ACCP Position Statement

Pharmacists and Industry: Guidelines for Ethical Interactions

American College of Clinical Pharmacy

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This position paper is an update to the original paper developed by the American College of Clinical Pharmacy (ACCP), Pharmacists and the Pharmaceutical Industry—Guidelines for Ethical Interactions, published in 1993.[1] The title has been changed to reflect the increased scope of its content. In addition to interactions with the pharmaceutical industry, pharmacists routinely interact professionally with a variety of vendors, including drug wholesalers, device manufacturers, computer hardware and software manufacturers, and other technology entities. Businesses and manufacturers not generally perceived by pharmacists as being part of the industrial sector, such as for-profit medical education and communication companies, also are included. Because ethical considerations are not limited to one industry sector, the following guidelines should be applicable to any situation.

In addition to expanding the guidelines to all industry sectors, this update recognizes new and revised federal and organizational guidelines for industry that address real and perceived ethical conflicts with health care professionals. These guidelines include the Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Healthcare Professionals published in 2002,[2] the United States Department of Health and Human Services Office of Inspector General's (OIG) Compliance Program Guidance for Pharmaceutical Manufacturers published in 2003,[3] the Standards for Commercial Support from the Accreditation Council for Continuing Medical Education (ACCME) to Ensure the Independence of CME Activities published in 2004,[4] and the Accreditation Council on Pharmaceutical Education (ACPE) update to their Criteria for Quality and Interpretive Guidelines related to commercial support of continuing education activities approved at the end of 2006.[5]

The ACCP recognizes that certain relationships between industry and pharmacists are ethically appropriate, often beneficial, and unavoidable. The challenge for pharmacists is to ensure those relationships remain within acceptable boundaries and to avoid inappropriate interactions that have the potential to impact negatively on each of us, as well as our profession and, most important, our patients. As our roles as pharmacists evolve, we will continue to be challenged by ethical dilemmas. Pharmacists should familiarize themselves with the new guidelines, as well as the position statements outlined in this document, to ensure that they have a sound decision-making framework when confronted with an ethical dilemma.

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Guideline 1

As health care professionals responsible for managing drug therapy, the welfare of patients should be the pharmacist's primary concern in all aspects of pharmacy practice, including interactions with industry.

Pharmacists should act with honesty and integrity in all professional relationships to fulfill their responsibilities as described in article IV of the pharmacists' code of ethics.[6] The culture of honesty and integrity is important to the success of the profession of Pharmacy. As a valued member of the health care team, pharmacists should apply their knowledge, experience, and skills to ensure optimal drug therapy outcomes and thereby improve the quality of life of the patients they serve. In addition, pharmacists should manage products and services in a fiscally responsible manner in order to provide cost-effective quality health care.[7–9]

Guideline 2

Pharmacists should not solicit or accept gifts from industry that might influence or appear to influence objectivity, independence, or fairness in clinical and professional judgment.

The most contentious issue that sparks discussion about the appropriateness of behavior between industry and health care professionals is gifts. Gifts include monetary remuneration, as well as attendance at social events, hospitality, trips, acceptance of material items, and subsidies in any form. Many health professionals continue to believe that industry gifts do not influence their behavior, despite mounting evidence to the contrary.[10–15] Despite the recent publication of multiple guidelines,[2–5] numerous articles in medicine,[12, 14, 15, 16–29] nursing,[30] dental,[31] and pharmacy[32, 33] literature continue to document the ethical dilemma associated with industry gifts to health care professionals. Individual approaches and recommendations from the literature range from complete avoidance now voiced by many individuals and organizations,[12, 14, 18, 19, 26–28, 34, 35] through a gradient of acceptance based on factors such as type of gift or cost.[20, 36, 37]

The ACCP suggests that, when confronted with ethical dilemmas regarding gifts, pharmacists should exercise sound and practical judgment. The acceptance of gifts that influence or even appear to influence objectivity, independence, or fairness in clinical and professional judgment constitutes a conflict of interest. Gifts that are not directly beneficial to patient care, education, or research should not be accepted; some argue that this applies to even small gifts, such as pens, pads, and paper-weights.[12, 14, 18, 21, 34] In addition, the following points should be considered before accepting any gift:

- Whenever a gift is offered, ask yourself what the purpose of the gift is and does the gift truly benefit your patients in some manner. Social scientists caution that acceptance of a gift, even one of minor value, obligates the recipient to reciprocate in a like manner.[13, 14]
- The American College of Physicians[36] suggests that, as an informal measure of the propriety of accepting a gift from industry, the following questions be addressed openly and reasonably: What would my patients think about this arrangement? What is the purpose of the industry offer? What would my colleagues think about this offer?
- Individuals may not appreciate their own inability to assess the potential for conflicts of interest. In a survey of medical residents, 61% of respondents described themselves as not being vulnerable to the influences of industry marketing efforts, although only 16% had the same high regard for their peers.[38] Although a similar study has not been conducted with pharmacists, there is little reason to suspect the outcome would differ. Because ethics deals with perception, the risk for underestimating the potential for conflicts of interest is always present.
- Despite physicians' confidence that industry interactions have no effect on their behavior, results from numerous studies contradict that belief. As summarized in a comprehensive review of the studies evaluating the impact of industry interaction on physician behavior published in 2000, a strong correlation does exist between industry benefits and positive product endorsement, including influences on prescribing practices, formulary choices, and assessment of information provided by sales representatives.[10] Pharmacists would likely espouse similar sentiments.

