PRICE-CAP REGULATION, UNCERTAINTY AND THE PRICE EVOLUTION OF NEW PHARMACEUTICALS†1,2

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ABSTRACT

This paper examines the effect of the regulations restricting price increases on the evolution of pharmaceutical prices. A novel theoretical model shows that this policy leads firms to price new drugs with uncertain demand above the expected value initially. Price decreases after drug launch are more likely, the higher the uncertainty. We empirically test the model’s predictions using data from the Canadian pharmaceutical market. The level of uncertainty is shown to play a crucial role in drug pricing strategies. © 2014 The Authors. Health Economics Published by John Wiley & Sons Ltd.

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KEY WORDS: price-cap regulation; uncertainty; price evolution; pricing strategies; new pharmaceuticals

1. INTRODUCTION

A common regulatory intervention in pharmaceutical markets is to prohibit price increases above the rate of inflation. Following Abbott (1995), we label this policy “price-cap regulation”. This paper offers a simple theoretical model of price-cap regulation in a context with a new drug facing uncertain demand and an empirical test of the model using Canadian data. The theoretical model shows that the policy leads to high introductory prices for drugs with uncertain demand because of the inability to increase prices. Surprisingly, we show that welfare effects can be positive, to the extent that price influences consumption, and price-cap regulation can thus be efficiency enhancing because it shifts consumption toward higher quality drugs. Consistent with theory, our empirical analysis of Canadian drug prices shows that price-cap regulation selectively affects drugs with uncertain demand: Drugs with new active substances have a bimodal distribution of price evolution, either staying at the initial high price or else dropping their price substantially after the drug is introduced to the market. In comparison, new drugs with known demand—such as reformulations of old drugs—have a unimodal distribution of price evolution, with no substantial decreases.

Most industrialized countries regulate pharmaceutical prices in one way or another. The most common regulation starts with constraining initial prices. Price increases after launch are then restricted according to price-cap regulation, typically allowing for increases at the rate of inflation (Jacobzone, 2000). Even in the

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USA, which has relatively little use of price regulations, the Omnibus Budget Reconciliation Act of 1990 limits price increases of brand drugs sold to Medicaid to the rate of inflation. Pharmaceutical expenditures have been one of the fastest-growing components of health care expenditures globally, suggesting that understanding price-cap regulation in pharmaceutical markets is important. Despite its widespread use, little is known about the effect of price-cap regulation on the price evolution of new pharmaceuticals.

Although safety and efficacy of all new drugs are assessed by regulatory agencies before coming to the market, these assessments do not eliminate all uncertainty. The limited size and short duration of premarketing clinical trials mean that not everything can be fully learned about the safety profile (side effects and drug–drug interactions) of a new drug before its approval. Patients are carefully screened and closely monitored throughout premarketing clinical trials, which reduces the risk of poor product choice and poor compliance in this controlled environment, relative to situations in real world (Food and Drug Administration, 2007). Much more information, including a more complete safety profile of drugs, is learned through wide usage by patients after approval.

Assuming the safety standard is met, firms are required to verify only that the new drug is more effective than placebo, not more effective than existing products. Thus, there is a great deal of uncertainty for patients, physicians, payers, and even firms regarding the likely population and their use of drugs, or in short, the factors that influence demand for the drug after approval. As patients with heterogeneous characteristics use a newly approved drug, information is acquired about the match between a new drug, its indications, and patients with different characteristics.

The extent of demand uncertainty, however, varies across drugs and across time. First, more novel drugs face higher uncertainty, as consumers have less experience with the use of similar products and firms have less information about demand parameters. Second, the less the cumulative use of a specific drug and the shorter the time since first usage, the less knowledge there is about the drug itself and its effects. Empirically, safety warnings are more likely to be issued within the early years following a drug’s introduction (Lasser et al., 2002). We identify the effect of this uncertainty on the price evolution of drugs using novelty and the experience of drugs in the US market.

