Managed Markets Foundational Concepts and Emerging Legal Issues

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*The views expressed in this presentation are those of its author and do not reflect the official policy or position of Gilead Sciences, Inc.

What Is Managed Markets?

- “Managed Markets” customers include a variety of entities involved with the distribution, coverage, or payment of pharmaceutical products.
- Managed Markets Segments include:

Commercial
- PBMs
- Health Plans
- IDNs
- GPOs

Government
- Medicare Part D
- Medicaid (FFS)
- Managed Medicaid
- VA
- Corrections

Trade
- Wholesalers
- Specialty Distributors
- Pharmacies

Pharmaceutical Discount Arrangements

- Manufacturers typically offer discounts to Managed Care Customers in exchange for favorable coverage or formulary placement
  - Off-Invoice Discounts & Rebates

- Discount arrangements should be structured to comply with applicable safe harbors to the Anti-Kickback Statute (AKS)
  - Discount Exception & Safe Harbor
  - GPO Safe Harbor
  - Managed Care Exception & Safe Harbors
  - Personal Services and Management Contracts Safe Harbor

Areas For Compliance Policies: Interactions With Managed Care Customers

- Compliance safeguards for interactions with Managed Care Customers, include:
  - **Promotion:** Policies governing "promotional" interactions
    - Evolving FDA guidance regarding HEOR & PIE
  - **P&T Committee Members:** Policies governing interactions with Pharmacy and Therapeutics (P&T) Committees Members
  - **Swapping:** Separate negotiations for commercial/government segments
  - **Patient Privacy:** Policies governing the receipt, use, and disclosure of PHI; Business Associate Agreements; and Data Security
  - **Copay Coupons:** Policies governing discussion of copay coupon programs

Emerging Legal Issues
Managed Markets

Federal Anti-Kickback Statute (AKS)

- The AKS prohibits:

  anyone from offering, paying, soliciting, or receiving anything of value in return for referring an individual for an item or service reimbursed under a federal or state healthcare program

- Criminal and civil penalties

- Anyone = Manufacturers, HCPs, pharmacies, patients
- Anything of value = Payments, meals, gifts, entertainment, back-office services, increased business
- In return for = Some intentional connection
- Referring an individual = Prescribing, recommending
- An item or service = Pharmaceuticals, devices, procedures
- Federal healthcare program = Medicare Part D, Medicaid, and others
- Penalties = Prison + fines + other serious penalties

United States ex rel. Herman v. Coloplast Corp., et al
Evolving Interpretation of the Discount Safe Harbor

- DOJ has sought to interpret the discount safe harbor narrowly

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

THE UNITED STATES OF AMERICA, and)
THE STATE OF CALIFORNIA,)
ex rel. KIMBERLY HERMAN, AMY LESTAGE)
and KEVIN ROSEFF,)
)
Plaintiffs,)

v.

COLOPLAST CORP

Defendants.

UNITED STAT
MOTION FOR

II. ARGUMENT

A. A Price Reduction Conditioned On the Performance of Promotional or Conversion Campaign Activities Is Not a "Discount" Under 42 U.S.C. § 1320a-7b(b)(3)

A discount is a reduction in price conditioned only on th

service at issue. If a reduction in price is conditioned on more than a simple purchase, it is not a mere "discount," but rather a form of remuneration whose legitimacy must be evaluated under the anti-kickback statute separate and apart from the statutory discount exception or regulatory discount safe harbor. In other words, if a price reduction is conditioned on more than the purchase of a product, then it is not a mere discount and it is irrelevant whether that price reduction was "properly disclosed."

"If a reduction in price is conditioned on more than a simple purchase, it is not a mere 'discount,' but rather a form of remuneration . . ." (Emphasis added)

Brief of the United States, August 8, 2016.

