Non-Tariff Barriers and Bargaining in Generic and Off-Patent Pharmaceutical Markets*

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Abstract

Pharmaceutical prices are widely dispersed across countries with comparable quality standards. We study two elements of this dispersion; non-tariff trade barriers and buyer bargaining power. Under monopoly, off-patent drug prices are 1.5-2 times higher in the United States. With more than 6 competitors, off-patent drug prices are similar or lower when compared to a set of benchmark countries. Motivated by this, we use a bargaining model to examine two policy solutions to reduce drug prices. First, we remove barriers to trade in the form of a reciprocal approval arrangement, which could increase the number of competitors through increased market entry. Second, we explore the US government's unexploited purchasing power to negotiate drug prices. Regarding Medicaid, the first measure can reduce total expenditures on off-patent drugs by 9% and the second by 20%. There are little additional savings from doing both procedures in tandem.

Keywords: Law of One Price, Competition, Bargaining, Pharmaceuticals, Non-Tariff Barriers, Healthcare Economics, International Trade

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1 Introduction

Would the US government benefit from bargaining over the prices of off-patent pharmaceuticals? The US relies largely on competitive forces to set the price of pharmaceuticals that are no longer protected from competition by patents (primarily, but not exclusively, generic drugs). It is assumed that once patents expire, generic versions of the drugs will enter and drive prices down to competitive levels. Recently, off-patent pharmaceutical prices have exhibited a series of extraordinary one-off price increases (GAO, 2016b). These broad-based and large price increases suggest that competition may not be a successful mechanism for achieving marginal cost pricing in all markets. In this paper, we first document that US generic and off-patent-drug's prices in markets with few competitors are higher than in comparable countries. We then study two mechanisms behind this price variation. First, the role of competition between pharmaceutical suppliers that face barriers to market entry. Second, the role of downstream buyer market power and leverage.

In the United States, generic drugs account for 90% of prescriptions and 23.2% of expenditures in the $324 billion prescription drug market (IQVIA, 2018). However, there is empirical evidence that off-patent drugs are not sold in perfectly competitive marketplaces at marginal cost. Since 2010, 20% of US generic or off-patent molecules have experienced a price increase of more than 100% (GAO, 2016b). For example, the price of pyrimethamine, an anti-parasitic developed in the 1950's, was infamously changed overnight from $13 to $750 per pill (Pollack, 2015). Although these drugs are no longer protected from competition by patents, many generic drug markets may not be large enough to attract the number of competitors needed to achieve marginal cost pricing (Berndt et al., 2017).[1] They may also be amenable to collusive behavior (Rowland, 2018).

Current policy is focused on encouraging more generic entry into the US market. For example, the Food & Drug Administration (FDA) 2019 Drug Competition Action Plan

[1] In the US, Berndt et al. (2017) and Dave et al. (2017) show that 50% of such markets are monopolies or duopolies.

proposes that the FDA work with its international counterparts to harmonize the generic approval process (Gottlieb, 2018). This would allow suppliers to gain approval to sell in multiple countries essentially using one application process, thereby effectively removing a non-tariff trade barrier — a restriction on international trade that is not a tariff. Such policies are also advocated by the European Union in preliminary negotiations for the Transatlantic Trade and Investment Partnership (TTIP), seeking the harmonization of procedures to "entail significant cost savings" (European Commission, 2014). While this is a sensible policy direction, the US is unique in that it effectively relies solely on competition to achieve low generic drug prices. In contrast, many countries with comparable safety standards use a combination of competition and government purchasing power to attain low generic drug prices. Hence, it makes sense to explore the effectiveness of both competition and bargaining based policies at reducing the prices of off-patent and generic drugs in these small markets.

Motivated by this observation, we compare final prices of pharmacy dispensed off-patent drugs across the US, Australia, Canada, New Zealand, and the United Kingdom.[2] We view this price as the welfare relevant price because it is the price paid by the consumer (either directly or indirectly though taxation). This comparison reveals that the final price of off-patent drugs in the US relative to each of these other countries declines as more suppliers enter the market.[3] When there is only one American supplier, the price is on average 1.5-2 times higher.[4] However, when there are more than 6 suppliers, retail prices are either similar or lower. We focus our analysis on prices paid by the US Medicaid program, however, results for Medicare Part D and private insurance are broadly similar. Our results suggest that while

[2]These five developed nations were chosen primarily because there are no significant language barriers. For Canada we focus on the two largest English speaking provinces: Ontario and British Columbia. For the United Kingdom, we focus solely on England.

[3]While the US has higher prices for drugs with limited competition, it often has the lowest prices for the most widely disseminated drugs. For example, Gabapentin was first marketed in 1993 for partial epileptic seizures and went generic in 2004. By 2016, this drug had over 20 FDA-approved suppliers, with over 4 billion doses prescribed through Medicaid and Medicare Part D. Medicaid and Medicare Part D pharmacy reimbursements averaged $0.17 and $0.18 per dose respectively. By comparison, the Australian government reimbursed the equivalent of $0.21 cents per dose.

[4]These results are based on generic and off-patent drugs sold in either tablet or capsule forms and consider per-dose prices, net of pharmacy dispensing fees.

competition is an effective mechanism for lowering prices in markets with many suppliers, which tend to be large markets with many patients, bargaining may be necessary in markets with few suppliers, which tend to be smaller markets.

We study the mechanism behind this price variation using a structural model with Nash bargaining and a market entry game. The generic and off-patent drug market is modeled as a set of bilateral transactions between many suppliers and a representative buyer. The buyer and sellers split the surplus of the transaction based on bargaining weights and upstream seller competition. This setup nests bilateral Nash bargaining within a model of oligopoly, with sellers (of both original branded and generic versions of drugs) paying a fixed cost to enter a market, in the spirit of Bresnahan and Reiss (1991). Multiple buyers are parsimoniously captured through reduced bargaining leverage, a sufficient statistic that combines both bargaining power and the buyer's outside option (such as other drugs within a therapeutic category). We focus on the buyer and consider the total cost paid, holding fixed the prescribing behavior of pharmacists and doctors. This model is identified using cross-country variation in prices, generic and off-patent drug suppliers, and market sizes.[5]

Estimation using public data shows that the US currently applies substantially weaker bargaining leverage than any of the comparison countries. Furthermore, it is more expensive to enter the US market than a comparable country such as Australia or the UK, with the implied entry cost being \$8.4-\$15.5 million higher per year. The estimated costs cover not only regulatory costs, but the implied costs of collusion and bi-lateral downstream payments (Loftus et al., 2016; Hancock and Lupkin, 2019). We conduct four counterfactuals as they appertain to Medicaid: a reciprocity policy where once a generic drug is approved in one country it is approved in all; the US government directly bargaining prices; both; and the harmonization of entry costs. A reciprocity policy would reduce total drug expenditures

[5]We use an Nash-in-oligopoly setup that allows us to jointly identify the outside option and the bargaining parameters separately from the market competition. This is adapted from the Nash-in-Nash games described in Horn and Wolinsky (1988). See Chipty and Snyder (1999) for an implementation in cable TV markets and Ho and Lee (2017) regarding hospital-insurance networks. Collard-Wexler et al. (2014) provide microfoundations for such bargaining solutions.

by 9%. If the US bargained to the same degree as any comparison country, prices would be reduced by 20%. Implementing both policies has virtually the same effect as just the bargaining policy. If entry costs were brought in alignment with Australia or the UK, prices would be reduced by 17.5%. These results indicate that that downstream buyer leverage and entry costs are equally important in explaining the price variation we observe.

This paper examines the relative roles of competition and bargaining in generic drug markets using a structural framework. Previous empirical literature has examined cross-country differences in pharmaceutical prices (Danzon and Furukawa, 2003, 2011; Kanavos et al., 2013; Wagner and McCarthy, 2004). Danzon and Chao (2000) show the existence of price dispersion across countries and consider the effects of regulation and competition.[6] Other prior research on generic drugs considered the effect of exogenous entry on prices (Reiffen and Ward, 2005; Berndt et al., 2017; Grabowski and Vernon, 1992), or how competition-based policies could increase competition and hence lower prices (Scott Morton, 1999; Berndt et al., 2017; Gupta et al., 2018; Bollyky and Kesselheim, 2017; Berndt et al., 2018). This latter literature has been reduced form and descriptive. Another reduced form literature studies the substitution patterns between generic entrants and the original branded drug under various types of price regulation (Kanavos et al. (2008); Puig-Junoy (2010); Kanavos et al. (2013)). Structural policy work has focused on studying the effect of parallel imports (goods that are imported by non-authorized resellers) of patented/protected pharmaceuticals (Malueg and Schwartz, 1994; Ganslandt and Maskus, 2004; Grossman and Lai, 2008; Dubois and Saethre, 2018). This literature focuses on price discrimination and cross-border effects.

This paper quantifies non-tariff trade barriers (in this case created by regulations that restrict entry in foreign markets) in pharmaceutical markets and structurally models the trade off between non-tariff barriers and competitive concerns with both a pricing and market entry margin. An extensive literature studies both deviations from the law of one price and

[6] Danzon and Chao (2000) compare average drug prices across countries and hence create a price index that takes into account the basket of drugs consumed in each country. With a different objective, we compare the price of the same drug across countries and then average this price difference across drugs that have the same number of suppliers.

non-tariff barriers. The lack of a single global price for goods is explained through many channels, such as incomplete exchange rate pass-through, local costs, pricing to market, market power, information frictions and sticky prices.[7] Within health care, Cooper et al. (2018) and Craig et al. (2018) show that monopoly power and bargaining have significant relationships with procedure and procurement prices, but do not model endogenous market entry.

2 Institutional Background

Competition in off-patent drug markets is shaped by the nature of manufacturing regulation, the insurance system, and pharmacy regulation. This section describes how these elements affect prices at each stage of the supply chain in each country as it applies to the drugs considered in this paper: patient-administered drugs purchased in pharmacies. The supply chains in all five countries include suppliers or importers obtaining approval from a regulatory body to market their products. Manufacturers sell to wholesalers, who sell to pharmacies who retail the products to consumers.

The retail price paid depends on the consumer's health insurance policy. In all five countries, the major insurers offer a set price schedule for generic drugs and pharmacies must take it or leave it. Reimbursements take two parts, the cost of the pharmaceutical and the dispensing fee. We focus on the cost of the pharmaceutical and net out the dispensing fee paid to the pharmacy. In the US, there are many insurers (or their subcontracted pharmacy benefit managers) arranging their own price agreements with pharmacies and suppliers. In Australia, the UK, and New Zealand, a single insurer — the government — uses its purchasing power to set pricing rules for drugs. Canada sits in the middle with a public-private system similar to the US, except that the government actively seeks to minimize drug prices for the public health plan. The covered generic formulary is rarely bargained over in

[7] See Isard (1977), Goldberg et al. (1997), and Burstein and Gopinath (2014) for early work and two literature reviews. Selected recent examples include Amiti et al. (2014); Auer and Schoenle (2016); Steinwender (2018).

any of the countries. Generic drugs are almost never excluded from public formularies for prescription coverage (unlike with on-patent drugs). Pharmacy regulation plays an important role in the competitiveness and size of the generic market in all five countries, and hence the number of suppliers, because it affects whether or not pharmacists can substitute branded drugs for generics.

2.1 Manufacturing and Entry Regulations

Before a drug can be sold to consumers, the supplier must apply for authorization from the local regulatory authority. These regulators monitor quality both in terms of the safety and efficacy of the drugs and in terms of manufacturing quality. The approval requirements depend on whether or not the drug is classified as an innovative drug or a generic. Innovative drugs require extensive (and costly) testing with clinical trials to demonstrate their safety and efficacy profile. Generic approval requires demonstration that the generic is bioequivalent to an innovative drug.[8] Bioequivalence typically requires a clinical trial that shows the generic delivers the same amount of active ingredients into a patient's bloodstream in the same amount of time as the original drug. The generic must also be identical in terms of dosage form, strength, route of administration, and intended use. All five countries follow the International Conference on Harmonization (ICH) Good Clinical Practice Guidelines in assessing bioequivalence.

In addition to demonstrating therapeutic equivalence, suppliers must also demonstrate compliance with production quality standards. All five countries have Good Manufacturing Practice (GMP) guidelines that comply with the ICH. These regulations ensure that products are properly produced, packaged, and safe (FDA, 2018). To ensure compliance, regulatory authorities conduct plant inspections. Such inspections are costly and complicated by the globalization of manufacturing. A large proportion of the US drug supply is manufactured overseas, with 40% of finished drugs and 80% of active ingredients produced abroad (GAO, 2016a).

[8] The innovative drug must already be approved in the applicable country.

2.2 Insurance & Pricing

The US has three major insurance regimes covering prescription drugs sold in pharmacies: private insurance, Medicare Part D, and Medicaid.[9] However, all three frequently outsource the management of their prescription drug plans to pharmacy benefit managers (PBMs). PBMs have substantial market power with three companies controlling 66% of the market (Sood et al., 2017). PBMs act as intermediaries in contracts between health plans, pharmacies, and suppliers, as well as set the formularies and network of covered pharmacies. For drugs with a single supplier, PBMs negotiate directly with suppliers for favorable placement on formularies (when there are drugs in the same therapeutic class that are close substitutes) in return for rebates, some or all of which they keep as profit. When there are multiple suppliers, PBMs provide a Maximum Allowable Cost (MAC) list to pharmacies, which states how much they will pay for the drugs. While MAC lists for private insurers and Part D are between the insurer and the PBM, Medicaid reimbursement rates are subject to statutory rules. These vary by state, but broadly, they compute potential prices using four different methods and set the reimbursement at the level of the lowest one.[10] In addition, a federally mandated manufacturer rebate is set by statute.[11]

Australia, the UK, and New Zealand have government-operated universal health insurance plans. Canada has a mixed public private system. Similar to the US, working age people have private insurance and each province has its own public drug plan, which cover disadvantaged segments of the population. We focus on the two largest English-speaking provinces: Ontario and British Columbia. Ontario covers the elderly, poor, and disabled,

[9] In 2016, private insurance accounted for 41% of retail prescription drug spending, while Medicare and Medicaid accounted for for 30% and 10%, respectively (the remainder is out of pocket payments (15%) and other US government insurance programs (4%))(CMS, 2018).

[10] The first is the acquisition cost plus a dispensing fee. States generally estimate the acquisition costs as either a discount on the average wholesale price (AWP) or a markup on the wholesale acquisition cost (WAC). Both the AWP and WAC are list prices and are not based on actual sales data. The second are usual and customary pharmacy charges to the public. Third is the federal upper limit (FUL), which is calculated by the CMS as 175% of the average manufacturer price (AMP). The AMP is based on data reported to the CMS quarterly for the purpose of computing rebates. Fourth is the State MAC price.

[11] During our study period this rebate was the greater of 15.1% of the AMP or the difference between the AMP and best price per unit for innovative drugs and 11% of AMP for generic drugs.

while British Columbia covers everyone but uses an income test to determine the subsidy rate of the beneficiary. Unlike the US, in all of these countries, the government uses its purchasing power to obtain lower drug prices. For on-patent drugs, governments directly bargaining with the supplier. In the case of generics, each country stipulates how it will pay for generics and the suppliers can take it or leave it.

The method used for setting generic drug prices differs across countries. Australia and the UK both use a reference price system, based on reported supplier prices. Suppliers report their sales prices and the health plan reimburses at the average. In Australia, prices are not revised upwards without approval, whereas in the UK, the price fluctuates with the market. Australia also has a mandatory price reduction of 16% when the first generic enters the market. New Zealand uses a competitive tendering system to obtain low generic drug prices. The supplier of the winning tender has their product exclusively eligible for reimbursement by the national health plan. All Canadian provinces except Quebec have agreed to set the price of generics entering the market from 2014 onwards using a tiered pricing system.[12].

2.3 Pharmacies & Wholesalers

Pharmacies and wholesalers are not explicitly included in our model. However, these players affect the final price of drugs as they form part of the supply chain and receive a mark-up over the manufacturing price. Although the the wholesale market is very concentrated in all five countries — Australia, the US, the UK (Europe), and Canada have three dominant wholesalers, while NZ has just two wholesalers — wholesaler ability to increase prices is likely restricted by the market power of the insurers, particularly in countries with national health insurance plans, and do not appear to vary across drugs. A similar concern affects pharmacies.[13]

[12]The reimbursement rate is set at 85% of the price of branded drug when there is one generic, 50% with two generics and 25% when there are three or more. For generics introduced before 2014 the provincial reimbursement rates are used. Ontario sets the reimbursement rate at 25% while British Columbia sets it at 20%.

[13]After directly accounting for pharmacy costs, we take these setups as given in estimation and do not change their structure in computing counterfactuals.

3 Conceptual Framework

In this section we present a framework that links the institutional environment with key elements of the structural model as well as the empirical analysis and the available data. Our measure of welfare in this paper is changes in the price of off-patent drugs. Off-patent drugs are molecules that are no longer protected by patents. These drugs/molecules can be the original brand name or a generic copy. The welfare implications of price changes to off-patent drugs are primarily distributional. We consider this market to have a surplus that can be captured by the different actors in the market: consumers, insurers and their agents, governments, pharmacies, wholesalers and manufacturers. Our objective is to determine how consumers can capture a greater share of the surplus from suppliers and other upstream players. We view this as a policy relevant objective because in this market the government is ultimately the largest payer and its objective should be to minimize its expenditure.

Markets are defined in the analysis in terms of a unique molecule-doses-form. This definition is chosen because it aligns with the regulatory definition of a substitute and provides a grouping that allows for direct comparison across countries.[14] Suppliers choose whether or not to produce a version of each of the molecules, which we refer to as products. Since the market is at the molecule level, all products are identical, with the exception that we distinguish between the original branded product and a set of homogenous generic products. Given that the generic product is homogenous in the market we assume that firms take prices as given when making the choice of whether or not to enter the market. We utilize a static entry model in the spirit of Bresnahan and Reiss (1991) and Scott Morton (1999). This model is chosen because we consider a stable market for molecules that are long off patent. Thus a static model represents the relationships in the data well.

[14] An alternative market definition is therapeutic substitutes. Therapeutic substitutes are molecules that are used to treat the same disease but are not necessarily the same molecule. This definition is complicated in a cross-country comparison because it requires information how drugs are used in each country, which is not available in our dataset. We conduct several robustness exercises that suggest that the results are not explained by the choice of market definition

In this framework, generic suppliers of molecules make a decision to enter the market in each destination f and provide a product d if the profit of doing so ($\pi_{f,d}$) is greater than the fixed cost of entry F_f. We assume that there is a fixed cost of entry into each destination (F_f) that is (a) destination specific and (b) independent across destinations.[15] Hence the a supplier s enters a destination d if and only if:

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

Where $\pi_{f,d}(s;S)$ is the profit of the marginal s^{th} supplier over the set of S suppliers.

The profitability ($\pi_{f,d}$) of entering each market is the net present value of revenue less variable costs. This is the product of the price the supplier receives, which is a destination specific mark-up $\mu_{f,d}$ over marginal cost $c_{f,d}$, multiplied by the quantity sold $q_{f,d}$. Both the size of the generic mark-up and the quantity sold are a function of the number and identity of competitors in the market:

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

We assume that the marginal cost within a market in a destination is constant across generic suppliers ($c_{f,d,s} = c_{f,d}$). This means that the marginal cost of producing a product is the same across products in a market.[16]

Next we consider the welfare relevant price. As described in Section 2, there are many actors that are involved in setting the price of a product along the supply chain. These actors include but not limited to wholesalers, benefit managers, pharmacies, consumers, insurers and governments. Given our welfare objective, the most appropriate choice of outcome price

[15]The second part of this assumption is less restrictive than it initially seems. First, we consider marginal generic entrants - as opposed to the original innovator. Second, many of the implied fixed costs are country-specific, such as the regulations, lobbying, bilateral payments, and/or campaign contributions. Third, physical manufacturers are often "contract" manufacturers, which are separate from the official government-approved supplier. These contract manufacturers receive a specification and produce final packaged products for the government-approved supplier. These myriad contract manufacturers simply have to pass safety related inspection measures and are not responsible for the vast majority of entry costs, which are borne by the government approved supplier (Miller, 2017). Lastly, a survey of foreign factories for a sample of drugs shows that there are a large mass of potential suppliers that do not appear in our sample. For example there are only 10 FDA approved US suppliers for acyclovir, but at least 148 brands approved for sale somewhere(MedIndia, 2019).

[16]We flexible allow for differences in the identity of the competitor s, thus branded suppliers and generic suppliers may have differences in both market shares and markups.

is the retail price of each market (molecule-dose-route) in each destination averaged across products $p_{f,d}$. The retail price p of a product comprises an amount paid by consumers (a copay δ_{copay}) and the amount the government contributes (δ_{gov}) : $p = \delta_{gov} + \delta_{copay}$. The retail price $p_{s,f,d}$ of a product d in destination f can be represented as as as a series of mark-ups ($\mu_{s,f,d}$) over the common marginal cost of producing the product:

$$p_{s,f,d} = \mu_{s,f,d}^{pharmacy} \times \mu_{s,f,d}^{PBM} \times \mu_{s,f,d}^{wholesaler} \times \mu_{s,f,d}^{factory} \times c_{f,d}.$$

We choose to use the entire retail price rather than just the government contribution as the government may subsidize markets for redistribution purposes. We take the average of the retail price across products because we view changes in the average price as best capturing what the government ultimately pays. Retail prices differ across pharmacies as individual consumers select the pharmacy to fill their prescription. There is generally no restriction on pharmacy choice in the non-US countries. In the US there is the possibility to exclude a pharmacy from a health plan. We take the view that no individual product would be large enough to affect an insurance plan's decision to include a pharmacy in its network.[17]

The price we measure is therefore:

$$p_{f,d} = \sum_{s \in S} share\,(s) \times p_{s,f,d}.$$

This market weighted average share allows for differential pricing (and markup) between different suppliers. In some markets, there is substantially different pricing and market shares between the original branded entrant and other generic entrants (Kanavos et al., 2008). In our structural model, we directly model this behavior, recovering a welfare-relevant set of sufficient statistics, without directly modeling how market shares are determined.