In 2002, the PhRMA adopted a voluntary code to guide interactions between member companies and health care professionals.[2] The issue of gifts is pervasive throughout the code and includes the following guidance specific to gift giving: "No grants, scholarships, subsidies, support, consulting contracts, or educational or practice-

related items should be provided or offered to a health care professional in exchange for prescribing products or for a commitment to continue prescribing products. Nothing should be offered or provided in a manner or on conditions that would interfere with the independence of a health care professional's prescribing practice." The following year, the Department of Health and Human Services OIG published their Compliance Program Guidance for Pharmaceutical Manufacturers.[3] The OIG guidance asserts that gifts, entertainment, and personal service compensation "have a high potential for fraud and abuse and, historically, have generated a substantial number of anti-kickback convictions." The document then notes that compliance with the PhRMA code "will substantially reduce the risk of fraud and abuse." It should be noted that both the PhRMA and OIG guidelines are self-regulatory, with no complaints procedure or sanctions for non-compliance outlined when violations are identified.[15, 39] Nonetheless, the pharmaceutical industry in general reacted to both sets of guidelines by implementing new procedures for health care professional interactions, including the development and implementation of compliance programs.[15, 39] In addition, several states have enacted legislation that mandates disclosure of payments made to health care professionals by pharmaceutical companies.[15, 17, 39] Unfortunately, preliminary inspection of state records after legislation was enacted in the states of Vermont and Minnesota revealed a large number of such payments still exceeding the $100 limit.[40, 41]

Appropriate Gifts (per the PhRMA code)

Gifts of a minimal (< $100) value (e.g., pens, pads, cups, and paperweights) are acceptable, although any potential for undue influence must always be considered. Educational materials such as slides, patient information guides, monographs, or books are acceptable gifts, as long as they promote objective and scientific knowledge that will benefit patient care. Although these types of gifts may be acceptable under the PhRMA code, the pharmacist must be cognizant of the potential for lack of completeness or bias in the content of material supplied by the sponsor. The use of these materials must be within the full discretion of the pharmacist.

Industry-sponsored activities are considered gifts and must be no more than modest in scope (e.g., a meal without entertainment or recreational event). Social activities should only be associated with continuing education events. Reimbursement of travel, lodging, and dining expenses, and an appropriate honorarium are acceptable for acting as a consultant, expert, or specialist. (A consultant, expert, or specialist has special knowledge, experiences, or functions within a health care system or with drug products, diseases, or patient care that are of significant value to industry to assist with their research, patient care, education, or marketing goals.) Reimbursement and an honorarium are also acceptable for providing a service (including a wide range of activities, such as speaking and moderating educational programs, administrating clinical, pharmacoeconomics, or other research studies, evaluating drug utilization reviews, and serving on advisory boards, expert panels, or focus groups) and attending an investigator (training) meeting. An educational grant may be used to lower the overall registration fee for all meeting participants.

Inappropriate Gifts (per the PhRMA code)

The temporal relationship of any gift, even if minimal, to key decision-makers (e.g., those involved in formulary product decisions), consultants, experts, and specialists is a major component in determining the potential for undue influence of the gift. Any cash payment not associated with provision of a service should be considered an unacceptable gift. Expensive gifts are never appropriate. Invitations to social events not associated with educational events should not be accepted. Provision of entertainment by industry is also not acceptable. Items intended for personal benefit (such as floral arrangements, artwork, music CDs, or tickets to a sporting event) should not be accepted by pharmacists.

Prepaid travel to an industry-sponsored symposium and lodging for solely attending such a symposium are considered expensive gifts and are unacceptable. Pharmacists should not accept gifts, monetary or otherwise, as reimbursement for their professional time for solely attending meetings. In addition, pharmacists should not accept the cost of meeting registration. Travel and related expenses to visit a company should be associated with a service being provided; otherwise, they are considered expensive gifts. As a meeting attendee, pharmacists should not accept donation of money or gifts to a charity in lieu of payment; this should be considered the same as a direct payment.

The acceptance of any (even if modest) gift or compensation, such as research grants, in conjunction with drug purchases is not acceptable. Pharmacists should never accept gifts or any compensation from industry based on clinical practices involving any recommendations (e.g., formulary decisions, product choices for patients, or dispensing practices). Even unrestricted educational or research grants given in close proximity to key decisions or recommendations may appear to be undue influence and should be considered unacceptable.

Guideline 3

Pharmacists should disclose financial, consulting, or other relationships that are or appear to constitute conflicts of interest. Although disclosure is an important tool in the management of potential conflicts of interest, it does not absolve pharmacists from avoiding situations in which potential conflicts would make their participation inappropriate.

