## Understanding Drug Rebates and Their Role in Promoting Competition

By Alex Brill | March 2022





### **Executive Summary**

In the US healthcare system, insurance providers routinely contract with pharmacy benefit managers (PBMs) to handle beneficiaries' prescription drug claims. One of the functions PBMs perform is establishing formularies that help guide patients to the most appropriate, cost-effective medicines. Because formulary placement drives higher utilization of products on the formulary, PBMs can negotiate volume rebates from manufacturers that get passed back to health insurers.

In recent years, misconceptions have arisen about drug rebates. Policymakers, members of the media, and others have pointed at rebates as a cause for rising drug prices. While there is a lack of evidence that rebates increase list prices, as well as evidence to the contrary, this misconception persists.

MGA has undertaken a new analysis looking at the potential impact of rebates on drug prices. Using the formularies of the largest three PBMs from 2018 through 2021, MGA identified drugs that are most likely non-rebated and drugs that are most likely rebated. Using criteria described in the full paper, the analysis identified 92 likely non-rebated drugs and 39 likely rebated drugs and compared trends in wholesale acquisition cost (WAC) between the two groups.

The results of the analysis are illustrated in the following chart, which represents each of the identified drugs ranked by its price change. The median WAC price change from 2018 to 2021 was roughly the same for both groups of drugs— 13.9 percent for the sample of non-rebated drugs and 15.6 percent for the sample of rebated drugs. In other words, the analysis finds that price increases for rebated and non-rebated drugs were generally comparable during this period.

Despite the lack of evidence that drug rebates are the culprit behind high drug prices, policymakers remain concerned about the cost of prescription medicines. The market-based strategies most likely to constrain prices are robust competition among drug manufacturers and insurancedesign mechanisms that incentivize cost-effective treatments.



NUMBER OF DRUGS USED IN ANALYSIS

MGA

## Introduction

In the US healthcare system, insurance providers routinely contract with pharmacy benefit managers (PBMs) to handle beneficiaries' prescription drug claims. One of the functions PBMs perform is establishing formularies that encourage patients to choose the most appropriate, costeffective medicines. Because formulary placement drives higher utilization of products on the formulary, PBMs can negotiate volume rebates from manufacturers. These rebates end up having a threefold benefit to the healthcare system: they lower health insurance premiums for beneficiaries, they drive price competition among drug manufacturers, and they help facilitate PBMs' clinical tools. In recent years, however, misconceptions have arisen about drug rebates. Policymakers, members of the media, and others have pointed at rebates as a cause for rising drug prices. This paper demonstrates how drug rebates, when used appropriately, are an important tool in encouraging competition in the pharmaceutical market.<sup>1</sup> The paper also presents an original analysis of price trends in rebated drugs and non-rebated drugs over the last four years. This analysis finds that, contrary to claims about rebates driving up prices, the price changes for drugs identified as rebated are comparable to the price changes for drugs identified as non-rebated.

### How Rebates Work

To understand rebates, it is helpful to start with the pharmaceutical supply chain and drug reimbursement in the United States, which can be complex. In general, a drug manufacturer will make a medicine and sell it to a wholesaler, who then sells it to a pharmacy.<sup>2</sup> When a patient with health insurance fills a prescription for the drug at a pharmacy, the patient usually pays a copay or coinsurance while the health insurance provider covers the rest of the cost. It is in the interest of the patient as well as all members of the health insurance plan for the insurance company to help the patient choose the most cost-effective option. This is where a PBM comes in.

<sup>&</sup>lt;sup>1</sup> There has been evidence of some drug manufacturers using tactics known as "rebate walls" or "rebate traps" to block competitors. As the Federal Trade Commission (2021) explains, "Rebate walls refer to a situation in which a dominant pharmaceutical manufacturer uses rebate strategies in its contracts with third party payors to maintain market power, by giving its products preferred status in drug formularies, and to prevent sales of competing products." Sometimes traditional, pro-competitive rebates are conflated with this kind of practice, which impedes competition. It is important to distinguish this anticompetitive behavior from traditional drug rebates that foster competition, contain costs, and benefit consumers.

<sup>&</sup>lt;sup>2</sup> There are sometimes secondary players in the supply chain, such as repackagers.

