REPORT 1 OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS (A-11)
Financial Relationships with Industry in Continuing Medical Education
(Reference Committee on Amendments to Constitution and Bylaws)

EXECUTIVE SUMMARY

Relationships between medicine and industry—such as pharmaceutical, biotechnology, and medical device companies—have driven innovation in patient care, contributed to the economic well-being of the community, and provided significant resources (financial and otherwise) for professional education, to the ultimate benefit of patients and the public. The interests and obligations of medicine and industry diverge in important ways, however. An increasingly urgent challenge for both partners is to devise ways to preserve strong, productive collaborations for the benefit of patients and the public at the same time they each take clear, effective action to avoid relationships that could undermine public trust.

This report examines financial relationships between medicine and industry in the specific context of continuing medical education. It summarizes the ethical foundations of medicine's obligation to ensure that physicians acquire and maintain the knowledge, skills, and values that are central to the healing profession. The report analyzes the ethical challenges that can be posed when physicians who organize, teach in, or serve other roles in continuing medical education have financial relationships with companies that have a direct interest in physicians' recommendations and illustrates strategies for mitigating the potential of such financial relationships to influence professional education in undesired ways. It identifies core ethical principles of transparency, independence, and accountability and provides practical ethical guidance to maintain the independence and integrity of continuing professional education and promote public trust.

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REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS*

CEJA Report 1-A-11

Subject: Financial Relationships with Industry in Continuing Medical Education

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Referred to: Reference Committee on Amendments to Constitution and Bylaws
(Patricia L. Austin, MD, Chair)

Relationships between medicine and industry—such as pharmaceutical, biotechnology, and medical device companies—have driven innovation in patient care, contributed to the economic well-being of the community, and provided significant resources (financial and otherwise) for professional education, to the ultimate benefit of patients and the public.[1,2] The interests and obligations of medicine and industry diverge in important ways, however. An increasingly urgent challenge for both partners is to devise ways to preserve strong, productive collaborations for the benefit of patients and the public at the same time they each take clear, effective action to avoid relationships that could undermine public trust.

As relationships between medicine and industry have evolved, major national organizations, such as the Institute of Medicine (IOM)[3] and the Association of American Medical Colleges (AAMC)[4,5,6] have explored the challenges that these relationships can pose in research, clinical care, education, and beyond. Key stakeholders, including (among others) the Accreditation Council for Continuing Medical Education (ACCME),[7] the Council of Medical Specialty Societies (CMSS),[8] and the Pharmaceutical Research and Manufacturers Association (PhRMA)[9] have developed guidance to help their constituents sustain appropriate, productive, and professional interactions.

The American Medical Association was founded on the vision that as medical professionals, physicians should represent the highest standards of competence, integrity, and professionalism. This report carries that vision forward. It examines ethical aspects of medicine-industry relationships in continuing medical education (CME), explores ethical challenges that can be posed by financial relationships from the perspective of physicians, and provides guidance for members of the medical profession who attend or who organize, teach in, or serve other roles in CME.

The Council on Ethical and Judicial Affairs recognizes that pharmaceutical, biotechnology, and medical device companies are not the only entities with which financial relationships can raise concerns. CEJA likewise recognizes that CME is not the only domain of potential concern. However, narrowing our focus to CME allows us to explore the complex considerations at stake in

* Reports of the Council on Ethical and Judicial Affairs are assigned to the Reference Committee on Amendments to Constitution and Bylaws. They may be adopted, not adopted, or referred. A report may not be amended, except to clarify the meaning of the report and only with the concurrence of the Council.

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a manageable context and to provide practical ethical guidance on issues that increasingly challenge physicians as professionals.

