



## KEY RISK AREAS:

Business Courtesies & Off-Label  
Promotion

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## Because the government cares!

- Cases
- OIG Guidance
- OIG Work Plan
- States

## WHY WE CARE (cont'd)

### **SETTLEMENTS**

TAP (2001): \$875M, indictments of individuals (dismissed and acquitted in 2004)

Bayer (2001): \$14M

Abbott (2003): \$600M

AstraZeneca (2003): \$355M

Guidant (2003): \$94M

Pfizer (2004): \$430M

Schering (2004): \$345M

Serono (2005): \$725M set-aside

# KICKBACKS

## Elements of Violation

Knowingly

Offering/receiving or  
paying/soliciting

Remuneration (including  
kickback, rebate, bribe)

In cash or in kind

Directly or indirectly

To induce someone to refer  
a patient or to purchase,  
lease, or order or  
recommend these activities

Any goods or services

Reimbursable under  
Medicare/Medicaid/  
CHAMPUS

# ANTI-KICKBACK LAW—PENALTIES



- Up to \$250,000 in fines for individuals
- Up to 5 years in jail
- Or Both
- Up to \$500,000 in fines for corporations
- Exclusion
  - Now applicable to manufacturers (1998)
- Civil monetary penalties: \$50,000 for each act plus 3x amount of illegal remuneration

# OIG GUIDANCE: AREAS COVERED



## Relationships with purchasers and their agents

- Discounts and other remuneration to purchasers: Discounts, Product Support Services, Educational Grants, Research Funding, other remuneration
- Formularies: Relationships with formulary committee members, Payments to PBMs, Formulary placement payments
- AWP

## Relationships with referral sources

- Switching
- Consulting and Advisory payments
- Payments for detailing
- Business courtesies
- Educational & research funding

## Relationships with Sales Agents

**NOTE:** Application of Guidance to medical device mfrs: "In addition, the compliance program elements and potential risk areas addressed in this compliance program guidance may also have application to manufacturers of other products that may be reimbursed by federal health care programs, such as medical devices and infant nutritional products." OIG Guidance, Footnote 5.



## **Compliance Program Guidance for Pharmaceutical Manufacturers**

- Kickbacks: 1 of 3 specific areas highlighted
- 24 of 52 pages devoted to kickbacks



## **PhRMA CODE: INDEPENDENCE AND DECISION MAKING**

No grants, scholarships, subsidies, support, consulting contracts, or educational or practice related items should be provided or offered to a healthcare professional in exchange for prescribing products or for a commitment to continue prescribing products. Nothing should be offered or provided in a manner or on conditions that would interfere with the independence of a healthcare professional's prescribing practices.

## **ADVAMED CODE: PURPOSE**

"Members shall encourage ethical business practices and socially responsible industry conduct and shall not use any unlawful inducement in order to sell, lease, recommend, or arrange for the sale, lease or prescription of, their products."

# **BUSINESS COURTESIES: ENTERTAINMENT WITH INFORMATIONAL PRESENTATIONS**



**“[C]ompliance with the PhRMA Code . . . should substantially reduce a manufacturer’s risk.”**

## PhRMA CODE

- **Meals**
  - Must be occasional and modest
  - Venue and manner conducive to informational communication
  - No dine and dashes
- **Entertainment: No**
  - Sporting events, including ballgames, golfing, fishing, hunting, skiing
  - Entertainment, including theatre, opera, movies, cooking classes, spa visits
  - No dash programs (including dine & dash, pumpkin & dash, turkey & dash, Xmas tree & dash, etc.)
- **Guests: No**

## **Note: At advisory board or speaker training meetings**

- Modest entertainment or activities
- Clearly subordinate in time and emphasis

# ADVAMED CODE: HOSPITALITY



- Training & Education
  - Hospitality limited to meals and receptions
  - Modest and subordinate in time and focus to the educational or training purpose of the meeting
  - Guests: NO
- Sales & Promotion
  - occasional, modest meals and receptions
  - “conducive to the exchange of information” and
  - incidental to business purpose

# REALITY: ENTERTAINMENT

***TAP: \$875M (2001): indictments of individuals  
4 physician customers and 3 members of sales  
organization pled guilty to felonies.***

***2004 saw 11 TAP employees on trial, 3 dismissed and  
8 acquitted***

## Alleged Illegal Remuneration

- Free travel and entertainment to resorts (including golf outings)
- Payments for attendance at seminars, lavish dinners

## BEST PRACTICES: ENTERTAINMENT

- Develop policies adopting PhRMA Code
  - Specific examples!
  - Who, what, when, where, how
  - Dos & don'ts
- Train appropriate personnel (e.g., sales, marketing, meeting planning, finance)
- Consider adopting templates for consistency
- Involve Legal Dept, when appropriate
- Monitor activities periodically
- Remember California!
  - Consider a tracking system

# **BUSINESS COURTESIES: GIFTS**



## EDUCATIONAL AND PRACTICE-RELATED ITEMS

### Ok if:

- Primarily benefit patients
  - \$100
  - Offered only occasionally
  - E.g., stethoscopes, anatomical models, textbooks, medical journal subscriptions, clipboards
- Associated with HCP's practice
  - Minimal Value
  - E.g., pens, notepads, reminder items

