

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**

Presenter's Guide

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**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)

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## Disclosure of Conflict of Interest

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**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.

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## Presenter Tools

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### Read This First!

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This section is designed to assist you in delivering any of the four modules in the American Medical Association's (AMA) *What You Should Know About Gifts to Physicians from Industry* with a minimum of preparation time. It will take approximately 15 minutes to read this *Presenter Tools* material.

*Presenter Tools* is divided into five sections:

- A. *Overview* gives you a brief background on the rationale behind the AMA's *What You Should Know About Gifts to Physicians from Industry*, and a synopsis of the content within each module.
- B. *Module Resources* suggests additional resources and their references for use as support material in the presentation of that particular module.
- C. *Preparation* provides a pre-presentation checklist.
- D. *Presentation Tools* shows you how to effectively deploy the supplied material.
- E. *Presentation Tips* provides general guidelines for a smooth and successful delivery.

**Presentation Time:** Each module presentation package is designed for a 60- to 90-minute presentation. You can eliminate sections of the module to meet your time requirements, or pick and choose sections of each module to make up a presentation to meet your particular needs.

**Audience Size:** 6 or more participants

### A: Overview

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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.<sup>1</sup> In 2001, there were more than 87,000 pharmaceutical sales representatives in the US, twice the number recorded in 1996.<sup>2</sup> In 2000, the companies they represent spent \$15.7 billion on promotion, an increase of 43% since 1997.<sup>3</sup>

With a ratio of 1 industry representative for every 4.7 physicians,<sup>2</sup> the average physician sees about 10 pharmaceutical sales representatives each month,<sup>4</sup> with the average visit lasting less than one minute.<sup>3</sup> 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.<sup>3</sup>

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: *AMA Ethical Guidelines on Gifts to Physicians from Industry* 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*.

## B: Module 4 Resources

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Once extracted (unzipped), the folder should contain the following files:

- AMA\_M4\_PG.pdf (this Presenter's Guide in Acrobat® format)
- AMA\_M4\_PH.pdf (Participant's Handout material in Acrobat® format)
- AMA\_M4.ppt (the PowerPoint™ slide show for Module 1 in PowerPoint™ 97 or later)

The Presenter's Guide and Participant's Handout are in the Adobe® Acrobat® portable document format (.pdf). The Acrobat® Reader can be downloaded free of charge from the Adobe® website at <http://www.adobe.com> (select "Download Acrobat Reader"). Follow the instructions to install and run Acrobat® on your Mac® or PC computer.

### Additional Downloadable 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](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](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](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

## C: Preparation Checklist

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### Materials needed:

- PC computer (with MS PowerPoint™ 97 or later and AMA\_M4.ppt presentation)
- Compatible LCD projector and screen suitable for use with both LCD and whiteboard
- Whiteboard or flipchart and markers

### Preparations:

- Select/invite/confirm participants (6 to 10 is ideal, but the presentation easily adapts to larger groups)
- Reserve presentation room, refreshments, etc.
- Print out *Presenter's Guide* and *Participant's Handout* material and review
- Enter your disclosure information on slide 3 of the PowerPoint presentation
- Download any of the suggested reference material
- Arrange for photocopies of the *Participant's Handout*

## D: Presentation Tools

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The key to a successful presentation is *interaction*. The Presenter's Guide and Presentation Tips have been designed to ensure that you:

- are comfortable and confident in delivering the program material
- have the appropriate resources to ensure a professional presentation
- keep participants engaged and active by asking thought- and discussion-provoking questions
- keep the pace moving so you address the required issues within the allotted time

### Using the guide

It is recommended that you follow the guide for your first presentation. As you become familiar with the material, you can customize your delivery to suit your presentation style.

The following icons are designed to assist you in keeping track of where you are – and what you are doing – by simply glancing at the page.

	<b>4</b>	Advance PowerPoint™ slide to slide number 4 Slide numbers also appear in the bottom right-hand corner of each slide
	<b>17</b>	Advance PowerPoint™ slide to slide number 17. First frame of a slide “build-up”.
	<b>18</b>	Advance PowerPoint™ slide to slide number 18. Subsequent frame in a “build-up”.
		Case study
		Refer participant to handout or reference material
		Cautionary note
		Presentation direction or tip
		Exercise or form to be completed

Other presentation aids:

- A timing box in the left-hand margin **23** represents elapsed time in minutes, starting on the hour. Adjust your pace and coverage of material accordingly.
- Text in *italicized serif script* indicates what to do.
- Text in **non-serif script** indicates what to say.
- A header on each page indicates the current *Module P Topic P Subject*.
- **Boxed text summarizes an important issue.**
- **Q:** identifies questions for rapid response or open discussion.
- Underlined text identifies an important underlying issue that should be reinforced.