In our framework the final buyer does not care about the exact division of surplus amongst firms along the supply chain, they simply care about the sales-weighted average markup μ:

$$p_{f,d} = \mu_{f,d}\,(S) \times c_{f,d}. \tag{1}$$

This mark-up is a function of the number of suppliers of the product in the market. In our

[17]Moreover, most generic drugs are sold by the big four retail chain pharmacies.

structural model, we collapse the market into a problem between two agents: a buyer and a seller. The seller represents both the suppliers and all intermediaries in the supply chain. In our preliminary empirical analysis we estimate variants of Equation 1.

4 Data

The empirical analysis compares prices, competition structure, and market size across countries for off-patent patient administered drugs.[18] This requires data on the prices, quantities of prescriptions, and the number of suppliers of each drug for all five countries. We define a drug market as all products with the same molecule-dose-route.[19] This follows the definition used by the US Food and Drug Administration (FDA) in determining generic entry eligibility. We allow for imperfect substitutability between branded and unbranded generics, which has been shown in the literature to be an important distinction (for a summary see Kanavos et al., 2008).

Data on molecule-dose-routes in the US are obtained from the drugs@FDA database. We include molecules administered as "capsule" or "tablet". We only include markets where the original product is off-patent and hence generics can enter (regardless of whether they have). A molecule-dose-route is classified as off-patent if an Abbreviated New Drug Application (ANDA) has been approved or if there are no patents or exclusivities listed in the FDA orange book. We compute similar statistics at the molecule level. As it takes time for the first generic to be reviewed, and the first approved generic receives 180 days of exclusivity against additional generic entry, we exclude markets with the first FDA approval within 20 years.[20] The number of suppliers supplying each included US market reflects the number

[18] We mix the usage of the term generic and off-patent, even though not all off-patent drugs are the generic copy.

[19] For robustness, we also conduct the analysis with markets defined at the molecule level. We also examine the potential role of therapeutic substitutes as defined by the Anatomical Therapeutic Chemical (ATC) Classification level five codes. The ATC system classifies drugs according to the organ or system on which the drug acts as well as their therapeutic, pharmacological and chemical properties.

[20] This is similar, but not identical to patent protection, a period that typically starts at discovery, but before clinical trials and FDA approval, a process that can take upwards of 10 years. The US Hatch-Waxman Act effectively allows for five years of exclusivity after the patent expiry, allowing for 25 total years of near exclusivity. Our window effectively omits drugs in this period.

of approved ANDAs. Data on drugs for corresponding foreign markets are obtained from the relevant regulatory authorities. We merge each of these data sets together and keep the subset of drugs that are available in both the US and the other country. Further details are provided in Appendix A.

The retail price and quantity prescribed in each off-patent market in the US is obtained from the Medicaid State Utilization data.[21] This data contains the retail price paid for drugs covered through Medicaid, which we average across states. We compute per-unit prices net of dispensing fees and manufacturer rebates. We focus the analysis on Medicaid because it is the only publicly available source of prices that can be adjusted for manufacturer and pharmacy dispensing fees, which is needed in order to make the US data directly comparable with international data. As Medicaid only accounts for 10% of US prescription drug spending, we include data from Medicare Part D and private insurance (through National Average Drug Acquisition Cost dataset), as a robustness check. These datasets and the analysis are described in the Appendix.

Data on retail drug prices and ex-manufacturer prices in Australia, Ontario, British Columbia, the UK, and NZ are obtained from the national health plan administrative statistics. We convert all prices into US dollars using the average annual exchange rate for each calendar year. We recover the per-unit price of a drug, net of a fixed per-prescription pharmacy dispensing charge. For Australia, we use the price paid by Pharmaceutical Benefits Scheme (PBS) to the pharmacy, available from Pharmaceutical Benefits Scheme Schedule of Benefits for 2009-2017. This price excludes the dispensing fee and the allowed pharmacy mark-up.[22] For Ontario, we use the Ministry of Health and Long-Term Care's drug benefit

[21] Drug prices in the US are difficult to measure. There are many different types of drug prices available, many of which are not true prices but rather list prices. We choose to use the retail price in this paper because this is the only observable price available in the US. It is also a price that is policy relevant, as it is the final price paid by Medicaid. We also obtain data on ex-manufacturer prices, which is the price received by the supplier. Wholesale prices are not available.

[22] Patient copays in Australia are variable and are capped at $AU30.70-$AU38.80 during this period. Generic drugs often have patient copays below the cap, as maximum co-pays are capped at the combined cost of the pharmaceutical, dispensing, and preparation fees. Reported prices are inclusive of this variable patient copay.

prices (DBP) 2017. This price omits the fixed dispensing fee and variable patient copayment, which can only offset the dispensing fee. Data on British Columbia from British Columbia PharmaCare for 2014-2017. We use the maximum allowable price, the maximum amount the drug benefit will reimburse, net of dispensing fees.[23] Any difference between the retail price and this price is paid by the patient. For New Zealand, we obtain data on retail prices from PHARMAC. This price excludes the patient copay, a flat rate of $NZ5, and fees paid to the pharmacist for dispensing. To be consistent, we add the copay to the reported price. Prices for the UK are obtained from the NHS England Drug Tariff.[24] These prices are the amount of the NHS subsidy. It does not include patient out of pocket costs or professional fees paid to pharmacists for dispensing the products.

Table 1 shows the number of observations for each country and the years included in the analysis. Prices for all non-US markets are net of fixed per-prescription pharmacy dispensing fees. The key variable of interest is the relative price of each drug in the US compared with the same drug in each of the other countries. The mean and variance of the US price ratio, with respect to each base country are shown in the fifth and sixth columns of Table 1. On average, prices are extremely similar, with US prices only slightly higher than foreign prices. We present both adjusted and unadjusted prices. Adjusted prices subtract out the average pharmacy dispensing fee as well as the statutory manufacturer rebate of 13% for non-innovator drugs.

Table 2 highlights the variation in suppliers in the United States (for 2017 Medicaid data) for our sample. While drugs with just one supplier account for 1% of doses, they make up 10% of off-patent Medicaid spending. Drugs with five or less suppliers account 25% of doses, but for 50% of total spending. While the majority of doses sold are in competitive markets, likely priced near marginal cost, many drugs have a limited number of suppliers.

[23] Which are currently capped at $C10.

[24] We focus only on England and leave Northern Ireland, Wales, and Scotland for further analysis.

Table 1: Summary Statistics

Comparison	Obs	Start Year	End Year	$\log(P_{US}/P_{Dest})$ Adjusted Mean	$\log(P_{US}/P_{Dest})$ Adjusted Std. dev.	$\log(P_{US}/P_{Dest})$ Unadjusted Mean	$\log(P_{US}/P_{Dest})$ Unadjusted Std. dev.	Mean First FDA Approval	Mean # US Sellers
AU	1582	2009	2017	0.542	1.706	1.158	1.211	1980	4.31
BC	858	2015	2017	0.282	1.783	0.735	1.314	1983	4.3
NZ	1470	2009	2017	0.332	1.571	1.090	1.033	1982	4.23
ON	344	2017	2017	0.346	1.578	0.886	1.110	1984	4.88
UK	1625	2010	2017	0.221	1.839	0.899	1.321	1981	4.17

Notes: Based on authors' calculations of public expenditure, price, and seller data. Raw prices for Medicaid refers to prices before accounting for rebates. Adjusted prices reflect rebates and accounting for dispensing fees. See text for further details.

Table 2: Medicaid Off-Patent Supplier Data - 2017

Suppliers	**Doses Sold**	**Prescriptions**	**Value ($)**
1 Supplier	257,998,493	7,114,496	919,318,884
2 Suppliers	306,887,650	7,715,258	331,637,050
3 Suppliers	579,407,652	12,895,900	1,052,758,754
4 Suppliers	1,313,802,332	30,574,310	1,120,181,810
5 Suppliers	2,011,558,200	46,263,697	976,936,333
6-10 Suppliers	8,960,672,054	216,520,993	2,749,776,720
11+ Suppliers	4,064,083,412	81,402,692	1,529,467,082
Total	17,494,409,794	402,487,346	8,680,076,633

Notes: Based on authors' calculations. See text for further details.

5 Empirical Evidence

In this section, we present a key fact to motivate the entire analysis: *in markets with few domestic suppliers, Americans pay substantially higher prices than in foreign markets*. We then show two robustness results. Firstly, that this finding is not purely a result of the inclusion of branded generic drugs, which a large literature has shown are not considered by consumers as perfect substitutes even though they are chemically identical (for a summary see Kanavos et al., 2008). Second, that this finding is unlikely to be due to the definition of the market. In Appendix C, we present additional empirical facts that motivate our model and counterfactual analysis. We additionally highlight that there is significant variation in the number of pharmaceutical providers and that US generic pharmaceutical demand is highly inelastic.

5.1 US prices are only higher in markets with low competition

We compare the price differential between the US and foreign market by number of approved US suppliers. Prices are computed as the weighted average of off-patent branded and generic versions of the drug. We compute the relative price differential between the US price and a foreign price as:

$$\text{premium}_{fdy} = \frac{\text{price}_{USdy}}{\text{price}_{fdy}}. \tag{2}$$

Subscript d references a molecule-dose-route combination. Subscript y refers to the year of the observation and f refers to the country of the observation. The price ratio allow for the differencing out of multiplicative market-level fixed effects between country pairs. We non-parametrically recover the relationship between the premium and the number of suppliers participating in the US marketplace with US FDA regulatory approvals to distribute drugs:

$$\ln\left(\text{premium}_{fdy}\right) = \sum \beta_s \mathbb{I}_S\left(S_{USdy}\right) + \delta_{fy} + \epsilon_{fdy}. \tag{3}$$

We use $\mathbb{I}_S$ as an indicator function for the number of US approved suppliers: S_{dyUS}. β_s are a vector of relative prices differences, δ_{fy} are year-comparison market fixed effects, and

ϵ_{fdy} represent measurement error. This is a version of Equation 1, using the foreign price to directly control of marginal costs.

Figure 1 shows the coefficients β_s from Equation 3 of the premium paid by Medicaid relative to each foreign country on the number of suppliers in the US market (standard errors are robustly clustered at the molecule-level). These results are generated using separated regressions for each comparison for the year 2017.[25]

As the number of suppliers increases, the premium declines towards zero. When there is a single supplier to the US, the price is on average 150%-220% higher than in the comparison destinations. The price premium declines as there are more suppliers in the US market. There is is only a small difference (or cheaper US drugs) in the price premium once the US has more than 6 suppliers. This pattern holds across all 5 comparison destinations and for all various types of US insurance (see Appendix E for analysis using other insurance types, including private data and Medicare). However, the rate of decline differs (for example, the relative price is not statistically significant between the US and Australia when there are more than two US suppliers). This suggests that competition is effective in larger markets with more suppliers, but strong buyer bargaining achieves lower prices in smaller markets with fewer entrants.

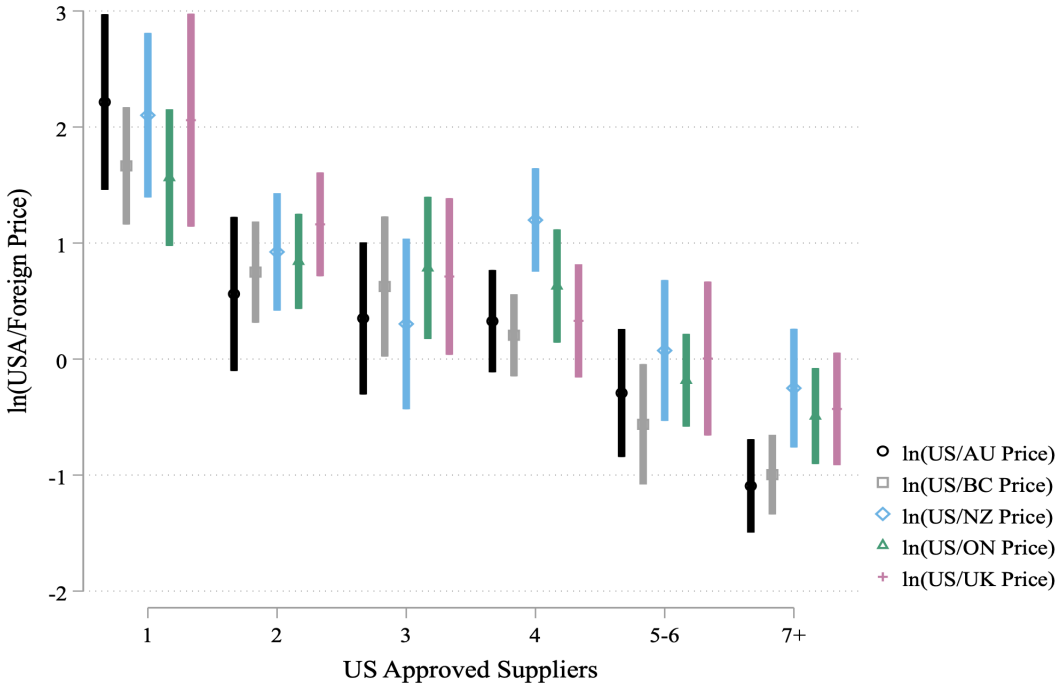
These results are formalized by estimating regressions of the price differential between US Medicaid and another country $\left(\ln(\text{premium}_{fdy})\right)$ on the log of the number of US suppliers $(\ln(S_{USdy}))$. Fixed effects for the year are included to capture time trends.

$$\ln\left(\text{premium}_{fdy}\right) = \beta \ln\left(S_{USdy}\right) + \delta_{fy} + \epsilon_{fdy}. \tag{4}$$

The coefficient of interest, the elasticity of the price premium to the number of suppliers in the US (β), is identified by variation in the number of suppliers across drug markets. As is standard in demand estimation, we assume prices are more flexible than market entry and have no dynamic effects. Under these assumptions, and if ϵ represents a mean zero

[25] 2017 is the only year for which we have data for all five comparison groups. Pooling the data across years, with year fixed effects, and estimating the coefficients relative to the 7+ category yields a similar pattern but has less clear interpretation because the estimates are relative to the base categories. These results are show in Figure 6 in the Appendix.

Figure 1: Role of Competition - Price Difference and Competition



Notes: Average price difference between the two countries taken across drugs (molecule-dose-route) compared with the number of FDA approved competitors of the US. Regression specification from Equation 3 with standard errors clustered at the molecule level. Each comparison is estimated separately with y=2017. 95% confidence intervals displayed. See text for data sources and details. Results generated by pooling all years and including year fixed effects with the 7+ supplier category omitted produce similar results.

Table 3: Relationship between Price Premiums and Number of US Suppliers

	(1) $ln(p_{US}/p_{AU})$	(2) $ln(p_{US}/p_{BC})$	(3) $ln(p_{US}/p_{NZ})$	(4) $ln(p_{US}/p_{ON})$	(5) $ln(p_{US}/p_{UK})$
ln(US Suppliers)	-1.140***	-1.140***	-0.734***	-0.871***	-0.904***
	(0.113)	(0.0902)	(0.102)	(0.108)	(0.127)
Adj. R-Square	0.290	0.257	0.134	0.160	0.127
Observations	1582	858	1479	344	1625
Fixed Effects	Year	Year	Year	Year	Year

Notes: * p<.05, ** p<.01, *** p<.001. Average price difference between the two countries taken across drugs (molecule-dose-route). Regression specification from Equation 4 with standard errors clustered at the molecule level. See text for data sources and details.

Table 4: Relationship between Price Differentials and Suppliers

	(1) $ln(p_{US}/p_{AU})$	(2) $ln(p_{US}/p_{BC})$	(3) $ln(p_{US}/p_{NZ})$	(4) $ln(p_{US}/p_{ON})$	(5) $ln(p_{US}/p_{UK})$
ln(US Suppliers)	-0.979***	-1.019***	-0.761***	-0.830***	-0.976***
	(0.131)	(0.111)	(0.119)	(0.125)	(0.176)
ln(Foreign Suppliers)	-0.292**	-0.239*	0.0919	-0.0826	-0.0540
	(0.101)	(0.0953)	(0.113)	(0.109)	(0.172)
Adj. R-Square	0.304	0.274	0.127	0.166	0.137
Observations	1582	756	1417	335	273
Fixed Effects	Year	Year	Year	Year	Year

Notes: * p<.05, ** p<.01, *** p<.001. Average price difference between the two countries taken across drugs (molecule-dose-route). Regression specification from Equation 5 with standard errors clustered at the molecule level. See text for data sources and details.

shock after supplier entry, we can interpret β as a causal relationship between the number of suppliers and the pricing differences (but not absolute price levels).

Table 3 shows the results. The interpretation of the coefficients is as follows. A one percent increase in the number of suppliers in the US reduces the price differential between US Medicaid and Australia by 1.1% (British Columbia 1.1%; NZ 0.73%; Ontario 0.87%, UK 0.90%). Similar results hold for the NADAC data and for Medicare Part D (see Appendix E).

There are a few clear threats to identification, from both the supply side and the demand side. On the supply side, ϵ may allow for differences in marginal cost between markets. Marginal costs may be systematically related to the number of suppliers. However, we

directly control for the marginal cost of production by considering the relative prices between two nations and absorb differences in distribution costs and exchange rate using the country-year fixed effect δ_{fy}.

On the demand side, there may be differences in substitutability between markets. For example, there may be many cardiovascular over-the-counter alternatives, but very few such anti-epileptic alternatives. However, our relative price differences are robust, controlling for the age of a drug, the number of similar drugs (with country-pair fixed effects on Anatomical Therapeutic Chemical (ATC) code-year combinations), the number of other available dosage forms (controlling for molecule data), and using the lagged number of suppliers to control for sticky prices.[26] Additionally, these relationships have been stable since 2010, with limited observable changes in the relationship between suppliers and price premiums.[27] Having controlled for the US supplier side, we now take a look at competition in foreign markets.

It is possible that the price differential can be explained by differences in the market size across destinations, due to differences in preferences for new versus generic drugs or differences in the prevalence of diseases. We examine this issue by estimating Equation 1, across two markets. Taking the logarithm of the price ratio, and assuming marginal cost are the same across countries, gives Equation 5:

$$\ln\left(\text{premium}_{fdy}\right) = \beta_{US}\ln\left(S_{fdy}\right) + \beta_{F}\ln\left(S_{fdy}\right) + \delta_{fy} + \epsilon_{fdy}. \tag{5}$$

If the price premium can be explained by the foreign markets having more suppliers than the same US market, controlling for the foreign supplies should explain the price premium. If not, this suggests that bargaining plays a role in the price differential. Table 4 shows the results for the regression with both the number of US and comparison country suppliers. The foreign suppliers are insignificant for three comparisons (Ontario, New Zealand, and

[26] See the Appendix B.2 for robustness checks. An ideal instrument for for S would be some sort of a shock that allows for an additional entrant. Controlling for ATC codes (by year) should absorb country differences in preferences in pharmaceutical demand. We find that this has no statistical effect on the relationship of relative prices to the number of suppliers. Finally if we assume that demand is exogenous, we can use the number of doses sold as an instrument for the number of suppliers. Results are largely unchanged.

[27] There are level changes, which can often be accounted for by large shifts in exchange rates. Australia and Canada are natural resource-driven economies and have volatile currencies. The United Kingdom initiated proceedings in 2016 to disengage from the global economy, which further influenced exchange rates.

the United Kingdom). These results imply that a change in the number of competitors in a foreign market are not correlated with either higher or lower prices (relative to the US). One possible reason is that buyers in foreign countries set strict price controls. These price controls limit producer surplus, irrespective of the number of sellers present. The coefficients are negative for Australia and British Columbia, however, they have little impact on the estimated impact of the US suppliers on the price premium. We will directly model this difference in outcomes between the US and foreign markets in our structural model.

5.2 Higher branded prices do not explain the price premium

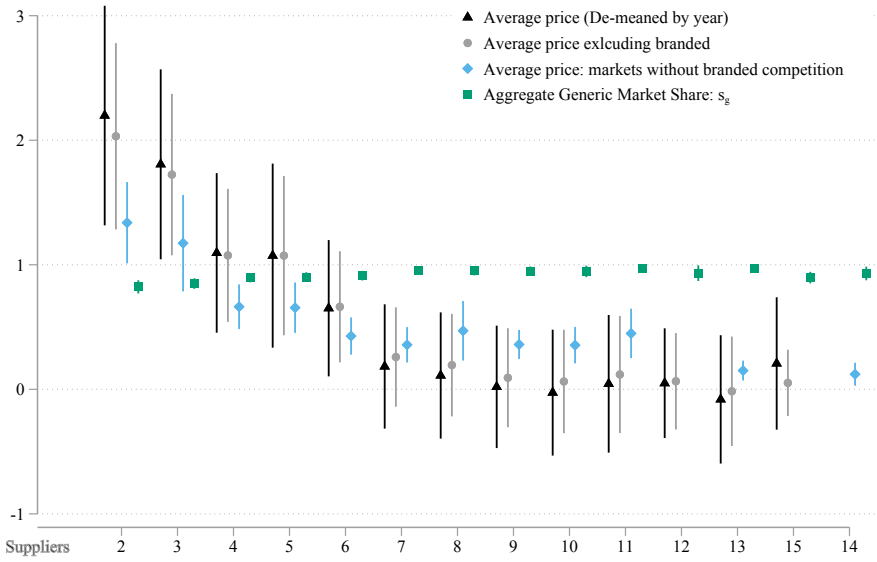
A large literature finds that branded molecules command a higher price than chemically identical generic competitors, as consumers do not consider generics as perfect substitutes (for a summary see Kanavos et al., 2008). Our first empirical result averages the price of all molecules in the market regardless of brand status. These results may be driven by cross-country differences in the premium and market share for the branded version of the molecule. If this mechanically generates our results, the branded molecules in the US will have higher premiums and or market shares than in the other destinations. We directly disentangle the effects of branded molecules from the US data.[28] By removing branded molecules from the US data, we consider two scenarios. Either there is no brand effect in the other destination markets or there is a branding effect, driving up the prices in the other markets relative to the US and working in the opposite direction to our finding.

We examine the effect of branding on the results in two ways. First, we show that the influence of branded drugs on the calculated US price is small. Second, we limit the sample to markets without an original branded entrant.

While branded entrants have a significant role with just one manufacturer, their influence on markets with multiple suppliers diminishes rapidly. The triangles in Figure 2 depict the average per-dose US price (with yearly fixed effects removed) from in the main results. The circles show this same price computed without including the original branded molecules.

[28] Our data does not allow us to remove the effect of branded molecules in the other destinations.

