Prescription Drug Program Trends and Litigation

KIMBERLY L. BRADLEY

ABATO, RUBENSTEIN AND ABATO, P.A.
BALTIMORE, MD

AL HOLIFIELD

HOLIFIELD JANICH RACHAL FERRERA, PLLC
KNOXVILLE, TN

GRETCHEN S. OBRIST

KELLER ROHRBACK L.L.P.
SEATTLE, WA

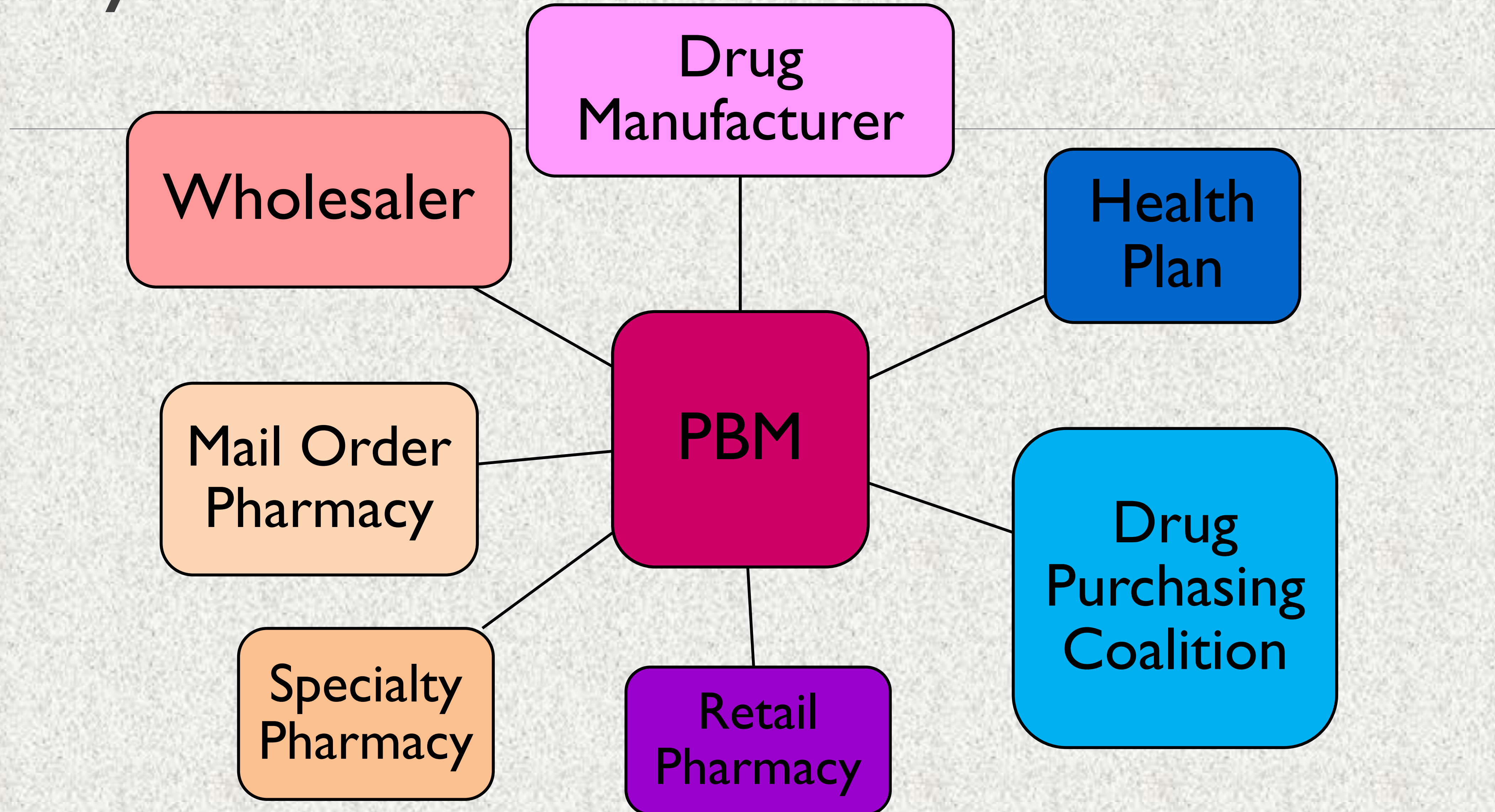
Trends

- **Prescription Cost Trends**
- **PBM Revenue Streams and Pricing Models**
- **Rebates, Discounts, and Coupons**
- **Performance Guarantees**
- **Drug Purchasing Coalitions and Alliances**
- **Audit Rights**

