9.6.2 Gifts to Physicians from Industry

Relationships among physicians and professional medical organizations and pharmaceutical, biotechnology, and medical device companies help drive innovation in patient care and contribute to the economic well-being of the community to the ultimate benefit of patients and the public. However, an increasingly urgent challenge for both medicine and industry is to devise ways to preserve strong, productive collaborations at the same time that they take clear effective action to prevent relationships that damage public trust and tarnish the reputation of both parties.

Gifts to physicians from industry create conditions that carry the risk of subtly biasing—or being perceived to bias—professional judgment in the care of patients.

To preserve the trust that is fundamental to the patient-physician relationship and public confidence in the profession, physicians should:

(a) Decline cash gifts in any amount from an entity that has a direct interest in physicians’ treatment recommendations.

(b) Decline any gifts for which reciprocity is expected or implied.

(c) Accept an in-kind gift for the physician’s practice only when the gift:

   (i) will directly benefit patients, including patient education; and

   (ii) is of minimal value.

(d) Academic institutions and residency and fellowship programs may accept special funding on behalf of trainees to support medical students’, residents’, and fellows’ participation in professional meetings, including educational meetings, provided:

   (i) the program identifies recipients based on independent institutional criteria; and (ii) funds are distributed to recipients without specific attribution to sponsors.

AMA Principles of Medical Ethics: II

Background report(s):

CEJA Report 2-I-13 Amendment to Opinion 8.061, Gifts to physicians from industry
CEJA Report F-I-90 Gifts to physicians from industry
CEJA Report G-I-90 Gifts to physicians from industry
REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS*

CEJA Report 2-I-13

Subject: Amendment to E-8.061, “Gifts to Physicians from Industry”

Presented by: Susan Dorr Goold, MD, Chair

Referred to: Reference Committee on Amendments to Constitution and Bylaws
(Larry E. Reaves, MD, Chair)

Opinion E-8.061, “Gifts to Physicians from Industry,” was originally issued in 1992 to provide guidance for physicians in their relationships with industry in clinical practice. The American Medical Association (AMA) was a pioneer in turning physicians’ attention to the ethical concerns posed by gifts from industry. However, medicine-industry relationships have evolved significantly since E-8.061 was last updated in 1998 and so has public and professional unease about the possibility that gift relationships between physicians and pharmaceutical, medical device and equipment, and biotechnology companies will have inappropriate effects. Over the intervening years empirical research has explored the question of gift relationships and other organizations have reflected on the ethical implications and issued policies in this area, many of which have built on the foundations of E-8.061. As it stands, E-8.061 no longer represents best thinking with respect to gifts to physicians from industry. The Council on Ethical and Judicial Affairs (CEJA) has thus concluded that this opinion should be updated.

THE CURRENT ETHICAL CONSENSUS

Since CEJA’s original report, concerns about physicians’ relationships with industry, including the acceptance of gifts, have continued to grow as evidence has accumulated about the influence of such relationships on physician practice.[1-5] A consensus has emerged over the past decade or so that recognizes the enormous value of maintaining strong relationships between medicine and industry, notably in research and innovation, but equally recognizes the need for circumspection where gifts to individual physicians are concerned. This is the case whether gifts are large or small, financial or in-kind, office supplies or patient educational materials.[6-8]

Calls for physicians to decline industry gifts of any size or nature have become prominent among many scholars of medicine-industry relationships,[2,3,9] in reports by distinguished national bodies,[4,5] and among national professional organizations and in advocacy campaigns.[10-12] In 2007, the American Medical Student Association began surveying the conflict of interest policies of all allopathic medical schools in the U.S. to create its “PharmFree Scorecard,” scoring medical schools with respect to their policies on gifts and pharmaceutical samples, among other domains.[13] In 2008 the Association of American Medical Colleges urged academic medical centers to “establish and implement policies that prohibit the acceptance of any gifts from industry

* Reports of the Council on Ethical and Judicial Affairs are assigned to the Reference Committee on Amendments to Constitution and Bylaws. They may be adopted, not adopted, or referred. A report may not be amended, except to clarify the meaning of the report and only with the concurrence of the Council.
by physicians and other faculty, staff, students, and trainees.”[4] The following year, in its report on conflicts of interest in medicine, the Institute of Medicine similarly recommended that all physicians decline “items of material value” from industry and urged professional societies to amend their policies to support its recommendations.

