REPORT

Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices

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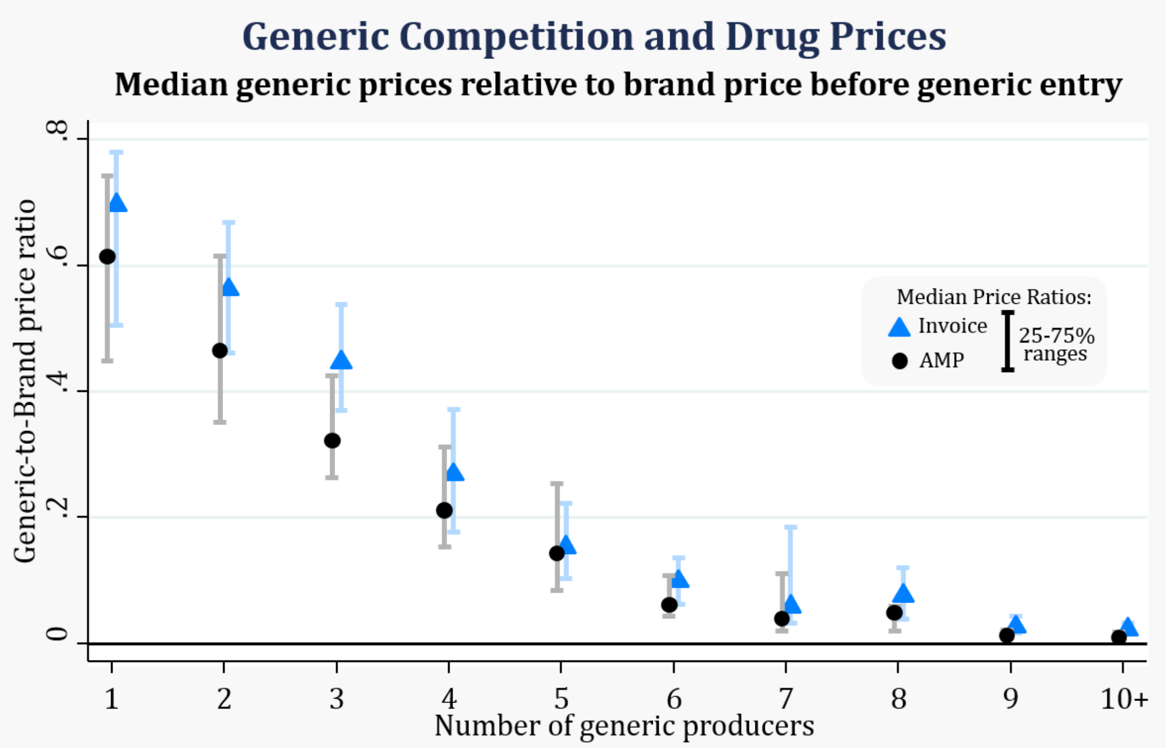
Greater competition among generic drug makers is associated with lower generic drug prices, according to a new analysis using two different sources for wholesale prices. We show that generic drug prices after initial generic entry decline with additional competition using both the average manufacturer prices (AMP) reported to the Centers for Medicare and Medicaid Services (CMS) and invoice-based wholesale prices reflecting pharmacy acquisitions from IQVIA's National Sales Perspective database (NSP). Estimates using AMP show price declines associated with additional generic competition steeper than those based on invoices for pharmacy acquisitions, though most of the difference comes from wholesaler markups.

The figure below presents our analysis of prices and competition for all drug products that had initial generic entry between 2015 and 2017, showing median generic-to-brand price ratios and their ranges by the number of generic producers.



Generic drug products with initial generic entry from 2015-2017.
Based on IQVIA NSP invoice-based sales and units sold to pharmacies (▲) and average manufacturer prices (AMP) reported to CMS (●).

We find that for products with a single generic producer, the generic AMP is 39% lower than the brand AMP before generic competition, compared to a 31% reduction using invoice prices. With two competitors, AMP data show that generic prices are 54% lower than the brand drug price before generic competition, compared to 44% when calculated using invoice-based drug prices. With four competitors, AMP data show that the generic prices are 79% less than the brand drug price before generic entry, compared to 73% when calculated using invoice-based drug prices. With six or more competitors, generic prices using both AMP and invoice prices show price reductions of more than 95% compared to brand prices. Combining all competition groups, we find median price of generics relative to brands using AMP is 40% for the drugs in our sample, while the median price ratio using invoice prices is 49%. Most of this difference appears driven by wholesale markups, which we discuss below.

