



The American College of
Obstetricians and Gynecologists

WOMEN'S HEALTH CARE PHYSICIANS

COMMITTEE OPINION

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Committee on Ethics

This Committee Opinion was developed by the Committee on Ethics of the American College of Obstetricians and Gynecologists as a service to its members and other practicing clinicians. While this document reflects the current viewpoint of the College, it is not intended to dictate an exclusive course of action in all cases. This Committee Opinion was approved by the Committee on Ethics and the Executive Board of the American College of Obstetricians and Gynecologists.

Professional Relationships With Industry

ABSTRACT: The American College of Obstetricians and Gynecologists (the College) has a long history of leadership in ensuring that its educational mission is evidence based and unbiased. A predecessor to this Committee Opinion was published in 1985, making the College one of the first professional associations to provide guidance on this issue. The College has continued to update the ethical guidance on physician interactions with industry periodically. Obstetrician–gynecologists' relationships with industry should be structured in a manner that will enhance, rather than detract from, their obligations to their patients. The ideal behaviors set forth in this Committee Opinion will contribute toward maintaining patient trust in the specialty and avoiding conflicts of interest by College members.

Industrial development of pharmaceutical agents and medical devices is important for continuing improvement in health care. Developers and manufacturers of pharmaceutical agents and medical devices assist physicians in the pursuit of their educational goals and objectives through financial support of various medical, research, and educational programs. The goals of industry, however, may conflict with physicians' duties to their patients. Industry in general has the goal of optimizing profit by providing useful goods and services. Physicians have a primary responsibility to act as protectors of the interests of their patients (1). In many cases, industry's goals and physicians' duties converge; however, physicians must be aware that industry's interests and patients' interests may significantly diverge. The guidance on relationships with industry in this document is for members of the American College of Obstetricians and Gynecologists (the College).

In the past, physicians accepted gifts from the health care industry with the belief that such gifts did not necessarily create undue influence on medical practice. Examples of such gifts include, but are not limited to, office supplies, meals, trips, gift certificates, cash, and honoraria. As used in this document, "gifts" refers to items and services that are intended to influence the relationship between a physician and a pharmaceutical or medical device company or that, regardless of the giver's intent, may be perceived by the public as influencing

the relationship. Evidence has accumulated that gifts from industry often misdirect physicians from their primary responsibility, which is to act consistently in the best interests of their patients (2). Several studies have demonstrated that the prescribing practices of physicians are influenced by both subtle and obvious marketing messages and gifts. Marketing influence on prescribing was found even when the gifts were of nominal value and delivered in an educational context. The physicians studied did not recognize or admit to any changes in their practice of medicine (3–5).

Corporations may seek to influence physician behavior in several ways. In 2010, IMS HEALTH estimated that \$5.8 billion was spent on sales representative detailing to professionals (6). In data disclosed by 12 drug companies, the public interest group ProPublica reported that more than \$761.3 million was given to physicians from 2009 to early 2011 (7). The combined prescription drug sales of these companies comprised approximately 40% of the U.S. market in 2010, but ProPublica reported that "the data may not be wholly representative of the industry." Data may be influenced by differing definitions of payments, data updates, different ways of reporting, or reporting of data from a minority of corporations.

In a survey of more than 3,000 physicians conducted in 2003–2004, 78% reported that they received pharmaceutical samples, 83% received meals, 35% received reimbursement for continuing medical education (CME)



expenses, and 28% received payment for consulting or serving on an advisory board or speakers' bureau (8). According to a recent study of College members, obstetrician–gynecologists who received more meals or samples from pharmaceutical representatives were more likely to agree strongly that those representatives were a valuable source of information about products (9).

