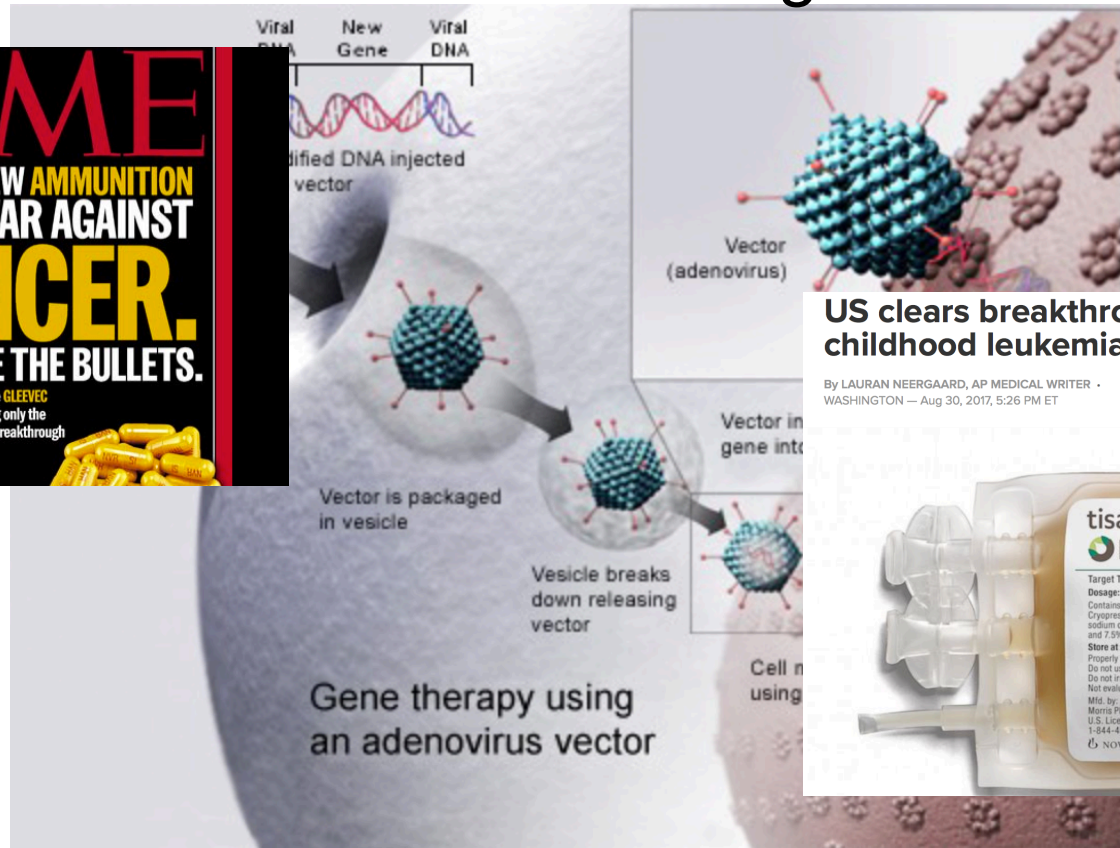


Acknowledgements and disclaimer

- The basis of this presentation is work done in collaboration with Peter Bach, Ernst Berndt, Melinda Buntin, Stacie Dusetzina, David Howard, Sayeh Nikpay, Blasé Polite, Meredith Rosenthal, Josh Sharfstein, Jeff Ward.
- I am grateful for the support of the NIH NCI, National Institute on Aging, The Commonwealth Fund, the American Cancer Society and the National Bureau of Economic Research.
- I have benefited from extraordinary data support from IQVIA/QuintilesIMS, and from discussion of regulatory and legal issues with Karl R. Karst of Hyman, Phelps and McNamara PC.
- I am undergoing the last stages of vetting to be an economist at the FDA.
- Opinions expressed are mine alone and publicly available in a series of peer reviewed publications.

We stand in the midst of incredible scientific breakthroughs



US clears breakthrough gene therapy for childhood leukemia

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

[Share with Facebook](#)

[Share with Twitter](#)



Unprecedented wave of new drugs: >7,000 in development



Alzheimer's



Cancer



High
Cholesterol

PREVALENCE	5.4 million	14 million	71 million
ANNUAL COST	\$35,000	>\$100,000	>\$14,000

Patients' access to some effective treatments is limited



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

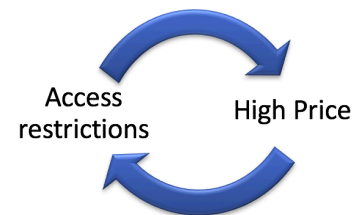
 @contirena1

HOME BUSINESS MARKETS WORLD POLITICS TECH OPINION BREAKING

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

BY DEENA BEASLEY

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



Hepatitis C Treatments

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



High morbidity, mortality
Increased transmission

Slide: Josh Sharfstein

Medicines are increasingly salient to national spending

Table 1

Expenditures on Personal Health Care Services and Prescription Drugs,
2009 to 2018, in Billions of Nominal Dollars

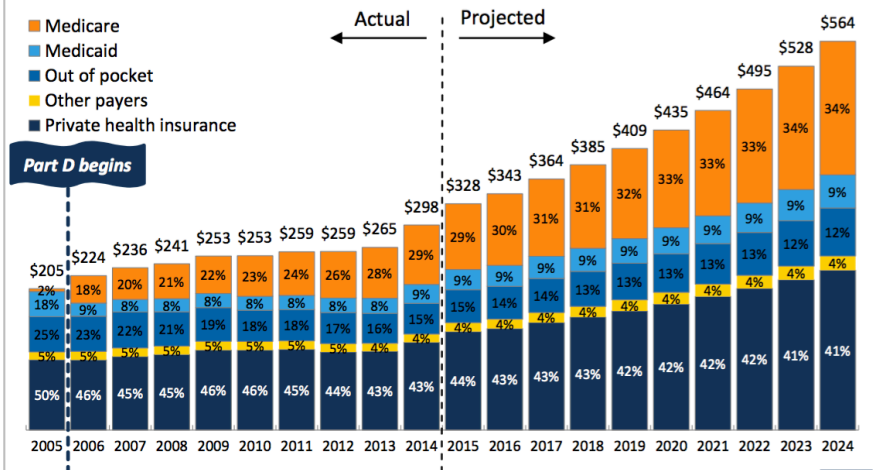
	Personal Health Care (PHC)	Retail Prescription Drugs	Percent of all PHC %	Non-Retail Prescription Drugs ¹	Percent of all PHC %	Total Prescription Drugs	Percent of all PHC %
2009	2,118	255	12.0	99	4.7	354	16.7
2010	2,196	256	11.7	100	4.5	356	16.2
2011	2,282	263	11.5	103	4.5	366	16.0
2012	2,379	264	11.1	103	4.3	367	15.4
2013	2,469	271	11.0	106	4.3	377	15.3
2014*	2,596	305	11.8	119	4.6	424	16.3
2015*	2,729	328	12.0	128	4.7	457	16.7
2016*	2,862	343	12.0	134	4.7	477	16.7
2017*	3,016	364	12.1	142	4.7	506	16.8
2018*	3,184	385	12.1	150	4.7	535	16.8
Projected Growth 2013- 2018	5.2%					7.3%	

* Projected.