The Pharmaceutical Research & Manufacturers Association (PhRMA) 2008 Code on Interactions with Healthcare Professionals bans noneducational and practice-related gifts (other than samples), items intended for the physician’s personal benefit, and cash or cash-equivalents other than compensation for bona fide services, though it permits “items designed primarily for the education of patients or healthcare professionals” valued at under $100.[14] The 2009 Code of Ethics of the Advanced Medical Technology Association (AdvaMed) similarly restricts gifts to physicians.[15]

According to data collected for AMSA’s most recent “PharmFree Scorecard,” 73 of 149 U.S. medical schools responding to the survey now prohibit gifts from industry entirely, while another 36 have policies restricting acceptance of gifts in various ways.[13]

PROTECTING PATIENTS’ INTERESTS & PUBLIC TRUST

Patients must be able to trust that their physicians have based treatment recommendations on the physician’s independent professional judgment and knowledge of the patient’s unique circumstances. Gifts from industry can undermine physicians’ objectivity and put at risk physicians’ ability to fulfill their primary professional commitment to serve patients’ interests.

RECOMMENDATION

In light of these considerations, the Council on Ethical and Judicial Affairs recommends that Opinion E-8.061, “Gifts to Physicians from Industry,” be amended by substitution as follows, its accompanying clarification be rescinded, and the remainder of this report filed:

Relationships among physicians and professional medical organizations and pharmaceutical, biotechnology, and medical device companies help drive innovation in patient care and contribute to the economic well-being of the community to the ultimate benefit of patients and the public. However, an increasingly urgent challenge for both medicine and industry is to devise ways to preserve strong, productive collaborations at the same time that they take clear effective action to prevent relationships that damage public trust and tarnish the reputation of both parties.

Gifts to physicians from industry create conditions that carry the risk of subtly biasing—or being perceived to bias—professional judgment in the care of patients.

To preserve the trust that is fundamental to the patient-physician relationship and public confidence in the profession, physicians should:

(a) Decline cash gifts in any amount from an entity that has a direct interest in physicians’ treatment recommendations.

(b) Decline any gifts for which reciprocity is expected or implied.

(c) Accept an in-kind gift for the physician’s practice only when the gift:

(i) will directly benefit patients, including patient education; and
(ii) is of minimal value.

(d) Academic institutions and residency and fellowship programs may accept special funding on behalf of trainees to support medical students’, residents’, and fellows’ participation in professional meetings, including educational meetings, provided:

(i) the program identifies recipients based on independent institutional criteria; and

(ii) funds are distributed to recipients without specific attribution to sponsors.

(Modify HOD/CEJA Policy)

Fiscal Note: Less than $500 to implement.
REFERENCES

F. OPINION OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS:
GIFTS TO PHYSICIANS FROM INDUSTRY

HOUSE ACTION: FILED

The Council on Ethical and Judicial Affairs submits the following opinion to the House of Delegates for its information and recommends that this report be filed.

GIFTS TO PHYSICIANS FROM INDUSTRY. Many gifts given to physicians by companies in the pharmaceutical, device and medical equipment industries serve an important and socially beneficial function. For example, companies have long provided funds for educational seminars and conferences. However, there has been growing concern about certain gifts from industry to physicians. Some gifts that reflect customary practices of industry may not be consistent with principles of medical ethics. To avoid the acceptance of inappropriate gifts, physicians should observe the following guidelines:

1. Any gifts accepted by physicians individually should primarily entail a benefit to patients and should not be of substantial value. Accordingly, textbooks, modest meals and other gifts are appropriate if they serve a genuine educational function. Cash payments should not be accepted.

2. Individual gifts of minimal value are permissible as long as the gifts are related to the physician’s work (e.g., pens and notepads).

3. 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 sales representative may create a relationship which 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.

4. Subsidies from industry should not be accepted to pay for the costs of travel, lodging or other personal expenses of physicians attending conferences or meetings, nor should subsidies be accepted to compensate for the physician’s time. Subsidies for hospitality should not be accepted outside of modest meals or social events held as a part of a conference or meeting. 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 compensating physicians for their time or their travel, lodging and other out-of-pocket expenses.

5. 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.

