

**STATE OF COMPETITION IN THE
PHARMACY BENEFITS MANAGER AND
PHARMACY MARKETPLACES**

HEARING
BEFORE THE
SUBCOMMITTEE ON
REGULATORY REFORM,
COMMERCIAL AND ANTITRUST LAW
OF THE
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OFFICIAL HEARING RECORD

UNPRINTED MATERIAL SUBMITTED FOR THE HEARING RECORD

Material submitted by the Honorable Tom Marino, a Representative in Congress from the State of Pennsylvania, and Chairman, Subcommittee on Regulatory Reform, Commercial and Antitrust Law. These submissions are available at the Subcommittee and can also be accessed at:

<http://docs.house.gov/Committee/Calendar/ByEvent.aspx?EventID=104193>.

Material submitted by the Honorable David N. Cicilline, a Representative in Congress from the State of Rhode Island, and Member, Subcommittee on Regulatory Reform, Commercial and Antitrust Law. This submission is available at the Subcommittee and can also be accessed at:

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Material submitted by the Honorable Doug Collins, a Representative in Congress from the State of Georgia, and Member, Subcommittee on Regulatory Reform, Commercial and Antitrust Law. This submission is available at the Subcommittee and can also be accessed at:

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**STATE OF COMPETITION IN THE PHARMACY
BENEFITS MANAGER AND PHARMACY MAR-
KETPLACES**

TUESDAY, NOVEMBER 17, 2015

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON REGULATORY REFORM,
COMMERCIAL AND ANTITRUST LAW
COMMITTEE ON THE JUDICIARY,
Washington, DC.

The Subcommittee met, pursuant to call, at 3:33 p.m., in Room 2124, Rayburn House Office Building, the Honorable Tom Marino (Chairman of the Subcommittee) presiding.

Present: Representatives Marino, Goodlatte, Issa, Collins, Ratcliffe, Bishop, Johnson, Conyers, DelBene, Cicilline, and Peters.

Staff Present: (Majority) Anthony Grossi, Counsel; Andrea Lindsey, Clerk; (Minority) Slade Bond, Counsel; and James Park, Counsel.

Mr. MARINO. Good afternoon. The Subcommittee on Regulatory Reform, Commercial and Antitrust Law will come to order. Without objection, the Chair is authorized to declare recesses of the Committee at any time. I don't foresee any because that was the last vote for the day.

We welcome everyone to today's hearing on the State of Competition in the Pharmacy Benefits Manager and Pharmacy Marketplace. And I now recognize myself for my opening statement.

When a patient visits a doctor who recommends and prescribes medication, the patient rarely receives the prescription drug directly from the doctor. Instead, the patient submits his prescription to a pharmacy which then dispenses that ordered medicine. While this may appear to the patient as a relatively simple exchange, behind the scene exists a complex system. Within this system is a variety of different players who engage in millions of interactions that influence the types of drugs that are available and the prices that patients pay for them.

Two of the key players in this process are pharmacy benefit managers and pharmacies. Today's hearing will examine the state of competition in these two important markets. Pharmacy benefit managers or known as PBMs, play an important role in the healthcare system. PBMs oversee and administer the prescription drug benefits for more than 247 million Americans, or approximately 95 percent of Americans who receive drug benefits.

Through the management of these benefits, PBMs perform a number of varied services. They negotiate the prices of prescription drugs with manufacturers and wholesalers. PBMs design drug formularies that dictate the drugs that will be covered under a benefit plan and the cost-sharing portion the patient will bear for each drug. PBMs also negotiate with pharmacies to determine which pharmacies will participate in their networks, the fees that each pharmacy will receive for dispensing drugs, and the amount the pharmacy will be reimbursed for each drug.

By virtue of their central position in the administration of prescription drug benefits, some would argue that PBMs have the ability to place downward pressure on the prices of drugs. PBMs also can achieve efficiencies that result in savings both to the ultimate patient and the payer of health benefits. Pharmacies also play a critical role in the delivery of medicine to Americans. In addition to purchasing prescription drugs, they typically are the entities that directly engage with the patients. As someone who represents a district with many rural communities, I know firsthand how important pharmacies, particularly independent pharmacies, are to their customers. Many times these independent pharmacies develop meaningful relationships with their customers and provide essential assistance when dispensing the prescription drugs.

Together with doctors, pharmacies are part of an integral team that ensures patients are receiving the proper drugs in the correct amounts and administered in the appropriate fashion. I have been an ardent supporter of independent pharmacies throughout my time in Congress. In both the 112th and the 113th Congress, I introduced legislation that would grant independent pharmacies a specific exemption to the antitrust laws when negotiating contract terms for provisions of healthcare items or services. This would have potentially given the vast network of isolated independent pharmacies a stronger competitive footing relative to larger national pharmacies.

Whether this exemption is needed is another item to consider today. Many PBMs also provide pharmacy services, either through their own brick-and-mortar locations or through mail-order services. As a result, PBMs may negotiate services with competitors to their own pharmacies. Over the years, this has resulted in tensions between certain pharmacies and PBMs. The antitrust enforcement agencies have periodically reviewed PBM activities, finding in some instances that these activities are appropriate and stepping in when they are not.

Today's hearing will allow us to become better educated about the services that PBMs and pharmacies provide. The hearing also will allow us to review whether the proper economic incentives are in place to ensure that customers are receiving affordable prescription drugs and to explore some of the historic tensions between certain PBMs and pharmacies.

The public record generated today will also assist the Committee with its oversight authority of the antitrust enforcement agencies. We have before us Express Scripts and CVS Caremark, two of the largest PBMs and pharmacy companies. They will provide an inside and first-hand perspective of PBM and pharmacy operations, as well as an invaluable viewpoint into the prescription and pharmacy

industry at large. Additionally, we will hear from a representative of independent pharmacies and one of the experts covering both of these markets. I look forward to today's discussion from this excellent panel of witnesses.

The Chair now recognizes the Ranking Member of the Subcommittee on Regulatory Reform, Commercial and Antitrust Law, Mr. Johnson of Georgia, for his opening statement.

Mr. JOHNSON. Thank you, Mr. Chairman. Today's hearing is a welcome opportunity to continue this Subcommittee's examination of competition in the healthcare marketplace. The topic of today's hearing, competition in the pharmacy marketplace, will explore the role of pharmacy benefit managers, or PBMs, in ensuring competitive and affordable drug prices for American consumers. In the pharmacy marketplace, PBMs serve as the intermediary between the manufacturers and wholesalers of prescription drugs and the payers of health insurance benefits. In their role as the intermediary in this market, PBMs administer prescription drug benefits to approximately 95 percent of Americans who receive prescription drug benefits. Furthermore, through their contracts with health payers such as health insurance companies, PBMs are responsible for negotiating the cost and availability of prescription drugs with manufacturers and wholesalers.

In short, PBMs are a critical gatekeeper in the prescription drug benefit system. It is, therefore, imperative that we fully understand the functioning of this market from both a competition and regulatory perspective to determine whether consumers are receiving the most affordable prices for prescription drugs. From a competition perspective, some have suggested that there is significant horizontal consolidation in the PBM market.

And, furthermore, that this horizontal consolidation is compounded by the vertical integration of certain PBMs into the mail order and retail pharmacy market. While the Federal Trade Commission has studied this issue on several occasions and reached the conclusion that the PBM market is adequately competitive, as Commissioner Julie Brill has noted, the FTC has not conducted a further study of the PBM industry since 2005, other than to review the ESI Medco merger in 2012, which did not examine issues surrounding PBM, plan designs such as PBM fee and compensation transparency.

It is therefore incumbent upon this Subcommittee to conduct a thorough inquiry on this matter which I hope that today's hearing provides. From a regulatory perspective, it has also been suggested that PBMs pricing techniques, rebate schemes and formulary designs have resulted in higher costs to consumers. I hope that today's hearing also serves as a fruitful discussion of this topic particularly with regard to the Department of Labor's inquiry into this matter last year.

As Consumers Union has noted, effective regulation and effective competition work hand in hand. And the less we can rely on effective competition, the more important it is that regulation ensures effective transparency to reduce the potential for abuse. I strongly agree. While the PBM marketplace is undoubtedly convoluted, today's hearing will serve as an important basis for determining whether consumers are receiving the best prices for prescription

drugs or whether we should do more to ensure affordable and transparent markets for prescription drugs.

I thank the Chair for continuing this series. And before closing I ask unanimous consent that the written statement of Lynn Quincy and George Slover of Consumer's Union be made a part of the record.

Mr. MARINO. Without objection, so ordered.
[The information referred to follows:]



Written Statement of

Lynn Quincy, Director, Health Care Value Hub
George P. Slover, Senior Policy Counsel
Consumers Union

on

The State of Competition in the
Pharmacy Benefits Manager and Pharmacy Marketplaces

Before the

Subcommittee on Regulatory Reform,
Commercial and Antitrust Law

Committee on the Judiciary
United States House of Representatives

November 17, 2015

Introduction

Consumers Union, the policy and advocacy arm of Consumer Reports,¹ appreciates this opportunity to provide our views on how the Prescription Benefit Management marketplace is functioning and whether it is delivering on its promised benefits for the health care system and for consumers.

We are an expert, independent, nonprofit organization whose mission is to work for a fair, just, and safe marketplace for all consumers, and to empower consumers to protect themselves.

As part of our work on behalf of consumers in health care, one important service we provide is to help consumers find the best value when purchasing prescription drugs. In 2004, we launched *Consumer Reports Best Buy Drugs*. This program uses evidence-based systematic reviews of prescription drugs to clearly demonstrate the efficacy and safety in over 30 categories of commonly used medicines.² What's more, we combine this information with reliable cost information – enabling consumers to truly identify the “best buy” for many drugs. To our knowledge, we are the only source of this type of information for consumers that is not supported by commercial funding.

As many have observed, consumers benefit when there is effective competition at all levels in the supply chain.

Unfortunately, the pharmaceutical marketplace, and the PBM marketplace in particular, is not functioning competitively. The PBM marketplace is highly concentrated – following the 2012 merger of Medco and Express Scripts, the top two PBMs control between 80 percent and 90 percent of the market for health plans sponsored by large employers, and 73 percent for plans sponsored by employers of any size.

The anticompetitive effects and risks of this high horizontal concentration are further increased by the vertically-integrated cross-ownerships and financial partnerships between PBMs, drug manufacturers, mail order services, and retail pharmacies.

PBMs administer prescription drug benefits for more than 235 million Americans.³ PBMs can perform an important function in negotiating with

¹ Founded in 1936, *Consumer Reports* is an expert, independent, nonprofit organization whose mission is to work for a fair, just, and safe marketplace for all consumers, and to empower consumers to protect themselves. Using its more than 50 labs, auto test center, and survey research center, the nonprofit rates thousands of products and services annually. Consumer Reports has over 8 million subscribers to its magazine, website, and other publications. Its policy and advocacy division, Consumers Union, works for health reform, food and product safety, financial reform, and other consumer issues in Washington, D.C., the states, and the marketplace. This division employs a dedicated staff of policy analysts, lobbyists, grassroots organizers, and outreach specialists who work with the organization's more than 1 million online activists to change legislation and the marketplace in favor of the consumer interest.

² <http://www.consumerreports.org/health/best-buy-drugs/index.htm>.

³ <http://www.pcmnet.org/about-pcma/about-pcma>.

pharmaceutical manufacturers to help keep drugs more affordable. The PBM industry has also helped spur important innovations that have streamlined and modernized management of pharmaceutical delivery. They've helped propel the shift to generic drugs, encouraged the use of "step therapy," introduced techniques for improving medication adherence, and brought focus to safer use of drugs through monitoring of drug interactions and dosage reviews.

But to ensure that PBMs bring maximum benefit to the health care system and to consumers, it is important that PBMs act openly, and not on hidden conflicts of interest that skew their incentives.

Improved transparency of PBM business practices would better enable health insurance plans and self-insured employers to ensure that prescription drug formulary designs reflect appropriate safety, efficacy, and value considerations, without impeding consumers' ability to obtain the prescription drugs they need.

Ideally, effective regulation and effective competition work hand in hand. And the less we can rely on effective competition, the more important it is that regulation ensure effective transparency to reduce the potential for abuse.

Approximately 10 percent of our nation's health spending is for prescription drugs,⁴ and clear, transparent information about clinical effectiveness and pricing are paramount in ensuring that we spend this money wisely. But, as explained below, the opaque business practices that are commonplace in the PBM industry can result in unfair arrangements between health plan sponsors and PBMs. Without a ready ability to audit these business practices, the arrangements can drive up costs for both plan sponsors and consumers; they also have the potential to put the wrong prescription drugs into consumers' hands.

Lack of Transparency in PBMs

The PBM industry has come under fire for a number of anti-consumer practices, including:

- (1) using opaque rebate schemes to inflate PBM profits;
- (2) using opaque pricing spreads to inflate PBM profits;
- (3) tailoring formulary designs and drug switching to inflate PBM profits; and
- (4) steering plans and consumers to use of mail order for filling prescriptions even when consumers prefer to obtain prescriptions locally.

⁴ Micah Hartman et al, National Health Spending In 2013: Growth Slows, Remains in Step with the Overall Economy, *Health Affairs*, December 2014.

Concern about these practices has resulted in litigation, in antitrust complaints, and in calls for reform.⁵ In response, more than two dozen states have passed laws that attempt to regulate certain PBM practices.⁶ However, many PBM contracts are not subject to state law, because most health benefits plans offered by self-funded employers are exempted from state regulation under ERISA.⁷

Based on its own examination of these issues, the ERISA Advisory Council last November unanimously called for the Department of Labor to require that PBMs disclose to health plan sponsors all forms of direct and indirect compensation received in connection with providing services to the health plan.⁸ The Council found that increased disclosure would reduce potential PBM conflicts of interest and better enable health plan sponsors to assess the reasonableness of what they were being charged for PBM services. The Council also recommended that the Department of Labor issue guidance to assist health plan sponsors in more effectively auditing of PBM direct and indirect compensation.

As consumer advocates, we strongly support this effort to give plan sponsors greater ability to keep drug prices in check.

As detailed below, today's complex and opaque contract arrangements and pricing spreads result in increased costs to health plan sponsors and enrollees, and can lead to formulary designs that inappropriately steer consumers toward or away from certain medication choices that might be more suitable for their needs.

At the most basic level, accessible and transparent disclosures about PBM pricing practices will help employers and other plan sponsors ensure that drugs are priced more affordably and that the financial incentives facing consumers more accurately reflect the clinical safety and effectiveness of the drug.

⁵ Mark Meador, "Squeezing the Middleman: Ending Underhanded Dealing in the Pharmacy Benefit Management Industry through Regulation," 20 *Annals of Health Law*, 77 (2011).

⁶ See State Laws Reforming the Practices of Pharmacy Benefit Managers, http://www.ncpanet.org/pdf.fcgi/nov12/pbm_enacted_legislation.pdf; State Regulation of Pharmacy Benefit Management, http://www.approrx.com/media/documents/PUTT_State%20Regulations_061713a.pdf

⁷ The Employee Retirement Income Security Act of 1974, or ERISA, establishes employee protections that apply to private employers that offer employer-sponsored health insurance coverage and other benefit plans to employees. ERISA does not require employers to offer plans; it only sets rules for benefits that an employer chooses to offer.

⁸ Advisory Council on Employee Welfare and Pension Benefit Plans, *PBM Compensation and Fee Disclosure*, November 2014, <https://www.dol.gov/ebsa/pdf/2014ACreport1.pdf>.

Rebates

A rebate in the context of PBM practices refers to an incentive payment made by a drug manufacturer to the PBM based on how much the PBM increases the market share or sales of a drug. Rebate arrangements vary widely, and a PBM may not be required to disclose to plan sponsors the details of its rebate arrangements.

In some cases, it is possible that, unbeknownst to the plan sponsor, a PBM may pocket a substantial rebate, while imposing the full cost of the drug onto enrollees. For example, one industry analyst estimates that more than 80% of rebates are passed on to the health plan sponsors.⁹ From that, we could conclude that the remaining 20% of rebates may never be passed on. In a more competitive and transparent environment, a PBM would not be able to retain rebates of this magnitude. Moreover, this figure does not even take into account rebate administrative fees that are often paid to the PBM by a drug manufacturer, which typically are not disclosed, or passed on.

Rebates based on volume metrics can undermine a PBM's role as an intermediary working on behalf of health plan sponsors to negotiate lower costs. This is especially the case when the PBM obscures the actual net costs of the drugs to the plan sponsor.

Lucrative rebate deals may encourage the placement of more expensive drugs onto a formulary. If profit considerations distort formulary design, they also undermine the consumer's – and the physician's – choice of drug based on the best medical evidence available, and the medical needs of that consumer.

For example, formularies that once placed the popular brand-name heartburn drug Nexium (now a generic) on its preferred-brand list could have been steering consumers toward using that drug because the PBM had negotiated a rebate deal with a manufacturer. In 2014, we estimated that a month's supply of 20-mg of Nexium might have a total cost (health plan plus consumer's cost-share) of about \$240. But another drug, equally safe and effective, and in the same class as Nexium, was an over-the-counter generic called omeprazole. A similar quantity of this drug could be bought for just \$17, or even less – no prescription needed.¹⁰

In a perfect world, rebates based on prescription volume metrics should be eliminated. We believe there's no way to structure rebates that does not essentially constitute a form of kickback. In the intermediate term, we recommend strengthening transparency requirements so that the net cost that the PBM pays, after all rebates are factored in, is disclosed to plan sponsors.

⁹ Adam J. Fein, Pembroke Consulting, January 2014, 2013-14 *Economic Report on Retail, Mail and Specialty Pharmacies*.

¹⁰ See "Got heartburn? The best treatment for you" Consumer Reports Online, March 2014 available at: <http://www.consumerreports.org/cro/2014/03/find-the-best-heartburn-treatments/index.htm>.

Pricing Spreads

Another source of profit for PBMs is pocketing what can be a significant price difference between what a PBM actually pays a pharmacy for a prescription drug and what it charges the health plan sponsor and consumer.¹¹ This pricing difference is known as the “spread.” To get this spread, the PBM often anchors what the plan sponsor is charged using a pricing reference list such as the Manufacturers’ Average Cost list, or “MAC.”

Unlike volume discounts or rebates, which may be shared with plan sponsors and consumers, plan sponsors and consumers are not typically told of, and do not typically share in, the price spread – it is a “hidden mark-up” revenue mechanism. Moreover, this pricing scheme adds another layer of complexity to an already complex chain of supply, distribution, and pricing. Thus, even in rare cases where transparency around spread pricing is written into a PBM contract, it can be difficult, if not impossible, for the health plan sponsor to police.

Some savvy plan sponsors have begun to prohibit hidden pricing spreads in their contracts with PBMs. Following the lead of the Medicare program in 2009, many have adopted straightforward “pass-through” pricing, wherein the PBM fully discloses the actual price it pays the pharmacy. The PBM then either passes the discount on to the plan sponsor, charging a transaction fee instead, or it shares an agreed-upon proportion of the transparent price spread. All things considered, we find this fee-based mechanism to be preferable. It is simpler, easier to administer, and less vulnerable to manipulation and gamesmanship. It also promotes competition among PBMs by allowing a plan sponsor to more easily compare drug prices offered in its plan against those from other plans.

As a byproduct, the higher potential profits connected to spread pricing could give PBMs an additional financial motivation to favor and push the greater use of generics, but this is not a compelling reason to support this mechanism. Spread pricing is too susceptible to PBM manipulation, and too difficult for plan sponsors and others to monitor. We could find no credible evidence that the size or amount of hidden PBM pricing spreads increases the rate of generic prescription use. And there is already sufficient incentive for the use of generics, as their underlying cost is a fraction (often 10% or less) of the cost of the brand name drugs. Generic pricing should adhere as closely as possible to this underlying cost, and those savings should be disclosed to and passed on to consumers.

Formulary Design and Drug Switching

Formulary design is an essential component of pharmacy management. Formularies can be successful at compelling doctors and consumers to choose effective, less expensive medicines. However, when formulary design is used to amplify the benefits to the PBM of rebate concealment and spread pricing profits, it ill serves plan

¹¹ See, e.g., “Painful Prescription,” *Fortune Magazine*, Oct. 10, 2013, <http://fortune.com/2013/10/10/painful-prescription/>.

sponsors and consumers.

Drug switching is a practice where the doctor has prescribed one drug for a patient, but the PBM uses “therapeutic substitution” and changes the prescription to a different drug it deems to be of similar therapeutic value. When structured appropriately, PBM intervention in this process can serve the dual beneficial purposes of saving money while ensuring that consumers get an effective and safe medication for their treatment.

However, drug switching can also be motivated by pure financial self-interest on a PBM’s part – in pursuit of manufacture rebates, or spread pricing, or targeted discounts. In 2006, for example, Medco paid \$163 million to settle federal charges that it defrauded customers by shorting, changing and canceling their prescriptions. In a three-month period, Medco had persuaded doctors to switch more than 71,000 prescriptions from Lipitor, made by Pfizer, to Zocor, a more costly drug from Merck (then Medco’s owner).¹²

In May 2015, Medco paid \$7.9 million to settle federal charges that it took kickbacks in exchange for identifying AstraZeneca’s product Nexium as the “sole and exclusive” proton pump inhibitor on certain of its formularies. AstraZeneca had previously agreed to pay \$7.9 million for its role in the kickback scheme. As the Justice Department noted in announcing the settlement, “Hidden financial agreements between drug manufacturers and pharmacy benefit managers can improperly influence which drugs are available to patients and the price paid for drugs.”¹³

Formulary design must be fully transparent to the health plan sponsor. Assignment to formulary tiers, as well as the rules for therapeutic substitution, must reflect the best medical evidence regarding clinical effectiveness and safety, followed by the fully transparent bottom-line cost reflecting all rebates, other fees, and the actual price pharmacies are paid for generics. This will help ensure that formulary design is not swayed by the relative prospects for PBM revenue or profits on one drug over another.

Mail Order Services

When properly designed and offered as a choice for consumers, not as a mandatory measure, a PBM’s mail order delivery option can provide consumers with cost savings, convenience, and potentially improved medication compliance.

However, it is critical to employers and other health plan sponsors, and to consumers, that PBMs not use mail order services as a vehicle for further opaque drug switching driven by rebates or generic spread pricing, or other anticompetitive self-dealing.

¹² “PBM Fiduciary Duty and Transparency,” Prescription Policy Choices, www.policychoices.org.

¹³ <http://www.justice.gov/opa/pr/medco-pay-79-million-resolve-kickback-allegations>.

Our main concern, as also identified by industry analysts, is that PBMs who provide their own mail order services have the opportunity to both set the price of a drug for mail-order using a different reference pricing or MAC list than they do with retail pharmacies, and then also determine how much they will charge the plan sponsor. Plan sponsors are likely to be unaware of this pricing mechanism, and unaware that different reference price lists are being used to determine how much the plan sponsor will pay for an enrollee's medications. For example, one recent survey of employers found that a quarter of them said they did not know what pricing mechanism was in place for mail order services provided by their PBMs.¹⁴

These and other concerns have already prompted several states to pass legislation to regulate aspects of pharmacy mail order.¹⁵ Transparency around mail order services is an important part of any effort to make PBM practices better understood by employers, other plan sponsors, and consumers – and to give them a basis for comparison and choice.

The new regulations by the Centers for Medicare and Medicaid Services for Medicare Part D, scheduled to take effect for contract year 2016, should help. The final rule will promote increased price transparency by requiring Part D plans and their PBMs to make available to pharmacies contracted in their networks the reimbursement rates for drugs under Maximum Allowable Cost pricing standards.

Conclusion

As currently structured, the highly convoluted drug supply and pricing chain offers too many opportunities for deception by PBMs and may be raising costs for consumers. The high levels of concentration and vertical integration in the PBM marketplace increase those risks.

As an indication of how substantial the cost of price spreads and rebates can be, in 2009 the U.S. Military's health care provider, TRICARE, estimated it could save more than \$1.7 billion dollars by negotiating its own pharmacy benefits instead of using a PBM for its nine million covered lives.¹⁶

But it is often the case that employers and other health plan sponsors – let alone

¹⁴ Pharmacy Benefit Manager (PBMs): *Generating Savings for Plan Sponsors and Consumers*, Visante, September 2011, 3. Available at:

<http://pcpanet.org/images/stories/uploads/2011/Sept2011/pbms%20savings%20study%202011%20final.pdf>.

¹⁵ Adam J. Fein, Pembroke Consulting, *Economic Report on Retail, Mail and Specialty Pharmacies*, January 2014, 2013-14.

¹⁶ Kevin Schweers, *Community Pharmacists Hear Mail Order Complaints; Debunk PBM Myths*, NCPA Commentary (Sept. 23, 2009), <http://www.ncpanet.org/advocacy/pbm-resources>.

consumers – lack the tools to discipline PBM profiteering, because they do not know the extent to which it is practiced. In most cases, plan sponsors do not have access to PBM rebate agreements and other contract terms.

Consumer Union supports efforts to more effectively enable purchasers, government enforcers, and consumer watchdog organizations to better monitor prevailing, average, and actual pricing so there is meaningful access to pricing information by which to judge the effectiveness of PBMs in negotiating good net prices for prescriptions.

We appreciate the Subcommittee's attention to this issue of profound importance to our health care system and to consumers.

Mr. JOHNSON. I yield back.

Mr. MARINO. The Chair now recognizes the full Judiciary Committee Ranking Member, Mr. Conyers of Michigan for his opening statement.

Mr. CONYERS. Thank you, Mr. Chairman. I join you in welcoming the witnesses and look forward to a very frank and analytical discussion of the subject matter.

Once when I was Chairman of the House Judiciary Committee, the Committee reported legislation that would have granted a limited antitrust exemption for independent pharmacies to allow them to collectively bargain as to the terms and conditions of reimbursements from pharmacy benefit managers. This legislation arose from the recognition that small independent pharmacies struggle to compete against large pharmacy chains, particularly with respect to their ability to negotiate reimbursements from pharmacy benefit managers.

Pharmacy benefit managers administer the prescription drug benefit portion of health insurance plans for private companies, unions, and governments. They're responsible for processing and paying prescription drug claims, contracting with pharmacies, and negotiating discounts and rebates with drug manufacturers, all for the ostensible purpose of keeping drug prices low for health plans.

The hearing today gives us an opportunity to delve more deeply into the state of competition in the marketplace for pharmacy benefit managers and to consider its possible effects on consumers. To that end, we should keep the following in mind.

As an initial matter, we should assess whether the market for pharmacy benefit managers is too concentrated and structurally problematic to maximize consumer benefits. Although estimates vary, most studies indicate that just three companies may control up to almost 80 percent of the pharmacy benefit manager market. Such concentration in any industry necessarily raises questions about whether the dominant firms can use their power to the detriment of their competitors and consumers.

The largest pharmacy benefit managers also own retail pharmacy businesses which can be in the form of a large national retail chain, specialty pharmacy business, or online mail-order pharmacies. According to some experts, these ownership arrangements create an inherent conflict of interest because a large pharmacy benefit manager can leverage its market power to benefit its retail pharmacy business by using exclusivity arrangements, providing more generous reimbursements to the detriment of small independent retail pharmacy competitors. Moreover, such concerns may be further exacerbated when the industry is relatively unregulated, as may be the case with pharmacy benefit managers.

In addition, we should consider whether a lack of transparency with respect to operations of pharmacy benefit managers helps or hurts competition. Some critics of pharmacy benefit managers assert that the lack of transparency makes it difficult to assess whether they are fully passing on whatever savings they may have obtain from drug manufacturers. These critics contend that the substantial rise in profits for pharmacy benefit managers in recent years suggest that such savings are not in fact being passed on to consumers.

Critics further assert that it is hard to know whether pharmacy benefit managers are providing fair reimbursements for generic drugs to small independent retail pharmacies given the lack of publicly available information about how pharmacy benefit managers determine such reimbursements. If these allegations are true, the lack of transparency may well make it difficult for health insurance plans to secure the lowest costs or the best quality service for consumers.

Now, while some criticize what they see as lax antitrust enforcement in the pharmacy benefit manager marketplace, there is a broader question of whether more direct regulatory measures are needed beyond stronger antitrust enforcement. And that's what makes what the witnesses have to say here today very important as we on this Committee decide what direction we should pursue.

And I thank the Chairman for the time.

Mr. MARINO. Without objection, other Members' opening statements will be made part of the record and I ask unanimous consent to enter in some statements and documents for the record. Representative Carter, Republican from Georgia; Representative Blum, Republican from Iowa; America's Health Insurance Plans; American Pharmacist Association; and Pharmaceutical Care Management Association.*

Hearing no objection, so ordered.

I will begin by swearing in our witnesses before introducing them. So would you please stand and raise your right hand.

Do you swear that the testimony you are about to give before this Committee is the truth, the whole truth and nothing but the truth, so help you God?

Let the record reflect that all of the witness have responded in the positive.

Please take your seat.

We have four distinguished witnesses today. And starting at my left is Ms. Bricker. She is the Vice President of retail channel management, contracting and strategy at Express Scripts, Incorporated. Prior to joining Express Scripts, Ms. Bricker was the Regional Vice President of account management at Walgreen's Health Services as well as the Director of community retail pharmacy at BJC Healthcare. Ms. Bricker is a graduate of St. Louis College of Pharmacy, and is a registered pharmacist in Missouri. Welcome.

Mr. Balto, who has been with us before on other occasions is an antitrust attorney with over 15 years of government antitrust experience. Mr. Balto worked as a trial attorney in the antitrust division of the Department of Justice and in several senior level positions at the Federal Trade Commission during the Clinton administration. He received his B.A. From the University of Minnesota and his J.D. From the Northeastern University School of Law. Welcome, sir.

Ms. Pons is the Senior Vice President and assistant general counsel at CVS Health. Prior to joining CVS in 2011, Ms. Pons was the chief compliance officer at AdvancedPCS and a senior legal counsel at PCS Health Systems. Ms. Pons earned her bachelor's de-

***Note:** The material submitted by Mr. Marino is not printed in this hearing record but is on file with the Committee. See also "For the Record Submission—Rep. Marino" at:

<http://docs.house.gov/Committee/Calendar/ByEvent.aspx?EventID=104193>.

gree in business administration from the University of Iowa College of Business, and her J.D. From the University of Iowa College of Law. Welcome.

Mr. Arthur is the president of the National Community Pharmacist Association and the owner of two independent pharmacies in Buffalo, New York, which have been serving their community since 1957. Mr. Arthur is active in the pharmacist community and has served on various business and pharmacy boards during his career. Mr. Arthur earned his bachelor's of science degree from the University of Florida College of Pharmacy, and his micro MBA certificate from the State University of New York at Buffalo.

Each of the witnesses' written statements will be entered into the record in its entirety. I ask that each witness summarize his or her testimony in 5 minutes or less. And to help you stay within the time, there is a light in front of you. Now, as I'm intent on making my statements—I'm not looking at any lights and I'm not looking at any clocks. I have people up here that nudge me. What I will politely and diplomatically do when we're getting close, when you hit that 5-minute mark, I will again diplomatically raise the gavel and try to get your attention and ask you by doing that to wrap up your statement if you would do that, please.

Ms. Bricker, would you like to make your statement, please.
Turn on the microphone, please. Thank you.