## E: Presentation Tips

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The following general tips will help you keep your presentation on topic, on track, and on time:

- Keep a discussion “on topic” by:
  - aligning all participant responses (appropriate or otherwise) with the responses provided in the Presenter’s Guide
  - validating and refocusing even marginal responses (eg, “That’s a valid suggestion/observation/issue, however,...”)
- Defuse objections or conflicts between participants immediately (eg, “I think you [both] have a valid point, but if we could focus on the issue of...”).
- If a response to a question is not in the supplied material, ask the participant to:
  - write the question on the Follow-up Form at the back of the handout
  - hand it in at the end of the presentationConfirm that you will get back to that individual with the required information.
- For a thorough presentation, it is important to cover all of the text in the *Presenter’s Guide*.
- Use PowerPoint™ slides as a background. You, your participants, and your discussions are the focus of the presentation. Avoid “reading out” PowerPoint™ slides:
- Use the suggested Guidance Questions only as needed.
- When presenting to highly educated and experienced professionals, a presenter can rarely provide *answers* that will be satisfactory to all. Therefore, the best strategy is to ask appropriate *questions*. If necessary, reinforce that the presentation material reflects only the *opinions* of the program designers.

**As with any discussion regarding healthcare, the final decision on any issue always rests with the healthcare professional.**

## What You Should Know About Gifts to Physicians from Industry

# Module 4: AMA Ethical Guidelines on Gifts to Physicians from Industry

## Introduction

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### Warm-up

- *Welcome and thank participants for attending*
- *Introduce yourself and related background, experience, etc.*
- *If people do not already know each other, have participants briefly introduce themselves (name, practice)*
- *Explain that this presentation is the last of four AMA modules on What You Should Know About Gifts to Physicians from Industry ([www.ama-assn.org/go/ethicalgifts](http://www.ama-assn.org/go/ethicalgifts))*



1

Module 1: Overview of Ethical, Professional, and Legal Issues for Physicians' Relationships with Industry

Module 2: Physicians' Expectations of Industry and Sales Personnel

Module 3: Professional Issues Concerning Gifts to Physicians from Industry

<p>Module 4: AMA Ethical Guidelines on Gifts to Physicians from Industry</p>
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### Disclosure

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2

*The slide containing the faculty disclosure statements for this module appears here.*



3

*The slide with your own disclosure statement appears here.*



## This Module's Goals and Objectives



4

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



**Note:** In the context of this program, "Gifts to physicians" includes issues such as incentives, inducements, and rewards.



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### 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.

## Presentation Format and Schedule

The presentation will be an open format in which issues and questions will be introduced for discussion.

- The more you participate, the greater the benefit to all.
- We only have **XX** minutes (*indicate the planned length of the presentation*), so please keep all responses and discussions brief.
- To keep things moving and on schedule, I may have to interrupt discussions, so please accept my apologies in advance.
- If we get off topic, or bogged down on an issue, I'll suggest we move that issue "off-line" for discussion later in another forum.



## Topic 1:

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### Gifts, Medical Ethics, and Professionalism

#### Topic Objectives



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This topic addresses:

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



#### 1.1 The Common Understanding of Gifts

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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.

**Q:** Should you accept this offer?



8

A dictionary definition of the word “gift” refers to “that which is given without charge.” However, gift-giving can also be seen as an act that is symmetrical and reciprocal, with components<sup>5</sup>:

- to give;
- to receive; and...
- to repay.



9

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

#### Guidance question:

- *How would these three norms manifest themselves in the relationship between a physician and an industry representative?*



#### Option:

*Write down participant suggestions on whiteboard or flipchart or overhead transparency projected next to the PowerPoint slides.*



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#### Discussion end-point (summary)

**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

## 1.2 Basic Ethical Principles

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When discussing physician-industry relations and their impact on the patient-physician relationship, it is important to keep in mind some of the common ethical principles relevant to the practice of medicine.

### Non-Maleficence and Beneficence

One of the lasting effects of the Hippocratic tradition is the notion that first, physicians should do no harm (*non-maleficence*).

*Beneficence* results from ethical conduct that contributes to the welfare of patients.

