Barriers to Competition in the US pharmaceutical industry

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Background

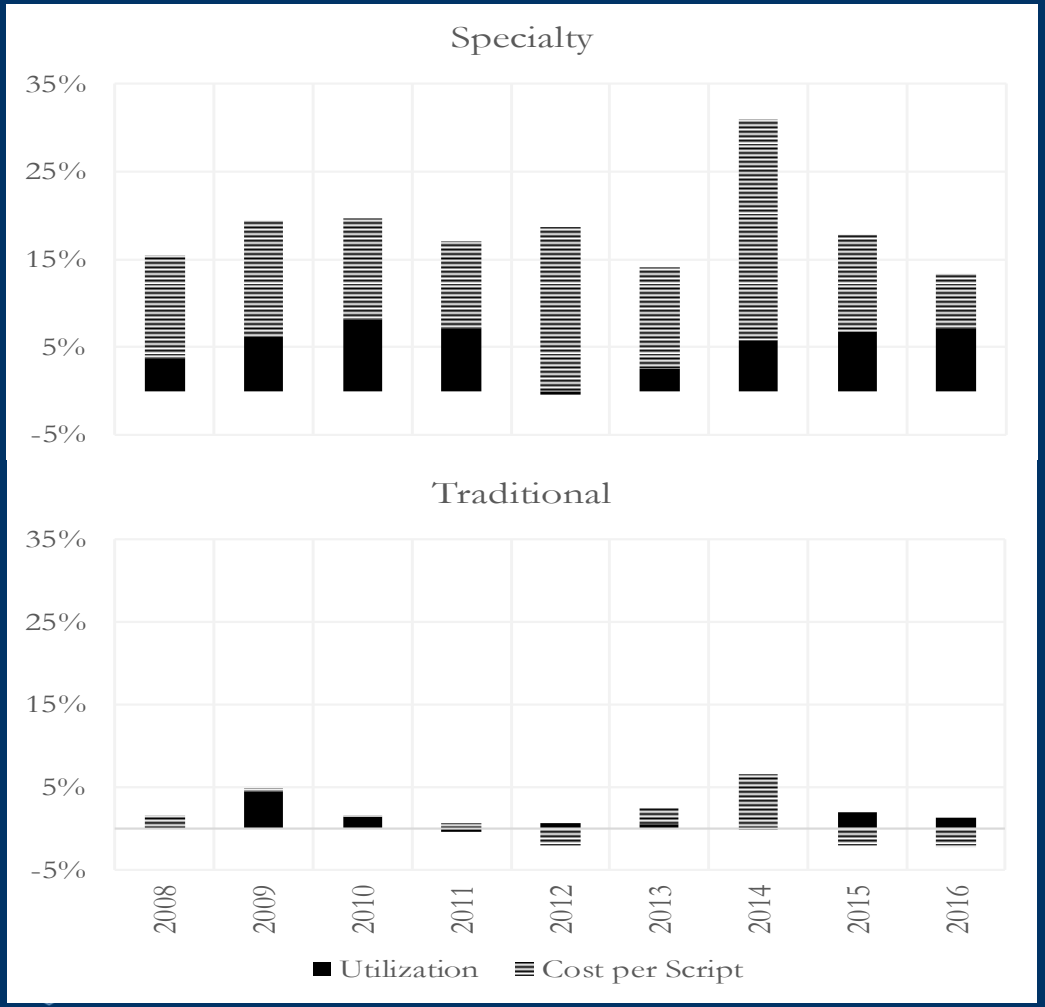
- Expenditures on pharmaceuticals are high and rising; there are too many examples of prices unrelated to value
- Regulation is really hard to get right when innovation is important, innovation costs are sunk, and marginal costs are low

$\Rightarrow$ Competition between drugs in well-functioning markets can bring down prices and also generate innovation that people value

- Exactly because competition is so effective, manufacturers attempt to avoid it –
  - Use influence with regulators to get regulations that dampen competition
  - Use influence with legislators to prevent pro-competitive legislation
  - Utilize creativity in complex markets to reduce rivalry

