

American Medical Association

What You Should Know About Gifts to Physicians from Industry

MODULE 4:

American Medical Association Ethical Guidelines on Gifts to Physicians from Industry

Participant's Handout

**Author:
Karine Morin, LLM**

An American Medical Association initiative to increase awareness and support of ethical guidelines

In collaboration with the Working Group for the Communication of Ethical Guidelines on Gifts to Physicians from Industry (See <http://www.ama-assn.org/ama/pub/category/8405.html> for information on the Working Group)

The development and distribution of these materials is made possible through unrestricted educational grants from: American Medical Association, AstraZeneca, Bayer Corporation, Eli Lilly & Co., Glaxo, Merck & Company, Pfizer Inc., Pharmacia Corporation, Procter and Gamble Pharmaceuticals, and Wyeth-Ayerst Labs.

About the Author

Karine Morin, LLM joined the AMA's Ethics Standards Group in August 1999 and became secretary of the Council on Ethical and Judicial Affairs in 2000. Ms. Morin was promoted to Director of Ethics Policy in April 2002. She is a graduate of McGill University School of Law in Montreal, Canada. She also received a Master's in Law (LLM) from the University of Pennsylvania in Philadelphia. She worked at the American College of Physicians-American Society of Internal Medicine in Philadelphia as the Ethics and Health Policy Associate, was adjunct faculty at the Allegheny University of the Health Sciences in the fall of 1997, and served on the Crozer Keystone Health Systems home care/hospice ethics committee. She is now adjunct faculty at Northwestern University School of Law, where she teaches biomedical ethics.

Reviewers for this module included AMA staff and Kenneth V. Iserson, MD, MBA, Director, Arizona Bioethics Program, University of Arizona.

In collaboration with the Working Group for the Communication of Ethical Guidelines on Gifts to Physicians from Industry and its Educational Advisory Committee chaired by R. Van Harrison, PhD, University of Michigan School of Medicine. (See <http://www.ama-assn.org/ama/pub/category/8405.html> for information on the Working Group)

Project Manager: Beverley D. Rowley, PhD, Medical Education and Research Associates, Inc., Tempe, Arizona.

Disclosure of Conflict of Interest

Disclosure: Authors have no relationship with companies who provided unrestricted educational grants to this program.

Off-label usage: The content of this CME publication does not contain discussion of off-label uses.

Table of Contents

PARTICIPANT’S HANDOUT	ii
<i>Read This First!</i>	<i>ii</i>
<i>Program Overview</i>	<i>ii</i>
<i>Additional Resources</i>	<i>iv</i>
<i>Participation</i>	<i>iv</i>
MODULE 4.....	1
FOLLOW-UP FORM.....	25
PRESENTATION EVALUATION FORM.....	26
REFERENCES	27

Participant's Handout

Read This First!

This handout contains:

- An abbreviated outline of the presentation *Module 4: American Medical Association Ethical Guidelines on Gifts to Physicians from Industry*
- Some supplementary material for reference during or after the presentation
- Thumbnails of the PowerPoint™ presentation
- A *Follow-up Form* to submit issues that could not be adequately addressed during the presentation
- A *Presentation Evaluation Form* to assist the presenter and designers of the program to improve the quality of this and future presentations
- Other miscellaneous reference material that the presenter may have added

Program Overview

By 1998, the cost of healthcare in America surpassed the \$1 trillion-dollar mark – four times that spent in 1980. It is expected that this figure will double again in the next five years.¹ In 2001, there were more than 87,000 pharmaceutical sales representatives in the US, twice the number recorded in 1996.² In 2000, the companies they represent spent \$15.7 billion on promotion, an increase of 43% since 1997.³

With a ratio of 1 industry representative for every 4.7 physicians,² the average physician sees about 10 pharmaceutical sales representatives each month,⁴ with the average visit lasting less than one minute.³ In a competitive trillion-dollar industry, sales personnel are finding creative strategies to “detail” physicians, spending between \$8,000 and \$13,000 a year per physician.³

Many gifts given to physicians serve important and beneficial functions. However, as the media increase their attention on the spiraling cost of healthcare, marketing practices – including the ethics of gifts to physicians – are being closely scrutinized.