### **Quick Question**



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**Q:** How do these two standards also apply to the pharmaceutical and medical device industry?



12

**A:** When developing new products, industry is required to demonstrate that a new product is safe, and provides a benefit to patients.

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### Respect for Autonomy

In healthcare, autonomy broadly refers to the individual's right to self-determination, ie, making decisions regarding their medical care that take into account relevant information and that are aligned with their personal values and preferences.

This ethical principle is often considered paramount in the context of the patient-physician relationship, especially in the context of:

- protecting the relationship from intrusion by third parties
- respecting the patient's autonomy (disclosure, informed consent)



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**Q:** Can you suggest two examples of these two principles?

1. In the context of general healthcare today?
2. In the context of the physician-industry relationship?

### Guidance questions:

*How could one of these principles apply to:*

- *a drug formulary?*
- *the prescribing of a product?*



### Option:

*Write down participant suggestions under two columns on whiteboard or flipchart or overhead transparency projected next to the PowerPoint slides.*



*Discussion end-point (summary)*



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



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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

Justice is an ethical principle that underlies many debates in health care, including some related to the pharmaceutical and medical device industry (eg, the cost of drug and insurance coverage).



*Notion of Professionalism*



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Three key features that have traditionally separated 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<sup>6</sup>
- 3) The self-regulation of professionals according to a code of conduct

Modules 1 and 3 of the AMA's *Gifts to Physicians* series address the issue of professionalism in greater detail.





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### Fiduciary Relationships

The term “fiduciary” is often used to describe uniquely protected characteristics of 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



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### Physicians and Conflicts of Interest

In general, a conflict of interest may exist if a professional judgment concerning a primary interest (eg, positive therapeutic outcome for patient) stands to be unduly influenced by a secondary interest (eg, financial gain for physician).

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.

Modules 1 and 3 of the AMA’s *Gifts to Physicians* series address the issue of conflicts of interest in greater detail.



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### **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.

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

### Guidance questions:

- *Is a primary interest being compromised by a secondary interest?*
- *Is there an actual conflict of interest?*
- *Is there a perceived conflict of interest?*
- *What would your patients think if they knew about this?*
- *Would disclosure have defused the situation?*



Option:

Write down participant suggestions on whiteboard or flipchart or overhead transparency projected next to the PowerPoint slides.



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*Case Summary*

- 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.

### 1.3 Gifts, Medical Ethics, and Professionalism Summary

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Because physicians are in a position of trust, they are expected to provide services based on expert knowledge, motivated by the promotion of patient health and well-being rather than personal gain.

This topic reviewed issues related to physician-industry relations raised in Module 1: *Ethical, Professional, and Legal Issues*, and Module 3: *Professional Issues Concerning Gifts to Physicians from Industry*.



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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

**Q:** Are there any questions before we proceed to the next topic?

## Topic 2:

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### The AMA's Council on Ethical and Judicial Affairs

#### Topic Objectives



22

This topic addresses:

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



### 2.1 The AMA Policy-Making Process

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The AMA's House of Delegates (HOD) is the policy branch of the Association; it is composed of representatives from all state medical societies and more than 100 national specialty societies.

Through their membership in those organizations, a large proportion of physicians are represented in the AMA; the policies of the AMA may potentially affect a large proportion of physicians.



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Policy can be created through two main channels:

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

For a resolution or report to become a policy of the AMA, it must be adopted by a majority of the delegates.



## 2.2 CEJA and the Code of Medical Ethics

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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.

### **Quick Questions**

**Q:** Does CEJA have the authority to enforce its guidelines?

**A:** No. CEJA's role does not extend beyond the development of policy.



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**Q:** 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.



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**A:** 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.



## The AMA's Council on Ethical and Judicial Affairs Summary

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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.



**Q:** Are there any questions before we proceed to the next topic?

## Topic 3:

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

### Topic Objectives



28

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*



### 3.1 Relevant Principles of Medical Ethics

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The AMA's Code is based on nine principles that help define ethical standards of conduct. Of particular relevance to the discussion in this module are Principles I, II, IV, V, and VIII.



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

Principle I emphasizes integrity of medical care.



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**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.*

Principle II defines professionalism in regard to self-regulation, the importance of honesty and condemning misrepresentation.



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**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.*

As discussed earlier in this module, physicians must respect patient privacy and confidentiality, ie, an industry representative can never be involved in a patient encounter or discussion about a patient's care without the patient's prior consent.

Principle IV also suggests that physicians should avoid giving information regarding products used by their patients to industry representatives.



