

TESTIMONY OF DAVID BALTO TO MEMBERS OF THE VERMONT HEALTH AND WELFARE COMMITTEE AND THE HOUSE COMMITTEE ON HEALTH CONCERNING H. 97

FEBRUARY 26, 2015

I. Introduction and Expertise

Members of the Senate Health and Welfare Committee and the House Committee on Health and other distinguished legislators, I want to thank you for the opportunity to testify today on pending legislation H.97 and the need to regulate Pharmacy Benefit Managers (PBMs). My testimony today documents the compelling need for this legislation to protect consumers and regulation PBMs in Vermont. As I explain in my testimony the proposed legislation includes policies that are a sound approach in providing a regulatory framework to protect consumers and provide a more competitive marketplace.

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. At the FTC, I helped direct the first antitrust cases against PBMs. 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, twelve state legislatures and three times before the Department of Labor on PBM regulation, and was an expert witness for the State of Maine on its PBM legislation.²

My testimony explains why the proposed legislation is necessary to protect consumers and competition:

- PBMs are one of the least regulated sectors of the healthcare system. Vermont does not currently adequately regulate the conduct of PBMs. This legislation is vital to do so.
- PBMs engage in fraudulent and deceptive practices that are harmful to consumers. Further, the market is lacking the essential elements for a competitive market: (1) transparency, (2) choice and (3) a lack of conflicts of interest. All of these factors are lacking in PBM markets as my testimony describes.
- 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 profit by “playing the spread” -- failing to adequately disclose and pass on the compensation received (typically from manufacturers), or reducing reimbursement to pharmacies and pocket the difference. As a result PBM profits have skyrocketed. Over

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.

² The views expressed herein are my own and do not necessarily represent the views of any individual clients.

the last 10 years, the two largest PBMs— Caremark and Express Scripts—nearly more than quadrupled their annual profits from \$966 million to over \$6 billion.

- The lack of regulation provides a fertile environment for deceptive and fraudulent practices – in recent years the two major PBMs have settled a number of major cases brought by state attorneys generals resulting in over \$370 million in penalties and fines.
- Community pharmacy access is crucial for Vermont customers. Community pharmacies serve underserved populations, particularly in rural and low-income urban locations. For many consumers, the community pharmacy is the only accessible health care provider. Community pharmacies are particularly important for the elderly and disabled who rely on their services. Not only do community pharmacists dispense drugs, but they also provide vital counseling and health care services. Consumers lose when PBMs take advantage of community pharmacies and harm their viability.
- The proposed legislation properly increases transparency in generic drug reimbursement pricing (as explained below “MAC pricing”). PBMs manipulate MAC pricing to profit off of community pharmacies that do not know the basis of reimbursement and often are forced to dispense below cost. MAC pricing creates a spread between what pharmacies are reimbursed for and what plans believe pharmacies are receiving. The requirements of the legislation will help address PBMs “playing the spread and profiting at the expense of pharmacies and consumers. By requiring disclosure of MAC pricing, H.97 will help ensure Vermont consumers, plans and pharmacies do not pay more for generic drugs than they should.
- Consumers need to be protected from restrictive PBM networks that deny them choice and access. The proposed legislation will help to protect patient choice while also helping to eliminate 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.
- Vermont is a leader in sound health care reform. Much of the reforms at issue in this legislation are consistent with actions taken by Congress and other state legislatures and federal regulators. 16 states have enacted MAC transparency legislation. Including Vermont, seven states have introduced and are currently considering MAC legislation. Additionally, 33 states have enacted fair pharmacy audit legislation; and eight states have enacted patient choice legislation.

II. Problematic Conduct of PBMs: Background

The PBM market is highly concentrated, and has become even more so over the last few years with a number of mergers recently consummated. PBM contracting practices are complex and the markets are opaque. This provides a fertile environment for deceptive and fraudulent practices – in recent years the two major PBMs have settled a number of major cases brought by state attorneys generals resulting in over \$370 million in penalties and fines. The Vermont Attorney General played a leading role in bringing actions with penalties and fines against the PBMs. Additionally, the FTC and Department of Health and Human Services have brought cases against one of the largest PBMs, CVS Health, for deceptive pricing practices concerning Medicare Part D.