The American Medical Association, in collaboration with the Working Group for the Communication of Ethical Guidelines on Gifts to Physicians from Industry, has designed this awareness program for the benefit of medical students, residents, practicing physicians, and pharmaceutical and medical-device industry marketing and sales personnel.

The overall intent of the program is to sensitize these audiences to issues and ethical guidelines associated with gifts to physicians from industry, and related relationships between physicians and industry, such as consulting, inducements, and rewards.

Laws are in constant evolution, as are the underlying precepts of professionalism and medical ethics. Federal agencies are constantly updating their regulations and providing interpretive guidance concerning the pharmaceutical industry and its relationship with physicians. As enforcement policies evolve and regulations change, taking any gift intended to affect prescribing may be defined as a bribe or kickback and may entail legal difficulty. Every physician should be aware of both current laws and ethical guidelines, and should consult with qualified legal counsel.

Module 1: *Overview of Ethical, Professional, and Legal Issues for Physicians' Relationships with Industry* introduces general concepts related to professionalism, ethics and laws that pertain to interactions between physicians and industry.

Module 2: *Physicians' Expectations of Industry and Sales Personnel* provides insight into the protocol of interaction between physicians and industry representatives – from the perspective of the physician.

Module 3: *Professional Issues Concerning Gifts to Physicians from Industry* explores in greater detail the issue of professionalism as it relates to conflicts of interest and gifts.

Module 4: *The AMA's Ethical Guidelines on Physician-Industry Relations and Gifts* explores the ethical Opinions of the AMA's Council on Ethical and Judicial Affairs that affect physician-industry relations, including Opinion 8.061: *Gifts to Physicians from Industry*, E-Addendum II: Council on Ethical and Judicial Affairs *Clarification of Gifts to Physicians from Industry (E-8.061)*, and E-9.011: *Continuing Medical Education*.

Additional Resources

<http://www.ama-assn.org/go/ethicalgifts>

E-8.061 *Gifts to Physicians from Industry*, E-Addendum II: Council on Ethical and Judicial Affairs (CEJA) *Clarification of Gifts to Physicians from Industry (E-8.061)*, and E-9011 *Continuing Medical Education*; bibliography of related articles

http://www.ama-assn.org/apps/pf_online/pf_online

E-8.031 *Conflicts of Interest: Biomedical Research*

E-8.0315 *Managing Conflicts of Interest in the Conduct of Clinical Trials*

<http://www.ama-assn.org/ama/pub/article/5310-5094.html>

When to accept and when not to accept: A few thoughts... (opinion/editorial)

<http://www.ama-assn.org/ama/pub/article/5310-5093.html>

AMA Newsletter Article For Physicians: *AMA launches gift education initiative*

http://www.accme.org/incoming/17_system98_essential_areas.pdf

The ACCME's Essential Areas and Their Elements: *Standards for Commercial Support of Continuing Medical Education* (p. 7)

<http://www.phrma.org>

Pharmaceutical Research and Manufacturers of America: *Code on Interactions with Healthcare Professionals* (or call 202-835-3400)

<http://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html>

Dept. of Health and Human Services, Special Fraud Alert, Oct 2002, *Publication of OIG Special Fraud Alerts* [59 Fed. Reg. 65,376]

<http://oig.hhs.gov/fraud/complianceguidance.html>

Dept. of Health and Human Services, Draft OIG Compliance Program Guidance for Pharmaceutical Manufacturers [67 Fed. Reg 62057 (2002)]

http://www.access.gpo.gov/su_docs/fedreg/a010104c.html

The Federal Register: *Medicare and Medicaid Programs; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships* [Fed. Reg. 920 Vol. 66 No.3 08/04/2001]

<http://uscode.house.gov/usc.htm>

The Public Health and Welfare; Social Security; Health Insurance for Aged and Disabled: *Limitation on certain physician referrals* [42 USC Sec. 1395nn (a)(1)(B)]

<http://www.fda.gov/cder/guidance/1397fnl.pdf>

FDA Guidance for Industry: Providing Clinical Evidence of Effectiveness of Human Drug and Biological Products

If you know of any additional information that is of value to this discussion, please bring it to the attention of the presenter at the end of the presentation.

Participation

The success of this presentation relies on your participation. Please feel free to comment on any of the issues and to respond to the numerous questions that will be raised.

