

Increasing Prices Set by Drugmakers Not Correlated With Rebates

An analysis prepared by Visante on behalf of



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Executive Summary

As the debate over high drug prices has intensified, drugmakers have attempted to shift focus away from the increasing prices they set towards the price concessions (rebates) that they negotiate with pharmacy benefit managers (PBMs), entities that work on behalf of employers, unions, health plans, and government programs that offer prescription drug coverage. Indeed, some manufacturers even argue that increasing drug prices are somehow caused by or correlated with rebates. The Pharmaceutical Care Management Association (PCMA) commissioned Visante to study this issue and this expanded analysis shows that there is no correlation between rebate levels and price increases.

Major findings

No Correlation Between Increasing Prices Set by Drugmakers and Rebates for Top 200 Brand Drugs

- Based on an analysis of price growth and estimated rebate levels for the top 200 brand drugs by 2016 U.S. sales, we find no correlation between the increasing prices that drugmakers set on individual drugs and the rebates that they negotiate with PBMs on those products.
- Top brand drugs that offered little to no commercial-sector rebates during the 2011-2016 time period still increased their prices.
- Manufacturers are increasing drug prices regardless of rebate levels negotiated by PBMs, based on an analysis of drug prices and rebates in the commercial sector.

Drugmakers Raise Prices Even When Rebates are Low in Major Drug Categories

• Drugmakers have increased list prices an average 125% on multiple sclerosis drugs from 2011 to 2016, despite relatively low rebates on these medications. This has resulted in an average net price increase of \$3,232 per prescription for MS drugs over that time period.

Executive Summary (continued)

Major findings

Drugmakers Raise Prices Even When Rebates are Low in Major Drug Categories

 Large list price increases for rheumatoid arthritis drugs and anticonvulsants—two categories with relatively low rebates—have resulted in similarly high net price increases for those medications after rebates are deducted.

Rebates Unrelated to the Launch Prices of New Drugs

- In addition to price increases on existing drugs, higher launch prices on new medications have also contributed to rising prescription costs, however these trends are not correlated with drug rebate levels negotiated by PBMs.
- Among the top 200 brand drugs by 2016 sales, the launch prices for drugs introduced from 2012 to 2016 were double the launch prices for those introduced prior to 2012.
- While rebates for the second drug introduced into a competitive class are higher than the first drug's rebate 72% of the time, the chance of the second drug having a higher launch price than the first drug is only 50%.

Top 200 Brand Drugs: Growing Drug Prices Show No Correlation With Average Rebate Levels Over the 2011-2016 Period

- Among the top 200 brand drugs, there is no correlation between the growing prices set by drugmakers and the average rebate levels that they negotiate with PBMs.
- Drugs with little to no commercial-sector rebates still increased their prices during the 2011-2016 period.
- For each of the top 200 brand drugs by 2016 sales that were launched prior to 2012, Figure 1 plots the compound annual growth rate (CAGR) in its list price against its estimated average percent rebate over the 2011-2016 period.
- The flat trend line in Figure 1 suggests that drug prices are increasing regardless of rebate levels across all top brand drugs.
- Statistical analysis shows the trend line's R² value equals 0.018 on a zero to one scale, where zero equals no correlation and one equals perfect correlation.
- A similar analysis also shows no correlation between <u>changes</u> in rebate levels and list price growth for these products.

Figure 1:
No Correlation Between Increasing Drug
Prices and Average Rebate Levels

