Testimony of Mark Merritt

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Before the

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COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

"Developments in the Prescription Drug Market: Oversight."

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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 to contribute our suggestions for ways to increase competition to better manage drug spending. PCMA is the national association representing America's pharmacy benefit managers (PBMs). PBMs administer prescription drug plans for more than 266 million Americans who have health insurance from a variety of sponsors including: commercial health plans, self-insured employer plans, union plans, Medicare Part D plans, the Federal Employees Health Benefits Program (FEHBP), state government employee plans, managed Medicaid plans, and others.

PBMs reduce drug costs by:

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

From 2016 to 2025, the use of PBM tools will save employers, unions, government programs, and consumers $654 billion—or up to 30%—compared with programs that make little use of proven PBM tools.[i]

PBMs are the key industry in America addressing the challenge of reducing costs, expanding access, and improving the quality of pharmacy benefits. Potential solutions that will enhance competition and help lower drug prices include:

- Getting speedier approval of drugs based on economic need;
- Solving the problem of off-patent drugs not subject to competition;
- Removing the generic drug backlog;
- Ensuring access to brand drug and biologic samples for development of generics and biosimilars; and
- Unlocking more innovative pricing arrangements.

This testimony will outline how PCMA's member companies harness competition to get lower prices from manufacturers and pharmacies. It will also discuss PBMs' role in combatting fraud and abuse, raise concerns about use of copay coupon programs, and offer policy solutions to increase competition among drug manufacturers to bring down drug costs, especially where drugs are long off patent.

PBMs Create Market Competition Among Drug Manufacturers

The PBMs competing in the marketplace, across all lines of business, represent total patient populations of tens of millions of individuals, bringing significant negotiating leverage to the table with brand manufacturers.[ii]

Recent events demonstrate how competition in the marketplace can drive significant savings on expensive drugs. A few months ago, a drug manufacturer reported that PBMs were able to negotiate a 46 percent rebate discount for one new hepatitis C drug—saving billions—when a direct competitor drug was introduced into the market.[iii] Indeed, while some PBMs preferred the first drug in their formulary, competing PBMs opted to prefer a competing manufacturer's drug, realizing equally large discounts. Other PBMs chose to keep both on their formulary, and ultimately, the market competition has allowed for this steep discount as compared with when the first drug was originally introduced.

Commercial clients and PBMs negotiate the proportion of rebate savings returned to the plan and the proportion used by the PBM in lieu of other fees to pay for their services. As passed through to clients, rebates reduce the cost that they pay for their prescription drug benefit. In Medicare, the rebate is largely applied to reduce premiums for beneficiaries.

Using Competition to Make Medicare Part D a Success

Medicare Part D was designed to encourage private health plans—MA-PDs and PDPs—to compete for beneficiaries, on the principle that competition keeps costs lower. The private plans in turn have engaged PBMs to negotiate with drug manufacturers and pharmacies, administer the benefits, recommend formularies, and otherwise implement Part D. Over the past 10 years, Part D has realized costs well under the original projections, benefiting beneficiaries and taxpayers alike, as PBMs have innovated to keep costs as low as possible.

Just as in the commercial sector, Medicare Part D plans negotiate to capture the largest possible discounts and rebates by using cost sharing and utilization management tools to encourage patients to choose preferred drugs where appropriate. CBO has found that Part D plans "have secured rebates somewhat larger than the average rebates observed in commercial health plans."[iv] Further, the Medicare Trustees note that "many brand-name prescription drugs carry substantial rebates, often as much as 20-30 percent."[v] Analysis of Medicare Trustee data shows that negotiated rebates have increased in each year of the program, repeatedly exceeding projected levels.[vi]

Indeed, the Government Accountability Office (GAO) reported that Medicare Part D plans lowered costs for beneficiaries, "through their ability to negotiate prices with drug manufacturers and pharmacies…Sponsors must . . . pass price concessions on to beneficiaries and the program through lower cost sharing, lower drug prices, or lower premiums."[vii] Growth in the reported average levels of negotiated rebates in Part D show competition at work, and competition among Part D plans to attract enrollees translates into savings for Medicare beneficiaries.