A. PBMs no longer serve as “honest brokers” and engage in a wide range of anticompetitive conduct.

PBMs entered the health care market as “honest brokers” or intermediaries between health care entities. Health plans and plan sponsors agree to a negotiated fee and contract with PBMs to administer drug claims and serve as a third-party broker with pharmaceutical manufacturers. PBMs can play an important function in health care markets by setting up pharmaceutical benefit networks and adjudicating pharmaceutical claims. However, the role of the PBM has evolved over time and increasingly PBMs have found sources of indirect compensation, and by failing to adequately disclose the compensation (typically from manufacturers), or engaging in misleading disclosures they are able to “play the spread” and pocket the indirect compensation.

Although PBMs offer a great deal of promise in terms of the potential to control pharmaceutical costs, there is a pattern of conflicts of interest, self-dealing and anticompetitive conduct, all of which ultimately means that consumers pay far more for drugs than necessary. The two dominant PBMs (i.e., CVS Caremark and Express Scripts),³ have been plagued with opaque business practices, limited market competition and widespread allegations of fraud. The facts are clear: while PBMs may well prove a necessary expedient in lowering the cost of healthcare, measures must be taken to ensure that they operate as they are supposed to.

The fundamental elements for a competitive market are transparency, choice and 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, there are agency relationships and securing adequate information may be difficult.⁴

Why are choice, transparency, and a lack of conflicts of interest important? It should seem obvious.

- **Meaningful alternatives.** Consumers need meaningful alternatives to force competitors to vie for their loyalty by offering fair prices and better services. This is especially true in highly concentrated markets, such as with PBMs. There has been tremendous consolidation among PBMs, so the largest PBMs (CVS/Caremark, Express Scripts and OptumRx) now have over 70% of the national PBM market. CVS and Express Scripts alone control between 80-90% of the large employer market, the market the FTC has traditionally used in evaluating PBMs.⁵
- **Transparency is necessary.** Transparency is necessary for consumers to evaluate products carefully, to make informed choices, and to secure the full range of services they desire.
- **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. In the PBM market, the service a PBM is supposed to provide is that of being an “honest broker” bargaining to secure the lowest price for drugs and drug dispensing services.

³ Medco Health Solutions, the largest PBM in the United States, was acquired by Express Scripts in 2012.

⁴ Testimony of David Balto, Before the House Judiciary Committee, Subcommittee on Courts and Competition Policy on H.R. 3596 (Oct. 8, 2009).

⁵ Commissioner Julie Brill, Letter to DOL ERISA Advisory Council (August 19, 2014).

When a PBM has an ownership interest in a drug company or a pharmacy chain, or has its own pharmacy dispensing operations, it is effectively serving two masters.

What is the result?

- **Enforcement Actions.** In the past decade, a coalition of over 30 state attorneys general, led by the Vermont attorney general, have brought several cases attacking unfair, fraudulent and deceptive conduct. **The major PBMs have been 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.** These cases listed below, resulted in over \$371.9 million in damages to states, plans, and patients so far.
 - United States v. Merck & Co., Inc., et.al – \$184.1 million in damages for government fraud, secret rebates, drug switching, and failure to meet state quality of care standards.
 - United States v. AdvancePCS (now part of CVS/Caremark) – \$137.5 million in damages for kickbacks, submission of false claims, and other rebate issues.
 - State Attorneys General v. Caremark, Inc. – \$41 million in damages for deceptive trade practices, drug switching, and repackaging.
 - State Attorneys General v. Express Scripts – \$9.5 million for drug switching and illegally retaining rebates and spread profits and discounts from plans.

And most recently in 2014 Express Scripts was served with two subpoenas from the attorneys general of New Jersey and Rhode Island concerning its relationship with drug makers who are accused of false claims and kickbacks in marketing of several drugs.⁶

- **Skyrocketing Profits.** As a result PBM profits have skyrocketed. Over the last 10 years, the two largest PBMs— Caremark and Express Scripts—nearly more than quadrupled their annual profits from \$966 million to over \$6 billion. CVS Caremark generated \$126.8 billion in revenues in 2013, while Express Scripts generated \$104.6 billion in revenues in 2013.⁷ CVS Caremark and Express Scripts rank as number 12 and 20, respectively, on the 2014 Fortune 500 list.⁸ And both CVS Caremark and Express Scripts' 2013 revenues exceed that of the largest U.S. drug manufacturer, Johnson and Johnson, by over \$30 billion.

III. MAC Pricing, The Spread and Effect on Retail Pharmacies

Critical importance of community pharmacies for Vermont consumers. For many consumers community pharmacy is the only accessible health care provider. Community pharmacies serve underserved populations, particular those in rural and underserved urban

⁶ Linda Moss, *Express Scripts Subpoenaed on Drug Contracts*, The Record (May 1, 2014), available at <http://www.northjersey.com/news/business/express-scripts-served-1.1005739?page=all>.

