

American Medical Association

What You Should Know About Gifts to Physicians from Industry

MODULE 2:

Physicians' Expectations of Industry and Sales Personnel

Participant's Handout

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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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About the Author

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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)

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Disclosure of Conflict of Interest

Disclosure: Ms. Rose works as a consultant to numerous pharmaceutical, biologics, advertising, and public relations firms. Additionally, she worked several years for the FDA. None of these relationships represent a conflict of interest in this context, as the content is factual only (not editorial or opinion), not related to any specific company (companies), does not mention any drugs, and Ms. Rose does not stand to gain anything from any company based on the content herein.

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

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Participant's Handout

Read This First!

This handout contains:

- An abbreviated outline of the presentation *Module 2: Physicians' Expectations of Industry and Sales Personnel*
- 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: *American Medical Association 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*.

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/docs/complianceguidance/042803pharmacymfgnonfr.pdf>

Dept. of Health and Human Services, 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 2

Physicians' Expectations of Industry and Sales Personnel

Consider this...

During a sales call with an industry representative, the physician mentions a recent study involving the successful use of an agent – but a use that does not appear in the package insert.

- In servicing your clinical needs regarding their products, what are the responsibilities of industry representatives?
- Exactly what can they do and not do?
- Who establishes regulations and guidelines and regulates sales representatives' interactions with you in your office?

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Module Overview

While a professional sales presentation can be educational, to maintain a balanced perspective, physicians must understand:

- the training and background of the industry representative
- the regulatory expectations that govern the interaction and relationship

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Module Goals and Objectives

1. Educate physicians regarding the duties of industry representatives, their selection, training, and evaluation.
2. Educate physicians regarding FDA regulatory requirements for promotion of prescription drugs.
3. Educate physicians regarding their responsibilities for safety reporting.

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Topic 1: The Role of an Industry Representative

This topic addresses:

1. The job
2. The training
3. Accountability
4. Evaluation and compensation

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Topic 1: The Role of an Industry Representative

The material here is intended to convey common practices within the pharmaceutical and medical device industry. Within the law, each company may handle specific situations differently as decided by their leadership.

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The Job

Industry representatives...

- are responsible for:
 - increasing product sales
 - one or more products
 - a geographical territory for a group of physicians *or*
 - a specific area of healthcare (eg, oncology, pediatrics)
- provide disease information to healthcare professionals
- provide product-specific information to healthcare professionals, such as physicians, nurses, physician assistants, pharmacists, etc.

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The Job

The FDA regulates pharmaceutical sales personnel according to their activity, not by title, including:

- prospective visits to physicians' offices
- promotional presentations to physicians at group events

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Training Standards

No national standards for experience, educational background, or training of industry representatives.

- some have science or clinical training
- most have an undergraduate or graduate degree

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Training

Corporate Training

Training varies by pharmaceutical manufacturer; many provide an initial six months or more of training such as:

- three weeks of in-house selling skills training
- product-related disease training, accompanied by extensive testing
- drug-specific training

Periodic retraining is also offered as representatives achieve different levels of experience, competency, and responsibility

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Training

Corporate Training

Sales representatives often receive field sales training through:

- calling on physicians accompanied by experienced industry representatives, district sales managers, or sales trainers
- in-office or hospital preceptorships working one-on-one with specialists known for their expertise in specific diseases

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Accountability

Territory

Industry representatives are:

- assigned a territory (usually a group of zip codes)
- managed by a District Sales Manager (or similar title)

One or more District Managers report to a Regional Sales Manager or Director.