Pharmacists should recognize the potential for conflicts of interest arising from their financial relationships with industry. A conflict of interest is a set of conditions in which professional judgment concerning a primary interest (e.g., research or patient welfare) tends to be unduly influenced by a secondary interest (e.g., financial gain).[42] Disclosures of real, potential, and perceived conflicts of interest are in the best interest of patients and thus in the best interest of pharmacists. In the case of publications and presentations, disclosure allows the reader or listener to decide whether or not the real or potential conflict might influence the content. Conflicts of interest can take a variety of forms, with some more obvious than others. Examples of such relationships that could be perceived by our patients or colleagues as potential conflicts of interest include employment, consultancies, honoraria, stock ownership or options (excluding diversified mutual funds; sector funds with large holdings in a few companies could be a problem), expert testimony, grants received, grants pending, patents received, patents pending, royalties, or any other financial relationships of significance, including those that may be held by the pharmacist's spouse or dependent children. Although the presence of a potential conflict of interest "does not necessarily result in an outcome different than the result would have been without a conflict,…the potential for differing results is the problem at hand."[9]

Pharmacists who have financial or other personal arrangements with industry, whether as speakers, consultants, or investors, should not compromise their objective clinical judgment or the best interests of their patients as a result of these arrangements. Pharmacist relationships with industry and other entities should be transparent and available for examination by the public and members of the profession. Prior to any interactions, pharmacists should make a good-faith effort to evaluate the potential for influence and determine which relationships are ethically appropriate, and should not enter into relationships that could affect objectivity in decision-making. For example, pharmacists involved in formulary or drug-purchasing decisions should not make decisions based on relationships (e.g., owning stock or having previous or ongoing financial support) with industry. Drug products should be chosen on the basis of their therapeutic value, potential benefit to patients, and cost.

Disclosure of all interactions with industry is a key component for managing potential conflicts of interest.[43] Disclosure is vital to ensure the trust of the public and the trust of colleagues in pharmacy and other health professions. Pharmacists and other health care professionals should comply with disclosure policies established by their institution, as well as other relevant third parties (e.g., journal editors or professional or institutional committees). Pharmacists have the responsibility to know, understand, and follow the requirements for disclosure associated with each professional activity undertaken. Disclosure of all relationships with industry should be mandatory when undertaking any activity involving decision-making so that colleagues, students, trainees, and patients can evaluate these activities for themselves.

Although disclosure is an important tool in the management of potential conflicts of interest, it does not absolve pharmacists from avoiding situations in which potential conflicts would make their participation inappropriate.[28, 33, 42, 43] For example, disclosure of a relationship followed by a passionate appeal to support a product for which the pharmacist has a relationship with the manufacturer is still inappropriate. Whenever possible, pharmacists should recuse themselves from all deliberations and decisions when these situations arise.

The OIG guidelines identify specific financial arrangements between industry and health care professionals that may present a significant

potential for abuse.[3] Specific individuals or entities with special influence are also identified, including purchasers, benefit managers, formulary committee members, and group purchasing organizations. The guidelines offer the following questions to help identify problematic arrangements:

- Does the arrangement or practice have the potential to interfere with, or skew, clinical decision-making?
- Does the arrangement or practice have a potential to increase costs to the federal health care programs, beneficiaries, or enrollees?
- Does the arrangement or practice have a potential to increase the risk of overutilization or inappropriate utilization?
- Does the arrangement or practice raise patient safety or quality-of-care concerns?

Guideline 4

Pharmacists who make decisions regarding the purchase, prescribing, or use of drugs or devices by others through formulary committee deliberations, clinical practice guideline development, or administrative responsibilities should avoid financial, consulting, or other relationships with industry that are or appear to constitute conflicts of interest. Pharmacists may serve as expert consultants at the request of formulary committees and clinical practice guideline panels; however, those with industry relationships should not participate in the final deliberations or vote. Furthermore, expert consultants must disclose all relationships with industry that might influence or appear to influence their objectivity.

Pharmacists may serve on committees, boards, and councils or have administrative responsibilities that determine specific drugs or devices to be purchased, prescribed, preferred, and/or recommended for use by individuals and organizations. In these activities, pharmacists must be guided by principles of honesty, fairness, and objectivity.

The pharmacist's role on a formulary committee, including full voting privileges, is particularly critical, as decisions made by the committee determine which products are available within the health care system. These decisions ultimately affect the quality of patient care by influencing the practices of prescribers, especially physicians in residency training programs. As noted previously, the OIG guidelines have identified membership on a formulary committee as a position with significant potential for abuse.[3] A pharmacist is usually responsible for developing the agenda, presenting clinical and economic information, and composing the minutes for the formulary committees—all of which are activities at risk for influence from vendors and the health care industry.[44, 45] Pharmacists must fulfill these responsibilities without bias to ensure integrity in the committee decision-making process. Pharmacists involved with formulary committees also should assist with the development of a policy (if none exists) on disclosing potential conflicts of interest for committee members to avoid any appearance of impropriety with deliberations and requiring members to abstain from voting when a true conflict of interest exists with the product under discussion, the class of products, or a competitive product.[46–48]

Pharmacists are also involved in the development of clinical practice guidelines that address prevention, prophylaxis, and treatment. These guidelines may be institution specific, regional, national, or international in scope. As such, they guide drug therapy decisions for large numbers of patients and influence the prescribing practices of many providers. Pharmacists must maintain a strong commitment to use evidence-based evaluations in developing drug use guidelines and strive to achieve optimal outcomes. Once again, disclosure of all relationships with industry should be mandatory for all participants involved in developing the practice guideline, and the potential conflicts of interest should be published as a component of the practice guideline.[49, 50]