Figure 2: Branded vs Generic Prices using US Medicaid



Notes: The x-axis depicts the number of suppliers in markets with both branded and generic competitors. The triangle, circle and diamond are in $USD, demeaned with yearly fixed effects. The squares are interpreted as a proportion, the share of units sold that are sourced from generic suppliers. Robust standard errors with 95% CI.

The branded drugs do command a premium, but play a small role in the average price. This is due in part to the small market share of branded drugs. In markets with fewer suppliers, branded drugs have a larger market share, however, even in markets with only two suppliers branded drugs account for less than 20% of the market (the average aggregate generic market share is depicted using squares in Figure 2).

In the second exercise, we limit the analysis to markets where there the original branded drug is no longer in the market. Just under half of the US markets in our sample (48%) have no original branded product. Appendix Figure 7 shows these results are broadly similar.[29]

5.3 The price premium is not a result of the market definition

The price premium could be an artifact of the narrow definition of the market. There could, for example, be differences across countries in the number and or price of patent protected therapeutic substitutes. Alternatively, the number of alternative generic therapeutic substi-

[29] Of particular interest is the comparison with New Zealand. Since New Zealand uses a competitive tender process to select which supplier will be covered by the national health plan we would not expect there to be a brand premium in New Zealand markets.

tutes could be different. We conduct a set of exercises to examine this. First we include a control for the number patent-protected therapeutic substitutes within an ATC 5-digit category in the US (our data does not allow us to control for patent protected substitutes in the other destinations). These results are shown in Panel A of Table 5. With the exception of the comparison with Australia, the number of patent protected therapeutic competitors in the US does not affect the price premium. Although the coefficient is statistically significant in the Australia comparison it does not appear mitigate the relationship between the number of suppliers in the market and the price premium. Second, we include a control for the number of therapeutic substitutes within an ATC 5-digit category. These results are shown in Panel B. Again, these are largely small and statistically insignificant with the exception of one comparison (with the UK). In this case the effect of a greater number of (potential) substitutes has little impact on the effect of the US suppliers on the price premium. Finally, we consider ATC 5-digit by year fixed effects, to absorb most plausible variation between the United States and foreign countries within a therapeutic category. These results are shown in Panel C. We find some weak evidence that alternatives at the therapeutic substitute level influence cross-country price difference. However, this does not attenuate the role played by market entry within a molecule-dose level.

6 Structural Model

For the purpose of comparing policies and conducting counterfactuals, we construct a structural model of the off-patent and generic drug market. We first consider a canonical model with a single monopolist buyer and a single monopolist drug seller, and then extend this to cover different levels of oligopoly. As described in Section 3, we are interested in the actions and outcomes of two key players. Drug sellers maximize profits and drug buyers minimize costs. Prices are determined through Nash bargaining. Markets with more than one seller are defined implicitly, weighted between the results for a monopolist seller and perfect com-

Table 5: Relationship between Price Premium and Number of US Suppliers: Controls for Therapeutic Substitutes.

Panel A: Controlling for Patented Competition

	(1) $ln(p_{US}/p_{AU})$	(2) $ln(p_{US}/p_{BC})$	(3) $ln(p_{US}/p_{NZ})$	(4) $ln(p_{US}/p_{ON})$	(5) $ln(p_{US}/p_{UK})$
ln(US Suppliers)	-1.132***	-1.142***	-0.726***	-0.870***	-0.902***
	(0.113)	(0.0891)	(0.103)	(0.108)	(0.127)
ln(Patent Comp + 1)	-0.311*	0.0519	-0.277	-0.0813	-0.216
	(0.126)	(0.264)	(0.238)	(0.168)	(0.330)
Adj. R-Square	0.291	0.256	0.135	0.158	0.128
Observations	1580	858	1477	344	1624
Fixed Effects	Year	Year	Year	Year	Year

Panel B: Controlling for Number of Broad Therapeutic Alternatives

	(1) $ln(p_{US}/p_{AU})$	(2) $ln(p_{US}/p_{BC})$	(3) $ln(p_{US}/p_{NZ})$	(4) $ln(p_{US}/p_{ON})$	(5) $ln(p_{US}/p_{UK})$
ln(US Suppliers)	-1.159***	-1.111***	-0.741***	-0.935***	-0.941***
	(0.113)	(0.0900)	(0.106)	(0.117)	(0.134)
ln(Alteratives)	0.0831	-0.0941	0.0263	0.163	0.231*
	(0.0791)	(0.0891)	(0.0887)	(0.0958)	(0.101)
Adj. R-Square	0.291	0.258	0.134	0.166	0.140
Observations	1580	858	1477	344	1624
Fixed Effects	Year	Year	Year	Year	Year

Panel C: Controlling for all Variation within Therapeutic Alternatives

	(1) $ln(p_{US}/p_{AU})$	(2) $ln(p_{US}/p_{BC})$	(3) $ln(p_{US}/p_{NZ})$	(4) $ln(p_{US}/p_{ON})$	(5) $ln(p_{US}/p_{UK})$
ln(US Suppliers)	-0.992***	-1.003***	-0.599**	-0.770***	-1.210***
	(0.143)	(0.137)	(0.183)	(0.186)	(0.158)
Adj. R-Square	0.610	0.569	0.463	0.506	0.515
Observations	1580	858	1477	344	1624
Fixed Effects	Year-ATC5	Year-ATC5	Year-ATC5	Year-ATC5	Year-ATC5

Notes: * p<.05, ** p<.01, *** p<.001. Average price difference between the two countries taken across drugs (molecule-dose-route). Regression specification from Equation 4 with standard errors clustered at the molecule level. See text for data sources and details.

petition.[30] We model total demand as exogenously determined, due to the inelasticity of demand.[31]

The model has two stages. The first stage involves recovering the determinants of pricing differentials, conditional on the number of market participants. The second stage recovers marginal relative entry costs (on an discounted yearly-basis) to rationalize the number of market participants. Critically, we do not directly model the mode of competition between pharmaceutical companies, instead we recover a policy and counterfactual-relevant competition parameter (a sufficient statistic). Additionally, we do not model the set of drugs covered by various public plans (the formulary), as this set is rarely bargaining over in generic prescription drug markets.

Our model essentially has four degrees of freedom: First, the average price difference across all drugs between two nations. Second, the rate of convergence in prices between two nations, as the number of suppliers increases. Third, we have the price differential as the number of competitors becomes large. Fourth, for a subset of countries, we have the number of doses sold. We can capture all these moments in a parsimonious way, allowing for the computation of our main counterfactuals: creating a single market in the English speaking world and allowing US buyers to bargain with drug makers in a similar fashion to the rest of the English speaking world.

6.1 Price Setting

6.1.1 Baseline Scenario

We model the simplest case with one buyer and one seller as a Nash bargaining game. Drug sellers maximize profits and drug buyers minimize costs. Profits for a monopolist seller are

[30] Alternatively, markets with more than one seller can be defined recursively, with the outside option for sellers being zero (being shut out of the market), and the outside option for buyers being the price charged in a market with one less seller. This is discussed in further detail in Appendix D.2.

[31] For empirical evidence from US markets see Appendix C.4. In particular, patients covered by US Medicaid programs face minimal cost sharing and are not constrained by sticker prices. In all non-US markets we consider, with rare exceptions, prescribers for non-patented medications do not share variable costs.

$\pi_s = (p - c)\, q$, where prices are p and constant marginal costs are c. The drug buyer is attempting to minimize costs $p \times q$. If the buyer and seller cannot come to an agreement the seller receives nothing. The buyer still needs to supply local patients and must pay per-unit price $\bar{p}$, where $\bar{p} \in [c, \infty)$. This 'choke' price $\bar{p}$ represents the cost of a local insurer or government either compounding the drug locally, paying for a new supplier of the drug, or the imputed loss of social welfare from not providing the drug.[32]

The price is determined by the Nash surplus, $NS = (pq - cq)^{w_s} (\bar{p}q - pq)^{w_b}$, where the weights w_s and w_b are the positive seller and buyer bargaining weights that sum to 1 (without loss of generality).[33]

Taking a logarithmic transformation of the Nash Surplus and then first order conditions over the price, the monopoly bargaining price is:

$$p_m = w_s \bar{p} + (1 - w_s)\, c. \tag{6}$$

Thus when the buyer has no bargaining weight, $w_s = 1$, the seller appropriates all surplus and charges $p = \bar{p}$. When the seller has no bargaining weight, $w_s = 0$, the buyer gives a take-it-or-leave-it offer where $p = c$ and appropriates all the surplus.

6.1.2 Generalization

In the bulk of our considered markets, all non-US markets and the US Medicaid market, there are multiple drug sellers, but only one buyer. In classical economic markets, with infinite entrants and zero seller market power, the price in the marketplace is simply the average cost:

$$p_c = c. \tag{7}$$

[32] This treatment is isomorphic to considering a social welfare function: $\bar{p}_b$ is a stand-in for the welfare-relevant term. Legally, the Medicaid choke price is bounded by a function of the private insurance price (the Federal Upper Limit or FUL). However the FUL is easily manipulated through two-part payments and rebates - which are not included in the calculation of the FUL.

[33] In some markets, a buyer may have the ability to drop a medication from the list of subsidized or covered molecules (formulary changes). We indirectly model this through the bargaining weights and leave detailed study for future work.

With an intermediate number of entrants, we directly model the price premium over marginal cost as a markup weighted between the monopolist solution from Equation 6 and the perfect competition solution in Equation 7. We allow for three features. First, the differentiation between name brand and off-brand generic entrants. The existence of a branded supplier is a binary variable and takes the set $B \in \{0, 1\}$. Second, the number of off-brand generic entrants. This is a natural number (including 0), $S \in \mathbb{N}^0$. Lastly, we include the degree of competition from other therapeutic substitutes $t \in \mathbb{R}^+$, such that the outside price is:

$$\bar{p} = c \times \bar{\mu}(t) \quad \bar{\mu}(t) : \mathbb{R} \to (1, \infty).$$

The perfect competition and monopoly solutions are:

$$p_c = c\ , \qquad p_m = w_s \bar{\mu}(t)\, c + (1 - w_s)\, c.$$

We first will focus on the aggregate market outcomes, looking at the weighted average between the branded entrant and the un-branded entrant.

The third feature is a competition function $\theta(B, S) : \{0, 1\} \times \mathbb{N}^0 \to \mathbb{R} \in [0, 1]$ weights between these two solutions in a parsimonious manner:

$$p_\cdot = \theta(B, S)\, p_m + (1 - \theta(B, S))\, c. \tag{8}$$

This Nash-in-oligopoly setup makes three major assumptions. First, the competitive parameter is multiplicatively separable from monopolist price and the marginal cost. Second, we generalize away from any market size issues other than what is included in the function $\theta(\cdot)$ and assume that other than the outside option, firms compete in an identical manner across markets. Lastly, we assume that all pharmaceutical suppliers have identical marginal costs. The price p charged does not need to be identical across sellers. Rather, p is simply the average price charged; in particular, this is a weighed average between the branded and generic entrants. The end payer (mostly governments), simply seek to minimize expenditures, holding the behavior of prescribers fixed.[34] Four cases that are subsumed by this model are highlighted in Appendix D.1: Bertrand competition with a homogenous good; Bertrand

[34] In the market entry game, we take seriously the notion that there may be differences between the prices, markups, and market shares of the original legacy branded supplier and other generic suppliers. However this distinction is not relevant for this stage.

competition with differentiated goods; a repeated game; and an extension to multiple buyers.

Rewriting our generalized price from Equation 8, we obtain the price paid by a particular buyer as a function of the competition parameter:

$$p = \theta(S)\left[w_s\bar{\mu}(t) + (1 - w_s)\right]c + (1 - \theta(S))\,c.$$

This requires the identification of the function θ, bargaining weight w_b, outside option price $\bar{\mu}$ and marginal cost c. However, our data is not refined enough to identify all these elements using only data on p and S. In particular, the outside option $\bar{\mu}$ and w_s are hard to separately identify.

We define a buyer-specific leverage parameter:

$$\kappa(t) = \left[w_s\bar{\mu}(t) + 1 - w_s\right] \in [1, \infty).$$

We call this term the 'buyer's leverage'. As a buyer's bargaining weight goes to zero, this term goes to $\bar{\mu}(t)$, with the buyer facing the outside option. The term κ varies across different buyer-seller pairs, who may face differences in their outside options or bargaining weights, including political risk and variation in the availability of substitute pharmaceuticals.

Equation 8 becomes:

$$p = c\left[\theta(B, S) \cdot \kappa(t) + (1 - \theta(S))\right] = \mu(S, t)\,c. \tag{9}$$

This pricing equation has two functions that we parameterize, the competition function $\theta(\cdot)$ and the market-specific leverage function $\kappa(\cdot)$. We parsimoniously define the two functions:

$$\theta(B, S) = \exp(\alpha \log(B + S)), \quad \kappa(t) = \exp(\kappa_1 + \kappa_2 \log(t)).$$

We parsimoniously define $\theta(B, S) = \exp(\alpha \log(B + S))$, which implicitly defines $\theta(1, 0) = 1$ and $\theta(\infty, \cdot) = 0$ and matches our reduced form logarithmic relationships. We consider $B + S$, as most markets retain either the original branded entrant, or a dominant generic producer, and it would be redundant to consider B and S separately for average market prices. In the next section, we consider the prices and profits of the branded and generic participants separately. Thus, $\mu(S)$ is the average markup charged to the end seller in a market with $B + S$ suppliers. The leverage term, κ, reflects two elements - a buyer specific

shifter, κ_1, and a buyer-specific sensitivity to other products in the marketplace, κ_2. We model t as the number of exogenous formulations approved for use in the same ATC 5-digit code.

6.2 Market Entry: Maximum Effective Entry Costs

Our goal is to recover the entry cost of a marginal generic entrant, not the original branded manufacturer, or an infra-marginal firm. We consider the imputed per-period fixed costs for entry into a single country. (As opposed to global entry costs of creating a new factory). This can be interpreted as the present discounted value of entry.[35] The US, using a strict interpretation of the law, does not appear to have higher regulatory entry costs than similar counties, such as Australia, which have similar safety and documentation requirements. In practice, the US takes a lengthy period to review the entry of generic pharmaceuticals, averaging 44 months in 2016 (Lupkin, 2015). However, the US is also larger country, so there may naturally be higher entry costs related to true fixed costs for delivery and distribution. Generic markets are also rife with collusion (Wall Street Journal 2016) and bi-lateral payments from incumbents to entrants (Kaiser Health News 2019). We conflate all these costs to infer imputed entry costs, recovering the effective market value of entry.

Market entry in the Australia, Canada, New Zealand, and the UK is straightforward as institutional rules effectively mandate uniform reimbursements across suppliers of a particular molecule. However, this is not necessarily true in the United States. In Medicare and Medicaid about 10% of doses are sold by the original branded supplier, charging 20% over the generic price.[36] While there are institutional rules in Medicaid and Medicare Part D to encourage the use of cheaper generics over nearly identical branded drugs, prescribers and patients may have other incentives. This is a complicated problem. Instead of directly modeling consumer behavior, we consider the direct role played by the number of suppliers on the share of the original pharmaceutical and the price premium charged by the original

[35] Our model here is static. We do not consider the inter-temporal dynamics of these complex markets.
[36] Similar patterns hold in Continental Europe (Kanavos et al., 2008).

pharmaceutical supplier.

We assume that marginal costs are identical across suppliers. With competition $\theta(\cdot)$ and buyer leverage $\kappa(\cdot)$ recovered from demand estimation, we recover an estimate for average costs c for an observation at the drug (d), year (y), country/market (f) level:

$$c_{fdy} = \frac{R_{fdy} \times S_{fdy}}{\mu_f(S_{fdy}) \times q_{fdy}}. \tag{10}$$

We use data on average revenues (R), pharmaceutical suppliers (S) and sold doses (q). The markup function $\mu_f(\cdot)$ is derived from Equation 9.

Combining marginal cost and price data, we can recover average markups μ as a function of the markups of the original branded drug and the markups of the generic competitors (omitting drug and year subscripts for clarity):

$$\mu = \mu_n(S) \times s_n(S) + \mu_g(S) \times s_g(S). \tag{11}$$

This is a function of the markup (μ_g) charged by the generic suppliers (which we assume are identical) and the the original branded supplier (μ_n), weighted by their respective total market shares $s_i(\cdot)$. We recover μ_n and μ_g by assuming common marginal costs, thus $\mu_n = p_n/c$ and $\mu_g = p_g/c$. As our counterfactual will not consider the role played by the original branded entrant (which happened at least 20 years prior to the generic entrants), we simply take the combined markup and resulting market share behavior jointly: $\mu s_n(S) = \mu_n(S) \times s_n(S)$. With the markup function $\mu_g(S)$ and total generic market share $s_g(S)$, the profits of a marginal entrant in the United States are bounded by:[37]

$$\Pi_{US,generic} = \frac{q \times s_g(S) \times c \times [\mu_g(S) - 1]}{S - 1}.$$

If there are no markups, then there are no excess profits over average cost. However if markups are greater than one, we consider the notion of "excess" profits for generic suppliers in the USA market relative to another as:

$$\Pi_{excess} = \frac{q_{US} \times s_{g,US}(S_{US}) \times c_{US} \times [\mu_{g,US}(S_{US}) - 1]}{S_{US} - 1} - \frac{q_F \times c_F \times [\mu_F(S_F) - 1]}{S_F} \tag{12}$$

As an upper bound for the number of additional entrants, we consider how many more

[37] Empirically there appears to be very little variation in price (and therefore markups) among generic competitors. Thus we treat these firms as identical competitors.

entrants the US market could support if $\Pi_{excess} \to 0$. We compute the largest S^* such that the following inequality is satisfied:[38]

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

We consider this as an upper-bound as it is possible that $S^*_{US} > S_{World}$. This is due to two limitations, both data-based. First, we do not know the total number of suppliers that operate outside the English speaking world. Second, we do not know the total number of global suppliers. A marginal new global supplier must not only cover the average cost of manufacturing and distribution in a particular country (which we account for), but must also set up a new manufacturing line (for example in India, Puerto Rico, or Bulgaria).[39]

7 Identification & Estimation

Estimation works through backward induction. We first identify the policy relevant parameters in θ and κ, using observed variation in the number of suppliers present in various international markets. The central assumption here is that, conditional on the number of entrants, prices are fully determined in a market. This assumption is valid if there aren't dynamic concerns, such as if prices today determine entry tomorrow. With data on prices and suppliers for a variety of countries and regulatory schemes, we seek to recover data on α and κ where $b \in \{US, UK, NZ, AU, CA_{ON}, CA_{BC}\}$. Identification stems from cross-country price comparisons using cross-country variation in market entry.

7.1 Pricing Identification and Estimation

For every pair of buyers, there are four types of parameters to be identified, a global competition α, buyer leverages κ_a, κ_b, and relative average cost differences $c_{a/b}$. These parameters are identical across all countries. All four variables have natural simple analogs in the data, using variation in the number of firms participating and in relative prices.

[38] As $\Pi_{excess}\left(S_{US}\right) > 0 \; \forall S$ and $\Pi'_{excess}\left(S^*_{US}\right) < 0$ in the empirical setting, there is always a solution where $S^*_{US} \in [S_{US}, \infty)$.

[39] All developed English-speaking counties have zero tariff barriers to entry for nearly all pharmaceutical products in tablet or capsule form. Further discussion of this issue is provided in Appendix A.6.

All intuition can be derived from taking the ratios of the prices between two countries for an identical molecule/dose:

$$\frac{p_a}{p_b} = \frac{\exp(\alpha \log S_a)\left[\exp\left(\kappa_{a,1} + \kappa_{a,2}\log(t)\right) - 1\right] + 1}{\exp(\alpha \log S_b)\left[\exp\left(\kappa_{b,1} + \kappa_{b,2}\log(t)\right) - 1\right] + 1} c_{a/b}.$$

Here, S_a and S_b denote the number of suppliers in country 1 and 2, respectively. To identify cost differences $c_{a/b}$, take $S_a, S_b \to \infty$, then the price ratio in asymptotes to the cost ratio $c_{a/b} = c_a/c_b$. When the number of entrants in both countries is extremely large, the market should resemble perfect competition. The difference in prices is simply the difference in marginal costs. Costs such as distribution, labelling, and packaging may vary between countries.

For the buyer leverage κ_1, fix the number of sellers in one country at 1 and let the number of sellers in another country grow larger. Then the price ratio asymptotes to $\exp(\kappa_a)/c_{a/b}$. Similarly, variation in outside competition t identifies κ_2 Implicitly, we assume exogenous variation in total units demanded in each country. For example, there may be more patients that require the anti-malarial Chloroquine in Australia than in Canada. This will drive a difference in the number of entrants and thus help identify $\kappa_{b,1}$ and $\kappa_{a,1}$. This difference can also be driven by differences in the number of suppliers due to variation in country and market-level fixed entry costs.

Intermediate variation in the number of entrants in each market S_a and S_b identify the competition parameter α.[40] We assume the competition parameter α is identical across countries.[41] Robustness checks, allowing for variations in α along pair-wise comparisons finds similar results using a common α. Effectively, when there is one strong bargainer ($\kappa_a(t) = 0$), α is primarily estimated by another country with weak bargaining. Empirically, this weak bargainer is the United States.

The estimated parameter $c_{a/b}$ defines the average difference in marginal cost between

[40] While we impose a logarithmic structure on $\theta(\cdot)$, in principle we can estimate this function non-parametrically. We perform a simple extension in the Appendix and find consistent results.

[41] The parameter α is only identified for countries where $\kappa > 1$. That means that the seller has some bargaining power. However, as shown below - in nearly all countries outside of the US, κ is very close 1; preventing α from being identified on a market-by-market basis.

market a and b. We assume differences in $c_{a/b}$ markets idiosyncratic terms that are uncorrelated with market entry. Identification assumes that the the estimated price ratios deviated from predicted price ratios with a zero mean:

$$E\left(\log\frac{p_a}{p_b} - \log\hat{p}\left(\alpha,\kappa,c_{a/b}\right)\right) = 0.$$

We stack moments for the price differentials of the United States with various comparison countries/provinces as $m\left(\cdot\right)$ and place them into a two-step generalized method of moments (GMM) estimation routine,

$$C = m\left(\alpha,\kappa,c_{a/b}\right) W m\left(\alpha,\kappa,c_{a/b}\right)',$$

where W is the optimal weighting matrix, computed from a first stage using $W = I$. Standard errors are bootstrapped, resampling over pharmaceutical observations. We constrain $\kappa_b\left(t\right) \geq 0$ to be consistent with the Nash bargaining and competition in Equation 9.[42]

7.2 Entry Cost Estimation

Entry cost estimation is straightforward by comparison. We require one additional piece of data, the number of purchased doses. For Australia and the UK, we have the entire universe of purchases made through their respective public health systems.[43] However, we do not know the total market size by drug in the US, only the market size of Medicare and Medicaid. We compensate by by adjusting purchases with aggregate market data.[44] While not perfect, as Medicare, Medicaid, and private insurers serve different patients suffering from different maladies; it is a first order approximation of the total US market size.

