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Atanu Saha & Yong Xu

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Atanu Saha and Yong Xu

StoneTurn, New York, NY, USA

ABSTRACT

Using a panel dataset of 78 branded drugs for the period January 2009 through March 2020, we examine whether brand prices react to the onset of generic competition. Contrary to the findings of several prior academic studies, we show that the rate of change of brand prices (both nominal and CPI-deflated) are significantly lower after generics enter the market; notably, we also find branded drug manufacturers raise their prices in the sixmonth period just before generic entry and lower them in the sixmonth period after, with the differences in the rates of change being highly significant. We also show in markets with an authorized generic and in ones with large pre-entry brand sales, manufacturers raise prices at a higher (or decrease CPI-deflated prices at a shallower) rate.

KEYWORDS

Brand price; generic entry; generic competition paradox

1. Introduction

The competitive landscape undergoes a marked change when generic manufacturers enter a pharmaceutical market. In most cases, an increase in the number of generics leads to a steady, often pronounced, decline in generic to brand price ratios over time. Yet, many widely-cited studies have shown, while generic prices fall, brand prices do not react to the onset of generic competition, and the rate of increase in brand prices do not change even though the brands suffer a steady loss of market share to the generics. In the prior literature, the lack of brand price reaction to generic competition has been characterized as a 'paradox,' as it defies the expected economic effect of increased competition. However, we believe the findings regarding the unresponsiveness of brand prices to generic entry are primarily from papers published in the decade right after the passage of Hatch-Waxman Act and they do not fully reflect the profound changes that occurred in the pharmaceutical landscape in the last twenty years. As we discuss later, the findings from a few recent studies are generally consistent with the results of our paper.

In this paper, using a dataset of 78 drugs that first faced generic competition over the period 2009 through 2020, we show the paradox does not exist. We demonstrate brand prices *do* react to generic competition. Specifically, we show that brands increase nominal prices at a significantly lower rate (and decrease CPI-deflated real prices at a faster rate) after generic entry. We also find, although brands raise inflation-adjusted prices at a higher rate right before generic entry, they lower them right after, and in the overall post-entry period brand prices increase at a significantly lower rate. Furthermore, we show that in markets where the brands have introduced an authorized generic, they tend to raise prices at a higher rate, although the rate is lower than that in the pre-entry period. Similar results are also found for brands with large markets before generic entry.

Our results reflect the changing market dynamics in the pharmaceutical industry. As has been documented in several recent studies and industry publications, in the last twenty years, the role of pharmacy benefit management firms (PBMs) has become increasingly important as managers of pharmaceutical reimbursement programs for both managed care providers (i.e. HMOs, PPOs, etc.) and employers and they have actively promoted the use of generic drugs as a cost-saving measure. Insurers have fostered generic substitution by the design of tiered formularies in which generics are placed in the lowest co-payment tier. Most states have passed laws requiring the comparable generic drug be dispensed in place of the brand unless the doctor's prescription specifically prohibits generic substitution. These powerful industry forces have had profound effects on the competitive landscape in the pharmaceutical industry (see Saha and Roberts (2020)). We believe the results in our paper reflect the brand name pharmaceutical companies' acknowledgement of the ever-changing competitive landscape and their attempt to moderate price increases in response to the ever-growing market presence of generics.

After reviewing the relevant literature, we set out the model for the estimation of brand prices pre- and post-generic entry; we then discuss our results and describe several additional analyses to confirm the robustness of our findings.

2. The prior literature

The literature on the competition between branded and generic pharmaceuticals is extensive. In this section, our goal is not to provide an exhaustive review of this literature, but rather to discuss selected articles relevant to the two major themes central to our study: (a) brand price changes pre- and post-generic entry; and (b) the impact of authorized generics on brand prices.

