

# Practical Tips for Dealing with Drug Reps in the Physician Practice

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# TAP Settlement (started it all...)

- October 3, 2001
- One of the Largest settlements to date
- In excess of \$875 million
- Lupron issue
  - Allegedly offered false information to inflate Medicaid/Medicare reimbursements
  - Gave physicians kickbacks & bribes for prescribing

# Pharma Industry Quick Facts

- Drug makers spent \$16 billion in 2000 promoting their products
- 8 billion drug samples were given to physicians in 2000
- In 2001 there were more than 87,000 pharma reps in the U.S. – this is a ratio of 1 rep for every 4.7 physicians
- The average physician sees about 10 reps a month with an average visit lasting less than 1 minute
- Sales personnel spends 8-13 thousand per year per physician

## 2000 AMA Study

- Doctors who spend more time with sales representatives were less likely to prescribe generic medicines



## 2003 AMA

- There was found to be a positive association between meetings of pharma reps and physicians and a change in prescribing practices

# AMA/JAMA Noteworthy Facts

- Physician interactions with pharmaceutical representatives were generally endorsed, began in medical school, and continued at a rate of about 4 times a month (2000)
- 97% of residents surveyed were carrying items w/ a pharma company logo or product name (2003)
- 98% also had at least one sponsored/provided meal sometime in the last year (2003)

# AMA/JAMA Noteworthy Facts

- Meeting with pharmaceutical representatives were associated with requests by physicians for adding the drugs to the hospital formulary and changes in prescribing practice (2000)
- It was found that physician's were more likely to request that specific brand name drugs be added to the formulary if they had accepted gifts/money from the pharma industry to attend, speak or participate in a conference or research project (2003)

# AMA/JAMA Noteworthy Facts

- Studies and literature show that gifts from the pharma industry directly influence:
  - Prescribing patterns of residents and physicians
  - Formulary requests from physicians

# The Health Provider's Conflict of Interest

- “It makes the doctor feel beholden...it suborns the judgment of the doctor.” *Dr. Arnold Relman, former editor, New England Journal of Medicine*
- Creates and inexplicable loyalty to the gift giver – a need to respond in some fashion
- Gifts could lead to a form of repayment such as:
  - Developing into a form of brand loyalty
  - Creating an obligation to prescribe
  - Making an automatic rather than a conscious decision to prescribe

# Potential Risks Identified by the OIG's Guidance for Pharma

- Relationships with purchasers and their agents
- Relationships with physicians and other persons and entities in a position to make or influence referrals
- Relationships with sales agents
- Compliance with laws and regulations regarding drug samples
- Supports the PhRMA Code

# Pharmaceutical Research and Manufacturers of America (PhRMA)

- Took effect July 1, 2002
- Focuses on Interactions with Healthcare Professionals
- Known often as:
  - “The Code” or
  - “The PhRMA Code”

# Advanced Medical Technology Association (AdvaMed) Code of Ethics

- Adopted by AdvaMed September 3, 2003
- Focuses on interactions with healthcare professionals and those individuals or entities that purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe medical technology products in the U.S.

# A PhRMA Code Quandary

- We know the code applies to healthcare professionals, but what about pharma interactions with office managers, receptionists and similar personnel who may not be healthcare professionals?

# PhRMA Code Quandary

“Although the code does not directly apply to persons who are not healthcare professionals, it would be difficult to separate a company’s interactions w/any of a physicians employees from those directly w/ the physician. Therefore, the code should be followed under the circumstances.”

# What is Allowed Under the PhRMA Code

- Informational presentations accompanied by occasional meals
  - Modest in value as judged by local standards
  - Occurs in a venue and manner conducive to informational communication & provide scientific or educational value
- Financial support given directly to sponsors of CME or third party conferences
- Occasional gifts if they *primarily benefit patients* and are valued under \$100 practice related gifts – pens, notepads, etc.

