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Medicare Part D: Competition and Generic Drug Prices, 2007-2018

When a generic drug first enters the market, and for the first 2-3 years thereafter, Part D generic drug prices fall as the number of competitors increase. Generic markets that are initially competitive tend to remain so over time.

KEY POINTS

- The study demonstrates that, in general, markets for generic drugs are competitive and result in prices substantially below the prices of the brand drugs prior to generic entry.
- Most new markets for generic drugs are characterized by rapid entrance of suppliers and significant reduction in prices relative to the original brand price.
- Over the first 24-36 months of new generic markets, drug prices decline by 20% relative to the brand drug price in markets with three generic competitors. During this time period, prices continues to decline by 80% relative to the pre-generic entry brand price in markets of 10 or more competitors
- The impact of competition on prices differs by market size. Additional competitors result in larger incremental price reductions in larger markets (top 20th percentiles of market size in terms of expected patients) than in smaller markets (bottom 20th percentile).
- The impact of competition on relative prices was similar for generic drugs first entering the market in either 2007-11 or 2012-15.
- Competitiveness in each generic drug market, measured either by numbers of suppliers or HHI, varies by market size but tends to remain constant over time.
- The number of very large generic drug price increases grew until 2014 and have declined rapidly through 2018. These price increases were associated with small markets with only one or two competitors.

This Issue Brief:

- Estimates the impact on generic drug prices of additional competitors in the 24 and 36 months following the expiration of the brand drugs market exclusivity period
- Examines any differences in competitive effects for new generic markets (numbers of entrants and price) in two time periods (2007-2011, 2012-2015)
- Examines differences in competitive effects in markets of different sizes
- Examines measures of generic market competition and prices over the twelve year period 2007 - 2018

Using the Medicare Part D drug claims data (PDE) for single-ingredient drug products from 2007 through 2018, we find that generic drug prices fall with increasing number of competitors. The results support efforts to

promote generic entry, as a critical tool for obtaining value from prescription drug utilization.[1] Medicare Part D paid for about 36% of national retail drug spending in 2019.

BACKGROUND

The United States relies on the interactions of private entities – drug manufacturers, health plans and pharmaceutical benefit managers (PBMs) - to achieve value by negotiating prices, operating formularies and implementing other benefit management strategies. The U.S. does not establish or negotiate prices for prescription drugs, as do some other countries.[2] A critical part of the U.S. strategy for achieving value is the competition of lower price generics for brand drugs, once the generics become available for sale. Thus, whether generic drug markets remain competitive or not is of significant policy interest.

Generic competition has intensified in the last decade with the expiration of market exclusivity of a large number of branded drugs in 2011 and 2012 (the so-called "patent cliff"), creating opportunities for entry and expanded use of lower cost generic drugs.[3] Then, in July 2012, Congress enacted the Generic Drug User Fee Amendments ("GDUFA I"), as part of the Food and Drug Administration Safety and Innovation Act. GDUFA provided additional resources for FDA to address the backlog of Abbreviated New Drug Applications ("ANDAs") and expedite its reviews of new ANDA submissions.[4] These developments resulted in a large shift toward the use of generic drugs, whose share of all retail and mail order dispensed drugs increased from 36% in 1994 to 75% in 2009 and 90% in 2017.[5] In clearing a historic backlog of ANDAs, FDA approved a record number of generics during 2017 - 2019.[6] These new generic drugs are expected to further moderate the rate of growth in drug spending.[7] Indeed, most previous studies demonstrate that increased competition – measured by number of suppliers - in new generic markets has a substantial impact in terms of reducing prices relative to the brand drug.

However, in recent years, a number of concerns about competition and pricing in the generic industry have arisen. Recent mergers and acquisitions have resulted in consolidation in generic manufacturing. There were 22 mergers and acquisitions in 2014 worth $1.86 billion, in 2015 there were 34 totaling $33.56 billion, and in 2016, there were 42 worth in excess of $44 billion.[8] Thus, there is a concern about whether new generic markets will get the same competitive response as in the past, as well as whether low profit margins will result

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[1] We estimate that total spending (program and beneficiary) for Part D drugs was 36% of total retail drug spending in 2019.

[2] Office of the Assistant Secretary for Planning and Evaluation, "Medicare FFS Part B And International Drug Prices: A Comparison Of The Top 50 Drugs. Issue Brief, November 20,202, https://aspe.hhs.gov/system/files/pdf/264421/Part-B%20Drugs-International-Issue-Brief.pdf

[3] Aitken, M., E.R. Berndt, D.M. Cutler, M. Kleinrock and L. Maini (2016), "Has The Era Of Slow Growth for Prescription Drug Spending Ended?" Health Affairs 35(9):1595-1603.

[4] Berndt, E.R., R.M. Conti and S.J. Murphy (2017), "The Generic Drug User Fee Amendments: An Economic Perspective", Cambridge, MA: National Bureau of Economic Research, Working Paper No. 23642, August.

[5] *Ibid.*

[6] 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/

[7] US Department of Health and Human Services. 2017: A Year of Accomplishment. Available at https://www.hhs.gov/sites/default/files/hhs-end-of-year-accomplishments-2017.pdf.

[8] Marc-André Gagnon and Karena D. Volesky "Merger mania: mergers and acquisitions in the generic drug sector from 1995 to 2016", Globalization and Health (2017) 13:62, https://globalizationandhealth.biomedcentral.com/articles/10.1186/s12992-017-0285-x

in an increasing number of noncompetitive generic markets and price spikes.[9] During 2012-15, there were price increases, some very large, for many generic drugs that are the standard of care for certain diseases.[10] 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. There is concern that such approvals do not have the same price reducing effect as approval for the first three competitors in the market.[11]

DATA

The study analyzes Medicare Part D drug events data (PDE) from 2007 to 2018.[12] A drug is defined by a combination of molecule (active ingredient), route of administration, and dosage form.[13,14] The unit of analysis is a drug month (molecule-form-month). We restrict the analysis to single-ingredient drugs[15] with at least 24 to 36 months of generic competition following entry. Therefore, we restrict the data to drugs that had generic entry from 2007 through 2015 as this would allow us to follow a drug that entered in 2015 the full 36 months after first generic. 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 prices of each drug by averaging ingredient costs across the NDC-level to the drug-level, separately for brand and generic. We also compute average prices in two ways: the arithmetic average of median prices and quantity-weighted average prices; both methods yield similar results.

The baseline price of each drug is the average brand price of the drug during 6 months prior to the first generic entry.[16] This pre-generic brand price is the baseline against which we compare the trajectory of prices by month following the first generic entry.[17] We limit the data to single-ingredient drug products in order to have

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[9] Andrea Mozzocchi and Ashwin Admala Reddy, " Will more generic drug approvals push prices down, or push manufacturers away?", Health Forward Blog, Deloitte, January, 23 2020, https://www2.deloitte.com/us/en/blog/health-care-blog/2020/will-more-generic-drug-approvals-push-prices-down.html

[10] U.S. Senate Special Committee on Aging (2016), "Sudden Price Spikes in Off-Patent Prescription Drugs: The Monopoly Business Model that Harms Patients, Taxpayers, and the U.S. Health Care System", Special Report, December. U.S. Government Printing Office. Available online at www.aging.senate.gov.

