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### **Bargaining and International Reference Pricing in the Pharmaceutical Industry**

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## Bargaining and International Reference Pricing in the Pharmaceutical Industry

#### **Abstract**

The United States spends twice as much per person on pharmaceuticals as European countries, in large part because prices are much higher in the US. This fact has led policymakers to consider legislation for price controls. This paper assesses the effects of a US international reference pricing policy that would cap prices in US markets by those offered in reference countries. We estimate a structural model of demand and supply for pharmaceuticals in the US and reference countries like Canada where prices are set through a negotiation process between pharmaceutical companies and the government. We then simulate the counterfactual equilibrium under such international reference pricing rules, allowing firms to internalize the cross-country externalities introduced by these policies. We find that in general, these policies would result in much smaller price decreases in the US than price increases in reference countries. The magnitude of these effects depends on the number, size and market structure of references countries. We compare these policies with a direct bargaining on prices in the US.

JEL Classification: L22, I18, C51

Keywords: pharmaceuticals, International Reference Pricing, Bargaining, empirical industrial organization

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Bargaining and International Reference Pricing in the

Pharmaceutical Industry

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April 2022 §

Abstract

The United States spends twice as much per person on pharmaceuticals as European countries, in large part because prices are much higher in the US. This fact has led policymakers to consider legislation for price controls. This paper assesses the effects of a US international reference pricing policy that would cap prices in US markets by those offered in reference countries. We estimate a structural model of demand and supply for pharmaceuticals in the US and reference countries like Canada where prices are set through a negotiation process between pharmaceutical companies and the government. We then simulate the counterfactual equilibrium under such international reference pricing rules, allowing firms to internalize the cross-country externalities introduced by these policies. We find that in general, these policies would result in much smaller price decreases in the US than price increases in reference countries. The magnitude of these effects depends on the number, size and market structure of references countries. We compare these policies with a direct bargaining on prices in the US.

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#### 1 Introduction

The pharmaceutical industry represents a significant and growing part of the global economy: pharmaceutical sales amounted to \$1.1 trillion in 2016 and grew by over 30% in the following six years (IQVIA Institute, 2016, 2021). Given the scale of spending, policymakers around the world consistently face political pressure to lower drug prices. But expensive drugs are frequently recent innovations under patent protection, and many of them represent substantial improvements to the treatment and prevention of serious diseases and ailments. Policymakers therefore face the challenge of balancing the immediate benefits of regulating or negotiating for lower drug prices against the long-term benefits of incentivizing pharmaceutical R&D (Lakdawalla et al., 2009; Lakdawalla, 2018).

Innovating new drugs is expensive. The vast majority of attempted pharmaceutical innovations fail to achieve the necessary safety and efficacy to make it to market (DiMasi et al., 2016). The expected cost of innovating a new drug therefore includes not only the highly skilled labor, facilities, and materials needed to develop and test a single successful product, but also the costs of failures along the way. DiMasi et al. (1991, 2003, 2016) document a steady increase in the pre-approval cost of innovating new drugs over time: from \$231 million in 1987 to \$802 million in 2000 to \$2,558 million in 2013. For such large investments to be worthwhile, pharmaceutical firms must expect to make substantial profit in the case that their product does make it to market. The patent protection system aims to accomplish this by shielding new and innovative drugs from generic competition so that innovators may charge prices that are significantly above marginal cost. For example, Gilead Sciences priced its breakthrough Hepatitis C drug, Sovaldi, at \$1,000 per pill in the United States (Pollack, 2015), well above the marginal cost of manufacturing each dose.<sup>1</sup>

While most countries recognize the benefits to incentivizing innovation, few countries aside from the United States allow pharmaceutical companies free reign to set drug prices. Instead, most developed countries negotiate or regulate prices that are much lower than in the US—even for novel patented drugs.<sup>2</sup> For example, the Canadian government negotiated a discount of over 40% on Sovaldi (Miller, 2014).

Americans' outsized spending on pharmaceuticals—40% of total global expenditure and twice as much per person as European countries—has led many in US policy circles to advocate for

 $<sup>^{1}</sup>$ As a measure of marginal cost, note that Sovaldi agreed to sell at 100th the price in developing countries like India (Harris, 2014).

<sup>&</sup>lt;sup>2</sup>In developing countries, on the other hand, lower prices frequently represent highly elastic demand or weak intellectual property protections. In such markets, high prices can dramatically harm consumers without generating substantial profit (Chaudhuri et al., 2006).

price controls (Salter, 2015; OECD, 2017). Every US administration in the last three decades has proposed a flagship program to try to lower prices and shrink the gap. Most recently, the H.R.3 Lower Drug Costs Now Act of 2019 and the H.R.5376 Build Back Better Act of 2021 proposed to do this by requiring that prices in both government and commercial markets not exceed 120% of prices for the same drugs in a set of reference countries.<sup>3</sup> Policies of this form are known as "international reference pricing" (IRF) rules and are commonly used as price controls for pharmaceuticals around the world (Maini and Pammoli, 2022).

Analyses of reference pricing rules being considered in the US—such as those from the Congressional Budget Office (Swagel, 2019; Adams and Herrnstadt, 2021) and academic researchers (Mulcahy et al., 2021)—typically assume that reference pricing would push US prices down to the prices that are currently observed in reference countries. These analyses do not consider the possibility that, in equilibrium, pricing may adjust in reference countries as well, in recognition of the fact that those prices will act as a price ceiling in the US.

In this paper, we develop a model of equilibrium price setting for pharmaceuticals that allows us to predict how prices would adjust in both the US and in reference countries if the US were to implement price controls. To accomplish this, we first estimate models of pharmaceutical demand and pricing under the current regimes in the US and Canada. We then leverage estimated primitives from these models—consumer preferences, marginal costs, and governments' negotiating powers—to simulate equilibrium prices under counterfactual US drug pricing policies. To contribute to the ongoing policy debate, we consider counterfactuals with various forms of international reference pricing rules as well as direct bargaining on behalf of US consumers.

To model demand in the US and Canada, we estimate country-specific random coefficient logit models (Berry et al., 1995) using detailed data from IMS Health (now called IQVIA) on drug prices and quantities across a large number of major therapeutic classes. These demand models capture country-specific preferences for each drug, as well as consumers' price elasticities and branding preferences in each country.

We then estimate a supply model for how prices are set in each country. In the United States, we assume that firms set drug prices to maximize profits without any constraints from regulators. Correspondingly, the marginal costs for US products can be inferred from the estimated elasticities of demand. In Canada, however, we do not assume that prices are set at the profit maximizing levels. Instead, we model prices in Canada as being determined by Nash bargaining (Horn and Wolinsky, 1988; Crawford and Yurukoglu, 2012; Grennan, 2013; Gowrisankaran et al., 2015;

<sup>&</sup>lt;sup>3</sup>Specifically, the bills task the Secretary of Health and Human Services to negotiate prices on behalf of government and private purchasers that are lower than 120% of the average of Australia, Canada, France, Germany, Japan, and the United Kingdom. The law also sets a "target" of the minimum price offered by any one of the countries.

Dubois and Sæthre, 2020) between the firm and the Canadian government. This model can be thought of either as representing negotiations (Collard-Wexler et al., 2019) between firms and the Canadian government or as the Canadian regulator unilaterally setting prices to maximize a combination of consumer surplus and firm profits. We leverage an assumption that cost shocks in the US should be predictive of cost shocks in Canada to simultaneously estimate the Nash bargaining parameters and marginal costs for drugs in Canada.

Using our estimates of consumer preferences, marginal costs, and bargaining parameters, we assess the impact of a counterfactual in which US pharmaceutical prices are subject to international reference pricing with respect to Canada or an average of several similar countries. Crucially, in each of these counterfactuals, we allow negotiations with reference countries like Canada to incorporate the fact that any negotiated price will affect the drug's price ceiling and therefore profitability in the US. This knowledge bears heavily on the negotiations with reference countries, as both firms and governments recognize that firms will not sell in reference markets where the government insists on a price that reduces their US profits too greatly. In other words, the reference price rule means that lower prices in reference countries entails lower profits in the US. This gives firms a credible threat of leaving reference country markets altogether and allows them to insist on higher prices in negotiations with reference country regulators. However, the extent to which reference pricing would result in higher prices in reference countries rather than lower prices in the US depends on many factors, including the competitive structure and size of each market, the elasticities of demand in each country and the bargaining power that regulators have. Moreover, equilibrium price changes depend on the details of the reference pricing rule, such as the number of countries referenced, the amount of premium allowed in the US, and how US regulators respond to instances where firms exit reference countries.

Our results suggest that international reference pricing on its own is unlikely to produce dramatic savings to US consumers. Overall, reference pricing induces a substantial increase in the prices charged in reference countries but only a modest decrease in the prices charged in the US. There is substantial variation in the extent of price changes across therapeutic markets with different types and numbers of alternatives, different marginal costs and different bargaining parameters. Reference pricing is more effective when more countries are included in the reference index: US prices decrease by a greater amount, while prices in reference countries increase by less. It is also more effective when the countries being referenced are larger in size and have more lucrative markets. Still, the size of the US market and the willingness to spend on novel treatments among US consumers makes reference pricing pale in comparison to policies that

would allow regulators to negotiate on behalf of US consumers.<sup>4</sup> Interestingly, we find that global pharmaceutical profits may increase slightly as a result of international reference pricing, as lost profits in the US are offset by increased profits in reference countries.

Our paper contributes most directly to the literature studying externalities from reference pricing and other price controls. Previous work has shown, for example, that international reference pricing can lead to delayed entry in reference countries (Danzon and Chao, 2000; Danzon et al., 2005; Maini and Pammoli, 2022), and that that Medicaid's "most-favored customer" procurement rule (a form of reference pricing) creates cross-market externalities with the commercial market (Scott-Morton, 1997; Feng et al., 2021). Previous work has also shown that global pharmaceutical profits may influence pharmaceutical innovation (Acemoglu and Linn, 2004; Acemoglu et al., 2006; Filson, 2012; Blume-Kohout and Sood, 2013; Dubois et al., 2015). Our work demonstrates how reference pricing rules affect not only total global profits, but also the split of contributions from different countries.

Our paper is structured as follows. Section 2 presents the data underlying our empirical exercise. Section 3 presents the demand model and identification that we use for each market and country. Section 4 introduces the supply side models—both for regulated and unregulated pharmaceutical markets—that we estimate in order to identify structural supply side parameters. It then presents supply side identification and the estimation results. Finally, section 5 develops a counterfactual model of international reference pricing, presents our main results and compares the efficacy of reference pricing policies to reduce US drug expenditures relative to a policy of direct bargaining in the US. Section 6 concludes.

#### 2 Data and Descriptive Statistics

We use data from IMS Health (now called IQVIA) on quarterly revenues and quantities of drugs sold to hospitals from 2002 to 2013. Our data spans the United States and Canada—the markets we study—as well as France, Germany, the UK, Italy, and Spain, which provide auxiliary information on the international market for each drug. Observations in our data are at the product-dosage level by country and quarter, and by hospital, retail or other channel of use. The data also includes product characteristics and the manufacturer name. Since frequently the same drug can be be purchased in multiple dosages (e.g., 50 mg or 100mg) or sometimes even with multiple methods of administration (e.g., tablets and injections), we aggregate across across

<sup>&</sup>lt;sup>4</sup>The notable exception is if the reference pricing rule requires firms to sell in reference countries in order to sell in the United States. Such a rule dramatically reduces the credibility of firms' threats to exit when negotiating prices with reference country governments.

all dosage and administration formats of the same drug using "standard units"—the minimal dosage of a given drug. Finally, we aggregate sales to the molecule-corporation-market level and aggregate all of the generics that are available for each molecule. We compute quarterly drug prices as the ratio of total revenue and total quantity in standard units. We focus on prescription drugs, leaving the question of the consequences of having country-specific definitions of OTC versus prescription drugs for future research.

We define markets for drugs based on the fourth level of the Anatomical Therapeutic and Chemical classification (ATC-4). As the name suggests, the ATC system classifies each drug according to part of the body affected, as well as based on the drug's therapeutic effects and chemical properties. There are five nested levels to the classification, each increasing in specificity from the first level (ATC-1), which specifies the anatomical group, to the fifth level (ATC-5), which specifies the chemical substance. The ATC-4 class of a drug therefore best captures the set of drugs that may reasonably be thought of as substitutes, as they have a similar chemical structure and are used for a similar treatment purpose. We restrict our focus to the ATC-4 classes for which we have at least one on-patent molecule both in Canada and in the US.<sup>5</sup>

Table 2.1 shows descriptive statistics on the number of molecules by on-patent/off-patent branded and generic status within each ATC-4 class, in the US and in Canada. In addition, Table 2.1 displays the share of expenditures of US and Canadian hospital sector pharmaceutical spending that each ATC-4 class represents. There is variation across ATC-4 classes in the proportion of drugs with enforceable patents and correspondingly the proportion of drugs for which generics are available. There is also variation in the share of expenditures that different ATC-4 classes represent between Canada and the US. In Canada, anti-cancer drugs (L1 class) and Immunosuppressants (L4) represent a relatively larger share of total expenditure (around 35%) than the 20% that they represent in the US. By contrast, the share of US spending on injectable anesthetics (N1A2) is much larger (around 15%) than in Canada around (9%) as well as Antiepileptics (N3A0). The distribution of relative expenditures across drug classes is thus different between the two countries, even though the US spends more in absolute value in every ATC-4 class and pays higher prices on almost all drugs, as shown in Table 7.1 in Appendix 7.1.

Although the composition of drugs sold within each class in each country is different, the ATC-4 level average price is much higher in the US in almost every class and quarter. Figure 2.1 shows a scatter plot of log prices in the US against log prices in Canada for the on-patent drugs present in both countries. Almost all drugs are substantially more expensive in the US than in

<sup>&</sup>lt;sup>5</sup>That is, we exclude ATC-4 classes in which Canada does not have any on-patent molecules, while the US does. This typically happens because of the delayed entry of new molecules in Canada.

Canada. While the absolute difference in prices is generally larger for more expensive drugs, the percentage difference in price is relatively small for many of the most expensive drugs.

Table 2.1: Number of molecules and expenditure shares by ATC-4

		Canada				US			
		Number				Number			
ATC4	Label	On Patent	Branded Off Patent	Generics	Expenditure Share (%)	On Patent	Branded Off Patent	Generics	Expenditure Share (%)
A10H0	SULPHONYLUREA A-DIABS	1	1	4	0.05	1	1	5	0.10
C2A2	ANTIHYPER.PL MAINLY PERI	1	3	4	0.49	1	1	4	0.81
C7A0	B-BLOCKING AGENTS,PLAIN	3	3	8	0.20	2	5	10	0.64
C8A0	CALCIUM ANTAGONIST PLAIN	2	3	3	2.10	3	5	5	2.85
C9A0	ACE INHIBITORS PLAIN	7	2	4	2.33	4	3	7	0.99
L1B0	ANTIMETABOLITES	6	2	4	11.96	6	1	7	10.61
L1X9	ALL OTH. ANTINEOPLASTICS	3	1	1	11.32	8	0	3	5.71
L4X0	OTHER IMMUNOSUPPRESSANTS	4	1	2	23.51	6	2	4	13.56
M1A1	ANTIRHEUMATICS NON-S PLN	1	3	6	0.62	1	2	10	0.69
N1A2	INJECT GEN ANAESTHETICS	2	2	5	9.32	2	4	7	17.09
N1B1	ANAESTH LOCAL MEDIC INJ	2	2	3	2.17	2	1	5	2.71
N3A0	ANTI-EPILEPTICS	3	4	10	4.56	6	3	10	12.36
N5A1	ATYPICAL ANTIPSYCHOTICS	3	3	2	28.60	5	1	2	27.40
N5A9	CONVNTL ANTIPSYCHOTICS	6	3	8	0.17	3	2	8	0.24
N5B3	BARBITURATE PLAIN	1	0	1	0.02	1	0	2	0.06
N6A4	SSRI ANTIDEPRESSANTS	1	2	5	1.82	2	1	4	3.05
N6A9	ANTIDEPRESSANTS ALL OTH	3	3	12	0.76	3	2	12	1.15

Note: Average number of molecules (rounded to closest integer) and expenditure shares within country over 2002-2013, by ATC-4 classes (Details on classification in European Pharmaceutical Market Research Association (2018)).

10000 1000 10000 10000 Price in Canada (Log Scale)

Figure 2.1: Comparisons of Prices of On-Patent Drugs Present in Both the US and Canada

Note: Circle sizes are proportional to the sales value of this drug in the US. Prices are in US\$. The red line is positioned at 45 degrees.

Figure 7.1 in Appendix 7.1 presents an analogous plot for generic drugs. Like on-patent drugs, generics are generally more expensive in the US than in Canada. This is especially true for the cheapest generics. However, the ranking of generic prices between the two countries is less systematic than it is among patent products. This reflects the variation in competitive pressures across drug markets. For generics with heavy within-molecule competition, prices are less dependent on local demand and more dependent on marginal costs, and so there is less price differentiation across countries.

#### 3 Demand Model

The extent to which regulators bargaining with pharmaceutical firms can achieve lower prices for consumers depends, in large part, on consumers' willingness to substitute between competing drugs at different price levels. For instance, profit maximizing firms need to consider the ways in which consumer demand will adjust across multiple drugs in order to predict the extent to which additional purchases might compensate for a lower price. Regulators interested in maximizing consumer surplus need to take into account the extent to which consumers priced out of one drug would be willing to switch to an alternative that may deliver similar benefits. In each case, a key determinant of the prices that may arise in equilibrium is the shape of consumer demand.

We estimate a flexible model of aggregate consumer demand for drugs within each market in our data. In order to best capture the substitution patterns that reflect a representative consumer, we focus on drug purchases in the hospital sector. In the US, Canada and most other western countries, hospitals typically internalize the prices of drugs that they purchase on behalf of patients, who pay for treatments and hospital stays through their insurance policy on a per-diem basis. Drug consumption choices by hospitals can therefore be seen as reflecting knowledgeable, price-conscious prescribers who evaluate the merits of each available drug and choose the best option given the available price menu. We model variation in preferences across hospitals with a standard random utility discrete choice framework in which consumers' utility is a function of prices and available drug characteristics.

We do not study the retail sector for pharmaceuticals, as retail demand is likely to conflate a mix of patients' preferences, physicians prescribing incentives, and insurance rules on out-ofpocket cost sharing. Data on the underlying behavior of insurers, health care providers or other intermediaries between patients and drug manufacturers are more difficult to obtain, and are out of scope for our study.

#### 3.1 Demand Specification

We model the pharmaceutical choice problem of a representative consumer as follows. A pharmaceutical market is defined by a level 4 Anatomical Therapeutic Chemical (ATC-4) class, a country (e.g. Canada or the US), and a fiscal quarter. We denote fiscal quarters by t, countries by t and ATC-4 classes by t. Consumer preferences for each drug in a market are defined according to a random coefficient logit framework for differentiated products, following Berry et al. (1995) and Nevo (2001).

Within each country c, a representative consumer i chooses to purchase a drug j from the set of choices  $j = 0, 1, ..., J_{m(j)}$  available in j's drug class,  $m(j)^6$ , according to the indirect utility:<sup>7</sup>

$$U_{ijt} = u_{ijt} + \varepsilon_{ijt}$$

where

$$u_{ijt} = \alpha_i \ln p_{jt} + \beta_{im(j)} g_j + \gamma_i + \lambda_{m(j)} x_{jt} + \phi_j + \mu_{m(j)t} + \xi_{jt}.$$

<sup>&</sup>lt;sup>6</sup>We do not index drug classes by time for simplicity but of course account for the fact that drug classes grow over time as there is entry of drugs along time.

<sup>&</sup>lt;sup>7</sup>All parameters and variables in the utility function, as well as the choice set within an ATC-4 class, are country-specific. We suppress the country index c for ease of exposition. Since each drug is only available in one ATC-4 class, we also suppress the m subscript in market denotations. That is, we consider the demand model country by country, and each unique market that a drug j is available in is denoted by t.

We normalize the utility for the outside good (choosing not to purchase a drug),  $u_{i0t}$ , to zero. We denote the price of drug j at t by  $p_{jt}$ . Drug characteristics are captured by the drug's molecule identifier, patent status and generic status. In our utility specification,  $g_j$  is a binary variable indicating whether drug j is generic,  $x_{jt}$  is a binary variable indicating whether j's molecule patent has expired by quarter t and  $\phi_j$  is a molecule fixed effect. An unobserved shock at the drug-quarter level is denoted by  $\xi_{jt}$ .

Our model captures heterogeneity of preferences across consumers through three types of random effects. Individual utility for purchasing an inside good is captured by the random effect  $\gamma_i$ . Individual disutility from higher prices is captured by the random coefficient  $\alpha_i$  on log prices.<sup>8</sup> Individual preferences for branded drugs are captured by the random coefficient  $\beta_{im}$  on the branded indicator variable. We assume that random coefficients are independently normally distributed with  $\alpha_i \sim \mathcal{N}(\alpha, \sigma_{\alpha})$ ,  $\beta_{im} \sim \mathcal{N}(\beta_m, \sigma_{\beta})$ ,  $\gamma_i \sim \mathcal{N}(0, \sigma_{\gamma})$ , and denote the vectors of parameters  $\theta = (\sigma_{\alpha}, \sigma_{\beta}, \sigma_{\gamma})$ . The mean utility for drug j in quarter j is thus given by

$$\delta_{jt} = \alpha \ln p_{jt} + \beta_{m(j)} g_j + \lambda_{m(j)} x_{jt} + \phi_j + \mu_{m(j)t} + \xi_{jt}.$$

Assuming that idiosyncratic demand shocks  $\varepsilon_{ijt}$  are i.i.d. extreme value distributed, the expected market share of drug j in market mt where m=m(j) is given by the aggregate probability that j will be chosen from the choice set in m:

$$s_{jt}(\delta_{jt}, \theta) = \int \frac{\exp(u_{ijt})}{1 + \sum_{k=1}^{J_m} \exp(u_{ikt})} dF(\nu_{im}; \theta)$$
 (3.1)

where  $\nu_{im}$  denotes the vector of random coefficients  $\{(\alpha_i - \alpha), (\beta_{im} - \beta_m), \gamma_i\}$  and  $F(.; \theta)$  denotes their joint c.d.f.

#### 3.2 Demand Identification

We estimate our demand model according to the standard BLP method with instrumental variables for prices (Berry et al., 1995; Conlon and Gortmaker, 2020). We construct drug-quarter demand shocks  $\xi_{jt}(\delta_{jt}, s_{jt}, \theta)$  by inverting a system that matches the theoretical market shares in equation (3.1) to observed market shares. We then form moment conditions by interacting

<sup>&</sup>lt;sup>8</sup>We use a log price specification because our data covers drugs with prices that vary by orders of magnitude across different ATC-4 markets. While widely used in the literature (Björnerstedt and Verboven, 2016; Gowrisankaran and Rysman, 2012; Berry et al., 1995), this specification does not correspond to a closed form solution for its direct utility function.

the inverted demand shocks with a set of orthogonal instruments  $Z_{jt}$  so that

$$\mathbb{E}\left[Z_{jt}\xi_{jt}(\delta_{jt},s_{jt},\theta)\right]=0.$$

The key challenge to estimation is the identification of the price coefficient distribution. We expect the process of price-setting to be affected by unobserved demand shocks  $\xi_{jt}$ , and so observed prices are likely to be correlated with  $\xi_{jt}(\delta_{jt}, s_{jt}, \theta)$ . Our identification thus depends on the use of instruments that affect prices but are orthogonal to  $\xi_{jt}$ . While the gold standard would be to collect direct cost-shifters for each drug, this is impractical for the scope of our exercise. As we examine a large number of drugs across a large number of therapeutic classes, it is unlikely that we would be able to find detailed cost-shifters that are relevant to all of the classes of drugs that we cover. One possibility would be to restrict our analysis to a few therapeutic classes, find class-specific cost shifters and identify the price coefficient for those classes alone. However, this would limit the scope of our empirical assessment.

Instead, we leverage observed differences and changes in consumers' choice sets from quarter to quarter as our primary source of identification. In particular, we form instruments by collecting, for each drug j in each quarter t, the number of products in j's ATC-4 class, its (broader) containing ATC-3 class, the numbers of generics and off-patent branded drugs that are available—both for j's molecule specifically, and generally within j's therapeutic class—and the number of countries (among France, Germany, Canada, Spain, Italy, the UK and the US) in which j is offered in the hospital sector. These variables capture the variation in the composition of drug j's competition that is driven by the entry of new drugs, expiration of patents, and the exit of outdated drugs. As with BLP instruments, this variation identifies the price coefficient under the assumption that isolation in the product space predicts prices through the competitive channel. To maximize the precision of our estimates, we compute optimal instruments in the style of Chamberlain (1987) using our initial estimation results, and rerun the estimation with the optimal instruments.

