Supplemental Statement of the Pharmaceutical Care Management Association (PCMA) to the Federal Trade Commission on:

"Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics"

PCMA is submitting the following Statement as a supplement to its presentation before the Federal Trade Commission on November 8, 2017, as part of "Panel 2: Understanding Intermediaries: Pharmacy Benefit Managers." PCMA is the national association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 266 million[1] Americans with health coverage provided through self-insured employers, health insurers, labor unions, Medicare, Medicaid, CHIP, and the Federal Employees Health Benefits Program (FEHBP).

We commend the Commission for its decades-long involvement in the mission to enhance competition in the pharmaceutical marketplace, pursuant to its statutory mandate to identify business practices and regulations that impede competition without any countervailing benefits to consumers. The agency's ground-breaking report on health care competition, *Improving Health Care: A Dose of Competition*, which was issued in conjunction with the Department of Justice, contains an extensive discussion of why the growth of PBMs constitutes "an important development in providing consumer access to prescription drugs."[2]

The FTC has also been at the forefront in studying the PBM industry, including its comprehensive study, *Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies*, undertaken at the direction of Congress. This study found that prices were generally lower at PBM-owned mail-order pharmacies than at independent mail-order and retail pharmacies. This study also found that to the extent that the payer's relationship with the PBM creates potential conflicts of interest, vigorous competition among PBMs affords those payers the ability to safeguard their interests through the provisions they negotiate in their PBM contracts as well as their multiple options on plan design.[3]

The Commission has also weighed in over the last decade and a half in its influential competition advocacy letters on numerous federal and state legislative or regulatory attempts to regulate PBMs' contractual relationships with customers and pharmacies,

---

[1] Visante, "Pharmacy Benefit Managers: Generating Savings for Plan Sponsors and Consumers," February 2016, page 3 – Available at https://www.pcmanet.org/wp-content/uploads/2016/08/visante-pbm-savings-feb-2016.pdf

[2] FTC and DOJ, "Improving Health Care: A Dose of Competition," July 2004, Chapter 7 – Available at https://www.justice.gov/atr/improving-health-care-dose-competition-report-federal-trade-commission-and-department-justice#toc

[3] FTC, "Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies," August 2005 – Available at https://www.ftc.gov/sites/default/files/documents/reports/pharmacy-benefit-managers-ownership-mail-order-pharmacies-federal-trade-commission-report/050906pharmbenefitrpt_0.pdf

impose disclosure obligations on them in the name of "transparency," and otherwise interfere with PBMs' flexibility to work with their customers to design drug benefits that lower costs and expand access for consumers.

In this Statement, we hope to assist the Commission by presenting additional information on topics related to PBMs in which it has expressed interest, namely:

- **PBM Value:** How PBMs reduce prescription drug costs to provide patients, employers, and public programs with the highest value prescription drug benefits.
- **Information:** Whether PBM customers have enough information to make informed purchasing decisions and whether contracted pharmacies have sufficient information on compensation under PBM contracts.
- **Gross and Net Pricing in the Supply Chain:** The role of PBMs in encouraging competition in the supply chain and negotiating price concessions from manufacturers and pharmacies and how this impacts gross and net prices.
- **Selective Contracting and Plan Design:** Whether plan design decisions implemented by PBMs—including formulary tiers and pharmacy networks—generate cost savings and whether payers can compare costs and benefits accurately.

We suggest that the starting point for the FTC's broader objective of understanding competition in prescription drug markets is understanding the role of manufacturers in determining prices and price increases.

The Role of Manufacturers in Setting Drug Prices

In its simplest terms, the prescription drug marketplace is like any other: a market of sellers and buyers. Drugmakers are the sellers and, like all sellers, set prices according to whatever the market will bear. This is particularly evident in the case of new breakthrough brand name drugs under patent protection.

By virtue of their patents and, in some cases, market exclusivities such as orphan drug status, the manufacturers of breakthrough brand drug products have the equivalent of monopoly pricing power. They alone set the launch price for their products and control how those prices change over time.

When other drug manufacturers develop and gain FDA approval for therapeutically similar brand drugs that compete with the breakthrough drug, they also determine launch prices and price changes for their products. At that point, however, PBMs are able to leverage competition between the brand drugs within a therapeutic class in order to negotiate price concessions.

As detailed in recent research, the overall level of rebates provided by a drug manufacturer is closely correlated with the uniqueness of its drug product portfolio.[4]

[4] Credit Suisse, "Global Pharma and Biotech, Exploring Future US Pricing Pressure," April 2017 – Available at https://research-doc.credit-

Likewise, other research suggests there is no correlation between manufacturer price increases and changes in the rebates they negotiate with PBMs.[5] We discuss this research in greater depth later in this Statement.

Value: How PBMs Reduce Drug Costs for Payers and Cost-Sharing for Patients

As stated previously, PBMs now implement prescription drug benefits for a variety of plan sponsors, including commercial health plans, self-insured employer plans, union plans, Medicare Part D plans, FEHBP, state government employee plans, managed Medicaid plans, and others. Working under contract for these plan sponsors, PBMs use advanced tools to manage drug benefit programs that give consumers more efficient and affordable access to medications. PBM tools focus on six primary areas to produce savings:

- Negotiating rebates from drug manufacturers;
- Negotiating discounts from drugstores;
- Offering more affordable pharmacy channels;
- Encouraging use of generics and affordable brands;
- Reducing waste and improving adherence; and
- Managing high-cost specialty medications.

