ISSN: 2281-1346

UNIVERSITÀ DI PAVIA
Department of Economics and Management

DEM Working Paper Series

Competition between Generic and Brand Name Drugs:

New Evidence from the U.S. Pharmaceutical Market

Alberto Cavaliere
(University of Pavia)

Afshin Moayedizadeh

 # 209 (12-22)

Via San Felice, 5
I-27100 Pavia

https://economiaemanagement.dip.unipv.it/it

Competition between Generic and Brand Name Drugs: New Evidence from the U.S. Pharmaceutical Market

A. Cavaliere* and A. Moayedizadeh**

Abstract

This paper explores different aspects of competition in the U.S. pharmaceutical industry in order to broaden our insight into price competition in the pharmaceutical market. The main focus is on the effects of patent expiry and generic entry on the brand and generic name drug prices. Using an unbalanced panel dataset of 19 branded and corresponding generic drugs, which faced their first generic entry between 2010 and 2014, we discovered that the Generic Competition Paradox does not arise according to the results obtained with our dataset. Though prices of brand-name drugs are continuously rising, each new generic entrant is associated with an average 2.6 percent decrease in the brand-name drug price. Moreover, the empirical findings in this study fully support the idea of market segmentation based on insurance coverage. We can state that after generic entry, the originator firms appear to demand higher prices in order to exercise price discrimination and exploit the market segment that is less price sensitive.

Keywords: Pharmaceutical industry, Generic entry, Brand drug price, Generic Competition Paradox, Market segmentation theory

JEL: I11, L11, L65, D4

*Università degli Studi di Pavia

**Former student at Università degli Studi di Pavia

1 Introduction

The relationship between price and the number of sellers is a crucial subject in the pharmaceutical industry, particularly after generic entry. The economic literature has been attempting to understand this relationship for a long time.

When a patent expires, generic pharmaceutical companies often enter the market with drugs that are functionally equivalent to the original (brand) drug. Only a few months after generic competition, brand-name companies' sales tend to plummet dramatically. The impacts of generic entry on brand-name drug prices have been widely discussed in the literature dealing with prescription drug markets, but the pricing response of brand-name products to generic entry has been a contentious issue. Some studies (e.g., Wiggins and Maness (2004), Caves et al. (1991), Saha et al. (2006), who also use US data, and Stargardt (2011), who uses German data) have estimated a negative relationship while others (e.g., Frank and Salkever (1997), Grabowski and Vernon (1996, 1992), Regan (2008)) have uncovered a positive relationship. In this last case the fact that the price of brand-name drugs even increased after generic entry was identified as the "Generic Competition Paradox". Also Based on US data, Ching (2010a, b) reports mixed results; that some brand-name prices increase and a few decreases, as the number of generics entrants grows.

In 1984, the drug price competition and patent term restoration act (also known as the Hatch-Waxman Act) created an abbreviated approval process for generic prescription drugs in the U.S. and at the same time extended patent terms for innovator drugs. Since that time the U.S. pharmaceutical market has become increasingly competitive as far as brand-name drugs and generic are concerned.

This paper focuses on the Generic Competition Paradox and market segmentation phenomena, employing an unbalanced panel of 19 brand-name and their corresponding generic drugs that experienced their first generic entry between 2010 and 2014. The study's findings suggest that the Generic Competition Paradox does not arise in our sample, and each new generic entrant is associated to an average decrease of 2.6% in the price of brand-name drugs. Additionally, the empirical results of this study clearly support the concept of market segmentation that is based on various insurance coverage categories.

The structure of the paper is as follows: Section 2 provides an overview of the pharmaceutical sector in the United States as well as of several forms of market competition. Review of the literature is presented in section 3. The model specification is presented in section 4, sample data, descriptive statistics, and data collection methods are presented in section 5, in section 6 we report the estimation and results, and conclusion is presented in section 7.

2 Drug expenditure in the U.S.

Only 19% of prescription medications in the United States were generic in 1984 (as assessed in total countable units, such as pills and capsules). However, 12 years later, this percentage had risen to 43%[1]. The percentage of generic medicine prescriptions continued to rise over time, reaching 88.5 percent in 2020[2].

[1] Congressional Budget Office (CBO), (1998)

[2] Food and Drug Administration (Center for Drug Evaluation and Research (CDER))

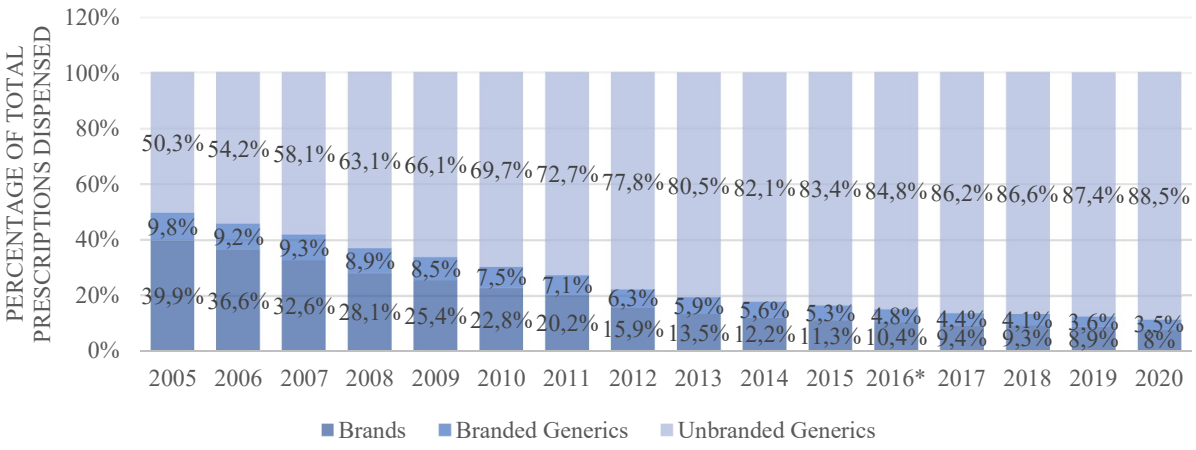

Figure 1: Percentage of total prescriptions dispensed (2005-2020)
Source: IMS health data

Since generic drugs are less expensive than brand-name or "innovator" drugs, they've played a key part in keeping prescription drug spending in the United States lower than it would have been otherwise[3].

According to the Association for Accessible Medicines (IQVIA) generic product sale and usage, saved more than 338 billion U.S. dollars just in 2020 in the United States. Over a 10-year period (2010-2019), the U.S. saved about 2.4 trillion U.S. dollars through the diffusion of generic drugs and biosimilars. Figure two displays savings through generic drug usage in the United States from 2008 to 2020[4].

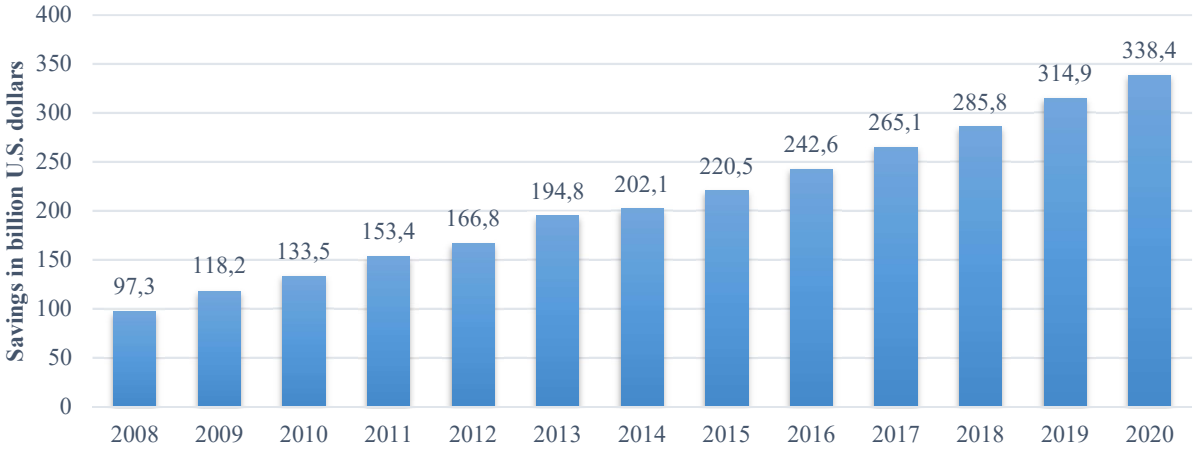

Figure 2: Savings through generic drug usage in the United States (2008-2020)
Source: IMS health data

This figure demonstrates how important generic competition is for facilitating widespread access to novel brand medications as soon as they become generic and for keeping public budgets under control.

The enormous increase in generic medicine sales that has enabled such savings is due to three things. First, from 1984 the Hatch-Waxman Act made it easier and less expensive for

[3] EUC; European Commission, (2009)
[4] IQVIA; Association for Accessible Medicines, (2021)

manufacturers to enter the market for generic medications. Second, by 1980, drug substitution rules had been enacted in the majority of states, enabling pharmacists to distribute generic medications even when a brand-name medication was called for in the prescription. Third, several government health-care programs, such as Medicaid, and many private health-care plans explicitly encourage generic substitution. More recently, Pharmacy Benefit Managers, acting as intermediaries in the pharmaceutical industry, have contributed to make substitution mandatory when a generic is available[5].

During the past decade, health care spending has increased steadily, and pharmaceuticals have been a key factor driving the growth in health care costs. Prescription drug spending is one of the major factors behind the growing expenditures on health care services in the U.S. and abroad. In the United States drug expenditure increased from 195 to 539 billion dollars over the period 2002-2020. The figure below shows the details of spending on medicines in the U.S[6].

