

# Compliance Issues in Dealing With Drug and Device Manufacturers

---

Presentation to The Sixth Annual National  
Congress On Health Care Compliance

Paul E. Kalb, M.D., J.D.  
Sidley Austin Brown & Wood LLP  
(202) 736-8050  
pkalb@sidley.com

# Manufacturers are Under Intense Scrutiny

---

- Prior to the late '90s manufacturers received relatively little attention
  - Do not generally submit “claims”
  - Drug pricing very complex
- Surge of interest in late '90s
  - Manufacturers allegedly “influence” government reimbursement through AWP, Direct Price
  - Manufacturer relationships with purchasers and prescribers

# The TAP Settlement

---

- September 2001
- \$875 million total
  - \$585 million Civil penalties
  - \$290 million Criminal penalties
- Issues
  - Free samples
  - Grants
  - AWP spread



# Activities Under Scrutiny

---

## **AWP**

- Excessive reimbursement
- “Marketing the spread”

## **Medicaid rebates**

- Bundled goods
- Grants
- Nominal pricing
- “Private labeling”

## **“Kickbacks”**

- Grants
- Administrative fees
- Gifts, “business courtesies”

## **Samples**

# Role of Customers?

## Complicit?

- Anti-kickback statute is bilateral: prohibits both the giving and receiving of improper remuneration
  - TAP physicians
  - Caremark physicians
- Aiding and abetting false claims

## Whistleblowers?

- *Qui Tam* relator can be anyone
  - Recipient of TAP grant
  - Ven-A-Care





# Industry Self-Regulation: The PhRMA Code

---

- Developed by PhRMA
- Effective July 1, 2002
- Voluntary guidance



# Highlights of The PhRMA Code

---

- No entertainment or recreational events
- Occasional meals allowed in conjunction with presentations, but must be modest and in appropriate venue
- Manufacturers may directly support CME and other third-party scientific and educational programs so long as independent
- Manufacturers may retain consultants
  - Written contract
  - Pre-identified, “legitimate” need
  - Appropriate selection criteria
  - Reasonable number of consultants
  - Records of work
  - Venue and circumstances of meetings must be conducive to consultant work; social events must be “clearly subordinate”



## Highlights of The PhRMA Code (cont'd)

---

- Manufacturers may support speaker bureaus
  - Extensive training
  - Valuable service
  - Participants must meet criteria for consultants
- Manufacturers may support attendance at educational conferences by medical students, residents and fellows if selected by institution
- Manufacturers may provide:
  - Items for the benefit of patients
  - Practice-related items of *de minimis* value



# OIG Draft Compliance Program Guidance

## Standard Procedural Recommendations

- ✓ Compliance officer
- ✓ Compliance committee
- ✓ Policies and procedures
- ✓ Training
- ✓ Regular compliance audits

**DEPARTMENT OF HEALTH AND  
HUMAN SERVICES**

**Office of Inspector General**

**Draft OIG Compliance Program  
Guidance for Pharmaceutical  
Manufacturers**

**AGENCY: Office of Inspector General  
(OIG), HHS.**

**ACTION: Notice and comment period.**

# OIG Draft Compliance Program Guidance (cont'd)

---

## “Risk Areas”

- Integrity of data
- Inducements
  - Relationships with purchasers
    - ▶ Discounts
    - ▶ AWP
  - Relationships with physicians and other health care professionals
    - ▶ Direct and indirect “switching”
    - ▶ Gifts and other gratuities
    - ▶ PhRMA Code as “minimum” standard
  - Relationships with sales agents
- Samples



# The Customer Perspective

---

Your Perspective Depends on Where You Sit



# The Purchaser Perspective

---

- Discounts:
  - Are they safe-harbored?
  - If not, is the arrangement nonetheless legal?
  - Special issues re: bundling
  - Special issues re: “market share” arrangements
  - AWP spread
- Other “remuneration”
  - FMV for services rendered?
  - Grants for legitimate scientific or educational purposes?
  - Are “grants” really “price terms”?



# The “Recommender” Perspective (PBMs, HMOs, Pharmacies, Consultants)

---

- AKS prohibits payments “to recommend or arrange for”
- Can’t mean what it says: The First Amendment
- OIG concerns:
  - “Switching”
  - “White coat marketing”
- Key issues:
  - Disclosure?
  - Truthful/non-deceptive?

# The Prescriber Perspective

---

- Gifts
- Business courtesies
- Samples
- Key issues
  - Nominal value?
  - Patient benefit?
  - Independent judgement?



# Compliance

---

- Are policies, procedures adequate for:
  - Contracting
  - Price reporting
  - Recommending
  - Acceptance of benefits from manufacturers

Paul E. Kalb, M.D., J.D.  
Sidley Austin Brown & Wood LLP