Based on many factors, plan sponsors decide how extensively PBM tools will be used to manage drug benefits for their enrollees. If plan sponsors elect to have PBMs use their full range of tools, they can save up to 30% on drug benefit costs compared to sponsors that opt for a limited range of tools. Across the entire marketplace, the decisions of plan sponsors result in PBM tools producing savings that average 10-20% relative to plans with limited management.[6]

By negotiating price concessions from drug companies and recommending strategies that promote the use of generics and more affordable pharmacy options, PBMs have played a key role in restraining the rise of overall drug costs to low single-digit increases in recent years. And while the recent wave of high-priced specialty drugs has imposed unique challenges, the role of PBMs in negotiating significant price concessions on high-cost hepatitis C treatments demonstrates how PBMs leverage competition in the marketplace to drive significant savings and deliver value to their clients.

In 2013, the first highly effective cure for hepatitis C—a small-molecule drug—was priced at $84,000 for a cycle of treatment. By 2015, after that drug faced competition

---

cuisse.com/docView?language=ENG&format=PDF&sourceid=em&document_id=1073763651&serialid=%2foS2%2f%2buhfn1K9jHaHOw40qPqJMxew63e%2f6kudOybyhM%3d

[5] Visante, "No Correlation Between Increasing Drug Prices and Manufacturer Rebates in Major Drug Categories," April 2017 – Available at https://www.pcmanet.org/wp-content/uploads/2017/04/Visante-Study-on-Prices-vs.-Rebates-By-Category-FINAL-3.pdf

[6] Visante, "Pharmacy Benefit Managers: Generating Savings for Plan Sponsors and Consumers," February 2016, page 3 – Available at https://www.pcmanet.org/wp-content/uploads/2016/08/visante-pbm-savings-feb-2016.pdf

from additional market entrants, PBMs were able to negotiate a 46% rebate—saving billions.[7] Market competition and the threat of formulary exclusion compelled the manufacturer to agree to this steep rebate. Indeed, after some PBMs excluded the first drug and opted to prefer a competing manufacturer's drug when the competing drug's manufacturer was willing to drop the cost, other PBMs were able to prefer the first drug in their formulary, when the first manufacturer matched the competition. Still other PBMs were then able to keep both products on their formulary as the market evolved.

By 2015, when competition had emerged, average PBM-negotiated hepatitis C drug costs in Medicare Part D were lower than costs in many price-controlled European countries and Japan.[8] This clearly illustrates the effectiveness of the threat of formulary exclusion to bring manufacturers to the negotiating table and to be able to obtain significant discounts that are critical to ensuring consumer access to these new drugs and medications.

In the case of generic drugs, PBMs also leverage marketplace competition to drive significant unit cost savings for their clients. Based on a recent Visante analysis, PBMs save patients and plans an average of $10 off the average $33 price of a generic prescription that an uninsured patient would pay at the pharmacy counter.

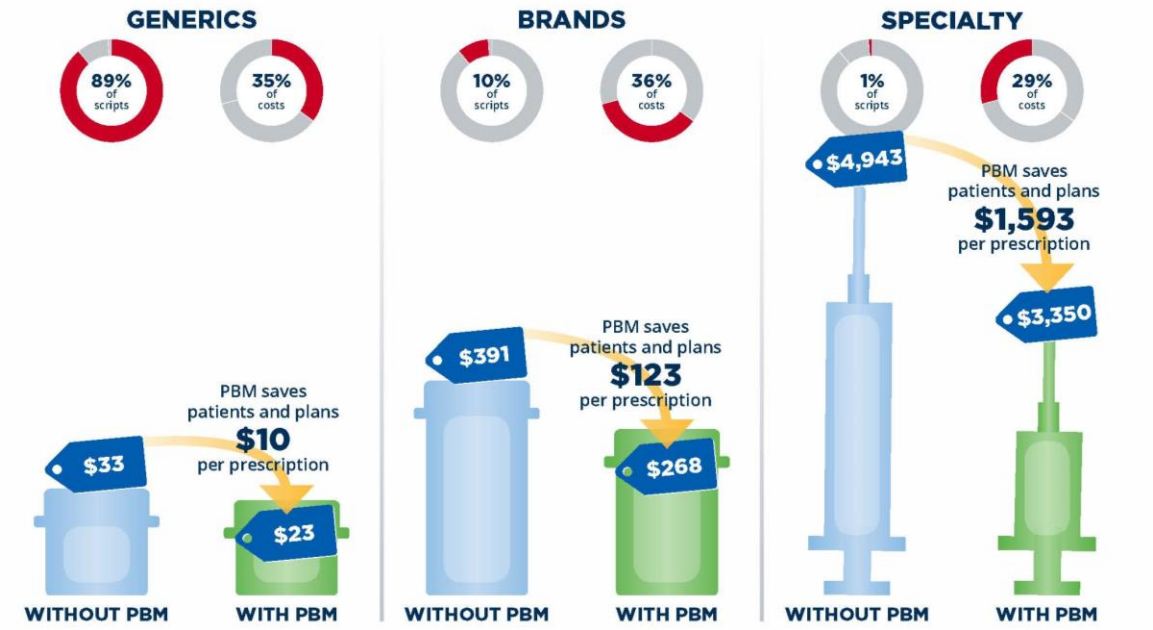
The same analysis shows that on brand prescriptions, PBMs save patients and plans an average $123 compared to the average $391 price faced by an uninsured patient. On specialty medications, PBMs save an average of $1,593 off the average $4,943 price faced by an uninsured consumer. These savings are net of any administrative fees and rebates retained by PBMs (see exhibit 1).