6. 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.
G. GIFTS TO PHYSICIANS FROM INDUSTRY

HOUSE ACTION: ADOPTED IN LIEU OF RESOLUTION 135

INTRODUCTION

While relationships between industry and the medical community have resulted in important benefits for patient care, there has been growing concern about the potential negative consequences of the relationship. In particular, commentators have increasingly questioned the appropriateness of some of the gifts that are given to physicians by companies in the pharmaceutical, device and medical equipment industries. Many gifts serve an important and socially beneficial function. For example, companies have long provided funds for educational programs and facilities. Some gifts, however, may have inappropriate effects and are therefore cause for concern. This report discusses the ethical issues raised by the practice of industry gift giving and proposes guidelines for physicians to distinguish appropriate from inappropriate gifts.

GIFT GIVING PRACTICES

Gift giving by industry can take many forms. Companies typically provide physicians with ball point pens, penlights, note pads and other inexpensive items upon which is printed the name of the company or one of its products. Hospital residents are often treated to lunches or dinners by sales representatives. Companies also sponsor medical conferences that have been developed by hospitals, medical schools or professional associations. Their sponsorship often takes the form of a speaker, general support or specific underwriting grants and includes hospitality suites, dinners and cash payments to registrants to defray the costs of attending the conference. In some cases, companies will pay the full costs for a physician to attend a conference in another state or another country and offer to pay for additional days of vacation at the conference site.

Some companies put on conferences with speakers who are selected by the company and who discuss the company’s products. These conferences are typically held at attractive locations, and some physicians are flown in with their spouses for a weekend of presentations, recreation and entertainment, all at company expense. Often a company will direct its invitations at physicians who are viewed as leading practitioners by other physicians in their community. The companies recognize that practices adopted by these “leaders” are generally followed by their peers. Companies schedule individual speakers to speak to groups of physicians over dinner at no cost to the physicians, and some companies will pay $100 to each physician who attends the dinner to compensate for the physician’s time. It has been reported that a few companies also have given physicians gifts or cash payments for every patient who was started on a particular drug.

Some of these practices are entirely ethical and beneficial to patients, and not all companies engage in them. In addition, the rules regarding the propriety of the practices have not been clear. Recognizing the lack of clarity, the medical profession and the pharmaceutical industry have been supportive of change. A Task Force on Pharmaceutical Industry/CME Cooperation chaired by the AMA is now actively reviewing the guidelines for industry support of continuing medical education.

ETHICAL CONCERNS

The practice of gift giving raises a number of ethical concerns.

1. Influence on Physician Practices

Industry invests in promotional activities because promotions increase sales. As one commentator has observed, no company “gives away its shareholders’ money in an act of disinterested generosity.” There is
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1. Influence on Physician Practices

Industry invests in promotional activities because promotions increase sales. As one commentator has observed, no company “gives away its shareholders’ money in an act of disinterested generosity.” There is
no evidence that physicians knowingly or intentionally compromise their patients’ care as a result of gifts from industry. Nevertheless, the practice of gift giving may mobilize subtle influences that can result in practice patterns based on considerations that go beyond scientific knowledge and patient needs.

In a recent article examining the cultural phenomenon of gift giving, researchers observed that the giving and accepting of a gift can lead to important social relationships with real obligations. By accepting a gift, an individual “assumes certain social duties, such as grateful conduct, grateful use and reciprocation.” Salespersons have long recognized the social implications of gift giving; surveys indicate that gifts to potential buyers are given in the belief that gifts tend to obligate their recipients and that they are therefore useful for increasing sales.

Physicians do not respond to gifts from industry by giving gifts in return. However, there are other ways to reciprocate and express gratitude. The physician may be more responsive in granting interviews to sales representatives and may, on the basis of the information presented, decide to use a new drug or device on a trial basis with his or her patients. In a study of industry funding for continuing medical education (CME), researchers found a relationship between the source of funding and physician prescribing practices. The study examined prescribing patterns of physicians both before and after they attended one of three CME courses. The courses in the study met the following criteria: a single drug company was the major financial supporter of the course, the course topic was directly related to a single class of drugs with at least three drugs in the class, and the drugs were essentially similar in terms of benefits, side effects and costs. While after each course there were increases in the prescribing of all drugs in the class, the greatest effect occurred for the drug whose company was the major financial supporter of the course.