2.1. Brand price pre- and post-generic entry

To the extent more entrants increase competition in a market, one might expect the introduction of generics would induce a decrease in all prices, including the branded price. However, several studies have found evidence to the contrary. The observation of increased brand prices in the face of generic entry has been dubbed the 'the generic competition paradox' (Scherer 1993). Several studies have explained the phenomenon by positing that the pharmaceutical market is segregated into two segments: a price insensitive brand-loyal segment, and a price sensitive one (Grabowski and Vernon 1996; Frank and Salkever 1997; Kamien and Zang 1999). Some key studies that have documented the continuing increase in brand price after generic entry include

Grabowski and Vernon (1996), Frank and Salkever (1997) and Suh et al. (2000). Regan (2008) recreated the Frank and Salkever (1997) study using data from 1998 to 2002 and Regan's results corroborated those from the predecessor study. Conti and Berndt (2018) found for branded specialty drugs commonly used to treat cancer, after the loss of exclusivity, prices increase as the number of generic manufacturers grows, with the price increase being steeper for injected/infused than oral formulations.

Not all studies, however, have documented a positive relationship between brand price and generic entry. The differences in findings might, in part, be explained by differing prices used in the various studies, particularly whether they were adjusted for inflation or whether they examined wholesale versus retail prices. For example, Lakdawalla, Philipson, and Wang (2006) found that brand prices were, on average, mostly unaffected by generic competition. Caves, Whinston, and Hurwitz (1991) and Wiggins and Maness (2004) found that, after generic entry, both overall prices and branded drug prices declined. An FTC (2011) report concluded that post-generic entry brand *wholesale* prices were 4–11% below the pre-generic level, while the retail prices continued to rise at roughly the same rate as pre-entry. Saha et al. (2006) provided evidence on brand prices' reaction to generic competition. They found, on average, each additional generic entrant was associated with a 0.2% decline in brand prices; however, individual responses varied widely by drug. In our paper, we find that, on average, the rate of brand price change, moderates after the onset of generic competition.

As noted earlier, the mixed findings on brand price response in the prior literature is, in part, explained by the time-period of the data examined in the papers. For example, several prior studies have analyzed datasets from the mid-1980s to early 1990s; however, in the last two and a half decades the competitive landscape in the pharmaceutical industry has undergone profound changes. A recent paper in this journal by Saha and Roberts (2020), using a dataset of 82 drugs that lost market exclusivity between 2009 and 2018, finds evidence of higher market concentration among generic manufacturers and also marked consolidation among PBMs, with the top three PBMs accounting for 90% of all purchasing in 2017. We believe the findings in our paper about brands' price responsiveness to the onset of generic competition, reflects, in part, these profound changes in the competitive landscape in the pharmaceutical industry.

2.2. Authorized generics

The introduction of an authorized generic enables the branded company to retain a share of the generic market segment after the loss of patent protection for the brand. Chen (2007) proposed a model of the healthcare market to explain how an authorized generic may lead to higher profits for the brand manufacturer.

Berndt et al. (2007) examined data from 1999 to 2003 to see if the presence of authorized generics could affect the timing of generic entry, brand and generic prices, and generic penetration. They found that the introduction of authorized generics led to a lowering of generic-to-brand price ratios in the short run, although the effect was not discernable in the long run. The Berndt et al. (2007) study did not specifically

examine the effect of authorized generics on brand prices. Berndt and Newhouse (2010) found that an authorized generic did not appear to adversely impact generic entry after the 180-day exclusivity period, except in cases where the size of the potential market was small. In 2011, the FTC issued a report on the impact of authorized generics; it found that with AG competition during the six-month exclusivity period, generic prices were lower than otherwise and brand wholesale prices were 8–12% lower, whereas the effect of introducing an AG on brand retail prices was not statistically significant. The FTC study also found that brand prices were 22% higher if the AG is a subsidiary of the brand and 6.8% lower when the brand-name firm was party to a settlement agreement involving the AG.

3. Empirical analysis

This section is organized as follows: first, we specify the regression model to analyze the impact of generic entry on the rate of change of brand prices; second, we describe the panel dataset and summarize the descriptive statistics for the key variables used in the regression; third, we discuss the results from the regression analysis; fourth, we explore the robustness of our results by estimating the rate of price change individually for each branded drug; finally, we attempt to explain the findings of our regression analysis by examining the brand price elasticities for drugs with different characteristics.