The logic of our identification strategy holds whether prices are set to maximize profits or set through bargaining with a regulator. In the case of profit maximization, firms with fewer competitors may exercise more market power and extract more consumer surplus. Similarly, in the case of bargaining, firms with innovative products that do not have clear substitutes may be able to extract higher rents from regulators. Moreover, while changes in the competitive landscape for drug j is likely to impact j's price, the changes themselves are largely driven

 $<sup>^{9}</sup>$ As Reynaert and Verboven (2014) and Conlon and Gortmaker (2020) show, optimal instruments improve the precision, efficiency and stability of BLP estimates.

by technological progress and the ascendance of time. Drugs produced in the US often face delays in entering markets outside the US due to additional regulatory hurdles, and vice versa. Furthermore, patent protection is determined long in advance and entry decisions can take years. Even generic entries often face delays from regulations, start-up costs, etc. and so they provide an additional source of choice set variation. Given all of these factors, it is unlikely that any of our instruments will correlate with the drug-quarter level idiosyncratic demand shocks  $\xi_{it}$ .

Finally, it is important to note that the estimation of BLP-type demand models requires the definition of market shares for products within each market. Our data reports quantities of each drug that is sold. To construct market shares out of these quantities, we require a definition of each drug's market size. Market sizes across countries and ATC-4 drug classes can be very different and change over time. As we do not observe an external estimate of market sizes or the outside share (which would be equivalent), we approximate the aggregate yearly market size denoted by  $M_{mt}$  for each ATC-4 market using a nonlinear least squares calibration procedure similar to that in Huang and Rojas (2013, 2014). We describe this procedure in detail in Appendix 7.2.1. On average, we find that the estimated outside market share is 27.9% in Canada and 22.8% in the US with some variation across ATC-4 classes (see detailed estimates in Appendix 7.2.2).

#### 3.3 Empirical Results on Demand Estimation

We present the estimated demand parameters for the US and Canada in Table 3.1. We find that the random coefficients on log prices ( $\alpha$ ) in Canada and the US have similar negative means. However, while the standard deviation of the price coefficient ( $\sigma^{\alpha}$ ) is relatively small in the US, it suggests substantial heterogeneity in price sensitivity in Canada. There are a number of reasons that might underlie this finding. For instance, price sensitivity may vary across hospital providers or for the same provider, across patients with differences in disease severity. Since Canadian hospitals are publicly funded, they may be more inclined to economize on less severe cases and to vary their expenditure depending on their patient pools.

The random coefficient on preference for generics  $(\sigma^{\beta})$  is large and significant in Canada but statistically indistinguishable from zero in the US. This likely also captures heterogeneity among different types of Canadian hospitals in their purchasing policies and brand exposure. By contrast, the random coefficient on the constant  $(\sigma^{\gamma})$  suggests that there is substantial heterogeneity in the intensity of drug treatments across hospitals in the US, but not in Canada. We account for molecule fixed effects, ATC-4 specific year effects, and ATC-4 specific off-patent and generic effects as well, but do not report these in the table for the sake of exposition.

Table 3.1: Demand Estimates for US and Canada

Country		US		Can	ada
Log Price	$\alpha$	-1.584	(0.10)	-1.273	(0.06)
	$\sigma^{\alpha}$	0.028	(0.07)	0.273	(0.13)
Generic Dummy	$\sigma^{eta}$	0.126	(0.17)	3.313	(0.41)
Constant	$\sigma^{\gamma}$	0.891	(0.16)	0.102	(0.24)
Molecule dummies		Yes		Yes	
Off patent * ATC-4 dummies		Y	es	Yes	
Generic * ATC-4 dummies		Yes		Yes	
Year * ATC-4 dummies		Yes		Yes	
Quarter dummies		Yes		Yes	

Note: Standard error in parenthesis.

We report the corresponding average own- and cross-price elasticities for hospitals in the US and Canada in Table 3.2. To compute these elasticities we first compute own- and cross-price elasticities for each drug using our estimated demand functions in every country, ATC-4 market and quarter. We then aggregate to compute average elasticities across ATC-4 classes and quarters within each country, by branded status and in total. Overall, average price elasticities are a bit higher in the US than in Canada. Within each country, own-price elasticities are slightly higher for branded drugs than for generics. Table 7.3 in Appendix 7.3 breaks down the average elasticities by ATC4 market, showing that there is substantial variation across markets in both own- and cross-price elasticities.<sup>10</sup>

Table 3.2: Average Price Elasticities for Canada and US

	U	S	Canada			
	Own	$\operatorname{Cross}$	Own	$\operatorname{Cross}$		
Branded	-1.512	0.133	-1.110	0.126		
Generic	-1.376	0.147	-1.080	0.137		
All	-1.430	0.142	-1.093	0.132		

Note: Average own price elasticities across all products of ATC-4 markets and over quarters.

<sup>&</sup>lt;sup>10</sup>The estimates are reported for all classes of drugs that we use for demand estimation in the US and in Canada. In some classes, the total quantities sold in Canada are too small to allow for meaningful estimation of demand. These classes are dropped from the Canadian sample, and so we do not report demand elasticities for them in Canada, even though we do estimate and report estimates for the same ATC-4 class in the US. We report elasticities for these classes for completeness even though only ATC-4 classes in which at least one drug is sold (in substantial quantities) in both the US and Canada are used for evaluating counterfactual policies.

#### 4 Supply Side Modeling and Estimates

#### 4.1 Price Setting with Bargaining

We model equilibrium price setting for pharmaceuticals in a regulated market using a Nash bargaining model in which firms maximize profits while government regulators maximize consumer welfare. In our paper, this model will be used to represent the process of price setting in Canada alone, but it could just as well apply to other regulated markets, such as those in the European Union. Nash Bargaining models of this sort—see for instance, Crawford and Yurukoglu (2012); Grennan (2013); Gowrisankaran et al. (2015); Ho and Lee (2017); Dubois and Sæthre (2020); Dafny et al. (2022)—provide a parsimonious way to characterize multiple bilateral negotiations. In our context, they provide a clear way to capture the trade-offs facing policy-makers, who must balance producer profits against consumer welfare in each pairwise negotiation over prices with pharmaceutical firms.

Collard-Wexler et al. (2019) show that "Nash-in-Nash" bargaining equilibria can be microfounded through an extensive form game with alternating offers. Rey and Vergé (2020) provide another microfoundation for such equilibria using a sequential game of delegated negotiations where each firm (here, the regulator) relies on different agents to negotiate with its different partners (here, the pharmaceutical firms) and where one side is randomly selected to make a take-it-or-leave-it offer. We abstract from modeling the exact process of negotiations and use the Nash-in-Nash concept as a tractable way to model equilibrium outcomes. However, in Canada, the bargaining model may be interpreted literally, as the Canadian Patented Medicine Prices Review Board routinely negotiates over prices with drug manufacturers to ensure that they are not "excessive".

As there is currently no nation-wide regulation of pharmaceutical prices in the US, we model price setting in the US through a classic model of Bertrand competition. There is also no international reference pricing rule linking the US market to other markets currently, nor any parallel trade of drugs between the US and other countries (as there is within Europe, Dubois and Sæthre (2020)). This implies that drug prices in the US are determined independently from other markets. We therefore assume that US prices are set in equilibrium through each firm's profit maximizing strategy.

Firm profits are defined as follows. Within a market m at time t, firm f selling products  $j \in F_{fm}$  receives flow profits:

$$\Pi_{fmt} \equiv \sum_{j \in F_{fm}} \Pi_{jmt} \equiv \sum_{j \in F_{fm}} (p_{jt} - c_{jt}) q_{jt}(\mathbf{p}_{mt}).$$

Here,  $c_{jt}$  and  $p_{jmt}$  are respectively the marginal cost and price of drug j. Their difference (the firm's markup) multiplies  $q_{jt}$ , the total quantity of drug j demanded in market m, given the vector of prices  $\mathbf{p}_{mt} = (p_{1t}, ..., p_{J_m t})$  of drugs available in the market. The quantity demanded is given by the size of the market  $M_{mt}$  multiplied by drug j's market share:  $q_{jt} = M_{mt}s_{jt}$ . Firm f's total profit is the sum of its profits across markets:

$$\Pi_{ft} \equiv \sum_{m} \Pi_{fmt}.$$

We assume that government regulators maximize aggregate consumer welfare as revealed by the demand model in their country. We denote the welfare for consumers in market m at period t by (Small and Rosen, 1981):

$$W_{mt}(\mathbf{p}_{mt}) \equiv M_{mt} \int W_{imt}(\mathbf{p}_{mt}) dF(\nu_{im}; \theta) = M_{mt} \int \ln\left[1 + \sum_{j} \exp\left(u_{ijt}\right)\right] dF(\nu_{im}; \theta)$$

$$= M_{mt} \int \ln\left[1 + \sum_{j} \exp\left(\alpha_{i} \ln p_{jt} + \beta_{im} g_{j} + \gamma_{i} + \lambda_{m} x_{jt} + \phi_{j} + \mu_{mt} + \xi_{jt}\right)\right] dF(\nu_{im}; \theta).$$

$$(4.1)$$

That is, consumer welfare is given by the sum of the expected utility produced by each drug available in market m.

We assume that regulators engage in bargaining market-by-market. Since most firms sell a single product within an ATC-4 market, this is equivalent to bargaining product-by-product in the vast majority of cases. As such, neither firms nor regulators are able to bargain jointly over their portfolio of pharmaceutical drugs across markets. We make this assumption for simplicity. As most firms in our sample sell only one drug per ATC-4 class and we exclude the possibility of using bundling arrangements across ATC-4 classes, this assumption does not have a big impact on feasible equilibrium outcomes. We leave the study of equilibrium bundling arrangements as an interesting extension for future research.

As such, prices are set product-by-product in each market m and quarter t, via Nash bargaining between the producer and the market m regulator, to maximize the Nash product of firm profits and consumer welfare. Denoting  $\rho_{jm} \in [0,1]$  as the bargaining parameter that determines the relative weight of the firm's (profit) objective in the Nash bargaining solution, we account for heterogeneity cross drug types in the bargaining process by allowing  $\rho_{jm}$  to vary across ATC-4 markets and by each drug's status as on-patent, branded off-patent or generic. The Nash bargaining solution thus chooses  $p_{jt}$  for each j in market m to maximize:

$$\underbrace{\left(\Delta_{jm}\Pi_{ft}\left(p_{jt},\mathbf{p}_{-jmt}\right)\right)^{\rho_{jm}}}_{\text{Profit from } j \text{ in } m}\underbrace{\left(\Delta_{j}W_{mt}(p_{jt},\mathbf{p}_{-jmt})\right)^{1-\rho_{jm}}}_{\text{Welfare gain from } j \text{ in } m}.$$
(4.2)

Here,  $\mathbf{p}_{-jmt}$  denotes the vector of prices for all drugs other than j in market m and quarter t. The firm's objective is defined as additional profit generated by offering drug j at price  $p_{jt}$  in equilibrium, given by:

$$\Delta_{jm}\Pi_{ft}(p_{jt}, \mathbf{p}_{-jmt}) \equiv \Pi_{ft} - \sum_{j' \neq j, j' \in F_f} \Pi_{j'm(j')t} = \Pi_{jmt}(p_{jt}, \mathbf{p}_{-jmt}). \tag{4.3}$$

Note that eq. (4.3) presents only the profit directly accrued from the sale of drug j, as most firms do not own several drugs per market. If a firm owns several drugs within the same market, Nash bargaining must take into account substitution across the different drugs in their portfolios when setting prices. On the welfare side,  $\Delta_j W_{mt}(p_{jt}, \mathbf{p}_{-jmt})$  denotes the additional consumer surplus generated by the presence of drug j in market m and quarter t, given by:

$$\Delta_j W_{mt}(p_{jt}, \mathbf{p}_{-jmt}) \equiv W_{mt}(p_{jt}, \mathbf{p}_{-jmt}) - W_{mt}(\infty, \mathbf{p}_{-jmt}), \tag{4.4}$$

where  $W_{mt}(\infty, \mathbf{p}_{-jmt})$  denotes, by convention, the consumer surplus when j is absent from the market.

We assume a Nash-in-Nash equilibrium Horn and Wolinsky (1988); Crawford and Yurukoglu (2012); Collard-Wexler et al. (2019). That is, we assume that the vector of competitors' prices  $\mathbf{p}_{-jmt}$ , for competitors of j, are equal to the equilibrium prices in the case of agreement or disagreement. The necessary first-order conditions of the Nash bargaining equilibrium definition in equation (4.2) therefore imply that for all  $j = 1, ..., J_m$ :

$$c_{jt} = p_{jt} + \frac{1}{\underbrace{\frac{\partial \ln q_{jt}(\mathbf{p}_{mt})}{\partial p_{jt}} + \frac{1 - \rho_{jm}}{\rho_{jm}}}_{\text{Demand semi-elasticity}} \underbrace{\frac{\partial \ln \Delta_{j} W_{mt}(\mathbf{p}_{mt})}{\partial p_{jt}}}_{\text{Welfare semi-elasticity}}.$$
(4.5)

Equation (4.5) links the marginal cost to equilibrium demand and welfare-price semi-elasticities, and shows that the equilibrium price should be increasing with the bargaining parameter  $\rho_{jm}$ . Note that the semi-elasticity  $\frac{\partial \Delta_j W_{mt}(\mathbf{p}_{mt})}{\partial p_{jt}}$  is a function of consumer demand itself:

$$\frac{\partial \Delta_{j} W_{mt}\left(\mathbf{p}_{mt}\right)}{\partial p_{jt}} = \frac{\partial W_{mt}\left(\mathbf{p}_{mt}\right)}{\partial p_{jt}} = M_{mt} \int \frac{\partial W_{imt}\left(\mathbf{p}_{mt}\right)}{\partial p_{jt}} dF(\nu_{im};\theta) = M_{mt} \int s_{ijt} \frac{\partial u_{ijt}}{\partial p_{jt}} dF(\nu_{im};\theta).$$

This shows that equilibrium prices can be fully characterized by marginal costs, the bargaining parameter and the shape of consumer demand.

#### 4.2 Supply Side Parameters Identification and Estimation

When the bargaining parameters  $\rho_{jm}$  are known, the set of first-order conditions defined by equation (4.5) pins down the vector of marginal costs  $c_{jmt}$  for the set of estimated demand parameters. When  $\rho_{jm} = 1$ , prices are set according to an unrestricted Bertrand-Nash equilibrium in which firms set prices to maximize profits. In this case, equation (4.5) simplifies to the usual Bertrand-Nash first-order conditions:

$$c_{jt} = p_{jt} + \frac{q_{jt} \left(\mathbf{p}_{mt}\right)}{\partial q_{jt} \left(\mathbf{p}_{mt}\right) / \partial p_{jt}}, \tag{4.6}$$

and we can identify the marginal cost for each product as in Nevo (2001). We will use this special case to identify marginal costs for branded drugs in the US, as there is no central regulation of hospital prices akin to a bargaining game in the US. For generics in the US—which are typically sold at competitive prices by a number of different firms—we assume that  $\rho_{jm} = 0$  so that price is equal to marginal cost  $p_{jt} = c_{jt}$ .<sup>11</sup> The marginal costs of generic drugs in the US are therefore identified directly from observed prices.

In Canada, regulators may have different levels of bargaining power across different types of drugs, and so  $\rho_{jm}$  is a priori unknown. In this case, the identification of marginal costs is less straightforward, and we require additional restrictions on the relationships between marginal costs in the US and Canada in order to identify both bargaining weights and marginal costs (Berry et al., 1995; Dubois and Lasio, 2018).<sup>12</sup> We assume that log marginal costs can be parameterized as additively separable functions of supply-side covariates and an orthogonal error term as follows:

$$\log\left(c_{it}\left(\rho_{im}\right)\right) = z'_{it}\lambda + \omega_{it} \tag{4.7}$$

with

$$\mathbb{E}\left[z_{it}\omega_{it}\right] = 0\tag{4.8}$$

and where  $c_{jt}$  ( $\rho_{jm}$ ) is the solution to equation (4.5). In our application,  $z_{jt}$  includes an intercept and  $\log(c_{jUSt})$  from equation (4.6), with slopes that may vary by patent-status, branding, and year. Our parameterization of marginal costs (4.7) therefore relates the cost of each drug in Canada to the cost of the same drug in the US—which we estimate separately through the unconstrained Bertrand-Nash pricing condition.

<sup>&</sup>lt;sup>11</sup>Generic drugs are often assumed to operate in highly competitive conditions. See, for instance, Reiffen and Ward (2005) for a discussion of industry dynamics.

<sup>&</sup>lt;sup>12</sup>An alternative is to use sign restrictions on marginal costs and markups in order to obtain lower and upper bounds on the bargaining parameter. See Tuncel (2022) for a recent example.

The orthogonality condition in equation (4.8) allows us to define moment conditions using the cost model residuals in each market m in Canada and all j such that m(j) = m:

$$\omega_{jt}\left(\rho_{jm}\right) = \left[1 - z_{jt}'\left(z_{jt}'z_{jt}\right)^{-1}z_{jt}'\right]\log\left(c_{jt}\left(\rho_{jm}\right)\right).$$

We estimate the  $\{\rho_{jm}\}$  for each ATC-4 class m in Canada by minimizing the sum of the squared residuals across the products in m.

$$\{\rho_{jm}\}_{\{j=1,..,J\}} = \arg\min_{\{\rho_{jm}\}_{\{j=1,..,J\}}} \sum_{j,t} \omega_{jt}^2(\rho_{jm})$$
 (4.9)

Intuitively, this procedure identifies the bargaining parameters  $\{\rho_{jm}\}$  by finding the parameters that rationalize the variation in Canadian marginal costs—through equation (4.5)—that is best predicted by variation in US marginal costs. In other words, this approach identifies the parameters that predict the cost shocks in Canada that are best explained by simultaneous cost shocks in the US.

Note that point identification for marginal costs and bargaining parameters relies on our cost equation restriction even if natural bounds that require marginal costs to be positive and lower than prices bind to provide some identification power. Thus, once the shape of demand is identified (parametrically but flexibly through our BLP demand model), identification for the bargaining parameter relies on the fact that the demand semi-elasticity and welfare semi-elasticity generate sufficient variation. We show that this condition is, in general, satisfied in appendix 7.4.

Table 4.1: Estimates of  $\rho_{jm}$  by ATC-4

		On	Branded	
ATC4		Patent	Off	Generic
A10H0	SULPHONYLUREA A-DIABS	0.91	0.51	0.00
C2A2	ANTIHYPER.PL MAINLY PERI	0.66	0.48	0.00
C7A0	B-BLOCKING AGENTS,PLAIN	0.87	0.80	0.04
C8A0	CALCIUM ANTAGONIST PLAIN	0.80	0.53	0.10
C9A0	ACE INHIBITORS PLAIN	0.56	0.50	0.57
L1B0	ANTIMETABOLITES	0.34	1.00	0.32
L1X9	ALL OTH. ANTINEOPLASTICS	0.41	0.00	0.23
L4X0	OTHER IMMUNOSUPPRESSANTS	0.80	0.71	0.15
M1A1	ANTIRHEUMATICS NON-S PLN	0.34	0.48	0.13
N1A2	INJECT GEN ANAESTHETICS	0.58	0.87	0.64
N1B1	ANAESTH LOCAL MEDIC INJ	0.89	1.00	0.57
N3A0	ANTI-EPILEPTICS	0.71	0.38	0.00
N5A1	ATYPICAL ANTIPSYCHOTICS	0.55	0.82	0.00
N5A9	CONVNTL ANTIPSYCHOTICS	0.89	0.00	0.00
N5B3	BARBITURATE PLAIN	0.00		0.00
N6A4	SSRI ANTIDEPRESSANTS	0.76	0.79	0.34
N6A9	ANTIDEPRESSANTS ALL OTH	0.72	0.36	0.04

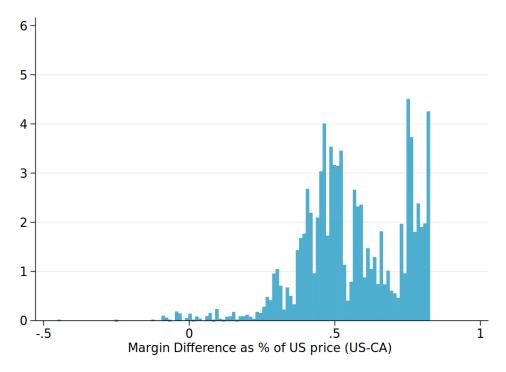
Table 4.1 presents our estimated bargaining parameters in Canada. All on-patent bargaining parameters are between .34 and .91, suggesting that the data cannot be rationalized by unrestricted pricing (which would correspond to a bargaining parameter equal to 1). The median on-patent bargaining parameter is .71 with an interquartile range of .55 to .80. Likewise, the bargaining parameters for branded products that are off-patent are also typically less than 1 with two exceptions, which can be explained by the fact that within-molecule competition may substitute for the regulator's willingness to forcefully bargain over prices.

Our estimates for the bargaining parameters for generics are frequently near-zero, implying that our model best rationalizes many Canadian generic prices as being equal to marginal cost. However, a few exceptions show that in some ATC-4 classes, generic producers do manage to obtain higher prices. We leave for future research, the analysis of bargaining abilities across firms in different markets and market structures. For instance, issues like the risk of shortages are known to be influenced by price levels, and incentives to limit uncertainty in availability could lead regulators to be more or less lenient in price bargaining (Yurukoglu et al. (2017) shows evidence on the role of prices in shortages for the US in this vein). Regulators may also be less aggressive in bargaining in some ATC-4 classes if these classes involve local producers, and faster approvals of some classes of drugs due to the need for orphan designations may justify stronger or weaker price negotiation in some cases.

Our estimates for the bargaining parameters in each drug class also pin down estimates for the marginal cost for each drug through equation (4.5). Table 7.5 in Appendix 7.5 presents the estimated average marginal costs estimates for each class and drug type in the US and Canada. Average marginal drug costs vary across ATC-4 classes, in part because the composition of drugs present varies substantially from market to market. However, marginal costs are in general substantially higher in the US than in Canada for the same product.

Table 7.4 in Appendix 7.5 shows the estimated average margins as a percentage of the maximum average price between the US and Canada (which is almost always the price in the US) by ATC-4 class. The results show relatively large margins—which is not surprising in the case of pharmaceuticals. We also find that margins are larger in the US than in Canada for most drugs. Figure 4.1 draws the distribution of the differences of margins between the US and Canada as a percentage of the US price, weighting the distribution by the quantity sold in the US. The difference is almost always positive, as very few drugs have higher margins in Canada than in the US. Moreover, the graph shows that many products have margins that are 25%-50% the size of the US price. Given that US prices are already quite high, this suggests extremely large differences in profits between the US and Canadian markets in absolute terms.

Figure 4.1: Estimated Margins Differences between US and Canada for On-Patent Drugs



Note: Illustrates the distribution of margin differences weighted by the US quantities of the drug for on-patent drugs present in both the US and Canada. See Figure 7.2 in Appendix 7.5 for weighting by Canadian quantities.

#### 5 Counterfactual Policies

In this section, we apply our structural model to evaluate the impact of a counterfactual international reference pricing policy on equilibrium prices, expenditures, and profits.

Our baseline counterfactual considers a reference pricing rule—also referred to as a "most favored nation" clause—that prohibits pharmaceutical companies from setting higher prices for on-patent drugs in the United States than in Canada. Proponents of reference pricing policies, such as the H.R.3 Lower Drug Costs Now Act that was introduced before the US Congress in 2019 and reintroduced in 2021 under the H.R.5376 Build Back Better Act, often argue that a reference pricing rule would reduce US prices to the pre-policy prices in referenced countries (Mulcahy et al., 2021). However, there is no guarantee that prices will remain at the same low level in referenced countries once such a policy is enacted.

In order to simulate counterfactual equilibrium prices under a reference pricing rule, we extend our model of bargaining between pharmaceutical firms and Canadian authorities to incorporate the knowledge that the negotiated price for an on-patent drug in Canada also acts as a price-ceiling for that drug in the US. Since firms simultaneously set US prices and negotiate in Canada, the equilibrium prices in the US and Canada do come together. But the extent to which prices in the US fall and the resulting consumption, expenditure, and profits in each country increases or decreases is an empirical question, governed by our parameter estimates from Sections 3.3 and 4.2.