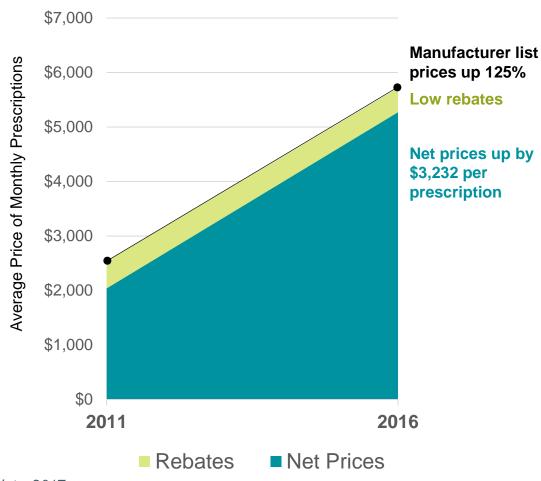


Drug Category: Multiple Sclerosis

Drugmakers Raise Prices Even When Rebates are Low

- Multiple sclerosis (MS) drugs have had high price increases yet rebates on MS drugs are low
- Visante analyzed data on gross vs. net expenditures for six MS drugs on the market for each year of the 2011-2016 time period.
- The estimated average list price (WAC)* per month was \$2,536 in 2011, increasing 125% to \$5,717 in 2016.
- The estimated average net price (net of rebate) per month was \$2,038 in 2011, increasing by \$3,232 to \$5,270 in 2016.
- The weighted average rebate level for these drugs for the 2011-2016 period was 7%.

Figure 2: List Prices for Multiple Sclerosis Drugs Up 125%, With Net Prices Increasing Similarly



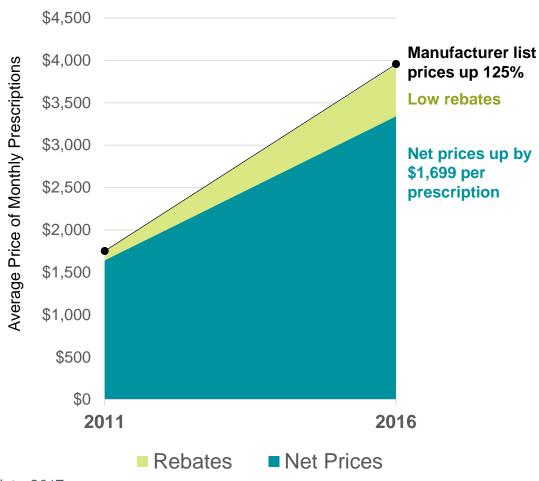
* Wholesale Acquisition Cost

Drug Category: Rheumatoid Arthritis

Drugmakers Raise Prices Even When Rebates are Low

- Rheumatoid arthritis drugs (DMARDs) have high price increases, yet rebates on these drugs are low.
- Visante analyzed data on gross vs. net expenditures for five drugs for rheumatoid arthritis (DMARDs) on the market for each year of the 2011-2016 time period.
- The estimated average list price (WAC)* per month for these drugs was \$1,753 in 2011, increasing 125% to \$3,944 in 2016.
- The estimated average net price (net of rebate) per month for these drugs was \$1,641 in 2011, increasing by \$1,699 to \$3,340 in 2016.
- The weighted average rebate level for these drugs for the 2011-2016 period was 11%.

Figure 3: List Prices for Rheumatoid Arthritis Drugs Up 125%, With Net Prices Increasing Similarly



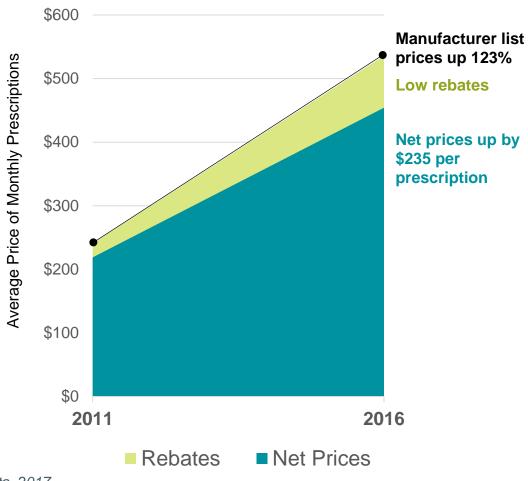
* Wholesale Acquisition Cost

Drug Category: Anticonvulsants

Drugmakers Raise Prices Even When Rebates are Low

- Anticonvulsant drugs have high price increases, yet rebates on these drugs are relatively low.
- Visante analyzed data on gross vs. net expenditures for three anticonvulsant drugs on the market for each year of the 2011-2016 time period.
- Estimated average list price (WAC)* per month was \$241 in 2011, increasing 123% to \$536 in 2016.
- Estimated average net price (net of rebate) per month was \$219 in 2011, increasing by \$235 to \$454 in 2016.
- The weighted average rebate level for these drugs for the 2011-2016 period was 14%.