**TESTIMONY OF AMY BRICKER, R.Ph., VICE PRESIDENT,
RETAIL CONTRACTING AND STRATEGY, EXPRESS SCRIPTS**

Ms. BRICKER. Chairman Marino, Ranking Member Johnson, and other Members of the Subcommittee, my name is Amy Bricker. I'm a licensed pharmacist and serve as vice president retail contracting and strategy for Express Scripts. Thank you for the opportunity to be here today and share our perspective on competition in the pharmacy benefits manager and pharmacy marketplaces.

Express Scripts is the Nation's largest pharmacy benefit manager or PBM. We provide pharmacy services to roughly 86 million Americans covered by our clients which are large employers, health insurers, labor unions, TRICARE, Medicare, Medicaid, and marketplace plans. Express Scripts employs more than 25,000 hard working dedicated employees nationally. We have more than 2,000 employees in Pennsylvania, and more than 700 in the State of Georgia. Our number one goal is to make prescription drugs safe and more affordable for our patients and clients. Everything we do at the company is aimed at that goal. In a changing system, the demand for pharmacy services and prescription drugs has never been stronger. When used properly, prescription drugs keep patients healthy and costs lower for everyone. As the Subcommittee examines PBM and pharmacy competition, we want to emphasize three takeaways.

First, the PBM marketplace is extremely competitive. Dozens of national and regional PBMs offer payers competing services and products. PBMs compete on price, data analytics, customer service, pharmacy access, clinical support services, and many other factors. Payers have a wide choice of PBMs and use that power to demand favorable pricing and contract terms. Express Scripts is an independently operated PBM. Some PBMs are owned by chain drug

stores while others are owned by health insurers. We believe our independent business model provides our clients with a clear choice when choosing a PBM. By operating separately from both the supply chain and the distribution channels, we stand alongside our clients as an independent counterweight in the marketplace.

Second, scale matters. Express Scripts scale allows it to negotiate discounts from drug manufacturers and pharmacies that lower costs for our clients and patients. Express Scripts creates competition by forcing drug makers to compete against one another for placement on planned formularies and to gain market share. In a similar way, Express Scripts creates competition among more than 68,000 retail pharmacies nationwide. We contract either individually with retail pharmacies or through group purchasing organizations called PSAOs which represent networks of pharmacies. Like large chain pharmacies, PSAOs combine the bargaining power of thousands of independent pharmacies when negotiating with PBMs. In fact, the largest PSAOs are as sizable as chain pharmacies.

Under Medicare part D, the TRICARE program and some private plans, we must ensure patients have access to a minimum number of pharmacies within a region. In rural areas, independent pharmacies know that Express Scripts needs them in our network to meet Medicare access rules and thus command a premium. In a changing system, our scale helps drive savings. Brand drug makers may have short term pricing power when bringing a breakthrough drug to market. However, our scale helps level the playing field when a brand or generic competitor merges. Scale also allows us to drive a hard bargain and lower costs for patients, clients, and taxpayers.

In 2014, prescription drug spending grew more than recent years. Much of this growth was driven by an increase in the unit cost of prescriptions, the prices manufacturers charge. But across our clients, closely managed plans spent nearly one-third less per member on traditional medications when compared to unmanaged plans. The tools we use help lower costs for clients and patients. Any effort to undermine our tools will mean higher costs for patients and payers.

The third takeaway relates to independent pharmacies. In a changing system, independent pharmacies are more than holding their own. This is great news. The National Community Pharmacist Association recently published its annual digest, and it contains important data. One, the number of independent pharmacies has held steady over the past 4 years, even with the increasing rate of acquisition of independents by retail chains. Two, over the past decade gross profits have held steady at around 23 percent. And, third, over the past decade, annual sales per store have hovered between \$3.6 and \$4 million per year.

In conclusion, Express Scripts values our relationships with our pharmacy partners, including independent pharmacies. Without independent pharmacies we could not offer clients and patients a high quality pharmacy benefit. The key lesson of the past 5 years is that effecting change requires stakeholders to work together. Rather than pit one part of the pharmacy against another, we can

and must work together to lower costs for payers and improve patient outcomes.

Thank you again for the opportunity to be here today. Chairman Marino and Ranking Member Johnson and other Members of the Subcommittee, I am happy to answer any questions that you might have.

Mr. MARINO. Thank you.

[The prepared statement of Ms. Bricker follows:]

Testimony of

Amy Bricker, R.Ph.
Vice President, Retail Contracting & Strategy
Express Scripts

Before the
House Judiciary Committee
Subcommittee on Regulatory Reform, Commercial & Antitrust Law

“The State of Competition in the Pharmacy Benefit Manager & Pharmacy Marketplaces”

November 17, 2015

Chairman Marino, Ranking Member Johnson, and other Members of the Subcommittee, my name is Amy Bricker. I am a licensed pharmacist and serve as Vice President, Retail Contracting & Strategy at Express Scripts. Thank you for the opportunity to be here today and share our perspective on competition in the pharmacy benefits manager and pharmacy marketplaces.

Express Scripts is the nation's largest pharmacy benefit manager, or PBM. We provide pharmacy services to about 86 million Americans covered by our clients: large employers, health insurers, labor unions, TRICARE, Medicare, Medicaid, and Marketplace plans. Express Scripts employs more than 25,000 hard-working, dedicated employees nationally. We have more than 2,000 employees in Pennsylvania and more than 700 employees in Georgia.

Our number one goal is to make prescription drugs safer and more affordable for our patients and clients. Everything we do as a company is aimed at that goal. In a changing system, the demand for pharmacy services and prescription drugs has never been stronger. When used properly, prescription drugs keep patients healthy and costs lower for everyone.

As the Subcommittee examines PBM and pharmacy competition, we want to emphasize three takeaways:

First, the PBM marketplace is extremely competitive. Dozens of national and regional PBMs offer payers competing services and products.¹ PBMs compete on price, data analytics, customer service, pharmacy access, clinical support services, and many other factors. Payers have a wide choice of PBMs and use that power to demand favorable pricing and contract terms. Express Scripts is an independently operated PBM. Some PBMs are owned by chain drugstores while others are owned by health insurers. We believe our independent business model provides our clients with a clear choice when choosing a PBM.

Second, scale matters. Express Scripts' scale allows it to negotiate discounts from drug manufacturers and pharmacies that lower costs for our clients and patients. Express Scripts creates competition by forcing drug makers to compete against one another for placement on plan formularies and to gain market share. In a similar way, Express Scripts creates competition among more than 66,000 retail pharmacies nationwide. We contract either individually with retail pharmacies or through group purchasing organizations, called PSAOs,² which represent networks of pharmacies. Like large chain pharmacies, PSAOs negotiate discounts in return for a higher volume of patients. Under Medicare Part D, the TRICARE program, and some private plans, we must ensure patients have access to a minimum number of pharmacies within a region.³ In rural areas, independent pharmacies know that Express Scripts needs them in our network to meet Medicare access rules and thus command a premium.

¹ [Statement of the Federal Trade Commission Concerning the Proposed Acquisition of Medco Health Solutions by Express Scripts, Inc.](#) FTC File No. 111-0210, April 2, 2012

² Government Accountability Office, *The Number, Role, and Ownership of Pharmacy Services Administrative Organizations*, GAO-13-176, January 29, 2013.

³ Code of Federal Regulations, Title 42, § 423.120

In a changing system, our scale helps drive savings. Brand drug makers may have short-term pricing power when bringing a breakthrough drug to market. However, our scale helps level the playing field when a brand or generic competitor emerges. Scale also allows us to drive a hard bargain and lower costs for patients, clients, and taxpayers.

In 2014, the rate of growth in prescription drug spend grew rapidly. Much of this growth was driven by an increase in the unit cost of prescriptions.⁴ Closely managed plans spent nearly one-third less per member on traditional medications, when compared to unmanaged plans. In short, the tools we use can – and do – help keep costs lower for clients and patients. Any effort to undermine our proven tools will mean higher costs for patients and payers.⁵

The third takeaway relates to independent pharmacies. In a changing system, independent pharmacies are more than holding their own. This is great news. The National Community Pharmacists Association recently published its annual digest⁶ and it contains important data:

- One, the number of independent pharmacies has held steady over the past four years, even with the increasing rate of acquisition of independents by retail chains.
- Two, over the past decade, gross profits have held steady at around 23 percent.
- And three, over the past decade, annual sales *per store* have hovered between \$3.6 million and \$4 million per year.

In conclusion, Express Scripts values our relationships with our pharmacy partners, including independent pharmacies. Without independent pharmacies, we could not offer clients and patients a high-quality pharmacy benefit. The key lesson of the past five years is that effecting change requires stakeholders to work together. Rather than pit one part of pharmacy against another, we can and must work together to lower costs for payers and improve patient outcomes. Thank you again for the opportunity to be here today. Chairman Marino and Ranking Member Johnson, and other Members of the Subcommittee, I am happy to answer any questions that you may have.

⁴ *The 2014 Drug Trend Report*, Express Scripts, March 2015

⁵ *Pharmacy Benefit Managers: Generating Savings for Plan Sponsors & Consumers*, Visante, prepared for the Pharmaceutical Care Management Association, September 2011.

⁶ *NCPA Press Release*, October 13, 2015

Mr. MARINO. Mr. Balto.

**TESTIMONY OF DAVID A. BALTO, ESQ.,
LAW OFFICES OF DAVID A. BALTO, PLLC**

Mr. BALTO. Thank you, Mr. Chairman, Ranking Member, for inviting me to testify today. This is a very important subject. My testimony today is based on my years as a government enforcer and in representing consumers, public interests groups, PBMs, payors, and pharmacies, and PBM matters. And I've testified on several occasions for consumer groups. I have a simple message. By any measure the PBM market is severely broken.

If you look at my testimony on pages 7 and 8 you see that profits are increasing rapidly. Margins are increasing rapidly. By any measure this market is not behaving competitively. Why is that? Normally for a market to function effectively, you need three things: choice, transparency, and a lack of conflicts of interest. On all three of these measures, the PBM market receives a failing grade. Think about just the issue of—my testimony documents how as drug prices are increasing PBMs are increasing their profits too. They're profiting from increased prices through increased rebates. You don't have to guess about this. If you look at page 7 of the Consumer Union testimony, they document instances where there have been government enforcement actions where PBMs have forced consumers to higher priced, less efficacious drugs in order to maximize their rebates. Now, normally a payor faced with this situation would go and ask for information on rebates. But the PBMs won't provide that. They won't provide that kind of transparency.

Now, in the Department of Labor proceeding that the Ranking Member mentioned, the Department of Labor is considering careful regulation to require transparency. And on one side of the table, you have Fortune 50 corporations, Consumers Union, and the AFL-CIO all saying: We want that greater transparency. And who pops into the room but the FTC. And the FTC says: No. Transparency regulation would be a bad idea. We know what marketplace realities are, but economic theory teaches us that transparency would be bad.

I don't know what counts as regulatory chutzpah to this Committee, but to me that's really regulatory chutzpah. Obviously the Department of Labor and other entities should go and regulate and require the kind of transparency that these PBMs fight tooth and nail to try to avoid.

Why do these problems occur? Because the FTC has effectively made this a regulatory free zone. They have stopped investigating mergers. The last two big PBM mergers they didn't even require a document or conduct a deposition. Including CVS' acquisition of Omnicare which major consumer groups cried out do an investigation, but the FTC says, no.

What does this mean for consumers? First it means these folks can go and merge at will. If these two companies wanted to merge tomorrow, if they wanted to go to the FTC's marriage chuppah, and ask it be merged, we don't know what would keep the FTC from saying no by the standards they are applying today. But there are worse effects. When you wonder about why Walgreens would ac-

quire Rite Aid, it is so that they can battle against the dominance of these PBMs so they can have a fair seat at the table. Now that may or may not be a good merger, but the need for that merger is on the FTC's doorstep.

But, when you create an enforcement free zone, everybody listens. It is not just the PBMs who will engage in increasingly abusive conduct, increasingly abusive conduct. It's everybody else. So a pharmaceutical manufacturer who says what keeps me from increasing prices 6,000 percent? The FTC is asleep at the switch, let me do that.

What does this Committee need to do? First, pass legislation to provide for a fair MAC transparency. The consumers care about whether or not community pharmacists know what they are buying a drug for, because that pharmacist is the consumer's agent. And when they are forced to dispense drugs below cost, everybody suffers except PBMs which are increasing their profit.

Second, go and investigate in restricted networks, restricted part D networks but especially restricted networks for vulnerable consumers who have critical disabilities and specialty drugs. Specialty drug spending is increasing dramatically. That's the major mover to drug spending. And having a market where the PBMs increasingly force consumers into their own specialty pharmacies is sort of like putting the fox in charge of the hen house.

Third, the PBMs have a new—there's a new approach in going and attacking patient assistance programs. Patient assistance programs are programs by pharmaceutical manufacturers to enable patients to afford drugs they might otherwise not be able to afford. Those also should be investigated.

The most important thing I say in my testimony, and I really urge the Committee to spend time looking at this is what I say on page 6, it is really heartfelt and it is based on years of representing consumers. Who represents the consumer when in getting drugs it's the pharmacist who represents the consumer. The pharmacist, as the Chairman has indicated, will go to battle with the PBMs to make sure the consumer receives the right drug at the right price and they need to be protected. I welcome any questions you have.

Mr. MARINO. Thank you, sir.

[The prepared statement of Mr. Balto follows:]

Testimony of David A. Balto

**“The State of Competition in the Pharmacy Benefits Manager and
Pharmacy Marketplaces.”**

**Before the House Judiciary Subcommittee on Regulatory Reform,
Commercial and Antitrust Law**

November 17, 2015

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Mr. Chairman Marino, Vice-Chairman Farenthold, Ranking Member Johnson, and other members of the Regulatory Reform, Commercial and Antitrust Law Subcommittee of the House Judiciary Committee, I thank you for giving me the opportunity to testify today on the State of Competition in the Pharmacy Benefit Management and Pharmacy Market. My testimony today documents the tremendous competitive and consumer protection problems in the pharmacy benefit management (“PBM”) market and the need for stronger enforcement and legislation.

My comments in this testimony are based on my 30 plus years of experience as a private sector antitrust attorney and an antitrust enforcer for both the Department of Justice and the Federal Trade Commission (“FTC”). From 1995 to 2001, I served as the Policy Director for the FTC’s Bureau of Competition and the attorney advisor to Chairman Robert Pitofsky. Currently, I work as a public interest antitrust attorney in Washington, DC. I have represented consumer groups, health plans, unions, employers, and even PBMs on PBM regulatory and competitive issues.¹ I have testified before Congress and eleven state legislatures on PBM regulation, and was an expert witness for the State of Maine on its PBM legislation.

My testimony makes the following points:

- PBMs are one of the least regulated sectors of the health care system. There is no federal regulation and only a modest level of state regulation.
- The PBM market lacks the essential elements for a competitive market: (1) transparency, (2) choice and (3) a lack of conflicts of interest.
- The Federal Trade Commission has practically abandoned enforcement against PBMs, permitting major PBMs to consolidate without a significant investigation. This consolidation has led to three large PBMs – ExpressScripts, CVSHealth (also referred to as “CVS Caremark”) and OptumRx – controlling approximately 80% of the PBM market, consisting of over 180 million lives in the United States. Moreover, when states have tried to regulate PBMs the FTC frequently opposes these efforts at sensible regulation.
- The lack of enforcement, regulation, and competition has created a witches brew in which PBMs reign free to engage in anticompetitive, deceptive and fraudulent conduct that harms consumers, employers and unions, and pharmacists. The profits of the major PBMs are increasing at a rapid pace, exceeding \$6 billion annually. As drug prices increase rapidly, PBMs are not adequately fulfilling their function in controlling costs – indeed PBM profits are increasing at the same time drug costs increase because they secure higher rebates from these cost increases. Plan sponsors (employers and unions) cannot attack this problem because PBMs fail to provide adequate transparency on rebates and fail to provide adequate or accurate information on generic drug reimbursement (MAC pricing).
- In addition, PBMs increasingly use restricted pharmacy networks. These restricted networks are especially harmful to vulnerable consumers who require specialty

¹ I have testified in the past on PBM issues for several consumer groups including Consumers Union, Consumer Federation of America, USPIRG, Community Catalyst, and others. I operate a website www.pbmwatch.com which provides resources on PBM issues. In addition I am counsel to the Independent Specialty Pharmacy Coalition. My testimony reflects my own views and not those of my clients.

medications and the elderly and disabled for Part D plans. And these networks drive up costs, reduce patient access to vital healthcare services from their pharmacist of choice, and threaten adequate healthcare.

I provide four recommendations:

- 1) **FTC Nonenforcement Must Be Reversed.** The lack of FTC enforcement has also led to greater consolidation in other markets such as pharmacies and pharmaceutical manufacturing, as those firms perceive generally weakened antitrust standards and a need to secure power to battle against the PBMs. The Walgreens – Rite Aid merger is a case in point – this consolidation is a problem of the FTC’s own making, a defensive measure to battle against the PBMs’ market power. The lack of FTC enforcement leads to increasing disregard of the antitrust laws in the pharmaceutical area – as demonstrated by the recent storm of dramatic drug price increases. The Subcommittee should use all its powers to investigate the lack of FTC enforcement including an oversight hearing.
- 2) **Greater Transparency is Essential.** Transparency is a critical issue for health plans, employers, unions, and pharmacies. Plan sponsors need greater transparency in order to be able to make sure they are receiving the full benefits of the PBM’s bargaining power and to make sure PBMs effectively reign in drug costs. Pharmacies need greater transparency on generic reimbursement (the MAC price). H.R. 244 is a sound effort to provide greater transparency for pharmacies and should be enacted.
- 3) **Protect Patient Choice and Limit Restrictive Networks.** Consumers need to be protected from restrictive PBM networks that deny them choice and access, especially for those vulnerable consumers who use specialty drugs and for seniors. PBMs increasingly restrict networks for specialty patients and force them to use the PBM’s own specialty pharmacy and increasingly restrict Part D networks. PBMs have a conflict of interest when they own their own specialty pharmacy. The Subcommittee should support legislation to protect seniors and assure access to their community pharmacy under Part D. It should also consider legislation to protect patient choice while also ensuring that PBMs do not alter physicians’ treatment plans in favor of purchasing drugs that provide the PBM with higher profits. In addition, the Subcommittee should consider legislation to prevent some of the conflicts of interest in the market by prohibiting PBMs from issuing mandates to their customers that they must use a specific pharmacy when the PBM has an ownership interest in the pharmacy.
- 4) **Protect Patient Assistance and Access Programs.** PBMs should not be permitted to endanger patient access and support programs of pharmaceutical manufacturers. These programs often provide vulnerable consumers access to very expensive drugs. Some PBMs are using the guise of attempting to police these programs as a back door effort to force consumers to use the PBM’s own specialty pharmacy. These practices should be investigated by this Subcommittee and the FTC. Although PBM monitoring of pharmacies can be important, we should be suspicious where it appears to be an effort to increase its own business and deny consumers access to vital drugs.

This hearing is a start. But for the PBM market to function we need sound oversight, regulation, and greater antitrust and consumer protection enforcement.

I. Background

PBMs increasingly engage in anticompetitive, deceptive or egregious conduct that harms consumers, health plans, and pharmacies alike. In a nutshell, both consumers and pharmacies suffer as consumers are increasingly denied a choice in their level of pharmacy service by PBMs. PBMs exercise their power to restrict consumers to the PBM's own captive mail order and specialty pharmacy operations, reducing choice and quality for many. Consumers and their health plans also suffer when health plans are denied the benefits of the PBMs' services as an honest broker, which drives up drug costs, and ultimately leaves consumers footing the bill for higher premiums.²

As consumer advocate Lynn Quincy has testified:

Approximately 10 percent of our nation's health spending is for outpatient prescription drugs and clear, transparent information about clinical effectiveness and pricing are paramount in ensuring that we spend this money wisely. But...the opaque business practices that are commonplace in the PBM industry can result in unfair arrangements between employers and PBMs. Lacking a ready ability to audit these business practices, the arrangements can drive up costs for both employers and consumers, and has the potential to put the wrong prescription drugs into consumers' hands.³

Why do consumers care about restricted access to pharmacies? Because community pharmacists are the most accessible health care professionals; and in many markets, such as rural or inner city markets, they may be the only accessible professional. Because retail pharmacies provide consumers with valuable clinical services and counseling, often free of charge. Because some pharmacies, especially supermarket pharmacies, offer drugs at lower prices than the PBMs. Egregious PBM conduct jeopardizes these types of programs that consumers highly value. As retail pharmacies are already economically efficient and operate on very minimal margins, reduced consumer access to these pharmacies would, in the end, likely result in harm to other consumers who rely on these community pharmacies.

This is especially true for specialty pharmacies. Specialty pharmacies manage the highly-expensive and very complex treatments for the most intricate and serious illnesses. The service they provide is both distinct and significant from other retail pharmacies. Beyond merely dispensing drugs, specialty pharmacies help administer complex treatments, assist physicians in monitoring patient therapy, and play an important role in medication compliance and improved

² Often health plans and large employers are silent on complaining about the PBMs out of fear of retaliation since they must do business with PBMs. In response to criticism during the Express Scripts/Medco merger that employers did not publicly express concern over the merger, Senator Herb Kohl stated that "it is notable that no large employer who privately expressed concerns to us wished to testify at today's hearing, often telling us that they feared retaliation from the large PBMs with whom they must do business." Statement of U.S. Senator Herb Kohl on the ExpressScripts/Medco merger (12.6.2011).

³ Lynn Quincy, Consumers Union, Testimony before the Department of Labor ERISA Advisory Council at 1 (June 12, 2014), available at <http://www.dol.gov/ebsa/pdf/ACQuincy061914.pdf>.

health outcomes. Specialty pharmacies educate patients on effective utilization, monitor side effects, and partner with physicians to identify ineffective medications and recommend treatment changes. Specialty pharmacies play an active role in providing continuity of patient care to ensure that costs are minimized and health outcomes improve. And there is clear evidence that patients needing specialty medications have better health outcomes when they have the services of a community pharmacy rather than being forced into a PBM-owned mail order operation.

This Committee's attention to PBM regulation is extremely timely. PBMs are one of the least regulated sectors of the healthcare system. Because there is very limited federal regulation – basically a single provision in the Affordable Care Act – state regulation has increased. Both state and federal regulation are necessary to reign in these practices.

Similarly, consumers also care about rising health care costs, including out-of-pocket costs for prescription drugs. PBMs have a profound impact upon drug costs. If PBMs are unregulated they can continue to engage in conduct that is deceptive, anticompetitive, and egregious. For this system to work effectively PBMs must be free of conflicts of interest that arise from owning their own pharmacies. What health plans and employers are fundamentally purchasing is the services of an “honest broker” to secure the lowest prices and best services from both pharmaceutical manufacturers and from pharmacies. When the PBM is owned by the entity it is supposed to bargain with or has its own mail order operations there is an inherent conflict of interest, which can lead to fraud, deception, anticompetitive conduct, and higher prices. The three major PBMs clearly face that conflict since they own mail order operations, specialty pharmacies, and in the case of CVS Caremark – the second largest retail pharmacy chain and the dominant long-term care pharmacy.

Conflicts of interest raise severe concerns in the health care system. Where a payor is also a provider they can manipulate the relationship to raise health care costs. That is why, when pharmaceutical manufacturers obtained PBMs in the 1990's, the FTC acted to eliminate those conflicts of interest. The FTC challenged the acquisition of PCS by Lilly and Medco by Merck, because of the concern that having a manufacturer own a PBM would be giving the “fox the keys to the hen house door”—and would lead to higher prices for consumers.

In recent years, the major PBMs—including those with a clear conflict of interest in their cross-ownership with pharmacies—have engaged in a variety of anticompetitive and anticonsumer practices.

II. Chronic Anticompetitive and Consumer Protection Problems in the PBM Market

PBMs are like other healthcare intermediaries that manage transactions by forming networks and transferring information and money. As a former antitrust enforcer I know that there are three essential elements for a competitive market: (1) transparency, (2) choice and (3) a lack of conflicts of interest. This is especially true when dealing with health care intermediaries such as PBMs and health insurers where information may be difficult to access, arrangements are complex and clouded in obscurity, and there may be principal-agency problems. **As I explain below on all three of these elements the PBM market receives a failing grade.**

Why are choice, transparency, and a lack of conflicts of interest important? It should seem obvious. Consumers need meaningful alternatives to force competitors to vie for their loyalty by offering fair prices and better services. Transparency is necessary for consumers to evaluate products carefully, to make informed choices, and to secure the full range of services they desire. In both of these respects the PBM market is fragile at best. There is certainly a lack of choice especially for those plans that are dependent on the top tier big three PBMs (Express Scripts, CVS Caremark and Optum) which have an approximate 80% share of the market. And PBM operations are very obscure and a lack of transparency makes it difficult for plans, including government buyers, to make sure they are getting the benefits they deserve.

When dealing with intermediaries, it is particularly critical that there are no conflicts of interest. A PBM is fundamentally acting as a fiduciary to the plan it serves. The service a PBM provides is that of being an “honest broker” bargaining to secure the lowest price for drugs and drug dispensing services. When a PBM has an ownership interest in a drug company or has its own mail order or specialty pharmacy dispensing operations, it is effectively serving two masters and may no longer be an “honest broker.”

Moreover, when a PBM has its own pharmacy operations there are a myriad of competitive problems. Who will effectively monitor and audit the company-owned pharmacies? A pharmacy chain can use its PBM affiliate to disadvantage rival pharmacies, reducing reimbursement, and excluding pharmacies from networks. What about competitively sensitive information such as prices and costs? Where a pharmacy knows its rivals costs and pricing, it does not have to compete as hard. Ultimately consumers lose through less choice and higher prices.

As I detail below, the rapidly increasing drug costs which effectively lead to higher drug rebates for the PBMs leads one to question which master the PBM is serving. It increasingly appears that PBMs profit from higher drug prices, because they lead to higher rebates.

Finally, where these factors – choice, transparency and lack of conflicts of interest are absent – regulation is often necessary to fill the gap. And Congress has enacted some regulation that provides a degree of transparency under the Affordable Care Act.⁴ But unlike other aspects of the healthcare delivery system, PBMs remain basically unregulated.

Competition and choice are crucial for a market to work effectively. Ideally consumers throughout the country should have the choice in how they value pharmacy services. Some choose community pharmacies, others who value one-stop shopping choose their local supermarkets, and others choose chains. This choice is important because competitors have to respond to this choice by improving services and lowering prices.

Who Speaks for the Consumer – The Community Pharmacist

One important aspect of pharmacy services is the service pharmacists provide in assisting consumers in dealing with insurance companies and PBMs. Too often consumers are lost in a system where the PBM says “we don’t have any choice, it’s the employer who refuses coverage”

⁴ See Section 6005 of the Patient Protection and Affordable Care Act, 42 U.S.C. § 18001.

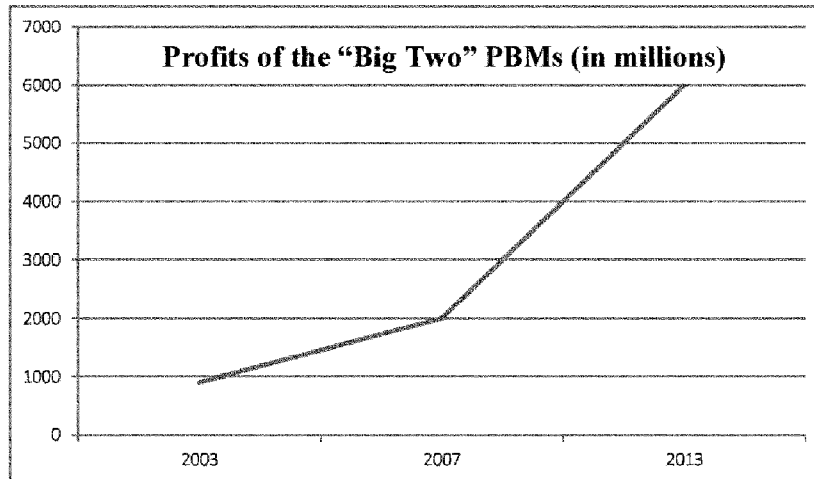
and the employer says “we just do what the PBM tells us to do.” No one takes responsibility or provides an answer. Who is there to protect the consumer?

The pharmacist is the advocate for the consumer. When PBMs create barriers patients typically seek help from their pharmacist to navigate their pharmacy benefit. Consumers can not battle with the PBM or insurance company. For these consumers, pharmacists act as an advocate, guiding consumers to use the lowest price drugs, explaining co-pays, and determining access. When a particular policy is problematic, the pharmacist will often work through it with the patient, providing explanation and even advocating on behalf of the patient with the PBM—going far beyond the tasks for which the pharmacist is paid.

In effect, pharmacists are the consumers best friend, advocating for coverage and protecting them from egregious practices. That is another reason why regulation in this market is so necessary.

III. A Broken Market Leads to Escalating Drug Costs and Rapidly Increasing PBM Profits

What is the result of this dysfunctional market? PBMs entered the health care market as “honest brokers” or intermediaries between health care entities. However, the role of the PBM has evolved over time and increasingly PBMs are able to — “play the spread” — by not fully sharing the savings they purportedly secure from drug manufacturers. As a result PBM profits have skyrocketed over the past dozen years. Since 2003, the two largest PBMs—Express Scripts/Medco and CVS Caremark— have seen their profits increase by almost 600% from \$900 million to almost \$6 billion.



If the market was competitive one would expect profits and margins would be driven down. But as concentration has increased the exact opposite has occurred.

There is tremendous concern over rapidly increasing drug prices which threaten our nation's ability to control the cost of health care. While PBMs suggest that they are there to control these costs these claims must be carefully scrutinized. The concern of a PBM is to maximize profits and that means maximizing the amount of rebates they receive. Since rebates are not disclosed this is an incredibly attractive source of revenue. PBMs can actually profit from higher drug prices, since this will lead to higher rebates. **While PBMs tout their ability to lower drug costs, the gross profit the major PBMs reap on each prescription covered is increasing year after year. For example, Express Scripts' gross profit on an adjusted prescription increased from an average of \$4.16 in 2012 to \$6.68 in 2015 to an estimated \$7.00 by 2017. In other words the gross profits have increased by almost 75% since Express Scripts acquired its biggest rival Medco.**

Would PBMs withhold their negotiating punch to secure higher rebates? We do not have to guess that this is occurring. PBMs have used similar strategies in the past. Indeed, as noted below state enforcers have attacked sweetheart deals PBMs arranged with drug manufacturers to force consumers to use higher cost, less efficacious drugs, in order to maximize rebates and secure kickbacks. They held back their negotiating muscle to allow prices to escalate to maximize rebates.

You do not need a Ph.D. in economics to figure out that the market is not competitive and that plans and consumers are paying more than they otherwise would. This Subcommittee should investigate whether PBMs are effectively controlling drug costs.