By reducing average unit costs across all of types of drugs, PBMs achieve an average unit cost savings ranging from 31-36% compared to unmanaged drug costs equivalent to the cash prices paid at the pharmacy counter by uninsured consumers. These unit cost savings, however, are just one way PBMs generate value for their clients.[9] PBMs also manage drug mix and utilization to generate an additional 11-15% savings compared to unmanaged drug expenditures.[10] For example, each time PBMs are able to encourage the clinically appropriate use of a generic over a brand, or a more affordable brand over a higher-cost or specialty medication, both patients and plans reap tremendous savings. Likewise, PBMs generate an additional 2% savings by reducing inappropriate utilization and encouraging patients with chronic medications to take their medications as prescribed.[11] On average, PBMs save patients and plans an average $6 for every $1 spent on their services.[12]

---

[7] New York Times, "Costly Hepatitis C Drugs for Everyone?" September 2, 2015.
[8] IMS Institute, "Comparison of Hepatitis C Treatment Costs Estimates of Net Prices and Usage in the U.S. and Other Major Markets," September 2016.
[9] Visante, "The Return on Investment (ROI) on PBM Services," November 2016 https://www.pcmanet.org/wp-content/uploads/2016/11/ROI-on-PBM-Services-FINAL.pdf
[10] Ibid.
[11] Ibid.
[12] Ibid.

Exhibit 1: PBM Savings Per Prescription Nationally



Source: Visante analysis prepared for PCMA, 2017.

The Commission has also asked whether there are any alternatives to PBMs that would provide customers with better value. Thousands of America's largest, most sophisticated health purchasers—Fortune 500 companies, insurers, state employee programs, state Medicaid programs, unions, and Medicare Part D plans—choose to hire PBMs, even though none are required to do so. The vast majority of PBM customers choose to either extend their contracts or go through a "request for proposal" process and choose another PBM among many possible options. A few employers and insurers choose to perform some functions, such as negotiating manufacturer or pharmacy contracts on their own, but even those use PBMs to administer other aspects of their benefits.

PBM Customers and Pharmacies Have Adequate Information to Make Informed Decisions

The Commission has asked whether health care payers have sufficient information to compare PBMs in order to make informed purchasing decisions and similarly whether pharmacies are able to obtain sufficient information to evaluate prospectively how they will be compensated under PBM contracts. The answer to these inquiries is that both do indeed have sufficient information.

PBM/Payer Contracting

In its years of experience studying PBMs, the FTC itself has concluded that competitive market forces afford plan sponsors sufficient information to assess the reasonableness of

PBM compensation.
Payers in the commercial market have an array of tools to negotiate arrangements that result in payment to their PBM service providers of no more than "reasonable compensation." In the words of URAC, the independent accrediting agency, transparency has become central to the PBM industry. PBMs work hard to be competitive and satisfy the market demand of both current and potential clients. These clients increasingly demand pricing transparency to ensure that they can "more effectively compare service, evaluate the costs, and determine if the PBM is acting in the plan sponsor's best interests."[13] Payers not only have myriad choices in terms of both price and non-price terms, but also auditing rights and guarantees. Further, PBM-client negotiations are almost always driven by specialized consultants that assist in choosing the terms the client wants. Finally, the payers are choosing PBM services in a marketplace where competition for clients is intense.

Client use of request for proposals

The competition among PBMs for clients is spurred by the "request for proposal" (RFP) process, by which clients seek PBM services. Payers are almost universally represented in that process by one of the many expert consultants that specialize in PBM RFPs, who prepare the RFP and then assist in analyzing the various and multiple PBM bid responses and help negotiate the eventual contract with the chosen PBM.

RFPs are typically sent to a number of PBMs, ranging from at least four to as many as 12, so that the client is assured of a sufficient number of bids to assure that it has adequate selection of price and non-price terms for its particular needs.[14] PBM-plan negotiations are primarily driven by these consultants, who are chosen by, paid by, and act in the interests of their clients to assure that clients have sufficient information to make informed purchase decisions. These consulting companies include widely recognized names such as Towers Watson, Mercer, and Aon Hewitt, and are staffed by experts, including executives who formerly worked for PBMs or health plans. The consultants rely on sophisticated tools and algorithms to compare the offerings of multiple PBMs, all competing for the client's business. They then help each client select the "best possible plan" for its needs by scoring and substantiating the bids from multiple PBMs.

Finally, consultants know that PBMs, operating in a marketplace where plan sponsors have multiple choices, are eager to put together packages and offer the most competitive price to either obtain or retain business. Consultants can encourage PBMs to develop unique offerings, based on the particular requirements of a given client, or customize

[13] URAC, "PBM Purchasers Guide From URAC and NBCH Will Help Employers and Business Coalitions Evaluate, Manage Pharmacy Benefit Services," January 2009 – Available at https://www.urac.org/news/pbm-purchasers-guide-from-urac-and-nbch-will-help-employers-and-business-coalitions-evaluate-manage-pharmacy-benefit-services/

[14] Statement of the Federal Trade Commission Concerning the Proposed Acquisition of Medco Health Solutions by Express Scripts, Inc. FTC File No. 111-0210, April 2, 2012 – Available at https://www.ftc.gov/sites/default/files/documents/public_statements/statement-commission-concerning-proposed-acquisition-medco-health-solutions-express-scripts-inc./120402expressmedcostatement.pdf

offerings to assure that the PBM bids bring additional value for that particular client. As a result, PBMs "price to" the client's particular needs and customize the offering.