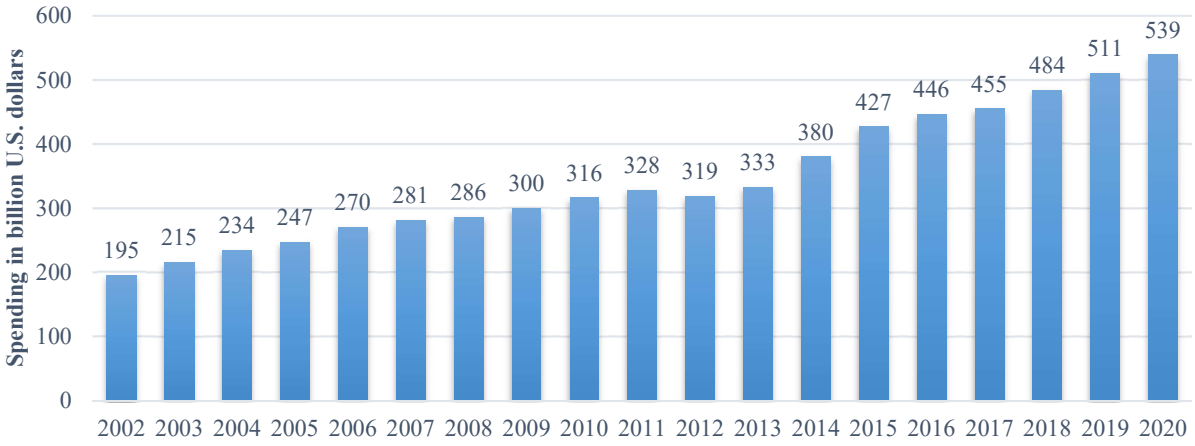

Figure 3: Spending on medicines in the United States (2002-2020)
Source: IMS health data

Effective pricing competition among generic and brand manufacturers should be encouraged, in order to completely benefit from the potential savings brought about by generic products. Furthermore, demand should respond to price differentials to contain healthcare costs.

Competition in pharmaceutical industry

Competition in the pharmaceutical market can be divided into three categories: 1) Competition among therapeutically equivalent brand-name pharmaceuticals; 2) Competition between brand-name drugs and generic substitutes; 3) Competition between generic versions of the same drug. Brand-name medicine manufacturers compete for market share primarily through advertising and product quality, as well as price. Generic medication manufacturers gain market share mostly through cutting prices both compared to brand-name drugs and to generic competitors.

[5] Over 95% of US outpatients with prescription drug coverage at present receive their benefits through Pharmacy Benefit Managers (PBMs) acting as intermediaries among the drug insurance plans, pharmacies and drug manufacturers. PBMs often require that pharmacies substitute generic drugs for brand-name drugs by default, if a generic is available (Shepherd, 2020).

[6] EFPIA Key Data, (2021)

Competition among branded drugs

In the pharmaceutical industry, patents not necessarily grant monopolistic power because firms can routinely find and patent multiple medications for the same illness. At least for some medications we can observe oligopolistic competition, implying less market power by manufacturers. When there are multiple therapeutically equivalent medications, according to economic theory, manufacturers cannot raise prices as much as would otherwise be the case. Furthermore, if customers have the option of switching to generic, brand-name producers are more likely to agree to give discounts. Manufacturers of brand-name medications compete with each other through pricing. The mark-ups they charge over the marginal cost of producing a medicine are compatible with economic models of price competition in which manufacturers' entry is restricted. Offering discounts to some customers could be a significant aspect of competition between brand-name medicine. So, when there are multiple brands available and there is competition between brands, the inclusion of this demand-side variable should affect the price of brand-name drugs and the price varies between drugs that are therapeutically equivalent but contain different active principles (different molecules)[7].

Competition among branded and generic drugs

In the U.S., prior to 1984, manufacturers of generic pharmaceuticals had to confirm independently the safety and efficacy of their product, by replicating costly clinical trials that had been already carried out by off-patent drug producers to get the marketing authorization by the FDA. Generic manufacturers were not allowed to use the original innovator drug's unpublished test findings, which were considered trade secrets by its manufacturer. The Hatch Waxman Act eliminated the need to duplicate clinical tests in order for a generic medication to be approved by the FDA[8]. The Act was designed to balance two countervailing tasks: facilitating market entry of lower priced generic imitations of brand-name drugs, while at the same time preserving brand-name pharma‘s incentives to continue discovering and developing new drugs. Pursuing the first goal, the Act streamlined the process for approving generic drugs by requiring to manufacturers just to demonstrate “bioequivalence” with an already approved innovator drug.

The Hatch-Waxman Act therefore promoted generic market entry by accelerating the approval process for a generic drug, also allowing its producer to start bioequivalence tests, before the patent granted to the innovator drug had expired. The regulatory burden for generic manufacturers was significantly reduced, and the new legislation was helping firms to challenge the validity of brand-name pharmaceutical patents that might be hindering market entry, even before the patent had expired[9]. Also, the Act reduced the average delay between patent expiration and generic entry from more than three years to less than three months for

[7] Reiffen, D., Ward, M.R., (2005)

[8] That change applied only to nonantibiotic drugs, since antibiotics already had an abbreviated approval process

[9] Temporarily exclusivity, lasting six months, were given firstly in the US and then also in Europe, to the first generic entrant challenging patents that were going to expire, on the basis of the so called “Bolar Provisions”. These provisions consist in legal exemptions (or research exemptions) from infringement for certain acts relating to the development and submission of testing data to a regulatory agency. These exemptions are often referred to as “Bolar” provisions, in reference to a US law enacted to overturn a prior court ruling holding that the US did not provide for a research exemption

top selling drugs. As a result, as seen in figure one, generic versions of a drug quickly obtained a major share of the market when the patent expired, by providing less expensive versions of thousands of drugs that used to be available only as higher priced brand-name versions.
While the loss of brand-name drugs market share was indisputable, evidence about the effect of generic entry on the price of the branded product is somewhat mixed; Some researches have discovered a negative relationship, while others have found a positive one. However, since more than 88 percent of US prescriptions were for generic products in 2020, it is clear that between generics competition has significantly reduced US drug prices. Darrow and Kesselheim (2018)[10] argued that "the introduction of generic substitutes for brand-name drugs tends to exert unambiguous, downward price pressure". Also, we have to consider the fact that the entry of new drugs in a class is very likely to cause rebates on existing branded drugs and it's another source of negative effect of generic entry on branded price[11].

Competition among generic drugs

By making generic entry easier and less costly and introducing competition into the pharmaceutical market, the Hatch-Waxman Act helped also to increase the number of generic manufacturers producing the same drug. The average price per prescription of a generic drug then falls (as reported in section 2) with the number of new generic entrants. Since the law's passage, the generic industry's share of the prescription drug market has jumped from just under twenty percent to just under fifty percent[12]. Likewise, the number of generic drugs available jumped from just thirty-six percent of the top-selling brand-name drugs to virtually one hundred percent coverage of all such drugs[13]. And most importantly, generic entry has dramatically reduced the price of the affected drugs anywhere from forty to seventy percent and even ninety percent of their brand-name prices, as the trend of relative prices shows. Caves (1991) found that as the number of generic manufacturers increased from one to 10, the average generic price fell from 60 percent to just 34 percent of the brand-name price. With 20 manufacturers, the generic price was only 20 percent of the brand-name price.

Generic competition paradox

The 1984 Waxman-Hatch Act was expected to stimulate strong competition from generics against drugs whose patent protection had expired. This expectation was met in certain ways. Under faster procedures, the FDA authorized hundreds of generic alternatives. By 1989, more than a third of all filled prescriptions were for generic drugs. However, there was no evidence of any real price competition between "branded" and generic drug producers. Some studies indicate that on average, branded drug prices rose when generic competition materialized[14]; another study found that on average, generic competition reduced incumbent brands' prices by just 2 percent[15]. And it did even though generic drug manufacturers set their prices substantially lower than those of brand-name drugs. It's alleged that a few behavioural factors could explain

[10] Darrow, J. J., & Kesselheim, A. S, (2018)
[11] Hernandez et al., (2020)
[12] Wansheng Jerry Liu, (2008)
[13] David A. Balto, (2000)
[14] Frank and Salkever, (1992); Grabowski and Vernon, (1992)
[15] Caves et al., (1991)

this seeming paradox. First, individual physicians tend to be risk-averse, insensitive to outpatients' costs, and creatures of habit (Coscelli, 2000), prescribing drugs by brand-name even when much less expensive generic substitutes exist. Second, consumers purchasing drugs at a retail pharmacy normally lack sufficient knowledge to evaluate the alternatives and (typically small) risks of substituting away from a prescribed brand-name drug, even when state laws permit or encourage generic substitution (as is now typical). Third, consumer heterogeneity in price sensitivity matters.

We can therefore suppose that, in the face of generic alternatives, customers can be divided into two groups: those who are price sensitive and those who are not. Therefore, it is expected that the incumbent firm will increase its price for price-insensitive buyers while exiting the price-sensitive market[16].

The most commonly accepted explanation to this "generic competition paradox" lies in the segmentation of the market[17]. When faced with generic competition, branded firms may forego the cross-price sensitive segment of the market in favor of the brand-loyal segment. Caves et al., (1991), Grabowski and Vernon, (1992), Frank and Salkever, (1997) argue that those consumers who are more sensitive to price, or who are covered by health plans that encourage generic substitution, are more likely to buy a generic drug when it becomes available. As the more price sensitive consumers switch to the generic version, demand for the original brand-name drug declines and may become less sensitive to price. If that happens, the price of the brand-name drug, in principle, could rise more quickly over time than it would have without generic competition. According to Frank and Salkever (1992), a profit-maximizing branded pioneer may not drop (and may even increase) price in response to generic competition under certain circumstances. The branded company must be able to divide its customer base into groups of brand-loyal customers who will keep buying the product and price-sensitive customers who will switch to cheaper generic alternatives. However, we can remark difference between what is claimed in the few theoretical studies on which is based the theory of market segmentation and the data used in empirical analysis to demonstrate the existence of the Generic Competition Paradox. For example, in their theoretical analysis Frank and Salkever (1992) claim that the price sensitive market segment includes hospitals and managed care organizations, while customers at the pharmacy are brand-loyal, then included in the price-insensitive market segment. However, in their empirical analysis (Frank and Salkever 1997), supporting the Generic Competition Paradox, they just make use of "transaction prices" paid by retail pharmacies, neglecting health-care organizations and hospitals. Also, the empirical analysis of Grabowski and Vernon (1992) and Regan (2008) provide further evidence about the existence of a GCP by just considering data from retail pharmacies and retail outlets. However, Regan, contributing also to the theory of market segmentation, distinguish payer types: cash, Medicaid and third party. Such a distinction allows Regan to point out that after generic entry, the brand price increases more in the market segment including customers with insurance coverage. On the contrary the analysis of Caves et al (1991), find no support for the GCP, as their results show a reduction of the price of brand-name drug after generic entry. But it is worthwhile to point out that they consider both the pharmacy market and the hospital

[16] This two-markets phenomenon is modelled in Frank and Salkever (1992)

[17] Frank and Salkever, (1992)

market and show that it is the hospital market share that is mainly responsible for the decrease of the brand-name price. Therefore, health care organizations not only may largely contribute to the growth of the generic market share (as supposed by traditional market segmentation theory) but also be responsible for the price decrease of originators after generic entry. Kong (2009) points out that market segmentation according to insurance coverage may be important in explaining price differences and that the existence of a GCP would require a comparison of originators prices during the patent period and after patent expiration when generic entry takes place.

