Non-Tariff Barriers and Bargaining in Generic and Off-Patent Pharmaceuticals

Sharat Ganapati - Georgetown University
Rebecca McKibbin - University of Sydney

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Generic Pharmaceutical Markets

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- UK Price: Daraprim: $10 -1 Mfg

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  - Entry costs/trade barriers?
  - Differences in market size?

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Policy Question: Why are only some drugs so expensive in the USA?

- 2% of US GDP // 1% of UK GDP *(OECD 2017)*
- But low US prices for many popular generics/OTC medications

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- » Pharma: large issue in new trade agreements
- » Role of potential market size (Big vs small markets)

Q2. What is the role played by buyer/government bargaining?

- » What is the role of downstream monopsony?

Literature

- Health care competition & price dispersion: **Cooper et al. (2018)**, Craig et al. (2018), Ho and Lee (2017)
  - Pharma: Berndt et al., 2017; Gupta et al., 2018; Grabowski and Vernon, 1992, 1996; Bollyky and Kesselheim, 2017; **Reiffen and Ward, 2005**; Danzon and Chao, 2000; Danzon and Furukawa, 2003, 2011; Wagner and McCarthy, 2004
- Law of one price: Isard (1977), Goldberg et al. (1997), Burstein and Gopinath (2014), Goldberg and Verboven (2001), Goldberg and Hellerstein (2008)
  - Non-tariff barriers: Olarreaga et al. (2006); Egger et al. (2015), Arkolakis et al (2017)
  - In Pharma (parallel imports): Malueg and Schwartz, 1994; Ganslandt and Maskus, 2004; Grossman and Lai, 2008; **Dubois and Saethre, 2018**
- Market Entry: Melitz (2003); Mazzeo (2004); Ciliberto, Tamer (2009) Morales et al (2014)
- Modeling: **Horn and Wolinsky (1988)**, Chipty and Snyder (1999), Collard-Wexler et al. (2014)

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- Pharmaceuticals are nearly identical worldwide, but safety/language issues
  - Look only at rich English-speaking countries

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- Role of innovation?
  - Only look at off-patent drugs in shelf-stable pill/capsules
- Role of formulary design?
  - Limited with off-patent drugs
- But! Many prices:
  - Wholesale before lump-sum rebates (E.g. from IMS Health)
  - Buyer co-pays
  - Drug plan premiums

What is a price?

» **This paper**: Per-pill price, net of all rebates, discounts, and pharmacy dispensing fees, paid by end users **and** their government

- US Medicaid, UK NHS, AU PBS, NZ Pharmac, BC PharmaCare, ON Ontario Drug Benefit

What is a price?

- **This paper**: Per-pill price, net of all rebates, discounts, and pharmacy dispensing fees, paid by end users **and** their government
  - US Medicaid, UK NHS, AU PBS, NZ Pharmac, BC PharmaCare, ON Ontario Drug Benefit
- Robustness:
  - Medicare Part D (Not inclusive of two-part pricing/rebates/discounts)
  - NADAC Wholesale price (Not inclusive of two-part pricing/rebates/discounts)

Data

- Data is made comparable across all countries
- Unit of observation: Molecule - Dose - Form

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- Key innovation:
  - Actually use public data! (No expensive, non-transparent private data)
  - Link data on consumption, prices, and number of approved manufacturers
- Lots of data work (thank you RAs/co-authors!)

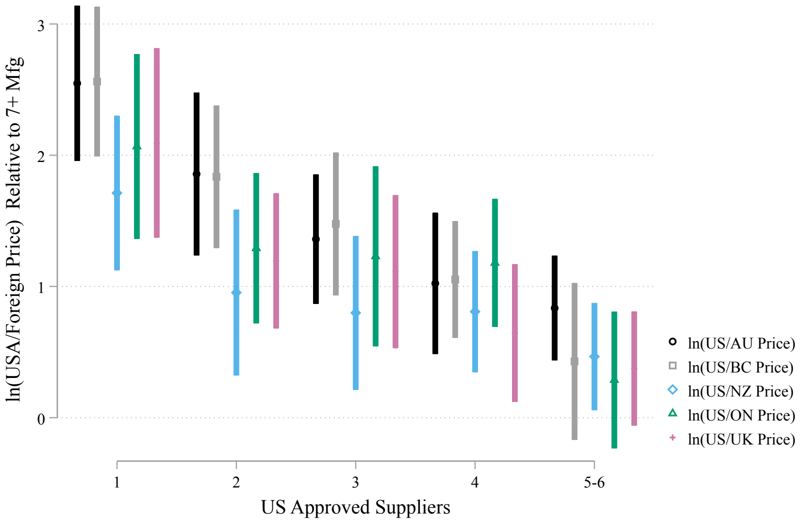
Example Data - British Columbia vs U.S. Medicaid - 2016