PBMs have Innovated Preferred Pharmacy Networks in Part D

PBMs have innovated in Medicare Part D by negotiating with pharmacies to offer lower costs in exchange for higher volume, as well as better value and higher quality, as part of preferred pharmacy networks. These networks comprise all types of pharmacies, including independent pharmacies. Plans using pharmacies offering preferred cost sharing have proven enormously popular—currently 75 percent 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, giving beneficiaries the opportunity to stay with a pharmacy with preferred cost sharing by carefully choosing their Part D plan every year.

Evidence shows Part D enrollees have embraced the savings that preferred pharmacies bring. A national poll conducted by Hart Research Associates shows that seniors in plans with preferred pharmacy networks are overwhelmingly satisfied, citing lower costs and convenient access to pharmacies, among other benefits. The survey revealed that 80 percent of those in preferred pharmacy plans—which translates to over 7 million seniors—would be very upset if their plan was no longer available.[viii]

For Part D overall, 89 percent of Americans age 65 and older are satisfied with their coverage and 85 percent say that they consider their Medicare drug plan to be a good value.[ix]

PBMs Drive Efficiency through MAC Reimbursement

Maximum allowable cost (MAC) is one of the most common methodologies used in paying pharmacies for dispensing generic drugs. By definition, MAC is the maximum allowable reimbursement by a PBM for a particular generic drug that is available from multiple manufacturers and sold at different prices. Each manufacturer has its own price for a particular generic drug and these prices can differ extensively by manufacturer. The use of MAC encourages competition: the purpose of MAC pricing is to encourage pharmacies to obtain the lowest-cost generic from among identical products from various manufacturers.

PBMs use MAC lists to balance providing fair compensation to pharmacies with being able to provide a cost-effective drug benefit plan to their health plan and employer clients. MAC pricing has become the industry standard—it is used by 79 percent of private employer prescription drug plans for retail generic prescriptions. In addition, 45 state Medicaid programs now use MAC lists. States adopted MAC lists after government audits showed that Medicaid reimbursements based on cost-plus reimbursement for generic drugs far exceeded a pharmacy's acquisition costs.

MAC reimbursement is a negotiated point in contracts between pharmacies and PBMs. Far from being at a contract negotiating disadvantage, independent pharmacies typically pool their collective purchasing power to increase leverage. More than 80 percent of independent pharmacies (18,103 of the 21,511 pharmacies identified by National Council for Prescription Drug Programs data) use large third-party organizations known as pharmacy services administrative organizations or group purchasing organizations to increase their leverage in negotiating their payment terms and conditions with PBMs. [x]

PBMs Fight Fraud and Abuse

PBMs exert great efforts to combat fraud, waste, and abuse with respect to prescription drugs. Pharmacy fraud, waste, and abuse costs the overall Medicare program billions. PBMs use data analytics to identify fraudulent pharmacies and fraudulent patients and then go after the perpetrators. PBMs also perform audits, where records from pharmacies are compared to claims data records. Additionally, PBMs make site visits to ensure that a pharmacy reporting claims is actually occupying physical space and has customers.

To address increasing opioid abuse, PBMs are using sophisticated analytics to uncover patterns of potential fraud or abuse, and scanning for behavioral red flags to identify when someone may be inappropriately seeking opioids. To further combat opioid abuse, PCMA strongly supports creation of a lock-in program in Medicare Part D, to allow Part D plans to work with at-risk Part D beneficiaries to choose a single pharmacy to dispense their controlled substances. Such a policy would maintain beneficiary access to needed medications, but prevent inappropriate shopping for opioids.

