Testimony of David A. Balto

Pharmacy Benefit Managers 101

Before the Maine Committee on Health Coverage, Insurance and Financial Services

April 24, 2019

David A. Balto
Law Offices of David A. Balto
8030 Ellingson Drive
Chevy Chase, MD 20815
202-577-5424
David.balto@dcantitrustlaw.com

Senator Sanborn, Representative Tepler, members of the Committee on Health Coverage, Insurance and Financial Services, thank you for giving me the opportunity to testify on the concerns and the need for regulation and accountability in the pharmacy benefit management ("PBM") market. My testimony documents the tremendous competitive and consumer protection problems in the PBM market and the need for stronger enforcement and legislation. LD 1504 is an important piece of consumer protection legislation that will help control and lower drug costs, ensure that drug rebates are used to lower healthcare and drug costs, and provide for greater enforcement than currently exists.

My testimony is based on my thirty 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 am a public interest antitrust attorney in Washington, D.C. I have represented consumer groups, health plans, unions, employers, and even PBMs on PBM regulatory and competitive issues. I led the successful consumer opposition to the proposed mergers of Anthem and Cigna and Aetna and Humana, and have worked with consumer groups on numerous health care competition and consumer protection issues. I have authored dozens of articles about problems in the PBM market,[1] have testified before Congress and fourteen state legislatures on the need for PBM regulation, and served as an expert witness for the State of Maine on its PBM legislation.[2] Recently we submitted comments on behalf of consumer groups to the Department of Health and Human Services in support of its proposed rule to eliminate safe harbor protection for most PBM rebates.

In my testimony I make the following points:

- PBMs are one of the least regulated sectors of the health care system. There is almost 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) consumer choice, and 3) a lack of conflicts of interest.

- The lack of enforcement, regulation, and competition has created a situation where PBMs freely engage in anticompetitive, deceptive, and fraudulent behavior that harms consumers, employers, unions, and pharmacists. The Council of Economic Advisors and many other commentators have found that the PBM market is not competitive and the result is that drug costs are inflated and PBM profits are skyrocketing. As drug prices

---

[1] PBM Watch: A Site Dedicated to Informing Consumers About Problems with Pharmacy Benefit Managers and Helping Identify Avenues to a More Transparent PBM Market, available at http://www.pbmwatch.com. Coalition to Protect Patient Choice, available at https://www.thecppc.com.

[2] *Pharma. Care Mgmt. Assoc. v. Rowe*, Case. No. 03-cv-153 (D. Me. 2005).

rapidly increase, 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 rebates from those cost increases. Plan sponsors cannot attack this problem because PBMs fail to provide adequate transparency.

- LD 1504 will help regulate PBMs and lower drug prices and health care costs. It will make markets work more effectively, ensure PBMs are well regulated, require that insurance companies receive the rebates that PBMs receive from drug manufacturers, and require the companies to use those savings to lower premiums for consumers.

We welcome this hearing as an excellent starting point. But in order for the PBM market to function properly for Maine residents, we need strong oversight, regulation, and greater antitrust and consumer protection enforcement.

Background

Rapidly increasing drug costs threaten our ability to control healthcare costs and ensure everyone has access to affordable, quality care. Unreasonably high costs for prescription drugs also threaten patient access to medicines, as some may choose to stop or delay treatment because they cannot afford it. Ensuring that patients can afford life-saving and life-managing prescription drugs is critically important to public health, because it will increase usage of necessary medications that help patients live longer and healthier lives.

Early last year the Administration put forward a blueprint on ways to lower drug prices which contained an in-depth discussion of PBMs. The report identified how a lack of transparency and competition in the PBM market, and conflicts of interest, result in higher drug costs. It observed that, "Because health plans, pharmacy benefit managers (PBMs), and wholesalers receive higher rebates and fees when list prices increase, there is little incentive to control list prices. Consumers, however, pay higher copayments, coinsurance, or pre-deductible out-of-pocket costs when list prices rise."[3]

Why are choice, transparency, and a lack of conflicts of interest important? It should seem obvious. Consumers need alternatives to force competitors to vie for their loyalty by offering fair prices and better services. Meaningful 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 – CVS Caremark, Express Scripts, and OptumRx – which control an approximately 85% share of the market. And PBM operations are very obscure and lack transparency making it difficult for plans, including government buyers, to determine whether they are getting the benefits they deserve.

---

[3] American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs, U.S. Department of Health and Human Services ("HHS"), May 14, 2018, pg. 17. Available at https://uspirg.org/sites/pirg/files/resources/Consumer%20group%20comments%20on%20HHS%20Blueprint%20--%207-16-18%20--%20FINAL.pdf.

These observations were supported by the White House Council of Economic Advisors (CEA) recent report on drug competition. CEA singled out PBMs as a competitively problematic market. They noted that pricing in the pharmaceutical drug market suffers from high PBM market concentration in the pharmaceutical distribution system and a lack of transparency:

- Three PBMs account for 85 percent of the market, which allows them to exercise undue market power against manufacturers and against the health plans and beneficiaries they are supposed to be representing, thus generating outsized profits for themselves (Sood et al. 2017).
- Over 20 percent of spending on prescription drugs was taken in as profit by the pharmaceutical distribution system (Sood et al. 2017).
- Policies to decrease concentration in the PBM market and other segments of the supply chain (i.e., wholesalers and pharmacies) can increase competition and further reduce the price of drugs paid by consumers (Sood et al. 2017).

