

Professional Relationships With Industry

Committee on Ethics. This Committee Statement was developed by the American College of Obstetricians and Gynecologists' Committee on Ethics in collaboration with committee member David I. Shalowitz, MD, MSHP.

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. In general, industry seeks to optimize profit by providing useful goods and services. However, industry priorities may not always align with the ethical responsibilities of clinicians to promote the best interests of their patients, of educators to provide evidence-based instruction, and of researchers to ensure the scientific integrity of their investigations. To minimize both actual and perceived conflicts of interest, physicians and institutions should set guidelines for themselves and their employees regarding acceptable interaction with industry representatives. In this Committee Statement, the American College of Obstetricians and Gynecologists' Committee on Ethics provides recommendations for the management of professional relationships with industry, with an updated literature review and discussion of prevalence, regulations, and the effects of industry involvement in clinical care, education, and research.

SUMMARY OF RECOMMENDATIONS AND CONCLUSIONS

On the basis of the principles outlined in this Committee Statement, the American College of Obstetricians and Gynecologists (ACOG) makes the following recommendations and conclusions:

Acceptance of cash donations, vacations, and medical or personal services, however nominal, directly from industry by practicing physicians, their families, or their clinic staff is unethical.

The acceptance of gifts to physicians or their practices tied to promotional material (including food and office supplies) is strongly discouraged because such gifts are designed to, and succeed in, biasing physicians' behavior.

Obstetrician–gynecologists involved in institutional decision making for formularies should disclose financial ties with industry and any other relevant conflicts of interest. Institutions should have a management protocol for persons with declared conflicts, including possible recusal.

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Medication samples should be provided to patients only when the medication is an appropriate treatment and when patients' financial hardship is prohibitive of any other course of action.

Receipt from industry of any payment of substantial value, including from consultation or royalties, should be disclosed to patients when related to care being offered. For example, disclosure is warranted when a physician may derive direct, substantial financial benefit from the prescription of a particular medication or the use of a specific device or piece of equipment.

Because of clear financial conflict of interest and the high potential for data presented to be biased in favor of the sponsoring company, participation in speakers' bureaus is strongly discouraged.

Direct involvement of industry funds in the education of trainees (eg, medical students, residents, and fellows) should be approached with caution given the potential—and intent—of such funding to encourage preferential treatment of the sponsoring company.

Obstetrician–gynecologists who conduct biomedical research have a responsibility to adhere to practice standards that support research as being driven by unbiased science rather than personal gain.

It is unethical for investigators to accept research funding or payments that are contingent on requested trial results.

Industry funding of research, as well as individual investigators' financial conflicts of interest, should be disclosed in publications and presentations of research findings, consistent with relevant journal or conference policies.

Disclosure of financial conflicts of interest to institutions, funders, journals, conferences, and the public is a necessary strategy for identifying financial ties to industry; however, disclosure is not sufficient on its own for managing conflicts.

Investigators should ensure that their authorship on published or presented data or recommendations reflects adequate intellectual contribution to the manuscript or presentation.

BACKGROUND

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. In general, industry seeks to optimize profit by providing useful goods and services. However, industry priorities may not always align with the ethical responsibilities of clinicians to promote the best interests of their patients, of educators to provide evidence-based instruction, and of researchers to ensure the scientific integrity of their investigations. Physicians have a responsibility to self-regulate when the primary aims of patient care, education, and clinical research may be threatened by secondary financial or other interests, because such conflicts may substantially decrease public trust in physicians' ethical standards. The American College of Obstetricians and Gynecologists has a long history of leadership in ensuring that its mission is patient-focused and evidence-based. The first version of this Committee Statement was published in 1985, making ACOG one of the first professional associations to provide guidance on physicians' interactions with industry. The College has also signed on to the Code for Interactions with Companies, published by the Council of Medical Specialty Societies, which includes guidelines intended to keep industry "at arm's length" from societies' governance, policies, official journals, and educational events (1).

