

Comments of David A. Balto on behalf of Consumer Action: Pharmacy Benefit Managers and Their Contribution to Rising Drug Prices

**Submitted to the Federal Trade Commission
December 6, 2017**

Thank you for giving us the opportunity to comment on competition issues and prescription drug markets. Our comments document the widespread and systemic competition and consumer protection problems in the pharmacy benefit manager (PBM) market and how PBMs contribute to higher drug prices. They are submitted on behalf of Consumer Action.

These comments are 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 testified numerous times before Congress, the Department of Labor, and state legislatures on PBM regulation and competition issues. Most recently, I testified in favor of bills to regulate PBM conduct in Hawaii, California, and North Dakota.

My comments make the following points:

- PBMs are one of the least regulated sectors of the health care system. There is very little federal regulation and only modest state regulation, which contributes to higher drug prices.
- The PBM market lacks the vital 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 greatly contribute to higher drug prices and harm consumer access and quality of care. As drug prices continue to skyrocket. The system incentivizes PBMs to promote more costly drugs.

We welcome this workshop as an excellent starting point. But for PBMs to truly contribute to lowering drug prices, we need strong oversight, regulation, and greater antitrust and consumer protection enforcement from the FTC and other authorities.

I. Background

PBMs are one of the least regulated sectors of the healthcare system. Because there is very limited federal regulation, recognizing the need for oversight, state regulation of PBMs has increased over the last few years. Approximately half of the states have some form of legislation concerning PBM conduct, but increased federal regulation is needed to ensure they are held accountable.

PBMs were originally formed in the late 1960s, initially to assist with processing claims. Insurance plans were offering prescription drug benefits and PBMs filed out the paperwork, ensuring that reimbursements were passed along to pharmacies. Over time, PBMs portrayed themselves as cost-reducers who could form large patient networks, negotiate discounts from drug companies and pharmacies, and pass savings through to health plans and consumers. They claimed to be honest brokers and simple intermediaries between the health care entities.

But today's reality is very different. Three PBMs—Express Scripts, CVS/Caremark, and OptumRx—control at least 75% of the market share for prescription drug access and around 180 million prescription drug customers. In 2016, CVS Health (the parent corporation of CVS/Caremark) was ranked #7 in the Fortune 500 rankings, with revenues of \$177.5 billion. And Express Scripts was ranked #22 in the Fortune 500 rankings, with revenues of \$100.3 billion.

PBM profits have increased at an exponential rate since the early 2000s. According to one report, Express Scripts's adjusted profit per prescription has gone up 500% since 2003. Moreover, there is a distinct lack of transparency in the PBM market, so it is almost impossible to determine whether PBMs are, in fact, reducing drug prices. Market-based evidence suggests the opposite.

II. Problems in the PBM Market

As a former antitrust enforcer I know there are three essential elements for a competitive market: 1) transparency, 2) choice, and 3) lack of conflicts of interest. These elements are especially important when dealing with health care intermediaries such as PBMs and health insurers where information is often difficult to access and arrangements are complex and opaque. **On all three of these elements, the PBM market receives a failing grade.**

Consumers require meaningful alternatives to force competitors to contest for their business by offering good prices and better services. Transparency is necessary for consumers to evaluate products carefully, to make informed choices, and to get the full range of services they want.

The PBM market falls flat in both areas. As previously mentioned, Express Scripts, CVS/Caremark, and OptumRx control approximately 75% of the market for

prescription drug access. That means roughly two-thirds of all Americans who have a drug benefit through an insurance plan or an employer-sponsored health plan are beholden to one of these companies in order to obtain their prescription drugs. And PBM operations are very obscure. A lack of transparency makes it difficult for plans, including government buyers, to make sure they are getting the benefits they deserve. This situation enables PBMs to enjoy multiple hidden revenue streams from other players in the healthcare system. PBMs receive rebates from drug companies as a condition of putting their drugs on the formularies, but they are under no obligation to disclose those rebates to health plans or pass them along to patients. Health plans have no way to obtain drug-by-drug cost information to know if they are getting discounts or savings.

Additionally, substantial conflicts of interest arise in the PBM market. As PBMs are largely unregulated they can easily engage in conduct that is deceptive and anticompetitive. For this system to work effectively, PBMs must be free of the conflicts of interest that arise from them owning their own pharmacies. Health plans and employers want to purchase the services of an honest broker to secure the lower prices and best services from drug manufacturers and pharmacies. When PBMs are owned by the entities they are supposed to bargain with or possess their own mail order pharmacies, there is an inherent conflict of interest, which often leads to fraud, deception, anticompetitive conduct, and higher prices. The three largest PBMs clearly face that conflict because 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.

And when PBMs have ownership interests in their own mail order and specialty pharmacies, they are effectively serving two masters and can no longer be honest brokers. There are also a host of competitive problems. Who effectively monitors and audits company-owned pharmacies? What if the PBMs use their pharmacy chains to disadvantage rival pharmacies, reduce reimbursements, and exclude pharmacies from networks? Ultimately consumers lose through less choice and higher prices.

III. How PBMs Contribute to Higher Drug Prices

The problem of rising drug prices is well known and needs no introduction. In 2015 Americans spent \$425 billion on prescription drugs.¹ And PBMs have a profound impact on drug costs. The rapidly increasing drug costs effectively lead to higher rebates for the PBMs, and this raises questions as to which master the PBMs are serving.

A substantial portion of PBM revenue is derived from rebates paid to PBMs by drug manufacturers for placement of their products on the PBMs' formulary.