Gift giving can influence physician practices also because a person’s judgment about a product is affected by considerations other than the product’s quality. When a physician receives a gift from a company’s sales representative, the physician may associate his or her feelings about the gift or the sales representative with his or her feelings about the company’s products. A recent study indicates that the receipt of a gift may have an important effect on a potential customer’s perception of a product, even when the gift is a small one.

Gifts may affect a physician’s education regarding new developments in medicine by influencing the physician’s choice of medical conferences. Physicians frequently rely upon medical conferences to update their knowledge and expertise. Among the available conferences, physicians have time to attend a limited number, and industry can make certain conferences more attractive by subsidizing the costs of attending. Companies will direct their subsidies at conferences that provide the most favorable view of their products.

Through the presentations of sales representatives to physicians, companies tend to emphasize the results of clinical research supporting both the efficacy and the lower cost of their products as compared to competing products of other companies. Physicians, in prescribing for their patients, therefore must ensure that they are knowledgeable about the full range of research regarding the benefits and possible adverse reactions to pharmaceutical and other products and must provide their patients with full information on risks and potential complications. The continued use of new or established products must be based on the response of the individual patient and the preponderance of evidence from all clinical trials, as well as neutral sources of information such as the American Medical Association’s widely used “Drug Evaluations.” Gifts should have no part in influencing these decisions.

The concern about undue influence from a gift is particularly strong when the gift comes with strings attached. A company that donates funds to underwrite a continuing medical education conference may want a role in shaping the program, for instance by selecting speakers from its own panel of experts, selected for their knowledge and experience in the use of the company’s products. These experts may show bias with regard to use of the company’s products, thereby undermining the objectivity and impartiality of the educational activity.
While there is little evidence that physicians consciously make practice decisions on the basis of factors other than a product’s clinical properties and the patient’s particular needs, some research suggests that physicians unknowingly may be influenced by promotional techniques. In a study of physician prescribing of propoxyphene (Darvon) for analgesia and cerebral vasodilators for senile dementia, researchers found that physicians in substantial numbers were likely to use these drugs in situations that could not be justified by evidence in the clinical literature. Instead, these physicians held beliefs about the efficacy of the drugs that were consistent with information found in commercial advertisements for the drugs.

In describing these potential problems with gifts to physicians, the Council has not lost sight of the need for physicians to receive the broadest possible exposure to new and different health care products and their clinical applications. Unquestionably, patients have obtained some benefit even from gifts and other practices which may, on balance, be too substantial to be considered appropriate. For some physicians, the events and conferences described above have been a means through which they stay abreast of rapidly occurring advances in medicine and hear and interact with noted colleagues discussing new products and developments in their field. These events have been of genuine educational value to this extent, and they have expanded the universe of clinicians receiving research support from pharmaceutical and other companies.

2. Appearance of Impropriety

Even when gifts from industry have no effect on a physician’s practice, there may be a public impression of impropriety, especially if the gifts are of substantial value. The trust of the public that physicians are dedicated foremost to the welfare of their patients may be undermined when there is a possibility that the choice of a drug, device or other product is influenced by the fact that the physician had received a gift from the company that manufactures the product. For example, when companies schedule their own conferences at resorts and pay for physicians and their spouses to attend for a weekend that includes only a few hours of lectures and many hours of recreation, lavish meals and expensive entertainment, it is difficult to view the conference as serving a legitimate educational purpose.

Strict limits on the acceptance of gifts to avoid even the appearance of impropriety have been adopted in other contexts. Federal government employees, including physicians at Veterans Administration hospitals, may not accept gifts from companies whose products or services they are using, and federal judges may not accept gifts from persons whose interests have come or are likely to come before the judge. Companies in industry also generally impose limits on the acceptance of gifts by their employees. In a survey of manufacturing firms, a researcher found that 50 percent of the firms did not permit their employees to accept gifts other than pens, pads or items of comparable value. Twenty-four percent of the firms permitted gifts up to $50 in value to be accepted but only on an occasional basis. In addition, in a survey of purchasing agents for industrial companies, the agents agreed that it is unethical to accept entertainment, tickets, gifts or other favors from sellers.

The appearance of impropriety may also arise because of the magnitude of company spending on promotional activities, including gifts. According to one estimate, pharmaceutical companies spent about $2.5 billion per year for all their promotional activities in 1988. Specific data on what portion of this can be attributed to gifts to doctors is not available beyond estimates that $200 million is spent annually by the pharmaceutical industry for medical education. It is not clear how much is spent on promotional activities for physicians by companies that manufacture or distribute devices and medical equipment.