[11] Pew Charitable Trusts, "FDA Approves More Generic Drugs, but Competition Still Lags: FY 2012-17 program achieves mixed results", February, 2019, https://www.pewtrusts.org/-/media/assets/2019/02/fda_approves_more_generic_drugs_but_competition_still_lags.pdf

[12] 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.

[13] 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 (s.a. 10mg) and defines a drug product by a combination of therapeutic class, drug name, dosage form or route of administration (s.a. capsule).

[14] To construct the drug, we cross-walk the PDE data 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.

[15] We exclude biosimilars, orphan drugs, and prices for over-the-counter drugs equivalent except in strength to prescription products. In addition, we restrict to single-ingredient drugs in order to obtain a clean price of a drug defined as the ingredient cost.

[16] 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. (Ryan Conrad, Lutter R., 2019)

[17] 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.

a clean price average. We also exclude biosimilars[18] and orphan drugs[19], as well as molecule-form-months where the drug/drug-class becomes available over the counter (OTC). To allow for cross-year comparison, all prices are inflation-adjusted to January 2016 prices using the Consumer Price Index.[20]

METHODS

We use multivariate regressions to estimate the effect of the number of competitors on the relative price. Competitors are measured by either labelers or manufacturers of a drug.[21] The main dependent variable is the generic price relative to the baseline pre-generic-entry brand price. Price ratios vary by month for a given drug.

The main independent variable is the number of labelers (or manufacturers) offering the drug for sale.[22] A labeler can be either a manufacturer or marketer of a drug. We also examined the number of companies manufacturing a drug (for the analysis, manufacturers of authorized generics are considered generic manufacturers even if they are the same as the brand manufacturer) as an alternative independent variable, and found the results at the aggregate to be similar in both time frames, 24 months and 36 months, after first generic entry.[23] The number of suppliers is represented in two ways in separate model specifications: 1) as the discrete count of the number of generic suppliers; or 2) as a set of binary variables to describe the number of competitors. We use 1) to display comparisons of the effects for different time periods and markets sizes and 2) as our preferred estimate of the overall effects of competitors on prices.[24]

The study also controls for expected level of competition and market size in various ways: (1) the number of molecules in a therapeutic group, (2) the average monthly volume of sales measured by number of people instead of dollars[25], and (3) the predicted number of patients in the absence of the drug going off patent. We also break down the market size into 3 groups based on the number of beneficiaries in the pre-patent expiration period –bottom 20th percentile, middle 60th percentile, and top 20th percentile- and run a separate regression for each group.[26]

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[18] 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.

[19] Orphan drugs may behave unusually due to their special status. As they are usually low utilization, we excluded them.

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

[21] A labeler is any firm that manufactures (including repackers or relabelers), or distributes (under its own name) the drug. Since there are more labelers than manufacturers, the estimated impact of labelers on prices would be expected to be lower (hence more conservative estimate) than that of manufacturers.

[22] This analysis is presented at the "labeler" level, but results are robust at the "manufacturer" level as well. As a result of mergers and acquisition 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.

[23] The labeler identifies the manufacturer or distributor of the drug product (i.e., Pfizer, Allergan (Mylan), Watson, Teva, etc.)

[24] 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 suppliers and price.

[25] We adjust for market size by dividing drugs into the number of beneficiaries treated by the brand drug prior to generic entry per month (fewer than 5,000; 5,000 to 15,000; and more than 15,000 beneficiaries).

[26] We use both random effects and fixed effects at the molecule-form level in order to focus on the relationship of competitors and prices within each drug while controlling for factors across drugs. These methods, along with estimating separate models by market size, reduce the potential for bias that might exist due to unobserved cross-market influences. As both results are not substantially different, we report the fixed effects results, which tend to be estimates that are slightly more conservative. 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.

FINDINGS

Descriptive statistics

In total, our analysis included 299 drugs, marketed by 199 unique labelers, with at least one generic competitor in the 24 then 36-month follow-up period after first generic entry during 2007 to 2015. Expecting that the number of generic competitors is highly correlated to the market size within which they would compete –with larger markets drawing more suppliers into them- we categorized markets as small, medium, and large, by the total number of treated patients in Medicare Part D at the time of initial generic entry into the market.

Over half of the drugs in our study are in small markets with fewer than 5,000 patients treated monthly (167/299 in 2 years, and 165/299 in 3 years). Nearly all of the markets with 10 or more generics are categorized as "large" with more than 15,000 projected users per month (28/33 in 2 years; 32/40 in 3 years).

Exhibit 1

Competitors and Prices Among Study Drugs By Market Size in Medicare Part D Program: 2-YR vs. 3-YR After First Entry

Maximum Number of Labelers	2-Year After First Generic Entry by Market Size (by Average Number of Beneficiaries) and Total				3-Year After First Generic Entry by Market Size (by Average Number of Beneficiaries) and Total			
	Small (<5,000 per month)	Medium (5,000 -15,000 per month)	Large (>=15,000 per month)	Total	Small (<5,000 per month)	Medium (5,000 -15,000 per month)	Large (>=15,000 per month)	Total
1	62	9	8	79	49	10	7	66
2	45	8	7	60	48	8	5	61
3	25	7	7	39	25	5	7	37
4	10	9	7	26	16	5	7	28
5	8	9	4	21	7	9	5	21
6	5	2	4	11	4	4	6	14
7	5	1	3	9	5	3	2	10
8	4	0	5	9	4	3	3	10
9	1	2	9	12	3	1	8	12
10 & 10+	2	3	28	33	4	4	32	40
Number of Drugs	167	50	82	299	165	52	82	299
Average Number of Labelers	2.61	3.94	7.99	4.31	2.92	4.50	8.70	4.78

Source: Analysis of Medicare Part D claims, 2007-2018.

Summarize NDC to drug (molecule+form+route) level, select drugs with first generic entry between 2007-2015, include the 1st month to the 24th then 36th month after generic entry, get max count of labelers per drug and average market size (number of beneficiaries) per month

Exhibit 2 shows the number of competitors for drugs with first generic entry during the earlier period, 2007-2011, compared to those with first generic entry during the later period, 2012-2015. The 299 total number of drugs with generic entry during the entire period of study 2007-15 is equally split between those with generic entry during 2007-11 (146) vs during 2012-15 (153). There are fewer competitors in the second period (average number of labelers is 4.42) than those in the earlier period (average number of labelers is 5.15). The difference is most apparent in the numbers of the largest markets having 10 or more competitors. The following sections will examine whether the price effects of competition have changes between the two periods.

