

Ethics of the Physician-Pharmaceutical Industry Relationship

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Objectives

- Discuss the ethics of Industry-Physician relationships in the areas of:
 - Gifts
 - Research
 - Medical education
- Discuss standards for pharmaceutical company and physician relationships
- Introduce AMA webcourse:
soundprescribing.com

Industry and Gifts: A Case

- An industry representative invites you and a guest to dinner at an upscale restaurant for an educational presentation by a regional physician on a new medication. The industry representative of this highly promoted drug encourages you to share this information with the hospital's P&T committee for consideration on the formulary.

PHYSICIANS AND THE PHARMACEUTICAL INDUSTRY

- In 2000 – Pharma spent \$11 billion on promotions - \$5 billion went to sales representatives – an estimated \$8000 to \$13,000 per year on each physician. ¹
- In 1996 direct to consumer advertising (DTCA) of prescription medications was an expenditure of \$985 million, by 2006 DTCA expenditure reached \$15.43 billion. ²

1 Wazana, Ashley, JAMA, vol 283; pp 373 – 380.

2 Kao, Andicy, Manuscript to be published.

RESULTS 29 STUDIES PHYSICIAN – PHARMACEUTICAL INDUSTRY INTERACTION ¹

- Start as early as medical school and persist into practice
- Residents & faculty do not differ in interaction
- Most physicians met with pharmaceutical reps 4 per mo only
predictor of number of contacts was decreased availability of peer
physicians and positive attitude toward pharmaceutical rep
- Frequency of industry sponsored meals and samples decreases as
enter practice but honoraria, conference travel, and research
funding increases. ²

1 Wazana, Ashley, JAMA, vol 283; pp 373 – 380.

2 Kao, Andicy, Manuscript to be published.

Physician – Pharma Interaction (cont)

Attitudes Toward Interaction

- Residents and practicing physician believe reps provide accurate information about the drug being promoted but are ambivalent as to whether information on alternative drugs is accurate.
- Residents are less likely than practicing physicians to endorse the influence of the interaction on their behavior.
- Most physicians deny that gifts could influence their behavior and are equivocal about the ethics of such practice.

Physician – Pharma Interaction

Effect of Pharmaceutical Representative Interaction

- Interactions did influence prescribing of residents and practicing physicians in terms of Rx cost, non-rational Rx preference, and decreased Rx of generic drugs, as well as, rapid Rx of new drugs.
- Receiving gifts correlated with the belief that this had no impact on Rx behavior but did have a positive effect on the attitude toward pharma rep which was independent of the ability to recall the donor.

Physician – Pharma Interaction

Effect of Pharm Rep Interaction (cont)

- Accepting samples associated with awareness, preference, and rapid Rx of new drug also resulted in positive attitude toward pharm rep.
- Funding for travel or lodging to attend Educational Symposia resulted in increased formulary addition requests for the sponsor's drug.
- Physicians and residents are skeptical of the motives and comprehensive knowledge of pharm reps but there is a lack of concern about the influence of gifts, meals, CME, honoraria, etc.
- Documented that 3 interactions with pharm rep led to preference for drug promoted even though physicians forget the sponsor's names or the physicians' beliefs that they cannot be influenced.

Industry and gifts

- July 10, 2008, Pharmaceutical Research and Manufacturers of America guidelines
 - prohibits gifts of non-educational items to physicians
 - guidelines are voluntary
 - still allow payments for speaking and consulting, as well as the provision of in-office meals for a physician's staff.

Pause for Comments



Industry and Research

- Industry sponsored research Pharmaceutical companies typically focus on generating profit and increasing stock price and market share. Indeed, it is sometimes argued that corporations have an obligation to their shareholders to pursue increased market share and share price (Friedman 1970)

Industry and Research

- “...Sponsoring companies have become intimately involved in all aspects of research on their products. They often design the studies; perform the analysis; write the papers; and decide whether, when, and in what form to publish the results.”

Industry-Sponsored Clinical Research. A Broken System. Marcia Angell, MD. JAMA
September 3, 2008—Vol 300, No. 9, 1069

Industry and Research

- “...industry-sponsored research has consistently been shown to favor the sponsor’s drug—partly because negative results are often not published, partly because positive results are repeatedly published in slightly different forms, and partly because a positive spin is put on even negative results.”

