Growing Attention Being Paid to Pharma Company Rebates and Discounts

January 2019

Growing Attention Being Paid to Pharma Company Rebates and Discounts

George A. Chressanthis, Ph.D., Principal Scientist, Axtria Inc.
Devesh Verma, Ph.D., Principal, Axtria Inc.

> The free market is alive and well when it comes to drug prices – if you're an insurance company or a government program. But not if you're a consumer.[1]
>
> **Matthew Herper**
> *From "Inside The Secret World Of Drug Company Rebates",* Forbes *(2012)*

> To take one example, one of the dynamics I've talked about before that's driving higher and higher list prices, is the system of rebates between payers and manufacturers.
>
> **Scott Gottlieb**
> **M.D., FDA Commissioner**
> *Comments from his keynote address at the 2018 Food and Drug Law Institute Annual Conference, Washington, DC (May 3, 2018)*

1. Total US Pharma Industry Rebates and Discounts

Drug company rebates and discounts have always been an opaque aspect of the pharma industry as the above referenced title for the first opening quote suggests. There is little transparency in how much drug companies pay in rebates and discounts, though indications are it is annually in the tens of billions of dollars for the industry, and more importantly, the amount is growing. Price concessions can significantly vary by individual company depending on the portfolio mix and individual therapy class competition facing each drug. Also, rebate and discount amounts are growing over time, greatly affecting biopharma company margins. *Total 2017 US pharma industry from rebates, discounts, and other price concessions equaled $129 billion*, using $453 billion of total invoice spending and $324 billion on a net basis, for a reduction of gross to net spending by 28%.[2] This paper looks at the growing trend of rebates and discounts by addressing the following questions:

a. How much do selected companies pay in rebates and discounts (and by type)?

b. What are the reasons for this growing trend in rebates and discounts?

c. What are the implications for pharma companies on commercial decisions caused by paying greater rebates and discounts?

2. Selected Company-specific Rebates, Discounts, and Price Concessions

Interestingly, trying to determine rebates and discounts from individual company financial reports does not yield a

straightforward answer as to the total amount paid in price concessions and by type. There is no standard reporting across companies. We reviewed 3 company 2017 annual reports containing financial statements for Pfizer, GSK, and AbbVie.[3-5] All the reports noted specific challenges in calculating all price concessions and indicated the trend over time as a financial risk to company business performance. Here are some figures listed by company.

2.1 Pfizer

Pfizer listed $19.126 billion in total revenue reductions in their 2017 annual report.[3] This figure was broken down by the following specific reductions:[3]

- $1.316 billion – Medicare rebates
- $1.860 billion – Medicaid and related state program rebates
- $3.245 billion – Performance-based contract rebates (these are for both US and non-US performance-based contracts)
- $6.047 billion – Chargebacks (goes to US wholesalers for honoring contracted prices to third parties)
- $5.165 billion – Sales allowances (for price reductions outside the US)
- $1.483 billion – Sales returns and cash discounts

2.2 GSK

The GSK Independent Auditors' Report specifically highlighted rebates, discounts, allowances, and returns for the US pharmaceuticals and vaccines business as being complex and where the environment shows heightened price competition and the amount of discounts are increasing prevalent.[4] An accrual of £2.837 billion ($3.834 billion) on 31 December 2017 will be necessary to cover discounts, up from £2.218 billion ($2.737 billion) on 31 December 2016.[4]

2.3 AbbVie

AbbVie noted total rebates and chargebacks as $12.9 billion (2017), $10.8 billion (2016), and $8.6 billion (2015).[5] Cash discounts and product returns for the same period totaled $1.3 billion (2017), $964 million (2016), and $898 million (2015).[5]

2.4 Eli Lilly, J&J, Merck

Lastly, for a sample of other companies in 2017 gathered from a third-party source, Eli Lilly discounted list prices by 51%, while J&J offered $15 billion in discounts where average net prices fell by 4.6%, and for Merck net prices after discounts decreased by 1.7%.[6]

This reporting of selected companies reveals, though not comprehensive, is that rebates and discounts are significant, and as noted in the company financial reports we specifically reviewed, represent a financial risk to each organization. What then are possible reasons for this growing trend of greater rebates, discounts, and other price concessions?