Exhibit 2

Competitors and Prices Among Study Drugs By Market Size, 3-YR After First Entry During: 2007-11 vs. 2012-15

Maximum Number of Labelers	First Generic Entry During 2005-11 by Market Size (by Average Number of Beneficiaries)				First Generic Entry During 2012-15 by Market Size (by Average Number of Beneficiaries)			
	Small (<5,000 per month)	Medium (5,000 -15,000 per month)	Large (>=15,000 per month)	Total	Small (<5,000 per month)	Medium (5,000 -15,000 per month)	Large (>=15,000 per month)	Total
1	22	7	1	30	27	3	6	36
2	21	5	2	28	27	3	3	33
3	11	3	6	20	14	2	1	17
4	7	3	5	15	9	2	2	13
5	4	3	0	7	3	6	5	14
6	3	2	2	7	1	2	4	7
7	2	2	0	4	3	1	2	6
8	3	2	0	5	1	1	3	5
9	2	0	4	6	1	1	4	6
10 & 10+	2	2	20	24	2	2	12	16
Number of Drugs	77	29	40	146	88	23	42	153
Average Number of Labelers	3.10	4.03	9.90	5.15	2.75	5.09	7.55	4.42

Source: Analysis of Medicare Part D claims, 2007-2018.

Summarize NDC to drug (molecule+form+route) level, select drugs with first generic entry between 2007-2015, include the 1st month to the 36th month after generic entry, get max count of labelers per drug and average market size (number of beneficiaries) per month

Estimated Effect of Competition -measured by the number of competitors

This section displays and contrasts the relationship between the number of suppliers and generic prices. The results consistently show that lower drug prices are associated with more generic competition, higher degree of substitutability among the same drug-group (for example, antidepressant), as well as larger expected market size. In each case, the displayed estimates reflect the percentage point reduction in the ratio of generic to brand price for each additional supplier in the market.

Exhibit 4 examines the differences in estimates based on whether manufacturers or labelers are used as a measure of the number of suppliers. The coefficients of the variable “number of suppliers” suggest that each entry would decrease the generic drug’s relative price by approximately 5 percentage points to 8 percentage points. As expected, the effect of additional manufacturers is somewhat larger than for labelers. The results also suggest that the price impact after three years is only slightly larger than after two years.

Exhibit 3

Impact of Number of Suppliers on Generic Price: Manufacturers vs Labelers, follow 2-3 years after entry

All Drugs Controling for Expected Market Size

		Follow the drug 24 months after entry				Follow the drug 36 months after entry			
		Manufacturers		Labelers		Manufacturers		Labelers	
Regressor	**Label**	**Coefficient**	**P-value**	**Coefficient**	**P-value**	**Coefficient**	**P-value**	**Coefficient**	**P-value**
Number of Suppliers (Manufacturers/Labelers)	N/A	**-0.068**	0.000	**-0.053**	0.000	**-0.075**	0.000	**-0.057**	0.000
Number of molecules in the same drug group	N/A	-0.004	0.034	-0.004	0.049	-0.002	0.016	-0.002	0.026
Proxy for predicted number of patients in the absence of the drug going off patent	Number of Beneficiaries (in millions)	-1.498	0.093	-1.119	0.221	-0.448	0.506	-0.080	0.905

Source: Analysis of Medicare Part D claims, 2007-2018.
Regression with molecule-form fixed effects, clustering at drug group (GPI2) level, all drugs with generic entry between 2007-2015. Include the 1st month to the 24th/36th month after generic entry.

Exhibit 4

Impact of Number of Labelers on Generic Price by Maket Size: follow 2 years after entry

Percentile of Market Size (by Number of Beneficiaries)*		Bottom 20 Percentile		Middle 60 Percentile		Top 20 Percentile	
Regressor		**Coefficient**	**P-value**	**Coefficient**	**P-value**	**Coefficient**	**P-value**
Number of Labelers		-0.027	0.004	-0.051	0.000	-0.055	0.000
Number of molecules in the same drug group		-0.009	0.017	-0.002	0.150	-0.005	0.135

Source: Analysis of Medicare Part D claims, 2007-2018.
Regression with molecule-form fixed effects, clustering at drug group (GPI2) level, for all drugs with generic entry between 2007-2015.
Market size is based on the predicted number of patients in the absence of the drug going off patent

Exhibits 4 and 5 display the estimated effects for each of the three market sizes. As expected, after two years the effect of additional suppliers for medium and large markets is approximately twice the effect for small markets. These markets are likely less attractive to multiple competitors and thus the price effect is smaller. The difference narrows after three years suggesting that competitive effects in these smaller markets occur at a slower pace than the larger markets. The number of molecules in the same group is a measure of the potential for switching among therapeutically similar drugs and thus, the opportunity for market expansion. It is interesting that the number of molecules in the same therapeutic class has a larger price reducing effect for the smaller markets.

Exhibit 5

Impact of Number of Labelers on Generic Price by Maket Size: follow 3 years after entry

Percentile of Market Size (by Number of Beneficiaries)*		Bottom 20 Percentile		Middle 60 Percentile		Top 20 Percentile	
Regressor		**Coefficient**	**P-value**	**Coefficient**	**P-value**	**Coefficient**	**P-value**
Number of Labelers		-0.040	0.000	-0.054	0.000	-0.059	0.000
Number of molecules in the same drug group		-0.004	0.031	-0.002	0.060	-0.002	0.421

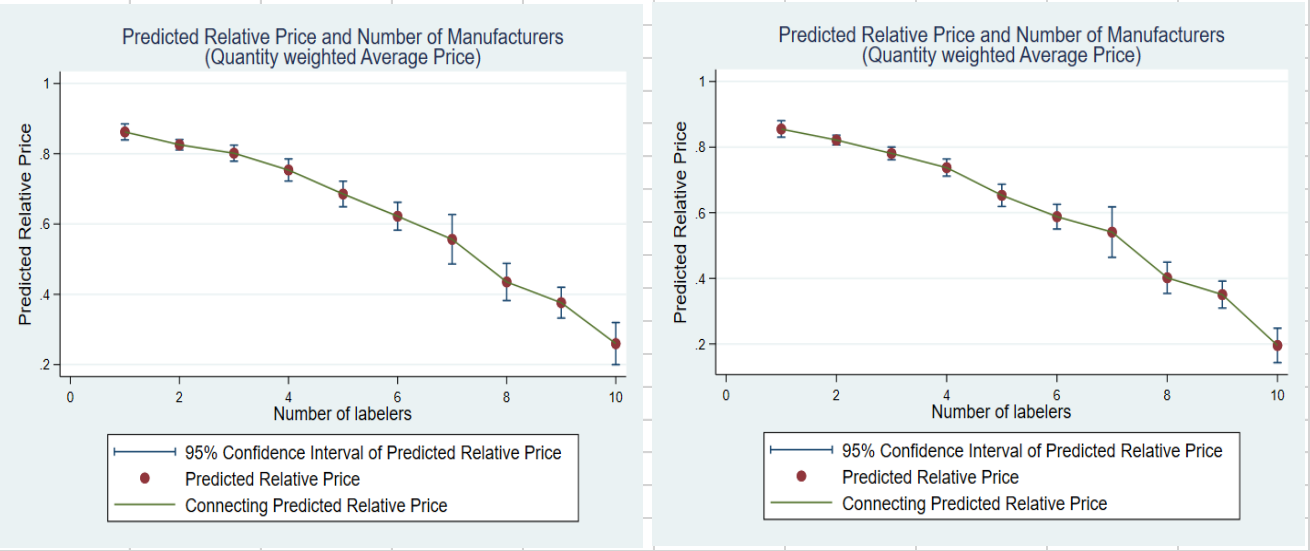
Source: Analysis of Medicare Part D claims, 2007-2018.
Regression with molecule-form fixed effects, clustering at drug group (GPI2) level, for all drugs with generic entry between 2007-2015.
Market size is based on the predicted number of patients in the absence of the drug going off patent

