

DAVID A. BALTO

ATTORNEY AT LAW
1325 G STREET, NW
SUITE 500
WASHINGTON, DC 20005

PHONE: (202) 577-5425
Email: david.balto@dcantitrustlaw.com

February 10, 2017

Sen. Ronald D. Kouchi
Hawaii State Capitol
Room 409

Sen. Rosalyn H. Baker
Hawaii State Capitol
Room 230

Sen. Stanley Chang
Hawaii State Capitol
Room 223

Re: Senate Bill 1158

Dear Senators:

Thank you for the opportunity to submit this letter on S.B. 1158, a bill relating to pharmacy benefit managers (PBMs) and the requirement for registration to do business within the state of Hawaii. Such a measure is a good step in protecting Hawaiian consumers as well as pharmacy providers from inconsistent and unfair practices by PBMs.

The comments in this letter are based on 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. I have represented consumer groups, health plans, unions, employers, and even PBMs on PBM regulatory and competitive issues. I have testified before Congress, numerous 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.¹

The following explains the problematic conduct of PBMs and the necessity of this regulation to protect consumers, health care providers and competition.

Background

PBMs increasingly 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. PBMs exercise their power to restrict consumers to the PBM’s own captive mail order and specialty pharmacy operations, reducing choice and quality for many. Consumers and their

¹ The views expressed herein are my own and do not necessarily represent the views of any individual clients. I operate a website www.pbmwatch.com which provides resources on PBM issues.

health plans also suffer when health plans are denied the benefits of the PBMs' services as an honest broker, which drives up drug costs, and ultimately leaves consumers footing the bill for higher premiums.

PBMs are able to get away with such conduct because they are the least regulated sector of the healthcare industry. With free reign, absent accountability to consumers and health care providers, PBMs can continue to engage in conduct that is deceptive, anticompetitive, and egregious.

PBMs are like other healthcare intermediaries that manage transactions by forming networks and transferring information and money. As a former antitrust enforcer, I can tell you that there are three essential elements for a functioning competitive market: (1) transparency, (2) choice and (3) 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, arrangements are complex and clouded in obscurity, and there may be principal-agency problems. On all three of these elements the PBM market receives a failing grade.

Why are choice, transparency, and a lack of conflicts of interest important? It should be obvious. Consumers need meaningful alternatives to force competitors to vie for their loyalty by offering fair prices and better services. 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 (Express Scripts, CVS Caremark and Optum) which have an approximate 80% share of the market. And PBM operations are very obscure and a lack of transparency makes it difficult for plans, including government buyers, to make sure they are getting the benefits they deserve.

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. The service a PBM provides is that of being an "honest broker" bargaining to secure the lowest price for drugs and drug dispensing services. When a PBM has an ownership interest in a drug company or has its own mail order or specialty pharmacy dispensing operations, it is effectively serving two masters and may no longer be an "honest broker."

Moreover, when a PBM has its own pharmacy operations there are a myriad of competitive problems. Who will effectively monitor and audit the company-owned pharmacies? A pharmacy chain can use its PBM affiliate to disadvantage rival pharmacies, reducing reimbursement, and excluding pharmacies from networks. What about competitively sensitive information such as prices and costs? Where a pharmacy knows its rivals costs and pricing, it does not have to compete as hard. Ultimately consumers lose through less choice and higher prices.

The rapidly increasing drug costs which effectively lead to higher drug rebates for the PBMs leads one to question which master the PBM is serving. It increasingly appears that PBMs profit from higher drug prices, because they lead to higher rebates.

Competition and choice are crucial for a market to work effectively. Hawaii residents should have the choice in how they value pharmacy services. Some choose community pharmacies, others who value one-stop shopping choose their local supermarkets, and others choose chains. This choice is important because competitors have to respond to this choice by improving services and lowering prices.

The proposed legislation, while limited to requiring the registration of PBMs in the state, is vital to provide a minimum level of oversight protection for consumers and healthcare providers, so the insurance commissioner is fully aware of who is engaging in conduct in the state.

The Unregulated Nature of PBMs Have Led to Wide-Scale Deceptive and Anticompetitive Conduct

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 their prescribed drug to a more expensive drug to take advantage of rebates that the PBM receives from drug manufacturers. PBMs often do not pass through rebates secured from drug manufacturers to payors, 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.²

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.³ These problems are only getting worse. Case in point is the number of recent cases which are either ongoing or have recently settled. In 2014, CVS alone was responsible for over \$30 million in penalties concerning

² 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.