⁷ Adam Fein, Pembroke Consulting Analysis of 2014 Fortune 500 List (June 11, 2014), available at http://4.bp.blogspot.com/-tt8L7nu4BTU/U5hJ10wc_2I/AAAAAAAAAFsA/t3dMR8Dcng0/s1600/Drug_Channels_Companies_in_the_2014_Fortune_500_List.png.

⁸ Fortune 500 2014, Fortune Magazine, available at <http://fortune.com/fortune500>.

locales. Not only do community pharmacies dispense drugs but they also provide vital counseling services and healthcare advice, medication therapy management, and adherence monitoring. Access for pharmacies is crucial for Vermont consumers.

PBMs earn enormous profits by playing the spread with drug manufacturers -- negotiating rebates and discounts with drug manufacturers in exchange for promoting certain drugs on their preferred formulary or engaging in drug substitution programs. Now that branded drug growth has fallen PBMs have sought out new means of increasing profits and they have turned to profiting off community pharmacies.

PBMs negotiate contracts with pharmacies to determine how much the pharmacists will be paid for dispensing medication and providing services. Recently PBMs have begun to manipulate those reimbursement rates creating a new spread to play. PBMs often decrease reimbursement rates to pharmacies, particular for generic drugs and fail to disclose the decreased reimbursement rates, leading to substantial uncertainty for pharmacies. Pharmacies are often unaware of the reimbursement until long after the drug is dispensed. Often they find they have dispensed a drug at a loss. These tactics allow PBMs to generate more revenue by pocketing the spread between the cost they charge plans and the low reimbursement rate paid to pharmacies. PBMs treatment of pharmacy pricing decrease the ability of pharmacies to effectively compete, denying services to consumers.

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.⁹

A. Maximum Allowable Cost is the newest profit center for PBMs

With the substantial increase in available generic drugs on the market, the PBMs’ biggest profits no longer lie in maximizing rebates on brand-name drugs or shifting patients to higher-cost medications. Instead, they come from maximizing spreads on generics. Generic prices are typically set through lists of maximum allowable cost (“MAC”), which the PBMs establish. The PBMs may use multiple MAC lists to maximize spread, giving one set of prices to pharmacies and another to clients.

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 determining MAC lists or how the maximum prices are determined. Neither plan sponsors nor retail pharmacies are informed how products

⁹ David A. Balto, Compendium of Federal and State Litigation Regarding Pharmacy Benefit Managers (Jan. 2011), available at <http://www.dcantitrustlaw.com/assets/content/documents/PBM/PBM%20Litigation%20Updated%20Outline%20-%20201-2011.pdf>.

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.

Additionally, this clearly harms pharmacies. Pharmacies are often forced to dispense generic drugs below cost as a result of PBM MAC pricing. This leads to tremendous uncertainty of pharmacy pricing when pharmacies do not know what they will be reimbursed, making it substantially difficult to serve consumers.

B. Real World Example

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.¹⁰ 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.¹¹ 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. This example demonstrates that disclosure of MAC pricing can improve competition and reduce costs to plans and ultimately consumers.

IV. H.97 will protect consumers, pharmacies and health plans.

The lack of transparency surrounding MAC pricing, allow PBMs to engage in illicit conduct that harms consumers. H97 is a tremendous step in addressing this conduct.

A. H97

H97 will provide for greater transparency of the MAC paid to retail pharmacies by PBMs. The importance of this legislation cannot be understated. PBMs use arbitrary and opaque MAC pricing to derive record profits at the expense of independent pharmacies, plan sponsors and consumers. In addition to the lack of transparency surrounding MAC pricing, the PBM market is fraught with other deceptive and fraudulent conduct that has led to independent pharmacies being driven from the market and harm to consumers. This legislation is a prudent response to

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

¹¹ *Id.*

this significant market imbalance PBMs hold, and its enactment will benefit the consumers of Vermont.

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.

H.97 will address these problems by, inter alia, ensuring that MAC prices are not set below costs (market-based sources available); setting specific requirements of drugs to be included on MAC lists; regularly updating MAC lists so pharmacies understand the most current pricing, which changes frequently; and requiring a process to ensure pharmacies are able to receive MAC list drugs at fair market value. By requiring disclosure of MAC pricing, H.97 will help ensure Vermont consumers, plans and pharmacies do not pay more for generic drugs than they should.