This guidance does not prevent clinical pharmacists with industry relationships from providing input into formulary or guideline development decisions. As experts in therapeutics and investigators in clinical studies, including industry-sponsored studies, clinical pharmacists are often requested by formulary committees and practice guideline development panels to serve as expert consultants. After providing expert testimony, these individuals should not participate in the final decision-making process or vote. Final decisions should be made by committee members without any relationships that could be perceived as a conflict of interest. As discussed above, industry relationships for all participants that might influence or appear to influence their objectivity, including those

providing expert testimony, should be disclosed during the deliberations and included in any publication summarizing the final decisions.

Guideline 5

Pharmacists who are members of an institutional review board (IRB) should avoid any real, potential, or perceived conflicts of interest that could occur in connection with industry-related matters before the IRB.

Federal regulations have empowered IRBs to review and then approve, require modifications, or disapprove any human-subject research.[51] There are specific federal regulations governing membership of IRBs.[52] The IRB is also required to ensure its members do not have conflicts of interests that would impair their ability to make a fair and reasonable judgment concerning a protocol under review.

Pharmacists participating as a member of an IRB should assess research protocols, drug therapy, and patient risk in a fair and unbiased manner. Pharmacists, as a result of their clinical expertise in pharmacotherapy and involvement in research, often participate in the IRB as chairs, members, or presenters. Conflicts of interest can occur when an IRB member has a financial interest or any other professional or personal relationship with industry that may compromise his/her independent judgment in safeguarding the rights and welfare of the research subjects. Conflicts of interest have the potential to directly affect the design, execution, interpretation, and/or approval of a study. Conflict of interest by an investigator of a clinical study or member of an oversight committee can result in regulatory action, negative publicity, and lawsuits.[53] For the pharmacist member of an IRB, full disclosure to the chair and/or IRB committee prior to any action on a research project is vital. As a result of the disclosure, the pharmacist may be required to abstain from voting if he/she or his/her immediate family members have a financial relationship with any company sponsoring a proposed study. In addition, if the pharmacist has access to confidential information, he/she must adhere to IRB policies and the U.S. Food and Drug Administration regulations.

Guideline 6

Pharmacists who participate in industry-associated research should only do so if that research meets accepted ethical, regulatory, and scientific standards.

The ACCP white paper, Ethical Issues Related to Clinical Pharmacy Research, originally published in 1993,[54] has recently been revised.[55] The discussion below highlights some of the issues addressed in the paper that relate to pharmacist-industry interactions.

Pharmacists participate in research on many levels beginning with hypothesis generation through publication of study results. Pharmacists must conduct high-quality clinical, translational, or health-system research according to established ethical, regulatory, and scientific standards to maintain credibility as competent scientific investigators. Pharmacists should not be involved in research in which the sponsor imposes any obstacle to publication of the study results. Research whose primary purpose is promotion of a drug product or device is not legitimate and does not hold patient welfare in the highest regard. As an example, pharmacists should not participate in studies for which the primary purpose is to familiarize prescribers with specific drug products (i.e., marketing or "seeding" studies).

Disproportionate fees for collection of patient data in a research study should lead one to evaluate closely the purpose of the study, as excessive compensation for conducting a study constitutes a gift. Payments to patients, subjects, or health professionals participating in studies should be reasonable and represent appropriate reimbursement for time and expenses (e.g., parking, travel). If allowed by the granting agency, money that remains after all study expenses (such as investigator and coordinator salaries and overhead) have been paid should be restricted to support research training programs (e.g., residencies, fellowships, graduate programs), enhance the educational or research mission of the institution, or improve patient care directly. Reimbursement of expenses for pharmacists attending clinical investigators' meetings is appropriate; however, study sponsors should avoid extravagance when choosing the setting for a meeting, and expenses should cover the period of the meeting and the investigators only.

Pharmacists involved in clinical research should also follow all pertinent federal and state disclosure guidelines. The 1995 federal guidelines for disclosure state that "all investigators must disclose significant financial interests that would 'reasonably' appear related to the sponsored research…significant is defined as $10,000 per year in income or 5% equity in a

company…This applies to the investigator, spouse, and dependent children."[56] Full disclosure of financial support for a research project should be made at the time of publication or presentation of study results.[57]

Most hospitals and other health care institutions have ongoing clinical trials, and the pharmacy staff may be involved in providing services related to the studies. The pharmacist providing these types of services should ensure that informed consent has been obtained from all study patients and that the study is being conducted in an ethical manner.

Guideline 7

Pharmacists should only participate as authors for publications that meet accepted ethical, regulatory, and scientific standards. In addition, pharmacists who serve as peer reviewers should disclose any conflicts of interest and/or recuse themselves from reviewing a manuscript for which they have a relationship with a sponsor or competitor of the sponsor.