In order that the presentation finish on time, we also ask that you:

- be brief
- limit your observations and discussions to the issues being addressed
- respect the presenter's prerogative to abbreviate discussions

What You Should Know About Gifts to Physicians from Industry

Module 4

American Medical Association Ethical Guidelines on Gifts to Physicians from Industry

Module Goals and Objectives

- To analyze physician-industry relations in light of concepts introduced in previous modules and other basic principles of medical ethics
- To introduce the AMA's Council on Ethical and Judicial Affairs and its policy-making process
- To analyze specific ethical Opinions from the AMA Code of Medical Ethics regarding physician-industry relations

American Medical Association

4

Legal Disclaimer

Laws are in constant evolution, as are the underlying precepts of professionalism and medical ethics. Federal agencies are constantly updating their regulations and providing interpretive guidance concerning the pharmaceutical industry and its relationship with physicians. As enforcement policies evolve or regulations change, taking any gift intended to affect prescribing may be defined as a bribe or kickback and may entail legal difficulty. Every physician should be aware of both current laws and ethical guidelines, and should consult with qualified legal counsel.

American Medical Association

5

Topic 1: Gifts, Medical Ethics, and Professionalism

This topic addresses:

1. The common understanding of “gifts”
2. Basic ethical principles
3. The notion of professionalism

American Medical Association

6

The Common Understanding of Gifts

An industry representative invites you and a guest to dinner and a lecture at an upscale restaurant at The Mall. Following dinner, you also receive a gift certificate for shopping at The Mall.

Should you accept this offer?

American Medical Association

7

The Common Understanding of Gifts

In the dictionary the word “gift” is defined as “that which is given without charge.”

Gift-giving can also be seen as an act that is symmetrical and reciprocal, with three components:

- To give
- To receive
- To repay

American Medical Association

8

The Common Understanding of Gifts

What are some of the implications of this understanding of “gifts” in the context of physician-industry relations?

American Medical Association

9

The Common Understanding of Gifts

Between physicians and industry representatives, gifts could lead to a form of repayment such as...

- developing into a form of brand loyalty
- promoting a sense of obligation to prescribe
- resulting in an automatic rather than conscious decision to prescribe

American Medical Association

10

Basic Ethical Principles *Non-Maleficence and Beneficence*

How do the standards of *non-maleficence* and *beneficence* apply to the pharmaceutical and medical device industry?

When developing new products, industry is required to demonstrate that a new product:

- is safe
- provides a benefit to patients

American Medical Association

12

Basic Ethical Principles
Respect for Autonomy

What are two examples of:

- Protecting the physician-patient relationship from intrusion by third parties
- Respecting the patient's autonomy

American Medical Association 13

Basic Ethical Principles
Respect for Autonomy

<p>Protection from Intrusion into the Physician-Patient Relationship</p> <ul style="list-style-type: none"> • Drug formulary may prevent MD from choosing most appropriate Rx • MD influenced to prescribe certain product 	<p>Respect for Patient Autonomy</p> <ul style="list-style-type: none"> • MD informs patient of therapy rationale, risks, benefits, and alternatives • Patient should know of any relationship between MD and company whose product is being recommended
---	--

American Medical Association 14

Basic Ethical Principles
Distributive Justice

The ethical principle of justice is often defined in terms of the fair or just distribution of rights and responsibilities, such as:

- to each an equal share
- to each according to need
- to each according to merit

American Medical Association 15

Notion of Professionalism

Three key features help separate professions from other occupations:

1. The learning and teaching of expert knowledge
2. The use of this knowledge to serve a purpose that is highly valued by society, or is of necessity to its members
3. The self-regulation of professionals according to a code of conduct

American Medical Association

16

Basic Ethical Principles

Fiduciary Relationships

“Fiduciary” is often used to describe the patient-physician relationship because:

- patients place their trust and well-being in the hands of physicians
- physicians are responsible for the welfare of patients
- physicians respond to patients’ actual (vs. perceived) needs
- physicians are responsible for controlling patient/third-party payer expenses for medications and other medical services

American Medical Association

17

Basic Ethical Principles

Physicians and Conflicts of Interest

A conflict of interest may exist if a professional judgment concerning a primary interest stands to be unduly influenced by a secondary interest.