We also consider several extensions of our baseline model that help us to disentangle the factors that determine the impact of reference pricing and to understand how variants of reference pricing rules may differ in their efficacy. We consider counterfactuals in which the referenced country is larger than Canada in market size, in which an *index* of multiple countries is used for referencing instead of one country, in which the reference rule allows for a small price premium in the US, and in which firms are required to sell in reference countries as a condition of selling in the US. Finally, we consider a counterfactual in which the US negotiates over prices directly instead of referencing the prices of another country whose regulators negotiate over prices.

#### 5.1 Counterfactual Policies Definitions

#### 5.1.1 International Reference Pricing with Respect to Canada

International reference pricing, as it is typically considered for policy, applies to on-patent drugs only and requires that for any drug j that is sold in both the United States (US) and Canada

(CA), the unit price in the US be weakly lower than the unit price in Canada: <sup>13</sup>

$$p_j^{US} \le p_j^{CA}. \tag{5.1}$$

As this constraint is not satisfied in the status quo environment, reference pricing acts by connecting price setting in the two countries: demand pressures in one country impact price setting in the other. Interconnected price setting has been shown to induce externalities on the availability and consumption of drugs in other contexts. For instance, Danzon and Chao (2000); Danzon et al. (2005); Maini and Pammoli (2022) demonstrate that pharmaceutical firms employ strategic delays in introducing their products to different European countries in order to relax the constraints of reference pricing rules across Europe. In our context, it is likely that the reference pricing constraint will be especially salient: the US market is approximately 10 times bigger than Canada's, and three times bigger than the biggest market (Japan) included in the price index of H.R.3 and H.R.5376. It is thus likely that pharmaceutical firms would comply with reference pricing by adjusting their price setting both in the referenced country and in the US (rather than accept massive losses from price changes in the US alone). We assume that firms optimize their price setting across countries so as to maximize their overall profits, subject to the reference pricing constraint. We do not account for country level differences in taxation of corporate profits because corporate tax rates are similar between the US and the referenced countries being considered. 14

International reference pricing implies that price competition and sales for a drug in the US impose an externality on competition and sales for the same drug in the reference country—and vice versa. The reaction function by which firms set their US prices must therefore take into account both the prices of competing products in the US and the prices set for their own products in Canada. This enters the firm's problem as a constraint on profit maximization. Formally, firm j's US reaction function can be written as:

$$p_{j}^{US}(p_{j}^{CA}, \mathbf{p}_{-j}^{US}) \equiv \arg \max_{p \in [0, p_{i}^{CA}] \cup \{\infty\}} \Pi_{j}^{US}(p, \mathbf{p}_{-j}^{US}) \mathbf{1}_{\{p \le p_{j}^{CA}\}}.$$
 (5.2)

For a given price  $p_j^{CA}$ , which determines the firm's profit in the Canadian market, the firm can either maximize its US profits over the restricted domain of prices below  $p_j^{CA}$  or it can choose not to sell in the US at all. As in Section 4, we use  $p_j^{US} = \infty$  to denote exit from the US market. Drug exit from the US market may be an equilibrium outcome if, for instance, the Canadian market in

 $<sup>^{13}</sup>$ To simplify notation, we exclude the time and drug-class subscripts in this section.

<sup>&</sup>lt;sup>14</sup>See OECD (2021). Note that tax rates may need to be taken into account in other applications. In this case, the objective function of the firm would maximize the sum of profits across countries, net of each country's specific taxes.

a particular ATC-4 class is large enough, Canadian consumers are sufficiently price sensitive, or Canadian marginal costs are sufficiently low relative to the US, that the firm ultimately prefers to sell large quantities in Canada at a price that is too low to be profitable in the US.

The bargaining process between pharmaceutical companies and the Canadian regulator must also adjust to account for international reference pricing. Given a negotiated price  $p_j^{CA}$  in Canada, firm j expects to earn  $\Pi_j^{CA}(p_j^{CA}, \mathbf{p}_{-j}^{CA})$  in Canada and  $\Pi_j^{US}(p_j^{US}(p_j^{CA}, \mathbf{p}_{-j}^{US}), \mathbf{p}_{-j}^{US})$  in the US, where  $p_j^{US}(p_j^{CA}, \mathbf{p}_{-j}^{US})$  is computed by equation (5.2). Firm j's profit from agreeing to a price of  $p_j^{CA}$  in Canada is therefore given by:

$$\Delta\Pi_{j}(p_{j}^{CA},\mathbf{p}_{-j}^{US},\mathbf{p}_{-j}^{CA}) \equiv \underbrace{\Pi_{j}^{US}(p_{j}^{CA},\mathbf{p}_{-j}^{US}),\mathbf{p}_{-j}^{US}) + \Pi_{j}^{CA}(p_{j}^{CA},\mathbf{p}_{-j}^{CA})}_{\text{global profit under agreement}} = \underbrace{\Pi_{j}^{US}(p_{j}^{CA},\mathbf{p}_{-j}^{US}),\mathbf{p}_{-j}^{US}) + \Pi_{j}^{CA}(p_{j}^{CA},\mathbf{p}_{-j}^{CA})}_{\text{global profit under agreement}} = \underbrace{\Pi_{j}^{US}(p_{j}^{CA},\mathbf{p}_{-j}^{US}),\mathbf{p}_{-j}^{US},\mathbf{p}_{-j}^{US})}_{\text{profit if in US only}}.$$

Note that firm j's profit in other countries does not affect this surplus as price setting in countries outside the reference pricing policy's reach is independent of prices in the US and Canada.

Following Horn and Wolinsky (1988), the negotiated price in Canada is given by the maximizer of the Nash product:

$$p_{j}^{CA}(\mathbf{p}_{-j}^{US}, \mathbf{p}_{-j}^{CA}) \equiv \arg\max_{p} \left(\underbrace{\Delta\Pi_{j}(p, \mathbf{p}_{-j}^{US}, \mathbf{p}_{-j}^{CA})}_{\text{profit gain from agreement}}\right)^{\rho_{j}} \left(\underbrace{\Delta_{j}W_{CA}(p, \mathbf{p}_{-j}^{CA})}_{\text{welfare gain from agreement in CA}}\right)^{1-\rho_{j}}.$$
(5.3)

Thus, in equilibrium, prices for on-patent drugs sold in the United States and Canada are jointly defined by equations (5.2) and (5.3).<sup>15</sup> In other words, equilibrium prices  $\{(p_j^{US*}, p_j^{CA*})\}_j$  for each firm j, are characterized by:

$$p_{j}^{US*} = p_{j}^{US}(\mathbf{p}_{j}^{CA*}, \mathbf{p}_{-j}^{US*}),$$

$$p_{j}^{CA*} = p_{j}^{CA}(\mathbf{p}_{-j}^{US*}, \mathbf{p}_{-j}^{CA*}).$$
(5.4)

In Appendix 7.6, we show that US prices must (weakly) decrease and Canadian prices increase in any equilibrium where the solution to equation (5.4) is interior and no firms exit the market.<sup>16</sup> However, the effectiveness of a reference pricing policy toward curbing expenditures in the US

<sup>&</sup>lt;sup>15</sup>The usual profit maximizing and bargaining conditions must also hold for all other products in both countries. <sup>16</sup>For simplicity, we focus our theoretical results on cases where the pharmaceutical firm is a monopolist or a

duopolist. We then show that the results generalize under mild assumptions on the concavity of each firm's profit in its own price and the strategic complementarity in prices across firms.

depends crucially on the magnitude of equilibrium price changes under reference pricing, as well as on the subsequent changes in domestic consumption.

#### 5.1.2 Variations of Reference Pricing Rules with Respect to Canada

Our baseline model of international reference pricing imposes several assumptions that may not be implemented exactly as is. First, we assume that reference pricing is exact: the price of a drug in Canada is a tight upper bound on the price in the US. A common alternative policy, often referred to as a "Most Favored Nation" clause would link the prices in the US and reference country, but allow a limited gap in between them. For example, H.R.3 and H.R.5376 consider a 20% additional premium over an average international market price. To see how this might change our results, we consider a modification of our reference pricing model in which the price constraint is relaxed according to:

$$p_i^{US} \le (1+\eta)p_i^{CA} \tag{5.5}$$

where  $\eta$  is the maximum premium above the Canadian price that is allowed in the US.

Whereas a "Most Favored Nation" clause is a relaxation of the reference pricing policy, we also consider a strengthening. Our baseline model assumes that firms may choose not to sell a drug in the reference country (Canada) if they would prefer to avoid the reference pricing constraint in the US market. This implies that the disagreement payoff of a firm negotiating in Canada is given by the unconstrained maximum profit in the US market (and zero in the Canadian market). An alternative policy might instead require that drug producers continue to sell any drug that had previously been offered in the reference country in order to also sell it in the US. This is a very strong constraint, as it implies that finding an agreement in Canada is necessary for selling in the US—and that the agreed upon price will serve as reference price for the US.

In this case, the Nash surplus of the firm negotiating over the price of drug j in Canada is:

$$\Delta\Pi_{j}(p_{j}^{CA}, \mathbf{p}_{-j}^{US}, \mathbf{p}_{-j}^{CA}) = \Pi_{j}^{US}(p_{j}^{US}(p_{j}^{CA}, \mathbf{p}_{-j}^{US}), \mathbf{p}_{-j}^{US}) + \Pi_{j}^{CA}(p_{j}^{CA}, \mathbf{p}_{-j}^{CA}).$$
(5.6)

In effect, this "required comparison" constraint provides the Canadian regulator with the ability to directly negotiate a price for both the Canadian and US markets. The firm's disagreement payoff when negotiating with the Canadian regulator becomes zero (due to zero sales in both countries), giving the regulator substantially more leverage to obtain a lower price for both countries in equilibrium. As such, a "required comparison" policy may seem highly desirable

from a US perspective. But this entails a very strong commitment on behalf of US consumers: it requires that the US market be willing to reject innovative drugs that can save lives and improve welfare on the basis of bargaining decisions made by an unaccountable Canadian regulator. It would also mean that the US would not be able to accept innovative drugs that cease to be reimbursed by the reference country—potentially abandoning fast access to innovation—and that price levels would be determined, in part, by the welfare gain that different drugs provide to reference countries that may have different health care needs and disease prevalence. Given the scale of the US market, it might therefore be more plausible for the US to instead negotiate on behalf of its own consumers without appealing to Canadian regulators at all. We detail this case in Section 5.1.4.

#### 5.1.3 International Reference Pricing with respect to a set of Countries

Although our baseline counterfactual considers reference pricing with respect to one country, many policies being considered in practice instead refer to an index of multiple countries. In order to account for this possibility, we consider the model where the US requires the price of each on-patent drug to be weakly lower than its average price across a set of countries  $\mathcal{C}$  in which the product is sold:

$$p_j^{US} \le \overline{p_j^{\mathcal{C}}} \equiv \frac{\sum_{c \in \mathcal{C}} p_j^c \mathbb{1}_{\{j \text{ is in } c\}}}{\sum_{c \in \mathcal{C}} \mathbb{1}_{\{j \text{ is in } c\}}}.$$

$$(5.7)$$

This reflects policies such as, for example, Title I of the H.R.3 Lower Drug Costs Now Act and Title XIII subtitle J of the H.R.5376 Build Back Better Act, which proposes a price index reference rule using an average of six countries prices (Australia, Canada, France, Germany, Japan, UK). As in equation 5.2, the US reaction to a given reference price index is characterized by:

$$p_{j}^{US}(\overline{p_{j}^{\mathcal{C}}},\mathbf{p}_{-j}^{US}) \equiv \arg\max_{p \in [0,\overline{p_{j}^{\mathcal{C}}}] \cup \{\infty\}} \Pi_{j}^{US}\left(p,\mathbf{p}_{-j}^{US}\right) \mathbf{1}_{\{p \leq \overline{p_{j}^{\mathcal{C}}}\}}.$$

Assuming that bargaining in all referenced countries occurs simultaneously, the price negotiation with each reference country c of firm j must therefore satisfy:

$$\max_{p_j^c} \quad \Delta \Pi_j(p_j^c, \mathbf{p}_{-j}^{US}, \mathbf{p}_{-j}^c, \overline{p_j^c})^{\rho_j} \Delta_j W_c(p_j^c, \mathbf{p}_{-j}^c)^{1-\rho_j}$$

where the Nash surplus of firm j's total profit from agreeing with country c and internalizing the reference pricing constraint in the US is:

$$\Delta\Pi_{j}(p_{j}^{c},\mathbf{p}_{-j}^{US},\mathbf{p}_{-j}^{c},\overline{p_{j}^{C}}) \equiv \underbrace{\Pi_{j}^{US}(\overbrace{p_{j}^{US}(\overline{p_{j}^{C}},\mathbf{p}_{-j}^{US})}^{\text{US price reaction}},\mathbf{p}_{-j}^{US}) + \Pi_{j}^{c}(p_{j}^{c},\mathbf{p}_{-j}^{c})}_{\text{global profit under agreement}} - \underbrace{\Pi_{j}^{US}(\overbrace{p_{j}^{US}(\overline{p_{j}^{C}},\mathbf{p}_{-j}^{US})}^{\text{US price reaction}},\mathbf{p}_{-j}^{US})}_{\text{profit if in US only}}.$$

Here,  $\overline{p_j^{C \setminus c}}$  denotes the average price of drug j in reference countries other than c. Note that the profits of countries other than the US and c do not appear in the firm's negotiation with c. This is because in a Nash equilibrium among all countries, the profits in other countries cancel out of the Nash surplus with country c. But, of course, equilibrium prices in other countries matter for overall profits. Under the indexed international reference pricing rule, equilibrium prices  $\{(p_j^{US*}, p_j^{c*})\}_{j,c}$  must satisfy the following conditions for all j and all  $c \in \mathcal{C}$ :

$$\begin{split} p_j^{US*} &= p_j^{US}(\overline{p_j^{\mathcal{C}^*}}, \mathbf{p}_{-j}^{US*})\\ p_j^{c*} &= p_j^{c}(\mathbf{p}_{-j}^{US*}, \mathbf{p}_{-j}^{c*}, \overline{p_j^{\mathcal{C}^*}}). \end{split}$$

Although we do not estimate supply and demand for all six countries being considered in the H.R.3 and H.R.5376 bills (Australia, Canada, France, Germany, Japan, UK), we simulate the indexed international reference pricing equilibria with varying number of replicas of Canada. Adding more countries to the index gives regulators more leverage over pharmaceutical firms, as exiting one country does not allow firms to evade the reference pricing constraint. Our simulations therefore highlight the impact of additional reference countries on driving lower equilibrium prices across different ATC-4 markets.

#### 5.1.4 National Bargaining in the US

Instead of relying on referencing pricing alone, a US regulator might instead prefer to bargain directly with pharmaceutical firms. The advantage of direct bargaining is that it is independent of other countries' pricing behavior. Direct bargaining allows US price setting to prioritize US consumer welfare, and to take into account observations of (often, earlier) entries of innovative drugs to other markets without being bound by their prices abroad. To evaluate this possibility, we consider a model of equilibrium bargaining over US prices by a hypothetical US regulator that aims to maximize US consumer surplus and can leverage a bargaining weight  $\rho_{jUS}$ . As in the case of baseline Canadian price setting, the counterfactual prices of this policy are given by

the solution to the following Nash in Nash bargaining equilibrium:

$$\underbrace{\left(\Delta_{jUS}\Pi_{ft}\left(p_{jt},\mathbf{p}_{-jUSt}\right)\right)^{\rho_{jUS}}}_{\text{Profit from } j \text{ in } US} \underbrace{\left(\Delta_{j}W_{USt}(p_{jt},\mathbf{p}_{-jUSt})\right)^{1-\rho_{jUS}}}_{\text{Welfare gain from } j \text{ in } US} \tag{5.8}$$

where  $\mathbf{p}_{-jUSt}$  denotes the vector of prices for all drugs other than j in the US that are available in quarter t. As before, the firm's objective is defined as the additional equilibrium profit generated by offering drug j at price  $p_{jt}$ :

$$\Delta_{jUS}\Pi_{ft}(p_{jt},\mathbf{p}_{-jUSt}) \equiv \Pi_{ft} - \sum\nolimits_{j' \neq j,j' \in F_f} \Pi_{j'm(j')t} = \Pi_{jUSt}(p_{jt},\mathbf{p}_{-jUSt}).$$

The welfare gain  $\Delta_j W_{USt}(p_{jt}, \mathbf{p}_{-jUSt})$  is the increase in consumer surplus obtained from purchases of drug j at price  $p_{jt}$ , given the prices of alternative drugs  $\mathbf{p}_{-jUSt}$  and the consumer demand estimated in section 3.

#### 5.2 Counterfactual Simulations

Using our estimates for the parameters governing supply and demand from Sections 3 and 4, we simulate the counterfactual equilibrium under each policy considered above. Although, by design, the reference pricing constraint applies only to drugs with active patents, the optimal pricing conditions for all drugs in a given market may shift in response to a change in the price of on-patent drugs. Our counterfactual simulations therefore compute new equilibrium prices and purchases for all drugs—including generics and branded off-patent drugs—in each affected market. For each counterfactual, we examine the effects on equilibrium prices in both the US and Canada, as well as the effects on total expenditures, consumer welfare and cross-country profits for firms. As reference pricing does not bind when there is no on-patent drug within an ATC-4 class in both the US and Canada, our counterfactuals concern only time periods and ATC-4 drug classes for which at least one on-patent drug is sold in both countries.

#### 5.2.1 Reference Pricing with respect to Canada

We first examine our baseline reference pricing policy, in which US prices for on-patent drugs are required to be weakly lower than their Canadian counterparts. Table 5.1 reports the impact that reference pricing has on the average price of the on-patent drugs themselves in each ATC-4 class. Our results indicate that the rule generates a binding price constraint: in equilibrium,  $p_j^{US} = p_j^{CA}$  for all on-patent drugs. Overall, this leads to small price decreases in the US and to large price

increases in Canada<sup>17</sup>. The effect on the prices of patented drugs in the US ranges from 0% to -21.18% across ATC-4 classes, but averages to only -7.54% across classes. By contrast, prices in Canada increase substantially—in some cases, more than ten-fold—with an average increase of 215.99% across ATC-4 classes.

The overarching result of international reference pricing with respect to Canada is to equate the prices for on-patent drugs in the US and in Canada at a price point that is a bit below the baseline US price. Intuitively, the reason for this effect is twofold. First, because baseline US prices are typically much higher than Canadian prices, the reference pricing rule implies that Canadian prices must increase, while US prices must (weakly) decrease if the product continues to be sold in both countries. Indeed, because the US market is much larger than the Canadian market, linking the two gives firm much more leverage than in their unilateral negotiations with the regulator in Canada in the status quo. Generally speaking, it is much more costly for firms to reduce the US price by one dollar than to increase the Canadian price by one dollar, and so we would expect prices in Canada to rise more than US prices fall. However, there is variation in the magnitude of the policy impact across drug markets with different market conditions and bargaining parameters.

For instance, the L1B0 class, for which the bargaining parameter is relatively low (as shown in Table 4.1), exhibits one of the largest price increases due to reference pricing. This suggests that bargaining confers a strong deflationary effect on Canadian prices for L1B0 drugs in the status quo. However, the efficacy of the Canadian regulator's bargaining power still falters under reference pricing, given the size and profitability of the US market. By contrast, while the L1X9 class also has a relatively small bargaining parameter—indicating that the Canadian regulator obtains lower prices than the profit maximizing ones—it exhibits a much smaller price increase as a consequence of the reference pricing policy. This is likely because L1X9 is a class where many on-patent drugs are not offered in Canada, while generics have a very large market share. The status-quo average prices for on-patent drugs that are sold in both countries are therefore closer together, and reference pricing does not have as much of an impact.

Figure 5.1 shows how the differences in profit margins for on-patent drugs between the US and Canada change under the reference pricing policy. In blue, we replicate the empirical distribution of margin differences under the status quo. In translucent red, we plot the empirical distribution of counterfactual margin differences under reference pricing with respect to Canada. While nearly all of the observationsh ave margin differences that are above 0 (meaning that  $(p^{CA} - c^{CA}) > (p^{US} - c^{US})$ ) in the status quo, this relationship is reversed in the counterfactual.

<sup>&</sup>lt;sup>17</sup>The drug class C2A2 is the unique exception in that it exhibits a larger price for on-patent drugs in Canada so that the reference pricing policy does not bind.

Table 5.1: Counterfactual Prices of On-Patent Drugs when International Reference Pricing w.r.t. Canada

	Befe	ore	Aft	fter		
	Canada	US	Canada		$\overline{\mathrm{US}}$	
ATC4	Price	Price	Price	$\Delta$ (%)	Price	$\Delta$ (%)
A10H0	0.63	1.03	1.03	62.58	1.03	-0.03
C2A2	57.76	17.32	57.76	0.00	17.32	0.00
C7A0	1.08	1.95	2.04	88.84	1.95	-0.40
C8A0	1.06	2.19	2.12	99.71	2.12	-3.34
C9A0	0.55	1.78	1.40	154.08	1.40	-21.18
L1B0	247.97	506.81	429.14	73.06	429.14	-15.33
L1X9	545.32	579.99	593.76	8.88	570.61	-1.62
L4X0	4.98	10.03	8.47	69.92	8.25	-17.70
M1A1	0.67	3.07	2.16	220.97	2.16	-29.72
N1A2	21.11	51.54	49.59	134.92	49.59	-3.78
N1B1	12.56	16.47	16.42	30.74	16.42	-0.30
N3A0	1.55	3.79	3.72	139.40	3.72	-1.71
N5A1	2.75	13.51	12.24	345.22	12.24	-9.43
N5A9	0.82	1.36	1.33	60.96	1.33	-2.51
N5B3	2.67	61.87	52.46	1863.08	52.46	-15.21
N6A4	1.53	3.68	3.61	135.45	3.61	-1.90
N6A9	0.39	1.15	1.10	184.14	1.10	-4.10
Unweighted Mean				215.99		-7.54

Note: Market shares weighted average price of patented drugs by ATC-4 and country for drugs present in both only. On-patent prices of drugs present in both countries are always equal after the reference pricing policy implementation but the average of these by drug class may differ because of different usage and because of some on-patent drugs present only in one country. Percentage changes are changes with respect to the initial situation. Unweighted mean is mean across ATC4 of the percentage price change.

The drastic shift in the distribution of margin differences suggests that while status quo margins are relatively large in the US, reference pricing would not only increase the margins in Canada, but also push them beyond the US margins for a substantial number of on-patent drugs. Since on-patent prices equalize between the two countries in the counterfactual equilibrium and US prices do not decrease very much, the change in margin differences is driven almost entirely by the large increase in Canadian prices due to reference pricing. Thus, without changing anything else in the Canadian market or regulatory structure, reference pricing allows firms to attain a much higher unit markup in Canada than they could sustain in equilibrium when negotiations are independent of the US.

Although the change in price-to-cost margins effectively demonstrates the direct impact of reference pricing, it is insufficient for describing the impact on national expenditures or firm profits—both of which account for the endogenous quantities purchased under counterfactual prices, as well as for substitution to/from competing off-patent and generic drugs. Table 5.2

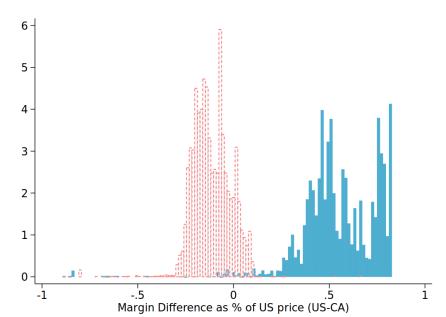


Figure 5.1: Current and Counterfactual Margins Differences for On-Patent Drugs

Note: The empirical distribution of the difference between margins in Canada and the US,  $(p^{CA} - c^{CA}) - (p^{US} - c^{US})$ , normalized by each drug's US price and weighted by the quantity of the drug sold in the US. The dotted distribution is the counterfactual while the solid one is the estimated current distribution. See Figure 7.3 in Appendix 7.5 for the equivalent figure normalizing by Canadian prices.

reports the changes in expenditures across all drugs in each ATC-4 class for each country. The effects are not uniform across ATC-4 classes. In the A10H0 class, effective expenditures change by less than .1% in both countries—likely because this class has only one on-patent drug whose market share is very small. Meanwhile, in the L1B0 class, Canadian expenditures increase by 62% while US expenditures decrease by 18.5%—likely because status quo negotiated prices in Canada are relatively low due to the regulator's bargaining power in this class. However, the overall effect on expenditures falls in line with the direct effect on prices. The average decrease in expenditure across affected classes in the US is 5.53%, while the average increase in Canada is 41.74%. On the other hand, as Table 7.10 in the appendix shows, these changes lead to a slight increase in firm profits overall. Although profits do decrease slightly in the US market due to price decreases, they are fully compensated by profit increases in Canada with a small additional net gain.