Clients have wide choices among multiple PBMs

As noted above, PBM clients, with the assistance of experienced, knowledgeable consultants, can insist on including a wide variety of terms in PBM contracts as well as the ability to audit those contracts to ensure that they obtain the "benefit of the bargain." But none of this would matter if it were not for the competitive nature of the PBM industry. Customers can "vote with their feet" and switch PBMs if they are unsatisfied and do not receive the information that they need. In its 2005 study, the Commission estimated that about 40 to 50 PBMs operated in the U.S.[15] In 2012, the agency reviewed the proposed merger between two PBMs and noted that the market for full-service PBMs consisted of "at least ten significant competitors," and found "intense" competition.[16]

That "intense" competition is an outgrowth of the sheer number of firms competing. Today, many different entities, not all of which are PBMs, provide a range of pharmacy benefit management (PBM) services. Appendix I includes a list of more than 80 such entities currently operating in the U.S.

PBMs vary greatly when it comes to the market they specialize in, e.g., larger versus smaller employers, or regional versus national markets. Even though a PBM may operate only locally or regionally, the FTC in the past has found them capable of competing with the big national PBMs.[17] Thus, it is not accurate to assert that large payers must choose only among the "Big Three" PBMs. As the Commission pointed out in 2012 in reviewing a PBM merger, "some health plan-owned PBMs have become viable competitors to the Big Three and have already won the business of a number of large self-insured employers."[18] Today, health-plan owned PBMs are among the largest competitors.

As noted, competition is the best way of assuring that payers are receiving the information that is essential and appropriate to make the best choice of a PBM. As the Commission itself has noted, imposing mandates for disclosure of categories of financial information is not a helpful approach in assuring that plans have useful and meaningful information. Plan sponsors, said the Commission, can choose varying levels of disclosure, and can use their preferred level as "one element of a negotiating strategy."[19]

---

[15] FTC, "Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies," August 2005 – Available at https://www.ftc.gov/sites/default/files/documents/reports/pharmacy-benefit-managers-ownership-mail-order-pharmacies-federal-trade-commission-report/050906pharmbenefitrpt_0.pdf

[16] Statement of the Federal Trade Commission Concerning the Proposed Acquisition of Medco Health Solutions by Express Scripts, Inc. FTC File No. 111-0210, April 2, 2012 – Available at https://www.ftc.gov/sites/default/files/documents/public_statements/statement-commission-concerning-proposed-acquisition-medco-health-solutions-express-scripts-inc./120402expressmedcostatement.pdf

[17] FTC Letter to Rep. Patrick McHenry, regarding No. Carolina HB 1374 (July 15, 2005)

[18] Statement of the Federal Trade Commission Concerning the Proposed Acquisition of Medco Health Solutions by Express Scripts, Inc. FTC File No. 111-0210, April 2, 2012 – Available at https://www.ftc.gov/sites/default/files/documents/public_statements/statement-commission-concerning-proposed-acquisition-medco-health-solutions-express-scripts-inc./120402expressmedcostatement.pdf

[19] FTC Letter to Larry Good, ERISA Advisory Council, August 19, 2014.

In essence, the vigorous competition in the industry gives plan sponsors the ability to safeguard their interests through freely-negotiated contracts and choice of plan designs.

Pharmacies have adequate information to evaluate their PBM contracts

PBMs work to maintain cost efficiencies for their clients and their plan participants at a time of escalating brand drug prices. As part of that effort, PBMs establish and maintain retail pharmacy networks, including credentialing pharmacies and monitoring them for patient safety, quality, and customer service. They negotiate discounts from network pharmacies for the cost of both the drug and the pharmacies' dispensing service.

Based on the terms of their "participating pharmacy agreements" with PBMs, pharmacies are able to obtain the information needed as to how they will be compensated for dispensing drugs. When a consumer goes to a pharmacy to fill a prescription, the pharmacy checks with the relevant PBM to confirm the applicable plan design for that individual in order to determine coverage and copay information. After the pharmacy fills the prescription, the PBM reimburses the pharmacy at a contractually agreed-upon rate minus the copay collected from the individual.

In addition, independent pharmacies have the advantage of hiring pharmacy services administrative organizations (PSAOs). A typical PSAO represents thousands of pharmacies. According to a GAO analysis, more than 80% of independent pharmacies use PSAOs.[20] These organizations negotiate and enter into contracts with third party payers on behalf of independent pharmacies. PSAOs provide access to pooled purchasing power, negotiating leverage, and contracting strategies similar to large, multi-location chain pharmacies.

Gross and Net Pricing in the Supply Chain

The third topic the Commission has asked about is information on PBM pricing, specifically the "gap between gross and net prices paid for branded drugs by commercial customers."

Given the continuing increase in manufacturer list prices for brand drugs, PBMs are obliged to negotiate as deep a rebate as possible on brand drugs to deliver the lowest net cost to payers, and increasingly payers are negotiating for 100% rebate pass-through. In addition, both research commissioned by PCMA and research undertaken by Wall Street analysts has demonstrated that rebates are not correlated with either launch prices or price increases, but rather are strongly correlated with competition. In classes with considerable competition, PBMs are able to negotiate significant rebates. In classes with virtually no competition (or the so-called protected classes in Medicare Part D), PBMs can obtain no or weak rebates. Indeed, Credit Suisse found that the largest rebates—60% and more—are concentrated on the "least unique" pharmaceutical products, whereas

[20] GAO, "The Number, Role, and Ownership of Pharmacy Services Administrative Organizations," February, 2013. Available at https://www.gao.gov/assets/660/651631.pdf

rebates may be lower or non-existent for the most unique products.[21]

When considering the difference between gross and net prices, it is important to note the limitations of the widely cited data from IQVIA (formerly QuintilesIMS) that has been central to the debate on this issue. Namely, that the gap between manufacturer list and net trends reflected in IQVIA data reflects not only PBM-negotiated rebates, but also many other key factors. These factors include Medicaid rebates, Medicare Part D coverage gap discounts, 340B discounts, the value of copay coupon programs, and volume discount and prompt payment discounts that manufacturers provide to wholesalers. Thus, the difference between gross and net trends seen in the IQVIA data over the past few years is explained by a range of factors, including:

- **New Rebates on Hepatitis C Drugs:** New head-to-head competition among blockbuster hepatitis C drugs like Sovaldi and Harvoni in recent years has resulted in substantial new rebates. These new rebates have both lowered overall costs and widened the overall difference between list and net prices.