This paper is the first study on the price evolution of patented pharmaceuticals in Canada. Drug companies encounter two distinct hurdles in freely implementing their pricing strategies in the Canadian market: the Patented Medicine Prices Review Board (PMPRB) and provincial drug plans. The PMPRB reviews the introductory prices set by firms and does not allow any increase in real prices following introduction. Public drug plans also limit price increases. Therefore, restrictions on initial prices and on price increases in the following years, as well as cost-sharing policies, may affect the pricing strategies of drug companies. We find that uncertainty associated with new drugs is an important factor in determining the pricing strategies of drugs in Canada. Innovative drugs are marketed in Canada with high introductory prices because firms know that price increases in the following years will not be permitted. Price-cap regulation motivates pharmaceutical firms to “explore” the highest achievable price in the market, by setting a high price in the introductory year and adjusting it down only if needed.

These findings are in contrast with the result of previous studies in the less heavily regulated market of the USA. Not surprisingly, the strategies of drug companies depend on the structure and regulatory context of the pharmaceutical market in each jurisdiction and vary between Canada and the USA.

This paper is organized as follows. In the next section, we review the literature on the pricing strategies of new pharmaceutical products. Section 3 describes the data used in this paper as well as the empirical model to be estimated. In section 4, we discuss the empirical results of the model. Section 5 concludes the paper.

2. LITERATURE ON THE DYNAMICS OF DRUG PRICES

The literature on the dynamics of pharmaceutical pricing reflects the different regulatory environments across countries. Reekie (1978), considering new drugs introduced to the US drug market between 1958 and 1975,
shows that firms set their pricing strategies based on therapeutic novelty. Using univariate analysis, he finds that major breakthrough drugs come to the market with high prices (relative to their rivals) with a gradual reduction over the product life cycle. This pricing strategy is called “skimming” because it seeks to obtain high prices from consumers with a high willingness to pay. Conversely, imitative drugs were found to follow a “penetration pricing” strategy; prices of drugs with minor advances relative to their rivals are set at a low level on market launch. The prices of these imitator drugs then increase over time. The intuitions for these two different pricing strategies are based on the seminal marketing analysis by Dean (1969).

Weston (1979) emphasizes another competitive aspect of the pricing behavior of firms by showing that the decrease in prices of innovative drugs is responsive to the entry of new drugs in the same therapeutic class. Lu and Comanor (1998) examine the pricing strategies of firms in a multivariate analysis. Considering new drugs introduced to the US market between 1978 and 1987, Lu and Comanor find that therapeutic novelty, the number of substitutes in a therapeutic class, and the anticipated number of repeat purchases are the main determinants of pricing strategies for new patented drugs. As a result, unregulated pharmaceutical markets can be characterized as oligopolistic markets where firms have some market power in pricing their products. Market power rises with the level of product novelty and falls as more branded competitors enter the market. Switching costs play a role for chronic drugs with repeat purchases.

Frank and Salkever (1997) show that branded drugs facing generic competitors increase their price to take advantage of the inelastic segment of the market, while competition reduces the price of generic drugs. As a result, off-patent branded competitors with generic rivals and patented branded drugs could have different effects on the pricing strategies of a new drug entering the same therapeutic class. Lu and Comanor (1998) find that while competition from patented branded drugs depresses the prices of new drugs, competition from off-patent drugs with generic rivals increases prices.

While the previous studies examine pricing strategies in the relatively less regulated US market, their predictions might not carry through in markets with more intrusive price regulations. Abbott (1995) studies the effect of implementing a policy restricting price increases in the pharmaceutical industry. Abbott compares the optimal prices of an unregulated firm to the optimal prices of a firm facing price-cap regulation over the life of the product. In doing so, he estimates a demand function for this industry based on a sample of 35 drugs during the 1970s and 1980s for which the average price increased substantially over time. He interprets the price increase as being caused by an unexplained decrease in price elasticity and assumes that this is a universal property of drugs. He argues that prohibiting price increases through price-cap regulation will cause firms to set a high price initially. Borrell (2003) extends this analysis within a monopolistically competitive setting with formularies and finds a similar result. In this paper, we do not make any assumptions about changes in elasticity but incorporate the uncertainty that firms face when introducing a new drug to the market. Moreover, we allow this uncertainty to vary across drugs.

