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Before the

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SUBCOMMITTEE ON HEALTH

"Examining the Drug Supply Chain"

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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 Subcommittee 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 with health coverage provided through self-insured employers, health insurers, labor unions, Medicare, Medicaid, SCHIP, and the Federal Employees Health Benefits Program (FEHBP).

At the outset, I want to thank the Energy and Commerce Committee for your work with the Senate HELP Committee to improve generic competition and lower the cost of prescription drugs. FDA's faster approvals for generics and the listing of single-source, off-patent brand drugs, as contained in the FDA Reauthorization Act of 2017 (FDARA), should 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. I also want to acknowledge the Committee's important work on Medicare Part D and Medicaid to ensure affordable prescription drug benefits for millions of vulnerable Americans.

My testimony will describe the role PBMs play in helping patients and payers get the most for their benefit dollars. I will also outline how the Part D program vividly illustrates the value that PBMs bring and that making major changes could destabilize that

successful program. Finally, I offer a number of common-sense, market-based policy proposals to reduce the cost of prescription drugs and to help curb the nation's opioid crisis.

What is a Supply Chain?

Manufacturers in all industries use supply chains to help bring their goods to market. Generally speaking, manufacturers sell in bulk to wholesalers, who then resell to retailers who in turn resell to consumers. Often manufacturers offer rebates, discounts, and other incentives to encourage greater sales of their products versus competing products. Since every supply chain involves some costs, manufacturers only use them to the degree they offer the most cost-effective means of distributing their product. Supply chains are not generally associated with why manufacturers raise prices. As always, pricing decisions and pricing power are primarily determined by supply, demand, and the level of competition a product faces in the marketplace—not distribution costs.

All this is true in the drug supply chain, too, except that third party payers (employers, unions, insurers, government programs)—not consumers—pay most of the costs of prescription drug coverage. Typically, payers cover two-thirds and patients pay the other one-third in the form of premiums and out-of-pocket costs. Payers hire PBMs (which are not part of the supply chain per se) to reduce costs by promoting generics and negotiating rebates and discounts from drugmakers and drugstores that want to be included in the benefit.

Operating in a competitive environment, PBMs typically reduce drug costs by 30%[ii]. Thousands of America's largest, most sophisticated payers choose to hire PBMs, even though none are required to. The Centers for Medicare & Medicaid Services' (CMS) latest National Health Expenditure data also shows that even in the midst of rising drug prices PBMs are continuing to keep overall spending and out-of-pocket costs down.

The Role of Rebates

Central to manufacturer-PBM negotiations, brand drug manufacturers compete for formulary placement 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, no discount at all. PCMA supports benefit designs that ensure patients do not pay more in cost-sharing than the actual cost of the drug and innovations like electronic prior authorization that reduce physicians' administrative burden.

Payers typically use rebate savings to reduce premiums and out-of-pocket costs for patients. Each payer determines what percentage of rebates is passed back 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] Some high-priced drugs have low rebates and some low-priced drugs have high rebates. Some high-priced drugs have no rebate at all. Like manufacturers in other industries, drugmakers set prices according to supply, demand, and the level of competitive alternatives available.

Competition drives manufacturer price concessions. Evidence shows a strong correlation between lower net prices for, and more competition between, substitutable drugs.[vi] An analysis by Credit Suisse finds “a strong correlation” between the size of drug rebates and the extent that drugs are substitutable.[vii] Thus, drug manufacturers with “more unique” products can negotiate lower rebates than companies with more

substitutable products.[viii] This analysis confirms that PBMs negotiate lower drug costs when they can bring competition to bear.

Exploring 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 when a drug is dispensed. In the commercial market, though PBMs could implement it, few payers have chosen to apply rebates at the pharmacy counter. Frustration over high drug prices has led some public policymakers to explore ways to reduce costs for consumers, including requiring health plans in government programs 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

POS rebates have proven unworkable in Medicare Part D and pose risks that could destabilize the program. Already permitted in Part D, POS rebates have been tried—unsuccessfully—in the past. They lead to significant adverse selection and would increase premiums for all Medicare beneficiaries while reducing costs for a small minority. Requiring POS rebates in Part D would significantly increase costs to the program and taxpayers. According to CMS estimates, requiring 100% of rebates to be passed through at POS would, over the next 10 years: increase government costs up to

$82.1 billion; increase beneficiary premiums up to $28.3 billion; and provide a windfall to drug manufacturers of up to $29.4 billion.[ix]

Additionally, requiring direct and indirect remuneration (DIR) pharmacy payments to be paid at POS would be a step backward from policymakers' goals to transform the Medicare program from a wasteful fee-for-service payment model to one based on quality and value. PDPs and PBMs use performance-based payments to reward pharmacies that improve quality through, for example, increasing generic dispensing, improving medication adherence, and reducing inappropriate drug use. Alternatively, pharmacies that underperform and do not meet the performance metrics may not earn contractually agreed-upon bonus payments. Because such value-based arrangements use quarterly or annually measured incentives, a typical pharmacy's performance cannot be determined at POS. These arrangements are agreed upon and acknowledged in advance by pharmacies in their network contracts.

Finally, mandating POS rebates and pharmacy DIR would expose plans to other risks, such as accusations of False Claims Act violations if they incorrectly estimated the size of rebates, which would be a virtual certainty. These points are especially important in light of CMS's current open docket request for information on the prospect of implementing POS rebates and POS pharmacy DIR in Part D.