Source: CMS, National Health Expenditure (NHE) Amounts by Type of Expenditure and Source of Funds: Calendar Years 1960-2024. The projections are based on the 2013 version of the NHE released in December 2014.

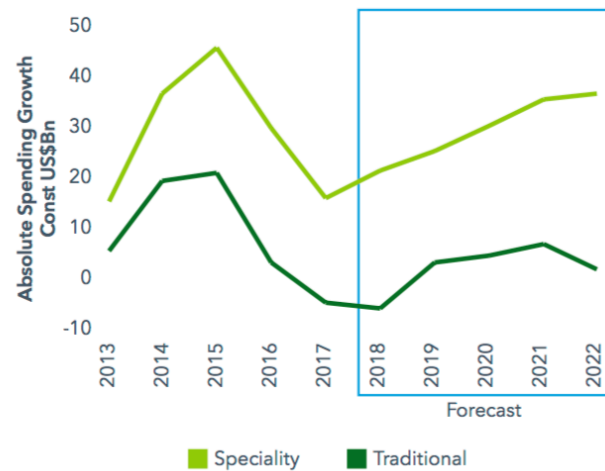
¹ Estimated based on the assumption that non-retail drugs are 28 percent of all drug expenditures.

Total U.S. Prescription Drug Spending, in \$ Billions



SOURCE: Kaiser Family Foundation analysis of CMS National Health Expenditure Data for Historical (CY2005-2014) and Projected (CY2015-2024) Retail Prescription Drug Expenditures, 2013-2024.

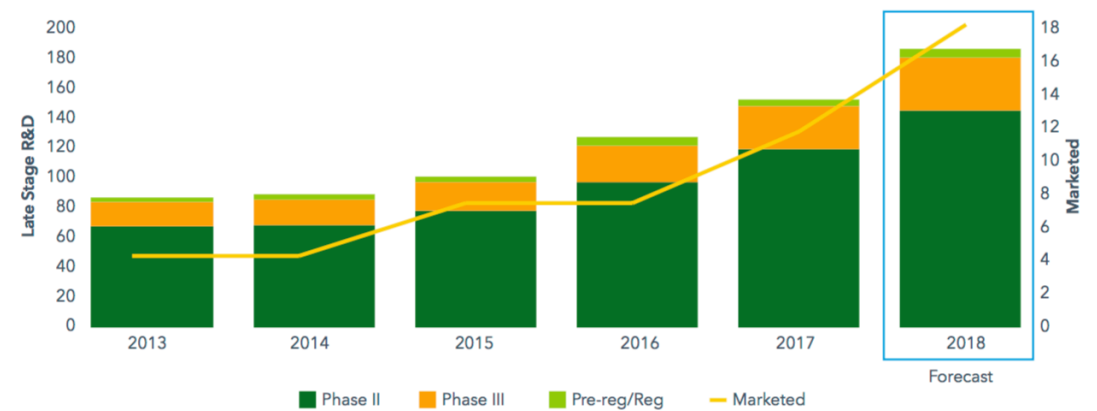
Exhibit 10: Brand Spending Growth of Specialty and Traditional Drugs 2013-2022 in the Developed Markets



Source: IQVIA Institute, Oct 2017

Notes: Developed markets include: U.S., Japan, Germany, France, Italy, U.K., Spain, Canada, S.Korea, Australia.

Exhibit 3: Number of Next Generation Biotherapeutics Currently Marketed or in Late-Stage Pipeline

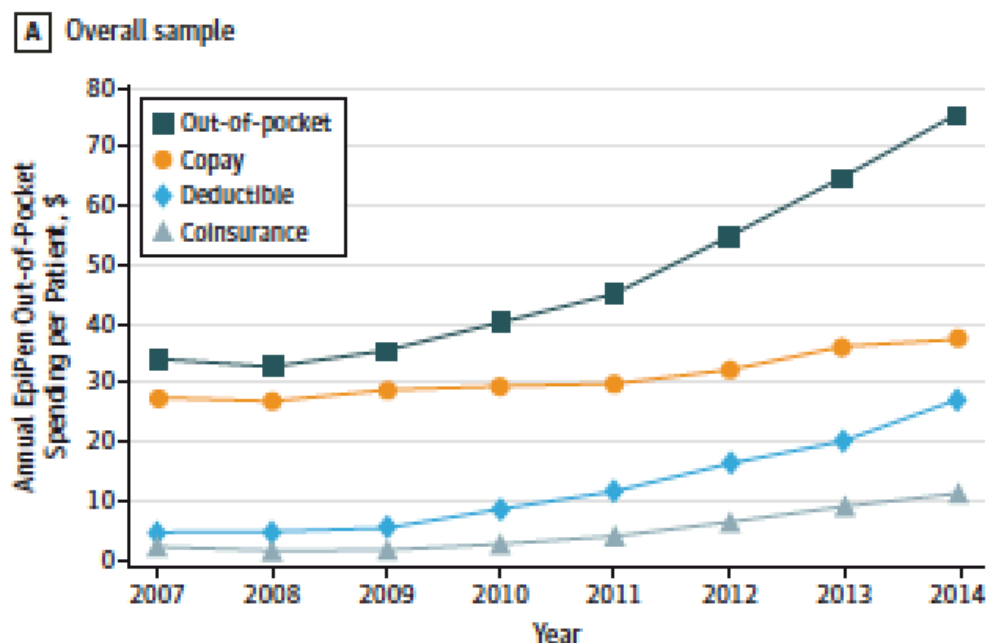


Source: IQVIA Institute, IQVIA R&D Insight, Jan 2018

Notes: Reg = Registered.

Patient out of pocket spending on drugs is growing

Figure. Trends in Annual EpiPen Out-of-Pocket Spending per Patient



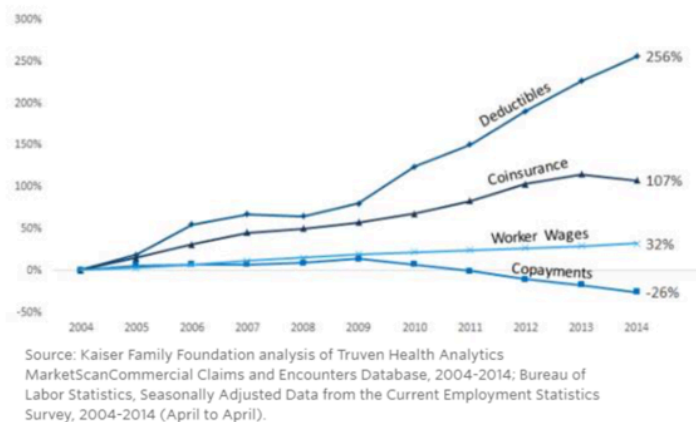
May 2017

Out-of-Pocket Spending Among Commercially Insured Patients for Epinephrine Autoinjectors Between 2007 and 2014

Kao-Ping Chua, MD, PhD^{1,2}; Rena M. Conti, PhD^{2,3}

@contirena1

Patient Spending on Deductibles Outpacing Wages



Who is to blame for high prices? 1961 to 2016

New Controls Proposed for Drug Industry

An article from CQ Almanac 1961

In 1961 both the Executive Branch and Congress moved to counter alleged malpractices in the drug industry.

