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An Ethical Framework  
for  
Clinician/Industry Interactions

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# Pretest

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- 
1. Which of the following statements regarding the pharmaceutical industry is not true?
    - a. Drugs represent about 10% of healthcare costs
    - b. Over 15% of total pharmaceutical costs are expended on research and development
    - c. Drug costs have risen 10-15% per year over the past 10 years
    - d. Profit margins in the pharmaceutical industry tend to be high
    - e. Nearly 35% of drug sales are expended on sales and drug promotion
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# Pretest

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- 2. Typical contract services physicians provide to industry include participation in:
    - a. Speakers bureaus
    - b. National advisory boards
    - c. Formulary committees
    - d. Regional advisory boards
    - e. CME presentations
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# Pretest



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3. Drug marketing may reasonably include all of the following except:
    - a. Notice that a drug has just received a new indication from the FDA
    - b. Industry sponsored clinical trials data
    - c. Industry acquired cumulative experience data
    - d. Information on common off-label uses of the drug
    - e. Industry sponsored cost effectiveness data



# Pretest

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- 4. Gifts to physicians:
    - a. Are appropriate recognition for increased prescription of a drug
    - b. Rarely have any impact on clinical decisions
    - c. Are prohibited by AMA guidelines
    - d. Are limited in value by PhARMA guidelines
    - e. Are regulated by the FDA
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# Pretest

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## 5. FDA Regulations:

- a. Prohibit “off-label” prescription of medications
- b. Limit what physicians can say in marketing talks
- c. Prohibit physicians from accepting gifts
- d. Prohibit pharmaceutical companies from conducting clinical studies involving competitors’ drugs
- e. Require companies to make public all information they have on drug trials



# Major Teaching Points

- Residents will become familiar with APA guidelines for physician-industry contacts
- Residents will understand the basic functions of the pharmaceutical industry
- Residents will be able to characterize the various types of interactions between physicians and the pharmaceutical industry
- Residents will discuss an ethical framework in which to evaluate physician interactions with industry

# Readings

- Lexchin J. Interactions between physicians and the pharmaceutical industry: What does the literature say? *Can Med Assoc J* 149:1401-07; 1993
- Rosner F. Pharmaceutical industry support for continuing medical education programs: A review of current ethical guidelines. *Mt. Sinai J Med* 62:427-63; 1995
- Wazana A. Physicians and the pharmaceutical industry: Is a gift ever just a gift? *JAMA* 283:373-80; 2000



# Outline



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- Background
    - Economic issues in development and marketing of drugs
    - Reasons for physician interactions with drug companies
  - Ethical framework for interactions
    - Goals and practices of clinical and academic medicine and industry
    - Types of interactions with industry
    - Legitimate and illegitimate marketing factors
    - Dangers of inappropriate interactions
  - Practical applications
    - AMA, PhARMA, FDA, and ACCME guidelines and regulations
    - Recommendations
    - Case scenarios



# Clinician-Industry Interaction

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Background

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# Economic Issues

## Pharmaceutical Sales and Costs (2004)

- \$243.8 billion total sales
- \$38.8 billion (15.9% of total sales) spent on research and development
- Drugs represent 10.7% of total US healthcare costs
- Drug costs have risen at a rate of 10-15% per year for the past 10 years

# Economic Issues

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## Promotional Costs (2001)

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- \$15.7 billion = 12.9% of sales (PhRMA)

VS

- \$27 billion = 22% of sales (No free lunch.com)

Why the difference?

Unrestricted education grants are tax-deductible charitable contributions, not promotion costs



# Economic Issues



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## Are Medicines Too Expensive?

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- Research and development costs are high
- A single lawsuit can be catastrophic
- Patent protection is time-limited



# Economic Issues

## ■■■ --- Are Medicines Too Expensive? ---

*but*

- Pharmaceutical stocks are considered among the most profitable and consistent investments available

# Economic Issues

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## Are Medicines Too Expensive?

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*but*

- High profitability is essential for the maintenance of an aggressive research and development program



# Why Do We Do It?

## ■■■ Contacts with industry are unavoidable

- Physician Desk Reference
- Prescription of proprietary drugs
- Sponsorship of professional meetings
- Advertisements in professional journals
- Response to academic activity



# Why Do We Do It?

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Contacts with industry are desirable

- 
- Sponsorship of educational programs
  - Sponsorship of professional organizations
  - Sponsorship of research
  - Notification of product availability
  - Exposure to proprietary information
  - Academic input into research and marketing
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# But...