3.1. Model specification

The principal goal of our empirical analysis is to examine the rate of change of brand prices before and after generic entry. In undertaking this analysis, we account for the pooled cross-sectional and time-series nature of our dataset. Additionally, in estimating the brand price changes we control for various drug characteristics and examine the effects of exogenous variables on the rate of price changes.

We estimate two random effects, generalized least squares models using our panel dataset. The first is a truncated version of the second:

$$\ln(P_{it}) = \alpha_0 + \alpha_1 \cdot D_{it} + \sum_{j=Pre, Post} \alpha_2^j \cdot T_{it}^j + \varepsilon_{it}$$
(1A)

$$\ln(P_{it}) = \alpha_0 + \alpha_1 \cdot D_{it} + \sum_{j=Pre, Post} \alpha_2^j \cdot T_{it}^j + \sum_{j=Pre, Post} \alpha_3^j \cdot T6_{it}^j + \sum_k \beta_k \cdot T_{it}^{Post} \cdot X_{k,it} + \sum_m \gamma_m \cdot TC_{m,i} + \varepsilon_{it}$$
(1B)

In Models (1A) and (1B), and in all equations in this paper, the subscript *i* denotes the *i*th branded drug and subscript *t* denotes the *t*th month. The superscript *j* denotes the period before or after generic entry, that is, j = Pre for the pre-entry period and j = Post for the post-entry period.

The variable P_{it} denotes the brand price normalized by the price in the first month of the sample period, January 2009; this transforms each brand price into an index,

Variable	Acronym	Mean	St. Dev.	Min	Max
Index of brand price	P-index	1.81	0.88	0.31	5.73
Time trend variable, pre generic entry	T ^{pre}	16.60	23.38	0.00	105.00
Time trend variable, post generic entry	T ^{post}	16.25	22.75	0.00	118.00
Time trend variable six months pre generic entry	T6 ^{pre}	2.86	13.18	0.00	105.00
Time trend variable six months post generic entry	T6 ^{post}	3.19	14.42	0.00	111.00
Pre-entry brand market size (annual revenue, \$ billions)	MSZ	0.22	0.29	0.00	1.33
Introduction of authorized generic	AG	0.25	0.43	0.00	1.00
Maximum number of generics per drug	NOG	7.29	3.18	1.00	15.00
CPI - pharmaceutical preparation manufacturing	CPI	457.26	44.65	383.12	539.26
Therapeutic classes		Number of brand/form		% of obs	ervations
		combinations			
Alimentary tract and metabolism insulins	tc1	3		3.4%	
Anti-infective for systemic use	tc2	12		16.1%	
Antineoplastic and immunomodulating agents	tc3	7		8.5%	
Blood and blood forming organs	tc4	2		2.7%	
Cardiovascular system	tc5	13		18.1%	
Dermatologicals	tcб	1		1.5%	
Genito urinary system and sex hormones	tc7	8		10.9%	
Musculo-skeletal system	tc8	7		7.3%	
Nervous system	tc9	23		30.0%	
Respiratory system	tc10	2		1.5%	
Total number of brand/form combinations		78			
Total number of observations		8,491			
Post-entry number of observations		4,246			

Table 1. Summary statistics.

with a starting value of one for each drug. We use the Consumer Price Index for Prescription Drugs, CPI, as the price deflator. The dependent variable in models (1A) and (1B), $\ln (P_{it})$, is the natural logarithm of the constructed brand price index, deflated by CPI.

We have also estimated a variant of model (1B), in which P_{it} is the nominal brand price index, not divided by the Consumer Price Index for Prescription Drugs, CPI_t . Appendix Table 1 presents the regression results for this variant of model (1B), with the nominal brand price being the explained variable.