Table 5.2: Counterfactual Expenditure Changes on All Drugs when International Reference Pricing w.r.t. Canada

		Canada			$\overline{\mathrm{US}}$	
ATC4	Before	After	$\Delta~(\%)$	Before	After	$\Delta~(\%)$
A10H0	392	392	-0.0	11065	11065	0.0
C2A2	1468	1468	0.0	34117	34117	0.0
C7A0	3027	3042	0.5	134842	134827	-0.0
C8A0	12454	14306	14.9	240970	237764	-1.3
C9A0	8646	11361	31.4	52300	52116	-0.4
L1B0	32322	52268	61.7	408366	332673	-18.5
L1X9	28033	28797	2.7	201395	200119	-0.6
L4X0	58224	83548	43.5	478261	433363	-9.4
M1A1	1666	1703	2.2	26388	26638	0.9
N1A2	23090	24018	4.0	602738	603092	0.1
N1B1	6434	6578	2.2	114498	114519	0.0
N3A0	11284	11477	1.7	436053	435938	-0.0
N5A1	70817	125231	76.8	966348	888414	-8.1
N5A9	2584	2586	0.1	51089	51084	-0.0
N5B3	138	145	4.8	5856	6118	4.5
N6A4	6018	6960	15.6	143410	142491	-0.6
N6A9	2509	2517	0.3	54167	54163	-0.0
Total	247648	351009	41.74	3527247	3332173	-5.53

Note: Expenditures are average yearly in 1000 US\$ (from the period 2002-2013).  $\Delta$  stands for the change in expenditure between after and before in percentage of initial expenditure.

#### 5.2.2 Alternative Specifications and Direct US Bargaining

Our counterfactual results in Section 5.2.1 suggest that reference pricing is not likely to be effective at reducing pharmaceutical expenditures in the US: despite the large gap in status quo prices between the US and Canada, average US expenditures decrease by less than 6% under reference pricing. Although this result is driven by a number of factors—the shape of demand in each country, the amount of bargaining power that the Canadian regulators have, the market structure of molecule entry as well as generic producer entry, and the marginal costs of different drugs—a key driver of the result is the discrepancy between the market size in Canada and in the US. Simply put, the US market is much larger than the Canadian market. Indeed, the US market is substantially larger than that of any Western economy. In this section we examine the extent to which reference pricing may be more effective under alternative specifications that give more weight to the referenced country.

First, we consider reference pricing with respect to an index of multiple countries as described in Section 5.1.3. We then consider reference pricing with a required comparison as characterized in Equation (5.6). Finally, we consider a counterfactual in which instead of reference pricing, US regulators directly bargain with firms as described in Section 5.1.4. As we cannot identify the

counterfactual bargaining weight that the US regulators would have, we consider 50-50 bargaining here as the benchmark bargaining outcome, and show the average effect on price with varying bargaining parameter for firms.

The top panel of Figure 5.2 plots counterfactual prices for all on-patent drugs in the US (on the vertical axis) against their status-quo prices in Canada (on the horizontal axis) in log scale. Each color corresponds to one counterfactual policy: international reference pricing with an index of six countries (IRF with six countries), international reference pricing with required comparison (IRF with required comparison) and US bargaining. Note that for all counterfactuals except for US bargaining, the counterfactual prices of on-patent drugs are equal in the US and the reference country. Under the US bargaining equilibrium, Canadian prices don't change from their status quo levels and the green dots need to be compared to the 45 degree line to infer if prices go up or down.

As a baseline, we plot the status quo prices in blue, replicating the points in Figure 2.1. As US prices are generally higher than their Canadian counterparts in the status quo, the blue prices are almost all above the 45-degree line. Moving down toward the 45-degree line, IRF with six countries policy—plotted in red—lowers US prices relative to the status quo across the board. This is seen most clearly for the cheapest and most expensive drugs at the bottom left and upper right corners of the figure, which are more easily discernable. As in the baseline IRF counterfactual, IRF with six countries equates US prices with Canadian prices for all drugs that continue to be sold in reference countries in equilibrium. Our simulations do not predict any drug exits in any of the Canada replicas, and so the equilibrium prices for affected drugs are guaranteed to be weakly lower than the initial US prices. As we show in Figure 5.3, the magnitude of the price decrease strengthens as the number of reference countries increases. As such, the red price points bound the price decrease under IRF policies with fewer reference countries.

Moving down further, IRF with required comparison policy, plotted in purple, pushes US prices to touch—and occasionally breach—the 45-degree line. That is, while it also equalizes prices between the US and Canada in equilibrium, IRF with required comparison brings US prices down much closer to the initial status quo prices in Canada than the basic IRF policy—even with six reference countries. While striking, this result is not theoretically surprising. Whereas basic IRF policies empower the firms' bargaining positions with reference countries by fortifying the relative attractiveness of their disagreement payoff, IRF with required comparison does the reverse. Under basic IRF, firms compare selling their drugs in both the US and the relatively smaller reference countries at a lower price against selling only in the US for a higher price. If

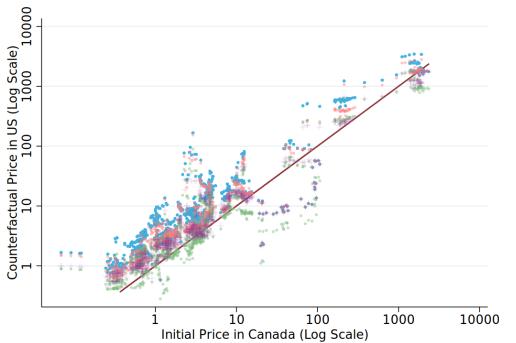
the common price is too low, the firms might prefer to just sell in the US. By contrast, in IRF with required comparison, firms weigh selling in both the US and in Canada at a (potentially) lower price against not selling the drugs at all. This gives the Canadian regulator significantly more bargaining power, and produces a much more favorable outcome for US consumers.

However, US bargaining with 50-50 bargaining weights, plotted in green, pushes US prices even further down, often exceeding the 45-degree line so that US prices become lower than even the status quo prices in Canada. Unlike the other counterfactual policies that we consider, US bargaining is not constrained by Canadian demand or regulatory strength. As such, prices could be lower in the US than in Canada or other reference countries. Indeed, prices could be lower in the US just on the basis of demand (e.g. differences in preferences for certain drugs due to domestic health care needs and disease prevalence), even if the US regulators had the same bargaining parameter that their Canadian counterparts do.

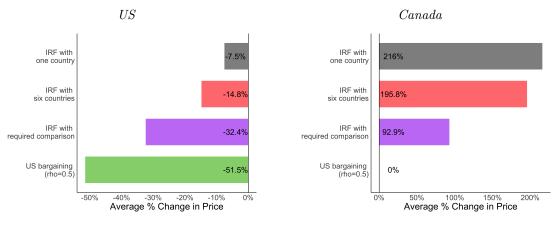
The bottom panel of Figure 2.1 summarizes the price differences between the counterfactual and status quo prices in each country. Although the IRF policies equalize prices in the US and Canada in equilibrium, the average on-patent drug price in Canada increases by nearly 200% under IRF with six countries, while the average price in the US decreases by about 15%. Comparing with IRF with only one country, the difference is meaningful for the US: the price difference is nearly doubled. Still the qualitative impact of IRF is the same: prices in the US decrease by far less than the status quo price gap, while prices in the reference countries face overwhelming increases. By contrast, compared to the baseline international reference pricing policy, IRF with required comparison doubles the price decreases in the US while increasing Canadian prices by about half on average. Thus, IRF with required comparison offers a substantial improvement over baseline IRF from the perspective of both US and Canadian consumers. That said, the bottom bar suggests that if direct US bargaining were a feasible alternative, the tradeoffs between benefiting US consumers and harming Canadian ones may not be necessary. Under 50-50 US bargaining, Canadian prices are not affected at all, while average US prices decrease by over 50\% on average and, as we explained earlier, become more aligned with the trade-offs between US consumer surplus from each drug and firms' profits.

Thus far in our discussion, we have considered reference pricing policies with respect to the Canadian market as it is—and potentially replicas of Canada as it is. However, most policies being considered refer to an index of different countries with different market sizes. To examine this possibility, we consider variations of the IRF with an index of countries counterfactual, in which the countries being referenced are two or three times the size of the Canadian market. While in practice, the reference index that will be used is likely to contain a variety of countries

Figure 5.2: Price Comparisons for Patented Drugs under Counterfactual Policies



 $\bullet \ \ Status \ \ Quo \ \bullet \ \ IRF \ with \ six \ countries \ \bullet \ \ US \ bargaining \ \bullet \ IRF \ with \ required \ comparison.$ 



Note: The top panel plots log-prices of on-patent drugs in the US against their analogues in Canada with the 45 degree line in red. The bottom panels plot the average change in price levels across all on-patent drugs in each country.

with different market sizes, our results can be thought of as bounds on how effective a mixed index might be. We consider reference indices with between 1 and 6 reference countries, each with a market that is the size of Canada, twice larger or three times larger than Canada. Among the six countries considered by the H.R.3 policy proposal (and H.R.5376), Germany, Canada, Japan spend approximately the same amount per capita on drugs, while Australia, France, and the UK spend approximately 30% less per capita (OECD, 2017). As the population of Japan is a bit more than three times as large than Canada's and Germany's population is a bit more than twice as large as Canada's, we are considering reference markets that are in the ball park of what these policy proposal include. <sup>18</sup>

Figure 5.3 plots the average ratio of the prices for on-patent drugs in the US under different IRF policies relative to the prices for the same drugs in Canada under the status quo. As equilibrium prices are the same in the US and in Canada under IRF, this also represents the average ratio of prices in Canada under the counterfactuals relative to the status quo. As a reference, the horizontal blue line plots the status quo, showing that the current ratio of US prices to Canadian prices for patented drugs available in both countries is 3.2 on average. The red lines represent the average price ratio under IRF with respect to replicas of the Canadian market (straight line), countries twice the size of the Canadian market (long dashes) and countries three times the size of the Canadian market (short dashes), as the number of reference countries increases from one to six.

The top left point of the straight red line indicates that IRF with respect to the status quo Canadian market (as in Section 5.2.1) brings the average price ratio down to 2.7. Moving across the horizontal axis, it is clear that increasing the number of reference countries decreases the average price ratio further, but even with 6 countries, the counterfactual price is 2.3 times higher than the status quo Canadian price on average. Referencing larger markets leads to higher efficacy for the policy as well. IRF with countries twice the size of Canada generates average price ratios from 2.1 to 2.5, and IRF with countries three times the size of Canada generates average price ratios from 2 to 2.3.

The straight green line plots the effect of the MFN premium rule on equilibrium prices. Unsurprisingly, allowing US prices to exhibit a 10% price premium above Canadian prices leads to higher prices in the US than under the baseline reference pricing rule. With a 10% price premium, we find that a 0.83 share of the 10% price premium goes into the reduction of Canadian prices, rather than an increase of the US price compared to the no premium equilibrium case.

<sup>&</sup>lt;sup>18</sup>Detailed results by ATC4 class of this international reference pricing policy with respect to six countries are reported in appendix 7.7.

However, the passthrough of the 10% premium becomes smaller when the number of reference countries increases, going down to 0.70 with six countries.

3.2 Status quo 3 Ratio of Counterfactual US Price to Status Quo Canadian Price 2.8 2.6 2.4 2.2 2 1.8 IRF with required comparison 1.6 1.4 1.2 1 2 3 5 6 1 Number of reference countries

Figure 5.3: Relative Prices for Patented Drugs: US vs Canada Across Counterfactual Policies

Note: Average of ratios of prices of on-patent drugs present in both countries across all classes between the US and the Reference Country under the different counterfactuals.

— Statu quo — IRF with respect to countries of Canadian size — IRF with respect to countries of two times the Canadian size — IRF with respect to countries of three times the Canadian size — IRF with 10% MFN — IRF with required comparison

Figure 5.4 compares the average price ratio for on-patent drugs under IRF with required comparison against direct bargaining by US regulators. Whereas in Figure 5.2, we consider US bargaining under the assumption of 0.5 bargaining weights (e.g. with the bargaining parameter  $\rho$  set to 0.5), Figure 5.4 shows that the efficacy of US bargaining in reducing prices, more generally, is concave in  $\rho$ . That is, even a small amount of bargaining power—say, when  $\rho$  is 0.9 rather than 1.0 as in the case of oligopolistic competition without bargaining—reduces the average price ratio substantially. Moreover, while lower values of  $\rho$  (such that US regulators have relatively more bargaining power) correspond to larger price savings, any  $\rho$  below approximately 0.6 improves upon IRF with required comparison on average.

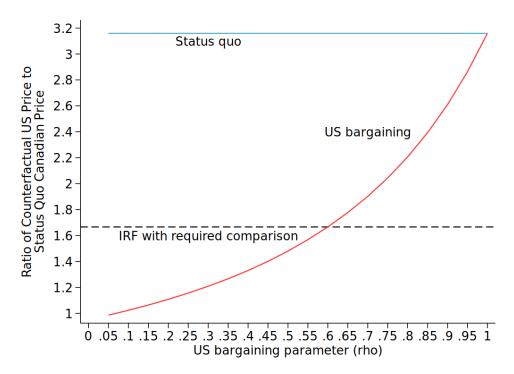


Figure 5.4: Average Effects on Prices if US Bargaining Only

Note: Average of ratios of prices of on-patent drugs present in both countries across all classes between the US and the Reference Country when the US bargains over price independently from the reference country. — Statu quo — US bargaining according to firms bargaining parameter  $\rho$ .

Table 5.3 presents the effects of IRF with one country, six countries or required comparison and of 50-50 US bargaining on total yearly expenditure across all drugs within each country and ATC-4 class. Whereas reference pricing with respect to six countries decreases expenditures in the US more than reference pricing with respect to one, expenditures in Canada increase less with six countries than with one. Similarly, reference pricing with required comparison generates a higher decrease in expenditure in most ATC-4 classes in the US, while increasing expenditures in Canadian markets by much less than the baseline IRF policies.

However, not all ATC-4s see decreases in expenditures in the US from IRF—even with required comparison. For several ATC-4s, such as N5B3 (sedative/hypnotic drugs in the "plain barbiturates" class), IRF causes US prices of on-patent drugs to decrease, but winds up increasing overall expenditures. The reason for this is that price decreases may cause market expansions that overwhelm the lower unit costs in markets with strong demand. Taking N5B3 as an example, the on-patent drug Pentobarbital is priced two to four times higher in the US than in Canada in the status quo (with variation in the exact ratio over time). Under the baseline IRF policy, the US price for Pentobarbital decreases by over 14% on average, but the price of the generic drug

in the class, Phenobarbital, does not substantially change.<sup>19</sup> As a consequence, the quantity of Pentobarbital that is demanded increases, drawing consumers from the cheaper generic and from the outside option. Given the shape of demand, the increase in Pentobarbital sales overwhelms the decrease in price, so that net expenditures in the ATC-4 rise by 4.5%. When the price decrease is higher, as under IRF with required comparison, this effect is even stronger and US expenditures rise by over a third.

Meanwhile, whereas direct US bargaining has no effect on expenditures in Canada, it leads to large overall expenditure decreases in the US, with a decrease of over 40% in the Antipsychotics class N5A1, the largest US ATC-4 class in our study. In fact, US bargaining leads to larger decrease in expenditures than the International Reference Pricing with required comparison in many of the ATC-4 classes. The reason for the difference between the two counterfactuals is that the determinants of equilibrium prices in each case are slightly different. Price setting under US bargaining depends entirely on the price elasticities among US consumers and their implications for profits in the US market. IRF with required comparison, on the other hand, trades off global profits against Canadian consumer welfare. In ATC-4 classes where Canadian consumers are willing to spend less than their US counterparts, IRF with required comparison may not reduce prices as much even if regulators had the same bargaining parameters. In the N5A1 class, in particular, the status quo difference in average prices was the largest among the classes we study, suggesting substantial differences between demand in the two countries.

Table 7.6 in appendix 7.7 shows the consumer welfare effects of each policy. It confirms the ranking of the effects of each policy on prices of on patent drugs in the US and the reference countries is the same as the ranking of welfare.

Table 5.4 presents the counterfactual profits that firms earn in each ATC-4 in each country under the same four policies. Table 5.5 then presents the total global firm profits for each ATC-4, summed across all countries under each policy. Overall, the changes in profits within each country are analogous to the changes in prices and expenditures: firm profits in the US fall by over 40% under direct 50-50 bargaining, by over 30% under IRF with direct comparison, by nearly 17% under IRF with six countries, and by nearly 8% under IRF with one country. Similarly, firm profits in Canada increase by over 60% under IRF with one country, by over 40% under IRF with six countries and by over 18% under IRF with required comparison.

However, these percent amounts reflect changes from status quo profits within each country. Once profits across all countries involved are summed, the total profits decrease by nearly 2% under IRF with one country, but increase by 2.21% under IRF with six countries. The reason

<sup>&</sup>lt;sup>19</sup>See Table 7.14 in the appendix for a detailed breakdown of price changes by the patent status of drugs in each ATC-4.

for the sign change rests in how many countries are involved in reference pricing. Although total profits under IRF with six countries are lower within each individual reference country than under the baseline IRF policy, the total sum of profits across all six countries compensate for the higher profit losses in the US. By contrast, global profits decrease by over 20% under required comparison, since profits in Canada are overwhelmed by profit losses in the US. Under direct 50-50 US bargaining, in which profits in Canada are unaffected, global profits decrease by over 27%.

Finally, note that while it is possible that the pharmaceutical industry would benefit from a version of international reference pricing—as in the case of the six country reference index—this does not mean that the industry could implement the same equilibrium outcome (and increase its profits) absent the broad implementation of such a policy by the US government. Indeed, not all firms would benefit from uniform pricing (across countries) and profitable deviations would likely be inevitable. Moreover, the overall increase in profits for the pharmaceutical industry would have non-uniform effects on firms' profit. This might, for example, benefit producers of generics disproportionately as price increases for on-patent drugs in reference countries would generate more substitutions towards generics. The dynamic effects of reference pricing on future innovation would depend on whether the profits on innovation increase or decrease. Determining the answer to these empirical questions is beyond the scope of our study and we leave the study of long term effects on innovation for future research.

 ${\bf Table~5.3:~Counterfactual~Expenditure~Changes~on~All~Drugs}$ 

		Can	ada				US		
		Int.	Ref. Pri	cing		Int.	Ref. Pric	cing	
		$(N \leq I)$	$(9 \Rightarrow_N)$	Comparison		$\stackrel{\widehat{M}}{\underset{\mathcal{S}}{\not\sim}} \Delta$	(N  eq 6)	Comparison	$\nabla B_{augaining} \\ (\%)$
ATC4	Before	$\Delta~(\%)$	$\Delta~(\%)$	$\Delta~(\%)$	Before	$\Delta~(\%)$	$\Delta$ $(\%)$	$\Delta~(\%)$	$\Delta~(\%)$
A10H0	392	-0.0	-0.0	-0.0	11065	0.0	0.0	-0.1	-7.0
C2A2	1468	0.0	0.0	0.0	34117	0.0	0.0	0.0	7.9
C7A0	3027	0.5	0.5	0.4	134842	-0.0	-0.1	-0.7	-7.8
C8A0	12454	14.9	12.4	3.8	240970	-1.3	-6.1	-20.6	-68.9
C9A0	8646	31.4	24.0	19.4	52300	-0.4	-2.2	-7.6	-9.7
L1B0	32322	61.7	48.1	30.1	408366	-18.5	-25.1	-32.4	-18.7
L1X9	28033	2.7	1.7	-10.8	201395	-0.6	-1.1	1.6	6.2
L4X0	58224	43.5	20.7	21.3	478261	-9.4	-23.0	-22.4	-40.7
M1A1	1666	2.2	2.1	1.9	26388	0.9	1.5	2.3	1.9
N1A2	23090	4.0	3.8	3.2	602738	0.1	0.2	2.7	3.4
N1B1	6434	2.2	2.1	0.6	114498	0.0	0.1	0.9	0.3
N3A0	11284	1.7	1.5	1.3	436053	-0.0	-0.2	-1.7	-4.8
N5A1	70817	76.8	50.4	21.5	966348	-8.1	-19.6	-38.5	-41.3
N5A9	2584	0.1	0.1	0.1	51089	-0.0	-0.0	-0.1	-0.5
N5B3	138	4.8	4.8	2.2	5856	4.5	4.4	33.6	19.5
N6A4	6018	15.6	13.7	10.7	143410	-0.6	-3.0	-7.7	-21.4
N6A9	2509	0.3	0.3	0.3	54167	-0.0	-0.0	0.2	-0.3
Total		41.74	26.78	14.65	3527247	-5.53	-11.46	-17.53	-21.15

Note: Expenditures are average yearly expenditure in 1000 US\$ (from the period 2002-2013).  $\Delta$  stands for the change in expenditures between after and before in percentage of initial expenditure. Column labeled "Before" shows the per country average yearly expenditures of the class. Int. Ref. Pricing stands for International Reference Pricing.