Drug-Price Inquiry Before Senate Unit Set to Begin Today

The New York Times
Published: May 15, 1967

June 9, 1992

Business and Health; Trying to Curb Price of Drugs

By MIT FREUDENHEIM

March 28, 1993
THE NATION

THE NATION; Exploring The Murky World of Drug Prices

By ELISABETH ROSENTHAL

DRUG FIRMS NOT KEEPING DRUG PRICE CONTAINMENT "PROMISES," SEN. PRYOR REPORT ASSERTS; PFIZER, MERCK, GLAXO, ICI AND ROCHE PRICE RISES STAY ON PAR WITH CPI

01 Feb 1993

by The Pink Sheet
pinkedtor@infoma.com

BUSINESS DAY

Patients Facing Steep Increases in Drug Costs as Insurers Seek to Contain Rising Outlays

By MIT FREUDENHEIM JAN. 25, 1999

Under assault, pharma increased campaign contributions

By JOSEFA VELASQUEZ and BILL MAHONEY | 07/27/16 05:41 AM EDT

BUSINESS | HEALTH CARE | HEALTH

Drugmakers Point Finger at Middlemen for Rising Drug Prices

Pharmacy-benefit managers and the rebates they command come in for criticism by pharmaceutical executives

A Medical Ecosystem Gone Awry

Wall Street's earning demands drive up drug prices amid complicated FDA drug approval processes.



Health Affairs, 23, no.1 (2004):208-212 As Drug Marketing Pays Off, My Mother Pay Up

WSJ

From Wall Street, a Warning About Cancer-Drug Prices

Morgan Stanley Analyst Creates Stir in Industry As He Sees a Backlash

By
GEETA ANAND
MARCH 15, 2007

The New York Times

Lives and Profits in the Balance: The High Stakes of Medical Patents

By CLYDE HABERMAN

Tensions inherent to drug pricing pit affordability against the need to recoup investment in research, raising questions about how much of the cost patients should have to bear.

Who is to blame?

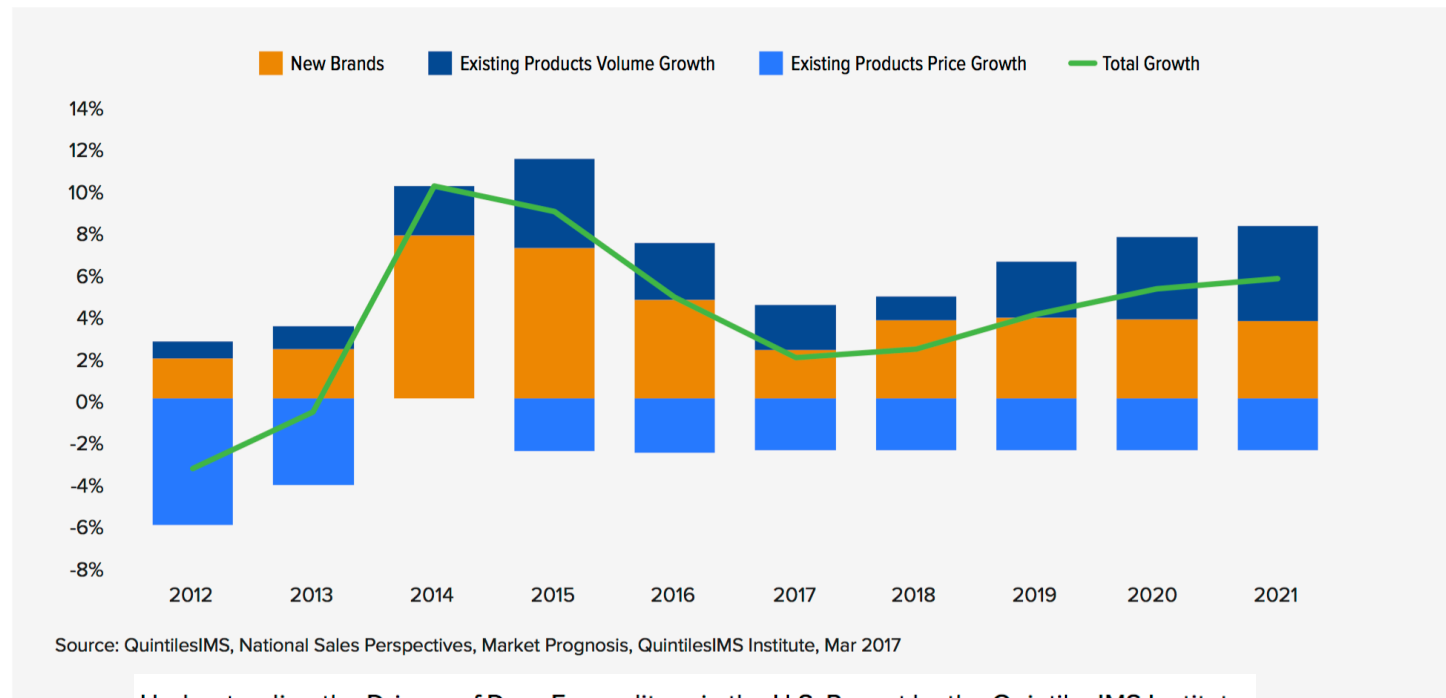
Greedy _____

- ✓ Pharmaceutical companies
- ✓ Insurers
- ✓ PBMs/Pharmacies
- ✓ Physicians/hospitals/patients