3 Literature review

Previous empirical research on the pharmaceutical industry has shown that generic entry has a mixed impact; generic prices fall rapidly with generic entry, whereas the reaction of brand prices is more ambiguous, increasing in some cases and decreasing in others.

An empirical study, by Caves, Whinston, and Hurwitz, (1991), examined 30 brand-name drugs that went off patent between 1976 and 1987. The regression model also included time-related dummy variables, a linear time trend, and a quadratic time trend in order to capture discontinuities in price behavior around the time of patent expiration. They concluded that although the prices of many brand-name drugs continued to rise after generic entry, those prices were still lower than they would have been otherwise. The study's results showed that the brand-name price actually increased slightly just after patent expiration and then declined by only 2 percent with the entry of the first generic manufacturer. After the entry of five generic manufacturers, the brand-name price was 8.5 percent lower than it would have been without generic entry, and after 10 generic manufacturers had entered the market, that price was 15 percent lower. As we said above, this is the only study with a data base that also includes sales to hospitals, beyond sales to pharmacies.

Grabowski and Vernon (1992) examined the effect of generic entry on prices for 18 high-sales pharmaceutical products, that were firstly exposed to generic competition during the years 1983 through 1987. They specified regression models where the dependent variable is the ratio of generic to brand-name price. They considered three independent variables: (1) the number of generic-product sellers, (2) the total dollar volume of sales in the market for the chemical, and (3) a time dummy variable. The estimated coefficient for the effect of the number of generics on the ratio of generic to brand-name price was negative and significantly different from zero showing brand-name prices rising relative to generic prices subsequent to generic entry.

Wiggins and Maness (1994, 2004) have studied price competition in the market for anti-infectives over the period 1984 to 1990. In their analysis, they found a response to entry that is consistent with the predictions of traditional market models: the pioneering brand price declines as entry expands. The estimated coefficients showed that market entry by generics results in significant reductions in the price of anti-infective products. The entry of other brand-name products was also reducing prices but was significant only at the 10% level.

Studying a sample of 32 drugs that lost patent protection during the early to mid-1980s, Frank and Salkever, (1997), found that prices of originators increased in response to generic entry. Their econometric analysis led to make several observations regarding price behavior in the pharmaceutical market. First, it appeared that more competition among generic drug producers

traduces into price reductions for those drugs. Second, increased competition from generics did not go along with lower prices for brand-name drugs.

Reiffen and Ward, (2005), estimated a system of structural relationships in this industry, including the relationship between price and the number of competitors, and between drug characteristics and the entry process. They find that generic drug prices fall with increasing number of competitors but remain above long-run marginal cost until there are eight or more competitors. They also find the size and time paths of generic revenues, rents, and the number of firms are greatly affected by expected market size.

Saha et al. (2006), who based their estimates on a panel data sample of 40 brand-name drugs that first experienced generic competition during 1992-1998, uncovered that the number of generic entrants is a key determinant of generic market share and the generic-to-brand price ratio. In addition, they found generic competition to be particularly intense for blockbuster drugs, which experience significantly more generic entrants, price erosion, and generic penetration than other drugs. Their results also show that brand prices do react to generic competition and each additional entrant is associated with a 0.2% average decline in brand prices.

Conducting an independent, validating test of the "generic competition paradox" for 18 prescription drugs exposed to competition between January 1998 and February 2002, Regan (2008), discovered that each generic entrant is associated with an average 1% increase in the branded price. Moreover, controlling for intermolecular substitution and accounting for the endogeneity of generic entry, with instrumental variables, caused the average price of a branded prescription to rise by an average amount of 2%.

Introducing an empirical demand model with aggregate learning and consumer heterogeneity in price sensitivity, Ching (2010), examines a sample consists of 14 drugs with patents expired during the four-year period from 1984 through 1987. He reports mixed results; some brand-name prices increase and a few decreases, as the number of generics becomes higher. Concerning the effect of generic entry on brand price, according to Ching, there are two effects. First, generic entry makes the environment more competitive, and this may tend to reduce the prices of brand-name drugs. Second, generic entry makes the market more segmented in terms of price sensitivity of consumers, and consequently, brand-name firms may raise prices in response to the lower average price elasticity of demand faced by them. Furthermore, the results suggest that the number of generics plays a role in lowering the generic prices.

Focusing solely on German data between January 2004 and June 2006, Stargardt (2011), provides evidence that two policy measures; reference pricing and a temporary price freeze; succeeded in reducing prices in Germany. This paper through a four-level random intercept model demonstrates the importance of competition between and within drug classes and provides evidence that generic entry has substantial negative effects on pricing of branded products.

Using a dynamic model, with a panel dataset on 1303 distinct pharmaceutical markets for 78 months within a reference-price system, Granlund and Bergman, (2018), found that the price of generics decreases by 42% in the short term and 81% in the long term. The price decrease occurs when the number of firms selling generics with the same strength, form and similar package size is increased from 1 to 10. Furthermore, the effect of firms selling other products with the same active substance, but with different package size, form, or strength, is only one

tenths as large. They also observed half of the price reductions takes place immediately and 70% within three months. Finally, they explained that the prices of originators react to competition, but far less and much slower. For instance, increasing the number of generic competitors from one to ten induces prices of originators to fall by 2% in the short term and 29% in the long term.

4 Model specification

We have constructed an unbalanced panel of 19 blockbuster drugs that went generic for the first time between 2010 and 2014. The branded (generic) medications were observed at one-year intervals as the unit of observation. The empirical approximations of what we have explained are as follows,

$$\begin{aligned}\ln\left(P^{*}_{b_{dt}}\right) = {} & \delta_0 + \delta_1 NoGenerics_{dt} + \delta_2 NoSubstitutes_{dt} + \delta_3 NoPresentations_{dt} \\ & + \delta_4 \%Medicare\_B_{dt} + \delta_5 \%Medicaid\_B_{dt} + \delta_6 \%Private\_B_{dt} \\ & + \delta_7 \%Others\_B_{dt} + \delta_8 Postpatent_{dt} + \delta_9 After_{dt} \\ & + \delta_{10} Therapeutic\_class_{d} + \varepsilon_{b_{dt}},\end{aligned} \tag{1}$$

$$\begin{aligned}\ln\left(P^{*}_{g_{dt}}\right) = {} & \lambda_0 + \lambda_1 NoGenerics_{dt} + \lambda_2 NoSubstitutes\_G_{dt} + \lambda_3 \%Medicare\_G_{dt} \\ & + \lambda_4 \%Medicaid\_G_{dt} + \lambda_5 \%Private\_G_{dt} + \lambda_6 \%Others\_G_{dt} \\ & + \lambda_7 Postpatent_{dt} + \lambda_8 Therapeutic\_class_{d} + \varepsilon_{g_{dt}},\end{aligned} \tag{2}$$

where $NoGenerics$ is the number of generic entrants, that is the number of Food and Drug Administration (FDA) approved therapeutically equivalent (in terms of active ingredient, strength, dosage form, and route of administration) generic drugs available on the market.
$NoSubstitutes$ is the number of other available substitute medications which equals the sum of the number of other branded and generic ($NoSubstitutes\_G$) prescription drug substitutes. Other prescription medications that are on the market now that treat the same diseases but have different active components are referred to by this variable.
$NoPresentations$ is the number of presentations. A drug's presentation is the unique combination of strength and dosage form. We mention the number of presentations that are available each year.
$\%Medicare\_B$ ($\%Medicare\_G$), is the fraction of branded (generic) prescriptions that were dispensed to Medicare patients, $\%Medicaid\_B$ ($\%Medicaid\_G$), is the fraction of branded (generic) prescriptions that were distributed to Medicaid patients, $\%Private\_B$ and $\%Others\_B$ ($\%Private\_G$ and $\%Others\_G$), are the fraction of branded (generic) prescriptions that were dispensed to private insurance and other insurances (like VETERANS, TRICARE, other federal, state & local) patients respectively. (The omitted reference category

is $\%Cash\_B$ ($\%Cash\_G$); the fraction of branded (generic) prescriptions paid out of pocket (in cash).
$Postpatent$ is the months since patent expiration or as we considered in the paper, the months since initial generic entry.
$After$ is a dummy variable that takes the value of one after generic entry and zero otherwise. This variable indicates the average of brand price increase after generic entry relative to the period before that.
$Therapeutic\_Class$ is another dummy variable and takes the same value for all drugs in the same class.
d and t represents the drug and time and ε_b and ε_g are the regression error terms.
We adopt a panel data econometric model, which allows for individual specific or temporal specific error components. The individual specific error component, μ_i, captures any unobserved effects that are different across individuals but fixed across time. When drug specific error component is assumed to be a fixed parameter, a fixed effect model is used and when μ_i is distributed randomly and varies, a random effect model is used.

5 Data

5.1 Data collection

Our framework requires the integration of data from a variety of sources, which we will now briefly summarize.
The data on total expenditure and quantity of prescriptions drugs are primarily derived from the Medical Expenditure Panel Survey (MEPS) Prescribed Medicines Files[18]. The aggregate of payments from all payers and the quantity were extracted from these files. The unit price is the ratio of the sum of payments to quantity. The dependent variable used in the empirical analysis is the logarithm of the price per quantity at pill level[19]. Most of the drugs come in a variety of forms, but for the sake of comparison between branded and generic we chose the most prescribed strength based on the data of MEPS files between 2010 and 2014. Since the MEPS files contain the payer type variable, we were able to distinguish for each drug in the sample the amount paid by Cash (out of pocket), Medicare, Medicaid, Private and Other type (like Veterans, Tricare, …) of insurances.
We used various sources to identify a set of block buster drugs which lost their patent protection during the early to mid-2010s (between 2010 and 2014). We verified these dates using the Federal Food and Drug Administration's Orange Books. The publication "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the Orange Book) identifies drug products approved on the basis of safety and effectiveness by the Food and Drug Administration (FDA). From this group of drugs, we eliminated the ones that (1) became over-the-counter products, that no longer required a prescription for purchase, (2) the ones that were combination products, or (3) that were not sold to drugstores in quantity (these include

[18] Agency for healthcare research and quality, (2021)
[19] Our inability to fully account for rebates may bias the estimates. This is a limitation of all studies on this industry. Alston, Dieguez, and Tomicki (2018) argued that rebates are rarely used for generics, so for generic products, net prices are likely to be very close to reported prices.

injectibles and infusibles which account for a very small part of the outpatient market). After applying the above exclusion criteria and focusing only on the "oral solid" (tablets and capsules) prescription block buster drugs, 19 drugs remained in the sample.
The main right-hand-side variable of interest in this analysis is the number of generic entrants in the market. This variable was constructed by using information from the Orange Book. The variables $NoSubstitutes$ and $NoSubstitutes\_G$ were made up using epocrates.com to find various brands and generics that could be prescribed instead of the chosen medicine. The Electronic Orange Book (EOB) was used for the number of presentation variable. To create the dummy $Therapeutic\_Class$ variable we used drugbank.com to identify which drug belongs to which class.