Industry-Sponsored Clinical Research. A Broken System. Marcia Angell, MD. JAMA September 3, 2008—Vol 300, No. 9, 1069

Industry, Research and Physicians

- Conflicts of interest
 - Paid consultants
 - Speakers' bureau
 - Advisory boards
 - Equity interest (by faculty or SOM)

Industry, Research and Ghostwriting

- Ghostwriting usually refers to medical writers, often sponsored by a drug or medical device company, who make major research or writing contributions to articles that are published under the names of academic authors.

Ghostwriting

- JAMA study (unpublished) defined a ghostwriter as any unnamed individual who made substantive intellectual contributions or writing other than copy-editing
 - 7.9 % in JAMA
 - 4.9 % in the Annals of Internal Medicine
 - 10.9 % rate NEJM
 - 7.6 % in The Lancet

http://www.nytimes.com/2009/09/11/business/11ghost.html?_r=1&ref=health results reported in Vancouver 9/10/09

Ghostwriting Problems

- breach of the public trust
- potential to bias the medical literature, affecting treatment decisions by doctors and, ultimately, patient care.

Resolving Ghostwriting

- Dr. Carl Elliott, a bioethics professor at the Center for Bioethics of the UM, said universities should go further than mere disclosure, prohibiting faculty members from working with industry-sponsored writers. Policies asking only for disclosure “allow pharmaceutical companies to launder their marketing messages”

“Senator Moves to Block Medical Ghostwriting” NYT, By NATASHA SINGER
Published: August 18, 2009

Pause for Comments



Industry and Education: Case

- Industry support of SD WY ACP Scientific meetings: do we continue?

2009
South Dakota/
Wyoming Chapters
Scientific Meeting
September 17–18, 2009

AMA: Industry and Medical Education

- June 2008, CEJA reported that “industry support of professional education has raised concerns that threaten the integrity of medicine’s educational function.”
- “the profession must obtain more noncommercial funding of professional education activities.”
- “the education of physicians is a public good whose burden should not be shared by the profession alone.”

http://www.ama-assn.org/ama1/pub/upload/mm/369/ceja-cme_1i08.pdf and
Relman, Industry Support of Medical Education JAMA 2008

AAMC: Industry and Education

- “AAMC task force did not reject industry support of medical education, but said that such support should be received and coordinated by a central CME office in each institution. It also strongly discouraged participation by medical faculty in industry-sponsored speakers’ bureaus. On the other hand, like CEJA, the AAMC task force took a strong stand against marketing by industry representatives in teaching institutions.”

Relman, Industry Support of Medical Education JAMA 2008

Industry and Education

- “...neither the AMA’s House of Delegates nor the Executive Council of the AAMC is prepared to cut off industry support of CME because at this time they see no other source of funding to replace it.”

Relman, Industry Support of Medical Education JAMA 2008

Other Options for CME

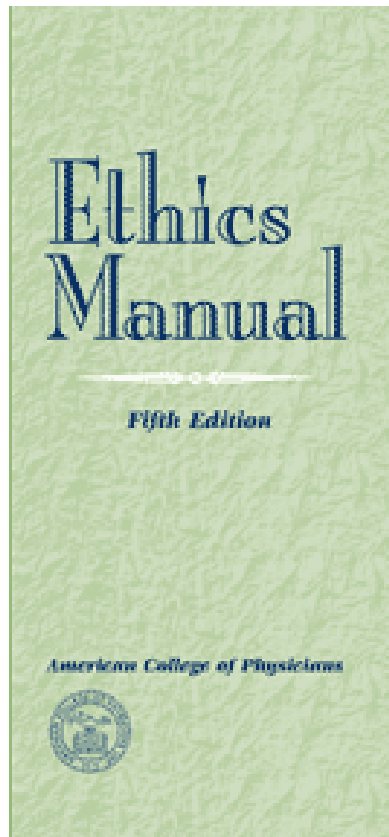
- Seeks other sources of financial support
- Physicians attending CME programs ought to be willing and able to pay something for their continuing education
- Faculty at schools and teaching hospitals should be expected to teach
 - reduce costs and probably improve quality.
- New educational approaches to delivering CME are in the offing

Relman, Industry Support of Medical Education JAMA
2008

Discussion of Industry Support of SD WY ACP Scientific Meetings



ACP and Industry



Physician – Pharma Interaction

ACP Ethics Manual ³

Minimal in direction 3 paragraphs pointing out conflict of interest and recommends asking the following questions:

- “Would I be willing to have this arrangement generally known?”
- “What would the public or my patients think of this arrangement?”
- “What is the purpose of the industry offer?”
- “What would my colleagues think about this arrangement?”
- “What would I think if my own physician accepted this offer?”