Spending growth: a mix of price and volume growth

Chart 8: Net Medicines Revenue Growth and Contribution by Type

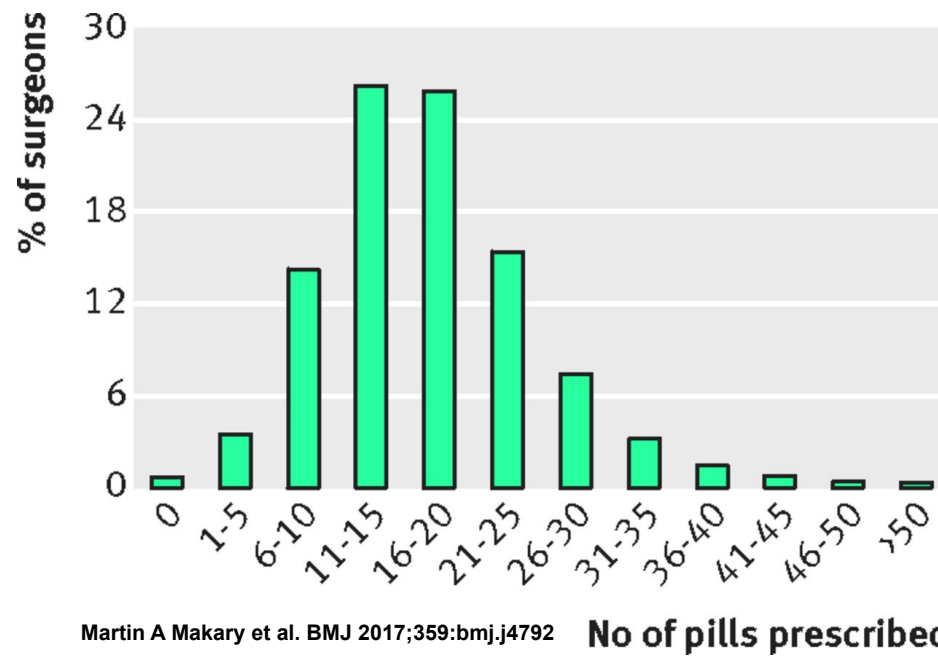


Understanding the Drivers of Drug Expenditure in the U.S. Report by the QuintilesIMS Institute

Overprescribing is major contributor to opioid crisis

BMJ 2017 ; 359 doi: <https://doi.org/10.1136/bmj.j4792> (Published 19 October 2017)

Fig 1 Distribution of surgeons by number of opioid pills they prescribed after laparoscopic cholecystectomy.



Why are prescription drug prices high and growing?

A closer look at current incentives for pricing
new drugs.



@contirena1



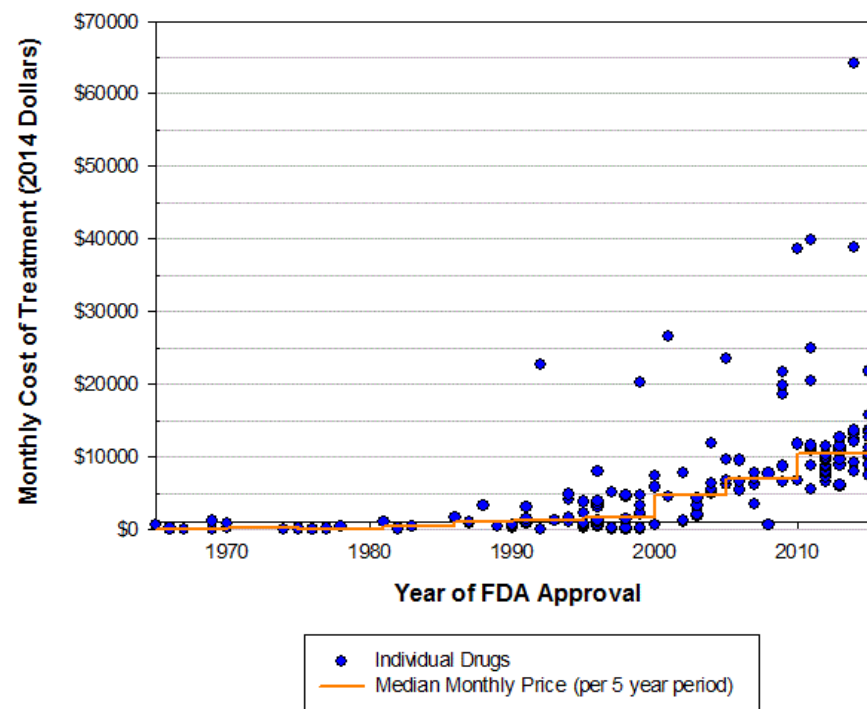
Manufacturers practice monopoly “by design” pricing

- Patent system fixes a “market failure” (time inconsistent preferences):
 - Encourages private flow of capital into risky, time intensive, uncertain investment in innovation.
- Manufacturers face an inelastic downward sloping demand curve.
- Where should pricing be set under these conditions?
 - Let’s draw a picture of demand for these drugs and discuss.

Does that mean that increasing prices reflect increased “value”?

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

Monthly and Median Costs of Cancer Drugs at the Time of FDA Approval 1965-2016



Source: Peter B. Bach, MD, Memorial Sloan Kettering Cancer Center

Data

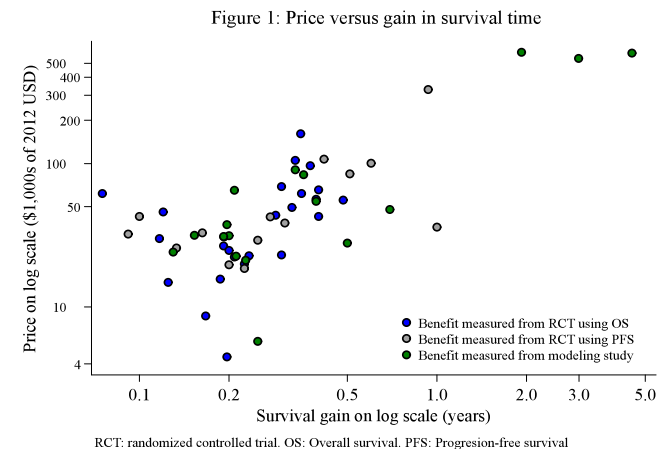
- Anticancer drugs approved 1995-2013.
- Price = amount paid by Medicare based on typical intensity and duration of use, stated in 2013 USD.
- Survival benefit = increase in median survival time in months between treatment and control.
- Other attributes: side effects, approval basis, administration route.

Pricing formula

Approval year	Route	
	IV	Oral
pre-1997	100% of AWP	100% of AWP
1997-2003	95% of AWP	95% of AWP
2004	85% of AWP	85% of AWP
2005-2006	106% of ASP	106% of ASP
2006-2007	106% of ASP	Medicare price
2008-2012	100% of WAC	Medicare price

Relationship between life years gained & approval year

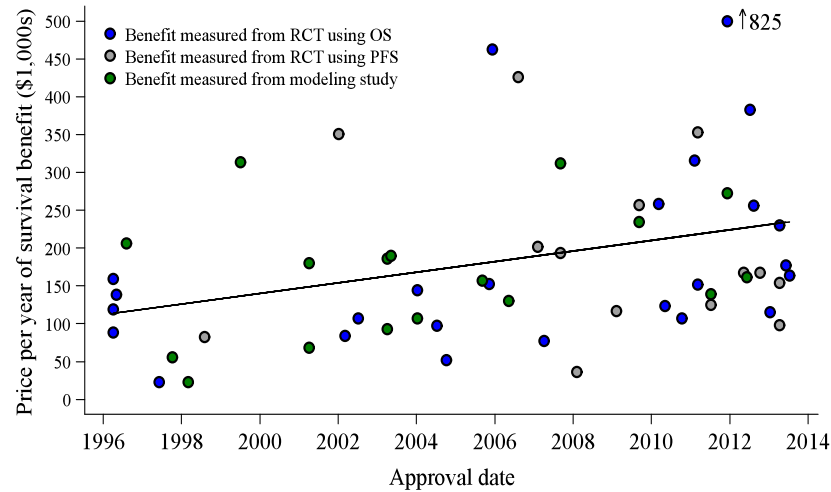
- Newer drugs are not associated with greater survival benefits compared to older drugs.
- Small and insignificant coefficient:
 - 0.005 years of life gained;
 - 95 percent CI: -0.024 to 0.034 years of life gained.