PBMs have an important function as intermediary between health insurance providers and drug manufacturers. In addition to processing patients' drug claims, PBMs develop, as mentioned above, what is called a formulary-that is, a list of drugs that are clinically appropriate for patients across a spectrum of diseases. Typically, an insurer will offer the greatest coverage for medicines on the formulary, thus encouraging patients to use these products first. Because preference for a medicine on a formulary will drive volume for that medicine, the PBM is able to negotiate a rebate—or volume discount—from that drug's manufacturer on behalf of the insurer. The manufacturer then pays the negotiated rebate to the PBM after patients receive the rebated product.

Rebates reduce the net cost of drugs for the insurance provider and can ultimately be used to lower insurance premiums for all members. In an analysis of PBMs' role in Medicare Part D, the Government Accountability Office found that, on average, PBMs passed on 99.6 percent of rebates to health insurers (*2019*).

One challenge related to rebates arises when a patient's cost sharing is a percentage of a drug's list price. In these cases, while rebates still facilitate lower health insurance premiums, patient out-of-pocket costs for a drug may not reflect the lower net price.

#### DRUG REBATES, COMPETITION, AND THE "REBATE RULE"

Three decades ago, recognizing that drug rebates serve a legitimate function, Congress created a safe harbor for rebates from the anti-kickback statute, the law that has long banned the use of remuneration to obtain business from federal healthcare programs. As the Federal Trade Commission (FTC) has explained, rebates promote competition in the prescription drug market, and PBMs can achieve the greatest savings precisely because rebates are confidential:

Whenever PBMs have a credible threat to exclude pharmaceutical manufacturers from their formulary, manufacturers have a powerful incentive to bid aggressively. Willingness to bid aggressively, however, is affected by the degree of transparency with respect to the terms that pharmaceutical companies offer PBMs. Whenever competitors know the actual prices charged by other firms, tacit collusion—and thus higher prices may be more likely. (*FTC, 2004*)

In recent years, however, some have targeted drug rebates as problematic and blamed them for rising drug prices. In February 2019, the Trump administration proposed a regulation restricting drug rebates in Medicare Part D and Medicaid Managed Care Organizations. This "rebate rule" was met with strong resistance from economists and health policy scholars, who articulated its threat to competition.

In testimony before the House Judiciary Subcommittee on Regulatory Reform, Commercial and Antitrust Law, Yale University economist Fiona Scott Morton assured members that the rebate rule would reduce competition. In her written testimony, she explained, "The PBM's role of seeking out discounts from manufacturers is critical because it is one of the few agents *in our commercial pharmaceutical marketplace that creates price competition*" (2019, emphasis in original).

Also responding to the rebate rule, Northwestern University health economist Craig Garthwaite wrote, "Confidential rebates are necessary to secure large discounts because when a manufacturer knows all of its customers won't observe a big discount it gives to a particular client, it is more willing to give such a large discount in the first place" (2019).



Indeed, the Office of the Actuary within the Centers for Medicare and Medicaid Services (CMS) found that, by banning rebates in Part D, the rebate rule would raise premiums for beneficiaries and increase Medicare spending by nearly \$200 billion over ten years (*HHS, 2019*). Given the opposition, the Trump administration announced in July that the rebate rule would not be finalized but then reversed that decision and pushed it through in the president's final months in office, to be effective January 2022. Its implementation was delayed by the Biden administration until January 2023. Then, in legislation enacted in August 2021, Congress further extended the delay to 2026.

## Evidence Related to Rebates and Drug Prices

Beyond the Trump administration's proposed rule, which lacked evidence that rebates increase list prices (*Brill, 2019*), the allegation that rebates drive up drug prices has been the subject of much discussion. Several analyses have taken up this claim.

- The consulting firm Visante conducted an analysis of rebates in the top 200 brand drugs in 2016. The findings showed that drug price increases and negotiated rebates were not correlated (*Visante, 2017*).
- An analysis from health insurance company Humana, which used CMS data to examine the price trends in 2013–2017 of three drugs without rebates (Imbruvica, Isentress, and Revlimid), "directly refutes the suggestion that rebates are the driver of increasing drug list prices" (*Fleming, 2019*).

• Most recently, the findings from an investigation by the House of Representatives Committee on Oversight and Reform rejected claims that drug rebates are responsible for price increases:

Internal data obtained by the Committee reveals that the net prices—the prices manufacturers collect after accounting for rebates, price concessions, and other discounts—of nearly all of the drugs in the investigation increased year over year.... This data, which has never before been shared with the public, undermines industry claims that price increases are primarily due to increasing rebates and discounts paid to pharmacy benefit managers. (*Oversight Committee, 2021*)

The next section of this paper presents a new analysis of rebates and drug prices.