3. Costs of Gifts

The costs of gifts from industry to physicians are ultimately passed on to the public. In effect then, patients may be paying for a benefit that in some cases is captured primarily by their physicians. Physicians should not accept inappropriate gifts because the cost is ultimately subsidized by patients.
The Council on Ethical and Judicial Affairs recognizes that many gifts from industry to physicians result in significant benefits to patients. For example, books and conferences contribute to the education of physicians, and meals at medical meetings or conferences provide a forum for colleagues to exchange information. These kinds of gifts can therefore be appropriate, depending on the extent to which the gift serves a function beneficial to patient care and on whether the same benefits can be realized through less costly promotional activities.

GUIDELINES FOR GIFTS FROM INDUSTRY TO PHYSICIANS

The ethical considerations discussed above suggest several principles.

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. On the other hand, cash payments serve only the physician’s personal interest and therefore should not be accepted from industry.

A gift which is appropriate because of its contribution to patient care may become inappropriate because of its extravagance.

Gifts of minimal value raise fewer concerns and are permissible as long as the gifts are related to the doctor’s work (e.g., pens, diaries, books or rulers).

2. Gifts by drug companies to underwrite medical conferences or other professional meetings enhance the ability of academic institutions, professional associations and health care organizations to provide continuing education to physicians. Consequently, such gifts make an important contribution to patient care. Subsidies from industry should not be accepted to pay for the costs of travel, lodging or other personal expenses of physicians attending conferences or meetings, nor should subsidies be accepted to compensate for the physicians’ time. Subsidies for hospitality should not be accepted outside of modest meals or social events held as a part of a conference or meeting.

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 compensating physicians for their time or their travel, lodging and other out-of-pocket expenses.

The giving of a gift directly to a physician from a company’s sales representative may create a personal relationship which could influence the use of the company’s products. Accordingly, when a company contributes funds for conferences that are sponsored by academic or other educational institutions, the funds should be given by the company to the conference 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.

3. 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.

4. Sponsors of continuing medical education conferences have a special responsibility to ensure that gifts are appropriate. The Accreditation Council for Continuing Medical Education has adopted a number of useful guidelines to prevent industry funding for continuing medical education conferences from leading to undue influence by the companies: (a) responsibility for and control over the selection of content,
faculty, educational methods and materials should belong to the accredited sponsors of conferences, 
(b) presentations must give a balanced view of all therapeutic options, and (c) financial support must 
be acknowledged in printed announcements and brochures, but reference should not be made to specific 
products.

The Task Force on Pharmaceutical Industry/CME Cooperation is currently developing an updated 
set of guidelines for industry funding of continuing medical education conferences.

Some of these guidelines are appropriate for smaller educational meetings and in other educational 
contexts, for example, when companies support meetings or lectures for medical trainees.

5. Financial support for conferences should be disclosed publicly. Physicians will be able to evaluate 
the information presented to them more appropriately if they are aware that companies have contributed 
funds to defray the costs of the presentation.

(References pertaining to Report G of the Council on Ethical and Judicial Affairs are available from the 
Office of the General Counsel.)

H. AFFILIATE MEMBERSHIP

HOUSE ACTION:  ADOPTED

The Council on Ethical and Judicial Affairs recommends the following individuals for Affiliate 
Membership in the American Medical Association:

U. S. Physicians in Foreign Countries

John C. Buterbaugh, M. D. Mutoko, Zimbabwe
John R. Fowler, M. D. Izmir, Turkey
Harry F. Gebert, M. D. The Gambia, West Africa
Janice W. Gebert, M. D. The Gambia, West Africa
John W. R. Harding, III, M. D. Kathmandu, Nepal
Joseph A. Hill, Jr., M. D. Paris, France
Walter B. Hull, M. D. Kananga, Zaire

David E. Matthews, M. D. Cameroon
Mary S. Schipper, M. D. Lesotho, Africa
Bonnie Sneed Stump, M. D. Sialkot, Pakistan
Dennis M. Sullivan, M. D. Haiti, West Indies
Ane Marie Amundsen Topple, M. D. Kikuyu, Kenya
Stanley C. Topple, M. D. Kikuyu, Kenya