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Accountability

Tracking

Representatives are generally required to note:

- samples disbursed (must document under special sampling law)
- literature left behind
- any physician questions
- physician clinical interests/preferences
- physician interest in giving/attending presentations/events
- product or disease information discussed
- plans for next sales call

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Evaluation and Compensation

Prescription Sales

Industry commonly tracks:

- the number of prescriptions written and/or product sales value for a defined territory
- sales measured against quarterly data, targets, and competitive sales figures
- information provided during sales calls, or requested as a result of a sales call
- changes in physician-prescribing patterns

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Evaluation and Compensation

Activity

Evaluation can include:

- the number of sales calls representatives make on physicians, pharmacies, hospitals, etc
- calls benchmarked against previous activity and/or targets for the number of daily sales calls

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Evaluation and Compensation

Compensation

Industry representatives:

- are often paid a combination of salary plus bonus based on sales goal attainment
- receive increasing bonuses if exceed sales goals
- receive incentives (trips and luxury items) for outstanding performance

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The Role of an Industry Representative: Summary

Industry representatives have a unique dual role as educators and sales personnel.

They share some characteristics common to traditional sales personnel:

- specialize in specific product areas
- trained through a combination of classroom and field activities
- have a reporting structure with a district and regional hierarchy
- compensated according to a combination of base salary and commission based on financial, volume, and/or activity measurements

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Topic 2: FDA Requirements

This topic addresses three areas in which the FDA enforces laws and regulations governing interactions between industry representatives and physicians:

1. Product labeling and package inserts
2. Sales activities
3. Advertising and marketing

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Product Labeling and Package Inserts

For package insert inclusion:

- data from adequate and well-controlled clinical trials that provide independent corroboration of a clinically relevant finding is the legal and scientific standard
- anecdotal or testimonial information is inadequate

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Product Labeling and Package Inserts

What are FDA requirements for prescription drug approval?

- a) Efficacy superior to placebo
- b) Efficacy superior to any other agent in its class
- c) Efficacy/benefit outweighs known risks for intended population

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Product Labeling and Package Inserts

Prescription drug approval requires that the demonstrated efficacy/benefit of the product outweigh the known risks of the product for the population for whom the drug is intended when used as described in the label.

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Sales Activities

Product Information

Based on the totality of clinical data submitted by the company, the FDA approves:

- the package insert (“PI”, a.k.a “professional labeling” or just “labeling”)
- the intended use (“indication” as written in the PI) of the product

Therefore, it is the information consistent with the package insert that the company can legally promote.

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Sales Activities

Product Information

Are promotional materials pre-reviewed or approved by FDA prior to publication?

- a) Yes
- b) No

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Sales Activities

Product Information

No. With a few limited exceptions*, regulations require manufacturers to submit promotional materials to the FDA at the time of publication or distribution, not prior to use. Therefore, most promotional materials have not been pre-reviewed or approved by the FDA.

*Such as special accelerated approval for drugs being approved for serious or life-threatening diseases.

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Sales Activities

Product Information

According to FDA regulations the manufacturer must ensure that:

- information about a prescription drug does not mislead
- anyone acting on their behalf does not mislead by implication
- prior to FDA approval, promotion does not occur for unapproved products or unapproved uses of approved products
- information is consistent with the approved package insert (PI) and truthful and not misleading according to the PI

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Sales Activities

Product Information

Industry representatives must:

- provide safety information about a drug (called "fair balance"*) when discussing product attributes with a physician
- leave a package insert (PI) with physicians when providing a sales call or printed information on a product

*Fair balance of safety information with efficacy claims

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Sales Activities

What an Industry Representative Can and Cannot Do

When calling on physicians on behalf of a pharmaceutical manufacturer, what can an industry representative do and not do?

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Sales Activities

Within FDA regulations, a representative CAN...

- as defined in the regulations, provide detailed information that is in the professional product labeling, or package insert (PI), or is consistent with the PI, or supported by substantial evidence
- display/distribute company-approved promotional and support materials
- refer "off-label" questions to the company's medical relations/professional relations dept.
- sell using all company-approved material

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Sales Activities

Within FDA regulations, a representative CANNOT...