Molecule	Dose	Form	Approval y	US Mfg	Medicaid p	BC p
pyrimethamine	25	tablet	1953	1	605.51	1.43
mebendazole	100	tablet	1996	1	312.69	5.91
penicillamine	250	capsule	1970	1	224.24	3.89
penicillamine	250	tablet	1970	1	90.04	0.68
procarbazine	50	capsule	1985	1	57.06	0.44
morphine sulfate	200	capsule	1987	1	54.05	1.19
methoxsalen	10	capsule	1954	2	49.72	0.65
oxymetholone	50	tablet	1972	1	35.24	1.77
hydromorphone	32	tablet	1926	1	37.20	11.49
ethacrynic acid	25	tablet	1967	2	18.46	0.97

Summary: Medicaid Comparison

Comparison	Obs	Start Year	End Year	Raw $\log\left(P_{US}/P_{Dest}\right)$ Mean	Std. dev.	Mean First FDA Approval	Mean # US Mfgs
AU	1706	2008	2017	1.139	1.195	1980	4.25
BC	858	2015	2017	0.735	1.314	1983	4.30
NZ	1470	2009	2017	1.090	1.033	1982	4.23
ON	344	2017	2017	0.886	1.110	1984	4.88
UK	1625	2010	2017	0.899	1.321	1981	4.17

Key Fact: US prices are high in markets with low competition



Motivating Fact: Generic drug demand is inelastic

- Largely inelastic when prescribers and patients do not shoulder the full cost.
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» What about Medicaid, which has minimal cost sharing?

$$\Delta_y \ln Q_{dyUS} = \Delta_y \ln P_{dyUS} + \delta_y + \epsilon_{dyUS}$$

- Classic issue: prices are endogenous
- Very large price changes (>75% within 12 months) Details
  - Usually due to ownership changes (Motivated by pyrimethamine)
- Exchange rate shocks: Details
  - Most US generics are manufactured abroad
  - Assumption: Exchange rate shocks are purely supply side.

Pricing Model

- Key elements:
  - Role of supplier competition, downstream buyer, market size
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» Reality:

$$p = \mu_{pharmacy} \times \mu_{PBM} \times \mu_{wholesaler} \times \mu_{manufacturer} \times mc$$

  - Past literature: uses $p_{ex-manufacturer} = \mu_{manufacturer} \times mc$ without accounting for either ex-ante or ex-post lump-sum payments.

» Our starting point:

$$p = \mu_{value\ chain} \times mc$$

  - What matters for welfare - is final price, not some intermediate price.

Two-Period Game

1. Generic suppliers choose to enter the market. Pay fixed costs (includes regulatory costs, as well as bi-lateral payments to PBMs, pharmacies, doctors, and wholesalers)

$$\pi_{f,d}(s;S) \geq F_f.$$

   $\pi_{f,d}(s;S)$: profit of the marginal s^{th} supplier

   1.1 Assume entry costs independent between markets, with an unlimited number of potential (mostly Indian/Chinese) entrants
   ex: there are 62 Pyrimethamine suppliers on Alibaba/10 on Trade India

2. Suppliers (after all payments), negotiate final price with final buyer

$$\pi_{f,d}(s;S) = \mu_{f,d}(s;S) \times c_{f,d} \times q_{f,d}(s;S).$$

   2.1 Will be agnostic on the type of competition

3. Sales are made
   - Most public plans have inelastic demand - shown with exchange rate shocks

How prices are determined: Monopolist seller and monopolist buyer

» Nash surplus between seller s and buyer b

$$NS = (pq - cq)^{w_s} \left(\bar{p}_b q - pq\right)^{1-w_s},$$

- $\bar{p}_b$: Choke price
  - acquisition price if negotiations break down
  - includes political risk