Facing weak transparency standards, the largest PBMs frequently engage in a wide range of deceptive and anticompetitive conduct that ultimately harms and denies benefits to consumers. Some PBMs secure rebates and kickbacks from drug manufacturers in exchange for exclusivity arrangements that may keep lower priced drugs off the market. PBMs may switch patients from prescribed drugs to an often more expensive drug to take advantage of rebates that the PBM receives from drug manufacturers. PBMs often do not pass through to payors rebates secured from drug manufacturers, and instead are accounted for as a reduction in cost of revenues, allowing the PBMs to hide profits. In fact, Medco was the last PBM to publicly disclose rebates in 2012. In short, PBMs derive enormous profits at the expense of the health care system from the ability to "play the spread" between pharmaceutical manufacturers, pharmacies and health care plans.

More recently, PBMs are finding new revenue sources through egregious conduct. Some PBMs are using audits not just as a means of supposedly combating fraud but rather as a mechanism to secure greater revenue. PBMs engage in a variety of audit tactics such as "extrapolating" errors to inflate recoveries. Some PBMs rely on unfair and technical errors to withhold substantial funds from providers despite evidence that patients properly received dispensed medications. And as we describe below many PBMs manipulate generic drug

reimbursement rates, known as MAC pricing, as a method of increasing profits. Often these generic rates force pharmacies to dispense drugs below cost.

No other segment of the health care market has such an egregious record of consumer protection violations as the PBM market. Between 2004 and 2008, Express Scripts and CVS were the subject of six major federal or multidistrict cases over allegations of fraud; misrepresentation to plan sponsors, patients, and providers; unjust enrichment through secret kickback schemes; and failure to meet ethical and safety standards. One of the most common forms of egregious conduct identified was PBMs switching consumers to higher cost drugs, that often were less efficacious, in order to maximize rebates. These cases appended to this testimony, resulted in over \$371.9 million in damages to states, plans, and patients so far.

Unfortunately the provisions in the orders in each of these cases have expired increasing the need for greater regulation and enforcement to ensure that the market functions with transparency, consumer choice, and free of conflicts of interest.⁵

These problems are only getting worse. Case in point are the number of recent cases which are either ongoing or have settled in 2015. Just this year alone, Express Scripts and CVS have paid settlement fines to the federal government and to numerous states of over \$129 million for illegal prescription dispensing and various violations of the false claims and anti-kickback laws.⁶ In 2014 CVS alone was responsible for over \$30 million in penalties concerning violations of the false claims act and SEC violations.⁷ And currently pending before the Delaware federal district court is a false claims act brought against Medco (now Express Scripts) on behalf of the U.S., California, Florida and New Jersey over claims the company defrauded state and federal health insurance programs by accepting undisclosed discounts from drug manufacturers and not passing on the savings to its clients, according to a recently amended complaint.⁸

Moreover, substantial private litigation is pending against major PBMs. For example, Catamaran Rx, a recent acquisition of Optum Rx, has several separate pending suits against it. One by retail chain Kmart alleging failure to pay reimbursements for dispensed drugs equating to \$38 million in damages;⁹ and the other by 55 independent pharmacies alleging illegal conduct serving to inflate patient costs while simultaneously underpaying pharmacies.¹⁰ Additionally, Express Scripts is facing an antitrust conspiracy suit in which the plaintiff has alleged Express Scripts engaged in a conspiracy with other major PBMs to exclude competing compounding pharmacies from their network, effectively forcing the competition to close and routing patients to the PBMs captive pharmacies. The case has survived a motion to dismiss.¹¹

⁵ For a more detailed analysis of the federal and state cases against the PBMs, see David A. Balto, *Federal and State Litigation Regarding Pharmacy Benefit Managers*.

<http://www.dcantitrustlaw.com/assets/content/documents/PBM/PBM%20Litigation%20Updated%20Outline%20-%202011.pdf>.

⁶ See Appendix A.

⁷ *Id.*

⁸ *John Doe v. Medco Health Solutions Inc., et al.*, Case No. 1:11-cv-00684 (D. Del.).

⁹ *Kmart Co. v. Catamaran Co.*, Case No. 2015-L-008290 (Ill. Ct. Cl. Aug. 31, 2015).

¹⁰ *Albert's Pharmacy, Inc. et al v. Catamaran Corporation*, Case No. 3:15-cv-00290 (M.D. Pa. Feb. 9, 2015).

¹¹ *HM Compounding Services v. Express Scripts*, Case No. 14-cv-01858 (E.D. Mo.).

There are three very important lessons here: (1) the fundamental elements of a well functioning market are absent; (2) plans and consumers have already suffered substantial harm from deception, fraud and other egregious practices; and (3) there is a tremendous need for comprehensive regulation of PBMs.

IV. The Effective Abandonment of Sound Enforcement by the Federal Trade Commission

The Federal Trade Commission is the nation's premier antitrust enforcer and in some respects a model of sound government enforcement. As a former FTC official I honor the agency and the hundreds of dedicated employees firmly committed to their role as public servants. In many respects it performs its mission well, but when it comes to PBMs the FTC has simply failed to serve the public.

The facts are distressing to anyone who cares about protecting consumers:

- The FTC permitted ESI to acquire Medco creating a PBM with over 40% of the market for large firms. It created the largest specialty drug pharmacy. (The Commission deadlocked 2-2 on whether to remedy concerns in the specialty market). The failure to take actions was in spite of extensive consumer, employer and union advocacy opposing the merger and concerns raised by over 70 Congressmen.
- In controversial cases like this sound enforcement principles call for an agency to review its decision, examine the market, and determine whether they "got it right." Yet in spite of calls for a review by Commissioner Julie Brill in Congressional testimony in 2013,¹² the FTC has declined to review the impact of its decision to determine whether it was right or wrong.
- State legislatures have tried to fill the regulatory vacuum. Yet when states or the Department of Labor (a fellow federal agency) have considered sound legislation or regulation to address the ongoing consumer protection or competition problems the FTC has opposed that regulation. (Most states ignore the FTC's advocacy which is based more on economic theory than marketplace realities). In some cases the FTC has opposed transparency in spite of the fact that consumer groups, employers and unions all called for greater transparency, an essential component of health care reform.
- The FTC has brought no enforcement actions against PBMs in spite of numerous complaints. None. In fact when a Federal Judge asked the FTC to investigate egregious conduct by CVS Caremark in excluding a community pharmacy in Hopkinton, Massachusetts from continued participation in the Caremark PBM network the FTC declined to do so.¹³

¹² See transcript of The FTC at 100: Where Do We Go From Here?: Hearing before the H. Subcommittee on Commerce, Manufacturing and Trade, 113th Cong. at 37 (Dec. 3, 2013), available at <http://www.gpo.gov/idsys/pkg/CHRG-113hhrg93483/pdf/CHRG-113hhrg93483.pdf>.

¹³ See *Hopkinton Drug v. CaremarkPCS et al*, Case. No. 14-cv-12794, Dkt. No. 70 (D. Mass.)

- The FTC chose not to conduct a significant investigation of the last two PBM mergers – United/Optum’s acquisition of Catamaran (the third and fourth largest PBMs) and CVS’ acquisition of Omnicare, the largest long-term care pharmacy. The decision not to conduct a significant investigation in CVS/Omnicare is particularly puzzling. First, it combined the largest PBM for Medicare Part D plans with the largest long term care pharmacy, which is heavily reliant on Part D enrollees. Leading consumer and senior groups, including Consumer Federation of America, US PIRG, Consumer Action, and Consumer Watchdog, raised significant concerns, noting “this acquisition poses significant risks for the users of long-term care (“LTC”) pharmacies, and in particular, the more than two million Part D Medicare beneficiaries that receive LTC while living in skilled nursing facilities throughout the United States. The acquisition also poses a significant risk of increasing costs for vulnerable senior citizens and the disabled, increasing out of pocket costs, and increasing costs for Medicare Part D.” Yet the FTC did not even so much as issue a second request for information.
- **The failure to conduct significant investigations in these two mergers send an unambiguous signal to the PBM industry to “merge at will.” This Subcommittee should ask: if these acquisitions are not worthy of an investigation what PBM merger would the FTC ever challenge? It should ask the FTC to explain its puzzling decision not to conduct a thorough investigation in CVS/Omnicare. And it should demand the FTC continue to closely monitor these markets to identify anticompetitive effects from these mergers.**

The failure not only to bring sound enforcement actions but even to conduct investigations send a clear signal to market participants that they are immune from antitrust scrutiny. Make no doubt about it, when that occurs firms act accordingly. Many pharmaceutical companies are ramping up drug prices unrelated to cost increases trying to take advantage of a lack of regulatory oversight.

And sometimes firms act defensively when there is a lack of enforcement. Walgreens proposed acquisition of Rite Aid, which will create a pharmacy giant with approximately 13,000 stores and a market share of over 46% nationally, is an effort to battle back against the tremendous power of the PBMs. If you do not like pharmacy consolidation you need look no further than the FTC’s green light to PBM consolidation to see the cause. Of course, getting bigger to fight against someone with market power rarely benefits consumers – as Professor Tom Greaney calls it the sumo wrestler theory – when both are big and fat they simply figure out a way to split the monopoly profits.¹⁴

This Subcommittee should act to investigate the FTC’s failure to bring sound enforcement actions in the PBM market. It should call on the FTC to investigate the impact of the ESI/Medco merger as suggested by Commissioner Brill. The Subcommittee should use its full investigatory powers to examine the level of investigation and determine why the FTC has chosen not to investigate or enforce. It should ask the Commission to

¹⁴ See Thomas Greaney, *Examining Implications of Health Insurance Mergers*, HEALTH AFFS. (July 16, 2015), <http://goo.gl/ETT1DB>.

explain why it opposes transparency when employers, unions and consumer groups support these efforts. Finally, it should hold an oversight hearing to examine the FTC's overall enforcement in this area and how the lack of enforcement affects competition in PBM, pharmaceutical and pharmacy markets.

The FTC is not doing its job and consumers are being harmed. This Subcommittee must act to reverse this misguided lack of enforcement.

V. The Need for Transparency and Legislation to Require Standards on MAC Pricing

A. Transparency Provisions are Necessary to Protect Plan Sponsors and Consumers

As a general matter it is essential to provide transparency for consumers, which helps them to adequately evaluate products carefully, to make informed choices, and to secure the full range of services they desire. In these respects the PBM market is fragile at best. PBM operations are very obscure and a lack of transparency makes it difficult for plan sponsors to make sure they are getting the benefits they deserve.

Responding to the numerous enforcement actions, both a handful of states and Congress have taken measures to enact transparency provisions by requiring some degree of disclosure of rebates and other revenue. In the multistate enforcement action against CVS Caremark, 30 state attorneys generals required rebate disclosure. Additionally, the Department of Labor ERISA Advisory Council recommended PBMs be required to disclose fees and compensation to sponsors of ERISA health plans.¹⁵ Finally, some large sophisticated health plans have negotiated for greater transparency.

Although settlements from litigation and negotiations have helped to address some issues, without legislation a lack of transparency allows PBMs to “play the spread,” leading to higher costs for plan sponsors and patients. PBMs earn enormous profits by negotiating rebates and discounts with drug manufacturers in exchange for promoting certain drugs on their preferred formulary or engaging in drug substitution programs. PBMs also negotiate contracts with pharmacies to determine how much the pharmacists will be paid for dispensing medication and providing services. By paying a lower reimbursement rate to pharmacies, but failing to adequately disclose reimbursement rates and manufacturer rebates PBMs can generate more revenue. In both respects, PBMs can play the spread by failing to disclose these forms of indirect compensation. The failure to disclose these payments denies purchasers important information that impacts their buying decisions. As a result, this lack of information often results in higher costs for consumers, health plans, employers, and other plan sponsors.

Large employers such as General Dynamics and Honeywell, two fortune 100 companies with roughly 100,000 employees each, and the National Coordinating Committee for Multiemployer Plans representing 20 million active and retired Americans have testified in favor

¹⁵ See PBM Compensation and Fee Disclosure, Report by the ERISA Advisory Council, Department of Labor (2014), available at <http://www.dol.gov/ebsa/publications/2014ACreport1.html>.

of transparency in the PBM market. Honeywell has specifically stated “PBMs are service providers in a position to have a material impact on the plan, PBM compensation structure is complex and there are potential conflicts of interest, I think it has become abundantly clear that developing appropriate regulations regarding PBM disclosure [is necessary].”¹⁶ And Robert Restivo, Director of Benefits at General Dynamics has noted that, “the [PBM] industry is beset with a lack of transparency that is difficult to deal with even for the largest employers.”¹⁷

PBMs are free to “play the spread” between manufacturers, pharmacists and plans because of a lack of disclosure. Unclear and inadequate disclosure of rebates and discounts undermine the ability of plan sponsors to compare competing proposals. Because rebates, discounts, and other fee structures remain undisclosed, plan sponsors cannot clearly identify and choose PBMs offering the highest value services. PBMs’ promise of controlling pharmaceutical costs has been undercut by a pattern of conflicts of interest, self-dealing, deception, and anticompetitive conduct. The dominant PBMs have been characterized by opaque business practices, limited market competition, and widespread allegations of fraud.

Increased disclosures by PBMs have resulted in price decreases and significant savings for health plans. Increasingly larger health plans are negotiating for transparency and securing significant savings. Large plan sponsors, such as universities, states, and federal programs have recently learned that they can achieve substantial cost savings by requiring transparency – i.e. requiring PBMs to disclose their negotiations and financial interactions with drug manufacturers.

For instance, through contracting with a PBM under transparent pass-through models, New Jersey projected savings of \$558.9 million over six years and Texas expected savings of \$265 million by switching to a transparent PBM contract for their state employee health plans.

Other plans have been forced to take even more extreme steps to ensure transparency and honest brokering in the negotiations of prices and rebates – they have simply eliminated their PBM and managed their own pharmacy benefits directly. For example, TRICARE, the federal health plan for military personnel and their families, anticipated savings of \$1.67 billion by negotiating its own drug prices, including rebates, rather than going through a PBM. The University of Michigan saved nearly \$55 million by administering its own plan.

In the corporate context, a recent report revealed that Meridian Health System discovered that its drug benefit increased by \$1.3 million within the first month of contracting with Express Scripts for PBM services.¹⁸ Meridian discovered that they were being billed for generic amoxicillin at \$92.53 for every employee prescription; however Express Scripts was paying only \$26.91 to the pharmacy to fill these same prescriptions.¹⁹ The result was a spread, also known as the difference between the PBM’s expenditure and the revenue it takes in, of \$65.62. Meridian canceled its contract and switched to a transparent PBM which saved Meridian \$2 million in the

¹⁶ Allison Klausner, Testimony before the Department of Labor ERISA Advisory Council at 8 (August 20, 2014), available at <http://www.dol.gov/ebsa/pdf/ACklausner082014.pdf>.

¹⁷ Robert Restivo, Testimony before the Department of Labor ERISA Advisory Council at 15 (August 20, 2014), available at <http://www.dol.gov/ebsa/pdf/ACrestivo082014.pdf>.

¹⁸ Katherine Eban, *Painful Prescription*, *Fortune Magazine* (Oct. 10, 2013).

¹⁹ *Id.*

first year of its contract. Each of these examples demonstrates that disclosure can improve competition and reduce costs to plans and consumers.

This Subcommittee should consider legislation to require transparency provisions for federal programs to require disclosure of rebates and discounts.

B. H.R. 244 should be enacted to address the abuse of generic drug reimbursement

Like many health care businesses PBMs must establish reimbursement rates for services and the dispensing of drugs. This system works best, for consumers, plans, and pharmacies when there is a transparent and consistent system for determining these reimbursement rates. When there is a transparent and consistent system all of the market participants can effectively plan, purchase goods and provide services. Where transparency and consistency are absent there is a significant opportunity for providers and ultimately consumers to be harmed by deceptive and unfair conduct.

Unfortunately, currently the reimbursement system for generic drugs often lacks these critical elements. Generic drug reimbursement is based on a so called “MAC” list, which sets the “Maximum Allowable Cost.” MAC lists are PBM-generated list of products that includes the upper limit or maximum amount that a PBM will pay for generic drugs and brand name drugs that have generic versions available. There is no standard methodology for derivation of MAC lists or how the maximum prices are determined. Neither plan sponsors nor retail pharmacies are informed how products are added or removed from a MAC list or the methodology that determines how this so-called “maximum” cost is calculated or adjusted. Moreover, PBMs often change the “MAC” benchmark, or utilize multiple MAC lists to create a spread between what they charge a plan versus the amount they reimburse a pharmacy. This lack of transparency and prevalence of nonstandard MAC list and pricing derivation allows PBMs to utilize an aggressively low MAC price list to reimburse their contracted pharmacies and a different, higher list of prices when they sell to their clients, plan sponsors. Essentially, the PBMs reimburse low and charge high with their MAC price lists, pocketing the significant spread between the two prices. Most plans are unaware that multiple MAC lists are being used and have no real concept of how much revenue the PBM retains.

The lack of transparency harms plan sponsors, employers and unions. Plans can not determine whether they are paying more than they should for some multisource generic products. Without the knowledge of whether certain generics are included or excluded on MAC lists, a plan does not know whether a member’s copay may increase due to drugs not being available on MAC lists. A member may complain that they cannot get access to a generic that should be available through their benefit and the plan is forced to pay a higher price to the PBM.

Such lack of transparency on MAC pricing also causes problems for consumers and the community pharmacies they utilize. The cost of many generic drugs has skyrocketed by 1,000 percent or more,²⁰ and often PBMs may wait months before they update reimbursement rates to correlate with the cost of the generic drug. This means the pharmacy is forced to pay more for

²⁰ Peter Jarct, Prices Spike for Some Generic Drugs, AARP Bulletin (July/August 2015), available at <http://www.aarp.org/health/drugs-supplements/info-2015/prices-spike-for-generic-drugs.html>.

the generic drug but continues to receive a low reimbursement on the old lower cost of the drug. This situation forces pharmacies to absorb losses and jeopardizes patients' access to medication.

Not surprisingly, 24 states have adopted sensible legislation to require MAC transparency.²¹ Additionally, despite legal challenges by the PBM lobby, Pharmaceutical Care Management Association, state MAC legislation has been upheld as constitutional.²²

There is a clear path to address this problem. Representative Collins introduced H.R. 244 earlier this year to require further transparency of payment methodologies to pharmacies under the Medicare prescription drug program. The proposed legislation is an excellent step in addressing these problems by, *inter alia*, requiring updates of reimbursement standards at least every 7 days to accurately reflect the market price of acquiring the drug; requiring PBMs to disclose the market-based sources they use to update reimbursement standards; and if those sources are not public, disclose the individual drug prices to be updated to pharmacies; and establishing a process for pharmacies to appeal pricing changes when the pharmacy acquisition price is more than the reimbursement price.

Importantly, H.R. 244 goes beyond just disclosure of MAC pricing, but includes drug pricing references and amounts that are based on average wholesale price, average wholesale cost, average manufacturer prices, average sales price, MAC, or other costs.

Where transparency and consistency are absent there is a significant opportunity for providers, plan sponsors, and ultimately consumers to be harmed by deceptive and unfair conduct. H.R. 244 will be a first step in solving the problem by requiring disclosure of pricing and consistently updating reimbursement standards to reflect the market price of drugs. The legislation would help ensure Medicare beneficiaries, plans, and pharmacies do not pay more for generic drugs than they should.

VI. Protecting Patient Choice and Eliminating Conflicts of Interest

As consumers and patients we all understand the critical importance of patient choice. Only where consumers have the full range of choices does the competitive market thrive. Unfortunately, because PBMs have their own pharmacy operations – through retail stores, mail order, or specialty pharmacy – they are increasingly engaging in conduct that restricts patient choice and leads to higher costs and worse health care.

Forcing Consumers to use Mail Order

The major PBMs make a large portion of their profits by forcing consumers to use mail order. The major PBMs often restrict network options to drive consumers to their operations. Mail-order may be more costly, may result in significant waste, and fails to provide the level of

²¹ For example, North Dakota enacted legislation to address the distortions created by use of MAC pricing by PBMs. See Letter to Sen. Judy Lee, Re: House Bill No. 1363 (March 25, 2013), available at http://www.dcantitrustlaw.com/assets/content/documents/NDPHA%20letter%202013_Lee.pdf.

²² See *PCMA v. Gerhart et al.*, Case No. 14-cv-000345 (S.D. Iowa)(granting State's motion to dismiss for failure to state a claim upon which relief can be granted).

convenience and counseling that many consumers require. Consumers may have existing relationships with a community pharmacy and may not wish to leave the pharmacist they know and trust to be served by a mail order robot. Others simply enjoy the ability to one-stop-shop and prefer the convenience of their supermarket pharmacy. The bottom line is that consumers are left worse-off when they are unable to choose the level of pharmacy care they desire.

Preventing Vulnerable Consumers from Using Their Community Specialty Pharmacy

The ownership of specialty pharmacies exacerbates the conflict of interest problem. Restrictive networks raise significant concerns for the over 57 million Americans that rely on specialty drugs.²³ Specialty drugs are typically expensive treatments that require special handling or administration. These drugs provide treatment for our nation's most vulnerable patient populations who suffer from chronic, complex conditions such as hemophilia, Crohn's Disease, Hepatitis C, HIV/AIDS, and many forms of cancer. The leading PBMs – Express Scripts and CVS Caremark own their own specialty pharmacies and increasingly force consumers to use their specialty pharmacy. Specialty drugs are expected to be the single greatest cost-driver in pharmaceutical spending over the next decade. The cost of specialty drugs is rising rapidly, increasing from approximately \$55 billion in 2005 to \$1.7 trillion in 2030.²⁴

The dominant PBMs are able to force consumers to use their own specialty pharmacies through restrictive networks. These networks can be higher cost and can also disrupt the continuum of care degrading health outcomes and increasing healthcare costs.²⁵ Patients on specialty drugs often require regular contact and counseling from their pharmacist (who is often assisted by a nurse). For many disease states, the pharmacist and nurse regularly contact the patient to make sure the drug is properly administered, taken on time, and the drug is working effectively. Disrupting this patient-provider relationship in complex and expensive treatment of very sensitive health conditions imposes significant harm to both the consumer and the health plan. We all know there is a profound difference between the personal treatment of an independent pharmacy and dealing with the automated telephone approach of the large PBMs.

Moreover, restrictive networks and steering practices rob consumers of the choice to use their preferred pharmacy and method of distribution; and—with this important rivalry gone—consumers also miss out on the benefits of vigorous competition, including lower prices and improved service. These restrictive networks deny patients a choice in provider and, given the high-touch nature of services in this area, this choice is highly valued by many consumers. The PBMs' ability to impose restrictive networks harms consumers that depend on the high-cost

²³ Laura Hines, *Soaring specialty drug prices leave patients seeking relief*, Houston Chron. (March 15, 2015).

²⁴ IMS Health, *Overview of the Specialty Drug Trend (2014)*, available at https://www.imshealth.com/deployedfiles/imshealth/Global/North%20America/United%20States/Managed%20Markets/5-29-14%20Specialty_Drug_Trend_Whitepaper_HI-Res.pdf.

²⁵ The vital service-related role of independent specialty pharmacies was described in my testimony before the United State Senate Judiciary Antitrust subcommittee concerning the Express Scripts-Medco merger. See David Balto, *Testimony regarding "The Express Scripts/Medco Merger: Cost Savings for Consumers or More Profits for the Middlemen?"* before the U.S. Senate Subcommittee for Antitrust, Competition Policy and Consumer Rights, December 6, 2011, available at <http://dcantitrustlaw.com/assets/content/documents/testimony/SenateJudiciary.ESIMedco.Balto.pdf>.

products and services that are of great, and even life-altering, significance to these vulnerable patients.

Finally, there is the fox guarding the hen house problem (not a wise strategy for running any business). When a PBM has its own specialty pharmacy it no longer clearly serves the plan – rather its incentive is to increase profits by forcing consumers into the PBM’s specialty pharmacy. The New York Times poses the appropriate question: “pharmacy benefit managers like CVS and Express Scripts...are supposed to help health plans control drug costs. But will they have the zeal to do that if they are making money dispensing these expensive medicines?”²⁶

Although the PBMs’ perverse incentives are too widespread to be addressed through litigation, fortunately, some payors utilizing the large PBMs have changed their policies somewhat on restrictive networks as a result of litigation. For example, Consumer Watchdog, a consumer advocate group, has sued four insurance companies over their policies of restricting the pharmacies that patients can use to obtain drugs for HIV. Three of the companies — Anthem Blue Cross of California (Express Scripts), UnitedHealthcare (Optum) and Aetna (CVS) — have since changed their policies to provide more options for H.I.V. patients. The most recent of the lawsuits, against Cigna, was filed in April.²⁷

The Subcommittee should consider legislation to preserve patient choice and access. I suggest two provisions. Any legislation should prevent PBMs from mandating that a patient use a specific retail pharmacy, mail order pharmacy, specialty pharmacy or other pharmacy if the PBM has an ownership interest in the pharmacy. Additionally, the proposed legislation could help to prevent fraud and abuse by requiring that PBMs disclose to covered entities the cost of both drugs and any benefit or payment directly or indirectly accruing to the PBMs if they make a substitution in which the substitute drug costs more than the prescribed drug.

Preventing Medicare Part D Beneficiaries from Utilizing Their Preferred Pharmacy

Medicare Part D is a critical benefit for American seniors offering comprehensive access to pharmaceuticals. However, an ever-increasing number of PBMs are moving vulnerable seniors into preferred pharmacy networks. In 2016, 85 percent of all Medicare Part D regional prescription drug plans will have a preferred cost sharing pharmacy network (“PCSPN”), also known as a limited network.²⁸ The nearly universal use of PCSPNs runs contrary to Medicare Part D’s enacting legislation, which stated that “a prescription drug plan shall permit the participation of any pharmacy that meets the terms and conditions under the plan.”²⁹ Since 2011 PBMs have expanded their use of these networks. In creating these limited networks, PBMs limit independent pharmacy access, often not allowing independent pharmacies even the ability

²⁶ Andrew Pollack and Katie Thomas, Specialty Pharmacies Proliferate, Along With Questions, New York Times (July 15, 2015), available at http://www.nytimes.com/2015/07/16/business/specialty-pharmacies-proliferate-along-with-questions.html?_r=0.

²⁷ Id.

²⁸ Adam J. Fein, *Exclusive: In 2016, 85% of Medicare Part D plans have a preferred pharmacy network*, DRUG CHANNELS (Oct 2, 2015), <http://www.drugchannels.net/2015/10/exclusivc-in-2016-85-of-medicare-part-d.html>.

²⁹ Medicare Prescription Drug, Improvement, and Modernization Act of 2003 – 1860D-4(b)(1)(A)

to bid for network participation. Instead, the networks rely on chain retailers or on the PBM's mail order operation. As a result, many beneficiaries do not have access to the pharmacy of their choice, while PBMs increase profits as consumers are forced to rely on the PBM's captive pharmacy.

By allowing PBMs to implement such limited networks, CMS has effectively limited independent pharmacy participation in these plans. Thirty Congressional members spoke out against this interpretation and wrote CMS to oppose and investigate the usage of preferred/limited Part D networks.³⁰ In 2014, CMS offered proposed rules that would focus on allowing any willing pharmacy access to a preferred network. On behalf of the New America Foundation, I authored a white paper in support of the proposed rule, documenting the increased costs to beneficiaries and decreased quality of services within preferred Part D networks.³¹ However, after political pressure on other aspects of the proposed rule, CMS withdrew its changes to Part D and the preferred networks.

Given CMS' failure, there is a need for legislation to increase access and ensure any willing pharmacy may participate in Part D preferred networks. H.R. 973/S 1190, the Ensuring Seniors Access to Local Pharmacy Act, for Competition in Medicare Part D, is one approach. With bi-partisan sponsorship, the bill allows pharmacies, within a professional shortage area or medically underserved area, participate in a preferred network if they can meet the plan's terms and conditions. This law does not favor independent and community pharmacies, but it does give them an opportunity to participate in networks to service elderly Part D beneficiaries. That was the true intent of the Medicare Modernization Act.

Of critical importance, here is the fact that community pharmacists are not looking for a "handout" from the PBMs or the federal government; they simply want the ability to compete on a level playing field. This further demonstrates the anticompetitive practices utilized by the PBMs. If a small business community pharmacy is willing to accept the same contract terms as, for example, CVS, and is not allowed to do so, one of two things is happening: either CVS's contract is raising costs for consumers by not offering the lowest price true competition would yield, or consumers are needlessly suffering poorer pharmacy access and choice. In Medicare Part D, the beneficiaries are meant to be our seniors, but in the current market the beneficiaries are the PBMs.

The PBMs Misguided Attack on Patient Assistance Programs

Recently, some PBMs have begun to attack patient assistance programs in which pharmaceutical manufacturers attempt to assist low income and vulnerable consumer to acquire critical drugs that are often expensive. These patient assistance programs have existed for decades and have benefitted millions of consumers. Some PBMs have raised concerns when the

³⁰ Letter from Morgan Griffith and 29 other Members of Congress, to Marilyn Tavenner, Acting Administrator Center for Medicare & Medicaid Services (Mar. 15, 2012), available at http://www.ncpanet.org/pdf/leg/mar13/part_d_pref_networks.pdf.

³¹ See David Balto & James Kovacs, *Increased Competition and Choice: Evaluating the Proposed Medicare Regulations and Their Impact on Pharmaceutical Access and Care*, NEW AMERICA FOUNDATION (2014), available at <http://goo.gl/paxuXk>.

manufacturer uses a small number of pharmacies for these patient assistance programs. Of course, the antitrust laws give manufacturers broad flexibility to enter into exclusive or near exclusive distribution arrangements. Limited distribution may be particularly appropriate if the patient population needs to be educated and there are outreach issues. More importantly, the PBMs efforts seem little more than a thinly guised scheme to force consumers to the PBMs' specialty pharmacies where the consumer will pay considerably more for these vital drugs.

It is hard to conceive how consumers will benefit from interfering with patient assistance programs. This Subcommittee should ask the FTC to investigate the PBMs' efforts to restrict these pro-consumer patient assistance programs.

VII. Conclusion

Consumers need greater protection from the egregious practices of PBMs. The Subcommittee should consider the above recommendations to help ensure PBMs act in a transparent manner to ensure health plans, employers, pharmacies and consumers are protected, and to ensure PBMs exist in a properly regulated environment. Moreover, it is incumbent upon the FTC to recognize the anticompetitive and consumer harm that is occurring as a result of unregulated PBM conduct and increasing consolidation in the market.

I look forward to answering any questions.

Appendix A: Cases against Pharmacy Benefit Managers

Appendix A offers a summary of a number of cases against pharmacy benefit managers (“PBMs”). This is not a complete list of all litigation against PBMs. The case summary focuses on cases claiming PBM deception, fraud, or antitrust violations.