The key explanatory variables in Model (1B) are: 1) T_{it}^{Pre} is a monthly time trend before generic entry and zero after; 2) T_{it}^{Post} is a monthly time trend after generic entry and zero before; 3) $T6_{it}^{Pre}$ is a time trend variable six months before generic entry, zero otherwise; 4) $T6_{it}^{Post}$ is a time trend variable six months after generic entry, zero otherwise; 5) D_{it} is an indicator variable for generic entry; it takes the value of one after generic entry and zero before. This variable allows the intercept of the estimation equation to be different pre and post generic entry; 6) $TC_{m, i}$ is a set of indicator variables for the ten therapeutic classes the drugs belong to (the last one is excluded from the estimation); 7) the set of exogenous variables, X_{it} , includes the following four variables: MSZ_i the brand market size, measured by the annual brand sales in dollars prior to generic entry; AG_{it} an indicator variable, taking the value of one starts in the year-month the AG was introduced and zero otherwise; and NOG_i , the maximum number of generics per drug. The number of generics in most markets increases over time; the variable *NOG_i* records the maximum number of generics in the entire post-entry period for each drug. Like the therapeutic class indicator variables, the variables, *MSZ_i*, and *NOG_i*, are invariant in time, but vary by drug.

It follows from the specification of the regression model in (1A) that the monthly rate of change of brand prices before generic entry is:

$$\alpha_2^{Pre} = \frac{\partial P_{it} / \partial T_{it}^{Pre}}{P_{it}}$$
(2)

Similarly, the monthly rate of change in brand pricing after generic entry is:

$$\alpha_2^{\text{Post}} = \frac{\partial P_{it} / \partial T_{it}^{\text{Post}}}{P_{it}}$$
(3)

If the impact of generic entry on the rate of brand change is negative, we should find $\hat{\alpha}_2^{Post} < \hat{\alpha}_2^{Pre}$, that is, a lower rate of change after generics enter the market.

Since in (1B), each exogenous variable is multiplied by the post-entry time trend variable, T_{it}^{Post} , the brand price change accounting for the effect of the k^{th} exogenous variable, X_k , is:

$$\Lambda_{k,it} = \frac{\partial P_{it} / \partial T_{it}^{Post}}{P_{it}} = \alpha_2^{Post} + \beta_k \cdot X_{k,it}$$
(4)

The regression coefficient, β_k , measures the incremental effect of X_k on the rate of brand price change, that is, $\beta_k = \partial \Lambda_{k,it} / \partial X_{k,it}$. If the k^{th} exogenous variable has a dampening (or enhancing) effect on the rate of change in brand prices, we would observe $\hat{\beta}_k < 0$ (or $\hat{\beta}_k > 0$).

3.2. The dataset and summary statistics

The prices examined for all analyses in this paper are Wholesale Acquisition Costs (WAC). WACs differ from the actual transaction prices because they do not account for rebates, chargebacks, and discounts and are, therefore, not the purchase prices paid by pharmacies or third-party payers. However, WACs are typically the starting point in negotiations for pharmacy prices and reimbursements and the actual transaction prices are based on discounts and other price concessions given by the manufacturer. Data on these discounts or the transaction prices, however, are not publicly available.

Data on monthly WACs for the drugs in our sample dataset were sourced from Symphony Health. Its pharmaceutical reporting starts in 2009, so for each branded drug data was gathered from January 2009 through March 2020. Monthly data on quantity were also gathered from Symphony Health, which provides quantity data using the combined metric of Total Prescription (TRx) Quantity and Non-Retail Volume Units, essentially breaking them out into dosage forms for unit addition.

Using data from Express Scripts Annual Drug Trend Reports for the years 2009 through 2017, we identified 82 branded drugs that were scheduled to lose patent protection in the following year. Many of these 82 drugs have multiple forms (e.g. injectable versus tablet). For these 82 branded drugs, there are 118 brand-name-drug-form combinations. Although drugs with multiple forms have the same underlying

molecule, the same set of generic manufacturers did not necessarily market a generic for both forms; nor did they enter the market on the same date; as a result, we have treated each brand-name-drug-form combination as a distinct 'drug' and have used the corresponding molecule and drug-form to link the branded 'drug' to its generics.¹

After retrieving the Symphony Health data on WAC prices, total unit sales, manufacturers, and molecules for these 118 brand and form combinations (henceforth we will call a 'brand-name-drug-form combination' simply a 'drug'), we removed any drugform that had less than 1% of the molecule unit sales or had a data period that was less than 12 months before or after generic entry. This filtering process left us with a final sample of a set of 78 drugs (with 71 distinct molecules). We then used data from Medispan to determine which of these 78 drugs had an authorized generic (AG) and using the AG manufacturer's sales data we determined the month of entry of the AG.