Relationship between “benefit adjusted prices” & approval year

- We focus on trends in the price per life year gained
 - equals price per treatment episode (in 2013 dollars) divided by survival benefits.
- The sample average is \$150,100 per year of life gained (SD: \$130,500).
 - Similar to willingness-to-pay for a quality-adjusted life year (Hirth et al. 2000).

Figure 2: Price per year of life gained versus approval date



The best fit line is: Price per year of life gained = \$101,077 + \$7,396 × Approval year.
 For purposes of display, we re-coded one value from \$825,000 to \$500,000.
 RCT: randomized controlled trial. OS: Overall survival. PFS: Progression-free survival

In other words, in 1995 patients and their insurers paid \$54,100 for a year of life. A decade later, 2005, they paid \$139,100 for the same benefit. By 2013, they paid \$207,000.

Table 2: Impact of approval year and other variables on the natural logarithm of the price per life year gained in \$1,000s of 2013 USD for 58 cancer drugs approved between 1995 and 2013

	A	B	C	D	E	F
Approval year	0.10 [0.06, 0.14]*	0.10 [0.06, 0.14]*	0.10 [0.06, 0.14]*	0.10 [0.06, 0.15]*	0.10 [0.06, 0.15]*	0.09 [0.05, 0.13]*
GI complication rate		1.70 [0.47, 2.94]*				
Neutropenia rate		0.26 [-0.76, 1.28]				
IV drug			0.26 [-0.22, 0.74]			
Biologic				-0.15 [-0.67, 0.36]		
Multiproduct firm				0.38 [-0.14, 0.90]		
Randomized controlled trial					0.12 [-0.45, 0.69]	
Progression free survival					-0.36 [-0.91, 0.20]	
Placebo comparator						0.46 [-0.02, 0.94]+
Constant	3.51 [2.99, 4.03]*	2.95 [2.31, 3.59]*	3.34 [2.73, 3.95]*	3.24 [2.58, 3.89]*	3.48 [2.89, 4.06]*	3.39 [2.87, 3.92]*
R-squared	0.28	0.37	0.29	0.31	0.30	0.32
	G	H	I	J	K	
Approval year	0.10 [0.07, 0.14]*	0.10 [0.06, 0.14]*	0.09 [0.05, 0.14]*	0.09 [0.05, 0.13]*	0.11 [0.06, 0.15]*	
Priority drug	0.93 [0.46, 1.40]*					
Orphan drug	-0.17 [-0.67, 0.33]					
Ln competitors		-0.64 [-0.99, -0.29]*				
Gene test			-0.59 [-1.05, -0.14]*			
Second line therapy			0.15 [-0.33, 0.62]			
Baseline survival				-0.29 [-0.53, -0.05]*		
Mortality rate					0.77 [-0.38, 1.92]	
Constant	2.83 [2.23, 3.44]*	4.92 [4.01, 5.83]*	3.75 [3.09, 4.42]*	3.89 [3.30, 4.48]*	3.20 [2.50, 3.90]*	
R-squared	0.44	0.41	0.36	0.35	0.30	

*P < 0.05, +P < 0.10

95% Confidence intervals are in brackets.

GI: gastrointestinal, IV: intravenous.

Other “obvious” explanations don’t make sense

- Demand:
 - Neither increases in income nor the income elasticity of the demand for health care appear to have shifted greatly.
- Supply:
 - Production costs likely stable over time
 - May have decreased due to firm choices and U.S. regulatory policy.

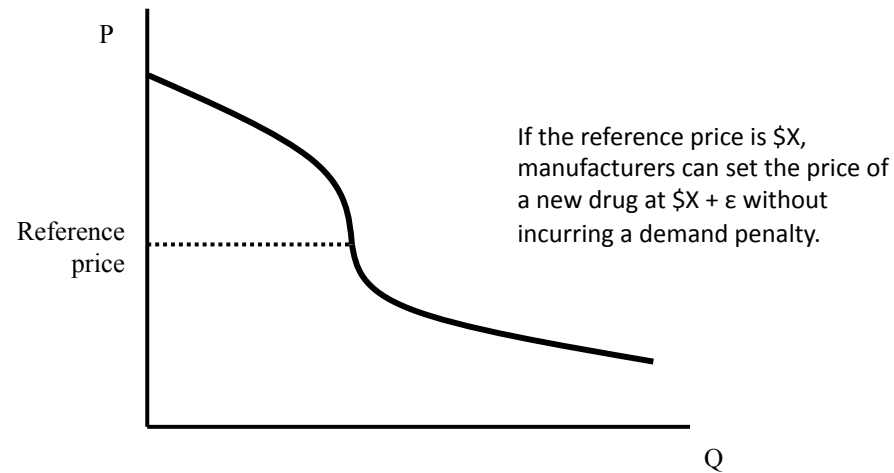
What about R&D costs?

- R&D costs are sunk, so they shouldn't influence price setting.
- Most economists think the relationship goes in the opposite direction:
 - High prices “pull” R&D, rather than R&D costs determine price of finished product.
 - We will come back to this later.

Manufacturers might be practicing “reference pricing”

- Demanders face no direct incentives to avoid costly drugs
 - All might balk at using drugs with prices they perceive as “unreasonable”.
- Perceptions of “unreasonableness” are malleable and influenced by the prices of previously approved drugs.
 - Not necessarily within class or disease because of limited entry (winner take all markets).

Demand curve w/ loss aversion

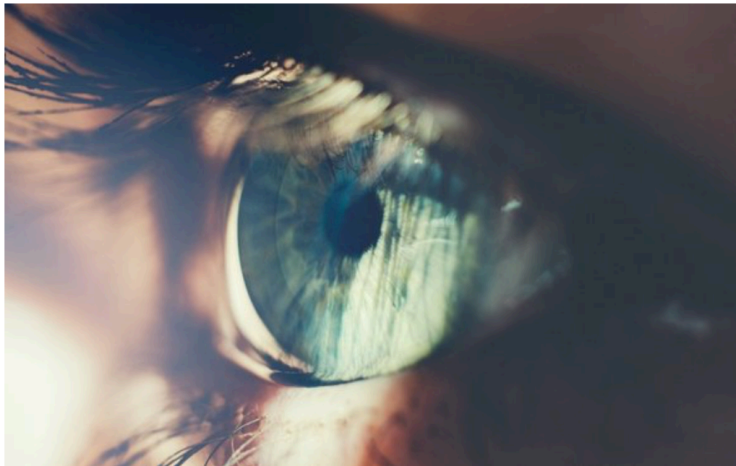


Reference pricing in action: Luxturna 😊

The Most Expensive U.S. Medicine Now Has an Official Sticker Price

This gene therapy for vision loss will initially cost \$850,000

By Adam Ehsanifard, Damian Carls, STAT on January 3, 2018



“As far as the price, and the structures to pay the price, I think it’s all pretty much in line with what we’re seeing in other innovative therapies,” said Dr. Stuart Orkin, a pediatric oncologist at the Dana-Farber Cancer Institute and Boston Children’s Hospital. He cited CAR-T therapies for cancer, which cost hundreds of thousands of dollars, and newfangled immuno-oncology treatments with similar price tags.