3. Reasons Behind Greater Use of Rebates and Discounts

This trend towards a greater use of rebates and discounts is due to a number of forces. One is the growing influence of payers and pharmacy benefit managers (PBMs) to extract payments from companies for a preferred formulary status of their growing list of expensive specialty medicines. These specialty medicines also face affordability and access issues, increasing pressures for patented branded to generic drug substitution, and similarly, increasing switching from reference biologic to biosimilar drugs, as payers focus on controlling drug costs. Pharma companies are also using co-pay discounts to increase patient drug adherence by increasing prescription coverage from 30 to 90 days.[2] What is becoming more evident is that as rebates and discounts grow in amounts, greater clarity has been shown onto this opaque world of the drug industry, with greater attention given in just the past six months, though for different reasons.

3.1 Reason #1 – Maintaining drug access and the growth of co-pay offset programs

The IQVIA Institute for Human Data Science found in their review of medicine use and spending in the US for 2017 published in April 2018 that overall net drug spending from 2016 to 2017 essentially remained flat, with rebates, discounts, and other price concessions accounted for 28% of the decline in invoice spending, and contributed to a slight *decrease* (-2.1%) for retail and mail order spending.[2]

PBMs have used rebates to offer favorable formulary positions to branded pharmaceutical drugs. These PBMs have used such rebates to let pharmaceutical brands in the same therapeutic category compete with each other to gain better formulary access. Good formulary access is a very important need for brand financial success as there is a very strong correlation between access and sales.

In response to PBM desires to extract greater rebates from pharma companies, brands have now designed various co-pay offset programs to work around PBM formulary designs. Usage of such co-pay cards has significantly increased over time and at the same time, their offers have become increasingly generous. It is not uncommon now to find a "pay $0 per month for a commercially insured patient" co-pay offset program. Many times, these co-pay offset programs are making a branded product cheaper than other generics in the marketplace. Pharma companies have started treating any co-pay benefit offer to the patients as part of gross-to-net conversion, hence reducing the topline sales in the same way as rebates would impact the P&L statement.

PBMs have started complaining about co-pay offset programs, as these programs also impact brand utilization, which can at times increase the cost burden for the payer and decrease the amount of rebates they can collect from a favorable tiered program. But given the popularity of such co-pay offset programs with healthcare providers and patients, most PBMs have not gone to government enforcement agencies to request any change. One notable difference on co-pay programs is that these programs are not available to patients on federally or state funded programs (Medicare and Medicaid). All government funded programs prohibit usage of co-pay offset programs and want pharma companies to ensure that their co-pay offset programs explicitly exclude patients on government programs. This helps the government agencies enforce their formulary designs, but at the same time negatively impacts economically vulnerable patients who have the greatest need for a reduced co-pay.

Lastly, one question to ask is whether this approach by pharma companies to maintain drug access, by reducing their own margins through increasing price concessions as R&D costs and risks rise to bring new novel medicines to the market,[7] is an economically viable long-run business strategy? What would be preferred is for companies to adopt a new commercial business model that is less reliant on rebates and discounts to gain market access and increase the diffusion of new drug technology to the healthcare system that ultimately benefits patients. Otherwise, better

resource management of rebates, discounts, and other price concessions are sorely needed.

3.2 Reason #2 – Lowering drug prices and out-of-pocket costs

The Trump Administration rolled out its *American Patients First* blueprint to lower drug prices and reduce out-of-pocket costs in May 2018.[8] Under the blueprint section on incentives to lower list prices are the following further opportunities noted to achieve this goal focusing on reforms of rebates and discounts:[8]

1. Measures to restrict the use of rebates, including revisiting the safe harbor under the Anti-Kickback Statute for drug rebates.
2. Additional reforms to the rebating system.
3. Using incentives to discourage manufacturer price increases for drugs used in Part B and Part D.
4. Considering fiduciary status for PBMs.
5. Reforms to the Medicaid Drug Rebate Program.
6. Reforms to the 340B Drug Discount Program.
7. Considering changes to US Department of Health and Human Services regulations regarding drug co-pay discount cards.

