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# -Drug Competition Series –
# *Analysis of New Generic Markets*
# Effect of Market Entry on Generic Drug Prices: Medicare Data 2007-2022

In this update to previous ASPE analyses, we find that in recent years new generic markets continue to be competitive. Drug prices fall with increasing number of generic competitors. Prices decline by 20% in markets with about 3 competitors. Prices continue to decline by 70% to 80% relative to the pre-generic entry price in markets of 10 or more competitors following 3 years after first generic entry.

## KEY POINTS

- Promoting substitution of lower priced generics for brand drugs once the market exclusivity period for the brand drug expires is a key component of the U.S. strategy for achieving value in prescription drugs. In 2022, it was estimated that 91% of all prescriptions in the United States were filled as generic drugs.
- Generic entry and effective supplier competition have served to moderate generic drug prices.
- Generic drug prices are consistently lower than brand-name prices across all market sizes and time periods, with the largest cost savings in medium markets (5,000-15,000 users per month) where generics dropped from 71% to 39% of brand prices from 2007-2011 to 2016-2019. Over half (60%) of the drugs in our study are in small markets with less than 5,000 users per month. The small markets are concentrated with an average of about 3 labelers per drug.
- Competition in the large markets with 15,000 or more users per month is most intense, averaging close to 10 labelers per drug.
- The impact of competition on relative drug prices is stable over time: the price reductions are similar for generic drugs first entering the market in the most recent period 2016-2019 compared to both earlier periods, 2007-11 and 2012-15.

## INTRODUCTION

The U.S. has a number of policies related to drug pricing, affordability, and availability. To encourage manufacturers to innovate with new therapies, patent policy rewards the creation of new branded medicines. As those patents come to an end, generic drug manufacturers may enter a market and seek to sell their products at lower prices than the competing brand drugs. Policies that support competition of lower price generics for brand drugs, once the generics become available for sale, helps to make drug prices more

affordable for taxpayers, payers, and patients.

Generic competition intensified in the 2010s with the expiration of market exclusivity of a large number of branded drugs in 2011 and 2012, followed by similarly large numbers of generic-drug approvals in 2016 and 2017.[1] In 2017, the Food and Drug Administration (FDA) also updated its policy to prioritize the review of generic applications up to the third generic approval of a drug as a means to further encourage drug competition.[a] In that year, the FDA approved 1,027 Abbreviated New Drug Applications (ANDAs), with 843 fully approved applications and 184 tentatively approved applications. 2017 broke the previous record set in 2016 of 813 ANDAs: 630 full approvals and 183 tentative approvals.[b] The 2017 approvals included 80 "first generic" drugs, which are the first generic alternatives to a brand-name product. This growth in generic drug approvals has continued in recent years with more than 956 approved or tentatively approved generic drug applications in 2023.[2,3]

These new generic drugs are expected to further moderate the rate of growth in drug spending.[4] In 2022, it was estimated that 91% of all prescriptions in the United States were filled as generic drugs.[5,6] The literature demonstrates that increased competition – measured by number of suppliers – in new generic markets has a substantial impact in reducing prices relative to the brand drug.[7,8,9]

At the same time, however, there have been concerns that mergers and acquisitions in generic manufacturing could impact the potential savings of increased generic use.[10] Between 2014-2016, there were nearly 100 mergers worth close to $80 billion[11] This raises the question whether new generic markets will get the same competitive response as in the past, as well as whether low profit margins will result in an increasing number of noncompetitive generic markets and price spikes.[12] During 2012-15, there were price increases, some very large, for many generic drugs that are the standard of care for certain diseases.[13] In addition, many of the ANDAs approved by FDA in recent years have been for subsequent generics – that is, generic versions for markets that already have at least three competitors, raising concerns that such approvals do not have the same price reducing effect as approval for the first three competitors in the market. [14]

This study evaluates these concerns by updating a previous ASPE Issue Brief that compared the effects of generic competition on prices of the earlier periods of 2007-2011 and 2012-2015[15] with adding the most recent period of 2016-2019. The study examines whether or not the expected effect of generic entry on prices is similar to the prior two periods.

## PRIOR LITERATURE

The literature consistently shows that the number of generic market competitors are associated with lower generic drug prices.[c] The studies and range of price reductions are summarized in Table 1. These studies found that prices declined by about 15% to 40% in markets with 3 to 5 competitors and by 60% to 90% in markets of 10 or more competitors.