Ethical Responsibilities of the Profession

Physicians have long been held to a high moral standard in the patient–physician relationship. This relationship is not egalitarian, but instead, physicians have control over knowledge and, often, access to treatment. This imbalance creates a beneficence-based duty to protect the patient's best interest. In this relationship the patient is given priority, and there is a responsibility to serve as personal advocate for the patient and to eliminate impediments to the promotion of patient welfare. Physicians are obligated to ensure that the best medical advice is transmitted to the patient and is not prejudiced in any manner by industry inducements. Interactions with industry carry some expectations of reciprocity. Even when most health care professionals deny that gifts could influence behavior, they often are unable to remain objective (3, 10).

When any product promotion or research project tied to a specific drug or device leads to inappropriate or unbalanced medical advice to patients, an ethical problem exists. The public expects physicians to avoid conflicts of interest in decisions about patient care. Conflicts of interest may involve the direct treatment of patients, although such conflicts also may arise in purchasing decisions by hospitals and group practices.

Although disclosure of conflict of interest is imperative to preserve transparency and trust in the profession, disclosure alone may not be sufficient to nullify the effect of the conflict (11). The Institute of Medicine (IOM) opines that disclosure is a necessary first step for management of conflict of interest, but it is insufficient on its own. The "degree of severity" of the conflict of interest also must be considered (11). The duration of the conflict of interest, amount of money involved, and role of the physician in relation to the conflict of interest are all salient points for consideration. Depending on the nature of the activity, peer review can be effective in mitigating bias for a presentation; recusal can be considered in the case of a consultative activity, such as a formulary committee; or referral for a second opinion can be offered in the case of a clinical patient recommendation.

Recommendations of Other Organizations

Several professional and regulatory organizations have put forth positions regarding industry's relationship to individual physician practices and educational activities (12–22). The Council on Ethical and Judicial Affairs of the

American Medical Association played an early and pivotal role in defining physician relationships with industry.

In 2009, the IOM published a report on conflicts of interest in medical research, education, and practice (23). The IOM recommendations discourage physicians from accepting items of material value from companies outside of a legitimate service contract. Physicians may participate in consulting if the consulting services are stipulated in a contract at fair market value. The IOM also calls for a national reporting program to increase disclosure of individual physician–industry relationships. In addition, the IOM opines that physicians should not participate in educational presentations or writings in which the physician does not have full control of the content or if industry provides the content. Physicians are discouraged from meeting with industry representatives in the medical office, except by appointment and invitation from the physician. Finally, the IOM discourages the use of medication samples except for patients who lack access to medications as a result of financial barriers.

Faculty, medical students, and residents in academic medical centers have taken the lead in restricting relationships with industry. The Pew Prescription Project, developed by Pew Charitable Trusts in 2007, organized exemplary policies from various medical institutions (24). For example, several prominent teaching institutions have taken the step of banning gifts, lunches, samples, and educational events sponsored by industry both on and off campus (25). The American Medical Student Association launched the "PharmFree Campaign" initiative in 2002, which encouraged medical students to use evidence-based prescribing and to avoid all pharmaceutical advertisements and sponsorships (26).

A growing number of professional leaders have called for similar restrictions on industry–physician interactions in educational settings other than training programs. They postulate that conflict of interest is inherent in all educational ventures promoted by the health care industry, despite restrictions put in place by industry, professional societies, and government agencies (10, 27). The Council of Medical Specialty Societies adopted a code for interactions with companies to ensure that educational programs are nonpromotional, transparent, and free of commercial influence and bias (28). The Accreditation Council for Continuing Medical Education has bolstered its stance to increase transparency and disclosure of commercialism (19). In response to this increased scrutiny and call for transparency, many pharmaceutical companies have changed their practice of providing direct funding for CME by providing unrestricted educational grants to academic institutions, hospitals, and professional organizations. Those contributions are made via a central office to preserve CME independence and avoid the appearance of conflict of interest. The IOM has gone so far as to endorse industry-free CME (23).

The Pharmaceutical Research and Manufacturers of America developed guidelines for the pharmaceutical



industry's relationship with health care professionals (20). These voluntary guidelines took effect in 2009. Similarly, in 2009 the Advanced Medical Technology Association adopted a code of ethics to guide its members (medical technology companies) in interacting with health care professionals. This code of ethics generally addressed the same issues as the Pharmaceutical Research and Manufacturers of America guidelines but also addressed grants to institutions to subsidize fellows (21).

