

UB Graduate Medical Education

Vendor Interactions with Residency Programs

May, 2007

The University at Buffalo, Office of Graduate Medical Education (GME) is dedicated to fostering an environment that promotes scholarship and professionalism. The Graduate Medical Education Committee (GMEC) endorses and adopts the AMA Ethical Opinions and Guidelines, opinion 8.061 "Gifts to Physicians from Industry" (see below) and the Accreditation Council for Graduate Medical Education white paper titled "Principles to Guide the Relationship between Graduate Medical Education and Industry" (see below). Residency programs are required to follow the ethical guidelines established in these documents as they pertain to vendor interactions with their trainees. Individual programs are encouraged to develop an evidence-based component of the curriculum so as to teach residents to properly analyze and better understand the information with which they are presented. Faculty members are expected to be present and participate at interactions so as to be able to model proper behavior.

It is acknowledged that many educational conferences are sponsored by vendors, and it is expected that the educational component is independent of any meal or promotional component. Vendors are to be allowed to have an area of exhibition apart from the main educational function, available for residents and faculty to meet and interact at their prerogative. Educational meals and conferences must adhere to ACCME guidelines for standards of commercial support (see below).

AMA Ethical opinions and guidelines

About Opinion 8.061, "Gifts to Physicians from Industry"

Over time, many gifts to physicians from pharmaceutical, device and medical equipment industry sales-representatives have served an important and beneficial function. For example, industry has provided funds for educational seminars and conferences for many years.

During the late 1980s, however, some of these gifts were becoming lavish, ranging from frequent flier miles to cash and trips to luxury resorts, and their appropriateness was increasingly being called into question. The AMA studied the issue, and in December of 1990, the AMA's House of Delegates adopted CEJA's ethical guidelines to prevent inappropriate gift-giving practices. The AMA's "Guidelines on Gifts to Physicians from Industry" later appeared in its Code of Medical Ethics (CEJA Ethical Opinion 8.061).

The Pharmaceutical Manufacturer's Association (PMA), which later became Pharma (Pharmaceutical Research and Manufacturers of America), also adopted the guidelines.

Opinion 8.061, "Gifts to Physicians from Industry"

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

(1) Any gifts accepted by physicians individually should primarily entail a benefit to patients and should not be of substantial value. Accordingly, textbooks, modest meals, and other gifts are appropriate if they serve a genuine educational function. Cash payments should not be accepted. The use of drug samples for personal or family use is permissible as long as these practices do not interfere with patient access to drug samples. It would not be acceptable for non-retired physicians to request free pharmaceuticals for personal use or use by family members.

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

(3) The Council on Ethical and Judicial Affairs defines a legitimate "conference" or "meeting" as any activity, held at an appropriate location, where (a) the gathering is primarily dedicated, in both time and effort, to promoting objective scientific and educational activities and discourse (one or more educational presentation(s) should be the highlight of the gathering), and (b) the main incentive for bringing attendees together is to further their knowledge on the topic(s) being presented. An appropriate disclosure of financial support or conflict of interest should be made.

(4) Subsidies to underwrite the costs of continuing medical education conferences or professional meetings can contribute to the improvement of patient care and therefore are permissible. Since the giving of a subsidy directly to a physician by a company's representative may create a relationship that could influence the use of the company's products, any subsidy should be accepted by the conference's sponsor who in turn can use the money to reduce the conference's registration fee. Payments to defray the costs of a conference should not be accepted directly from the company by the physicians attending the conference.

(5) Subsidies from industry should not be accepted directly or indirectly to pay for the costs of travel, lodging, or other personal expenses of physicians attending conferences or meetings, nor should subsidies be accepted to compensate for the physicians' time. Subsidies for hospitality should not be accepted outside of modest meals or social events held as a part of a conference or meeting. It is appropriate for faculty at conferences or meetings to accept reasonable honoraria and to accept reimbursement for reasonable travel, lodging, and meal expenses. It is also appropriate for consultants who provide genuine services to receive reasonable compensation and to accept reimbursement for reasonable travel, lodging, and meal expenses. Token consulting or advisory arrangements cannot be used to justify the compensation of physicians for their time or their travel, lodging, and other out-of-pocket expenses.