The CEA concluded that this market failure "allows [PBMs] to exercise undue market power against manufacturers and against health plans and beneficiaries they are supposed to be representing, thus generating outsized profits for themselves."[4] Indeed, PBMs make larger profits than any other players involved in the drug supply chain (distributors, insurers, or pharmacies).[5] PBMs take advantage of a lack of transparency, misaligned incentives, and conflicts of interest. Ultimately this leads to higher drug costs.[6]

PBMs 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. Vertically integrated PBMs (PBMs that own their own pharmacies such as CVS Caremark or own their own mail order of specialty pharmacies) exercise their power to restrict consumers to their own captive mail order and specialty pharmacy operations, reducing choice and quality for many. Ultimately consumers pay more and are denied the vital relationship with their community pharmacist. Consumers and their health plans also suffer when health plans are denied the benefits of the PBMs' services as an honest broker,[7] which drives up drug costs, and ultimately

---

[4] Reforming Biopharmaceutical Pricing at Home and Abroad," The Council of Economic Advisors, White Paper, February 2018, at https://www.whitehouse.gov/wp-content/uploads/2017/11/CEA-Rx-White-Paper-Final2.pdf.
[5] *Hidden Profits in the Prescription Drug Supply Chain*, Charlie Grant, February 24, 2018, Wall Street Journal, at https://www.wsj.com/articles/hidden-profits-in-the-prescription-drug-supply-chain-1519484401.
[6] *Id.*
[7] PBMs were initially formed to be "honest brokers" intermediaries who entered into relationships with pharmacies and drug manufacturers to create networks and as intermediaries worked to keep pharmacies and manufacturers in line with their clients' interests. However, when a PBM also owns a pharmacy it has a conflict of interest and may no longer act as an honest broker. Indeed, there are many complaints that CVS Caremark uses its dual role as a PBM and a pharmacy to disadvantage rival community pharmacies. See *Pharmacy Middlemen Made $223.7 Million From Ohio Medicaid*, Kaitlin Schroeder, June 23, 2018, Dayton Daily News, at https://www.daytondailynews.com/news/pharmacy-middlemen-made-223-from-ohio-medicaid/JsPLtbs3wfKoBmaGbF9GrK/ See also *House and Senate Pass Legislation to Rein in Pharmacy Benefit Managers*, Benjamin Hardy, March 14, 2018, Arkansas Times, at https://www.arktimes.com/arkansas/house-and-senate-pass-legislation-to-rein-in-pharmacy-benefit-managers/Content?oid=15678012.

leaves consumers footing the bill for higher premiums.[8] Making matters worse is that PBMs are one of the least regulated sectors of the healthcare system.

Consumers care deeply about rising healthcare costs including out of pocket costs for prescription drugs. The market failure in the PBM market has a profound impact on drug costs. If PBMs remain 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 and health insurers. 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 the conflict since they are vertically integrated with health insurers, 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.

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

PBMs entered the health care market as "honest brokers" or intermediaries between health care entities. However, over time their role evolved and PBMs are increasingly able to "play the spread" by not sharing the savings they supposedly secure from drug manufacturers. As a result PBM profits have skyrocketed over the last dozen years. Since 2003, the two largest PBMs, Express Scripts/Medco and CVS Caremark, have seen their profits increase from $900 million to over $6 billion annually.[9]

Evidence is mounting that PBMs are exploiting both government and independent pharmacies. To give just one example: last year in Ohio, CVS sued the state to prevent the release of a report that illustrated how much of a spread CVS received from Ohio's Medicaid program. The report found that Ohio paid $223.7 million in hidden fees in a twelve month period due to spread pricing. Following the report, Ohio ordered its managed-care plans to end their spread pricing contracts for 2019.[10]

---

[8] Often health plans, pharmacies, and large employers are silent about PBM misbehavior because of fears 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 they feared retaliation from the large PBMs with whom they must do business." Statement of U.S. Senator Herb Kohl on the Express Scripts/Medco merger (12.6.2011).

[9] "Reforming Biopharmaceutical Pricing at Home and Abroad." The Council of Economic Advisors, White Paper, February 2018.

[10] *The Secret Drug Pricing System Middlemen Use to Rake in Millions.* Robert Langreth, David Ingold, and Jackie Gu. Bloomberg, September 11, 2018. At https://www.bloomberg.com/graphics/2018-drug-spread-pricing/?srnd=premium.

If the market were competitive and there was adequate transparency, we would expect profits and margins to be driven down. But as PBM 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 harm patients, increase costs for federal and state health programs, and threaten our nation's ability to control the cost of health care. While PBMs claim they control drug costs, these claims must be carefully scrutinized. A PBM's goal 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.[11] 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 $7.00 in 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 state enforcers have attacked sweetheart deals PBMs arranged with drug manufacturers to force consumers to use higher cost, less efficacious drug, in order to maximize rebates and secure kickbacks. 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.[12] They held back their negotiating muscle to allow prices to escalate to maximize rebates.