- **Growing Medicaid Rebates:** A large portion of the recent trend difference between gross and net prices is due to the growth of statutorily required rebates in the Medicaid program. Medicaid has seen expansion under the Affordable Care Act. Likewise, among the factors in the complex statutory Medicaid rebate formula is a "CPI penalty" which penalizes manufacturers for price inflation that exceeds the Consumer Price Index (CPI), which has been typical for many branded drugs. PBMs are not responsible for Medicaid rebates, yet Medicaid rebates explain a large part of the difference between gross and net trends.

- **Growing 340B Discounts:** Likewise, the rapid growth of discounts in the government's 340B program, which has nothing to do with PBM-negotiated rebates, explains part of the difference between gross and net price trends.

- **Growth of Copay Coupons:** The rapid growth of manufacturer copay coupons also factors into IMS data and explains part of the difference between gross and net price trends. Copay coupons also have nothing to do with PBM-negotiated rebates. Indeed, such copay coupon programs can actually undermine other PBM cost control efforts by encouraging the use of brand over generic drugs.

As the Commission has suggested in many of its studies and advocacy letters, rebates are pro-competitive. Both "market share" and "formulary payments" give PBMs the incentive to negotiate aggressively with manufacturers, resulting in better deals for clients. Indeed, it was pharmaceutical manufacturers that created the rebate system to reduce the net cost of brand drugs.

---

[21] Credit Suisse, "Global Pharma and Biotech, Exploring Future US Pricing Pressure," April 2017 – Available at https://research-doc.credit-cuisse.com/docView?language=ENG&format=PDF&sourceid=em&document_id=1073763651&serialid=%2foS2%2f%2buhfn1K9jHaHOw40qPqJMxew63e%2f6kudOybyhM%3d

As part of manufacturer-PBM negotiations, brand drug manufacturers compete for formulary placement for therapeutically equivalent products by offering rebates for moving market share. These rebates are typically calculated and paid weeks or months after a drug is dispensed. As a result of these negotiations, PBMs can recommend benefit designs that stretch payers' dollars and reduce premiums and cost-sharing. These designs include cost-sharing incentives for patients to use the most affordable drugs, usually generics. The highest cost-sharing is typically reserved for drugs with the least competitive price concessions, or in the case of many high-priced, single-source drugs (e.g., cancer therapies), no concession at all. PBMs also support benefit designs that ensure patients do not pay more in cost-sharing than the cost of an actual drug and innovations like electronic prior authorization that reduce physicians' administrative burden.

Rebate savings are often used by payers to reduce premiums and out-of-pocket costs for patients. In Medicare Part D, 100% of rebates in the Medicare Part D program are required to be reported to CMS. In the commercial market, each payer determines what percentage of rebates it wants passed through to it, and how much (if any) it wants the PBM to retain as payment for services. While on average payers elect to receive 90% of rebates negotiated by PBMs,[22] an increasing number require PBMs to pass through all of them. About 46% of commercial PBM contracts are negotiated with full pass-through of rebates to payers.[23] PBMs are committed to providing rebate transparency to their clients, as well as audit rights, as noted in detail above.

Rebates paid by drug manufacturers can vary depending on the characteristics of the particular plan. The FTC has noted that plans with relatively restrictive formularies often receive higher rebates, and manufacturers can "adjust the rebates they are willing to offer based on plan design."[24]

There is No Connection between the Prices Drugmakers Set and the Rebates They Negotiate with PBMs

A recent study of the top 200 self-administered, patent-protected, brand-name drugs shows no correlation between the launch prices or price increases manufacturers set and the rebates they pay to PBMs.[25] There are many cases of high-priced drugs that carry low rebates and low-priced drugs that carry high rebates. Some high-priced drugs have no rebate at all. The figure below illustrates the lack of correlation of price changes to rebates, by drug class (see Exhibit 2)