5.2 Sample

The drugs in our sample are among the most popular drugs. Usually, blockbuster drugs experience significantly more generic entrants and consequently more price erosion. So, we would expect to see a negative effect of generic entry on branded price in our sample. Here the table below shows the top 20 branded drugs based on total retail sale in the U.S. pharmaceutical industry in 2011. As indicated, our sample contains 7 of the top 20 medicines just in 2011.

Table 1: Top 20 branded drugs based on total retail sale in the U.S. pharmaceutical industry in 2011

	Drug Name (Producer)	Total retail sale (in million U.S. $)
1	**Lipitor (Pfizer)**	7,430
2	**Plavix (Bristol-Myers Squibb)**	6,560
3	Nexium (AstraZeneca)	5,964
4	Abilify (Otsuka)	5,032
5	Advair Diskus (GlaxoSmithKline)	4,492
6	Seroquel (AstraZeneca)	4,492
7	**Singulair (Merck & Co.)**	4,450
8	Crestor (AstraZeneca)	4,266
9	**Cymbalta (Eli Lilly)**	3,552
10	Humira (Abbott)	3,422
11	Enbrel (Amgen)	3,398
12	Remicade (Centocor Ortho Biotech)	3,367
13	**Actos (Takeda)**	3,331
14	Neulasta (Amgen)	3,213
15	Rituxan (Genentech)	2,912
16	**Zyprexa (Eli Lilly)**	2,872
17	Copaxone (Teva)	2,864
18	**Lexapro (Forest Pharm.)**	2,835
19	OxyContin (Purdue Pharma)	2,791
20	Epogen (Amgen)	2,686

Source: IMS health data

Table two shows the list of 19 brands and their correspondent generic drugs in our sample, the therapeutic class, and the date of first generic entry in the market. These drugs belong to 7 therapeutic classes. The Nervous System has the larger number of drugs in the sample with seven products, followed by Cardiovascular medications with five products, Genito-Urinary System and Musculo-Skeletal System with two medications each, and finally the Respiratory System, Blood and Blood-Forming Organs, Alimentary Tract, and Metabolism with one drug

each. In 2010, 2 medications became generic for the first time, followed by 4 pharmaceuticals in 2011, 6 drugs in 2012, 2 drugs in 2013, and 5 drugs in 2014.

Table 2: The 19 brand and their generic drugs experiencing first generic entry between 2010 and 2014

	Branded Drug	Generic Drug	Date of first generic entry	therapeutic class
1	Actonel	Risedorante Sodium	June 2014	Musculo-skeletal system
2	Actos	Pioglitazone Hydrochloride	October 2012	alimentary tract and metabolism
3	Aricept	Donepezil Hydrochloride	May 2011	nervous system
4	Avapro	Irbesartan	September 2012	cardiovascular system
5	Celebrex	Celecoxib	May 2014	Musculo-skeletal system
6	Cozaar	Losartan Potassium	October 2010	cardiovascular system
7	Cymbalta	Duloxetine Hydrochloride	December 2013	nervous system
8	Diovan	Valsartan	June 2014	cardiovascular system
9	Evista	Raloxifene Hydrochloride	March 2014	Genito urinary system
10	Flomax	Tamsulosin Hydrochloride	April 2010	Genito urinary system
11	Focalin Xr	Dexmethylphenidate Hydrochloride	November 2013	nervous system
12	Lexapro	Escitalopram Oxalate	March 2012	nervous system
13	Lipitor	Atorvastatin Calcium	November 2011	cardiovascular system
14	Lunesta	Eszopiclone	May 2011	nervous system
15	Micardis	Telmisartan	January 2014	cardiovascular system
16	Plavix	Clopidogrel Bisulfate	May 2012	blood and blood forming organs
17	Provigil	Modafinil	September 2012	nervous system
18	Singulair	Montelukast Sodium	August 2012	respiratory system
19	Zyprexa	Olanzapine	October 2011	nervous system

Source: EOB, FDA

5.3 Descriptive statistics

Table three presents some descriptive statistics; the mean and standard deviation; for the variables used in the analysis, separately for generics and originators. The empirical study is based on an average of 1.05 years of post-patent data for the branded drug model and 1.5 years for the generic drug model[20]. The average number of generic entrants is 3.19. There is an average of 4.9 generic entrants in the year of patent expiration following by an average of 7.4, one year after patent expiration. So, the average number of generic entrants doubles within one year after the year of first generic entry.

[20] Grabowski and Vernon (1996) focus on the first and second year following initial generic entry and Reiffen and Ward (2005) consider up to three years after patent expiration.

Table 3: Descriptive statistics

Variables	Mean	Standard deviation
Price Variables		
Branded price		
Pre entry	7.237	7.697
Post entry	9.791	11.374
Pre and post entry	8.7	10.002
Generic price	3.219	5.069
Market Share Variables-Brand		
Cash share of branded prescription		
Pre entry	0.195	0.0757
Post entry	0.199	0.218
Pre and post entry	0.197	0.171
Medicare share of branded prescription		
Pre entry	0.348	0.167
Post entry	0.36	0.293
Pre and post entry	0.355	0.246
Medicaid share of branded prescription		
Pre entry	0.115	0.144
Post entry	0.162	0.244
Pre and post entry	0.142	0.208
Private share of branded prescription		
Pre entry	0.271	0.114
Post entry	0.212	0.242
Pre and post entry	0.237	0.199
Others share of branded prescription		
Pre entry	0.069	0.037
Post entry	0.065	0.091
Pre and post entry	0.067	0.073
Market Share Variables-Generic		
Cash share of generic prescription	0.169	0.188
Medicare share of generic prescription	0.324	0.3
Medicaid share of generic prescription	0.082	0.17
Private share of generic prescription	0.194	0.24
Others share of generic prescription	0.229	0.33
Other Variables		
Number of other branded and generic substitutes		
Pre entry	0.894	1.133
Post entry	1.333	1.807
Pre and post entry	1.146	1.563
Number of generic entrants	3.196	2.856
Number of presentations		
Pre entry	3.263	1.671
Post entry	3.333	1.796
Pre and post entry	3.303	1.734
Years since initial generic entry-Brand drug model	1.058	1.047
Years since initial generic entry-Generic drug model	1.515	1.15

Source: EOB, Epocrates and Druginfo, MEPS

The graph four reflects the fact that, on average, roughly 5 generic producers enter the market during the year of patent expiration. It demonstrates that competition is more severe among blockbuster pharmaceuticals, and generic firms aim to join the market earlier to capitalize on the first mover advantage phenomenon. As the figure shows, by the end of second year after the reference year, the average number of generic entrants exceeds 9 and after three years, it has surpassed nearly 11. In our panel data sample, there are essentially no generic firms exiting.

There might be a simultaneous generic entry, or it might be spread out over time depending on the economic and market regulation and the implemented policies. In any event, when the total number of generic competitors increases, total generic shares of the market increase, generic prices decrease, and additional entry becomes less desirable.

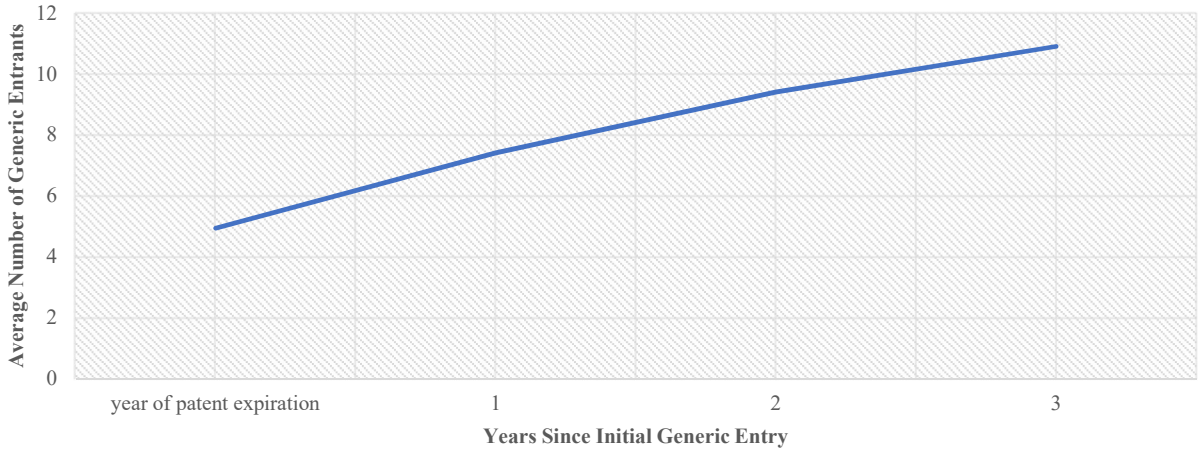

Figure 4: Average number of generic entrants over time
Source: Medical expenditure panel survey

The average number of other branded and generic substitutes is 1.14, most of them are branded drugs competing with other brands in our sample. An average of 3.3 exists for oral presentations per drug. The average price per unit (quantity) of a branded drug pre-entry is 7.23$ and for the post entry period is 9.79$. So, there is an obvious increasing trend in the branded drug price across time. The average price per unit of a generic drug in the sample is 3.2$. Thus, the average generic to brand price ratio is 0.32$ which represents the meaningful gap between branded and generic drug prices. In the pre-entry period, 19%, 35%, 11%, 27% and 7% of the brand-name drugs prescriptions were respectively paid for by Cash, Medicare, Medicaid, Private and Other types of insurances. For the post entry period, these figures are 20%, 36%, 16%, 21% and 7%. For the generic market, these fractions are the following; 17%, 32%, 8%, 19% and 23%. The way that prescriptions on average were dispensed between the 5 categories of Cash, Medicare, Medicaid, Private and Others across time is represented in the Figures shown below.

