
■ ■ ■

An Ethical Framework for Clinician/Industry Interactions

Michael D. Jibson, M.D., Ph.D.

Professor of Psychiatry

University of Michigan

■ ■ ■

Author Disclosure

- Over the past 3 years, I have received \$5000-10,000 per year from the AstraZeneca speakers bureau for promotional programs on quetiapine.

Outline



-
- Background
 - Economic issues in research, marketing and healthcare costs
 - Reasons for interactions with industry
 - Ethical framework
 - Goals and practices of medicine and industry
 - Types of interactions – contracts, marketing, gifts
 - Factors in clinical decision-making
 - Sources of bias
 - Self-serving bias



Outline



- Practical applications
 - AMA guidelines
 - Other guidelines and regulations – FDA, ACCME, PhRMA
 - Peer review
- Case scenarios



Major Teaching Points

- Understand the role of the pharmaceutical industry in medicine
- Be familiar with APA guidelines for physician-industry contacts
- Be able to characterize the various types of interactions between physicians and the pharmaceutical industry
- Recognize sources of bias and how to overcome them
- 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
- Dubovsky AN, Dubovsky SL. *Psychotropic Drug Prescriber's Survival Guide: Ethical Mental Health Treatment in the Age of Big Pharma*. Norton, 2007



Pretest

- _____
1. Which of the following statements regarding the pharmaceutical industry is true?
 - a. Drugs represent about 10% of healthcare costs
 - b. Less than 5% of total pharmaceutical costs are expended on research and development
 - c. Drug costs have been stable over the past 10 years
 - d. Nearly 50% of drug sales are expended on sales and drug promotion
 - e. Profit margins in the pharmaceutical industry tend to be low
- _____ ■■■

Pretest



-
2. Which of the following statements regarding FDA regulations is true?
- a. They govern physicians' use of drugs
 - b. They prohibit physicians from accepting gifts of more than \$100 from industry
 - c. They prohibit "off label" promotion of drugs
 - d. They require disclosure of negative drug trials
 - e. They prohibit industry from sponsoring CME programs



Pretest

- _____
3. Which of the following statements regarding AMA guidelines is true?
- a. They are binding on all AMA members
 - b. They prohibit physicians from accepting gifts of more than minimal value from industry
 - c. They permit “off label” prescription of drugs
 - d. They require disclosure of industry relationships to patients
 - e. They prohibit industry from sponsoring CME programs
- _____ ■■■

Pretest



-
4. Empirical studies demonstrate which of the following?
 - a. Physicians are good judges of their own biases
 - b. Small gifts, such as pens, have minimal impact on physicians' prescribing practices
 - c. Most marketing materials are accurate and objective
 - d. Industry representatives are excellent sources of objective information about medications
 - e. Sponsorship strongly predicts outcome in published research studies



Pretest



-
5. Which of the following has been shown to overcome self-serving bias?
- a. Development of extensive clinical experience
 - b. Role-playing exercises
 - c. Disclosure of financial interests
 - d. Familiarity with peer-reviewed literature
 - e. Use of personal insight and self-awareness



Clinician-Industry Interaction

Background

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 the same rate as total healthcare costs over the past 10 years

Economic Issues

Promotional Costs (2001)

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

VS

- \$27 billion = 22% of sales (www.nofreelunch.org)

Why the difference?

Unrestricted education grants and free samples were not included in the PhRMA estimate



Economic Issues



Are Medicines Too Expensive?

- 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



Are Medicines Too Expensive?

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?

■■■

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
-

■■■

But...