From Equation 11, we require the function $\mu s_n\left(N\right)$, $\mu_g\left(N\right)$, and $s_g\left(N\right)$ for the US market. The first is the market share-weighted markup for the existing brand-name drug, the second is the markup for generic suppliers, and the last the aggregate market share of generic

[42] Results without this constraint are highlighted in Appendix E.2.

[43] We do not have sales for all EU countries. Our estimate will measure the marginal cost of entering just the English market.

[44] We use the Medical Expenditure Panel Survey (MEPS) Prescribed Medicines File for this. In 2014, Medicaid paid for 11% of doses, Medicare paid for 33% of doses and other sources paid for 56% of doses. Other includes all-cash, private insurance, and specialized programs such as the US Defense Department's Tricare and through Veterans Affairs.

suppliers. We non-parametrically recover these functions using available data, computing:

$$\mu s_n = \sum_s \beta_s^{\mu sn} \mathbb{I}\left(S = s\right) + \epsilon$$

$$\mu_g = \sum_s \beta_s^{\mu g} \mathbb{I}\left(S = s\right) + \epsilon$$

$$s_g = \sum_s \beta_s^{sg} \mathbb{I}\left(S = s\right) + \epsilon.$$

We then construct counterfactual profits for an marginal generic entrant following Equation 12. By comparing figure between the United States and both Australia and the UK, we compute $\Pi_{excess}\left(S_{US}^*\right)$. Standard errors are conducted with a bootstrap procedure, resampling over pharmaceutical observations.

8 Results & Counterfactuals

This section presents the results from four counterfactual simulations. The goal of these counterfactuals is to compare the potential impact of policies that promote bargaining versus policies that promote competition. These counterfactuals are motivated based on several empirical facts. 1) Markets with few patients have few generic entrants and these markets with few US patients have the highest prices in the US relative to foreign countries. This indicates that there may be natural bounds on the number of competitors that the market can support, which would limit the effectiveness of a competition policy. (2) Demand in Medicaid is highly inelastic, highlighting the possible need for bargaining power to control buyer costs. In addition, there is significant variation in the number of pharmaceutical providers across countries, suggesting that there is potential to expand competition through reducing non-tariff barriers. The analysis behind these facts is presented in Appendix C.

8.1 Competition, Buyer Leverage and Excess Entry Results

Table 6 shows the estimates for the two parameters of the model, α and κ as well as the average residual $\hat{c}_{12}$ for US Medicaid (results for other insurance types are shown in Appendix E). There is a leverage parameter (κ) for each country and a cost difference for the US

Table 6: Joint GMM Estimation Table

Medicaid Comparison	US	AU	BC	NZ	ON	UK
Competition α	-1.07					
	(0.13)					
Leverage κ_1	1.72	0.00	0.00	0.50	0.00	0.77
	(0.12)	(0.03)	(0.00)	(0.11)	(0.07)	(0.13)
Competition κ_2	0.06	0.03	-0.02	0.03	0.15	-0.19
	(0.03)	(0.08)	(0.01)	(0.06)	(0.09)	(0.05)
Cost Difference $c_{1/2}$		0.97	0.54	1.00	0.75	1.70
		(0.15)	(0.08)	(0.14)	(0.13)	(0.22)

Notes: Results are for Medicaid data aggregated to the molecule-dose-form level. This table uses a GMM estimator to estimate three types of parameters: (1) the estimated intensity of competition, (2) the joint outside option/bargaining parameter, and (3) mean logarithmic cost differences. Competition intensity α is estimated with a single parameter. The leverage parameter κ_1 is decreasing in the outside option $\bar{p}$ and the buyer bargaining parameter w_b, and increasing in the seller bargaining parameter w_s. Leverage parameter κ_2 is decreasing in the number of therapeutic substitutes t calculated at the ATC 5-digit level. United Kingdom supplier data based on 2017 supplier data, not considering possible cross-importation policies. Bootstrapped standard errors reported in brackets.

compared with each country ($\hat{c}_{US,F}$).[45] The competition parameter α is the rate at which the weight between the monopoly and competitive price ($\theta_b(S)$) declines as the number of competitors increases. A larger value indicates a speedier approach to competition. The buyer leverage (κ) parameters are decreasing in the outside option $\bar{p}$ and the buyer bargaining parameter w_b, and increasing in the seller bargaining parameter w_s. A lower κ_1 is interpreted as the country having greater bargaining power or a better outside option than the base country. [46] The average cost difference captures the unexplained variation in the data. The results are similar across the versions of the data (See Appendix E.1 for full details). The UK and New Zealand have the largest average differences with the US.[47]

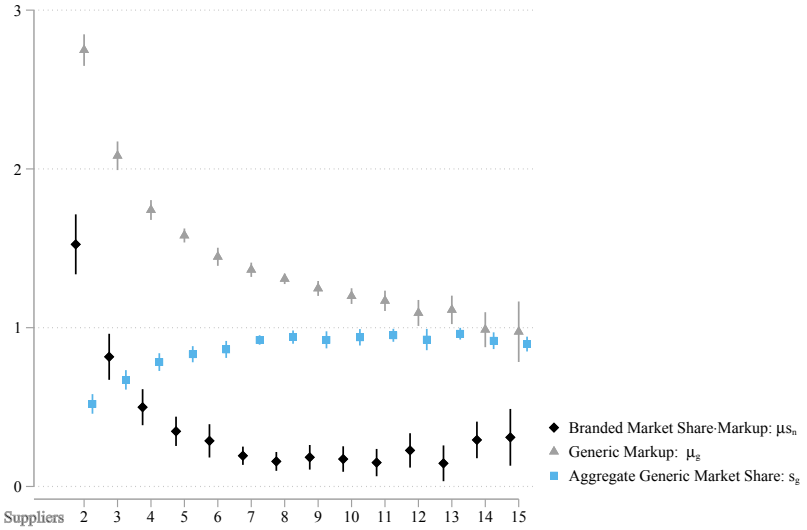
A reason for high US generic drug prices could be higher implied costs of entry. Although the entry requirements across countries are broadly similar, differences in how long or cumbersome the application process is can affect the entry cost. For example, in the years leading up to 2012 resource constraints at the FDA resulted in a large backlog of applications for generic approval (Berndt et al., 2018). This has since largely been addressed through the

[45] Since we assume that competition functions the same in each country for identification there is just one α parameter.

[46] κ_1 is often is at the constraint where $\kappa_1 = 0$. If κ was unbounded, this would mean governments have the ability to force firms to sell with $\gamma < 1$, under the estimated marginal cost. While this may occur, we leave this discussion to the appendix.

[47] Comparing prices with the UK/NZ and Australia confirm this trend, as the number of entrants increases, UK/NZ prices fall faster than Australian prices.

Figure 3: Branded versus Generic Markup and Share Functions using US Medicare



Notes: The x-axis depicts the number of suppliers in markets with both branded and generic competitors. There are three trends here. First, the triangles show that generic markups fall as the number of suppliers increase, effectively reaching marginal cost pricing at 15 suppliers. Second, the squares show that generic market share, compared to the branded off-patent market share, increases as the number of suppliers increase. Lastly, the diamonds show that the effect of the branded off-patent drug on average markups falls as the number of total suppliers increases. Robust standard errors with 95% CI.

introduction of application fees (GAO, 2017), but the issues of collusion and pay-to-stay-out remain (Wall Street Journal 2016) (Kaiser Health News 2019). To examine differences in entry costs, we compute the implied cost of a supplier entering the US relative to Australia and the United Kingdom.[48] These excess entry costs in estimated in two stages. First, for the US, we estimate the functions μs_n, μ_g and s_g in Figure 3.[49] We then estimate Equation 12. Using estimates for Medicaid, costs must be between \$8.4-\$15.5 million per year (shown in in Table 7).[50] Results using other types of insurance are shown in Appendix E.1.

[48]These costs represent entering England, not the entire European Union, and should be interpreted as an upper bound for the entire European market.

[49]Figure 3 shows trends concerning the interplay between branded and unbranded generics in US Medicaid data. The branded market-share weighted markup function μs_n quickly decreases with the first non-branded generic entrant. Similarly, the average markup of generic suppliers μ_g falls to nearly marginal cost pricing, while the market share of the non-branded suppliers nears 100%.

[50]Entry is a largely one-time cost to pay for regulatory compliance. As we use annual data, the results reflect the discounted cost of entry. If we assume an annual discount rate of 10-20%, all these figures should be multiplied by between 5 and 10.

Table 7: Imputed Excess Entry Cost Estimates

scenario/est ($M)	Medicaid Molecule-Dose
AU	15.51
	(0.79)
UK	8.44
	(0.67)

Notes: This table takes the estimates and data from the GMM estimation and computes "excess entry costs", which are necessary to justify the fixed costs of entry between the United States and a comparison nation. Bootstrapped standard errors reported in brackets.

Table 8: Percentage Change in Drug Expenditures

(a) Aggregate Savings

scenario/est (%)	Medicaid Molecule-Dose
CF 1: Single Market	-9.0%
	(0.9)
CF 2: Foreign Negotiation	-20.3%
	(6.9)
CF 3: Both	-20.7%
	(6.9)
CF 4: Free Entry	-17.5%
	(1.2)
Markets	7536

(b) Mean Savings

scenario/est (%)	Medicaid Molecule-Dose
CF 1: Single Market	-11.8%
	(0.4)
CF 2: Foreign Negotiation	-35.6%
	(5.7)
CF 3: Both	-36.1%
	(5.6)
CF 4: Free Entry	-34.1%
	(1.6)
Markets	7536

Notes: In the first panel, each statistic represents the total cost savings across all off-patent drugs in a particular counterfactual using Medicare data. In the second panel, each statistic represents average cost savings across all off-patent drugs in a particular counterfactual. Bootstrapped standard errors reported in brackets. This table takes the estimates and data from the GMM estimation and computes the policy relevant counterfactuals. The columns represent different estimates using different data sources. The rows represent the different counterfactuals. See text for further details.

8.2 Counterfactuals

Our counterfactuals revolve around two major concepts. The first involves regulatory changes on entry and the second involves structural changes in the nature of bargaining and buyer power. Both sets of policies have attracted substantial political support. We explore various implementations and combinations of these policies. In Table 8 we show the aggregate affect of these policies on total generic and off-patent drug expenditures and the effect on the average drug. In general, the aggregate effects of these policies are smaller than the average effect, as popular drugs with millions of doses face small or no changes in counterfactual prices, operating close to perfect competition.

Counterfactual 1: Single Market The first counterfactual simulates a reciprocity policy, effectively eliminating non-tariff barriers within the rich English-speaking world. It supposes that once a supplier was approved in Australia, Canada, New Zealand or the UK then it can sell its product in the US without any further entry costs. We simulate this policy by increasing the number of entrants in each market to the maximum unique entrants across all 4 foreign markets. Mathematically, we consider the change in the US price to be:

$$\frac{p_{CF1}}{p_{US}} = \frac{\exp\left(\alpha \log S_{World}\right)\left[\kappa_{US}\left(t\right) - 1\right] + 1}{\exp\left(\alpha \log S_{US}\right)\left[\kappa_{US}\left(t\right) - 1\right] + 1}.$$

To be conservative, S_{World} is the maximum number of suppliers approved to sell that drug in any other country.

The first row of Table 8 shows the percentage change in total drug expenditure for Medicaid A single market would reduce total Medicaid expenditure by 9%. Intuitively, results comes from increasing the number of competitors S_{US} and considering the effect of competition through the parameter α on pharmaceutical prices. While these figures seem small, they are pulled towards zero by a set of extremely popular drugs with many competitors. In the second panel of Table 8, we consider the change in the average drug price. In general, we find larger cost savings.

Counterfactual 2: Strong US Buyer Leverage (Bargaining/Outside Option) This counterfactual estimates the savings to Medicaid, by using improving buyer leverage to bargain drug prices. Results are simply derived from the observed price change when κ_{US} is changed to the average of κ in all other countries. It is implemented by considering the average cost savings if the US has the same buyer leverage as competitor nations:

$$\frac{p_{CF2}}{p_{US}} = \frac{\exp\left(\alpha \log S_{US}\right)\left[\bar{\kappa}_f\left(t\right) - 1\right] + 1}{\exp\left(\alpha \log S_{US}\right)\left[\kappa_{US}\left(t\right) - 1\right] + 1},$$

where κ_f is the average buyer leverage over all foreign markets. Since the US is a much larger market, this is likely a lower bound. The results in the second column of Table 8 show the savings estimates in Medicaid are 20.3% When considering cost saving for the average drug, savings are much larger at 35.6%.

Counterfactual 3: Both single market and US Buyer Leverage (Bargaining) Next we estimate the effect of both increasing competition through reciprocity and the US improving their buyer leverage. This is simulated assuming that all potential foreign entrants enter and that the US buyer leverage is changed to the average of all other countries:

$$\frac{p_{CF3}}{p_{US}} = \frac{\exp\left(\alpha \log S_{World}\right)\left[\bar{\kappa}_f\left(t\right) - 1\right] + 1}{\exp\left(\alpha \log S_{US}\right)\left[\kappa_{US}\left(t\right) - 1\right] + 1}.$$

The results, in row three of Table 8, show savings similar to those from just implementing the bargaining policy, reducing Medicaid expenditure by 20.7% When considering cost saving for the average drug, savings are much larger at 36.1%.

Counterfactual 4: Elimination of Excess Entry Costs We show in Section 8.1 that the US has higher implied entry costs than Australia and the UK. A reciprocity policy would inherently lower the cost of entry. Therefore, our estimates of the number of new entrants to the US in Counterfactual 1, which keeps the fixed cost of entry constant, may underestimate the effect. In this counterfactual we show the effect of lowering the fixed entry costs (the excessive profits) to foreign levels:

$$\frac{p_{CF4}}{p_{US}} = \frac{\exp\left(\alpha \log S_{Entry}\right)\left[\kappa_{US}\left(t\right) - 1\right] + 1}{\exp\left(\alpha \log S_{US}\right)\left[\kappa_{US}\left(t\right) - 1\right] + 1},$$

where S_{Entry} is the maximum number of profitable entrants if US entry costs for generic suppliers were the maximum of either Australia or the United Kingdom.

This provides an estimate of the maximum number of entrants that would be likely to enter following a liberalization of drug policy. To be as conservative as possible, we consider buyer-leverage to be computed as the maximum from comparison destinations.[51] We find gains larger than those from under a single market, and comparable to better bargaining by the US government. The estimates show a reduction in Medicaid expenditure of 17.5% . This occurs as the massive US market , dwarfing the size of Australia and the United Kingdom, would allow for significant freer entry. We consider these estimates a hard upper bound on

[51] If we use the minimum, we effectively get the same result as perfect competition. We find that Australia and British Columbia effectively have no markups. Thus, we would have an infinite number of entrants in the US counterfactual. In addition, we convert the dollar figures from Table 7 to percentages when calculating counterfactuals.

the gains from regulatory barriers, as it is possible that $S^*_{US} > S_{World}$. We do not know the total number of suppliers operating outside the English speaking world. A marginal new global supplier must not only cover the average cost of manufacturing and distribution in a particular country (which we account for), but also set up a new production facilities.

9 Discussion & Conclusion

We study generic and off-patent drug marketplaces across five nations, focusing on a broad set of pharmaceuticals sold in either tablet or capsule form. This paper empirically shows that the average price in the US is **200-400%** higher than the average in four countries where the government intervenes in generic drug prices — Australia, the UK, Canada and New Zealand — when there is only one supplier in the US market. This price differential declines as there are more suppliers in the market. Once there are **six or more suppliers**, there is little difference in the price.

We use a structural model of the generic drug market to compare the relative effectiveness of two policy solutions: international reciprocity and government bargaining. A well-implemented bargaining policy is far more effective than a reciprocity policy, with savings to Medicaid of as much as 120% and compared with savings of 9%. Better bargaining can also reduce the harms from collusion between suppliers, as buyers can band together and make "take-it-or-leave-it" offers near marginal cost.

Pharmaceutical manufacturing is a global business. Other than regulatory barriers, pharmaceuticals face low effective tariff and non-tariff barriers. Hence when a new supplier decides to set up manufacturing, the decision is not a purely local decision, it is a global decision, taking to account the fixed costs of production, number of competitors and each market's regulatory conditions. If pharmaceutical entry is liberalized in the United States, it could stimulate additional entry into production and manufacturing. Accordingly we consider how this affects our results using two counterfactual exercises. Counterfactual #1 presents an lower bound. We assume that all supplier already approved can now costlessly enter the US

market. Counterfactual #4 providers an upper bound by liberalizing entry. Lowering entry costs in one country might lead to completely new suppliers entering the market due to the global nature of the supplier's entry decision.

Underlying our conclusions are some important assumptions. We are implicitly assuming that the US government has the state capacity to effectively bargain with pharmaceutical suppliers.[52] Mistakes in bargaining and political entanglements could lead to prices below free-market levels and market exit. In contrast, a free-market approach may be easier to implement with less political interference, and has little to no downside. In addition, a market-based policy like that currently being pursued by the FDA through the 2019 Drug Action Plan, could have additional benefits that we have not captured in our model. Increased competitors could reduce the risk of shortages caused by plant specific quality failures. Furthermore, an important weakness of our approach is that we are not able to decompose the components underlying fixed costs of entry; can they be directly addressed by the FDA or are they the result of complex downstream bargaining between PBMs, suppliers, and pharmacies?

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[52] See Carril and Duggan (2018) for an example with respect to defense procurement and market concentration.

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Online Appendix

A Data Details

A.1 United States Data

Each market contains a set of similar pharmaceuticals with an associated NDC code. The manufacturer can be identified from the first 5 digits of the NDC code. A list of approved molecules are obtained from the drugs@FDA database. We include molecules for which the form of administration is listed as "capsule" or "tablet". The application numbers are matched with the 2009 FDA Orange Book. The orange book lists all unexpired patents and exclusivities. A molecule is classified as off-patent if there are no exclusivities listed in the Orange Book or if there is ANDA approval.

There are several potential sources of price data. For the primary analysis we use data from Medicaid, however, our results are robust to data from Medicare Part D and private insurance data. The data on reimbursement and quantities comes from the State Utilization Data:

> *Since the start of the Medicaid Drug Rebate Program, states report drug utilization for covered outpatient drugs paid for by state Medicaid agencies. In order for pharmaceutical manufacturers to obtain Medicaid coverage for their prescription drugs, they must sign a rebate agreement with the Secretary of Health and Human Services (HHS) to provide rebates for those drugs when purchased by Medicaid. The reported data includes two fields: Medicaid Amount Reimbursed and NonMedicaid Amount Reimbursed. The sum of these two fields should generally equal the Total Amount Reimbursed on an NDC by NDC basis; Rebates are paid on both brand name and generic drugs. Total amount reimbursed by both Medicaid and non-Medicaid entities to pharmacies or other providers for the 11-digit NDC drug in the period covered (two previous fields added together). This total*

is not reduced or affected by Medicaid rebates paid to the state. This amount represents both federal and state reimbursement and is inclusive of dispensing fees.[53]

A.1.1 FDA Approvals and Drug Codes

Historical National Drug Code (NDC) and approval data is acquired from the National Bureau of Economic Research (NBER). Each drug for sale package includes data on the manufacturer, active ingredients, dosage, form, and packaging details. This data additionally includes details regarding the firm that applied for approval, the date of approval, and the current status of the drug. We stack this data across time to merge to the Medicare, Medicaid, and NADAC data. We retain data on all approved drugs that appear in either tablet or capsule form.

We additionally make use of the NBER's NDC crosswalk that concords two different version of drug codes. An NDC is a composite of three variables: the drug code, the manufacturer, and the package's details. One version reports all three variables separately and another concatenates the variables in a semi-arbitrary fashion. We convert all data to the former form.

A.1.2 State Medicaid Data

State-level Medicare data is sourced from the Centers for Medicaid and Medicare Services (CMS) and is published at the monthly level.[54] We collapse this data by year, molecule, dose and form, harmonizing names across years. This data is originally collected by individual states and reported to the CMS.

With this aggregated data, we perform three procedures to align it better with global data. First, the CMS reports that "Amounts reimbursed by Medicaid are pre-rebate, not

[53] From https://www.medicaid.gov/medicaid/prescription-drugs/state-drug-utilization-data/state-drug-utilization-data-faq/index.html

[54] We leave the separate state-by-state analysis to further work and consolidate the data to the national level.

net of rebates." The 1993 Medicare and Healthcare Act instituted a system of system of manufacturer rebates of the net price. For multiple source drugs, the statutory reimbursement rate is 13% of the average manufacturers price. For single-source, non-innovator drugs, the statutory reimbursement rate is calculated with a similar formula based on the average manufacturer. We directly account for these differences.

Second, the CMS reports that "This amount represents both federal and state reimbursement and is inclusive of dispensing fees." As all other countries separately report dispensing fees, we further account for this. In 2007, the median dispensing fee was approximately $5 and in 2017 the median dispensing fee was approximately $10. We code this in.

Finally, as part of the Affordable Care Act (ACA), US states instituted Federal Upper Limits (FUL), the maximum allowable price. We consider any prices above these FUL in ACA years to be computed in error and thus exclude them from our analysis.

A.1.3 Federal Medicare Part D Data

Medicare Part D plans are regulated prescription drug plans that cover 75% of the United States Medicare population (Cubanski et al., 2018). We use national-level aggregates from the Centers for Medicaid and Medicare Services (CMS) that are constructed from the complete universe of Part D patients. CMS maintains a Chronic Condition Data Warehouse (CCW), "a database with 100% of Medicare enrollment and final-action Part D prescription drug event (PDE) data."

Publicly available information does not report on individual dose sizes and forms. Rather, this data is reported at only the molecule level. We aggregate this data by year in order to perform analysis. In addition, there are two further caveats: the molecule level data is inclusive of manufacturer rebates and dispensing fees. This makes it harder to align with foreign data, leaving this as a robustness check with our mainline results.