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» First order conditions imply:

$$p_m = w_s \bar{p} + (1 - w_s)\, c. \tag{1}$$

» If $w_s = 0$, essentially perfect competition:

$$p_c = c \tag{2}$$

If $w_b = 0$, monopolist choke price:

$$p_m = \bar{p}_b \tag{3}$$

Generalization

» What if there is more than one upstream seller?
» How to account for upstream market power?
  - Competition function:

$$\theta\left(S\right) : \mathbb{I}^{+} \rightarrow \mathbb{R} \in [0, 1]$$

    - Maps the number of competitors between monopoly and perfect competition

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  - Weights between the Nash solution and perfect competition:
    $$p = \theta(S)\, p_m + (1 - \theta(S))\, c \tag{4}$$

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» Extensions to Bertrand, Discrete choice, Multiple buyers, Repeated game Details

» Intuition: Conditional on the number of entrants, pricing is fully determined.

» Assume that the choke price $\bar{p}$ is a multiplicative function of the marginal cost:

$$\bar{p} = \gamma_b c$$

» Parameterize competition:

$$\theta(S) = \exp(\alpha \log S)$$

» Define a buyer-specific leverage parameter κ_b:

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  - Under constant marginal costs, how much more operating profit is required to enter a particular country to cover fixed entry costs?

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  - Under constant marginal costs, how much more operating profit is required to enter a particular country to cover fixed entry costs?

- How much more does it cost to enter the US, than other markets?
  - Data for market size in US, UK, AU

Role of market size

- Recover fixed cost differences between two markets:

$$\Pi_{excess} = \Pi^{US}\left(S_{US}\right) - \Pi^{Foreign}\left(S_{Foreign}\right) \tag{5}$$

  - Only done for the marginal generic entrant (as opposed to an incumbent brand)

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- Only done for the marginal generic entrant (as opposed to an incumbent brand)

» Bound how many more entrants the US 'could' support:

$$\Pi_{excess}\left(S^{*}_{US}\right) \geq 0$$

» Intuition: Revealed preference + backward induction.

Estimates for α and κ

	Medicaid Molecule-Dose	Medicare(d) Molecule	NADAC Molecule
Competition α	-1.18	-1.43	-1.25
	(0.08)	(0.14)	(0.19)
Bargaining US	5.50	6.38	5.87
	(0.38)	(0.95)	(0.60)
Bargaining AU	1.00	1.02	1.00
	(0.00)	(0.06)	(0.00)
Bargaining BC	1.00	1.00	1.00
	(0.00)	(0.02)	(0.00)
Bargaining NZ	1.73	1.18	1.02
	(0.08)	(0.15)	(0.08)
Bargaining ON	1.09	1.00	1.11
	(0.19)	(0.09)	(0.24)
Bargaining UK	1.66	1.75	1.81
	(0.17)	(0.26)	(0.19)

Unbounded estimates: details

Excess Entry Cost Estimates

scenario/est ($M)	Medicaid Molecule-Dose	Medicare(d) Molecule	NADAC Molecule
AU	13.68 (0.42)	9.54 (1.20)	5.65 (1.26)
UK	7.94 (0.38)	8.00 (1.12)	7.11 (1.14)

Unbounded estimates: details

Counterfactuals

- Questions:
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  - What is the role of market barriers in price dispersion?
  - What is the role of downstream buyer leverage (combining market power and bargaining weights)?
- Four counterfactuals
  - Different permutations of policies.

Counterfactual 1: Single Market

- Lots of variation in number of sellers.
- Simple idea: if profitable in one, then allow entry in all markets.

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- Current FDA proposal.