LIFELONG LEARNING & MEDICINE'S DUTY TO EDUCATE

> *Publicly in his oath and privately in his encounter with the patient, the physician professes two things—to be competent to help and to help with the patient's best interests in mind.*
>
> — Edmund Pellegrino[10]

The practice of medicine is inherently a moral activity, founded in a "covenant of trust" between patient and physician.[10,11,12] The respect and autonomy that medicine enjoys rest on the profession's commitment to fidelity and service in the patient-physician relationship. To sustain that commitment, medicine must ensure that physicians acquire and maintain the knowledge, skills, and values that are central to the healing profession. In return, society grants medicine considerable authority to set the ethical and professional standards of practice and the autonomy to educate practitioners.[13,14]

The special moral character of the interaction between patient and physician arises from the need—illness or the prevention of illness—that brings the patient into the relationship. Physicians are granted extraordinary privileges to intervene in patients' lives. Patients entrust to physicians the care of their bodies and the protection of sensitive information revealed in confidence for the purpose of seeking healing. Educating current and future generations of physicians to fulfill the responsibilities that flow from the patient-physician relationship is the foundation of medicine's status as a caring and competent profession. Thus medicine's ethical duty to educate cannot be delegated to others.

Individual physicians have an ethical obligation to dedicate themselves to "continue to study, apply, and advance scientific knowledge" and to "maintain a commitment to medical education."[15] As professionals, practicing physicians are expected to commit themselves to lifelong learning and to maintain their clinical knowledge and skills through CME and other professional development activities.[16] That commitment is reflected not only in ethical expectations and standards, but also in requirements for licensure and specialty certification, as well as hospital credentialing.

Physicians and the patients who rely on them must be confident that treatment recommendations and clinical decisions are well informed and reflect up-to-date knowledge and practice. CME activities that are pedagogically sound, scientifically grounded, and clinically relevant are essential to ensure that physicians can provide the high quality of care their patients deserve. To achieve these goals, medicine has an ethical obligation to ensure that the profession independently sets the agenda and defines the goals of physician education; controls what subject matter is taught; determines physicians' educational needs; and takes steps to ensure the independence of educational content and of those who teach it. The importance of doing so may extend well beyond continuing education—as one commentary noted, "[w]hat is at stake is nothing less than the privilege of autonomy in our interactions with patients, self-regulation, public esteem, and a rewarding and well-compensated career."[17]

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CONTINUING MEDICAL EDUCATION

Continuing medical education today takes place in an environment that includes "promotional" activities, "certified CME," and noncertified CME. Promotional activities lie outside the scope of the present analysis and recommendations. As defined by the Food and Drug Administration (FDA), these are activities developed by or on behalf of a commercial entity and under the substantive influence of that entity to provide information on the therapeutic use of a product or service. They are governed by the labeling and advertising provisions of the Food, Drug, and Cosmetic Act,[18,19] and may constitute protected commercial speech.

"Certified CME" refers to educational activities developed and implemented in compliance with the certification requirements of the American Medical Association Physician Recognition Award (PRA) CME Credit System or the accrediting policies of the American Academy of Family Physicians or American Osteopathic Association.[20] Certified CME meets the requirements for Category 1 credit under AMA's PRA program, including compliance with Accreditation Council for Continuing Medical Education (ACCME) standards and with relevant AMA ethics policy.[21]

Beyond these formal categories lie activities designed to inform and educate practicing physicians that are neither promotion nor certified CME. These other activities may or may not be commercially supported, may or may not voluntarily adhere to AMA policy or ACCME Standards for Commercial Support℠ (even if they are not formally certified or offered by formally accredited providers), and may or may not be recognized by licensing bodies or credentialing boards as fulfilling CME requirements.

Physician involvement is critical in CME. Individually and collectively, physicians play key roles in educating their peers, as teachers, content developers, organizers of CME, or in other capacities.

Financial Relationships with Industry in CME

In the context of continuing medical education, relationships with industry that may pose challenges for the independence and objectivity of physician education include not only direct industry support of CME activities, but also financial relationships between industry and individual physicians involved in CME as faculty, content developers, or in other capacities.