(6) Scholarship or other special funds to permit medical students, residents, and fellows to attend carefully selected educational conferences may be permissible as long as the selection of students, residents, or fellows who will receive the funds is made by the academic or training institution. Carefully selected educational conferences are generally defined as the major educational, scientific or policy-making meetings of national, regional or specialty medical associations.

(7) No gifts should be accepted if there are strings attached. For example, physicians should not accept gifts if they are given in relation to the physician's prescribing practices. In addition, when companies underwrite medical conferences or lectures other than their own, responsibility for and control over the selection of content, faculty, educational methods, and materials should belong to the organizers of the conferences or lectures. (II) Issued June 1992 based on the report "Gifts to Physicians from Industry," adopted December 1990 (JAMA. 1991; 265: 501 and Food and Drug Law Journal. 2001; 56: 27-40); Updated June 1996 and June 1998.

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The Standards for Commercial Support
Standards to Ensure Independence in CME Activities

STANDARD 1: Independence

1.1 A CME provider must ensure that the following decisions were made free of the control of a commercial interest. The ACCME defines a “commercial interest” as any proprietary entity producing health care goods or services, with the exemption of non-profit or government organizations and non-health care related companies.

- (a) Identification of CME needs;
- (b) Determination of educational objectives;
- (c) Selection and presentation of content;
- (d) Selection of all persons and organizations that will be in a position to control the content of the CME;
- (e) Selection of educational methods;
- (f) Evaluation of the activity.

1.2 A commercial interest cannot take the role of non-accredited partner in a joint sponsorship relationship. □

STANDARD 2: Resolution of Personal Conflicts of Interest

2.1 The provider must be able to show that everyone who is in a position to control the content of an education activity has disclosed all relevant financial relationships with any commercial interest to the provider. The ACCME defines “‘relevant’ financial relationships” as financial relationships in any amount occurring within the past 12 months that create a conflict of interest.

2.2 An individual who refuses to disclose relevant financial relationships will be disqualified from being a planning committee member, a teacher, or an author of CME, and cannot have control of, or responsibility for, the development, management, presentation or evaluation of the CME activity.

2.3 The provider must have implemented a mechanism to identify and resolve all conflicts of interest prior to the education activity being delivered to learners. □

STANDARD 3: Appropriate Use of Commercial Support

3.1 The provider must make all decisions regarding the disposition and disbursement of commercial support.

3.2 A provider cannot be required by a commercial interest to accept advice or services concerning teachers, authors, or participants or other education matters, including content, from a commercial interest as conditions of contributing funds or services.

3.3 All commercial support associated with a CME activity must be given with the full knowledge and approval of the provider.

Written agreement documenting terms of support

3.4 The terms, conditions, and purposes of the commercial support must be documented in a written agreement between the commercial supporter that includes the provider and its educational partner(s). The agreement must include the provider, even if the support is given directly to the provider’s educational partner or a joint sponsor.

3.5 The written agreement must specify the commercial interest that is the source of commercial support.

3.6 Both the commercial supporter and the provider must sign the written agreement between the commercial supporter and the provider.

Expenditures for an individual providing CME

3.7 The provider must have written policies and procedures governing honoraria and reimbursement of out-of-pocket expenses for planners, teachers and authors.

3.8 The provider, the joint sponsor, or designated educational partner must pay directly any teacher or author honoraria or reimbursement of out-of-pocket expenses in compliance with the provider's written policies and procedures.

3.9 No other payment shall be given to the director of the activity, planning committee members, teachers or authors, joint sponsor, or any others involved with the supported activity.

