Testimony of Scott Woods

Pharmaceutical Care Management Association

Before the

PENNSYLVANIA STATE SENATE BANKING & INSURANCE COMMITTEE

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Introduction

Mr. Chairman, Minority Chairman Street, and Members of the Committee: My name is Scott Woods, Senior Director, State Affairs at the Pharmaceutical Care Management Association (PCMA). Thank you for the invitation to appear before the Committee at this hearing to discuss S.B. 637 and for including PCMA and its member companies in the stakeholder discussions on this bill over the last few months.

PCMA is the national association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 266 million[i] Americans and nearly nine million Pennsylvanians 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.

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, let me say that while we understand the Committee's intent to capture the "whole picture" with regard to drug pricing, we are concerned that the rebate disclosure language included in S.B. 637 will increase costs to the Commonwealth and could negatively impact competition among drug manufacturers, thereby limiting the ability of PBMs and plan sponsors to push drug manufacturers to lower drug prices.

Requiring disclosure of individual drug rebate information will allow sensitive information to be released that competing drug manufacturers can easily use to back out what their competitors are paying using other publicly reported information on sales volume. If one manufacturer knows what another is paying, then they have no incentive to compete to offer greater discounts to plan sponsors and consumers.

As currently drafted, the Committee's proposed amendments require that the publicly available report include a list of individual drug rebate information. This would provide drug manufacturers a wealth of competitive commercial market information that would disincentivize them from offering greater discounts—resulting in higher costs for the Commonwealth's patients.

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.

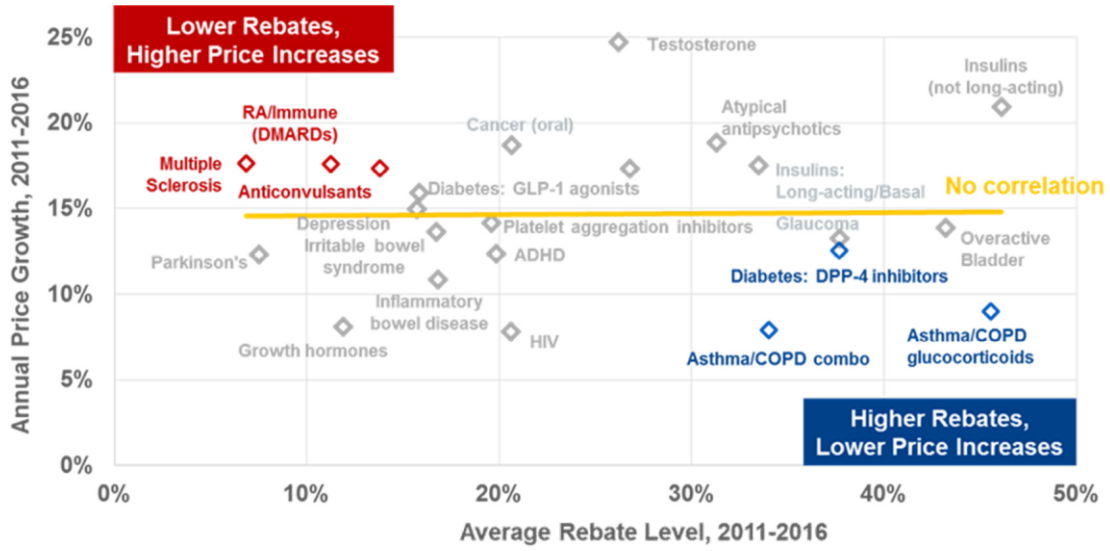
Rebate savings are used by payers to reduce premiums and out-of-pocket costs for patients. Each payer determines what percentage of rebates is passed through to it, and how much (if any) it wants the PBM to retain as payment for services. While on average payers elect to receive 90% of rebates negotiated 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:

Figure 1. No Correlation Between Rebates and Changes in Drug Prices



Source: Visante estimates and analysis of SSR Health data, 2017.

Like manufacturers in other industries, drug manufacturers 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 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.

Policy Recommendations to Improve Competition and Reduce Costs

PCMA supports policies to lower drug costs through increased competition. We believe that rather than a patchwork of state proposals that do not address the root causes of high drug prices—the pricing by drug manufacturers—the federal government must act to catalyze more drug competition.

Pennsylvania lawmakers can—and should—send a resolution to Congress to advocate for immediate federal action in the following areas to help increase competition in the marketplace:

- **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 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.
[vii] 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.