We identified the therapeutic class of each of the 78 drugs (based on the underlying 71 molecules) using the Anatomical Therapeutic Chemical (ATC) Classification System published by the World Health Organization. This system classifies the active ingredients of drugs according to the organ or system on which they act and their therapeutic, pharmacological and chemical properties. Our dataset includes the following ten therapeutic classes: alimentary tract and metabolism insulins, anti-infective for systemic use, antineoplastic and immunomodulating agents, blood and blood forming organs, cardiovascular system, dermatologicals, genitourinary system and sex hormone, musculoskeletal system, nervous system, respiratory system and sensory organs. Finally, data on the U.S. Consumer Price Index for Prescription Drugs (CPI), were downloaded from the Bureau of Labor Statistics.

Table 1 presents the summary statistics for the key variables used in regression Models (1A) and (1B). The statistics are for the 78 drugs, each of which is the i^{th} cross sectional unit in the panel dataset. Our dataset spans the time-period January 2009 to March 2020, with each month being the t^{th} time-series unit in the panel data. The data sample has a total of 8,491 observations, with an average of approximately 109 monthly observations per drug. Of the total, the subset of post-entry observations is 4,246, which means there are on average approximately 55 monthly observations per drug in the period after generic entry.

Table 1 shows that in our sample the average brand market size prior to generic entry is approximately \$220 million. Although not shown in this table, of the 78 branded drugs in our dataset, 45 have AGs. The maximum number of generics is, on average, about seven per branded drug. The number of drugs in the ten therapeutic classes vary considerably, ranging from one in the class of 'Dermatologicals' to 23 in 'Nervous System'.

3.3. Regression results

The results of the pooled cross-sectional time-series regression analysis are presented in Table 2. Table 3 contains the estimated rates of brand price changes based on the regression coefficient estimates. In Table 2, the coefficients of the time-trend variables reflect the monthly rates of change; these were converted to annualized rates and presented in Table 3.

In Table 2, we do not report the estimated coefficients of the therapeutic class indicator variables in the interest of brevity and because none of them was found to be

Table 2. Regression analysis of inflation-adjusted brand prices.

Dependent variable: Logarithm of inflation-	
adjusted brand price	

adjusted brand price					
		Coefficient		Coefficient	
Regressors	Acronym	estimate	Z-Stat	estimate	Z-Stat
Time trend variable, prior to its generic entry	T ^{pre}	0.0055**	37.96	0.0050**	31.13
Time trend variable, post its generic entry	T ^{post}	0.0016**	10.63	-0.0011**	-3.14
Time trend variable six months prior to its generic entry	T6 ^{pre}			0.0015**	7.92
Time trend variable six months post its generic entry	T6 ^{post}			-0.0003	-1.82
Pre-Entry Brand Market Size	MSZ			0.0013**	3.16
Introduction of authorized generic	AG			0.0023**	10.57
Maximum number of generics per drug	NOG			0.0001**	2.80
Post-Entry Intercept	D	0.4761**	60.13	0.4797**	56.27
Intercept		-5.9976**	-198.85	-5.8263**	-34.85
R-square:					
Within		0.4664		0.4813	
Between		0.0074		0.2591	
Overall		0.2385		0.3758	
Number of observations		8,491		8,491	
Observations per cross-sectional unit					
(brand/form)					
Minimum		47		47	
Average		108.9		108.9	
Maximum		135		135	

Model 1A

Model 1B

Note: **denotes statistically significant at 99% level of confidence; *denotes statistically significant at 95% level of confidence.

general sector s			
Regressor	Annual Rate (%)	Z-Stat	Chi ² -Stat
Annualized rate of price change pre-entry	6.00	31.13**	