In this Committee Statement, ACOG's Committee on Ethics provides recommendations for the management of professional relationships with industry, with an updated literature review and discussion of prevalence, regulations, and the effects of industry involvement in clinical care, education, and research. The use of the professional setting to sell or advertise medical and nonmedical goods or services is addressed separately (2).

ETHICAL ISSUES AND CONSIDERATIONS

Obstetrician–gynecologists (ob-gyns) may serve as clinicians, educators, and researchers. Each of these roles carries a primary ethical obligation. Clinicians are entrusted with the health of their patients and have a duty to promote patients' best interests when selecting an approach to treatment. Educators are obliged to impart information to colleagues and trainees that is up-to-date, evidence-based, and balanced. Researchers are responsible for ensuring that investigations are conducted using the highest standards of scientific integrity and protections for human and non-human subjects research. Financial conflicts of interests exist when primary commitments to patient care, education, or research have the potential to be compromised by a secondary interest in financial gain. Financial conflicts of interest have the potential to exist on the part of industry and may exist for ob-gyns who interact with industry. Knowledge and management of financial conflicts of interest are essential to maintaining our commitment to and the public's trust in high-quality health care.



The Sunshine Act and Transparency of Payments from Industry

In 2013, the Centers for Medicare & Medicaid Services implemented the Physician Payments Sunshine Act as part of the Patient Protection and Affordable Care Act. The Sunshine Act is intended to improve transparency of financial connections between health care professionals and device, pharmaceutical, and medical supply manufacturers by mandating that manufacturers report all single payments or in-kind compensation of \$10 or greater (or totaling more than \$100 per year) to the Centers for Medicare & Medicaid Services. The Centers for Medicare & Medicaid Services has subsequently maintained a public, searchable database of payments made by manufacturers, the institutions and professionals to whom the payments were made, and the purposes of the payments (3). The database is further subdivided into direct funding of research from industry sources and “general payments,” which include honoraria and payments for consulting, travel and lodging, meals, and educational lectures.

Industry Payments Related to Clinical Practice, Education, and Consultation

In 2019, 1,602 companies made 10.37 million discrete “general” payments to 615,000 physicians and hospitals, totaling \$3.56 billion (3). Most of these payments were categorized as related to education, consultation, travel and lodging, honoraria, food and beverage, and speaker fees for noneducational events. In 2014, ob-gyns received the seventh highest number of payments of 35 specialties; approximately \$60 million (across 311,485 payments) was disbursed to 29,783 physicians (4, 5). Slightly more than half of ob-gyns received payments ranging from \$101 to \$1,000 between August 2013 and December 2015 (4). Industry contributions to subspecialists are higher than to generalists, with female pelvic medicine and reconstructive surgery specialists receiving the highest payments (4).

Evidence from three systematic reviews of the effect of industry interactions on physicians’ behaviors and attitudes show two key findings: 1) meals, travel, lodging, honoraria, and other interactions with pharmaceutical representatives consistently increased preferential prescribing of advertised products and led to increased requests to include advertised products in hospital formularies; and 2) exposure to various promotional information by pharmaceutical companies may be associated with more frequent prescribing, increased prescribing costs, and poor quality of prescriptions (6–8).

Physicians generally are unable to identify or correct for industry influences on their behavior (9–11). Likewise, even if informed of their physicians’ financial ties to indus-

try, patients generally are unable to “de-bias” clinical recommendations and may instead paradoxically comply with recommendations to avoid appearing to mistrust their physicians (12). Although some patients may choose not to receive care from an ob-gyn with disclosed ties to industry, other patients may not have access to an alternate physician. Patients should not be placed in the position of being the primary arbiters of acceptable interaction between industry and their physicians. To minimize both actual and perceived conflicts of interest, physicians and institutions should set guidelines for themselves and their employees regarding acceptable interaction with industry representatives, consistent with this Committee Statement.

Gifts

Acceptance of cash donations, vacations, and medical or personal services, however nominal, directly from industry by practicing physicians, their families, or their clinic staff is unethical.