---

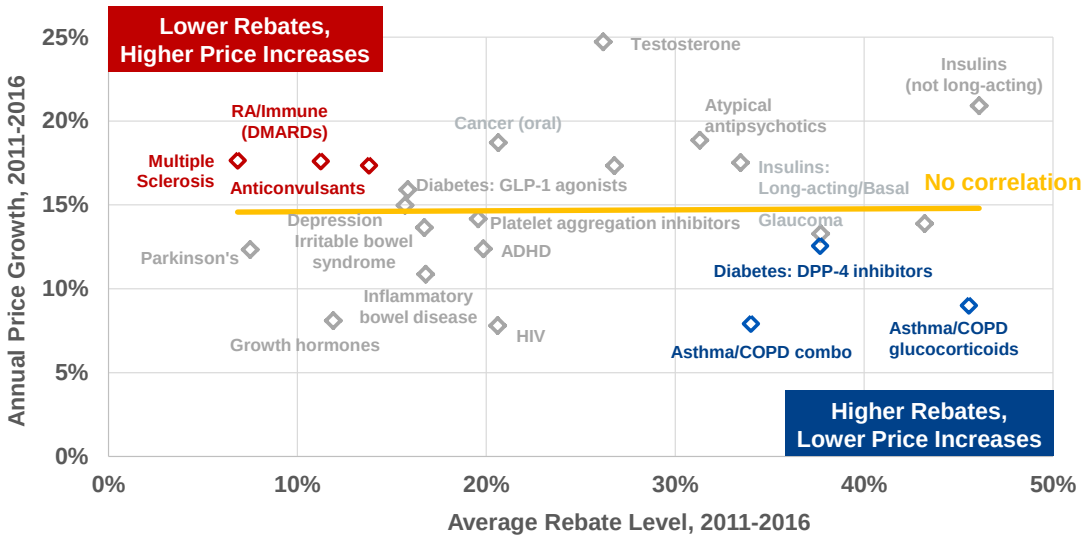
[22] Written Testimony of Joanna Shepherd, Ph.D., Emory University for the ERISA Advisory Council Hearing on PBM Compensation and Fee Disclosure, June 19, 2014, Citing J. P. Morgan, "Pharmacy Benefit Management, Takeaways from Our Proprietary PBM Survey," May 21, 2014.

[23] Pharmacy Benefit Management Institute, "PBMI Research Report: Trends in Drug Benefit Design," 2016.

[24] FTC Letter to Larry Good, ERISA Advisory Council, August 19, 2014.

[25] Visante, "Increasing Prices Set by Drugmakers; Not Correlated With Rebates," June 2017.

Exhibit 2: No Correlation Between Drug Rebate Levels and Price Increases



Source: Visante, "Increasing Prices Set by Drugmakers Not Correlated With Rebates, June 2017.

Like manufacturers in other industries, drugmakers set prices according to supply, demand, and the level of competitive alternatives available. Considering the confusion surrounding rebates, PBMs encourage manufacturers to offer payers other ways to reduce net costs.

The Benefits to Both Plan Sponsors and Consumers of Selective Contracting

The final topic the Commission has inquired about is selective contracting, namely (1) whether restricted formularies or narrow retail pharmacy networks create cost savings or impose inconvenience or negative health consequences on patients, and (2) whether plan sponsors are able to compare costs and benefits when picking a plan design.

Selective contracting: pharmacy networks

Selective contracting—that is, the ability of health plans and PBMs to construct networks that include some, but not all, providers—has long been used to enhance competition and lower costs in the markets for health care goods and services. Nonetheless, for decades, pharmacies have lobbied to force PBMs to open up their networks to "any willing provider" meeting the same terms and conditions as other network members.

If providers like pharmacies know they will automatically be included in networks, they have a reduced incentive to offer PBMs the most competitive terms. Thus, any willing pharmacy (AWP) laws significantly reduce providers' incentive to engage in price competition. As the Commission has pointed out in letters advising against adoption of such laws, they may reduce incentives for PBMs to invest in new plan designs or undertake complex negotiations with manufacturers (see FTC Letter to CMS, March 7, 2014, advising against adopting "any willing pharmacy" provisions in proposed Part D

rule). Ultimately, that reduction in competition harms consumers, who may have higher premiums as well as fewer choices (See FTC Letter to Rep. McHenry; FTC Letter to Rep. Terry G. Kilgore). That conclusion was affirmed by an analysis of AWP legislation at the state and federal level which concluded that such laws "lead to less competition and higher prices for consumers while providing no compensating benefits."[26]

Such laws interfere with efficient contracting, both in the commercial market and in Medicare Part D. States that have AWP laws have higher prescription drug prices than those without them. [27] Such preferred pharmacy networks save money in Medicare for the program and individual beneficiaries. The Moran Company estimated for PCMA the additional costs imposed if preferred pharmacies were disallowed in Medicare based on a bill called "Ensuring Seniors Access to Local Pharmacies Act of 2014" which would have allowed any willing pharmacy to opt into the prevailing terms of preferred network contracts in areas designated as having a shortage of health professionals. The Moran Company concluded that the enactment of this type of legislation would increase Federal mandatory spending by $21.32 billion over the 2015-2024 scoring window.

Preferred networks, by holding preferred pharmacies to a higher standard, also help PBMs ensure the quality of the pharmacies in their networks. As noted, PBM/pharmacy contracts, especially those for preferred pharmacies, often contain terms related to performance, to ensure the integrity and quality of the PBM's pharmacy networks. Thus, the contracts may require certain performance standards related to pharmacy-performance metrics, and at times, PBM clients may require such metrics. These metrics ensure that the pharmacies are responsible for a variety of important activities, such as generic and cost-effective dispensing, improving adherence so patients actually are monitored to ensure they take the drugs prescribed, reducing inappropriate drug use, accurately dispensing drugs, and promptly answering calls from individuals.

There is little empirical evidence to suggest that preferred networks in any way inconvenience patients. In Medicare Part D program, where preferred pharmacy networks originated, nearly 9 out of 10 Part D plans give beneficiaries the option of using a "preferred pharmacy" to lower their out-of-pocket costs. These networks comprise all types of pharmacies, including independent pharmacies. Plans using preferred networks have proven very popular, and nearly 75% of Medicare Part D beneficiaries have chosen these types of plans. While not every pharmacy achieves preferred status in every plan, the vast majority of pharmacies are in at least one plan as a preferred pharmacy. While individuals can get their prescriptions filled at virtually any pharmacy, whether mail-service, independent, chain pharmacies, or pharmacies located in supermarkets, big-box retailers, or wholesale clubs, choosing a preferred pharmacy helps them lower their costs. A survey by Hart Research Associates shows that seniors in plans with preferred pharmacy networks are overwhelmingly satisfied, citing lower costs and convenient access to pharmacies. The survey revealed that 80% of those in preferred pharmacy plans

[26] Jonathan Klick, Joshua Wright, "The Anti-Competitive Effects of Any Willing Provider Laws: Legal Backgrounder, March 23, 2012.
[27] Christine Durrance, The Impact of Pharmacy Specific AWP Legislation on Prescription Drug Expenditures, 37 Atlantic Econ. J. 409 (2009).