A.1.4 National Average Drug Acquisition Cost (NADAC) Data

For a subset of drugs, we additionally append price data with National Average Drug Acquisition Cost (NADAC) data. This data is collected by the CMS to help aid states in setting Medicaid reimbursement costs. Prior to 2011, many states used the average wholesale price (AWP) as a benchmark. However, the Office of Inspector General found that that the AWP methodology was "fundamentally flawed". It was replaced by the NADAC, which reflects the average drug acquisition costs for retail, consumer-facing pharmacies from a nationally representative sample. While sampling variation is not revealed by the CMS, they reveal that the NADAC sampling average margin of error is below 2.5%.

This data is collected by a federal subcontractor and released weekly and reflects the price paid by the retailer to the pharmaceutical distributor. This data does not include the dispensing fee, any upstream rebates, nor the retailer markup. It includes all transactions paid using cash, private insurance (including Medicare Part D plans), and public insurance.[55]

Data is released at the National Drug Code level, and includes both selected over-the-counter medications and prescription pharmaceuticals. We aggregate this data to a year-molecule-dose-form using national Medicare market shares for all prescription pharmaceuticals that appear in either a tablet or capsule form.

A.2 Canadian Data

A.2.1 Canadian Manufactures Data

Data on approved Canadian pharmaceutical providers is obtained from Health Canada, which maintains their Drug Product Database (DPD). This database includes all "human, veterinary, disinfectant, and radiopharmaceutical products approved for use by Health Canada". The database includes all approved, marketed, cancelled, and dormant products. We consider all pharmaceutical products that are produced in a tablet or capsule form. Then we consider the start year of Canadian availability, i.e. the year the drug was first approved or

[55] Patients on 340b plans are excluded.

marketed. The last day of Canadian availability is the first year when a drug is flagged as "cancelled" or made "dormant". Since active ingredients in the DPD have slight variations with corresponding US and provincial drug names, we perform manual cleaning to align drug names. We create a manufacturing database with the (1) list of active ingredients, (2) year, and (3) number of approved companies.

A.2.2 British Columbia Price Data

Data on British Columbia pharmaceutical prices is obtained from PharmaCare, which has eight plans that cover all patients under the Medical Services Plan of B.C. (MSP), the statewide sing-payer health insurance plan for all province residents that are either Canadian citizens or legal permanent residents. This plan is targeted to achieve universal health care.

PharmaCare covers both pharmacy dispensing fees as well the maximum price it will recognize for each drug in the British Columbia PharmaCare formulary. The PharmaCare plan operates on a income-based subsidy scheme, where lower income participants are reimbursed for a proportion of all pharmaceutical costs. The provincial government maintains an online database for the last three years of prices, including data on discontinued drugs. We consider only the unsubsidized price, which is the maximum that can be charged. Any subsidy simply offsets this cost.[56]

For drugs in this formulary, we consider all doses markets as either a tablet or capsule. For each active ingredient we extract out the dosage of each active ingredient. As active ingredients in PharmaCare have slight variations with corresponding US and other provincial drug names, we perform manual cleaning to align drug names. We create a provincial database with the (1) list of active ingredients, (2) form, (3) dosages, (4) year, and (5) average price. We additionally create a second database that averages drug prices across forms and dosages for comparability to US Medicare Part D data. Data is converted from Canadian Dollars to United States Dollars using exchange rate data from the Board of

[56] As with all non-US sources, the final dispensing fees are not included.

Governors of the Federal Reserve System access through the FRED database.

A.2.3 Ontario Price Data

Data on Ontario pharmaceutical prices is obtained from the six main Ontario Public Drug Programs that cover 43% of all provincial spending on prescription drugs. This plan has coverage primarily targeted at the poor, disabled, and elderly. This is roughly comparable to the population coved by the US Medicaid and Medicare programs. These plans cover the cost of drugs in monthly published formularies.

We use the 42nd Edition edition formulary for 2017, considering all drugs classified as either a tablet or capsule. We then extract out both the active ingredients and respective dosages. As active ingredients in Ontario's Public Drug Formulary have slight variations with corresponding US and other provincial drug names, we perform manual cleaning to align drug names. We create a provincial database with the (1) list of active ingredients, (2) form, (3) dosages, (4) year, and (5) average price. We additionally create a second database that averages drug prices across forms and dosages for comparability to US Medicare Part D data. Data is converted from Canadian Dollars to United States Dollars using exchange rate data from the Board of Governors of the Federal Reserve System access through the FRED database.

A.3 Australian Data

A.3.1 Australian Price and Manufacturer Data

Australian data comes from the Australian Government's Department of Health, which runs the national and universal Pharmaceutical Benefits Scheme (PBS). It maintains a monthly database of drug prices both inclusive and exclusive of the government subsidy. We take this data for January of each year and concord molecule names, routes, and dosages across time. These prices include both the price to the manufacturer and the price to the pharmacy.[57] In

[57] As with all non-US sources, the final dispensing fees are not included.

contrast to databases maintained by some other nations, this data also includes names on all of the approved manufacturers.

For drugs in this formulary, we consider all doses markets classified as either a tablet or capsule. We then extract out the dosage of each active ingredient. As active ingredients in the PBS have slight variations with corresponding US drug names, we perform manual cleaning to align drug names. We create a database with the (1) list of active ingredients, (2) form, (3) dosages, (4) year, (5) average price across packages. We additionally create a second database that averages drug prices across forms and dosages for comparability to US Medicare Part D data. Data is converted from Australian Dollars to United States Dollars using exchange rate data from the Board of Governors of the Federal Reserve System access through the FRED database.

A.3.2 Australian Prescribed Doses Data

Until 2015, the Drug Utilisation Sub-Committee (DUSC) of the Pharmaceutical Benefits Advisory Committee published an annual report on all prescription drugs by dose, form and molecule. This annual database, the Australian Statistics on Medicines (ASM), is sourced from all the underlying reimbursed dosages from the PBS. This includes both the number of prescriptions written and the total expenditure at a molecule, dose, and route level.

The ASM data is currently available through 2015. For data on 2016 and 2017, we turn to a slightly different database, the Section 85 PBS, RPBS Section 85 Date-of-Processing and Date-of-Supply data. This data is updated monthly and includes the number of prescriptions written and the total expenditure at a molecule, dose, and route level.

A.4 United Kingdom

A.4.1 Manufacturer Data

We obtain manufacturer data for the entirety of the United Kingdom from the electronic Medicines Compendium (eMC). This resource is run by the non-profit Datapharm, which

coordinates data between the UK Medicines and Healthcare products Regulatory Agency (MHRA) or the European Medicines Agency (EMA), and drug companies.

Since this data is not available for bulk download, we web scraped the website in 2017 for data on nearly 2,000 active molecules available for sale. We create a database that includes all products that are available in either tablet of capsule form. As we do not have time variation, we use this database for all years of United Kingdom Data.

A.4.2 National Health Service

English National Health Service price data is not directly available online from NHS Business Services Authority (NHSBSA). We repurpose data acquired from a freedom of information request from the Centre for Evidence-Based Medicine (EBM Datalab) within the Nuffield Department of Primary Care Health Sciences at University of Oxford. EBM Datalab cleaned the messy and inconsistent data into a usable format. As active ingredients in the NHS data have slight variations with corresponding US and other provincial drug names, we perform manual cleaning to align drug names. We collapse the data down to year-molecule-dose-form with average prices.[58] We create a similar, second database with data collapsed to the year-molecule form. Data is converted from British Pounds to United States Dollars using exchange rate data from the Board of Governors of the Federal Reserve System access through the FRED database.

A.4.3 UK Prescribed Doses Data

While the formulary data from the UK does not include the number of prescribed doses, a separate database is maintained by the NHS Business Services Authority for England. This data is classified as the Prescription Cost Analysis (PCA) data and collected monthly. We collect all data and collapse by year to get the total number of prescribed doses by "Pharmacy & Appliance Contractor", which refer to local pharmacies. Data is converted from British

[58] As with all non-US sources, the final dispensing fees are not included.

Pounds to United States Dollars using exchange rate data from the Board of Governors of the Federal Reserve System access through the FRED database.

A.5 New Zealand

A.5.1 Manufacturers

New Zealand manufacturer data for 2006-2018 is obtained from Medicines and Medical Devices Safety Authority, which operates under the auspices of the Ministry of Health. From their online product search, we obtain a list of all pharmaceutical products, with data on the active ingredient, manufacturer, status, approval date, and notification date (for drugs with lapsed or not available approvals). As this data does not exist in an easily readable format, we use a web-scraping program to download the relevant data. We first download a list of all drugs by their first letter and then iterate through all the listed molecules.

New Zealand additionally collects information, not only on the marketer of the drug, but also details on the original manufacturer, product tester, and packaging plant. We leave the analysis of this data for future work.

A.5.2 Prices

Prices for consumers in New Zealand are obtained from the Pharmaceutical Management Agency, a government agency referred to as Pharmac. It maintains a monthly database of drug prices both inclusive and exclusive of the government subsidy. We take this data for January of each year and concord molecule names, routes, and dosages across time. In New Zealand, consumers are also required to pay a $5 per prescription co-pay. We add this price back into the cost of the drug.[59][60]

For drugs in this formulary, we consider all doses sold as either a tablet or capsule. We then extract out the dosage of each active ingredient. As active ingredients in Pharmac have

[59] This fee is subsidized by the government for special categorizes of patients, such as those under the age of 13, and those with over 20 prescriptions.

[60] As with all non-US sources, the final dispensing fees are not included.

slight variations with corresponding US drug names, we perform manual cleaning to align drug names. We create a database with the (1) list of active ingredients, (2) form, (3) dosages, (4) year, and (5) average price across packages. We additionally create a second database that averages drug prices across forms and dosages for comparability to US Medicare Part D data.

Data is converted from New Zealand Dollars to United States Dollars using exchange rate data from the Board of Governors of the Federal Reserve System access through the FRED database.

A.6 Pharmaceutical Tariffs

One possible source of pricing difference would be differential tariff regimes. However, in our sample, tariffs are zero or negligible. As of 2017, Australia, Canada, the European Union, New Zealand, and the United States all apply zero or near zero tariff rates for all pharmaceutical imports. In particular the European Union does not apply any tariffs whatsoever on all pharmaceutical supplies. Canada, New Zealand, and the United States applies small tariffs on surgical and medical devices, which are not included in our sample. Australia additionally places a 2.5% tariff on all immunological products. These products are primarily vaccines that are largely injected, but there are a few generic vaccines available in pill or capsule dosages, such as Ty21a for typhoid. (UNCTAD, 2018; WTO, 2018)

B Robustness Checks

This section presents robustness checks for our main empirical result, which was presented in Section 5. Section B.1 shows the results using data from Medicare Part D and he National Average Drug Acquisition Cost data (NADAC), which covers all types of insurers including private. Section B.2 shows results from alternative specifications of estimation of Equation 4, including alternative fixed effects, changes in data definition and use of weights.

Table A1: Summary of Data Sources

Data Type	**Data Type**	**Observation Level**
US FDA Manufacturer Data (via National Bureau of Economic Research)	Manufacturers	Molecule-Dose-Form and Molecule
US Medicaid Data (Centers for Medicaid and Medicare Services)	Prices, Quantities	Molecule-Dose-Form and Molecule
US Medicare Part D (Centers for Medicaid and Medicare Services)	Prices, Quantities	Molecule
US National Average Drug Acquisition Cost (NADAC) Data	Prices	Molecule-Dose-Form and Molecule
British Columbia PharmaCare formulary	Prices	Molecule-Dose-Form and Molecule
Ontario Public Drug Programs	Prices	Molecule-Dose-Form and Molecule
Health Canada Drug Product Database (DPD)	Manufacturers	Molecule-Dose-Form and Molecule
UK National Health Service (England) - Centre for Evidence-Based Medicine Datalab (via Oxford)	Prices	Molecule-Dose-Form and Molecule
UK National Health Service (England) - Prescription Cost Analysis	Prices, Quantities	Molecule-Dose-Form and Molecule
UK Datapharm	Manufacturers	Molecule-Dose-Form and Molecule
Australia Pharmaceutical Benefits Scheme	Prices, Manufacturers	Molecule-Dose-Form and Molecule
Australia Australian Statistics on Medicines/Section 85	Quantity	Molecule-Dose-Form and Molecule
New Zealand Pharmac	Prices	Molecule-Dose-Form and Molecule
New Zealand Medicines and Medical Devices Safety Authority	Manufacturers	Molecule
US Federal Reserve	Exchange Rates	

Notes: See text for full details.

Table A2: Example Data - British Columbia - 10 Largest Price Differences - 2016

Molecule	Dose	Form	FDA Approval	US Suppliers	Medicaid Price	BC Price	Medicaid Prescriptions
pyrimethamine	25	tablet	1953	1	605.51	1.43	981
mebendazole	100	tablet	1996	1	312.69	5.91	5970
penicillamine	250	capsule	1970	1	224.24	3.89	732
penicillamine	250	tablet	1970	1	90.04	0.68	205
procarbazine	50	capsule	1985	1	57.06	0.44	799
morphine sulfate	200	capsule	1987	1	54.05	1.19	287
methoxsalen	10	capsule	1954	2	49.72	0.65	226
oxymetholone	50	tablet	1972	1	35.24	1.77	58
hydromorphone	32	tablet	1926	1	37.20	11.49	1269
ethacrynic acid	25	tablet	1967	2	18.46	0.97	2408

Table A3: Summary Statistics

(a) Medicare Part D - Molecule Comparison

Comparison	Obs	Start Year	End Year	$\log(P_{US}/P_{Dest})$ Mean	$\log(P_{US}/P_{Dest})$ Std. dev.	Mean First FDA Approval	Mean # US Sellers
AU	764	2012	2016	1.076	1.410	1981	9.98
BC	288	2015	2016	0.838	1.529	1981	9.51
NZ	803	2012	2016	1.046	1.241	1981	9.78
ON	237	2016	2016	1.011	1.337	1983	10.17
UK	852	2012	2016	0.671	1.350	1981	9.32

(b) NADAC - molecule-dose-route Comparison

Comparison	Obs	Start Year	End Year	$\log(P_{US}/P_{Dest})$ Mean	$\log(P_{US}/P_{Dest})$ Std. dev.	Mean First FDA Approval	Mean # US Sellers
AU	1250	2013	2017	0.831	1.494	1982	5.63
BC	1099	2015	2017	0.230	1.510	1983	5.24
NZ	1180	2013	2017	0.629	1.288	1983	5.58
ON	463	2017	2017	0.349	1.341	1984	5.80
UK	1467	2013	2017	0.389	1.571	1983	5.40

Notes: Based on authors' calculations of public expenditure, price, and seller data. Data for Medicaid Part D and from NADAC are not adjusted for rebates or dispensing fees. See text for further details.

B.1 Medicare Part D & Private Insurance

Since Medicaid only accounts for 10% of US prescription drug spending, we repeat our analysis using data on Medicare and private providers. We use two datasets for this analysis: the Medicare Provider Utilization and Payment Data: Part D Prescriber Public Use File, and the National Average Drug Acquisition Cost data (NADAC). The NADAC data is collected by the Centers for Medicare and Medicaid Services and reflects the price paid by retail pharmacies to acquire prescription pharmaceuticals. Both the Part D and NADAC data are much more limited than the Medicaid data, and we cannot compute an equivalent retail price at the molecule-dose-route level. In both cases the price cannot be corrected for manufacturer rebates and pharmacy reimbursements. The Medicare Part D data is also limited as it does not distinguish between molecule dosages. As such the analysis for Medicare Part D is conducted at the molecule level rather than the molecule-dose-route level. Table A3 shows the number of observations for each country and the years included in the analysis. We

recompute the analysis from Section 5.1 using the Part D and NADAC dataset in place of the Medicaid data. Figure 4 shows the coefficients β_s from Equation 3 of the premium relative to each foreign country on the number of suppliers in the US market. The premium is computed using prices Medicare Part D (Sub-Figure 4b), and average prices across all types of insurance (Sub-Figure 4c). For comparison Sub-Figure 4a presents the results for Medicaid identical to Figure 1). Standard errors are robustly clustered at the molecule-level. The nature of the relationship between the price premium and number of US suppliers is similar across all three datasets. Table A4 shows the results of estimation of Equation 4 and Table A5 the results from estimation of Equation 5. Again we present the results for the main analysis for ease of comparison.

Medicare Part D data is not publicly released to the public by molecule-dose-route. Rather, data is released by molecule, averaging across all doses. This in principle should not hinder our analysis, however, the US FDA regulates drugs at the molecule-dose-route level, which is how we define markets. We replicate our analysis from before using this average Medicare Part D data. As shown in Figure 5, international price comparisons at the molecule level are extremely similar between Medicare Part D and Medicaid. While the number of observations is reduced, as different dosages are aggregated, trends are statistically similar.

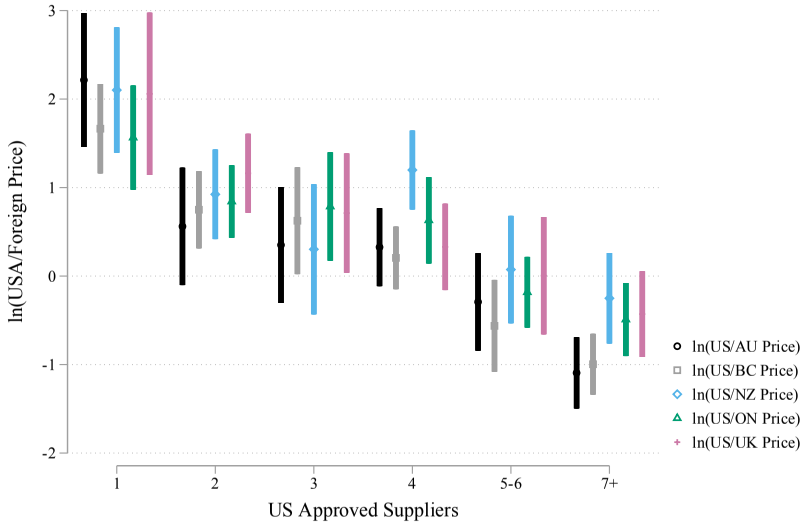
B.2 Additional Specifications

B.2.1 Price Adjustments

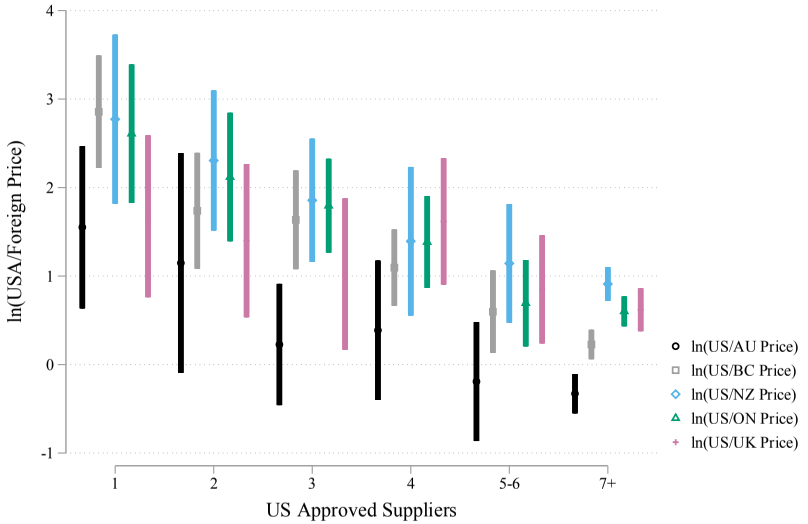
Table A6 shows the effect using 'un-adjusted' data, where Medicaid data is not adjusted for manufacturer rebates and pharmacy dispensing fees.

B.2.2 Weighted Regression Results

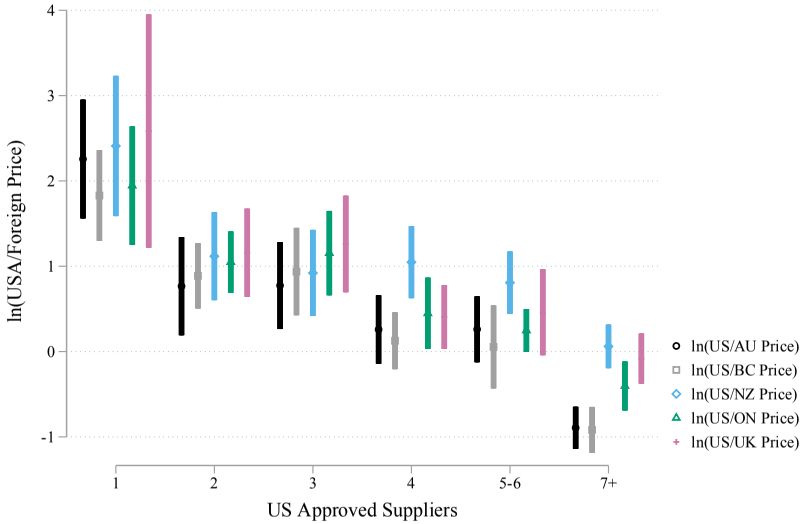
In Table A7, we recreate Table 3 using weights for the number of doses sold. For NADAC data, we simply use the number of Medicaid doses sold.



(a) Medicaid Data - Molecule-Dose-Route



(b) Medicare Data - Molecule



(c) NADAC Data - Molecule-Dose-Route

Figure 4: Role of competition - Non-parametric Regressions

Notes: Average price difference between the two countries taken across drugs (molecule-dose-route for panel A and C and molecule for Panel B) with the number of FDA approved competitors of the US. Regression specification from Equation 3 with standard errors clustered at the molecule level. 95% confidence intervals displayed. See text for data sources and details. Year-destination fixed effects are removed by de-meaning. Results with all base years, omitting the 7+ supplier category produce similar results.

