

Strategic Defenses to Pharmaceutical Investigations

(We're right, they're not)

Michael Kendall
McDermott Will & Emery
28 State Street
Boston, MA 02109
(617) 535-4085

Katherine A. Lauer
Latham & Watkins
701 B Street, Suite 2100
San Diego, CA 92101
(619) 236-1234

Form of Enforcement Actions

- Criminal and Civil / Qui tam
- Federal & State MFCU

Prosecution Theories

Antikickback Cases and False Statements

- **Conventional and Imaginative Theories**
- **Variety of Exotic Alternatives**
- **No Case Law Precedents**
- **Settlements \neq Law**

Conventional Antikickback Theories

1. Obvious Remuneration

- Trips
- Cash
- The Unexplainable -- Motorboat Fuel

Defense: Argue Intent

Probable Jury Instruction: “One Purpose,” “Any motivation”

- Woodward
- Greber

Wedge Prosecution

Conventional Antikickback Theories

2. Ambiguous Remuneration

Pretextual Clinical Study

- Does doctor do more than use drug in clinical treatment?**
- Does company use data submitted by doctor?**

Educational Grant to Physician, PBM

Disease Management Program

Data Mining

Defense - Legitimate Purpose Shows Lack of Intent

Imaginative Antikickback Theories

1. Inflated Spreads = Kickback

Drug companies compete by moving AWP or Contract Price

Defense: Government Created Reimbursement System

How many sales at WAC? (20% is good)

Can you explain price decisions?

Brand/Generic Competition Move Price

Imaginative Antikickback Theories

2. Are free samples a kickback?

Defenses:

Reimbursement not based on true acquisition cost, so sample has no impact on payor

Free samples = volume discount that circumvents Best Price obligations

PDMA (21 U.S.C. § 353) Approves physician billing free samples; it does not apply to reimbursement for medically necessary uses

“Sell” ≠ “Bill” (Compare § 353(c)(1) and (3)(A))

Conventional False Statement Theories

1. Companies Manipulate Best Price

- Repackaging sales to HMOs with manufacturing licenses**
- Omit industry sectors from Best Price calculation -- nursing home**
- Do invoices include all discounts, rebates, chargebacks, etc?**
- Free samples = volume discount**

Defense: Include all discounts in calculation, or inform government.

Imaginative False Statement Theories

1. Inflated Spreads are a false statement.

AWP is 10 or 20 X Contract Price

Spread on Injectable > Oral

What does AWP mean?

What does WAC mean?

Defense: Government Knew, No False Statement

– Don't Supply AWP to Redbook, et al.

Standing Alone -- Weak Theory of Prosecution

President William Clinton, 1997

Sometimes the waste and abuse aren't even illegal; they're just embedded in the practices of the system... [O]ur Medicare program has been systematically overpaying doctors and clinics for prescription drugs.... Now these overpayments occur because Medicare reimburses doctors according to the published average wholesale price - the so-called sticker price - for drugs.

Imaginative False Statement Theories

2. Texas and other states require special disclosure forms?

Texas: Average of suggested wholesale price

Price to wholesaler

Direct price for pharmacists

Update every 15 days

Good Compliance Tradecraft

- **Audit Sales, Marketing, Contracting, Formulary Staff**
 - Paper Audit
 - In person interviews
 - Avoid Compliance Pornography
 - Deadly E-mails
 - Policy on contacts by government

Document #1218353