Motivation

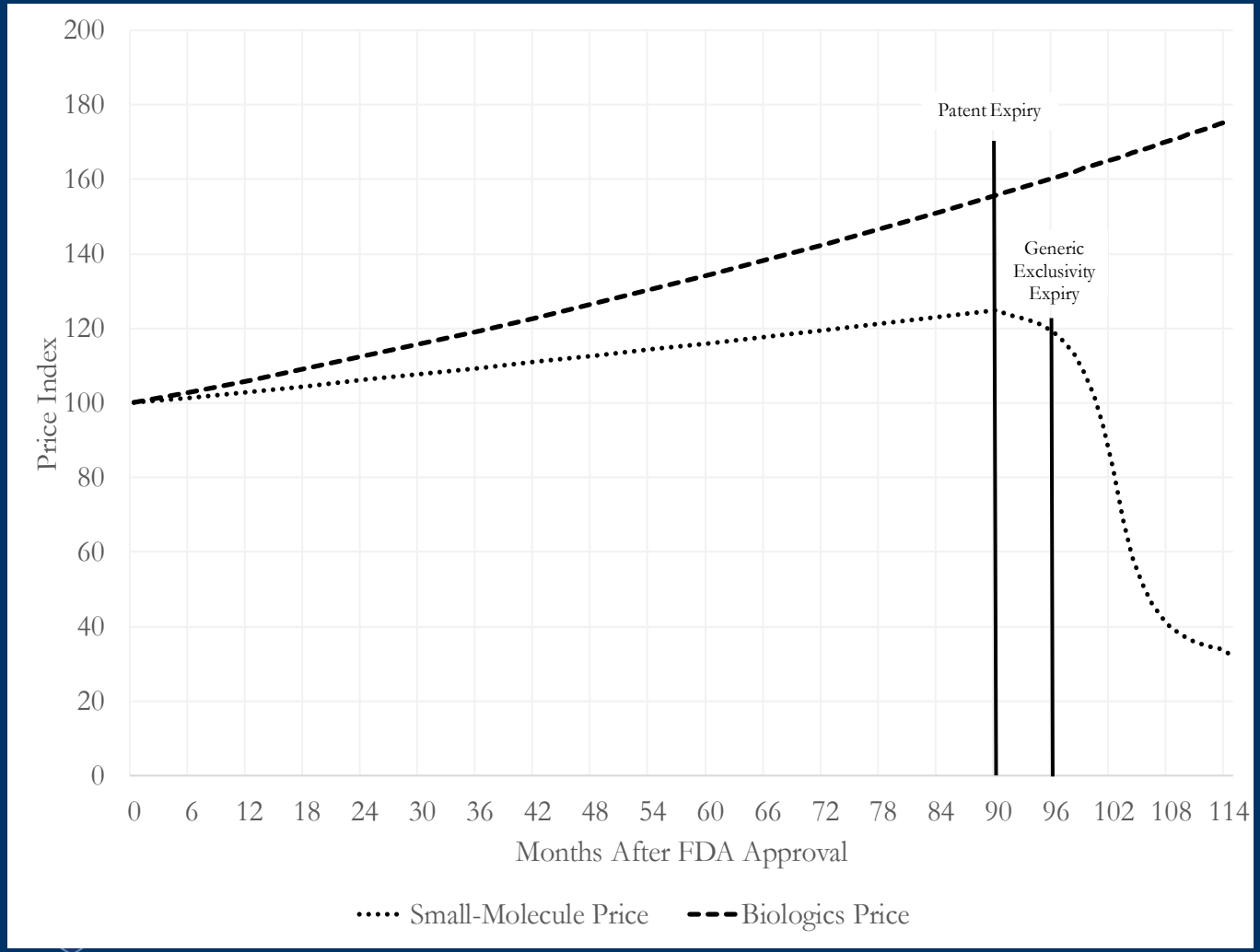
- This paper argues that enabling vigorous competition should be the first response to the problem of high pharma spending
- Remove barriers to competition
  - Some created by manufacturers
  - Some created by science
  - Some created by regulators
- If regulators pay attention to competition, enhance and enable it, may get lower prices, innovation, and no need to regulate
- Caveat: Paper does not address unique patented valuable treatments. For that you need NICE or some equivalent



