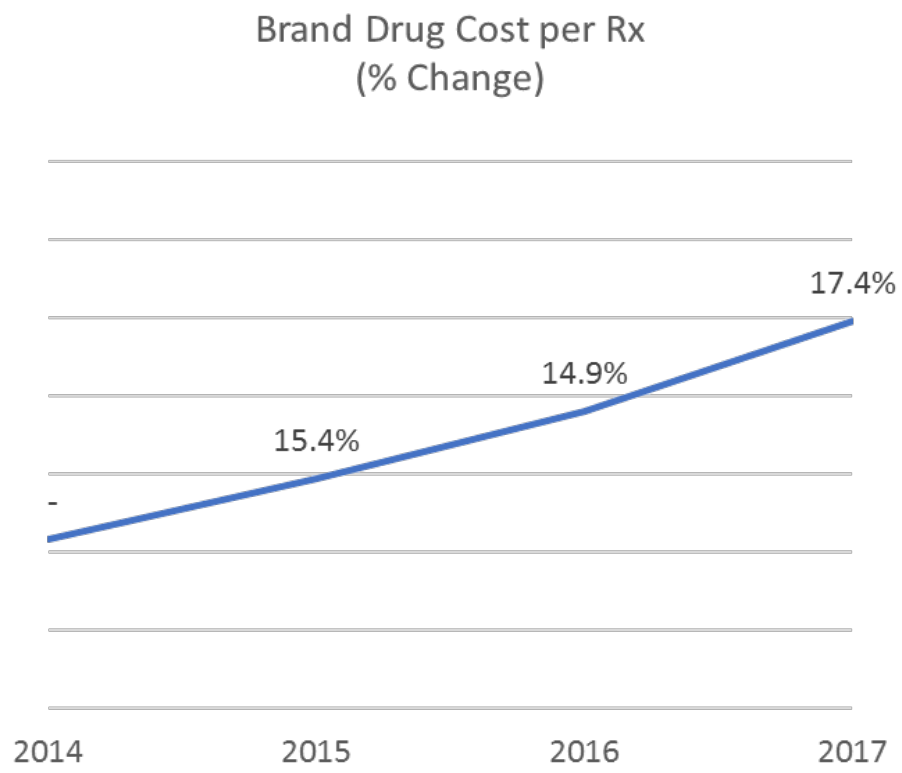
al Pharmacy Programs & Services

er 2017

ER PERMANENTE®

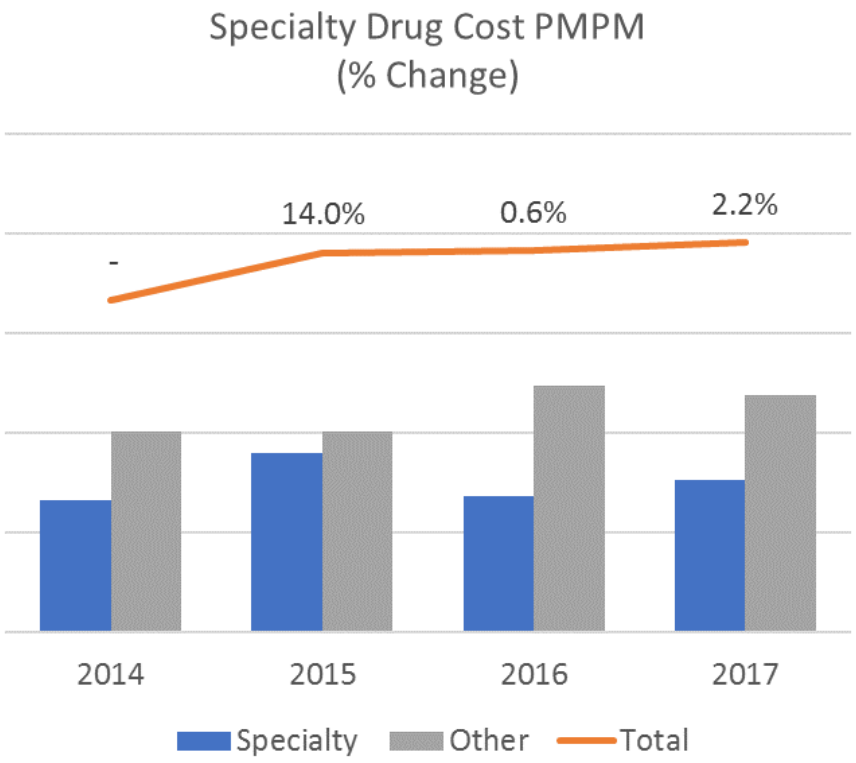
ent Brand Drug Cost Trend

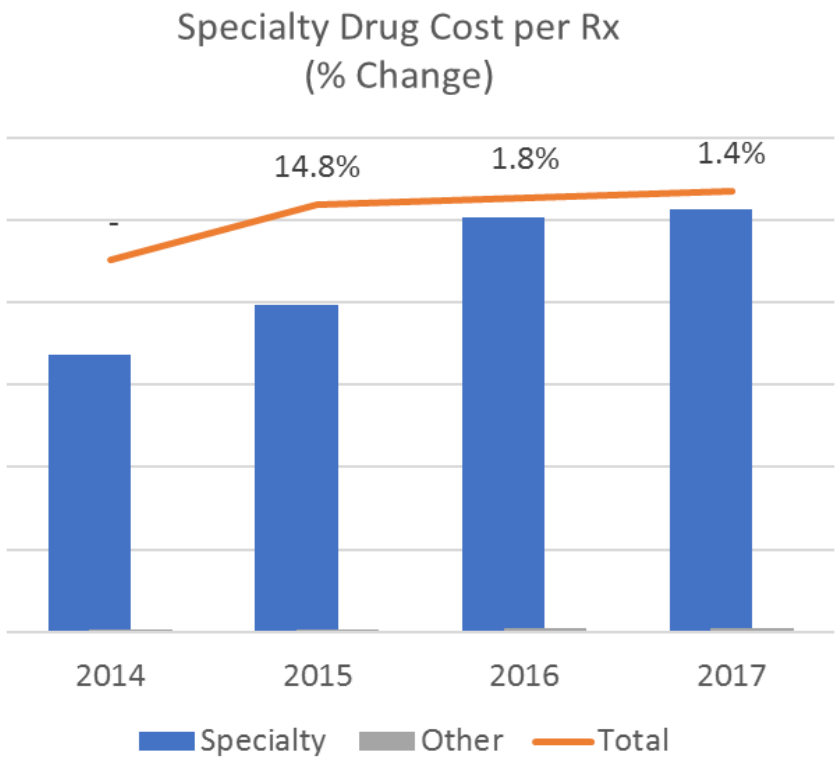




- Outpatient drug spend on brand medications has increased steadily over the last four years, averaging 16% in annual growth on a cost per prescription (RX) basis. On a PMPM basis, brand drug cost growth plateaus in 2016 due largely to lower hepatitis C utilization.

