Barriers to Competition in the US pharmaceutical industry

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Background

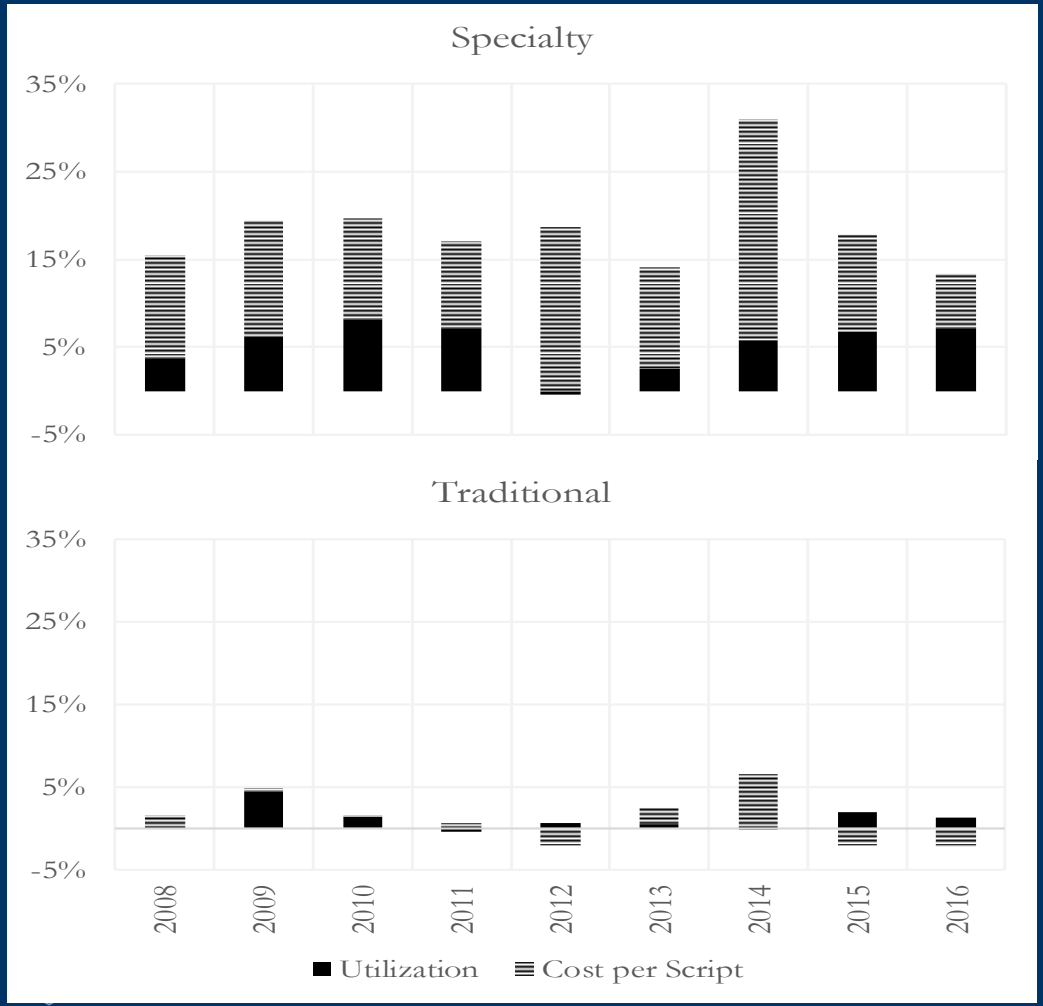
- Expenditures on pharmaceuticals are high and rising; there are too many examples of prices unrelated to value
- Regulation is really hard to get right when innovation is important, innovation costs are sunk, and marginal costs are low