3 Annals of Internal Medicine, 2005: 142: pp 560 – 582.

Physician – Pharma Interaction

Sound Prescribing

- Developing educational strategies to help physicians manage the influence of pharmaceutical industry marketing and promotional materials on physician prescribing.

Longitudinal Cohort Pilot

- Planning for a “Framingham-like” large scale medical student/physician longitudinal cohort study across multiple sites.
- A committee chaired by Tom Houston, MD and Monika Stafford, MD from the University of Alabama was established in 2008 to write protocols develop through research pilot studies in medical education that will serve as the conceptional, methodological, and practical launching pad for a larger cohort study.

Physician – Pharma Interaction

Sound Prescribing (cont)

1. Plan for the launch of a large-scale medical student/physician longitudinal cohort study by 2010 or 2011.
2. Conduct a detailed analysis of available resources.
3. Expand existing projects and sites.
4. Explore new assessment and intervention of projects in medical education.
5. Strengthen internal and external relationships.

Physician – Pharma Interaction Sound Prescribing (cont)

Contact Information

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Cases

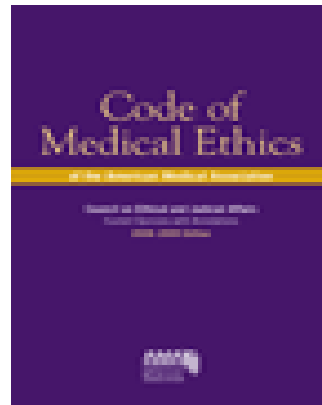
Questions/Comments



For your reference: Codes of Ethics

- AMA
- ACP
- PhRMA

AMA Code of Ethics: Opinion 8.061 - Gifts to Physicians from Industry



<http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics.shtml>

AMA Code of Ethics: Opinion 8.061 - Gifts to Physicians from Industry

To avoid the acceptance of inappropriate gifts, physicians should observe the following guidelines:

1. Any gifts accepted by physicians individually should primarily entail a benefit to patients and should not be of substantial value.
2. Individual gifts of minimal value are permissible as long as the gifts are related to the physician's work (eg, pens and notepads).

Opinion 8.061

3. The Council on Ethical and Judicial Affairs defines a legitimate "conference" or "meeting" as any activity, held at an appropriate location, where
 - (a) the gathering is primarily dedicated, in both time and effort, to promoting objective scientific and educational activities and discourse (one or more educational presentation(s) should be the highlight of the gathering), and
 - (b) (b) the main incentive for bringing attendees together is to further their knowledge on the topic(s) being presented.

Opinion 8.061

4. Subsidies to underwrite the costs of continuing medical education conferences or professional meetings can contribute to the improvement of patient care and therefore are permissible.
5. Subsidies from industry should not be accepted directly or indirectly to pay for the costs of travel, lodging, or other personal expenses of physicians attending conferences or meetings, nor should subsidies be accepted to compensate for the physicians' time.

Opinion 8.061

6. Scholarship or other special funds to permit medical students, residents, and fellows to attend carefully selected educational conferences may be permissible as long as the selection of students, residents, or fellows who will receive the funds is made by the academic or training institution.
7. No gifts should be accepted if there are strings attached.

<http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion8061.shtml>

ACP: Physician Industry Relations

- http://www.acponline.org/running_practice/ethics/issues/relations/

Physician–Industry Relations. Part 1: Individual Physicians

Susan L. Coyle, PhD, for the Ethics and Human Rights Committee, American College of Physicians–American Society of Internal Medicine*

5 March 2002 Annals of Internal Medicine Volume 136 • Number 5

- Part 1 offers advice to individual physicians

“This paper offers two positions to help guide individual physicians in making ethical decisions about interacting with industry. The positions are based on the profession’s fundamental principles of responsibility, that is, acting in a patient’s best interests (beneficence), protecting the patient from harm (nonmaleficence), having respect for the patient and fostering informed choice (autonomy), and promoting equity in health care (justice). To uphold these principles, the primary purpose of entering relationships with industry should be the enhancement of patient care and medical knowledge.”