Price growth:
speciality / biologic

versus

small-molecule drugs



Stylized price paths:

biologics (top line)

v

small-molecule drugs with generic entry (bottom line)

Biologics

1) ***Biosimilar entry needed***: quicker entry and approval of interchangeable biosimilars

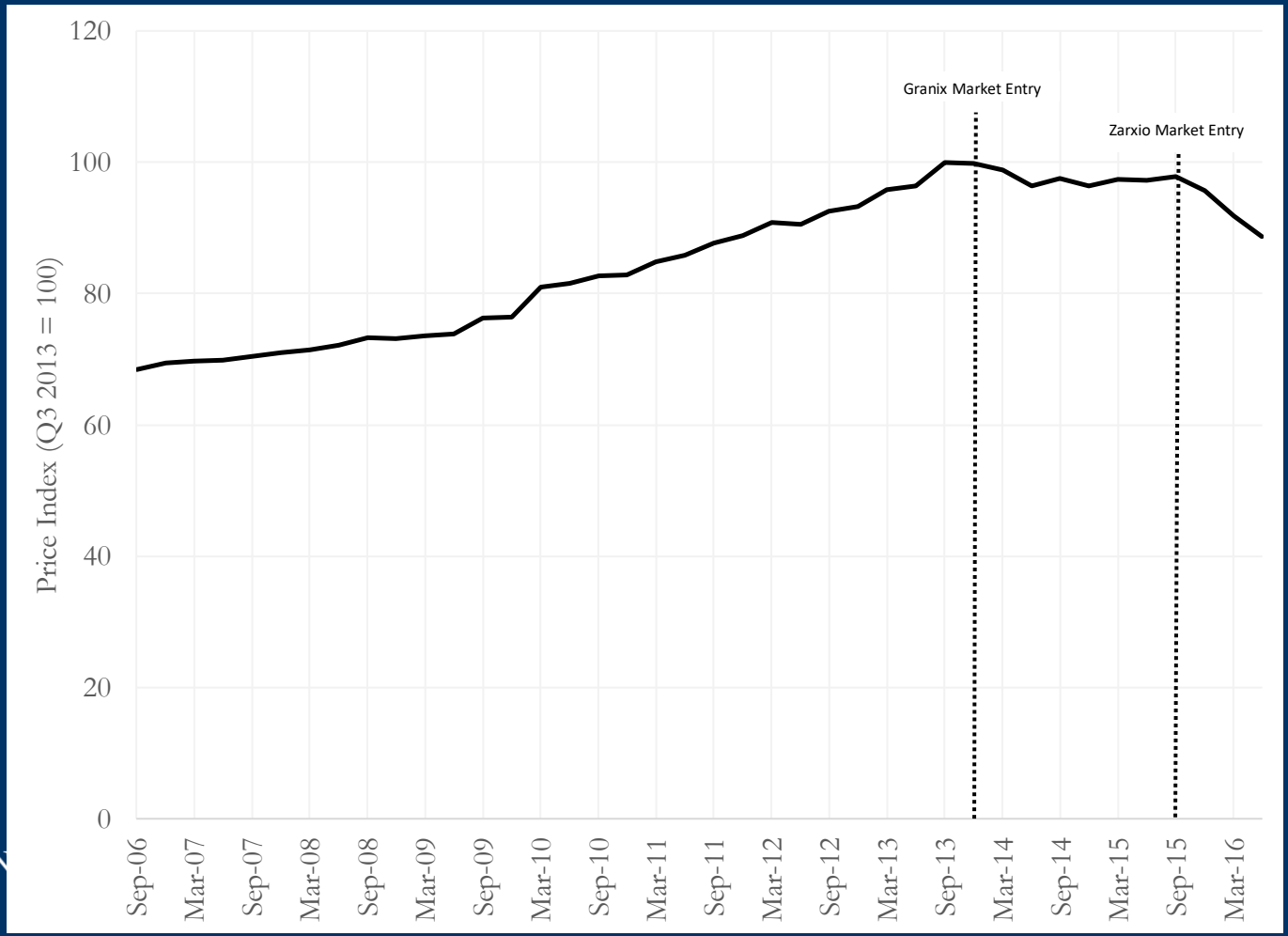
Europe has had biosimilars since 2006. More than 20 on the market today generating significantly lower prices.

