PBM Abuse

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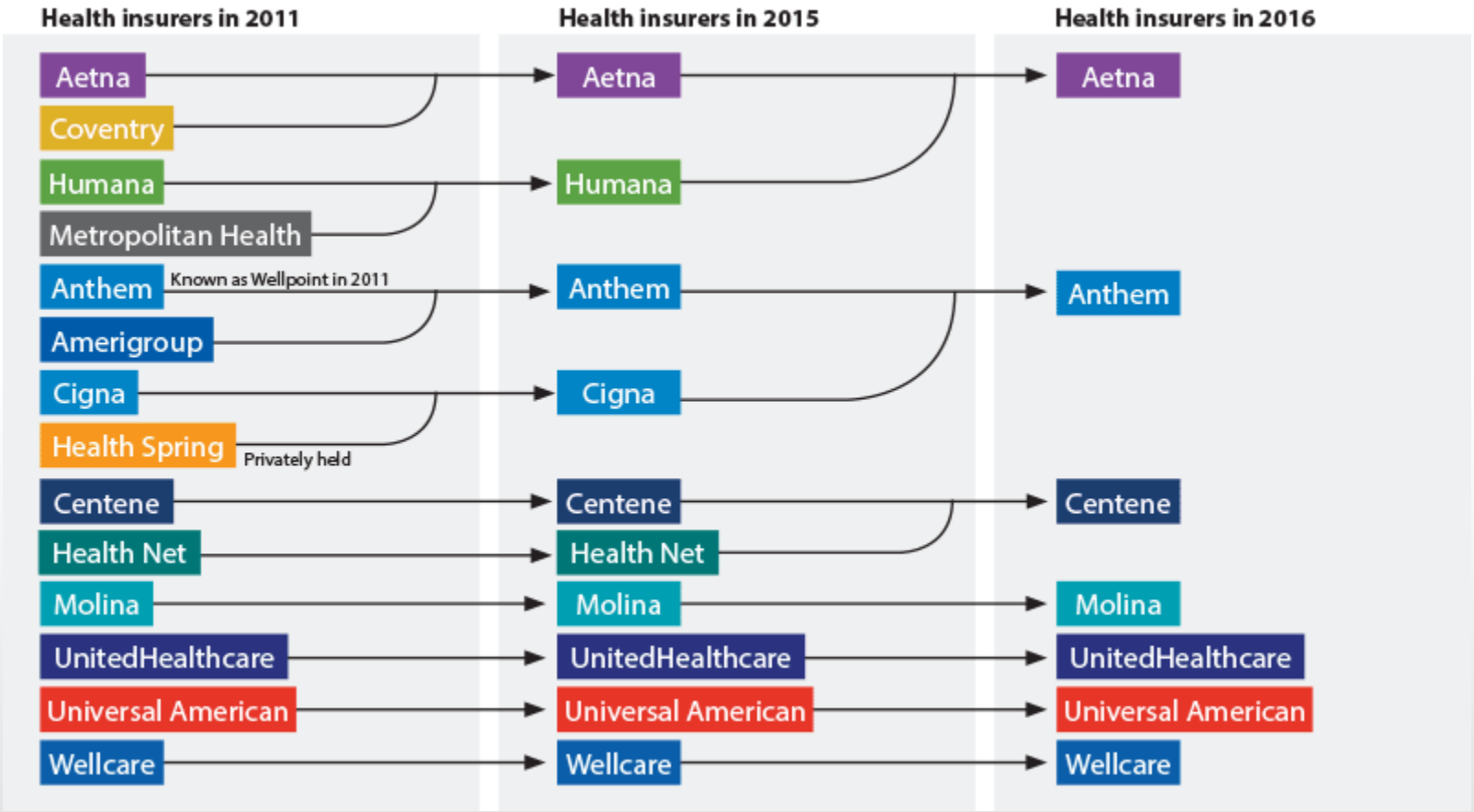
The Big Three