The current drug pricing system not only discourages reducing list prices but also raises questions as to whether these rebates and discounts paid to PBMs are indeed being passed onto consumers in the form of lower out-of-pocket costs. The suspicion is that consumers are not benefitting from these higher levels of rebates and discounts.[9] Evidence supporting this suspicion is the lack of transparency on the distribution effects of rebates and discounts and higher drug cost shifting by payers happening to patients.[2] Additional factors are concerns of greater economic burdens for drug spending placed on people and the healthcare system,[2,10-12] and especially on the elderly (where higher medical bills are a key factor driving more elderly into bankruptcy)[13] to pay for prescription drugs. The dilemma for pharma companies is just as the science of medicine is unlocking the secrets on how to combat the most difficult diseases, we are also reaching limits on what society is willing and able to pay for the development and diffusion of this drug innovation. While solutions to this dilemma will be difficult to find, this much we likely know as to what will be needed: (1) the application of advanced analytics on new datasets, that can generate insights into patient and healthcare system health and economic outcomes, and (2) using technology such as AI/ML (artificial intelligence/machine learning) to provide faster insights, quicker response times, and more accurate predictions.

3.3 Reason #3 – Delaying the diffusion of lower-cost biosimilars

FDA Commissioner Scott Gottlieb recently charged in July 2018 that rebates provided by reference biologic companies are being used to prevent the diffusion of lower-cost biosimilars, thus contributing to lower competition and higher prices to patients, and higher cost burdens to the healthcare system. In a recent statement, FDA Commissioner Scott Gottlieb noted the following regarding the improper use of rebates (italic highlight added):[14]

> "While the FDA has approved 11 biosimilars through 2018, only three are now marketed in the US. Competition is, for the most part, anemic. It's anemic because consolidation across the supply chain has made it more attractive for manufacturers, Pharmacy Benefit Managers, Group Purchasing Organizations and distributors to split monopoly profits through lucrative *volume-based rebates on reference biologics* - or on bundles of biologics and other products - rather than embrace biosimilar competition and lower prices."

The above remarks are part of a broader initiative entitled the FDA Biosimilars Action Plan unveiled in July 2018 to promote greater innovation and competition in the market for biologics and biosimilars.[15] The irony in reviewing reasons #2 and #3 is that on one hand research-based pharma companies complain how rebates and discounts to PBMs are not filtering down to benefit patients in lowering out-of-pocket costs, while at the same time allegedly using rebates and discounts to limit competition of biosimilar entry that would lower patient out-of-pocket costs.

4. What Does Greater Attention to Rebates and Discounts Mean for Pharma Company Commercial Decisions?

Pharma companies will need greater insights into how to manage more efficiently rebates and discounts. They also need to see a clear pathway on how to operate in a system where rebates either do not exist or occur at a substantially

lower level than current practice, especially given recent signals from the Trump Administration and comments by the US HHS Secretary Alex Azar.[16] While there exists many different viewpoints when discussing key pharma industry topics, there is one area that virtually everyone agrees on – the current opaque system of pharma rebates paid to PBMs is in need of an extensive overhaul.[17] This means moving away from a system with rebates and instead moving toward a more value-based commercial model showing how new drug adoption and utilization results in greater overall healthcare system benefits as higher attention is focused on providing more clarity into this opaque world of drug rebates.

The following non-exhaustive list of commercial relationships come to mind that are in need of further analysis by pharma companies:

a. *Rebate and discount optimization models and their connection to sales and marketing allocation and optimization.* All too often, pharma companies operate where the managed markets strategy and contracting groups work independent of commercial operations with processes like promotion-response analysis, and sales force and marketing-mix optimization. This must change. Rebate/discount and sales/marketing allocations should be seen both as complements and substitutes to each other. The traditional view is that sales/marketing allocation works to "pull-through" a managed care contracting advantage, thus seen as complements. However, maybe they can operate as substitutes. An econometric model framework at the payer plan level by commercial third-party, Medicare Part B and D, and Medicaid can determine the optimal mix in plan control and access design attributes with sales and marketing allocation.