Facing weak transparency and oversight standards, the largest PBMs often engage in a variety of deceptive and anticompetitive conduct that ultimately harms and denies benefits to consumers. They secure rebates and kickbacks from drug manufacturers in exchange for exclusivity 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. 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.

This "spread pricing" leads to higher costs for plan sponsors and consumers. 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,

---

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

[12] See 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, Appx. A (Nov. 17, 2015), at https://docs.house.gov/meetings/JU/JU05/20151117/104193/HHRG-114-JU05-Wstate-BaltoD-20151117.pdf.

PBMs can generate more revenue. This behavior results in higher costs for consumers, health plans, employers, and other plan sponsors.

These rebates have more than doubled to $153 million in the last five years.[13] How much of these rebates and other discounts were actually passed on to consumers? PBMs claim that the vast majority are passed on, but they refuse to disclose in-depth information on the rebates, and what we do know is that consumers' out-of-pocket costs are going up. Ensuring that rebates actually benefit consumers would dismantle the incentive structure that has perversely encouraged PBMs to negotiate for higher list prices and to choose medications that are more expensive for consumers.

As Health and Human Services Secretary Alex Azar has highlighted, the PBM rebate system exacerbates the conflicts of interest, which leads to inflating the list prices of prescription drugs, ultimately making consumers pay more. In an interview, Secretary Azar spoke about how "we have to fundamentally examine and re-examine the role of pharmacy benefit managers."[14] As the state auditor's office notes, prescription drugs make up 20 to 30% of Montana's insurance costs and are the fastest growing cost in insurance plans.

Proposed Legislation LD 1504 Represents a Sound Approach to Regulating PBMs

LD 1504 would regulate health insurers' administration of pharmacy benefits for consumers, indirectly combat PBM abuses, ensure that drug manufacturer rebates received by PBMs get passed on to health insurers with the goal of lowering premiums to consumers, and provide for good enforcement mechanisms.

To begin with, LD 1504 requires PBMs to obtain a license from the Superintendent beginning on January 1st, 2020, and that this license must be renewed every three years. The Superintendent may suspend or revoke the license if the PBM engages in fraudulent activity or fails to comply with requirements, or if the Superintendent receives consumer complaints. This is the most basic regulation of PBMs, but it is vital that PBMs be clearly subject to authority and robust oversight.

The bill then states that insurance companies will henceforth be responsible for monitoring all activities carried out by PBMs that they contract with, and that they cannot enter into contracts with PBMs that prohibit pharmacies from letting consumers know if it is cheaper to pay for prescription drugs without insurance than by using their insurance. It also prohibits insurance companies and PBMs from requiring consumers to pay for more for a covered prescription drug than the applicable copayments for the drug, or the amount from the pharmacy will be reimbursed by the PBM or insurance company. These provisions ensure that insurance companies will hold PBMs accountable, and they will benefit consumers by combating price gouging and help lower costs.

---

[13] *The Gross to Net Bubble Topped $150 Billion in 2017.* Adam Fein, Drug Channels, April 24, 2018, at https://www.drugchannels.net/2018/04/the-gross-to-net-rebate-bubble-topped.html.

[14] Secretary Alex Azar Interview on CNBC's Squawk Box, May 11, 2018 at https://www.cnbc.com/2018/05/11/azar-says-everybody-is-wetting-their-beak-on-high-drug-list-prices.html.

Most importantly, LD 1504 requires all compensation (i.e. rebates and discounts) that PBMs or insurance companies receive from drug manufacturers to go to insurance companies, who must use it to lower health insurance premiums and costs. And starting on March 1, 2021, insurance companies must file annual reports with the Superintendent demonstrating how they have complied with these requirements. Insurance companies and PBMs are also required to avoid conflicts of interest, publicly display their formularies to covered persons, and keep accurate records of their data on the administration and provision of prescription drug benefits.

It is a unique approach, but the Montana legislature recently passed a similar bill, SB 71, that also requires rebates be used to lower premiums for consumers. We submitted testimony in support of that bill as well.[15]

Conclusion

Consumers need greater protection from the deceptive, anticompetitive, and egregious practices of PBMs. The Committee should support LD 1504 to ensure that manufacturer rebates are passed on to health insurers, which should result in lower health care costs and prescription drug prices for consumers. Justice Louis Brandeis wrote that states may serve as laboratories of democracy. I urge the Committee to pass this bill as it will further restrict PBMs' abilities to engage in spread pricing, which will result in consumers gaining access to more affordable drugs.

I look forward to answering any questions.

David Balto
David.balto@dcantitrustlaw.com
202-577-5424
Law Offices of David Balto
8030 Ellingson Drive
Chevy Chase, MD 20815

[15] Testimony of David A. Balto, "Pharmacy Benefit Managers 101," before the Montana Senate Business, Labor, and Economic Affairs Committee. February 1st, 2019.