The United States has 2 biosimilars for sale.

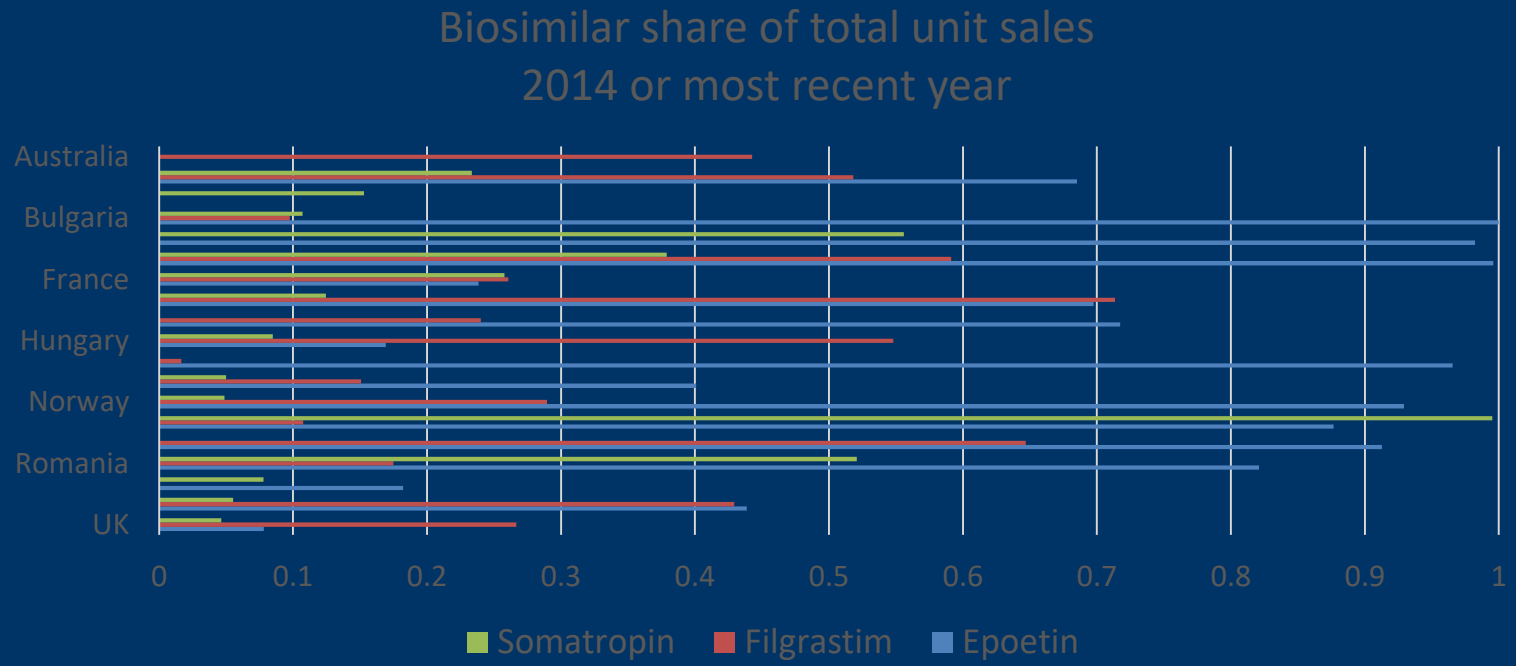
FDA has approved a grand total of 5 biosimilars to date. Disputes over patents (enabled by additional law) are blocking the sale of 3 others.