Estimated Effect of Competition -measured by a set of binary variables for each number of competitors

The following graphs display the predicted relationship between the number of suppliers and relative prices. These predictions use the binary variables to represent number of suppliers in the market. The plots show that prices continue to decline with increasing competition, controlling for market size. Based on data that follow each generic drug for 2 years after first entry, the expected price ratio in markets with about 3 competitors is 80%, implying a 20% decline in prices. In markets of 10 or more competitors, the expected price ratio is about 30%, implying a 70% decline in prices relative to the pre-generic entry price (Exhibit 6). Extending to 3 years after first entry, the expected price ratio declines further. In markets of 10 or more competitors, the expected price ratio is less than 20%, implying an 80% or greater decline in prices relative to the pre-generic entry price.

Exhibit 6

Predicted Relative Price of Generics by the Number of Labelers: Entry 2007-2015



Source: Analysis of Medicare Part D claims, 2007-2018 (regressors set to their means, fixed effects set at zero)

Results based comparing the impact of entry during 2007-11 vs. 2012-15 periods

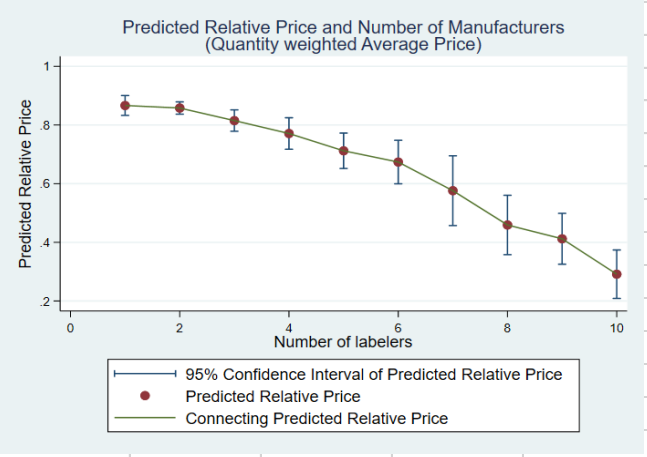
In addition to examining the competition-price relationship for drugs with generic entry throughout the whole 2007-15 period, we partition the data into 2 sub-periods, 2007-2011 and 2012-2015, to investigate whether the competitive effects of generic entrants might differ between the two periods. Exhibits 7 and 8 displays the impact of entry on the average relative price of generics for each period. Visually, the impact of competition on relative prices for generic drugs first entering the markets in either 2007-11 or 2012-15 are similar. In addition, the estimates are not different from each other based on standard statistical criteria.[27]

[27] The 95 percent confidence intervals for the estimates suggest that the estimated price impacts are not statistically different in the 2 periods.

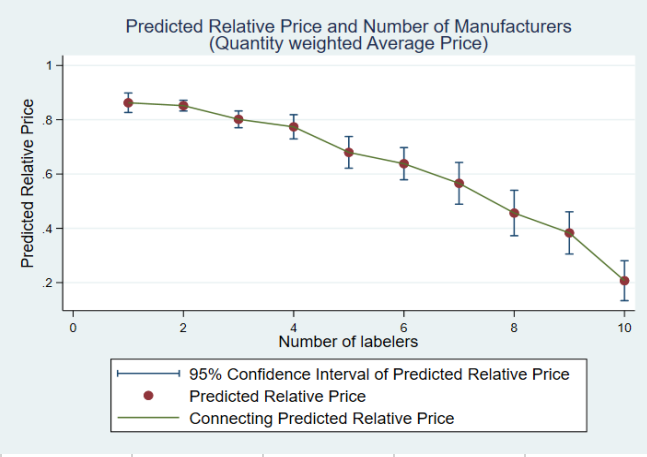
Exhibit 7

Predicted Relative Price of Generics by the Number of Labelers: Entry 2007-2011

Following **2** years after entry



Following **3** years after entry

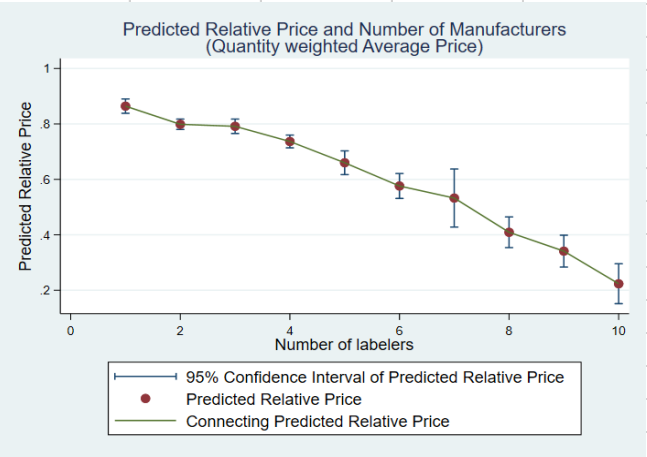


Source: Analysis of Medicare Part D claims, 2007-2018 (regressors set to their means, fixed effects set at zero)

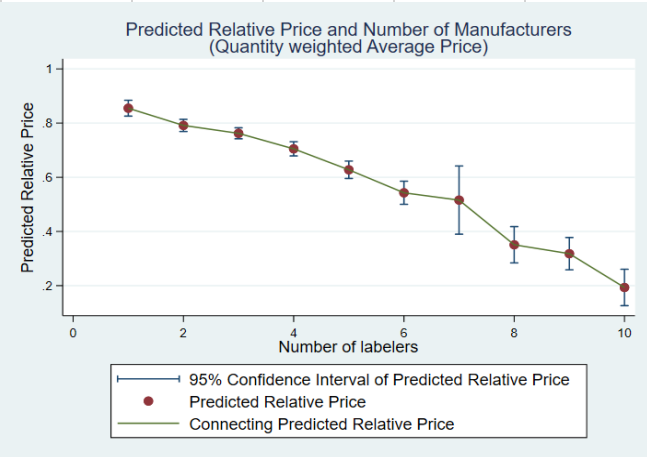
Exhibit 8

Predicted Relative Price of Generics by the Number of Labelers: Entry 2012-2015

Following **2** years after entry



Following **3** years after entry



Source: Analysis of Medicare Part D claims, 2007-2018 (regressors set to their means, fixed effects set at zero)

COMPETITION IN GENERIC MARKETS, 2007 – 2018

The analyses presented above suggest that in general, new markets for generic drugs are characterized by rapid entrance of suppliers and significant reduction in prices relative to the original brand price. In this section we examine whether markets maintain their competitiveness over time, or the extent to which they become less competitive and subject to large price increases. We measure competitiveness at the molecule level by numbers of labelers and manufacturers as well as the Herfindahl-Hirschman Index (HHI). The Exhibits include all generic drugs billed under Part D during the 2007-2018 period.[28] We conducted the same analyses

[28] The analyses include 1689 generic drugs at the GPI12 level.

using only drugs available for the full time period to examine whether any of the trends were substantially affected by entrance of new drugs or exit of older drugs. In general, the trends were comparable for the two analyses and we note in the discussion below any specific differences.