Table 5.4: Counterfactual Profits Changes on All Drugs

A10H0         33         1.8         1.8         1.4         4633         -0.0         -0.0         -1.7         -28.           C2A2         783         0.0         0.0         0.0         6195         0.0         0.0         0.0         -28.           C7A0         1505         2.3         2.3         1.8         61310         -0.0         -0.2         -2.0         -17.           C8A0         8385         14.6         12.2         4.0         141424         -1.1         -5.2         -18.0         -65.           C9A0         4815         53.1         40.7         32.4         20654         -4.7         -14.2         -31.5         -38.           L1B0         12479         144.5         110.0         43.6         243432         -24.7         -36.2         -59.0         -45.           L1X9         16275         5.9         3.5         -39.7         121461         -1.0         -2.1         -15.5         -25.										
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$			US				ada	Can		
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$		cing	Ref. Pri	Int.		cing	Ref. Pri	Int.		
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	saining	$^{\it Ipariso}_{\it I}$	(9=	( <i>I</i> =		$^{npariso}_{0}$	$(g_{z}$	$(I_{z}$		
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	$B_{a_l}$	5	₹"	₹"		Š	₹"	₹"		
C2A2       783       0.0       0.0       0.0       6195       0.0       0.0       0.0       -28.         C7A0       1505       2.3       2.3       1.8       61310       -0.0       -0.2       -2.0       -17.         C8A0       8385       14.6       12.2       4.0       141424       -1.1       -5.2       -18.0       -65.         C9A0       4815       53.1       40.7       32.4       20654       -4.7       -14.2       -31.5       -38.         L1B0       12479       144.5       110.0       43.6       243432       -24.7       -36.2       -59.0       -45.         L1X9       16275       5.9       3.5       -39.7       121461       -1.0       -2.1       -15.5       -25.	$\Delta^{'}(\%)$	$\Delta~(\%)$	$\widetilde{\Delta}\left(\% ight)$	$\widetilde{\Delta}\left(\% ight)$	Before	$\Delta~(\%)$	$\widetilde{\Delta}\left(\% ight)$	$\widetilde{\Delta}\left(\% ight)$	Before	ATC4
C7A0       1505       2.3       2.3       1.8       61310       -0.0       -0.2       -2.0       -17.         C8A0       8385       14.6       12.2       4.0       141424       -1.1       -5.2       -18.0       -65.         C9A0       4815       53.1       40.7       32.4       20654       -4.7       -14.2       -31.5       -38.         L1B0       12479       144.5       110.0       43.6       243432       -24.7       -36.2       -59.0       -45.         L1X9       16275       5.9       3.5       -39.7       121461       -1.0       -2.1       -15.5       -25.	-28.7	-1.7	-0.0	-0.0	4633	1.4	1.8	1.8	33	A10H0
C8A0       8385       14.6       12.2       4.0       141424       -1.1       -5.2       -18.0       -65.         C9A0       4815       53.1       40.7       32.4       20654       -4.7       -14.2       -31.5       -38.         L1B0       12479       144.5       110.0       43.6       243432       -24.7       -36.2       -59.0       -45.         L1X9       16275       5.9       3.5       -39.7       121461       -1.0       -2.1       -15.5       -25.	-28.4	0.0	0.0	0.0	6195	0.0	0.0	0.0	783	C2A2
C9A0       4815       53.1       40.7       32.4       20654       -4.7       -14.2       -31.5       -38.         L1B0       12479       144.5       110.0       43.6       243432       -24.7       -36.2       -59.0       -45.         L1X9       16275       5.9       3.5       -39.7       121461       -1.0       -2.1       -15.5       -25.	-17.9	-2.0	-0.2	-0.0	61310	1.8	2.3	2.3	1505	C7A0
L1B0 12479 144.5 110.0 43.6 243432 -24.7 -36.2 -59.0 -45. L1X9 16275 5.9 3.5 -39.7 121461 -1.0 -2.1 -15.5 -25.	-65.6	-18.0	-5.2	-1.1	141424	4.0	12.2	14.6	8385	C8A0
L1X9 16275 5.9 3.5 -39.7 121461 -1.0 -2.1 -15.5 -25.	-38.8	-31.5	-14.2	-4.7	20654	32.4	40.7	53.1	4815	C9A0
	-45.7	-59.0	-36.2	-24.7	243432	43.6	110.0	144.5	12479	L1B0
L4X0 46707 53.6 25.6 26.3 193670 -9.4 -24.0 -23.2 -44.	-25.3	-15.5	-2.1	-1.0	121461	-39.7	3.5	5.9	16275	L1X9
	-44.4	-23.2	-24.0	-9.4	193670	26.3	25.6	53.6	46707	L4X0
M1A1 375 54.4 49.3 42.7 3640 -2.4 -6.1 -14.5 -8.	-8.9	-14.5	-6.1	-2.4	3640	42.7	49.3	54.4	375	M1A1
N1A2 17924 6.7 6.3 5.2 212219 -0.1 -0.3 -4.5 -8.	-8.4	-4.5	-0.3	-0.1	212219	5.2	6.3	6.7	17924	N1A2
N1B1 4954 3.5 3.3 0.9 36128 -0.0 -0.1 -1.4 -27.	-27.5	-1.4	-0.1	-0.0	36128	0.9	3.3	3.5	4954	N1B1
N3A0 2857 20.2 18.3 14.5 171438 -0.2 -1.0 -6.1 -16.	-16.6	-6.1	-1.0	-0.2	171438	14.5	18.3	20.2	2857	N3A0
N5A1 44548 123.8 80.5 35.1 678053 -11.4 -27.4 -53.2 -57.	-57.8	-53.2	-27.4	-11.4	678053	35.1	80.5	123.8	44548	N5A1
N5A9 1101 0.3 0.3 0.3 10707 -0.0 -0.1 -0.2 -1.	-1.2	-0.2	-0.1	-0.0	10707	0.3	0.3	0.3	1101	N5A9
N5B3 0 1827 -1.5 -1.5 -92.2 -28.	-28.3	-92.2	-1.5	-1.5	1827				0	N5B3
N6A4 3221 30.3 26.8 20.6 93089 -1.1 -5.3 -15.8 -43.	-43.3	-15.8	-5.3	-1.1	93089	20.6	26.8	30.3	3221	N6A4
N6A9 550 2.6 2.5 2.2 23932 -0.1 -0.3 -2.4 -7.	-7.5	-2.4	-0.3	-0.1	23932	2.2	2.5	2.6	550	N6A9
Total 166512 63.75 40.86 18.66 2023809 -7.98 -16.86 -31.61 -41.2	-41.22	-31.61	-16.86	-7.98	2023809	18.66	40.86	63.75	166512	Total

Note: Profits are average yearly in 1000 US\$ (from the period 2002-2013).  $\Delta$  stands for the change in expenditures between after and before in percentage of initial expenditure. Column labeled "Before" shows the per country average yearly profits of the class. Int. Ref. Pricing stands for International Reference Pricing.

Table 5.5: Counterfactual World Profits Changes on All Drugs

			Int. Ref.	Pricing		
		$\Delta (\%)$	$\Delta^{(g)} \stackrel{(g)}{\underset{\sim}{\nearrow}} \Delta^{(g)}$	Comparison	$\begin{array}{c} P_{a} \\ \nabla \\ $	
ATC4	Before	$\Delta$ (%)	$\Delta~(\%)$	$\Delta~(\%)$	$\Delta$ (%)	
A10H0	4829	0.0	0.1	-1.6	-27.5	
C2A2	10895	0.0	0.0	0.0	-16.2	
C7A0	70338	0.0	0.1	-1.7	-15.6	
C8A0	191736	-0.2	-0.6	-13.1	-48.4	
C9A0	49546	3.2	17.8	-10.0	-16.2	
L1B0	318308	-13.2	-1.8	-43.4	-35.0	
L1X9	219110	-0.1	0.4	-11.5	-14.0	
L4X0	473909	1.4	5.3	-6.9	-18.1	
M1A1	5891	2.0	15.1	-6.3	-5.5	
N1A2	319764	0.3	1.9	-2.7	-5.6	
N1B1	65850	0.3	1.5	-0.7	-15.1	
N3A0	188578	0.1	0.7	-5.3	-15.1	
N5A1	945339	-2.4	3.1	-36.5	-41.5	
N5A9	17315	0.0	0.0	-0.1	-0.7	
N5B3	1827	-0.0	7.7	-91.0	-28.3	
N6A4	112414	-0.1	0.2	-12.5	-35.9	
N6A9	27234	0.0	0.1	-2.0	-6.6	
Total	3022881	-1.83	2.21	-20.13	-27.59	

Note: Profits are average yearly in 1000 US\$ (from the period 2002-2013) for the US and the 6 reference countries using Canada as representative countries whether one or six of these are used as reference.  $\Delta$  stands for the change in expenditure between after and before in percentage of initial expenditure. Int. Ref. Pricing stands for International Reference Pricing.

### 6 Conclusion

This paper evaluates the impact of prospective policies that tie US drug prices to prices charged for the same drugs abroad through an international reference pricing requirement. Whereas public discourse often takes prices abroad as fixed, our paper models the endogenous effect that reference pricing would have on the prices that could be set in equilibrium. To do this, we develop a structural model for pharmaceutical price setting in the US and in a foreign market similar to those typically cited as potential referencing targets. We then extend our model to allow prices to re-equilibrate under different specifications of reference pricing policies, highlighting the mechanism by which reference pricing in the US may generate an externality on both prices and quantities sold abroad.

We employ detailed quantity and price data from IMS Health to estimate a random coefficients logit demand model with a structural quality metric for each drug. Under the assumption that prices are set according to Nash bargaining (Horn and Wolinsky, 1988; Crawford and Yurukoglu, 2012; Grennan, 2013; Gowrisankaran et al., 2015) between firms and regulators in a country with regulated pharmaceutical prices such as Canada, we are able to separately identify costs and bargaining parameters. Since Nash bargaining involves maximizing the weighted log-sum

of both parties' transaction utility, we can interpret the bargaining parameters as the degree to which countries' policymakers choose to trade off firm profits against immediate consumer welfare. We then perform counterfactual simulations of a most favored nation policy in the US involving international reference pricing constraints based on other markets.

In the main specification, an international reference pricing policy where the price in the US cannot be higher than in Canada, Canadian prices become effective price ceilings for the same drugs sold in the US. This constraint binds when firms negotiate prices with the regulator in Canada, but the effect on reducing expenditures in the US is relatively small. Moreover, we find that while baseline reference pricing decreases prices a bit in the US, it increases prices dramatically in Canada because the firms' disagreement payoff in negotiations becomes tethered to unconstrained US profits. Expenditure on pharmaceuticals therefore increases considerably in Canada but does not change significantly in the US. When comparing unit profit margins of on-patent drugs offered in both Canada and the US, we find that while the distribution of margin differences between the US and Canada is skewed towards higher margins in the US in the status quo, an international reference pricing policy would flip the skew of this difference towards higher margins in Canada. Overall, we find that that firm profits would increase significantly in Canada while profits in the US would decrease slightly.

We then consider several extensions to our model that capture realistic variations of the reference pricing policy. We find that referencing an index of countries or increasing the size of the country being referenced both lower equilibrium prices for US consumers. However, the price reductions are surprisingly small relative to the status quo price differences between the US and Canada. A key reason is that US market is so unrivaled in its size that even when referencing larger countries or more countries, profitability in the US market still drives negotiations in the referenced country/ies rather than the other way around. Similarly, we find that when the reference pricing rule allows a 10% price premium in the US, this results in higher US prices but primarily acts to lower Canadian prices a bit relative to the baseline counterfactual.

On the other hand, requiring firms to continue selling their drugs in the reference country as a precondition to selling them in the US is very effective at lowering US prices. This type of rule dramatically strengthens the bargaining position of the reference country since firms know that failing to come to an agreement will prohibit any sale in the lucrative US market. Still, this type of agreement is not renegotiation proof, and we find it unlikely that its provisions could be enforced in case of disagreement between pharmaceutical firms and the Canadian regulator. If direct bargaining by a US regulator were instead feasible, we find that prices and expenditures

in the US would decrease substantially—significantly more than baseline IRF or IRF with an index, and often more than under IRF with required comparison as well.

While our work has implications for policy designs involving international reference pricing by the US, it also has possible applications in other contexts like the European one where external referencing is widely used or in contexts where parallel trade of drugs implicitly creates similar externality effects across markets. Allowing parallel imports of patented drugs to the US from other countries is another policy that could be modeled using the framework developed here. However, we leave for future research the extension of the effects of such policies in dynamic contexts, taking into account product entry, delays as in Maini and Pammoli (2022), or even longer term effects on innovation.

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# 7 Appendix

# 7.1 Descriptive Statistics

Table 7.1: Average Prices in the US and Canada

		I	<b>A</b> 11	Pate	nted	Brand	ded Off	Gen	eric
ATC4		CA	US	CA	US	CA	US	CA	US
A10H0	SULPHONYLUREA A-DIABS	0.05	0.35	0.64	1.04	0.35	0.79	0.05	0.20
C2A2	ANTIHYPER.PL MAINLY PERI	0.67	1.38	55.32	12.43	4.03	2.24	0.15	1.05
C7A0	B-BLOCKING AGENTS,PLAIN	0.19	1.14	0.32	6.91	1.41	1.49	0.10	0.45
C8A0	CALCIUM ANTAGONIST PLAIN	0.89	2.99	1.25	2.30	0.78	17.56	0.50	1.38
C9A0	ACE INHIBITORS PLAIN	0.57	0.60	0.66	1.67	0.54	1.51	0.31	0.33
L1B0	ANTIMETABOLITES	17.25	113.27	19.64	333.05	12.74	125.50	10.42	18.16
L1X9	ALL OTH. ANTINEOPLASTICS	21.49	130.27	420.67	734.94	0.94		0.89	14.23
L4X0	OTHER IMMUNOSUPPRESSANTS	2.95	25.87	2.97	27.02	2.66	9.57	2.87	38.32
M1A1	ANTIRHEUMATICS NON-S PLN	0.20	0.26	0.67	3.67	0.50	0.91	0.13	0.21
N1A2	INJECT GEN ANAESTHETICS	5.29	7.68	11.55	74.26	6.52	15.68	4.51	4.61
N1B1	ANAESTH LOCAL MEDIC INJ	4.35	4.30	11.10	15.77	4.52	6.00	3.15	2.83
N3A0	ANTI-EPILEPTICS	0.26	1.58	1.37	4.28	0.19	4.70	0.20	0.83
N5A1	ATYPICAL ANTIPSYCHOTICS	1.67	8.59	1.85	10.69	3.11	9.73	0.40	3.17
N5A9	CONVNTL ANTIPSYCHOTICS	0.29	1.54	1.98	2.36	0.25	14.27	0.14	1.11
N5B3	BARBITURATE PLAIN	0.14	0.56	2.08	26.51			0.11	0.29
N6A4	SSRI ANTIDEPRESSANTS	0.47	1.65	1.33	3.61	1.43	4.17	0.30	0.47
N6A9	ANTIDEPRESSANTS ALL OTH	0.21	0.71	0.63	2.83	0.61	3.43	0.15	0.33

 $Note:\ Average\ price\ by\ ATC\text{-4, country, in } \textit{US\$ per std. unit.}$ 

Price in the US (Log Scale)

1 10 100 1000

Figure 7.1: Comparisons of Prices of Generic Drugs present in both the US and Canada

Note: Circle sizes are proportional to the sales value of this drug in the  $\it US.$ 

Price in Canada (Log Scale)

10

100

i

1000

#### 7.2 Market Size Approximation

#### **7.2.1** Method

We use Huang and Rojas (2013, 2014) to calibrate the potential market size using a simpler logit demand model. With a logit specification, we have:

$$\ln q_{it} - \ln q_{0mt} = \alpha_{m(i)} \ln p_{it} + \beta_{m(i)} g_i + \lambda_{m(i)} x_{it} + \phi_i + \mu_{m(i)t} + \xi_{it}$$

with 
$$M_{mt} = q_{0t} + \sum_{j=1}^{J_m} q_{jt}$$
.

As  $q_{0mt}$  or  $M_{mt}$  are not observed, we can use the difference across inside goods to identify some of the parameters of the model:

$$\ln q_{it} - \ln q_{i't} = \alpha_{m(i)} \left( \ln p_{it} - \ln p_{i't} \right) + \beta_{m(i)} \left( g_i - g_{i'} \right) + (\phi_i - \phi_{i'}) + (\xi_{it} - \xi_{i't})$$

which does not depend on unobserved  $q_{0mt}$  or  $M_{mt}$  in order to identify  $\alpha_m$  and  $\beta_m$  that are denoted  $\hat{\alpha}_m$ ,  $\hat{\beta}_m$  from these last specifications. For a given  $M_{mt}$  we have

$$\ln q_{jt} - \ln \left( M_{mt} - \sum_{j=1}^{J_m} q_{jt} \right) = \alpha_m \ln p_{jt} + \beta_m g_j + \lambda_m x_{jt} + \phi_j + \mu_{mt} + \xi_{jt}$$

whose estimation with two stage least squares using the same instruments as with our BLP demand model leads to the estimates  $\hat{\alpha}_m(M_{mt})$ ,  $\hat{\beta}_m(M_{mt})$ ,  $\hat{\lambda}_m(M_{mt})$ .

Then, we look for  $M_{mt}$  that solves the following minimization problem:

$$\min_{M_{mt} \ge \sum_{j=1}^{J_{m}} q_{jt}} \sum_{t=1}^{T} (\hat{\alpha}_{m} (M_{mt}) - \hat{\alpha}_{m})^{2} + (\hat{\beta}_{m} (M_{t}) - \hat{\beta}_{m})^{2} + (\hat{\lambda}_{m} (M_{t}) - \hat{\lambda}_{m})^{2}$$

### 7.2.2 Outside Good Market Shares Estimates

Table 7.2: Outside Good Market Share Estimates by country and ATC-4

			$s_{0mt}$
ATC4		US	Canada
A10H0	SULPHONYLUREA A-DIABS	0.08	0.19
C2A2	ANTIHYPER.PL MAINLY PERI	0.14	0.19
C7A0	B-BLOCKING AGENTS,PLAIN	0.15	0.25
C8A0	CALCIUM ANTAGONIST PLAIN	0.13	0.21
C9A0	ACE INHIBITORS PLAIN	0.14	0.22
L1B0	ANTIMETABOLITES	0.13	0.19
L1X9	ALL OTH. ANTINEOPLASTICS	0.13	0.20
L4X0	OTHER IMMUNOSUPPRESSANTS	0.14	0.20
M1A1	ANTIRHEUMATICS NON-S PLN	0.14	0.21
N1A2	INJECT GEN ANAESTHETICS	0.14	0.20
N1B1	ANAESTH LOCAL MEDIC INJ	0.15	0.22
N3A0	ANTI-EPILEPTICS	0.14	0.20
N5A1	ATYPICAL ANTIPSYCHOTICS	0.13	0.19
N5A9	CONVNTL ANTIPSYCHOTICS	0.15	0.24
N5B3	BARBITURATE PLAIN	0.10	0.20
N6A4	SSRI ANTIDEPRESSANTS	0.16	0.22
N6A9	ANTIDEPRESSANTS ALL OTH	0.15	0.23

Note: Estimated outside good market shares obtained from the market size estimates by ATC-4, country and quarter. This Table presents average across quarters.

## 7.3 Demand Elasticities by ATC4

 $\label{lem:average Price Elasticities for Canada and US for Branded or Generic drugs and by ATC4 class$ 

		Ţ	JS	Car	nada
ATC4 Class		Own	Cross	Own	Cross
A10H0	Branded	-1.4942911	0.18870959	-1.0860793	0.19736979
	Generic	-1.3159676	0.21979924	-0.9546113	0.22014856
A2B1	Branded	-1.5152315	0.21517432	-1.0848269	0.24501748
	Generic	-1.2444818	0.24469155	-0.8780188	0.25223733
B1B1	Branded	-1.5426189	0.24658761	-1.2884390	0.32522780
	Generic	-1.1369432	0.27678549	-0.6769721	0.42358261
B2A1	Branded	-1.4542279	0.56864347	NA	NA

	Generic	-0.5724812	0.59057725	NA	NA
B2G0	Branded	-1.1641988	0.52388993	NA	NA
	Generic	-0.8945154	0.61746712	NA	NA
B3A1	Branded	-1.5636435	0.32726816	NA	NA
	Generic	-1.1772620	0.37152563	NA	NA
B3A2	Branded	-1.5302343	0.05639156	NA	NA
	Generic	-1.5157631	0.06251615	NA	NA
B3X0	Branded	-1.5716252	0.19721732	NA	NA
	Generic	-1.1760446	0.27887549	-0.5176230	0.50505314
C10A2	Branded	-1.3109951	0.32864992	-1.1165662	0.21602872
	Generic	-1.1110397	0.34643945	-0.8862687	0.24659964
C2A1	Branded	-1.5434303	0.21773279	-1.1343419	0.36980288
	Generic	-1.2727449	0.23311667	-0.7496918	0.40283322
C2A2	Branded	-1.5430697	0.19596512	-1.0556571	0.12928930
	Generic	-1.2609796	0.23094543	-1.0028312	0.16062615
C7A0	Branded	-1.5225954	0.08140770	-1.1544918	0.07573027
	Generic	-1.4758567	0.08918033	-1.1348824	0.08268607
C7B1	Branded	-1.5515267	0.16736302	NA	NA
	Generic	-1.2397906	0.19203998	NA	NA
C8A0	Branded	-1.5201152	0.10406011	-1.1281688	0.13412558
	Generic	-1.4061916	0.11911454	-1.1350842	0.13684071
C9A0	Branded	-1.5415338	0.09380079	-1.1423198	0.08662940
	Generic	-1.4300000	0.10934890	-1.1758407	0.09214362
L1A0	Branded	-1.5127775	0.08883271	NA	NA
	Generic	-1.4102918	0.09468077	NA	NA
L1B0	Branded	-1.5120779	0.09288873	-1.0654421	0.09200356
	Generic	-1.4334406	0.09812485	-1.0789801	0.09125910
L1C0	Branded	-1.4905145	0.11252435	NA	NA
	Generic	-1.4135952	0.11792859	NA	NA
L1X9	Branded	-1.5446695	0.11363301	-0.9601175	0.21334842

	Generic	-1.1745444	0.12519897	-0.6154447	0.23554148
L2A2	Branded	-1.4552138	0.62749022	NA	NA
	Generic	-0.2889246	0.68852517	NA	NA
L4X0	Branded	-1.4539215	0.11676248	-1.0398490	0.17095603
	Generic	-1.4454776	0.11814214	-1.2217461	0.17110540
M1A1	Branded	-1.5558699	0.09806386	-1.1403284	0.10809910
	Generic	-1.4472668	0.10899561	-1.0905096	0.11884356
M1C0	Branded	-1.5468360	0.15436655	NA	NA
	Generic	-1.0971664	0.16881815	NA	NA
N1A2	Branded	-1.5381796	0.09583931	-1.1365013	0.10573899
	Generic	-1.4145795	0.10393228	-1.0929991	0.11179181
N1B1	Branded	-1.4884714	0.15268970	-1.1469470	0.14978078
	Generic	-1.3510902	0.16566433	-1.0139503	0.15489291
N1B3	Branded	-1.5225329	0.28592607	-0.5687945	0.32964770
	Generic	-1.1182851	0.32033762	-1.1492827	0.35418571
N2A0	Branded	-1.5318372	0.09733111	-1.2028092	0.08586507
	Generic	-1.4555158	0.10729789	-1.1593344	0.08859004
N2B0	Branded	-1.5566200	0.08849977	-1.1435220	0.11517178
	Generic	-1.4559112	0.10354999	-1.0495434	0.12870232
N3A0	Branded	-1.5410147	0.07146262	-1.1438252	0.06380140
	Generic	-1.4682858	0.07298318	-1.1688601	0.06889266
N5A1	Branded	-1.4325883	0.15923412	-1.0438251	0.14885769
	Generic	-1.3348840	0.14654554	-1.1024702	0.13396985
N5A9	Branded	-1.5689278	0.10878572	-1.1422646	0.06935789
	Generic	-1.4134348	0.12795686	-1.1710016	0.08122847
N5B3	Branded	-1.5656956	0.48183507	-1.0560144	0.45645669
	Generic	-0.7831270	0.48614769	-0.1291302	0.57427448
N5C0	Branded	-1.5753682	0.11862044	-1.1388552	0.10165958
	Generic	-1.4196950	0.14993512	-1.1690914	0.10665044
N6A4	Branded	-1.3960100	0.18112970	-1.1195133	0.13900737

	Generic	-1.3594402	0.19680851	-1.0695640	0.15707022
N6A9	Branded	-1.5419200	0.07511176	-1.1733263	0.06326497
	Generic	-1.4769645	0.08648495	-1.1793534	0.06730979
N6B0	Branded	-1.4731393	0.13266753	NA	NA
	Generic	-1.3654408	0.13928647	NA	NA

Note: Average price elasticities across all products of each ATC-4 market over all quarters. Some ATC-4 markets may not be available in both countries.

### 7.4 Identification of bargaining model

Denoting  $\tilde{\rho}_{jm} = \frac{1-\rho_{jm}}{\rho_{jm}} \in [0, +\infty]$ , and introducing the US and CA exponent to clearly distinguish price and demands from the US or Canada, we have for each drug j and period t the marginal cost in the US and Canada that satisfy the following equations:

$$c_{jt}^{CA}(\tilde{\rho}_{jm}) = p_{jt}^{CA} + \left(\frac{\partial \ln q_{jt}^{CA}(\mathbf{p}_{t}^{CA})}{\partial p_{jt}^{CA}} + \tilde{\rho}_{jm} \frac{\partial \ln \Delta_{j} W_{mt}(\mathbf{p}_{mt}^{CA})}{\partial p_{jt}^{CA}}\right)^{-1}$$

$$c_{jt}^{US} = p_{jt}^{US} + \left(\frac{\partial \ln q_{jt}^{US}(\mathbf{p}_{mt}^{US})}{\partial p_{jt}^{US}}\right)^{-1}$$

We consider the demand shape known (obtained form the demand estimation). Then, in order to identify this model given the observable prices and quantities, we add a cost restriction equation. For this, we define

$$\omega_{jt}\left(\tilde{\rho}_{jm},\lambda,\tau\right) = \ln\left(c_{jt}^{CA}\left(\tilde{\rho}_{jm}\right)\right) - x_{jt}'\lambda - \tau\ln c_{jt}^{US}$$

and we add the following moment equation

$$\mathbb{E}\left[z_{jt}\omega_{jt}\left(\rho_{jm},\lambda,\tau\right)\right]=0$$

with 
$$z_{jt} = [\ln c_{jt}^{US}, x_{jt}].$$

With  $\omega_t(\tilde{\rho}_{jm}, \lambda, \tau)$  stacking all  $\omega_{jt}(\tilde{\rho}_{jm}, \lambda, \tau)$  for each products j of period t, the theoretical identification condition is that the matrix  $E\left[\frac{\partial \omega_t(\tilde{\rho}_{jm}, \lambda, \tau)}{\partial \tilde{\rho}_m}, \frac{\partial \omega_{jt}(\tilde{\rho}_{jm}, \lambda, \tau)}{\partial \tau}, \frac{\partial \omega_{jt}(\tilde{\rho}_{jm}, \lambda, \tau)}{\partial \lambda}\right]$  has full rank of dimension  $\dim(\lambda) + \dim(\tilde{\rho}_m) + 2$ . We also need that  $\dim(\tilde{\rho}_m) + \dim(\lambda) + 2 \leq \sum_t J_t$  where  $J_t$  is the number of products by period.