Prescription Cost Trends

- 2017 Milliman Medical Index found that prescription drugs are 17% of total healthcare spend—and can be much higher
- 2017 prescription drug inflation was 8%, which is more than double medical inflation at 3.6%
- Specialty drug spend was $92B in 2012; rose to $179B in 2016; expected to exceed $400B by 2020
- Many specialty drugs are biologics; no inexpensive generic substitutes expected because they cannot be chemically reproduced

Players in the PBM Business



PBM Revenue

- From Drug Manufacturers: base rebates, administrative fees, formulary and market share rebates, clinical program support, price protection payments, sale of data/research, "bona fide service fees," and "educational" or "procurement" fees (this is a non-exhaustive list—there are many labels)
- From Retail Networks: spread on prescription sales, network participation fees
- From Proprietary Pharmacies: margin on mail order and specialty drug sales—and additional fees
- From Health Plans: administrative fees, clinical program fees

PBM Pricing Models

- Spread Pricing
  - PBM retains the difference between what it charges the health plan and what it pays to the pharmacy
  - PBM discounts typically marked to Average Wholesale Price (AWP)
  - Not a transparent pricing model because the plan sponsor must have the pharmacy network spreads to make sure that the PBM charge to the plan is correct

PBM Pricing Models

- Pass-Through Pricing
  - PBM passes all AWP discounts received from the pharmacy network to the plan and does not retain any spread
  - PBM receives payment from health plan through PEPM administrative fees
  - More transparent than spread pricing model
  - Audit still required to verify discounts

Rebates, Discounts, and Coupons

- PBMs negotiate rebates and other payments from drug manufacturers—not all are passed through to plans and many are undisclosed
- Rebate pumping: funneling expensive drugs to the PBM formulary to maximize rebates to the PBM (Nexium)
- Current trend shows PBMs retaining bigger rebates / fees and not passing them along to plan sponsors (Anthem v. Express Scripts)
- When rebates are passed through to plans, however, they may not reach participants to assist with their share of drug spend

Rebates, Discounts, and Coupons

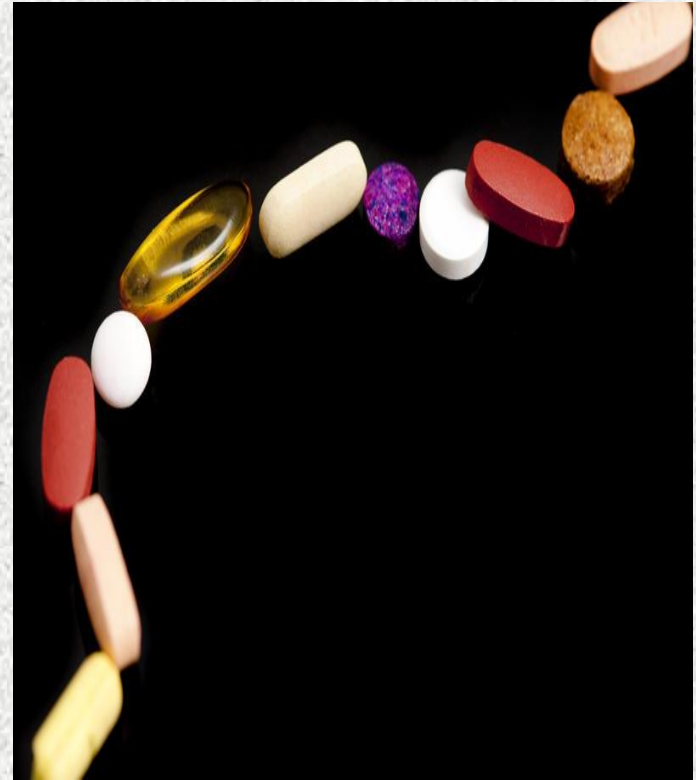
- Trend has been for greater use of manufacturer coupons
- Apps and websites for determining availability of coupons and drug prices without insurance
  - GoodRx
  - RefillWise
  - www.internetdrugcoupons.com
- Plan sponsors do not see these savings, which are offered directly to the consumer