[a] See https://blogs.fda.gov/fdavoice/index.php/2018/02/2017-was-another-record-setting-year-for-generic-drugs/. FDA approved 843 full approvals and 184 tentative approvals in 2017 alone. For 2019, see https://blogs.fda.gov/fdavoice/index.php/2018/02/2017-was-another-record-setting-year-for-generic-drugs/.

[b] On September 30, 2022, the President signed into law the FDA User Fee Reauthorization Act of 2022, which includes the reauthorization of the Generic Drug User Fee Amendments (GDUFA) through September 2027 (GDUFA III). Congress first enacted GDUFA in 2012 (GDUFA I), then re-authorized GDUFA II in 2017 which authorized the continued collection of user fees from generic-drug manufacturers to provide additional resources to the FDA for generic-drug reviews through fiscal year 2022 (https://www.fda.gov/industry/fda-user-fee-programs/generic-drug-user-fee-amendments).

[c] For this literature review focusing on the U.S. market, we exclude studies using pre-1984 data, the year the Waxman Hatch Act was passed that dramatically changed the landscape of the generic drug industry.

**Table 1. Summary of Estimated Generic Drug Price Reduction Associate with the Number of Competitors**

| Studies | Estimated Generic Drug Price Reduction Following Entries of | | Data |
|---|---|---|---|
| | About 3 or 5 sellers | 6 to 10 or more sellers | |
| Frank and Salkever (1995) | 17% to 35% from 3-5 sellers | 56% to 72% from 6-10 or more | IMS data from 1980 through 1991 |
| Wiggins and Maness (2004) | | 83% between 6 or 10 sellers | National Prescription Audit of IMS data 1984-90 |
| Reiffen and Ward (2005) | about 15% with 3 sellers | 30% to 40% with 10 or more | IMS data in the late 1980s and early 1990s |
| Chintan, Hartzema, and Kesselheim (2017) | 40% with 3 sellers | 80% with 10 or more | MarketScan data 2008-14 |
| Berndt, Conti, and Murphy (2017) | about 15% to 30% with 3 sellers | | IMS National Sales Perspective data, 2004-2016 |
| Food and Drug Administration (FDA, 2019) | 73% to 79% with 4 sellers | 95% with 6-10 or more | IQVIA's National Sales Perspective daa (NSP) |
| Nguyen, Sheingold, Tarazi, Bosworth (2021) | 20% with 3 sellers | 80% with 10 or more | Medicare Part D data, 2007-2018 |
| Serra-Burriel M et al. (2024) | 32% in year 1 after entry, 82% after 8 years | | IQVIA's MIDAS database from 2011 to 2020 |

Two key differences among these studies include the specification of competition and the use of different data sources and time periods.

First, the specification of competition can be categorized into two approaches: (1) using a discrete number of competitors (N) or some variant of N,[a] or (2) using a set of binary variables to describe the number of competitors. The first approach, by using the number of firms as an explanatory variable, assumes that the effect of an increase by 1 in the number of firms is independent of the initial number of firms and that the relationship between the number of suppliers and price is predetermined in the equation. For example, generic price is assumed to vary linearly with N, the number of firms;[16,17,18] with N and $N^2$;[19] or with N and 1/N.[20] The second approach for measuring competition uses a set of binary variables to represent the number of competitors.[b] Unlike using a single number as a dependent variable, this specification would not assume a priori functional form on the effect of additional competitors on price but would allow the marginal effect of an additional firm to vary with the number of firms.[21] Lower estimates of price reduction are associated with the flexible specification using a set of binary variables to represent the number of competitors.

Second, many studies predate Medicare Part D and as such use IMS national sales data or private payers claims data. In contrast, our study uses the latest Medicare Part D drug events data (PDE) data from 2007 through 2022 to examine all generics entering the Part D markets during 2007-2019 and follow these drugs for 24 and 36 months after entry.

## DATA AND METHODS

### *Data*

To examine the relationship between number of suppliers and price, we use the latest Medicare Part D (PDE) data from 2007 to 2022, hence, complementing most work in the literature that relies on the IMS national sales data or private payers claims data.[c] We restrict the data to only drugs that had generic entry from 2007 through 2019 to allow us to follow a drug that entered in 2019 for 36 months. We follow each drug for exactly

[a] The number of competitors, N, enters the model as a continuous variable.