# What is Allowed Under the PhRMA Code

- Reasonable compensation and reimbursement for travel, lodging and meal expense for bona fide consultants
- Funding to allow healthcare professional in training to attend major educational, scientific, or policy-making meetings (*selected* by the institution)

# What is **NOT** Allowed under the PhRMA code

- ANYTHING provided or offered to a healthcare professional in exchange for prescribing or for a commitment to continue prescribing products

# What is **NOT** Allowed under the PhRMA code

- Entertainment and recreational events/tickets – golf, spa, football, etc.
- “Dine and dash” programs  
(“take out” meals in the absence of a company rep)
- Inclusion of spouse or guest in sponsored meals/receptions
- Individual financial support for third party conference attendees
- Cash, except as compensation for bona fide consulting

# What is **NOT** Allowed under the PhRMA code

- Honoraria, travel or lodging expense to non-faculty and non-consulting meeting attendees
- Gifts that are not practice related or benefit patients
- Items intended for personal benefit
- Cash equivalents – gift certificates
- Items intended for the personal benefit of the healthcare professional (i.e. floral arrangements, artwork, music CD's, tickets to sporting events, etc.)

# What Should Providers do if Offered an Inappropriate Gift?

- Examine OIG Guidance
- Examine the PhRMA code: This should be the minimum standard
- Examine internal policies on gifts
- Raise the issue with the manufacturer or contact:

FDA MedWatch Program

1-800-FDA-1088

[www.accessdata.fda.gov/scripts/medwatch/](http://www.accessdata.fda.gov/scripts/medwatch/)

# Use Informal Decision Making

- Do what is ethically right:
- Would you like to see your actions on front front page of your local newspaper?
- Could you stand in front of a group of senior citizens and defend your actions?
- Look at the situation thru your patient's eyes? Would they see it the same way you would?

# But What Can and Cannot a Pharma Sales Rep Do?

- Reps CAN within FDA regulations:
  - Provide health professionals with detailed information included in the professional product labeling or package insert
  - Handout or display company approved promotional materials
  - Refer “off-label” questions to the company’s medical relations dept.
  - Sell using all company-approved material

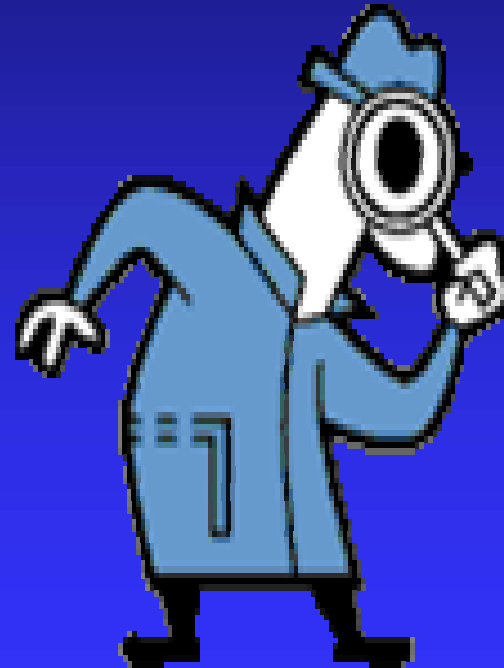
# But What Can and Cannot a Pharma Sales Rep Do?

- Reps CANNOT within FDA regulations:
  - Induce “off label” questions
  - Discuss information that is not included the product labeling or not company-approved
  - Compare package inserts of one product to another competing product (data is cannot be compared as “apples to apples”)

# But What Can and Cannot a Pharma Sales Rep Do?

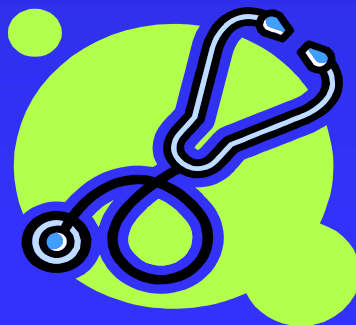
- Pharma Reps should:
  - Comply with the OIG Phrma guidance
  - Comply with the PhRMA code
  - Comply with FDA regulations

# CASE STUDIES



A pharmaceutical Representative visits a physician's office and offers the provider a stethoscope.

Is this allowed under the PhRMA Code?