(over 7 million seniors) would be very upset if their plans were no long available.[28]

Narrow formularies aid consumers

The Commission also seeks information about the plan sponsor design choices, such as low-cost restricted formularies, that might have "negative health consequences on patients."

Formularies are among the most important tools that PBMs use to manage prescription benefits for both quality and cost effectiveness. Plan sponsors—not PBMs—decide on the exact formulary to be used for the plan and approve the use of any techniques that will be applied to encourage formulary compliance, such as "tiering" or step-therapy.

In all cases, the primary consideration in the development of a formulary is clinical appropriateness. PBMs rely on Pharmacy and Therapeutics (P&T) Committees, to develop formulary recommendations and options for plan sponsors. P&T Committees are made up of largely independent clinical experts in disease states, including physicians, pharmacists, and others with clinical expertise. Critically, the vast majority of P&T Committee members—to avoid any conflict of interest—are not employed by the PBM, do not have any business relationship with the PBM, and are not directly involved in rebate negotiations with any pharmaceutical manufacturers. P&T committees typically meet quarterly to assess the most up-to-date treatments for a given disease state, and recommend drugs based on whether they must be covered, should never be covered, or are among those with therapeutic equivalents. Among those with therapeutic equivalents, PBMs can then negotiate with manufacturers and arrange the formulary to encourage the use of the most cost-effective drugs for the plan sponsor.

The plan sponsor has the ability to adopt the PBM's suggested formulary as recommended, or use it as the foundation for its own customized formulary. Sponsors can choose to have open formularies, where they pay a portion of the cost for all drugs, regardless of formulary status. More usual is a formulary containing drugs in each therapeutic category, with generic drugs available at a first-tier copay level and preferred products available at a second-tier copay level. Other branded and specialty drugs may be included on a third and fourth tier if the sponsor chooses. In all cases, it should be noted that (1) the physician ultimately decides what medications the particular patient is prescribed, and (2) insurers have processes for timely procurement of non-formulary products when they are clinically necessary for a particular patient, as well as access to a formal appeal process if a request for a non-formulary drug is denied. Enrollees whose appeals are successful can obtain benefits for the non-preferred product as if it had preferred status on the formulary.

Formularies are critical to keeping costs down for consumers. For therapeutically equivalent drugs, PBMs use the leverage provided by formulary placement in their

[28] Hart Research Associates, "A survey of Seniors About Their Medicare Part D Preferred Pharmacy Network Plan," May 2013 – Available at https://www.pcmanet.org/wp-content/uploads/2016/08/pr-dated-05-22-13-hart-research-preferred-networks-pp.pdf

negotiations with drug manufacturers. This is a key part of benefit design and management and allows PBMs to assist plan sponsors to provide coverage at a reasonable price.

In Medicare Part D, Congress has given the Secretary authority to require coverage of all or substantially all drugs in six "protected classes." The result, predictably, is higher prices and lower rebates as manufacturers know their products in those classes must be included on Part D formularies regardless of price. PCMA has spoken out against such protected classes repeatedly, noting their anti-competitive impact, that P&T committees in the private sector recommend clinically appropriate formularies, and that CMS already applies an outlier analysis to ensure that formularies are not designed to cherry pick enrollees.

Plan sponsor ability to compare costs/terms:

The process by which clients use RFPs to solicit PBM bids for their business is covered in depth earlier in this Statement. With respect to whether plan sponsors are able to compare costs and benefits accurately, the RFP process facilitates this. PBMs submitting a responsive proposal will supply the information and comparative metrics that plan sponsors have requested. In addition, PBMs work with their clients, the plan sponsors, in consultative capacities to design a prescription drug benefit package that meets the clients' needs. The plan sponsor ultimately determines coverage, the scope of the formulary, plan design features (like copays, benefit caps), and utilization management techniques to be applied, such as step therapy, prior authorization, and quantity limits.

As noted above, before the contract with the PBM is final, plan sponsors are assisted by expert consultants that evaluate multiple PBM proposals and analyze the various offerings of PBMs competing vigorously for the contract. In the post-contract realm, the majority of PBM/client contracts include a comprehensive auditing process as well as performance-based guarantees and reporting to assure clients that they are getting the benefit of the bargain. If a plan sponsor is entitled to a portion or all of the rebates under its PBM contract, for example, the sponsor will be provided with reports to assure accuracy of that information. And again, the sponsor can turn to multiple other PBMs that will compete for that business if those performance guarantees and contracted-for reports are not forthcoming.

It cannot be stressed enough that myriad choices as to plan design, including the scope of the pharmacy network and the design of the formulary, are topics best left to the judgment of the plan sponsors.

Conclusion

PBMs evolved because they increase the value of prescription drug benefits. PCMA's member companies harness market forces and competition to restrain drugs costs and deliver high-quality benefits and services to their payer clients and enrollees. In its search for solutions to address high drug costs, PCMA encourages the Commission to pursue policies that foster and encourage competition to keep prescription drug costs and pharmacy benefits more affordable for employers, enrollees, taxpayers, and government programs.

