Guidelines on Gifts to Physicians from Industry: An Update

COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS*
AMERICAN MEDICAL ASSOCIATION

I. INTRODUCTION

On December 3, 1990, the Council on Ethical and Judicial Affairs issued its six guidelines on gifts to physicians from industry. Since then, the Council has received numerous requests for interpretations of the guidelines. Many questions about the application of the guidelines can be answered by referring to the full report of the Council that was presented with the guidelines to the American Medical Association’s (AMA’s) House of Delegates. The report provides the reasoning behind the guidelines. In addition, the Council has prepared a number of interpretations in response to representative questions about the guidelines. These interpretations were issued on October 9, 1991.

The remainder of this article includes the text of the full report of the Council, the six guidelines, and the representative questions and interpretations. Each of the questions and interpretations is listed under the applicable guideline.

II. THE REPORT

A. 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, medical equipment and other health care 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.

* The Council on Ethical and Judicial Affairs issues the American Medical Association’s code of ethics. The members of the Council on Ethical and Judicial Affairs when the gifts guidelines were issued were: Richard J. McMurray, M.D., Chair; Oscar W. Clarke, M.D., Vice-Chair; John A. Barrasso, M.D.; Dexanne B. Clohan; Charles H. Epps, Jr., M.D.; John Glasson, M.D.; Robert McQuillan, M.D.; Charles W. Flows, M.D.; and Michael A. Puzak, M.D.

The staff authors of this article are Kirk B. Johnson, J.D., General Counsel, American Medical Association, and David Orentlicher, M.D., J.D., Secretary, Council on Ethical and Judicial Affairs.

by the practice of industry gift-giving and proposes guidelines for physicians to distinguish appropriate from inappropriate gifts.

B. 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.2

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.

C. 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 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

---

5. See id.
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 AMA’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 phy-

10. Avorn, Chen & Hartley, Scientific Versus Commercial Sources of Influence on the Prescrib-
sicians 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 practices, 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.\footnote{11}

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,\footnote{12} and federal judges may not accept gifts from persons whose interests have come or are likely to come before the judge.\footnote{13} 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% 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.\footnote{14}

\begin{footnotes}
\end{footnotes}
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.\textsuperscript{16}

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 at least $2.5 billion per year for all their promotional activities in 1988.\textsuperscript{16} 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.\textsuperscript{17} It is not clear how much is spent on promotional activities for physicians by companies that manufacture or distribute devices and medical equipment. [According to data released after the Council’s report was issued, pharmaceutical companies spend at least $5 billion a year on marketing activities. Eighteen of the major pharmaceutical companies spent $165 million on symposia and other gifts in 1988, a five-fold increase since 1975, after adjusting for inflation.]\textsuperscript{18}

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.

III. The Guidelines and Interpretations

General Questions:

a. Do the guidelines apply only to pharmaceutical, device, and equipment manufacturers?

\textsuperscript{15} Browning & Zabriskie, How Ethical are Industrial Buyers?, 12 Indus. Marketing MGMT. 219 (1983).
\textsuperscript{16} Wilkes & Shuchman, Pitching Doctors, N.Y. Times Magazine, at 88 (Nov. 5, 1989).
\textsuperscript{17} American College of Physicians, Physicians and the Pharmaceutical Industry, 112 Annals Internal Med. 624 (1990).
\textsuperscript{18} Randall, Kennedy Hearings Say No More Free Lunch—or Much Else—from Drug Firms, 265 JAMA 440 (1991).
"Industry" includes all "proprietary health-related entities that might create a conflict of interest," as recommended by the American Academy of Family Physicians.

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.

   a. May physicians accept gram stain test kits, stethoscopes or other diagnostic equipment?

   Diagnostic equipment primarily benefits the patient. Hence, such gifts are permissible as long as they are not of substantial value. In considering the value of the gift, the relevant measure is not the cost to the company of providing the gift. Rather, the relevant measure is the cost to the physician if the physician purchased the gift on the open market.

   b. May companies invite physicians to a dinner with a speaker and donate $100 to a charity or medical school on behalf of the physician?

   There are positive aspects to the proposal. The donations would be used for a worthy cause, and the physicians would receive important information about patient care. There is a direct personal benefit to the physician as well, however. An organization that is important to the physician—and one that the physician might have ordinarily felt obligated to make a contribution to—receives financial support as a result of the physician’s decision to attend the meeting. On balance, physicians should make their own judgment about these inducements. If the charity is predetermined without the physician’s input, there would seem to be little problem with the arrangement.

   c. May contributions to a professional society’s general fund be accepted from industry?

   The guidelines are designed to deal with gifts from industry which affect, or could appear to affect, the judgment of individual practicing physicians. In general, a professional society should make its own judgment about gifts from industry to the society itself.

   d. When companies invite physicians to a dinner with a speaker, what are the relevant guidelines?