Because of the fiduciary nature of the patient/physician relationship, it is generally expected that physicians should avoid conflicts of interest that may undermine patient care.

For actual or perceived conflicts that cannot be avoided, disclosure may function as the primary mechanism to reduce the effect of the conflict.

American Medical Association

18

Basic Ethical Principles

Quick Case 1

An industry representative of a highly promoted drug invites all the physicians in your practice, their families and friends, for a private screening of a blockbuster movie.

What are the ethical issues an investigative journalist would raise in publicizing this outing?

American Medical Association

19

Basic Ethical Principles

Quick Case 1

- Your judgment in prescribing the company's product will be questioned in the future.
- The appropriateness and relevance of the event will be questioned.
- Even if the entire practice had never prescribed the industry representative's product, the public may not believe it.
- The public will also assume you will now be prone to prescribe the company's products, even if you never do.

American Medical Association

20

Gifts, Medical Ethics, and Professionalism Summary

When addressing the issue of gifts to physicians from industry, it is important to understand:

- the concept of "gifts"
- basic ethical principles as they pertain to healthcare
- the notions of professionalism and conflicts of interest

American Medical Association

21

Topic 2: The AMA's Council on Ethical and Judicial Affairs

This topic addresses:

- The AMA policy-making process
- The Council on Ethical and Judicial Affairs (CEJA) and the Code of Medical Ethics

American Medical Association

22

The AMA Policy-Making Process

Policy can be created through two main channels:

- Resolutions presented by groups (state and national specialty societies) with representation in the AMA's House of Delegates (HOD)
- Reports presented by councils of the Association or the Board of Trustees

American Medical Association

23

CEJA and the Code of Medical Ethics

The Council on Ethical and Judicial Affairs (CEJA) develops most ethics policies for the AMA.

It is composed of seven physicians, one medical resident, and one medical student, and is assisted by staff with expertise in bioethics.

American Medical Association

24

Enforcement of Ethical Conduct

If CEJA does not have the authority to enforce the Opinions found in the *Code of Medical Ethics*, who does?

- a) The AMA
- b) State licensing boards
- c) The Dept. of Health and Human Services
- d) No one. Opinions cannot be enforced.

American Medical Association

25

Enforcement of Ethical Conduct

State licensing boards have the authority to enforce the Opinions found in the *Code of Medical Ethics*

In some states, the Medical Practice Act establishes the AMA Code of Medical Ethics as the standard of conduct to which physicians in that state will adhere. In other states, the code can serve as an important guide to determine the standard of conduct. As such, state licensing boards are empowered to enforce standards contained in the code.

American Medical Association

26

The AMA's Council on Ethical and Judicial Affairs Summary

Ethics policies developed by the AMA's Council on Ethical and Judicial Affairs constitute the AMA's Code of Medical Ethics, which sets ethical guidance for the entire medical profession.

American Medical Association

27

Topic 3: AMA's Opinion 8.061: *Gifts to Physicians from Industry* and other related ethical guidance from the *Code of Medical Ethics*

This topic addresses:

1. Relevant AMA Principles of Medical Ethics
2. Opinion 8.03 *Conflicts of Interests: Guidelines*
3. Opinion 8.061 *Gifts to Physicians from Industry* and Addendum *Council on Ethical and Judicial Affairs Clarification of Gifts to Physicians from Industry*
4. Opinion 9.011 *Continuing Medical Education*

American Medical Association

28

Relevant Principles of Medical Ethics *Principle I*

A physician shall be dedicated to providing competent medical care, with compassion and respect for human dignity and rights.

American Medical Association

29

Relevant Principles of Medical Ethics *Principle II*

A physician shall uphold the standards of professionalism, be honest in all professional interactions, and strive to report physicians deficient in character or competence, or engaging in fraud or deception, to appropriate entities.

American Medical Association

30

Relevant Principles of Medical Ethics

Principle IV

A physician shall respect the rights of patients, colleagues, and other health professionals, and shall safeguard patient confidences and privacy within the constraints of the law.

American Medical Association

31

Relevant Principles of Medical Ethics

Principle V

A physician shall continue to study, apply, and advance scientific knowledge, maintain a commitment to medical education, make relevant information available to patients, colleagues, and the public, obtain consultation, and use the talents of other health professionals when indicated.