Table A4: Relationship between Price Premiums and Number of US Suppliers

Medicaid - molecule-dose-route

	(1) $ln(p_{US}/p_{AU})$	(2) $ln(p_{US}/p_{BC})$	(3) $ln(p_{US}/p_{NZ})$	(4) $ln(p_{US}/p_{ON})$	(5) $ln(p_{US}/p_{UK})$
ln(US Suppliers)	-1.140***	-1.140***	-0.734***	-0.871***	-0.904***
	(0.113)	(0.0902)	(0.102)	(0.108)	(0.127)
Adj. R-Square	0.290	0.257	0.134	0.160	0.127
Observations	1582	858	1479	344	1625
Fixed Effects	Year	Year	Year	Year	Year

Medicare Part D - Molecule

	(1) $ln(p_{US}/p_{AU})$	(2) $ln(p_{US}/p_{BC})$	(3) $ln(p_{US}/p_{NZ})$	(4) $ln(p_{US}/p_{ON})$	(5) $ln(p_{US}/p_{UK})$
ln(Part D Suppliers)	-0.485***	-0.884***	-0.494***	-0.695***	-0.325**
	(0.123)	(0.0930)	(0.0891)	(0.102)	(0.106)
Adj. R-Square	0.134	0.339	0.157	0.229	0.0477
Observations	781	288	803	237	852
Fixed Effects	Year	Year	Year	Year	Year

NADAC - molecule-dose-route

	(1) $ln(p_{US}/p_{AU})$	(2) $ln(p_{US}/p_{BC})$	(3) $ln(p_{US}/p_{NZ})$	(4) $ln(p_{US}/p_{ON})$	(5) $ln(p_{US}/p_{UK})$
ln(US Suppliers)	-1.249***	-1.130***	-0.818***	-0.984***	-0.852***
	(0.0925)	(0.0710)	(0.0838)	(0.0860)	(0.114)
Adj. R-Square	0.403	0.309	0.232	0.244	0.148
Observations	1266	1099	1180	463	1467
Fixed Effects	Year	Year	Year	Year	Year

Standard errors in parentheses, * p<.05, ** p<.01, *** p<.001.
Notes: Average price difference between the two countries taken across drugs (molecule-dose-route for panel A and C and molecule for Panel B). Regression specification from Equation 4 with standard errors clustered at the molecule level. See text for data sources and details.

Table A5: Relationship between Price Differentials and Suppliers

Medicaid - molecule-dose-route

	(1) $ln(p_{US}/p_{AU})$	(2) $ln(p_{US}/p_{BC})$	(3) $ln(p_{US}/p_{NZ})$	(4) $ln(p_{US}/p_{ON})$	(5) $ln(p_{US}/p_{UK})$
ln(US Suppliers)	-0.979***	-1.019***	-0.761***	-0.830***	-0.976***
	(0.131)	(0.111)	(0.119)	(0.125)	(0.176)
ln(Foreign Suppliers)	-0.292**	-0.239*	0.0919	-0.0826	-0.0540
	(0.101)	(0.0953)	(0.113)	(0.109)	(0.172)
Adj. R-Square	0.304	0.274	0.127	0.166	0.137
Observations	1582	756	1417	335	273
Fixed Effects	Year	Year	Year	Year	Year

Medicare Part D - Molecule

	(1) $ln(p_{US}/p_{AU})$	(2) $ln(p_{US}/p_{BC})$	(3) $ln(p_{US}/p_{NZ})$	(4) $ln(p_{US}/p_{ON})$	(5) $ln(p_{US}/p_{UK})$
ln(US Suppliers)	-0.485***	-0.710***	-0.440***	-0.538**	-0.383*
	(0.137)	(0.181)	(0.119)	(0.178)	(0.161)
ln(Foreign Suppliers)	-0.162	-0.147	0.0297	-0.0994	0.0932
	(0.0980)	(0.129)	(0.115)	(0.123)	(0.165)
Adj. R-Square	0.152	0.225	0.0903	0.133	0.0215
Observations	771	244	760	226	191
Fixed Effects	Year	Year	Year	Year	Year

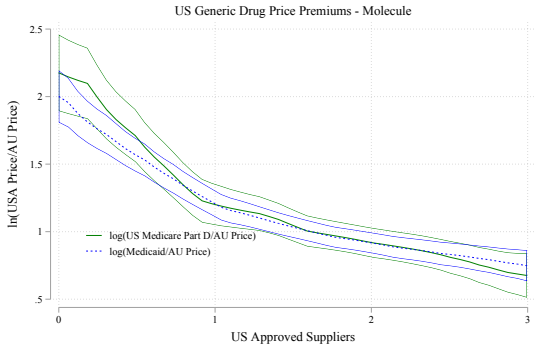
NADAC - molecule-dose-route

	(1) $ln(p_{US}/p_{AU})$	(2) $ln(p_{US}/p_{BC})$	(3) $ln(p_{US}/p_{NZ})$	(4) $ln(p_{US}/p_{ON})$	(5) $ln(p_{US}/p_{UK})$
ln(US Suppliers)	-1.147***	-0.989***	-0.827***	-0.929***	-0.939***
	(0.114)	(0.0843)	(0.102)	(0.105)	(0.167)
ln(Foreign Suppliers)	-0.144	-0.252***	0.0115	-0.0928	0.0989
	(0.0735)	(0.0683)	(0.0992)	(0.0770)	(0.131)
Adj. R-Square	0.408	0.336	0.229	0.254	0.126
Observations	1266	1023	1153	455	358
Fixed Effects	Year	Year	Year	Year	Year

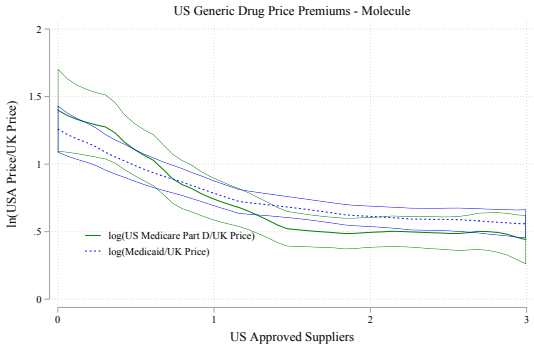
Standard errors in parentheses, * p<.05, ** p<.01, *** p<.001.
Notes: Average price difference between the two countries taken across drugs (molecule-dose-route for panel A and C and molecule for Panel B). Regression specification from Equation 5 with standard errors clustered at the molecule level. See text for data sources and details.

Figure 5: Medicare and Medicaid International Price Differences

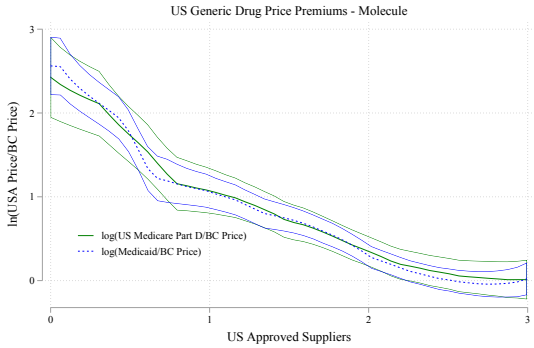
(a) Australia



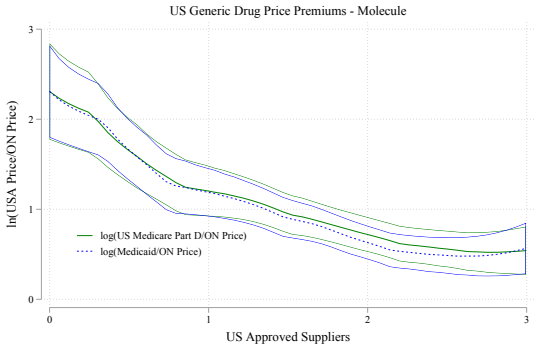
(b) United Kingdom



(c) Canada - British Columbia



(d) Canada - Ontario



(e) New Zealand

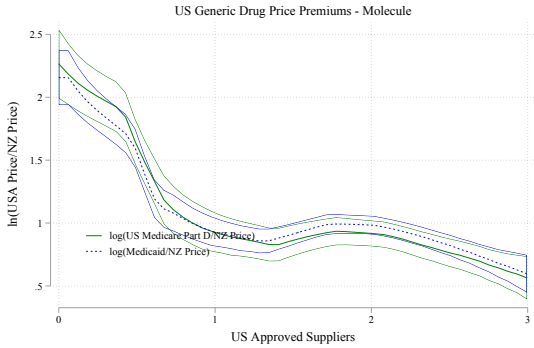


Table A6: Relationship between Price Premiums and Number of US Suppliers - Medicaid Prices Unadjusted for Manufacturer Rebates and Dispensing fees

Notes: Average price difference between the two countries taken across drugs. Regression specification from Equation 4 with standard errors clustered at the molecule level. See text for data sources and details. The sample size changes in the second panel, as the data adjustment procedure leads to a subset of observations with negative prices. It is possible that some states net out dispensing fees, even though the CMS data claims otherwise.

Table A7: Relationship between Price Premiums and Number of US Suppliers - Weighted Regressions

	(1) $ln(p_{US}/p_{AU})$	(2) $ln(p_{US}/p_{BC})$	(3) $ln(p_{US}/p_{NZ})$	(4) $ln(p_{US}/p_{ON})$	(5) $ln(p_{US}/p_{UK})$
ln(US Suppliers)	-1.140***	-1.140***	-0.734***	-0.871***	-0.904***
	(0.113)	(0.0902)	(0.102)	(0.108)	(0.127)
Adj. R-Square	0.290	0.257	0.134	0.160	0.127
Observations	1582	858	1479	344	1625
Fixed Effects	Year	Year	Year	Year	Year

Notes: Average price difference between the two countries taken across drugs (molecule-dose-route). Regression specification from Equation 4 with standard errors clustered at the molecule level. See text for data sources and details.

Table A8: Relationship between Price Premiums and Number of US Suppliers - Molecule Fixed Effects

	(1) $ln(p_{US}/p_{AU})$	(2) $ln(p_{US}/p_{BC})$	(3) $ln(p_{US}/p_{NZ})$	(4) $ln(p_{US}/p_{ON})$	(5) $ln(p_{US}/p_{UK})$
ln(US Suppliers)	-0.988***	-1.046***	-0.634***	-0.789***	-1.276***
	(0.133)	(0.127)	(0.165)	(0.227)	(0.123)
Adj. R-Square	0.699	0.823	0.635	0.771	0.676
Observations	1582	858	1479	344	1625
Fixed Effects	year,drug	year,drug	year,drug	year,drug	year,drug

Notes: Average price difference between the two countries taken across drugs. Regression specification from Equation 4 with standard errors clustered at the molecule level. See text for data sources and details. The sample size changes in the second panel, as the data adjustment procedure leads to a subset of observations with negative prices. It is possible that some states net out dispensing fees, even though the CMS data claims otherwise.

B.2.3 Fixed Effects

Year Fixed Effects

Figure 6 shows the results from estimation of Equation 4 with all years of data pooled. We include year fixed effects and estimate the model relative to the base category 7+ suppliers.

Molecule Fixed Effects

Table A8 shows the results from estimation of Equation 4 with the addition of molecule-level fixed effects.

Figure 6: Medicaid Data - Molecule-Dose-Route: All years

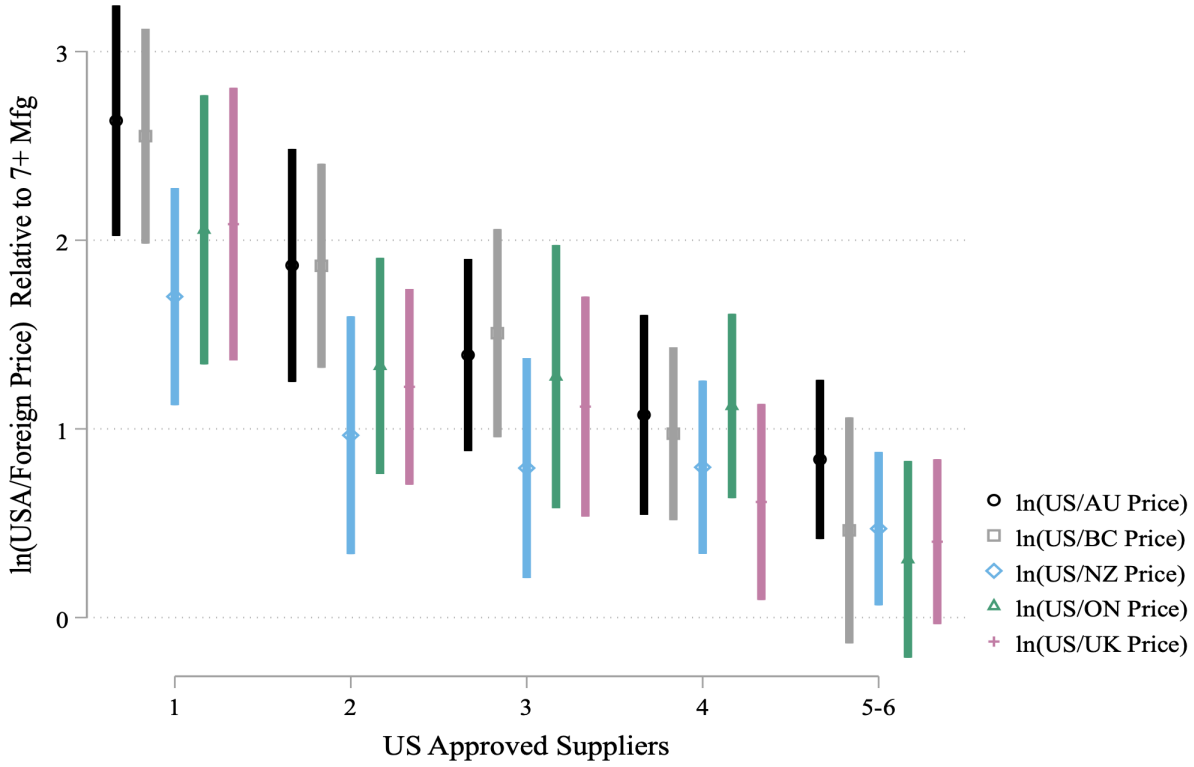


Table A9: Relationship between Price Premiums and Number of US Suppliers - 3 Digit ATC Code Fixed Effects

	(1) $ln(p_{US}/p_{AU})$	(2) $ln(p_{US}/p_{BC})$	(3) $ln(p_{US}/p_{NZ})$	(4) $ln(p_{US}/p_{ON})$	(5) $ln(p_{US}/p_{UK})$
ln(US Suppliers)	-1.123***	-1.071***	-0.712***	-0.851***	-0.881***
	(0.103)	(0.0946)	(0.103)	(0.116)	(0.133)
Adj. R-Square	0.446	0.392	0.282	0.318	0.261
Observations	1580	858	1477	344	1624
Fixed Effects	year,ATC3	year,ATC3	year,ATC3	year,ATC3	year,ATC3

Average price difference between the two countries taken across drugs (molecule-dose-route). Regression specification from Equation 4 with standard errors clustered at the molecule level. See text for data sources and details.

Table A10: Relationship between Price Premiums and Number of US Suppliers - 3 Digit ATC Code-Year Fixed Effects

	(1) $ln(p_{US}/p_{AU})$	(2) $ln(p_{US}/p_{BC})$	(3) $ln(p_{US}/p_{NZ})$	(4) $ln(p_{US}/p_{ON})$	(5) $ln(p_{US}/p_{UK})$
ln(US Suppliers)	-1.066***	-1.069***	-0.659***	-0.851***	-0.886***
	(0.116)	(0.0981)	(0.116)	(0.116)	(0.154)
Adj. R-Square	0.442	0.366	0.240	0.318	0.208
Observations	1580	858	1477	344	1624
Fixed Effects	year-ATC3	year-ATC3	year-ATC3	year-ATC3	year-ATC3

Notes: Average price difference between the two countries taken across drugs (molecule-dose-route). Regression specification from Equation 4 with standard errors clustered at the molecule level. See text for data sources and details.

With ATC Code Fixed Effects In Table A9, we recreate 3 with controls for the 3-digit ATC code, to control for differences in outside options between different drug types.

With ATC Code-Year Fixed Effects In Table A10, we recreate Table 3 with controls for the 3-digit ATC code-year combinations, to control for differences in time-varying outside options between different drug types. Table A11, we recreate Table 4 including foreign entry.

B.2.4 Allowing for Lagged Number of Suppliers

In Table A12, we recreate Table 3 with controls for the 3-digit ATC code-year combinations, to control for differences in time-varying outside options between different drug types.

Table A11: Relationship between Price Premiums and Number of US and Foreign Suppliers - 3 Digit ATC Code-Year Fixed Effects

Medicaid - molecule-dose-route - Year-ATC 3-digit Fixed Effects

	(1) $ln(p_{US}/p_{AU})$	(2) $ln(p_{US}/p_{BC})$	(3) $ln(p_{US}/p_{NZ})$	(4) $ln(p_{US}/p_{ON})$	(5) $ln(p_{US}/p_{UK})$
ln(US Suppliers)	-0.911***	-0.927***	-0.645***	-0.718***	-0.947***
	(0.133)	(0.125)	(0.139)	(0.139)	(0.192)
ln(Foreign Suppliers)	-0.307*	-0.349**	-0.0427	-0.223	0.0331
	(0.119)	(0.120)	(0.161)	(0.128)	(0.208)
Adj. R-Square	0.454	0.379	0.201	0.322	0.260
Observations	1580	756	1415	335	273
Fixed Effects	year-ATC3	year-ATC3	year-ATC3	year-ATC3	year-ATC3

Medicare Part D - Molecule - Year-ATC 3-digit Fixed Effects

	(1) $ln(p_{US}/p_{AU})$	(2) $ln(p_{US}/p_{BC})$	(3) $ln(p_{US}/p_{NZ})$	(4) $ln(p_{US}/p_{ON})$	(5) $ln(p_{US}/p_{UK})$
ln(Part D Suppliers)	-0.503***	-0.855***	-0.501***	-0.727***	-0.225
	(0.144)	(0.185)	(0.119)	(0.174)	(0.171)
ln(Foreign Suppliers)	-0.0758	0.00729	0.117	0.0300	0.127
	(0.120)	(0.144)	(0.153)	(0.132)	(0.194)
Adj. R-Square	0.287	0.382	0.200	0.280	0.0474
Observations	781	245	770	230	192
Fixed Effects	year-ATC3	year-ATC3	year-ATC3	year-ATC3	year-ATC3

NADAC - molecule-dose-route - Year-ATC 3-digit Fixed Effects

	(1) $ln(p_{US}/p_{AU})$	(2) $ln(p_{US}/p_{BC})$	(3) $ln(p_{US}/p_{NZ})$	(4) $ln(p_{US}/p_{ON})$	(5) $ln(p_{US}/p_{UK})$
ln(US Suppliers)	-1.148***	-0.978***	-0.770***	-0.912***	-1.093***
	(0.109)	(0.0871)	(0.112)	(0.103)	(0.177)
ln(Foreign Suppliers)	-0.178*	-0.181*	-0.0954	-0.0734	0.215
	(0.0837)	(0.0769)	(0.130)	(0.0883)	(0.159)
Adj. R-Square	0.528	0.480	0.310	0.410	0.264
Observations	1266	1023	1153	455	358
Fixed Effects	year-ATC3	year-ATC3	year-ATC3	year-ATC3	year-ATC3

Notes: Average price difference between the two countries taken across drugs (molecule-dose-route for panel A and C and molecule for Panel B). Regression specification from Equation 4 with standard errors clustered at the molecule level. See text for data sources and details.

Table A12: Relationship between Price Premiums and Number of US Suppliers - Lagged Number of Suppliers

	(1) $ln(p_{US}/p_{AU})$	(2) $ln(p_{US}/p_{BC})$	(3) $ln(p_{US}/p_{NZ})$	(4) $ln(p_{US}/p_{ON})$	(5) $ln(p_{US}/p_{UK})$
L.ln(US Suppliers)	-1.191***	-1.198***	-0.799***	-1.014***	-1.034***
	(0.132)	(0.105)	(0.119)	(0.120)	(0.143)
Adj. R-Square	0.297	0.256	0.146	0.202	0.149
Observations	1203	748	1120	295	1388
Fixed Effects	Year	Year	Year	Year	Year

Notes: Average price difference between the two countries taken across drugs (molecule-dose-route) . Regression specification from Equation 4 with standard errors clustered at the molecule level. See text for data sources and details.

B.2.5 Instrumenting number of entrants with number of patients.

We may worry that the number of suppliers is correlated with a shock that differentially affects marginal cost across different destinations. To control for that possibility, we assume that the number of patients is exogenous. See Table A13.

B.2.6 Non-parametric Results

In Table A14, we recreate Table 3 dummy variables for the number of competitors.

B.2.7 Non-Branded Only Results

We re-estimate the relationship between the price premium and the number of US suppliers (the coefficients β_s from Equation 3) for US Medicaid using only molecules that do not have any branded US suppliers. The results are shown in Figure 7. Comparing this with Figure 1 suggests that the results are not driven by the inclusion of branded versions of the off-patent drugs.

Table A13: Relationship between Price Premiums and Number of US Suppliers

Medicaid - molecule-dose-route - Number of Approved Sellers Instrumented by number of doses sold

	(1) $ln(p_{US}/p_{AU})$	(2) $ln(p_{US}/p_{BC})$	(3) $ln(p_{US}/p_{NZ})$	(4) $ln(p_{US}/p_{ON})$	(5) $ln(p_{US}/p_{UK})$
ln(US Suppliers)	-1.454***	-1.467***	-1.318***	-1.146***	-1.592***
	(0.172)	(0.138)	(0.151)	(0.168)	(0.170)
Adj. R-Square	0.271	0.236	0.0566	0.144	0.0576
Observations	1582	858	1479	344	1625
Fixed Effects	year	year	year	year	year
First Stage F	266.6	694.9	349.7	360.1	299.0

Medicaid- Molecule- Number of Approved Sellers Instrumented by number of doses sold

	(1) $ln(p_{US}/p_{AU})$	(2) $ln(p_{US}/p_{BC})$	(3) $ln(p_{US}/p_{NZ})$	(4) $ln(p_{US}/p_{ON})$	(5) $ln(p_{US}/p_{UK})$
ln(Part D Suppliers)	-0.485**	-1.004***	-0.514***	-0.587***	-0.366*
	(0.149)	(0.128)	(0.109)	(0.121)	(0.148)
Adj. R-Square	0.126	0.261	0.146	0.188	0.0464
Observations	771	285	793	233	842
Fixed Effects	year	year	year	year	year
First Stage F	429.4	619.1	465.4	496.5	508.5

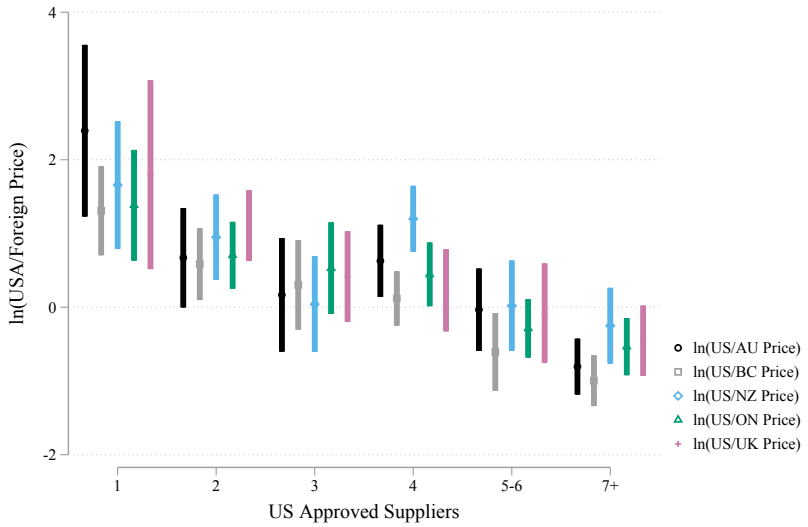
Notes: Average price difference between the two countries taken across drugs (molecule-dose-route for panel A). Regression specification from Equation 4 with standard errors clustered at the molecule level. See text for data sources and details.

