

Testimony of Mark Merritt

Pharmaceutical Care Management Association



Before the

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SPECIAL COMMITTEE ON AGING

“Sudden Price Spikes in Off-Patent Drugs: Perspectives from the Front Lines”

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Introduction

Good afternoon. My name is Mark Merritt, President and CEO of the Pharmaceutical Care Management Association (PCMA). I appreciate this opportunity to appear before the Committee for this hearing examining sudden price spikes in off-patent drugs. PCMA is the national association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 253 million Americans with health coverage provided through Fortune 500 employers, health insurers, labor unions, Medicare, Medicaid, the Federal Employees Health Benefits Program (FEHBP), and the ACA Exchanges.

PBMs offer a wide variety of services aimed at making prescription drug benefit programs operate safely, efficiently, and affordably for their clients, including health plans, employers, unions, and governments.

While many PBMs are independently owned and operated, some are subsidiaries of managed care plans, major chain drug stores or other retail outlets. PBMs compete to win business by offering their clients a range of sophisticated administrative and clinically based services, enabling them to manage drug spending by enhancing price competition and increasing the cost-effectiveness of covered medications.

All PBMs offer a core set of services to manage the cost and utilization of prescription drugs and improve the value of plan sponsors' drug benefits. Some offer additional tools, such as disease management, that can target specific clinical problems for intervention. It is up to the client of the PBM, however, to determine the extent to which these tools will be employed.

PBMs aggregate the buying clout of millions of enrollees through their client health plans, enabling plan sponsors and individuals to obtain lower prices for their prescription drugs through price discounts from retail pharmacies, rebates from pharmaceutical manufacturers, and the efficiencies of mail-service pharmacies.

PBMs typically form pharmacy networks and bargain to set a rate at which the PBM will reimburse the pharmacy for each prescription that the pharmacy fills as a network provider. Most PBMs also operate their own mail-service and specialty pharmacies, and fill prescriptions through these outlets. PBMs also take the lead role in helping patients adhere to their prescribed therapies to improve medical outcomes.

This testimony will outline the services that PBMs perform to provide patients, employers, and governments at all levels with the highest value prescription drug benefits. It will also contrast the valuable services that true specialty pharmacies provide to patients, versus the actions of certain "bad apple" pharmacies that are little more than a marketing outlet. In addition, it will

discuss challenges arising from price shocks when competition among drugs—specifically, those off patent but without a generic or other brand substitute—is lacking. It also will highlight the exploiting of legitimate drug safety protections to inappropriately thwart generic competition. Finally, it will discuss potential policy solutions to increase such competition to better manage drug spending.

Lowering Costs, Managing Benefits

It is important to note that PBMs do not make patient coverage decisions; rather, they provide their clients—health plan sponsors—with various options for savings on prescription drug costs. PBMs advise their clients on ways to structure drug benefits to encourage the use of lower cost drug alternatives—such as generics—when appropriate. The PBM’s role is advisory; the plan sponsor client retains responsibility for establishing the plan design. Plan sponsors themselves guide how actively pharmacy benefits are managed. For example, plan sponsors determine formulary coverage, copayment tiers, utilization management, and pharmacy channel options based on PBM recommendations. In addition, PBMs use a variety of tools such as drug utilization review and medication management to encourage the best clinical outcomes for patients. In making these choices, the plan sponsors weigh a multitude of factors, including cost, quality, and their employee/enrollee needs, and member satisfaction.

Leveraging Market Competition among Manufacturers

PBMs are able to extract savings from brand drug manufacturers directly through rebating. Rebating is a practice in which manufacturers pay negotiated, after-the-fact rebates to PBMs upon demonstration that the PBM has moved market share to that manufacturer’s brand drug.

PBMs typically negotiate with their commercial health plan and large employer clients the proportion of rebate savings returned to the plan—in some cases 100 percent—and the proportion used by the PBM in lieu of other fees to pay for their services. When passed through to clients, rebates reduce the cost that they pay for their prescription drug benefit; when not passed through fully, rebates reduce fees owed the PBM. In Medicare Part D—which is of particular interest to the Special Committee on Aging—these rebates must largely be passed back to the beneficiary or federal government through reduced premiums or other means.

The rebate amount is generally based on the market share a PBM can demonstrate it moved, through formulary and drug benefit design, to that drug. In these cases, the end or “net” price of a product to the client cannot be determined until after the end of the time period for the agreement and the resulting total sales volume is known.