“I feel like we made the right middle ground decision,” Marrazzo said in an interview, balancing the company’s desire to capture the economic value of Luxturna while ensuring patients will have access to the therapy.

Let's talk more about “demand” for prescription drugs

Inelasticity of demand appears to be reinforced by payer policies

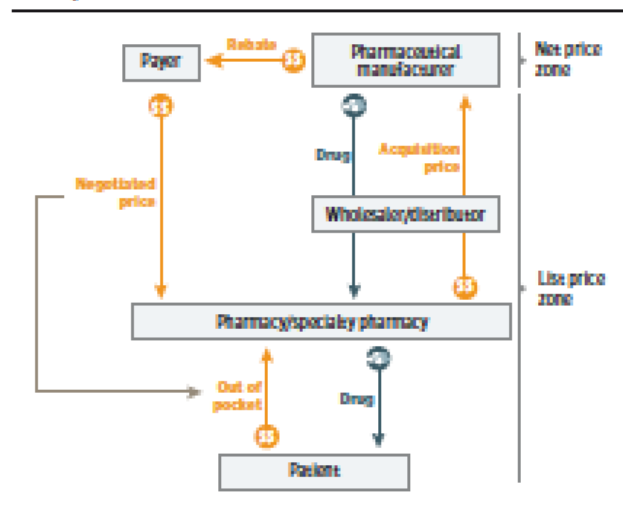
- Insurers cover specialty drugs for FDA-approved & off-label uses; no coverage exclusions.
- Limited reliance on generics, no automatic generic substitution in specialty drug classes.
- Patients face low cost sharing at the margin.
- Physicians face very limited incentives/information to be cost conscious:
 - Specialty physicians pride themselves on an attitude of “progress at any cost”.
 - Limited comparative/cost effectiveness evidence (ICER fills this void).

Different prices coexist for the same drug in the US

- Full, “list” price: What manufacturers charge purchasers for their product.
- Wholesale/acquisition costs: list - rebates and discounts
- Net “paid” amount: Negotiated by payer = insurer.
- Out of pocket costs: Determined by insurer.

Middlemen make money off supply chain

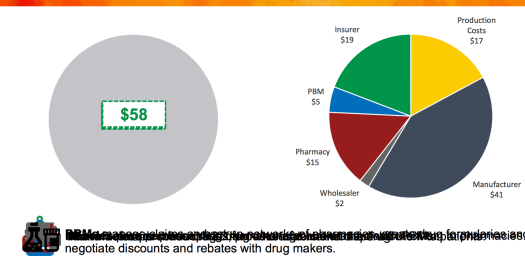
Figure 1. Drug Distribution and Payment System in the United States for Prescription Medications



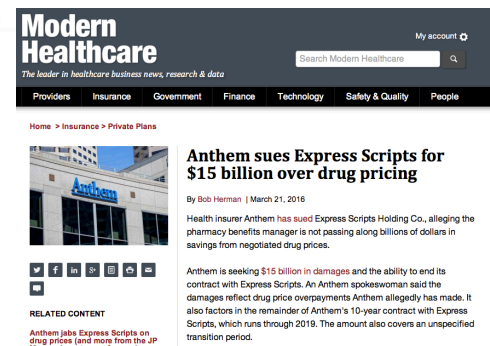
This schematic shows the differences between net price zone and list price zone.

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

Flow of \$100 spent on pharmaceutical drugs, overall industry



USCSchaeffer | USCPrice



The ability of intermediaries to extract rents is growing

- Insurers/Hospitals/PBMs/Pharmacies/Practices are “merging” and “affiliating”.
 - Causes are likely complex.

CVS-Aetna Deal Could Mean End of Era in How Drugs Are Paid For

By **Robert Langreth** and **David McLaughlin**

October 27, 2017, 2:41 PM CDT Updated on October 27, 2017, 11:01 PM CDT

- Express Scripts, Walgreens might feel pressure to combine
- Tie-up talks seen as reaction to possible arrival of Amazon

This Is How Amazon Could Invade the Pharmacy Business

Usually easy to ship, drugs look to be an ideal Prime product.

By **Robert Langreth** and **Spencer Soper**

November 7, 2017, 9:10 AM CST Corrected November 8, 2017, 11:06 AM CST

Impact of consolidation is ripe for empirical study

- Vertical consolidation promises significant social and patient benefit in the form of lower prices/spending, improved access/quality of care (reduce double marginalization, Chicago school).
- Policymakers worry vertical consolidation may have perverse effects on consumers (foreclosure; post-Chicago school).
 - Entry, exit heavily regulated.
 - Assymmetric information, agency.



Available online at www.sciencedirect.com

SCIENCE @ DIRECT®

Journal of Health Economics 25 (2006) 175–180

JOURNAL OF
HEALTH
ECONOMICS

www.elsevier.com/locate/econbase

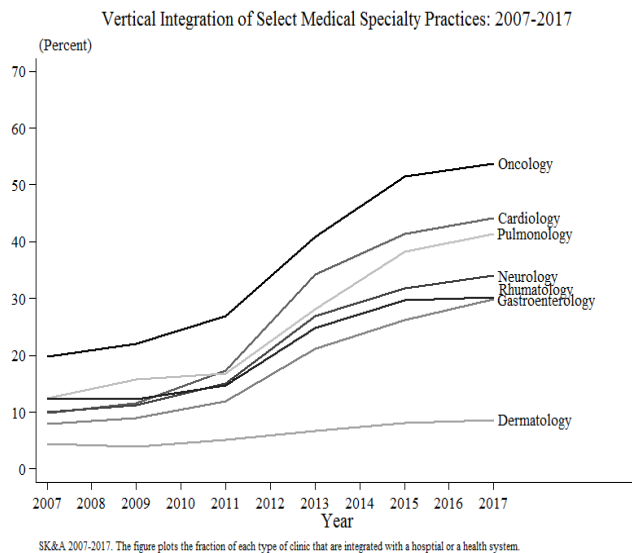
Editorial

Is vertical integration anticompetitive?
Definitely maybe (but that's not final)

Riordan M, Salop S, Evaluating Vertical Mergers: A Post-Chicago Approach. ANTITRUST L. J. 1995.