[b] This semi-parametric or more flexible specification would be able to detect any non-linear relationship between the number of competitors and prices.

[c] The PDE contains drug ingredient costs, dispensing fees, and benefit design and payment data that enable CMS to make payments to the plans and otherwise administer the Part D benefit. It does not have prices net of rebates and discounts paid to payers. Brand prices may be overstated. For example, in 2014, the CMS Office of the Actuary estimates that rebates average 17.5% for brand drugs, varying widely across therapeutic classes (https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/information-on-prescription-drugs/partd_rebates).

36 months after generic entry. We also exclude biosimilars[a] and orphan drugs, as well as molecule-form-months where the drug/drug-class becomes available over the counter. Finally, we restrict to single-ingredient drugs with at least 24 months of generic competition following entry. For the purposes of this study, a drug is defined by a combination of molecule (active ingredient), route of administration, and dosage form.[b,c] We consider an entry to occur in the first month in which a drug has positive sales following at least a quarter of zero sales.

We compute average prices of each drug by averaging ingredient costs across the NDC-level to the drug-level separately for brand and generic drugs.[d] We also compute average prices in two ways: (1) the arithmetic average of median prices and (2) quantity-weighted average prices; both methods yield similar results. To allow for cross-year comparison, all prices are inflation-adjusted to January 2016 prices using the Consumer Price Index.[e]

***Methods***

Our unit of analysis is a drug month (molecule-form-month). We assessed both a random effects and molecule-form level fixed effects multivariate regression models at the drug level to focus on the relationship of competitors and prices within each drug while controlling for factors across drugs.[f]

We use multivariate regressions to compare the monthly price trajectory following the first generic entry[g] to the baseline price (the average brand price of the drug during 6 months prior to the first generic entry).[h,22] This ratio, $\frac{p_{ift}}{P_{ifu}}$ described below, is our main dependent variable.

We use the model:

[a] Biosimilars undergo a different approval process and have fundamentally different manufacturing processes so are expected to have very different generic pricing schemes relative to small-molecule drugs. During the time period of this study only 0-2 are in the market, so we excluded them.

[b] This is equivalent to a GPI-12 drug designation. The Generic Product Identifier (GPI) is a 14-character hierarchical classification system available in MediSpan that identifies drugs from their primary therapeutic use down to the unique interchangeable product regardless of manufacturer or package size. The GPI-12 summarizes the GPI-14 across strength (i.e., 10mg) and defines a drug product by a combination of therapeutic class, drug name, dosage form or route of administration (i.e., capsule).

[c] To construct the drug, we crosswalk the Medicare part D event data (PDE) at the NDC level to MediSpan at the GPI-14 level then summarize across strength to the GPI-12 level. Labelers at the NDC level are summarized to the GPI-12 level as well.

[d] Drugs are identified and reported using a unique, three-segment number called the National Drug Code (NDC) which serves as the FDA's identifier for drugs. FDA publishes the listed NDC numbers in the NDC Directory which is updated daily. More information at: https://www.fda.gov/drugs/drug-approvals-and-databases/national-drug-code-directory.

[e] For sensitivity analyses, we will also extend the baseline pre-generic brand price from 6 months to 2 years prior to first generic entry.

[f] We would argue that the number of competitors is exogenous in this study's construct, hence, a single reduced form equation is adequate for two reasons. First, the current change in price shouldn't affect the current change in the number of firms in the market since it takes several years of preparatory activities before a generic firm can enter the market. Therefore, if we exclude "late entrants," which we are doing by limiting the time period to the 2 years or 3 years after 1st generic entry, we should not have a reverse causality problem between prices and number of firms producing the molecule-form.

[g] For sensitivity analyses, we also extend the baseline pre-generic brand price from 6 months to 2 years prior to first generic entry. The results do not differ significantly.

[h] Following the FDA, using the average brand price of the drug during 3 months prior to the first generic entry, we extend to 6 months to ensure exogeneity of the baseline price given that the brand drug manufacturer might vary its price in anticipation of imminent generic competition.[22]

$$\frac{p_{ift}}{P_{ifu}} = a + \sum_{k=2}^{10} \beta_k 1(n_{ift} = k) + yN_{ct} + \omega V_{ifu} G_{cu}^{t-u} + \phi_{if} + \epsilon_{ift},$$

$$\forall t \in (u+1, u+24\ then\ u+36)$$

Where:

*i* denotes the molecule, *f* denotes the form, and *c* denotes the therapeutic class the molecule is in.

