

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**

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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.

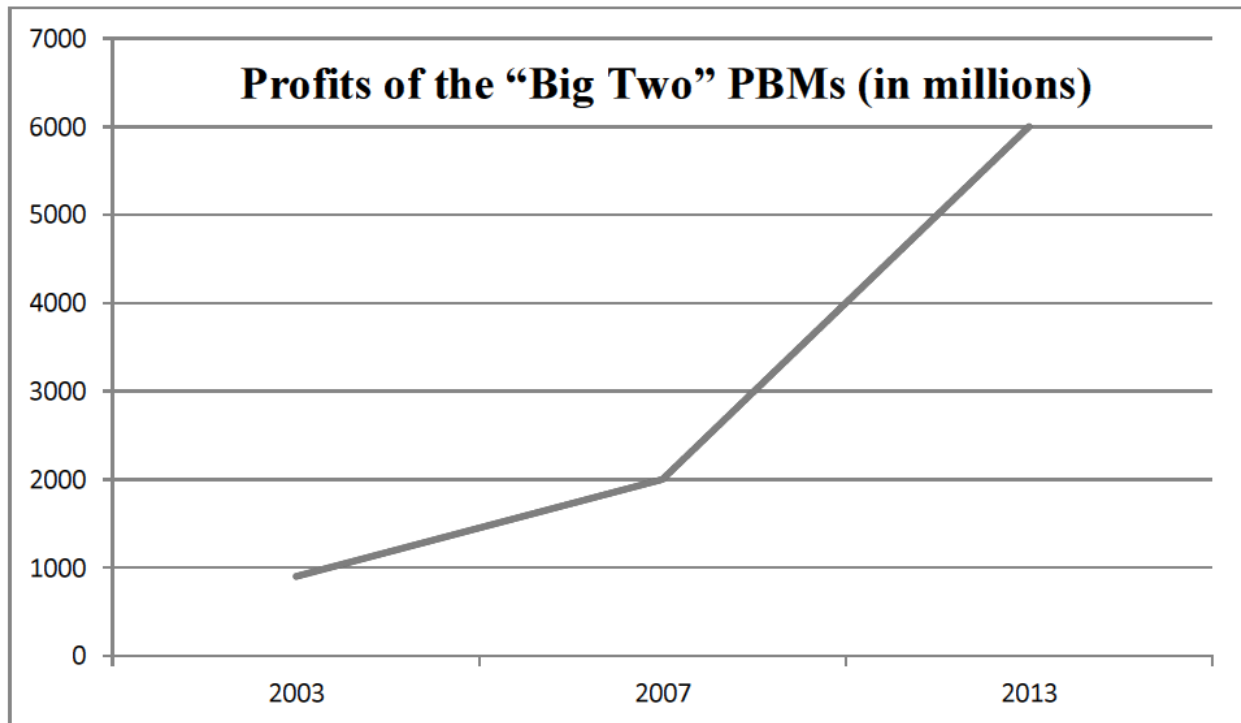
and the employer says “we just do what the PBM tells us to do.” No one takes responsibility or provides an answer. Who is there to protect the consumer?

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-%202011-2011.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/fdsys/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 Jaret, 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 prices 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.ESIMedci.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/exclusive-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.