Cost Saving(%)	Medicaid Molecule-Dose	Medicare(d) Molecule	NADAC/Medicaid Molecule
CF 1: Single Market	-7.8 (-0.7)	-2.9 (-0.4)	-3.8 (-0.8)

Counterfactual 2: Strong US Buyer Leverage (Bargaining)

- What if the USA bargaining was an average of the rest of the English speaking world?
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- Effectively a "take-it-or-leave-it" offer

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CF 1: Single Market	-7.8	-2.9	-3.8
	(-0.7)	(-0.4)	(-0.8)
CF 2: Bargaining	-18.3	-12.3	-20.8
	(-4.1)	(-3.5)	(-8.3)

Counterfactual 3: Both Single Market and US Buyer Leverage

- Do both?
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- Results similar to better buyer leverage

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CF 1: Single Market	-7.8 (-0.7)	-2.9 (-0.4)	-3.8 (-0.8)
CF 2: Bargaining	-18.3 (-4.1)	-12.3 (-3.5)	-20.8 (-8.3)
CF 3: Both	-18.6 (-4.1)	-12.4 (-3.5)	-21.0 (-8.3)

Counterfactual 4: Elimination of Excess Entry Costs

- CF 1: Didn't allow new market entry. If US fixed entry costs were in line with ROW, what would happen?
- Caveat: We don't have data on the entire world. Manufacturing fixed costs could now play a role.

Counterfactual 4: Elimination of Excess Entry Costs

» CF 1: Didn't allow new market entry. If US fixed entry costs were in line with ROW, what would happen?

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» View this as upper bound on market entry:

Cost Saving(%)	Medicaid Molecule-Dose	Medicare(d) Molecule	NADAC/Medicaid Molecule
CF 1: Single Market	-7.8 (-0.7)	-2.9 (-0.4)	-3.8 (-0.8)
CF 2: Bargaining	-18.3 (-4.1)	-12.3 (-3.5)	-20.8 (-8.3)
CF 3: Both	-18.6 (-4.1)	-12.4 (-3.5)	-21.0 (-8.3)
CF 4: Free Entry	-16.0 (-2.2)	-8.9 (-2.0)	-6.1 (-0.7)

What about the average drug?

- These results are heavily weighted by “blockbuster” drugs.
  - Generic Lipitor, Xanax, etc..

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  - Generic Lipitor, Xanax, etc..
- But what about the 'average' drug?

scenario/est (%)	Medicaid Molecule-Dose	Medicare(d) Molecule	NADAC/Medicaid Molecule
CF 1: Single Market	-10.6 (-0.3)	-5.0 (-0.4)	-6.1 (-0.4)
CF 2: Leverage	-33.3 (-3.4)	-29.2 (-4.0)	-39.1 (-7.5)
CF 3: Both	-33.8 (-3.4)	-29.4 (-4.0)	-39.4 (-7.5)
CF 4: Free Entry	-32.4 (-2.2)	-25.7 (-3.0)	-17.0 (-0.7)

Conclusion

- Use generics to isolate market away from the role of innovation
- Understand the effects of competition and buyer leverage
  - leverage = combination of downstream market power and bargaining
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  - What are these fixed costs? Pay to play? Locked distribution? Equivalence study cost?

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- Next steps:
  - Can we take this model and reintroduce the role of innovation for on-patent drugs?

Thank You!

•

Motivating Fact: Generic drug demand is inelastic (Price Jumps)

	(1) D.log(q)	(2) D2.log(q)	(3) D3.log(q)	(4) D4.log(q)
Log Price Change	-0.00398	-0.0371	-0.0246	-0.0189
	(0.00638)	(0.0271)	(0.0334)	(0.0369)
Observations	1081	1886	1430	1081
R^2	0.015	0.077	0.044	0.022
FE	year	year	year	year

» In counterfactuals - will fix drug demand exogenously. Return

Motivating Fact: Generic drug demand is inelastic (Exchange Rates)

	(1) Least Squares	(2) First Stage	(3) Instrumental Variables
D.ln(P)	-0.0308*		0.337
	(0.0134)		(0.182)
ln(Expected Price Change)		0.0515***	
		(0.00799)	
Observations	5556	5556	5556
FE	Year	Year	Year
F-stat	5.281	41.60	3.402

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Unbounded Estimates for α and κ