ent Specialty Drug Cost Trend

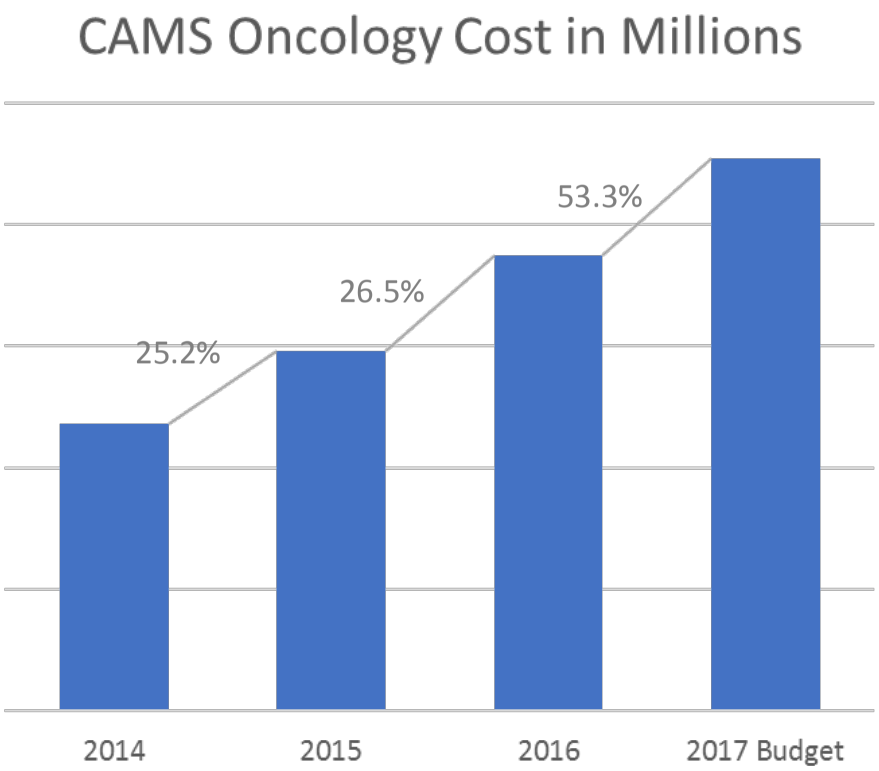


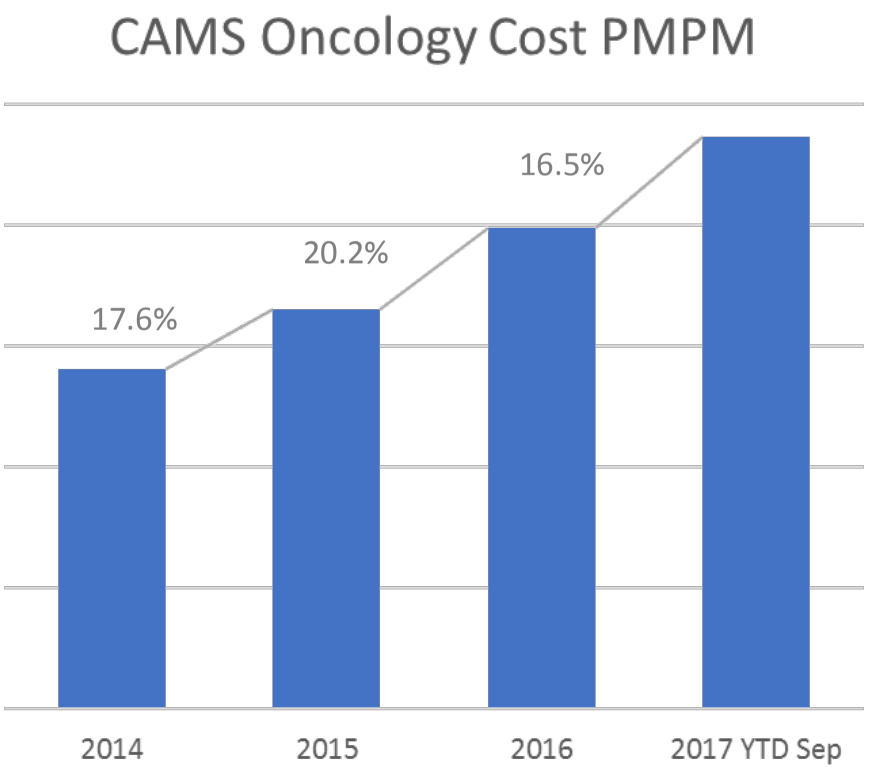


- Specialty drug is defined as cost of $600 or more for a 30 day prescription. As of YTD Sep 2017, specialty drugs represented 39% of the total outpatient drug spend but only 1% of the total outpatient prescription volume.
- Specialty drug cost on a PMPM basis has increased steadily with the exception 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.