■■■

**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?**

■■■



An Ethical Framework



Ethical Duties

Clinical and
Academic Medicine

- Beneficence
- Integrity
- Social justice

Medical Industry

- Integrity
 - Legality
 - Fiscal responsibility
-

Primary Aims

Clinical Medicine

- Patient benefit
- Societal benefit

Academic Medicine

- Acquisition and dissemination of knowledge

Medical Industry

- Financial gain
-

Positive Practices

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
-

Negative Practices

Clinical Medicine

- Paternalism
- Boundary violations
- Incompetent practice
- Financial concerns

Academic Medicine

- Career development

Medical Industry

- Marketing bias in research and education
 - Excessive profits
-

Oversight

Clinical Medicine

- Professional standards
- Moderate government regulation

Academic Medicine

- Academic standards
- Minimal government regulation

Medical Industry

- Extensive government regulation
-

Industry Interactions with Physicians

Contract Services

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



Industry Interactions with Physicians

Contract Services

- Promotional Talk - \$500-5000
- Grand Rounds - \$500-5000
- National Advisory Meeting - \$1000-5000
- APA Symposium - \$3500



Industry Interactions with Physicians

■■■ Educational Programs

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

Industry Interactions with Physicians



Marketing Contacts

- Physician detailing
- Speakers Bureau presentations
- Advertisements



Industry Interactions with Physicians

Physician Detailing

- Marketing representative meets individually with a physician
- Only FDA-approved materials may be shared and FDA indications discussed
- Branded gifts may be offered
- Free samples may be provided
- Requests for proprietary information will be passed on to the company's scientific liaison



Industry Interactions with Physicians

Physician Detailing

Positive Aspects

- Latest FDA indications and warnings are highlighted
- Patients may benefit from free samples

Negative Aspects

- Marketing information is highly biased
- Gifts (including samples) may inappropriately influence physicians' judgment



Industry Interactions with Physicians

Speakers Bureau Presentations

- Presentation by a physician on contract with a pharmaceutical company
- Usually in conjunction with a lunch or dinner
- May only deal with FDA indications; all slides and the speaker's script must be FDA approved
- Includes review of efficacy and safety data for the drug and indication



Industry Interactions with Physicians

Speakers Bureau Presentations

Positive Aspects

- Includes detailed review of efficacy and safety data
- FDA “fair balance” rule requires as much attention to safety as to efficacy

Negative Aspects

- Associated meal may bias participants
- Speakers’ personal opinions are difficult to regulate



Industry Interactions with Physicians

■ ■ ■ Advertisements

- Advertising in professional journals and at meetings targets physicians
 - Higher quality journals group ads at the beginning and end of the issue, separate from scientific papers
 - Professional organizations are encouraged to separate advertising booths from the rest of the meeting
 - Direct-to-consumer advertising targets potential patients
 - FDA requires “fair balance” in DTC advertising
-

Industry Interactions with Physicians

Advertising

Positive Aspects

- Alerts physicians to new products
- Pays for publication and organization costs
- May increase patient awareness of illness and treatment

Negative Aspects

- Usually receives only cursory reading
- Includes superficial data on efficacy and safety
- May encourage unrealistic patient expectations



Marketing and Clinical Practice

Factors in clinical decision-making

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



Marketing and Clinical Practice



Legitimate marketing factors

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



Marketing and Clinical Practice



Illegitimate marketing factors

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



Confusion of Boundaries

■ ■ ■

Marketing contact

vs

Educational
program

Promotional literature

vs

Research literature

Contract service

vs

Gift

■ ■ ■

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



Physician Bias

■■■

A substantial body of empirical studies shows that:

- Even small gifts influence physicians' practices
- Physicians have poor insight into their own biases
- Marketing materials are highly biased
- Industry representatives vary widely in reliability and expertise

Physician Bias

Self-serving Bias

- We tend to make judgments that serve our own interests
- We believe these judgments to be objective and balanced
- Disclosure is not sufficient to overcome this bias (and may even make it worse)



Physician Bias

Self-serving Bias

- Effective remedies include
 - Peer review
 - Role playing (i.e., assuming the role of other interested parties, such as patients, payors, or competitors)
 - Changing reward systems



Research Bias

- Sponsorship strongly predicts outcome in industry-sponsored research
- Research questions can be framed to favor a specific outcome
- Data can be framed to accentuate specific outcomes
- Some study results may not be disclosed (now limited by FDA regulations and some journal requirements)

Academic Corruption



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



Clinician-Industry Interaction

Practical Applications

Peer Review



-
- 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



Peer Review



-
- Clinical practice may benefit from peer review in the form of:
 - Individual case discussion
 - Chart reviews
 - Comparison of practice data to peer norms