	Medicaid Molecule-Dose	Medicaid(d) Molecule	Medicare(d) Molecule	NADAC Molecule
Competition α	-1.12	-1.64	-1.41	-1.12
	(0.09)	(0.23)	(0.12)	(0.25)
Bargaining US	5.14	3.98	6.18	5.26
	(0.36)	(0.31)	(0.67)	(1.81)
Bargaining AU	0.85	0.77	1.01	0.75
	(0.04)	(0.06)	(0.12)	(0.09)
Bargaining BC	0.57	0.51	0.67	0.63
	(0.07)	(0.08)	(0.14)	(0.10)
Bargaining NZ	1.68	1.15	1.17	0.98
	(0.08)	(0.09)	(0.11)	(0.13)
Bargaining ON	1.04	0.74	0.94	1.05
	(0.22)	(0.16)	(0.28)	(0.25)
Bargaining UK	1.64	1.61	1.73	1.75
	(0.17)	(0.17)	(0.34)	(0.28)

Return to bounded estimates

Unbounded Excess Entry Cost Estimates

scenario/est ($M)	Medicaid Molecule-Dose	Medicaid(d) Molecule	Medicare(d) Molecule	NADAC Molecule
AU	15.47 (6.68)	10.04 (10.39)	11.00 (19.79)	7.76 (40.06)
UK	8.11 (4.59)	9.06 (9.04)	9.07 (13.81)	8.07 (33.68)

Return to bounded estimates

Aside: Bertrand

$$\theta\left(S\right)=\begin{cases}1 & S=1\\ 0 & S\geq 2.\end{cases}$$

Return to Return

Aside: Discrete Choice

$$\theta\left(S\right)=\frac{1}{\alpha\left(1-\frac{1}{S}\right)}\times\frac{1}{p_m-p_c}$$

Return to Return

Aside: Multiple Buyers

- » Rationalize this in a Nash-in-Nash setup
  - Simplification: if segmented markets, allow for variation in w_s

Return to Return

Estimation

GMM estimation for α, κ, c_r:

$$E\left(\log \frac{p_{b1}}{p_{b2}} - \log \hat{p}\left(\alpha, \kappa, c_r\right)\right) = 0$$

$$C = M\left(\alpha, \kappa, c_r\right) W M\left(\alpha, \kappa, c_r\right)'$$

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$$C = M\left(\alpha, \kappa, c_r\right) W M\left(\alpha, \kappa, c_r\right)'$$

Bound estimation for fixed entry costs:

$$\Pi_{excess}\left(S_{US}^{*}\right) > 0$$

Identification - Common Drugs

» Average cost difference between countries at perfect competition:

$$\frac{p_1}{p_2} \rightarrow_{S_{b1}, S_{b2} \rightarrow \infty} \frac{c_1}{c_2} = c_{1/2}$$

Identifies $c_{1/2}$

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$$\frac{p_1}{p_2} \rightarrow_{S_{b1}, S_{b2} \rightarrow \infty} \frac{c_1}{c_2} = c_{1/2}$$

Identifies $c_{1/2}$

» Real world identification:

- Extremely common heart and diabetes medication
- Dozens of entrants -> identifies levels of marginal cost differences

Return

Identification - Variation in Entrants

» Using variation in number of competitors between countries:

$$\frac{p_1}{p_2} \rightarrow_{S_1=1, S_2\rightarrow\infty} \frac{\kappa_1}{1} c_{1/2}$$

Identifies κ_1, κ_2

Identification - Variation in Entrants

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$$\frac{p_1}{p_2} \to_{S_1=1, S_2\to\infty} \frac{\kappa_1}{1} c_{1/2}$$

Identifies κ_1, κ_2

» Real world identification:

- Some drugs have more entrants in different countries
- Driven by unobservable difference in drug demand (i.e. Australia has relatively higher demand for anti-malaria medication than Canada)

Return

Identification - Intermediate Price Differences

» Price variation according to the number of competitors:

$$\frac{p_1}{p_2} = \exp\left(\alpha \log S_1\right) + 1.$$

Identifies α

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» Price variation according to the number of competitors:

$$\frac{p_1}{p_2} = \exp\left(\alpha \log S_1\right) + 1.$$

Identifies α

» Real world identification

- Suppose we net out the role of κ and α
- High relative US prices when there are few entrants
- Only identified when bargaining parameter significantly different from perfect competition

Return