Year	Case	Summary
2015	<i>United States ex rel. DiMattia et al. v. Medco Health Solutions, Inc.</i> , No. 13-1285 (D. Del.)	The United States alleged that Medco (now part of Express Scripts) violated the False Claims Act. In particular, it was alleged that Medco solicited remuneration from AstraZeneca in exchange for identifying Nexium as the “sole and exclusive” proton pump inhibitor on certain of Medco’s prescription drug lists. As a result of this deal, Medco received reduced prices on AstraZeneca drugs: Prilosec, Toprol XL and Plendil. Medco settled the case and agreed to pay \$7.9 million to resolve the kickback allegations.
2015	<i>Kmart Co. v. Catamaran Co.</i> , No. 2015-L-008290 (Ill. Ct. Cl.)	Kmart alleges that Catamaran “improperly manipulated prescription reimbursements.” In particular, Kmart alleges that Catamaran cut payments to Kmart pharmacies and failed to reimburse Kmart for almost 28,000 pricing appeals. As a result of these pricing appeals, Kmart has suffered \$38 million in damages . This case is ongoing.
2015	<i>Albert’s Pharmacy, Inc. et al v. Catamaran Corporation</i> , Civ. No. 3:15-cv-00290-UN2 (M.D. Pa.)	Fifty-five independent pharmacies sued Catamaran for illegal conduct. The parties allege that Catamaran inflated patient costs while simultaneously underpaying pharmacies. Specifically, the pharmacies argue that Catamaran set rates below cost, made pricing data inaccessible, did not update data, and provided no transparency on how drugs rebates are applied. As a result of Catamaran’s practices, the pharmacies’ business and continued delivery of patient care are at risk. This case is ongoing.
2015	<i>U.S. ex rel., et al. v. Novartis Pharmaceuticals Corp.</i> , No. 1:11-cv-08196 (S.D. N.Y.)	The United States sued Accredo (owned by Express Scripts) claiming that Accredo recommended the drug Exjade to Medicaid patients in exchange for kickbacks from Novartis Pharmaceuticals Corp., which markets the drug. Accredo settled the matter paying \$60 million to the federal government and various states.

2015	<i>John Doe v. Medco Health Solutions Inc., et al.</i> , Case No. 1:11-cv-00684 (D. Del.)	A relator on behalf of the United States, California, Florida and New Jersey brought a False Claims Act case against Medco. The case claims Medco (now a part of Express Scripts) defrauded state and federal health insurance programs by accepting undisclosed discounts from drug manufacturers and not passing on the savings on to its clients. This case is ongoing.
2015	<i>HM Compounding Services v. Express Scripts</i> , Case No. 14-cv-01858 (E.D. Mo.)	Express Scripts is facing an antitrust conspiracy suit in which the plaintiff a compounding pharmacy, has alleged Express Scripts engaged in a conspiracy with other major PBMs to exclude competing compounding pharmacies from their network. As a result, competition within the compounding industry has been foreclosed and consumers have been routed to the PBMs captive pharmacies. The case is ongoing, and the plaintiffs have survived a motion to dismiss.
2015	<i>United States v. CVS</i> See: http://goo.gl/Ks3FqR	CVS was forced to pay \$22 million to resolve federal allegations that its pharmacies sold narcotic painkillers not prescribed for legitimate medical purposes.
2014	<i>Grasso Enterprises, LLC, et al., v. Express Scripts, Inc.</i> , Case No: 4:14-cv-01932 (E.D. Mo.)	Numerous compounding pharmacies sued Express Scripts alleging that the company intentionally cut compounding spending and illegally terminated compounding pharmacies from the Express Scripts' network. This case is ongoing.
2014	<i>United States ex rel. Well v. CVS Caremark, Inc.</i> , Civil Action No. SA:11-CV-00747 (W.D. Tex.).	The United States filed a False Claims Act suit against Caremark for knowingly failing to reimburse Medicaid for prescription drug costs paid on behalf of Medicaid beneficiaries who also were eligible for drug benefits under Caremark-administered private health plans. Caremark settled the case, paying the federal government \$6 million.
2014	<i>Securities and Exchange Commission v. CVS Caremark Corp.</i> , Civil Action No. 14-177-ML (D.R.I.)	Stemming from 2009, CVS Caremark agreed to pay \$20 million to settle charges brought by federal securities regulators that it misled investors and committed accounting violations.
2012	<i>Uptown Drug v. CVS Caremark</i> , Case No. 12-cv-6559 (N.D. Cal.)	Class of independent pharmacies filed suit against CVS Caremark alleging violations of California's unfair trade practice law by forcing maintenance prescriptions adjudicated by CVS Caremark's PBM business into CVS retail pharmacies, to the detriment of California pharmacies. The case is pending before the Ninth Circuit Court of Appeals.

2012	<i>In the Matter of CVS Caremark Co.</i> , FTC No. 112 31210	The Federal Trade Commission filed a complaint against CVS Caremark for misrepresenting the prices of certain Medicare Part D prescription drugs at CVS and Walgreens pharmacies. The misrepresentation caused seniors and disabled consumers to pay significantly more for critical medications. CVS Caremark settled, paying refunds to 13,000 consumers for a total of \$5 million.
2009	<i>HHS v. CVS</i> See: https://goo.gl/tHIXcM	CVS agreed to pay \$2.25 million to resolve allegations by both the Department of Health and Human Services and Federal Trade Commission that it violated the Health Insurance Portability and Accountability Act (HIPAA).
2008	<i>Washington v. Caremark Rx.</i> , No. 08-2-06098-5-SEA (Wash. Sup. Ct.)	29 attorney generals, including the Washington Attorney General, alleged that Caremark engaged in deceptive trade practices, did not inform clients of retained profits from drug switches, and improperly restocked and reshipped previously dispensed drugs. Caremark settled the matter paying \$41 million to the states and agreed to a change in business practices.
2008	<i>In re Express Scripts, Inc. PBM Litigation</i> , No. 4:05-md-1672-HEA (E.D. Mo.)	Numerous states sued Express Scripts alleging numerous violations of consumer protections. The violations included deceptive business practices by illegally encouraging doctors to switch patients to different brand name medications and increased spreads and rebates from manufactures without passing the savings onto the plans. Express Scripts paid \$9.3 million to settle the case, accepted restrictions on its drug switching practices, and adopted a code of professional standards.
2006	<i>United States of America v. Merck-Medco Managed Care L.L.C., et al.</i> , No.: 00-cv-737 (E.D. Pa.)	A multistate whistle blower lawsuit filed against Medco for violations of both federal and state False Claims Acts alleging defrauding the government, increasing drug prices, and failing to comply with state-mandated quality of care standards. Medco settled and paid a total of \$184.1 million.
2005	<i>United States of America, et al. v. AdvancePCS, Inc.</i> , No. 02-cv-09236 (E.D. Pa.)	A whistleblower suit against Advanced PCS (now a part of CVS Caremark) alleged that Advanced received kickbacks from drug manufacturers, induced customers to sign contracts with the PBM, and submitted false claims. Along with a \$137.5 million in settlement , Advanced received a five-year injunction and was forced to enter into a Corporate Integrity Agreement.

Mr. MARINO. Ms. Pons.

TESTIMONY OF NATALIE PONS, SENIOR VICE PRESIDENT, ASSISTANT GENERAL COUNSEL, HEALTH CARE SERVICES, CVS CAREMARK CORPORATION

Ms. PONS. Thank you. Good morning, Chairman Marino, Ranking Member Johnson and Members of the Subcommittee. My name is Natalie Pons and I'm senior vice president and assistant general counsel with CVS Health. We appreciate the opportunity to testify on the critical role that pharmacists and pharmacies play in local community all across America in providing convenient access to affordable high quality prescription drugs within the vibrant marketplace in which we compete.

From our company's earliest days CVS Health has been singularly focused on helping people on their path to better health. Our values are the same as those of our consumers, businesses and communities we serve. We want to make health care more accessible and help improve health outcomes in more affordable effective ways.

Our goal is to work with health plans, employer plans and government plans who contract with us to ensure that their enrollees have access to a well coordinated, safe and affordable prescription drug benefit.

Our patient centered model is organized around how consumers access and use medication. It provides multiple points of care and extends across all of our business units. Our pharmacy benefit management program, our retail mail specialty and long-term care pharmacies, our Medicare part D plan and our MinuteClinics.

In addition to our active medication adherence and care coordination for chronically ill patients, we also provide access to key preventative care such as vaccinations, smoking cessation and weight loss programs.

Our overriding commitment to improving American's health is the main reason we decided to end tobacco sales last year and forego \$2 billion in annual revenue. CVS Health is proud of its commitment to and success in constraining prescription drug costs through the discounts in savings we share with our consumers business, labor, health plan and government partners while helping to improve outcomes.

Using our clinical tools we're able to help keep premiums low and save tens of billions of dollars for patients, employers and taxpayers. Our success is driven by on how effectively we help our partners and patients achieve the best return on their health care dollars. We manage prescription drug benefits on behalf of a diverse set of purchasing partners that include health plans, as well as employer and government plans including Medicare part D and State managed Medicaid programs.

Health care purchasers rely on pharmacy benefit managers to negotiate the lowest possible prices from drug manufacturers, put together networks that provide convenient access to pharmacists and pharmacy services and provide a portfolio of clinical programs and services that help ensure positive outcomes and secure overall value for both the patients and clients alike.

To help us achieve this outcome, we encourage the use of cost effective generics over more expensive branded products which helps consumers and plans save money on prescription drugs, without compromising clinical efficacy. To be clear though, our role in the design of these plans is advisory, the plans always have the final say when creating their drug benefit and how it is implemented.

Competition in the PBM industry has aptly described as vigorous by the Federal Trade Commission. In fact there are 30 different large and mid sized PBMs that offer businesses, Labor, consumers and government a variety of choices when considering options for best managing of pharmacy benefit.

In addition, the pharmacy marketplace is a very competitive one, with over 60,000 pharmacies in the United States, consumers in all parts of the country have many outlets to fill their prescriptions. To ensure broad based access our PBM contracts with every category of pharmacy, including drugstore chains, grocery stores and over 20,000 independent pharmacies. We welcome competition indeed our success is predicated on it. Healthy competition drives innovation and allows us to effectively help the consumer business labor health plan and government partners that we serve achieve the best returns on their health care investments.

We look forward to working with the Members of this Committee and others to continue promoting a competitive health care landscape. Thank you for this opportunity to testify and I'll be happy to take your questions.

[The prepared statement of Ms. Pons follows:]

Prepared Statement of

**Natalie Pons, Senior Vice President, Assistant General Counsel,
Health Care Services
CVS Caremark Corporation**

Before the

**Subcommittee on Regulatory Reform, Commercial and Antitrust Law
Judiciary Committee
United States House of Representatives**

On

November 17, 2015

**Written Testimony of Natalie Pons
Senior Vice President, Assistant General Counsel, CVS Health
Hearing on “The State of Competition in the Pharmacy Benefit Manager and Pharmacy
Marketplaces”
November 17, 2015
Washington, DC**

Opening Statement and Introduction

Good afternoon, Chairman Marino, Ranking Member Johnson, and Members of the Subcommittee. My name is Natalie Pons, and I am Senior Vice President and Assistant General Counsel at CVS Health. We appreciate this opportunity to testify on the critical role that pharmacists and pharmacies play in local communities all across America in providing convenient access to affordable prescription medication and the vibrant marketplace in which we compete.

CVS Health

From our company’s earliest days until now – where we stand at the forefront of a changing health care landscape – CVS Health has been singularly focused on helping people on their path to better health. Every action we take and every decision we make is viewed through this lens. Our values are the same as those of consumers, businesses and communities—we want to make health care more accessible and help improve health outcomes in more affordable, effective ways. Our patient-centric model is organized around how consumers access and use medications. It is a focus and approach that provides multiple points of care and extends across all our business units – our pharmacy benefit management program; our retail, mail, specialty and long-term care pharmacies; our Medicare Part D plan and our MinuteClinics.

Our goal is to more effectively meet the needs of the health plans, employer plans, and the government plans we serve by providing convenient, affordable access to medications and to play a collaborative role in helping them manage chronic diseases. We also provide access to key

preventative care such as vaccinations, smoking cessation and weight loss counseling. Our overriding commitment to improving Americans' health is a main reason we decided to end tobacco sales last year and forgo \$2 billion in annual revenue.

We partner with health providers to support the entire continuum of care and have forged clinical collaborations with more than 60 major health systems and health care providers across the country.

CVS Health is proud of its commitment to and success in constraining prescription drug costs through the discounts and savings that are shared directly with our consumer, business, labor, health plan and government partners while helping to improve health outcomes. We are able to help keep premiums affordable and save tens of billions of dollars for patients, employers and taxpayers. Our success is predicated on how effectively we help our partners achieve the best return on their health care dollars. We are able to achieve these results by working every day to ensure that patients receive the right prescription drugs for their condition, at the right time, in the right setting, and at the right price.

What Pharmacy Benefit Managers Do

Pharmacy Benefit Managers, commonly referred to as PBMs, manage prescription drug benefits on behalf of a diverse set of purchasing partners that include health plans, employer plans, and government plans – including Medicare Part D – large private employers, state employer plans, state Medicaid programs for managed Medicaid and the Federal Employees Health Benefits Program. Today, more than 215 million Americans nationwide receive prescription drug benefits administered by PBMs.¹ With over 30 different PBMs, the PBM industry is highly competitive with a number of large and mid-sized players that offer businesses, labor, consumers and government a variety of choices when considering options for best managing their pharmacy benefit. With over 60,000 pharmacies in the United States, consumers in all parts of the country have many outlets to fill their prescriptions. In this highly competitive marketplace, PBMs

¹ Pharmacy Benefit Managers (PBMs): Generating Savings for Plan Sponsors and Consumers, Visante prepared for PCMA, Sept. 2011.

contract with every category of pharmacy, including independents, drugstore chains and grocery stores, among others.

Health care purchasers rely on PBMs to extract the lowest possible price from drug manufacturers, assemble pharmacy networks that provide convenient access to affordable medications, and provide a portfolio of clinical programs and services that deliver the best value for our purchasing partners' health care dollars while helping to improve members' health outcomes.

The degree to which drug benefits are managed efficiently has a significant impact on consumers' premiums and cost sharing. According to a 2011 Visante study, PBMs will save plan sponsors and consumers almost \$2 trillion, or nearly 35%, between 2012 and 2021 when compared with prescription drug expenditures made without pharmacy benefit management.² PBMs are able to do all of this in a health care landscape that has changed profoundly over the last several years – and continues to change as companies respond to market dynamics.

How We Do It

Pharmacy Benefit Managers use a variety of strategies and tools to help the health plans, employer plans, and government plans that PBMs serve manage the cost and utilization of prescription drugs, improve patient outcomes and lower overall health care system costs. Each plan determines what tools and strategies work best for them, and the PBM implements this plan design. The role of PBMs is advisory only; the plans always have the final say when creating a drug benefit plan and the plans are free to negotiate the best strategies for their members at the best available price.

PBMs design plan features that encourage the use of cost effective generics over more expensive branded products, which helps consumers and plans save money on prescription drugs without compromising clinical efficacy. PBMs also offer the plans clinically based programs that help improve patient adherence to medications, which helps lower costly hospital readmissions and reduce aggregate health care system costs. For example, PBMs check for drug interactions and

² Pharmacy Benefit Managers (PBMs): Generating Savings for Plan Sponsors and Consumers, Visante prepared for PCMA, Sept. 2011.

inappropriate or duplicate prescription and monitor prescription safety across all our network pharmacies, alerting pharmacists to potential drug interactions even if a consumer uses multiple pharmacies – something an individual pharmacy cannot do.

Pharmaceutical Manufacturer Rebates and Discounts: PBMs negotiate with pharmaceutical manufacturers to obtain discounts called rebates to help achieve the lowest drug prices for the plans to help keep patient premiums and cost-sharing manageable. PBMs are able to negotiate lower prices from pharmaceutical manufacturers because they have multiple clients, and therefore are able to negotiate larger volume discounts than individual plans.

Formularies: PBMs use panels of independent physicians, pharmacists, and other clinical experts to develop lists of drugs that plans can adopt as part of their plan design. One of the ways PBMs do this is by driving higher utilization of generics, which now account for more than 86 percent of prescriptions in the US. According to a August 2015 Generic Pharmaceutical Association (GPhA) report, generic utilization has saved patients and purchasers more than \$1 trillion dollars over the last decade.³

Network Management: PBMs provide plans with options for pharmacy networks that provide consumers with convenient access to affordable medications. When establishing networks, PBMs negotiate contracts with pharmacies throughout the country that are willing to provide discounted rates in exchange for access to a plan's members, prompting competition among many different types of pharmacies to offer the best prices and services in order to be included in the network. PBM network management helps plans reduce their healthcare costs.

According to industry reports, 80 percent of independent pharmacies use Pharmacy Services Administration Organizations (PSAOs), which are group purchasing organizations, to collectively negotiate on behalf of independent pharmacies with pharmaceutical manufacturers

³ GPhA. "Generic Drug Savings in the U.S." Generic Pharmaceutical Association, 15 Aug. 2015. <http://www.gphaonline.org/media/wysiwyg/PDF/GPhA_Savings_Report_2015.pdf>

and PBMs.⁴ Many independent pharmacies participate in one or more of the three leading PSAsOs to lower their drug purchasing costs and better manage their network arrangements.

Plans select PBMs based on their ability to provide their members with convenient access to affordable medications. To provide the type of coverage clients expect, independent community pharmacies play a particularly important role in PBM network management because they allow PBMs to fill in gaps in network coverage in many parts of the country.

With approximately 23,000 independent community pharmacies – over a third of all retail pharmacies nationwide – independents are a healthy and profitable industry segment, representing an \$88.8 billion in revenue annually. The number of independent pharmacies has grown more than 15% since 2002 as overall profit margins for the average independent pharmacy grew to 23% of revenues.⁵ On average, our independent pharmacies generally receive higher reimbursement than other network participants.

Selective Networks: PBMs also offer a choice of more selective networks as a way to help health plans, employer plans and government plans further reduce costs while still providing their members with convenient access to affordable medications. Typically, health plans will offer their members a lower copay at certain pharmacies as a way to encourage them to fill prescriptions at those pharmacies. Pharmacies that are part of these networks can benefit from greater prescription volume in return for a lower reimbursement rate. PBMs therefore stimulate competition between pharmacies for positions in these networks, which lowers costs in the healthcare system.

Selective networks have proven successful in negotiating competitive reimbursement rates and contributing to improved prescription drug adherence, which leads to better medical outcomes. For example, a CMS analysis of Medicare Part D 2015 enrollment data showed that 81% of

⁴ GAO. PRESCRIPTION DRUGS: The Number, Role, and Ownership of Pharmacy Services Administrative Organizations. Published: Jan 29, 2013. Publicly Released: Feb 28, 2013

⁵ 2002 independent pharmacy data from IMS Health showing 19,700 independent pharmacies. 2013 pharmacy data from 2014 NCPA Digest showing 22,814 independent pharmacies. $(22,814 - 19,700) / 19,700 = 15.8\%$ increase; Fein, Adam, Ph.D. "Profits Up Again for Independent Pharmacy Owners." Drug Channels. Pembroke Consulting, 2 Dec. 2014. Web. 03 Sept. 2015

Medicare beneficiaries chose plans with preferred pharmacy networks.⁶ A 2013 CMS study analyzing prescription drug data for Part D plans concluded that on average, branded drugs cost 3.3 percent less, and generic drugs cost 11 percent less at preferred pharmacies.⁷ Over the next ten years, preferred pharmacy network plans are estimated to reduce federal Medicare spending by \$7.9 to \$9.3 billion.⁸

Mail-Service Pharmacy: PBMs allow plans to choose to provide efficient mail-service pharmacies to members that supply home-delivered prescriptions with great accuracy and safety and at a substantial savings. This can be a valuable service for a company, government agency, health plan or union that might wish to have this convenience.

In a 2005 report, the FTC determined that there is no conflict of interest in a PBM owning a mail-order pharmacy and that PBM-owned mail-order pharmacies offer lower prices on prescription drugs than retail and non-PBM owned mail pharmacies. The FTC also determined that PBM-owned mail-order pharmacies are very effective at capitalizing on opportunities to dispense cost-effective and generic alternatives, and have incentives closely aligned with their customers.⁹ It is also important to note that mail order utilization has remained steady over the last decade.¹⁰

A Highly Competitive Marketplace

Competition in the PBM industry has been aptly described as “vigorous” by the Federal Trade Commission (FTC).¹¹ After a thorough investigation in which the FTC “interviewed over 200 market participants, including customers, other PBMs, retail and specialty pharmacies, pharmacy

⁶ PCMA, “New Analysis: 81 Percent of Medicare Part D Seniors Choose “Preferred Pharmacy” Plans in 2015,” <www.pcmant.org/newsroom/new-analysis-81-percent-of-medicare-part-d-seniors-choose-preferred-pharmacy-plans-in-2015>

⁷ FTC Letter to CMS, March 7, 2014. https://www.ftc.gov/system/files/documents/advocacy_documents/federal-trade-commission-staff-comment-centers-medicare-medicaid-services-regarding-proposed-rule/140310cmiscomment.pdf

⁸ Milliman, prepared for PCMA. “The Impact of Preferred Pharmacy Networks on Federal Medicare Part D Costs, 2014-2023.” Oct. 2013. Web. 9 Nov. 2015. <<http://www.pcmant.org/images/stories/uploads/2013/milliman%20preferred%20pharmacy%20networks.pdf>>

⁹ Federal Trade Commission, “Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies,” August 2005

¹⁰ Drug Channels, “Profits Up Again for Independent Pharmacy Owners”, 2 December 2014

¹¹ US Federal Trade Commission & US Department of Justice Antitrust Division, “Improving Health Care: A Dose of Competition,” July 2004

trade groups, pharmaceutical manufacturers, and healthcare benefit consulting firms” and reviewed “millions of documents,” the FTC concluded that “competition for accounts is intense, has driven down prices, and has resulted in declining PBM profit margins.”¹²

Competition for the right to manage health plan members’ and employers’ drug benefits involves intense negotiation and competitive bidding ability – in fact, the efficient functioning of the PBM industry relies on competition. And, as Professor Gerard Anderson, the Director of Johns Hopkins’ Center for Hospital Finance and Management has said, “without competition, there would be no market forces to limit prescription drug price increases.”¹³

At our PBM, CVS/caremark, we welcome competition; indeed, our success is predicated on thriving competition in the health care marketplace. After all, it is healthy competition that drives innovation and allows us to effectively help the consumer, business, labor, health plan and government partners we serve achieve the best returns on their health care investments. As costs continue to rise, our purchasing partners will expect us to demonstrate value for their health care dollars. If we are unable to do so, they will look elsewhere.

We look forward to working with the Members of this Committee and others to continue promoting a competitive health care landscape that provides access to affordable medications while helping control health care costs.

I ask that the full text of my written testimony be submitted for the record along with supporting documents.

Thank you for this opportunity to testify.

¹² Statement of the Federal Trade Commission Concerning the Proposed Acquisition of Medco Health Solutions by Express Scripts, Inc., FTC File No. 111-0210, April 2, 2012.

¹³ Surowiecki, James. "Taking on the Drug Profiteers." *The New Yorker*. 12 Oct. 2015.
<<http://www.newyorker.com/magazine/2015/10/12/taking-on-the-drug-profiters>>.

Mr. MARINO. Thank you. Mr. Arthur.

**TESTIMONY OF BRADLEY J. ARTHUR, R.Ph.,
OWNER, BLACK ROCK PHARMACY**

Mr. ARTHUR. Thank you, Chairman Marino, Ranking Member Johnson and Members of the Subcommittee. Thank you for conducting this hearing today and providing me the opportunity to share my views and personal experiences regarding the state of competition in the pharmacy benefit manager and pharmacy marketplace.

My name is Brad Arthur and I'm a pharmacist owner of the two independent pharmacies in the Black Rock community of Buffalo, New York, a very historic, ethnically diverse and predominantly blue color community. My pharmacies have been serving these communities since 1957 when my dad opened his first pharmacy. I'm also the President of the National Community Pharmacists Association which represents the pharmacists owners, managers and employees of nearly 23,000 independent community pharmacies across the United States.

I'm here today as a healthcare provider, a small-business owner and hopefully to present some of my experiences and those of my fellow independent pharmacists in dealing with the PBM industry.

Community pharmacies represent the most accessible point in patient centered health care, where typically consumers do not need an appointment to talk with a pharmacist about prescription medications, over-the-counter products or really any health related concern.

In this way community pharmacies also serve as the safety net health care provider on the front lines. Not only in natural disasters which occur often in Buffalo, tornados, hurricanes, flooding, whatever it may be, everyday when patients need help, their independent pharmacies are there to assist.

According to the Pharmaceutical Care Management Association, PBM has managed pharmacy benefits for over 253 million Americans. Three large companies lead the PBM market. Express Scripts, CVS Health, and OptumRx. In total they cover more than 180 million lives in the United States or roughly 78 percent of Americans whose pharmacy benefits are managed by a PBM. In addition, the annual revenues for these three entities are staggering. In 2014, annual revenues for Express Scripts were approximately \$100.9 billion. Annual revenues for CVS Health were 139.4 billion, and for OptumRx \$31.97 billion. In 2015, OptumRx acquired Catamaran and other PBM which reported annual revenues to combine into that number of \$21.67 billion.

Why should the Federal Government be concerned about this dynamic for large plans? Including the Federal Medicare part D program which was mentioned today, TRICARE and the FEHBP. There are only three PBMs to choose from. Because although there are other PBMs, none of them in spite of what we've heard are large enough to administer the prescription drug benefits for these programs. The big three PBMs control almost 80 percent of the entire market and these PBMs have the upper hand, both in negotiating the contract of the payer, as well as strongly influencing the actual plan design itself. The PBM industry typically states that they can

use their economic power to harness enhance market efficiencies, but for whom? However, the staggering annual revenue that continue to grow each year of the big three suggest that these efficiencies are going directly to their corporation's bottom lines.

Small community pharmacies like mine are faced on a daily basis with the impact of the PBM's disproportionate market power. Community pharmacies routinely must agree to take it or leave it contracts from the PBMs just to continue to serve our long-standing patients.

As if that weren't, enough, the PBMs also directly set the reimbursement rates for pharmacies, the very same pharmacies that stand in direct competition of some of these PBM owned mail order and specialty pharmacies. Therefore it comes as no surprise when the PBMs present employer and government payers with carefully tailored suggested plan designs that steer beneficiaries to these PBM owned entities.

As the owner of two pharmacies, I have limited ability to negotiate network participation or reimbursement terms with these entities. However, from a business standpoint, community pharmacies can't just walk away from these contracts. If we did, I would lose a significant amount of the prescription revenue given the large share of these covered lives that these PBMs represent.

Although many independent community pharmacies rely on pharmacy services organizations to contract on their behalf, these PSAOs are no match for the PBMs. In 2013, the GAO conducted a study on the role and the ownership of the PSAOs and stated that over half we spoke with reported having little success in modifying certain contract terms as a result of the negotiations. This may be due to the PBMs use of standard contract terms in the dominant market share of the largest PBMs. Many PBM contracts contain standard terms and conditions that are largely nonnegotiable.

Mr. Chairman, that's the conclusion of my testimony. I welcome any questions.

Mr. MARINO. Thank you.

[The prepared statement of Mr. Arthur follows:]

**Prepared Statement of Bradley J. Arthur, R.Ph., Owner,
Black Rock Pharmacy**

United States House Judiciary Committee

Subcommittee on Regulatory Reform, Commercial and Antitrust Law

**“The State of Competition in the Pharmacy Benefit Manager and
Pharmacy Marketplace”**

**Testimony of Brad Arthur, Independent Pharmacist and President of
the National Community Pharmacists Association**

November 17, 2015

Chairman Marino, Ranking Member Johnson and Members of the Subcommittee:

Thank you for conducting this hearing and providing me the opportunity to share my views and personal experiences regarding the state of competition in the pharmacy benefit manager and pharmacy marketplace. My name is Brad Arthur and I am a pharmacist owner of two independent pharmacies in the Black Rock community of Buffalo, New York-- an historic, ethnically diverse and predominantly blue-collar community. My pharmacies have been serving this community since 1957 when my dad opened his first pharmacy. I am also the President of the National Community Pharmacists Association (NCPA), which represents the pharmacist owners, managers and employees of nearly 23,000 independent community pharmacies across the United States. These pharmacies dispense approximately 40 percent of all community pharmacy prescriptions. I am here today as a healthcare provider and small business owner to present some of my experiences and those of my fellow independent pharmacists in dealing with the pharmacy benefit manager industry.

Community pharmacies represent the most accessible point in patient-centered health care where typically consumers do not need an appointment to talk with a pharmacist about prescription medication, over-the-counter products or really any other health-related concern. In this way, community pharmacies also serve as safety-net health care providers on the frontlines—not only when a natural disaster, such as a tornado, hurricane or flooding occurs, but every day when patients need help with their medications. Community pharmacists provide expert medication counseling and other cost-saving services that help mitigate the \$290 billion annual cost of treating patients that do not adhere to their medication regimen.

Concentrated PBM Marketplace

According to the Pharmaceutical Care Management Association (PCMA), the trade group that represents the PBM industry, PBMs manage pharmacy benefits for over 253 million Americans.¹ Three large companies lead the PBM market: ExpressScripts, CVSHealth (formerly CVS/Caremark), and OptumRx. In total, they cover more than 180 million lives in the United States, or roughly 78% of Americans whose pharmacy benefits are managed by a PBM.² In addition, the annual revenues for these three entities are staggering. In 2014, annual revenues for ExpressScripts were approximately \$100.9 billion, annual revenues for CVSHealth were \$139.4 billion and annual revenues for OptumRx were \$31.97 billion. (In 2015, OptumRx acquired Catamaran, which reported annual revenues of 21.6 billion).³

Concentrated PBM Marketplace is Detrimental to Government Payers

You may ask, why should the federal government be concerned about this dynamic? For large plans, including the federal Medicare Part D program, TRICARE and FEHBP, there are only three PBMs to choose from. Because although there are other PBMs, none of them are large enough to administer the prescription drug benefit for these programs. The “Big Three” PBMs control almost 80% of the entire market, and these PBMs have the upper hand both in negotiating the contract with the payer as well as strongly influencing the actual plan design itself. In response to concerns about market concentration, the PBM industry typically states that they can use their economic power to harness enhanced “market efficiencies.” But, even assuming such claims are true, these companies are not obligated to “pass along” any savings to plans and consumers. The staggering annual revenues—that continue to grow each year—of the “Big Three” suggest that these “efficiencies” are going directly to their corporations’ bottom lines.

Community Pharmacies Lack Effective Negotiating Power

On a more personal level, small community pharmacies like mine are faced on a daily basis with the impact of the PBM’s disproportionate market power. Community pharmacies routinely must agree to “take it or leave it contracts” from the PBMs just to continue to serve their longstanding patients. Such contracts often include blind price terms, onerous obligations including gag clauses, and other provisions that disadvantage community pharmacies. As if that wasn’t enough, PBMs also directly set the ever-shrinking reimbursement rates for retail

¹ Testimony of Mark Merritt, President and CEO of the Pharmaceutical Care Management Association before the U.S. House of Representatives Committee on Energy and Commerce Subcommittee on Health, October 21, 2015

² HealthStrategiesGroup, “Research Agenda 2015: Pharmacy Benefit Managers,” available online: http://www.healthstrategies.com/sites/default/files/PBM_Research_Agenda_PBM_RA101513.pdf

³ Ibid.

pharmacies—the very same pharmacies that stand in direct competition to the PBM-owned retail (in the case of CVSHealth) and PBM-owned mail order and specialty pharmacies. Therefore, it should come as no surprise when these PBMs present both employer and government payers with carefully tailored suggested plan designs that steer beneficiaries to PBM- owned mail order and specialty pharmacies.