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**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.*

Principle V promotes life-long learning, continuing medical education, medical research, disclosure of medical or scientific information, and collaboration.



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

This principle places protection for the integrity of the patient-physician relationship first.

*Summarize the Principles*

These principles can be found at the AMA's Web site ([www.ama-assn.org/go/ceja](http://www.ama-assn.org/go/ceja)), and are further elaborated on through the many opinions that make up the AMA's Code of Medical Ethics – some of which will be discussed in greater detail next.



## 3.2 Opinion 8.03: Conflicts of Interest: Guidelines



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Many opinions in the AMA's Code of Medical Ethics address situations where conflicts of interest may arise. Central among them is Opinion 8.03, *Conflicts of Interest: Guidelines*, which states:

1. The primary objective of the medical profession is to render service to humanity; reward or financial gain is a subordinate consideration.
2. Under no circumstances may physicians place their own financial interests above the welfare of their patients.
3. It is unethical for a physician to unnecessarily hospitalize a patient, prescribe a drug, or conduct diagnostic tests for the physician's financial benefit.
4. 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.

### **Quick Question**

Two drugs from the same class 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.



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

### Guidance questions:

- *What would your patients think if they knew about this?*
- *How could a physician tell if they were indeed in violation of one of the guidelines?*
- *Is the incentive of nominal value?*
- *Does the incentive benefit patients?*



### Option:

*Write down participant suggestions on whiteboard or flipchart or overhead transparency projected next to the PowerPoint slides.*

### **Summary**



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**A:** 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.

A physician must adequately investigate and evaluate the clinical advantages and disadvantages of all drugs in that class – and make the decision based solely on the most appropriate drug for that patient's condition.



Note: As discussed in Module 1 of this series: *Overview of Ethical, Professional, and Legal Issues*, Opinion 8.031, *Conflicts of Interest: Biomedical Research*, along with the more recently issued Opinion 8.0315, *Managing Conflicts of Interest in the Conduct of Clinical Trials*, offer guidance regarding conflicts that arise in the context of research, including those that may arise from industry-sponsored research.



### 3.3 Opinion 8.061: *Gifts to Physicians from Industry*, and Addendum: *CEJA Clarifications of Gifts to Physicians from Industry*

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Since its adoption in 1990 by the AMA's House of Delegates,<sup>7</sup> Opinion 8.061 has played a central role in establishing norms of conduct for physicians' interaction with industry representatives.

In response to early inquiries for clarification, the Council published a full-length report<sup>8</sup> in 1992 providing the rationale for the ethical recommendations that made up the opinion, along with a series of questions and answers that now make up the Addendum.

On occasion, Opinion 8.061 has been amended, and additional questions and their answers added to the *Addendum, CEJA Clarifications of Gifts to Physicians from Industry*.<sup>9</sup>

The Pharmaceutical Research and Manufacturers of America's (PhRMA) *Code on Interactions with Healthcare Professionals*, issued in 2002, addresses many of the same issues from a more contemporary perspective.

Module 1 of this series discusses related legal issues, including recent developments.



**Note:** The most current set of guidelines can be obtained from the AMA's Council on Ethical and Judicial Affairs or from the AMA's electronic policy database, PolicyFinder under the rubric "Ethical Opinions."

*(refer participants to pg. iv of their handouts for URLs)*



#### Guidelines 1 and 2



#### Tip:

*Underlined text emphasizes the core issue addressed by each guideline.*



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**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.*



### 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.



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**Q:** Is this offer appropriate under the guidelines?



39

**A:** No. While the presence of a speaker infers that the invitation may be of benefit to patients in the context of an educational interaction, Addendum 1 (d) clarifies that when companies invite physicians to a dinner with a speaker, the dinner must be “a modest meal” (“not of substantial value”), which is unlikely if the dinner is at the most expensive restaurant in the area.



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**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).*



### Quick Case 3

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



41

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



42

**A:** Yes. A glucose monitoring kit would “primarily entail a benefit to patients”; is not “of substantial value” (less than \$100) [Guideline 1]; and is “related to the physician's work”[Guideline 2].



### 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).



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**Q:** Is this offer appropriate within the guidelines?



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**A:** No. Although a tank of gas is well within the limits of “gifts of minimal value,” this offer is not “a benefit to patients”; does not “relate to the physician's work”; or “serve a genuine educational function.”