Such gifts have no direct relation to patient care and create the impression of payments by industry to clinicians for preferential treatment.

The acceptance of gifts to physicians or their practices tied to promotional material (including food and office supplies) is strongly discouraged because such gifts are designed to, and succeed in, biasing physicians’ behavior.

These gifts should be accepted only when they would provide direct benefit to patients (eg, patient education) (13).

Product Promotion

Obstetrician–gynecologists are obligated to use the most accurate, current, and complete sources of information when deciding whether to initiate or continue use of medications and devices. Primary reliance on industry-provided data is strongly discouraged. For this reason, attendance of industry-sponsored symposia is discouraged but may be permissible if sponsorship occurs through an unrestricted grant and the sponsor has no role in editing or approving the presented material. Conference sponsors are encouraged to disseminate the role of funding so attendees can make informed decisions. However, practices may accept and use industry-developed educational material for patients prescribed or considering a medication, device, or procedure (13). Sponsorship by industry of institutional activities (eg, grand rounds) may be permissible if there is no associated discussion or promotion of products or services other than acknowledgment of sponsorship. Attendance at industry-sponsored social events (for example during a conference) may be considered acceptance of a gift if



any particular product or service is discussed or promoted during the event or if significant advertisement of the sponsor is present. Institutions and organizations should follow relevant guidance by the Accreditation Council for Continuing Medical Education to ensure minimization of financial conflict of interest in this setting.

Obstetrician–gynecologists involved in institutional decision making for formularies should disclose financial ties with industry and any other relevant conflicts of interest. Institutions should have a management protocol for persons with declared conflicts, including possible recusal.

Obstetrician–gynecologists should not agree to donations by industry to a third party (eg, hospital or charity) contingent on the use of, or advocacy for, a product. Although practices and institutions may individualize financial conflict of interest policies, the Committee suggests that the type and magnitude of financial interest be considered in determining the types of relationships that are permitted. For example, the value of a physician's stock in or royalty payments from a pharmaceutical manufacturer may change substantially depending on formulary decisions. Individual stock ownership and royalty agreements, therefore, generally should be grounds for exclusion from institutional decision making related to formulary or devices. However, the value of a diversified mutual fund containing the same pharmaceutical manufacturer is unlikely to change substantially and, therefore, is less ethically problematic. For discussion of the potential risk of conflicts of interest associated with various assets, see, for example, the guidance provided by the U.S. Office of Government Ethics (14).

Medication samples should be provided to patients only when the medication is an appropriate treatment and when patients' financial hardship is prohibitive of any other course of action.

Data support that patients who start a course of medication through samples are more likely to continue on that medication and, therefore, are more likely to bring revenue to particular industry members (15). Whenever possible, a full treatment course should be dispensed, and distribution of samples should be tracked in case of recall or adverse effect. For medications that generally are prescribed on a long-term basis, ob-gyns should consider patients' ability to continue on treatment after the sample is used. Some manufacturers may have financial-assistance programs for devices or medications; it may be preferable to refer patients to these programs rather than to dispense samples in-office. Obstetrician–gynecologists who dispense samples

should be aware of the applicable state and federal laws, regulations, and guidance regarding this practice (16).

Consultation to Industry

Receipt from industry of any payment of substantial value, including from consultation or royalties, should be disclosed to patients when related to care being offered (17). For example, disclosure is warranted when a physician may derive direct, substantial financial benefit from the prescription of a particular medication or the use of a specific device or piece of equipment.

Consulting with industry on the development of new medical devices or pharmaceutical agents can play an important role in scientific discovery. Obstetrician–gynecologists may be reasonably compensated for travel, food and lodging, and time related to consultation to industry. Physicians should, however, be aware of the possibility of bias toward a particular product or company arising from these transactions and disclose consultative relationships according to institutional protocols. 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 that industry may use consulting arrangements to influence the consultant.