B. Patient choice provision of H.97

I have focused mainly on the MAC provisions of H97. However the Choice of Pharmacy provision is vitally important to consumers.

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 retail 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.

H.97 helps preserve patient choice by limiting the ability of PBMs to mandate the pharmacy a consumer uses. This provision can play a crucial role in preserving patient choice. Additionally, the proposed legislation could help to prevent fraud and abuse by requiring that PBMs not impose differential cost-sharing requirements based on the pharmacy a patient chooses.

The major PBMs make a large portion of their profits by forcing Vermont consumers to use out of state 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.

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 that is particularly important for vulnerable and elderly patient populations who rely on community pharmacies, who often provide valuable services including home delivery. Additionally, many consumers in need of specialty pharmaceuticals rely on their community pharmacies for vital drug monitoring and counseling. 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 services of their local pharmacists, which can often be life-altering and significant to the most vulnerable patients.

C. Other transparency advocacy strongly supports the need for this legislation.

Because of the importance to consumers, there has been a great deal of attention surrounding transparency by other states as well as Congress.

Transparency is a somewhat ambiguous term, but in this context, David Calabrese in *Managed Care Executive* provides a useful definition:

Transparency is a form of business practice involving full disclosure of costs and revenues, allowing the customer to make more well-informed decisions regarding purchases. In the PBM industry, transparency lays the groundwork for more simplified PBM-client business relations, more accurate financial modeling and performance metrics and a greater comfort level among PBM consumers. 'Transparency,' however, is a relative term used freely in the marketing efforts of many PBMs. The genuine commitment to transparency lies in the actual business practices the PBM invokes to support this claim. 'True transparency' is a model in which all PBM revenue streams [drug-level rebates, funding of clinical programs, administrative fees, service fees, management fees, research/educational grants, etc.] are fully disclosed to the payer; the full value of retail and mail-order pharmacy discounts is passed onto the client; data is shared with the client; and the client is given ultimate decision-making control over its drug benefit design and formulary management. It is this commitment to true transparency which has begun to differentiate newer PBMs.¹²

16 states have enacted some form of MAC transparency requirements, and seven other states are considering such legislation in the 2015 sessions, including Vermont, Georgia, Hawaii and Kansas. 33 states have enacted fair pharmacy audit legislation, and eight states have enacted patient choice legislation. Even Congress and federal regulator have taken measures to enact transparency provisions by requiring some degree of disclosure of rebates and other revenue.

The most significant disclosure requirements are incorporated in The Patient Protection and Affordable Care Act of 2010.¹³ PPACA works to shine light on spread pricing and undisclosed manufacturer agreements by requiring additional data reporting from PBMs that manage

¹² Calabrese, David. *Managed Care Executive*. May 1, 2006.

¹³ I will discuss the transparency provisions under PPACA. However, Under the MMA, PBMs that serve Part D Plans are also required to disclose to HHS all manufacturer rebates and price concessions.

contracts under Medicare Part D or the state Exchanges. These PBMs must provide regulators with data on the percentage of all prescriptions that are provided through retail pharmacies compared to mail-order facilities and the generic dispensing rates for each type. PBMs must also submit the aggregate amounts and types of rebates and discounts or price concessions that the PBM negotiates on behalf of a plan. Importantly, PBMs must disclose how much of these rebates and discounts are “passed through” to the plan versus kept as company profits. In addition to this information, PBMs must also supply regulators with the aggregate difference between the amount paid by the plan and the amount the PBM pays the retail and mail-order pharmacy and number of prescriptions dispensed.¹⁴

And in May of 2014, the Centers for Medicare and Medicaid Services enacted final rules to the Medicare Part D Program which included the requirement that Part D plans and their PBMs make available to all contracted pharmacies the reimbursement rates for drugs under MAC pricing standards. This requirement will be effective for the 2016 contract year.

V. Summary

The transparency and patient choice provisions of H.97 will have a significant positive impact on Vermont consumers and the local pharmacies that serve these consumers. PBMs operate with little transparency and engage in deceptive practices such as drug switching and spread pricing. Without transparency, PBM profits will continue to rise exponentially at the expense of small business and patients. Broadening transparency requirements on PBMs will allow pharmacies to better ably serve their patients by being able to receive fair reimbursement. And patients will be better off having choice in the market and maintaining control over their own healthcare choices. Increasing the level of PBM transparency will foster competition among pharmacies as well as cost control within the PBM market, to benefit plans and ultimately to consumers.

¹⁴ PPACA. Title VI, Subtitle A, Section 6005.