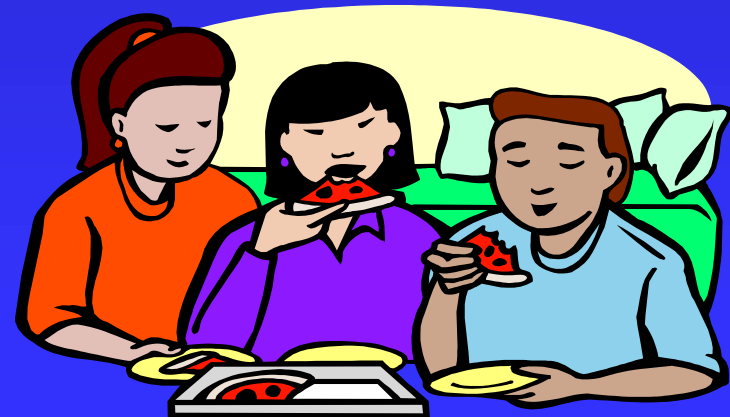


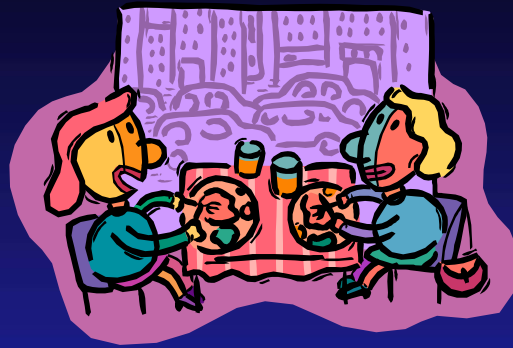
A pharmaceutical rep visits a physician and provides drug samples along with education on the sample drug, as a gift the provider is offered golf balls with the product name imprinted on them.

Is this acceptable under the PhRMA Code?

At lunchtime a pharma rep comes to the office and brings pizza for the staff. He also leaves sample drugs and informational brochures on the drugs he is promoting.

Is this allowed under the PhRMA Code?





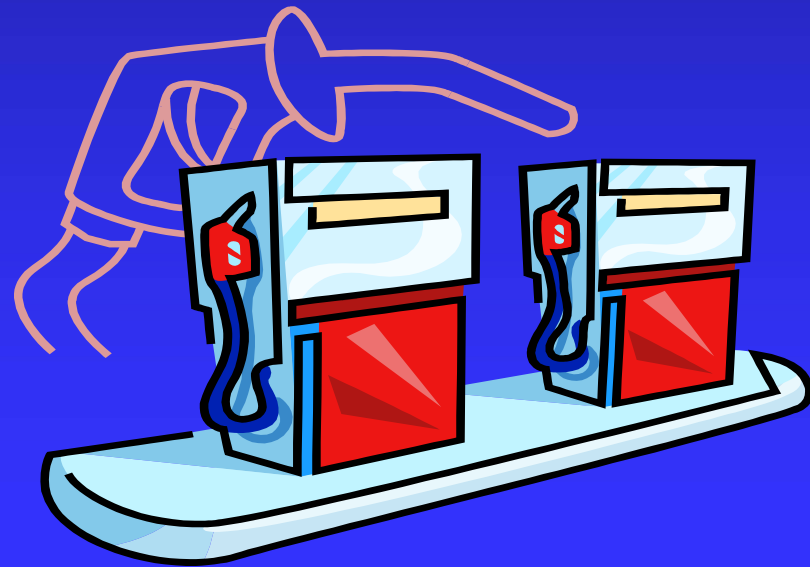
A pharma rep pays for an informal lunch presentation on a new drug at a quiet restaurant of modest value. Several health professionals attend. Is this covered by the code? If one of the health providers brings a guest and offers to pay for their meal would it be covered under the code?

You have been chosen to decide which type of new scanner to purchase for your clinic. After speaking with several manufacturers, the rep for scanner “X” offers to fly you, the physician making the assessment, to a training seminar at a distant resort area for two days with all expenses paid.

What are the conflicts?



A physician is provided with gasoline for his car and at the same time provided with product information – would this comply with the code?



A sales rep invites a physician out for a round of golf and lunch following. The physician is very busy and is difficult to see in her office. The cost of the golfing fees and lunch combined is \$70.00.



Does this comply with the Code?

The superior man seeks what is right; the inferior one, what is profitable.

*Confucius*