In effect, this prohibits all forms of “dine'n'dash,” whereby physicians are invited to receive a gift or service at a location where representatives are present, but which requires no educational interaction. [Addendum 1(d)]

## Summary of Guidelines 1 and 2



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

### Guidelines 3, 4, 5, 6

These four guidelines establish norms of conduct related to educational or scientific meetings, and compensation to physicians. (For more guidance on accredited CME activities, see section 3.4 of this module on Opinion 9.011: Continuing Medical Education.)



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**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.*



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### **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.

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



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**A:** No. Since the majority of the time will be spent on recreation, the gathering does not appear to be “*primarily dedicated, in both time and effort, to promoting objective scientific and educational activities and discourse,*” and therefore it is doubtful that “*the main incentive for bringing attendees together is to further their knowledge on the topic(s) being presented.*” [Guideline 3]



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**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.*



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**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.

**Q:** Is this offer appropriate under the guidelines?



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**A:** No. While subsidies to underwrite the costs of continuing medical education conferences or professional meetings are permissible, Guideline 4 stipulates that “*Payments to defray the costs of a conference should not be accepted directly...*” and that “*...any subsidy should be accepted by the conference's sponsor... to reduce the conference's registration fee.*”



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**CEJA Guideline 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 physicians' time. Subsidies for hospitality should not be accepted outside of modest meals or social events held as a part of a conference or meeting.*



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

For a discussion of legal implications, please refer to Module 1 of this series.



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### 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.

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



55

**A:** Yes. The relevant nature and modest value of the gift are well within the criteria of Guidelines 1 and 2, and, as per Guideline 5, the physician is providing "genuine services" for "reasonable compensation." A 50-minute telephone conference with colleagues could be considered a focus group that serves "a genuine and exclusive research purpose." [Addendum 5(f)]



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### 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.

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



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**A:** No. Paying physicians \$500 for completing a 10-minute survey far exceeds the definition of "reasonable compensation" and "genuine service," placing this offer within the definition of "token consulting or advisory arrangements." [Guideline 5]



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**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.*



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### 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.



60

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

**A:** No. While the conference may fall within Guideline 6's definition of "carefully selected educational conferences," the selection of attendees must be made "by the academic or training institution."



### **Guidelines Summary**

#### Option:

*Write down participant suggestions on whiteboard or flipchart or overhead transparency projected next to the PowerPoint slides.*

**Q:** What are the "take-home" points from the four guidelines that address conferences, subsidies, and scholarships?



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**A:** Summary of Guidelines 3 through 6:

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.



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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.



Note: As discussed in detail in Module 1: *Overview of Ethical, Professional, and Legal Issues for Physicians' Relations with Industry*, The PhRMA Code on Interactions with Healthcare Professionals addresses some of these issues as well.

For a discussion of legal implications please refer to Module 1 of this series.



### Guideline 7

This final guideline addresses the issue that, whereas a gift should be unconditional, physician-industry relations may be motivated by ulterior motives, from which conflicts of interest can arise.



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**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.*



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### **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..."

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



65

**A:** No. Although it may be coincidental, physicians should not accept gifts if they are given in relation to their prescribing practices. [Guideline 7]



### **Guideline Summary**

Option:

*Write down participant suggestions on whiteboard or flipchart or overhead transparency projected next to the PowerPoint slides.*

**Q:** What is the "take-home" point from the last guideline?



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**A:** Summary of 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.



### 3.4 Opinion 9.011: Continuing Medical Education

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Opinion 9.011 builds on Principle V of the AMA's Principles of Medical Ethics and the notion of professionalism. Opinion 9.011 complements the guidelines included in Opinion 8.061 that address educational or scientific meetings, subsidies, and compensation.



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Specifically, Opinion 9.011 addresses:

- attendees
- faculty
- sponsors



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**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

Meetings that are not accredited under ACCME standards should:

- conform to Opinion 8.061
- be clearly identified as promotional



**Note:** Recall that the educational value of an activity must be the primary consideration in the physician's decision to participate. [Opinion 8.061, Guideline 3(a)]



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**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]



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**Physicians** involved with sponsoring entities should ensure:

- the professional integrity of the educational activity
- activities conform to relevant guidelines, including Opinion 8.061 and the principles established for the American Medical Association's Physician Recognition Award
- proper disclosures are made

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

The AMA's Code of Medical Ethics provides general and specific guidance for all physicians regarding their relations with industry, including Opinion 8.061, which sets parameters around the practice of gift giving.