Rebates, Discounts, and Coupons

- Plan Sponsor Options
  - Exclude manufacturer coupons from deductibles and out-of-pocket maximums
  - Variable copay programs (increase copays when coupons are available)
  - Identify availability of coupons for expensive drugs

Drug Purchasing Coalitions and Alliances

- Multi-State Alliances
  - Sovereign States Drug Consortium
  - National Medicaid Pooling Initiative
- Consultant-Led Purchasing Alliances
  - Towers Watson, Aon Hewitt
- Employer-Led Purchasing Alliances
  - National Drug Purchasing Coalition



Drug Purchasing Coalitions and Alliances

- Set financial and clinical goals
- Integrate prescription drug delivery with medical treatments
- Set performance guarantees and/or outcome-based pricing
- Use combined number of covered lives to negotiate favorable terms with PBM
- Increase transparency in pricing (similar to 401k plan fee transparency initiatives)
  - Campaign for Sustainable Drug Pricing (www.csrxp.org)

Audit Rights

- Trend is toward ongoing monitoring
- Highly specialized audit firms
- PBM approval of audit firm - NO
- Scope, extent, and frequency of audits
- Additional fees for audits
- What documents must be made available?

Prescription Drug Program Alternatives

Benefit designs most commonly implemented by purchasers and health plans to steer consumers towards high-value care:

- Value-based Insurance Design (V-BID)
- Reference Pricing

Value-based Insurance Design (V-BID)

Aligns patients' out-of-pocket costs with value of service

- Costs are lowered for services considered to be clearly beneficial
- Can be used for pharmaceuticals, preventative services or services related to chronic conditions
- Increased medication use would improve health outcomes and reduce overall health care spending
- Encourages consumers to receive medical services needed by reducing financial barriers
- Prevent adverse health effects

Value-based Insurance Design (V-BID)

Strengths:

- Encourages consumers who refrain from seeing care due to financial barriers to seek beneficial services.
- Financial incentives can signal to consumers the importance of seeing certain services, particularly for a given condition
- Increases medication use
- Can target high-value services for specific conditions - aligning patients' needs with providers' initiatives to improve care and make it affordable
- Health plans offer more generous coverage of high-value care, but less generous coverage of services that provide little or no health benefit

Value-based Insurance Design (V-BID)

Weaknesses:

- Financial concern of higher health care costs in short term
- Cost not always the barrier to patients' seeking the care they need
- Consumers may still not appreciate the importance of seeking particular services
- If high deductible health plan with an HSA, V-BID may have little effect
- Concern that costs of implementing V-BID may be greater than savings
- Concern that V-BID will not address problems with drug pricing and rebating / fee arrangements that currently cause consumers to pay more out of pocket, in part due to lack of transparency

Value-based Insurance Design (V-BID)

Current status of the design

- The Affordable Care Act includes a V-BID provision
- In 2017, Centers for Medicare and Medicaid Services began five-year test of value-based design
- In 2018, Department of Defense will pilot a V-BID, trying to improve the care and outcomes for American military personnel

Reference Pricing

- A payer establishes a standard price for a drug, procedure, service or bundle of services and requires that plan member pay any allowable charges above this price
- Consumers' out-of-pocket costs are the difference between the actual price of services received and the established reference price
- Can apply to services that vary substantially in price, yet are commonly perceived to have little variation in quality (laboratory services, imaging, colonoscopies, MRIs and drug prices)
- Does not restrict consumers from receiving care from particular providers – even if there is a large difference between the reference price and allowable charge, consumers can receive care from any provider as long as they pay difference.
- Can educate consumers about how much prices can vary in health care
- Allows consumers to have a choice of providers for a given service

