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Before the

UNITED STATES SENATE

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

The Cost of Prescription Drugs: How the Drug Delivery System Affects What Patients Pay, Part II

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Introduction

Good morning. My name is Mark Merritt, President and CEO of the Pharmaceutical Care Management Association (PCMA). I appreciate this opportunity to appear before the Committee at this hearing examining the drug supply chain. PCMA is the national association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 266 million[i] Americans across dozens of PBMs with health coverage provided through self-insured employers, health insurers, labor unions, Medicare, Medicaid, CHIP, and the Federal Employees Health Benefits Program (FEHBP).

The cost of prescription drugs has understandably garnered a lot of attention, particularly with the recent wave of high priced, high profile specialty drugs like Sovaldi. This development has imposed unique challenges on patients and the employers, unions and government programs that hire PBMs to help make coverage more affordable. By negotiating price concessions from drug companies and recommending strategies that promote generics and more affordable pharmacies, PBMs have played a key role in retraining the rise of overall drug costs to low single-digit increases over the past few years. It is also important to note that prescription drug launch prices and price increases are determined by the same supply-and-demand dynamics of countless other industries that manufacture products and use supply chains to get them to market. Pricing decisions are made unilaterally by manufacturers. There's no correlation between manufacturer price increases and the rebates and discounts they negotiate with PBMs.

At the outset, I want to thank this Committee for its actions to improve generic competition and lower the cost of prescription drugs as part of the Food and Drug Administration (FDA) Reauthorization Act. In addition, I'd like to recognize Senators Collins and Franken for your work on the amendment that addresses clearing the FDA's application backlog as well as expediting generic drug development and promoting competition. Title VIII will help foster a more competitive marketplace to improve the affordability and accessibility of prescription drugs for patients and guard against sudden, astronomical price hikes of decades-old prescription drugs. The HELP Committee has played an important role in fostering the competition that will both reward innovation and maintain affordability.

This testimony will outline how PBMs reduce prescription drug costs to provide patients, employers, and public programs with the highest value prescription drug benefits. Additionally, it will suggest a set of policy options to increase competition in the prescription drug marketplace to help reduce costs.

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

The role of PBMs is to help our clients, including the employers, unions, and health insurers who provide prescription drug benefits, to reduce costs and improve health outcomes for consumers. PBMs have a proven track record of delivering high-quality, affordable benefits that address the individual needs of their clients and patients.

PBMs play a crucial role in keeping drug costs down for payers. PBMs operate outside of the "pharmacy supply chain" that physically moves prescription drugs from manufacturers to drug wholesalers to the pharmacy, where they are ultimately dispensed to patients. Rather, PBMs represent insurers and health plans, on the buy side of the economic transaction. In their capacity as benefit managers, PBMs do not take possession of pharmaceuticals, but work on behalf of health care payers to reduce costs.

Given current drug pricing trends, the role of PBMs has become more important than ever. While few plans can afford to offer true "first-dollar" prescription drug coverage, all want to offer the most affordable benefits for consumers. That is why 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.

PBMs typically reduce costs by 30%[ii] by, among other things, using their substantial scale and expertise to promote generics and negotiate aggressive rebates, discounts, and other price concessions with manufacturers to reduce premiums and cost-sharing.

The Role and Background of Rebates

Long before PBMs became prominent in the marketplace, the rebate system was created by manufacturers (and in the case of programs like Medicaid and 340B, used by public programs) to reduce the net cost of brand drugs. Most rebates reported by manufacturers are actually paid pursuant to these government discount programs, not to plans administered by PBMs.

As part of manufacturer-PBM negotiations, brand drug manufacturers compete for formulary placement for therapeutically equivalent products by offering rebates for moving market share, which 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' finite dollars and reduce premiums and cost-sharing. These