American Medical Association

32

Relevant Principles of Medical Ethics

Principle VIII

A physician shall, while caring for a patient, regard responsibility to the patient as paramount.

American Medical Association

33

Opinion 8.03 Conflicts of Interest: Guidelines

- The primary objective of the medical profession is to render service to humanity; reward or financial gain is a subordinate consideration.
- Under no circumstances may physicians place their own financial interests above the welfare of their patients.
- It is unethical for a physician to unnecessarily hospitalize a patient, prescribe a drug, or conduct diagnostic tests for the physician's financial benefit.
- If a conflict develops between the physician's financial interest and the physician's responsibilities to the patient, the conflict must be resolved to the patient's benefit.

American Medical Association

34

Opinion 8.03 Conflicts of Interest: Guidelines

Two drugs have similar, but not identical, clinical profiles. The physician has received many incentives, including theatre tickets, from the representative of the manufacturer with the more expensive drug. The physician has only met the representative of the other manufacturer to discuss the labeled use of the drug.

What guidance would Opinion 8.03 offer to a physician in this scenario?

American Medical Association

35

Opinion 8.03 Conflicts of Interest: Guidelines

What guidance would Opinion 8.03 offer to a physician in this scenario?

The second guideline that warns against physicians placing “...*their own financial interests above the welfare of their patients,*” could be compromised, if the physician were to choose the drug on the basis of the relationship with the drug representative.

American Medical Association

36

Opinion 8.061: Gifts to Physicians from Industry

CEJA Guideline 1:

Any gifts accepted by physicians individually should primarily entail a benefit to patients and should not be of substantial value. Accordingly, textbooks, modest meals, and other gifts are appropriate if they serve a genuine educational function. Cash payments should not be accepted. The use of drug samples for personal or family use is permissible as long as these practices do not interfere with patient access to drug samples. It would not be acceptable for non-retired physicians to request free pharmaceuticals for personal use or use by family members.

American Medical Association

37

Opinion 8.061: Gifts to Physicians from Industry – Quick Case 2

An industry representative invites a physician to participate in a dinner with a local speaker, held at the most expensive restaurant in the area.

Is this offer appropriate under the guidelines?

American Medical Association

38

Opinion 8.061: Gifts to Physicians from Industry – Quick Case 2

Is this offer appropriate under the guidelines?

No.

Addendum 1(d) states that the dinner must be “a modest meal” (“not of substantial value”).

American Medical Association

39

Opinion 8.061: Gifts to Physicians from Industry

CEJA Guideline 2:

Individual gifts of minimal value are permissible as long as the gifts are related to the physician's work (eg, pens and notepads, home-test kit for patient use).

American Medical Association

40

Opinion 8.061: Gifts to Physicians from Industry – Quick Case 3

An industry representative offers you a complimentary glucose-monitoring home-test kit.

Is this offer appropriate under the guidelines, and what part of which guideline addresses it?

American Medical Association

41

Opinion 8.061: Gifts to Physicians from Industry – Quick Case 3

Is this offer appropriate under the guidelines, and what part of which guideline addresses it?

Yes.

A glucose monitoring kit:

- would “*primarily entail a benefit to patients*”
- is not “*of substantial value*” (less than \$100) [Guideline 1]
- is “*related to the physician’s work*” [Guideline 2].

American Medical Association

42

Opinion 8.061: *Gifts to Physicians from Industry* – Quick Case 4

An industry representative invites a practitioner to drop by the local gas station on the way home from work for a “gas’n’go” (an offer of a free fill-up of gasoline and some literature from the company).

Is this offer appropriate within the guidelines?

American Medical Association

43

Opinion 8.061: *Gifts to Physicians from Industry* – Quick Case 4

Is this offer appropriate within the guidelines?

No.

This offer:

- is within the limits of “*gifts of minimal value*”
- is not “*a benefit to patients*”
- does not “*relate to the physician’s work*”
- does not “*serve a genuine educational function*”

This guideline prohibits all forms of “dine’n’dash.”
[Addendum 1(d)]

American Medical Association

44

Summary: Guidelines 1 and 2

- Gifts should be modest – no greater than approximately \$100 (cost to the physician if the item were purchased on the open market).
- Gifts should entail a benefit to patients, or be related to the practice of medicine.