### NOT ok:

- CASH, including gift certificates (exception: A gift certificate that can only be used to buy a medical textbook or other gift that supports patient care)
- Personal Items
  - E.g., VCRs, CD players, golf balls, golf bags, gasoline, art, tickets to sporting events, flowers

**Samples: must comply with PDMA**

# ADVAMED CODE: GIFTS



## Ok if:

- Medical texts and anatomical models for educational function
- Benefit patients or serve a genuine educational function if
  - Fair market value of under \$100
  - Occasional
- Branded Promotional Items
  - Occasional & minimal value
  - Benefit patients or relate to HCP's work
  - Branded pens and note pads of minimal value are appropriate
  - No golf balls or T-shirts or flowers, gift baskets, meals, snacks, wine, other refreshments to HCP or HCP office staff

## Not Ok:

- Cash and cash equivalents

**Samples:** Code doesn't address

***SERONO: individual indicted and pled guilty (12/04); 4 execs indicted (4/05); \$725M set-aside (4/05)\****

- **Purported Motive**

- BU was “falling far short” of its sales goals and sales needed to “dig their way out” of this fiscal crisis.

- **Conspiracy Alleged**

- Who: high prescribing physicians and “thought leaders”
- What: devised the “\$6m-6 Day Plan”
  - Offer financial incentives to obtain the number of RXs increase sales by \$6M;
  - Reps told they were to LIVE with targets “until they get the required number” of RXs per targeted doctor.
- How: by offering an all-expenses paid trip for each HCP and guest to the Cannes Conference in return for the physicians writing scripts for Serostim within 1 week
- Value: approximately \$630,000 per Dr. X 10 = \$6m

***TAP: \$875M (2001)***

- Allegedly provided free items (such as computers and fax machines)

\* From Information and Indictment

# BEST PRACTICES: GIFTS

- Develop policies adopting PhRMA Code
  - Provide specific examples
  - Set out dos & don'ts
- Train appropriate personnel (e.g., sales, marketing, procurement, legal)
- Monitor activities periodically
- Remember California!
  - Consider a tracking system

# OFF-LABEL PROMOTION

## Food Drug & Cosmetic Act ...The Pharmaceutical World's "Bible"

- Labeling
  - A drug or device is misbranded if its *labeling* is false or misleading in any particular
  - Labeling is broadly defined as including any written or graphic material on or accompanying a drug

21 CFR § 201.56(c): "no implied claims or suggestions of drug use may be made if there is inadequate evidence of safety or a lack of substantial evidence of effectiveness."

## Remedies

- Regulatory letter (a/k/a notice of violation or untitled letter)
- Warning letter
- Other remedies:
  - Immediate cessation of all materials containing violative statements or graphics
  - Dear Doctor letters
  - Corrective advertising
  - Pre-clearance

## Enforcement Powers:

- Injunction
- Seizure
- Consent decree
- Fines
- Criminal prosecution

# OIG WORK PLAN FY 2005



**WHAT:** OIG will assess FDA's oversight and review of allowable promotion of off-label drug uses by pharmacos and describe FDA's oversight and enforcement of prohibited promotion of off-label drug uses by mfrs, including challenges to monitoring and enforcing compliance.

**WHY:** "[W]ell-publicized accounts of off-label use of drugs suggest that off-label prescribing practices may put patients at risk. Prohibited off-label promotion of drugs presents particular challenges and vulnerabilities because FDA generally does not have access to internal information on drug manufacturers' marketing practices and materials and cannot systematically monitor manufacturers' compliance."



# REALITY: OFF-LABEL PROMOTION



## ***PFIZER (\$430M) (2004)***

### **PROSECUTOR'S VIEW\***

- Government's Concern: Concerted effort to promote Neurontin off-label
  - Pushed the drug in higher doses forms – where there was insufficient data to support seeking FDA approval.
  - Sales reps probed doctors on off-label uses: “Doctor, are you aware that over half the patients on Neurontin do not have epilepsy?”
  - Used physician conferences to push off-label indications – such as targeting pain and psych market.
  - Had specifically determined not to seek FDA approval for the additional indication.

**\*Presentation by Boston AUSA (March 2005)**



## GOVERNMENT'S EVIDENCE

- Voice mail transcription (to MSAs): “Medical Liaisons, this is [the northeast Associate Director]. I am calling in regard to the – you know, there’s a Neurontin push that’s supposed to be on. ....So, what we need to do is focus on Neurontin. When we get out there, we want to kick some ass on Neurontin, we want to sell Neurontin on pain. All right? And monotherapy and everything that we can talk about, that’s what we want to do. Cause I’m embarrassed. But I’m embarrassed about where we are with Neurontin. We’ve got to take it into our own hands and really kick some ass on it, all right? Let’s do it up.”\*

**\*Presentation by Boston AUSA (March 2005)**

# BEST PRACTICES: OFF-LABEL PROMOTION



- Develop policies requiring compliance with FDA rules
  - Materials must be consistent with approved product labeling
  - May not engage in off-label promotion
  - Responses to unsolicited requests for information
- Consider policy requiring review of all voice mail and e-mail messages to the field
- Train appropriate personnel (Sales & Marketing) in FDA rules and appropriate use of voice mail and e-mail