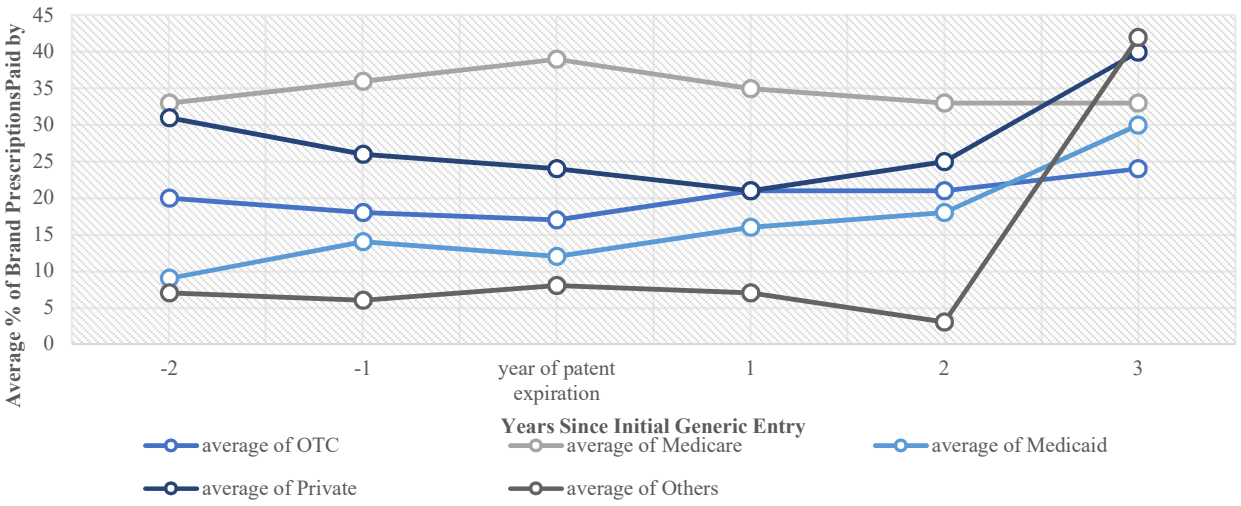

Figure 5: Average percentage of brand-name prescriptions paid by different payer-types
Source: Medical expenditure panel survey

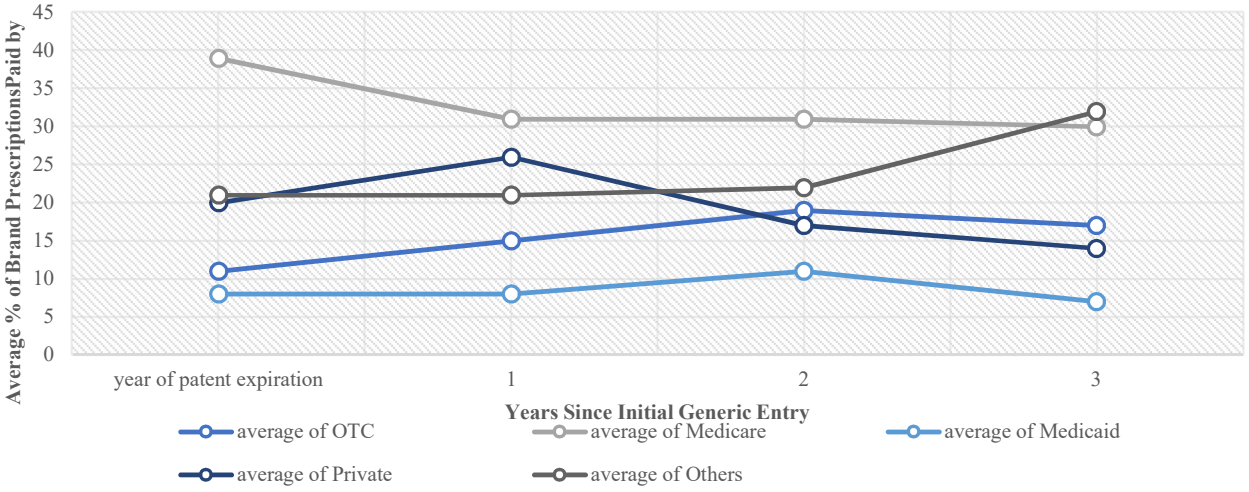

Figure 6: Average percentage of generic name prescriptions paid by different payer-types
Source: Medical expenditure panel survey

Figures seven and eight display the average brand-name drugs and the average generic drug prices in different years in the sample. As one can see the average brand-name drug price has always been increasing both before and after generic entry. These findings are consistent with Grabowski and Vernon's (1992) results. The graph depicts a 25 percent increase in the average price of brand-name drugs the year after the reference year or the year of generic entry. It also shows that even if the generic entry has a negative effect on the brand-name drug price, this effect should be small enough or must be neutralized by other important variables. In return the average generic drug price has been decreasing since the first generic entry in the market. As the number of generic entrants increases in the market and also as time passes, the price of generic drugs decreases. These figures also reveal that the price gap between branded and generic drugs is increasing over time.

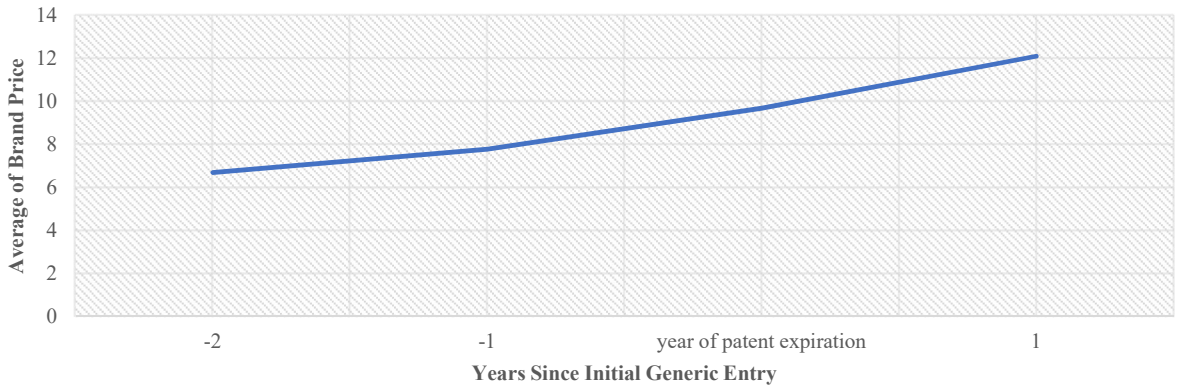

Figure 7: Average of brand-name drug prices over time
Source: Medical expenditure panel survey

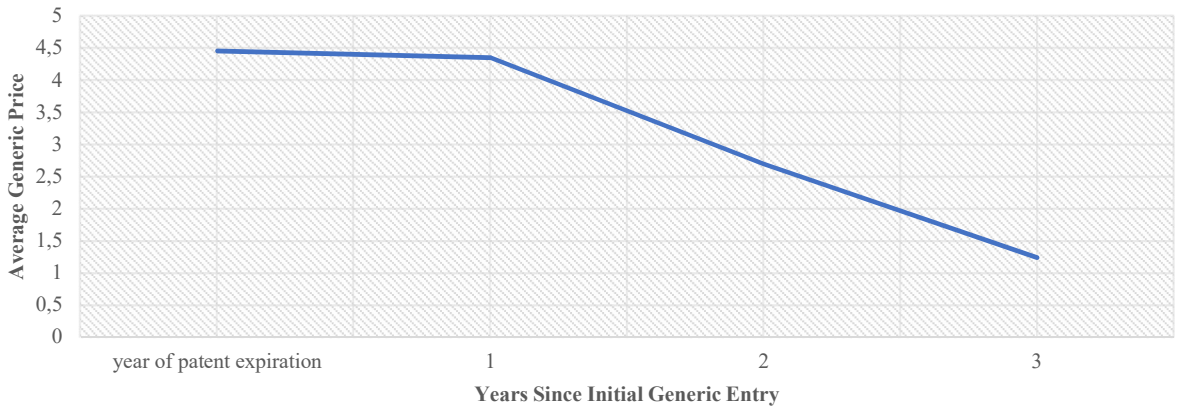

Figure 8: Average of generic name drug prices over time
Source: Medical expenditure panel survey

Figure nine shows the average generic to branded price ratio as a function of the years since initial generic entry. As expected, the declining ratio is evident and is also consistent with evidence from literature. Recent studies have indicated that generic drug prices are significantly cheaper than branded drug prices, and that the generic-to-brand price ratio decreases with generic entry. According to Frank and Salkever (1997), whereas brand prices rise following generic entry, the average price of generics lowers. As a result, the generic-to-brand price ratio gradually decreases. It is worth noting that three years after the initial generic introduction onto the market, generic prices are less than 20 percent of the brand-name price.

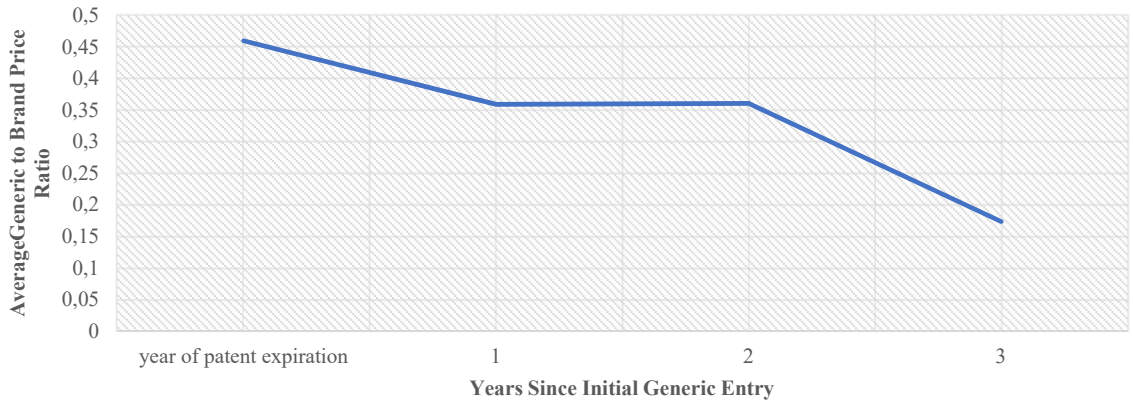

Figure 9: Average generic over brand-name drug prices over time
Source: Medical expenditure panel survey

Figures ten, eleven, twelve and thirteen depict the brand-name price (and also the generic price in one case) as a function of years, for four branded drugs whose price has always been increasing over time even in the specific year of generic entry or some years after generic entry. As we said, the price of brand-name drugs in our sample has always been increasing even 2 years before patent expiration. The rise is more significant for some medicines and less evident for others. According to Reekie (1978), drug prices are associated with the degree of therapeutic novelty that the product has in relation to the existing products. So, based on the general evidence we can observe various pricing strategies like skimming pricing and competitive price cutting regarding the therapeutic advantages of different drugs.