Pharmaceutical Pricing

Insulin Manufacturer Cases: Complaints filed against manufacturers and PBMs in response to pharmaceutical price increases

- Three ongoing cases against Eli Lilly, Novo Nordisk and Sanofi
- Two of these cases also pursue major PBMs: CVS/Caremark, ESI, and Optum

Plaintiff Theories:

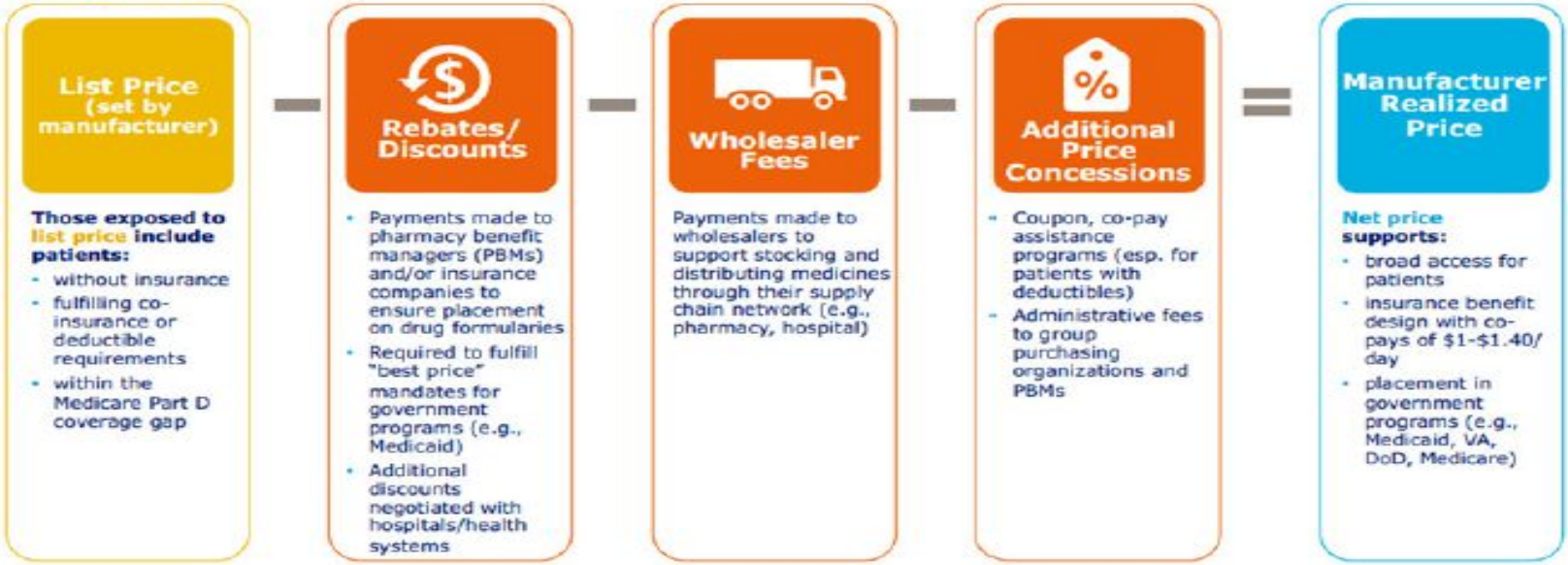
- **State Consumer Protection / Deceptive Practices**: Allegations that manufacturers inflate WAC prices in order to offer large rebates to PBMs resulting in profits at the expense of consumers
- **Anti-Trust:** Allegations that price increases are the result of an agreement not to compete
- **RICO:** Allegations that manufacturers and PBMs formed a RICO "enterprise" to inflate benchmark prices while deceiving the public that the increased prices fairly and accurately reflected actual drug costs

Exhibit from an Insulin Complaint

Figure 1:

List Price vs Net Price

Patients' out-of-pocket experience for buying medicines will depend on their health plan's benefit design and any financial obligations required in those plans



Copay Coupon Best Price/AMP Theory

- The U.S. Attorney for the District of Massachusetts is investigating manufacturer commercial copay coupons
- Novel theory articulated at conferences in 2017:
  - Manufacturer payments for copay support to patients should be included in government pricing calculations
    - PBM/Plan efforts to negate copay cards result in discounts to plans (and not patients)
    - The copay assistance amount should be stacked on top of discounts to plans for the same product for purposes of government price reporting
- Inconsistent with traditional interpretation of CMS Guidance
  - Code of Federal Regulations expressly exclude coupons from the definition of “Best Price” and “Average Manufacturer Price”

QUESTIONS?