3.10 If teachers or authors are listed on the agenda as facilitating or conducting a presentation or session, but participate in the remainder of an educational event as a learner, their expenses can be reimbursed and honoraria can be paid for their teacher or author role only.

Expenditures for learners

3.11 Social events or meals at CME activities cannot compete with or take precedence over the educational events.

3.12 The provider may not use commercial support to pay for travel, lodging, honoraria, or personal expenses for non-teacher or nonauthor participants of a CME activity. The provider may use commercial support to pay for travel, lodging, honoraria, or personal expenses for bona fide employees and volunteers of the provider, joint sponsor or educational partner.

Accountability

3.13 The provider must be able to produce accurate documentation detailing the receipt and expenditure of the commercial support. □

STANDARD 4. Appropriate Management of Associated Commercial Promotion

4.1 Arrangements for commercial exhibits or advertisements cannot influence planning or interfere with the presentation, nor can they be a condition of the provision of commercial support for CME activities.

4.2 Product-promotion material or product-specific advertisement of any type is prohibited in or during CME activities. The juxtaposition of editorial and advertising material on the same products or subjects must be avoided. Live (staffed exhibits, presentations) or enduring (printed or electronic advertisements) promotional activities must be kept separate from CME.

- For **print**, advertisements and promotional materials will not be interleaved within the pages of the CME content. Advertisements and promotional materials may face the first or last pages of printed CME content as long as these materials are not related to the CME content they face **and** are not paid for by the commercial supporters of the CME activity.
- For **computer based**, advertisements and promotional materials will not be visible on the screen at the same time as the CME content and not interleaved between computer 'windows' or screens of the CME content
- For **audio and video recording**, advertisements and promotional materials will not be included within the CME. There will be no 'commercial breaks.'
- For **live, face-to-face CME**, advertisements and promotional materials cannot be displayed or distributed in the educational space immediately before, during, or after a CME activity. Providers cannot allow representatives of Commercial Interests to engage in sales or promotional activities while in the space or place of the CME activity.

4.3 Educational materials that are part of a CME activity, such as slides, abstracts and handouts, cannot contain any advertising, trade name or a product-group message.

4.4 Print or electronic information distributed about the non-CME elements of a CME activity that are not directly related to the transfer of education to the learner, such as schedules and content descriptions, may include product promotion material or product-specific advertisement.

4.5 A provider cannot use a commercial interest as the agent providing a CME activity to learners, e.g., distribution of self-study CME activities or arranging for electronic access to CME activities. □

STANDARD 5. Content and Format without Commercial Bias

5.1 The content or format of a CME activity or its related materials must promote improvements or quality in healthcare and not a specific proprietary business interest of a commercial interest.

5.2 Presentations must give a balanced view of therapeutic options. Use of generic names will contribute to this impartiality. If the CME educational material or content includes trade names, where available trade names from several companies should be used, not just trade names from a single company. □

STANDARD 6. Disclosures Relevant to Potential Commercial Bias

Relevant financial relationships of those with control over CME content

6.1 An individual must disclose to learners any relevant financial relationship(s), to include the following information:

- The name of the individual;
- The name of the commercial interest(s);
- The nature of the relationship the person has with each commercial interest.

6.2 For an individual with no relevant financial relationship(s) the learners must be informed that no relevant financial relationship(s) exist.

Commercial support for the CME activity.

6.3 The source of all support from commercial interests must be disclosed to learners. When commercial support is 'in-kind' the nature of the support must be disclosed to learners.

6.4 'Disclosure' must never include the use of a trade name or a product-group message.

Timing of disclosure

6.5 A provider must disclose the above information to learners prior to the beginning of the educational activity. □

Principles to Guide the Relationship between Graduate Medical Education and Industry

The Accreditation Council for Graduate Medical Education (ACGME) establishes educational standards for, and monitors compliance by, more than 7,700 residency programs and 700 institutional sponsors of graduate medical education (GME) in the United States. This paper sets forth principles inherent in these standards that address the relationship between GME and industry, with particular emphasis on pharmaceutical companies. The principles outlined herein should guide the efforts of teaching institutions and residency programs to promote reflective and unbiased learning and thus to help form competent professionals who serve the best interests of patients in a consistently ethical and exemplary fashion.