*t* denotes the number of months since the beginning of 2007 starting with January 2007 having *t*=1.

*u=u(if)* is the month before generic competition for drug *i* in form *f*.

$P_{ifu}$ is the price of the branded drug with molecule *i* and form *f* during the baseline period. Price is the quantity weighted average price computed as the total Part D ingredient cost divided by the total quantity dispensed.

$p_{ift}$ is the price of generics of molecule *i* in form *f* and month *t*. This represents the average price of generics across all generic manufacturers.

$n_{ift}$ is the number of generic labelers of molecule *i* in form *f* in month *t*.

$N_{ct}$ is the number of molecules in therapeutic class *c* in month *t*.

$V_{iu}$ is the average number of beneficiaries taking the drug in the baseline period.

$G_{cu}$ is the geometric average of $r_{ct}$ over the baseline period:

- $r_{ct}$=$S_{ct}$/$S_{c,t-1}$, i.e., $r_{ct}$ is the growth in the number of beneficiaries taking a drug from class *c* in month *t* relative to month *t-1*
- $S_{ct}$ is the total number of beneficiaries taking a drug from class *c* in month *t.*

$\phi_{if}$ is a fixed effect for the molecule-form. This captures all the variables that aren't time varying such as drug form, class, year of patent expiration, pre-patent expiry market size, marginal cost as a fraction of price, etc.

Competition, the main independent variable $n_{ift}$, is based on the number of labelers (manufacturers or marketers) of the drug.[a] We also examined the number of companies manufacturing a drug as an alternative independent variable, and found similar results.[b] For this sensitivity analysis, manufacturers of authorized generics were considered generic manufacturers even if they are the same as the brand manufacturer.

Rather than using the concentration ratio or the Herfindahl-Hirschman Index, a commonly accepted measure of market concentration, we measure the number of labelers as this is the policy lever the FDA exercises to

[a] A labeler is any firm that manufactures (including repackers or relabelers), or distributes (under its own name) the drug. In other words, a labeler identifies the manufacturer or distributor of the drug product (i.e., Pfizer, Allergan (Mylan), Watson, Teva, etc.).

[b] This analysis is presented at the "labeler" level, but results are robust at the "manufacturer" level as well. As a result of mergers and acquisitions in these markets, a manufacturer may be responsible for multiple labeler codes. As there are more labelers than manufacturers, the estimated effect of competition when the number of competitors is based on labelers is likely to be conservative, at the least, not overstated.

affect competition when it approves an ANDA. We describe the number of competitors, $n_{ift}$[a] using a series of binary variables to capture the number of generic manufacturers/labelers and truncating those with more than 10, adapted from Reiffen and Ward in 2005.[23] This specification allows us to estimate a non-linear relationship between number of entries and price reductions. As the excluded category is one labeler, $n_{ift}$ is represented by 9 binary variables, where 1($n_{ift}$=10) represents ($n_{ift}$≥10) and where the control is $n_{ift}$=1.

The regression controls for the size of the market, $V_{ifu}G_{cu}^{t-u}$ with fixed effects for the molecule-form. We take the number of beneficiaries taking the drug during the baseline period (6 months prior to the first generic entry) and apply the associated growth rate for the drug class to project what the current market size would have been in the absence of changes. Thus, the term $V_{ifu}G_{cu}^{t-u}$ is a proxy for the current size of the market that should be unaffected by the current prices. We also assume exponential growth after generic entry; the (t-u) term is a power so, for instance, 3 months after generic entry we cube the growth rate.

The regressions are also clustered at the drug-group level (such as antidepressants) in order to adjust for potential correlation among drugs within the same drug-group.[b]

The interpretation of *a* is the relative generic price when there is 1 generic competitor to the branded drug. The other $\beta_k$ are the reductions in the relative price from *a* when there are *k* labelers.

We use the model results to predict relative prices for each corresponding number of labelers, holding all regressors at their mean and setting the fixed effects to zero. These marginal effects are presented in the results below.

