Vermont H.97

David A.Balto

1325 G Street NW, Suite 500
Washington, DC
(202) 577-5424
david.balto@dcantitrustlaw.com

The Law Offices of David Balto

- ▶ Preeminent expert on Pharmacy Benefit Managers and he represents pharmacies, payors, health plans and others in PBM matters.
- Testified before Congress and several states on PBM reform legislation and has worked for several states on PBM issues.
- ▶ Testified before the Department of Labor on PBM transparency regulations
- ▶ Former Policy Director of the Federal Trade Commission and helped bring some of the first cases against PBMs.
- Single best source of resources on PBMs,
- www.pbmwatch.com



Advocacy on PBM issues

Advocating before Congress, regulators, key market participants, and the Courts

- As FTC Policy Director brought first two cases against PBM mergers
- Testified before **Congress** on PBM competition issues 4 times, including on the Express Scripts-Medco merger and Affordable Care Act (ACA)
- Hired as an expert witness on PBM competition by Maine and Ohio
- Testified before 12 state legislatures
- Neutered FTC opposition to state PBM legislation
- Testified before the **Department of Labor** on PBM transparency regulations
- Called on by the Congressional Budget Office to provide a briefing on the benefits of PBM transparency which led to passage of provision in ACA
- Counsel Congressional Research Service to provide a briefing on the PBM Market
- Counsel GAO on report on Pharmacy Services Administrative Organizations
- Asked to be a guest on CNBC's Street Signs as the "Chief PBM Industry Critic"





Honest brokers gone rogue

- Pharmacy Benefit Manager (PBM) markets are plagued with conflicts of interests, fraud, abuse, and egregious conduct.
- PBMs are the only unregulated industry in health care.
- Substantial lack of transparency allows PBMs to harm competition and consumers



PBM Tactics

Plan sponsors and their enrollees don't necessarily see the savings promised by PBMs, thanks to a lack of transparency:



- PBMs "play the spread," charging plan sponsors more per prescription than what they reimburse the pharmacy for it.
- PBMs do not necessarily pass on rebates to plan sponsors in the form of savings.

Do Drug Benefit Managers Reduce Health Care Costs? USA Today (3/3/14)

- PBMs' cut of transactions can double drug costs for consumers or employers.
- "The more obscure a line of business, the easier it is to exploit consumers," says attorney David Balto, a former Federal Trade Commission policy official
- Now that consumers are paying a bigger chunk of their health care dollars, including for prescription drugs that often have their own deductibles, PBM critics hope employers and consumers will pay closer attention to why their out-of-pocket drug costs are so high.
- "Employers don't look at the micro level or intensely supervise PBMs," says Balto.

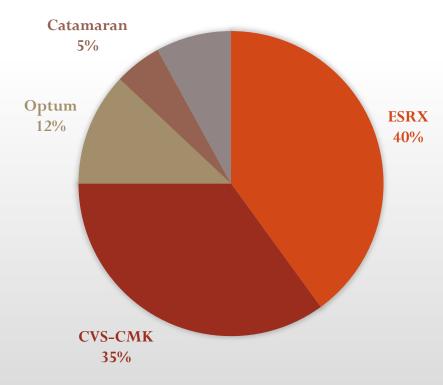
Competitive Concerns in the PBM Industry

- Highly Concentrated Market:
 - CVS Caremark, Express Scripts control over 80 percent of the large employer market.
 - High market concentration is conducive to cartel-like behavior
 - Substantial increase in concentration during the last decade
 - Lack of Transparency allows PBMs to exacerbate egregious behavior
- High Barriers to Entry:
 - No successful PBM market entry by new companies for a long time

Current PBM Landscape

Express Scripts and CVS Caremark control the vast majority of the large employer market, with OptumRx and Catamaran close behind

PBM BY MARKET SHARE 2013*



Competitive Concerns in the PBM Industry

- CONFLICTS OF INTEREST
 - Consumers are often "locked in" and have difficulty switching PBMs
 - This allows PBMs to opportunistically increase prices and decrease services without consequence
 - This is why the FTC placed the two largest PBMs under regulatory consent orders (Eli Lilly/PCS, Merck/Medco)
 - The FTC found that the PBMs had improperly favored the drugs of their manufacturer-owners, resulting in higher prices and less consumer choice

PBM REPORT CARD

- FLOOD OF ANTITRUST AND CONSUMER PROTECTION LITIGATION WWW.PBMWATCH.COM
- LESS THAN A FIG LEAF OF REGULATION
- NO FEDERAL REGULATION
- LACK OF CHOICE, TRANSPARENCY
- CONFLICTS OF INTEREST

• RESULT....