Impact of second filgrastim brand (granix)

Impact of first 6 months of generic entrant (zarxio)



Biosimilars in Europe



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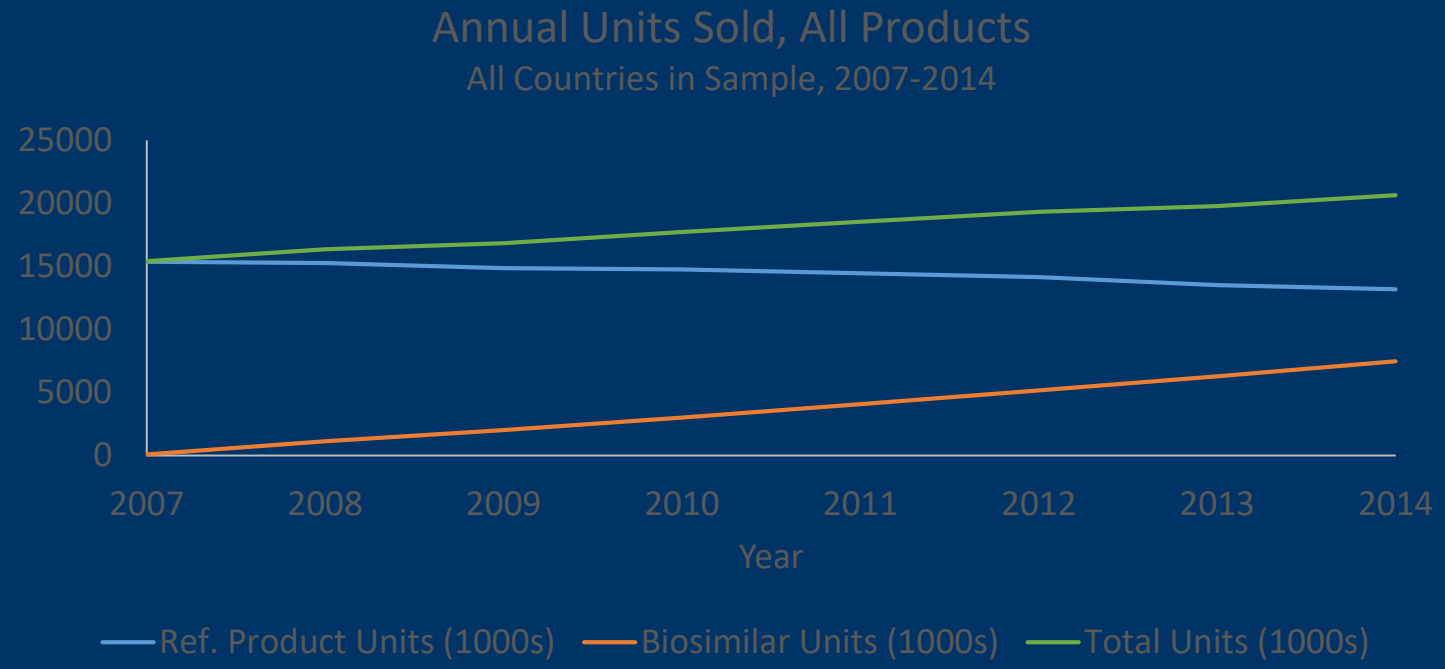
Units in Europe



