DAVID A. BALTO

ATTORNEY AT LAW
1350 I STREET, NW
SUITE 850
WASHINGTON, DC 20005

PHONE: (202) 789-5424
Email: david.balto@yahoo.com

March 25, 2013

Senator Judy Lee
Chairman
North Dakota Senate Committee on Human Services
State Capitol
600 East Boulevard
Bismarck, ND 58505-0360

Re: House Bill No. 1363

Dear Madam Chair Lee:

I write in support of House Bill No. 1363 ("H.B. 1363"), on which the Senate Committee on Human Services will hold a hearing on Tuesday, March 26, 2013. The bill would provide guidelines for the transparency of the maximum allowable cost ("MAC") of generic pharmaceuticals paid to retail pharmacies by Pharmacy Benefit Managers ("PBMs"). The importance of this legislation cannot be understated. PBMs use arbitrary and opaque MAC pricing to derive record profits at the expense of independent pharmacies, plan sponsors and consumers. In addition to the lack of transparency surrounding MAC pricing, the PBM market is fraught with other deceptive and fraudulent conduct that has led to independent pharmacies being driven from the market and harm to consumers. This legislation is a prudent response to this significant market imbalance PBMs hold, and its enactment will benefit the consumers of North Dakota.

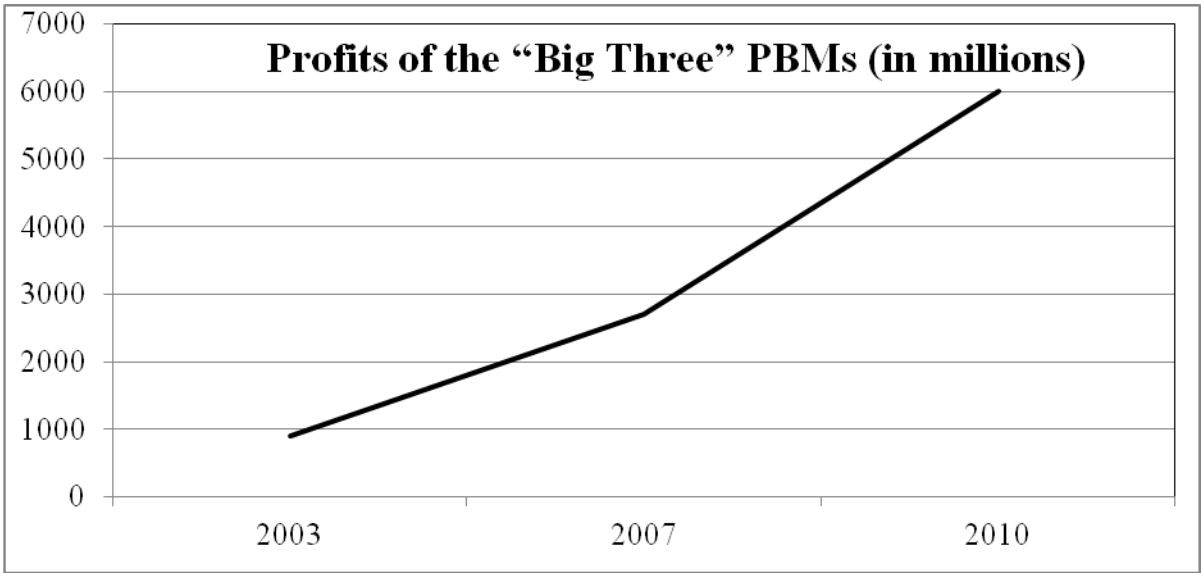
I write to you based on my experience of over a quarter century as an antitrust practitioner, the majority of which was spent as a trial attorney in the Antitrust Division of the United States Department of Justice, and in several senior management positions, including Policy Director at the Federal Trade Commission's ("FTC") Bureau of Competition and attorney advisor to Chairman Robert Pitofsky. I helped bring some of the first antitrust cases against PBMs and have testified before Congress, regulators, and state legislatures over ten times on PBM competition. I have testified before Congress four times and before ten state legislatures on PBM reform issues and have served as an expert witness for the State of Maine on PBM regulation.[1]

[1] *See* David Balto, Advocacy and Testimony, available at http://www.dcantitrustlaw.com/index.php?id=9

BACKGROUND

Pharmacy Benefit Managers are one of the most problematic, least regulated and least understood aspects of the healthcare delivery system. Over 80% of pharmaceuticals in the United States are purchased through PBM networks. PBMs serve as intermediaries between health plans, pharmaceutical manufacturers and pharmacies, and PBMs establish networks for consumers to receive reimbursement for drugs. Although the primary function of a PBM initially was simply to create networks and process pharmaceutical claims, these entities have exploited the lack of transparency and created conflicts of interest which have significantly distorted competition, reduced choices for consumers and ultimately increased the cost of drugs.

The PBM market is dominated by two PBMs, ESI/Medco and CVS Caremark who together control over 80% of the market for large health plans. Because the two largest PBMs' operations are clouded in secrecy and are replete with significant conflicts of interest, PBMs have effectively increased the cost of drugs over the past several years and have seen their profits skyrocket from $900 million a year to over $7 billion a year at the expense of payors and consumers.



MAC PRICING IS A SIGNFICANT SOURCE OF PBM REVENUE AT THE EXPENSE OF CONSUMERS AND RETAIL PHARMACY

Like many health care businesses PBMs must establish reimbursement rates for services and the dispensing of drugs. This system works best, for consumers, plans, and pharmacies when there is a transparent and consistent system for determining these reimbursement rates. When there is a transparent and consistent system all of the market participants can effectively plan, purchase goods and provide services. Where transparency and consistency are absent there is a significant opportunity for providers and ultimately consumers to be harmed by deceptive and unfair conduct.