dministered Medications (CAMS) for Oncology

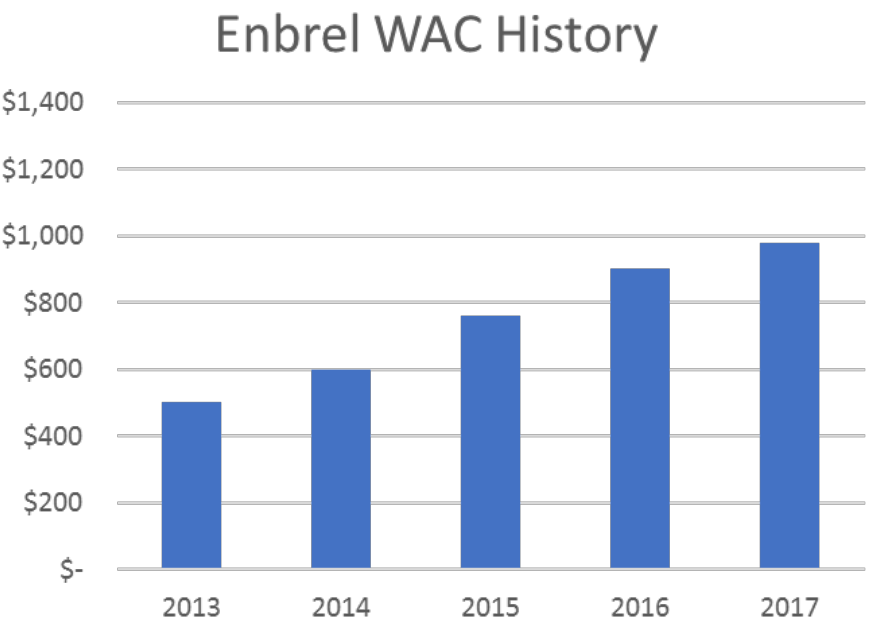
KAISE

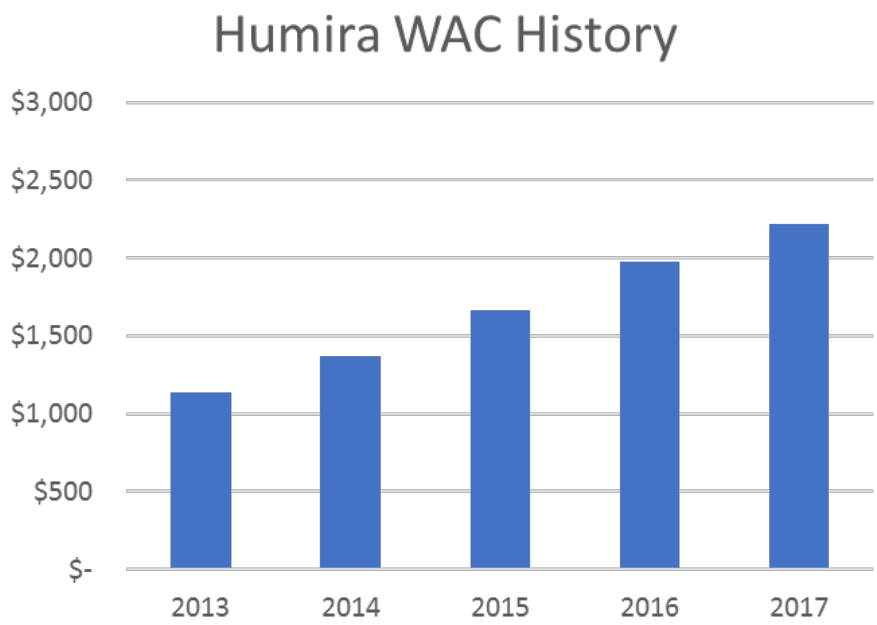




- Clinic pharmacy drug spend for oncology have increased by double digit percentages annually on a dollar and dollar PMPM basis.
- The increase in spend is driven by increases in both utilization from expanded FDA indication approvals and by unit cost increases.

ale 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.

nderstanding Competitio
Prescription Drug Market
ntry and Supply Chain Dynamic

anel 3: Understanding Intermediaries: Group Purchasing Organizatio

BREAK

nderstanding Competitio
Prescription Drug Market
ntry and Supply Chain Dynamic

iscussion: Potential Next Steps to Encourage Entry and Expand Access throug
Lower Prices

FEDERAL TRA

November 8, 2017

High prescription drug prices: Balancing access and affordability

Rena Conti, PhD
Associate Professor
Departments of Pediatrics & Public Health Sciences
The University of Chicago
rconti@uchicago.edu