Ridley (2011) analyzes regulation of price increases in a more general context, incorporating forward-looking consumers and switching costs, which are relevant for many medications used for chronic conditions. He shows that price regulation can help both consumers and the firm because the regulations allow the firm to commit to a lower price path and attract more consumers at launch, extending the seminal results of Farrell and Gallini (1988).

Empirical papers assessing the initial prices of firms in price-cap regulated markets find that therapeutic novelty is not an important determinant of initial prices in this market framework. Lexchin (2006) observes that “me-too” drugs introduced in the Canadian market between 1994 and 2003 are priced close to their brand-name substitutes in the same therapeutic class. Moreover, the prices of new drugs are lower only when there are more than four competitors in the class. Lopez-Valcarcel and Puig-Junoy (2012) studied the regulated Spanish market, in which, as they noted, the rarely adjusted price cap is a key regulatory constraint. They find that therapeutic novelty does not seem to impact price significantly.

We discuss the relevance of the skimming strategy in the online Appendix 3.
Ekelund and Persson (2003) examine the pricing strategies of new drugs introduced into Sweden between 1987 and 1997. Sweden, like Canada and Spain, had a system of price-cap regulation. They find that the average relative introductory prices were higher for new drugs in Sweden than the USA, while real prices declined over time for both innovative and me-too drugs, with a greater rate for innovative ones. Their results show that market structure factors, such as the number of branded competitor with and without generic rivals, are not statistically significant determinants of initial prices and the price evolution of new drugs. Their results on Swedish price changes are consistent with our findings in the Canadian market, which gives us some confidence that the empirical findings in this paper are robust. Our paper expands their results to compare across different degrees of uncertainty and offers a simple novel theoretical model to explain the results.

3. EMPIRICAL ANALYSIS

In the online Appendix 2, we present a simple model that generates several interesting predictions. First, the initial prices for drugs in a market with price-cap regulation will be, on average, higher than in markets without upward price rigidity when demand is uncertain. Second, prices in regulated markets should fall, on average, for products with unknown demand (and an ex ante unknown full-information price). The greater the uncertainty, the greater the expected price reduction is. The data that we have in this paper allow us to explore only the second prediction. The first prediction is difficult to test because price comparisons across countries tend to be confounded by many other explanatory differences, including regulation of introductory prices and differential demand across countries.

We describe in the succeeding texts the identification strategy and then the data that are used in this paper in the following subsections. The identification strategy relies on the association between the demand uncertainty of a drug and its US experience and therapeutic novelty when listed by public drug plans in Canada.

3.1. Identification strategy

As our theoretical model shows, price-cap regulation influences price changes, mediated by the level of demand uncertainty:

\[ \Delta P_j = \varphi + \delta (q_h - q_l)_j + \Delta X_j \beta + \epsilon_j \]  

where \( \Delta P_j \) is the price change for drug \( j \), \( (q_h - q_l)_j \) is the level of uncertainty for this drug, and \( \Delta X_j \) is the change in market factor structure from the first year to \( t \) years after marketing. \( \varphi \) captures the level of price change for drugs with no uncertainty and no change in market structure. The problem here is that the level of uncertainty is not observable. To identify the effect of uncertainty on price changes, we use two independent types of information: the therapeutic novelty of the drug and the time span between the drug approval date in the USA and listing date in public drug plans.

Consumers (physicians and patients) learn the effectiveness of a drug through experimentation; physicians learn about the right match between a new drug and their heterogeneous patients’ conditions, and patients find out if the new drug is the right match for them. Demand uncertainty is associated with the degree of a drug’s novelty. Pioneer drugs, which may represent the first medicine in a therapeutic class, are more uncertain because of the lack of patient experience with this drug or others with a similar mode of action. These drugs require more extensive experimentation as patients and physicians have less information and familiarity about their effectiveness, side effects, and optimal compliance. Therefore, firms have less information about the demand parameters of more novel drugs a priori.