Table 5. Statistical tests for fates of change of initiation-adjusted brand price	Table 3.	Statistical	tests for	rates o	of change	of infla	tion-ad	justed	brand	prices
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Annualized rate of price change pre-entry	6.00	31.13**	
Annualized rate of price change post-entry	-1.29	-3.14**	
Test statistic (null: the above two rates are equal)			257.12**
Annualized rate of price change 6 months pre-entry	1.80	7.92**	
Annualized rate of price change 6 months post-entry	-0.38	-1.82	
Test statistic (null: the above two rates are equal)			49.4**

Note: **denotes statistically significant at 99% level of confidence; *denotes statistically significant at 95% level of confidence.

statistically significant. Table 2 shows that each of the other explanatory variables, except 'maximum number of generics' and the intercept, has a statistically significant coefficient. The overall fit of the model is guite good, with a R-square of 0.47.

In Table 3 we present the pre- and post-entry annualized rate of changes of brandprices based on the estimated time-trend coefficients. We also undertake tests to examine whether there is a statistically significantly difference between the two rates.

We find, while the annual average rate of brand price change is 6.0%, pre-generic entry, the annual rate of change post entry is -1.3%; that is, the post-entry rate is negative. These rates are estimated using Model (1B). The difference in the annual rates of change pre- and post-generic entry is highly significant, as evidenced by the Chi² test statistic. These results clearly demonstrate that brand prices do react to generic entry. The results presented in Technical Appendix Table 1 are for the regression



Figure 1. Inflation-adjusted brand price index before and after generic entry.

analysis of nominal (i.e., inflation-unadjusted) brand prices. These results are fully consistent with the findings presented in Tables 2 and 3 above. The nominal brand prices are found to rise at a significantly slower rate after generic entry.

Table 3 also shows that inflation-adjusted brand prices change significantly in the periods six months before and six months after generic entry: brand manufacturers raise prices right before generic entry and lower them right after. The decline in the rate of real brand price change in the six-month period right after generic entry is noteworthy because often the first generic entrant is granted a 180-day exclusivity.²

These patterns of price changes are depicted in Figure 1, where the rates of changes of the inflation-adjusted price index are computed using the estimated regression coefficients from model (1B), specifically, α_2^{Pre} , α_2^{Post} , α_3^{Pre} and α_3^{Post} .

From Table 2, we find that in larger brand markets (proxied by annual brand sales prior to generic entry), brand prices increase at a higher rate after generic entry relative to smaller markets. This is evidenced by the positive and highly significant coefficient of the variable 'Pre-Entry Brand Market Size' in Table 2. This implies that manufacturers for drugs with larger markets tend to have higher pricing power.

For brands with AGs, economic intuition suggests that brands would have more muted price response to generic entry. One would expect the brand to be competing with other generics via its own AG; as a result, it is plausible to infer that brands would have a lower incentive to moderate its prices with the onset of generic entry. Our findings are consistent with this expectation. We find that in markets where brands have introduced AGs, prices increase at a higher rate after generic entry

Regressor	Average Annual Rate (%)
Percentage of 78 regressions that have a lower rate for Pre than that for Post	75.6%
Percentage of 78 regressions that reject the hypothesis	84.6%
of equal Pre and Post rate at 95% confidence level.	

 Table 4. Comparative analysis of rates of inflation-adjusted price change using data for each 78 drugs.

relative to brands without AGs. This is evidenced by the positive and highly significant coefficient for the indicator variable 'AG' in Table 2. However, it is important to note, even in large markets and in markets with AGs, brand prices increase at a slower rate post than pre generic entry.