THE UNIVERSITY OF CHICAGO
BIOLOGICAL SCIENCES

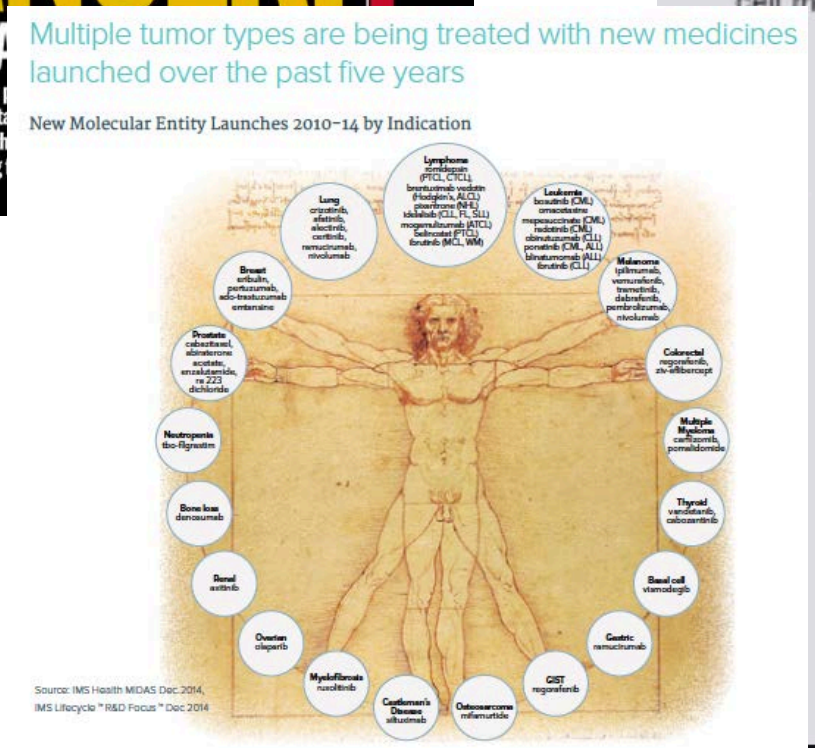
owledgements and disclaimer

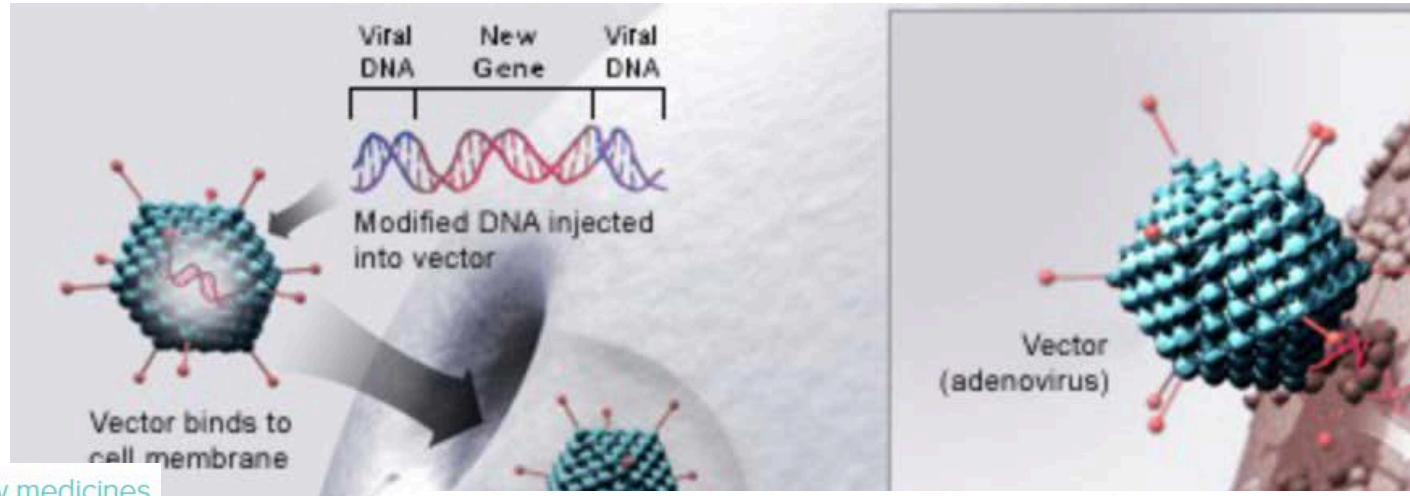
basis of this presentation is work done in collaboration with Peter
t Berndt, Melinda Buntin, David Howard, Sayeh Nikpay, Meredith
enthal and Josh Sharfstein.

are grateful for the support of the NCI, the Commonwealth Fund a
American Cancer Society.

nions expressed are mine alone and publicly available in a series of
ewed publications.

tand in the midst of incredible scientific breakthrough





US clears breakthrough gene therapy for childhood leukemia

By LAURAN NEERGAARD, AP MEDICAL WRITER •
WASHINGTON — Aug 30, 2017, 5:26 PM ET

adox: access to cures limited, high out of pocket cost

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 OP

Exclusive: Costs to public of $84,
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

ding 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.

facturers practice monopoly “by design” pricing

t system: encourages innovative activity, private flow of capital into

ntensive, uncertain investment.

that mean that increasing prices reflect increased value?