b. *The relationship between rebate and discount allocation to changes in patient health outcomes and overall treatment costs.* The cynical public policy view, as noted in reasons #2 and 3, is that neither patients nor the healthcare system benefit from pharma company rebates and discounts. Again, an econometric model framework at the payer plan level can estimate the effect of rebates and discounts employed by a company on patient access and affordability, which in turn would affect patient adherence. A separate analysis can be employed to measure the relationship between changes in patient adherence to health/economic outcomes using clinical trial data and real world evidence (RWE) to complete the relationship chain. The use of AI/ML may be employed to predict how employing rebates and discounts can produce changes in outcomes using results from tested econometric models.

c. *Specific tests on the relationship between instituting and expanding co-pay offset programs with patient drug adherence and outcomes.* As noted earlier, payers have balked at the expansion of co-pay offset programs. Pharma companies balk that traditional rebates and discounts paid through PBMs may not be translating into lower out-of-pocket costs to patients, thus the expansion of co-pay offset programs. Empirical evidence showing that such programs improve health and economic outcomes would mollify those criticisms

and show they produce social healthcare system benefits. AI/ML can be employed using empirical model results to predict how expanding these co-pay offset programs can produce improvements in health and economic outcomes.

d. *The development of a new commercial model design that is value/outcomes-based (not volume based) and less reliant on rebates and discounts to gain market access (or where rebates do not exist).* The current commercial model design (CMD) emphasizes prescription volume generated in the pursuit of increasing company value measures. Rebates, discounts, and other price concessions are seen through a more myopic lens of affecting drug utilization. Would the development and execution of a value/outcomes-based commercial model design reduce the overall level of rebates and discounts, and if so, by how much? This would mean beta testing a new CMD without the use or significant allocation of rebates and discounts.

5. Closing Remarks

More attention is being given to pharma company rebates and discounts. Fortunately for pharma companies, the prevailing view is that rebates and discounts as currently applied likely do more social harm than good. The elimination of rebates will likely improve pharma company margins, allowing more resources to be plowed back into R&D of new novel medicines, thereby improving patient and healthcare outcomes. This also means moving toward a system where rebates are either less significant or non-existent – the result being greater transparency on pricing. Markets work much more efficiently when key economic signals such as prices are easily known by all key healthcare stakeholders and decision-makers on both the demand and supply side. Pharma companies need to understand how to manage better rebates and discounts, while also develop a broader view of their effect on patients and the healthcare system. The use of advanced analytics, coupled with the application of newer databases and technologies such as AI/ML are needed to generate insights to guide better decisions on the use of rebates, discounts, and other price concessions.

In addition, pharma companies need to be fully conversant with all aspects of co-pay offset programs, the role they play as a marketing channel, and as an "access modifying" tool. Pharma company brand teams need to know the right level of benefit to offer to their patients. The answer to this optimization question requires understanding the application of all available relevant data, modeling tools, AI/ML technologies, strategic thinking, and the right tactics to help pharma companies make the right decision on such programs.