Negotiations with Pharmacies Reduce Costs for Consumers and Payers

PBMs also use value-based contracting to build a network of high-performing pharmacies. As noted above, based on negotiated, agreed-upon performance metrics, PBMs hold pharmacies accountable for performance on certain activities such as generic dispensing, cost-effective dispensing, improving medication adherence, and reducing inappropriate drug use. In turn, pharmacies performing well on such metrics earn bonus payments and preferred status. The ability of health plans and PBMs to construct networks that include some, but not all, providers—has long been used to increase quality of care and lower costs for patients.

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 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 and be held accountable for the quality of their care. An “any-willing pharmacy” bill introduced in Congress last year would undermine the availability of lower cost, preferred pharmacies and increase Medicare spending by $21 billion over the next 10 years, according to an analysis.

PBM pharmacy networks include independent pharmacies that usually hire pharmacy services administrative organizations (PSAOs) to negotiate and contract with PBMs and other third-party payers on their behalf. A typical PSAO represents thousands of pharmacies. More than 80% of independent pharmacies (18,103 of the 21,511 pharmacies identified by National Council for Prescription Drug Programs data) use

PSAOs. PSAOs provide access to pooled purchasing power, negotiating leverage, and contracting strategies similar to those of large, multi-location chain pharmacies.

The Success of Part D Showcases the Value of PBMs

In the decade plus since the creation of the Medicare Part D Prescription Drug Benefit, policymakers and other observers have taken heightened interest in the work of PBMs. Widely recognized as one of the more successful government programs in recent history, Part D has provided unprecedented access to needed drugs for millions of Medicare beneficiaries, while consistently spending far below estimated levels. This success has been due to the structure of Part D, which allows PBMs to use the negotiating and management tools at their disposal to manage drug benefits. To make major changes to this successful system would be a mistake.

Medicare Part D: A Case Study for How PBMs Use Direct and Indirect Remuneration (DIR) to Keep Part D Costs Down and Beneficiary Premiums Low

PBMs have been able to replicate the successful drug benefit management techniques they have long used in the private sector to benefit Medicare Part D. The program works through DIR, which is a technical term created by CMS specific to Part D that includes both manufacturer rebates and certain incentive payments to pharmacies. The vast majority of DIR payments in Part D comprise PBM-manufacturer negotiated rebates. A much smaller share is made up of incentive payment terms that pharmacies (or their PSAOs on their behalf) contractually negotiate with PBMs.

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 stand-alone 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 vast majority of the policy proposals outlined below to help increase competition in the marketplace and in federal programs would come under Energy and Commerce Committee jurisdiction. Our industry would be pleased to work with you and other stakeholders on the following proposals.

- **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. The Fair Access for Safe and Timely Generics "FAST" Act, introduced by Representatives McKinley and Welch and cosponsored by Representatives Schrader, DeGette, and Schakowsky would address these abuses.

- **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.

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 Medicare 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.

In addition to proposals to find savings and efficiencies in the market and public programs, we also commend the Subcommittee for its work in helping to curb the

nation's opioid crisis. Below are three policy proposals that we believe would help that effort.

- **Require E-prescribing (e-Rx) for Controlled Substances.** Requiring e-prescribing for controlled substance prescriptions would circumscribe pharmacy shopping, enable better prescription tracking, and reduce fraud. I want to thank Representative Mullin and the other cosponsors on the Energy and Commerce Committee, Representatives Kennedy, Tonko, and Long, for your work on H.R. 3528, the Every Prescription Conveyed Securely Act.

- **Seven Day Opioid Prescription Limits for Acute Pain.** To prevent patients from getting addicted to pain medication, prescriptions for acute pain should be limited to a seven days' supply. The limit would not apply to treatment of cancer or chronic pain, or the use of opioids in treating addiction or for patients in hospice care. This aligns with a recent recommendation of the Centers for Disease Control and Prevention.

- **Achieve Timely and Flexible Implementation of the Comprehensive Addiction and Recovery Act (CARA) Lock-In.** CMS included in its recent proposed Part D rule suggested regulations for implementing the CARA pharmacy and prescriber lock-in. Inexplicably, CMS has proposed that once beneficiaries are identified as being at-risk, they should have a six-month delay before being locked-in for controlled substances to a pharmacy. PCMA believes that at-risk beneficiaries should be locked in as quickly as possible to avoid

further harm to themselves and also to prevent fraud if they are diverting drugs. This program was established by Representative Bilirakis' *Medication Safety and Drug Abuse Prevention Act*, which passed last Congress and was cosponsored by Representatives Lujan and Long. Thank you for your leadership and we hope you will express concerns to CMS about their proposal.

Conclusion

PBMs evolved into their current role 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 Subcommittee 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.

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

[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] Credit Suisse, "Global Pharma and Biotech: Exploring Future U.S. Pricing Pressure," April 18, 2017
[vii] Credit Suisse, "Global Pharma and Biotech: Exploring Future U.S. Pricing Pressure," April 18, 2017.
[viii] Credit Suisse, "Global Pharma and Biotech: Exploring Future U.S. Pricing Pressure," April 18, 2017.
[ix] CMS, " Medicare Program: Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program," Federal Register, November 28, 2017.

[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/