Therapeutic novelty is also associated with the number of safety warnings after approval. Olson (2004) finds that the novelty status of drugs is associated with the number of reported adverse drug reactions.\(^6\) More novel

\(^6\)Adverse drug reactions are typically reported by health professionals when patients experience adverse health effects while taking the prescribed dosage of medicines.
drugs face higher safety uncertainty owing to less cumulative experience with the drug. Another factor that may contribute to uncertainty is that Health Canada accelerates the approval of pioneer drugs with the justification of their therapeutic advantages over existing medicines. A shorter review process may result in more uncertainty about drug safety. Begosh et al. (2006) show that priority review drugs tend to have more black box warnings than nonpriority review drugs in the US market. This evidence suggests that therapeutic novelty is positively correlated with the level of safety uncertainty. Other new, but not pioneer, drugs are deemed to be equivalent to existing therapies. As such, they are less uncertain as consumers have already accumulated experience with their existing substitutes in the market.

Because many drugs enter the Canadian market long after their introduction in other markets, even drugs that have pioneer status could have a lengthy history with patients before arriving in Canada. Lasser et al. (2002) found that recently approved drugs are more likely to be tagged with safety warnings, and the probability of a new safety warning decreases as the drug ages. Therefore, the time lag from marketing approval in other countries until listing in Canadian public drug plans would reduce the probability of getting an unexpected quality shock. Moreover, demand uncertainty studies show that demand parameters are learned as patients and physicians gain experience with the drug over the first few years. This information is not specific to a market and can be exploited in other markets. Therefore, the time lag from marketing approval in other countries until coverage by Canadian public drug plans would reduce demand uncertainty. We classify a drug as having “US experience” if the time elapsed between the approval of the drug by the US regulatory authority (the FDA) and listing by Canadian public drug plans is 2 years or more to capture the information accumulation about the demand of a drug from US consumers’ experience.

We thus have two mechanisms to identify the effect of uncertainty on price: therapeutic novelty and US experience. We also consider the interaction factor of the novelty status and the drug’s US experience. Suppose \( D_g \), a set of dummies, is equal to 1 when a drug’s therapeutic novelty is equal to \( g (=0, 1, \ldots, G) \) and is equal to zero when otherwise. \( D_e \) represents a set of dummies being equal to 1 for drugs with a given level of US experience and zero otherwise:

\[
\Delta P_{jge} = \varphi + \sum_{e=0}^{1} \sum_{g=0}^{G} \delta_{ge} D_g D_e + \Delta X_{jge} \beta + \epsilon_{jge}
\]

where \( \Delta P_{jge} \) is the price change of drug \( j \) belonging to therapeutic novelty group \( g \) and experience cohort of \( e \). \( \Delta X_{jge} \) are market structure factors for each drug. \( \varphi \) is the common price change between all groups of drugs. \( \delta_{ge} \) are the price changes specific to experience cohort \( e \) with the therapeutic group \( g \). We use Eqn 2 to estimate price changes from the first year to the third, fourth, fifth, and sixth year.

3.2. Data

The primary estimates are performed on new, patented drugs approved by Health Canada and listed in public plans between 2000 and 2009. Sales data are drawn from the PharmaStat database of Brogan Inc, and prices are the ones paid by public plans.\(^7\) A full description of the data is provided in the online Appendix 4. We constructed competition indicators relating to the number of drugs in the therapeutic class and the number of those drugs in generic form.

Health Canada’s classification of drugs is used to proxy uncertainty. As Health Canada classifies newly patented drugs into different categories, our ranking of uncertainty proceeds according to the following:

\(^7\)The data were supplied through an arrangement courtesy of Alberta Health and Wellness. Brogan has now merged with IMS Health Canada.
• **Pioneer**: The most uncertain products are new molecules ranked as priority review. Health Canada offers priority review to new drug submissions for which there is substantial evidence of clinical effectiveness that the drug addresses an unmet need or achieves a significant increase in efficacy or safety.

• **Me-too**: We use this term to indicate new molecules without priority review. These drugs are typically similar to existing therapies and will generally have a similar or identical means of action, with a risk profile similar to the pioneer drug in the class.