Industry support for CME has declined in recent years, but commercial funding still accounts for approximately 40 percent of overall CME-related revenue, ranging from less than one percent to just over 60 percent across accredited CME providers.[22] A growing number of accredited providers—20 percent as of July 2009—no longer accepts any commercial support at all.[23]

Industry support helps to meet the costs of CME activities in the face of uncertain funding from other sources[24] and may help make CME more accessible, especially for physicians in resource-poor communities.[25] Industry engagement and support can be especially helpful in ensuring affordable CME when educational activities need high cost, sophisticated, rapidly evolving technology or devices. Along with lower costs, industry support may encourage greater participation than would otherwise be the case by providing amenities. As yet there is no peer-reviewed evidence to support or to refute the effect of industry funding on accessibility of or participation in CME activities.[26]

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However, there is growing concern within and outside medicine that industry funding for CME could have undesirable effects, including potentially biasing content toward funders' products and influencing the overall range of topics covered.[27,28,29,30] Importantly, where patients' health and public trust are concerned, the perception of bias, even if mistaken, can be as potentially damaging as the existence of actual bias.

Influence, Evidence & Ethics

Whether or how financial relationships influence CME activities or the overall CME curriculum is an important question. But answering this empirical question cannot resolve the core ethical challenge, no matter what the evidence should prove to be. Physicians are entrusted with the interests of patients. Where trust is central, the *appearance* of influence or bias can be as damaging as actual influence. Empirical evidence alone is not enough to overcome public skepticism. Even evidence that undesired consequences have not occurred cannot be expected by itself to restore confidence when trust has been compromised.

The available data neither support nor disprove that financial relationships influence CME. Standards have been established to address concerns about possible influence in CME, such as the ACCME Standards for Commercial Support.^{SM} The efficacy of those standards or other processes to address the potential for industry influence on content or the overall range of CME topics is difficult to determine. Several recent studies have suggested that the great majority of physicians attending CME activities do not perceive bias in the content of those activities, based on their responses to questions about bias on standard evaluations of CME activities.[31,32,33] As the authors themselves note, these studies are subject to limitations, such as the "insensitivity of simple 'yes/no' questions to assess learners' perceptions of bias."[33, cf. 32, cp., 34]

Other research indicates that individual physicians, like everyone else, are subject to influence, even if they are not aware of how industry support of a CME activity could affect their clinical decisions.[35,36,37,38,39] Further, a recent review of the relevant literature found that although there is clear evidence that CME influences physicians' prescribing practices, the question of what effect changes in prescribing have on actual patient outcomes has not specifically been studied.[39]

To maintain productive relationships with industry that benefit patients and to sustain the trust on which the patient-physician relationship and public confidence in the profession depend, medicine must take steps to safeguard the independence and integrity of physician education.

ENSURING THE INDEPENDENCE & INTEGRITY OF CME

CEJA recognizes that competing interests are a fact of life for everyone, including but not limited to physicians. For physicians, however, even very modest potential or perceived competing interests can put trust at risk. As individuals and as a profession, physicians have a responsibility to protect the quality of professional education and the reputation of medicine. While competing interests cannot be eliminated entirely, prudent judgments can be made about how to minimize potential influence and prevent or reduce undesired consequences.

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Minimizing the Opportunity for Influence

Physicians should aspire to avoid the potential for influence or the chance that confidence in the integrity and independence of their professional education could be diminished. Avoiding entirely situations in which there is potential for influence has the virtue of ethical clarity and practical simplicity. CME that is free of financial relationships with companies that have direct interests in physicians' recommendations strongly underscores medicine's defining professional commitment to independence and fidelity to patients. Avoiding such relationships also has the practical advantage of eliminating the administrative and resource costs that must otherwise be devoted to mitigating influence,[40] costs that may be particularly challenging for smaller CME providers.[25]

In their roles as CME providers, content developers, and faculty, physicians should strive to avoid financial relationships with industry. The Institute of Medicine has called for development of a new system of funding CME that is free of industry influence.[3] Medicine should cultivate alternative sources of support, should design and conduct educational activities so as to reduce costs, and should insist that content developers and faculty members not have problematic ties with industry to ensure independent, unbiased, high quality educational programming that best meets physicians' needs and is accessible and affordable for all practitioners.