Speakers' Bureaus

Speakers' bureaus are used to promote products to clinicians or the public by employing recognized professional leaders as paid spokespersons. Studies have shown that health care professionals who receive payment from a company are more likely to prescribe or order that company's product (18).

Because of clear financial conflict of interest and the high potential for data presented to be biased in favor of the sponsoring company, participation in speakers' bureaus is strongly discouraged.

Clinicians can obtain the substantive information provided by industry-sponsored speaker programs from other sources that do not involve remuneration, such as online medical resources, product package inserts, third-party educational conferences, and medical journals (18).

Support of Trainees

Direct involvement of industry funds in the education of trainees (eg, medical students, residents, and fellows) should be approached with caution given the potential—and intent—of such



funding to encourage preferential treatment of the sponsoring company.

Sponsorship of a particular training program (eg, residency or fellowship) by a pharmaceutical or device manufacturer creates the appearance of bias and the potential for expectation of quid pro quo. Such sponsorship is, therefore, highly ethically problematic and is strongly discouraged. Academic medical centers may accept scholarship funds from industry provided that 1) funds are given centrally to the medical center, 2) there is no expectation of favorable treatment of the industry sponsor, and 3) the sponsor has no role in selection of specific trainees or programs to whom funds will be directed (19). Likewise, gifts of funds from industry to permit trainees to defray the cost of attending educational conferences may be permissible if the trainees are selected by the academic or training institution rather than the industry sponsor. Funds should be disbursed to trainees from the institution, not directly from the sponsor (19).

Unless separately part of, and compliant with the guidelines for, an accredited continuing medical education (CME) activity, industry-supplied food should be considered a personal gift to faculty and trainees and, therefore, not accepted (19).

Industry-Sponsored Device Training

Training in the proper use of devices encountered in the practice of obstetrics and gynecology is ideally provided through professional societies with CME accreditation. To qualify for CME credit, training providers must ensure that industry involvement is minimized and disclosed to attendees when present (20). If device training is available only through industry, ob-gyns may attend if the only compensation provided is for travel, meals, and lodging and the event takes place over the shortest time period feasible (21). Similar to guidelines for disclosure to patients, ob-gyns involved in training colleagues in the use of a device should disclose any involvement in consultation or development of the device or if they receive any financial incentives (eg, royalties) from the device's use.

Industry Sponsorship of Research

When drug, device, and medical supply manufacturers conduct clinical research to obtain approval for the marketing of new products, collaboration with physicians and health care institutions is essential. Industry ties to biomedical research are substantial and widespread. In 2019, industry funding of such research totaled \$5.23 billion across 614,000 payments (3). A systematic review of the empirical literature suggests that approximately one fourth of investigators receive industry funding for research and that one third of investigators have personal financial ties to industry funders (eg, through paid consulting or advisory board positions) (22). In another

study, 235 of 328 (72%) leaders of U.S. professional medical associations had financial ties to industry (23). A random sampling of 1,002 articles across 269 journals revealed disclosure of conflicts of interest in 23%; 64% disclosed no conflict, and the remaining 13% contained no conflict of interest statement (24). Industry funding of research is associated with publication of pro-industry findings, although it is debated whether this finding is a result of preferential funding of promising research, publication bias, or suboptimal research design (eg, selection of a placebo comparator when an alternative active treatment exists) (22, 25).

Federal requirements for disclosure and review of financial conflicts of interest in biomedical research are found in regulations governing the conduct of clinical research (26–28); individual institutions also may have specific guidelines for investigators conducting research.

Obstetrician–gynecologists who conduct biomedical research have a responsibility to adhere to practice standards that support research as being driven by unbiased science rather than personal gain.

Best-practice guidelines regarding the conduct of research investigators exist to avoid both real and apparent conflict, given that the influence of financial interest on research may be conscious or unconscious and, even if recognized, not necessarily identified as ethically problematic (29).