Figure 4: List Prices for Anticonvulsant Drugs Up 123%, With Net Prices Increasing Similarly

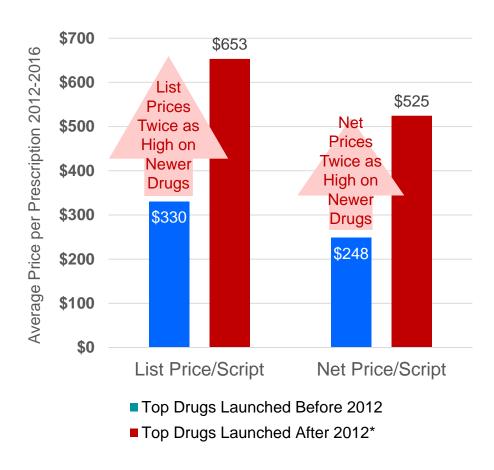


* Wholesale Acquisition Cost

Prices For Top Brand Drugs Launched After 2012 Are Double The Prices For Top Brand Drugs Launched Before 2012

- In addition to price increases on existing products, higher launch prices on new brands have also contributed to rising prescription costs, however these trends are not correlated with drug rebate levels negotiated by PBMs.
- Within the top 200 brand drugs by 2016 sales, drugs launched after 2012 are priced twice as high as drugs launched before 2012.
- The average list price for a top 200 brand drug launched after 2012 was \$653 over the 2012-2016 time period, while the average list price for a top 200 brand drug launched before 2012 was just \$330.

Figure 5: Prices for Newer Drugs Twice as High

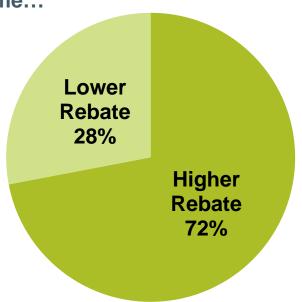


^{*} Excludes drugs for Hepatitis C, which would significantly skew both list and net costs for drugs launched after 2012 even higher. Source: Visante estimates and analysis of SSR Health data, 2017.

Rebates Unrelated to the Launch Prices of New Drugs

Figure 6

Rebates for the 2nd drug introduced into a competitive class are higher than the 1st drug's rebates 72% of the time...



... but although rebates are often higher, the chance of the 2nd drug having a higher price than the 1st drug is only 50%.

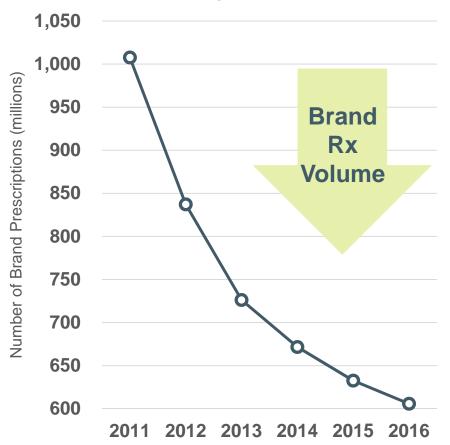


Visante analyzed data on the top 200 drugs by 2016 gross sales. We examined list prices (WAC) and net prices (net of estimated rebate) during period 2007-2016, where a category had only one drug, and then a second drug entered the category as a new competitor. Rebates for the new competitor in the category are usually more than the rebates for existing product, but the entry list price for the new competitor is often less than or equal to the existing product.

Why Are Manufacturers Increasing Prices? Perhaps To Counter Shrinking Prescription Volume For Brand Drugs

Figure 7

Brand Prescription Volume Has Plummeted As Generics Have Replaced Brands



Meantime, Brand Drug Prices Have Skyrocketed To Maintain Revenues



Source: Visante analysis data published by the QuintilesIMS Institute, 2017.