Since

$$\frac{\partial \omega_{jt} \left(\tilde{\rho}_{jm}, \lambda, \tau\right)}{\partial \tilde{\rho}_{jm}} = \frac{\partial \ln \Delta_{j} W_{mt}^{CA} (\mathbf{p}_{mt}^{CA})}{\partial p_{jt}^{CA}} \frac{\left(\frac{\partial \ln q_{jt}^{CA} (\mathbf{p}_{mt}^{CA})}{\partial p_{jt}^{CA}} + \tilde{\rho}_{jm} \frac{\partial \ln \Delta_{j} W_{mt}^{CA} (\mathbf{p}_{mt}^{CA})}{\partial p_{jt}^{CA}}\right)^{-2}}{p_{jt}^{CA} + \left(\frac{\partial \ln q_{jt}^{CA} (\mathbf{p}_{mt}^{CA})}{\partial p_{jt}^{CA}} + \tilde{\rho}_{jm} \frac{\partial \ln \Delta_{j} W_{mt} (\mathbf{p}_{mt}^{CA})}{\partial p_{jt}^{CA}}\right)^{-1}}$$

$$\frac{\partial \omega_{jt} \left(\tilde{\rho}_{jm}, \lambda, \tau\right)}{\partial \tau} = -\ln c_{jt}^{US} = -\ln \left(p_{jt}^{US} + \frac{1}{\frac{\partial \ln q_{jt}^{US} (\mathbf{p}_{mt}^{US})}{\partial p_{jt}^{US}}}\right)$$

$$\frac{\partial \omega_{jt} \left(\tilde{\rho}_{jm}, \lambda, \tau\right)}{\partial \lambda} = -z'_{jt}$$

the terms  $\frac{\partial \omega_{jt}(\tilde{\rho}_{jm},\lambda,\tau)}{\partial \tilde{\rho}_{jm}}$ ,  $\frac{\partial \omega_{jt}(\tilde{\rho}_{jm},\lambda,\tau)}{\partial \tau}$ ,  $\frac{\partial \omega_{jt}(\tilde{\rho}_{jm},\lambda,\tau)}{\partial \lambda}$  are in general not colinear and thus the matrix should have full rank and the model be identified.

We however need that the dimension of unknown bargaining parameters  $\dim(\tilde{\rho}_m)$  be less than  $\sum_t J_t - \dim(\lambda) - 2$  which is the case for us as we have many time periods and do not allows the bargaining parameters to vary over time.

### 7.5 Supply sides estimates

Table 7.4: Margins Estimates by ATC-4

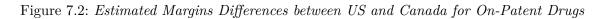
Margins			Can	ıada			US	
ATC4	Label	All	On Patent	Branded Off Patent	Generics	All	On Patent	Branded Off Patent
A10H0	SULPHONYLUREA A-DIABS	1.10	1.38	2.93		41.66	73.84	76.66
C2A2	ANTIHYPER.PL MAINLY PERI	24.59	74.94	48.90		17.11	65.40	3.50
C7A0	B-BLOCKING AGENTS,PLAIN	7.47	6.08	21.26	1.99	45.39	65.06	67.63
C8A0	CALCIUM ANTAGONIST PLAIN	18.20	48.62	6.34	1.63	58.38	95.33	64.21
C9A0	ACE INHIBITORS PLAIN	48.70	58.35	40.50	11.71	38.58	46.33	69.26
L1B0	ANTIMETABOLITES	5.29	5.14	10.38	5.30	59.45	66.81	65.15
L1X9	ALL OTH. ANTINEOPLASTICS	8.81	9.56		1.40	60.02	66.07	
L4X0	OTHER IMMUNOSUPPRESSANTS	8.47	16.67	3.48	0.21	40.41	69.46	73.71
M1A1	ANTIRHEUMATICS NON-S PLN	15.40	30.38	42.56	6.33	13.88	44.37	50.03
N1A2	INJECT GEN ANAESTHETICS	47.57	11.22	71.35	51.82	35.39	65.76	77.59
N1B1	ANAESTH LOCAL MEDIC INJ	71.46	59.65	92.85	52.91	31.47	70.67	27.05
N3A0	ANTI-EPILEPTICS	3.92	7.30	4.86		39.12	67.38	65.87
N5A1	ATYPICAL ANTIPSYCHOTICS	11.30	4.73	81.31		69.17	77.21	28.45
N5A9	CONVNTL ANTIPSYCHOTICS	7.14	83.93			20.77	33.60	65.30
N5B3	BARBITURATE PLAIN					31.73	63.91	
N6A4	SSRI ANTIDEPRESSANTS	14.25	11.58	12.04	26.21	65.09	80.10	70.75
N6A9	ANTIDEPRESSANTS ALL OTH	6.18	36.61	3.58	2.90	42.91	68.63	72.63

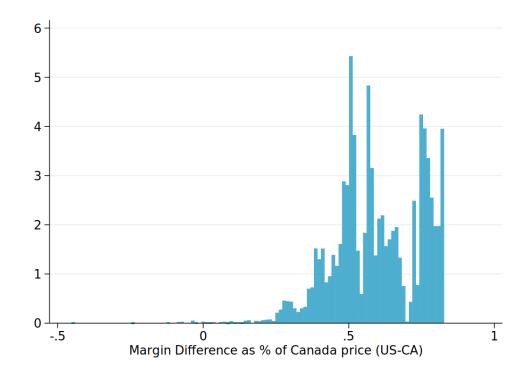
Note: Average margins in percentage of US average price  $((p_{jt}-c_{jt})/p_{jUSt})$  by ATC-4 across all quarters. Average across drugs within category is weighted by market share. For generics in the US we impose price equal to marginal costs and do not estimate margins but they are taken into account in the average margin for all drugs in the US.

Table 7.5: Marginal costs Estimates by ATC-4

Margins			Cana	da			U	S	
ATC4	Label	All	On Patent	Branded Off Patent	Generics	All	On Patent	Branded Off Patent	Generics
A10H0	SULPHONYLUREA A-DIABS	0.05	0.11	0.19	0.05	0.21	0.27	0.18	0.20
C2A2	ANTIHYPER.PL MAINLY PERI	0.31	13.26	2.06	0.15	1.14	4.30	0.81	1.05
C7A0	B-BLOCKING AGENTS,PLAIN	0.10	0.07	0.34	0.09	0.63	2.42	0.48	0.45
C8A0	CALCIUM ANTAGONIST PLAIN	0.29	0.08	0.43	0.46	1.25	0.11	6.29	1.38
C9A0	ACE INHIBITORS PLAIN	0.25	0.28	0.29	0.16	0.37	0.51	0.46	0.33
L1B0	ANTIMETABOLITES	10.77	12.23	1.18	7.43	45.93	110.56	43.74	18.16
L1X9	ALL OTH. ANTINEOPLASTICS	9.10	171.62	0.94	0.59	52.09	249.36	0.00	14.23
L4X0	OTHER IMMUNOSUPPRESSANTS	0.59	0.47	0.82	2.41	15.42	8.25	2.52	38.32
M1A1	ANTIRHEUMATICS NON-S PLN	0.15	0.47	0.29	0.11	0.23	1.31	0.30	0.21
N1A2	INJECT GEN ANAESTHETICS	1.35	5.82	0.55	1.41	4.97	25.43	3.51	4.61
N1B1	ANAESTH LOCAL MEDIC INJ	1.01	2.06	0.32	1.07	2.95	4.63	1.90	2.83
N3A0	ANTI-EPILEPTICS	0.20	0.44	0.13	0.20	0.96	1.40	1.60	0.83
N5A1	ATYPICAL ANTIPSYCHOTICS	0.63	0.86	0.58	0.40	2.65	2.44	2.79	3.17
N5A9	CONVNTL ANTIPSYCHOTICS	0.16	0.32	0.25	0.14	1.22	0.84	4.95	1.11
N5B3	BARBITURATE PLAIN	0.14	2.08		0.11	0.39	9.57		0.29
N6A4	SSRI ANTIDEPRESSANTS	0.21	0.28	0.40	0.20	0.58	0.72	1.22	0.47
N6A9	ANTIDEPRESSANTS ALL OTH	0.17	0.21	0.41	0.14	0.41	0.89	0.94	0.33

Note: Average marginal costs by ATC-4 across all quarters. Average across drugs within category is weighted by market share. For generics in the US we impose price equal to marginal costs and do not estimate margins but they are taken into account in the average margin for all drugs in the US.





 $Note: Illustrates \ the \ distribution \ of \ margin \ differences \ weighted \ by \ the \ Canadian \ quantities \ of \ the \ drug \ for \ on-patent \ drugs \ present \ in \ both \ the \ US \ and \ Canada.$ 

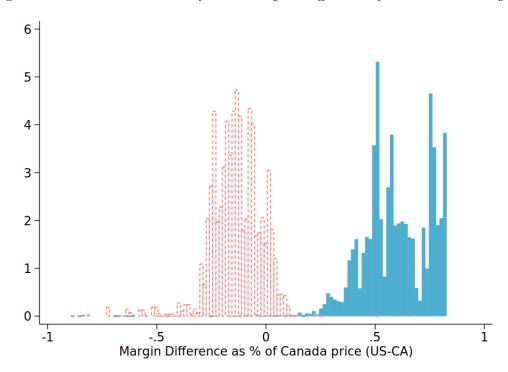


Figure 7.3: Current and Counterfactual Margins Differences for On-Patent Drugs

Note: The empirical distribution of the difference between margins in Canada and the US,  $(p^{CA} - c^{CA}) - (p^{US} - c^{US})$ , normalized by each drug's US price and weighted by the quantity of the drug sold in Canada. The dotted distribution is the counterfactual while the solid one is the estimated current distribution.

### 7.6 Theoretical Results

This section shows that under "regularity" conditions of the profit function and when the same drugs are present in the referencing and referenced country, a single country international reference pricing policy can only increase price in the referenced country and decrease it in the referencing country. We start by showing it when we have a monopoly drug in each country, then when we have a duopoly.

### 7.6.1 Monopoly case

Let's start with a monopoly firm in each country A and B. Consider one firm producing a product, at marginal costs c. Denote  $D_A(p_A)$  and  $D_B(p_B)$  the demands in countries A and B, respectively, when their prices are  $p_A$  and  $p_B$ . We assume that each profit function  $\Pi_A(p_A) \equiv (p_A - c) D_A(p_A)$  and  $\Pi_B(p_B) \equiv (p_B - c) D_B(p_B)$  is strictly concave in price and have a finite maximum above marginal cost.

Under regulation, we suppose that a governmental agency negotiates price by engaging in Nash bargaining with the firm. The government's objective function takes the general form  $W(p_B)$  in country B, where W(.) is decreasing over  $[c, +\infty)$ . For instance,  $W(p_B)$  could be consumer surplus, social welfare or coverage.

Thus, the unregulated price in country A solves

$$p_A^* = \underset{c \le p_A}{\operatorname{arg\,max}} \Pi_A \left( p_A \right)$$

and the price in country B under regulation solves the following maximization program:

$$p_B^* = \underset{p_B > c}{\operatorname{arg}} \max \Pi_B (p_B)^{1-\rho} \Delta W (p_B)^{\rho}$$

where  $\Delta W(p_B) \equiv W(p_B) - W(\infty)$  is decreasing in  $p_B$  and  $\rho \in (0,1]$  captures the bargaining power of the governmental agency.

Now with international reference pricing imposing that the firm can sell in country A only if  $p_A \leq p_B$ , the new price equilibrium  $(p_A^{**}, p_B^{**})$  simultaneously solves:

$$\begin{cases} p_A^{**} = \tilde{p}_A(p_B^{**}) \equiv \underset{c \le p_A \le p_B^{**}}{\arg \max} \Pi_A(p_A) \\ p_B^{**} = \underset{p_B \ge c}{\arg \max} \left[ \Pi_A(\tilde{p}_A(p_B)) + \Pi_B(p_B) - \Pi_A(p_A^*) \right]^{1-\rho} \Delta W(p_B)^{\rho} \end{cases}$$

where  $\Pi_A(\tilde{p}_A(p_B)) + \Pi_B(p_B)$  is the firm profit in A and B if selling if both countries and  $\Pi_A(p_A^*)$  is the firm profit in A only if disagreeing with B.

**Proposition** The international reference pricing policy implies that the price in country A decreases and the price in country B increases:

$$p_A^{**} \le p_A^*$$
 and  $p_B^{**} \ge p_B^*$ 

**Proof** Let's start with proving that  $p_A^{**} \leq p_A^*$ :

From its definition,  $p_A^{**} \equiv \tilde{p}_A(p_B^{**}) = p_A^*$  if  $p_A^* \leq p_B^{**}$ . If  $p_A^* > p_B^{**}$ , then  $p_A^{**} \equiv \tilde{p}_A(p_B^{**}) \leq p_B^{**}$  because  $\tilde{p}_A(p) \leq p$  for all p and thus  $p_A^{**} < p_A^*$ . This proves that in all cases  $p_A^{**} \leq p_A^*$ .

Let's prove now that  $p_B^{**} \ge p_B^*$ :

Let's define

$$\Delta\Pi_A\left(p_A^*, p_B\right) \equiv \Pi_A\left(\tilde{p}_A(p_B)\right) - \Pi_A\left(p_A^*\right)$$

 $\Delta\Pi_{A}\left(p_{A}^{*},p_{B}\right)$ ) is negative increasing in  $p_{B}$  and equal to zero when  $p_{B}\geq p_{A}^{*}$ : It is negative because  $p_{A}^{*}=\underset{p_{A}\geq c}{\arg\max}\Pi_{A}\left(p_{A}\right)$  and thus  $\Pi_{A}\left(\tilde{p}_{A}(p_{B})\right)\leq\Pi_{A}\left(p_{A}^{*}\right)$ . By concavity of  $\Pi_A$  (.), it is increasing on  $[0, p_A^*[, \tilde{p}_A(p_B)$  is also weakly increasing in  $p_B$ , thus  $\Pi_A$  ( $\tilde{p}_A(p_B)$ ) is increasing in  $p_B$  because  $\tilde{p}_A(p_B) \leq \tilde{p}_A(p_A^*) \leq p_A^*$ .

Then, using  $p_B^{**} = \underset{p_B \geq c}{\operatorname{arg\,max}} \left[ \Pi_B \left( p_B \right) + \Delta \Pi_A \left( p_A^*, p_B \right) \right] \Delta W \left( p_B \right)^{\frac{\rho}{1-\rho}}$  and  $p_B^* = \underset{p_B \geq c}{\operatorname{arg\,max}} \Pi_B \left( p_B \right) \Delta W \left( p_B \right)^{\frac{\rho}{1-\rho}}$ , we have

$$\begin{split} &\Pi_{B}\left(p_{B}^{**}\right)\Delta W\left(p_{B}^{**}\right)^{\frac{\rho}{1-\rho}} + \Delta\Pi_{A}\left(p_{A}^{*}, p_{B}^{**}\right)\Delta W\left(p_{B}^{**}\right)^{\frac{\rho}{1-\rho}} \\ &= \left[\Pi_{B}\left(p_{B}^{**}\right) + \Delta\Pi_{A}\left(p_{A}^{*}, p_{B}^{**}\right)\right]\Delta W\left(p_{B}^{**}\right)^{\frac{\rho}{1-\rho}} \\ &\geq \left[\Pi_{B}\left(p_{B}^{*}\right) + \Delta\Pi_{A}\left(p_{A}^{*}, p_{B}^{*}\right)\right]\Delta W\left(p_{B}^{*}\right)^{\frac{\rho}{1-\rho}} \text{ because of the definition of } p_{B}^{**} \\ &= \Pi_{B}\left(p_{B}^{*}\right)\Delta W\left(p_{B}^{*}\right)^{\frac{\rho}{1-\rho}} + \Delta\Pi_{A}\left(p_{A}^{*}, p_{B}^{*}\right)\Delta W\left(p_{B}^{*}\right)^{\frac{\rho}{1-\rho}} \\ &\geq \Pi_{B}\left(p_{B}^{**}\right)\Delta W\left(p_{B}^{**}\right)^{\frac{\rho}{1-\rho}} + \Delta\Pi_{A}\left(p_{A}^{*}, p_{B}^{*}\right)\Delta W\left(p_{B}^{*}\right)^{\frac{\rho}{1-\rho}} \text{ because of the definition of } p_{B}^{**} \end{split}$$

Thus

$$\Delta\Pi_{A}\left(p_{A}^{*}, p_{B}^{**}\right) \Delta W\left(p_{B}^{**}\right)^{\frac{\rho}{1-\rho}} \geq \Delta\Pi_{A}\left(p_{A}^{*}, p_{B}^{*}\right) \Delta W\left(p_{B}^{*}\right)^{\frac{\rho}{1-\rho}}$$

If  $p_B^* \geq p_B^{**}$  then  $\Delta \Pi_A\left(p_A^*, p_B^*\right) \Delta W\left(p_B^*\right)^{\frac{\rho}{1-\rho}} \geq \Delta \Pi_A\left(p_A^*, p_B^*\right) \Delta W\left(p_B^{**}\right)^{\frac{\rho}{1-\rho}}$  because  $\Delta \Pi_A\left(p_A^*, p_B^*\right) \leq 0$  and  $\Delta W\left(.\right)$  is positive decreasing. Using the above inequality, it implies

$$\Delta\Pi_A\left(p_A^*, p_B^{**}\right) \ge \Delta\Pi_A\left(p_A^*, p_B^*\right)$$

and thus  $p_B^{**} \geq p_B^*$  because  $\Delta \Pi_A(p_A^*, p_B)$  is increasing in  $p_B$ , which contradicts  $p_B^* \geq p_B^{**}$  implying that it must be that  $p_B^{**} \geq p_B^*$ .

#### 7.6.2 Duopoly case

Consider two firms competing against each other and producing two differentiated products, 1 and 2, at marginal costs c, respectively. Denote  $D_{1c}(p_{1c}, p_{2c})$  and  $D_{2c}(p_{1c}, p_{2c})$  as demands for products 1 and 2 in country c, respectively, when their prices are given by  $p_{1c}$  and  $p_{2c}$ . We assume that each firm i's profit function  $\Pi_{ic} \equiv (p_{ic} - c) D_{ic}(p_{ic}, p_{-ic})$  is strictly concave in its own price, weakly increasing in the rival's price, and that its best-response price is increasing in its rival's price (i.e., prices are strategic complements). We suppose further that a Nash equilibrium  $(p_{1c}^*, p_{2c}^*)$  to the Bertrand game exists and is unique.

Under regulation, we suppose that a governmental agency negotiates prices by engaging in simultaneous Nash bargaining with both firms. We assume that the governmental agency's objective function of country B takes the general form  $W(p_{1B}, p_{2B})$ , where W(., .) is decreasing

over  $[c, +\infty) \times [c, +\infty)$ . For instance,  $W(p_{1B}, p_{2B})$  could be consumer surplus, social welfare or coverage.

The prices that arise in country A solve the Bertrand-Nash equilibrium

$$\begin{cases} p_{1A}^* = \underset{p_{1A} \ge c}{\arg \max} \Pi_{1A} (p_{1A}, p_{2A}^*) \\ p_{2A}^* = \underset{p_{2A} \ge c}{\arg \max} \Pi_{2A} (p_{1A}^*, p_{2A}) \end{cases}$$

and in country B, the regulation solves the following system of maximization programs:

$$\begin{cases}
p_{1B}^* = \underset{p_{1B} \ge c}{\arg \max} \Pi_{1B} \left( p_{1B}, p_{2B}^* \right)^{1-\rho_1} \Delta W_1 \left( p_{1B}, p_{2B}^* \right)^{\rho_1} \\
p_{2B}^* = \underset{p_{2B} \ge c}{\arg \max} \Pi_{2B} \left( p_{1B}^*, p_{2B} \right)^{1-\rho_2} \Delta W_2 \left( p_{1B}^*, p_{2B} \right)^{\rho_2}
\end{cases} (7.1)$$

where  $\Delta W_1(p_{1B}, p_{2B}^*) \equiv W(p_{1B}, p_{2B}^*) - W(\infty, p_{2B}^*)$ ,  $\Delta W_2(p_{1B}^*, p_{2B}) \equiv W(p_{1B}^*, p_{2B}) - W(p_{1B}^*, \infty)$ , and  $\rho_1, \rho_2 \in (0, 1]$  capture the bargaining power of the governmental agency in its negotiation with firms 1 and 2, respectively. We assume that the pair  $(p_{1B}^*, p_{2B}^*)$  solving the system exists and is unique.

We now consider the international reference pricing equilibrium that satisfies

$$\begin{cases} p_{1A}^{**} = \tilde{p}_{1A} \left(p_{1B}^{**}, p_{2A}^{**}\right) \equiv \underset{p_{1A} \leq p_{1B}^{**}}{\arg \max} \Pi_{1A} \left(p_{1A}, p_{2A}^{**}\right) \\ p_{2A}^{**} = \tilde{p}_{2A} \left(p_{1A}^{**}, p_{2B}^{**}\right) \equiv \underset{p_{2A} \leq p_{2B}^{**}}{\arg \max} \Pi_{2A} \left(p_{1A}^{**}, p_{2A}\right) \\ p_{1B}^{**} = \underset{p_{1B} \geq c}{\arg \max} \left[\Pi_{1A} \left(\tilde{p}_{1A} \left(p_{1B}, p_{2A}^{**}\right), p_{2A}^{**}\right) + \Pi_{1B} \left(p_{1B}, p_{2B}^{**}\right) - \Pi_{1A} \left(p_{1A}^{*}, p_{2A}^{**}\right)\right]^{1-\rho_{1}} \Delta W_{1} \left(p_{1B}, p_{2B}^{**}\right)^{\rho_{1}} \\ p_{2B}^{**} = \underset{p_{2B} \geq c}{\arg \max} \left[\Pi_{2A} \left(p_{1A}^{**}, \tilde{p}_{2A} \left(p_{1A}^{**}, p_{2B}\right)\right) + \Pi_{2B} \left(p_{1B}^{**}, p_{2B}\right) - \Pi_{2A} \left(p_{1A}^{**}, p_{2A}^{**}\right)\right]^{1-\rho_{2}} \Delta W_{2} \left(p_{1B}^{**}, p_{2B}\right)^{\rho_{2}} \end{cases}$$

Remark that imposing the reference pricing constraint on one product only would generate the same proposition, but for simplicity of exposition we consider the symmetric case.

**Proposition** The international reference pricing policy implies that the prices in country A decrease and the prices in country B increase:

$$p_{iA}^{**} \le p_{iA}^{*}$$
 and  $p_{iB}^{**} \ge p_{iB}^{*}$  for  $i = 1, 2$ 

**Proof** Let's start with proving that  $p_{iA}^{**} \leq p_{iA}^{*}$  for i = 1, 2:

By definition of the solution of

$$\begin{cases} p_{1A}^* = \tilde{p}_{1A}\left(\infty, p_{2A}^*\right) = \underset{p_{1A}}{\arg\max} \Pi_{1A}\left(p_{1A}, p_{2A}^*\right) \\ p_{2A}^* = \tilde{p}_{2A}\left(p_{1A}^*, \infty\right) = \underset{p_{2A}}{\arg\max} \Pi_{2A}\left(p_{1A}^*, p_{2A}\right) \end{cases}$$

and

$$\begin{cases} p_{1A}^{**} = \tilde{p}_{1A} \left( p_{1B}^{**}, p_{2A}^{**} \right) \equiv \underset{p_{1A} \leq p_{1B}^{**}}{\arg \max} \Pi_{1A} \left( p_{1A}, p_{2A}^{**} \right) \\ p_{2A}^{**} = \tilde{p}_{2A} \left( p_{1A}^{**}, p_{2B}^{**} \right) \equiv \underset{p_{2A} \leq p_{1B}^{**}}{\arg \max} \Pi_{2A} \left( p_{1A}^{**}, p_{2A} \right) \end{cases}$$

Then

$$p_{1A}^{**} = \tilde{p}_{1A} (p_{1B}^{**}, p_{2A}^{**}) \le \tilde{p}_{1A} (\infty, p_{2A}^{**}) \le \tilde{p}_{1A} (\infty, p_{2A}^{**}) = p_{1A}^{*} \text{ if } p_{2A}^{**} \le p_{2A}^{*}$$

$$p_{2A}^{**} = \tilde{p}_{2A} (p_{1A}^{**}, p_{2B}^{**}) \le \tilde{p}_{2A} (p_{1A}^{**}, \infty) \le \tilde{p}_{2A} (p_{1A}^{**}, \infty) = p_{2A}^{*} \text{ if } p_{1A}^{**} \le p_{1A}^{*}$$

If  $p_{1A}^{**} > p_{1A}^*$  then  $p_{2A}^{**} = \tilde{p}_{2A} \left( p_{1A}^{**}, p_{2B}^{**} \right) \geq \tilde{p}_{2A} \left( p_{1A}^{*}, p_{2B}^{**} \right) = p_{2A}^{*}$  if  $p_{2B}^{**} \geq p_{2A}^{*}$ . Thus  $p_{1A}^{**} > p_{1A}^{*}$  implies  $p_{2A}^{**} > p_{2A}^{*}$  if  $p_{2B}^{**} \geq p_{2A}^{*}$ , but both prices increasing is not possible by definition of the unconstrained Nash equilibrium. Thus, it must be that if  $p_{1A}^{**} > p_{1A}^{*}$  then  $p_{2B}^{**} < p_{2A}^{*}$ , but then  $p_{2A}^{**} \leq p_{2A}^{**}$ . But we have shown that if  $p_{2A}^{**} \leq p_{2A}^{*}$  then  $p_{1A}^{**} \leq p_{1A}^{*}$  which proves that we must have both  $p_{iA}^{**} \leq p_{iA}^{*}$  for i=1,2.