Publication of research results, editorials, and review articles is an important component of an academic or research pharmacist's professional life. Collaboration with industry may be necessary in these writing endeavors. Guidelines for author responsibilities when submitting an article linked to industry are available from the International Committee of Medical Journal Editors.[58] The guidelines address ethical considerations in the conduct and reporting of research and include such topics as defining authorship, editorial freedom, peer review, conflicts of interest, and privacy and confidentiality. An ad hoc industry group also drafted a publication guideline, Good Publication Practice Guidelines for Pharmaceutical Companies, designed to establish standards for the publication of industry-sponsored trials.[59] This guide addresses publication standards, relationships between the company and external investigators, authorship, and ghost writers.

Pharmacists should understand that if they meet the criteria to be a study author, they accept responsibility for conducting the study, ensuring that they had full access to all of the data, and actively participated in the decision to publish the study results.[58] When publishing articles in peer-reviewed pharmacy or medical journals, pharmacists should consider themselves authors only if criteria for authorship are met and may take credit only for work they have done themselves; taking public credit for work prepared by others (e.g., ghost writers) is unacceptable.[58, 59] Pharmacists should request peer review of their work prior to publication.

Full disclosure is mandatory whenever pharmacists are paid by industry (e.g., pharmaceutical companies or medical education companies) to prepare articles for publication.[57–59] Disclosure of potential conflicts of interest is a well-defined component of the International Committee of Medical Journal Editors' requirements for manuscripts submitted to biomedical journals, stated as follows: "Public trust in the peer review process and the credibility of published articles depend in part on how well conflict of interest is handled during writing, peer review, and editorial decision-making. Conflict of interest exists when an author (or the author's institution), reviewer, or editor has financial or personal relationships that inappropriately influence (bias) his or her actions (such relationships are also known as dual commitments, competing interests, or competing loyalties). These relationships vary from those with negligible potential to those with great potential to influence judgment, and not all relationships represent true conflict of interest. The potential for conflict of interest can exist whether or not an individual believes that the relationship affects his or her scientific judgment. Financial relationships (such as employment, consultancies, stock ownership, honoraria, paid expert testimony) are the most easily identifiable conflicts of interest and the most likely to undermine the credibility of the journal, the authors, and of science itself. However, conflicts can occur for other reasons, such as personal relationships, academic competition, and intellectual passion. All participants in the peer review and publication process must disclose all relationships that could be viewed as presenting a potential conflict of interest."[58]

This definition serves as the basis for the disclosure requirements for many major biomedical journals. Most pharmacy journals also adhere to these requirements, but specific instructions on disclosure of conflicts of interest are often vague or absent. Journal editors recognize that industry ties or involvement do not automatically produce loss of objectivity,[60] and that industry connections may provide access to data not otherwise available. However, full disclosure of potential conflicts of interest allows the reader to use the information in assessing the merits of any article.

The anonymous nature of the peer review

process makes it particularly vulnerable to the possibility of industry-associated conflicts of interest. The reviewer could have an ongoing relationship with the sponsor of the research or a competitor of the research sponsor, which could affect the reviewer's recommendation to the editor (positively or negatively). Disclosure of these conflicts to the editor is appropriate.[58] Declining the invitation to review a manuscript for which there is a potential conflict is a reasonable option.

Guideline 8

Pharmacists participating in continuing education programs or preparing written material on drug therapy should deliver fair and unbiased presentations. Pharmacists should disclose any apparent or potential conflicts of interest. The presentation of continuing education free from bias is in the best interest of health care providers as well as patients.

One of the most common ways in which industry now interacts with practicing pharmacists is through continuing education programs. The interaction can entail the pharmacist as facilitator, organizer, presenter, and attendee of the continuing education program. The revised, voluntary PhRMA code outlines in detail acceptable procedures for industry support of continuing education activities that allow independence for the provider.[2] The OIG guidelines state that companies face little risk of noncompliance if the recommendations provided by the PhRMA code are followed.[3] More recently, the ACCME updated their guidance to enhance and protect the independence and integrity of CME activities.[4] At its October 2006 board meeting, the ACPE approved an update to their Criteria for Quality and Interpretive Guidelines related to commercial support of continuing education activities.[5] Providers have been evaluated using the updated ACPE guidelines since January 1, 2008. All of the revised and updated guidelines provide consistent recommendations for industry, including for-profit medical education and communication companies, continuing education sponsors, speakers, and participants, which are reflected in the discussion below.

The ACPE defines continuing education for the profession of Pharmacy as "a structured educational activity designed or intended to support the continuing development of pharmacists and/or pharmacy technicians to maintain and enhance their competence. Continuing pharmacy education should promote problem-solving and critical thinking and be applicable to the practice of pharmacy."[61] The educational value of the continuing education conference or activity must be the primary consideration in the pharmacist's decision to attend or participate. Pharmacists choosing among continuing education activities should assess their educational value and select only those activities that are of high quality, conducted by qualified faculty, and appropriate for the pharmacist's professional needs. Although amenities unrelated to the educational purpose of the activity may play a role in the pharmacist's decision to participate, this should be considered secondarily. Pharmacists should claim credit commensurate only with the actual time spent attending a continuing education activity or in studying the continuing education material.