The Problem

A variety of industries have an impact on health care delivery in the United States. These include, but are not limited to, insurers, manufacturers of medical devices, pharmaceutical companies, and developers of educational products and offerings. While each represents a potential source of influence on physician practice, the pharmaceutical industry is decidedly one of the largest and most influential. As reported in 2001, investments in research to discover and identify new medicines by pharmaceutical manufacturers amounted to at least \$30.5 billion.¹ Wazana reports that pharmaceuticals' annual promotion and marketing expenditures are estimated to be in excess of \$11 billion, with \$8,000 to \$13,000 of these promotional dollars spent directly or indirectly per year on each physician.² While major benefits result from research and development by the pharmaceutical industry, the potential for conflict of interest from promotion and marketing also has been proven.^{3,4} This influence presents a serious threat to the professionalism both of physicians and the institutions that sponsor their educational programs.^{5,6}

In their broadest context, the goals of the medical profession and the pharmaceutical industry are aligned around efforts to improve human health through a direct and positive effect on patient care. Benefits to patients result from services provided by both doctors and drug companies. Closer scrutiny, however, of the core relationships maintained by each of these entities reveals an irreconcilable difference. The relationship to its shareholders defines values influences behaviors held by industry. Thus, for example, the responsibility of the pharmaceutical industry must be to act in the best interests of its shareholders by maximizing their return on investment. In so doing, much good is clearly accomplished for patients. In contrast, however, the altruism expected of medical professionals dictates that doctors put patients first. The doctor-patient relationship, with all its ensuing values, is the foundation of medical professionalism; the good of the patient must be preeminent.

The Challenge for Medical Education

The conflict of values between the professional ethics of the physician and the business ethics of industry is impossible to ignore. Nowhere is this conflict more apparent than in the conduct of promotional activities. Industry engages in advertising campaigns and associated marketing activities because they work; successful promotion increases shareholder value. It is the chief means by which industry relates to physicians, residents, and medical students. Promotion by industry, and pharmaceutical companies in particular, frequently occurs through financial support for a broad array of educational programs, industry-sponsored research, and social events. Many residency programs and clinical departments not only accept but also often actively seek such support, justifying this dependence on the serious budgetary constraints under which they must operate in an increasingly constrained financial environment. Unfortunately, such promotional support has been proven to influence medical decision-making, and studies have found decision makers unable to recognize its impact.^{7,8}

Faculty and residents alike communicate professional values through the learning environment created by sponsoring institutions and individual residency programs. The structured curriculum, i.e., conferences, grand rounds, and other formal learning activities, is the most obvious of the contexts in which transmittal of values occurs. While less apparent, though with equal and sometimes even greater intensity, the hidden or informal curriculum communicates values at the level of organizational structure and culture, influencing such areas as policy development, evaluation, resource allocation, and institutional slang.⁹ Transmittal of values thus becomes a pervasive component of the educational process relative to all manner of professional relationships within the sponsoring institution and individual training program. Residents learn to relate to industry in much the same manner they develop other professional relationships, by observing individual administration and faculty behavior in the context of the program and sponsoring institution. The learning environment, therefore, has a direct bearing on the "learned" professionalism of the residents training within it.¹⁰ Regrettably, with regard to support from industry, the learning environment often manifests an "entitlement to largesse of drug companies."⁵

Instances of inappropriate relationships with industry and its "largesse" are frequently found in the expectations for outside support demonstrated by residency programs and sponsoring institutions. Examples that have become all-too-familiar practices include: "drug lunches" with obvious promotional intent; industry-

sponsored lectures with negative results of clinical trials conveniently given less or no attention; and social functions attached to “information sessions” having a clearer marketing objective than scientific purpose. Recently, concern has arisen over a new variation of a promotional activity in which residents and even medical students receive slides, lecture materials and honoraria and subsequently act as “experts,” delivering the packaged information at continuing medical education events. The risk of compromising professional judgment resulting from these and other activities can be egregious, and both the profession and the public continue to express concern over blatant misuse of industry support.^{11,12,13}