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
- www.thecppc.com

Health Insurance Merger Frenzy in 2015-2016



Led Successful Opposition to Health Insurance Mergers

- In 2015, Anthem announced it would merge with Cigna and Aetna announced it would merge with Humana
- We led consumer opposition to the mergers, arguing they would lead to higher prices, less consumer choice, and reduced quality of care
- Organized state and federal consumer groups to raise concerns and challenge the mergers in many states
- Submitted comments and testified before state insurance commissioners in a dozen states-California, Delaware, Florida, Georgia, Illinois, Indiana, Iowa, Missouri, New York, Ohio, Virginia, Wisconsin
- Gave presentations to DOJ and state Attorneys General about how the mergers would harm consumers
- Efforts paid off—DOJ sued to block both mergers as anticompetitive, and judges ruled

Consumers Groups We Coordinated to Oppose Mergers

ConsumersUnion®

Consumer Watchdog
EXPOSE. CONFRONT. CHANGE.

CFA

SEIU

U.S. PIRG

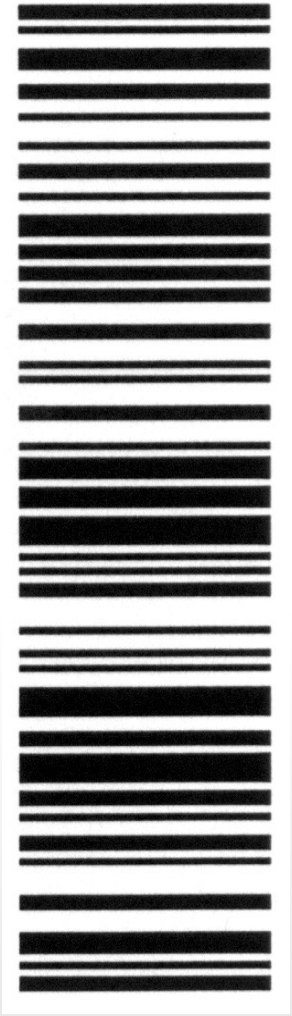
FAMILIESUSA
THE VOICE FOR HEALTH CARE CONSUMERS

consumeraction

Advocacy on PBM issues

Advocating before Congress, regulators, key market participants, state legislatures, 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 many state legislatures, most recently **California, Hawaii, & North Dakota**
- 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
- Counseled **Congressional Research Service** to provide a briefing on the PBM Market
- Counseled GAO on report on Pharmacy Services Administrative Organizations
- Asked to be a guest on **CNBC**'s Street Signs as the **"Chief PBM Industry Critic"**



Prescription

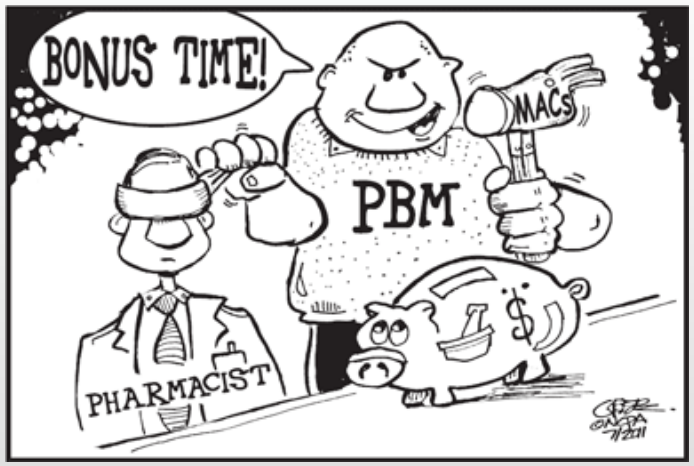
FOR COMPETITION

- Choice
- Transparency
- Lack of Conflicts of Interest

PBM Market Fails on All Counts

PBMs: 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, and Optum Rx control between 75 and 80 % of the market—over 180 million customers.
  - 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

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.