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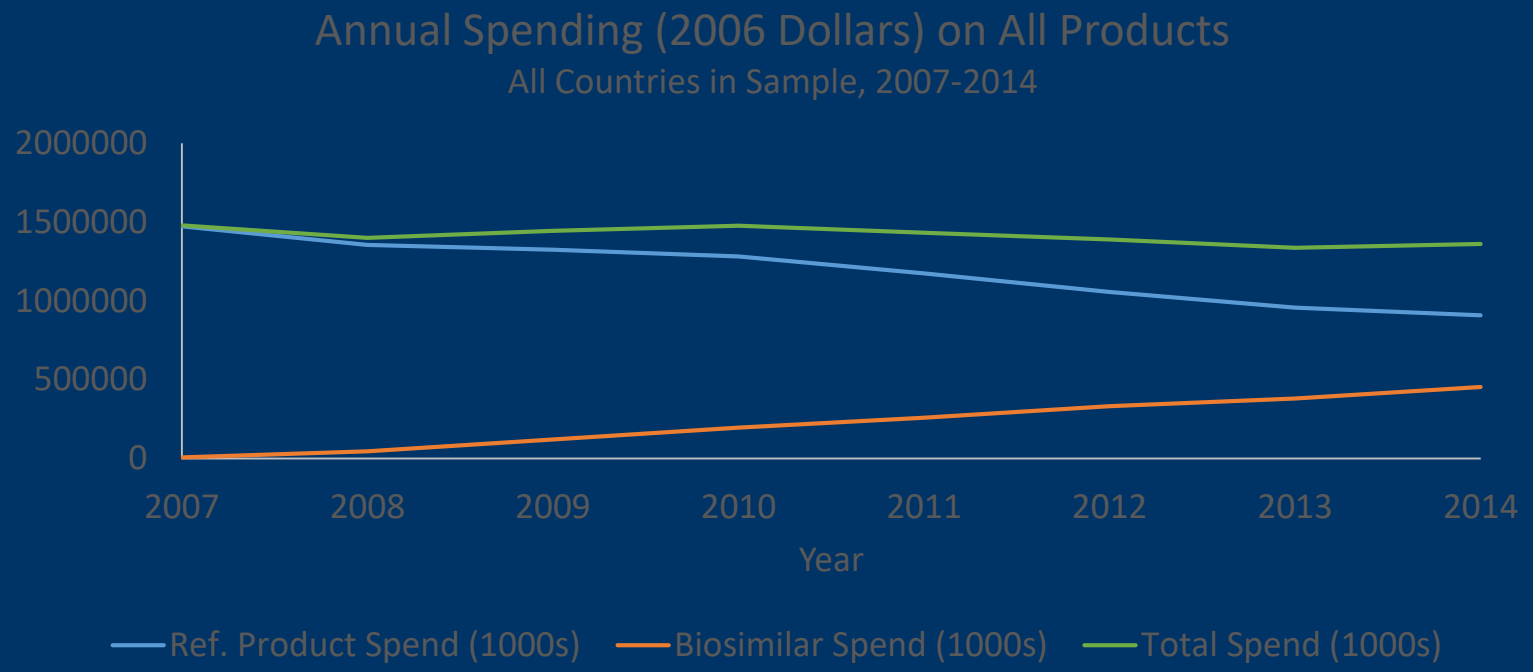
Expenditure in Europe



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US biosimilar problems

Biosimilar entry needed: approve exchangeable biosimilars

Biosimilar naming: artificial differentiation due to 4 letter "nonsense suffix" mandated by the FDA

Procurement by CMS: redesign procurement of physician administered drugs to incentivize use of lowest cost product (e.g. reference pricing rather than cost-plus pricing)

Brand attempts to block generic entry

- Pay for delay
  - Brand contracts with entering generic to stay out
  - In US, the effectively blocks 2nd and subsequent entrants
  - Even without regulatory help, may not enough generic entrants to make strategy unprofitable
- Block the development of the generic product
- Product hopping

Exclusionary conduct by brand

- Pay for Delay
- Block development: Exclusionary tactics by brand
  - Restricted distribution classification (dangerous, addictive medications): Voluntary REMS designation
  - Refusing to sell samples to brand
  - Patenting of REMS system
  - Refusing to share REMS IT system
- Product Hopping

Exclusionary conduct by brand

- Product Hopping
  - Introduce a new version of the product just before the patent expires on the original product
  - Soft switching: advertise vigorously and shrink market available for auto switching to generic
  - Hard switching tactics: Orange book withdrawing, drug compendia change – no reference product for generic to imitate
  - Avoid market competition on the merits