Reference Pricing

Strengths:

- Potential to save the plan, the purchasers, and the system money if incentives are structured so that consumers seek care from lower-cost providers
- When used to highlight providers based on price and adherence to quality criteria, it could direct consumers to higher-quality, lower-price providers
- Reference price chosen can signal providers about what the plan and its employer-purchaser customers think is reasonable

Reference Pricing

Weaknesses:

- Typically limited to shoppable "commodity" services
- Educating consumers on how to make decisions using available price and quality information can take significant time and resources
- Providers may raise their prices if reference price is higher
- Obstacles in establishing a reference pricing program
- Provider may try to make up the difference by increasing how often it performs a service or raise price of other services

Reference Pricing

Current status of design:

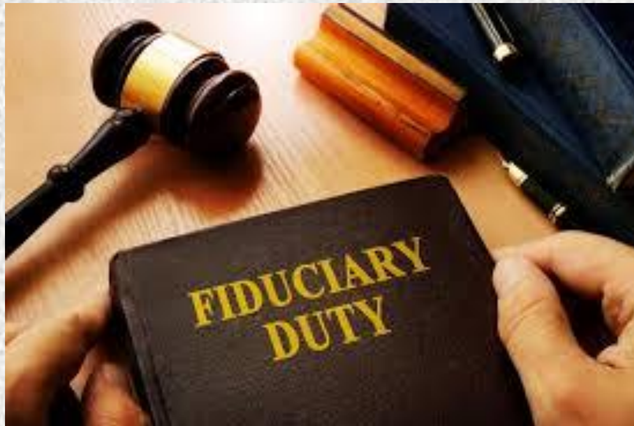
- Concept first applied to drug pricing
- Used successfully on complex, high-cost procedures, where quality is more likely to vary and potential for saving is far greater
- Various factors, such as range of prices, number of providers, geography, play part in pricing

Other Alternatives

Other alternatives that are available:

- High Deductible Health Plans (HDHP)
- Tiered Networks
- Narrow Networks
- Centers for Excellence
- Alternative Sites of Care

ERISA: Plan Fiduciaries



Named Fiduciaries:

Every ERISA plan must have one or more "named fiduciaries." 29 U.S.C. § 1002(a)(1).

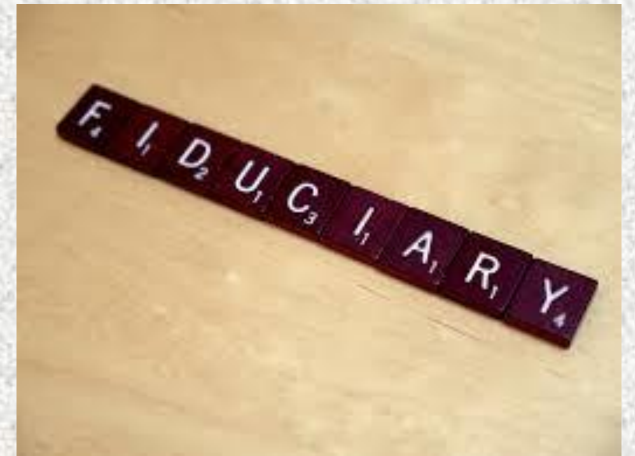
- Person named as "administrator" in plan instrument is automatically a named fiduciary.
- If no such designation, then the plan sponsor (*i.e.*, employer or insurance plan provider) is the administrator.

ERISA: Plan Fiduciaries

***De Facto* Fiduciaries:**

Any other persons who perform fiduciary functions are functional fiduciary. 29 U.S.C. § 1002(21)(A).

- A person is a functional fiduciary if:
  - (i) he or she **exercises any <u>discretionary</u> authority or control** over the **management** of the **plan *<u>or</u>* exercises <u>any</u> authority or control** over **management or disposition** of **plan assets**; ***<u>or</u>***
  - (ii) he or she renders **investment advice for a fee** or other compensation, direct or indirect, with respect to any moneys or other **property of the plan**; ***<u>or</u>***
  - (iii) he or she **has any <u>discretionary</u> authority or responsibility** over the **administration** of the **plan**.