Exhibit 9 examines markets based on their 2018 HHI. As would be expected, the most competitive markets in terms of HHI (HHI<.25) also have the most suppliers and the least competitive markets (HHI>.75) the fewest. The least competitive markets account for 38% of generic drugs but only 9% of gross drug costs. Conversely, the most competitive markets account for 7% of generic drugs but 35% of gross drug costs. As would also be expected, average annual price change was negative for competitive markets and high (17.6%) for the least competitive.

Exhibit 10 and 11 display in each year the share of drugs and the share of GDC accounted for by markets with various numbers of suppliers. These shares have remained stable over time. Less competitive markets tend to be numerous but small in terms of sales. In each year, markets with 1 or 2 suppliers account for approximately 40% of the generic drugs dispensed in Part D but less than 10% of the GDC. Markets with 10 or more suppliers account for approximately 10% of the generic drugs dispensed but 50-60% of the GDC in each year.

Exhibit 9 – Characteristic of Generic Drug Markets by HHI

HHI	# manufacturers	# labelers	% of markets	% of Gross drug cost	Weighted Average Annual Price Change, 2007-2018
0 -.25 (most competitive)	11.1	14.8	7%	35%	-10.99%
.25 -.50	5.5	7.1	33%	44%	-0.81%
.50 - .75	3.0	3.7	21%	12%	2.81%
.75+ (monopolistic)	1.4	1.6	38%	9%	17.63%

Exhibit 10 – Percent of Markets with Specified Number of Labelers, 2007 -2018

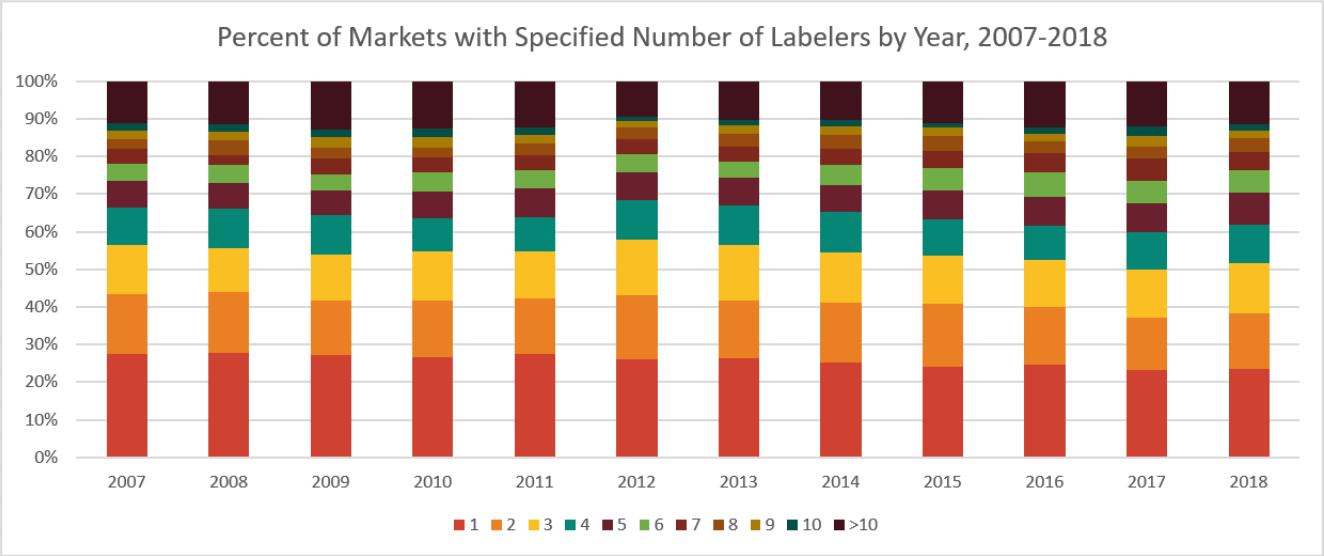
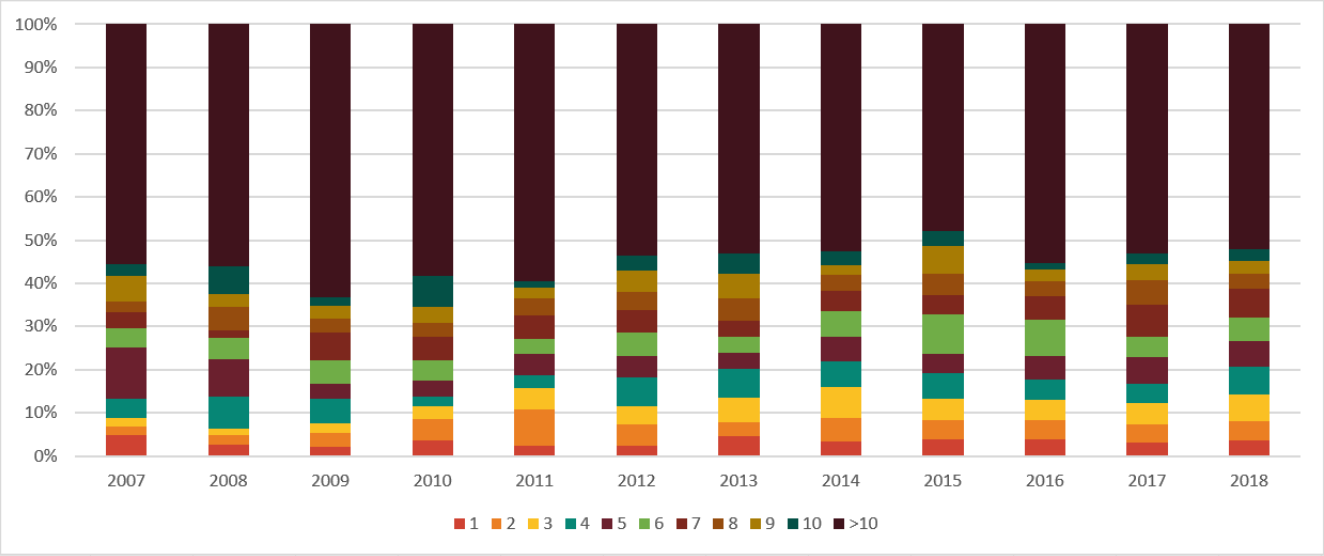


Exhibit 11 - Spending in Markets with the Specified Number of Labelers as a Percentage of GDC



Exhibits 12 -14 examine competitiveness over time by market size based on GDC. The average number of labelers or manufacturers in each year varies directly with market size. Market size is measured by quartiles based on GDC. Exhibits 12 and 13 demonstrate that the largest markets (75th percentile and above based on GDC) average the greatest number of suppliers and the smallest markets (25th percentile and below) have the least number of suppliers. Exhibit 14 demonstrates that HHI in each year varies inversely with market size. The smallest markets have the highest HHI on average (least competitive) while the largest markets have the lowest average HHI (most competitive). Of equal importance, degree of competitiveness remains constant over this twelve-year period – that is, markets that are more or less competitive tend to maintain that status over time.

