

Statement for the record:

**DEVELOPMENTS IN THE PRESCRIPTION DRUG MARKET:
OVERSIGHT**

Before the Full House Committee on Oversight and Government Reform

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Dear Chairman Chaffetz, Ranking Member Cummings, and Members of the Committee,

Please accept this statement for the record. The following statement documents substantial concern over pharmacy benefit managers and the lack of market transparency, which is a concern of this Committee and part of today's hearing.

I write the below statement based on my expertise 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. I have testified before Congress and eleven state legislatures on PBM regulation, and was an expert witness for the State of Maine on its PBM legislation.

PBMs have a profound impact upon drug costs. If PBMs are unregulated, which they mainly are, they can continue to engage in conduct that is deceptive, anticompetitive, and egregious. For the healthcare 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 second largest retail 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.

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, 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.

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. 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, 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.

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 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.

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.¹

These problems are only getting worse. Case in point are the number of recent cases which are either ongoing or have settled in 2015. In 2015 alone, Express Scripts and CVS have

¹ 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-%20201-2011.pdf>.

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.² In 2014 CVS was responsible for over \$30 million in penalties concerning violations of the false claims act and SEC violations.³ And currently pending before the Delaware federal district court is a false claims act 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 insurance programs by accepting undisclosed discounts from drug manufacturers and not passing on the savings to its clients, according to a recently amended complaint.⁴

Moreover, substantial private litigation is pending against major PBMs. For example, Catamaran Rx, a recent acquisition of Optum Rx, has several separate pending suits against it. One by retail chain Kmart alleging failure to pay reimbursements for dispensed drugs equating to \$38 million in damages;⁵ and the other by 55 independent pharmacies alleging illegal conduct serving to inflate patient costs while simultaneously underpaying pharmacies.⁶ Additionally, Express Scripts is facing an antitrust conspiracy suit in which the plaintiff has 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. The case has survived a motion to dismiss.⁷

As a general matter it is essential to provide transparency in the healthcare sector, which helps all participants 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, including the federal government, 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.⁸

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.

² See Appendix A.

³ Id.

⁴ *John Doe v. Medco Health Solutions Inc., et al.*, Case No. 1:11-cv-00684 (D. Del.).

⁵ *Kmart Co. v. Catamaran Co.*, Case No. 2015-L-008290 (Ill. Ct. Cl. Aug. 31, 2015).

⁶ *Albert's Pharmacy, Inc. et al v. Catamaran Corporation*, Case No. 3:15-cv-00290 (M.D. Pa. Feb. 9, 2015).

⁷ *HM Compounding Services v. Express Scripts*, Case No. 14-cv-01858 (E.D. Mo.).

⁸ 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>.

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.

In considering the role of PBMs in negotiating drug prices and concerns about the lack of transparency in pricing contracts we remind the Committee that where transparency and consistency are absent there is a significant opportunity for providers and plan sponsors to be harmed by deceptive and unfair conduct.

Thank you for your consideration of this statement.