As you can imagine, I, as an owner of two pharmacies, have a very limited ability to negotiate network participation or reimbursement terms with these entities. However, from a business standpoint, community pharmacies cannot just walk away from these contracts—because if we did, we would lose a significant amount of our prescription revenue given the large share of covered lives these PBMs represent. From a patient care and consumer services standpoint, if we drop a contract—we drop our patients. Independent community pharmacies across the country have been built on a philosophy of community service. However these one-sided contracts force us to provide pharmacy services at unsustainable rates. We are in a no-win situation.

Although many independent community pharmacies rely on a Pharmacy Services Administrative Organization or a PSAO to contract on their behalf, these PSAOs are no match for the PBMs. In 2013, the Government Accounting Office (GAO) conducted a study on the role and ownership of PSAOs and stated that “over half of the PSAOs we spoke with reported having little success in modifying certain contract terms as a result of negotiations. This may be due to PBMs’ use of standard contract terms and the dominant market share of the largest PBMs. Many PBM contracts contain standard terms and conditions that are largely non-negotiable.”⁴

Lack of Clarity in Generic Drug Reimbursement

One specific topic that I would like to highlight for the Committee, is the non-transparent process by which community pharmacies are reimbursed for generic drugs. A “Maximum Allowable Cost” or “MAC” list refers to a PBM-generated list of products that includes the upper limit or maximum amount that a plan will pay for generic drugs. There is no standardization in the industry as to the criteria for the inclusion of drugs on the MAC lists or the methodology as to how the PBM will determine the MAC price or how it is changed or updated. In short, contracted retail pharmacies have zero insight or transparency into the MAC process and sign contracts without having any idea the rate at which they will be reimbursed for generic drugs—which comprise approximately 86 percent of all prescriptions dispensed in

⁴ GAO-13-176 Pharmacy Services Administrative Organizations

the United States.⁵ There are typically two different sets of MAC lists—one that is used to reimburse the pharmacy and another one to charge the plan sponsor. Many plan sponsors are not aware of the fact that PBMs generate a significant amount of revenue by pocketing the difference between what they reimburse the pharmacy and the higher amount that they charge the plans sponsor for the same drug—otherwise known as “spread pricing.”

Generic Price Spikes and Payment Lags

The issue of generic drug price spikes is one that has received a lot of press attention lately and the volatility in these prices has caused significant issues for pharmacists, physicians, patients and payers alike. These dramatic spikes in the costs of these medications combined with the fact that the PBMs are not updating the MAC lists or reimbursement amounts in a timely fashion to keep up with these skyrocketing prices, is creating a situation in which many pharmacists are consistently underwater or under-reimbursed on an increasing number of medications. A survey of members of the National Community Pharmacists Association in January 2014 showed that over 75% of respondents reported instances of a large price increase in at least 26 generic drugs over the last six months of 2013. This same survey also showed that over 85% of survey respondents reported it could take a PBM between two to six months to update their reimbursement rates for generic drugs.

On a typical day in either of my pharmacies, I can expect to see no less than 12-18 prescriptions filled at a loss with the total losses from these prescriptions in the thousands of dollars each and every month.

Inherent Conflicts of Interest in PBM Ownership of Mail Order and Specialty Pharmacies

Another area where I see the anti-competitive effects of PBMs on the market is the PBM ownership of mail order pharmacies and specialty pharmacies. This creates a situation in which the PBM creates a plan design and establishes reimbursement rates for networks of retail pharmacies that are in direct competition with the mail order and specialty pharmacies owned by the PBM—and keep in mind that the PBM knows exactly what the reimbursement amounts are for all of the players in this equation. With regard to PBM-owned mail order pharmacies, not only do the PBMs incentivize beneficiaries to use PBM-owned mail order pharmacies, but they also may be motivated to switch patients to more costly medications on which the PBM receives additional rebate amounts from the manufacturer. In addition, PBMs typically charge customers or payers for the cost of a drug that is based on a package size that is commonly

⁵ PhRMA; *The Reality of Prescription Medicine Costs in Three Charts*; 5/27/14; available online: <http://www.phrma.org/catalyst/the-reality-of-prescription-medicine-costs-in-three-charts>

purchased by a retail pharmacy in spite of the fact that mail order pharmacies typically buy drugs in much larger package sizes or quantities at much lower prices. Also, medication waste is rampant in mail order pharmacy and it's not as anecdotal as the PBMs claim.

I can tell you story upon story of patients in my pharmacy who come in and bring boxes and bags of expensive drugs they received from a mail order pharmacy. One such example of the inappropriate use of mail-order in specialty was a 78 year old male in late 2014 with Hepatitis C, who presented at the pharmacy with a second round of the very expensive treatment of Solvadi+Ribavarin. Upon closer inspection, we learned that the patient had been mailed the 3 month course of therapy (approximately\$60,000 in total), and without any initial or follow up consultations, proceeded to take only one of the two medications prescribed as per the regimen. At the conclusion of the course of therapy, he returned to his physician to learn that as a result of the absence of any follow-up, the treatment was unsuccessful and would need to be repeated. In this case his coverage was thru a Medicare Part. D plan.

An area of increasing competitive concern is PBM's ownership of specialty pharmacies. There is no industry-wide definition of "specialty drug, but generally these are high cost medications that treat chronic, complex illnesses and are the wave of the future. It is estimated that eight of the top ten drugs in 2016 will be specialty drugs—compared with only five in 2008 and just one in 2000.⁶ Currently the largest PBMs already dominate this market due the fact that they have the ability to call any high cost drug in the commercial marketplace a "specialty" drug and effectively prevent retail pharmacies from filling these prescriptions. Instead, they redirect these highly lucrative prescriptions to their own specialty pharmacies.

Regulation of PBM Industry?

One question that I am asked when I describe some of the difficulties that I currently face in dealing with the PBM industry is whether this industry is regulated in any comprehensive fashion. This would seem to make sense given the fact that three PBMs control almost 80 percent of all prescriptions that are administered by a PBM. In addition, the influence of PBMs continues to grow with coverage expansions in Part D and the commercial markets, combined with an increase in prescription drug spending that has motivated commercial plans and self-insured employers to outsource the management of their drug spend.

⁶ CVSHealth; What's Special about Specialty; available online:<https://www.cvshealth.com/research-and-insights/expert-voices/whats-special-about-specialty>

One would expect these entities to be subject to the same type of comprehensive regulation that is currently required of commercial health insurers. Commercial health insurers that offer employer-sponsored health plans are regulated under the Employee Retirement Income Security Act (ERISA) as well as the Consolidated Omnibus Budget Reconciliation Act of 1986 (COBRA). In addition, Medicare Advantage plans are regulated by CMS and health plans offered to federal employees must meet requirements established by the Office of Personnel Management (OPM). However, the bulk of insurance regulation resides at the state level, where insurer solvency, underwriting, coverage mandates and access requirements are regulated.

In spite of the fact that PBMs play an integral role in how patients access their medications in both commercial health insurance and government programs, PBMs are not subject to industry-wide regulation similar to what is generally required of commercial health insurers. There are no federal laws or regulations specific to the PBM industry. Instead, PBMs face a patchwork of regulations at the state level that are designed to curtail some of the more onerous PBM business practices such as abusive PBM audits of pharmacies and requirements related to timely MAC updates. In addition, even in the states that have been able to pass these limited reforms, the PBMs typically resist complying with these laws and have recently filed lawsuits against two such states.

Conclusion

In conclusion, the healthcare industry in general seems to be at a crossroads. Large mergers seem to be announced every day in rapid succession while at the same time healthcare costs—and particularly prescription drug costs—are at an all-time high. I can tell you that as a small business owner and healthcare provider, the current situation and overall business climate that exists in which market power is increasingly concentrated in an ever-shrinking number of corporations—makes me apprehensive about what is around the bend. From my personal experience, the overly concentrated and largely unregulated PBM industry is wreaking havoc on small business pharmacy owners like myself.

If you haven't already done so, I urge you to support H.R. 244, a bipartisan bill that would require the same timely updates to MAC pricing lists in the Federal Employee Health Benefit Program and the military's TRICARE program that will be required in Medicare Part D in 2016. In addition, I urge you to support H.R. 793, a bipartisan bill that would allow any pharmacy located in a health professional shortage or medically underserved area to participate in any preferred pharmacy network if they are willing to meet comparable terms and conditions.

I want to thank you for affording me the opportunity to talk with you today and tell my story and I would be happy to answer any questions that you may have.

Mr. MARINO. The Chair now recognizes the Chairman of the full Judiciary Committee, Mr. Bob Goodlatte of Virginia for his opening statement.

Mr. GOODLATTE. Thank you, Mr. Chairman. In late July, Chairman Marino, Ranking Member Conyers, Ranking Member Johnson, and I announced a series of Committee hearings focused on competition in the health care marketplace. Today's hearing is the third in this series and will examine the competitive dynamics within the pharmacy benefit manager or PBM and pharmacy markets. PBMs oversee the administration and management of prescription drug benefits. In that capacity PBMs interact with nearly every step of the prescription drug supply chain. Consequently, they have the ability to extract lower prices for prescription drugs and have had some success in doing so.

However, notwithstanding pressure from PBMs drug prices continue to rise. A recent Wall Street Journal investigation found that increases in drug prices routinely outpaced inflation and often by a significant amount. These increases were found despite reduced demand drug studied and even in the face of new competing drugs.

If true, this represents a troubling trend as Americans face a progressively aging population and an ever growing amount of taxpayer money used to fund the purchase of prescription drugs. Through today's examination of competition within the PBM and pharmacy markets, we should explore whether the proper economic incentives exist for PBMs and pharmacies to place a genuine check on rising drug prices.

Another challenge facing the country and my constituents is affordable and accessible health care in rural communities. Independent pharmacies play a critical role in the delivery of personal prescription drug care, especially in rural areas.

During my tenure in Congress, I've seen many community pharmacies in my district shutter their doors. While we should allow the free market to operate, we should also ensure that there is a level playing field for both large and small pharmacies. Today's discussion will help shed some light on the nature of the competitive playing field in the pharmacy market.

Since the enactment of the Affordable Care Act, I consistently have expressed concern that the law would compel consolidation across a number of health care industries. My fears appear to be coming true. Both the PBM and the pharmacy markets have experienced consolidation in recent years. Indeed Walgreens and Rite Aid recently announced their intent to merge and CVS's purchase of Target's retail pharmacies is currently under review at the Federal Trade Commission.

This Committee has held hearings on past PBM consolidation, including the merger between Express Scripts and Medco. While this hearing is not intended to review the details of any particular transaction, we should examine how these trends have impacted competition in both the PBM and pharmacy markets. Specifically, it will be helpful to learn what affects these transactions have had on prices paid by Americans for prescription drugs. Most importantly, we should explore whether market forces compel these transactions or the Affordable Care Act and its regulatory progeny are prompting increased consolidation.

We have an excellent panel of witnesses before us today who can provide us with firsthand perspectives on the competitive issues facing the PBMs and pharmacies and I look forward to hearing their testimony.

Thank you, Mr. Chairman.

Mr. MARINO. We are going to go into our 5 minutes of questioning. And as is once in a while customary, I'm going to wait and ask my questions last today because I really want to hear what the panel has to say. And so I'm going to recognize the Chairman of the full Committee, Mr. Goodlatte for his 5 minutes of questioning.

Mr. GOODLATTE. Thank you, Mr. Chairman and I thank all the witnesses for their testimony today.

I want to direct this question to both Ms. Bricker and Ms. Pons. We've all heard about the dramatic spikes in the price of certain prescription drugs, that were previously in the market for a significant period of time at stable prices. In fact, I was speaking about this particular issue just yesterday with pharmacists in my district. On a number of these drugs pharmacies end up taking a loss if they dispense them. I understand that you're not the drug manufacturer. However, you do have a role to play in negotiating the price and reimbursement of these drugs. Can you comment on this current situation?

I'm familiar with one Ritalin generic drug that has gone from about \$125 for a 30-day supply to about \$600 for a 30-day supply just this year. I'm familiar with a tube of a medical cream that's gone from about \$100 for the tube to \$2,000 for one small tube. This very much concerns me and I would like to know what your perspective is on how this pricing is taking place and what you as the insurer are doing to try to hold down these prices and hold these companies accountable.

Ms. BRICKER. Thank you, Congressman, for the question. High drug prices are not a new phenomenon. We have seen this in, you know, over decades of managing prescription benefits. At Express Scripts, we encourage competition, we believe that competition results in a decrease in drug pricing. Oftentimes when drug prices increase, it's due to a shortage or it's due to a number of manufacturers coming out of the market. And so with competition you see a decrease in price.

We're advocates for biosimilars in technology and in negotiating inflation protection from our brand manufacturers to pass on to our clients, as well as their members. So with that, I understand the need we hear from our plan sponsors regularly about the concerns that they have around increased drug prices and through our tools from a clinical perspective it is our hope to continue to manage that drug benefit in partnership with our plan sponsors.

Mr. GOODLATTE. Ms. Pons—

Ms. PONS. Thank you—

Mr. GOODLATTE. Do you put pressure on these manufacturers to offer more reasonable prices since you're a large purchaser or you are a large insurer of—and CVS in your case a large purchaser of them as well.

Ms. PONS. Yes, yes. Every day our company gets up and what we do is try to get the best prices on behalf of our clients to help keep

their premiums down for their members and help keep costs affordable.

And, you know, we'll agree, there have been some very egregious examples in the marketplace that I think we all find shocking. Beyond that, as Ms. Bricker testified, we do think that a combination of the clinical tools that we have available as well as our ability to negotiate with pharmaceutical manufacturers, together with some of the important policies that she talked about in terms of getting more competitive products into the marketplace, whether that's, more generics, more biologics, lower cost of site of care, those things in combination can go a long way to helping curb these issues.

Mr. GOODLATTE. Let me ask Mr. Arthur if he'd like to respond.

Mr. ARTHUR. Yes. Thank you, Mr. Chairman. I would like to add that while prescription drug prices have historically gone up at a rate greater than the normal cost of inflation, throughout most of my career, the trend was just the opposite on the generic side. As more generic manufacturers enter the marketplace, the trend has been for the price to come down as the market responds.

What's interesting to note is that these extremely large business entities have the sophistication and the examples that you alluded to mete this out, they have the sophistication to respond to these market fluctuations very quickly. The pharmacists that you heard from are expressing frustrations because when the price of the drugs goes down, the PBMs have no problem implementing those as the basis for reimbursement sometimes overnight. But there is a significant lag that is seriously to the detriment of the independent community pharmacist, because they are often times saddled with dispensing these much needed medications at a loss.

Mr. GOODLATTE. Let me ask both Ms. Bricker and Ms. Pons, another question as well. Both Express Scripts and CVS operate PBMs as well as pharmacies. Some have raised concerns that PBMs in your position have a conflict of interest due to the fact that your PBMs negotiate contracts with pharmacies that directly compete with pharmacies owned by your corporate parent. What is the risk of your leveraging your role as a PBM to gain a competitive advantage against of pharmacies that are outside your corporate family?

And let me give you an example too as well. Pharmacist yesterday showed me a drug, I can't remember what it was, but the reimbursement rate from the PBM was 300 and some dollars less than the prescription of the prescription drug. Now they cannot because of their contract with the PBM, they can't turn around and tell the purchaser, well, I'm sorry I can't sell you that drug for that price. They can't turn around sell it to you, but you'll have to make up the difference. If they want to sell that prescription drug to that regular customer, they have to eat that 300 and some dollar cost. How is it that the insurance company can justify that, knowing the cost and knowing that you're in a competitive environment, but with a bigger company and therefore able to manage these costs in ways that a small pharmacy can't?

How can that policy be justified of having to say, sorry, this is all we're going to pay you and you can't do anything but eat the

rest of that cost. How can a small pharmacy stay in business in that environment?

Ms. PONS. That's an excellent question. And a fair question to ask. You know, we put together our MAC list so that we can encourage pharmacies to try to buy generic products at the lowest possible cost. Having said that—

Mr. GOODLATTE. Some of these were generic products, as Mr. Arthur noted. In fact, the Ritalin was a generic product that had quadrupled in price over a very short period of time.

Ms. PONS. Yeah. And so we want them to buy at lowest possible cost, but we also want them to get a fair margin. In order for us as a PBM to meet our commitments to our clients, we need to have our network have a very high dispensing of generic rates within the network. If we are paying pharmacies prices that are lower than their acquisition costs, pharmacies aren't going to go do that. So we try very, very hard to make sure that they get a fair margin.

Are there going to be times when a particular drug they dispensed are under water? Absolutely. But what we do look at the pharmacies overall reimbursement across all of their generic claims to try to ensure that they are getting a fair margin so that they are incented to dispense as many generic as possible.

Mr. GOODLATTE. They showed me their records for a particular day. On that day they sold—their two stores in their operation, they sold \$15,000 worth of drugs and the total across that entire was a net loss of a few hundred dollars. Again, I understand some are going to be high and you can't always get it right—but if the average is a net loss on a daily basis, how do pharmacies stay in business?

Ms. PONS. Yeah. The other thing I would say and I think it is typical for other companies in the industry, there is an appeals process so if that's happening, you know, we're making certain assumptions because we don't know what every pharmacy in the network is buying their product at. We are trying to do our best to estimate what their cost is.

And if there are situations where they are losing more than they are winning on, there is an appeals process where we can address that. Again, it is not in our interest to have pharmacies not want to dispense generics because it is going to cost our clients more money.

Mr. GOODLATTE. Thank you, Mr. Chairman. My time is long expired.

Mr. MARINO. The Chair now recognizes the Ranking Member, Mr. Johnson.

Mr. JOHNSON. Thank you, Mr. Chairman. Mr. Balto, please explain how a lack of transparency in the PBM marketplace may be undermining competition and consumer choice, and limit your answer to 1 minute, please.

Mr. BALTO. Oh, it is very simple, I mean, when you look at the problem of escalating drug prices one thing people would want to know is what's happening to the rebates. And since the merger of Express Scripts and Medco occurred it is even harder for plans, plans I represented to get that kind of rebate information. If they got the rebate information, they could make sure the right deci-

sions are being made and they could get more of the rebates and that would result in lower costs to consumers.

Mr. JOHNSON. Thank you. Mr. Arthur, some of your fellow witnesses contend that PBMs benefit consumers because their scale allows them to negotiate effectively with drug companies to keep patient premiums and cost sharing manageable. What's your response to that?

Mr. ARTHUR. Well, that's a noble go. I don't believe that to be the case. I think the scale that is employed is often for the betterment of the parent corporation. We see numerous examples with the implementation of Medicare part D and the doughnut hole. It wasn't uncommon for us to see patients due to the pricing methodologies at the large PBMs to be thrown in the doughnut hole prematurely.

So we have all discussed about the need to use scale to drive down costs to consumers the reality in the marketplace. We haven't necessarily seen that to be the case.

Mr. JOHNSON. All right. Thank you. Mr. Balto, why do you believe the Federal Trade Commission has not been vigorous enough in its enforcement efforts with respect to PBMs, give me this in 30 seconds?

Mr. BALTO. I think they allowed economic theory to replace marketplace realities and they are failing to see the real harm to consumers and plans and the limitation of their choices.

Mr. JOHNSON. Thank you. Ms. Bricker. Mr. Balto suggestions that rapidly rising profits in recent years suggest that PBMs are not fully passing on savings from drug manufacturer rebates and discounts on to health plans and consumers. What's your response to that?

Ms. BRICKER. Our clients demand transparency. I can't speak to, you know, clients that Mr. Balto represents, but the clients that Express Scripts represents, you know, demand transparency. We feel that the additional transparency that is being suggested could be harmful actually to competition, resulting in price fixing and potentially collusion.

Mr. JOHNSON. Your response, Mr. Balto, in 30 seconds?

Mr. BALTO. In a competitive market, profit per script would not be increasing by 75 percent in 3 year period. That is a clear sign that the Express Script, Medco merger has been anti competitive and consumers are being harmed.

Mr. JOHNSON. Okay. Ms. Pons, CVS recently completed the acquisition of Omnicare, a very large provider of long-term pharmacy services. From a consumer and patients perspective this could be concerning as now your company is both a retail pharmacy, PBM and LTC provider with a sizable market share. Although the acquisition is very new and you are still working on the integration, what assurances can you provide today that this will not negatively impact the level of service and care to some of the Nation's most vulnerable and fragile patients residing in nursing homes?

Ms. PONS. Thank you for that question, Ranking Member Johnson. It is a new acquisition, we are I think already 4 months into this after, you know, spending an extensive process with the FTC going through this. This is a completely new line of business for CVS Health, but one that we thought was very important to continue our various touch points that we have with patients. And as

you point out, a very vulnerable patient set. And we think that with our other assets that we have, for those patients that leave those facilities, that we can better integrate them and coordinate their care better.

So we feel like it's a great addition to what we do best, which is trying to coordinate care at the lowest possible cost and improve outcomes and we are anxious to move forward with it.

Mr. JOHNSON. All right. Thank you. Last, Mr. Arthur, some of you fellow witnesses—Well I see I'm out of time so I will—Okay. All right.

In response to concerns about unfair terms between independent pharmacies and PBMs, some have argued that pharmacies could simply refuse to accept the PBMs proposed terms and conditions or come together to negotiate more acceptable contract terms. Why is this not a sufficient answer in your view?

Mr. ARTHUR. Sir to answer the first part of your question, 98 percent of my business' is revenue comes from third party agreements, be they private from the private side, the commercial side, or from the government payer side in the form of Medicare—or Medicaid, excuse me. Turning away from that business is not a realistic option that I have. I would have no recourse but to close my doors. So we are in an extremely anticompetitive position from that point of view.

The second part of your question we have turned to these entities as an attempt to negotiate, but they have also faced some of the same barriers that we have to truly negotiate contracts. When given the opportunity I as a small independent business have tried to strike certain terms from agreements only to have them push back a take it or leave it answer. So we haven't been successful in negotiating these either independently. We certainly cannot get together as a bunch of independents, that would be collusion. We have tried to circumvent that—not circumvent it—we have tried to meet that challenge by using the contracted entities, but they have also shared with us that they are a have you small fish in a big pond and successful at truly negotiating terms.

Mr. JOHNSON. All right. Thank you Mr. Arthur. And thank you, Mr. Chairman.

Mr. MARINO. The Chair recognizes Mr. Ratcliffe from Texas.

Mr. RATCLIFFE. Thank you Chairman Marino. Of all the issues that we examine here in Congress perhaps none is more personal than that of health care. Americans literally trust our health care professionals with our lives. And pharmacists are an essential part of that health care, particularly in the communities in northern and east Texas that I represent. Because in many of those towns there are big chain drugstores, but most of the towns in the district that I represent depend on local community pharmacies that have been there for decades. And as the health care landscape evolves and becomes frankly increasingly complicated I want to make sure that we protect the pillars of the community in those types of towns in my district.

So Ms. Bricker, let me ask you a question. It is my understanding that your company may not update their reimbursement rate often enough to keep up with fluctuations in the marketplace. That concerns me because if a certain generic drug price drops rap-

idly and if that drop isn't updated quickly it would seem to me that Medicare could be paying more for a generic drug than it should. Is that a legitimate concern?

Ms. BRICKER. Thank you for the question, Mr. Congressman, in Express Scripts we have teams of people dedicated to this very subject ensuring that we are responsive to the marketplace, surveying the marketplace to ensure that our pricing is appropriate for our community and all retail pharmacies. We are updating no less frequently than every 7 days. There are laws on the books and over 20 States across the country that also enforce this very thing. And so Express Scripts is compliant and takes seriously those laws.

Mr. RATCLIFFE. Well, I get that it is compliant. And every 7 days is good but is it a legitimate concern in the 7 day period that that type of price fluctuation can occur so that Medicare is paying more for a drug than it should?

Ms. BRICKER. So the least frequently that it would occur is every 7 days. We're reviewing it daily. And if there is a dramatic price change that occurs within, you know, prior to that 7 day change, we'll make the change earlier as well.

Mr. RATCLIFFE. Okay. So I understand the cost of generic drugs has really skyrocketed in the last couple of years now. How often do you update your MAC list, those reimbursement lists?

Ms. BRICKER. No less frequently than every 7 days—

Mr. RATCLIFFE. Seven days okay.

Ms. BRICKER. But we are looking at it every single day. And so if there is change that needs to be made the following day we will do that.

Mr. RATCLIFFE. Okay. So, are pharmacists able to see in real-time what they are disbursing on a generic drug is, or are there fees being charged to pharmacies after the point of sale?

Ms. BRICKER. Directly at the point of sale? As you're standing at the counter the pharmacist is processing the prescription, submitting vital information to the PBM and in exchange roughly 3, 5, seconds they are receiving a response on what copay to collect if any, and what reimbursement they will receive.

Mr. RATCLIFFE. Okay thank you. Ms. Pons, the same question about the MAC list, how often are you updating them?

Ms. PONS. We have a team of people that are constantly monitoring various market sources, to see what's happening with drug acquisition costs and are compliant with State laws that if there are market forces that suggest we need to make updates sooner than that, we do.

Mr. RATCLIFFE. Okay. Thank you. So Mr. Arthur, we are frequently told that PBM contracting terms are unfavorable to many of the independent pharmacy owners out there, however the PBM industry claims that those issues really shouldn't be resolved by legislative bodies, but instead should be left to the contracting parties. I guess my question to you is if the terms contained in PBM contracts are egregious, why don't pharmacies simply refuse to accept the proposed terms and conditions or come together to negotiate more acceptable contract terms?

Mr. ARTHUR. I don't think it is really practical for us as small business owners to just refuse those contracts because as we learned earlier today, it impacts a significant portion of our busi-

ness, that to walk away from those contracts would be a death note to our businesses. And I think it is very telling to your question that the reason that there is timely update to MAC in 20 States is because the independent community marketplace push for that. That didn't come voluntarily. So we had to push for that timely—in 20 States, and we continued to push for that across the entire country.

So that has been our approach to try to create fairness some in the marketplace. We continue to try everyday to negotiate some of the egregious terms so that we can be more competitive. But the fact remains today that we're at such a disadvantage because a significant portion of our customer base, our patient base is impacted.

Mr. RATCLIFFE. Thank you.

I see my time has expired. I yield back.

Mr. MARINO. Thank you. The Chair now recognizes the Congressman from Rhode Island, Mr. Cicilline.

Mr. CICILLINE. Thank you, Mr. Chairman. And thank you to our witnesses. I want to welcome you, and certainly thank you for your testimony and I particularly want to acknowledge the extraordinary corporate citizenship of CVS, a company that I have admired for a long time, particularly when it made its very courageous and impactful decision to forego selling tobacco products at the loss of \$2 billion in revenue. But I think you have really set an example for health care companies and I just want to publicly applaud you for that.

I want to go first in response to you, Mr. Balto has said in his testimony, well it was in his written testimony here today that plan sponsors need more transparency in order to make sure they are receiving the full benefits of PBM bargaining power and to make sure that PBMs effectively rein in drug costs. It sounds like a reasonable proposition would you respond to that claim?

Ms. PONS. Yeah, no. We are fully supportive of transparency with our clients. What we are not supportive of is transparency of our proprietary information with our competitors and in fact I think the FTC has said on a number of occasions that that transparency can actually have the opposite affect in terms of reducing cost.

And so our clients have very extensive audit rights which they exercise regularly, and to ensure they are getting the benefit of the bargain that they struck with us, so we are completely supportive of transparency with our clients. And if we did not make that available to them, they would look for another vendor that did.

Mr. CICILLINE. And so is it fair to conclude that your assessment is that the transparency related to your relationship with the pharmaceutical company, that it could produce higher costs for the consumer?

Ms. PONS. We believe that if our competitive pricing that we have with our clients was made more publicly available and our competitors were aware of that, whether that's rebates or network rates or other proprietary terms, we believe that, that could actually result in higher prices, because there isn't an incentive to make your prices lower. Because then everybody's cannibalizing the market.

Mr. CICILLINE. And Mr. Balto also argued that PBMs exclusivity arrangements with some drug manufacturers can keep drug prices

artificially high by keeping lower-price drugs off the market and by incentivizing PBMs through manufacturer rebates to switch patients from prescribed drugs to more expensive alternatives. Would you respond to that argument.

Ms. PONS. Yeah. I guess I would just say that's a little foreign to my experience in working with the PBM day in, day out. We make formularies available to clients. Typically generics are on the first tier, preferred brands, and then nonpreferred brands, and the client can either elect to have that formulary or choose one for themselves—or make one up for themselves, and that's what is the foundation of their plan benefit.

You know, my experience is clients are very smart. They're very demanding. They're sophisticated. If they don't have that sophistication themselves, they'll higher consultants that do. And they're going to look for the best possible deal for themselves as well as offering an attractive benefit to their plan members.

Mr. CICILLINE. So some consumer groups have argued that PBMs keep the proceeds of rebates and discounts and keep a disproportionate share of that for themselves, and so that one could conclude from the rise in profits of PBMs that they're not fully passing on savings to health and to consumers.

But despite that, there is a report from the FTC, August 2005, that shows that PBM-administered prescription drug coverage pay between 15 and 50 percent less for drugs than non-insured consumers by an exact same drug. And so I first ask unanimous consent, Mr. Chairman, that this be made part of the record.**

Mr. CICILLINE. And I'd ask Ms. Pons if you could respond to that claim and the findings, because my interest is what will get my constituents the lowest cost. And we talk a lot about another effort to permit the Federal Government to negotiate discounted prices directly with pharmaceutical companies to the Medicare program, which they're prohibited from doing. It seems like PBMs are at least achieving that through their scale. It seems as if that's what the report concludes, and I would just like you to respond to that.

Ms. PONS. Yeah, and I think there have been a couple of different reports. The one I think you're referring to is the one in 2005 where they investigated whether there was, in fact, a conflict of interest between PBMs and owning mail service pharmacies. And the findings of that report was that they did not believe there was; and that, they saw that there were more savings with the PBM-owned mail versus a non-PBM-owned mail pharmacy as well as over retail pharmacies; and that mail service pharmacies were very good at generic dispensing and were very closely aligned with client incentives.

Mr. CICILLINE. And, Mr. Chairman, if I may just ask one final question. Mr. Balto argues in his written testimony that there is an "increasing disregard of the antitrust laws in the pharmaceutical area" and argues as a result that "consumers suffer from a lack of choice in the marketplace."

And in 2009, your company was actually investigated by the FTC based on allegations of anticompetitive behavior. I'd wonder if you

**Note: The material submitted by Mr. Cicilline is not printed in this hearing record but is on file with the Committee. See also "For the Record Submission—Rep. Cicilline" at:

<http://docs.house.gov/Committee/Calendar/ByEvent.aspx?EventID=104193>.

would just briefly state what the conclusions of that were, and I would ask unanimous consent that a letter from the Federal Trade Commission dated January 3, 2012, be introduced into the record.

Mr. MARINO. Without objection, so ordered.

[The information referred to follows:]



Office of the Secretary

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

January 3, 2012

Bruce Sokler, Esq.
Mintz, Levin, Cohn, Ferris, Glovsky and Popco, P.C.
701 Pennsylvania Ave., NW, Suite 900
Washington, DC 20004

Re: *CVS Caremark Corporation, FTC File No. 091 0106*

Dear Mr. Sokler:

The Federal Trade Commission has conducted a nonpublic investigation to determine whether CVS Caremark Corporation ("CVSC") has engaged in unfair methods of competition, or unfair or deceptive acts or practices, in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, or has effected acquisitions in violation of Section 7 of the Clayton Act, 15 U.S.C. § 18.