• **Reformulation**: New formulations typically have somewhat less uncertainty. For example, a new formulation combining two older drugs faces only the uncertainty of whether it can convince physicians that the new combination is superior to either or both of the old drugs prescribed separately.

• **Old**: These drugs form a baseline, from which we compare others. Rather than using all existing drugs, we use new dosage forms of patented drugs as the benchmark. These “old” drugs are likely to have very little uncertainty connected with them but are “new” given their revised dosage forms and their new drug information number (“DIN”).

To define whether there is experience of the drug in the USA before it is listed in Canadian public drug plans, we extracted approval dates from the US Food and Drug Administration website and listing dates from PharmaStat database. If the FDA approves a drug two or more years before being listed in Canadian public drug plans, we define this drug as having “experience” in the US market.

### 3.3. Empirical Model

To investigate how prices are changing over time, we specify the following difference in difference regression equation:

\[
\text{LRelative}_{ijt} = \beta_0 + \beta_1 \text{Pioneer}_j \times D_{NOX,j} + \beta_2 \text{Pioneer}_j \times D_{USX,j} + \beta_3 \text{Me-too}_j \times D_{NOX,j} \\
+ \beta_4 \text{Me-too}_j \times D_{USX,j} + \beta_5 \text{Reformulation}_j \times D_{NOX,j} \\
+ \beta_6 \text{Reformulation}_j \times D_{USX,j} + \beta_7 \text{Old}_j \times D_{NOX,j} + \beta_8 \Delta \text{NUMB}_j \\
+ \beta_9 \Delta \text{shareGEN}_j + \beta_{10} \text{LQshare}_j^2 + \epsilon_{ijt}
\]  

(3)

\(\text{LRelative}_{ijt}\) is the logarithm of the ratio of the price of a new drug to its launch price, where \(i\) indexes the DIN, \(j\) indexes the \(j\)th trade name, and \(t\) indexes the number of years from launch.\(^8\) \(\text{LQshare}_j\) is the logarithm of the market share (in terms of pill quantity) of drug \(j\) in its therapeutic class during the second year of marketing. Because the sales data are annual and it is possible that a DIN enters the market in the middle of the year, we used the share in the second year rather than in the first year.

\(\text{Pioneer}_j\), \(\text{Me-too}_j\), \(\text{Reformulation}_j\), and \(\text{Old}_j\) are dummy variables for drugs with various levels of uncertainty.

\(D_{NOX,j}\) is a dummy variable equal to 1 for all drugs with US experience less than or equal to 2 years when listed by public drug plans and zero when otherwise. \(D_{USX,j}\) equals 1 for drugs with US experience of more than 2 years when listed and zero otherwise. We explored alternate cutoffs for this dummy at 3 and 4 years of US experience. The estimation results were qualitatively unchanged. Note that the benchmark group is \(\text{Old}_j\) drugs with more than 2 years of US experience when listed in Canada.

\(\Delta \text{NUMB}_j\) is the change in the number of branded substitute drugs in a therapeutic class from year 1 to year \(t\).\(^9\) Notably, this number is not the number of substitute DINs: The number of substitutes is calculated based on the number of different drugs in the class. \(\Delta \text{shareGEN}_j\) is the change in a therapeutic class in the share of branded drugs with generic rivals from year 1 to year \(t\). Because branded drugs with generic rivals are generally

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\(^8\) Mathematically, \(\text{LRelative}(t) = \log\left(\frac{p_t}{p_1}\right)\) where \(p_t\) is the nominal price at time \(t\).

\(^9\) \(\Delta \text{NUMB}(t) = \text{NUMB}(t) - \text{NUMB}(1)\).
not supported by investment in promotion to physicians, such branded drugs become weaker competitors. Previous studies also treat these two types differently.

It should be noted that all regressions in this paper are conducted by treating different dosage forms of a patented drug as a cluster. Price trends of different dosage forms of a drug are more similar to each other than those of other drugs, and there is likely to be a correlation between error terms within clusters. Using cluster-robust standard errors mitigates this problem.