Pharmacists who participate in industry-sponsored speakers' bureau activities (e.g., accept support and expenses for attendance at speaker training or similar educational programs regarding specific statements about the industry product) should disclose this information in all of their activities relating to continuing education. In addition, any other conflicts of interest or biases, such as financial connection to a particular commercial firm or product, should be disclosed by faculty members to the activity's sponsor and to the audience. It is important to note that the updated ACCME and ACPE standards state that simple disclosure of potential conflicts of interest by providers, speakers, and authors of written materials is no longer sufficient. In addition to the requirement that all relevant financial relationships within the past 12 months be revealed, conflicts of interest must be resolved before the continuing education activity begins. The provider must be able to show that all individuals involved in the educational activity disclosed all relevant financial relationships with any commercial interest to the provider. Any individual who refuses to disclose relevant financial relationships will be disqualified from involvement with CME activities. Also of note, the ACCME and ACPE standards define financial relationship as "a salary, royalty, intellectual property rights, consulting fee, honoraria, ownership interests, or other financial benefit."[4, 61] No minimum dollar amount is established in the updated standards because the council has determined that "inherent in any amount is the incentive to

maintain or increase the value of the relationship."[4]

Pharmacists serving as presenters, moderators, or other faculty at an accredited ACPE or CME program, or any other health professional conference, should ensure that research findings and therapeutic recommendations are based on scientifically accurate, up-to-date information and are presented in a fair, balanced, and unbiased manner. The program development and execution should be consistent with guidelines outlined for ACPE or CME programs. It is the responsibility of sponsors, providers, and faculty members to ensure that the guidelines are met. Representatives of industry or other financial contributors should not exert control over the choice of moderators, presenters, or other faculty, or otherwise modify the content of faculty presentations. Funds from industry in support of an ACPE or CME activity may be accepted as long as the program provider controls the distribution of funds and the sponsor does not profit unfairly or charge a fee that is excessive for the content and length of the program.

Faculty may accept reasonable honoraria and reimbursement for expenses. Receipt of payment disproportionate to the amount of effort and time required may be considered a gift and should be avoided. Pharmacists who are routinely invited to speak or prepare written materials on behalf of industry may want to question their personal motives and the motives of the sponsors who fund their work. A subtle bias may be occurring. If the presenter or writer does not deliver the correct message, he or she will not be asked again to perform sponsored work. Also, is the invitation to give a presentation simply a means for providing a gift? This may be an issue to consider if multiple presentations are given that result in considerable income.

Nonfaculty or nonauthor participants of a continuing pharmacy education activity should not accept reimbursement for travel, lodging, honoraria, or personal expenses. Pharmacists should be wary of the liberal use of the terms "consultation" as a means of providing a gift of travel and lodging for a meeting and "consulting fee" as a means of providing a gift for attending a symposium at a meeting.

Guideline 9

Colleges of Pharmacy and postgraduate pharmacy training programs should incorporate formal instruction on professional ethics into their curricula for pharmacy students, residents, fellows, graduate students, preceptors, and faculty. These educational offerings should address appropriate relationships between pharmacists and industry. In addition, training programs should develop guidelines or formal policies governing interactions between trainees and representatives of industry.

Interactions between pharmacists and industry begin in pharmacy school, continue through training programs, and persist throughout a pharmacist's career. Educating pharmacy students early in the curriculum about the importance of professional ethics can promote and enhance their ethical behavior as practicing pharmacists.[62] In addition to discrete coursework on pharmacy ethics, ethical issues surrounding interactions with industry should be discussed across the professional degree curriculum and especially during the advanced practice experiences under the direction of practitioner role models. Moreover, continuing education of pharmacists at all stages of professional development on specific issues relating to ethical interactions between pharmacists and industry will facilitate maintenance of high ethical standards throughout the profession.

Training programs have unique characteristics, and residents and fellows would benefit from instruction in professional ethics. Companies target training programs because it is more efficient to approach groups than individuals and because faculty and preceptors are viewed as opinion leaders who can shape the behavior of future pharmacists and pharmacy leaders. Thus, pharmacy training programs should include specific learning or competency objectives on ethical interactions between pharmacists and industry, especially using discussion formats that emphasize the subtleties of these interactions. Most important, directors of and preceptors in training programs should lead by example and conduct their interactions with industry representatives in a principled manner.

Guideline 10

Pharmacists should ensure that patient confidentiality is maintained for all industry interactions. The confidentiality of prescriber information should also be respected.

The Health Insurance Portability and Accountability Act (HIPAA), enacted in 1996, protects patients' rights related to privacy and confidentiality through legislation.[63] Protecting patients' privacy and confidentiality is not only a

legal concern, it is an ethical obligation for all health care professionals involved in patient care. Pharmacists must ensure that patient privacy and confidentiality are maintained during any interaction with an industry representative, including representatives from the marketing, sales, or clinical research arms of the company. For example, meetings with industry representatives should not be held in patient care areas, and patient information should be protected from viewing. In addition, no patient information should be shared outside of a bona fide relationship with industry representatives (e.g., the medical division of a company involved in a research project or a technology company involved in the implementation of a technology that requires the industry representative to view actual patient data). An industry representative who observes ill patients just by being in a patient care area may be violating that patient's privacy because that industry representative is now aware of that patient's illness, which he or she had no legitimate professional "need to know."