Demand side problems

- Therapeutic substitution in Part D
  - Formularies restrict subst patterns
- Therapeutic substitution in Part B
  - No incentive for physician to use least cost alternatives
- PBM competition and incentives
  - High concentration; opaque contracts; misaligned incentives

PBMs

- Locus of price competition among therapeutic substs: good
- But not a perfect agent of the end consumer
  - E.g. Product hopping could not workif PBM switched consumers back to generic immediately
- PBMs would *have* to be better agents if market were perfectly competitive -- what is wrong? What is missing?
- Confidential rebates promote price competition.. But, make it hard for final payor to extract all of them, particularly with performance-based rebates, bundles, etc
- Market structure is concentrated so few choices
- If rebate not fully returned to consumers then both PBM and manufacturer gain from higher prices

Need PBM research

- Are employers informed and sophisticated? Are insurers who purchase from PBMs sophisticated?
- How does contract type impact competition?
  - Rebates flow back, percentage of list price of medication, percentage of rebates, admin fees per rx, per member per month
  - MFNs, loyalty rebates, deferred rebates
- Entry could be more difficult due to contract type
- Is employer a good agent for the final consumer/ employee?
  - Higher costs for employee reduce utilization and lower employer cost

Demand side

- Patient kickbacks
  - Coupons
  - Patient Assistant Programs (medication)
  - Patient financial aid (dollars)
- When patients have no co-pays, they are not price-sensitive => PBM can't shift share => manufacturer won't give rebates => manufacturers' prices are higher
- Government costs ultimately tied to market prices, so kickbacks in commercial markets *must* harm taxpayers
- We need research on impact of kickbacks on equilibrium prices

Rank	Foundation	Total Giving	PAP
1	Bill & Melinda Gates Foundation	$3,439,671,894	
2	Silicon Valley Community Foundation	$956,834,000	
3	The Abbvie Patient Assistance Foundation	$853,356,401	✓
4	The Bristol-Myers Squibb Patient Assistance Foundation, Inc.	$811,433,684	✓
5	Johnson & Johnson Patient Assistance Foundation, Inc.	$711,632,110	✓
6	Merck Patient Assistance Program, Inc.	$686,800,564	✓
7	Genentech Access To Care Foundation	$680,278,040	✓
8	Pfizer Patient Assistance Foundation, Inc.	$668,050,404	✓
9	GlaxoSmithKline Patient Access Programs Foundation	$625,427,284	✓
10	The Atlantic Philanthropies	$521,711,000	
11	Ford Foundation	$518,380,000	
12	Lilly Cares Foundation, Inc.	$503,299,479	✓
13	Sanofi Foundation for North America	$485,359,572	✓
14	Novartis Patient Assistance Foundation, Inc.	$456,825,176	✓
15	The Susan Thompson Buffett Foundation	$416,440,853	

Largest US foundations.

PAPs accept tax-free donations of medicine and then give them away as free samples.

Example in trade press to illustrate the profits gained from a $10million contribution to a Patient Assistance Program

1	Charitable Contribution	$10,000,000
2	Charity Overhead	20%
3	Net Contribution	$8,000,000
4	Market Share	25%
5	Subsidized Patient Revenue	$2,000,000
6	Insurer Cost Share	88%
7	Revenue	$16,000,000
8	**Charitable Margin**	**60%**

Note the role of the contributor's market share (25%).
Then $2m in "patient" co-payment generates $16m in insurer payments.

The $16m in incremental revenue is greater than the $10m contribution. Moreover, the contribution is subsidized by the taxpayer, as it is tax deductible.

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Conclusion: need more competition enforcement in pharma

- Encourage biosimilar entry!
- Generic entry
  - Enforce against exclusionary tactics (pay for delay, samples, product hopping)
- PBMs
  - more study; attention to consolidation; understanding of contracting and how to promote competition and entry
- Patient kickbacks
  - Research on how they disable price competition and affect equilibrium prices