Unfortunately, currently the reimbursement system for generic drugs often lacks these critical elements. Generic reimbursement is based on a MAC list, which sets the maximum allowable cost. MAC lists are PBM-generated list of products that includes the upper limit or maximum amount that a PBM will pay for generic drugs and brand name drugs that have generic versions available. There is no standard methodology for derivation of MAC lists or how the maximum prices are determined. Neither plan sponsors nor retail pharmacies are informed how products are added or removed from a MAC list or the methodology that determines how reimbursement is calculated. Moreover, PBMs often utilize multiple MAC lists to create a spread between what they charge a plan versus the amount they reimburse a pharmacy. This lack of transparency and prevalence of nonstandard MAC list and pricing derivation allows PBMs to utilize an aggressively low MAC price list to reimburse their contracted pharmacies and a different, higher list of prices when they sell to their clients, plan sponsors. Essentially, the PBMs reimburse low and charge high with their MAC price lists, pocketing the significant spread between the two prices. Most plans are unaware even that multiple MAC lists are being used and have no real concept of how much revenue the PBM retains.[2]

This can be additionally problematic from a plan sponsor perspective. The lack of transparency surrounding MAC list derivation causes plans worry that they are paying more than they should for some multisource products. Without the knowledge of whether certain generics are included or excluded on MAC lists, a plan does not know whether a member's copay may increase due to drugs not being available on MAC lists. A member may complain that they cannot get access to a generic that should be available through their benefit and the plan is forced to pay a higher price to the PBM.

H.B. 1363 will address these problems by, *inter alia*, requiring PBMs to disclose the specific market-based sources they use to determine and set MAC prices; ensuring that MAC prices are not set below costs (market-based sources available); setting specific requirements of drugs to be included on MAC lists; and requiring PBMs to disclose to plan sponsors whether the PBM is using an identical MAC list with respect to billing the plan sponsor and the network retail pharmacy. If a PBM is using multiple MAC lists the PBM must disclose to the plan sponsor any differences between the amount paid to any pharmacy and the amount charged to the plan sponsor. Where transparency and consistency are absent there is a significant opportunity for providers and ultimately consumers to be harmed by deceptive and unfair conduct. By requiring disclosure of MAC pricing, H.B. 1363 will help ensure North Dakota consumers, plans and pharmacies do not pay more for generic drugs than they should.

WEAK TRANSPARENCY STANDARDS ALLOW PBMS TO ENGAGE IN DECEPTIVE CONDUCT

In addition to MAC list and pricing, facing weak transparency standards, the major PBMs frequently engage in a wide range of deceptive and anticompetitive conduct that ultimately

[2] See Mark Meador, *Squeezing the Middleman: Ending Underhanded Dealing In the Pharmacy Benefit Management Industry Through Regulation*,20 Annals of Health L. 77, 80-81 (2011).

harms and denies benefits to consumers. Some PBMs secure rebates and kickbacks 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. In addition, PBMs derive enormous profits from the ability to "play the spread" between pharmaceutical manufacturers, pharmacies, and health care plans.

Ultimately, the US Department of Justice and 30 state attorneys general brought cases against each of the major PBMs for some of these actions, including allegations of fraud, misrepresentation to plan sponsors, patients, and providers; unjust enrichment through secret kickback schemes; and failure to meet ethical and safety standards. These cases have resulted in over $377 million in damages to states, plans, and patients, including the Federal Trade Commission's recent finding of Medicare fraud by CVS Caremark resulting in a multi-million dollar fine.[3]

Because the PBM system is unregulated, the lack of transparency can inflict significant harm. The dominant PBMs are not required to and therefore refuse to disclose the amount of rebates they receive, or other relationships they have, with drug manufacturers and their arrangements with pharmacies. This lack of transparency leaves payors having to rely on the pricing dictated by the PBMs, diminishing their ability to control costs. Because of the lack of transparency, PBMs are free to "play the spread" between manufacturers, pharmacists, and plans because of a lack of disclosure.[4] Unclear and inadequate disclosure of MAC pricing undermines the ability of plan sponsors to compare competing proposals, and effectively increases the costs for pharmaceuticals for plans and their beneficiaries.

Transparency and a lack of conflicts of interest are vitally important for payors and their beneficiaries. H.B. 1363 is essential to provide transparency for consumers, which will help them to adequate 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 payors to make sure they are getting the benefits they deserve. We urge the Legislative Assembly to enact H.B. 1363.

Sincerely,

David A. Balto

---

[3] *In the Matter of CVS Caremark* (Federal Trade Commission 2012) (**$5.5 million fine**); *United States v. Merck & Co., Inc., et. al* **(E.D. Pa. 2006) ($184.1 million fine);** *United States of America, et al. v. AdvancePCS, Inc. (E.D. Pa. 2005)* (**$137.5 million fine);** *States Attorneys General v. Caremark, Inc. (2008) (***$41 million fine);** *State Attorneys General v. Express Scripts (2008) (***$9.5 million fine).**

[4] See David Balto, Testimony Before S. Jud. Comm, Subcomm. on Antitrust, Competition Policy and Consumer Rights (Dec. 6, 2011), available at http://www.dcantitrustlaw.com/assets/content/documents/testimony/SenateJudiciary.ESIMedci.Balto.pdf.