Last Decade's ERISA Case Law on Drug Prices

Bickley v. Caremark, Inc., 361 F. Supp. 2d 1317 (N.D. Ala. 2004)

Glanton v. AdvancePCS Inc., 465 F.3d 1123 (9th Cir. 2006)

Mulder v. PCS Health Sys., Inc., 432 F. Supp. 2d 450 (D.N.J. 2006)

Chi. Dist. Council of Carpenters Welfare Fund v. Caremark, Inc., 474 F.3d 463 (7th Cir. 2007)

Moeckel v. Caremark, Inc., 622 F. Supp. 2d 663 (M.D. Tenn. 2007)

In re: Express Scripts, Inc. PBM Litig., 2008 WL 2952787 (E.D. Mo. July 30, 2008)

2000s Case Law: Claims

Plaintiffs have argued that insurers and PBMs acted as fiduciaries with respect to:

- Drug prices
- Rebates
- Formulary placement
- Drug-switching
- Drug classification

2000s Case Law: Conclusions

Courts have found that insurers and PBMs are not fiduciaries based on:

- Contract terms
  - If contract says X, no discretion as to X
  - Arm's-length negotiations
  - (It's just "contracts" and "business"—nothing fiduciary here, folks)
- General "business" v. plan-specific determinations
- Plan retaining *sole* discretion over price, formulary, etc.

Analogous Case Law on Rates for Hospital Stays, Etc.

- *Sixty-Five Sec. Plan v. Blue Cross and Blue Shield of Greater N.Y.*, 583 F. Supp. 380 (S.D.N.Y. 1984)
- *Seaway Food Town, Inc. v. Med. Mut. of Ohio*, 347 F.3d 610 (6th Cir. 2003)
- *DeLuca v. Blue Cross Blue Shield of Mich.*, 628 F.3d 743 (6th Cir. 2010)
- *United Teamsters Fund v. MagnaCare Admin. Servs.*, 39 F. Supp. 3d 461 (S.D.N.Y. 2014)

Recent Orders

- *In Re UnitedHealth Grp. PBM Litig.*, No. 16-cv-3352 (D. Minn.) (December 19, 2017)
- *In re Express Scripts/Anthem ERISA Litig.*, No. 16-cv-3399 (S.D.N.Y.) (January 5, 2018)

Clawback Litigation

Suits filed against some of the largest PBMs and their affiliated insurance providers (Cigna, UnitedHealth, and OptumRx):

- *In Re UnitedHealth Grp. PBM Litig.*, No. 16-cv-3352 (D. Minn.)
- *In Re Cigna Corp. PBM Litig.*, No. 16-cv-1702 (D. Conn.)

Clawback Litigation

What are "clawbacks"?

- The practice of collecting from a dispensing pharmacy a portion of the patient's required "copayment" or "coinsurance" that is not necessary to cover the cost of the prescription drug.

Clawback Litigation

** PAID CLAIM INFORMATION **

Patient: (redacted)
ADDR:

Drug: SPRINTEC 28 TAB 28 DAY Qty: 28 NDC: 00555-9016-58
Cvg: DTP Phone: 877-889-6510 Ref#: (redacted)

Rx# (redacted) Date: 12- -15 Trans. Date: 12- -15 Time: 09:16

	Transmitted	Received	Difference	
Cost	32.23	10.04	22.19	(68.85%)
Fee	17.36	1.00		
Tax		0.65		
Cost+Fee+Tax	49.59	11.65	0.00	Acq Cost
Copay		50.00-		
Amt.Paid		38.35-		

- Cost of the drug
- Pharmacist fee/tax
- Total cost to customer
- Customer's co-pay
- The clawback: overpayment to insurer/PBM

The customer's drug costs just $11.65. But the required co-pay is $50.00. Who gets the extra $38.35? The pharmacy benefits manager,

Clawback Litigation

The plaintiffs in **UnitedHealth** and **Cigna** asserted a number of claims including breaches of ERISA, breach of contract, RICO violations, and consumer protection violations, arising out of this provision included in many plan documents:

For Prescription Drugs at a retail Network Pharmacy, you are responsible for paying ***the lower of***:

- the applicable Copay;
- the Network Pharmacy's Usual and Customary Charge for the Prescription Drug; or
- the Prescription Drug Cost that UnitedHealthcare agreed to pay the Network Pharmacy.[30]

UnitedHealth – December 19 Order

The District of Minnesota granted the motion to dismiss, holding:

- Plaintiffs failed to exhaust, did not show futility
- Defendants did not act as fiduciaries when requiring pharmacies to charge and remit clawbacks, when misrepresenting and/or concealing this practice, or when negotiating discounted rates
- Copayments and coinsurance were not plan assets
- So then, who is a fiduciary…?

Anthem/ESI Litigation

- In March 2016, Anthem sued Express Scripts, Inc. (ESI) for allegedly overcharging for prescription drugs in breach of contract.
- Then the people paying the overcharges sued both of them.
- Consolidated action:
  In re Express Scripts/Anthem ERISA Litig.,
  No. 16-cv-3399 (S.D.N.Y.)

Anthem/ESI Litigation

Plaintiffs argued that, regardless of whether Anthem was correct in alleging that ESI charged more than the contract's "competitive benchmark pricing" provision allowed, Anthem breached its fiduciary duty by entering into that contract.

- Imprudence claim: the contract term was less favorable than a prudent fiduciary should have negotiated
- Self-dealing claim: the 10-year agreement for PBM services was negotiated simultaneously with a contract for sale to ESI of Anthem's PBM business; ESI gave Anthem a choice between receiving $4.65B for its business and the "competitive benchmark pricing" term, or receiving $500M for its PBM and a more favorable prescription pricing term

As a result, Plaintiffs (and Anthem) argued, plan participants/beneficiaries and self-insured plans paid too much—to the tune of $15 billion.

Participant/Payer Plaintiffs alleged violations of ERISA and RICO.

Anthem/ESI Litigation – January 5 Order

The Southern District of New York granted the motion to dismiss, holding:

- ESI was not a fiduciary when it set drug prices, allocated rebates, or performed drug-switching and drug classification
  - Primary reasoning: terms of the contract
- Anthem was not a fiduciary when it chose ESI to provide prescription drugs or when it negotiated the PBM agreement
- So, who, again, is a fiduciary…?