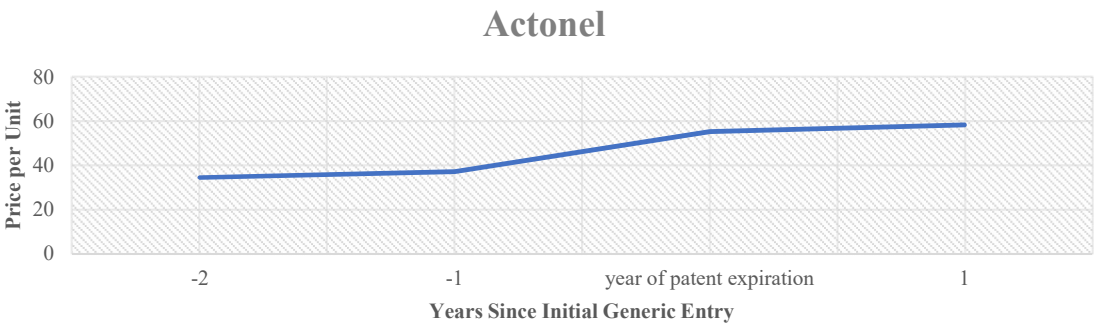

Figure 10: Average of brand-name drug, Actonel, over time
Source: Medical expenditure panel survey

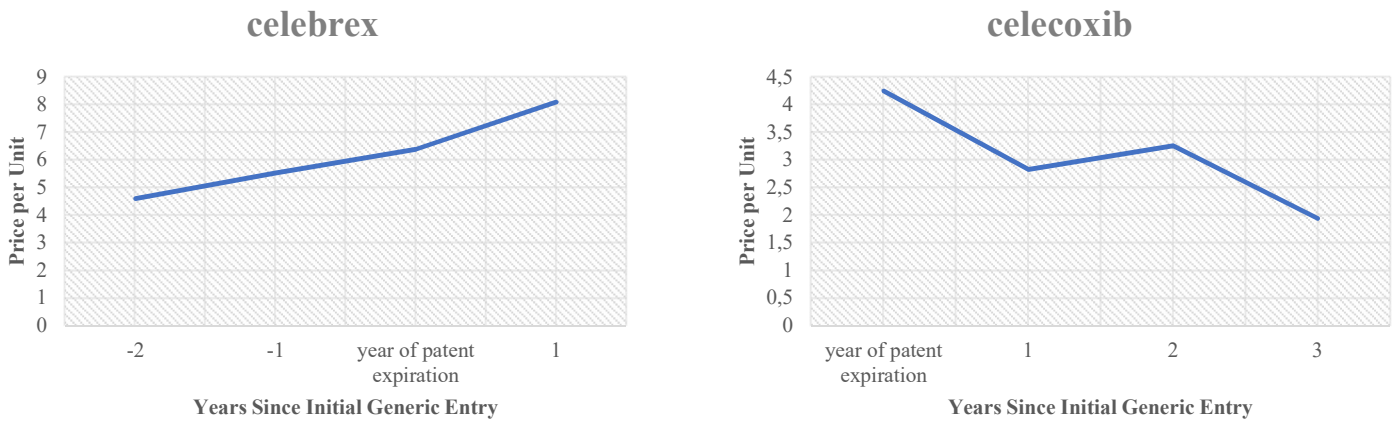

Figure 11: Average of brand-name drug, Celebrex, and its correspondent generic, Celecoxib, over time
Source: Medical expenditure panel survey

Figures eleven also shows that the price difference between brand-name drugs and generic drugs is widening as a result of generic entry into the market.

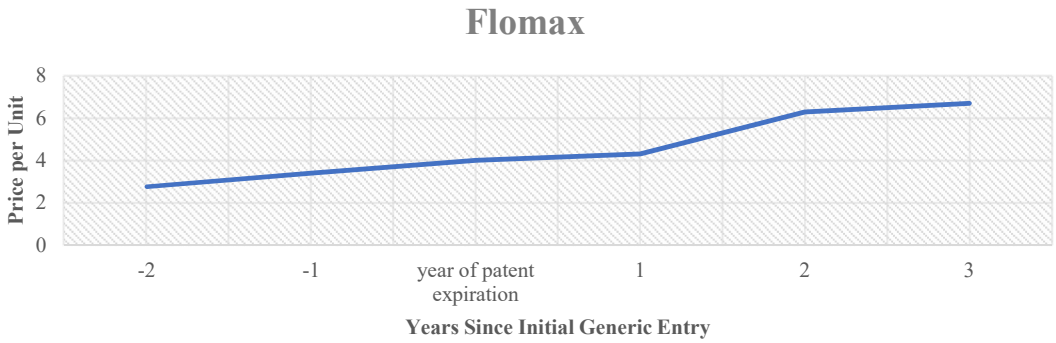

Figure 12: Average of brand-name drug, Flomax, over time
Source: Medical expenditure panel survey

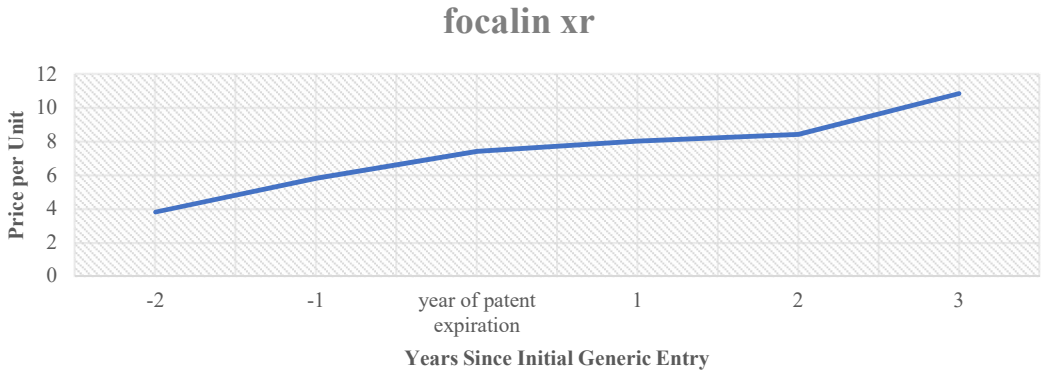

Figure 13: Average of brand-name drug, Focalin Xr, over time
Source: Medical expenditure panel survey

Figures fourteen, fifteen and sixteen show those cases in which generic entry created a price shock in the market and the price of brand-name drugs stopped its upward trend and decreased, but after a short time period started to increase again.

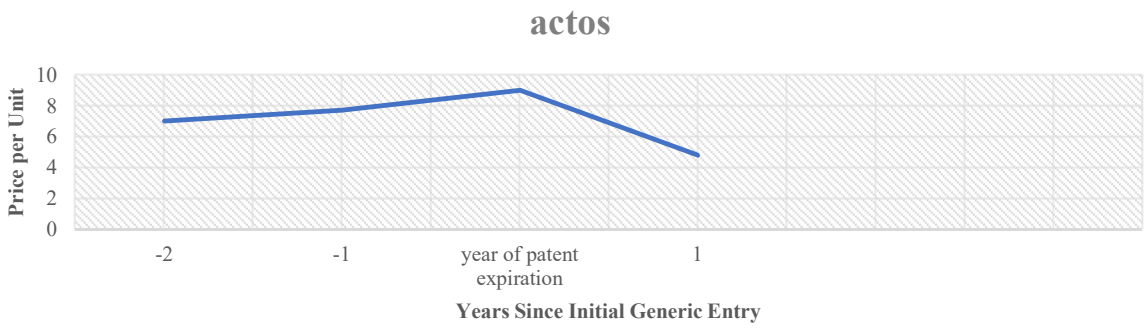

Figure 14: Average of brand-name drug, Actos, over time
Source: Medical expenditure panel survey

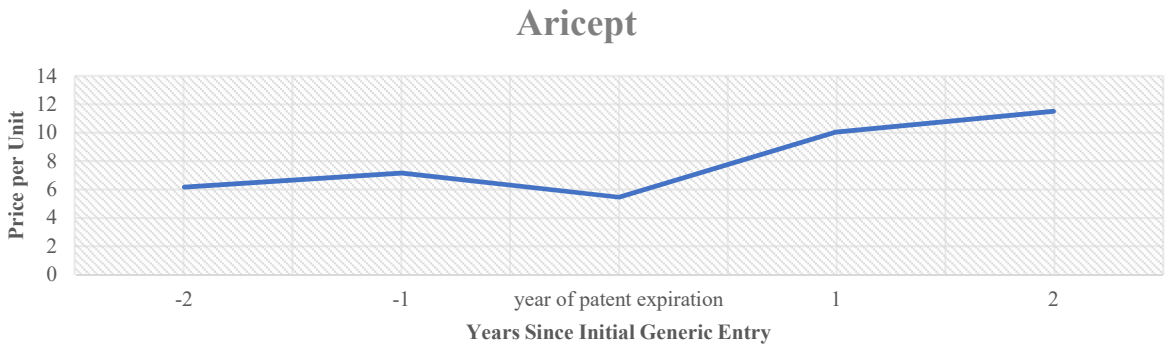

Figure 15: Average of brand-name drug, Aricept, over time
Source: Medical expenditure panel survey

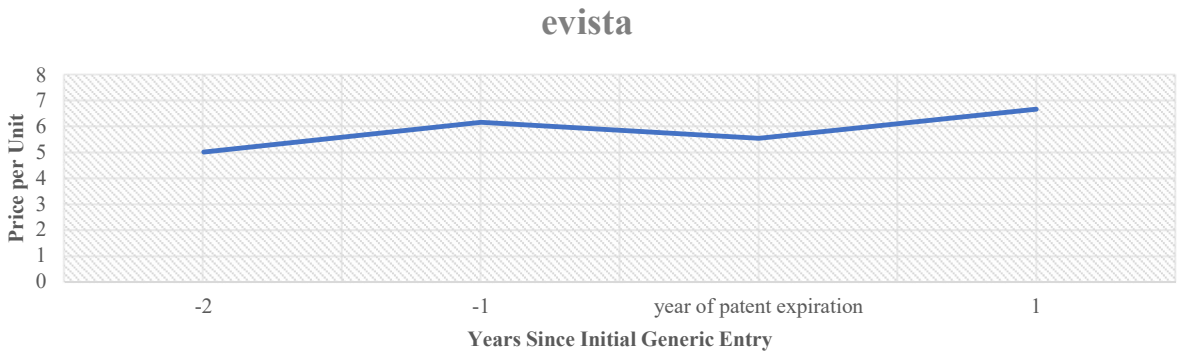

Figure 16: Average of brand-name drug, Evista, over time
Source: Medical expenditure panel survey

6 Estimation and results

In this section we shall examine the major hypotheses of this paper using our dataset. Our primary purpose is to understand the relationships between variables modelled in the current paper. We used the econometric panel data method to test the hypothesis and run the models.