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 Industry's priorities differ from those of clinical and academic medicine

Is it possible to benefit from industry contacts without compromising the integrity of clinical and academic medicine?

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# An Ethical Framework



# Primary Aims

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Clinical Medicine

- Patient benefit
- Societal benefit

Academic Medicine

- Acquisition and dissemination of knowledge

Medical Industry

- Financial gain
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# Positive Practices

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## Clinical Medicine

- Patient treatment
- Physician-patient relationship

## Academic Medicine

- Research
- Education

## Medical Industry

- Development of safe and effective treatments
  - Sponsorship of education
  - Sponsorship of research
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# Negative Practices

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## Clinical Medicine

- Paternalism
- Boundary violations
- Incompetent practice
- Financial concerns

## Academic Medicine

- Career development

## Medical Industry

- Marketing bias in research and education
  - Excessive profits
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# Oversight

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## Clinical Medicine

- Professional standards
- Moderate government regulation

## Academic Medicine

- Academic standards
- Minimal government regulation

## Medical Industry

- Extensive government regulation
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# Industry Interactions with Physicians

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## Contract Services

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- Scientific advisory boards
- Marketing advisory boards
- Speakers bureaus
- Research design, participation, and publication





# Industry Interactions with Physicians

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## Contract Services

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- Promotional Talk (Speakers Bureau) - \$1000-5000
  - CME Talks (e.g., Grand Rounds) - \$500-5000
  - District Advisory Meeting - \$1000-2000
  - National Advisory Meeting - \$1000-5000
  - APA Symposium - \$3500
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# Industry Interactions with Physicians

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## ■■■ Educational Programs

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- Unrestricted education/research grants
- Industry-sponsored symposia
- Patient education materials
- Journal sponsorship

# Industry Interactions with Physicians

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## Marketing Contacts

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- Physician detailing
- Lunch/dinner meetings and presentations
- Advertisements



# Marketing and Clinical Practice

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## Factors in clinical decision-making

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- Evidence-based clinical data
- Clinical experience
- Nonclinical complicating factors (self-serving bias)
  - financial reward
  - academic interest



# Marketing and Clinical Practice



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## Legitimate marketing factors

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- Notification of availability
- Clinical trials data
- Cumulative experience data
- Cost effectiveness data



# Marketing and Clinical Practice



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## Illegitimate marketing factors

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- Personal relationship with physician
- Incentives to decision-makers
- Gifts



# Gifts

- Gifts of “nominal” value are permitted by AMA guidelines and FDA regulations, but not by some other entities (e.g., VA).
- It is difficult to establish an ethical basis for physicians to accept gifts
- Even gifts of minimal value have an impact on physicians, whether they recognize it or not (Wazana, 2000)

# Confusion of Boundaries

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Marketing contact

vs

Educational  
program

Promotional literature

vs

Research literature

Contract service

vs

Gift

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# Major Dangers



- 
- Clinical compromise
  - Research bias
  - Academic corruption



# Clinical Compromise



- 
- Inaccurate or biased information
  - Biased clinical judgment
    - Financial incentive
    - Receipt of gifts
    - Personal relationship with pharmaceutical representative



# Research Bias

- Sponsorship strongly predicts outcome in industry-sponsored research
- Industry is not required to divulge all study results
- Research questions can be framed to favor a specific outcome
- Data can be framed to accentuate specific outcomes

# Academic Corruption



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- Selective input into research
  - Research driven by financial incentive
  - Education biased by financial incentive
  - Industry support of favorable opinions



# Clinician-Industry Interaction

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## Practical Applications

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# AMA Ethical Guidelines



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- Any gift should benefit patients
  - Gifts should be of minimal value and related to the physician's work
  - No gifts should be accepted with strings attached



# AMA Ethical Guidelines

- Support for legitimate conferences or meetings (including faculty honoraria) is permissible
- Subsidies for individual physicians to attend meetings are not permissible
- Scholarships for residents and fellows must be assigned by the training program