Table A14: Relationship between Price Premiums and Number of US Suppliers - Broken Out

	(1) $ln(p_{US}/p_{AU})$	(2) $ln(p_{US}/p_{BC})$	(3) $ln(p_{US}/p_{NZ})$	(4) $ln(p_{US}/p_{ON})$	(5) $ln(p_{US}/p_{UK})$
2	-0.767**	-0.688**	-0.735**	-0.722*	-0.863**
	(0.236)	(0.238)	(0.255)	(0.281)	(0.296)
3-5	-1.480***	-1.422***	-1.025***	-1.130***	-1.294***
	(0.223)	(0.198)	(0.229)	(0.259)	(0.298)
6-10	-2.329***	-2.638***	-1.414***	-2.064***	-1.999***
	(0.242)	(0.216)	(0.231)	(0.258)	(0.313)
11+	-2.669***	-2.294***	-2.310***	-1.553***	-1.870***
	(0.421)	(0.275)	(0.329)	(0.339)	(0.372)
Adj. R-Square	0.277	0.267	0.132	0.159	0.126
Observations	1582	858	1479	344	1625
Fixed Effects	Year	Year	Year	Year	Year

Notes: Average price difference between the two countries taken across drugs (molecule-dose-route) . Regression specification from Equation 4 with standard errors clustered at the molecule level. See text for data sources and details.

Figure 7: Medicaid Data - molecule-dose-route without any US Branded Entrants



Notes: Average price difference between the two countries taken across drugs (molecule-dose-route) with the number of FDA approved competitors of the US. Regression specification from Equation 3 with standard errors clustered at the molecule level. 95% confidence intervals displayed. See text for data sources and details. Year-destination fixed effects are removed by de-meaning.

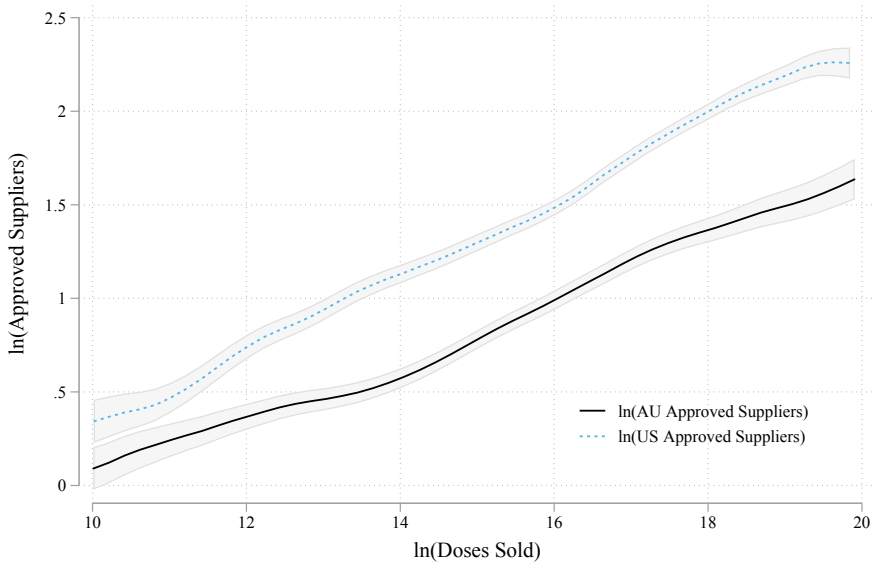
C Motivating Facts

This section presents a series of motivating facts to better understand the marketplace, support our model, and motivate counterfactual simulation. We conduct several empirical exercises with a view to understand the potential for competition policy to be an effective tool at lowering prices in these markets through additional entry. First we show two facts that suggest a link between fixed costs, market entry, and competition. (1) Markets with few patients have few generic entrants. (2) these markets with few US patients have the highest prices in the US relative to foreign countries. This indicates that there may be natural bounds on the number of competitors that the market can support, which would limit the effectiveness of a competition policy. We then continue with two facts that underpin our counterfactual and the estimated model. (3) There is significant variation in the number of pharmaceutical providers across countries. (4) Demand in Medicaid and Medicare Part D are highly inelastic, highlighting the possible need for bargaining power to control buyer costs. These findings all have broad support using three different US data sources: Medicaid, Medicare Part D, and NADAC.

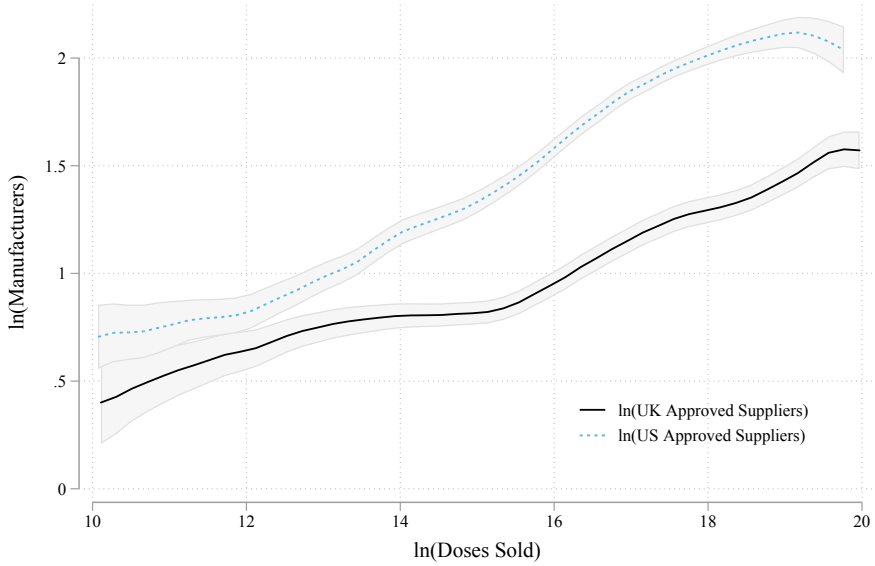
C.1 Market size is highly correlated with the number of competitors

The main finding shows the relationship between the number of suppliers and the price differential between the United States and foreign markets. However, a critical piece of information revolves around the incentives of a generic pharmaceutical supplier to enter a marketplace. If there are few treatable patients requiring a small number of doses, there may be a smaller incentive for a supplier to enter the marketplace. We directly consider the relationship of suppliers to market size in Figure 8. This comparison in only done between Australia, the United States (under Medicare Part D and Medicaid), and the United Kingdom, as these systems make publicly available the total number of capsules/tablets sold.

Figure 8: Relationship between Suppliers and Market Size



(a) Australia-US Medicaid Matched molecule-dose-route



(b) UK-US Medicaid Matched molecule-dose-route

As shown in Figure 8, an increase in the number of prescribed doses is correlated with an increase in the number of suppliers. Across all three countries a doubling in the number of patients is correlated with an approximately 20-30% increase in the number of pharmaceutical suppliers. This means that the marginal benefit of entry in terms of capturing profit from quantity (market size) is approximately the same across countries. This is in contrast to the results of Section 5.1, which showed that marginal benefit to entry to capture profit from higher prices is larger in the United States, than in either Australia or the United Kingdom. One possible rationalization is that the US has higher entry costs (or barriers to entry), preventing supplier entry and lower prices.

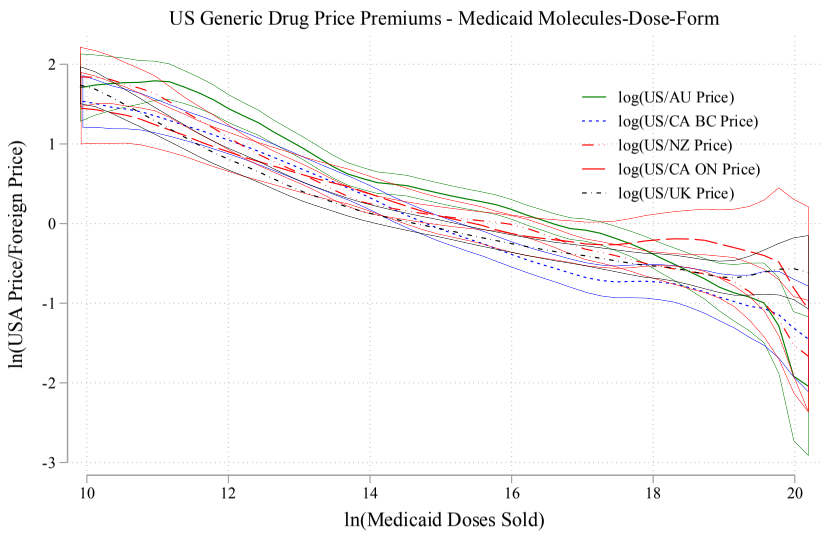
C.2 US Prices are relatively higher in markets with few patients

A natural policy response to insufficient competition would be to allow more entrants. In Figure 9 as market size increases, the US price premium decreases. This combined with the earlier finding that that drugs with few suppliers have large US price premiums indicates that the number of entrants is limited by the underlying demand for a particular molecule from patients and doctors. Reducing barriers to entry may allow more entrants, but there may be natural bounds on the total market size, limiting the effectiveness of such liberalization policies.

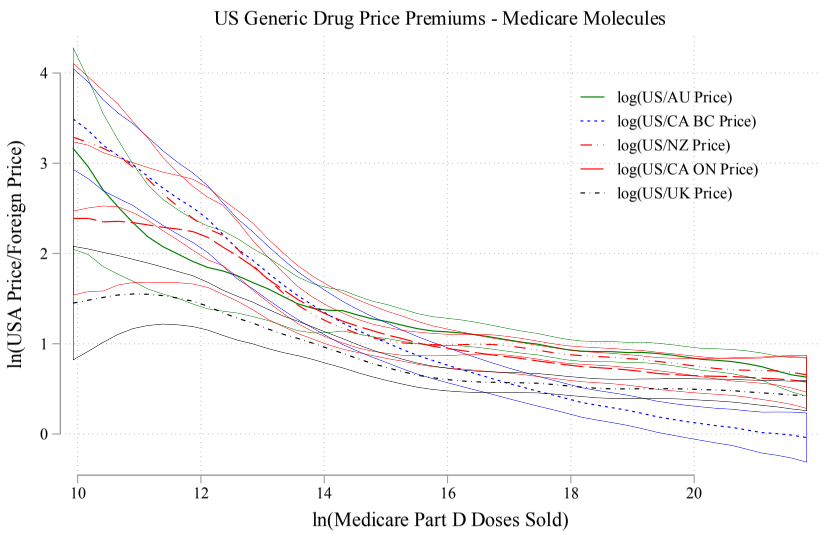
C.3 There is substantial variation in the number of approved drug suppliers by country

Harmonizing market entry across the English speaking world can only be effective at lowering prices if there exist additional entrants. Data from the five countries in our data sample show substantial variation in the number of suppliers at the molecule level. For example, the anti-epileptic generic gabapentin has 28 suppliers in Canada, but only 25 suppliers in the United States. Figure 10 systematically classifies this distribution. In some cases, the US, being a large market, has many more approved suppliers than our comparison countries. However,

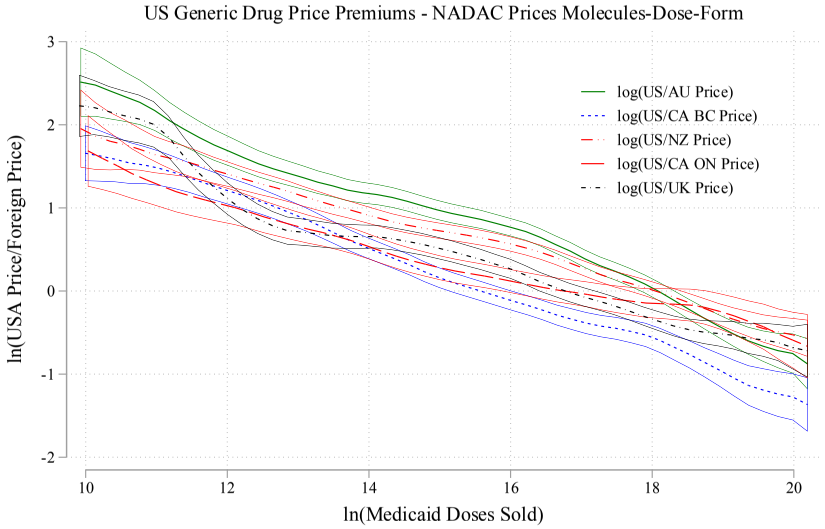
Figure 9: Role of Market Size



(a) Medicaid Data - molecule-dose-route



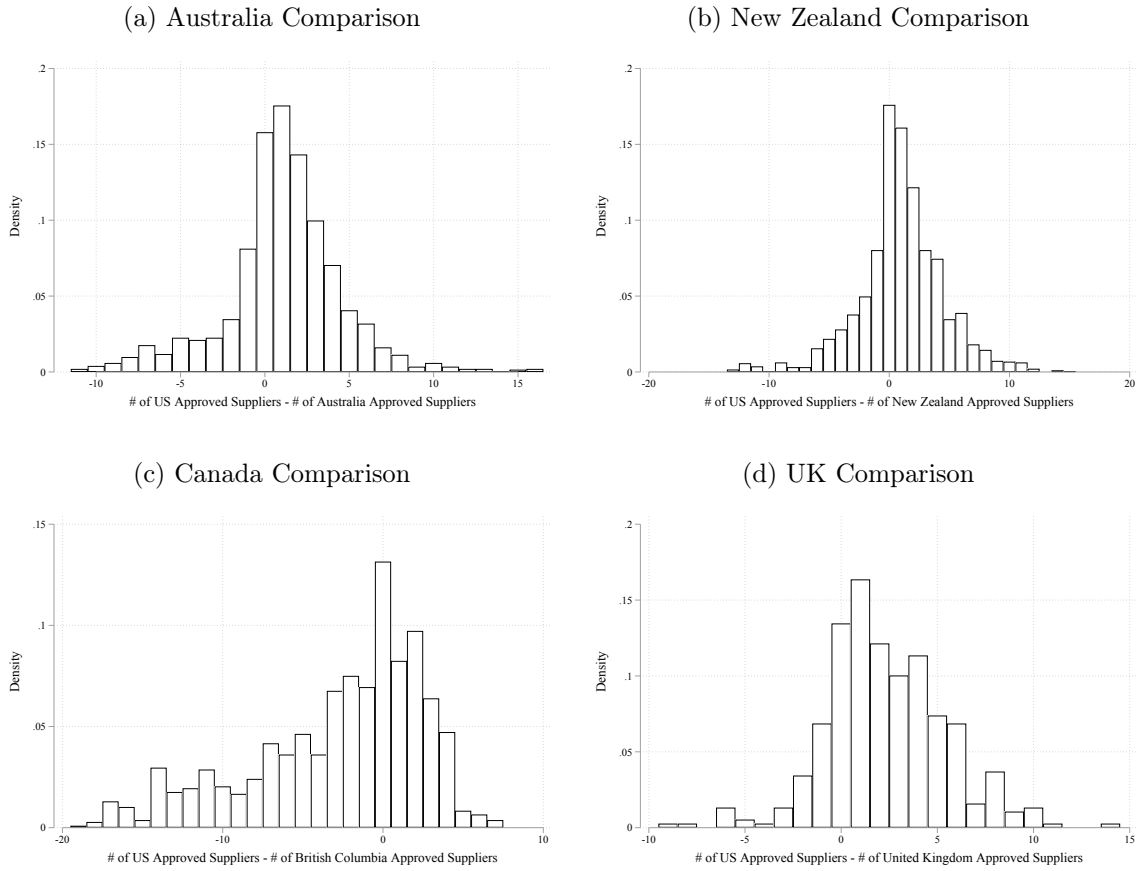
(b) Medicare Data - Molecule



(c) NADAC Data - molecule-dose-route

Notes: Average price difference between the two countries taken across drugs (molecule-dose-route for panel A and C and molecule for Panel B) within the market size of the US.

Figure 10: Differentials in Supplier Numbers



Notes: Supplier data sourced from public data of approvals. See text for further details.

there is a significant left tail of molecules with suppliers that have entered foreign markets, but have not entered the US market. This suggests that allowing such suppliers better access to the US market could have the effect of reducing pharmaceutical prices through competition.

C.4 Validating Assumption: Inelastic Demand

To close out our exploration of off-patent and generic pharmaceuticals, we estimate the elasticity of quantity to the price.[61] This is a molecule-market level demand elasticity, not

[61] There are many studies that compute the elasticity of demand with respect to consumer prices in the United States under various insurance regimes (see Abaluck et al. (2018); Einav et al. (2016, 2015)). However, these elasticities are relative to consumer co-pays, not the supplier's price. Even still, they find extremely small elasticities not far from completely inelastic demand.

a firm-level elasticity. We want to understand how the market size changes with respect to market-level prices. For a model, we need this demand elasticity to understand the incentives of suppliers in their pricing decisions. In many non-American markets, generic demand can be considered completely inelastic as patients and prescribers do not observe costs. This is also largely true for Medicaid patients in the United States. A consumer may pay a nominal fixed co-pay that varies at the state level and is typically either constant or zero for all generic drugs.[62] However, patients in both Medicare Part D and private insurance plans face co-payments and/or co-insurance. For these patients, a straightforward regression of quantity on price at the molecule level is likely to suffer from simultaneity issues.[63]

We propose and implement two independent strategies. We first consider at a subset of drugs with sudden price changes. We then consider global exchange rate fluctuations, that influence marginal costs, but not demand. Both produce similar results, substantially inelastic demand, less than one and near zero. While we are only estimating point elasticities, not the entire demand curve, we do not conduct counterfactual analyses with large upward price changes, and use this local approximation to guide our exercise.

Large Price Increases: We partially circumvent this issue by considering off-patent pharmaceuticals with an overnight price increase of more than 100%. This is plausibly exogenous variation because these price increases primarily occur when the molecules change hands (Berndt et al., 2017). Additionally, we do not believe that such increases in price are driven by demand side factors, but rather supply-side changes regarding drug ownership. We run the following first difference regression to remove the molecule/dose level fixed effects on this subset of pharmaceuticals:

$$\Delta_y \ln Q_{USdy} = \beta \Delta_y \ln P_{USdy} + \delta_y + \epsilon_{USdy}. \tag{13}$$

[62] While this is true for generic pharmaceuticals, this is not entirely true for on-patent and/or innovator drugs.

[63] We also do not consider the entry and exit of related molecules, both generic and under patent. In a robustness exercise, we find that including ATC3-year fixed effects, to control for changes in such markets, has little effect.

The fixed effects δ_y control for time trends in overall prescription trends. We assume ϵ reflects a set of orthogonal shocks and that any demand shifters are differenced out.

Table A15 shows the results for different intervals of time for both Medicaid and Medicare Part D patients using various prices. Panel A considers Medicaid prices and Medicaid doses at the molecule-dose-route level. Panel B considers Medicare Part D prices and Medicare Part D doses at the molecule level. Panel C considers NADAC prices and Medicaid doses at the molecule-dose-route level.

All the results are either economically small or statistically insignificant, suggesting that quantity is very inelastic to price changes. It appears that in both Medicaid and Medicare Part D, off-patent and generic drug consumption is largely insensitive (to a first degree approximation) to prices. Due to institutional details, as Medicaid patients face minimal cost-sharing, we both expect and find almost no correlation with price to consumption. As for Medicare Part D, our results are possibly driven by our consideration of only off-patent pharmaceuticals. Even though there is cost-sharing in nearly all Part D plans, the vast majority of generic drugs appear in the lowest cost tiers and face the lowest levels of cost-sharing with patients.[64] These findings are in line with the extremely inelastic demand from Einav et al. (2016).[65]

International Exchange Rate Fluctuations In a second exercise, we assume that exchange rates are determined largely exogenously from generic pharmaceutical prices. As a large proportion of US generics are manufactured abroad, they are subject to exchange rate fluctuations. As is standard in the literature, we assume that these changes affect marginal

[64] Without individual data, it is impossible to determine the degree of patient-level cost-sharing. However, nearly all Part D plans from private insurance companies list most generic drugs (particularly those in tablet or capsule form) as part of "Tier 1" and "Tier 2", which refer to "Preferred Generic Drugs" and "Generic Drugs" with low co-pays typically ranging from \$0-\$20 for 30 days of treatment. While this is not universal, and insurers may change the tier a generic drug appears on, in our sample this does not seem to affect the quantity produced and purchased.

[65] We are only estimating demand elasticity for drugs that changed prices, over the range of the price change. These tend to be drugs that have limited substitutes. It may be possible that demand for other generic drugs is more elastic. However, a simple OLS regression using the entire pooled data finds similar results.