3.4. Robustness check

We have also estimated Model (1A) using data for *each* of the 78 drugs individually. Specifically, for each drug we estimated using ordinary least squares the following equation:

$$\ln(P_t) = \alpha_0 + \alpha_1 \cdot D_t + \sum_{j=Pre, Post} \alpha_2^j \cdot T_t^j + \varepsilon_t$$
(5)

These regressions yielded 78 pairs of estimated coefficients, $\hat{\alpha}_2^{\text{Pre}}$, $\hat{\alpha}_2^{\text{Post}}$. In Table 4 we summarize the findings from these drug-specific regressions. We find that 75.6% of drugs has a lower rate of price change after generic entry. Also, for 84.6% of the $\hat{\alpha}_2^{\text{Pre}}$, $\hat{\alpha}_2^{\text{Post}}$ pairs, the coefficients are statistically different from each other. This drug-specific analysis confirms that the results presented in Tables 2 and 3 are robust.

As an additional robustness check, we have also estimated Model 1A for each of the ten therapeutic classes. We find that in eight out of the ten therapeutic classes the average rate of brand price change post entry is lower after generic entry. In only one of the ten therapeutic classes, 'Musculo-skeletal system,' the rate of brand price change is slightly higher post entry and the difference in the rate of change is statistically significant.³

4. Concluding comments

In this paper, using a dataset of 78 drugs that first faced generic competition over the period 2009 through 2020, we show the 'paradox' of brand prices not reacting to generic competition is not a paradox at all: we find prices *do* react to generic competition. Specifically, we show that brands increase nominal prices at a significantly lower rate (and decrease inflation-adjusted prices at a faster rate) after generic entry.

An important extension of our research would be to explore whether our results hold for follow-on branded drugs, which are becoming increasingly common in the pharmaceutical industry. Another possible area of future research would be to examine the price elasticities of the various branded products in our dataset and explore whether the results of this paper are consistent with the estimated price elasticities. We intend to pursue this avenue of research in a subsequent study.

Disclosure statement

No potential conflict of interest was reported by the authors.

Notes

- However, as a robustness check, we have also examined whether the key results of the paper hold, if we did not treat multiple forms as separate 'drugs.' All the principal findings of our paper stay unchanged when we use the dataset of 71 branded drugs, i.e., distinct molecules. For example, we find that, on average, brands increase nominal prices at an annualized rate of 9.9% in the pre-entry period and at 4.4% in the period after generic entry.
- 2. 'The statute provides that the first applicant to file a substantially complete ANDA containing a paragraph IV certification to a listed patent will be eligible for a 180-day period of exclusivity beginning either from the date it begins commercial marketing of the generic drug product, or from the date of a court decision finding the patent invalid, unenforceable or not infringed, whichever is first'. The Food and Drug Administration website.
- 3. This is verified by estimating two separate regressions (Model 1B) using: (a) data for the subset of drugs with AG; and (b) data for the subset of drugs whose pre-entry brand market size is larger than the median market size. These results are available from the authors.

References

- Berndt, Ernst R., and Joseph P. Newhouse. 2010. Pricing and Reimbursement in U.S. Pharmaceutical Markets. National Bureau of Economic Research, Working Paper No. 16297.
- Berndt, Ernst R., Richard Mortimer, Ashoke Bhattacharjya, Andrew Parece, and Edward Tuttle. 2007. Authorized Generic Drugs, Price Competition, and Consumers' Welfare. *Health Affairs* (*Project Hope*) 26 (3): 790–799. doi:10.1377/hlthaff.26.3.790.
- Caves, Richard E., Michael D. Whinston, and Mark A. Hurwitz. 1991. Patent Expiration, Entry, and Competition in the U.S. Pharmaceutical Industry. *Brookings Papers on Economic Activity: Microeconomics* 22: 1–66.
- Chen, Tom. 2007. Authorized Generics: A Prescription for Hatch-Waxman Reform. *Virginia Law Review* 93 (2): 459–513.
- Conti, Rena M., and Ernst R. Berndt. 2018. Specialty Drug Prices and Utilization after Loss of US Patent Exclusivity, 2001-2007. In *Measuring and Modeling Health Care Costs*, Vol. 76. NBER Studies in Income and Wealth.
- Frank, Richard G., and David S. Salkever. 1997. Generic Entry and the Pricing of Pharmaceuticals. *Journal of Economics & Management Strategy* 6 (1): 75–90. doi:10.1162/105864097567039.
- FTC. 2011. Authorized Generic Drugs: Short-Term Effects and Long-Term Impact. A Report of the Federal Trade Commission.
- Grabowski, Henry G., and John M. Vernon. 1996. Longer Patents for Increased Generic Competition in the US: The Waxman-Hatch Act after One Decade. *Pharmacoeconomics* 10 (Supplement 2): 110–123. doi:10.2165/00019053-199600102-00017.
- Kamien, Morton I., and Israel Zang. 1999. Virtual Patent Extension by Cannibalization. *Southern Economic Journal* 66 (1): 117–131. doi:10.2307/1060838.
- Lakdawalla, Darius N., Tomas J. Philipson, and Y. Richard Wang. 2006. Intellectual Property and Marketing. National Bureau of Economic Research, Working Paper 12577.
- Regan, Tracy. 2008. Generic Entry, Price Competition, and Market Segmentation in the Prescription Drug Market. *International Journal of Industrial Organization* 26 (4): 930–948. doi: 10.1016/j.ijindorg.2007.08.004.
- Saha, Atanu, and Heather Roberts. 2020. Pharmaceutical Industry's Changing Market Dynamics. *International Journal of the Economics of Business* 27 (2): 159–175. doi:10.1080/13571516.2020. 1752044.