Pharmacists should not provide information about individual prescribers who order or prescribe particular products to any company that will use it for commercial purposes (e.g., sales or marketing), including vendors that specialize in collecting this type of data.[64]

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References

1. **American College of Clinical Pharmacy**. Pharmacists and the pharmaceutical industry: guidelines for ethical interactions. Pharmacotherapy 1993;13:531–3.
2. **Pharmaceutical Research and Manufacturers of America**. Code on interactions with healthcare professional. Available from http://www.phrma.org/code_on_interactions_with_healthcare_professionals/. Accessed March 7, 2007.
3. **U.S. Department of Health and Human Services Office of Inspector General**. OIG compliance program guidance for pharmaceutical manufactures. Federal Register 2003;68(86):23731–43.
4. **Accreditation Council for Continuing Medical Education**. 2004 Updated standards for commercial support with background, rationale and answers to questions about compliance. Chicago, IL: Accreditation Council for Continuing Medical Education, 2004.
5. **Accreditation Council for Pharmacy Education**. Criterion 17. Non-commercialism. Adopted October 2006. Available from http://www.acpe-accredit.org/pdf/CE_NEW_CommercialismStandard17%20-%202006.pdf. Accessed March 9, 2007.
6. **American Pharmaceutical Association**. Code of ethics for pharmacists. Adopted October 27, 1994. Available from http://www.aphanet.org. Accessed March 7, 2007.
7. **American Society of Health-Systems Pharmacists**. Code of ethics for pharmacists. Am J Health-Syst Pharm 1995;52:2131.
8. **Benner J, Breadsley R**. White paper on pharmacy student professionalism. J Am Pharm Assoc 2000;40:96–102.
9. **American Pharmacists Association**. Principles of practice for pharmaceutical care. Available from http://www.aphanet.org. Accessed March 7, 2007.
10. **Wazana A**. Physicians and the pharmaceutical industry: is a gift ever just a gift? JAMA 2000;283:373–80.
11. **Turton FE, Syndor L**. Physician-industry relations [letter]. Ann Intern Med 2007;146:469.
12. **Komesaroff P, Kerridge IH**. Ethical issues concerning the relationships between medical practitioners and the pharmaceutical industry. Med J Aust 2002;176:118–21.
13. **Dana J, Lowenstein G**. A social science perspective on gifts to physicians from industry. JAMA 2003;290:252–5.
14. **Katz D, Caplan AL, Merz JP**. All gifts large and small: toward an understanding of the ethics of pharmaceutical industry gift-giving. Am J Bioeth 2003;3:39–46.
15. **Blumenthal D**. Doctors and drug companies. N Engl J Med 2004;351:1885–90.
16. **American College of Obstetricians and Gynecologists**. Committee on ethics. ACOG committee opinion. Guidelines for relationships with industry. No. 259, October 2001. Obstet Gynecol 2001;98:703–6.
17. **Tsai AC**. Policies to regulate gifts to physicians from industry. JAMA 2003;290:1776.
18. **Chlong W**. Industry-to-physician marketing and the cost of prescription drugs. Am J Bioeth 2003;3:W28–9.
19. **Abbasi K, Smith R**. No more free lunches [editorial]. BMJ 2003;326:1155–6.
20. **Brett AS, Burr W, Moloo J**. Are gifts from pharmaceutical companies ethically problematic? A survey of physicians. Arch Intern Med 2003;163:2213–18.
21. **Panush RS**. Why I no longer accept pens (or other "gifts") from industry (and why you shouldn't either). J Rheumatol 2004;31:1478–82.
22. **Alpert JS**. Doctors and the drug industry: how can we handle potential conflicts [editorial]? Am J Med 2005;118:99–100.
23. **Gosfield AG**. The hidden costs of free lunches: fraud and abuse in physician-pharmaceutical arrangements. J Med Pract Manage 2005;20:253–8.
24. **Marco CA, Moskop JC, Solomon RC, Geiderman JM, Larkin GL**. Gifts to physicians from the pharmaceutical industry: an ethical analysis. Ann Emerg Med 2006;48:513–21.
25. **Scott IA**. On the need for probity when physicians interact with industry. Intern Med J 2006;36:265–9.
26. **Kassirer JP**. When physician-industry interactions go awry. J Pediatr 2006;149(1 suppl):S43–6.
27. **Minnigan H, Chisholm CD**. Conflict of interest in the physician interface with the biomedical industry. Emerg Med Clin North Am 2006;24:671–85.
28. **Brennan TA, Rothman DJ, Blank L, et al**. Health industry practices that create conflicts of interest: a policy proposal for academic medical centers. JAMA 2006;295:429–33.
29. **Standridge JB**. Of doctor conventions and drug companies. Fam Med 2006;38:518–20.
30. **Day L**. Industry gifts to healthcare providers: are the concerns serious? Am J Crit Care 2006;15:510–13.
31. **Schwartz B**. Receiving gifts: a conflict of interest discussion. J Can Dent Assoc 2005;71:561–2.
32. **Haines ST, Dumo P**. Relationship between the pharmaceutical industry and pharmacy practitioners: undue influence? Am J Health-Syst Pharm 2002;59:1871–4.
33. **Banks D**. Pharmacists, pharmaceutical manufacturers, and conflicts of interest. Am J Health-Syst Pharm 2005;62:1827–32.
34. **Paris JJ**. Large or small, a gift is a gift is a gift. Am J Bioeth 2003;3:W30.
35. **Wager E**. How to dance with porcupines: rules and guidelines on doctors' relations with drug companies. BMJ 2003;326:1196–8.
36. **Coyle SL**. Physician-industry relations. Part I. Individual physicians. Ann Intern Med 2002;136:396–402.