This analysis builds on earlier FDA work comparing generic and brand drug prices and follows related studies.[1, 2]

Discussion

Using average manufacturer prices instead of invoice-based pharmacy costs may lead to better measurement of the association between competition and price because AMPs are more directly under the control of the manufacturer. Average manufacturer prices also account for discounts, rebates and other adjustments excluded from invoices sent to pharmacies.[3] Neither AMPs nor invoice-based prices paid by pharmacies fully capture prices paid by patients and third-party payers for drugs dispensed to patients.

AMPs exclude wholesale drug distributor price markups, which Sood et al. (2017), suggest are 19% for generics and 1% for brand drugs.[4] Assuming these markups apply to the drugs in our sample this eliminates most of the observed difference in price ratios. For example, as shown in the technical appendix, for the observations with 2 competitors, the median ratio of generic to brand price was 0.465 using the AMP data and 0.562 using the invoice-based data, leaving a difference of nearly 20%. Multiplying the former figure by a factor of 1.19 / 1.01 to adjust for the ratio of wholesale price markups, yields 0.548, which can be interpreted as the ratios of wholesale prices reflecting pharmacy acquisitions. This adjusted price ratio is only 1.4% below the median ratio of 0.562 using IQVIA's NSP data a small fraction of the unadjusted difference.

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[1] See ARCHIVED 2005 STUDY.
https://wayback.archive-it.org/7993/20190914072411/https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices

[2] See slide 9 in presentations to the FTC,
https://www.ftc.gov/system/files/documents/public_events/1255653/understanding_competition_in_prescription_drug_markets_workshop_slides_11-8-17.pdf.

[3] The CMS 2016 Final Rule (81 FR 5107) states that "when a sale to a retail community pharmacy is determined to be included in AMP, any rebate, discount, payment or other financial transaction associated with that sale should also be included in the determination of AMP." However, with the exception of some drugs sold to non-retail settings, the calculation of the AMP does not subtract rebates and discounts negotiated with PBMs (see 42 CFR 447.504(c)(18) and 447.504(d)). Both AMP and invoice-based prices from IQVIA exclude discounts to Medicaid programs.

[4] See Sood et al. (2017), "Follow the Money: the Flow of Funds in the Pharmaceutical Distribution System", available at https://www.ftc.gov/system/files/documents/public_events/1255653/understanding_competition_in_prescription_drug_markets_workshop_slides_11-8-17.pdf.

Both invoice-based wholesale prices paid by pharmacies and average manufacturer prices do not include payments made by manufacturers to pharmacy benefit managers, who may share them with the health plan. It is unclear, however, how such payments may be related to the price of specific drug products.[5]

Some limitations apply to this work. First, it reflects only drugs sold to retail pharmacies because AMP data exist only for those drugs. Differences in prices between brand and generic drugs sold to hospitals may be different than we report here. Second, as earlier noted, these data do not include rebates to plans or PBMs, and to the extent that these are drug-specific and vary between brand and generic products in the same markets, our results do not include such rebates when measuring the relationship between generic competition and prices. Third, to focus on initial entry, and limit effects of self-selection of new competitors to large profitable markets, we limit the sample to only drug products that experienced an initial generic entry during three recent years of data. Analysis of samples over more years and with generic products that have been on the market for longer periods may lead to different results because they would include more observations of small markets where total revenue is insufficient to attract many competitors. Fourth, the prices that we analyze reflect sales by manufacturers (AMP) and purchases by pharmacies (IQVIA NSP) and not prices paid by consumers, either insured or uninsured. Differences in consumer prices may vary according to whether and how they are insured and other factors. Finally, very low generic prices may in some instances be related to drug shortages, a topic that FDA has analyzed separately.[6]

[5] See Figure 1 in Sood et al. "The Flow of Money Through the Pharmaceutical Distribution System", USC Schaeffer, June 2017, https://healthpolicy.usc.edu/wp-content/uploads/2017/06/USC_Flow-of-MoneyWhitePaper_Final_Spreads.pdf. As these payments are based on contracts that are not publicly available, it is unclear whether and to what extent such formulary payments, market share payments, performance incentives, and rebates should be seen as omitted adjustments to drug prices. More specifically, if such payments are contingent on sales of an individual drug product, e.g., a product that is unique in terms of molecule, route of administration, dosage form, and strength, they would represent an adjustment to price that should be made if data on its magnitude were available. If on the other hand they are conditional on general measures of performance, such as sales of a wide set of drugs, then adjusting the price of individual drugs to such payments, even if they were observable, may be conceptually very challenging.

[6] See https://www.fda.gov/drugs/drug-shortages/agency-drug-shortages-task-force.