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- Saha, Atanu, Henry Grabowski, Howard Birnbaum, Paul Greenberg, and Oded Bizan. 2006. Generic Competition in the US Pharmaceutical Industry. *International Journal of the Economics* of Business 13 (1): 15–38. doi:10.1080/13571510500519905.
- Scherer, Frederic M. 1993. Pricing, Profits, and Technological Progress in the Pharmaceutical Industry. *Journal of Economic Perspectives* 7 (3): 97–115. doi:10.1257/jep.7.3.97.
- Suh, D. C., W. G. Manning, Stephen W. Schondelmeyer, and R. S. Hadsall. 2000. Effect of Multiple-Source Entry on Price Competition after Patent Expiration in the Pharmaceutical Industry. *Health Services Research* 35 (2): 529–547.
- Wiggins, Steven N., and Robert Maness. 2004. Price Competition in Pharmaceuticals: The Case of anti-Infectives. *Economic Inquiry* 42 (2): 247–263. doi:10.1093/ei/cbh058.

Technical appendix

Appendix Table 1.

Regression analysis of nominal brand prices

Dependent variable: Logarithm of nominal brand price				
Regressors	Acronym	Coefficient estimate		Z-Stat
Time trend variable, prior to its generic entry	T ^{pre}	0.0070	**	41.62
Time trend variable, post its generic entry	T ^{post}	0.0015	**	4.26
Time trend variable six months prior to its generic entry	T6 ^{pre}	0.0019	**	9.82
Time trend variable six months post its generic entry	T6 ^{post}	-0.0001		-0.38
Pre-Entry Brand Market Size	MSZ	0.0017	**	3.74
Introduction of authorized generic	AG	0.0023	**	10.45
Maximum number of generics per drug	NOG	0.0001		1.67
Dummy variables for Therapeutic Classes				
Alimentary tract and metabolism insulins	tc1	0.0537		0.25
Anti-infective for systemic use	tc2	-0.2645		-1.47
Antineoplastic and immunomodulating agents	tc3	-0.1975		-1.04
Blood and blood forming organs	tc4	-0.4280		-1.81
Cardiovascular system	tc5	-0.0982		-0.55
Dermatologicals	tc6	0.0978		0.34
Genito urinary system and sex hormones	tc7	0.0598		0.32
Musculo-skeletal system	tc8	-0.3383		-1.79
Nervous system	tc9	-0.1024		-0.59
Post-Entry Intercept		0.6249	**	70.16
Intercept		0.1172		0.70
R-square:				
Within		0.6374		
Between		0.2203		
Overall		0.4717		
Number of observations		8,491		
Observations per cross-sectional unit (brand/form)				
Minimum		47		
Average		108.9		
Maximum		135		

Note: ** denotes statistically significant at 99% level of confidence and * denotes statistically significant at 95% level of confidence.