37. **Trachtman H**. The death of common sense. Am J Bioeth 2003;3:W31–2.
38. **Chren MM**. Interactions between physicians and drug company representatives. Am J Med 1999;107:182–3.
39. **Chimonas S, Rothman DJ**. New federal guidelines of physician-pharmaceutical industry relations: the politics of policy formation. Health Affairs 2005;24:949–60.
40. **Ross JS, Lackner JE, Lurie P, Gross CP, Wolfe S, Krumholz HM**. Pharmaceutical company payments to physicians: early experience with disclosure laws in Vermont and Minnesota. JAMA 2007;297:1216–23.
41. **Brennan TA, Mello MM**. Sunshine laws and the pharmaceutical industry. JAMA 2007;297:1255–7.
42. **Thompson DF**. Understanding financial conflicts of interest. N Engl J Med 1993;329:573–6.
43. **Dickens BM, Cook RJ**. Conflict of interest: legal and ethical aspects. Int J Gynaecol Obstet 2006;92:192–7.
44. **American Society of Hospital Pharmacists**. ASHP statement on the pharmacy and therapeutics committee. Am J Hosp Pharm 1992;49:2008–9.
45. **American Society of Health-Systems Pharmacists Coalition Working Group**. Principles of a sound drug formulary system. Available from http://www.ashp.org/bestpractices/formulary-mgmt/Formulary%20Management%20Endorsed.pdf. Accessed July 11, 2003.
46. **Katz S, Dudley EW, Veatch RM**. Potential conflict of interest of a pharmacy and therapeutics committee member. Am J Hosp Pharm 1989;46:2047–51.
47. **Zilz DA**. Interdependence in pharmacy: risks, rewards, and responsibilities. Am J Hosp Pharm 1990;47:1759–65.
48. **Frye CB**. Disclosing conflicts of interest involving clinicians who prepare therapeutic guidelines. Am J Health-Syst Pharm 2005;62:361–2.
49. **Anonymous**. Clinical practice guidelines and conflict of interest [editorial]. Can Med Assoc J 2005;173:1297.
50. **Choudhry NK, Stelfox HT, Detsky AS**. Relationships between authors of clinical practice guidelines and the pharmaceutical industry. JAMA 2002;287:612–17.
51. **U.S. Department of Health and Human Services**. Protection of human subjects. Code of federal regulations, title 21, vol 1, pt 50. Washington, DC: U.S. Government Printing Office, April 1, 2002:285–96.
52. **U.S. Department of Health and Human Services**. Institutional review boards. Code of federal regulations, title 21, vol 1, pt 56. Washington, DC: U.S. Government Printing Office, April 1, 2002:299–308.
53. **Nabel EG**. Conflict of interest or conflict of priorities [editorial]? N Engl J Med 2006;355:2365–7.
54. **American College of Clinical Pharmacy**. ACCP white paper: ethical issues related to clinical pharmacy research. Pharmacotherapy 1993;13:523–30.
55. **American College of Clinical Pharmacy**. ACCP white paper: ethical issues related to clinical, translational, and health systems research. Pharmacotherapy, in press.
56. **U.S. Food and Drug Administration, Department of Health and Human Services**. Objectivity in research; investigatory financial disclosure policy; final rule and notice. Federal Register 1995;60(132):35809–19.
57. **Davidoff F, DeAngelis CD, Drazen JM, et al**. Sponsorship, authorship, and accountability [editorial]. Ann Intern Med 2001;135:463–6.
58. **International Committee of Medical Journal Editors**. Uniform requirements for manuscripts submitted to biomedical journals: writing and editing for biomedical publication. February 2006. Available from www.icmje.org. Accessed March 7, 2007.
59. **Wager E, Field EA, Grossman L**. Good publication practice for pharmaceutical companies. Curr Med Res Opin 2003;19: 149–54.
60. **Hasegawa GR**. Full disclosure [editorial]. Am J Health-Syst Pharm 2002;59:1835.
61. **Accreditation Council for Pharmacy Education**. Definition of continuing education for the profession of pharmacy, released January 2007. Available from http://www.acpe-accredit.org/pdf/CE_Definition_Pharmacy_Final_1006–2007.pdf. Accessed March 9, 2007.
62. **Hammer DP, Berger BA, Beardsley RS, Easton MR**. Student professionalism. Am J Pharm Educ 2003;67(3):article 96.
63. **U.S. Department of Health and Human Services.** Office for civil rights—HIPAA. Available from http://aspe.hhs.gov/admnsimp/pl104191.htm. Accessed March 24, 2007.
64. **Steinbrook R**. For sale: physicians' prescribing data. N Engl J Med 2006;354:2745–7.