   First, the dinner must be a modest meal. Second, the guideline does allow gifts that primarily benefit patients and that are not of substantial value. Accordingly, textbooks and other gifts that primarily
benefit patient care and that have a value to the physician in the general range of $100 are permissible.

e. May physicians accept vouchers that reimburse them for uncompensated care they have provided?

No. Such a voucher would result directly in increased income for the physician.

f. May physicians accumulate "points" by attending several educational or promotional meetings and then choose a gift from a catalogue of educational options?

This guideline permits gifts only if they are not of substantial value. If accumulation of points would result in physicians receiving a substantial gift by combining insubstantial gifts over a relatively short period of time, it would be inappropriate.

g. May physicians accept gift certificates for educational materials when attending promotional or educational events?

The Council views gift certificates as a grey area which is not *per se* prohibited by the guidelines. Medical text books are explicitly approved as gifts under the guidelines. A gift certificate for educational materials, *i.e.*, for the selection by the physician from an exclusively medical text book catalogue, would not seem to be materially different. The issue is whether the gift certificate gives the recipient such control as to make the certificate similar to cash. As with charitable donations, pre-selection by the sponsor removes any question. It is up to the individual physician to make the final judgment.

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.

a. Are conference subsidies from the educational division of a company covered by the guidelines?
Yes. When the Council says "any subsidy," it would not matter whether the subsidy comes from the sales division, the educational division or some other section of the company.

b. May a company or its intermediary send physicians a check or voucher to offset the registration fee at a specific conference or a conference of the physician's choice?

Physicians should not directly accept checks or certificates which would be used to offset registration fees. The gift of a reduced registration should be made across the board and through the accredited sponsor.

4. Subsidies from industry should not be accepted directly or indirectly to pay for the costs of travel, lodging or other personal expenses of physicians attending conferences or meetings, nor should subsidies be accepted to compensate for the physicians' time. 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.

a. If a company invites physicians to visit its facilities for a tour or to become educated about one of its products, may the company pay travel expenses and honoraria? This question has come up in the context of a rehabilitation facility that wants physicians to know of its existence so that they may refer their patients to the facility. It has also come up in the context of surgical device or equipment manufacturers who want physicians to become familiar with their products.

In general, travel expenses should not be reimbursed, nor should honoraria be paid for the visiting physician's time since the presentations are analogous to a pharmaceutical company's educational or promotional meetings. The Council recognizes that medical devices, equipment and other technologies may require, in some circumstances, special evaluation or training in proper usage which can not practicably be provided except on site. Medical specialties are in a better position to advise physicians regarding the appropriateness of reimbursement with regard to these trips. In cases where the company insists on such visits as a means of protection from liability for improper usage, physicians and their specialties should make the
judgment. In no case would honoraria be appropriate and any travel expenses should be only those strictly necessary.

b. If the company invites physicians to visit its facilities for review and comment on a product, to discuss their independent research projects or to explore the potential for collaborative research, may the company pay travel expenses and an honorarium?

If the physician is providing genuine services, reasonable compensation for time and travel expenses can be given. However, token advisory or consulting arrangements cannot be used to justify compensation.

c. May a company hold a sweepstakes for physicians in which five entrants receive a trip to the Virgin Islands or airfare to the medical meeting of their choice?

No. The use of a sweepstakes or raffle to deliver a gift does not affect the permissibility of the gift. Since the sweepstakes is not open to the public, the guidelines apply in full force.

d. If a company convenes a group of physicians to recruit clinical investigators or convenes a group of clinical investigators for a meeting to discuss their results, may the company pay for their travel expenses?

Expenses may be paid if the meetings serve a genuine research purpose. One guide to their propriety would be whether the NIH conducts similar meetings when it sponsors multi-center clinical trials. When travel subsidies are acceptable, the guidelines emphasize that they be used to pay only for "reasonable" expenses. The reasonable-ness of expenses would depend on a number of considerations. For example, meetings are likely to be problematic if overseas locations are used for exclusively domestic investigators. It would be inappropriate to pay for recreation or entertainment beyond the kind of modest hospitality described in this guideline.

e. How can a physician tell whether there is a "genuine research purpose?"

A number of factors can be considered. Signs that a genuine research purpose exists include the facts that there are (1) a valid study protocol, (2) recruitment of physicians with appropriate qualifications or expertise, and (3) recruitment of an appropriate number of physicians in light of the number of study participants needed for statistical evaluation.
f. May a company compensate physicians for their time and travel expenses when they participate in focus groups?

Yes. As long as the focus groups serve a genuine and exclusive research purpose and are not used for promotional purposes, physicians may be compensated for time and travel expenses. The number of physicians used in a particular focus group or in multiple focus groups should be an appropriate size to accomplish the research purpose, but no larger.

g. Do the restrictions on travel, lodging and meals apply to educational programs run by medical schools, professional societies or other accredited organizations which are funded by industry, or do they apply only to programs developed and run by industry?