Some previous work pointed out that competition was intense for a period after a brand's loss-of-exclusivity (LOE), but then could wane over time.[24] This study follows a drug 24 months as well as 36 months after first generic entry in order to see whether the relationship between number of labelers and price would change over time. We also test the hypothesis that drugs with more recent LOE might face less competition than those earlier by estimating separately the competition-price relationship for drugs with first generic entry during 2007-2011, 2012-2015, and the latest period of 2016-2019.[c]

## RESULTS

### *Descriptive statistics*

Table 2 presents descriptive statistics on the number of drugs with first generic entry during the 3 periods, 2007-2011, 2012-2015, and 2016-2019, their associated number of labelers, and average brand and generic prices.

The level of competition, measured by the average number of labelers per drug, remains relatively stable over the 3 periods: 5.15 average labelers per drug in 2007-2011, 4.42 average labelers per drug in 2012-2015, and

[a] Using binary variables is often preferred because it does not assume a particular functional form (e.g., linear) for the relationship between the number of labelers and price.

[b] The drug-group is defined based on the GPI-2, Generic Product Identifier classification level 2. More information are available at: https://www.wolterskluwercdi.com/drug-data/gpi/. In addition, our 95% confidence intervals reported in Table 3 reflect the clustered standard errors (or Liang-Zeger standard errors) by assuming that the variance is non-constant between clusters, but constant within clusters.

[c] This split in 2012 is important given the finding that generic churning (entry and exit) generally increases until around 2012 then decreases or remains flat thereafter.[24]

5.13 average labelers per drug in 2016-2019 (Table 2).

**Table 2. Generic Drug Characteristics by Market Size, 3 Years after First Entry**

| Characteristics | First Generic Entry During 2007-11 by Market Size (by Average Number of Beneficiaries) | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Small (<5,000 users per month) | | | Medium (5,000 - <15,000 users per month) | | | Large (>=15,000 users per month) | | | Total | | |
| **Time Period** | 2007-2011 | 2012-2015 | 2016-2019 | 2007-2011 | 2012-2015 | 2016-2019 | 2007-2011 | 2012-2015 | 2016-2019 | 2007-2011 | 2012-2015 | 2016-2019 |
| **Number of Drugs** | 77 | 88 | 100 | 29 | 23 | 18 | 40 | 42 | 29 | 146 | 153 | 147 |
| **Average Number of Labelers** | 3.10 | 2.75 | 3.51 | 4.03 | 5.09 | 7.67 | 9.90 | 7.55 | 9.14 | 5.15 | 4.42 | 5.13 |
| **Mean Brand Price** | $44 | $59 | $141 | $11 | $15 | $140 | $13 | $26 | $17 | $28 | $42 | $115 |
| **Mean Generic Price** | $34 | $45 | $93 | $8 | $8 | $55 | $7 | $14 | $10 | $22 | $31 | $71 |
| **Generic Price as Percent of Brand Price** | 77% | 76% | 66% | 71% | 55% | 39% | 56% | 55% | 61% | 76% | 73% | 62% |

We grouped markets into three categories based on the number of treated Medicare Part D patients at time of initial generic entry: small (less than 5,000 users per month), medium (5,000 to 14,999 users per month), and large (15,000 or more users per month). Sixty percent of the drugs in our study are in small markets (265/446). The small markets are concentrated with an average of about 3 labelers per drug. As expected, competition in the large markets is more intense, averaging close to 10 labelers per drug.

Figure 2 shows the average number of labelers from Table 2 graphically. We find that the larger the size of the markets -measured by the number of users per month- the greater the number of entrants and, therefore, competitors. In addition, Figure 3 shows that a large number of drugs have 1 to 3 competitors in the 3 years after first entry.