Future Litigation – Pending Cases

- *In re: Cigna*
- EpiPen
- Diabetes Drugs
- Hepatitis C

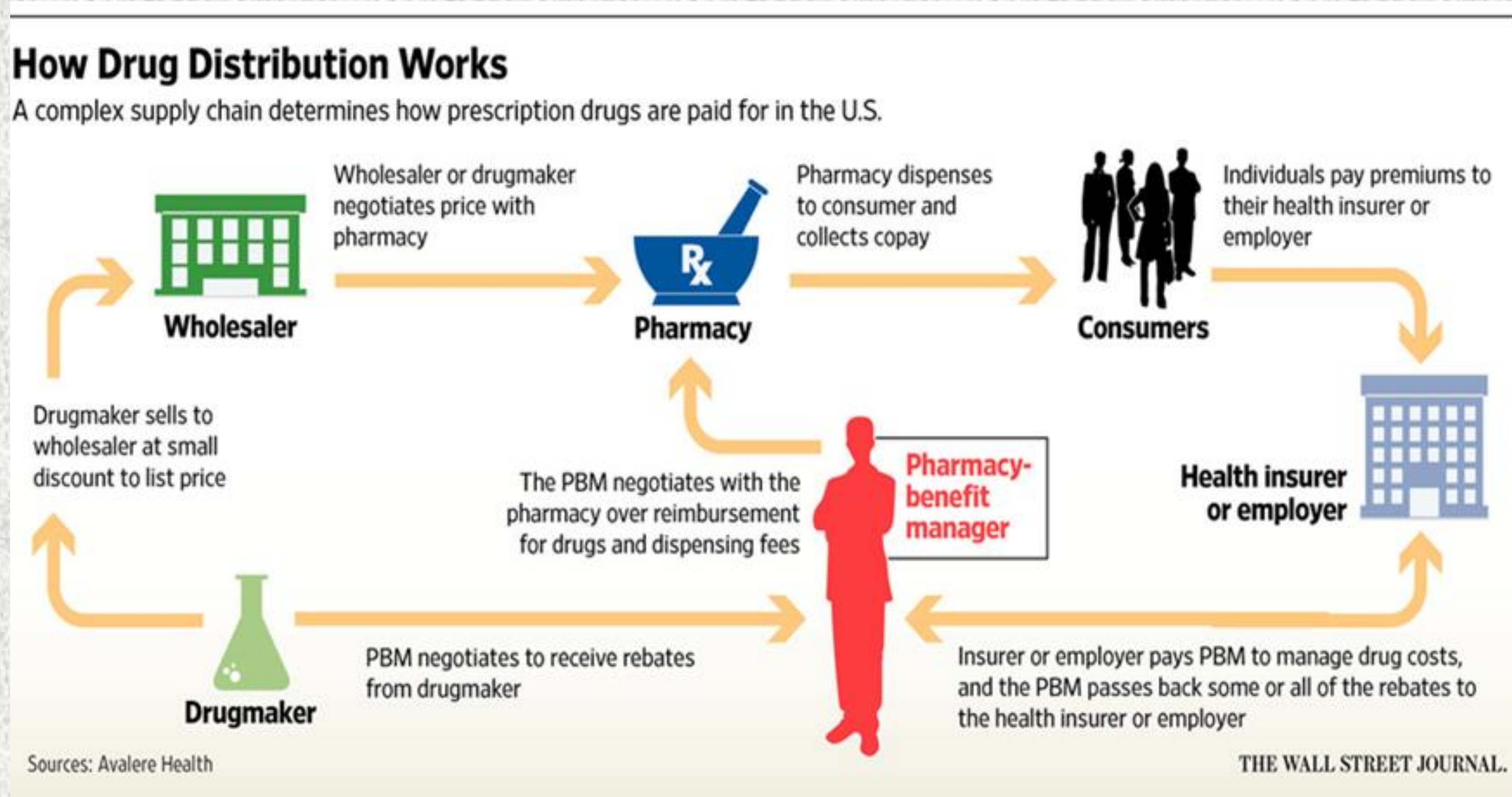
Future Litigation – *In Re: Cigna*

In Re Cigna Corp. PBM Litig., No. 16-cv-1702 (D. Conn.)

Pending M2D raises the following ERISA issues:

- Plaintiffs' entitlement to certain drug pricing
- Exhaustion
- Discrimination
- Fiduciary acts
- Plan assets
- Remedy

Future Litigation – Inflated Drug Prices



Future Litigation – Inflated Drug Prices

- New cases against PBMs and manufacturers in connection with the steadily increasing price of prescription drugs
- These cases allege violations of ERISA, RICO, the Sherman Act, and state consumer protection statutes
- The primary conduct challenged is the industry-wide practice of negotiating and collecting kickbacks

Future Litigation – Inflated Drug Prices

“Kickbacks”: Payments extracted by PBMs from drug manufacturers—in the form of “rebates,” “fees,” or “discounts”—in exchange for preferential formulary placement or inclusion.

Instead of passing the rebates along to patients or payers, many PBMs simply take the payments as profit. This drives up drug prices for participants and many plans.

Future Litigation – Inflated Drug Prices

Three related ERISA EpiPen cases (D. Minnesota):

- *Klein v. Prime Therapeutics, LLC*, No. 17-cv-1884
- *Illis v. Optum, Inc.*, No. 17-cv-5154
- *Brannon v. Express Scripts Holding Co.*, No. 18-cv-0018

Related case against Mylan (MDL in D. Kansas)

Victoza (diabetes drug):
Johnson v. OptumRx, Inc.,
No. 17-cv-7198 (D. New Jersey)

Future Litigation – Hepatitis C

- Treatment is very effective, but *very* expensive
- As a result, insurance companies decline coverage
- *Roebuck v. Highmark, Inc.*, No. 17-cv-0296 (S.D. Ala. 2017) – case settled, but more litigation could arise