³ 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>.

violations of the False Claims Act and SEC violations.⁴ 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.⁵ Currently pending before the Delaware federal district court is a False Claims Act violation 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.⁶

Moreover, substantial private litigation is pending against major PBMs. For example, Optum Rx, has several separate suits filed against it. One by retail chain Kmart which alleged failure to pay reimbursements for dispensed drugs equating to \$38 million in damages;⁷ another by 55 independent pharmacies alleging illegal conduct serving to inflate patient costs while simultaneously underpaying pharmacies;⁸ and several others filed in 2016 alleging that Optum is overcharging patients for prescription drugs and pocketing the overcharge.⁹ Express Scripts is currently facing a \$13 billion lawsuit by its largest client Anthem for overcharges for prescription drugs.¹⁰ Additionally, Express Scripts is facing several antitrust conspiracy suits in which plaintiffs have 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. These cases have survived Express Scripts' motions to dismiss and one is set for a jury trial beginning in May 2018.¹¹

Legislation is Vital to Inform Payors, Providers and Protect Consumers

As a general matter it is essential to provide transparency for consumers and other stake holders in the market. Transparency helps consumers adequately evaluate products carefully, to make informed choices and to secure the full range of services they desire. Likewise it helps healthcare providers understand the entities they can contract with in the state, and helps them make informed choices about the best care for their patients. PBM operations are very obscure, and the proposed legislation will help clarify who can act in the state on behalf of consumers.

Approximately 33 states have enacted some type of legislation pertaining to the business and operations of PBMs. Some of that legislation includes similar requirements as the pending legislation at issue here, to register with the state in order to ensure all stakeholders recognize the

⁴ See Testimony of David A. Balto, "The State of Competition in the Pharmacy Benefits Manager and Pharmacy Marketplaces," before the House Judiciary subcom. On Regulatory Reform, Commercial and Antitrust Law, Appx. A (Nov. 17, 2015), http://dcantitrustlaw.com/assets/content/documents/testimony/PBM%20Testimony_Balto_November%2017%202015.Final.pdf.

⁵ Id.

⁶ *John Doe v. Medco Health Solutions Inc., et al.*, Case No. 1:11-cv-00684 (D. Del.).

⁷ *Kmart Co. v. Catamaran Co.*, Case No. 2015-L-008290 (Ill. Ct. Cl. Aug. 31, 2015).

⁸ *Albert's Pharmacy, Inc. et al v. Catamaran Corporation*, Case No. 3:15-cv-00290 (M.D. Pa. Feb. 9, 2015).

⁹ See, e.g., *Stevens v. UnitedHealth Group, Inc. et al.*, Case No. 16-cv-03496 (D. Minn.).

¹⁰ *Anthem v. Express Scripts*, Case No. 16-cv-2048 (S.D.N.Y.)

¹¹ *HM Compounding Services v. Express Scripts*, Case No. 14-cv-01858 (E.D. Mo.); *Precision RX Compounding, LLC et al. v. Express Scripts*, Case No. 16-cv-00069 (E.D. Mo.).

PBM's ability to lawfully operate in the state. As is found in much of the legislative history of the states who have enacted legislation concerning PBM's, for example, the state of Washington in enacting similar legislation relied on testimony that such law was needed because it "passed a bill last year" which didn't solve the problematic conduct of PBM's. Some of the problems cited were "reimbursements are below costs while the [PBM's] reap hundreds of billions in profits...The [PBM's] are not following the law...[PBM's] continue to deny requests for reimburse of the cost of drugs...The PBM's are not updating the costs of drugs to reflect the market prices..." All of this conduct, coupled with the anticompetitive conduct and consumer harm described above, are constant and ongoing practices of the PBM's requiring the necessity of further regulation of PBM's at the state level.

Of critical importance here is the fact that this legislation will go a long way to help provide transparency in a fantastically opaque industry, and provide added accountability for PBM's serving the citizens of Hawaii. Broadening requirements for PBM's to operate in the state will allow consumers and payor to better understand who they can deal with in the state, and will allow healthcare providers to better ably serve their patients. We urge you to vote to pass S.B. 1158.

If you have any questions, please feel free to contact us.

Sincerely,

/s/

David A. Balto

Bradley A. Wasser