**Figure 2. Generic Drug Characteristics by Market Size, 3 Years after First Entry, 2016-19**

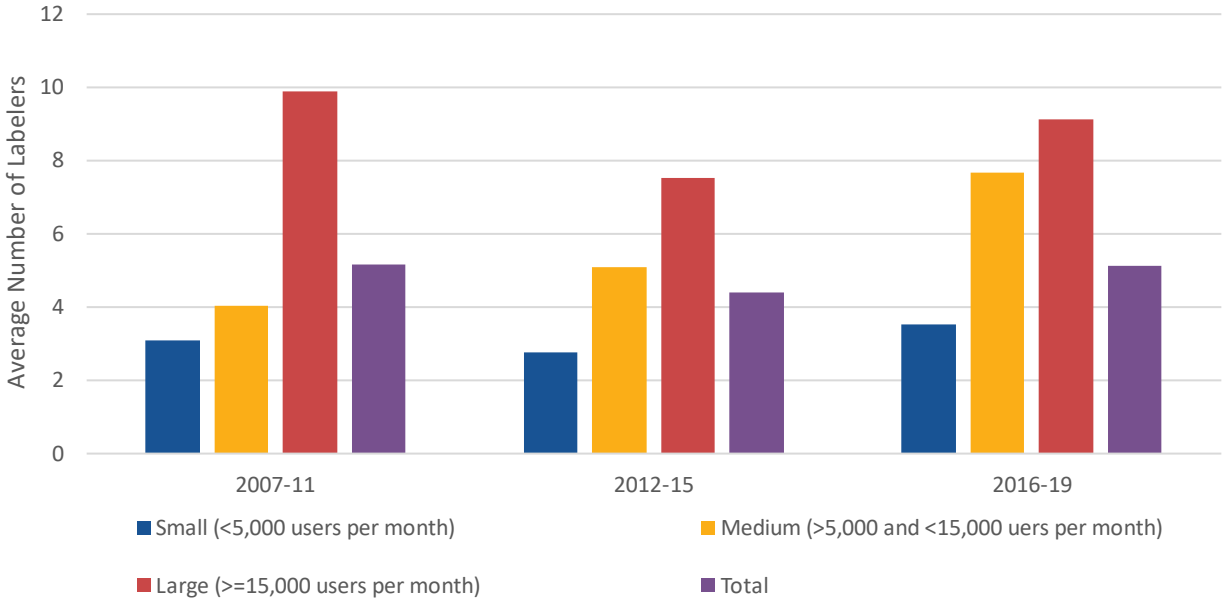
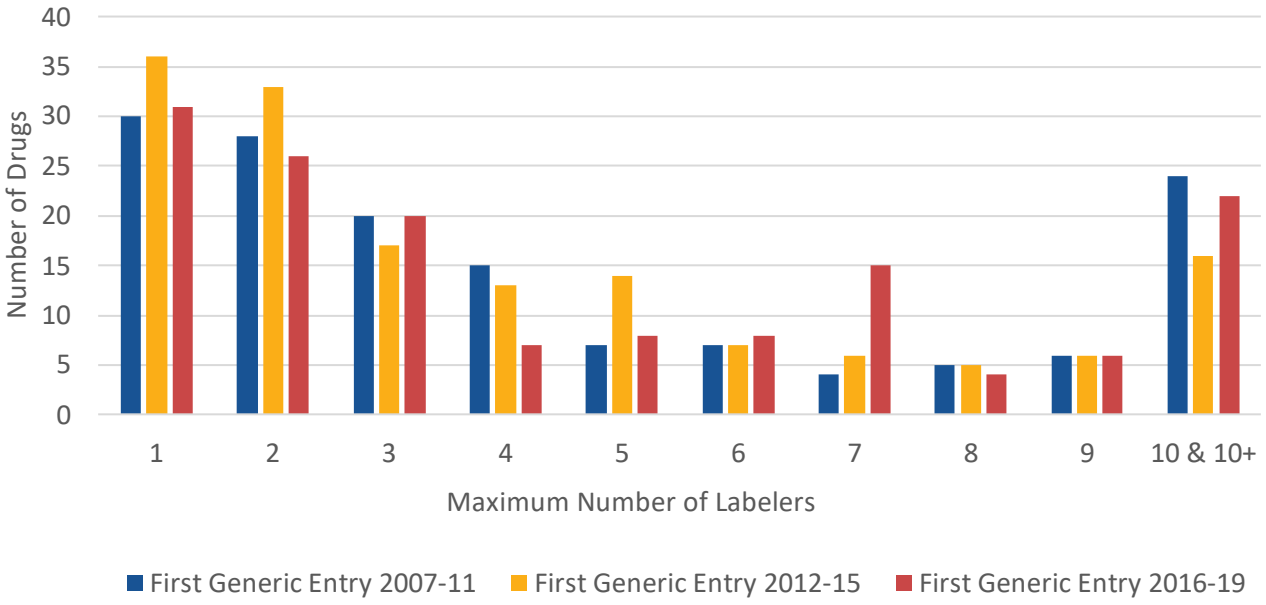



**Figure 3. Generic Drugs by Maximum Number of Labelers, 3 Years after First Entry**




## Number of Labelers and Relative Prices after First Generic Entry

Table 3 shows the regression results for all 3 time periods: 2007-2011, 2012-2015, and 2016-2019. We find that prices continue to decrease as the number of labelers increases up to 10 or more labelers. Following 3 years after first generic entry, relative prices are about 55 to 65 percentage points lower in markets with 10 or more labelers relative to markets with only 1 generic labeler. This implies that, for example, if the generic-to-

brand price ratio is about 75% to 85% when there is 1 generic labeler, then the price ratio could be as low as 20% in markets of 10 or more labelers.