Painful Prescription*

- Express Scripts promised savings of over \$750,000 to Meridian
- After 3 months costs *increased* by \$1.3 million
- PBMs pad bills by \$8-\$10 for every single prescription charged to an employer
- Lack of transparency allows PBM drug pricing to be an "impenetrable blog". Drug companies offer undisclosed rebates to PBMs in exchange for market share.
- PBMs biggest profits now come from maximizing the spread on generics PBMs use multiple MAC lists to maximize the spread, giving one set of prices to pharmacies and another to employers

"PBMs 'introduce a layer of fog to the market that prevents benefits providers from fully understanding how to best minimize their net prescription-drug cost."

Past PBM Enforcement Actions

Multistate enforcement actions resulting in <u>over \$371.9</u> <u>million</u> in damages:

- **United States v. Medco, et.al** \$184.1 million in damages for government fraud, secret rebates, drug switching, and failure to meet state quality of care standards.
- **United States v. AdvancePCS** (now part of CVS/Caremark) \$137.5 million in damages for kickbacks, submission of false claims, and other rebate issues.
- **United States v. Caremark, Inc.** pending suit alleging submission of reverse false claims to government-funded programs.
- State Attorneys General v. Caremark, Inc. \$41 million in damages for deceptive trade practices, drug switching, and repacking.
- State Attorneys General v. Express Scripts \$9.5 million for drug switching and illegally retaining rebates and spread profits and discounts from plans.

CVS Caremark: DOJ/States case

December 2013 CVS Caremark required to pay \$4.25 million in fines for Medicaid fraud

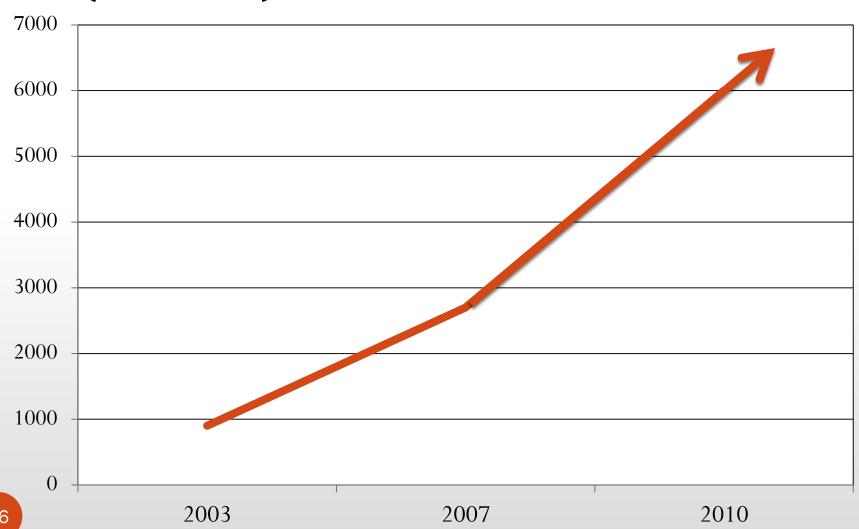
- CVS Caremark knowingly did not reimburse Medicaid for prescription drug costs that were paid on behalf of beneficiaries
- Federal government received \$2.31 million in the settlement, while \$1.94 million was split among 5 states: Arkansas, California, Delaware, Louisiana and Massachusetts

Express Scripts: AG Investigation

Last year Express Scripts was served with two subpoenas from the attorneys general of New Jersey and Rhode Island concerning its relationship with drug makers who are accused of false claims and kickbacks in marketing of several drugs

Skyrocketing Profits of the "Big Two"

(in millions) from \$900 million to over \$6 billion



Skyrocketing Profits of the "Big Two"

- CVS Caremark generated \$126.8 billion in revenues in 2013.
- Express Scripts generated \$104.6 billion in revenues in 2013.
- CVS Caremark and Express Scripts rank as number 12 and 20, respectively, on the 2014 Fortune 500 list.
- Both CVS Caremark and Express Scripts' 2013 revenues exceed that of the largest U.S. drug manufacturer, Johnson and Johnson, by over \$30 billion.