Existing Guidelines

A number of organizations have developed guidelines for physicians and organizations about accepting gifts and support from industry. Most widely recognized among these guidelines are: the ethical opinion “Gifts to Physicians from Industry” found in the American Medical Association’s Code of Medical Ethics;¹⁴ the American College of Physicians-American Society of Internal Medicine position statement on “Physicians and the Pharmaceutical Industry”;^{15,16} “Physicians and the Pharmaceutical Industry” promulgated by the Canadian Medical Association;¹⁷ and, the Accreditation Council for Continuing Medical Education, through its Standards for Commercial Support.¹⁸ The Association of American Medical Colleges (AAMC) has specifically addressed issues regarding financial conflicts of interest in research through the work of its Task Force on Financial Conflicts of Interest in Research.¹⁹

These guidelines outline what constitutes ethical behavior for both physicians and organizations. Without exception, they establish that it is unethical for physicians to accept gifts or support in any form that results in recommendation of a particular product or delivery of particular clinical action. The Standards for Commercial Support¹⁸ regulate use of funds provided by pharmaceutical and other proprietary interests in the sponsorship of continuing medical education events.

The Role of the ACGME:

The General Competencies

The ACGME, through its Residency Review and Institutional Review Committees, has identified six general competencies for all physicians in its Program and Institutional Requirements. These competencies--Patient Care, Medical Knowledge, Practice-based Learning and Improvement, Interpersonal and Communication Skills, Professionalism, and Systems-based Practice--serve as organizing principles around which all GME residency curricula should be developed.²⁰ Residents must demonstrate achievement in these competencies during and upon completion of their residency program through appropriate educational outcomes. The residency program itself must demonstrate improvement based upon the outcomes identified through these assessment activities.

The competencies are not prescriptive rules; they are, however, a conceptual framework for defining program and institutional policies regarding all professional relationships in GME. At present, ACGME standards do not directly address the nature of the professional relationships that exist between residency programs, their sponsoring institutions, and industry. As such, they shed light on behaviors appropriate to the integrity and objectivity that must be maintained within a teaching environment. Using a framework shaped by the general competencies, the principles that follow should guide the conduct of the relationships maintained by residency programs and their sponsoring institutions with industry.

Professionalism

Professionalism is an expression of the norms that guide the relationships in which physicians are engaged.²¹ It is, therefore, the competency that stands at the core of how programs and institutions model behavior with regard to relationships with industry. In her review of the literature, Arnold has identified those traits commonly associated with professionalism as altruism, respect for others as embodied in humanistic qualities, honor, integrity, ethical behavior, accountability, excellence, a sense of duty, and advocacy.²² Ginsburg,

et.al., have described these traits as context-dependent, that is, demonstrated through behaviors that occur in particular circumstances, often manifesting themselves in conflicts between values.²³

Programmatic and institutional policies must therefore guide action in light of the inherent conflict of values between industry and the medical profession. The following principles promote Professionalism in programs and sponsoring institutions with regard to relationships with industry:

1. Ethics curricula must include instruction in and discussion of published guidelines regarding gift-giving to physicians. Among these guidelines are the ethical opinion “Gifts to Physicians from Industry” found in the Code of Medical Ethics of the American Medical Association,¹⁴ the Policy on Physician-Industry Relations of the American College of Physicians-American Society of Internal Medicine,^{15,16} “Physicians and the Pharmaceutical Industry” promulgated by the Canadian Medical Association,¹⁷ and the ethics statements of various medical specialty societies.
2. Full and appropriate disclosure of sponsorship and financial interests is required at all program and institution-sponsored events, above and beyond those already governed by the Standards for Commercial Support promulgated by the ACCME.¹⁸ Likewise, full disclosure of research interests must be published in keeping with the local policies of institutional review boards and following the recommendations of the Association of American Medical College’s (AAMC) Task Force on Financial Conflicts of Interest in Research.¹⁹
3. Programs and sponsoring institutions must determine through policy, which contacts, if any, between residents and industry representatives may be suitable, and exclude occasions in which involvement by industry representatives or promotion of industry products is inappropriate.