3.4. Summary statistics

Table I shows summary statistics for new DINs entering the Canadian market between 2000 and 2009. As predicted by the model, the average price decreases more, the higher the level of uncertainty. Drugs classified as pioneers and me-toos, on average, experienced a 4% price decrease in the 4 years after launch, while the mean fall in prices for reformulations is only 1%, and old drug prices, on average, rise 1%.

Figure 1 also depicts the distributions of price changes in the first 4 years of marketing for different groups of DINs. While some DINs in the pioneer and me-too groups experience extensive price reductions, the price changes for reformulations and old drugs are more or less in the same range. Even after eliminating the outlier DINs, the average price decreases for pioneers are larger than those for other groups. This shows that the primary inference is consistent with the theory presented previously, as more uncertain drugs tend to decrease their prices more than other groups, on average.

4. RESULTS

All estimation results are reported for different durations (3, 4, 5, and 6 years)\(^ {10} \) after the introductory year. Using different durations enables us to investigate the effect of the explanatory variables on the pricing behavior of firms at varying points after launch.

Table II reports the estimation results for equations having only therapeutic novelty indicators. We start the interpretation of results by exploring the coefficients for therapeutic novelty indicators in the fourth-year estimation (column 2). The prices for pioneer and me-too drugs tend to fall faster than DINs in other groups. Column 2 shows that the total price decrease in the first 4 years of marketing for these DINs is, on average, 4.4% more than old DINs, while this number for reformulation DINs is 1%. The coefficients for pioneer and me-too DINs are significant at the 5 and 10% level, respectively, while the coefficient for reformulation DINs is not significant. It should be noted that the intercept reflects the rate of price changes for old DINs because these drugs are considered as the benchmark. These DINs experience more than 2% price increase, although this is not statistically significant.

We now consider how the estimation results differ across time, as shown in Table II. The pioneer and me-too indicators are significant for all periods except the third-year estimation. However, the difference between pioneers and me-toos is not statistically significant. The coefficients for reformulation drugs are not statistically different from zero in all of estimations, indicating that reformulation drugs are following the same price trends as old drugs. Moreover, the prices for DINs embodying new active substances (pioneers and me-toos) decrease faster in the first 3 and 4 years of marketing as these coefficients in the following years remain at same level of those in the fourth-year estimation. In other words, pharmaceutical firms tend to cut the prices of novel drugs faster in the early years of marketing and then follow the general trend in the following years. The results in Table III confirm this finding as these estimation results show the price changes between the third year and the sixth year (LRelative\(^ {36} \)) and between the fourth year and the sixth year (LRelative\(^ {46} \)) as the dependent

\(^ {10} \)As mentioned before, the data are annual, and it is possible that a drug (DIN) enters into the market at the end of the year. The second year estimation is not included to make sure that firms have had enough time to get feedback from the market and adjust the price in response to this new information.

### Table I. Summary statistics for four types of drugs

<table>
<thead>
<tr>
<th>Variables</th>
<th>Pioneer</th>
<th></th>
<th>Me-too</th>
<th></th>
<th>Reformation</th>
<th></th>
<th>Old drugs</th>
<th></th>
</tr>
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<tr>
<td></td>
<td>N</td>
<td>Mean</td>
<td>Median</td>
<td>SD</td>
<td>N</td>
<td>Mean</td>
<td>Median</td>
<td>SD</td>
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<tr>
<td>LRelative4</td>
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<td>-0.01</td>
<td>0.09</td>
<td>28</td>
<td>-0.04</td>
<td>-0.01</td>
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<td>Qshare2</td>
<td>19</td>
<td>28.02</td>
<td>2.14</td>
<td>40.65</td>
<td>28</td>
<td>15.99</td>
<td>2.90</td>
<td>32.10</td>
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<tr>
<td>ΔNUMB4</td>
<td>19</td>
<td>1.89</td>
<td>1.00</td>
<td>1.59</td>
<td>28</td>
<td>0.89</td>
<td>1.00</td>
<td>0.88</td>
</tr>
<tr>
<td>ΔshareGEN4</td>
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<td>-0.02</td>
<td>0.00</td>
<td>0.03</td>
<td>28</td>
<td>0.10</td>
<td>0.00</td>
<td>0.20</td>
</tr>
</tbody>
</table>