Technical Appendix

This analysis uses AMP data from the Center for Medicare and Medicaid Services from 2015 through 2017, and IQVIA's proprietary National Sales Perspective database for prescription drug products.[7] We define a product as having the same active ingredient, route of administration, dosage form, and strength, ignoring differences in package sizes. For every brand product in the database, we computed the price per unit during the three months prior to generic entry.[8] For the generics, we computed for all manufacturers of a product, the mean price per unit each month, weighting the prices by each manufacturer's share of the total quantity sold, and the number of manufacturers.[9] We then merged these two datasets, by product and month, and computed for each product the ratios of the mean generic price to the corresponding brand product's price.

Our sample is based on IQVIA NSP unit sales of drug products and is limited to products that had an initial generic entry from 2015 through 2017. IQVIA NSP provides monthly units sold, invoice dollar sales, and invoice price for each drug product at the national drug code (NDC) 9-digit level. The average manufacturer prices (AMPs) per unit are from CMS by month and identified by NDC. We merge monthly average manufacturer price per unit for each NDC to sales data from IQVIA NSP, resulting in two different measures of price for each NDC—the invoice price and the average manufacturer price.

The sample inclusion criteria are as follows:

1. Generic drugs must have observed initial market entry from January 2015 through December 2017. Initial generic entry is defined as having observed only brand drug sales followed by at least three consecutive months of generic sales.
2. Products with generic entry but without brand sales during the three months prior to generic entry are excluded because there is no baseline brand price for comparison.
3. Generic entrants with fewer than three consecutive months of generic sales after entry are excluded. Such occurrences usually represent repackagers selling the brand drug and are not generic entry.
4. The remaining products were cross-checked with the FDA publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") to ensure that generic approvals (i.e. abbreviated new drug applications) for these products appeared in the correct time period, allowing generic versions to market.

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[7] A more complete description of the IQVIA NSP data is available in an annual report available at https://www.iqvia.com/insights/the-iqvia-institute/reports/medicine-use-and-spending-in-the-us-a-review-of-2018-and-outlook-to-2023.

[8] A unit is defined as a single tablet, capsule, etc. for oral solid products, and typically a milliliter for products of other dosage forms.

[9] We count both generic producers marketing via an approved ANDA and those marketing as authorized generics. Authorized generics have a unique NDC number and compete with generics but are technically produced under the brand product's new drug application (NDA). This is in line with previous work. See, for example, Berndt et al., (2007) available at https://www.healthaffairs.org/doi/full/10.1377/hlthaff.26.3.790.

Summary of Product and NDC Counts	Unique Products	Unique NDCs, generic products	Number of NDC-Months
Products with initial generic entry, 2015-2017, per IQVIA NSP retail settings	240	1,088	21,536
Products with available AMP data	207	753	12,528
Final sample, after applying inclusion criteria listed above	**181**	**711**	**11,442**

Collapsing NDCs into unique products based on their ingredient, dosage form, route of administration, and strength we have observations representing 3,688 product-months.

For each product-month we compute two measures of price, AMP and invoice. Both measures of price are weighted by units sold and represent the average generic price for the product in a given month. All dollars are inflation-adjusted to a January 2018 base.[10]

For each product we focus on generic price relative to the average brand price during the three months prior to generic entry.

1a. Pre-generic brand price for product "p" using AMP, where $m = -3, -2, -1$ represents the three months immediately preceding generic entry:

$$BasePrice(AMP)_P = \left[\sum_{m=-1}^{-3} Units(Brand)_{p,m} * Price(AMP)_{p,m}\right] \div \left[\sum_{m=-1}^{-3} Units(Brand)_{p,m}\right]$$

1b. Pre-generic brand price for product "p" using invoice prices:

$$BasePrice(Invoice)_P = \left[\sum_{m=-1}^{-3} DollarSales(Brand)_{p,m}\right] \div \left[\sum_{m=-1}^{-3} Units(Brand)_{p,m}\right]$$
$$= \left[\sum_{m=-1}^{-3} Units(Brand)_{p,m} * Price(Invoice)_{p,m}\right] \div \left[\sum_{m=-1}^{-3} Units(Brand)_{p,m}\right]$$

Generic prices using AMP are equal to the NDC-specific monthly sales volume, multiplied by the NDC-specific monthly price. This results in the total NDC-specific sales revenue for a given month. We then compute the weighted price for each product-month by summing these revenues and unit sales for each NDC within a product-month, and dividing the sum

[10] Using BLS CPI data, available at: https://data.bls.gov/PDQWeb/cu.

of revenues by the sum of unit sales. Generic prices using wholesale prices are calculated similarly.