American Medical Association

45

Opinion 8.061: *Gifts to Physicians from Industry*

CEJA Guideline 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).*
- (b) the main incentive for bringing attendees together is to further their knowledge on the topic(s) being presented. An appropriate disclosure of financial support or conflict of interest should be made.*

American Medical Association

46

Opinion 8.061: *Gifts to Physicians from Industry* – Quick Case 5

A pharmaceutical company invites physicians to Whitewater Adventure, a weekend of rafting and continuing education. Physicians will spend Saturday conquering the river, followed by a speaker who will lead a brief medical discussion Saturday evening.

Is this offer appropriate under the guidelines, and which guideline addresses it?

American Medical Association

47

Opinion 8.061: *Gifts to Physicians from Industry* – Quick Case 5

Is this offer appropriate under the guidelines, and what part of which guideline addresses it?

No.

- This offer does not appear to be “*primarily dedicated, in both time and effort, to promoting objective scientific and educational activities and discourse*”
- It is doubtful that “*the main incentive for bringing attendees together is to further their knowledge on the topic(s) being presented*” [Guideline 3]

American Medical Association

48

Opinion 8.061: Gifts to Physicians from Industry

CEJA Guideline 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. Since the giving of a subsidy directly to a physician by a company's representative may create a relationship that could influence the use of the company's products, any subsidy should be accepted by the conference's sponsor who in turn can use the money to reduce the conference's registration fee. Payments to defray the costs of a conference should not be accepted directly from the company by the physicians attending the conference.

American Medical Association

49

Opinion 8.061: Gifts to Physicians from Industry – Quick Case 6

A primary care physician receives a notice from a pharmaceutical representative that their company is offering free registration to the upcoming conference on obstetrics being held in her city this year.

Is this offer appropriate under the guidelines?

American Medical Association

50

Opinion 8.061: Gifts to Physicians from Industry – Quick Case 6

Is this offer appropriate under the guidelines?

No.

Guideline 4 stipulates:

- *“Payments to defray the costs of a conference should not be accepted directly...”*
- *“...any subsidy should be accepted by the conference's sponsor... to reduce the conference's registration fee.”*

American Medical Association

51

Opinion 8.061: Gifts to Physicians from Industry

CEJA Guideline 5:

Subsidies from industry should not be accepted for the costs of travel, lodging, or other personal expenses of physicians attending conferences or meetings, nor to compensate for their time. Subsidies for hospitality should not be accepted outside of modest meals or social events held as a part of a conference or meeting.

American Medical Association

52

Opinion 8.061: Gifts to Physicians from Industry

CEJA Guideline 5 cont'd:

It is appropriate for faculty at conferences or meetings to accept reasonable honoraria and reimbursement for travel, lodging, and meal expenses. It is also appropriate for consultants who provide genuine services to receive reasonable compensation and to accept reimbursement for travel, lodging, and meal expenses. Token consulting or advising cannot be used to justify the compensation of physicians for their time or their travel, lodging, and other out-of-pocket expenses.

American Medical Association

53

Opinion 8.061: Gifts to Physicians from Industry – Quick Case 7

A physician is invited to participate in a 50-minute telephone conference with colleagues on treatment issues related to a medical condition common to their practices. Specifically, physicians are asked to evaluate how the company's product may be used on a practical basis. On completion of the conference, in recognition of participation, the physician would receive an anatomical model valued at approximately \$100.

Is this offer appropriate under the guidelines, and what part of which guideline addresses it?

American Medical Association

54

Opinion 8.061: *Gifts to Physicians from Industry* – Quick Case 7

Is this offer appropriate under the guidelines, and what part of which guideline addresses it?

Yes.

- The nature and value of the gift are well within the criteria of Guidelines 1 and 2.
- As per Guideline 5, the physician is providing “*genuine services*” for “*reasonable compensation.*”
- The telephone conference with colleagues could be considered a focus group that serves “*a genuine and exclusive research purpose.*” [Addendum 5(f)]

American Medical Association

55

Opinion 8.061: *Gifts to Physicians from Industry* – Quick Case 8

A physician’s opinion is solicited for the development of future educational programs. Compensation is \$500 for completing a 10-minute survey.