MAC Pricing

- PBMs' biggest profits come from maximizing spreads on generic drugs.
- MAC lists are PBM-generated lists of generic drug products that includes the upper limit or maximum amount that a PBM will pay for generic drugs and brand name drugs with generic version available.
- Pharmacies are not informed of the MAC prices, or how products are added or removed from MAC lists, let alone the methodology used to derive MAC prices

MAC Pricing

- PBMs use various MAC lists to create spreads between what they charge a plan versus what they reimburse a pharmacy.
- Such lack of transparency and prevalence of nonstandard MAC lists and pricing derivation allows PBMs to utilize aggressively low MAC price list to reimburse pharmacies.
- Lack of transparency = financial uncertainty and increased costs to consumers

MAC Pricing: Real World Example

• A recent report revealed that Meridian Health System discovered that its drug benefit increased by \$1.3 million within the first month of contracting with Express Scripts for PBM services. Meridian discovered that they were being billed for generic amoxicillin at \$92.53 for every employee prescription; however Express Scripts was paying only \$26.91 to the pharmacy to fill these same prescriptions. The result was a spread, also known as the difference between the PBM's expenditure and the revenue it takes in, of \$65.62. Meridian canceled its contract and switched to a transparent PBM which saved Meridian \$2 million in the first year of its contract. This example demonstrates that disclosure of MAC pricing can improve competition and reduce costs to plans and ultimately consumers.

Weak Transparency Standards

- Weak transparency standards allow PBMs to engage in a wide range of deceptive and anticompetitive conduct that ultimately harms and denies benefits to consumers. See conduct outlined in slides above.
- A transparent and consistent system allows all market participants to 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.
- H.97 will combat weak transparency standards and provide for greater transparency of MAC pricing and drug availability.

Vermont H.97

• MAC Pricing Transparency.



 H.97 will address problems by, ensuring that MAC prices are not set below costs (market-based sources available); setting specific requirements of drugs to be included on MAC lists; regularly updating MAC lists so pharmacies understand the most current pricing, which changes frequently; and requiring an appeals process to ensure pharmacies are able to receive MAC list drugs at fair market value. By requiring disclosure of MAC pricing, H.97 will help ensure Vermont consumers, plans and pharmacies do not pay more for generic drugs than they should.

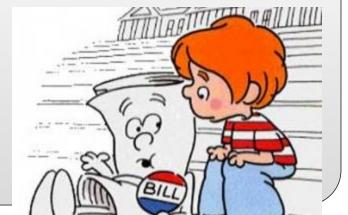
Vermont H.97

Patient Choice Provision

- This provision is critical to consumers. Only where consumers have the full range of choices does the competitive market thrive.
- H.97 prevents against restrictive networks which can rob consumers of the choice of their preferred pharmacy. Restrictive networks harm consumers that depend on the services of their local pharmacists, which can often be life-altering and significant to the most vulnerable patients

Other Transparency Advocacy

- State PBM Legislative Reform Efforts:
 - MAC Transparency: 16 states (AK, CO, IA, KY, LA, MD, MN, MI, ND, NM, OR, OK, TN, TX, UT, WA)
 - Current MAC legislation pending in seven other states, including: Vermont, Georgia, Hawaii and Kansas
 - 33 states have enacted fair pharmacy audit legislation
 - 8 states have enacted patient choice legislation



Other Transparency Advocacy

- Affordable Care Act PBM Transparency Requirements, Title VI, Subtitle A, Section 6005)
- PBMs must provide regulators with data on the percentage of all prescriptions that are provided through retail pharmacies compared to mail-order facilities and the generic dispensing rates for each type.
- PBMs must also submit the aggregate amounts and types of rebates and discounts or price concessions that the PBM negotiates on behalf of a plan.
- Importantly, PBMs must disclose how much of these rebates and discounts are "passed through" to the plan versus kept as company profits.
- In addition, PBMs must also supply regulators with the aggregate difference between the amount paid by the plan and the amount the PBM pays the retail and mail-order pharmacy and number of prescriptions dispensed.

Other Transparency Advocacy

- CMS Medicare Part D rule
 - Requires that Part D plans and their PBMs make available to all contracted pharmacies the reimbursement rates for drugs under MAC pricing standards.
 - *This requirement will be effective for the 2016 contract year.



In conclusion...

- The transparency and patient choice provisions of H.97 will have a significant positive impact on Vermont consumers and the local pharmacies that serve these consumers.
- PBMs operate with little transparency and engage in deceptive practices such as drug switching and spread pricing.
- Without transparency, PBM profits will continue to rise exponentially at the expense of small business and patients.
- Broadening transparency requirements on PBMs will allow pharmacies to better ably serve their patients by being able to acquire necessary inventory at a fair market value.
- And patients will be better off having choice in the market and maintaining control over their own healthcare choices.
- Increasing the level of PBM transparency will foster competition among pharmacies as well as cost control within the PBM market, to benefit plans and ultimately to consumers.

Questions?



David A.Balto

Law Offices of David Balto 1325 G Street, NW Suite 500 Washington, DC 20005 202-577-5424

david.balto@dcantitrustlaw.com www.dcantitrustlaw.com