2a. Average price for all producers of generic product “p” in month “m” using AMP. The index $i = 1, \ldots, N_{P,m}$ represents unique NDCs within product “p” marketed during month “m”:

$$AvgGenPrice(AMP)_{p,m} = \left[\sum_{i=1}^{N_{P,m}} Units(Generic)_{p,m,i} * Price(AMP)_{p,m,i}\right] \div \left[\sum_{i=1}^{N_{P,m}} Units(Generic)_{p,m,i}\right]$$

2b. Average price of all producers of generic product “p” in month “m” using invoice prices:

$$AvgGenPrice(Invoice)_{P,m} = \left[\sum_{i=1}^{N_{P,m}} DollarSales(Generic)_{p,m,i}\right] \div \left[\sum_{i=1}^{N_{P,m}} Units(Generic)_{p,m,i}\right]$$

Finally, we use the baseline brand price and the monthly average generic price to compute the generic-to-brand price ratios.

3a. Generic-to-brand price ratio for product “p” in month “m” using AMP:

$$GenBrandRatio(AMP)_{p,m} = AvgGenPrice(AMP)_{p,m} \div BasePrice(AMP)_{p}$$

3b. Generic-to-brand price ratio for product “p” in month “m” using invoice prices:

$$GenBrandRatio(Invoice)_{p,m} = AvgGenPrice(Invoice)_{p,m} \div BasePrice(Invoice)_{p}$$

For each product-month we also observe the number of producers actively marketing a generic version. The main figure presents generic-to-brand price ratios for generics with the same number of competitors.

We estimate median price ratios for the two price measures, treating monthly data on each product as independent observations. We do this separately using AMPs and invoice prices.

4a. Median generic price relative to brand price using AMP:

$$MedianGenBrandRatio(AMP)_{p,m} = \left(\frac{1}{n}\right)\sum\left[MedianBrandRatio(AMP)_{p,m}\right]$$

4b. Median generic price relative to brand price using invoice prices:

$$MedianGenBrand(Invoice)_{p,m} = \left(\frac{1}{n}\right)\sum\left[MedianBrandRatio(Invoice)_{p,m}\right]$$

We find the median generic-to-brand price ratio using AMPs to be 40%. This is equivalent to a 60% reduction in price from generics when using AMP data. Using invoice prices, we find the median generic-to-brand price ratio to be 49%. This is equivalent to a 51% reduction in price from generics compared to brand drugs when using data on invoice prices. For perspective, 61% percent of all observations of generic drug products in the sample had one or two generic competitors. In summary, estimates of median price reductions based on AMPs are 18% greater than those using invoice-based price data from IQVIA's NSP. (60% ÷ 51% = 118%).

To see the similarity between the AMP and invoice-based price ratios, recall that Sood et al. (2017), reported average wholesale markups of 19% for generic drugs and 1% for brand drugs. Using these values, we can adjust the generic-to-brand invoice price ratios to calculate an imputed manufacturer's price:

$$\begin{aligned} &GenBrandRatio(Imputed\ Manufacturer's\ Price)_{p,m} \\ &\quad = GenBrandRatio\ (Invoice)_{p,m} \div \left(\frac{1.19}{1.01}\right) \end{aligned}$$

This adjustment yields differences that are much smaller than between the AMP data and the unadjusted invoice prices. Specifically, applying this adjustment factor yields an imputed median manufacturer's price ratio of 41.6% (41.6% = 49%/ (1.19/1.01)), slightly above the median generic-to-brand AMP price ratio of 40%.

The following table lists the numerical estimates reported in the main figure.

Generic-to-Brand Price Ratios in the Main Figure				
Average Manufacturer Price				
Generic Producers	**Product-Months**	**25th pctl**	**Median**	**75th pctl**
1	1,231	0.448	0.614	0.743
2	1,015	0.351	0.465	0.615
3	482	0.263	0.322	0.425
4	267	0.153	0.212	0.312
5	170	0.084	0.144	0.254
6	86	0.043	0.061	0.107
7	130	0.019	0.040	0.111
8	49	0.020	0.049	0.058
9	51	0.009	0.012	0.021
10+	207	0.007	0.010	0.018
Invoice-Based Wholesale Price				
Generic Producers	**Product-Months**	**25th pctl**	**Median**	**75th pctl**
1	1,231	0.506	0.696	0.780
2	1,015	0.461	0.562	0.667
3	482	0.370	0.447	0.538
4	267	0.177	0.268	0.371
5	170	0.103	0.152	0.222
6	86	0.063	0.099	0.137
7	130	0.032	0.059	0.184
8	49	0.038	0.076	0.120
9	51	0.016	0.027	0.044
10+	207	0.015	0.022	0.032