Is this offer appropriate under the guidelines, and what part of which guideline addresses it?

American Medical Association

56

Opinion 8.061: *Gifts to Physicians from Industry* – Quick Case 8

Is this offer appropriate under the guidelines, and what part of which guideline addresses it?

No.

- Far exceeds the definition of “*reasonable compensation*” and “*genuine service*”
- This offer constitutes “*token consulting or advisory arrangements*” [Guideline 5]

American Medical Association

57

Opinion 8.061: Gifts to Physicians from Industry

CEJA Guideline 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.

Carefully selected educational conferences are generally defined as the major educational, scientific, or policy-making meetings of national, regional, or specialty medical associations.

American Medical Association

58

Opinion 8.061: Gifts to Physicians from Industry – Quick Case 9

A medical device manufacturer offers to send residents specializing in their area of bioengineering to a national conference that focuses on scientific developments related to the manufacturer's field.

Is this offer appropriate under the guidelines, and what part of which guideline addresses it?

American Medical Association

59

Opinion 8.061: Gifts to Physicians from Industry – Quick Case 9

Is this offer appropriate under the guidelines, and what part of which guideline addresses it?

No.

The selection of attendees must be made “*by the academic or training institution.*” [Guideline 6]

American Medical Association

60

Summary: Guidelines 3 and 4

3. Conferences or meetings should be held at appropriate locations, where the gathering is dedicated to valid scientific and educational activities motivated by the pursuit of knowledge.
4. Direct subsidies to physicians to attend medical education conferences or professional meetings could create a conflict of interest; therefore, funding should be offered to the event's sponsor.

American Medical Association

61

Summary: Guidelines 5 and 6

5. In terms of compensation from industry, physicians:
 - who are attending meetings should not receive compensation for their travel, lodging, personal expenses, or their time
 - who are on faculty may accept reasonable honoraria and reimbursements
 - who provide genuine services may receive reasonable compensation
6. Scholarship or other special funds to permit medical students, residents, and fellows to attend educational conferences must be awarded by the academic or training institution.

American Medical Association

62

Opinion 8.061: *Gifts to Physicians from Industry*

CEJA Guideline 7:

No gifts should be accepted if there are strings attached. For example, physicians should not accept gifts if they are given in relation to the physician's prescribing practices.

In addition, when companies underwrite medical conferences or lectures other than their own, responsibility for and control over the selection of content, faculty, educational methods, and materials should belong to the organizers of the conferences or lectures.

American Medical Association

63

Opinion 8.061: *Gifts to Physicians from Industry* – Quick Case 10

A general practitioner receives an invitation from a local sales representative that reads: “For having contributed to making our angiotensin II antagonist the therapy of choice for control of hypertension in America, we would like to invite you to a complimentary sushi dinner this Thursday at...”

Is this offer appropriate under the guidelines, and what part of which guideline addresses it?

American Medical Association

64

Opinion 8.061: *Gifts to Physicians from Industry* – Quick Case 10

Is this offer appropriate under the guidelines, and what part of which guideline addresses it?

No.

Physicians should not accept gifts if they are given in relation to their prescribing practices.
[Guideline 7]

American Medical Association

65

Summary: Guideline 7

- Gifts considered appropriate under the Guidelines cannot have any “strings attached.”
- All decisions about the CME program should be absolutely independent of subsidies.

American Medical Association

66

Opinion 9.011 Continuing Medical Education

Opinion 9.011 complements the guidelines included in Opinion 8.061 that address educational or scientific meetings, subsidies, and compensation, specifically:

- attendees
- faculty
- sponsors

American Medical Association

67

Opinion 9.011 Continuing Medical Education

Attendees

- Are permitted to attend meetings, whether accredited under Accrediting Council on Continuing Medical Education (ACCME) standards or not
- Must conform to all applicable guidelines, including those of the ACCME

American Medical Association

68

Opinion 9.011 Continuing Medical Education

Faculty

Physicians serving as presenters or moderators at a conference:

- Should present up-to-date, scientifically relevant information in a balanced and objective manner
- Should ensure presentation content is not influenced by industry
- Should disclose any financial ties with industry
- May accept reasonable honoraria and reimbursement for expenses [opinion 8.061, guideline 5]