Let's prove now that  $p_{iB}^{**} \ge p_{iB}^*$  for i = 1, 2:

Remark that  $\tilde{p}_{1A}(p_{1B}, p_{2A})$  is weakly increasing in the second argument  $p_{2A}$  because of strategic complementarity in profit, and symmetrically for  $\tilde{p}_{2A}(.,.)$ .

Moreover,  $\tilde{p}_{1A}(p_{1B}, p_{2A})$  is weakly increasing in the first argument  $p_{1B}$  because of the concavity of the profit function in its own price.

Moreover,  $\tilde{p}_{1A}(p_{1B}, p_{2A}^{**}) \leq \tilde{p}_{1A}(p_{1B}, p_{2A}^{*})$  and  $\tilde{p}_{2A}(p_{1A}^{**}, p_{2B}) \leq \tilde{p}_{2A}(p_{1A}^{**}, p_{2B})$  since  $p_{iA}^{**} \leq p_{iA}^{*}$ .

Then,  $\tilde{p}_{1A}(p_{1B}, p_{2A}^*) \leq p_{1A}^*$  and thus  $\tilde{p}_{1A}(p_{1B}, p_{2A}^{**}) \leq p_{1A}^*$  which implies that

$$\Delta\Pi_{1A}\left(p_{1B}, p_{1A}^{*}, p_{2A}^{**}\right) \equiv \Pi_{1A}\left(\tilde{p}_{1A}\left(p_{1B}, p_{2A}^{**}\right), p_{2A}^{**}\right) - \Pi_{1A}\left(p_{1A}^{*}, p_{2A}^{**}\right) \leq 0$$

because the reaction function of firm 2 is increasing in the price of firm 1. Similarly  $\Pi_{2A}\left(p_{1A}^{**}, \tilde{p}_{2A}\left(p_{1A}^{**}, p_{2B}\right)\right) - \Pi_{2A}\left(p_{1A}^{**}, p_{2A}^{**}\right) \leq 0.$ 

Moreover,  $\Pi_{1A} \left( \tilde{p}_{1A} \left( p_{1B}, p_{2A}^{**} \right), p_{2A}^{**} \right) - \Pi_{1A} \left( p_{1A}^{*}, p_{2A}^{**} \right)$  is then weakly increasing in  $p_{1B}$  as well as  $\Pi_{2A} \left( p_{1A}^{**}, \tilde{p}_{2A} \left( p_{1A}^{**}, p_{2B}^{*} \right) \right) - \Pi_{2A} \left( p_{1A}^{**}, p_{2A}^{*} \right)$  in  $p_{2B}$ .

 $\Delta W_1(p_{1B}, p_{2B}^*) \equiv W(p_{1B}, p_{2B}^*) - W(\infty, p_{2B}^*) \ge 0$  is decreasing in  $p_{1B}$  and  $\Delta W_2(p_{1B}^*, p_{2B}) \equiv W(p_{1B}^*, p_{2B}) - W(p_{1B}^*, \infty) \ge 0$  is decreasing in  $p_{2B}$ .

Define

$$\tilde{\Pi}_{1B}\left(p_{1B},p_{1A}^{*},p_{2A}^{**},p_{2B}^{**}\right) = \Pi_{1A}\left(\tilde{p}_{1A}\left(p_{1B},p_{2A}^{**}\right),p_{2A}^{**}\right) + \Pi_{1B}\left(p_{1B},p_{2B}^{**}\right) - \Pi_{1A}\left(p_{1A}^{*},p_{2A}^{**}\right)$$

and

$$\tilde{\Pi}_{2B}\left(p_{2B}, p_{2A}^{*}, p_{1A}^{**}, p_{1B}^{**}\right) = \Pi_{2A}\left(p_{1A}^{**}, \tilde{p}_{2A}\left(p_{1A}^{**}, p_{2B}\right)\right) + \Pi_{2B}\left(p_{1B}^{**}, p_{2B}\right) - \Pi_{2A}\left(p_{1A}^{**}, p_{2A}^{*}\right)$$

As  $\Pi_{1B}(p_{1B}, p_{2B})$  is increasing in  $p_{1B}$  for  $p_{1B} \leq \bar{p}_{1B}(p_{2B})$  and increasing in  $p_{2B}$ , we have that  $\tilde{\Pi}_{1B}(p_{1B}, p_{1A}^*, p_{2A}^{**}, p_{2B}^{**})$  is increasing in  $p_{1B}$  for  $p_{1B} \leq \bar{p}_{1B}(p_{2B})$  and increasing in  $p_{2B}^{**}$ . Symmetrically,  $\tilde{\Pi}_{2B}(p_{2B}, p_{2A}^*, p_{1A}^{**}, p_{1B}^{**})$  is increasing in  $p_{2B}$  for  $p_{2B} \leq \bar{p}_{2B}(p_{1B})$  and increasing in  $p_{1B}^{**}$ .

Moreover, because of the previous inequalities,  $\tilde{\Pi}_{1B}\left(p_{1B},p_{1A}^{*},p_{2A}^{**},p_{2B}^{**}\right) \leq \Pi_{1B}\left(p_{1B},p_{2B}^{**}\right)$  and  $\tilde{\Pi}_{2B}\left(p_{2B},p_{2A}^{*},p_{1A}^{**},p_{1B}^{**}\right) \leq \Pi_{2B}\left(p_{1B}^{**},p_{2B}^{*}\right)$ .

Then

$$\left[\Pi_{1A}\left(\tilde{p}_{1A}\left(p_{1B}^{**},p_{2A}^{**}\right),p_{2A}^{**}\right)-\Pi_{1A}\left(p_{1A}^{*},p_{2A}^{**}\right)\right]\Delta W_{1}\left(p_{1B}^{**},p_{2B}^{**}\right)^{\frac{\rho_{1}}{1-\rho_{1}}}+\Pi_{1B}\left(p_{1B}^{**},p_{2B}^{**}\right)\Delta W_{1}\left(p_{1B}^{**},p_{2B}^{**}\right)^{\frac{\rho_{1}}{1-\rho_{1}}}$$

$$= \left[ \Pi_{1A} \left( \tilde{p}_{1A} \left( p_{1B}^{**}, p_{2A}^{**} \right), p_{2A}^{**} \right) + \Pi_{1B} \left( p_{1B}^{**}, p_{2B}^{**} \right) - \Pi_{1A} \left( p_{1A}^{*}, p_{2A}^{**} \right) \right] \Delta W_{1} \left( p_{1B}^{**}, p_{2B}^{**} \right)^{\frac{\rho_{1}}{1 - \rho_{1}}}$$

$$\geq \left[\Pi_{1A}\left(\tilde{p}_{1A}\left(p_{1B}^{*},p_{2A}^{**}\right),p_{2A}^{**}\right) + \Pi_{1B}\left(p_{1B}^{*},p_{2B}^{**}\right) - \Pi_{1A}\left(p_{1A}^{*},p_{2A}^{**}\right)\right] \Delta W_{1}\left(p_{1B}^{*},p_{2B}^{**}\right)^{\frac{\rho_{1}}{1-\rho_{1}}}$$
 because of the definition of  $p_{1B}^{**}$ 

$$= \left[\Pi_{1A}\left(\tilde{p}_{1A}\left(p_{1B}^{*}, p_{2A}^{**}\right), p_{2A}^{**}\right) - \Pi_{1A}\left(p_{1A}^{*}, p_{2A}^{**}\right)\right] \Delta W_{1}\left(p_{1B}^{*}, p_{2B}^{**}\right)^{\frac{\rho_{1}}{1-\rho_{1}}} + \Pi_{1B}\left(p_{1B}^{*}, p_{2B}^{**}\right) \Delta W_{1}\left(p_{1B}^{*}, p_{2B}^{**}\right)^{\frac{\rho_{1}}{1-\rho_{1}}}$$

$$\geq \left[\Pi_{1A}\left(\tilde{p}_{1A}\left(p_{1B}^{*},p_{2A}^{**}\right),p_{2A}^{**}\right)-\Pi_{1A}\left(p_{1A}^{*},p_{2A}^{**}\right)\right]\Delta W_{1}\left(p_{1B}^{*},p_{2B}^{**}\right)^{\frac{\rho_{1}}{1-\rho_{1}}}+\Pi_{1B}\left(p_{1B}^{**},p_{2B}^{**}\right)\Delta W_{1}\left(p_{1B}^{**},p_{2B}^{**}\right)^{\frac{\rho_{1}}{1-\rho_{1}}}$$
 because of the definition of  $p_{1B}^{*}$ 

then, using the fact that  $\Delta\Pi_{1A}\left(p_{1B}^{**},p_{1A}^{*},p_{2A}^{**}\right)=\Pi_{1A}\left(\tilde{p}_{1A}\left(p_{1B}^{**},p_{2A}^{**}\right),p_{2A}^{**}\right)-\Pi_{1A}\left(p_{1A}^{*},p_{2A}^{**}\right)$  and  $\Delta\Pi_{1A}\left(p_{1B}^{*},p_{1A}^{**},p_{2A}^{**}\right)=\Pi_{1A}\left(\tilde{p}_{1A}\left(p_{1B}^{*},p_{2A}^{**}\right),p_{2A}^{**}\right)-\Pi_{1A}\left(p_{1A}^{*},p_{2A}^{**}\right)$  the previous inequality implies that

$$\Delta\Pi_{1A}\left(p_{1B}^{**},p_{1A}^{*},p_{2A}^{**}\right)\Delta W_{1}\left(p_{1B}^{**},p_{2B}^{**}\right)^{\frac{\rho_{1}}{1-\rho_{1}}} \geq \Delta\Pi_{1A}\left(p_{1B}^{*},p_{1A}^{*},p_{2A}^{**}\right)\Delta W_{1}\left(p_{1B}^{*},p_{2B}^{**}\right)^{\frac{\rho_{1}}{1-\rho_{1}}}$$

thus

$$\left(\frac{\Delta W_1\left(p_{1B}^{**}, p_{2B}^{**}\right)}{\Delta W_1\left(p_{1B}^{*}, p_{2B}^{**}\right)}\right)^{\frac{\rho_1}{1-\rho_1}} \leq \frac{\Delta \Pi_{1A}\left(p_{1B}^{*}, p_{1A}^{*}, p_{2A}^{**}\right)}{\Delta \Pi_{1A}\left(p_{1B}^{**}, p_{1A}^{*}, p_{2A}^{**}\right)}$$

because  $\Delta\Pi_{1A}(p_{1B}^{**}, p_{1A}^{*}, p_{2A}^{**}) \leq 0$ .

This inequality if not possible if  $p_{1B}^{**} < p_{1B}^*$  because in such case  $\frac{\Delta W_1(p_{1B}^{**}, p_{2B}^{**})}{\Delta W_1(p_{1B}^{**}, p_{2B}^{**})} > 1$  because  $\Delta W_1(p_{1B}, p_{2B})$  is decreasing in  $p_{1B}$ , and  $\frac{\Delta \Pi_{1A}(p_{1B}^{**}, p_{1A}^{**}, p_{2A}^{**})}{\Delta \Pi_{1A}(p_{1B}^{**}, p_{1A}^{**}, p_{2A}^{**})} \leq 1$  because  $\Delta \Pi_{1A}(p_{1B}, p_{1A}^{**}, p_{2A}^{**})$  is increasing in  $p_{1B}$  but negative. This implies that necessarily  $p_{1B}^{**} \geq p_{1B}^{*}$ . Symmetrically  $p_{2B}^{**} \geq p_{2B}^{*}$ .

### 7.7 Additional Tables of counterfactuals

Table 7.6: Counterfactual Welfare Changes on All Drugs

		Can	ada				US		
		Int.	Ref. Prie	cing		Int.	Ref. Prie	cing	
			$(9{\rightleftharpoons}N)$	Comparison		$N \!\!\!=\!\! I_J$	$(N_{=6})$	Comparison	Bargaining
ATC4	Before	$\overset{\frown}{\Delta}$ (%)	$\overset{\cdot}{\Delta}$ (%)	$\Delta$ (%)	Before	$\overset{\frown}{\Delta}$ (%)	$\overset{\cdot}{\Delta}$ (%)	$\Delta$ (%)	$\overset{\sim}{\Delta}$ (%)
A10H0	39835	-0.0	-0.0	-0.0	111958	0.0	0.0	0.8	7.3
C2A2	11807	0.0	0.0	0.0	82759	0.0	0.0	0.0	1.4
C7A0	78531	-0.3	-0.3	-0.2	376421	0.0	0.1	0.6	4.8
C8A0	71924	-4.5	-3.8	-1.2	262422	0.6	3.0	10.9	77.7
C9A0	77971	-7.4	-5.8	-4.8	280640	1.3	3.2	6.6	7.9
L1B0	10520	-12.4	-10.4	-7.4	11972	8.2	12.9	22.9	16.3
L1X9	6327	-0.6	-0.5	0.1	4997	0.3	0.7	3.3	4.0
L4X0	104068	-9.3	-5.1	-5.2	56111	6.2	17.3	17.1	40.0
M1A1	44613	-1.2	-1.1	-0.9	337359	0.1	0.2	0.4	0.3
N1A2	22889	-1.0	-1.0	-0.8	260498	0.0	0.1	0.5	0.7
N1B1	7581	-0.8	-0.8	-0.3	85787	0.0	0.1	0.8	5.7
N3A0	223974	-0.7	-0.6	-0.5	890829	0.1	0.4	1.5	3.6
N5A1	224108	-10.5	-7.9	-4.1	348676	5.8	15.8	34.9	38.4
N5A9	45364	-0.0	-0.0	-0.0	108728	0.0	0.0	0.0	0.2
N5B3	5520	-0.2	-0.2	-0.1	37825	0.0	0.0	0.4	0.6
N6A4	69080	-2.4	-2.1	-1.7	269684	0.3	1.4	6.6	18.2
N6A9	59708	-0.1	-0.1	-0.1	240621	0.0	0.1	0.4	1.1
Total	862368	-5.02	-3.67	-2.42	2831736	1.05	2.91	6.7	12.1

Note: Welfare are average yearly (from the period 2002-2013).  $\Delta$  stands for the change in welfare between after and before in percentage of initial welfare. Column labeled "Before" shows the per country average yearly welfare of the class. Int. Ref. Pricing stands for International Reference Pricing.

Table 7.7: Counterfactual Expenditures Changes on All Drugs when International Reference Pricing w.r.t. Six Countries

		$ ho_{jm}$			Canada			US	
ATC4	$O_n \; P_{atent}$	Branded Off	$G_{e}$ $er_{i}$ $c$	Before	After	$\Delta~(\%)$	Before	After	$\Delta~(\%)$
A10H0	0.91	0.51	0.00	392	392	-0.0	11065	11065	0.0
C2A2	0.66	0.48	0.00	1468	1468	0.0	34117	34117	0.0
C7A0	0.87	0.80	0.04	3027	3041	0.5	134842	134754	-0.1
C8A0	0.80	0.53	0.10	12454	13993	12.4	240970	226362	-6.1
C9A0	0.56	0.50	0.57	8646	10722	24.0	52300	51154	-2.2
L1B0	0.34	1.00	0.32	32322	47885	48.1	408366	305662	-25.1
L1X9	0.41	0.00	0.23	28033	28508	1.7	201395	199150	-1.1
L4X0	0.80	0.71	0.15	58224	70289	20.7	478261	368499	-23.0
M1A1	0.34	0.48	0.13	1666	1701	2.1	26388	26786	1.5
N1A2	0.58	0.87	0.64	23090	23966	3.8	602738	603968	0.2
N1B1	0.89	1.00	0.57	6434	6571	2.1	114498	114618	0.1
N3A0	0.71	0.38	0.00	11284	11457	1.5	436053	435239	-0.2
N5A1	0.55	0.82	0.00	70817	106483	50.4	966348	777296	-19.6
N5A9	0.89	0.00	0.00	2584	2586	0.1	51089	51064	-0.0
N5B3	0.00		0.00	138	145	4.8	5856	6116	4.4
N6A4	0.76	0.79	0.34	6018	6842	13.7	143410	139140	-3.0
N6A9	0.72	0.36	0.04	2509	2516	0.3	54167	54150	-0.0
Total				191240	256270	34	1229013	1223082	4

Note: Expenditures are average yearly expenditure in 1000 US\$ (from the period 2002-2013).  $\Delta$  stands for the change in expenditure between after and before in percentage of initial expenditure. The parameter  $\rho_{jm}$  is the one estimated from the supply model in Canada and used for counterfactual simulations.

Table 7.8: Counterfactual Quantity Changes on All Drugs when International Reference Pricing w.r.t. Canada

		$\rho_{jm}$			Canada			US	
ATC4	$O_{n}$ $P_{atent}$	Branded Off	$G_{eneric}$	Before	After	$\Delta~(\%)$	Before	After	$\Delta~(\%)$
A10H0	0.91	0.51	0.00	7456	7454	-0.0	31368	31368	0.0
C2A2	0.66	0.48	0.00	2192	2192	0.0	24541	24541	0.0
C7A0	0.87	0.80	0.04	15534	15509	-0.2	117554	117564	0.0
C8A0	0.80	0.53	0.10	13914	13590	-2.3	81326	81552	0.3
C9A0	0.56	0.50	0.57	15207	14629	-3.8	86360	86913	0.6
L1B0	0.34	1.00	0.32	1946	1826	-6.2	3663	3786	3.4
L1X9	0.41	0.00	0.23	1197	1192	-0.4	1513	1515	0.2
L4X0	0.80	0.71	0.15	19670	18573	-5.6	18152	18619	2.6
M1A1	0.34	0.48	0.13	8517	8462	-0.6	101113	101191	0.1
N1A2	0.58	0.87	0.64	4337	4314	-0.5	79637	79646	0.0
N1B1	0.89	1.00	0.57	1483	1477	-0.4	26664	26666	0.0
N3A0	0.71	0.38	0.00	42538	42387	-0.4	274139	274260	0.0
N5A1	0.55	0.82	0.00	42657	39891	-6.5	112294	114402	1.9
N5A9	0.89	0.00	0.00	9071	9069	-0.0	33114	33115	0.0
N5B3	0.00		0.00	1054	1053	-0.1	10569	10572	0.0
N6A4	0.76	0.79	0.34	13482	13302	-1.3	86964	87068	0.1
N6A9	0.72	0.36	0.04	11806	11797	-0.1	74626	74632	0.0
Total				79783	78151	-2	726100	729009	.4

Note: Quantity are average yearly standard units (on period 2002-2013).  $\Delta$  stands for the change of quantity between after and before in percentage of initial quantity. The parameter  $\rho_{jm}$  is the one estimated from the supply model in Canada and used for counterfactual simulations.

Table 7.9: Counterfactual Quantity Changes on All Drugs when International Reference Pricing w.r.t. Six Countries

		$ ho_{jm}$			Canada			US	
ATC4	$O_n \; P_{atent}$	Branded Og	$G_{eneric}$	Before	After	$\Delta~(\%)$	Before	After	$\Delta~(\%)$
A10H0	0.91	0.51	0.00	7456	7454	-0.0	31368	31370	0.0
C2A2	0.66	0.48	0.00	2192	2192	0.0	24541	24541	0.0
C7A0	0.87	0.80	0.04	15534	15509	-0.2	117554	117614	0.1
C8A0	0.80	0.53	0.10	13914	13645	-1.9	81326	82344	1.3
C9A0	0.56	0.50	0.57	15207	14758	-3.0	86360	87653	1.5
L1B0	0.34	1.00	0.32	1946	1848	-5.0	3663	3843	4.9
L1X9	0.41	0.00	0.23	1197	1193	-0.3	1513	1518	0.4
L4X0	0.80	0.71	0.15	19670	19099	-2.9	18152	19238	6.0
M1A1	0.34	0.48	0.13	8517	8467	-0.6	101113	101255	0.1
N1A2	0.58	0.87	0.64	4337	4316	-0.5	79637	79669	0.0
N1B1	0.89	1.00	0.57	1483	1477	-0.4	26664	26675	0.0
N3A0	0.71	0.38	0.00	42538	42401	-0.3	274139	274693	0.2
N5A1	0.55	0.82	0.00	42657	40649	-4.7	112294	117188	4.4
N5A9	0.89	0.00	0.00	9071	9069	-0.0	33114	33120	0.0
N5B3	0.00		0.00	1054	1053	-0.1	10569	10572	0.0
N6A4	0.76	0.79	0.34	13482	13322	-1.2	86964	87455	0.6
N6A9	0.72	0.36	0.04	11806	11797	-0.1	74626	74656	0.0
Total				153840	150727	-2	481416	483422	.4

Note: Quantity are average yearly standard units (on period 2002-2013).  $\Delta$  stands for the change of quantity between after and before in percentage of initial quantity. The parameter  $\rho_{jm}$  is the one estimated from the supply model in Canada and used for counterfactual simulations.

 ${\it Table 7.10: Counterfactual Profits \ on \ All \ Drugs \ when \ International \ Reference \ Pricing \ w.r.t. \ Canada}$ 

		$ ho_{jm}$			Canada			US	
ATC4	$O_n \; P_{atent}$	$B_{randed}O_{ff}$	$G_{eneric}$	Before	After	$\Delta~(\%)$	Before	After	$\Delta~(\%)$
A10H0	0.91	0.51	0.00	33	33	1.8	4633	4633	-0.0
C2A2	0.66	0.48	0.00	783	783	0.0	6195	6195	0.0
C7A0	0.87	0.80	0.04	1505	1539	2.3	61310	61288	-0.0
C8A0	0.80	0.53	0.10	8385	9608	14.6	141424	139837	-1.1
C9A0	0.56	0.50	0.57	4815	7373	53.1	20654	19687	-4.7
L1B0	0.34	1.00	0.32	12479	30515	144.5	243432	183327	-24.7
L1X9	0.41	0.00	0.23	16275	17238	5.9	121461	120210	-1.0
L4X0	0.80	0.71	0.15	46707	71725	53.6	193670	175378	-9.4
M1A1	0.34	0.48	0.13	375	579	54.4	3640	3552	-2.4
N1A2	0.58	0.87	0.64	17924	19126	6.7	212219	212111	-0.1
N1B1	0.89	1.00	0.57	4954	5128	3.5	36128	36124	-0.0
N3A0	0.71	0.38	0.00	2857	3433	20.2	171438	171108	-0.2
N5A1	0.55	0.82	0.00	44548	99688	123.8	678053	600493	-11.4
N5A9	0.89	0.00	0.00	1101	1105	0.3	10707	10704	-0.0
N5B3	0.00		0.00	0	28		1827	1799	-1.5
N6A4	0.76	0.79	0.34	3221	4198	30.3	93089	92037	-1.1
N6A9	0.72	0.36	0.04	550	565	2.6	23932	23918	-0.1
Total				76322	121016	58.5	1322671	1241364	-6.1

Note: Profits are average yearly profits in 1000 US\$ (from the period 2002-2013).  $\Delta$  stands for the change in profits between after and before in percentage of initial profits. The parameter  $\rho_j$  is the one estimated from the supply model in Canada and used for counterfactual simulations.