Study Design and Approval

Investigators should adhere to their institutions' policies regarding approval and conduct of clinical research. All trial protocols should undergo unbiased scientific review to ensure validity of the technical background, methods, interventions, and outcomes. Trials involving animals or humans should also be reviewed by the appropriate Institutional Animal Care and Use Committee or IRB, respectively, for adherence to appropriate ethical standards (30). Trial-related obligations of the sponsor and of the investigator should be clearly defined in writing (eg, data collection, data analysis, drafting of manuscripts).

Investigators may accept reasonable compensation at fair market value for consultation related to the design of industry-sponsored research. Reimbursement to investigators and their institutions for involvement in research, including recruitment of participants, should not exceed reasonable costs of these activities. "Finder's fees" or bonuses specifically for recruitment of patients are discouraged and should be disclosed to both the IRB for consideration during the review process and potential study participants before trial enrollment.



It is unethical for investigators to accept research funding or payments that are contingent on requested trial results.

Researchers should feel empowered to withdraw from industry-supported trials if they have concerns that the study is not being conducted according to best practices. In such a case, any human trial participants enrolled by the researcher should be notified of the researcher's concerns per the requirements of the Common Rule (31).

Communication of Results

Ideally, investigators should be involved in publication decisions regarding research data generated in industry-sponsored trials. However, investigators should be aware that industry may "own" the research data and, therefore, make final decisions related to release of results to the public. Investigators should be aware that, although publication of all results, including negative findings, is good scientific practice, publication of negative findings may conflict with the financial interests of the industry sponsor. Delays in or suppression of information to protect a sponsor's interests may be unethical, and, if concerns arise about the management of results of industry-sponsored trials, expert legal consultation is recommended.

Investigators participating in industry-sponsored research should be aware that buying or selling equity in the sponsor or discussing confidential trial-related information with potential investors may be considered insider trading. Investigators should, therefore, avoid initiating financial relationships with industry sponsors of their research until the research relationship ends and results are publicly available. Investigators should seek expert legal advice if needed (32).

Disclosure of Industry Involvement in Publications and Presentations

Industry funding of research, as well as individual investigators' financial conflicts of interest, should be disclosed in publications and presentations of research findings, consistent with relevant journal or conference policies (33). Disclosure of financial conflicts of interest to institutions, funders, journals, conferences, and the public is a necessary strategy for identifying financial ties to industry; however, disclosure is not sufficient on its own for managing conflicts.

The International Committee of Medical Journal Editors (33) and most professional medical societies (eg, ACOG and the American Society of Clinical Oncology [34, 35]) have disclosure policies for investigators considering publication or presentation of research findings. Despite

these disclosure policies, conflicts are likely underreported and misrepresented (36–38). In one recent prominent case, a senior physician–scientist received millions of dollars of personal income from industry sponsors of his clinical research and failed to disclose this tie to industry in “dozens” of high-profile publications (39). This case prompted a re-examination of the consequences of non-disclosure of financial ties to industry by researchers and a proposal that nondisclosure should be treated as research misconduct, similar to falsification of data (40).

Investigators should ensure that their authorship on published or presented data or recommendations reflects adequate intellectual contribution to the manuscript or presentation.

Ghostwriting, in which an unacknowledged professional writer produces work credited to others, is unethical.

CONCLUSION

Professional interactions with industry are ubiquitous in the practice of obstetrics and gynecology. However, ob-gyns have a responsibility to minimize real and apparent financial conflicts of interest arising through relationships with industry. The recommendations set forth in this Committee Statement contribute to maintaining public trust in the ethical standards of the specialty's conduct of research and clinical care.

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CONFLICT OF INTEREST STATEMENT

All ACOG committee members and authors have submitted a conflict of interest disclosure statement related to this published product. Any potential conflicts have been considered and managed in accordance with ACOG's Conflict of Interest Disclosure Policy. The ACOG policies can be found on acog.org. For products jointly developed with other organizations, conflict of interest disclosures by representatives of the other organizations are addressed by those organizations. The

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