American Medical Association

69

Opinion 9.011 Continuing Medical Education

Sponsors

Physicians involved with sponsoring entities should ensure:

- The professional integrity of the educational activity
- Activities conform to relevant guidelines
- Proper disclosures are made

American Medical Association

70

Relevant Guidance From the AMA's Code of Medical Ethics on Gifts to Physicians From Industry

AMA's Code of Medical Ethics provides nine principles of medical ethics supplemented by several important Opinions that address:

- Conflicts of interests [Opinion 8.03]
- Gifts to physicians from industry [Opinion 8.061]
- Continuing medical education [Opinion 9.011]

American Medical Association

71

Module Review

- General concepts related to gifts, medical ethics, and professionalism in physician-industry relations
- The AMA's Council on Ethical and Judicial Affairs (CEJA)
- Relevant guidance from the AMA's Code of Medical Ethics on Physician-Industry Relations

American Medical Association

72

Take-Away Points

If an incentive is offered to a physician, ask these questions:

- Is the incentive of nominal value?
- Is the incentive of value to patients or related to practice?
- Is the incentive offered with “no strings attached”?
- Would your patients be pleased if they knew about the incentive?

If the answer to any of these questions is “no,” physicians should decline the gift or else consult qualified legal counsel to determine if the activity would violate federal or state law.

Follow-up Form

Module 4: American Medical Association Ethical Guidelines on Gifts to Physicians from Industry

Thank you for participating in today's session!

If you have any questions that could not be addressed during the session, please include them on this form, along with your contact information (or business card).

The presenter will research the issue, and forward the appropriate information in as short a delay as possible.

Session Date: _____ **Time:** _____ **Presenter:** _____
mm / dd / yyyy

Name: _____

Company: _____

Address: _____

Unit/Suite/Apt: _____

City: _____ **State:** _____ **Zip:** _____

Phone: _____ **e-mail:** _____

Topic: _____

Details: _____

Topic: _____

Details: _____

Topic: _____

Details: _____

Presentation Evaluation Form

Module 4: American Medical Association Ethical Guidelines on Gifts to Physicians from Industry

Course Content		☹				☺
1	How appropriate was the content for the module Topic?	1	2	3	4	5
2	What did you think of the amount of content covered?	1	2	3	4	5
3	How thoroughly was the content covered?	1	2	3	4	5
4	How relevant is the content to your professional situation?	1	2	3	4	5
5	What is the overall value of this module's content to you?	1	2	3	4	5

Instructional Media		☹				☺
6	Did the media (slides, handouts) contribute to the presentation objectives?	1	2	3	4	5
7	Were the media (PowerPoint™ slides, handouts) of good quality ?	1	2	3	4	5
8	Were the questions useful in mastering course objectives?	1	2	3	4	5
9	Were the exercises useful in mastering course objectives?	1	2	3	4	5
10	What is the overall value of this module's media to you?	1	2	3	4	5

Presentation		☹				☺
11	How would you rate the quality of the presenter's delivery of the material?	1	2	3	4	5
12	How suitable was the amount of discussion among participants?	1	2	3	4	5
13	Did you have sufficient opportunity to present your opinions ?	1	2	3	4	5
14	Was the duration of the presentation satisfactory?	1	2	3	4	5
15	How would you rate the overall value of this module's presentation?	1	2	3	4	5

Opinions

The **most effective** part of this presentation was:

The **least effective** part of this presentation was:

Date: _____ **Time:** _____ **Presenter:** _____
mm / dd / yyyy

References

-
- 1 Morrison AW. **An Analysis of Anti-Kickback and Self-Referral Law in Modern Health Care.** J Leg Med 2000 Sep;21(3):351-94
 - 2 Chin T. **Drug firms score by paying doctors for time.** American Medical News (amednews.com) 2002 May 6 [referenced from Scott-Levin]
 - 3 Gammage J, Stark K. **Under the Influence.** Philadelphia Inquirer 2002 Mar 9 [referenced from IMS Health]
 - 4 Greene J. **AMA Spearheads Gift Education Crusade.** American Medical News (amednews.com) 2001 Jul 2 [referenced from Scott-Levin]