$\Rightarrow$ 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

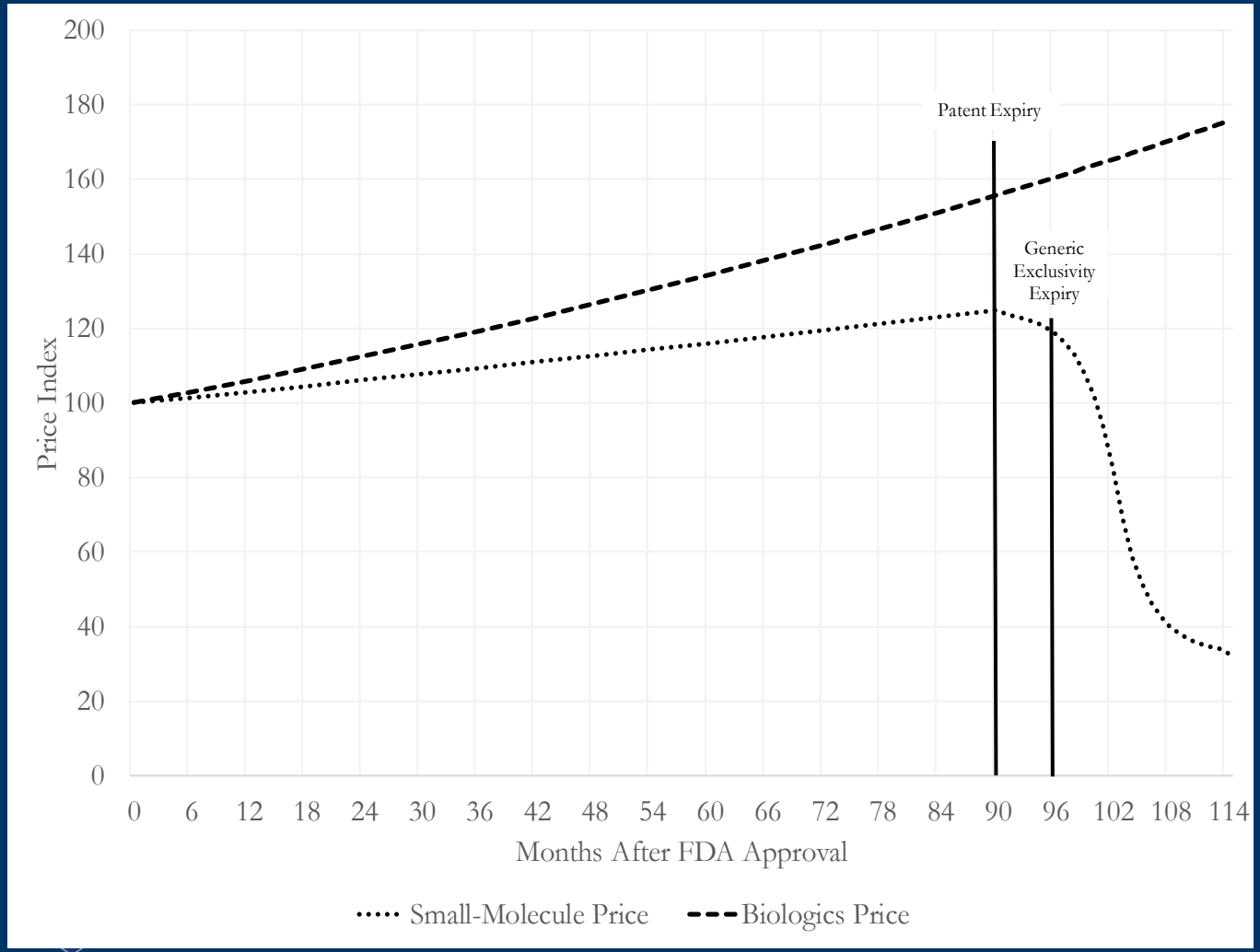
- This paper argues that enabling vigorous competition should be the first response to the problem of high pharma spending
- Remove barriers to competition
  - Some created by manufacturers
  - Some created by science
  - Some created by regulators
- If regulators pay attention to competition, enhance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



Price growth:
specialty / biologic

versus

small-molecule drugs



Stylized price paths:

biologics (top line)

v

small-molecule drugs with generic entry (bottom line)

Biologics

	policy	agency	action
1)	***Biosimilar entry needed***	FDA	quick entry and approve interchangeable biosimilars