Many states have implemented regulations that require industry to register gifts or payments of any value in a national and publicly accessible database. Many pharmaceutical companies have exceeded these recommendations and have changed their practice of providing funding for CME through grants toward academic institutions, hospitals, and professional organizations and now make those contributions via a central office to preserve CME independence and avoid the appearance of conflict of interest.

The federal government has issued guidance as well. In 2003, the Office of Inspector General at the U.S. Department of Health and Human Services issued a notice regarding voluntary compliance programs for pharmaceutical manufacturers. Among the written policies and procedures suggested by the Office of Inspector General were a code of conduct and identification of specific risk areas, including relationships with purchasers, physicians, and sales agents. The Office of Inspector General guidance covered gifts, entertainment, personal compensation, education grants, and research funding and referenced and endorsed the voluntary Pharmaceutical Research and Manufacturers of America guidelines (22). The National Institutes of Health (NIH) also has acted to proscribe interactions of NIH employees with pharmaceutical and device industries, among other "significantly affected organizations." Employees of NIH may not be employed by a significantly affected organization, engage in a self-employed business activity with a significantly affected organization, or receive compensation for teaching, speaking, writing, or editing for a significantly affected organization (29, 30). These policies regarding the disclosure of conflict of interest also apply to principal investigators for NIH-funded research (31). Significant financial interests for investigators include a minimal value of \$5,000 for payments and equity interests, including any equity interest in nonpublicly traded entities. The NIH specifically excludes income from seminars, lectures, teaching, and service on advisory panels for the government, higher education, and academic centers. The NIH also excludes investment income if the account is not directly managed by the physician or principal investigator.

As a part of the Patient Protection and Affordable Care Act, manufacturers of "a covered drug, device, biological, or medical supply" that provide "payment or other transfer of value" to physicians are required to submit information on the payment or transfer to the

Secretary of Health and Human Services, who will make the disclosures publicly available (32, 33). Although the statute indicated that information was to be collected beginning January 1, 2012, the Centers for Medicare and Medicaid Services did not meet the deadline stipulated in the Affordable Care Act for finalizing procedures for submitting and publishing the information. In its proposed rule, the Centers for Medicare and Medicaid Services suggests requiring applicable manufacturers to collect data as of January 1, 2013 (34).

Recommendations of the American College of Obstetricians and Gynecologists' Committee on Ethics

The American College of Obstetricians and Gynecologists has a long history of leadership in ensuring that its educational mission is evidence based and unbiased. A predecessor to this Committee Opinion was published in 1985, making the College one of the first professional associations to provide guidance on this issue. The College has continued to update the ethical guidance on physician interactions with industry periodically. The following discussion updates recommendations to address College members' current relationships with industry.

Industry-physician interactions can be divided into major types, as characterized in the following sections. Ethical implications specific to each type of interaction are discussed. In providing recommendations, the Committee on Ethics recognizes both the effort its Fellows and other members have made to meet past recommendations and the challenges in meeting the ideal behaviors outlined. In presenting these paradigms, the Committee wishes to commend behaviors that will reduce influence that may bias College members' practice and behavior and promote continued confidence in individual health care providers and the specialty.

Product Promotion to Individual Physicians by Advertising, Personal Communication, and Provision of Samples

Because acceptance of even small gifts may influence or appear to influence prescribing practices and, thereby, have an effect on patient care, the Committee on Ethics makes the following recommendations:

- To minimize both true and perceived conflicts of interest, physicians have an ethical obligation to set guidelines for themselves and their office staff for interaction with representatives.
- Physicians have an obligation to seek the most accurate, up-to-date, evidence-based, and balanced sources of information about new products that they contemplate using. They should not base decisions solely or primarily on information provided by the products' marketers.
- Physicians involved in institutional decision making for formularies should declare financial ties



with industry and disclose any conflict of interest. Institutions should have a management plan for any declared conflicts, including possible recusal.