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**Key points:**

There are 9 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]



**Q:** Are there any questions before we proceed to the module review?

## Module Review

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This module, *AMA Ethical Guidelines on Gifts to Physicians from Industry*, has addressed three topics:

1. General concepts related to gifts, medical ethics, and professionalism in physician-industry relations, including:
  - the common understanding of gifts
  - basic ethical principles
  - the notion of professionalism
2. The AMA's Council on Ethical and Judicial Affairs (CEJA), including:
  - the AMA policy-making procedure
  - the Code of Medical Ethics
3. Relevant guidance from the AMA's Code of Medical Ethics on Physician-Industry Relations, including:
  - the relevant Principles of Medical Ethics
  - conflicts of interest
  - gifts to physicians from industry
  - continuing medical education for attendees, faculty, and sponsors



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### Take-Home Message:

If an incentive is offered to a physician, the following questions should be asked:

- 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.



## Conclusion

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### Wrap-up

- *Ask if anyone has anything to add or ask before you conclude the presentation*
- *Thank attendees for their participation and contribution to an excellent session*
- *Mention the other three modules in the series:*



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Module 1: Overview of Ethical, Professional, and Legal Issues for Physicians' Relationships with Industry

Module 2: Physicians' Expectations of Industry and Sales Personnel

Module 3: Professional Issues Concerning Gifts to Physicians from Industry

See [www.ama-assn.org/go/ethicalgifts](http://www.ama-assn.org/go/ethicalgifts)

### Feedback



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- *Ask attendees to please take a minute to complete **Presentation Evaluation Forms** [in handout material],*
- *Remind participants that if they have any questions that could not be addressed during the session, to include them on the **Follow-up Form** [in handout material], along with a business card (or contact information)*



End of Module

**What You Should Know About Gifts to Physicians From Industry**

**Module 4: AMA Ethical Guidelines on Gifts to Physicians from Industry**

## 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]
- 5 Mauss M. **The Gift: The Form and Reason for Exchange in Archaic Societies**
- 6 **Encyclopedia of Bioethics, Revised Edition.** Warren T. Reich, editor in chief, Simon & Schuster, Macmillan, NY, 1995
- 7 **Gifts to Physicians from Industry.** *JAMA* 1991 Jan 23-30;265(4):501
- 8 **The Council on Ethical and Judicial Affairs of the American Medical Association Guidelines on Gifts to Physicians from Industry: An Update.** *Food and Drug Law Journal* 1992;47:445-458
- 9 **The Council on Ethical and Judicial Affairs of the American Medical Association Guidelines on Gifts to Physicians from Industry: An Update.** *Food and Drug Law Journal* 2001;56:27-40

## Gifts to Physicians from Industry Classroom Materials Evaluation Form

Please take a moment to help us better meet the needs of others who will use these teaching modules. The AMA and the Working Groups on Gifts to Physicians commissioned these modules to assist individuals responsible for the education of physicians and others. We would like feedback about your experience using these educational materials. Your comments will help confirm the most important aspects of the material and identify changes or additions that may be useful for others. Your comments will be kept confidential, with feedback to authors and others provided only on an aggregate basis. After you have used the materials, please complete this evaluation form and **fax to 312-464-5830**

1. **Module(s).** Which module(s) did you present: *Check all that apply.*

- Module 1: An overview of ethical, professional, and legal issues for physicians' relationships with industry
- Module 2: Physicians' expectations from industry and sales personnel
- Module 3: Professionalism and gifts to physicians from industry
- Module 4: The AMA ethical guidelines on gifts to physicians from industry

2. **Audience(s).** To whom did you make your presentation(s)? *Check all that apply.*

- Practicing physicians
- Residents
- Medical students
- Industry personnel
- Other

*Circle the response that best reflects your opinion:*

	<b>Poor</b>		<b>Satisfactory</b>		<b>Excellent</b>
3. Extent to which the content met the <u>stated objectives</u> for the module.	1	2	3	4	5
4. Extent to which the content met <u>your objectives</u> for the module.	1	2	3	4	5
5. Organization and formatting of the material	1	2	3	4	5
6. Materials avoided commercial bias or influence	1	2	3	4	5
7. Participants' general view of the presentation	1	2	3	4	5
8. Ease in accessing and downloading materials	1	2	3	4	5
9. Your overall evaluation of the classroom materials	1	2	3	4	5
	<b>Yes</b>		<b>No</b>		<b>Not Sure</b>
10. Do you plan to use other modules in the series?	1	2	3		
11. Will you recommend these educational materials to others?	1	2	3		

**Comments**

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