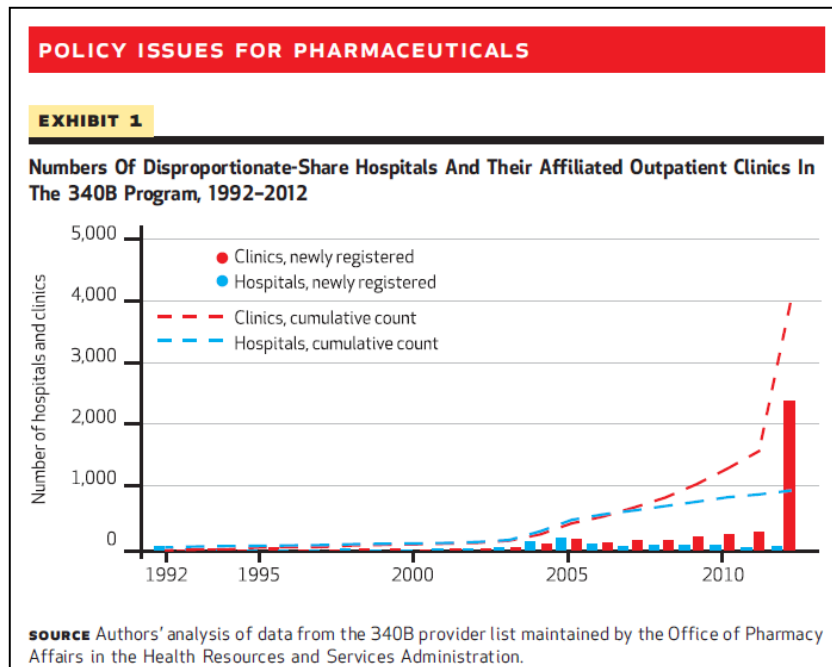
Wright JD. "Abandoning Antitrust's Chicago Obsession: The Case for Evidence-based Antitrust." Antitrust Law Journal. 2012.

Hospital consolidation with specialty practices contributes directly to pricing perversity

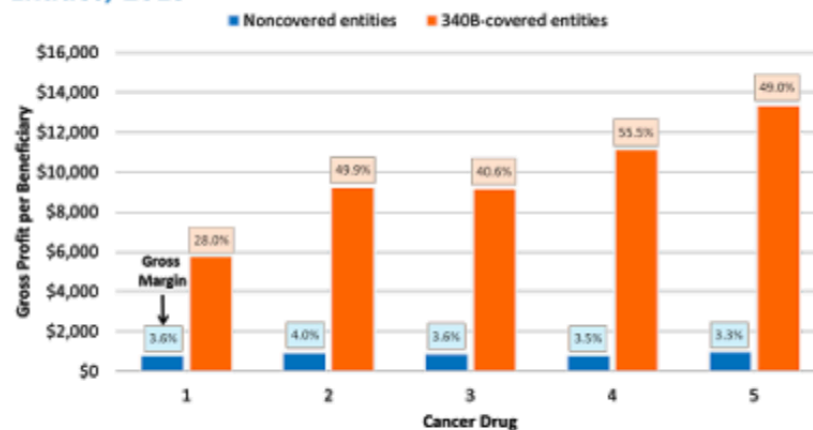


By Rena M. Conti and Peter B. Bach

**The 340B Drug Discount Program:
Hospitals Generate Profits By
Expanding To Reach More Affluent
Communities**



Oncology Drug Profits, 340B-Covered Entities vs. Noncovered Entities, 2013



Sources: Pembroke Consulting analysis of Part B Payments For 340B-Purchased Drugs, OIG, November 2015.
Published on Drug Channels (www.DrugChannels.net) on December 1, 2015.

Complexity of system contributes to firms' pricing practices

- Manufacturers build rent seeking activities into launch prices, price setting over time.
- Multi-product firms face choices where to rent seek off current system:
 - A subject of ongoing empirical study
 - We find preliminary evidence to suggest price increases concentrate among drugs where:
 - product characteristics or market more generally breeds inelastic demand.

Isn't increasing reliance on generic drugs the answer?

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

Three Sleazy Moves Pharmaceutical Companies Use to Extend Patents

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

30.3K 59 2




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

By KATIE THOMAS SEPT. 8, 2017



RELATED COVERAGE

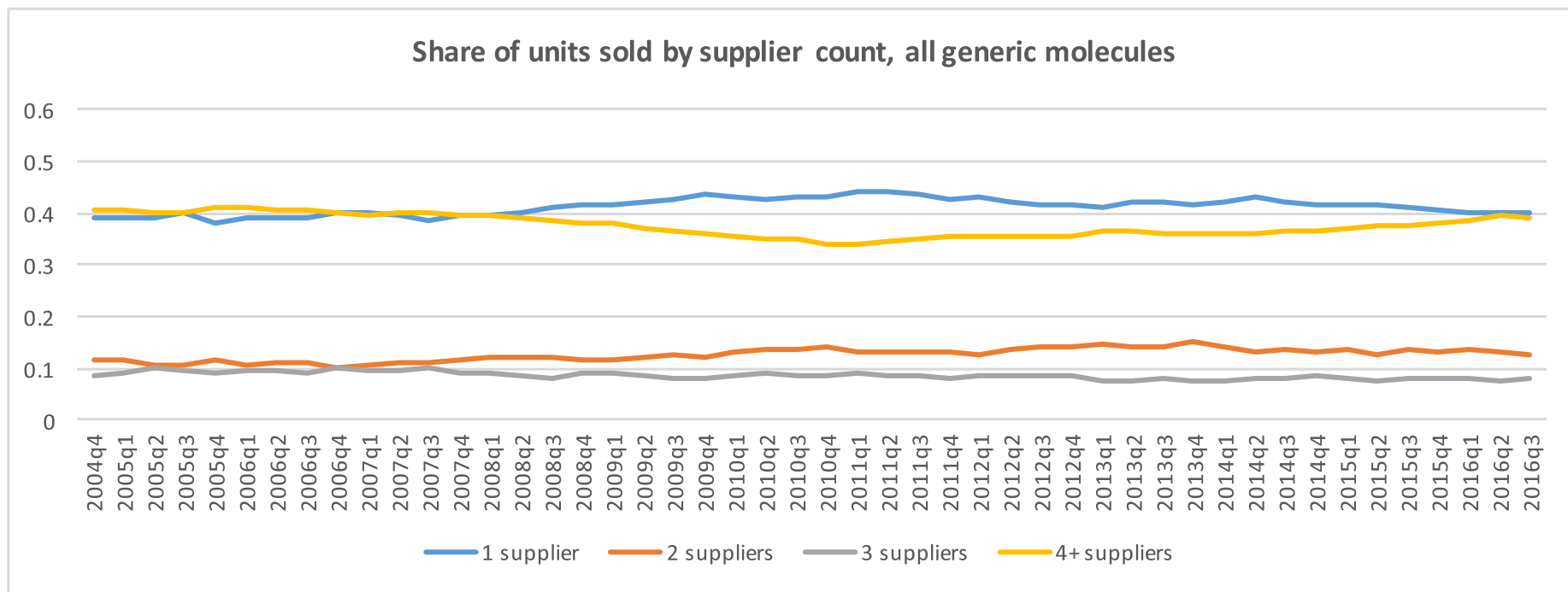
 **Teva Pharmaceuticals to Buy Allergan's Generics Business**
JULY 27, 2015