Hepatitis C Drugs: A Classic Case of Leveraging Competition

The recent introduction of effective drugs to treat—and cure—hepatitis C demonstrates how effectively competition can work to bring down high drug costs when there are two or more substitutable drugs on the market. A breakthrough hepatitis C drug entered the market two years ago priced at \$84,000. Upon the subsequent introduction of a competitor product, PBMs immediately drove manufacturers to compete to include their drugs in their formularies. Ultimately, market competition forced a steep drop in cost for those enrolled in Medicare Part D and commercial insurance, as compared to each drug’s original price. Earlier this year, one hepatitis C manufacturer publicly stated that PBMs had negotiated a roughly 46 percent rebate,ⁱ saving billions of dollars, and equally importantly, allowing insurers to make the drug available to far more people. The large negotiated discount resulted in a price tens of thousands of dollars lower than the drug’s initial price in countries with government-driven drug price regimes such as Germany and the United Kingdom.ⁱⁱ

Delivering Quality Care and Value through Specialty Pharmacies

Another important service PBMs offer is the range of patient supports in specialty pharmacies. The number and range of specialty drug and biologic products available to patients has increased dramatically in recent years. As a general rule, specialty drugs treat more complex conditions requiring greater clinical oversight, may have more side effects requiring active clinical management, and involve more intense patient education. They are also typically very expensive—the highest priced specialty drugs can cost over \$400,000 per patient per year. Thus, it is critical to help patients comply with their treatment regimens and ensure they are receiving the greatest value from their medications.

Payers increasingly rely on specialty pharmacies to dispense these medications. Specialty pharmacies are distinct from retail pharmacies in that they coordinate the many aspects of care for people with complex and chronic conditions and provide robust offerings of clinical and operational specialty pharmacy services. These entities manage drug regimens for those with complex, chronic conditions, such as multiple sclerosis, hepatitis C, and rheumatoid arthritis; or rare medical conditions, such as cystic fibrosis, hemophilia, or multiple myeloma. Using dedicated, specialized personnel, a specialty pharmacy provides patient education and clinical support beyond traditional dispensing activities. Specialty pharmacies typically manage therapies where the drug is an oral, injectable, inhalable, or infusible drug product with unique storage or shipment requirements, such as refrigeration.

Recent Incidents Highlight Problems of Manufacturer-Controlled Specialty Pharmacies

Recent reports have shown the actions and practices of certain bad apple pharmacies—controlled or owned by drug manufacturers—that call themselves specialty pharmacies, but in reality, represent a marketing strategy to skirt plan formularies, which are time-tested tools to provide for the dispensing of safe, high-value drugs. These pharmacies often: generate a disproportionate share of sales from a single manufacturer’s products; dispense primarily non-specialty branded generics; and processes a large number of co-pay offset programs for non-specialty products.

These “bad apple” pharmacies typically fill brand-name drug prescriptions for the brand manufacturer’s own drugs, often providing a manufacturer-sponsored co-pay offset for the patient, instead of a more affordable generic. This raises costs in the drug benefit system, because most other pharmacies would substitute a more affordable alternative or generic drug. This, in turn, results in higher benefit costs for employers and the government, and higher premiums for patients and their families.

A few examples will better illustrate the problem. Recent investigations have found that the manufacturer Horizon Pharma was employing an affiliated pharmacy to sell low-value drugs, such as Duexis. The pain reliever Duexis is a combination of two old and common drugs, the generic equivalents of Motrin and Pepcid. If prescribed separately, the two drugs together would cost no more than \$20 or \$40 a month.ⁱⁱⁱ By contrast, Duexis, which contains both in a single pill, costs about \$1,500 a month.^{iv} This price represents poor value for both patient and payer when much cheaper generic drugs are available. Nevertheless, Horizon has urged doctors to submit prescriptions directly to a so-called specialty pharmacy affiliated with the drug company.^v The pharmacy delivers the drug to the patient, circumventing the insurers’ formulary and utilization management systems, which are designed to deliver the safest, highest-value drugs.

Similar is the case of the drug manufacturer Valeant’s affiliated pharmacy, Philidor, which encouraged doctors to have prescriptions filled through itself, rather than by traditional pharmacies.^{vi} That made it harder for pharmacists and insurers to substitute a less expensive drug. Reports emerged that Philidor had used questionable tactics—such as changing doctor’s prescriptions and using other pharmacies’ identification numbers—to get insurers to pay for the drugs it dispensed.^{vii} As a result, PBMs have cut business ties with Philidor.

Moreover, these cases illustrate the danger of policies, such as any-willing-pharmacy laws, that would require insurers and payers to include any pharmacy in a pharmacy network. Such policies greatly increase the possibility of fraud and unnecessary inefficiencies by tying the hands of payers from excluding such bad apples or dubious actors from their networks.

The Need to Increase 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 recent high-profile cases of drug price increases shows the effects of a lack of generic competition. One recent case is Daraprim. The drug was first approved by the FDA in 1953.^{viii} Through a chain of title that included three different manufacturers, Turing Pharmaceuticals acquired the rights of Daraprim in August 2015. Daraprim is a listed drug in the FDA's Orange Book^{ix} with no generic version currently available, despite having no patent protection.^x

Shortly after Daraprim's acquisition last August by Turing Pharmaceuticals, the manufacturer raised the price to \$750 a tablet from \$13.50, bringing the annual cost of treatment for some patients to hundreds of thousands of dollars.

One reason no generic may have been available is the small number of patients who take Daraprim. The U.S. market for the drug is estimated to be about 2,000 patients. The relatively small number of patients, coupled with a previous comparatively modest price of \$17.50 per pill for the brand product (which a generic would likely lower), seems not to have created a sufficient financial incentive for a generic manufacturer to enter the market.