Exhibit 12 – Average Number of Labelers by Market Size, Quarterly 2007 - 2018

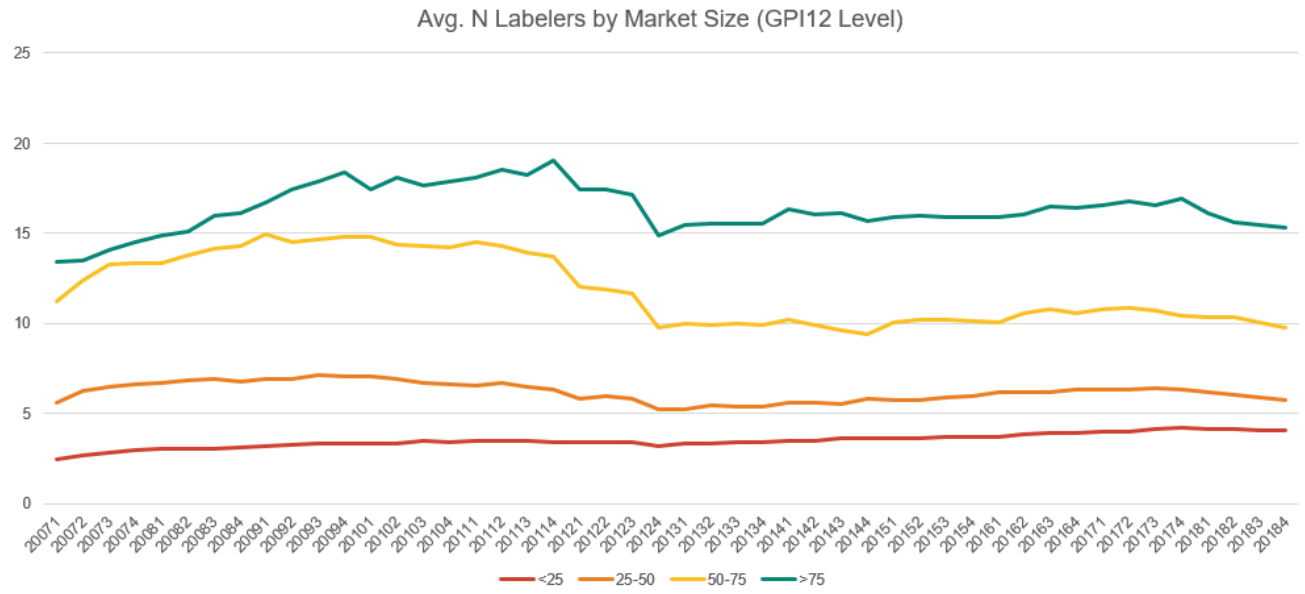


Exhibit 13 - Average Number of Manufacturers by Market Size, Quarterly 2007 - 2018

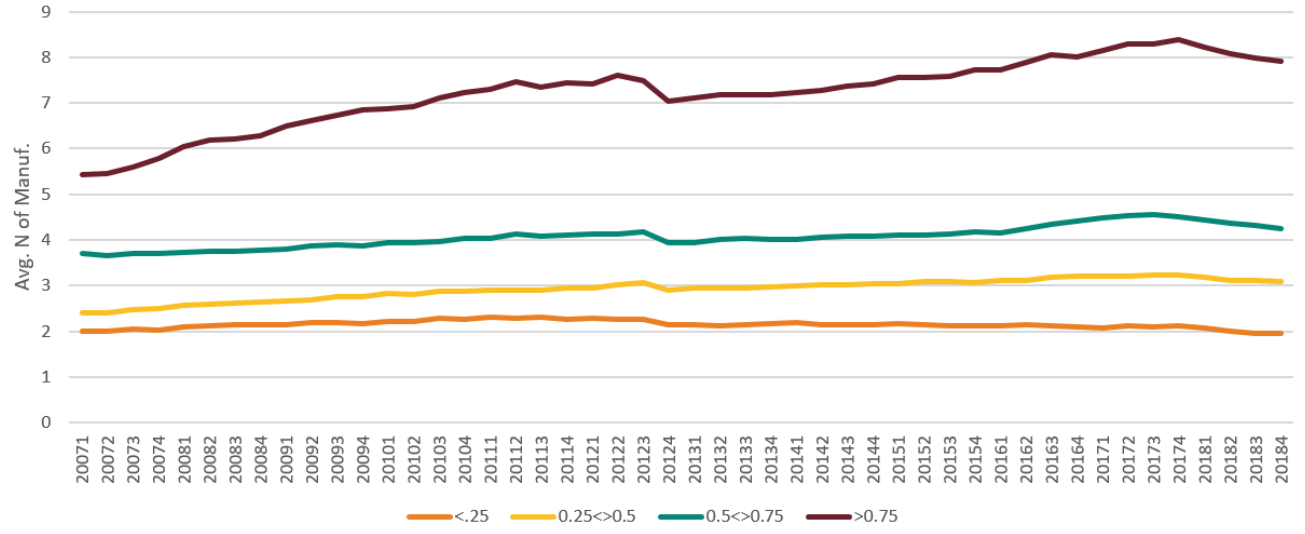
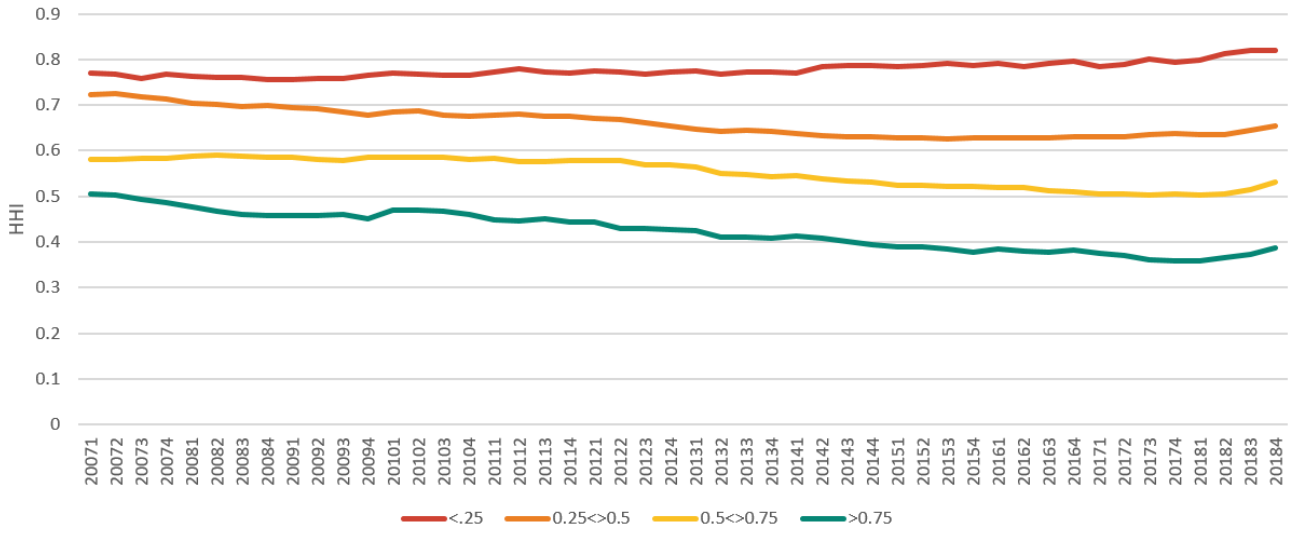