# Peer Review



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- Publications, posters, and slide sets may be reviewed by recognized experts in the field to ensure that:
    - Appropriate scientific methods were employed
    - Defensible conclusions were reached
    - Bias is avoided in reporting results





# PhRMA Ethical Guidelines



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- Dinner programs should be limited to a “modest” meal, without guests
  - CME programs should be planned and conducted by academic and clinical centers
  - Consultants must provide legitimate services for reasonable fees
  - Speakers’ training may include reimbursement for time, travel, and expenses



# PhRMA Ethical Guidelines

- Scholarships should be for major scientific and clinical conferences, and should be awarded by the sponsoring academic institution
- Gifts should be of modest value (<\$100), and should benefit the physician's practice
- No gift, scholarship, or contract should compromise the clinician or academician's independence of decision making

# FDA Regulations

- All marketing materials must be FDA approved, and information shared during marketing contacts may not exceed the boundaries of approved packaging information
- Sponsored speakers may answer questions, but may not initiate or perpetuate discussion of “off-label” drug uses

# FDA Regulations

- Sponsored speakers may only discuss information derived from accepted research methods or recognized expert consensus opinion
- Research studies involving a competitor's drug must follow packaging guidelines for the drug

# ACCME Regulations for CME Programs

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- Potential or perceived conflicts of interest regarding the topic of the presentation must be disclosed
- Presentations must include specific learning objectives
- The speaker's qualifications must be appropriate to the topic covered



# What We Can Do



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- Observe AMA Guidelines regarding gifts
  - Be clear about the nature of our interactions with industry
  - Disclose everything
  - Limit gifts and personal contacts



# What We Can Do



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- Use peer review and consultation to detect diagnostic and therapeutic “drift”
  - Be aware of sponsorship of research and educational programs
  - There is no substitute for constant attention to personal integrity and professional rigor



# Case Scenario 1

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 During a detail visit by a pharmaceutical representative, a psychiatrist is congratulated on being the top prescriber of the company's product in that area. In recognition of this, the psychiatrist is given a gift certificate for dinner at a popular restaurant.

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- What APA guidelines apply to this situation?
  - What ethical issues are involved?
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## Case Scenario 2



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An academic psychiatrist with an interest in antidepressant medications is offered \$1000 to speak at a symposium on treatment of depression.

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- What ethical issues must be considered if
  - a. the symposium is sponsored by an unrestricted education grant to the hosting institution?
  - b. the symposium is industry-sponsored?



# Case Scenario 3

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A psychiatrist is invited by a pharmaceutical representative to hear a speaker at a popular restaurant. Afterward, attendees are invited to a performance of an award-winning stage production.

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- What APA guidelines apply to this situation?
  - What ethical issues are involved?
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## Case Scenario 4

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A psychiatrist is invited to participate in a regional advisory board for a pharmaceutical company. The meeting is for one day at a major hotel in San Francisco. The psychiatrist will be paid a \$1000 honorarium for participation.  

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- What APA guidelines apply to this situation?
  - What ethical issues are involved?
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# Case Scenario 5

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A psychiatrist is invited to attend a CME conference in Hawaii at the expense of a pharmaceutical company. The meeting includes two hours of workshops each morning for three days.

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- What APA guidelines apply to this situation?
  - What ethical issues are involved?
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## Case Scenario 6

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A psychiatrist attends a dinner talk on a new antipsychotic medication with which he is unfamiliar. The next day he prescribes the medication for a newly diagnosed schizophrenic patient.

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- What ethical issues are involved?
  - What legitimate marketing factors may be involved?
  - What illegitimate factors may be involved?
- 

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# Case Scenario 7

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A psychiatrist with a newly opened private office evaluates a patient for depression. The psychiatrist strongly recommends psychotherapy as the superior treatment option.

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- What ethical issues must be considered?
  - What legitimate clinical factors should be considered in making this recommendation?
  - What illegitimate factors should be avoided?
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## Case Scenario 8

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A psychiatrist is on the speakers bureau for companies A and B, which manufacture competing antidepressants. In a marketing talk for company A, she is asked for a personal recommendation regarding the drugs.

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- How should she respond?
  - How should she respond when speaking for company B?
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# Test Answer Key



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1. e

2. c

3. d

4. a

5. b