Practice-based Learning and Improvement and Medical Knowledge

Practice-Based Learning and Improvement refers to how physicians apply Medical Knowledge by investigating and evaluating their own patient care, appraising and assimilating scientific evidence, and making subsequent improvements in the care of their patients. The following principles informed by Practice-Based Learning and Improvement and Medical Knowledge, apply to the relationship between GME and industry:

1. Clinical skills and judgment must be learned in an objective and evidence-based learning environment.
2. Residents must learn how promotional activities can influence judgment in prescribing decisions and research activities through specific instructional activities.
3. Residents must understand the purpose, development, and application of drug formularies and clinical guidelines. Discussion should include such issues as branding, generic drugs, off-label use, and use of free samples.

Systems-based Practice

Systems-based Practice includes behaviors that demonstrate an awareness of and responsiveness to the larger context of health care and the ability to engage system resources to provide care that is of optimal value. The following principles of Systems-based Practice apply to relationships with industry:

1. Sponsoring institutions and programs must develop policies to assure that clinical skills and judgment are learned in objective and evidence-based clinical and teaching environments free from inappropriate influence. These policies must clarify the differences between education and promotion.
2. Teaching institutions must ensure that programs have sufficient funds from appropriate sources to conduct their educational activities.
3. Resident curricula should include how to apply appropriate considerations of cost-benefit analysis as a component of prescribing practice.

4. Advocacy for patient rights within health care systems should include attention to pharmaceutical costs.

Interpersonal and Communication Skills

Interpersonal and Communication Skills provide the foundation upon which the satisfactory relationship between doctor and patient central to medicine is established. With regard to relationships with industry, particular aspects of Interpersonal and Communication Skills should be fostered through application of the following principles:

1. Resident curricula should include discussion and reflection on managing encounters with industry representatives.
2. Illustrative cases of how to handle patient requests for medication, particularly with regard to direct-to-consumer advertising of drugs, should be included in communication skills curricula.

Conclusion

The principles outlined in the previous paragraphs cannot guarantee individual or institutional professional behavior. Evidence exists, however, that policies relating to sources of educational support appear to affect what physicians believe and how they behave.²⁴ The value of these principles, therefore, lies in their ability to inform policy and to represent to the public the integrity and objectivity of the professional relationships expected by residency programs and their sponsoring institutions. The ultimate goal of these relationships is to foster effective Patient Care, the general competency that underlies the mission of medical education.

Inappropriate promotional activities by industry seriously compromise the professional relationships maintained by residents, faculty, and patients that form the substance of medicine. These inappropriate activities must not be allowed to continue where they exist. The interests of the patient must be paramount and not contaminated by the profit-driven interests of industry for their shareholders. Residency programs and their sponsoring institutions must teach and model core values that are demonstrated by the general competencies. The public and the profession look to teaching institutions to demonstrate particular clarity around issues of patient advocacy, complete and unbiased medical knowledge, and the application of that knowledge to continually improve the practice of medicine.

¹ The Pharmaceutical Research and Manufacturers of America (PhRMA). New medicines new hope (annual report). 2001-2002. Available from URL: www.phrma.org/publications/publications/annual2001. accessed 10/18/01.

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⁴ Ross J, Lurie P, Wolfe S. Medical education service suppliers: a threat to physician education. Public Citizen's Health Research Group 2000 July 19. Available from URL: <http://www.citizen.org/publications/release.cfm?ID=7142>. accessed 01/14/02.

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