# Analysis of Price Trends in Rebated and Non-Rebated Drugs

The analysis presented here identifies two subsets of drugs—rebated and non-rebated—and examines list prices in 2018–2021 to compare price changes between the two groups.

#### METHODOLOGY

The two subsets of drugs were created using data extracted from 2018-2021 formularies published by the three largest PBMs (CVS Caremark, Express Scripts, and OptumRx). Given the confidential nature of rebate agreements between PBMs and manufacturers, the drugs identified for this analysis were determined to be most likely rebated and most likely not rebated based on the following criteria: Single-source brand drugs were assumed to be rebated if they were included on at least one of the three PBM formularies for every year. Single-source brand drugs were assumed to be non-rebated if they were excluded from or on Tier 3 (that is, non-preferred) on all three PBM formularies for every year. Additional details on the sample construction are provided in the appendix.

To compare price trends between these two subsets, the analysis used the wholesale acquisition cost (WAC)—an estimate of the manufacturer's list price not including discounts or rebates for each drug's national drug codes (NDCs) for every year from 2018 through 2021. WAC prices by NDC were obtained from the Medi-Span Price Rx database. The simple average WAC price was calculated across each drug's NDCs for each year and the percentage change observed over the period.

#### RESULTS

**Chart 1** shows the WAC price change from 2018 to 2021 for each of the identified drugs ranked by the price change. The median price change from 2018 to 2021 was roughly the same for both groups of drugs—15.6 percent for the sample of 39 rebated drugs and 13.9 percent for the sample of 92 non-rebated drugs. Half of the rebated drugs experienced WAC price increases between 9 percent and 24.2 percent while the same 25th–75th percentile range for the non-rebated drugs was 9.4 percent to 21 percent. A few of the non-rebated drugs in the sample experienced very large price increases.

In short, the analysis finds that price increases for rebated and non-rebated drugs, identified using the methodology detailed above, were generally comparable during this period.

The median price change from 2018 to 2021 was roughly the same for both groups of drugs.



#### CHART 1. WAC PRICE CHANGES 2018-2021: REBATED VS. NON-REBATED DRUGS



NUMBER OF DRUGS USED IN ANALYSIS

**Source:** MGA analysis of PBM formularies to identify drugs that are likely non-rebated and drugs that are likely rebated in all years (2018–2021). WAC prices derived from Medi-Span's Price Rx database.

**Note:** Five non-rebated drugs are not shown here because of the impact they would have on the scale. One product experienced a WAC price decrease of 35%, and four products experienced WAC price increases of 104%, 238%, 367%, and 884%.

## Need for Meaningful Solutions to Lower Drug Prices

Despite the lack of evidence that drug rebates are the culprit behind high drug prices, policymakers remain concerned about the cost of prescription medicines. Some patients experience very high out-of-pocket costs for medicines, costs that can inhibit access to these medicines and impose other financial hardships. Other individuals have experienced burdensome increases in health insurance premiums in part due to new and/or expensive medicines. The market-based strategies most likely to constrain prices are robust competition among drug manufacturers and insurance-design mechanisms that incentivize cost-effective treatments. Policymakers and regulators should ensure that payers can realize the benefits of drug competition achieved by PBMs and promote both robust generic drug competition and effective brand-to-brand competition through timely and efficient drug approval processes.



## Appendix

To construct our samples of rebated and non-rebated drugs, we collected formularies for 2018-2021 from the three largest PBMs (CVS Caremark's Performance Drug List — Standard Control, Express Scripts' National Preferred Formulary, and OptumRx's Select Standard Formulary) and extracted data from each. The OptumRx formularies identify three tiers of drugs: Tier 1 are the lowest-cost drugs (primarily generics), Tier 2 are midrange cost (preferred brand drugs), and Tier 3 are the highest-cost drugs (non-preferred). The Express Scripts formularies list preferred drugs and excluded medications, and CVS Caremark's formularies list preferred drugs with preferred options.