¹ Peter Loftus, *U.S. Drug Spending Climbs*, Wall Street Journal, April 14, 2016, <https://www.wsj.com/articles/u-s-drug-spending-climbs-1460606462>.

Formularies are lists of reimbursable drugs from the PBMs network. If a drug is not on a PBM's formulary, the PBM does not receive a rebate from the drug manufacturer for the processing of that drug. Consequently, PBMs often reject pharmacy claims for non-formulary drugs or alternatively require the patient to pay more out of pocket for the non-formulary drug. As a result, when a PBM misses a rebate, the patient loses out by paying more out of pocket. This notion certainly cannot be how PBMs claim to reduce drug costs and save patient money. Rather, controlling the formulary gives PBMs a crucial point of leverage over the system, which they use to extract supra-competitive profits. **There is increasing evidence that PBMs place drugs on their formularies based on how high of a rebate they can extract from the drug manufacturer, instead of the lowest cost and what is most effective for patients.**

While PBMs claim they control drug costs, these claims must be carefully scrutinized. PBMs seek to maximize profits, and that means maximizing the amount of rebates they receive. Since rebates are not disclosed (again, due to the lack of transparency discussed above), this is an extremely attractive source of revenue. PBMs can actually profit from higher drug prices, since this will lead to higher rebates.² The gross profit the major PBMs reap on each prescription they cover is increasing year after year. For example, Express Scripts' gross profit on an adjusted prescription went up from an average of \$4.16 in 2012 to \$6.68 in 2015 to \$7.00 in 2017. In other words, its gross profits have increased by almost 75% since Express Scripts acquired its biggest rival Medco in 2012.

And PBMs have withheld their negotiating power in order to secure higher rebates and promote the use of more expensive drugs. State enforcers have attacked deals that PBMs strike with drug manufacturers to force consumers to use higher cost, less efficacious drugs, in order to maximize rebates and get greater profits.³

IV. The PBM market is not competitive and plans and consumers are paying far more than they should.

The largest PBMs engage in a wide range of deceptive and anticompetitive conduct that ultimately harms consumers and denies them access to affordable medicines. For such evidence, one does not need to look beyond the \$400 million plus in fines

² 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>.

³ 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), http://dcantitrustlaw.com/assets/content/documents/testimony/PBM%20Testimony.Balto_November%202017%202015.Final.pdf.

levies on the top three PBMs over the past decade, or the litany of existing litigation against the major PBMs. For example, some PBMs secure rebates and kickbacks from drug manufacturers in exchange for arrangements that keep lower priced drugs off the market. PBMs also switch patients from prescribed drugs to more expensive drugs to obtain high rebates from drug manufacturers. PBMs often do not pass through to payors rebates secured from drug manufacturers, and instead they are accounted for as a reduction in the cost of revenues, allowing PBMs to hide their profits. In fact, Medco was the last PBM to publicly disclose rebates in 2012.

Drug companies invest in research and development to bring innovative prescription drugs to market, ideally for the betterment of patients' health and wellbeing, all while taking substantial financial risks. By contrast, PBMS conduct no research, make no medicines, and take very little risk. They are just middlemen who are increasing costs to the fragile healthcare system.

V. Legislation and Solutions

The provision of transparency for consumers, businesses, and regulators is substantially important. Transparency helps these stakeholders adequately evaluate products and determine whether drug prices are really being reduced. Transparency has been a fundamental failure in the PBM market. PBM contracting and pricing practices are very obscure. Accordingly, it is almost impossible to determine whether PBMs are actually reducing drug prices.

Some states and Congress have taken measures to enact transparency provisions by requiring disclosure of rebates and other PBM revenues. In an enforcement action against CVS, thirty State Attorneys General required rebate disclosure. And in 2014 the Department of Labor recommended PBMs have to disclose fees and compensation to sponsors of ERISA health plans.⁴

In March 2017, Senator Ron Wyden (D-OR) introduced S. 638, the Creating Transparency to Have Drug Rebates Unlocked (C-THRU) Act. This bill has several provisions:

- It would require greater transparency of the rebates and discounts that PBMs negotiate and the percentage of these rebates and discounts that gets passed on to health plans.

⁴ 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>

- It would require greater transparency of the PBM practice called spread pricing (the difference in payments made by PBMs to pharmacies compared to the payments that PBMs get from health plans).
- It would require this information, aggregated by PBM, to be posted on the Center for Medicare and Medicaid Services's website. Consumers and employers could see whether PBMs are actually bringing down prescription drug costs as they claim.
- The bill would also require that after two years of this public reporting, a minimum percentage of rebates and discounts must be passed on from PBMs to health plans. This will lower premiums, prescription drug costs, and other cost-sharing amounts paid by patients.

Businesses, consumer groups, and healthcare providers support the C-THRU Act, which is a modest measure intended to promote transparency and ensure that savings are being passed on to consumers. Yet PBMs are fiercely opposing the bill, despite their assurances that they reduce drug prices and pass the savings on to patients.

VI. Conclusion

Regulators must take action to ensure that PBMs truly lower drug prices and pass the savings on to consumers, and consumers need greater protection from PBM abuses. The Federal Trade Commission should:

- Promote competition and entry in PBM markets;
- Investigate and file suit against anticompetitive mergers and acquisitions;
- Come out in support of the C-THRU Act;
- Encourage state legislation to regulate PBMs and ensure that they are held accountable and lower drug costs.

Please do not hesitate to contact us if you have any questions.

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