6.1 Hypothesis to test

- *Generic entry has a positive effect on the brand-name drug prices (Generic Competition Paradox)*
- *After loss of patent exclusivity, the brand-name company takes advantage of the price insensitive customers and charges higher prices (Market Segmentation Theory)*
- *Generic entry has a negative effect on generic drug prices*

6.2 Brand-name drugs price regression

Using the unbalanced panel datasets, in the first model, we examine the impact of generic entry, (number of generic entrants) along with nine other variables, on the brand-name drug price. we estimated the first model, omitting the time-invariant variables: $Numpres$, $After$ and $Therapeutic\_class$. Based on the Hausman χ^2 test result, at five percent significance level we cannot reject the null hypothesis and the Random Effect approach is preferred.

After testing for heteroskedasticity and autocorrelation, two of the most important classical regression assumptions, it was discovered that the model suffers from both heteroskedasticity and autocorrelation. So, we handled the heteroskedasticity and autocorrelation issues and estimated the model using the random effect robust and cluster approach. The estimation results are shown in table four.

As you can see, generic entry has a statistically significant negative effect on the logarithm of brand-name drugs price. It decreases the average brand drug price by 2.6 percent. This finding demonstrates that price competition is not limited just to the generic drug market and is consistent with the findings of other research such as Wiggins and Maness (2004), Caves et al. (1991), Saha et al. (2006), and Stargardt et al. (2011).

The coefficient of the variable $\%Private\_B$ is positive and statistically significant. It suggests that a 1 percent increase in the fraction of branded prescriptions that are dispensed to customers under Private insurance, will increase the branded prescription price by 0.44 percent. These results clearly and strongly lend support to the notion of market segmentation based on insurance coverage in the branded prescription drug market.

When generics enter the market, brand-name firms raise their prices for price-sensitive clients (those with prescription drug coverage) in order to enhance their total income in this submarket. Branded firms, on the other hand, suffer significant market share losses. The coefficients estimate on $\%Medicare\_B$ and $\%Medicaid\_B$ are negative and statistically insignificant. Also, the coefficient of $\%Others\_B$ is positive but not statistically significant. The small coefficient of $NoPresentations$ does not gain statistical significance. The coefficient of $NoSubstitutes$ is negative and statistically insignificant.

The coefficient estimate on $Postpatent$ is positive and statistically significant, specifying that the branded prescription drug price increases on average by 12.8 percent each year. This is consistent with figure seven in the descriptive statistics section, depicting the average brand-name drug price over time. As we saw, the average brand drug price in our sample is steadily increasing over time. The positive and statistically significant coefficient of the dummy variable, $After$, states that on average brand drug prices has increased after generic entry relative to the time before that. And the statistically significant coefficient of

$Therapeutic\_class$ proves that there are significant differences in the price change patterns across various therapeutic classes.

Table 4: Branded price regression

Branded price regression		
Dependent variable	ln (Brand Drug Price)	ln (Brand Drug Price)
Estimation strategy	Random Effect	Random Effect
Variables	**Coefficients**	**Coefficients**
NoGenerics	-0.0263 (0.008)***	-
4-7Generics	-	-0.1908 (0.0956)**
8+Generics	-	-0.3544 (0.068)***
NoSubstitutes	-0.0136 (0.0483)	0.0045 (0.0477)
NoPresentations	-0.0451 (0.0858)	-0.0503 (0.0853)
Medicare_B	-0.0208 (0.1242)	0.0303 (0.1187)
Medicaid_B	-0.1319 (0.2776)	-0.0843 (0.2679)
Private_B	0.4454 (0.1954)**	0.4981 (0.1755)***
Others_B	0.074 (0.282)	0.1956 (0.2609)
Postpatent	0.128 (0.0299)***	0.1070 (0.0307)***
After	0.3351 (0.0571)***	0.3370 (0.0524)***
Therapeutic_class	-0.2498 (0.1483)*	-0.2495 (0.1475)*
constant	2.655 (0.8173)***	2.609 (0.8064)***
(within)	0.687	0.699
(between)	0.185	0.177
(overall)	0.932	0.939

(Standard error)

*, **, ***= significant at the 10, 5, and 1% level

Because $NoGenerics$ is the most important variable of interest in this study, the coefficient estimate on that deserves special attention. We considered an alternate $NoGenerics$ specification to better account for the dynamics of competition following generic entry into the market. It is reasonable to believe that the number of entrants is one of the most relevant problem in generic entry. Because when the number of generic entrants hits a certain threshold, price competition between generic and brand-name drug producers in the market may increase.

As a result, we created a set of dummy variables[21] for one, two, and three entrants ($1-3Generics$), four, five, six, and seven entrants ($4-7Generics$), and eight or more entrants ($8+Generics$). The omitted reference group is the $1-3Gen$. We chose this kind of classification because in our sample the average number of generic entrants is 3.19. So, we chose to pick the first set of up to three generic entrants to examine what effect it has on the price of the brand-name drug if the number of generic entrants overcomes the average number. The results of the brand-name drug model based on this specification are shown in the column two of the table four.

The coefficient estimates on both variables $4-7Generics$ and $8+Generics$ are negative and statistically significant. Thus, relative to the first category; that is one, two, and three entrants ($1-3Generics$), the second category, 4-7 entrants lowers the average brand-name drug price by 17 percent and the third category, 8 and more entrants decreases the average brand-name drug price by 29 percent. As it's evident, the coefficient estimate on $8+Generics$ variable is greater than $4-7Generics$, specifying that as the number of generic entrants increases and exceeds a threshold, price competition drastically intensifies and leads not only to a decrease of the generic price but also to a reduction of the brand-name drug price. Of course, one should consider that our sample contains only blockbuster drugs and in this kind of market competition may be stronger, since generic firm try to enter the market as soon as possible after patent expiration to get more market share and to exploit the first mover advantage. Our result could also be affected by the small sample size and the yearly base dataset, but it merely illustrates that an increase in the number of competing firms in the pharmaceutical industry would result in somewhat lower prices.
As it's shown in the table four, our coefficient estimates are almost the same for other variables. For instance, the coefficient estimate of the variable $\%Private\_B$ is positive and significant, stating that if the amount of prescriptions dispensed to those patients covered by private insurance increases by 1 percent, the brand-name drug price increases on average by 0.49 percent. The coefficient estimate on $Postpatent$ is positive and statistically significant again, specifying that the branded prescription drug price increases on average by 10.7 percent each year. So, as it's shown in Figures fourteen, fifteen, and sixteen and confirmed by our regression result, price competition between brand and generic drug firms appears to intensify as the number of generic entrants increases and surpasses a certain threshold, leading to lower prices or at least stopping the rising trend of brand drug prices. However, this effect is temporary, and again, the results show that it is offset and overcome by other variables, allowing us to continue to see an increasing trend in brand drug prices after a while.
The coefficient estimate of the variable $After$ is positive and statistically significant as well and the statistically significant coefficient of $Therapeutic\_class$ proves that there is class-specific differences across drugs as well.

[21] As suggested by Reiffen and Ward (2005)

6.3 Generic price regression

Table five reports the estimated results of the equation 9 that is the model for generic drugs. Again, omitting the time invariant regressors, the Hausman test rejects the null hypothesis. Based on the χ^2 test result at five percent significance level the Fixed Effect is preferred. After testing for heteroskedasticity and autocorrelation, it turned out that the model suffers from heteroskedasticity. So, we handled the heteroskedasticity issue and estimated the model using the Fixed Effect Robust approach. The estimation results are shown in the table below.
Generic entry doesn't have a statistically significant effect on the logarithm of generic price. The coefficients of the variables $\%Medicare\_B$ is positive and statistically significant. It suggests that a 1 percent increase in the fraction of generic prescriptions that are dispensed to customers under Medicare type of insurance will increase the generic prescription price by 0.91 percent. We must consider that Medicare is the largest payer type in our sample, both in brand-name drugs and generic medications. This result could demonstrate that market segmentation theory may be relevant in both markets. Furthermore, there may be brand loyalty phenomena also in the generic market allowing generic manufacturers to claim larger markups as their consumer brand recognition and reputation grow. Economists explain the diversity in generic prices to differences in firm perceptions of quality (brand loyalty) and disparities in product. As a result, we can witness price adjustments (increases and decreases) in the generic name medicine market as well. The coefficients estimate on $\%Medicaid\_B$ and $\%Private\_B$ are also positive but not statistically significant. The coefficient of $\%Others\_B$ is negative and statistically insignificant. The coefficient of $NoSubstitutes\_G$ is negative and if statistically significant, would suggest that other available generic substitutes lower the generic prescription price by 12 percent. The coefficient estimate on $Postpatent$ is negative and statistically significant, specifying that the generic prescription drug price decreases on average by 27 percent each year. It demonstrates that as the number of generic entrants in the market increases, the average price of generic brand medications falls dramatically over time. It is consistent with figure eight showing average generic medicine price reduction based on our data.

Table 5: Generic price regression

Generic price regression	
Dependent variable	ln (Generic Drug Price)
Estimation strategy	Fixed Effect
Variables	**coefficients**
NoGenerics	0.0150 (0.0259)
NoSubstitutes	-0.1247 (0.1679)
Medicare_G	0.9154 (0.3677)**
Medicaid_G	0.1088 (0.4354)
Private_G	0.7374 (0.4775)
Others_G	-0.0554 (0.2881)
Postpatent	-0.2774 (0.0944)***
Therapeutic_class	omitted
constant	0.6015 (0.3139)*
(within)	0.579
(between)	0.138
(overall)	0.283

(Standard error)
*, **, ***= significant at the 10, 5, and 1% level

7 Conclusion

This paper investigates how generic entry affects price competition in the market for prescription drugs in the United States. We have chosen 19 blockbuster branded name and generic medications that had their initial generic entry between 2010 and 2014. In this paper, we attempted to explore the traditional industrial organization dilemma in terms of the economic rationale for the result that a rise in the number of suppliers is related with a lower equilibrium price. This study offers new empirical evidence on the impact of generic entry on branded and generic name drugs prices, with a focus on the generic competition paradox and market segmentation theory.