PCMA member companies welcome continuing discussion among all stakeholders to create a robust, sustainable market that will continue to deliver needed cures and treatments for patients who suffer through disease and chronic illness. PCMA looks forward to answering any questions the Commission may have.

Appendix I: Entities Providing Varying Levels of PBM Services in the U.S. in 2017

Entity Providing PBM Services	Website
Abarca Health	https://abarcahealth.com/
Aetna Pharmacy Management (APM)	www.aetna.com/members/pharmacy
American Health Care	https://www.americanhealthcare.com/
AmeriClear Rx	http://americlearrx.com/
AmWins Rx	http://www.amwinsrx.com/
Appro-Rx	https://www.approrx.com/home/
Araya Pharmacy Benefit Management	http://www.arayarx.com/
Arete Pharmacy Network	https://areterx.com/about.php
Avia Partners, Inc.	www.aviapartners.com
AWPRx	http://www.awprx.net/
BeneCard PBF	www.benecardpbf.com/PBF
Broadreach Medical Solutions	https://www.bmr-inc.com/
Capture Rx	https://capturerx.com/
Change Healthcare (aka Emdeon)	http://www.changehealthcare.com/
Choice Rx Solutions	http://www.choicerxsolutions.com/
CIGNA Pharmacy Management	www.cigna.com
Citizens Rx	http://citizensrx.com/
ClearScript	www.clearscript.org
Costco Health Solutions	https://www.costcohealthsolutions.com/
CVS Health	https://cvshealth.com/
Cypress Care, Inc.	http://www.cypresscare.com/
Diplomat Pharmacy	https://diplomat.is/
DST Pharmacy Solutions	http://www.dstsystems.com/
Emblem Health	www.emblemhealth.com
Employee Health Insurance Management (EHIM)	https://www.ehimrx.com/
EnvisionRx	www.envisionrx.com
Envolve Pharmacy Solutions	https://pharmacy.envolvehealth.com/
Express Scripts	www.express-scripts.com
First Script (Coventry)	http://www.coventrywcs.com/
Health Information Designs, Inc.	http://www.hidesigns.com/
Healthesystems LLC	http://www.healthesystems.com/
Healthsmart Rx	http://www.healthsmart.com/ContactUs/HealthSmart-Rx.aspx
Humana Pharmacy Solutions	https://www.humana.com/pharmacy/
Integrated Prescription Management	https://www.rxipm.com
KeyScripts LLC	https://www.keyscriptsllc.com/
Kroger Prescription Plans	www.kpp-rx.com
LDI Integrated Pharmacy Solutions	http://www.ldirx.com/
Magellan Rx Solutions	https://www.mrxinfo.com/
MaxCare Rx	https://www.maxcarerx.com/
MaxorPlus	http://www.maxor.com/

Appendix I (continued)

Entity Providing PBM Services	Website
MC-21 Corporation	http://mc-21.com/en/
MedImpact Healthcare Systems	https://pbm.medimpact.com/
MedOne Healthcare Systems	http://www.medonehs.com/
MedTrak Services	https://www.medtrakrx.com/
Meridian Rx	www.meridianrx.com
myMatrixx	http://www.mymatrixx.com/
National Pharmaceutical Services (NPS)	www.pti-nps.com
National Script	http://nationalscript.com/
Navitus	www.navitus.com
Northwest Pharmacy Services (NWPS)	www.nwpsrx.com
OmedaRx	https://www.omedarx.com/
OptumRx	www.optumrx.com
PBA Health	https://www.pbahealth.com/
PDMI (Pharmacy Data Management Inc)	www.pdmi.com
Pequot Pharmaceutical Network (PRxN)	www.prxn.com
PerformRx	http://www.performrx.com/
Pharmacy Benefit Dimensions	https://www.pbdrx.com/
PharmaStar, LLC	www.pharmastaronline.com
PharmAvail Benefit Management	https://www.pharmavail.com
PharmPix Corporation	http://www.pharmpix.com/
Phoenix Benefits Management	http://www.phoenixpbm.com/
PRAM Insurance Services, Inc.	www.pram.com
Prime Therapeutics	http://www.primetherapeutics.com/
PrismRx	http://prismpbm.com/
ProAct	https://secure.proactrx.com
ProCare Rx PBM	www.procarerx.com
Provider Synergies, LLC	www.providersynergies.com
Ramsell Pharmacy Benefit Management	http://www.ramsellcorp.com/solutions/ramsellpbm.aspx
Recept Specialty Pharmacy	http://receptrx.com/
RxAdvance	http://www.rxadvance.com/
RXPreferred Benefits	http://rxpreferred.com/
RxResults	https://rxresults.com/
RxStrategies, Inc.	http://rxstrategies.com/
Sav-Rx Prescription Services	http://util.savrx.com/
Script Care (SCL Pharmacy Benefit Management)	https://www.scriptcare.com
ScriptGuideRx, Inc	http://www.scriptguiderx.com/
ScriptSave WellRx	https://www.scriptsave.com/
Sentinel Rx	https://www.sentinelrx.com/
Serve You Custom Rx Management	http://www.serve-you-rx.com/
Southern Scripts	http://www.southernscripts.net/
Transparent Rx	https://www.transparentrx.com/

Appendix I (continued)

Entity Providing PBM Services	Website
Ventegra	http://www.ventegra.net/
VRx Pharmacy Services	https://vrxpharmacy.com/
WellDyneRx	https://www.welldynerx.com/

Source: Pharmacy Benefit Management Institute analysis for PCMA, 2017. Note some entities on the list are subsidiaries of parent corporations also on the list.