#### NON-REBATED SAMPLE CONSTRUCTION

We classified drugs as most likely non-rebated if they were listed as Tier 3 (that is, non-preferred) on OptumRx formularies, were excluded on Express Scripts formularies, or had preferred options on CVS Caremark formularies. Beginning with 2021 formularies, we used a partial string similarity matching algorithm to identify drugs that met these criteria. We then checked this list of drugs against data extracted from 2018–2020 formularies. Drugs that maintained our non-rebated classification criteria for 2018–2021 were retained for analysis. If a drug was preferred on any of the three formularies for any year, it was excluded.

#### **REBATED SAMPLE CONSTRUCTION**

We classified drugs as most likely rebated if they were listed as Tier 1 or Tier 2 on OptumRx formularies, were preferred on Express Scripts formularies, or were preferred on CVS Caremark formularies. Beginning with the top 200 prescription drugs by retail sales, based on 2020 data from LePro PharmaCompass OPC Private Limited, we identified drugs that met these criteria on 2021 formularies. We then checked this list of drugs against data extracted from 2018-2020 formularies. Drugs that were included on at least one of the three formularies for every year were assumed to be rebated.

#### FURTHER REFINEMENT OF SAMPLES

We restricted both samples to single-source brand drugs, using data from the Food and Drug Administration's (FDA) Drugs@FDA database and the "Purple Book," the FDA's database on biological products, to identify products without generic or biosimilar competitors. We also excluded drugs that were released during the period we analyzed.

Using the methodology described here, we arrived at a non-rebated sample of 92 drugs and a rebated sample of 39 drugs. Other plausible inclusion and exclusion criteria could generate more or fewer drugs in each sample and result in changes in the median increase in WAC during the sample period. Moreover, we make no claims about the impact for different time periods and recognize that consideration of other PBMs could also affect the sample. Because we are relying only on publicly available information, there is an inherent uncertainty about the construction of each sample. Nevertheless, we believe we have captured current and reliable data from the largest PBMs using a consistent and unbiased methodology.



#### SOURCES

Brill, Alex. 2019. "Concerns Regarding the Proposed Rule to Restrict Drug Manufacturer Rebates in Medicare Part D and Medicaid MCOs." April. www.GetMGA.com/wp-content/uploads/2019/04/ MGA-Report-on-Proposed-Rebate-Restriction-3.pdf.

Department of Health and Human Services (HHS). 2019. "Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees," *Federal Register* 84, no. 25 (February 6): 2340–63.

Federal Trade Commission (FTC). 2004. Letter to California Assembly Member Greg Aghazarian. September 7.

FTC. 2021. Report on Rebate Walls. May.

Fleming, William K. 2019. Testimony before the Senate Committee on Finance. "Drug Pricing in America: A Prescription for Change, Part III." April 9. Garthwaite, Craig. 2019. "Making Markets Work for Pharmaceuticals," Forbes.com. March 12.

Government Accountability Office (GAO). 2019. "Medicare Part D: Use of Pharmacy Benefit Managers and Efforts to Manage Drug Expenditures and Utilization." July.

Scott Morton, Fiona M. 2019. Testimony before the House Judiciary Subcommittee on Regulatory Reform, Commercial and Antitrust Law. "Diagnosing the Problem: Exploring the Effects of Consolidation and Anticompetitive Conduct in Health Care Markets." March 7.

US House of Representatives Committee on Oversight and Reform. 2021. *Drug Pricing Investigation: Majority Staff Report*. December.

Visante. 2017. "Increasing Prices Set by Drugmakers Not Correlated with Rebates." June.

#### **ABOUT THE AUTHOR**

Alex Brill is the founder and CEO of Matrix Global Advisors (MGA). He previously served on the staff of the House Ways and Means Committee and the White House Council of Economic Advisers.

#### **ABOUT MGA**

Matrix Global Advisors (MGA) is an economic consulting firm in Washington, DC, specializing in healthcare, tax, and fiscal policy. Drawing on years of policy experience, the MGA team uses analytics to help identify, quantify, and solve economic policy problems. On behalf of clients, we conduct original data analysis, construct economic models, conduct research, write white papers and expert reports, and offer strategic advice. Through the use of analytical tools and knowledge of the political and legislative process, MGA helps clients navigate legislative and regulatory proposals, craft policy reforms, and measure their own businesses' economic footprints.

This report was sponsored by the Coalition for Affordable Prescription Drugs. The author is solely responsible for the content. Any views expressed here represent only the views of the author.