PCMA also supports requiring drugstores and pharmacists to register with state prescription drug monitoring programs; allowing payers to coordinate with state drug monitoring databases; and allowing Part D plans to use the same fraud prevention tools for pharmacies—including predictive analytics and suspension of payment upon a credible allegation of fraud—as are used in Medicare Parts A and B.

Copay Coupons Undermine Efforts to Incent Patients to Take Cost-Effective Drugs

Drug companies now offer copay coupons to undermine efforts by employers, unions and state governments to reduce costs by assigning higher consumer copays to expensive drugs and lower copays to more affordable drugs. The economics of brand copay coupons are simple: each time a drug company can sell a $150 product by helping cover a $50 copay, it gains $100 in revenue, which is paid by the employer, union, or state government that offers coverage.

By definition, copay promotions target those who already have prescription drug coverage (i.e., those who pay copays). These programs are not means tested or designed to help the poor or uninsured. Instead, they are designed to encourage insured patients to bypass less expensive drugs (which typically have lower copays) when multiple options are on the formulary, raising the cost of drug coverage.

Such practices are illegal in federal programs and have long been under scrutiny by the Health and Human Services Office of Inspector General because they are viewed as "kickbacks" that encourage wasteful spending for the profit of an outside third-party. Copay offset programs are estimated to increase pharmacy spending by $32 billion.[xi] To help cover the $4 billion spent annually on copay coupons, manufacturers can simply raise prices. Manufacturers reportedly earn as much as a six-to-one return on investment on copay coupon programs. Because insurers and plan sponsors foot this bill, these programs increase premiums.

Additionally, drug companies often require consumers to submit confidential, personal information in order to redeem copay coupons. Manufacturers have long sought (but found difficult to obtain) such sensitive patient data, which enables them to identify and directly target individual patients with brand-loyalty marketing programs.

Increasing Competition in the Marketplace

While PBMs can negotiate significant discounts and rebates when drugs are subject to competition, the options to achieve lower prices are limited when there is an absence of it. When a sole-source brand drug with no close substitutes enters the market, often similar competing brand drugs will subsequently enter the market, and eventually the original drug's patent will expire and generic versions of it will be produced. However, for various reasons, generic versions of brand drugs do not always come to market after the original drug's market exclusivity has expired. A number of policy changes to enhance competition could lower the cost of drugs generally.

Getting Speedier Approval of Drugs Based on Economic Need: A number of recently approved drug and biologic therapies have entered the market with historically high manufacturer prices. While many of these drugs represent needed breakthroughs to fight devastating and debilitating illness, their cost can be a barrier to access for patients who need these drugs and strain health budgets in both the public and private sectors. Additionally, although drug trend has been historically low in recent years, current projections show that the greater availability and use of specialty drugs and clinical guidelines encouraging drug use at earlier stages are poised to dramatically increase overall drug trend. According to FDA, 16 of the 45 novel drugs approved in 2015 (36 percent) were first-in-class, implying they will face little if any competition in the marketplace.[xii] Rather than directly intervening in manufacturer pricing, policymakers could better encourage price competition in the marketplace by accelerating approval of drugs in development for conditions where the cost of existing medications is a barrier to treatment and where manufacturers of current therapies have little incentive to compete on price. For example, in classes where there are only one or two drugs, new brand applications could be fast-tracked.

Solving the Problem of Off-Patent Drugs not Subject to Competition: As a first step, the FDA or other qualified entity should compile a list of all drugs and concomitant indications for which market exclusivity has expired, but do not currently have generic or other brand substitutes. This initial indexing will allow stakeholders to understand the number and types of such products. Additionally, policymakers and stakeholders alike should explore ways to encourage competition for such drugs, to help prevent the kinds of pricing actions discussed in

this hearing. This might be accomplished through providing accelerated review of abbreviated new drug applications (ANDAs) for these products.