Methodology

- Visante examined commercially available data from SSR Health on list price (as measured by the widely-used Wholesale Acquisition Cost (WAC) price benchmark) and gross sales, as well as net prices and net sales (net of estimated rebates) for the 2007-2016 time period for the top 200 self-administered, patent-protected, brand-name drugs by 2016 gross sales. For methodological use, SSR Health also provided summary statistics for gross and net sales for all 1000+ brand-name drugs in their database.
- Visante excluded intravenous drugs and other products administered in hospitals, clinics, or physician offices, because these products are often reimbursed outside the pharmacy benefit administered by PBMs, and often have different types of discounts from manufacturers.
- Within the sample of the top 200 self-administered, patent protected, brand-name drugs, 24 drugs were excluded because of incomplete data for the study time period, leaving a remaining sample of 176 drugs for analysis.
- The sample of 176 drugs was divided into two subsets: one subset of 118 drugs launched before 2012, and another subset of 58 drugs introduced after 2011. We focused our analysis on the former, so we had complete data for the entire study period of 2011-2016. However, we found similar results (i.e., no correlation between price increases and rebates or rebate increases) in the latter subset.
- SSR Health estimates "total discounts" for each drug by estimating total gross expenditures from a commercial
 proprietary database, and total net sales based on figures reported by manufacturers in 10-Q reports and other public
 data.
- SSR Health provided quarterly estimates for each drug on total sales and price-per-unit for gross expenditures and net sales (net of discounts) for Medicaid and non-Medicaid markets.
- Visante used non-Medicaid markets as a proxy for commercial and Medicare Part D, where PBMs predominate.
 Visante estimates that commercial and Medicare Part D make up more than 90% of the drug spend in non-Medicaid markets.
- Average rebate levels (percentages) for each year were calculated by comparing total WAC sales vs. total net sales (i.e., sales net of rebates, using adjusted discounts reflecting estimated rebates, excluding other discounts).

Methodology

- Estimated rebates for each drug reflect an average across the entire U.S. for non-Medicaid markets. In other words, some PBMs or plan sponsors may have higher rebates and some may have lower rebates.
- Since the timing of manufacturer net sales to wholesalers does not always match up with the dispensing of prescriptions to pharmacies, we used a three-quarter moving average.
- In order to estimate rebates in the commercial and Medicare Part D markets, Visante made adjustments to the "total discounts" by excluding:
 - Medicaid rebates estimated by SSR Health for each individual drug based on statutory required rebates plus CPI-penalties for historical price increases greater than the CPI.
 - Prompt pay discounts and other discounts to wholesalers and distributors estimated at 4.75% based on Pembroke estimates.¹
 - Copay and patient assistance programs were estimated at 2% of gross brand expenditures in non-Medicaid markets based on a recent report.²
 - Part D coverage gap discounts were estimated at 2% of total gross expenditures in non-Medicaid markets based on a recent report.³
 - 340B discounts were not explicitly excluded. Although 340B discounts are increasing in total size, they are spread between brands/generics, self-administered/take-home prescriptions vs. physician/clinic administered, and Medicaid vs. non-Medicaid.
- Drugs were placed in categories determined by therapeutic classes or FDA-approved indications. Categories with two
 or more drugs were included in the "category analyses."
- Based on published data, an average of 90% of rebates are passed through to plan sponsors.^{4,5}
- ¹ The 2017 Economic Report On US Pharmacies and Pharmacy Benefit Managers, Drug Channels Institute, February 2017.
- ² The Pharmaceutical Supply Chain: Gross Drug Expenditures Realized By Stakeholders, The Berkeley Research Group, January 2017.
- ³ Ibid.
- ⁴ "Solving the Mystery of Employer-PBM Rebate Pass-Through," Drug Channels, January, 2016.
- ⁵ "Primer: Deconstructing the PBM Business Model in Today's Marketplace," Bank of America Merrill Lynch, March, 2017.