Thwarting Generic Competition

In June 2015, apparently as a condition of the sale to Turing, the previous maker Impax Laboratories by fiat switched to an unnecessarily anticompetitive system, making it extremely difficult for potential generic competitors to obtain samples needed for bioequivalence testing.^{xi} For a manufacturer to implement such a program, purely of its own volition, more than six decades after a drug's introduction, with an absence of any new emerging safety considerations is unusual and seems motivated by pricing concerns rather than patient concerns.

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."^{xii} Further, survey results indicate that brand manufacturers are indeed using REMS or similar systems to deny generic manufacturers' access to brand drug samples.^{xiii} Not only this, but 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,^{xiv} as seems to be the case with Daraprim.

Market Response

As is often the case, a market solution came about to address the price shock. The PBM Express Scripts said earlier this month it will partner with Imprimis Pharmaceuticals to provide a \$1 alternative to Daraprim.^{xv} Imprimis said it would make the alternative—a compounded formulation of the active ingredient in Daraprim, pyrimethamine, and another drug, leucovorin—available for \$99 for a 100-count bottle, or less than \$1 per pill.^{xvi} Under the partnership, Express Scripts added Imprimis to its pharmacy network and says it will work with organizations including the Infectious Diseases Society of America (IDSA) and the HIV Medicine Association (HIVMA) to communicate the availability of the Daraprim alternative to physicians.^{xvii} At \$1 per pill, Imprimis said it will still turn a profit on pyrimethamine.^{xviii}

While this example illustrates a creative solution to one particular problem, we will not be able to count on such actions for all drugs subject to such price hikes from lack of competition. Indeed, Express Scripts regarded the action as “unique” and that it would not be a new standard.^{xix} However, we believe a number of policy changes could enhance competition to eliminate or mitigate the kinds of exploitation of existing law that enable legal profiteering on off-patent prescription drugs.

Enhancing Competition to Manage Drug Spending

A number of policy changes to enhance competition could lessen the ability to exploit loopholes in the law that allow manufacturers to implement price gouging and anticompetitive distribution regimes, or to lower the cost of drugs generally:

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 or providing regulatory flexibility to allow more solutions similar to the Express Scripts/Imprimis solution discussed above.

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. The generic approval backlog, at 42 months, is longer than it has ever been.^{xx}

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 medications 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. 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.

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 (CER), evidence-based medicine (EBM), 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 schedules 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.^{xxi}

Price Controls and Cost Sharing Limits Are Not the Answers

We believe 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. We urge the Committee to pursue policies that foster and encourage competition to keep drug costs and pharmacy benefits affordable. We especially urge the Subcommittee 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 exist 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. We urge 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. 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^{xxii} to price their products high.

PCMA looks forward to working with the Congress to find additional ways to promote savings while continuing to deliver the highest quality, highest value prescription drug benefits for all.

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

ⁱⁱ PCMA calculation based on data in, Fierce Pharma, "Why Does Gilead's Sovaldi cost \$84K in the U.S. and \$57K in Britain?" May 29, 2014.

ⁱⁱⁱ New York Times, "Drug Makers Sidestep Barriers on Pricing," October 19, 2015.

^{iv} New York Times, "Drug Makers Sidestep Barriers on Pricing," October 19, 2015.

^v New York Times, "Drug Makers Sidestep Barriers on Pricing," October 19, 2015.

^{vi} New York Times, "Valeant Drops Philidor Mail-Order Pharmacy," October 30, 2015.

^{vii} New York Times, "Valeant Drops Philidor Mail-Order Pharmacy," October 30, 2015.

^{viii} See, FDA, "Drugs@FDA"

http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Label_ApprovalHistory#applist

^{ix} FDA, "Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations,"

<http://www.accessdata.fda.gov/scripts/cder/ob/docs/queryai.cfm>

^x FDA, Listing of Authorized Generics, September 30, 2015.

^{xi} Michael Carrier and Aaron Kesselheim "The Daraprim Price Hike And A Role For Antitrust," *Health Affairs* Blog, October 21, 2015

^{xii} 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.

^{xiii} 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

^{xiv} 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

^{xv} CNBC, "Express Scripts, Imprimis to Offer \$1 Daraprim Alternative, Dec 1, 2015 www.cnbc.com

^{xvi} CNBC, "Express Scripts, Imprimis to Offer \$1 Daraprim Alternative, Dec 1, 2015 www.cnbc.com

^{xvii} CNBC, "Express Scripts, Imprimis to Offer \$1 Daraprim Alternative, Dec 1, 2015 www.cnbc.com

^{xviii} CNBC, "Express Scripts, Imprimis to Offer \$1 Daraprim Alternative, Dec 1, 2015 www.cnbc.com

^{xix} Business Insider, "Martin Shkreli and his newest adversary just had an awkward public exchange," December 3, 2015. <http://www.businessinsider.com/martin-shkreli-and-express-scripts-cmo-steve-miller-at-forbes-conference-2015-12>

^{xx} 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>

^{xxi} Dana Goldman and Darius Lakdawalla, “Moving Beyond Price-Per-Dose In The Pharmaceutical Industry,” Health Affairs Blog, September 30, 2015

^{xxii} *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.