Removing the Generic Drug Backlog: PBMs could bring additional competition to the market for other drugs, but FDA prioritizes breakthrough therapies, leaving generic and "me-too" brand drugs languishing on the approval sidelines. FDA argues that it has largely cleared the historic 42-month generic backlog.[xiii] However, a mid-year industry estimate places the median approval time for 2015 at 48 months,[xiv] and, the agency's GDUFA goal of a 15-month review for new ANDAs is substantially longer than the 10-month PDUFA goal currently in place for new non-generic drugs. In addition, there are still over 1,000 applications that have received a complete response and therefore will soon be back in the agency's hands after the sponsor addresses the identified deficiencies.[xv]

This is still a significant backlog, and it will likely take the agency years to process. FDA says that the filing backlog has been virtually eliminated, but it should be noted that this does not mean the entire backlog has been resolved. This only means that there is no longer a backlog of applications waiting to be formally accepted for filing. There remains a substantial backlog of applications already accepted for filing, which are now pending review. Resolving the filing backlog is akin to eliminating the line to take a number at the deli counter—though patrons are no longer waiting in line to get in the queue, they still must wait for their turn to be served (or in this case, for FDA to review their application). Finally, it is critically important to examine FDA's ability to work with generic manufacturers toward successful applications in judging FDA's progress on the backlog, and indeed on getting generics to market timely.

Ensuring Access to Brand Drug and Biologic Samples for Development of Generics and Biosimilars: Some drug manufacturers, including some manufacturing off-patent brand drugs, have made it extremely difficult for potential generic competitors to obtain samples needed for bioequivalence testing, sometimes by invoking FDA Risk Evaluation and Mitigation Strategies (REMS) but other times simply using extremely limited distribution schemes.[xvi] The use of such schemes to thwart generic competition has gotten the notice of the Federal Trade Commission (FTC), which has expressed concern over "the possibility that procedures intended to ensure the safe distribution of certain prescription drugs may be exploited by brand drug companies to thwart generic competition."[xvii] Further, survey results indicate that brand manufacturers are indeed using REMS or similar systems to deny generic manufacturers' access to brand drug samples.[xviii] In addition, brand manufacturers have also begun applying these anticompetitive distribution practices to drugs carrying no notable safety concerns, and for which the FDA has not required a REMS program.[xix]

In the House, there is bipartisan legislation (FAST Act, "Fair Access for Safe and Timely Generics," introduced by Steve Stivers (R-OH) and Peter Welch (D-VT)) that would require brand manufacturers to allow competitors access to samples of their product as a condition of FDA approval. We are supportive of these kinds of ideas.

Unlocking More Innovative Pricing Arrangements: The rapid increase in the cost of specialty drugs is driving the market to begin to consider alternative ways of paying for expensive therapies. The move to bundled payments, accountable care, comparative effectiveness research,

evidence-based medicine, and payments linked to performance are the direct result of regulatory and market pressures to reduce health costs without compromising safety and quality. For PBMs and drug manufacturers, these trends will demand innovative approaches to pricing. To enable more creative, value-based arrangements, however, our laws and regulations will need to be updated. For example, Medicaid best price rules make drug manufacturers reluctant to offer pricing arrangements that could, in theory, result in very low unit prices for some groups of patients, because manufacturers must then give that price to all Medicaid enrollees.[xx]

Price Controls and Cost Sharing Limits Are Not the Answers

The U.S. drug manufacturing and distribution system is the best in the world because it relies on market forces and competition to deliver high quality benefits and services to patients who need them. I urge the Committee to pursue policies that foster and encourage competition to keep drug costs and pharmacy benefits affordable. I especially urge the Committee to consider carefully the likely harm of certain proposals that would impose federal price controls on drug products and pharmacy services, impose limits on patient cost sharing, or expand coverage mandates. Such policies do not address the underlying problem at hand—rising drug costs and spending—and only serve to shift costs or reduce availability. In particular, limits on cost sharing may only serve to allow drug manufacturers to further increase prices on drugs. Those increased costs are borne by employers, governments, and patients themselves in the form of higher premiums.