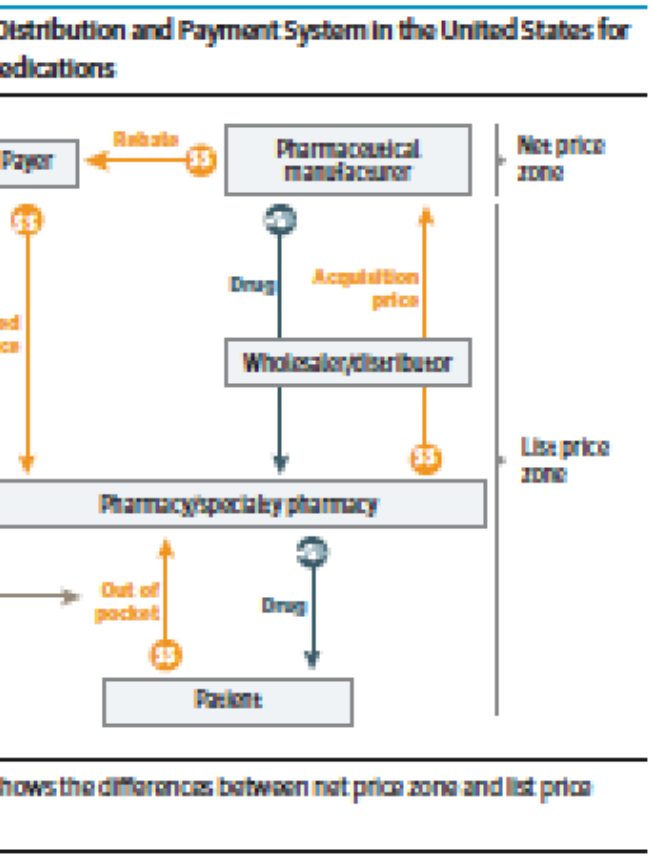
! Newer cancer drugs are not associated with greater survival compa

ler drugs.

e single biggest predictor of cancer drug launch price trend is time.

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

t capturing “value” chain impacts prices, spending



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

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

erics part of a “virtuous circle”, yet worry promise is g

eazy Moves Pharmaceutical Companies Use l Patents

m • Filed to: DRUGS

30.3K 59 2

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

By KATIE THOMAS SEPT. 8, 2017

RELATED COVERAGE

Teva Aller JULY 2

FAIR Worl Chal NOV. 2

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

PFIZER INC.,

Plaintiff,

v.