On January 3, 2012, the FTC accepted for public comment, subject to final approval, a consent agreement in *In the Matter of CVS Caremark Corporation, File No. 112 3210*. The proposed order would prohibit CVSC from misrepresenting the price or cost of Medicare Part D prescription drugs, or other prices or costs associated with Medicare Part D prescription drug plans. The proposed order would also require CVSC to pay \$5 million in consumer redress, to be distributed to Medicare Part D beneficiaries affected by CVSC's conduct.

After a thorough and comprehensive review of the other consumer protection and competition issues in this matter, the Commission has determined not to take any additional action at this time. Accordingly, the investigation has been closed. This action is not to be construed as a determination that a violation may not have occurred, just as the pendency of an investigation should not be construed as a determination that a violation has occurred. The Commission reserves the right to take such further action as the public interest may require.

By direction of the Commission.

Donald S. Clark
Secretary

Ms. PONS. Yes, we did go through an investigation after the CVS Caremark merger that started in 2009 and I believe ended in 2012 that looked at a number of activities but primarily trying to assess whether or not there was anything that was anticompetitive. And they looked at our firewall and a number of our programs.

And at the end of the review, they determined that there were no anticompetitive findings, and that's in the closing letter. There was, however, a legacy issue around one of—a company that we had acquired and some information that they had inaccurately placed on Plan Finder, and so we had a consent order around that. But there was nothing related to any anticompetitive activity.

Mr. CICILLINE. And finally, Ms. Pons, are you familiar with a 2011 Visante study that found PBMs will save plan sponsors and consumers almost \$2 trillion or nearly 35 percent between 2012 and 2021 when compared with the prescription drug expenditures made without pharmacy benefit management? Can you speak a little bit about that.

Ms. PONS. Yeah. And I've seen that study as well, and, you know, I would even say more practically day in, day out, you know, with the thousands of clients that we negotiate with, they've got very specific targets for us in terms of what we're going to do for savings for them in terms of, you know, generics and preferred brands. And so we have to live up to those commitments every day.

Mr. CICILLINE. Thank you.

And I Thank you, Mr. Chairman, for the indulgence.

I would just finally say that, you know, one issue, which is obviously not before this Committee, is the power and, you know, ability of pharmaceutical companies to really skew the marketplace with very little controls on their ability to increase drug prices. And, you know, that's an issue which I think is very much part of this conversation and hard to disaggregate, but it seems to me that the ability to at least have some bargaining power against these pharmaceutical companies in the marketplace is something that we should attempt to preserve as much as we can.

And with that, I yield back.

Mr. MARINO. Agreed.

Chair recognizes Mr. Collins from Georgia.

Mr. COLLINS. Thank you, Mr. Chairman.

You know, sometimes I think when I fly in here—I fly—and I've made this statement to my district before that we fly into a wonderland of where reality doesn't matter anymore. Case in point, many of the things that I've heard this afternoon give me cause to believe, yes, we're there again. And this is an issue with community and independent pharmacists that, you know, play a critical role in my district, in rural northeast Georgia.

Mr. Chairman, with the unanimous consent to enter into the record a report from the association representing senior care pharmacies on MAC pricing data, a letter from BlueCross BlueShield on compounding pharmacies, and several statements and examples of PBM interactions from community pharmacies.

Mr. MARINO. Without objection, so ordered.

Mr. COLLINS. Look, I appreciate our witnesses being here. I appreciate the chance to have a discussion, but to be truthful, I'm very discouraged about what I see in the pharmacy landscape.

Ms. Bricker, you state in your testimony PBM marketplace is extremely competitive. That's an interesting statement since three companies Express Scripts, CVS Health, and OptumRx control about 80 percent of the PBM market, which translates into 180 million lives. Not a great deal of competitiveness there.

Mr. Arthur knows too well community pharmacies routinely incur losses of approximately \$100 or more on many prescriptions, because PBMs or insurance middlemen reimburse pharmacies well below their cost to acquire and dispense, generic prescription drugs that have skyrocketed in price. This is one of the most pressing areas that I believe demands congressional action.

PBMs can wait weeks and months to update reimbursement benchmarks they use to compensate pharmacies while drug prices increase virtually overnight. That's why I introduced H.R. 244 dealing with this issue of transparency and would encourage folks to be a part of that.

Now, one of the things that has been interesting to me today is discussing mail order. Since PBMs own their own mail order pharmacies, I've seen information leading me to believe that a real incentive exists for them to steer patients toward mail order delivery.

In fact, I've seen firsthand that a fax received by a community pharmacist from OptumRx indicating that he could not mail patients their prescriptions. Less than a month later, a patient gave that pharmacist a letter mailed to them from OptumRx touting savings they could see if they got their prescriptions mailed from the PBM mail order pharmacy.

While the letter states the patient is free to continue using a retail pharmacy house elite, it requires notification to an insurance company, and it is likely that many patients won't have time or knowledge to know that the mail order is not mandatory. This is extremely concerning from an anticompetitive standpoint and a patient care perspective.

Mr. Chairman, I ask unanimous consent that both of these documents be made part of the record. Mr. Chairman, unanimous consent to make these part of the record.***

Mr. MARINO. They're admitted.

Mr. COLLINS. All right. And given that CMS has also recently finalized Medicare Part D requirement that allows PBMs to automatically auto ship new prescriptions without express beneficiary consent, this is of particular concern, and especially to one certain gentleman that happens to be very close to me, and that is my father.

Mr. Arthur, can you share your experiences regarding PBMs urging mail order delivery of medications over filling them in the store. Has this affected your pharmacies and other pharmacies? And regardless of your views about PBM and their prices, why should we be concerned? And if you could narrow that down.

Mr. ARTHUR. I'll take your last question first, if I may. And I think Chairman Conyers mentioned it was back in the early 2000's, Campbell-Conyers, which attempted to provide limited antitrust exemption for independent community pharmacy. I can assure you

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<http://docs.house.gov/Committee/Calendar/ByEvent.aspx?EventID=104193>.

that circumstances in the marketplace have deteriorated dramatically since that time.

So this is a very pressing issue, and I think, you know, it's interesting we spend a lot of time this morning—this afternoon talking about one of the primary goals being to drive generic utilization. It's interesting to note that the generic utilization rate and independent community pharmacy far exceeds that in mail order or any other sector.

Mr. COLLINS. Thank you, Mr. Arthur. I appreciate that.

Mr. ARTHUR. Thank you, sir.

Mr. COLLINS. I want to turn to Ms. Bricker. And you have talked about—and Ms. Pons as well, you have talked about teams of people that looked at your MAC list, your transparency list, teams of people that do this. I want to give you a couple of examples of how you actually look at this and you said within your 7 days.

This is a recent example released from Avera. It says, if a pharmacy filled a prescription of a Omeprazole, a common antipsychotic, on April 16, 2014, Express Scripts reimbursed that pharmacy \$1.20. If the pharmacy filled the same prescription the next day, the 17th, it reimbursed only \$0.20. On the 18th, you paid another amount, this time \$0.80. Another one was potassium chloride, \$0.45 on the 22nd of April; 26th of April, \$0.33; and on April 28, \$0.52.

One, I just have a direct question. Ms. Bricker, do you all have two sets of MAC lists? Is there two sets of lists out there? Do you have two lists for MAC pricing?

Ms. BRICKER. We have multiple MAC lists, yes.

Mr. COLLINS. Okay. What about you, Ms. Pons?

Ms. PONS. Yes.

Mr. COLLINS. Okay. Is that just to keep the ball from being hidden from community pharmacies?

Ms. PONS. No, we have multiple clients. We have thousands of clients, so—

Mr. COLLINS. You have multiple clients. So you prefer one's over the others?

Ms. PONS. We make—

Mr. COLLINS. Never mind.

Ms. PONS [continuing]. Our client list match what our—

Mr. COLLINS. The issue that I have—and I appreciate that. And the question is answered.

I hear from pharmacies in my community that reimbursement or MAC appears to be arbitrary and has little connection to actual price. These examples seem to indicate that. Can you please explain the disparities in MAC pricing you pay to these long-term care pharmacies? Ms. Bricker.

Ms. BRICKER. So I don't actually know the acquisition cost of any given pharmacy. Our policy is to survey the market based on a number of price points that are available, both confidentially to Express Scripts as well as publicly, and in an attempt to respond in kind to the market. And so it is—we make every effort to ensure that we are reimbursing a fair amount for prescription drugs from a generic perspective.

We have an appeals process, that if we get it wrong a, pharmacy can file an appeal and provide us additional evidence.

Mr. COLLINS. Ms. Bricker, have you ever told a pharmacy that if they appeal any more that they would be cut off from their plan?

Ms. BRICKER. No, I have not.

Mr. COLLINS. Not you personally, your company.

Ms. BRICKER. I am not aware of ever making that statement, no.

Mr. COLLINS. Ms. Pons.

Ms. PONS. I'm not aware either.

Mr. COLLINS. Will you answer the question long term, that I asked Ms. Bricker as well on MAC pricing disparities?

Ms. PONS. Yeah. I actually have a very similar answer to hers in the sense that we do our best to try to estimate what we think people are buying at and put a reasonable margin on that because we want them to dispense generics.

Mr. COLLINS. Okay. So if I told you that I know pharmacies who have been told if you appeal and—if you appeal, we will deal with it in your contract, you cannot appeal this, would you all both find that egregiously appalling?

Ms. BRICKER. I am not aware of Express Scripts ever making a statement like that.

Mr. COLLINS. That's not what I asked. I said, but if they were told that a pharmacy was told that, would you find that appalling that your companies would say that?

Ms. BRICKER. Yes, I actually would agree with you. You know, the appeals process is there to ensure that we are responsive to the market.

Mr. COLLINS. Well, I think there's a concern because there's a disconnect because this is what's being told.

I think the concern that I have here is all in all, in this playing field, there needs to be a level playing field. There needs to be a playing field for community pharmacies and independent pharmacies as well as PBM companies involved in this market. Right now there's not.

And you can talk about it all you want. We can go into different pricing. We've already talked about multiple lists, and we talked about the appeals process. And we also know from pharmacists who have been told, if you appeal more, we will cut you off.

What is even more appalling to me is when my local pharmacists across this country try to speak out about this, they received letters and discussions from PBM saying, if you make too much noise about this, your contract could be in jeopardy. That is not right. I will continue to fight this, and if you don't believe that it's true, it is true.

And when we understand this—here's my concern. That in the coming future, because I hear from my pharmacists all across this country and in northeast Georgia, if it continues the way it is, they will be closing. And all those wonderful savings that are being donated from PBMs are going to be lost and close businesses and close lives.

And I just have a question, who will my folks in the Ninth District of Georgia call when they need someone at night and their local pharmacist is the one they trust? Ms. Bricker, they're not going to call you. They're not going to find you in St. Louis. They're not going to find you, Ms. Pons. They're going to try and find their

local pharmacist who is being closed because of the anticompetitive nature of this field. This needs to be addressed.

With that, Mr. Chairman, I yield back.

Mr. MARINO. The Chair recognizes the gentleman from California, Mr. Issa.

Mr. ISSA. Okay. Well, I'm going to start off, Mr. Balto, in your statement, it's already been read a couple times, but I'll grab a couple of the key words you used. This is the PBMs are the least regulated sector of healthcare. I guess without the FDA they might be. Essential elements of competition are not there. The following are transparency, choice, and lack of conflict of interest. Right?

Mr. BALTO. Correct.

Mr. ISSA. And by the way, I'm not trying to make anybody a good guy or a bad guy. I just like to put this portion of the market in perspective. And I think, sort of as the witness against the PBM sitting between these two fine women from the industry, you're the one to ask.

If I told you that from the 2010 case published, for the two public companies on each side of you, that, for example, Express—and of course they've got mergers. There's other factors. But they're annual reports. Express Scripts went from about \$42 billion in 2010 to \$100 billion in gross revenues. Their profit, gross profit went from \$2 billion to \$3 billion during that period. After tax revenue went from \$1.2 billion to \$2 billion during that period of time.

On the other side, CVS, a bigger company, getting bigger, and in the retail space, so it's a little more complex to follow them, went from \$97 billion to \$139 billion. They went from \$6 billion in profit to \$9 billion in profit. And they both went up slightly in their per share.

Let me ask you a question. If somebody sells, for example, \$100 billion worth of product and makes \$2 billion after expenses and taxes, just one question: Where do you think those excess profits are that you say are there?

Mr. BALTO. Well, first of all, Congressman, what we're looking at are entities that are moving information and are moving—

Mr. ISSA. No, no. But I'm asking a question to you that is narrow, and I want to make sure that I don't get a—I don't know. You had an opening statement, so please stick to the question because I'm going to ask the others questions.

Mr. BALTO. I wanted to explain it—

Mr. ISSA. If a company makes—if you're qualified to answer on the financial part, if you sell \$100 billion and you make \$2 billion—and I checked, and they have had this same chairman for a long time and he gets decent compensation, but it's in the millions not the billions. So from a material standpoint, they don't have but 2 percent of gross sales in profit.

Now, unless there's money hidden under a mattress, my question for you—and I'll use Express Scripts. I could use either but Express Scripts is a much simpler company—they're basically a wholesaler middleman. They drive down their cost of distribution, particularly their mail order process; they negotiate the lowest prices they can; they squeeze, if you will, the retailer on one end as much as they can, Pfizer and the other pharmaceuticals on the other, and they end up with, you know, a buck and-a-half a share for their stock-

holders or about \$2 billion, and it hasn't gone up or down in a major percentage.

So my question to you is, is it the lack of, as you said, the lack of transparency in competition, is that really at any of these pharmaceutical companies—and I realize there's a difference in, if Ms. Bricker's company makes \$2 billion, it might drive Mr. Arthur's company out of business because of their ability to buy and so on.

There's no question—we could have a discussion between retail and wholesale and their tactics, and of course, with CVS, an integrated company that has both. And I'd like to give you a chance to answer that if you'd like to throughout the hearing.

But the real question is, where are these excess profits that you're alleging? If I go to Pfizer or any other number of large successful pharmaceutical companies, I will find after-tax revenues in as much as double digit of their gross sales.

So my question to you is, where is the evidence of that? Quickly. And then I'd like to others to answer. Because I'd like to understand that part, which I think for this Committee, looking at competition, and whether they need to be regulated, this is a big question.

Mr. BALTO. Sure. And I'd like to respond to you in writing because it's a complicated question.

Mr. ISSA. Okay.

Mr. BALTO. But in my testimony, looking at just their margins, their margins have increased substantially. But let me answer you more carefully in writing about what the answer is.

Mr. ISSA. Okay. And for the two wholesale pharmacies, and I'd like to also include the retail quickly, if there were more transparency and a more level pricing for what a particular pill or two cost, and instead of a complex set of rebates and negotiations, if we look to these monopolies, particularly, people who have an exclusive and said, look, we don't care what you sell it for and how much, but you can't be all over the place on prices such that these MACs are so different. Would that really affect your business model in an adverse way?

I know, quickly, for Mr. Arthur, he would love to see a price where the price is the price to a certain extent, and only discounts are truly based on volume, you know, the truck delivery versus the UPS delivery. Because that certainly would change these disparities that are driving retail out.

Quickly, I apologize, Mr. Chairman, if they could answer.

Ms. BRICKER. So scale matters. And, you know, in a free market where you're able to buy in a larger quantity, we've seen this not just in pharmacy but in other aspects in other industries. And, so yes, it would be absolutely detrimental to our plan sponsors to have fixed pricing, if you will. But with that said—

Mr. ISSA. Actually, it was cost bases from a monopoly, more like a public utility. You can buy your electricity cheaper from an exclusive source that has to sell it to you if you're a volume user, but the difference is based on actual earned discounts. But go ahead, please.

Ms. BRICKER. But our MAC is responsive to that very thing. I understand, you know, when I'm establishing MAC that I'm not going to establish MAC for an independent pharmacy the same as

that of a large retailer that can purchase the product at, you know, a much more deeply discounted rate. And so it's our attempt to do that.

Our plan sponsors, you know, count on us to keep costs down, and we have guarantees in our contracts. We are obligated to ensure that we're lowering costs year over year for our plan sponsors.

Mr. ISSA. Right. In your case, your MAC price is always higher than your cost, I assume?

Ms. BRICKER. I'm sorry?

Mr. ISSA. The pricing you're willing to pay the retailer is always higher than your actual cost?

Ms. BRICKER. Well, I couldn't say that with 100 percent certainty. That's definitely my intent. My intent is to——

Mr. ISSA. Well, you know your cost, don't you?

Ms. BRICKER. You're saying my cost at mail?

Mr. ISSA. Well, you buy. You're a large buyer. He's a small buyer.

Ms. BRICKER. Yes, sir.

Mr. ISSA. You set his price based on an assumption of what he paid for the product. I just want to understand, can you say here today under oath, both of you, that you always provide the retailer a "price" that is at least above what the two largest people in the pond pay?

Ms. BRICKER. Absolutely, 100 percent.

Mr. ISSA. Okay. So you can certify that. You can too?

Ms. PONS. Yes, that we make every effort to do that, yes.

Mr. ISSA. Well, every effort. You've got great computers.

Ms. PONS. No——

Mr. ISSA. Would you say with the certainty of somebody gets fired, if that's not the case, if you actually expect the small retailer to take less than, in fact, you're already paying?

Ms. PONS. Yeah. What I can tell you is that our independent pharmacy community gets paid a higher rate of reimbursement on generic products than our own pharmacies do.

And the other thing I would just add to the mix as well, because we haven't talked about this, is the fact that there are a number of very large what are called PSAOs, pharmacy service administrative organizations, that independents belong to. I believe over 80 percent of the independent pharmacies joined one of these big, three Fortune 50 companies, and there's some large independent PSAOs as well. Those are the actual entities that we're negotiating with.

We're not negotiating with, you know, typically, you know, a small, single, independent pharmacy. And so there is a lot of back and forth. And to the extent that we can't make changes sometimes, it's because we've got a contract that's 100 pages long with our client that says everything under the sun that they want in their network. So we're not truly trying to make people's lives difficult for the sake of——

Mr. ISSA. No, I know you're not.

Mr. Chairman, I know that I'm actually stealing from your time every minute that this goes on, but I would ask that Mr. Arthur give his opinion on this. Because I do think that—and I said this to two of the witnesses when I met with them in advance. You know, the hotel industry and the airplane industry used to suffer

from the fact that two people on an airplane sitting next to each other, one could pay four times more than the one next to them, and it was always very hard to understand.

At least now, if you go to an online Web site, you can at least get some transparency on what the best deal is. And I think for the retail industry, this is part of what's not existing in healthcare. And I'd just like Mr. Arthur to give his insight on not knowing what something gets bought for by anybody except what you get told on reimbursement.

Mr. MARINO. Go ahead, Mr. Arthur—

Mr. ISSA. I will owe you, Mr. Chairman.

Mr. ARTHUR. Very briefly, Mr. Congressman. One important distinction. You mentioned the role of the PBMs as a wholesale. The PBM stocks no product in inventory. It doesn't handle any product in inventory—

Mr. ISSA. I apologize. I called him a middleman, but you're right, except for their own mail order, they're working with you based on your inventory.

Mr. ARTHUR. Yes, sir. And the reason I mention that is when you give the numbers, the genesis of the PBM industry was due to their technical expertise in moving from a paper environment to an electronic environment for the processing of claims. We could have a discussion today, a very vibrant discussion about the other services that they do provide in that space. But essentially, they are negotiating those prices for purely an administrative function, in my view.

Mr. ISSA. Thank you very much, Mr. Chairman. And I will owe you that large poker chip.

Mr. MARINO. Thank you. I have about 30, 40 minutes of questions, but I know I'm limited to several minutes.

Mr. Balto, aren't we talking about—and I liked Mr. Issa's line of questioning concerning excess profits, but I'm a capitalist—are we really talking about excess profits or market shares?

Mr. BALTO. Well, look, I think the PBMs—there is a service that the PBMs perform, and the question is, is the market acting competitively? Is their ability to lower prices being fully translated in lower prices to consumers?

And we see these trends which the Ranking Member identified, which the Consumers Union statement identified that shows that with higher drug prices that their profits seem—their profits are going up.

Mr. MARINO. Okay. Let's set aside antitrust issues for a moment though. But isn't it just customary usually those that have a larger share in the market generate more profits?

Mr. BALTO. If the market is behaving competitively, you would expect price to be competed down to marginal costs. You wouldn't expect to see their profits per script increasing in this fashion or their profits increasing overall in this fashion.

Mr. MARINO. Okay. Let's move to—and I know what Mr. Arthur's answer is going to be on this. So I would like Mr. Arthur to answer it, and then I ask Ms. Bricker and Ms. Pons to give me their opinion of this.

What is the downside of independents coming together and buying prescription drugs in bulk? What's the downside of that? You

know, if there is an exemption to the antitrust law for pharmaceuticals, what is the downside of independents getting together and purchasing drugs?

Mr. BALTO. There's no downside. And somehow, in 19 pages of testimony, I did not deal with the collective negotiation point. I apologize.

Mr. MARINO. Well, no, let's not talk about the antitrust part of it. That's another hurdle.

Mr. BALTO. There is clearly a significant advantage to pharmacies coming together. There is antitrust uncertainty, and antitrust exemption would be appropriate. My colleagues on the panel tell you about PSAOs. Those PSAOs are ineffective. In fact, PSAOs are often prohibited by the PBMs of even turning over the contracts to individual pharmacies.

There needs to be greater ability of people like Mr. Arthur to collectively negotiate to protect their interests.

Mr. MARINO. Ms. Bricker.

Ms. BRICKER. A couple of things come to mind. So pharmacies absolutely can join group purchasing organizations and collectively buy drugs, or they can also join PSAOs to have them represent them in negotiations with PBMs. In our contracts at Express Scripts, it's explicitly written, you know, to Mr. Balto's statement, that we prohibit member pharmacy from seeing contract. It's required that the PSAO pass the contract that they have executed on behalf of a member pharmacy to that pharmacy.

So it's important to us to have independent pharmacies in network. We have 25,000 independent pharmacies in network. Just to give context, less than 5 percent of independent pharmacies service a rural area in the United States. These are still very vital. It's very important that those pharmacies stay in business, but they command a premium, as they should, because they're serving a population that no one else is.

Mr. MARINO. Ms. Pons, would you care—

Ms. PONS. Yeah. My comments will be similar to Amy's in the sense that we welcome pharmacies to join PSAOs. It helps us, obviously, to negotiate with, you know, five PSAOs as opposed to 20,000 individual pharmacies, and those PSAOs are able to negotiate very effectively on behalf of their clients. And similarly, we require that the PSAOs share that contract back with the pharmacy, and the pharmacy actually has to tell us in writing that they've designated a PSAO to be their agent for the negotiations.

Mr. MARINO. Why the disparity then in pricing? Because of volume? Is there a disparity in pricing with independents with some entity representing them, negotiating prices with pharmaceuticals compared to your companies?

Ms. PONS. We don't know, you know, the price that others pay. I would just say that—

Mr. MARINO. Well, we do know that independents pay significantly more across the board than examples of your companies. Why?

Ms. PONS. I was going to say, they're, you know, taking their volume through their PSAO to try to get the best deal that they can that is not going to be the same as a Walgreens who has a much greater footprint.

But, you know, as stated earlier in the testimony, we do factor that into the reimbursement that we provide to our independents, and, you know, again, they receive a richer reimbursement for their generics to take that into account.

Mr. MARINO. Mr. Arthur, I live in a rural area. We have independents and we have CVS and other pharmaceuticals—excuse me, pharmacies. What do you offer to your customers that you do not see the big chains offering, particularly if it's through the mail?

Mr. ARTHUR. Well, there's a whole host of services that we're offering on a very personalized way, you know, from comprehensive pharmacists, clinical services, immunizations, consultations, medication reconciliation. There's a whole host of services that are being provided. And the reason why the independents, in my view, are more successful is based on the relationships that we've developed in our communities over a great period of time.

Mr. MARINO. Again, this is for Ms. Pons and—excuse me, no, this is for Mr. Balto.

Mr. Balto, where do you see the transparency line concerning what companies, larger companies or any company for that matter, have to divulge? Who draws that line? Where is that line?

Mr. BALTO. By the way, just to supplement Mr. Arthur's comment about the services, one critical issue—

Mr. MARINO. You aren't dodging my question though, are you?

Mr. BALTO. I was trying not to.

Mr. MARINO. Okay. I was a prosecutor so that's not going to work.

Mr. BALTO. It didn't work.

In terms of the transparency line, I think we should listen to what, you know, what's going on in the market. The Department of Labor proceeding that the Ranking Member mentioned before the ERISA subcommittee, unions and major employers and consumer groups all talked about the kind of transparency was necessary for a plan sponsor to fulfill his fiduciary duty, to make sure he was receiving—that the plan was receiving the benefit of the bargain.

And that requires very robust disclosure of the rebates that the PBMs are receiving from the pharmaceutical manufacturers. And then the plan sponsor armed with that information can make sure that they're receiving the best deal in their arrangement with PBM.

Mr. MARINO. Okay. If I'm buying something from—somebody's selling antique cars and I buy antique cars. Why would I divulge? Why would I think of divulging what the person selling the antique car is going to sell it to me for compared to someone else who wants that same car?

Mr. BALTO. So for me as a plan, an employer or union, what I'm purchasing in part is their ability to negotiate rebates. And so I want to know how they're doing at that specifically, for those, you know, for the manufacturers. And then look drug by drug, over time and see how effective they're being at that. And then that way, I can figure out whether or not I'm getting the benefit of the bargain, whether those rebates are helping to lower my pharmaceutical costs.

Mr. MARINO. Ms. Pons and Ms. Bricker, I don't think I gave you the opportunity, although you probably thought I passed you on it, on the issue of the downside of independents, collectively purchasing. Now, there was some discussion about they're able to join groups to do that. But the numbers don't seem to be indicating that there is fairness or a level playing field there.

Could you expand on your answers there a little bit, Ms. Pons. Do you know—do you get my question?

Ms. PONS. I guess, what I would say is that we welcome anybody that's part of this value chain in helping reduce costs, provide access, and improve health outcomes. To the extent that they can be more efficient, just like we're trying to be more efficient in our PBM and in our pharmacies, we would welcome them to be able to do that because that's going to ultimately help our clients and help our patients that we're all trying to serve.

Mr. MARINO. Ms. Bricker, I'm assuming you would agree with that, or do you want to add something to it?

Ms. BRICKER. At Express Scripts, our mission is to make drugs safer and more affordable. And we welcome in working with you to have a robust dialogue about the entire supply chain from manufacturer to patient. And today, we're focused on, you know, a couple of areas of the supply chain, but we think there's actually an opportunity for us to work with wholesalers, with manufacturers, with PSAOs, with all of the constituents within the supply chain to continue to lower costs for plan sponsors and patients.

Mr. MARINO. Well, do you see—and I'll get back to you on that. Do you see independents eventually going out of business because of the volume that your companies are able to sell and able to keep the price lower than what a pharmacy can? Give me your opinion on what you see 5 years from now or 10 years from now for independent pharmacies.

Ms. BRICKER. We believe that independent pharmacy is viable. We believe that—and we're seeing it in the data. If history is, you know, any indicator of the future, then, no, this industry is quite robust. There are 68,000 pharmacies. That's up from the prior year. NCPA's own data suggest that independent pharmacies are remaining steady and constant.

And so, no, I believe that it's a viable business and one that students coming out of pharmacy schools are entering the business of opening retail pharmacies today because it actually will pay the bills and it's a wonderful career.

Mr. MARINO. Ms. Pons.

Ms. PONS. Yeah, no, I agree with that. And independents are a cornerstone of our networks. We don't have any networks that don't include independents. They're important to our clients to have that access. And as Ms. Bricker pointed out, the number that held steady. There were well over 20,000 in the country.

Mr. MARINO. You know, I have a dog in this hunt, and I've experienced this several times. My daughter has cystic fibrosis so there are dozens of drugs that she takes. Sometimes the prices go up; sometimes the prices go down. But what I find very, very important is the one-to-one, face-to-face communication with a pharmacist.

And believe me, on more than one occasion, our pharmacist here and even when we were traveling in England where we ran into a problem, they were able to communicate. What can you offer that the—can you offer that same thing that—that same service that the independents offer?

Ms. PONS. I would say we certainly do our best within our own pharmacy channels, whether it's our retail pharmacies or our specialty pharmacies, and particularly our specialty pharmacies that work with patients that have chronic, serious conditions, where they have expertise in particular disease states that a lot of normal pharmacists don't. And they do develop very close relationships with those patients and their caregivers.

Mr. MARINO. I'm going to wrap up here quickly, but I just want to give each of you 15, 20 seconds to make—give a closing statement. So Mr. Balto, you had your hand up, please.

Mr. BALTO. Sure. First of all, these firms own their own mail order and specialty pharmacies. It's in their incentive to drive consumers away from these community pharmacies that they want into their own pharmacies where they can maximize their profits. And especially for people who need specialty drugs like your daughter, that's a real critical concern, especially when specialty drug spend is increasing so dramatically. And that's why this Committee needs to look at the restricted networks these PBMs use.

Mr. MARINO. Ms. Bricker.

Ms. BRICKER. At Express Scripts we're committed to making prescriptions safer and more affordable. We stand ready to assist our plan sponsors and their patients in looking into the future to understand where drug pricing is going and attempt to partner with them in innovative ways to make prescription drugs safe, affordable, and accessible. Thank you for the opportunity.

Mr. MARINO. Ms. Pons.

Ms. PONS. Yes. And I would just, you know, continue to reiterate the importance of independent pharmacies to our company, and would note that in our preferred Medicare pharmacy networks, over 40 percent of the participants are independent pharmacies. They're just—they're critical to helping us deliver a service to our Medicare population. Thank you for having us.

Mr. MARINO. You're welcome.

Mr. Arthur.

Mr. ARTHUR. Mr. Chairman. Thank you.

As I sit here, if memory serves me correctly, I look up at the wall and I think that's former Congressman Jack Brooks on the left there. And going back for over 25 years, we have been fighting for equality in the marketplace using the antitrust law to examine the antitrust law to seek fairness. We have survived by evolving. My independent pharmacy is half the size; I employee half the people I did 20 years ago.

I think it's really telling that in this environment, and the reason I mention that, as you asked the question, what's the harm in allowing the pharmacies to do that, pharmacy has attempted to meet every challenge. We have attempted to get together to be able to purchase effectively.

But when we are successful in doing that, if we run into challenges with the MAC, with the timely updates of MAC, it's inter-

esting to note that, you know, we've heard today about compliance with timely updates, and I'm sure there are very robust departments within these large corporations. Why is it that in two States they have fought vigorously to repeal efforts to timely implement MAC updates?

We in pharmacy will continue—and independent community pharmacy—continue to find ways to survive and be able to provide the types of services that you alluded to, to the people that depend on us in our communities.

Mr. MARINO. Thank you.

Mr. JOHNSON and I were having a discussion really before the hearing began. And the two of us, most of the time we see eye to eye because we are looking for information. Right, Hank?

Mr. JOHNSON. That's right.

Mr. MARINO. We're looking to be educated. And we in Congress, we don't have all the answers. You know, when we get elected we think we're taller, smarter, and better looking right away. But we look to you people, experts in your area, how to improve the quality of life for all Americans. And I think each of you have a role to plan that.