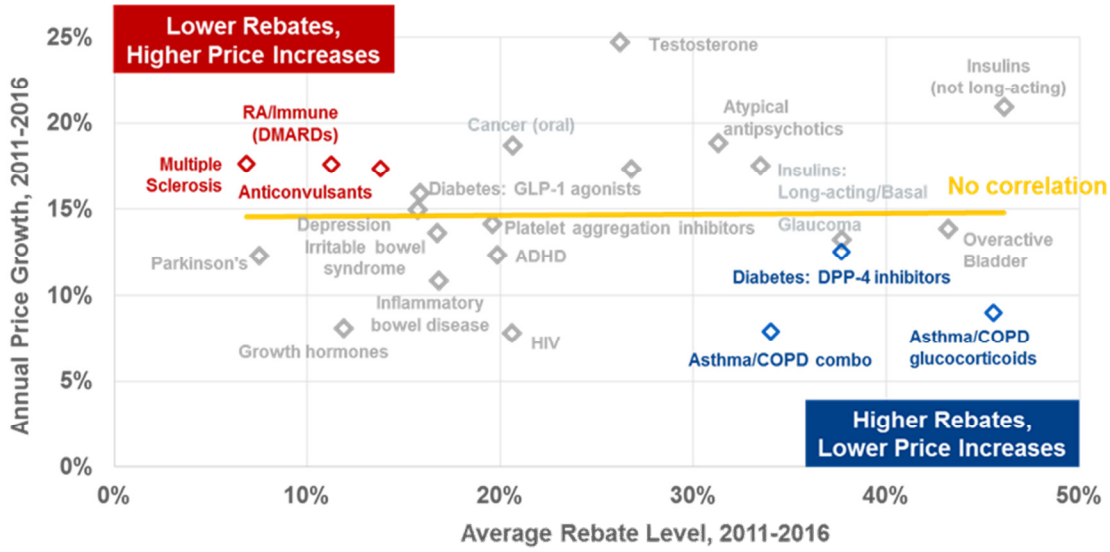
designs include cost-sharing incentives for patients to use the most affordable drugs, which often are generics. The highest cost-sharing is typically reserved for drugs with the least competitive discounts, or in the case of many high-priced, single-source drugs (e.g., cancer therapies), no discount 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 used by payers to reduce premiums and out-of-pocket costs for patients. Each payer determines what percentage of rebates is 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,[iii] 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,[iv] and 100% of rebates in the Medicare Part D program are required to be reported to CMS. PBMs are committed to providing rebate transparency and audit rights to their clients.

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.[v] 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[vi] illustrates the lack of correlation of price changes to rebates, by drug class.



Source: Visante estimates and analysis of SSR Health data, 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.

Hepatitis C Drugs: A Classic Case of Leveraging Competition

The introduction of new therapies for hepatitis C demonstrates how competition in the marketplace can drive significant savings on expensive drugs. In 2013 the first highly effective drug to cure hepatitis C was priced at $84,000 for a cycle of treatment. However, by 2015, after that drug faced competition from additional market entrants, PBMs were able to negotiate a 46% rebate —saving billions.[vii] 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 on their formulary as the market evolved.

Research on hepatitis C drug costs has subsequently shown that by 2015, when competition had emerged, hepatitis C drug costs negotiated in the U.S. by PBMs for Medicare Part D were usually lower than those in price-controlled European countries

and Japan.[viii] The case of hepatitis C drugs illustrates clearly the effectiveness of the threat of formulary exclusion to bring manufacturers to the negotiating table.

PBMs Help Commercial Clients Explore Trade Offs to Point-of-Sale (POS) Rebates

POS rebates refer to contract arrangements where negotiated price concessions are estimated before the transaction and then applied immediately at the point of sale. In the commercial market, PBMs already help payers implement POS rebates. Since moving rebates to POS does not reduce overall costs but only redistributes them among different enrollees, payers ask themselves the following questions before choosing this approach:

- Should rebate savings be used to reduce premiums for all enrollees or out-of-pocket costs for certain ones who take certain drugs?
- Do plans have the administrative and financial capacity to reduce costs at POS even though manufacturers do not pay rebates until months after a drug has been dispensed?
- Do plans understand the limitations of POS rebates? Some high-priced drugs carry no rebates at all and others are so expensive that rebates alone will not guarantee access. A $1,500 drug with a 30% rebate would still cost patients in the deductible $1,050.
- If plans are willing to exchange higher premiums for lower cost-sharing, would it be simpler to just reduce deductibles or co-pays on certain drugs?

Frustration over high drug prices has led some policymakers to explore ways to reduce costs for consumers, including forcing health plans to use rebates to reduce POS costs rather than premiums. However, such policies do not reduce costs; they only shift costs from one group of patients to another.