- prompt an "off-label" question
- discuss product information that is not in the product labeling (package insert – PI) or company-approved material
- in general, compare the package insert of one product with the package insert of a competing product, as data are not "apples to apples"

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Advertising and Marketing *Off-Label*

Industry representatives:

- can refer physicians' unsolicited off-label questions to their company's medical relations department
- cannot prompt discussions regarding use of prescription drugs inconsistent with labeling

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Advertising and Marketing

Off-Label

The pharmaceutical company medical information department will:

- answer the questions with a narrowly tailored response
- provide complete reprints (generally not just abstracts) of studies related to the question, even if off-label
- provide studies that accurately reflect the totality of the known data about that question, and not just the most favorable product profile

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Advertising and Marketing

Advertising and Promotion

Are physicians serving as paid speakers for a pharmaceutical company subject to FDA regulations?

- a) Yes
- b) No

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Advertising and Marketing

Advertising and Promotion

Physicians serving as paid speakers, or otherwise representing a company, are expected to:

- follow the same promotional regulations as company personnel, since they are acting on behalf of the company (FDA regulations)
- be trained by the pharmaceutical company on FDA regulations if they are being paid on behalf of the company (PhRMA Guidelines)

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Advertising and Marketing *Study Design and Findings*

When interpreting study publications and trial data, ascertain:

- Is the study designed to answer the question?
- Is the study adequately powered to answer the question?
- Is the study randomized, controlled, blinded, etc, and does it account for all patients, therefore minimizing bias?

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Advertising and Marketing *Study Design and Findings*

When interpreting study publications and trial data, also ascertain:

- Do the data support any comparative claims?
- Do the data support the conclusions?
- What are the authors' potential conflicts of interest, financial or other personal biases?

Ask your medical school biostatistician for help.

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Advertising and Marketing *Study Design and Findings*

FDA regulations do not permit using:

- mechanism of action
- in vitro information

...to support clinical claims or comparisons, unless there is proof that these cause clinical outcomes.

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Advertising and Marketing *Comparative Claims*

What are FDA requirements to support a comparative claim?

- a) One adequate and well-controlled trial
- b) At least two adequate and well-controlled trials – independently corroborated, adequate, and well-controlled data
- c) Three or more adequate and well-controlled trials
- d) None, providing the comparison between trials is balanced

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Advertising and Marketing *Comparative Claims*

FDA requirements to support a comparative claim are:

- in general, at least two adequate and well-controlled, head-to-head trials to support a comparative claim (and/or superiority and “equal efficacy or safety” claims) between two drugs
- the same for product promotion, whether the comparative data are in the label or not
- cannot make comparative claims unless both drugs are approved for the same indication

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Advertising and Marketing *Promotional & Educational Events*

What are the important differences between:

- an educational event presented by industry?
- an event supported by industry and sponsored by an ACCME accredited organization?

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Advertising and Marketing *Promotional & Educational Events*

Industry Promotional Education (Non-independent)

- Funded directly by industry
- Delivered by industry or somebody paid by industry
- Content developed by industry
- Only company-approved material can be presented and distributed
- Regulated by FDA
- Presentations must be consistent with labeling
- Speaker(s) usually from industry-approved speaker bureau and trained by the company
- Not eligible for CME credits
- Sales representatives can promote products consistent with labeling

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Advertising and Marketing *Promotional & Educational Events*

Accredited Sponsor Education (Independent)

- Often supported by industry through an unrestricted educational grant
- Delivered by ACCME accredited organization
- Content developed independently without industry influence
- Not subject to FDA regulation
- Off-label discussions permitted if clearly identified as such
- Speaker selected by accredited sponsor
- Full speaker disclosure required
- Eligible for CME credits
- Industry representatives cannot promote products in same room where education occurs

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Quick Case 1 *Promotional & Educational Events*

You attend a CME activity designated for AMA PRA Category 1 credit by an accredited provider and commercially supported by a pharmaceutical company. At the end of the program, the local industry representative stands up and thanks everyone for coming on behalf of the company. She also states that anyone who would like additional information on the drug discussed in the CME presentation should feel free to contact her.

How appropriate is this conclusion
to the program?