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

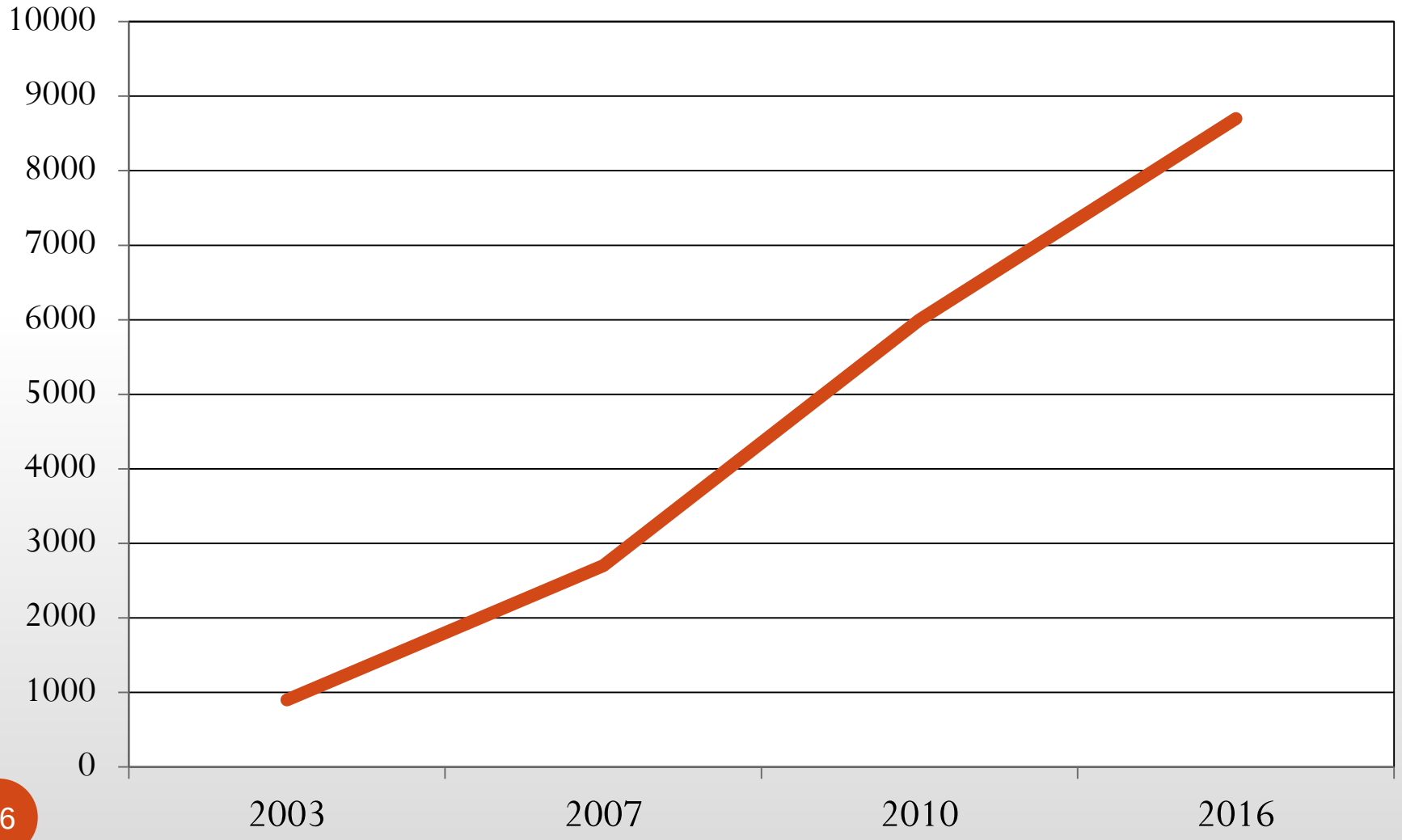
PBM REPORT CARD

- 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….

Skyrocketing Profits of the "Big Two"

(in millions) from **$900 million to almost $9 billion**



Massive Profits of PBMs

- Express Scripts/Medco generated $100.3 billion in revenues in 2016.
- CVS Caremark generated $177.5 billion in revenues in 2016.
- CVS Caremark and Express Scripts rank as number 7 and 22, respectively, on the 2017 Fortune 500 list.
- Both CVS Caremark and Express Scripts' 2016 revenues exceed that of the largest U.S. drug manufacturer, Johnson and Johnson, by at least $30 billion.
- *Source: Drug Channels, Profits in the 2017 Fortune 500: http://www.drugchannels.net/2017/06/profits-in-2017-fortune-500.html

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.'"

