Testimony of David A. Balto

Pharmacy Benefit Managers 101

Before the Minnesota Finance Committee

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Chair Rosen, Vice Chair Ingebrigtsen, and members of the Finance Committee, 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. SF 278 is an important piece of consumer protection legislation that will help lower drug costs, ensure that PBMs are properly regulated and held accountable, 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.

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 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.

- SF 278 will help regulate PBMs and lower drug prices for patients. It will require PBMs to be licensed by the Commissioner of Commerce and to have a fiduciary duty to their health plans. The bill also requires PBMs to provide an adequate and accessible

[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.

pharmacy network that provides access to pharmacies within a reasonable distance from a patient's residence, and to disclose ownerships interests that PBMs have with pharmacies. Finally, SB 278 limits PBMs from requiring patients to get their drugs exclusively from PBM-owned pharmacies and requires PBMs to report information annually.

We welcome this hearing as an excellent starting point. But in order for the PBM market to function properly for Minnesota 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.

Last year in May 2018 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."[2]

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.

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:

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[2] 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.

- 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."[3] Indeed, PBMs make larger profits than any other players involved in the drug supply chain (distributors, insurers, or pharmacies).[4] PBMs take advantage of a lack of transparency, misaligned incentives, and conflicts of interest. Ultimately this leads to higher drug costs.[5]

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,[6] which drives up drug costs, and ultimately leaves consumers footing the bill for higher premiums.[7] Making matters worse is that PBMs are one of the least regulated sectors of the healthcare system.

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[3] 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.

[4] *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.

[5] *Id.*

[6] 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.

[7] 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).

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.[8]

Evidence is mounting that PBMs are exploiting both state governments 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, the state ordered its Medicaid managed-care plans to end their spread pricing contracts for 2019.[9] And just last month, Ohio Attorney General Dave Yost announced he is seeking almost $16 million in repayment from OptumRx for overcharging the Bureau of Workers’ Compensation for failing to pass along discounts for generic drugs.[10]

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.

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

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

[10] Ed Silverman. “Ohio Seeks $16 Million From UnitedHealth’s PBM For Overcharging on Drugs.” STAT News, February 19, 2019. Available at https://www.statnews.com/pharmalot/2019/02/19/ohio-unitedhealth-pbm-drug-prices/.

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.

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."[13]

Proposed Legislation SF 278 Is an Important Step Toward Regulating PBMs and Lowering Drug Costs

SF 278 requires that starting on January 1st, 2020, all PBMs must be licensed by the Commissioner of Commerce. Within thirty days of receiving the application, the Commissioner can require additional information from applicants. The licenses are valid for three years and can be revoked if PBMs engage in fraud, fail to comply with regulations, or are the cause of consumer complaints. The Commissioner can also fine the PBMs, and they are required to have a fiduciary duty to the health plans. These are the most basic regulations of PBMs; it is important that they be subject to oversight, and that regulators be on the lookout for fraud and abuse.

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[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.

[13] 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.

Second, the bill requires PBMs to provide "adequate and accessible" pharmacy networks for providing prescription drugs at pharmacies that are a reasonable distance from people's residences. The networks have to include enough pharmacies so that consumers can get services without unreasonable delays, and the PBMs must submit reports on the networks to the Commissioner.

Third, PBMs must disclose certain information to their plan sponsors when they request it, and report much of this information annually to the Commissioner. This information includes: 1) the aggregate wholesale costs from drug manufacturers for prescription drugs, 2) the aggregate amount of rebates the PBMs receive by therapeutic category of prescription drugs, 3) the aggregate amount of rebates that the PBMs get from drug manufacturers, and 4) the aggregate amount of rebates that they retain and do not pass on to plan sponsors. This information is a very welcome step toward lowering drug prices and determining what PBMs do with their rebates. PBMs claim they are reducing drug prices and passing rebates on to consumers, but they fight transparency at every turn. Without information and transparency, it is almost impossible to determine where the money in the drug supply chain is going.

SF 278 also contains other good provisions. It requires PBMs that have ownership interests in pharmacies to disclose to their plan sponsors any difference in the amount paid to that pharmacy and the amount charged to the plan sponsor. It prohibits PBMs from owning mail order or specialty pharmacies unless they agree to fair competition and establish a firewall between the administrative functions and the mail order or specialty pharmacies. The bill also prohibits PBMs from requiring pharmacies to dispense equivalent drugs that cost more than prescribed drugs, unless the switching is needed for medical reasons and benefits patients. Finally, it prohibits "gag clauses" and prohibits PBMs from preventing pharmacies from telling consumers any information about drug costs, especially when paying out-of-pocket is more affordable than paying under health plans.

Conclusion

Consumers need greater protection from the deceptive, anticompetitive, and egregious practices of PBMs that contribute to rising drug costs. The Committee should support SF 278 to regulate PBMs, obtain needed information, and ensure that PBMs fulfill their duty of lowering drug prices. As Justice Louis Brandeis wrote, states may serve as laboratories of democracy and successful policies in one state can be observed and adopted by other states. I urge the Committee to pass this bill as it is an excellent step toward comprehensive PBM regulation and accountability, and will help lower prescription drug costs.

I look forward to answering any questions.

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