 **FAIR GAME**
Working to Lower Drug Costs by Challenging Questionable Patents
NOV. 27, 2015

 @contirena1



Suppliers of generic drugs are increasingly concentrated



 @contirena1



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

Table 5: Regression Results of Log Inflation-Adjusted Generic Price on Supplier Counts

	(1) Log Price	(2) Log Price	(3) Log Price	(4) Log Price	(5) Log Price	(6) Log Price	(7) Log Price	(8) Log Price	(9) Log Price	(10) Log Price	(11) Log Price	(12) Log Price	(13) Log Price
Log Corp		-0.736***	-0.737***	-0.799***	-0.806***	-0.738***	-0.378***						
Log Mnf								-0.720***	-0.721***	-0.774***	-0.780***	-0.712***	-0.374***
1_PreMMA	0.000	0.000						0.000					
2_MMA	0.101***	0.075***						0.081***					
3_ACA	0.401***	0.331***						0.337***					
4_GDUFA	0.751***	0.719***						0.724***					

- Prices of generic drugs are observed to increase statistically significantly over time; after MMA implementation prices rise 0.101 percentage points, after ACA prices rise 0.401 percentage points, and after GDUFA implementation prices rise 0.751 percentage points (Column 1) compared to the Pre-MMA period.
- We find prices are negatively associated with larger counts of corporations (Columns 2-7) and manufacturers (Columns 8-13) – a one percent increase in corporation count results in a 0.736 percentage point fall in price and a one percent increase in manufacturer count results in a 0.720 percentage point fall in price.

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

WHILE MOST GENERIC FIRMS HAVE SMALL DRUG PORTFOLIOS, THERE ARE A SMALL NUMBER OF “BEHEMOTH” PORTFOLIO HOLDERS

**TABLE 5: ANDA PORTFOLIO SIZE AND OWNERSHIP DISTRIBUTION
AS OF SEPTEMBER 8, 2017**

ANDA PORTFOLIO SIZE	NO. OF SPONSORS	SHARE OF SPONSORS	NO. OF ANDAS HELD	SHARE OF ANDAS HELD
1-5	306	71.7%	603	6.0%
6-10	35	8.2%	266	2.6%
11-50	52	12.2%	1181	11.7%
51-150	18	4.2%	1540	15.2%
151-300	9	2.1%	1816	18.0%
>300	7	1.6%	4700	46.5%
TOTALS	427	100.0%	10106	100.0%


Berndt, Conti, Murphy, “The Generic Drug User Fee Amendments: An Economic Perspective” *Journal of Law and the Biosciences*, April 2018

Who Are the “Behemoth” Portfolio Owners in 2017?

- 1. TEVA Pharmaceuticals USA  1,569 ANDAs
- 2. Mylan Inc.  699
- 3. Novartis Corporation (Sandoz)  649
- 4. Sun Pharma 580
- 5. Hikma Pharmaceuticals PLC  498
- 6. Endo International PLC 378
- 7. Aurobindo Pharma LTD 327
- 8. Apotex Inc  288
- 9. Pfizer Inc (Hospira, Greenstone) 262
- 10 Perrigo Company PLC 228

Total Top 10

5,478 (54.2% of total 10,106 ANDAs)

 Some of these firms also a major suppliers of branded drugs 😊

Berndt, Conti, Murphy, “The Generic Drug User Fee Amendments: An Economic Perspective” *Journal of Law and the Biosciences*, April 2018

We hypothesize:

- Number of firms able to make “generic” drugs decreasing
 - Some product markets may be experiencing reduced “contestability”
 - Ongoing empirical work with FDA office of generic drugs/commissioner
- Contracting practices with multi-product firms may reinforce “winner take all” markets across brands and generics
 - Ongoing empirical work with Tim Simcoe

HEALTH AFFAIRS BLOG DRUGS AND MEDICAL
INNOVATION
RELATED TOPICS:
PRESCRIPTION DRUGS | PHARMACEUTICALS | MARKETS | PRESCRIPTION DRUG COSTS
| COST REDUCTION | ECONOMIC BURDEN

Getting By On Their Own Supply: The Economics Of Hospitals As Generic Prescription Drug Manufacturers

Rena M. Conti, Joseph Krongold

MARCH 15, 2018

10.1377/hblog20180313.717895

Public concern creates an opportunity for reform.

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



@contirena1

Best reforms will embody three principals

- 1) Improve patient access/affordability.
- 2) Improve transparency, reduce rent seeking across the value chain.
- 3) Identify new paradigms for financing innovation.

NEWS

The National Academies of
SCIENCES • ENGINEERING • MEDICINE

Actions to Address the Rising Costs of Prescription Drugs – New Report and Briefing Nov. 30

 @contirena1



Improve generic supply competition

- FTC/DOJ has critical role to play:
 - Increase merger scrutiny, (Congress may need to reform Scott-Hart-Rodino thresholds).
 - Vigorously pursue pay for delay & other “evergreening” activities.
- FDA has critical role to play:
 - Lower barriers to entry through GDUFA fee revisions.
 - Preserve ability to reenter molecule markets after temporary supply disruptions/exits.
 - Identify alternative suppliers meeting quality manufacturing metrics.
- Increase coordination across FTC/DOJ/FDA/CMS to focus on specific areas that matter for patient access/affordability.

Reduce profit seeking in the value chain

- Policymakers should reduce intermediaries ability to profit off drugs.
 - Reimbursement should favor flat fees rather than price/revenue share arrangements.
 - Existing 340B reform, proposed Part D reform are good steps forward.
 - Transparency initiatives at state level (MD, IL)
- DOJ/FTC increasing their role:
 - Increased enforcement of anti-kickback & RICO statutes.
 - Expect great scrutiny of affiliations and proposed mergers between value chain actors.

What about high prices of new innovative drugs?

- Difficult because price/expected revenue a major driver of R&D investment.
- So, do we do nothing?
 - No: Not obvious current system rewards the “right” mix/quantity of drugs from society’s perspective.
- Some potential fixes already exist:
 - “Value based purchasing”, advance purchasing (price/quantity) commitments (NASEM committee rec on Hep C, CARB-X, Ran White (HIV))
 - Derisk R&D even more: difficult commitment enforcement
 - Likely need more thinking, likely pilot testing.

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

rconti@uchicago.edu

Thank you.



@contirena1



Manufacturers practice price discrimination across payers based on willingness to pay