POS Rebates Do Not Work in Medicare Part D

While plans with POS rebates can be implemented in the commercial market, they have proven unworkable in Medicare Part D and pose risks that could destabilize the program. In fact, POS rebates are already permitted in Part D and have been tried—unsuccessfully—in the past. They lead to significant adverse selection and expose plans to other risks, such as being accused of False Claims Acts violations if they incorrectly estimate the size of rebates. Requiring POS rebates in Part D would dramatically increase costs to the program and taxpayers. According to modeling by the actuarial firm, Milliman, this would result in widespread premium increases and cost taxpayers an additional $20 billion over the next decade.[ix]

PBMs Use Direct and Indirect Remuneration (DIR) to Keep Drug Costs and Beneficiary Premiums Low

DIR often refers to negotiated price concessions between pharmacies and health plans or PBMs. However, as coined, DIR is a technical term created by the Centers for Medicare and Medicaid Services (CMS) specific to Medicare Part D that includes both manufacturer rebates and certain incentive payments to pharmacies. These contractual arrangements—even if not specifically labelled DIR—also exist in the commercial market. The vast majority of DIR payments in Part D are PBM-manufacturer negotiated rebates. A much smaller share is made up of incentive payment terms that pharmacies (or their Pharmacy Service Administrative Organizations on their behalf)[1] contractually negotiate with PBMs. Pharmacy DIR payments based on performance metrics hold pharmacies accountable for certain activities such as generic dispensing, cost-effective dispensing, improving medication adherence, and reducing inappropriate drug use.

According to a recent study, the price concessions PBMs negotiate with drug manufacturers and drugstores and report to CMS as DIR are generating significant savings for the federal government and are projected to save enrollees in standalone Part D plans $48.7 billion on their premiums over the next 10 years.[x]

CMS has also found that DIR contributes significantly to keeping Part D premiums low. Earlier this year, CMS released a report that found negotiated DIR price concessions have grown in recent years to moderate beneficiary premiums and reduce costs for the government.[xi] The CMS report highlights how negotiated price concessions reduce premiums for Medicare Part D beneficiaries, which also lead to lower costs for the federal government—negotiated price concessions lowered per-beneficiary costs in Part D 28% on average.[xii] Stable and affordable premiums have contributed to a 90% satisfaction rate among Part D enrollees.[xiii]

Policy Recommendations to Improve Competition and Reduce Costs

PCMA supports policies to lower drug costs through increased competition. The policy proposals outlined below to help increase competition in the marketplace include some

[1] Parties especially noteworthy in the supply chain and key to negotiations between PBMs and pharmacies are large third-party organizations known as pharmacy services administrative organizations (PSAOs). These organizations allow independent pharmacies to pool their collective purchasing power. More than 80% of independent pharmacies (18,103 of the 21,511 pharmacies identified by National Council for Prescription Drug Programs data) use PSAOs or other group purchasing organizations to increase their leverage in negotiating their payment terms and conditions with PBMs. The largest PSAOs are controlled by three multi-billion dollar suppliers to pharmacies, providing a further negotiating advantage for independent pharmacies due to the size and sophistication of these parent companies.

under HELP Committee jurisdiction and some under Finance or Judiciary Committee jurisdiction.

- **Stop anticompetitive product adjustments, i.e., "evergreening."** Drug manufacturers sometimes use tactics such as "product hopping" or "evergreening," submitting applications to the FDA for approval of a "new" product that is essentially the same as the original product. These product lifecycle management tactics artificially extend drug exclusivity periods and delay the take-up of lower-cost generics.

- **Allow for FDA accelerated approval of brand drugs based on increasing competition**. Accelerated review is granted to new drug applications that address "unmet need." The economic need for competition to lower prices should be a criterion of unmet need.

- **Revisit and improve biosimilar labeling and naming**. Substitutable biosimilars should bear identical names and labels to their innovator analogs. Use of different names will confuse patients and providers and inhibit prescribing of biosimilars.

- **Reduce innovator biologic exclusivity to seven years.** Seven years of data exclusivity would still provide a sufficient return to manufacturers, while also speeding more affordable biosimilars to market.

- **Eliminate use of Risk Evaluation and Mitigation Strategies (REMS) to delay competition**. Some manufacturers have used REMS to prevent generic or biosimilar developers from getting sufficient quantities of a drug or biologic to develop a competitor to the innovator product. REMS were never intended for this purpose; this practice should be prohibited.