- Although the provision of pharmaceutical samples offers potential benefits to patients, samples may inappropriately influence prescribing behavior. Physicians may choose to provide samples or vouchers; however, they should be aware that providing samples may promote patients' ongoing use of a particular medication, when other potential alternatives exist. When vouchers or samples are dispensed, consideration should be given to providing them preferentially to those patients with a true need and dispensing a supply sufficient for a full course of therapy. Dispensing should be done from a central distribution source that can track to whom and where samples were given in the event of recalls or other problems with the medication (35). Physicians who choose to dispense samples should know the applicable state and federal regulations regarding this practice.
- Physicians should understand that gifts tied to promotional information, even small gifts and meals, are designed to influence their behavior. The acceptance of any gift, even of nominal value, tied to promotional information is strongly discouraged. However, acceptance of cash donations, trips, and services directly from industry by individual physicians raises clear conflicts and is not ethical.
- When an obstetrician–gynecologist receives anything of substantial value, including royalties, from companies in the health care industry, such as a manufacturer of pharmaceutical agents and medical devices, this fact should be disclosed to patients and colleagues when material (36).
- Physicians should not engage in agreements in which companies make donations to a third party (eg, a hospital or charitable organization) that is contingent on the physicians' use or advocacy of a product.

Support of Educational Activities for Individual Physicians

Limitations on commercial support of CME have been published by the Accreditation Council for Continuing Medical Education, the Council of Medical Specialty Societies, and the American Medical Association and are beyond the scope of the current document. Recommendations for educational support for individual physicians are as follows (12, 13, 19, 28):

- The gift of special funds to permit medical students, residents, and fellows to attend carefully selected educational conferences may be permissible as long as the selection of the students, residents, or fellows is made by the academic or training institution or by the accredited CME provider with the full concur-

rence of the academic or training institution. These funds should be deposited at a central office within the training institution that can disperse these funds directly to the designated trainee (ie, the company does not directly disperse funds to the trainee).

- Payments to defray the costs of attending a CME or professional conference should not be accepted directly from the company by physicians attending the conference. Subsidies from industry should not be accepted directly to pay for the costs of travel, lodging, or other personal expenses. Subsidies should not be accepted to compensate attendees for their time.
- Commercially supported social events and industry symposia, regardless of whether they are affiliated with a program offering CME credits, are essentially gifts and are designed to influence physician behavior.

Industry-Sponsored Device Training

When new medical devices are approved or cleared by the U.S. Food and Drug Administration (FDA), access to training on those devices may be tightly regulated by the FDA and may require training by the manufacturer. The company may require physicians to travel to non-CME seminars designed to familiarize the physician with the new equipment. This presents an ethical difficulty for the physician. This problem has been considered by other professional organizations, such as the Society of Thoracic Surgeons and the American Association for Thoracic Surgery. They suggest that their members may attend such industry-sponsored events “only when the major purpose of the event is education and training in the proper use of the company's products; the only financial considerations should be reimbursement for travel, meals, and lodging. Members should not accept reimbursement for attending such an education event if the event's location constitutes an inducement that is independent of the event's educational value.” (37). The Committee on Ethics makes the following recommendations regarding industry-sponsored device training:

- Training in proper use of devices encountered in the practice of obstetrics and gynecology is ideally provided through professional societies with CME accreditation.
- When training is not available from an accredited CME provider, or industry training is mandated by the FDA, and industry offers appropriate education, the obstetrician–gynecologist may participate if the training is focused on the safe, medically relevant, and FDA-cleared or FDA-approved indications for use of the equipment or device in the shortest possible time.