Disclosure

- Financial incentives creating real or apparent conflicts should be fully disclosed in order to:
 - Allow patients or audience members to evaluate the objectivity of a recommendation
 - Encourage the disclosing physician to exercise care in making recommendations
 - Encourage the disclosing physician to carefully consider the ramifications of contractual arrangements with industry

Disclosure



-
- Standard disclosure includes:
 - Existence of a relationship
 - Name of the company involved
 - Nature of the relationship (eg, speakers bureau, advisory board)



Disclosure



-
- Higher level disclosure includes:
 - Name of drugs or devices promoted
 - Amount of money involved
 - Percent of income derived from the activity



AMA Ethical Guidelines



-
- 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

PhRMA Ethical Guidelines

- 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 Guidelines



-
- 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 Guidelines

- 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 Guidelines for CME Programs

- 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



Recommendations for Professional Medical Associations

- No more than 25% of an association's total budget should be derived from industry
- Oversight committees should monitor industry-sponsored education programs or find alternative funding
- No gifts or industry-labeled items should be included with registration materials for association meetings

Recommendations for Professional Medical Associations

- Advertising booths should be in a separate area, not in the obligate path to a scientific or educational session
- Associations should not endorse, facilitate, or accept funding for satellite symposia sponsored by industry
- Industry funding of research, fellowships, and training programs must be administered by the professional association without industry input

Recommendations for Professional Medical Associations

- Groups that develop practice guidelines must be independent of actual or perceived industry influence
- Associations must have clear regulations governing industry advertising in their journals
- Officers of associations should be conflict-free during their tenure
- Associations should educate their members regarding conflict of interest

What We Can Do



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



What We Can Do



-
- 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

■■■

 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.

- What AMA guidelines apply to this situation?
 - What ethical issues are involved?
-



Case Scenario 2



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

- 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

■■■

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.

- What AMA guidelines apply to this situation?
 - What ethical issues are involved?
-

Case Scenario 4

■■■

A psychiatrist is invited to participate in a national 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.

- What AMA guidelines apply to this situation?
 - What ethical issues are involved?
-

Case Scenario 5

■■■

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.

- What AMA guidelines apply to this situation?
 - What ethical issues are involved?
-

Case Scenario 6

■■■ _____
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.

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

■■■

Post-test

- _____
1. Which of the following statements regarding the pharmaceutical industry is true?
 - a. Drugs represent about 10% of healthcare costs
 - b. Less than 5% of total pharmaceutical costs are expended on research and development
 - c. Drug costs have been stable over the past 10 years
 - d. Nearly 50% of drug sales are expended on sales and drug promotion
 - e. Profit margins in the pharmaceutical industry tend to be low
- _____ ■■■

Post-test



-
2. Which of the following statements regarding FDA regulations is true?
- a. They govern physicians' use of drugs
 - b. They prohibit physicians from accepting gifts of more than \$100 from industry
 - c. They permit "off label" promotion of drugs
 - d. They require disclosure of negative drug trials
 - e. They prohibit industry from sponsoring CME programs



Post-test

-
3. Which of the following statements regarding AMA guidelines is true?
- a. They are binding on all AMA members
 - b. They prohibit physicians from accepting gifts of more than minimal value from industry
 - c. They prohibit “off label” prescription of drugs
 - d. They require disclosure of industry relationships to patients
 - e. They prohibit industry from sponsoring CME programs
-

Post-test



-
4. Empirical studies demonstrate which of the following?
 - a. Physicians are good judges of their own biases
 - b. Small gifts, such as pens, have minimal impact on physicians' prescribing practices
 - c. Most marketing materials are accurate and objective
 - d. Industry representatives are excellent sources of objective information about medications
 - e. Sponsorship strongly predicts outcome in published research studies



Post-test



-
5. Which of the following has been shown to overcome self-serving bias?
- a. Development of extensive clinical experience
 - b. Role-playing exercises
 - c. Disclosure of financial interests
 - d. Familiarity with peer-reviewed literature
 - e. Use of personal insight and self-awareness



Pre- and Post-test Answers



1. a

2. c

3. d

4. e

5. b