Notes: LRelative4 is defined as the logarithm of the ratio of the price of a new drug in 4 years from lunch to its lunch price. Qshare2 is the market share (in terms of pill quantity). ΔNUMB4 is defined as the change in the number of branded substitute drugs in a therapeutic class from year 1 to year 4. ΔshareGEN4 represents the change in a therapeutic class in the share of branded drugs with generic rivals from year 1 to year 4.
variables. The coefficients for pioneer and me-too are not significant in these estimations. Moreover, the magnitudes are not different from zero for me-toos in both estimations and for pioneers in the second one. This result suggests that the price trends follow the same path for all drugs after the fourth year of marketing.

In summary, without considering the US experience of new drugs upon entry to Canada, the empirical results support the theoretical model, in that the greater the therapeutic novelty of a drug, the greater the average price decrease.

Table II. Price changes and therapeutic novelty indicators

<table>
<thead>
<tr>
<th>Variables</th>
<th>(1)</th>
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<th>(3)</th>
<th>(4)</th>
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<td>LRelative4</td>
<td>LRelative5</td>
<td>LRelative6</td>
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<td>Pioneer</td>
<td>−0.021</td>
<td>−0.044*</td>
<td>−0.048*</td>
<td>−0.052*</td>
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<tr>
<td></td>
<td>(0.023)</td>
<td>(0.024)</td>
<td>(0.029)</td>
<td>(0.028)</td>
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<tr>
<td>Me–too</td>
<td>−0.023</td>
<td>−0.044**</td>
<td>−0.041*</td>
<td>−0.049*</td>
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<td>(0.019)</td>
<td>(0.019)</td>
<td>(0.023)</td>
<td>(0.025)</td>
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<tr>
<td>∆NUMB(t)</td>
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<td>0.004</td>
<td>0.012**</td>
<td>0.009*</td>
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<td>(0.006)</td>
<td>(0.005)</td>
<td>(0.005)</td>
<td>(0.005)</td>
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<tr>
<td>∆shareGEN(t)</td>
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<td>−0.060</td>
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<td>(0.024)</td>
<td>(0.035)</td>
<td>(0.044)</td>
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<td>LQshare2</td>
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<td>0.006**</td>
<td>0.008</td>
<td>0.015***</td>
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<td>(0.003)</td>
<td>(0.003)</td>
<td>(0.004)</td>
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<td>0.023</td>
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<td>(0.015)</td>
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<td>(0.030)</td>
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</table>

Robust standard errors in parentheses
***p < 0.01, **p < 0.05, *p < 0.1

Figure 1. Distribution of current price changes in the first 4 years
Recall that the “US experience” of a drug in our regressions indicates that the drug was marketed in the USA for at least 2 years prior to being listed in Canadian public drug plans. It seems likely that the uncertainty related to a drug decreases, the greater is its US experience when it enters the Canadian market. We therefore interacted therapeutic novelty indicators and US experience dummy variables in the estimation. This specification identifies the effect of uncertainty more precisely. If uncertainty is resolved by experience in the market, then only pioneer and me-too drugs without US experience should have price reductions. As the literature on the safety and efficacy uncertainty of new drugs suggested, the level of demand uncertainty not only varies based on therapeutic novelty but also changes the more experience there is with the drug.

Table IV reports the estimation results for Eqn 2. The first row shows the specific price changes for pioneer drugs without US experience. This group of pioneer drugs experiences the largest price decreases. However, the coefficient for pioneer drugs with US experience is approximately zero. The coefficient for me-too drugs listed without delay is also negative and significant. The coefficient for me-toos listed with lag is negative, although not significant. Moreover, US experience does not have any significant effect on price changes for reformulation and old drugs. These estimation results further support the association of price decreases and demand uncertainty.11

In general, drugs with high uncertainty tend to set a high price in the introductory year, relative to subsequent years. This is a rational reaction to the regulations restricting price increases in the following years, as shown in the simple model presented in online appendix 2. The market exploration process for new innovative drugs should result in price decreases only after the market response is not favorable. Such an exploration strategy is followed only by pioneer and me-too drugs without extensive market exposure in the USA.