Industry Sponsorship of Research

When companies conduct clinical research to obtain approval for the marketing of new products, collaboration with physicians and clinical institutions is essential. The



Committee on Ethics recommends the following guidelines for engaging in industry-sponsored research:

- Research trials should be conducted in accordance with the federal guidelines for the protection of human participants (38). Approval by the institutional review board of a medical school or hospital provides adequate ethical and scientific review. If the project is to be conducted in a private medical office, investigators must ascertain the nature of the ethical and scientific review process by the sponsoring corporation. Submission of the project to the researcher's institution usually is required and helpful. If there is any question about the adequacy or efficacy of this review, investigators should seek independent consultation for research oversight.
- Reimbursement to investigators and their institutions for involvement in research, including recruitment of participants, should not exceed reasonable costs. Payments made specifically to physicians for recruitment of their patients should be disclosed to potential study participants before trial enrollment (39).
- Investigators may accept reasonable compensation (at fair market value) for consultation after participation in industry-sponsored research.
- Once a clinical investigator becomes involved in a research project for a company or knows that he or she might become involved, the investigator, as an individual, cannot ethically buy or sell the company's stock until the results of the research are published or otherwise disseminated to the public and the involvement ends (40).
- The following guidelines should govern control over information gained from research (41):
 - All obligations of investigators and sponsors should be contractually defined.
 - Scientific freedom of independent investigators (those not employed by the funding organization) should be preserved.
 - Principal investigators should be involved in decisions regarding the publication of data from their trials. Short delays in the dissemination of data generated by industry-sponsored research are acceptable to protect a patent or related proprietary interest. Prolonged delays, or suppression of information harmful to the sponsor's interests, are unethical.
 - Investigators should control the use of their names in promotions.
 - Project funding should not be contingent on results.
 - Investigators should disclose their relationships with industry funders in publications or lectures based on the research.

Speakers' Bureaus

Participating in an industry-sponsored speakers' bureau is strongly discouraged. Speakers' bureaus are a common marketing strategy to promote a particular product through the use of recognized professional leaders ("thought leaders") as paid spokespersons. Speakers' bureaus are an efficient way to communicate information about a specific product but are subject to a high potential for bias, unbalanced information, and conflict of interest. Audiences may not be able to identify bias when it occurs (10).

Physicians who choose to participate in industry-sponsored speaking should adhere to the following specific ethical guidelines to reduce the risk of undue influence:

- Speakers must disclose the extent and nature of their relationship with the sponsoring entity.
- Speakers must ensure that the information in their presentation is accurate, balanced, evidence based, and free of undue commercial influence. The speaker should have final control of any slides used in the presentation and should not sign a contract that gives the commercial entity control of the slide content.
- Speakers must accept only reasonable honoraria commensurate with the value of their time and reimbursement for travel, lodging, and expenses.

Physicians as Consultants to Industry

Consulting with industry on the development of new medical devices or pharmaceutical agents can play an important role in the progress of scientific discovery. It also is appropriate for consultants who provide genuine services to receive reasonable reimbursement for travel, lodging, and meal expenses, as well as value of their time. Token consulting or advisory arrangements cannot be used to justify the compensation of physicians for their time or their travel, lodging, and other out-of-pocket expenses. It must be recognized, however, that industry may use consulting arrangements in order to influence the consultant. Physicians who consult with industry on the development of new medical devices or pharmaceutical agents must disclose this information to their patients, colleagues, and medical institutions when material.

Ghostwriting

The practice of ghostwriting, or unacknowledged medical writing sponsored by the pharmaceutical or other industry, is unacceptable because it is inherently deceptive. Authors should write and assume responsibility for the content of all publications for which they receive authorship credit. Ghostwriting, in which a writer produces content attributed to another, should be distinguished from acknowledged authorship and peer editing, which may serve important communication functions.



Summary

Obstetrician–gynecologists' relationships with industry should be structured in a manner that will enhance, rather than detract from, their obligations to their patients. The ideal behaviors set forth in this Committee Opinion will contribute toward maintaining patient trust in the specialty and avoiding conflicts of interest by College members.

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