Exhibit 14 – Average HHI by Market Size, Quarterly 2007 - 2018



Competitiveness and Pricing

The previous analyses demonstrated that for the most part, new generic markets gain sufficient numbers of entrants resulting in generic prices declining substantially relative to the original brand price. Moreover, the Exhibits above suggest that competitive markets tend to remain so over time. Nonetheless, concern has been raised about price spikes that have been observed in recent years.[29]

Exhibits 15 and 16 examine the distribution of price increases in each of the years 2007 – 2018. In each year, the vast majority of price changes are either negative or reflect an increase of less than 10%.[30] The percent of very large price increases and their share of GDC did grow over several years through 2014. From 2015 through 2018, these numbers declined significantly. For example, the number of price increases of 100% or more (the tan sections of the vertical bars) peaked at approximately 5% in 2014 and as a share of GDC at about 8% in 2013. By 2018, such price increases accounted for a minimal percent of drugs and GDC.

Price increases in generic drugs at any time might occur due to a number of factors such as production line issues or increases in raw materials. However, the market power available in very concentrated markets can play a significant role. Exhibit 17 displays trends in generic prices by market concentration measured by the HHI. For all but one year (2013), average price change is directly related to HHI – that is greater concentration is associated with higher average price change. The largest average price change was associated with the monopolistic markets in 2015 – in particular, the increase of nearly 4000% for Daraprim. Again, these

[29] Geoffrey Joyce, Laura E. Henkhaus, Laura Gascue, and Julie Zissimopoulos, "Generic Drug Price Hikes And Out-Of-Pocket Spending For Medicare Beneficiaries", HEALTH AFFAIRS (2018), VOL. 37, NO. 10 :
3. Berndt, Ernst R.; Conti, Rena M.; Murphy, Stephen J., (2017). "The Landscape Of Us Generic Prescription Drug Markets, 2004-2016." National Bureau of Economic Research. Working Paper 2364. http://www.nber.org/papers/w23640

[30] In most years, more than 50% of price changes were negative.

monopolistic generic markets are numerous but tend to be small so their share of GDC is substantially lower than their share of markets.

Exhibit 15 – Percent of Generic Drugs at Selected Annual Changes in Prices, 2008 - 2018

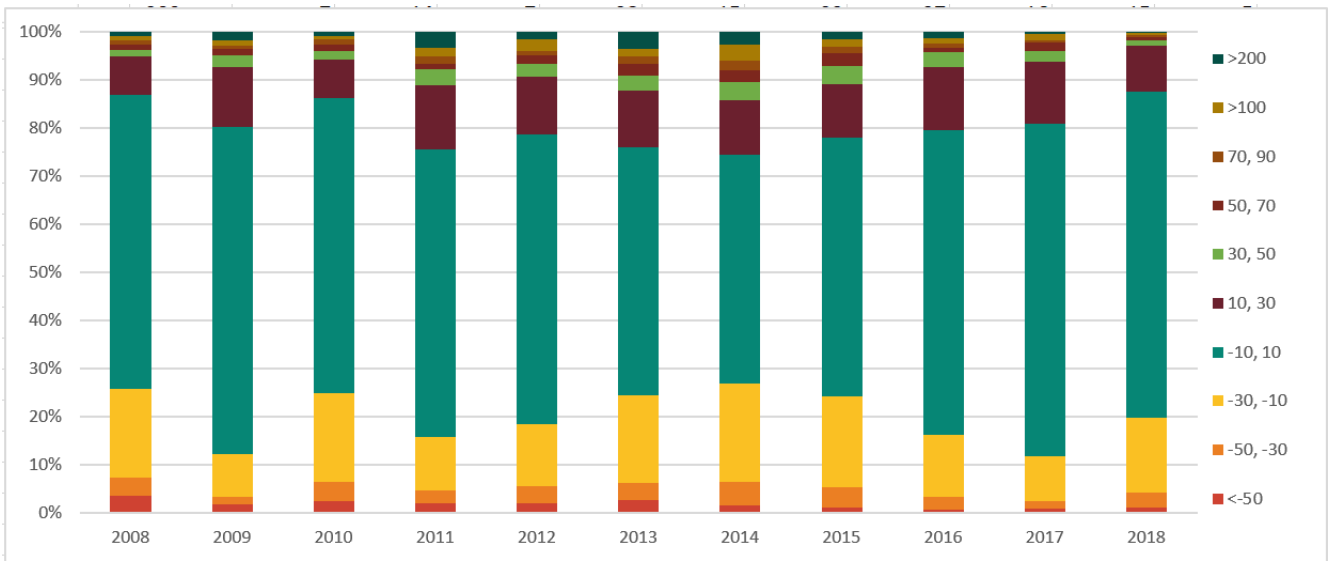


Exhibit 16 – Percent of GDC Accounted for by Generic Drugs at Selected Annual Changes in Prices, 2008 – 2018