Table 7.11: Counterfactual Profits on All Drugs when International Reference Pricing w.r.t. Six Countries

		$\rho_{jm}$			Canada			US	
ATC4	$O_n \ _{Patent}$	$B_{randed\ O_{ar{H}}}$	$G_{eneric}$	Before	After	$\Delta~(\%)$	Before	After	$\Delta~(\%)$
A10H0	0.91	0.51	0.00	33	33	1.8	4633	4632	-0.0
C2A2	0.66	0.48	0.00	783	783	0.0	6195	6195	0.0
C7A0	0.87	0.80	0.04	1505	1539	2.3	61310	61178	-0.2
C8A0	0.80	0.53	0.10	8385	9412	12.2	141424	134072	-5.2
C9A0	0.56	0.50	0.57	4815	6775	40.7	20654	17714	-14.2
L1B0	0.34	1.00	0.32	12479	26205	110.0	243432	155234	-36.2
L1X9	0.41	0.00	0.23	16275	16843	3.5	121461	118860	-2.1
L4X0	0.80	0.71	0.15	46707	58642	25.6	193670	147267	-24.0
M1A1	0.34	0.48	0.13	375	560	49.3	3640	3420	-6.1
N1A2	0.58	0.87	0.64	17924	19050	6.3	212219	211672	-0.3
N1B1	0.89	1.00	0.57	4954	5119	3.3	36128	36103	-0.1
N3A0	0.71	0.38	0.00	2857	3379	18.3	171438	169661	-1.0
N5A1	0.55	0.82	0.00	44548	80420	80.5	678053	491980	-27.4
N5A9	0.89	0.00	0.00	1101	1104	0.3	10707	10695	-0.1
N5B3	0.00		0.00	0	28		1827	1800	-1.5
N6A4	0.76	0.79	0.34	3221	4084	26.8	93089	88176	-5.3
N6A9	0.72	0.36	0.04	550	564	2.5	23932	23866	-0.3
Total				117614	180762	53.6	517316	506003	-2.1

Note: Profits are average yearly profits in 1000 US\$ (from the period 2002-2013).  $\Delta$  stands for the change in profits between after and before in percentage of initial profits. The parameter  $\rho_j$  is the one estimated from the supply model in Canada and used for counterfactual simulations.

 $\label{thm:continuous} \begin{tabular}{lll} Table 7.12: Counterfactual Expenditures On-Patent Drugs when International Reference Pricing w.r.t. \ Canada \\ \end{tabular}$ 

			C	anada				US	
ATC4	$O_n  P_{atent}$	$ ho_{jm}^{m}$ $ ho_{jm}^{q}$ $ ho_{jm}^{m}$	$G_{eneric}$	Before	After	$\Delta~(\%)$	Before	After	$\Delta~(\%)$
A10H0	0.91	0.51	0.00	17	16	-3.5	3764	3764	0.0
C2A2	0.66	0.48	0.00	801	801	0.0	9342	9342	0.0
C7A0	0.87	0.80	0.04	819	800	-2.3	69644	69652	0.0
C8A0	0.80	0.53	0.10	7351	8016	9.1	74427	74297	-0.2
C9A0	0.56	0.50	0.57	6647	8694	30.8	23929	24776	3.5
L1B0	0.34	1.00	0.32	26137	40586	55.3	354028	289568	-18.2
L1X9	0.41	0.00	0.23	27066	27806	2.7	183792	182654	-0.6
L4X0	0.80	0.71	0.15	52375	76385	45.8	232537	213420	-8.2
M1A1	0.34	0.48	0.13	457	423	-7.4	3405	3721	9.3
N1A2	0.58	0.87	0.64	1752	1654	-5.6	131440	131950	0.4
N1B1	0.89	1.00	0.57	1839	1841	0.1	41420	41465	0.1
N3A0	0.71	0.38	0.00	3499	3424	-2.2	194414	194818	0.2
N5A1	0.55	0.82	0.00	28076	61149	117.8	849308	774450	-8.8
N5A9	0.89	0.00	0.00	1312	1312	0.0	2207	2210	0.1
N5B3	0.00		0.00	29	35	19.7	2858	3124	9.3
N6A4	0.76	0.79	0.34	2473	2994	21.1	108980	108315	-0.6
N6A9	0.72	0.36	0.04	415	411	-0.9	5774	5787	0.2
Total				91107	130180	42.88	1500494	1425874	-4.97

 $Note: \textit{Expenditures are average yearly expenditures in 1000 US\$ (on period 2002-2013)}. \ Patented \ drugs \ only.$ 

Table 7.13: Counterfactual Expenditures On-Patent Drugs when International Reference Pricing w.r.t. Six Countries

			С	anada				US	
ATC4	$O_n  P_{atent}$	$ ho_{jm}$ HO papue $_{jm}$	$G_{eneric}$	Before	After	$\Delta~(\%)$	Before	After	$\Delta~(\%)$
A10H0	0.91	0.51	0.00	17	16	-3.5	3764	3766	0.1
C2A2	0.66	0.48	0.00	801	801	0.0	9342	9342	0.0
C7A0	0.87	0.80	0.04	819	801	-2.3	69644	69687	0.1
C8A0	0.80	0.53	0.10	7351	7916	7.7	74427	73537	-1.2
C9A0	0.56	0.50	0.57	6647	8221	23.7	23929	25263	5.6
L1B0	0.34	1.00	0.32	26137	37329	42.8	354028	267372	-24.5
L1X9	0.41	0.00	0.23	27066	27521	1.7	183792	181867	-1.0
L4X0	0.80	0.71	0.15	52375	63768	21.8	232537	184170	-20.8
M1A1	0.34	0.48	0.13	457	428	-6.4	3405	3922	15.2
N1A2	0.58	0.87	0.64	1752	1666	-4.9	131440	133250	1.4
N1B1	0.89	1.00	0.57	1839	1841	0.1	41420	41672	0.6
N3A0	0.71	0.38	0.00	3499	3429	-2.0	194414	195977	0.8
N5A1	0.55	0.82	0.00	28076	49148	75.1	849308	667724	-21.4
N5A9	0.89	0.00	0.00	1312	1312	0.0	2207	2218	0.5
N5B3	0.00		0.00	29	35	19.7	2858	3122	9.3
N6A4	0.76	0.79	0.34	2473	2931	18.5	108980	105845	-2.9
N6A9	0.72	0.36	0.04	415	411	-0.9	5774	5839	1.1
Total				119615	163754	36.9	508081	506999	21

 $Note: \textit{Expenditures are average yearly expenditures in 1000 US\$ (on period 2002-2013)}. \ Patented \ drugs \ only.$ 

 $\label{thm:continuous} \begin{tabular}{lll} Table 7.14: Counterfactual Price Changes by ATC-4 when International Reference Pricing w.r.t. \\ Canada \end{tabular}$ 

		$ ho_{jm}$		Price C All d	_	Price C Pater	_	Price C Brande	_	Price Change Generic	
ATC4	$O_n  P_{atent}$	$B_{randed\ Off}$	$G_{eneric}$	CA (%)	US (%)	CA (%)	US (%)	CA (%)	US (%)	CA (%)	US (%)
A10H0	0.91	0.51	0.00	1.4	-0.0	63.0	-0.0	0.0	-0.0	0.0	0.0
C2A2	0.66	0.48	0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
C7A0	0.87	0.80	0.04	7.2	-0.1	56.0	-0.1	-2.1	-0.0	-0.0	0.0
C8A0	0.80	0.53	0.10	22.1	-1.0	74.0	-3.2	2.0	-0.1	0.2	0.0
C9A0	0.56	0.50	0.57	33.7	-6.3	87.4	-13.9	0.7	-0.9	1.9	0.0
L1B0	0.34	1.00	0.32	44.7	-10.8	107.5	-12.4	-17.6	-1.5	0.2	0.0
L1X9	0.41	0.00	0.23	2.6	-0.7	5.3	-0.8	0.0	0.0	0.6	0.0
L4X0	0.80	0.71	0.15	32.5	-3.4	71.9	-6.6	2.9	-1.8	-0.3	0.0
M1A1	0.34	0.48	0.13	29.4	-1.6	211.7	-12.5	0.4	-0.1	0.3	0.0
N1A2	0.58	0.87	0.64	7.2	-0.2	141.1	-0.7	6.2	-0.0	1.7	0.0
N1B1	0.89	1.00	0.57	4.1	-0.1	23.2	-0.3	2.6	-0.0	2.0	0.0
N3A0	0.71	0.38	0.00	21.1	-0.3	137.3	-0.7	0.2	-0.0	0.0	0.0
N5A1	0.55	0.82	0.00	63.6	-8.7	257.4	-10.0	37.1	-0.2	0.0	0.0
N5A9	0.89	0.00	0.00	0.4	-0.0	1.7	-0.2	0.0	-0.0	0.0	0.0
N5B3	0.00		0.00	181.7	-7.1	1713.4	-14.3	0.0	0.0	0.0	0.0
N6A4	0.76	0.79	0.34	33.8	-1.2	156.6	-1.6	7.3	-0.5	1.1	0.0
N6A9	0.72	0.36	0.04	3.6	-0.1	40.6	-0.6	-0.1	-0.0	-0.0	0.0

Note: Changes in % of initial price using market shares weighted average prices.

 $\label{thm:counterfactual} \begin{tabular}{lll} Table 7.15: Counterfactual Price Changes by ATC-4 when International Reference Pricing w.r.t. \\ Six Countries \end{tabular}$ 

		$ ho_{jm}$		Price Change All drugs		Price C Pater	0	Price Change Branded Off		Price Change Generic	
ATC4	$O_n \ P_{atent}$	$B_{randed}O_{f}$	$G_{eneric}$	CA (%)	US (%)	CA (%)	US (%)	CA (%)	US (%)	CA (%)	US (%)
A10H0	0.91	0.51	0.00	1.4	-0.1	62.8	-0.2	0.0	-0.0	0.0	0.0
C2A2	0.66	0.48	0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
C7A0	0.87	0.80	0.04	6.9	-0.3	53.9	-0.5	-2.1	-0.0	-0.0	0.0
C8A0	0.80	0.53	0.10	16.5	-4.2	55.4	-13.2	1.6	-0.3	0.2	0.0
C9A0	0.56	0.50	0.57	21.2	-12.1	54.9	-26.4	0.5	-2.3	1.3	0.0
L1B0	0.34	1.00	0.32	30.9	-17.5	74.6	-20.2	-17.9	-2.1	-0.0	0.0
L1X9	0.41	0.00	0.23	1.5	-1.8	3.1	-2.0	0.0	0.0	0.4	0.0
L4X0	0.80	0.71	0.15	14.0	-7.2	31.0	-14.0	1.9	-4.6	-0.2	0.0
M1A1	0.34	0.48	0.13	22.0	-2.3	158.0	-17.9	0.3	-0.1	0.3	0.0
N1A2	0.58	0.87	0.64	6.1	-0.6	114.1	-2.3	5.9	-0.1	1.6	0.0
N1B1	0.89	1.00	0.57	3.9	-0.5	21.8	-1.5	2.5	-0.1	1.9	0.0
N3A0	0.71	0.38	0.00	17.1	-1.3	111.4	-2.9	0.1	-0.1	0.0	0.0
N5A1	0.55	0.82	0.00	38.9	-18.5	156.7	-21.5	23.1	-0.6	0.0	0.0
N5A9	0.89	0.00	0.00	0.3	-0.0	1.3	-0.9	0.0	-0.0	0.0	0.0
N5B3	0.00		0.00	181.7	-7.1	1713.4	-14.3	0.0	0.0	0.0	0.0
N6A4	0.76	0.79	0.34	26.8	-5.3	123.9	-6.9	5.9	-2.0	0.9	0.0
N6A9	0.72	0.36	0.04	3.3	-0.3	37.3	-3.1	-0.2	-0.1	-0.0	0.0

Note: Changes in % of initial price using market shares weighted average prices.

Table 7.16: Counterfactual Prices of On-Patent Drugs present in both US and Canada when International Reference Pricing w.r.t. Six Countries

	Befo	ore		After					
	Canada	US	Car	nada	U	$\Gamma$ S			
ATC4	Price	Price	Price	$\Delta~(\%)$	Price	$\Delta~(\%)$			
A10H0	0.63	1.03	1.03	62.31	1.03	-0.20			
C2A2	57.76	17.32	57.76	0.00	17.32	0.00			
C7A0	1.08	1.95	2.00	85.47	1.91	-2.25			
C8A0	1.06	2.19	1.88	77.37	1.88	-14.16			
C9A0	0.55	1.78	1.16	110.32	1.16	-34.75			
L1B0	247.97	506.81	372.30	50.14	372.30	-26.54			
L1X9	545.32	579.99	579.44	6.26	556.10	-4.12			
L4X0	4.98	10.03	6.54	31.34	6.31	-37.11			
M1A1	0.67	3.07	1.79	166.46	1.79	-41.63			
N1A2	21.11	51.54	45.65	116.26	45.65	-11.42			
N1B1	12.56	16.47	16.19	28.95	16.19	-1.66			
N3A0	1.55	3.79	3.52	126.17	3.52	-7.14			
N5A1	2.75	13.51	10.57	284.52	10.57	-21.78			
N5A9	0.82	1.36	1.21	47.29	1.22	-10.70			
N5B3	2.67	61.87	52.46	1863.08	52.51	-15.12			
N6A4	1.53	3.68	3.38	120.54	3.38	-8.11			
N6A9	0.39	1.15	0.98	152.76	0.98	-14.63			

 $Note: Market\ shares\ weighted\ average\ price\ of\ patented\ drugs\ by\ ATC-4,\ country\ for\ drugs\ present\ in\ both\ only.\ Percentage\ changes\ are\ changes\ with\ respect\ to\ the\ initial\ situation.$ 

Table 7.17: Counterfactual Consumer Welfare Changes on All Drugs when International Reference Pricing w.r.t. Canada

		Canada			US	
ATC4	Before	After	$\Delta~(\%)$	Before	After	$\Delta~(\%)$
A10H0	39835	39824	-0.0	111958	111960	0.0
C2A2	11807	11807	0.0	82759	82759	0.0
C7A0	78531	78312	-0.3	376421	376471	0.0
C8A0	71924	68689	-4.5	262422	264091	0.6
C9A0	77971	72234	-7.4	280640	284298	1.3
L1B0	10520	9220	-12.4	11972	12953	8.2
L1X9	6327	6286	-0.6	4997	5013	0.3
L4X0	104068	94355	-9.3	56111	59567	6.2
M1A1	44613	44072	-1.2	337359	337733	0.1
N1A2	22889	22654	-1.0	260498	260540	0.0
N1B1	7581	7520	-0.8	85787	85798	0.0
N3A0	223974	222397	-0.7	890829	891513	0.1
N5A1	224108	200673	-10.5	348676	369068	5.8
N5A9	45364	45346	-0.0	108728	108734	0.0
N5B3	5520	5511	-0.2	37825	37842	0.0
N6A4	69080	67444	-2.4	269684	270486	0.3
N6A9	59708	59622	-0.1	240621	240654	0.0
Total	414243	399144	-3.6	2333768	2359414	1

Note: Welfare values are average yearly on period 2002-2013 scaled by market size.  $\Delta$  stands for the change of welfare between after and before in percentage of initial welfare. The parameter  $\rho_{jm}$  is the one estimated from the supply model in Canada and used for counterfactual simulations.

 $\label{thm:counterfactual} \begin{tabular}{l} \textbf{Expenditures and Profits Global Changes on All Drugs when International Reference Pricing w.r.t. \end{tabular} \begin{tabular}{l} \textbf{Expenditures and Profits Global Changes on All Drugs when International Reference Pricing w.r.t. \end{tabular} \begin{tabular}{l} \textbf{Expenditures and Profits Global Changes on All Drugs when International Reference Pricing w.r.t. \end{tabular} \begin{tabular}{l} \textbf{Expenditures and Profits Global Changes on All Drugs when International Reference Pricing w.r.t. \end{tabular} \begin{tabular}{l} \textbf{Expenditures and Profits Global Changes on All Drugs when International Reference Pricing w.r.t. \end{tabular} \begin{tabular}{l} \textbf{Expenditures and Profits Global Changes on All Drugs when International Reference Pricing w.r.t. \end{tabular} \begin{tabular}{l} \textbf{Expenditures and Profits Global Changes on All Drugs when International Reference Pricing w.r.t. \end{tabular} \begin{tabular}{l} \textbf{Expenditures and Profits Global Changes on All Drugs when International Reference Pricing w.r.t. \end{tabular} \begin{tabular}{l} \textbf{Expenditures and Profits Global Changes on All Drugs when International Reference Pricing w.r.t. \end{tabular} \begin{tabular}{l} \textbf{Expenditures and Profits Global Changes on All Drugs when International Reference Pricing w.r.t. \end{tabular} \begin{tabular}{l} \textbf{Expenditures and Profits Global Changes on All Drugs when International Reference Pricing w.r.t. \end{tabular} \begin{tabular}{l} \textbf{Expenditures and Profits Global Changes on All Drugs when International Reference Pricing w.r.t. \end{tabular} \begin{tabular}{l} \textbf{Expenditures and Profits Global Changes on All Drugs when International Reference Pricing w.r.t. \end{tabular} \begin{tabular}{l} \textbf{Expenditures and Profits Global Changes on All Drugs when International Reference Pricing w.r.t. \end{tabular} \begin{tabular}{l} \textbf{Expenditures and Profits Global Changes on All Drugs when International Reference Pricing w.r.t. \end{tabular} \begin{tabular}{l} \textbf{Expenditures and$ 

		Expenses			Profits	
ATC4	Before	After	$\Delta$ (%)	Before	After	$\Delta~(\%)$
A10H0	11456	11456	-0.0	4665	4666	0.0
C2A2	35585	35585	0.0	6978	6978	0.0
C7A0	137869	137869	-0.0	62815	62827	0.0
C8A0	253424	252070	-0.5	149809	149445	-0.2
C9A0	60946	63477	4.2	25469	27061	6.2
L1B0	440688	384941	-12.6	255911	213842	-16.4
L1X9	229428	228917	-0.2	137736	137449	-0.2
L4X0	536485	516910	-3.6	240376	247103	2.8
M1A1	28055	28341	1.0	4015	4131	2.9
N1A2	625829	627110	0.2	230143	231237	0.5
N1B1	120932	121098	0.1	41082	41252	0.4
N3A0	447337	447414	0.0	174295	174541	0.1
N5A1	1037164	1013646	-2.3	722601	700181	-3.1
N5A9	53672	53670	-0.0	11808	11809	0.0
N5B3	5994	6262	4.5	1827	1827	-0.0
N6A4	149428	149451	0.0	96310	96235	-0.1
N6A9	56676	56679	0.0	24482	24483	0.0
Total	4230967	4134897	-2.2	2190321	2135067	-2.5

Note: All values are average yearly on period 2002-2013, summing US and Canada.  $\Delta$  stands for the change between after and before in percentage of initial value.

 ${\it Table 7.19: Counterfactual \ Prices \ when \ International \ Reference \ Pricing \ w.r.t. \ Canada}$ 

		A	.11		Patented				Branded Off				Generic			
	Before		After		Before		After		Before		After		Before		After	
ATC4	CA	US	CA	US	CA	US	CA	US	CA	US	CA	US	CA	US	CA	US
A10H0	0.05	0.35	0.05	0.35	0.64	1.04	1.05	1.04	0.35	0.79	0.35	0.79	0.05	0.20	0.05	0.20
C2A2	0.67	1.38	0.67	1.38	55.32	12.43	55.32	12.43	4.03	2.24	4.03	2.24	0.15	1.05	0.15	1.05
C7A0	0.19	1.14	0.22	1.14	0.32	6.91	0.49	6.91	1.41	1.49	1.38	1.49	0.10	0.45	0.10	0.45
C8A0	0.89	2.99	1.29	2.96	1.25	2.30	2.18	2.22	0.78	17.56	0.80	17.55	0.50	1.38	0.51	1.38
C9A0	0.57	0.60	0.95	0.56	0.66	1.67	1.24	1.43	0.54	1.51	0.55	1.50	0.31	0.33	0.32	0.33
L1B0	17.25	113.27	32.67	101.04	19.64	333.05	40.75	291.63	12.74	125.50	10.51	123.57	10.42	18.16	10.43	18.16
L1X9	21.49	130.27	22.59	129.33	420.67	734.94	443.17	729.15	0.94		0.94		0.89	14.23	0.90	14.23
L4X0	2.95	25.87	4.87	25.00	2.97	27.02	5.10	25.23	2.66	9.57	2.74	9.40	2.87	38.32	2.86	38.32
M1A1	0.20	0.26	0.31	0.26	0.67	3.67	2.09	3.21	0.50	0.91	0.50	0.91	0.13	0.21	0.13	0.21
N1A2	5.29	7.68	6.05	7.67	11.55	74.26	27.84	73.74	6.52	15.68	6.92	15.67	4.51	4.61	4.58	4.61
N1B1	4.35	4.30	4.70	4.30	11.10	15.77	13.68	15.73	4.52	6.00	4.64	5.99	3.15	2.83	3.21	2.83
N3A0	0.26	1.58	0.38	1.58	1.37	4.28	3.25	4.25	0.19	4.70	0.19	4.70	0.20	0.83	0.20	0.83
N5A1	1.67	8.59	3.80	7.85	1.85	10.69	6.61	9.62	3.11	9.73	4.27	9.71	0.40	3.17	0.40	3.17
N5A9	0.29	1.54	0.29	1.54	1.98	2.36	2.02	2.36	0.25	14.27	0.25	14.27	0.14	1.11	0.14	1.11
N5B3	0.14	0.56	0.63	0.52	2.08	26.51	37.67	22.71					0.11	0.29	0.11	0.29
N6A4	0.47	1.65	0.78	1.63	1.33	3.61	3.40	3.56	1.43	4.17	1.54	4.15	0.30	0.47	0.30	0.47
N6A9	0.21	0.71	0.23	0.71	0.63	2.83	0.88	2.81	0.61	3.43	0.61	3.43	0.15	0.33	0.15	0.33

Note: Market shares weighted average price by ATC-4, country.

Table 7.20: Counterfactual Prices when International Reference Pricing w.r.t. Six countries

		A	.11		Patented				Branded Off				Generic			
	Before		After		Before		After		Before		After		Before		After	
ATC4	CA	US	CA	US	CA	US	CA	US	CA	US	CA	US	CA	US	CA	US
A10H0	0.05	0.35	0.05	0.35	0.64	1.04	1.05	1.03	0.35	0.79	0.35	0.79	0.05	0.20	0.05	0.20
C2A2	0.67	1.38	0.67	1.38	55.32	12.43	55.32	12.43	4.03	2.24	4.03	2.24	0.15	1.05	0.15	1.05
C7A0	0.19	1.14	0.22	1.14	0.32	6.91	0.49	6.88	1.41	1.49	1.38	1.48	0.10	0.45	0.10	0.45
C8A0	0.89	2.99	1.19	2.87	1.25	2.30	1.95	1.99	0.78	17.56	0.80	17.52	0.50	1.38	0.51	1.38
C9A0	0.57	0.60	0.81	0.53	0.66	1.67	1.03	1.23	0.54	1.51	0.54	1.47	0.31	0.33	0.32	0.33
L1B0	17.25	113.27	27.92	93.46	19.64	333.05	34.28	265.90	12.74	125.50	10.46	122.90	10.42	18.16	10.42	18.16
L1X9	21.49	130.27	22.13	127.93	420.67	734.94	433.75	720.46	0.94		0.94		0.89	14.23	0.90	14.23
L4X0	2.95	25.87	3.78	24.01	2.97	27.02	3.89	23.24	2.66	9.57	2.71	9.13	2.87	38.32	2.86	38.32
M1A1	0.20	0.26	0.28	0.26	0.67	3.67	1.73	3.01	0.50	0.91	0.50	0.91	0.13	0.21	0.13	0.21
N1A2	5.29	7.68	5.93	7.64	11.55	74.26	24.72	72.53	6.52	15.68	6.90	15.66	4.51	4.61	4.58	4.61
N1B1	4.35	4.30	4.68	4.28	11.10	15.77	13.52	15.54	4.52	6.00	4.64	5.99	3.15	2.83	3.21	2.83
N3A0	0.26	1.58	0.36	1.56	1.37	4.28	2.90	4.16	0.19	4.70	0.19	4.70	0.20	0.83	0.20	0.83
N5A1	1.67	8.59	2.97	7.00	1.85	10.69	4.75	8.40	3.11	9.73	3.83	9.67	0.40	3.17	0.40	3.17
N5A9	0.29	1.54	0.29	1.54	1.98	2.36	2.01	2.34	0.25	14.27	0.25	14.27	0.14	1.11	0.14	1.11
N5B3	0.14	0.56	0.63	0.52	2.08	26.51	37.67	22.73					0.11	0.29	0.11	0.29
N6A4	0.47	1.65	0.72	1.56	1.33	3.61	2.97	3.37	1.43	4.17	1.52	4.09	0.30	0.47	0.30	0.47
N6A9	0.21	0.71	0.23	0.71	0.63	2.83	0.86	2.74	0.61	3.43	0.61	3.43	0.15	0.33	0.15	0.33

Note: Market shares weighted average price by ATC-4, country.