References

1. Herper M. Inside the secret world of drug company rebates. *Forbes*, published online 10 May 2012, available at https://www.forbes.com/sites/matthewherper/2012/05/10/why-astrazeneca-gives-insurers-60-discounts-on-nexiums-list-price/#2cb33c822b25.
2. IQVIA Institute for Human Data Science. Medicines use and spending in the U.S.: a review of 2017 and outlook to 2022. IQVIA Institute for Human Data Science, published online 19 April 2018, available at https://www.iqvia.com/institute/reports/medicine-use-and-spending-in-the-us-review-of-2017-outlook-to-2022.
3. Pfizer Inc. 2017 Pfizer annual report to shareholders, Appendix A: 2017 financial report. Published online, available at https://s21.q4cdn.com/317678438/files/doc_financials/Annual/2017/Financial-Report-2017.pdf.
4. GSK. GSK annual report 2017. Published online, available at https://www.gsk.com/media/4751/annual-report.pdf.
5. AbbVie. AbbVie 2017 annual report on form 10-K and 2018 proxy statement. Published online, available at http://investors.abbvie.com/static-files/8f8ea49f-4735-404c-be08-2f963441b74d.
6. Sagonowsky E. Half-off sales at Eli Lilly as drug rebating climbs to 51% in 2017. *FiercePharma*, published online 30 March 2018, available at https://www.fiercepharma.com/pharma/half-off-sale-at-eli-lilly-as-drug-rebating-climbs-to-51-2017.
7. DiMasi J, Grabowski H and Hansen R. Innovation in the pharmaceutical industry: new estimates of R&D costs. *Journal of Health Economics* 2016; 47: 20-33.
8. U.S. Department of Health & Human Services. American patients first, published online May 2018, available at https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf. Washington, D.C.: The U.S. Department of Health & Human Services.
9. Weintraub A. Patients don't benefit from drug discounts to insurers, PhRMA report says. Forbes, published online 30 November 2017, available at https://www.forbes.com/sites/arleneweintraub/2017/11/30/patients-dont-benefit-from-drug-discounts-to-insurers-phrma-report-says/#4ce5775d1ec1.
10. ISPOR (International Society for Pharmacoeconomics and Outcomes Research). Top 10 HEOR Trends, published online 8 January 2019, available at https://www.ispor.org/heor-resources/about-heor/top-10-heor-trends.
11. Kirzinger A, Wu B and Brodie M. Kaiser health tracking poll – March 2018: views on prescription drug pricing and Medicare-for-all proposals. *KFF* (Henry J. Kaiser Family Foundation), published online 23 March 2018, available at https://www.kff.org/health-reform/poll-finding/kaiser-health-tracking-poll-march-2018-prescription-drug-pricing-medicare-for-all-proposals/.
12. Tozzi J and Ockerman E. Drug prices drive many Americans to black market for medicines. *Bloomberg*, published online 20 May 2018, available at https://www.msn.com/en-us/news/us/drug-prices-drive-many-americans-to-black-market-for-medicines/ar-AAxsFTN?ocid=spartanntp.
13. Bernard T. 'Too little too late': bankruptcy booms among elder Americans. *The New York Times*, published online 5 August 2018, available at https://www.nytimes.com/2018/08/05/business/bankruptcy-older-americans.html?action=click&module=Top%20Stories&pgtype=Homepage.
14. U.S. Food & Drug Administration. Remarks from FDA Commissioner Scott Gottlieb, M.D., as prepared for delivery at the Brookings Institution on the release of the FDA's Biosimilars Action Plan. *News & Events, FDA Statement*, published online 18 July 2018, available at https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613881.htm.
15. U.S. Food & Drug Administration (FDA). Biosimilars action plan: balancing innovation and competition. FDA, published online July 2018, available at https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm613761.pdf.
16. Abutaleb Y. U.S. health secretary says agency can eliminate drug rebates. *Reuters*, published online 20 August 2018, available at https://www.reuters.com/article/us-usa-drugpricing-azar/u-s-health-secretary-says-agency-can-eliminate-drug-rebates-idUSKCN1L512H.
17. Welborn S and John P. Imagine there are no PBMs. It's easy if you try. *STAT*, published online 23 August 2018, available at https://www.statnews.com/2018/08/23/pbms-rebates-drug-purchasing/.

George A. Chressanthis, Ph.D.
Principal Scientist, Axtria Inc.
300 Connell Drive, Suite 5000
Berkeley Heights, NJ 07922
E: george.chressanthis@axtria.com

Devesh Verma, Ph.D.
Principal, Axtria Inc.
300 Connell Drive, Suite 5000
Berkeley Heights, NJ 07922
E: devesh.verma@axtria.com

Contact Us

+1-877-9AXTRIA
info@axtria.com

Disclaimer

Axtria® understands the compliance requirements behind personalization and we do not work with any personally identifiable data that can identify an end-customer of a business.

We have the strictest data security guidelines in place as we work with businesses to improve the experience for their customers.

www.axtria.com
info@axtria.com
@Axtria
facebook.com/AxtriaInc/
linkedin.com/company/axtria

Founded in 2010, Axtria® is a Big Data Analytics company which combines industry knowledge, analytics and technology to help clients make better data-driven decisions. Our data analytics and software platforms support sales, marketing, and risk management operations in the life sciences, finance, retail, and technology industries. We serve clients with a high-touch on-site and onshore presence, leveraged by a global delivery platform that focuses on reducing the total cost of ownership with efficient execution, innovation, and virtualization.

For more information, visit www.axtria.com

Follow Axtria on Twitter, Facebook and LinkedIn

Copyright © Axtria Inc. 2019. All Right Reserved