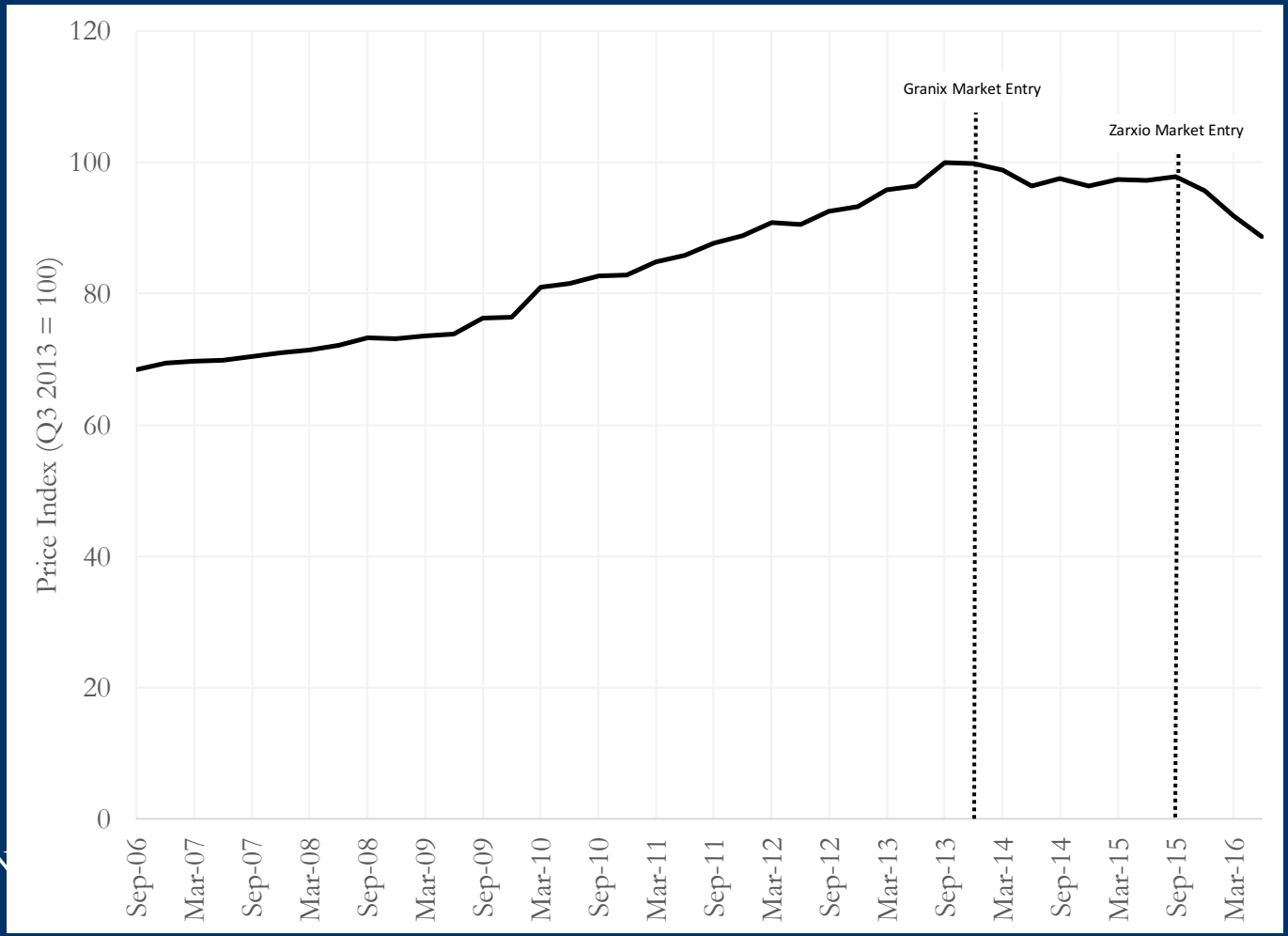
Europe has had biosimilars since 2006. More than 20 on the market today generating significantly lower prices.

The United States has 2 biosimilars for sale.

FDA has approved a grand total of 5 biosimilars to date (disputes over patents or regulatory procedure are blocking the sale of 3)

Impact of second filgrastim brand (granix)

Impact of first 6 months of generic entrant (zarxio)



Biologics

policy	agency	action
1) Biosimilar entry needed	FDA	quick entry and approve interchangeable biosimilars
2) Biosimilar naming	FDA	one scientific name
3) Procurement	CMS	redesign j codes
4) Orphan drugs	Leg	reform

Generics

• Pay for delay	FTC	antitrust enforcement
• REMS	FTC	antitrust enforcement
• Product hopping	FTC	antitrust enforcement
• Small market monopoly	Leg	importation
• Approval delays	FDA	quicker approvals
• Complex product	FDA	clearer guidelines
• Shortages	FDA	keep inspecting

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Demand side

- Ther subst Part D
- Ther subst Part B
- PBM competition
- PBM incentives

CMS

CMS/Leg

FTC

FTC/Leg

relax formularies

reference pricing

6(b) study

rebates flow directly

Confidential rebates promote price competition.

If 100% of rebates flow back to plan sponsor, can then negotiate PBM compensation from position of full information = > may intensify competition

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Demand side

• Ther subst Part D	CMS	relax formularies
• Ther subst Part B	CMS/Leg	reference pricing
• PBM competition	FTC	6(b) study
• PBM incentives	FTC/Leg	rebates flow directly
• Patient kickbacks		
– Coupons	OIG, States	ban
– PAPs	IRS, CMS	limit, make unprofitable
– Patient benefits	OIG, CMS	limit, ban

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.