Changing the terms of financial relationships likewise can help minimize the potential for influence. For example, physicians who have decision-making authority in organizations that provide CME could set an upper limit on how great a proportion of the organization's income derives from industry support to ensure that the organization does not become overly reliant on commercial funding. Asking physicians who teach in or develop content for a CME activity to refrain from accepting compensation (honoraria, consulting fees, etc.) for a defined period before and after the activity from a commercial supporter that has an interest in the educational subject matter could similarly promote independence. Decisions to require that physicians involved in CME as faculty members or in other roles change the terms of their relationships with industry must, of course, be made fairly and consistently across individual cases.

That said, it is not always feasible, or necessarily desirable, for professional education to disengage from industry completely. In some situations financial relationships with industry can be ethically justifiable. When not accepting support from a commercial source or not permitting participation by individuals who have financial interests in the educational subject matter would significantly undermine medicine's capacity to ensure that physicians have access to appropriate, high-quality CME, it can be acceptable to permit such support or participation. In these situations, vigorous efforts must be made to mitigate the potential influence of financial relationships.

Mitigating Potential Influence

While there should be a presumption that physicians who organize, design, develop content, or teach in CME should not have concurrent financial ties to industry related to their CME responsibilities, it is important to recognize that not all relationships with industry are equally problematic. A relationship that is only indirectly related to an educational activity, modest in scope, or distant in time is not likely to adversely affect—or be perceived to affect—the activity in question. For example, having once conducted sponsored research or accepted a modest honorarium for speaking on behalf of a company would not necessarily create such clear potential

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for bias as to preclude an individual with the appropriate expertise from developing content or serving as a faculty member for a given CME activity.[41]

Financial relationships that are direct or substantial, however, have significant potential to undermine confidence in educational activities, even if they do not actually compromise those activities. Examples of a direct or substantial financial interest include ownership or equity interest in a company that has an interest in the educational subject matter of a CME activity or royalties or ongoing compensated relationships (e.g., consulting arrangements or service on scientific advisory bodies or speakers bureaus).[4] Relationships that involve fiduciary responsibilities on behalf of the funder (such as service on a corporate board of directors) or decision-making authority in financial matters can be similarly problematic.[42] In such situations, ethically strong practice requires that steps be taken to mitigate the possible influence of financial relationships on educational activities.

PRINCIPLES FOR SUSTAINING TRUST

The goal of mitigation is to promote–and enhance confidence in–the integrity of continuing professional education. Commitment to transparency, independence, and accountability enables physicians to achieve that goal, whatever role they may play in CME. Moreover, being transparent about financial relationships that have the potential to influence CME and forthcoming about what steps have been taken to minimize possible influence supports physician-learners in exercising critical judgment individually as "consumers" of CME.

Transparency

As the ACCME Standards for Commercial Support[SM] recognize, transparency—i.e., disclosing the existence of a financial relationship—is a necessary first step in mitigating the potential of financial relationships to create bias (or the appearance of bias),[7] but it is not sufficient and may even have perverse effects. Disclosure places the burden on learners themselves to determine how skeptical they should be about possible bias in an educational activity.[43] To the extent that disclosure fosters the impression that the presenter is particularly honest and trustworthy, it can encourage false confidence in the activity. To the extent that the presenter believes disclosing a financial relationship is adequate to mitigate its potential influence, he or she may be less circumspect in ensuring content is free of such influence.

While transparency is essential, disclosing financial relationships is necessary but not sufficient to mitigate the potential for influence in CME.