Conclusion

PBMs were created 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 health plan clients and enrollees. In its search for solutions to what appear to be unusually high drug price increases, PCMA believes the Committee would be best served 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. Improving drug approval times and encouraging competition, as well as resisting the urge to unduly regulate PBMs and prescription drug benefits, will go a long way toward helping to constrain drug manufacturers' demonstrated impulses[xxi] to price their products high.

As just one part of the prescription drug marketplace, our companies welcome continuing discussion among all stakeholders in the drug distribution system to create a robust, sustainable market that will continue to deliver needed cures and treatments for patients who suffer through disease and chronic illness. Additionally, PCMA looks forward to working with Congress to find additional ways to promote savings while continuing to deliver the highest quality, highest value prescription drug benefits for all.

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[iii] New York Times, "Costly Hepatitis C Drugs for Everyone?" September 2, 2015.
[iv] CBO, Letter to the Honorable Joe Barton and the Honorable Jim McCrery, March 12, 2007, Page 3.
[v] Medicare Trustees, "2014 Medicare Trustees Report," p.150, footnote 63.
[vi] Medicare Trustees, "2015 Medicare Trustees Report," p. 144, Table IV.B8.

[vii] GAO, "Overview of Approaches to Control Prescription Drug Spending in Federal Programs." Statement of John E. Dicken, Director, Health Care, Government Accountability Office, before the Subcommittee on Federal Workforce, Postal Service, and the District of Columbia, Committee on Oversight and Government Reform, House of Representatives, June 24, 2009. http://www.gao.gov/new.items/d09819t.pdf

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[xi] "How Copay Coupons Could Raise Prescription Drug Costs By $32 Billion Over The Next Decade, Visante Study commissioned by PCMA. http://www.pcmanet.org/images/stories/uploads/2011/Nov2011/visante%20copay%20coupon%20study.pdf

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[xiii] HHS, "Department of Health and Human Services, Fiscal Year 2016 Justification of Estimates for Appropriations Committees, Food and Drug Administration." http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM432322.pdf

[xiv] http://www.gphaonline.org/gpha-media/press/statement-by-ralph-g-neas-president-and-ceo-gpha-on-the-june-15th-fda-public-meeting-on-gdufa

[xv] Implementation of the Generic Drug User Fee Amendments of 2012 (GDUFA).Testimony of Janet Woodcock, M.D. Before the Committee on Health, Education, Labor and Pensions. January 28, 2016, Page 5

[xvi] Michael Carrier and Aaron Kesselheim "The Daraprim Price Hike And A Role For Antitrust," *Health Affairs* Blog, October 21, 2015.

[xvii] Federal Trade Commission's Brief as Amicus Curiae, Actelion Pharmaceuticals Ltd. v. Apotex Inc., (No. 1:12-cv-05743-NLHAMD), (D.N.J. Mar. 2013), available at www.ftc.gov/os/2013/03/130311actelionamicusbrief.pdf.

[xviii] Alex Brill, "Lost Prescription Drug Savings from Use of REMS Programs to Delay Generic Market Entry," July 2014. http://www.gphaonline.org/media/cms/REMS_Studyfinal_July2014.pdf

[xix] Alex Brill, "Lost Prescription Drug Savings from Use of REMS Programs to Delay Generic Market Entry," July 2014. http://www.gphaonline.org/media/cms/REMS_Studyfinal_July2014.pdf [This could just be ibid]

[xx] Dana Goldman and Darius Lakdawalla, "Moving Beyond Price-Per-Dose In The Pharmaceutical Industry," *Health Affairs* Blog, September 30, 2015.

[xxi] *See, e.g.*, The Staffs of Ranking Member Ron Wyden and Committee Member Charles E. Grassley, Committee On Finance, United States Senate "The Price Of Sovaldi And Its Impact On The U.S. Health Care System," December 2015, pp. 45-46.