JOHNSON & JOHNSON and JANSSEN BIOTECH, INC.,

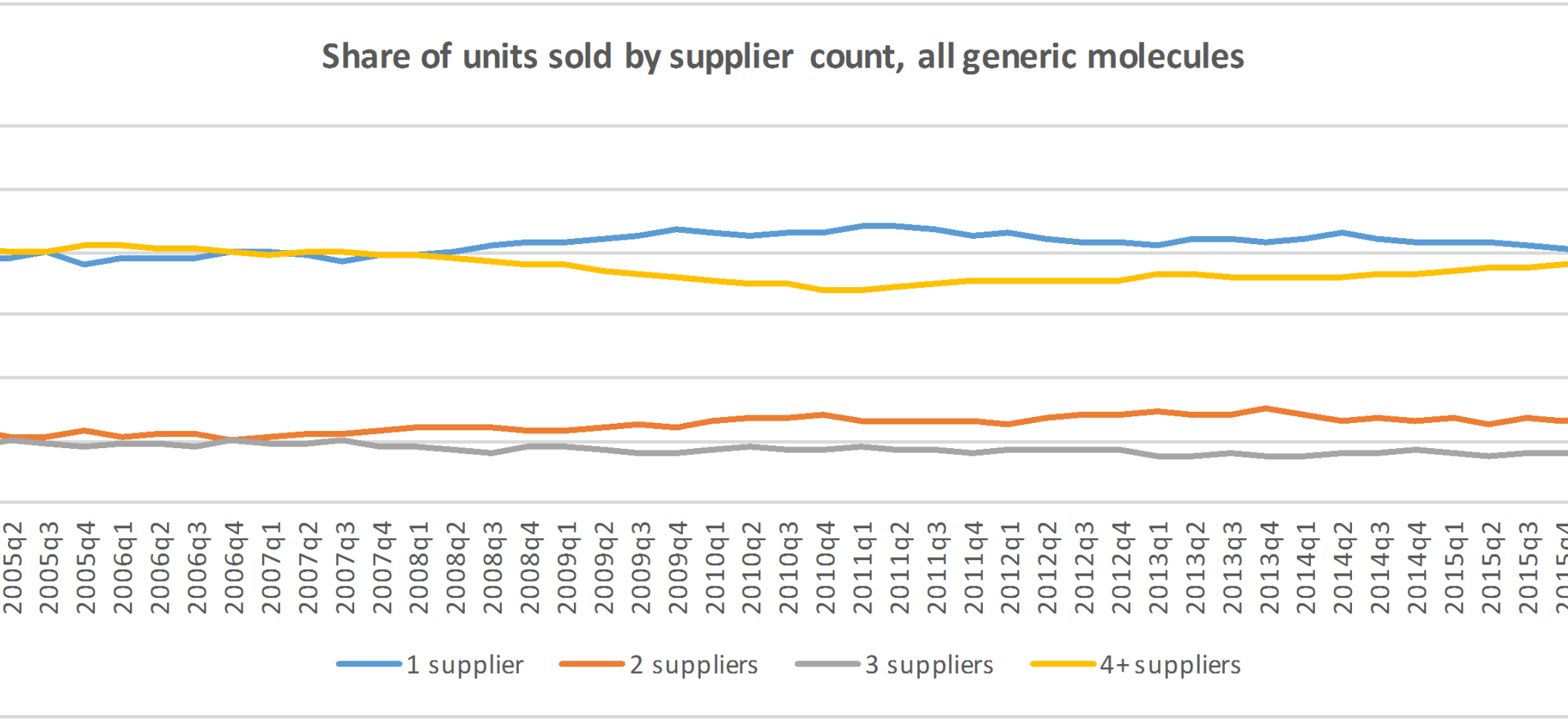
Defendants.

Case No.

JURY TRIAL DEMANDED

COMPLAINT

liers of generic drugs are concentrated



, **RM CONTI**, SJ Murphy. "The Landscape of US Generic Prescription Drug Markets, 2004-2016." NBER
23640. July 2017. Available at: http://www.nber.org/papers/w23640.

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

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

ising reform efforts balance access & affordability

rove generic supply competition.

ance transparency/reduce profit seeking in the value chain.

ove generic supply competition

has critical role to play:

- educe Scott-Hart-Rodino thresholds on merger revenue scrutiny.
- gorously pursue pay for delay, product hop, other evergreening activities.

has critical role to play:

- wer barriers to entry through GDUFA fee revisions.
- eserve ability to reenter molecule markets after temporary supply disruptions/
- entify alternative suppliers meeting quality manufacturing metrics.
- sure quality manufacturing, redundant supply through other activities.

nce transparency/reduce profit seeking in the value

ce physicians/hospitals/pharmacies ability to profit off high priced
s.

nas critical a role to play:

nforcement of anti-kickback & RICO statutes.

reater scrutiny of proposed merger, acquisitions between value chain actors.

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

rconti@uchicago.edu

Thank you.

David Mitchell

Founder &
President

November 8, 2017

ents For Affordable Drugs

ly national patient organization focused exclusively on policies to
ver drug prices

funding from any organizations that profit from development or
tribution of prescription drugs

Battle with Blood Cancer

gnosed with multiple myeloma in
0

h cost drugs keeping me alive

drugs don’t work if people can’t
ord them

A Patient Perspective

Key Points Made Today

Key Points Not Made Today


ntact and
ources:
David@patientsforaffordabledrugs.org
@DavidP4AD & @P4AD_
Patients For Affordable Drugs

nderstanding Competitio
Prescription Drug Market
ntry and Supply Chain Dynamic

iscussion: Potential Next Steps to Encourage Entry and Expand Access throug
Lower Prices

FEDERAL TRA

November 8, 2017

nderstanding Competitio
Prescription Drug Market
ntry and Supply Chain Dynamic

Closing Remarks