So my friend, Mr. JOHNSON and I, we're looking forward to hearing from you on how we can improve the quality of life for all Americans. So that is my request—our request of you. So please participate in this with us, send us information, give us your ideas so we can accomplish that.

And I want to thank everyone. This concludes today's hearing. Thanks to all the witnesses for attending.

Without objection, all Members will have 5 legislative days to submit additional written questions for the witnesses or additional materials for the record.

Mr. MARINO. The hearing is adjourned.

[Whereupon, at 5:24 p.m. The Subcommittee was adjourned.]

A P P E N D I X

MATERIAL SUBMITTED FOR THE HEARING RECORD

Material submitted by the Honorable Tom Marino, a Representative in Congress from the State of Pennsylvania, and Chairman, Subcommittee on Regulatory Reform, Commercial and Antitrust Law



CONCERNS REGARDING THE PHARMACY BENEFIT MANAGEMENT INDUSTRY

NOVEMBER 2015

INTRODUCTION

The purpose of this report is to provide an overview of three legislative and regulatory concerns that legislators, policymakers, customers, and pharmacies have raised regarding the pharmacy benefit management (PBM) industry:

1. The importance of accuracy and transparency in PBM revenue streams;
2. Potential conflicts of interest with PBM-owned mail-order and specialty pharmacies; and
3. Unclear generic drug pricing and maximum allowable cost payment calculations.

These issues are critical for policymakers and legislators to understand as they consider whether additional oversight of the PBM industry is warranted. Over the past decade, the role of PBMs in the delivery of health care has increased, due to a confluence of factors: coverage expansions under both the Medicare Part D prescription drug benefit and the Affordable Care Act, combined with an increase in prescription drug spending that has motivated commercial health plans and self-insured employers to outsource the management of their spending on outpatient prescription drugs. Adding to that, PBMs now offer customers entire suites of services, moving beyond claims processing to administering policies that affect the clinical management of patients. As the profile of the PBM industry has risen over the past decade, it has become increasingly important that policymakers fully understand the role that PBMs play in the prescription drug supply chain.

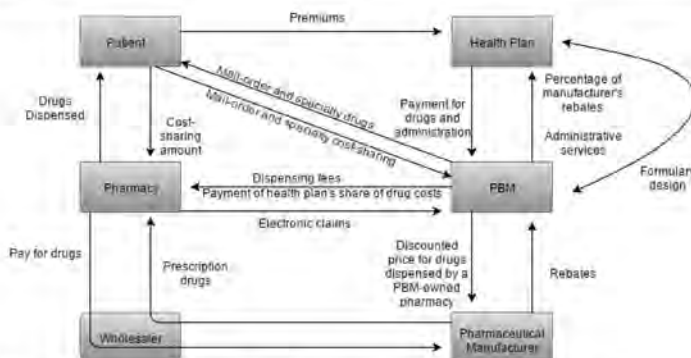
OVERVIEW OF PHARMACY BENEFIT MANAGERS

A PBM is an administrator of prescription drug programs. PBMs are responsible for developing and maintaining formularies and other clinical management programs, processing prescription drug claims for insurance companies or corporations, and negotiating contracts with pharmacies and pharmaceutical manufacturers.¹ Other responsibilities of PBMs include performing drug

utilization reviews, managing clinical programs targeted to specific disease states, and operating pharmacies, including mail-order and specialty pharmacies. PBM customers, which are called "plan sponsors," include commercial health plans, federal government programs such as Medicare, Tricare, and the Federal Employees Health Benefits Program (FEHBP), self-insured companies, unions, and public health programs.

PBMs generate revenue from pharmaceutical manufacturers through two main types of payments: formulary payments to obtain preferred formulary status, and market-share payments to encourage utilization of their drugs relative to competitors.² These payments are typically referred to as "rebates." PBMs negotiate rebates directly with pharmaceutical manufacturers, and they can be based on preferred placement on a formulary tier (e.g. placement on a "preferred brand" tier with more favorable cost-sharing amounts relative to products on a higher tier) or based on utilization (e.g. if the manufacturer is able to achieve a certain percentage of the PBM's utilization for a particular therapeutic class of drugs).² In addition, PBMs generate revenue through administration and service fees charged to plan sponsors for processing prescriptions; through operation of their own mail-order and specialty pharmacies; and on the margin between the amount charged to customers and the amount paid out to pharmacies for a prescription (also referred to as "spread pricing").

THE ROLE OF PBMS IN THE PRESCRIPTION DRUG SUPPLY CHAIN



The graphic above provides a high level illustration of some of the major players in the prescription drug supply chain, including PBMs:



- **Pharmaceutical manufacturers** negotiate rebates and other concessions with PBMs. They also supply pharmaceutical **wholesalers** with prescription drugs.
- **PBMs** contract with commercial health plans or self-funded insured groups to administer the plan's pharmacy benefit, including development of a formulary and terms for payment, including agreements to pass-through manufacturer rebates. PBMs contract with a network of retail and community pharmacies, and also are responsible for setting patient cost-sharing amounts and establishing clinical policies, such as prior authorization requirements. Finally, many PBMs also own mail-order and specialty pharmacies, which directly supply prescription drugs to patients.
- **Health plans** are responsible for paying PBMs for prescription drugs dispensed to plan members and collecting premiums from patients.
- **Pharmacies** contract directly with PBMs to dispense prescription drugs to patients. This includes negotiating a payment rate for each prescription, plus a dispensing fee. Pharmacies are also responsible for collecting patient cost-sharing payments and sending those to the PBM. Separately, pharmacies negotiate with **wholesalers** to purchase prescription drugs.
- **Patients** are responsible for paying cost-sharing to either a retail or community pharmacy, or to a mail-order or specialty pharmacy. They are also responsible for paying premiums to their health plan.

THE ROLE OF PBMS IN MEDICARE PART D

The Medicare Part D program was established by the Medicare Modernization Act of 2003 (MMA), and implemented in 2006. Medicare beneficiaries have coverage through either stand-alone prescription drug plans (PDPs) or Medicare Advantage Prescription Drug plans (MA-PDs).³ In 2015, more than 39 million beneficiaries are enrolled in Part D plans, including 24 million PDPs, and 15 million MA-PD plans.⁴ Part D plans receive payments from the government to provide subsidized drug coverage to beneficiaries. The Part D benefit is financed through general revenues (74%), beneficiary premiums (15%), and state payments (11%).⁵ Spending on Part D has grown from \$44.3 billion in 2006 to approximately \$88.6 billion in 2015, and is expected to grow to \$858 billion in 2024.^{6,7} In 2015, approximately 50% of beneficiaries are enrolled in a PDP or MA-PD plan sponsored by UnitedHealth, Humana, or CVSHealth.⁸

The Medicare statute (Title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.)) requires Part D plan sponsors to offer either a defined standard benefit or an alternative equal in value, and have the option of offering enhanced benefits. In reality, very few Part D plans offer the "standard" benefit, which includes a deductible and flat co-insurance after the deductible is met, a period of reduced coverage (i.e. the "doughnut hole") and then a catastrophic benefit. Instead, Part D plan sponsors offer "actuarially equivalent" plan designs that include a formulary with tiered cost-sharing, similar to those seen in commercial health plans, though most Part D plans use more tiers.⁹ Decisions on formulary design, beneficiary cost-sharing requirements, and pharmacy networks (including determinations of pharmacy reimbursement) are made by PBMs.



under contract with a plan sponsor; therefore, PBMs wield a great deal of influence in how beneficiaries access their needed medications in the Part D program as a whole.

THE "BIG THREE" PBMS

According to the Pharmaceutical Care Management Association, the trade group that represents the PBM industry, PBMs manage pharmacy benefits for over 253 million Americans.¹⁰ Three large companies lead the PBM market: Express Scripts[®], CVSHealth[®], and OptumRx[®]. In total, they cover more than 180 million lives in the United States, or roughly 78% of Americans whose pharmacy benefits are managed by a PBM.¹¹ Annual revenues for Express Scripts in 2014 were approximately \$100.887 billion while CVSHealth had the highest revenues of the big three coming in at \$139.367 billion in 2014.^{12,13} Finally, OptumRx reported \$31.97 billion annual revenues in 2014 (In 2015, OptumRx acquired Catamaran, which reported annual revenues of \$21.6 billion in 2014).^{14,15,16}

Express Scripts processes more than one billion prescriptions each year and covers approximately 85 million lives, making it the largest PBM in the country.^{17,18} Express Scripts maintains network contracts with more than 69,000 retail pharmacies as well offering home delivery services of prescriptions. Express Scripts offers its PBM services to managed care organizations, government health plans, health insurers, employers and a host of other organizations. In addition to contracting with retail pharmacies which comprises 98.4% of their business, Express Scripts also receives revenue from their specialty drug pharmacies.¹⁹

CVSHealth works with almost 68,000 retail pharmacies which includes their own CVS stores as well as 27,000 independent pharmacies.²⁰ CVSHealth covers approximately 85 million lives and processed more than 930 million prescriptions in 2014.²¹ CVSHealth clients include health plans, government payers and employers. CVSHealth also operates a mail order pharmacy.²²

UnitedHealthcare[®] operates its PBM business under OptumRx, which covered more than 30 million lives and processed more than 600 million prescriptions in 2014.²³ In 2015, OptumRx acquired Catamaran, another PBM that has more than 35 million covered lives and processed over 400 million prescriptions in 2014.²⁴ OptumRx's network consists of more than 67,000 retail pharmacies and includes two home delivery pharmacies.²⁵ Catamaran has a pharmacy network that covers all 50 states, including mail order and specialty pharmacies.²⁶

LEGISLATIVE AND REGULATORY CHALLENGES WITH THE PBM INDUSTRY

Several market dynamics have raised the profile of PBMs in recent years: the growth in prescription drug costs, the implementation of the Medicare Part D prescription drug benefit, and consolidation within the PBM industry itself. Below is a brief overview of three legislative and regulatory issues that legislators, policymakers, PBM customers, and pharmacies have raised regarding the PBM industry.

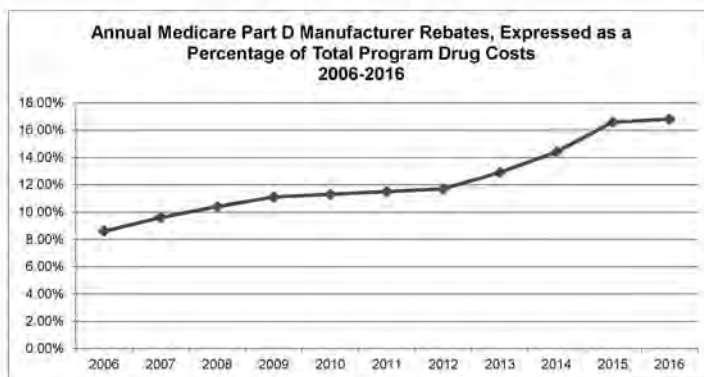


INCREASING ACCURACY AND TRANSPARENCY IN PBM REVENUES

PBMs generate revenues through rebates, or payments negotiated directly with pharmaceutical manufacturers, and from the margin, or difference, between what a PBM charges a customer for a prescription and what the PBM pays a pharmacy to fill that prescription. PBM contracts with customers often include revenue sharing provisions. However, PBM customers and pharmacy owners have complained that there is a lack of transparency in these revenue streams that make it difficult to know exactly how much revenue a PBM is generating, and whether or not that revenue is being shared in accordance with contract terms.²⁷ PBMs maintain that efforts to regulate disclosure and transparency requirements will lead to increased prices through reduced competition (between PBMs and drug manufacturers and PBMs and pharmacies) and increased administrative costs due to calculating and analyzing data that are not currently required.²⁸

However, experience with the Medicare Part D benefit indicates that concerns regarding increased transparency of rebates and other price concessions leading to reduced competition and preventing PBMs from negotiating the largest rebates possible, may be unfounded. Since the inception of the Medicare Part D benefit in 2006, all Part D plan sponsors have been required to disclose rebates and other price concessions to CMS. This, in turn, impacts the payments CMS makes to sponsors for providing the benefit.²⁹ An analysis of reported rebate amounts by plan sponsors, expressed as a percentage of overall Part D drug costs, shows rebates have increased or held steady each year, and are estimated to grow from 8.6% of overall Part D drug costs in 2006 to 16.8% of overall Part D drug costs in 2016.³⁰ This indicates that disclosure requirements, when properly protected with confidentiality clauses, do not necessarily hinder a PBM's ability to negotiate competitive rebates with manufacturers.





**2014 – 2016 denote estimates. Rebates are projected to increase for 2015 due to the high competition in the hepatitis C drug market. Source: Annual Reports of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, 2008 – 2015.*

The PBM industry also asserts that many customers are successful at negotiating “pass-through pricing,” in which a PBM passes through rebates and other concessions to the customer, or other disclosure provisions that have essentially created a transparent system.³¹ While this may be true in theory, in practice, there are examples of the difficulties that even large, sophisticated purchasers face when trying to analyze PBM contracts:

- Medicare Part D.** Both the U.S. Department of Health and Human Services’ Office of the Inspector General and the Government Accountability Office recommend requiring additional disclosures and reporting from the PBMs that serve the Part D program. These government agencies have found potential problems with both the way that Part D plan sponsors were calculating and reporting rebates, also known as “direct and indirect remuneration” (DIR), to CMS.³² In 2009, CMS required plan sponsors that contract with a PBM to report to CMS both the price the PBM charges a plan for a prescription, and the price that the PBM pays a pharmacy for the same prescription. Any difference between the two prices must be calculated as an “administrative cost” on behalf of the PBM. This change was made in an effort to achieve more accurate reporting of drug costs.³³ In proposed regulation released in January 2014, CMS expressed concerns that the existing calculation and reporting requirements may offer too much flexibility for plans to report price concessions separately, thereby artificially inflating the negotiated price, leading to higher costs for beneficiaries, the Medicare program, and manufacturers. Therefore, CMS proposed to revise the definition to better clarify how plan sponsors must report fees.³⁴ CMS finalized this revised definition in May



2014, but delayed implementation until 2016.³⁵ In September 2014, CMS issued a request for comments,³⁶ but the agency has yet to publically release final guidance. In October 2015, 11 members of the U.S. House of Representatives sent a letter to CMS in support of the revision, as well as an update on plans to finalize the definition.³⁷

- Large Employers.** The ERISA Advisory Council, established under the Employee Retirement Income Security Act of 1974 (ERISA), is responsible for advising the Secretary of Labor on issues surrounding employee welfare and pension benefit plans, including health benefits provided under ERISA.³⁸ In response to concerns about large, self-insured health plans' ability to negotiate competitive, transparent PBM contracts, the Council held a hearing in August 2014.

At the hearing, representatives of two large employers testified regarding difficulties they have faced in negotiating transparent contracts with PBMs. Testimony delivered on behalf of Honeywell International Inc., emphasized that, due to the complexity inherent in the PBM business model, it was essential that all contract terms are fully defined and that all agreements between the PBM and other third-party service providers are transparent.

The HR Policy Association's (HRPA) Pharmaceutical Coalition testified about experiences that the Coalition had in trying to negotiate transparent contract language with PBMs. In 2004, the Coalition established a set of transparency standards with the goal of certifying PBMs that agreed to the standards. Coalition members were then free to make certification a requirement before accepting bids from a PBM. The certification process was moderately successful; at the highest point, 15 of 30 PBMs were certified (though certification did not guarantee that all contracts offered by the PBM met the certification standards). The Coalition continued to innovate and established the PharmaDirect program, which essentially disaggregates PBM services to allow customers to select PBMs to deliver a specific set of services, instead of a complete suite of services. Under this paradigm, a PBM's revenue is mainly limited to administrative fees charged to the customer. However, the Coalition has struggled to increase adoption of the PharmaDirect program, even though participants reported savings of between 10% and 15%.³⁹ This example illustrates that even large employers, who ostensibly should be in a position to negotiate favorable contracting terms, can have trouble negotiating transparent contracts with PBMs.

The experiences of both CMS and large employers illustrate the difficulties that even large purchasers, including the federal government, can have in fully evaluating PBM contracts, even those contracts that are supposed to be transparent. Furthermore, the ERISA Advisory Council supports expanding regulations that require certain levels of transparency from PBMs contracting with health plans covered under the statute, in a similar manner that the financial services industry is now required to disclose direct and indirect disclosure to pension plans. In making the recommendation, the Advisory Council noted that the enhanced reporting



requirements would "greatly enhance the ability of [PBM customers] to provide prescription drug benefits to participants and beneficiaries, with minimal or no adverse impact on PBMs."⁴⁰

POTENTIAL CONFLICTS OF INTEREST WITH PBM-OWNED MAIL ORDER AND SPECIALTY PHARMACIES

Many PBMs own and operate their own mail-order and specialty pharmacies, and PBM customers, community pharmacies, and patients have raised concerns that the relationship introduces conflicts of interest. PBMs offer mail order pharmacy benefits to patients with chronic conditions who require daily (or regular) use of certain medications as a way to reduce costs. Generally, mail order pharmacies fill prescriptions in 90-day supplies, necessitating a refill once every three months instead of once a month. PBMs offer incentives to patients to use mail order via lower cost-sharing requirements. Some commercial plans require patients needing chronic medications to use mail order services. However, Medicare Part D prohibits mandatory mail order requirements.⁴¹ The research is inconclusive regarding the effect of mail order access on patient adherence. Some studies indicate that patient adherence may increase when prescriptions are filled through mail order, yet other studies indicate that mandatory mail order policies may actually discourage adherence.⁴² What is agreed upon is that face-to-face pharmacist counseling is valuable in improving adherence. CVSHealth has reported that face-to-face counseling can be "two to three times as effective as other forms of communication in driving adherence to prescription drug regimens."⁴³

Critics charge that PBM ownership of mail order pharmacies creates several conflicts of interest. A PBM may be incentivized to:

- Perform fewer generic substitutions;
- Switch patients to higher-cost therapeutic alternatives ("therapeutic interchange"); or
- Repackage drugs in a manner that could lead to increased costs to plan sponsors, while maximizing revenue for the PBM ("package size pricing").

Employers have specifically highlighted the issue of package-size pricing with PBM-owned mail order pharmacies as a challenge. Generally, PBMs charge customers a set discount off of a product's average wholesale price (AWP) (e.g. AWP minus 15%). However, the AWP may be set to a package size commonly purchased by a retail pharmacy (e.g. 100 tablets), whereas a mail-order pharmacy may be purchasing the drug in much larger package sizes (e.g. 50,000 tablets) at a much lower price. When a PBM owns a mail-order pharmacy, they may continue to charge the customer based on the AWP set to the smaller package size, while not passing on the savings associated with large-volume purchasing.⁴⁴

Finally, when a PBM both owns a mail order pharmacy, and is responsible for building a retail pharmacy network, the PBM is responsible for negotiating contracts with entities that are competitors to the PBM's mail order pharmacy.



As the utilization of specialty drugs has increased, the use of specialty pharmacies, which generally deliver medications directly to a patient's home, has likewise increased. Because the specialty pharmacy model is similar to the mail-order pharmacy model, concerns over conflicts of interest also apply. In addition, concerns have also been raised with how PBMs categorize particular drugs as "specialty" drugs.

Specialty drugs are generally subject to higher cost-sharing, as well as special handling requirements. There is no single agreed-upon definition of what classifies a drug as a "specialty" drug in the commercial health insurance market. While drugs that require specialized handling (such as refrigeration) or are subject to additional safety requirements as mandated by the U.S. Food and Drug Administration (FDA) clearly qualify as specialty drugs, PBMs also use high cost as a qualifying factor.⁴⁵ Cost of these therapies is a valid concern; spending on specialty drugs currently represents about one-third of all prescription drug spending, and PBMs contend that specialty pharmacies help ensure that patients are taking the drugs correctly and appropriately. However, because many large PBMs also own specialty pharmacies, and therefore generate direct revenue from filling patient prescriptions, it is essential for PBM customers to understand the methodology behind a PBM's classification of a product as a "specialty" product, especially if the PBM also owns a specialty pharmacy.⁴⁶ CMS establishes a specialty tier minimum threshold each year (currently \$600 per month) and only allows Part D plan sponsors to place drugs with costs exceeding that amount on the plan's specialty tier.⁴⁷ There is no such cost threshold in place for non-Medicare Part D health plans.

GENERIC DRUG PRICING, MAXIMUM ALLOWABLE COST, AND INDEPENDENT PHARMACIES

Independent pharmacies are important members of the U.S. healthcare system. Almost 23,000 independent pharmacies dispense close to 1.4 billion prescriptions annually, with over 80% of those prescriptions filled using a generic drug.⁴⁸ In recent years, volatility in the generic drug pricing marketplace has caused issues for pharmacists, physicians, patients, and payers alike.⁴⁹ A survey of members of the National Community Pharmacists Association (NCPA) in January 2014 showed that over 75% of respondents reported instances of a large price increase in at least 26 generic drugs over the last six months of 2013.⁵⁰

Commercial payers, including PBMs, as well as government payers, such as state Medicaid programs, can link reimbursement for a particular drug to a "maximum allowable cost" (MAC). This reimbursement method is intended to promote generic substitution, since reimbursement for a brand-name drug is set at reimbursement for a generic equivalent, as well as encourage pharmacies to purchase drugs from wholesalers at competitive prices.⁵¹ However, issues can arise when a payer's MAC price for a specific drug is not updated frequently enough to account for sudden increases in prices. In the same NCPA survey cited above, over 85% of survey respondents reported that it could take a PBM or other payer between two to six months to update their reimbursement rates for generic drugs.⁵²



Unlike commercial health plans, Medicare Part D plan sponsors are required to update their prescription drug pricing lists at least once a week for network pharmacies.⁵³ In May 2014, CMS finalized a regulation that clarified that this requirement applied to MAC listings and also required Part D plan sponsors, beginning January 1, 2016, to update reimbursement amounts, including MAC listings, in advance of their use for claim reimbursement. In proposing and subsequently finalizing this change, CMS noted the impact that inaccurate MAC prices have not only on pharmacies attempting to validate accurate payments, but also on beneficiaries who rely upon pricing information available via the Medicare Plan Finder tool. The majority of commenters on the proposal were supportive, according to CMS.⁵⁴

In recent years, 24 states have implemented legislation similar to CMS requirements for Medicare Part D.⁵⁵ While MAC list pricing is not the genesis of, nor the solution to, price volatility in the generic market, providing updated MAC prices in advance of reimbursement, in a timely manner, can help to avoid situations in which a pharmacy is under-reimbursed for a prescription due to large fluctuations in price.

CURRENT EFFORTS TO REGULATE PBMS

At the federal level, commercial health insurers that offer employer-sponsored health plans are regulated under the Employee Retirement Income Security Act (ERISA), as well as the Health Insurance Portability and Accountability Act (HIPAA) and the Consolidated Omnibus Budget Reconciliation Act of 1986 (COBRA).⁵⁶ The Affordable Care Act further expanded the federal government's regulation of the commercial insurance industry.⁵⁷ Finally, Medicare Advantage and Part D prescription drug plans are regulated by CMS,⁵⁸ and health plans offered to federal employees, which cover over 8 million Americans, must meet requirements established by the Office of Personnel Management.⁵⁹ However, the bulk of insurance regulation resides at the state level, where insurer solvency and underwriting requirements, coverage mandates, and access requirements are typically regulated.⁶⁰ The majority of states also have effective rate review programs that enable state regulators to review premium rate increases for approval or rejection.⁶¹

In spite of the fact that PBMs play such an integral role in how patients access their prescription drug benefit in both commercial health insurance and Medicare Part D, PBMs are not subject to industry-wide regulation similar to what is generally required of large commercial health insurers. Instead, PBMs face a patchwork of regulations at the state level. 33 states have passed legislation governing PBM audits of pharmacies, and 17 states have passed laws requiring PBMs to register with, or obtain a license from, the state department of insurance (though these requirements generally require only the payment of a nominal fee).⁶² There are no federal laws or regulations specific to the PBM industry (though commercial health plans are required to meet the prescription drug coverage requirements under the Affordable Care Act).⁶³



CONCLUSION

The U.S. healthcare system is in the midst of a large transformation. Research in the pharmaceutical sector continues to deliver innovative pharmacological treatments for many challenging and complex medical conditions. Likewise, the PBM industry has evolved beyond simply processing pharmacy claims and managing a formulary. Expansions of prescription drug coverage over the past 10 years mean that PBMs are involved in a majority of prescription drug transactions today. In light of that fact, transparency regarding the PBM industry is needed so that purchasers of these services in both in the commercial and government sectors can make well-informed decisions. Likewise, it is important for legislators and policymakers to better understand the complex PBM industry, and the role PBMs play in the pharmaceutical supply chain.

ACKNOWLEDGEMENT

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ABOUT APPLIED POLICY

Applied Policy, L.L.C., is a health policy and reimbursement consulting firm strategically located minutes from Washington, D.C. At Applied Policy, our governing principle is transforming intention into action. Our tactics are to identify new opportunities, reframe challenges, empower people with information and create long-term stakeholder relationships. These tactics facilitate our clients' desired outcomes by enabling effective navigation of the complex Medicare and commercial reimbursement landscape within the U.S.

We have consulted for hospitals and other health care providers, specialty societies and trade associations, device, diagnostic and drug manufacturers, group purchasing organizations and other health care supplier's health care policy and reimbursement issues. We are recognized health policy leaders, having been called upon to testify before the U.S. Senate Health, Education, Labor and Pensions Committee regarding the implementation of the Affordable Care Act, commissioned by the U.S. Senate Special Committee on Aging to conduct an analysis of Medicare reform options and being regularly invited to speak at international conferences regarding health policy and reimbursement issues. Applied Policy has an unmatched reputation in Washington for thoughtful analysis, reliability and credibility.

For more information about Applied Policy, please contact Jim Scott, President & CEO, at 202-558-5272. You may also visit our website at <http://www.appliedpolicy.com/>.



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Material submitted by the Honorable Doug Collins, a Representative in Congress from the State of Georgia, and Member, Subcommittee on Regulatory Reform, Commercial and Antitrust Law



NATIONAL ASSOCIATION OF
CHAIN DRUG STORES

Statement

Of

The National Association of Chain Drug Stores

For

United States House of Representatives
Committee on the Judiciary
Subcommittee on
Regulatory Reform, Commercial and Antitrust Law

Hearing on:

The State of Competition in the Pharmacy
Benefit Manager and Pharmacy Marketplaces

November 17, 2015

3:00 P.M.

2141 Rayburn House Office Building

National Association of Chain Drug Stores (NACDS)
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NACDS Statement to Judiciary Subcommittee:
The State of Competition in the Pharmacy Benefit Manager and Pharmacy Marketplaces
November 17, 2015
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The National Association of Chain Drug Stores (NACDS) thanks Chairman Marino and the members of the Subcommittee on Regulatory Reform, Commercial and Antitrust Law for the opportunity to submit the following statement for the record regarding The State of Competition in the Pharmacy Benefit Manager and Pharmacy Marketplaces. NACDS and the chain pharmacy industry are committed to partnering with Congress, HHS, patients, and other healthcare providers to improve the quality and affordability of healthcare services.

NACDS represents traditional drug stores and supermarkets and mass merchants with pharmacies. Chains operate more than 40,000 pharmacies, and NACDS' chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ more than 3.2 million individuals, including 179,000 pharmacists. They fill over 2.9 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 850 supplier partners and over 60 international members representing 22 countries. For more information, visit www.NACDS.org.

NACDS members are committed to and supportive of the goals of competition, consumer choice and quality of care. Each and every day, NACDS members make important contributions to the health and wellbeing of Americans across this nation.

As we know, efforts to transform healthcare are gaining momentum with broad support from both the public and private sectors. The federal government, major insurers and employers are driving the change towards patient-centered care, value-based payment systems and

NACDS Statement to Judiciary Subcommittee:
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alternative care delivery models. Key components of these approaches include care coordination across the broad medical neighborhood, patient performance metrics, quality care measures, and access to timely, affordable care. Success of these approaches depend upon, among other things, the ability to effectively and efficiently improve access to affordable, quality patient care across all sites of care in the medical community. Meanwhile, our industry faces significant federal and state impediments and overly restrictive state professional regulations in our endeavor to provide consumers with choices regarding enhanced and innovative, quality neighborhood care.

Importance of Beneficiary Access

Patients should be free to select a health plan that best fits their personal health needs and provides accessible pharmacy locations. Limited pharmacy networks impose restrictions on patient freedom to patronize the business of their choosing and cut off convenient access to knowledgeable professionals that play a critical role in providing care and producing cost savings. Limited networks also create the potential for an interruption in the continuity of care with unintended consequences for their total healthcare. H.R. 793, the *Ensuring Seniors Access to Local Pharmacies Act of 2015*, introduced by Rep. Morgan Griffith (R-VA), would help accomplish this goal by allowing pharmacies in medically underserved communities to participate in prescription drug plan networks in Medicare as a preferred pharmacy if they are willing to meet the terms and conditions of the plan. This model works well in commercial health plans, which allow pharmacies that are willing to meet the terms and conditions of the

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network to participate. Restricting pharmacies from participating in a network only limits patient choice in seeing the pharmacists they know and trust for improved care.

We urge Congress to help to ensure continued access to pharmacies for Medicare beneficiaries through support of H.R. 793. This important legislation would help maintain pharmacy access for Medicare beneficiaries who count on visiting the pharmacy of their choice to provide the services they so greatly need.

In addition to supporting H.R. 793, NACDS has promoted model PBM legislation that we believe will maintain patient access and reduce barriers to care, increase transparency in prescription medication pricing, protect patient data and eliminate fraud, waste and abuse through more efficient audit practices.

Value of Pharmacy

As the face of neighborhood healthcare, community pharmacies and pharmacists provide access to prescription medications and over-the-counter products, as well as cost-effective health services such as immunizations and disease screenings. Retail pharmacies are often the most readily accessible health care provider. Nearly all Americans (94%) live within five miles of a community retail pharmacy. Recognition of pharmacists as providers under Medicare Part B would help to provide valuable and convenient pharmacist services to millions of Americans, and most importantly, to those who are already medically underserved or reside in rural areas. Access to these types of services is especially vital for

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Medicare beneficiaries as nearly two-thirds are suffering from multiple chronic conditions. Through personal interactions with patients, face-to-face consultations and convenient access to preventive care services, local pharmacists are helping to shape the healthcare delivery system of tomorrow—in partnership with doctors, nurses, and others. For this reason, we support H.R. 592, the “Pharmacy and Medically Underserved Areas Enhancement Act,” which would allow Medicare Part B to utilize pharmacists to their full capability by providing medically-underserved beneficiaries with services not currently reaching them (subject to state scope of practice laws).

Conclusion

NACDS thanks the subcommittee for consideration of our comments. We look forward to working with policymakers and stakeholders on these important issues.



Response to Questions for the Record from Amy Bricker, R.Ph., Vice President, Retail Contracting and Strategy, Express Scripts



VIA ELECTRONIC SUBMISSION TO ANDREA LINDSEY

January 15, 2016

The Honorable Bob Goodlatte
Chairman, Committee on the Judiciary
United States House of Representatives
2138 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Goodlatte,

Express Scripts appreciates the opportunity to participate in the Judiciary Subcommittee on Regulatory Reform, Commercial and Antitrust Law's hearing entitled "The State of Competition in the Pharmacy Benefits Manager and Pharmacy Marketplace." The hearing was a meaningful opportunity to explain how pharmacy benefit managers, including Express Scripts, make prescription drugs safer and more affordable for millions of Americans.