The restrictions apply to all conferences or meetings which are funded by industry. The Council drew no distinction on the basis of the organizer of the conference or meeting. The Council felt that the gift of travel expenses is too substantial even when the conference is run by a non-industry sponsor. (Industry includes all “proprietary health-related entities that might create a conflict of interest” as recommended by the American Academy of Family Physicians.)

h. May company funds be used for travel expenses and honoraria of bona fide faculty at educational meetings?

This guideline draws a distinction between attendees and faculty. As was stated, “[i]t is appropriate for faculty at conferences or meetings to accept reasonable honoraria and to accept reimbursement for reasonable travel, lodging, and meal expenses.”

Companies need to be mindful of the guidelines of the Accreditation Council on Continuing Medical Education. According to those guidelines, “[f]unds from a commercial source should be in the form of an educational grant made payable to the CME sponsor for the support of programming.”

i. May travel expenses be reimbursed for physicians presenting a poster or a “free paper” at a scientific conference?

Reimbursement may be accepted only by bona fide faculty. The presentation of a poster or a free paper does not by itself qualify a person as a member of the conference faculty for purposes of these guidelines.

j. When a professional association schedules a long-range planning
meeting, is it appropriate for industry to subsidize the travel expenses of the meeting participants?

The guidelines are designed to deal with gifts from industry which affect, or could appear to affect, the judgment of individual practicing physicians. In general, a professional society should make its own judgment about gifts from industry to the society itself.

k. May continuing medical education conferences be held in the Bahamas, Europe or South America?

There are no restrictions on the location of conferences as long as the attendees are paying their own travel expenses.

l. May travel expenses be accepted by physicians who are being trained as speakers or faculty for educational conferences and meetings?

In general, no. If a physician is presenting as an independent expert at a CME event both the training and its reimbursement raise questions about independence. In addition, the training is a gift because the physician’s role is generally more analogous to that of an attendee than a participant. Speaker training sessions can be distinguished from meetings (See 4b) with leading researchers, sponsored by a company, designed primarily for an exchange of information about important developments or treatments, including the sponsor’s own research, for which reimbursement for travel may be appropriate.

m. What kinds of social events during conferences and meetings may be subsidized by industry?

Social events should satisfy three criteria. First, the value of the event to the physician should be modest. Second, the event should facilitate discussion among attendees and/or discussion between attendees and faculty. Third, the educational part of the conference should account for a substantial majority of the total time accounted for by the educational activities and social events together. Events that would be viewed (as in the succeeding question) as lavish or expensive should be avoided. But modest social activities that are not elaborate or unusual are permissible, e.g., inexpensive boat rides, barbecues, entertainment that draws on the local performers. In general, any such events which are a part of the conference program should be open to all registrants.

n. May a company rent an expensive entertainment complex for an evening during a medical conference and invite the physicians attending the conference?
No. The guidelines permit only modest hospitality.

o. If physicians attending a conference engage in interactive exchange, may their travel expenses be paid by industry?

No. Mere interactive exchange would not constitute genuine consulting services.

p. If a company schedules a conference and provides meals for the attendees that fall within the guidelines, may the company also pay the costs of the meals for spouses?

If a meal falls within the guidelines, then the physician’s spouse may be included.

q. May companies donate funds to sponsor a professional society’s charity golf tournament?

Yes. But it is sensible if physicians who play in the tournament make some contribution themselves to the event.

r. If a company invites a group of consultants to a meeting and a consultant brings a spouse, may the company pay the costs of lodging or meals of the spouse? Does it matter if the meal is part of the program for the consultants?

Since the costs of having a spouse share a hotel room or join a modest meal are nominal, it is permissible for the company to subsidize those costs. However, if the total subsidies become substantial, then they become unacceptable.

5. Scholarships 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.

a. When a company subsidizes the travel expenses of residents to an appropriately selected conference, may the residents receive the subsidy directly from the company?

Funds for scholarships or other special funds should be given to the academic departments or the accredited sponsor of the conference. The disbursement of funds can then be made by the departments or the conference sponsor.

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.

a. May companies send their top prescribers, purchasers, or referrers on cruises?

No. There can be no link between prescribing or referring patterns and gifts. In addition, travel expenses, including cruises, are not permissible.

b. May the funding company itself develop the complete educational program that is sponsored by an accredited continuing medical education sponsor?

No. The funding company may finance the development of the program through its grant to the sponsor, but the accredited sponsor must have responsibility and control over the content and faculty of conferences, meetings, or lectures. Neither the funding company nor an independent consulting firm should develop the complete educational program for approval by the accredited sponsor.

c. How much input may a funding company have in the development of a conference, meeting, or lectures?

The guidelines of the Accreditation Council on Continuing Medical Education on commercial support of continuing medical education address this question.

Any questions regarding the guidelines should be directed to the Council in care of:

Kirk B. Johnson, J.D.
General Counsel
American Medical Association
515 N. State Street
Chicago, Illinois 60610
FAX: 312-464-5896