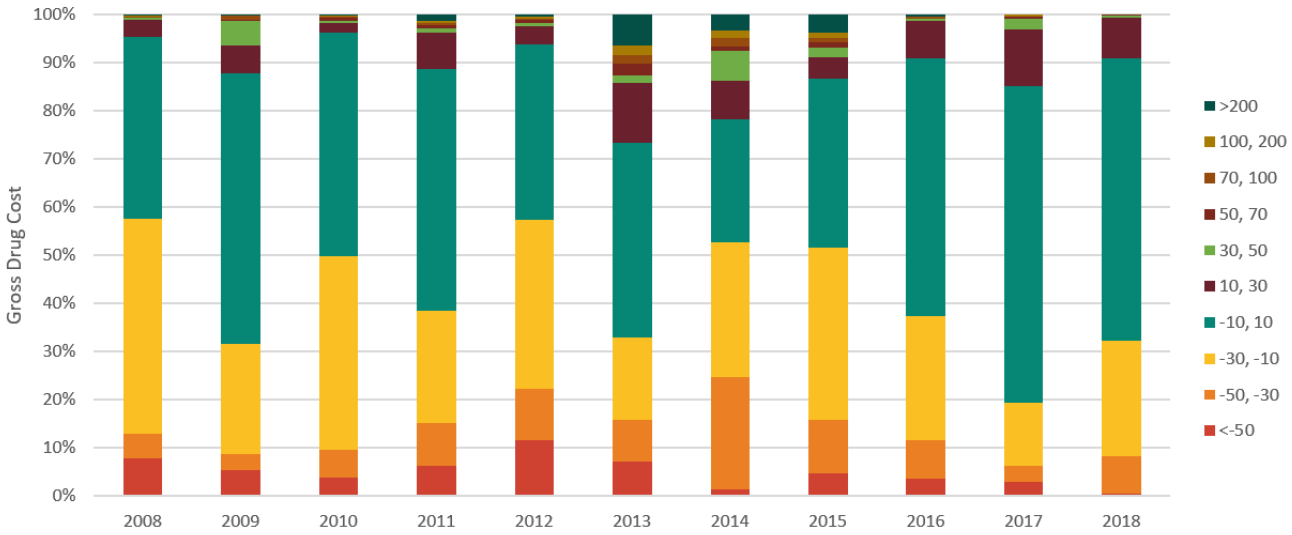
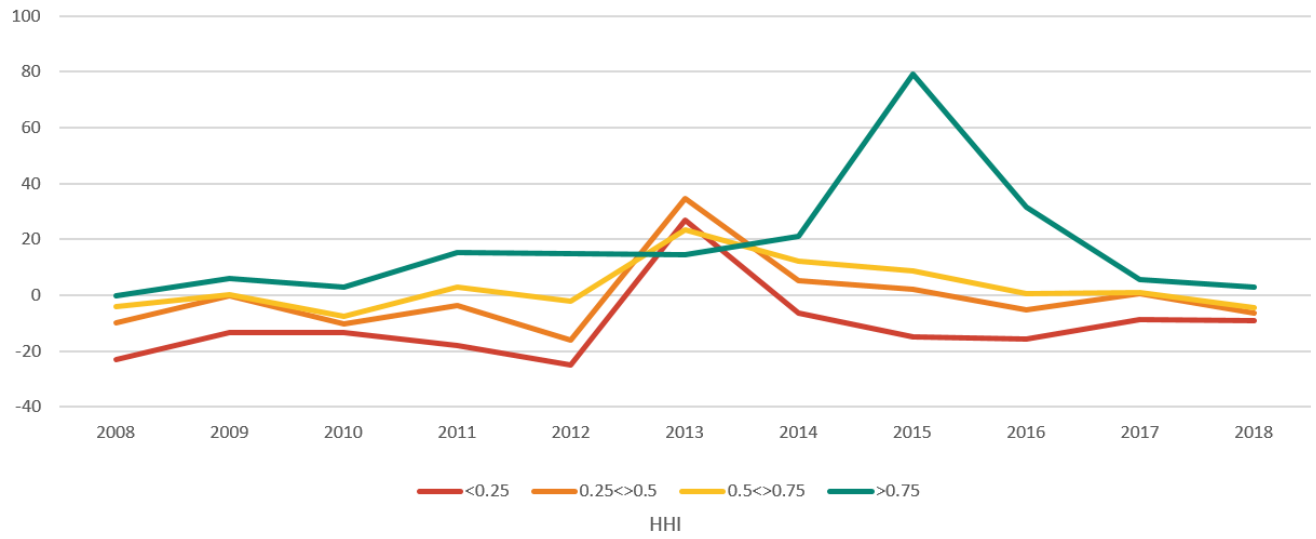


Exhibit 17 – Annual Price Changes by Market Concentration Measured by HHI



CONCLUDING REMARKS

The study demonstrates that in general, markets for generic drugs are competitive and result in prices substantially below the brand drugs. In most cases, competition is supported by a sufficient number of suppliers entering the market when market exclusivity expires for the brand drug. While there was some reduction in the number of entrants to new generic markets during 2012-2015 as compared with 2007–2011, the impact on lowering prices did not differ between the periods. In addition, competitive markets tended to remain competitive over the entire twelve years in this study. Larger price increases tend to be associated with smaller markets with few competitors.

We find that the impact of competition on prices differs by market size. Larger markets attract greater numbers of competitors and experience larger price reductions than do smaller markets. Again, initial differences in competitiveness between market sizes remain constant over time. Consistent with previous generic market studies, we find that the smaller markets account for a large share of the generic drugs, but a relatively small share of GDC. These markets tend to have few suppliers and are highly concentrated, resulting in higher price increases over time than the more competitive markets. In a small percent of cases, large price spikes have occurred in these markets.

It will be important for us to continue this study by adding additional years of data as it becomes available. In order to follow a new generic market for 3 years after first entry, we limited the study to drugs that entered the Part D markets ending in 2015. By ending in 2015, we miss the large influx of generic drugs that entered the market since 2015. In clearing a historic backlog of Abbreviated New Drug Applications (ANDA), FDA

approved a record number of generics in 2017 - 2019.[31] If the number of manufacturers does not increase commensurately with the increase in generic drugs being approved, manufacturers may engage in: (1) selecting strategically which generic product to enter (i.e., which product to file an ANDA for), or (2) select which old product to exit in order to free up resources to enter a newer drug. Entry still requires significant up-front expenditures, with a payoff that depends both on the FDA's approval of a firm's application as well as of rivals' ANDA applications. Scott Morton (1996) calculates 2 to 3 years elapsing from the time an applicant begins preparing to enter until it can begin selling a generic drug. Thus, it will be important to continually monitor the operation of these markets.

Nevertheless, the results of this study provide evidence that robust generic competition results in lower generic prices. The results suggest that FDA's efforts to both approve the first few entrants to new generic markets, as well as to approve subsequent suppliers, have resulted in greater competition and price reductions. The study also highlighted a number of smaller, noncompetitive markets that are potential risks for shortages and price spikes. Policy options to address these markets have included greater anti-trust oversight and allowing drug importation in select cases.[32]

[31] 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. See also https://www.fda.gov/drugs/generic-drugs/2019-office-generic-drugs-annual-report#:~:text=In%202019%2C%20the%20generic%20drug,New%20Drug%20Applications%20(ANDAs).

[32] Matthew Cohen Ravi Gupta Thomas J. Bollyky Joseph S. Ross Aaron S. Kesselheim, "Policy Options For Increasing Generic Drug Competition Through Importation", Health Affairs Blog, January 7, 2019, https://www.healthaffairs.org/do/10.1377/hblog20190103.333047/full/

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