**Table 3. Impact of Competition (Binaries for Number of Labelers) on Generic Relative Price**

| | | Entry during 2007-11 | | | Entry during 2012-15 | | | Entry during 2016-19 | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Coefficient | 95% Conf. Interval | | Coefficient | 95% Conf. Interval | | Coefficient | 95% Conf. Interval | |
| **Number of Labelers** | 1 | | | | | | | | | |
| | 2 | -0.011 | -0.047 | 0.026 | -0.064 | -0.094 | -0.033 | -0.025 | -0.072 | 0.022 |
| | 3 | -0.061 | -0.117 | -0.005 | -0.093 | -0.131 | -0.055 | -0.126 | -0.176 | -0.076 |
| | 4 | -0.089 | -0.160 | -0.018 | -0.150 | -0.191 | -0.109 | -0.184 | -0.234 | -0.135 |
| | 5 | -0.183 | -0.272 | -0.093 | -0.227 | -0.279 | -0.176 | -0.259 | -0.324 | -0.194 |
| | 6 | -0.224 | -0.313 | -0.136 | -0.312 | -0.380 | -0.244 | -0.314 | -0.376 | -0.252 |
| | 7 | -0.297 | -0.400 | -0.194 | -0.339 | -0.494 | -0.184 | -0.351 | -0.413 | -0.288 |
| | 8 | -0.406 | -0.511 | -0.301 | -0.504 | -0.599 | -0.410 | -0.388 | -0.452 | -0.324 |
| | 9 | -0.479 | -0.577 | -0.382 | -0.537 | -0.623 | -0.451 | -0.436 | -0.500 | -0.372 |
| | 10+ | -0.656 | -0.757 | -0.554 | -0.662 | -0.750 | -0.574 | -0.544 | -0.616 | -0.473 |
| **Number of molecules in the same drug group** | | -0.005 | -0.010 | 0.000 | -0.002 | -0.003 | 0.000 | 0.004 | 0.000 | 0.007 |
| **Proxy for predicted number of patients in the absence of the drug going off patent** | Number of Beneficiaries (in millions) | -0.781 | -3.205 | 1.643 | -1.126 | -2.093 | -0.158 | -0.041 | -0.047 | -0.036 |

Regression with molecule-form fixed effects, clustering at the drug group (GPI2) level, for all drugs with generic entry between 2007-11, 2012-15, and 2016-19. N=1 supplier is the reference group. Other controls include measures of market size and substitutability of the drugs within the therapeutic drug group.
The generic relative price, the dependent variable, is the price of the generic drug relative to that of the brand drug 6 months prior to generic entry.

Although the magnitude of the estimated impacts beyond about 7 labelers tends to be lower for the latest period (suggesting that the effect of entry beyond 7 labelers has diminished somewhat relative to earlier periods), these differences are not statistically significant.

Comparing this to the number of labelers per drug shown in Figure 3, there is potential for additional savings if more drugs were to have more labelers, rather than the current state where a large number of drugs have three or fewer labelers.