Table A15: Estimated Price Elasticities - Using Price Jumps

Medicaid - Molecule-Dose-Route

	(1) D.log(q)	(2) D2.log(q)	(3) D3.log(q)	(4) D4.log(q)
Log Price Change	-0.00360	-0.0280	-0.0188	-0.0170
	(0.00756)	(0.0257)	(0.0311)	(0.0373)
Observations	879	1584	1199	879
R^2	0.016	0.034	0.018	0.013
FE	year	year	year	year

Medicare Part D - Molecule

	(1) D.log(q)	(2) D2.log(q)	(3) D3.log(q)	(4) D4.log(q)
Log Price Change	0.0206	0.208	0.0911	0.271
	(0.116)	(0.143)	(0.0724)	(0.219)
Observations	193	143	44	44
R^2	0.071	0.038	0.048	0.047
FE	year	year	year	year

NADAC - Molecule-Dose-Route

	(1) D.log(q)	(2) D2.log(q)	(3) D3.log(q)	(4) D4.log(q)
Log Price Change	0.140	-0.0280	-0.0188	-0.0170
	(0.0917)	(0.0257)	(0.0311)	(0.0373)
Observations	1706	1584	1199	879
R^2	0.019	0.034	0.018	0.013
FE	year	year	year	year

Standard errors in parentheses, * p<.05, ** p<.01, *** p<.001.

Notes: Based on authors' calculations of public expenditures and price data. Adjusted Medicaid prices reflect rebates and accounting for dispensing fees. Data for Medicaid Part D and from NADAC are not adjusted. See text for further details.

costs and are independent of any US-specific demand shocks. Thus we create an instrument:

$$IV_{dy} = \log \sum_{i \in I} \frac{\Delta EP_{d,y,i} \times q_{d,y-1,i}}{\sum_{i' \in I} q_{d,y-1,i'}}$$

This takes the expected price change due to exchange rate variation between y and $y-1$ for drugs sourced from country i from the set of possible country sources I: $\Delta EP_{d,y,i}$ and weights by the lagged share of sales originating from country i. The first stage results in Table A16 show the explanatory power of this instrument. Primarily driven by exchange rate fluctuations to the Indian Rupee, Chinese Yuan, and the Euro, a weakening of the dollar leads to higher prices. The third column shows the estimates, with elasticities near zero.

Taken together, this inelastic nature of demand shows the possible welfare-enhancing role played by strong cost-controlling buyers, and further motivate both our model and our counterfactual with a strong bargaining monopolist buyer. In particular, with inelastic demand, a monopolist selling to a buyer without market power would not be profit maximizing. This motivates a model of bargaining between two sides, each with buying and selling power.

D Structural Model: Additional Discussion

D.1 Competition Examples

We highlight three plausible micro-foundations for $\theta(S)$: Bertrand competition with a homogenous good, Bertrand competition with discrete choice, and Bertrand competition as a repeated game (which can be made equivalent to variants of Cournot competition).

Bertrand Competition: Homogenous Good This case nests Bertrand competition with homogenous goods, where:

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

While this case seems to be rejected in the data, as there is not a stark difference between markets with one and two suppliers, but rather a smooth continuum; this provides a canonical baseline for our other possibilities.

Table A16: Estimated Price Elasticities - Exchange Rate Shocks

Medicaid - molecule-dose-route

	(1) Least Squares	(2) First Stage	(3) Instrumental Variables
D.ln(P)	-0.0350*		0.262
	(0.0146)		(0.194)
ln(Expected Price Change)		0.0479***	
		(0.00833)	
Observations	5016	5016	5016
FE	Year	Year	Year
F-stat	5.782	33.02	1.825

Medicare Part D - Molecule

	(1) Least Squares	(2) First Stage	(3) Instrumental Variables
D.ln(P)	0.0313		-0.103
	(0.0837)		(0.435)
ln(Expected Price Change)		0.0249**	
		(0.00762)	
Observations	1094	1094	1094
FE	Year	Year	Year
F-stat	0.140	10.69	0.0557

NADAC - molecule-dose-route

	(1) Least Squares	(2) First Stage	(3) Instrumental Variables
D.ln(P)	-0.0485*		-0.280
	(0.0237)		(0.346)
ln(Expected Price Change)		0.0241*	
		(0.0120)	
Observations	2490	2490	2490
FE	Year	Year	Year
F-stat	4.202	4.059	0.654

Standard errors in parentheses, * p<.05, ** p<.01, *** p<.001.

Notes: Based on authors' calculations of public expenditures and price data. Adjusted Medicaid prices reflect rebates and accounting for dispensing fees. Data for Medicaid Part D and from NADAC are not adjusted. The first column is a naive OLS estimate. The second column is the first-stage of the IV estimate. The last column presents the results of the IV estimate. See text for further details.

Bertrand Competition: Discrete Choice Analogously, if pharmacists make a discrete choice between S identical suppliers on the basis of price, and buyers have no market power, then:[66]

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

where the logit discrete choice probability of choosing supplier s conditional on prices $\vec{p}$ is (following McFadden et al. (1973)):

$$Pr(s;S) = \frac{\alpha p_s}{\sum_{s' \in S} \alpha p_{s'}}.$$

The parameter α governs the dispersion/sensitivity to price for the downstream pharmacist and is derived from the variance of a standard Gumbel random variable.

Bertrand Competition: Repeated Game Drug makers (both large developers and generic suppliers) tend to be long lived, exist in highly regulated environments, have high barriers to entry, and utilize extremely long and entrenched supply chains. Furthermore, there is extensive information sharing on both prices and quantities through third party organizations that report data with extremely high frequency (IHS Markit, 2018).[67] All of these characteristics (Ivaldi et al., 2003) make the drug supply amenable to tacit collusion, especially when the number of competitors is relatively low. Monitoring rivals is straightforward and threats are credible. We do not take an explicit stance on how this occurs, other than that we can model it through our function $\theta(S)$. The ability to maintain a collusive monopoly-like price is a function of the number of current market participants.

Extension to multiple buyers While all our foreign markets and US Medicaid have a single buyer representing a particular consumer, US Medicare Part D and other US private insurance markets have multiple buyers. These sales are run through many firms, each competing for customers on price. This changes the Nash problem; downstream pharmaceutical

[66] This is obtained since $p = \frac{1}{\alpha\left(1-\frac{1}{S}\right)} + c$ (Berry, 1994).

[67] An extensive economics and medical literature uses various slices of this data, however it is prohibitively expensive to acquire the entire dataset for analysis.

insurance firm profits directly enter into both the payoff and outside option (as opposed to cost minimization). However, we are unable to identify the profits of individual Medicare Part D Insurers. Rather, we continue modeling choices as with a monopolist buyer and consider different bargaining weights as well as different outside options.

D.2 Multiple Heterogenous Sellers

Monopolist buyer and oligopolist sellers In the bulk of our considered markets, all non-US markets and the US Medicaid market, there are multiple drug sellers, but only one buyer. For simplicity and due to data limitations, we assume that all S drug sellers are ex-ante identical. A drug seller maximizes profits $\pi_s = (p_s - c)\, m_s(\vec{p})\, q$, where $m_s(\vec{p})$ is the market share of seller s conditional on the vector of prices $\vec{p}$. A buyer minimizes costs again, where $C_b = \sum p_s m_s(\vec{p})\, q$. The outside option of the seller is to exit the market and make zero profits and the outside option of the buyer is to pay the equilibrium price in a market with $S-1$ sellers. This outside price $\bar{p}_{s,S-1}$ is defined recursively, starting from Equation 6.

As before, the price is determined by the Nash Surplus:

$$NS = (\pi_s)^{w_s} (\bar{p}_b q - C_b)^{w_b}.$$

We assume the same bargaining weights w as before. The major concern here is the determination of the function $m_s(\vec{p})$. Many consider the competition in drug marketplaces to be Bertrand, thus if $p_s > p_{s'}$, then $m_s = 0$. This would result in $p_s = c$ for $S > 1$. However, this seems contrary to our descriptive results, where the US price premium is strictly monotonically decreasing in sellers S and not constant for $S > 1$. We offer two other options, a discrete choice micro-foundation, where pharmacists make allocations based on price or Bertrand competition with capacity constraints.[68]

Taking the logarithm of the Nash Surplus, we obtain:

$$\log NS = w_s \log\left((p_s - c)\, m_s(\vec{p})\, q\right) + w_b \log\left(\bar{p}_{N-1} q - \sum_{s \in S} p m_s(\vec{p})\, q\right).$$

For brevity, we focus on the the first micro-foundation. Pharmacists allocate prescriptions

[68] Alternative explanations include Bertrand competition supported by a repeated game or standard cournot competition where capacity is pre-set.

between drug sellers according to both price and a random-component. Following McFadden et al. (1973), we assume the random component is distributed as a standard Gumbel random variable and that market shares for firm s are:

$$m_s\left(\vec{p}\right) = \frac{\exp\left(\alpha_b \log p_s\right)}{\sum_{s' \in S} \exp\left(\alpha_b \log p_{s'}\right)},$$

where the parameter α_b governs the important of the price in the pharmacists choice and/or the final payers ability to control costs.

Taking first order conditions, we generalize Equation 6, implicitly defining the price:

$$w_b m_s\left(p_s - c\right) = w_s\left(\bar{p}_{N-1} - p_s\right)\left[\alpha\left(1 - \frac{c}{p_s}\right)\left(1 - m_s\right) + 1\right].$$

When there is only one seller, then $m_s = 1$, mechanically simplifying to Equation 6. When buyers have zero bargaining weights, we have results that are aligned with Berry (1994):

$$p_s = \min\left\{\bar{p}_{S-1}, c\frac{\alpha\left(1-s\right)}{\alpha\left(1-s\right)+1}\right\}.$$

When sellers have zero bargaining power, $p_s = c$, as before.

While such estimation is appealing, it has a much higher data requirement for full estimation. In particular, the competition function is not only a function of the competitive structure, but also the relative bargaining weights. We currently do not have enough data, nor enough degrees of freedom, to estimate such a function with any confidence.

E Additional Results

E.1 Medicare and Private Insurance

This section presents the results of the model estimation and counterfactuals using Medicaid, Medicare and NADAC data. Column 1 are the main results (repeated here for convenience of comparison). Column (2) presents results using the Medicaid data but with the market defined at the molecule level so that it is comparable with the market definition used with the Medicare data. Column (3) shows results using the Medicare data and Column (4) using the NADAC data.

Table A17: Joint Estimation Table

	Medicaid Molecule-Dose	Medicaid(d) Molecule	Medicare(d) Molecule	NADAC Molecule
Competition α	-1.07	-1.73	-1.53	-1.34
	(0.13)	(0.26)	(0.27)	(0.25)
Leverage κ_1 US	1.72	1.66	1.89	1.57
	(0.12)	(0.11)	(0.18)	(0.21)
Leverage κ_1 AU	0.00	0.00	0.00	0.00
	(0.03)	(0.00)	(0.02)	(0.00)
Leverage κ_1 BC	0.00	0.00	0.00	0.00
	(0.00)	(0.00)	(0.05)	(0.07)
Leverage κ_1 NZ	0.50	0.20	0.06	0.24
	(0.11)	(0.08)	(0.12)	(0.16)
Leverage κ_1 ON	0.00	0.00	0.17	0.28
	(0.07)	(0.21)	(0.23)	(0.23)
Leverage κ_1 UK	0.77	0.56	0.26	0.65
	(0.13)	(0.12)	(0.23)	(0.14)
Cost Diff US/AU	0.97	1.93	1.89	1.07
	(0.15)	(0.11)	(0.17)	(0.16)
Cost Diff US/BC	0.54	1.02	1.03	0.53
	(0.08)	(0.10)	(0.09)	(0.08)
Cost Diff US/NZ	1.00	1.60	1.49	0.88
	(0.14)	(0.11)	(0.10)	(0.12)
Cost Diff US/ON	0.75	1.36	1.42	0.81
	(0.13)	(0.19)	(0.18)	(0.14)
Cost Diff US/UK	1.70	2.69	2.14	1.42
	(0.22)	(0.17)	(0.22)	(0.21)
Competition κ_2 US	0.06	-0.12	-0.14	0.15
	(0.03)	(0.06)	(0.13)	(0.10)
Competition κ_2 AU	0.03	0.20	0.27	-0.10
	(0.08)	(0.06)	(0.16)	(0.05)
Competition κ_2 BC	-0.02	-0.06	-0.01	-0.11
	(0.01)	(0.04)	(0.12)	(0.10)
Competition κ_2 NZ	0.03	0.02	-0.91	-0.51
	(0.06)	(0.10)	(0.28)	(0.21)
Competition κ_2 ON	0.15	-1.12	-0.47	-0.66
	(0.09)	(0.06)	(0.35)	(0.29)
Competition κ_2 UK	-0.19	-0.04	-1.48	-0.14
	(0.05)	(0.09)	(0.40)	(0.11)
N	7536	4669	2837	2825

Notes: This table uses a GMM estimator to estimate three types of parameters: (1) the estimated intensity of competition, (2) the joint outside option/bargaining parameter, and (3) mean logarithmic cost differences. Competition intensity α is estimated with a single parameter. The leverage parameter κ is decreasing in the outside option $\bar{p}$ and the buyer bargaining parameter w_b, and increasing in the seller bargaining parameter w_s. Results for column 1 are for Medicaid data aggregated to the molecule-dose-route level. Results for column 2 are for Medicare Part D data aggregated to the molecule-level. Results for column 2 are for Medicare Part D price data combine with US supplier data from Medicaid suppliers. United Kingdom supplier data based on 2017 supplier data, not considering possible cross-importation policies. Bootstrapped standard errors reported in brackets.

Table A18: Imputed Excess Entry Cost Estimates

scenario/est ($M)	Medicaid Molecule-Dose	Medicaid(d) Molecule	Medicare(d) Molecule	NADAC Molecule
AU	15.51	11.95	9.82	4.65
	(0.79)	(0.64)	(1.09)	(2.00)
UK	8.44	11.65	8.19	6.14
	(0.67)	(0.59)	(1.00)	(1.84)

Notes: This table takes the estimates and data from the GMM estimation and computes "excess entry costs", which are necessary to justify the fixed costs of entry between the United States and a comparison nation. Bootstrapped standard errors reported in brackets.

Table A19: Percentage Change in **Total** Drug Expenditures

scenario/est (%)	Medicaid Molecule-Dose	Medicaid(d) Molecule	Medicare(d) Molecule	NADAC/Medicaid Molecule
CF 1: Single Market	-9.0%	-3.7%	-2.9%	-2.8%
	(0.9)	(0.7)	(0.7)	(1.2)
CF 2: Foreign Negotiation	-20.3%	-11.5%	-12.3%	-13.8%
	(6.9)	(4.2)	(4.3)	(10.8)
CF 3: Both	-20.7%	-11.7%	-12.4%	-14.1%
	(6.9)	(4.3)	(4.3)	(10.9)
CF 4: Free Entry	-17.5%	-7.1%	-8.3%	-4.1%
	(1.2)	(0.9)	(1.7)	(0.8)
Markets	7536	4669	2837	2825

Notes: Each statistic represent the total cost savings across all off-patent drugs in a particular counterfactual using various data sources. Bootstrapped standard errors reported in brackets. This table takes the estimates and data from the GMM estimation and computes the policy relevant counterfactuals. The columns represent different estimates using different data sources. The rows represent the different counterfactuals. See text for further details.

Table A20: Percentage Change in **Average** Drug Costs

scenario/est (%)	Medicaid Molecule-Dose	Medicaid(d) Molecule	Medicare(d) Molecule	NADAC/Medicaid Molecule
CF 1: Single Market	-11.8% (0.4)	-5.7% (0.4)	-4.9% (0.6)	-5.3% (0.8)
CF 2: Foreign Negotiation	-35.6% (5.7)	-29.1% (4.5)	-28.8% (4.9)	-30.7% (10.5)
CF 3: Both	-36.1% (5.6)	-29.4% (4.6)	-29.1% (4.9)	-31.1% (10.5)
CF 4: Free Entry	-34.1% (1.6)	-21.2% (1.6)	-24.7% (3.1)	-14.3% (0.8)
Markets	7536	4669	2837	2825

Notes: Each statistic represent the average cost savings across all off-patent drugs in a particular counterfactual using various data sources. Bootstrapped standard errors reported in brackets. This table takes the estimates and data from the GMM estimation and computes the policy relevant counterfactuals. The columns represent different estimates using different data sources. The rows represent the different counterfactuals. See text for further details.

E.2 Unconstrained optimization

To be consistent with Nash bargaining, the competition parameter must be greater than 1. In the main text, estimation follows this restriction. In Table A21 and A22, this restriction is loosened. Results do violate the bounding condition, however entry cost estimates and US leverage parameters follow the baseline estimates, but with potentially large standard errors.

E.3 Pair-wise Country Results

In Table A23, we estimate pairwise results between the US and one other destination for Medicaid. In general, our results echo the baseline results. Rather than estimating κ_1 and κ_2, we simply estimate $\kappa = \exp(\kappa_1)$.

Table A21: Joint Estimation Table - Unconstrained Estimation

	Medicaid Molecule-Dose	Medicaid(d) Molecule	Medicare(d) Molecule	NADAC Molecule
Competition α	-0.99	-1.69	-1.48	-1.39
	(0.10)	(0.22)	(0.15)	(0.15)
Leverage κ_1 US	1.76	1.66	1.93	1.50
	(0.15)	(0.13)	(0.17)	(0.18)
Leverage κ_1 AU	-0.24	-2.00	-2.00	-1.99
	(0.09)	(0.01)	(0.01)	(0.22)
Leverage κ_1 BC	-1.97	-1.98	-0.75	-1.65
	(0.02)	(0.55)	(0.68)	(0.61)
Leverage κ_1 NZ	0.47	0.21	-0.15	0.20
	(0.10)	(0.11)	(0.13)	(0.37)
Leverage κ_1 ON	-0.15	-1.98	-2.00	-1.94
	(0.19)	(0.41)	(0.57)	(0.25)
Leverage κ_1 UK	0.74	0.56	0.69	0.61
	(0.14)	(0.14)	(0.18)	(0.19)
Cost Diff US/AU	0.88	1.84	1.74	1.11
	(0.15)	(0.12)	(0.12)	(0.10)
Cost Diff US/BC	0.48	1.03	1.01	0.54
	(0.09)	(0.07)	(0.10)	(0.06)
Cost Diff US/NZ	0.89	1.60	1.42	0.89
	(0.16)	(0.07)	(0.09)	(0.08)
Cost Diff US/ON	0.66	1.39	1.39	0.83
	(0.12)	(0.12)	(0.09)	(0.08)
Cost Diff US/UK	1.52	2.68	2.45	1.44
	(0.28)	(0.11)	(0.21)	(0.16)
Competition κ_2 US	0.09	-0.14	-0.12	0.22
	(0.03)	(0.09)	(0.09)	(0.10)
Competition κ_2 AU	0.17	1.27	1.37	1.26
	(0.06)	(0.05)	(0.08)	(0.14)
Competition κ_2 BC	0.75	0.95	0.50	0.92
	(0.02)	(0.28)	(0.45)	(0.37)
Competition κ_2 NZ	0.07	-0.00	-0.13	-0.29
	(0.05)	(0.10)	(0.10)	(0.29)
Competition κ_2 ON	0.22	1.31	1.36	1.42
	(0.13)	(0.31)	(0.43)	(0.21)
Competition κ_2 UK	-0.16	-0.06	-0.20	-0.09
	(0.05)	(0.13)	(0.11)	(0.14)
N	7536	4669	2837	2825

Notes: This table uses a GMM estimator to estimate three types of parameters: (1) the estimated intensity of competition, (2) the joint outside option/bargaining parameter, and (3) mean logarithmic cost differences. Results for column 1 are for Medicaid data aggregated to the molecule-dose-route level. Results for column 2 are for Medicare Part D data aggregated to the molecule-level. Results for column 2 are for Medicare Part D price data combine with US supplier data from Medicaid suppliers. United Kingdom supplier data based on 2017 supplier data, not considering possible cross-importation policies. Bootstrapped standard errors reported in brackets.

Table A22: Imputed Excess Entry Cost Estimates - Unconstrained Estimation

scenario/est ($M)	Medicaid Molecule-Dose	Medicaid(d) Molecule	Medicare(d) Molecule	NADAC Molecule
AU	10.35	23.03	5.17	2.02
	(1.14)	(55.55)	(277833908083.98)	(6.42)
UK	3.65	5.38	3.45	1.84
	(0.56)	(0.55)	(0.41)	(0.53)

Notes: This table takes the estimates and data from the GMM estimation and computes "excess entry costs", which are necessary to justify the fixed costs of entry between the United States and a comparison nation. Bootstrapped standard errors reported in brackets.

Table A23: Separate Estimation Table - Unconstrained Estimation

	US/AU	US/BC	US/NZ	US/ON	US/UK
Leverage κ US	6.48	4.84	4.29	5.80	9.80
	(0.77)	(0.52)	(0.38)	(1.40)	(1.16)
Leverage κ Foreign	0.94	0.78	1.44	1.26	1.76
	(0.06)	(0.09)	(0.12)	(0.29)	(0.26)
Competition α	-1.19	-2.29	-0.73	-1.47	-0.66
	(0.07)	(0.16)	(0.06)	(0.17)	(0.07)

Notes: This table uses a GMM estimator to estimate two types of parameters: (1) the estimated intensity of competition, (2) the joint outside option/bargaining parameter. Competition intensity $\alpha$is estimated with a single parameter. Results are for Medicaid data aggregated to the molecule-dose-route level. United Kingdom supplier data based on 2017 supplier data, not considering possible cross-importation policies. Bootstrapped standard errors reported in brackets.

Table A24: Monte Carlo Results

	Actual Value	Estimated Average	Standard Deviation
$\kappa_{a,1}$	1.00	1.01	0.10
$\kappa_{b,1}$	0.00	0.02	0.03
α	-1.00	-1.01	0.12
c_{12}	2.00	2.03	0.09
$\kappa_{a,2}$	0.00	0.00	0.04
$\kappa_{b,2}$	-0.05	-0.02	0.06

Notes: This table p resents Monte Carlo simulation results with 500 drugs, with the number of suppliers ranging from 1 to 20, and the marginal cost difference between the two countries drawn from a normal distribution with a mean of 2 and a standard deviation of 1/4. We run 1000 simulations.

E.4 Monte Carlo Results

In Table A24, we run a Monte Carlo simulation of our estimation procedure for two countries, a and b. One country has bargaining leverage $\kappa_{a,1} = 1$ and the other has $\kappa_{b,1} = 0$. The competition parameter α equals -1, illustrating a high level of competition. We take a mean cost difference of 2, with the degrees of competition outside the molecule $\kappa_{a,2} = 0$ and $\kappa_{b,2} = -.05$. We additionally add variation in marginal costs between the countries, drawn from a normal distribution and simulate 500 drugs over 100 simulations. We summarize the results in Table A24. We find that the Monte Carlo estimates largely mirror the actual parameters.