The findings strongly show that generic entry has a negative and considerable impact on the brand-name drugs prices. So, considering the first hypothesis of this study, we can say that based on the results, we can reject this hypothesis and state that the generic competition paradox is not applicable and does not occur in our sample. Instead, price competition is not limited to the generic market, and it affects brand-name drugs as well. This result is consistent with other research studies such as Wiggins and Maness (2004), Caves et al. (1991), Saha et al. (2006), and Stargardt et al. (2011). However, we should recall that this finding only captures the average movement of brand pricing. Of course, there are heterogeneities in brand-name drug

prices in reaction to generic competition. Also, we tried to examine a new specification of the variable $NoGenerics$, creating a set of dummy variables based on the average number of generic entrants in our sample. The results suggested that as the number of generic entrants increases in the market and exceeds a threshold, price competition between brand-name drugs and generic drastically increases and leads to lower prices for both kind of drugs.

Concerning the second hypothesis, based on the results; the fraction of prescriptions dispensed to Private and Medicare insurance types has a positive and significant effect on brand-name drugs and generic prices, we can state unequivocally that an increase in the proportion of prescriptions supplied to payers with insurance coverage will raise the prices of brand and generic name drugs. As a result, after generic entry, the originator firms appear to charge higher prices in order to exercise some price discrimination and exploit the market segment that is less price sensitive. Furthermore, it appears that generic producers make some pricing adjustments after the first phase of entrance and capitalize on their reputation and brand identification among customers based on variations in firm perceptions of quality (brand loyalty) and product discrepancies. As a result, we should expect to see price adjustments (increases and decreases) in the generic market as well. So, the empirical findings in this study fully support the idea of market segmentation. However, keep in mind that, as we already mentioned, the market segmentation explored in this paper is based on insurance coverage distinguishing between different insurance types. As a result, even though the manufacturer of the brand-name drugs raises prices in the price-insensitive section to make up for market share lost, this type of rise is intended to take advantage of clients who have some degree of insurance coverage, not merely because those customers are brand loyal.

Regarding the third hypothesis we must clarify that, according to the findings of our second econometric model, generic entry has no statistically significant impact on generic name drug prices. Additionally, defining a new specification for the variable $NoGenerics$ doesn't make any change and has no statistically significant effect in our sample. However, based on the descriptive statistics, we may conclude that average generic prices are constantly lowering following generic entry and over time. So, finding an insignificant result in our sample could be due to several factors, including: 1) the unbalanced nature of sample 2) the small generic sample size and 3) the nature of the yearly base dataset.

According to the positive and significant coefficient of the dummy variable, $After$, the average brand-name drug price has increased after generic entry compare to the period before that. The statistically significance of the variable $Therapeutic\_class$, demonstrates that each therapeutic class responds differently to generic entry in terms of price change patterns. Furthermore, the variable $Postpat$ has a considerable positive (negative) effect on brand (generic) name drug prices. According to the coefficient estimations, each year is consistent with a 12.8 percent increase in brand drug prices and a 27 percent decrease in generic drug prices. These findings are consistent with the descriptive statistics about the average price change of brand and generic pharmaceuticals in our sample over time. In terms of brand-name drug prices, companies raise their prices to exploit the price insensitive portion of the market and compensate for lost market share. So, this price increase is consistent with market segmentation theory. In terms of generic prices, given that our sample contains blockbuster pharmaceuticals, price erosion is likely to be higher, as it is price competition among generic suppliers.

As previously stated, generic entry has a negative impact on branded drug prices, and this negative impact grows as the number of generic entrants surpasses a specific threshold, resulting in more intense price competition in the market. However, as we observed in the descriptive statistics section, brand-name drug prices tend to rise with time. As a result, we can conclude that the negative effect of price competition must be offset by other important variables that have a positive effect on brand-name drug prices, or by brand drug producers acting in the market in ways such as exploiting the market segmentation phenomenon by setting higher prices. This is something that needs to be researched and analyzed further.

Of course, this study is not without limitations. The first and foremost one concerned data collecting for empirical analysis. During the data collection phase, we tried to use different sources to be able to get the required data. But lacking reliable sources of data would negatively affect both the accuracy of the data and the related results. Most studies in this field investigate price competition with monthly data. Unfortunately, only yearly data is at our disposal, reducing the frequency of observations in a market where price variations could take place over a much shorter period of time. Therefore, the regression results need to be considered cautiously for this reason. Also, our price measures may not be completely net of discounts and rebates; our estimates of the effect of generic entry on prices of branded drugs may therefore be conservative.

Concerning the future studies, we can say that similar studies on off-patent competition between generic entrants and originators, based on more detailed therapeutic classes or a wider range of therapeutic classes would be useful in order to capture the drug class specific differences to supplement this study's findings. Future studies could use data from more regulatory environments in order to examine the generic competition paradox in those markets. Building a more detailed, based on monthly nature, and longer dataset and evaluating the competition based on dynamic panel models like GMM, would help to provide deeper insights into the dynamics of competition in pharmaceutical sector. Also, focusing on different policies in both supply and demand sides, like price cap, reference pricing, price freeze, parallel important and how those policies affect pharmaceutical prices remains to be investigated and opens up a new avenue of research.

8 References

Agency for Healthcare Research and Quality, (2021), Medical expenditure Panel survey. Retrieved from https://www.meps.ahrq.gov/mepsweb/data_stats/download_data_files.jsp

Alston, M., Dieguez, G., Tomicki, S., (2018), A perimeter on prescription drug rebates: insights into why rebates are a target for reducing prices, Milliman white paper

Balto, D. A., (2000), Pharmaceutical patent settlements: The antitrust risks, *The Food and Drug Law Journal*, 55(3), 321-341

Bergman, M.A., Rudholm, N., (2003), The relative importance of actual and potential competition: empirical evidence from the pharmaceuticals market, *The Journal of Industrial Economics*, 0022-1821, No.4

Berndt, E.R., Kyle, M.K., Ling, D.C., (2003), The long shadow of patent expiration: generic entry and Rx to OTC switches, NBER Conference Volume on Scanner Data and Price Indexes, University of Chicago Press, Chicago, pp. 229–267

Berndt, E.R., Aitken, M.L., (2011), Brand loyalty, generic entry and price competition in pharmaceuticals in the Quarter century after the 1984 Waxman-Hatch legislation, *International Journal of Economics and Business Research*, 18 (2), 177–201

Caves, R.E., Whinston, M.D., Hurwitz, M.A., (1991), Patent expiration, entry, and competition in the U.S. Pharmaceutical Industry, *The Brookings papers on Economic Activity, Microeconomics*, 1991, pp. 1-66

Chen, Y., & Riordan, M. H., (2008), Price-increasing competition, *The RAND Journal of Economics*, 39, 1042–1058

Ching, A., (2010), Consumer learning and heterogeneity: dynamics of demand for prescription drugs after patent expiration, *International Journal of Industrial Organization*, 28 (6), 619–638

Coscelli, A., (2000), The Importance of Doctors' and Patients' Preferences in the Prescription Decision, *The Journal of Industrial Organization*, 48(3), 349-369

Darrow, J. J., & Kesselheim, A. S, (2018), Promoting competition to address pharmaceutical prices, *Health Affairs Policy Options Paper*, https://doi.org/10.1377/hpb20180116.967310/

Druginfo, (2020), drug bank online. Retrieved from https://drugbank.com/

EFPIA Key Data (2021), The Pharmaceutical Industry in Figures, page 9

European Commission: Pharmaceutical Sector Inquiry – Final Report

Food and Drug Administration, (2021), National drug code directory. Retrieved from https://www.fda.gov/drugs/drug-approvals-and- databases/national-drug-code-directory

Frank, R.G., Salkever, D.S., (1992), Pricing patent loss and the market for pharmaceuticals, *The Southern Economic Journal*, 165–179

Frank, R.G., Salkever, D.S., (1997), Generic entry and the pricing of pharmaceuticals, *Journal of Economics and Management Strategy*, 6, 75–90

Grabowski, H., Vernon, J., (1992), Brand loyalty. Entry, and Price Competition in Pharmaceuticals after the 1984 Drug Act, *Journal of Law and Economics*, 35, 331–350

Granlund, D., Bergman, M.A., (2018), Price competition in pharmaceuticals – Evidence from 1303 Swedish markets, *Journal of Health Economics*, 61, 1-12

Hernandez, I., San-Juan-Rodriguez, A., Good, CB., Gellad, WF., (2020), Changes in List Prices, Net Prices, and Discounts for Branded Drugs in the US, 2007-2018, *Journal of The American Medical Association*, 323 (9), 854-862

Kong, Y., (2009), Competition between brand-name and generics –Analysis on pricing of brand-name pharmaceutical, *Journal of Health Economics*, 18: 591–606

Lichtenberg, Frank R., (2020), Are drug prices subject to creative destruction? Evidence from the US, 1997–2017, *Journal of Health Economics*, 2021;1–23.

Regan, T. L., (2008), Generic entry, price competition, and market segmentation in the prescription drug market, *International Journal of Industrial Organization*, 26(4), 930–948

Reekie, W.D., (1978), Price and quality competition in the United States drug industry, *The Journal of Industrial Economics,* 26(3), 223-237

Reiffen, D., Ward, M.R., (2005), Generic industry dynamics, *The Review of Economics and Statistics*, 87, 37–49

Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc., 733 F.2d 858 (1984).

Saha, A., Grabowski, H., Birnbaum, H., Greenberg, P., (2006), Generic Competition in the U.S. Pharmaceutical Industry, *International Journal of The Economics of Businesses*, 13(1), 15-38

Scherer, F.M., (1993), Pricing, profits, and technological progress in the pharmaceutical industry, *Journal of Economic Perspectives*, 7, 97–115

Scherer, FM., (2004), The Pharmaceutical Industry – Prices and Progress, *The New England Journal of Medicine*, 351, 927–932

Shepherd, J., (2020), Pharmacy benefit managers, rebates, and drug prices: Conflicts of interest in the market for prescription drugs, Forthcoming in *The Yale Law & Policy Review*, 1(38)

Stargardt, T., (2011), Modelling pharmaceutical price changes in Germany: a function of competition and regulation, *The Journal of Applied Economics*, 43 (29), 4515–4526

Wansheng, J. L., (2008), Balancing Accessibility and Sustainability: How to Achieve the Dual Objectives of the Hatch-Waxman Act While Resolving Antitrust Issues in Pharmaceutical Patent Settlement Cases, *Albany Law Journal of Science & Technology*, 441-493

Wiggins, S.N., Maness, R., (2004), Price competition in pharmaceuticals, *Economic Inquiry Journal*, 42, 247–263