PCMA also supports enhancing tools in Medicare Part D, Medicaid, and commercial markets to increase competition and affordability. PBMs and health plans can best drive competition among drug manufacturers when they can give plan enrollees a strong incentive to use a competing, higher-value drug. This reduces costs and helps improve adherence among patients. Below are some strategies to strengthen these efforts.

- **Create a safe harbor for value-based drug price negotiations from Medicaid Best Price.** Today any drug manufacturer must offer state Medicaid programs the lowest price it offers any other payer. This provision is seen as a price floor and is inhibiting creative value-based pricing arrangements.

- **Expand drug coverage options for Health Savings Account (HSA)-eligible high-deductible health plans (HDHPs).** HDHPs associated with HSAs should have the option of covering prescription drugs with low or no cost-sharing prior to reaching the deductible, especially drugs that qualify for a preventive drug list. This policy can be achieved by expanding the current preventive drug list used by HDHPs.

- **Remove Part D's protected classes.** Designating "classes of clinical concern" where all or substantially all drugs in a class must be covered allows drug manufacturers to name their price. CMS already applies careful plan formulary coverage checks to assure proper coverage.

- **Make biosimilars subject to the 50% Part D coverage gap discount.** The ACA did not apply to biosimilars the 50% Part D coverage gap discount. This could have the unintended consequence of encouraging prescribing of more expensive innovator biologics when lower cost biosimilars are available.

- **Encourage greater use of generics for Medicare Part D Low Income Subsidy (LIS) enrollees.** MedPAC recommended allowing the Secretary of HHS to lower cost-sharing on generics and raise it for brands that have generic competition. Increasing the differential between brands and generics and allowing plans to lower generic cost-sharing would save money for enrollees and Medicare.

- **Eliminate the tax deduction for direct-to-consumer (DTC) drug ads that mention a specific product.** While DTC drug ads may encourage some people to see a doctor, they drive up unnecessary utilization and the cost of health care.

These are all common-sense ideas that would improve affordability for payers, taxpayers, and consumers, and increase competition.

Conclusion

PBMs evolved because they increase the value of prescription drug benefits. PCMA's member companies harness market forces and competition to corral 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 Committee 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 working with this Committee and the rest of Congress to find additional ways to promote savings consistent with high-quality, high-value prescription drug benefits.

Thank you for the opportunity to testify. I am happy to answer any questions.

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[i] PR Newswire, "PBMs Provide Policy Solutions to Increase Competition, Reduce Rx Costs," Feb 04, 2016.

[ii] Visante: Pharmacy Benefit Managers (PBMs): Generating Savings for Plan Sponsors and Consumers, February 2016.

[iii] 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.

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

[v] Visante, Inc. Increasing Prices Set by Drugmakers; Not Correlated With Rebates, June 2017. Analysis prepared for PCMA

[vi] Ibid.

[v] New York Times, "Costly Hepatitis C Drugs for Everyone?" September 2, 2015.

[viii] IMS Health, "Comparison of Hepatitis C Treatment Costs Estimates of Net Prices and Usage in the U.S. and Other Major Markets," September 2016. https://www.imshealth.com/files/web/IMSH%20Institute/Healthcare%20Briefs/IIHI_Comparison_of_HepatitisC_Treatment_Costs.pdf

[ix] Milliman, "Value of Direct and Indirect Remuneration (DIR): Impact on Medicare Part D Prescription Drug Plan (PDP) Program Stakeholders," Commissioned by Pharmaceutical Care Management Association, July 2017. https://www.pcmanet.org/wp-content/uploads/2017/07/Value-of-PDP-DIR_20170706.pdf

[x] Milliman, "Value of Direct and Indirect Remuneration (DIR): Impact on Medicare Part D Prescription Drug Plan (PDP) Program Stakeholders," Commissioned by Pharmaceutical Care Management Association, July 2017. https://www.pcmanet.org/wp-content/uploads/2017/07/Value-of-PDP-DIR_20170706.pdf

[xi] CMS, "Medicare Part D – Direct and Indirect Remuneration (DIR)" January 19, 2017. https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-01-19-2.html

[xii] CMS, Op. Cit.

[xiii] Morning Consult for Medicare Today, "Ten Years After Implementation, Nearly Nine in 10 Seniors are Satisfied with Part D," July 2016. http://medicaretoday.org/resources/senior-satisfaction-survey/