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Quick Case 1

Promotional & Educational Events

- The pharmaceutical representative thanking attendees was clearly at the boundary of acceptable behavior
- The pharmaceutical representative offering additional information was over the boundary, blurring lines between promotion and education
- ACCME Standards prohibit any behavior that might be construed as sales activities where educational activity occurs

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Quick Case 2

Comparative Claims

An industry representative is making a sales presentation about an antihypertensive drug to a resident physician. The industry representative states:

“According to the package inserts for our drug and our biggest competitor, our drug has 5% fewer incidents of cough than their drug.”

How should you interpret this statement?

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Quick Case 2

Comparative Claims

Comparative claims do not have to be in the labeling, but must be supported by the same evidence as required for a labeling claim. (These trials must involve an approved indication for both drugs.)

A valid comparison based on two products' respective package inserts is unusual because generally:

- the trial methodologies, reporting language, and endpoints are not identical
- the trials were not conducted at the same time on the same trial populations
- should ask to see head-to-head trial

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FDA Requirements Summary

FDA regulations help ensure:

- consistent, quality pharmaceutical products available to physicians and their patients
- physicians can rely upon accurate, standardized data with which to make informed clinical decisions
- a “promotional level playing field” within or between drug classes for all pharmaceutical products, regardless of the manufacturer

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Topic 3: Physician Responsibility

This topic addresses physicians' responsibility in reporting on the following two areas:

1. Safety issues regarding prescription drugs
2. Violations of promotional activity

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Physician Responsibility *Safety Alerts*

Are physicians required by law to report any adverse events or drug interactions observed with prescription drugs?

- a) Yes
- b) No

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Physician Responsibility

Safety Alerts

No.

- Physicians are not required by law to report prescription drug adverse events or interactions, BUT they are strongly encouraged to report suspected serious and/or life-threatening adverse events
- A direct cause does not have to be established

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Physician Responsibility

Safety Alerts

Physicians are strongly encouraged to report suspected serious prescription drug adverse events to:

- the pharmaceutical manufacturer, OR
- the FDA MedWatch program by:
 - calling 1-800-FDA-1088
 - completing the Voluntary Reporting Form 3500 online at <https://www.accessdata.fda.gov/scripts/medwatch/>
 - downloading the Voluntary Reporting Form 3500 at <http://www.fda.gov/medwatch/safety/3500.pdf> and faxing or mailing it in to the FDA

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Physician Responsibility

Promotional Concerns

Physicians should report industry representative violations of promotional activity regulations to:

- the responsible company's medical information department
- FDA's Division of Drug Marketing, Advertising and Communications within the Center for Drug Evaluation and Research at:
 - 5600 Fishers Lane, HFD, Rockville, Maryland 20857
 - Phone: 301-827-2828 or 301-827-2831
 - Fax: 301-594-6759 or 301-594-6771
 - <http://www.fda.gov/cder/ddmac/>
- HHS, Office of the Inspector General; telephone 1-800-447-8477

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Module Review

This module has addressed three topics:

1. The role of industry representatives that covered their:
 - job
 - training
 - accountability
 - evaluation and compensation
2. FDA regulatory requirements for the promotion of prescription drugs including:
 - product labeling and package inserts
 - sales activities
 - advertising and marketing
3. Physicians' responsibilities regarding:
 - safety reporting
 - promotional concerns

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Take-Away Points

1. Industry promotes their products to physicians, and relies on physicians to prescribe their product. Physicians rely on industry to provide reliable products and for *one source* of accurate information regarding those products.
2. Industry's promotional activities generally produce desired results.
3. While the sales job of a pharmaceutical industry representative shares many characteristics with sales personnel of other industries, their interactions with physicians are highly restricted and regulated.
4. Physicians have a professional responsibility to report any suspected serious or life-threatening adverse events associated with a drug to its manufacturer and/or the FDA.

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What You Should Know about Gifts to Physicians from Industry

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

Module 3: Professional Issues Concerning Gifts to Physicians from Industry

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

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Follow-up Form

Module 2: Physicians' Expectations of Industry and Sales Personnel

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 2: Physicians' Expectations of Industry and Sales Personnel

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

-
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 - 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]