* Katherine Eban, Painful Prescription, Fortune (10/10/13)

Past PBM Enforcement Actions

Multistate enforcement actions resulting in <u>over $371.9 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.

Express Scripts/Medco: DOJ Case

January 2015: Express Scripts/Medco required to pay $7.29 million in fines for engaging in kickbacks

- Medco solicited remuneration from AstraZeneca, a pharmaceutical manufacturer, in exchange for identifying Nexium as the "sole and exclusive" proton pump inhibitor on certain of Medco's prescription drug lists known as formularies.
- Medco received some or all of the remuneration from AstraZeneca in the form of reduced prices on the following AstraZeneca drugs: Prilosec, Toprol XL and Plendil
- Violated federal anti-kickback statute and caused submission of false & fraudulent claims to Retiree Drug Subsidy Program

Express Scripts: Investigation

Last year in 2016 DOJ demanded information from Express Scripts about financial ties with pharma companies and relationships among drugmakers, patient assistance programs, and specialty pharmacies that fill prescriptions

PBMs and Nonmedical Switching

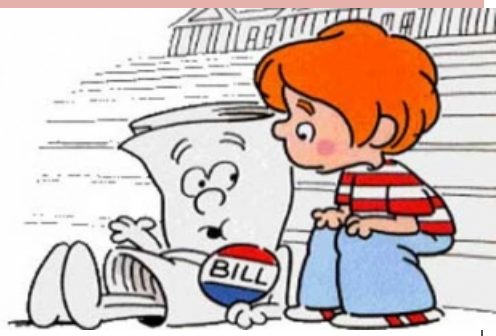
- A tactic that forces patients with difficult to treat conditions to take less costly and possibly less effective drugs for nonmedical reasons
- PBMs do this by dropping medications from formularies or increasing cost-sharing requirements, then notifying patients they have to switch to less expensive treatments
- PBMs have incentives to get higher rebates so they earn greater profits, set formularies based on rebates
- This forces doctors to switch from certain drugs to other, less expensive ones that may not work as well and harm patients. Leads to unnecessary risks and higher costs
- Interferes with doctor-patient relationship

PBMs and Nonmedical Switching

PBMs and Nonmedical Switching

- 2008-Express Scripts paid Ohio and 27 other states $9.3 million to settle a case. PBM illicitly switched patients from some drugs to others to make more money by earning higher rebates
- 2004-Medco pays $29.3 million to DOJ and 20 other states for switching patients to more expensive drugs
- Possible solutions: State legislation on rebates and switching, ensuring that rebates are not kept by PBMs but passed on
- California, Louisiana, Montana, and Nevada regulate non-medical switching
- Enforcement by state Attorneys General: encourage them to take action

Recent State PBM Legislation



- California-AB 315 would ensure PBMs are regulated and transparency and have a fiduciary duty to the clients, withdrawn until next year
- Connecticut-Approved SB 445, bans pharmacy gag clauses and certain contract provisions
- Nevada-Approved SB 539, requires price transparency on rebates from PBMs, bans gag clauses
- New Jersey-Considering 4676, requires PBMs to get certificate from Commissioner to operate in the state
- North Dakota-Approved SB 2258 and SB 2301, protects pharmacies from charges and patients from excessive co-pays, requires more transparency and a firewall between administration and mail order pharmacies. PBMs sued to block them

Federal PBM Legislation

- C-THRU(Creating Transparency to Have Drug Rebates Unlocked) Act, introduced by Senator Ron Wyden (D-OR)
- S. 637, has three Democratic sponsors, currently before the Senate Finance Committee
- Requires PBMs to publicly disclose data regarding rebates and discounts and their impact on Medicare Part D beneficiaries and the Part D program overall
- Requires greater transparency of spread pricing
- After two years of reporting, a minimum percentage of rebates and discounts must be passed from PBMs to health plans

Other PBM 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 PBM 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.

In conclusion…

- PBMs operate with little transparency or regulation and engage in deceptive practices such as drug switching and spread pricing.
- Without transparency and oversight, PBM profits will continue to rise exponentially at the expense of healthcare providers and patients.
- Increasing PBM transparency and regulation will foster competition and cost control within the PBM market, to benefit plans and ultimately to consumers.

Questions?

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