Below, I provide responses to questions for the record submitted to my attention.

Questions submitted for the Record from House Judiciary Committee Chairman Goodlatte

1. *I have been hearing concerns about the widening gap between the costs of prescription drugs to pharmacies and the corresponding reimbursement amounts from PBMs. Can you explain why such a gap exists, and why there are instances where there is a significant difference between the costs and reimbursement amounts? Additionally, are pharmacies contractually prohibited from passing on these costs to consumers? If so, why is there such a prohibition in the pharmacies' contracts?*

Bricker response: We respectfully disagree with the assertion that across the entire market for generic drugs, there is a widening gap between the prices available to pharmacies to purchase prescription drugs and the reimbursements from Express Scripts. In order to manage prescription drug spending, it is important for both pharmacies to seek out and negotiate the best deals from prescription drug wholesalers and pharmacy benefit managers to manage generic drug reimbursement. In any instance where a contracted pharmacy in our network believes a MAC reimbursement is inaccurate, or a sudden marketplace event like a shortage changes the pharmacy's acquisition cost, the pharmacy may appeal the reimbursement to Express Scripts for review.

Pharmacies may not charge patients more than the copayment provided for in the patient's benefit design. Prescription drug claim payments are governed by our contract with the pharmacy and Express Scripts' Provider Manual. The contract with the pharmacy includes the negotiated reimbursement between Express Scripts and the pharmacy. If pharmacies passed additional costs onto the patient, the pharmacy would be changing the benefit design for the patient, which could have significant downstream negative effects on patients, including erroneous maximum out of pocket limit calculations and coordination with the medical benefit. In our contracts, pharmacies agree to follow the benefit design that Express Scripts clients choose for their beneficiaries.

Questions submitted for the Record from Subcommittee Chairman Marino

1. *A news story by Jay Olstad and Steve Eckert entitled "What's the real cost of prescription drugs" details the experience of a CVS customer who was charged \$2,382 for a mail-order drug that he could obtain at another pharmacy for \$259. Can you explain the cause of this discrepancy and discuss whether similar pricing discrepancies exist for other drugs?*

Bricker response: I am unable to respond to the specifics of a CVS claim.

2. *I understand that there is a "firewall" between CVS' pharmacy services and Caremark's PBM services. Who monitors and polices this firewall?*

Bricker response: I am unable to respond to the specifics of a CVS claim.

3. *PBMs help to design the network of pharmacies that customers in a drug plan may visit to obtain their prescription drugs. When you are designing these pharmacy networks, how do you ensure that customers have access to their local pharmacies? Do you include pharmacies in these networks that compete with the pharmacies that you each own? Have you ever excluded a pharmacy solely on the basis that it is a competitor to your owned pharmacy?*

Bricker response: A convenient prescription drug benefit is essential to Express Scripts' clients and patients. We ensure patients have access to a robust network of providers by analyzing the geographic availability of network providers. Industry standards provide minimum access standards by geographic category, including Medicare Part D which requires:

- In urban areas, at least 90 percent of Medicare beneficiaries in the Part D sponsor's service area, on average, live within 2 miles of a retail pharmacy participating in the sponsor's network;
- In suburban areas, at least 90 percent of Medicare beneficiaries in the Part D sponsor's service areas, on average, live within 5 miles of a retail pharmacy participating in the sponsor's network; and
- In rural areas, at least 70 percent of Medicare beneficiaries in the Part D sponsor's service area, on average, live within 15 miles of a retail pharmacy participating in the sponsor's network.

Express Scripts contracts with pharmacies that compete with pharmacies that we own. We have never excluded a pharmacy solely on the basis that it is a competitor.

4. *Some pharmacies assert that they are unfairly excluded from the PBM-designed pharmacy networks. What steps, if any, do you take to ensure that you will not exclude from your networks a pharmacy that agrees to comply with all the contractual terms of pharmacies participating in the PBM network, including reimbursement levels?*

Bricker response: Where "Any Willing Pharmacy" mandates exist, we include all providers that meet standard terms and conditions and would like to participate in our network. In the absence of such mandates and with respect to preferred or limited networks, we negotiate with pharmacies which provide additional discounts for increased market share, all the while ensuring that network adequacy

standards are met. Pharmacies offer these discounts when they expect higher volume for their products and services, thus they would not be available if every pharmacy was in the network. Our obligation to our clients and our patients is to keep prescription drug costs lower and preferred pharmacy networks are an effective way to do this.

5. *Mr. Arthur states in his testimony that there is no concrete definition for specialty-drugs and that PBMs are directing these prescriptions, which may have higher profit margins than other drugs, to their own specialty pharmacies. How do you respond?*

Bricker response: While there is some variation in how plan sponsors define specialty drugs, they are consistently recognized as complex medicines that require special handling, additional patient education, or special reporting requirements by the FDA or manufacturer. Express Scripts cannot direct prescriptions to our own specialty pharmacy unless the plan sponsor, our client, chooses that benefit for it's beneficiaries. We cannot make this decision on behalf of our clients.

Question submitted for the Record from Representative Blake Farenthold

Three years ago the Federal Trade Commission (FTC) investigated Express Scripts' acquisition of Medco, which at the time were two of "The Big Three" pharmacy benefit managers (PBMs). Ultimately, the transaction created the largest PBM that also controlled a captive specialty pharmacy, Accredo, which at the time accounted for approximately 30 percent market share of the specialty pharmacy industry. After devoting significant FTC resources to the matter, and garnering substantial Congressional attention, by a slim margin the FTC ultimately allowed the merger to proceed without any divestitures. In concluding its review of the transaction, the FTC's closing statement expressed that it "was not an easy decision." A dissenting Commissioner voting to oppose the transaction called it "a game changer" and invited the FTC in the future to re-examine the industry three years after the transaction closed to consider whether market conditions have remained competitive.

Among the issues that the FTC considered at the time was whether the merger would likely result in anticompetitive effects with respect to specialty drugs, including whether Express Scripts would have an incentive or ability to disrupt the options of specialty pharmacies available to manufacturers of specialty pharmaceuticals, especially given that the combined company had a substantial position in the specialty pharmacy industry. Today Express Scripts' Accredo remains amongst the largest specialty pharmacies in the country.

Last week Stifel (an investment firm) called out Express Scripts on its recent aggressive tactics in eliminating competition from independent specialty pharmacies, noting,

By terminating relationships with smaller specialty pharmacies, ESI increases its competitive advantage [for Accredo]. In 2014, ESI recognized more than \$38bn in revenues from specialty and home-delivery services. A clear conflict of interest exists when ESI, who owns Accredo, begins to prioritize Accredo and eliminate non-ESI owned specialty pharmacies, especially if doing so is not in the best interest of the patient and hinders patient access to drugs.

To me, this inherent conflict of owning your own specialty pharmacy and terminating other competing specialty pharmacies in your network appears to be eliminating competition, disrupting choice and access to patients who are in critical need of specialty medicines that utilize these specialty pharmacies to obtain the treatments their doctors prescribe.

1. *How do you account for this competitive conflict?*

Bricker response: The issue of PBM conflicts of interest has been studied by the FTC, which found that PBM ownership of pharmacies does not disadvantage plan sponsors¹. Indeed, our network includes many specialty pharmacy competitors in addition to Accredo. Our clients, which include health plans, employers, and state and local governments, determine specialty pharmacy benefits. Express Scripts cannot unilaterally decide which pharmacies can dispense specialty medications.

Questions submitted for the Record from Representative Doug Collins

1. *Ms. Bricker, in regard to MAC prices, their fluctuation, and the frequency with which they are updated you stated that MAC prices are updated "no less frequently than every seven days." You said that Express Scripts has "teams of people dedicated to this" who review price fluctuations "daily" and that "if there is a dramatic price change that occurs prior to that seven day change, we (Express Scripts) will make that change earlier as well." If you have teams of people dedicated to this who can view a price fluctuation in real time and on a daily basis, then why are your MACs not updated in real time or at least on a daily basis?*

Bricker response: Our maximum allowable cost lists are updated as soon as possible. In almost all instances, maximum allowable cost lists do not need to be updated in real time or on a daily basis. In many cases, generic drug price changes by a manufacturer or wholesaler are temporary and are resolved within days. In other cases, generic drug price increases are isolated to a specific manufacturer or wholesaler and pharmacies can purchase generic alternatives for their pharmacy. Moreover, the day that a generic drug price increases is rarely the same day that a pharmacy must replenish its inventory for a given medication. All of these delays are accounted for in the management of a MAC list. Lastly, the MAC appeals process provides a mechanism for pharmacies to seek changes to the MAC list in the case of a marketplace disruption.

2. *Ms. Bricker, you stated in your testimony in regard to state MAC laws that "Express Scripts is compliant and takes seriously those laws." Could you please report back to the committee regarding how many lawsuits Express Scripts has filed in the past and also settled out of court in regard to contesting state MAC laws? Could you please also report as to the number of current or presently ongoing lawsuits Express Scripts has filed in any states regarding a state's MAC law?*

Bricker response: Express Scripts has not filed any lawsuits related to state MAC laws. Express Scripts is a member of the Pharmaceutical Care Management Association (PCMA), which has lawsuits pending in Arkansas and Iowa.

3. *Ms. Bricker, please respond to the committee with the raw number of total appeals by pharmacies of a MAC generic drug price in 2014 and in the first three quarters of 2015. Please also provide the committee with the raw total number of how many of your total appeals were accepted (in which you paid the pharmacy a higher*

¹U.S. Federal Trade Commission. (2005). Pharmacy Benefit Managers: Ownership of Mail Order Pharmacies. https://www.ftc.gov/sites/default/files/documents/reports/pharmacy-benefit-managers-ownership-mail-order-pharmacies-federal-trade-commission-report/050906pharmbenefitrtpt_0.pdf

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reimbursement) and how many were rejected? In your answer please include data from chain, independents, specialty and LTC pharmacies.

Bricker response: This information is confidential and cannot be released without divulging trade secrets.

4. *Ms. Bricker, please respond to the committee with the raw number of total appeals by PSAOs of a MAC generic drug price in 2014 and in the first three quarters of 2015. Please also provide the committee with the raw number total of how many of your total appeals were accepted (in which you paid the pharmacy a higher reimbursement) and how many were rejected.*

Bricker response: This information is confidential and cannot be released without divulging trade secrets.

5. *Ms. Bricker, does Express Scripts set contractual limits as to how many appeals a pharmacy can make per year?*

Bricker response: No, we do not.

6. *Ms. Bricker, does Express Scripts set contractual limits as to how many appeals a PSAO can make per year?*

Bricker response: No, we do not.

7. *Ms. Bricker, has Express Scripts ever terminated a contract with a PSAO due to its submission of what your company considers too many MAC appeals?*

Bricker response: No, we have not.

8. *Ms. Bricker, does Express Scripts pay independent pharmacies less on a per unit cost basis than you pay yourselves at mail?*

Bricker response: No, we do not.

9. *Ms. Bricker, in your testimony you stated that "less than 5 percent of independent pharmacies service a rural area in the United States." Please provide non-partisan, external data that supports or proves this assertion. How does this data define "rural?"*

Bricker response: My testimony is based on Express Scripts data and experience. The definition of a rural provider is one that is located greater than 10 miles from another network provider. There are approximately 25,000 independent pharmacies contracted with Express Scripts. Of those, only 1,330 independent pharmacies are located more than 10 miles from another pharmacy and thereby meet the "rural" pharmacy definition.

10. *Ms. Bricker, the Medicare Part D program requires plan sponsors and PBMs to report direct and indirect remuneration. Currently, CMS is working to provide further guidance as to how PBMs should report the undisclosed revenue streams they receive from pharmacies such as "network access fees," "DIR fees," "credentialing fees," etc.*

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This is necessary because manipulation and variation in how these price concessions are treated impacts beneficiary cost sharing, CMS payments to plans, Medicare plan finder data, federal reinsurance and low income cost sharing, manufacturer coverage gap discount payments and plan bids. Can you please explain how you report such revenue streams from pharmacies to CMS currently? Also, why are DIR fees not included in point-of-sale (real time) adjudication responses?

Bricker response: We would report DIR that is calculable at the point of sale on the PDE. Currently, DIR is reported to CMS annually. Not all DIR fees are calculable at the point of sale because they relate to quality metrics that are calculated over the term of the contract.

11. *Ms. Bricker, you stated that pharmacies find out the total amount of their reimbursement at the point of sale or when the claim is adjudicated. However, we have heard from pharmacies about various fees that are very often collected from pharmacies after the point of adjudication. Currently CMS is working to provide further guidance as to how PBMs should report these undisclosed revenue streams they receive from pharmacies such as "network access fees," DIR fees, and "credentialing fees." This is necessary because how these price concessions are treated impacts beneficiary cost sharing, CMS payments to plans, Medicare plan finder data, federal reinsurance, and low income cost sharing and plan bids. CMS proposed guidance would require plans/PBMs to estimate these fees at the point of sale which would provide all parties, including pharmacies, greater insight into their actual reimbursement. The PBM industry has expressed opposition to this proposed guidance. Will you please explain why there is Express Scripts and/or industry opposition? Also, how does your company currently report these fees?*

Bricker response: Express Scripts does not support *estimates* of actual costs when true costs are a more reliable and accurate measure for CMS, plans, and patients. All DIR is reported to CMS annually. Moreover, all DIR fees and incentives are both detailed and agreed to by the pharmacy within the contract between Express Scripts and the pharmacy.

Question submitted for the Record from Representative Mike Bishop

1. *How do you ensure that pharmacy owners with multiple stores are treated fairly and equitably-in the aggregate-if a technical issue is raised at one of their stores? For example, we understand that PBMs have language in their standard terms and conditions whereby a technical issue at one location gives them the right to terminate a relationship across all stores. This without cause/reason termination unfairly prejudices both the pharmacies and their patients which have nothing to do with the alleged issue.*

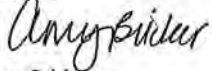
Bricker response: The only instances where network terminations occur at the pharmacy(s) owner level are instances of fraud or violations of our contract. We are not punitive in our relationship with pharmacies. Technical issues are typically correctable by the network provider without escalation.

Again, Express Scripts appreciates the opportunity to provide feedback for the record on the pharmacy benefit manager and pharmacy marketplace.

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If you have any questions about these comments, please don't hesitate to contact me or Gary Kline, Senior Director, Government Affairs at GJKline@express-scripts.com.

Sincerely,

A handwritten signature in black ink that reads "Amy Bricker". The signature is written in a cursive, flowing style.

Amy Bricker
Vice President, Retail Contracting & Strategy
Express Scripts



Response to Questions for the Record from Natalie Pons, Senior Vice President, Assistant General Counsel, Health Care Services, CVS Caremark Corporation

**The Committee on the Judiciary's Subcommittee on
Regulatory Reform, Commercial and Antitrust Law Hearing**

"The State of Competition in the Pharmacy Benefits Manager and Pharmacy Marketplaces"

Questions for the Record

Questions submitted for the Record from House Judiciary Committee Chairman Goodlatte

1. I have been informed that one of your Medicare Part D programs, SilverScripts, requires pharmacies to fill senior citizens' prescriptions with brand name medications and will not allow generic substitution. Is this true? If so, can you explain why you prohibit generic substitution?

This is not accurate. SilverScript Insurance Company is a Part D Prescription Drug Plan (PDP) sponsor offering 2 PDPs for 2016. Both PDPs have a formulary (drug list) that complies with CMS requirements to include a broad range of drugs that cover all disease states. CMS rigorously reviews and approves all Part D Plan formularies. In addition, pursuant to CMS rules, plans must require pharmacies to inform beneficiaries of a lower cost generic version that is therapeutically equivalent and bioequivalent, unless the drug being purchased is the lowest priced version available at the pharmacy, for all submitted claims.

With respect to your specific question, while generic prescription drugs are typically the lowest-cost option, and we encourage our beneficiaries to select lower cost generics, there are instances where a brand drug may be a lower cost alternative, such as when a generic form is initially launched by one or a few manufacturers.

2. I have been hearing concerns about the widening gap between the costs of prescription drugs to pharmacies and the corresponding reimbursement amounts from PBMs. Can you explain why such a gap exists, and why there are instances where there is a significant difference between the costs and reimbursement amounts? Additionally, are pharmacies contractually prohibited from passing on these costs to consumers? If so, why is there such a prohibition in the pharmacies' contracts?

Our goal is to help lower drug spend for our clients. One of the best ways we can do that is by increasing the generic dispensing rates in our networks. We have no incentive to pay our network providers in a manner that discourages dispensing generics as that would drive the use of more expensive branded products. We work to balance fairly compensating pharmacies while providing a cost-effective, clinically appropriate drug benefit plan for our clients. Like the government, we utilize Maximum Allowable Cost lists to incentivize pharmacies to negotiate more competitive rates for generic drugs with manufacturers and wholesalers in order to keep overall prices down.

Our PBM health plan sponsor clients require that member responsibility be limited to the amount of the cost share as determined by the plan benefit for the covered item, and in turn the PBM health plan sponsor clients require us to prohibit network pharmacies from charging the member more than what the plan benefit determines is the member responsibility for the prescription claim.

Questions submitted for the Record from Subcommittee Chairman Marino

1. PBMs help to design the network of pharmacies that customers in a drug plan may visit to obtain their prescription drugs. When you are designing these pharmacy networks, how do you ensure that customers have access to their local pharmacies? Do you include pharmacies in these networks that compete with the pharmacies that you each own? Have you ever excluded a pharmacy solely on the basis that it is a competitor to your owned pharmacy?

We respond to both Questions 1 and 2 below.

2. Some pharmacies assert that they are unfairly excluded from the PBM-designed pharmacy networks. What steps, if any, do you take to ensure that you will not exclude from your networks a pharmacy that agrees to comply with all the contractual terms of pharmacies participating in the PBM network, including reimbursement levels?

We establish retail pharmacy networks that provide plan members with retail pharmacy options that are easy to access, high quality and cost effective. Thousands of pharmacies, including pharmacies that are competitors to CVS Health-affiliated pharmacy, are included in a given network where they compete on service, convenience and quality to earn consumers' business. It is not our practice to exclude a pharmacy from a network solely on the basis of a pharmacy's competitor-status. The choice of which pharmacies are included in any given network is ultimately made by our PBM clients, not by CVS/caremark.

Our networks include a broad range of pharmacies, including CVS/pharmacy, other competitors such as Wal-Mart and Walgreens, and over 20,000 independent pharmacies (the majority of which contract through PSAOs, a Pharmacy Service Administration Organization which negotiate on behalf of independents).

3. Mr. Arthur states in his testimony that there is no concrete definition for specialty-drugs and that PBMs are directing these prescriptions, which may have higher profit margins than other drugs, to their own specialty pharmacies. How do you respond?

Specialty drugs are used to treat complex or rare conditions, such as multiple sclerosis, cancer, rheumatoid arthritis, and hemophilia. Health plan sponsors determine the list of drugs that are considered to be "specialty" within their benefit design. There is no nationally recognized definition of a specialty drug as there are variations of specialty criteria such as storage requirements, education, patient monitoring, cost, etc. Some common characteristics of specialty drugs include:

-
- Require a customized medication management program that includes medication use review, patient training, coordination of care, and adherence management for successful use
- More frequent monitoring and training
- May have FDA-mandated REMS program as condition of approval
- Unique handling, distribution, and/or administration requirements
- Often high cost
- Route of administration could be oral, inhaled, infused or injected

- Target chronic or complex disease states
- Produced through DNA technology or biological processes

Health plan sponsors may choose a PBM network offering with selected specialty pharmacies in their pharmacy networks to help assure high-quality services, to avoid waste, and to provide for appropriate use of the medications, as described above. As a PBM, our experience is that most traditional retail pharmacies do not offer the level of care required by our health plan sponsors to deliver the clinical management and services that these products require.

Questions submitted for the Record from Representative Doug Collins

1. Ms. Pons, in your testimony you stated that "we have a team of people that are constantly monitoring various market sources to see what's happening with drug acquisition costs and are compliant with state laws but if there are market forces that suggest that we need to make updates sooner than that then we do." If you have a team of people constantly monitoring market forces and price fluctuation in real time and on a daily basis, then why are your MACs not updated in real time or at least on a daily basis?

A MAC list generally includes hundreds of generic drugs and the pricing changes as market conditions change. We evaluate market inputs on a daily basis and regularly update the MAC list to reflect this information. While updates are generally done on a weekly basis, our daily review of market inputs can drive updates before the regularly scheduled update.

2. Ms. Pons, you stated that your "clients have very extensive audit rights that they exercise regularly to ensure that they get the benefit of the bargain they struck with us...We are completely supportive of transparency with our clients." Could you please elaborate and provide the Committee with the number of your clients that audited CVS Health (PBM) in 2014 and 2015. Also, please tell us whether or not in your contracts with PBM clients; whether CVS Health reserves the right to approve of the auditor?

In both 2014 and 2015, our PBM was audited over 1000 times. Our contracts generally require a mutually acceptable independent third party retained by the client. Historically, we have worked with over 100 different auditors. In the rare instance that an auditor is not acceptable, it is generally due to a conflict of interest or prior issues around adherence to confidentiality requirements.

3. Ms. Pons, please respond to the committee with the raw total number of appeals by PSAOs of a MAC generic drug price in 2014 and in the first three quarters of 2015. Please also provide the committee with the raw total number of how many of your total appeals were accepted (in which you paid the pharmacy a higher reimbursement) and how many were rejected.

We review MAC appeals that we receive to ensure that pharmacies are compensated at competitive rates based on market price conditions. We grant over 2,000 MAC appeals every month.

4. Ms. Pons, does CVS Health set contractual limits as to how many appeals a pharmacy can make per year?

No, we do not set contractual limits on how many MAC appeals can be submitted. Pharmacies can use our MAC appeals process if they feel they are not being fairly reimbursed.

5. Ms. Pons, does CVS Health set contractual limits as to how many appeals a PSAO can make per year?
- No, we do not set contractual limits on how many MAC appeals can be submitted. PSAOs can use our MAC appeals process if the PSAO feels that one of its pharmacies is not being fairly reimbursed.
6. Ms. Pons, has CVS Health ever terminated a contract with a PSAO due to its submission of what your company considers too many MAC appeals?
- No, we have not terminated a provider contract based on the volume of MAC appeals submitted.
7. Ms. Pons, Does CVS Health pay independent pharmacies less on a per unit cost basis than you pay yourselves at retail and mail?
- In aggregate, our independent pharmacies receive greater reimbursement than our affiliated retail and mail pharmacies across all prescriptions dispensed.
8. Ms. Pons, the Medicare Part D program requires plan sponsors and PBMs to report direct and indirect remuneration. Currently, CMS is working to provide further guidance as to how PBMs should report the undisclosed revenue streams they receive from pharmacies such as "network access fees," "DIR fees," "credentialing fees" etc. This is necessary because manipulation and variation in how these price concessions are treated impacts beneficiary cost sharing, CMS payments to plans, Medicare plan finder data, federal reinsurance and low income cost sharing, manufacturer coverage gap discount payments and plan bids. Can you please explain how you report such revenue streams from pharmacies to CMS currently? Also, why are DIR fees not included in point-of-sale (real time) adjudication responses?
- CMS promulgated a rule on May 23, 2014, amending the definition of negotiated prices to ensure that negotiated prices reported on Prescription Drug Events (PDEs) have a consistent meaning across the Part D program. The rule became effective on January 1, 2016, and requires that all pharmacy price concessions/discounts that can be predicted in advance and determined at point of sale be included in the point of sale negotiated price that is reported on the PDE. Pharmacy discounts that are based on contingencies that cannot be determined at the point of sale must continue to be reported as DIR. CMS has deferred issuing additional guidance pending discussion with industry.
- We offer a choice of pharmacy networks that allow our Part D health plan sponsors to be competitive in the marketplace. Pharmacies are contracted at competitive discount rates and dispensing fees that are applied during claim adjudication at the point of sale. Some of our networks that are designed to encourage efficiency, accuracy and optimal patient outcomes have additional discounts and incentive payments that are based on metrics and comparison of performance to other pharmacies. These amounts cannot be determined at the point of sale. Our own Medicare Part D plan, SilverScript Insurance Company, will report these contingent amounts to CMS as DIR. We provide the information necessary for our clients to determine what and how to report to CMS.

9. Ms. Pons, at the hearing Ms. Bricker of ESI stated that pharmacies find out the total amount of their reimbursement at the point of sale or when the claim is adjudicated. However, we have heard from pharmacies about various fees that are very often collected from pharmacies after the point of adjudication. Currently CMS is working to provide further guidance as to how PBMs should report these undisclosed revenue streams they receive from pharmacies such as "network access fees," DIR fees, and "credentialing fees." This is necessary because how these price concessions are treated impacts beneficiary cost sharing, CMS payments to plans, Medicare plan finder data, federal reinsurance, and low income cost sharing and plan bids. CMS proposed guidance would require plans/PBMs to estimate these fees at the point of sale which would provide all parties, including pharmacies, greater insight into their actual reimbursement. The PBM industry has expressed opposition to this proposed guidance. Will you please explain why there is CVS Health and/or industry opposition? Also, how does your company currently report these fees?

CMS solicited input from industry regarding the types of discounts that cannot be determined at point of sale and suggested that the type of discount that could be included in the negotiated price at point of sale are amounts that can reasonably be approximated at the point of sale. Generally, the industry commented that reporting amounts that can be reasonably approximated at the point of sale would result in very few exceptions from negotiated price reporting because virtually all price concessions can be approximated to some degree at the point of sale. CMS subsequently issued a memo stating that they did not intend to eliminate the regulatory exemption from negotiated price reporting and, after consideration of the comments and to provide time to fully assess the various payment arrangements that sponsors have with pharmacies, determined not to finalize the proposed guidance for 2016. CMS stated that plans should evaluate what can be reasonably determined at the point of sale and include those amounts in the negotiated price, and those amounts that cannot be reasonably determined at the point of sale should be reported as DIR. We believe the ability to provide incentive payments to pharmacies rewards the best performing pharmacies without increasing drug prices for the beneficiary that would make the pharmacy less attractive to the beneficiary.

Please see the answer to Question 9 above in response to your second question

Question submitted for the Record from Representative Mike Bishop

1. How do you ensure that pharmacy owners with multiple stores are treated fairly and equitably- in the aggregate – if a technical issue is raised at one of their stores? For example, we understand that PBMs have language in their standard terms and conditions whereby a technical issue at one location gives them the right to terminate a relationship across all stores. This without cause/reason termination unfairly prejudices both the pharmacies and their patients which have nothing to do with the alleged issue.

We enter into provider agreements with network pharmacies that set forth the conditions for participation in our networks. Our agreement covers a number of important topics, such as credentialing and quality management, pharmacy services and standards, claims submissions and audits, as well as the pharmacy's rights in connection with an audit. Our agreement is intended to help ensure the safety of medications dispensed to our health plan sponsor's members, as well as helping to prevent financial harm to our health plan sponsor clients. If a pharmacy does not adhere to these standards, the agreement provides that a pharmacy can be terminated. We do not make termination decisions lightly. We generally terminate less than 1% of the network pharmacies in a year. It is not our practice to terminate a pharmacy from our networks, whether a single pharmacy or multiple pharmacies owned by the same owner, based on a "technical" issue.

**Response to Questions for the Record from Bradley J. Arthur, R.Ph.,
Owner, Black Rock Pharmacy**

Mr. Bradley J. Arthur, R.Ph.

Questions submitted for the Record from Subcommittee Chairman Marino

Both of the PBMs have testified that the independent pharmacy industry is doing well. Specifically, CVS testified that the number of independent pharmacies has grown more than 15% since 2002 and that profit margins have increased to 23% of revenues. Do you agree with that assessment?

The National Community Pharmacists Association (NCPA) strongly disagrees with the assertion that the number of independent pharmacies has grown by more than 15% since 2002. In fact, due to adverse market conditions, the net number of independent community pharmacies has fallen by 2,363 stores since 2000. Over 550 stores have closed in the past two years alone. The impact of pharmacy closures is most severely experienced in rural communities where approximately 1,800 independent community pharmacies serve as the sole pharmacy within a 10 mile radius. Adequate access to these pharmacies is vital to ensuring that underserved patients can continue to obtain their medication and healthcare needs. Furthermore, chain pharmacies choose not to fill the void because profitability is not high enough to warrant expansion.

On the issue of profit margins, The 2015 NCPA Digest reported that gross margin on average annual sales per pharmacy was 22.9%, a decrease from the 23.6% reported in 2005. However, on this metric it is important to understand that this figure includes sales of non-prescription or non-traditional prescription medications that help sustain the viability of community pharmacies in the wake of declining, even negative, margins from prescription drug reimbursement. Common examples include OTC and DME products, compounded prescriptions, and other services provided by the surveyed pharmacies. Compounding and DME require extensive expertise and time and therefore generally have higher gross margins. Unfortunately average annual sales have fallen from \$4M to \$3.62M between 2010 and 2014, reducing gross profit necessary to maintain operations and pay employee salaries.

If pharmacies continue to get reimbursed at levels below cost, can we expect independent pharmacies to start going out of business? What will be the impact on the pharmacy industry as a whole?

Generic medications are in many instances subject to maximum allowable costs (MACs) which is the most a pharmacy benefit manager (PBM) will reimburse for these medications. In many instances MACs are not keeping up with costs. Some of the more egregious examples provided by NCPA members include:

- A loss of \$329.41 on one script of a combination product used to treat blood pressure (amlodipine/valsartan 5/160 mg)
- A loss of \$253.72 on one script of the generic liquid version of the very common pain reliever Vicodin (hydrocodone/acetaminophen 7.5/325 mg/15 ml)
- A loss of \$169.64 on one script of a common medication used to prevent seizures (lamotrigine ER 200 mg)

These are just a few of the many examples provided to us, and are indicative of losses suffered by other independent pharmacies nationwide. These below-cost reimbursements are particularly harmful to independent community pharmacies because of the fact that virtually all revenue (93%) generated in these stores is derived from prescription sales. In comparison, only 67% of all revenues are derived from prescription sales in chain pharmacies.

Unfortunately, below cost reimbursement has exacerbated the problem of independent community pharmacy closures. As stated above, over the past two years the net number of independent community pharmacies has fallen by 551 stores. This number represents roughly 25% of the net total decrease in closures over the past 15 years.

These closures are a serious concern. More than any other segment of the pharmacy industry, independent pharmacies are often located in the underserved urban and rural areas that are typically underserved by chain pharmacies and other healthcare providers. In fact, independent pharmacies represent 52% of all rural retail pharmacies and there are over 1,800 independent community pharmacies operating as the only retail pharmacy within their rural communities.¹ In addition, independent pharmacies that serve these communities typically offer additional, “above and beyond” services to vulnerable patients including free medication delivery, unique medication compounding solutions and oftentimes immunizations in homes or other institutional settings.

¹ Based upon NCPA Analysis of National Council for Prescription Drug Programs (NCPDP) data, Rural/Urban Community Area (RUCA) Codes, and 2000 U.S. Census data.