While the coefficients for the change in the number of patented substitutes are significant at the 5% level in the fifth and sixth year estimations, they are not significant for the other years as shown in Table II. The coefficients for the share of branded drugs with generic rivals are not significant for any period. The surprising aspects of these coefficients are the signs. The signs for the change in the number of branded drugs are positive meaning that the entry of a newly patented substitute is associated with an increase in the prices of existing drugs by roughly 1% by the fifth or sixth year of the original drug. While the result is not strong, it

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11 As a robustness check, we also included the calendar year in which a given drug was entered the Canadian market in the regression. The results did not change qualitatively (Appendix 5).
is consistent with a situation in which drugs with revealed high demand attract other firms to enter the category with me-too drugs.

Another competitive aspect of firms’ behavior is realized in the coefficients of the quantity share of drugs in the second year. These coefficients are significant for all estimations with a positive sign. The positive sign indicates that drugs starting with a larger share, on average, are less likely to decrease their prices in the following years. However, the magnitudes of these coefficients are very small.

5. CONCLUSION

This paper examines the pricing strategies of pharmaceutical firms in a regulated market with upward price rigidity. The level of uncertainty associated with a drug is found to be a crucial determinant of price evolution in the Canadian pharmaceutical market. Given that the established price in the introductory year is the highest achievable price in the drug’s life cycle in a regulated market with upward price rigidity, drugs facing uncertainty in their market reception tend to start with a high introductory price. Pharmaceutical firms will adjust their prices if the market reception is unfavorable. Such an exploration strategy is followed only by young innovative drugs because the old ones are exposed to less uncertainty. The simple theoretical model shows that this behavior is the profit-maximizing reaction to the Canadian pharmaceutical market environment.

ACKNOWLEDGEMENTS

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Table IV. Price changes and the interaction of therapeutic novelty and US experience dummies

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<th>Variables</th>
<th>(1)</th>
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<th>(3)</th>
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<tr>
<td>LRelative3</td>
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<td></td>
<td></td>
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<tr>
<td>Pioneer without US experience</td>
<td>−0.029</td>
<td>−0.052**</td>
<td>−0.056**</td>
<td>−0.052**</td>
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<tr>
<td></td>
<td>(0.026)</td>
<td>(0.026)</td>
<td>(0.027)</td>
<td>(0.025)</td>
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<tr>
<td>Pioneer with US experience</td>
<td>0.019</td>
<td>0.007</td>
<td>0.003</td>
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<td></td>
<td>(0.019)</td>
<td>(0.023)</td>
<td>(0.030)</td>
<td>(0.038)</td>
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<tr>
<td>Me-too without US experience</td>
<td>−0.035</td>
<td>−0.048**</td>
<td>−0.053**</td>
<td>−0.058**</td>
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<tr>
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<td>(0.022)</td>
<td>(0.021)</td>
<td>(0.023)</td>
<td>(0.025)</td>
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<tr>
<td>Me-too with US experience</td>
<td>−0.016</td>
<td>−0.038</td>
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</tr>
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<td>(0.027)</td>
<td>(0.028)</td>
<td>(0.032)</td>
<td>(0.033)</td>
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<tr>
<td>Reformulation without US experience</td>
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<td>−0.020</td>
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<td></td>
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<td>(0.017)</td>
<td>(0.019)</td>
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<td>(0.013)</td>
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<td>(0.024)</td>
<td>(0.016)</td>
<td>(0.021)</td>
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<td>ΔNUMB(t)</td>
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<td>0.004</td>
<td>0.011**</td>
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<td>(0.005)</td>
<td>(0.005)</td>
<td>(0.004)</td>
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<td>(0.011)</td>
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<td>0.279</td>
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</table>

Robust standard errors in parentheses

***p < 0.01, **p < 0.05, *p < 0.1
REFERENCES