POSITION 1. INDUSTRY GIFTS, HOSPITALITY, SERVICES, AND SUBSIDIES

The acceptance of individual gifts, hospitality, trips, and subsidies of all types from industry by an individual physician is strongly discouraged. Physicians should not accept gifts, hospitality, services, and subsidies from industry if acceptance might diminish, or appear to others to diminish, the objectivity of professional judgment.

POSITION 2. FINANCIAL RELATIONSHIPS BETWEEN PHYSICIANS AND INDUSTRY

Physicians who have financial relationships with industry, whether as researchers, speakers, consultants, investors, owners, partners, employees, or otherwise, must not in any way compromise their objective clinical judgment or the best interests of patients or research subjects. Physicians must disclose their financial interest in any medical facilities or office-based research to which they refer or recruit patients.

Physician–Industry Relations. Part 2: Organizational Issues

Susan L. Coyle, PhD, for the Ethics and Human Rights
Committee, American College of Physicians–American
Society of Internal Medicine*

Ann Intern Med. 2002; 136: 403-406

Part 2: “addresses ethical concerns relevant to medical
education providers, academic units that accept industry
support, and medical professional societies.”

POSITION 3. INDUSTRY-SUPPORTED GRADUATE AND CONTINUING MEDICAL EDUCATION

Public and private GME and CME providers that accept industry support for educational programs should be aware of potential conflicts of interest and should develop and enforce explicit policies that maintain complete control of program planning, content, and delivery.

POSITION 4. SUPPORT FOR MEDICAL SOCIETY ACTIVITIES

Medical professional societies that accept industry support or other external funding should be aware of potential bias and conflicts of interest and should develop and enforce explicit policies that preserve the independent judgment and professionalism of their members and maintain the ethical standards and credibility of the society.

Institute of Medicine Report April 2009

Bernard Lo and Marilyn J. Field, Editors;
Committee on Conflict of Interest in Medical
Research, Education, and Practice; Institute of
Medicine

<http://www.iom.edu/Object.File/Master/65/993/COI%20report%20brief%20for%20web.pdf>





- The committee recommends the implementation of policies and procedures that will reduce the risk of conflicts that can jeopardize the integrity of scientific investigations, the objectivity of medical education, the quality of patient care, and the public's trust in medicine

<http://www.iom.edu/?ID=65721>

Report recommends:

- Forgo gifts of any amount from medical companies
- Decline to publish or present material ghostwritten or otherwise controlled by industry
- Consulting arrangements should be limited to legitimate expert services spelled out in formal contracts and paid for at a fair market rate.
- Physicians should limit their interactions with company sales representatives and use free drug samples only for patients who cannot afford medications.

OIG Compliance Program Guidance for Pharmaceutical Manufacturers

Guidance document discusses the most common potentially illegal arrangements

- "switching" arrangements
- consulting and advisory payments
- payments for detailing
- business courtesies and other gratuities
- educational and research activities

PhRMA Code on Interactions with Healthcare Professionals

“The Code is based on the principle that a healthcare professional’s care of patients should be based, and should be perceived as being based, solely on each patient’s medical needs and the healthcare professional’s medical knowledge and experience.”

http://www.phrma.org/code_on_interactions_with_healthcare_professionals/

PhRMA Code on Interactions with Healthcare Professionals

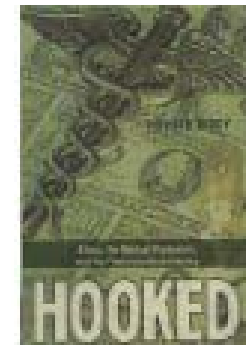
- voluntary guidelines for pharmaceutical manufacturers as related to marketing interactions with health care professionals, and specifically the gifts and gratuities given to health care professionals.
- "all interactions [between manufacturers and health care professionals are] focused on informing healthcare professionals about products, providing scientific and educational information, and supporting medical research and education,"

References

- The Truth about Drug Companies
Marcia Angell, MD



- Hooked: Ethics, the Medical Profession, and the Pharmaceutical Industry
Howard Brody, MD



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