Testimony of David A. Balto

Pharmacy Benefit Managers 101

Before the California Senate Committee on Business, Profession and Economic Development

March 20, 2017

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Senator Hill and other members of the Senate Committee on Business, Professions and Economic Development, I thank you for giving me the opportunity to testify today on the concern and regulatory opportunities in pharmacy benefit management 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. I have testified before Congress and fourteen 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 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.

We welcome this hearing as a good starting point. But for the PBM market to function properly for California residents 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.[1]

[1] 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

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.[2]

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 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, state regulation has increased. And while approximately half of the states have some form of legislation concerning PBM conduct, both increased state and federal regulation are necessary to reign in these practices.

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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).

[2] 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.

Similarly, consumers also care about rising health care costs, which are all too common these days, 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 largest retail and specialty 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. 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" 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 heath 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. That is why regulation is so necessary.

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.[3] 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.

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

[3] See, e.g., David Balto, How PBMs Make the Drug Price Problem Worse, The Hill (August 31, 2016), available at http://thehill.com/blogs/pundits-blog/healthcare/294025-how-pbms-make-the-drug-price-problem-worse.

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. PBMs are taing back arbitrary fees from pharmacies often months after adjudication – these fees are known as direct and indirect remuneration, or DIR fees. Some PBMs are using audits not just as a means of supposedly combating fraud but rather as a mechanism to secure greater revenue. Some PBMs rely on unfair and technical errors to withhold substantial funds from providers despite evidence that patients properly received dispensed medications. 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.[4]

These problems are only getting worse. Case in point are the number of recent cases which are either ongoing or have settled. In 2014, CVS alone was responsible for over $30 million in penalties concerning violations of the False Claims Act and SEC violations.[5] In 2015, Express Scripts and CVS 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] Currently pending before the Delaware federal district court is a False Claims Act violation 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

[4] 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-%201-2011.pdf.

[5] *See* Testimony of David A. Balto, "The State of Comeptition in the Pharmacy Benefits Manager and Pharmacy Marketplaces," before the House Judiciary subcom. On Regulatory Reform, Commercial and Antitrust Law, Appx. A (Nov. 17, 2015), http://dcantitrustlaw.com/assets/content/documents/testimony/PBM%20Testimony.Balto_November%2017%202015.Final.pdf.

[6] Id.

insurance programs by accepting undisclosed discounts from drug manufacturers and not passing on the savings to its clients, according to a recently amended complaint.[7]

Moreover, substantial private litigation is pending against major PBMs. For example, Optum Rx, has several separate suits filed against it. One by retail chain Kmart which alleged failure to pay reimbursements for dispensed drugs equating to $38 million in damages;[8] another by 55 independent pharmacies alleging illegal conduct serving to inflate patient costs while simultaneously underpaying pharmacies;[9] and several others filed in 2016 alleging that Optum is overcharging patients for prescription drugs and pocketing the overcharge.[10] Express Scripts is currently facing a $15 billion lawsuit by its largest client Anthem for overcharges for prescription drugs.[11] Additionally, Express Scripts is facing several antitrust conspiracy suits in which plaintiffs have 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. These cases have survived Express Scripts' motions to dismiss and one is set for a jury trial beginning in May 2018.[12]

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. Legislation is Vital to Inform Payors and Protect 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.[13] Finally, some large sophisticated health plans have negotiated for greater transparency.

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[7] *John Doe v. Medco Health Solutions Inc., et al.*, Case No. 1:11-cv-00684 (D. Del.).
[8] *Kmart Co. v. Catamaran Co.*, Case No. 2015-L-008290 (Ill. Ct. Cl. Aug. 31, 2015).
[9] *Albert's Pharmacy, Inc. et al v. Catamaran Corporation*, Case No. 3:15-cv-00290 (M.D. Pa. Feb. 9, 2015).
[10] *See, e.g, Stevens v. UnitedHealth Group, Inc. et al.*, Case No. 16-cv-03496 (D. Minn.).
[11] *Anthem v. Express Scripts*, Case No. 16-cv-2048 (S.D.N.Y.)
[12] *HM Compounding Services v. Express Scripts*, Case No. 14-cv-01858 (E.D. Mo.); *Precision RX Compounding, LLC et al. v. Express Scripts*, Case No. 16-cv-00069 (E.D. Mo.).
[13] *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.

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 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]."[14] 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."[15]

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.

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[14] 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.

[15] 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.

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.[16] 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.[17] 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 first year of its contract. Each of these examples demonstrates that disclosure can improve competition and reduce costs to plans and consumers.

This Committee should consider legislation to require transparency provisions to disclosure of PBM rebates and discounts.

V. 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 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

[16] Katherine Eban, *Painful Prescription*, Fortune Magazine (Oct. 10, 2013).
[17] Id.

specialty drugs.[18] 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, CVS Caremark and Optum 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, with a projected increase to $1.7 trillion in 2030.[19] The leading PBMs' specialty pharmacies account for over 50% of the specialty drug revenue in the United States.[20]

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.[21] 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 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

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[18] Laura Hines, *Soaring specialty drug prices leave patients seeking relief*, Houston Chron. (March 15, 2015).
[19] 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.
[20] Adam Fein, The Top 15 Specialty Pharmacies of 2016, Drug Channels (Feb. 22, 2017), http://www.drugchannels.net/2017/02/the-top-15-specialty-pharmacies-of-2016.html.
[21] 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.

pharmacy.[22] 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?"[23]

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 Committee 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.

VI. Proposed Legislation AB 315 Represents a Sound Approach to Regulating PBMs

At the outset we must recognize that the State of California has no regulatory body vested with the authority to regulate PBMs. The lack of a regulatory body is critical. As much as the State needs PBM regulation there must be an agency with jurisdiction to regulate. And that agency must be given the resources to fulfill its enforcement mandate.

The proposed legislation appropriately vests regulation of PBMs with the state Board of Pharmacy. The principal role of a state board of pharmacy or any professional licensing board in any state is that of consumer protection. The Board has the experience and expertise to fulfill the consumer protection provisions in the proposed legislation. Its members have significant expertise in drug dispensing and protecting privacy. It is responsible to ensure that all California consumers receive the highest level of service for drug dispensing.

Some may raise concerns about a Board of Pharmacy regulating PBMs because the Board includes pharmacists who may compete with the PBM. Those concerns are misplaced. There is no evidence that the Board of Pharmacy or any other state professional regulatory board has ever acted inconsistent with their duty to the public. Further, State boards of pharmacy deal on a daily basis with sensitive practitioner and consumer health information which they hold in

[22] Katie Thomas, Specialty Pharmacies Say Benefit Managers Are Squeezing Them Out, New York Times (Jan. 9, 2017), *available at* https://www.nytimes.com/2017/01/09/business/specialty-pharmacies-say-benefit-managers-are-squeezing-them-out.html.

[23] 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.

strict confidence. Moreover, if a Board member were found to be inappropriately using any of these data, that individual would be subject to significant legal consequences.

Consumers need a strong regulator of PBMs and that authority is best vested with the Board of Pharmacy. However, we believe the legislation should go further and provide an enforcement mechanism. Without an adequate enforcement mechanism, the Board of Pharmacy will be unable to reign in on abusive practices. The proposed legislation should contain a provision permitting individuals to remedy alleged violations of this legislation. This complaint process should involve an internal review and investigation as well as an appeals process to the Board.

VII. Conclusion

Consumers need greater protection from the egregious practices of PBMs. The Committee should consider the above 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.

I look forward to answering any questions.