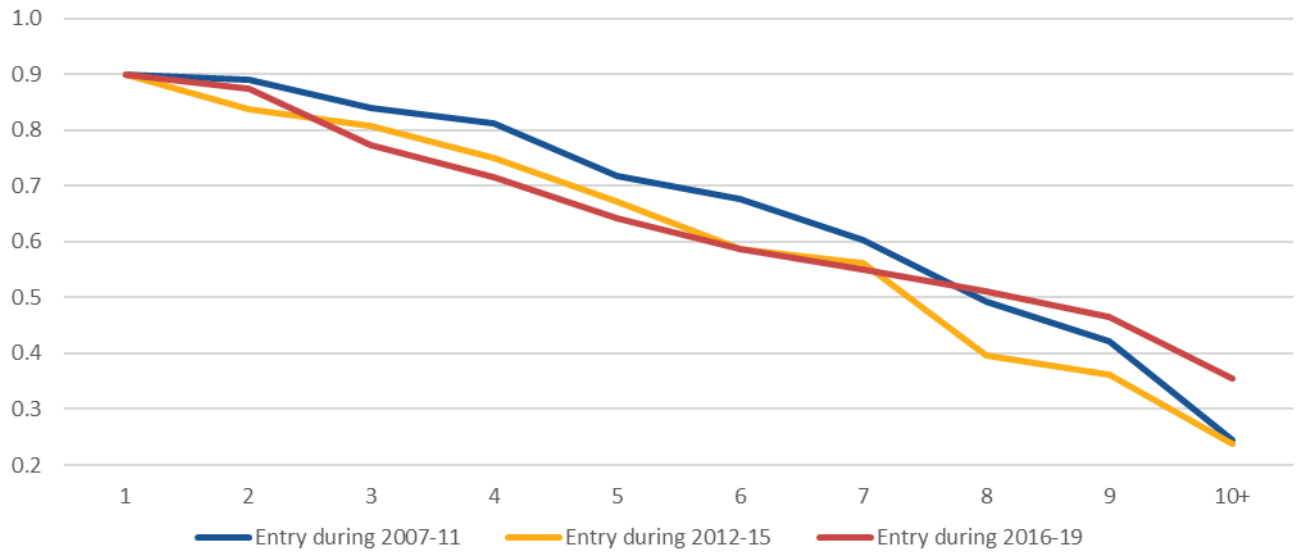
The results also show that the larger the market size, proxied by the predicted number of patients in the absence of the drug going off patent $V_{ifu}G_{cu}^{t-u}$, the greater the price reduction. The price effects of market size is significant across the 3 time periods. We also find that the higher the substitutability among drugs within a therapeutic class (measured $N_{ct}$, the number of molecules in therapeutic class c), the greater the price reduction for drugs whose first generic entry occurred in the periods of 2007-11 and 2012-15. The magnitude of the price impact of this variable, however, is small.

***Graphical Results: Number of Labelers and Relative Prices following 3 Years after First Generic Entry During 2016-2019 compared to 2007-2011 and 2012-2015***

The regression results in Table 3 are displayed graphically for the 3 periods in Figure 4. Figure 4 compares the relationship between the number of labelers and relative prices of generics entering during the 3 periods: 2007-2011, 2012-2015, and 2016-2019.[a] The plots show that prices continue to decline with increasing competition.

Based on data that follow each generic drug for 3 years after first entry during the latest period 2016-2019, the expected price ratio in markets with 10 or more labelers, the expected price ratio is close to 30%, implying an 70% decline in prices relative to the pre-generic entry price.[b] As suggested by the 95-percent confidence intervals in Table 3 (and the t-tests of the differences) the differences in the slopes of the 3 price lines in Figure 4 are not statistically significant at the 5 percent level.

**Figure 4: Predicted Relative Price of Generics by the Number of Labelers, 3 Years After First Entry**




In the earlier periods of 2012-2015 and 2007-2011, the pattern of higher competition leading to lower relative prices seems to be stronger as the expected price ratio is about close to 20%, implying an 80% decline in prices relative to the pre-generic entry price. Moreover, as shown in Table 3, the differences of the marginal price impacts among the 3 time periods are not statistically significant.[c]

## CONCLUSION

This study finds that generic competition is consistently associated with lower drug prices, and our estimated impacts are within the ranges found in the literature (see Table 1). We find that prices decline by about 20% in markets with about 3 competitors after 3 years of generic competition. Prices decline further with more

[a] Please see Table 3 for the regressions estimating the impacts on prices 3 years after generic entry.
[b] The predicted relative prices are estimated by the difference of 1 and the sum of the marginal impacts on relative prices associated with each number of competitors reported in Table 3 and the estimated impact of the reference group.
[c] An informal look at the confidence intervals in Table 3 suggests that these differences are not significant.

competitors; we find that prices decline by 70% to 80% after 2 to 3 years of first generic entry in markets that reach 10 or more competitors. This study supports prior findings that prices continue to decline with increasing entrants.[a]

In conclusion, the results provide clear evidence to support policies that promote generic entry. In addition to promoting generic entry, policy efforts to maintain effective supplier competition are important for containing drug prices in the longer run.

[a] Wiggins and Maness (2004), for instance, also found continuing price decline from a few sellers to more than 40[20]

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