Independence

Taking concrete steps to ensure that CME is independent and objective is equally important. Creating a "firewall" between funders and decisions about educational goals, content, faculty, pedagogical methods and materials, and other substantive dimensions of CME activities can help protect the independence of professional education. Both ACCME and the Inspector General of the Department of Health and Human Services have recommended clearly separating decisions about funding from substantive decisions about CME activities,[7,19] and many organizations are developing models, such as "blind trusts," to do so.[e.g.,44,45] Support of individual CME activities by multiple, competing funders may also help diffuse the potential influence of any one

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funder. Carrying out educational needs assessments prior to seeking or accepting commercial support or identifying faculty can similarly enhance the independence of the planning process and resulting CME programming. Likewise, having prospective peer review of a presentation (review of slides or other forms of communication in advance of the presentation by an objective and independent expert who has the power to require changes prior to the public showing) can help ensure that the presentation is free of commercial bias.

Accountability

Physician-learners, patients, the public, and the medical community as a whole should be able to be confident that physicians who organize, design, develop content, or teach in CME will uphold principles of transparency and independence. The expectation that physicians involved in CME will hold themselves accountable to address the potential that financial relationships with industry have to influence professional education is a cornerstone of self-regulation. That responsibility can be greatly enhanced by the efforts of accrediting and certifying bodies, but it cannot be supplanted by them. In particular, physician leaders in CME should be able and willing to discuss how the principles of transparency and independence have been applied in the educational activities with which they are involved or over which they have decision-making authority.

Exceptional Cases

At times it may be impossible to avoid a financial interest or extraordinarily difficult or even impossible to mitigate its potential impact on an educational activity. For the most part, accepting support from a company or permitting participation by an individual when there is an irreducible financial interest would not be ethically acceptable. However, in certain circumstances, it may be justifiable.

Such circumstances include instances when accessible, high-quality CME cannot reasonably be carried out without support from sources that have a direct financial interest in physicians' clinical recommendations, such as activities that require cadavers or high-cost, sophisticated equipment to train physicians in new procedures or the use of new technologies. Similarly, in the earliest stage of adoption of a new medical device, technique, or technology the only individuals truly qualified to train physicians in its use are often those who developed the innovation. These individuals may have the most substantial and direct interests at stake, whether through employment, royalties, equity interests or other direct financial interests in the adoption and dissemination of the new technology. Physicians who organize CME should be transparent about what considerations led them to decide to permit an individual with a problematic financial interest to participate in a particular CME activity to ensure that such decisions are justifiable and persuasive to the professional community at large.

Putting Principles into Practice – The Exercise of Judgment

Inevitably, putting principles of transparency, independence, and accountability into practice calls for the exercise of judgment. It requires knowledge of the particular circumstances and thoughtful deliberation. Yet this is no different from the kinds of judgments physicians routinely make in the context of caring for patients and applying other portions of the *Code of Medical Ethics* to their daily practice.

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One approach is to reflect on what "consumers" of CME (which arguably includes patients and the broader professional community, as well as individual physician-learners) would want to know to exercise their skills of critical judgment; that is, to make well-considered judgments for themselves about the objectivity and quality of a CME activity, its faculty, and its educational content. Such factors might include not only the existence of a financial interest(s), but equally the source of that interest, the type of interest (such as honoraria, consulting fees, equity, stock options, royalties), and the magnitude of the interest, e.g., dollar amount to the nearest $1,000, as currently required by the North American Spine Society.[46]

Similarly, consumers of CME could reasonably want to know how the potential influence of a financial interest has been addressed to protect the independence of the activity; or consumers may want to know on what grounds an individual who has a direct, substantial, and unavoidable financial interest has been permitted to participate in a CME activity. In the latter case, for example, reasonable decision-making criteria might include that the dissemination of the device, technique or technology will be of significant benefit to patients and to the public and the professional community; that the individual is uniquely qualified as an expert in the relevant body of knowledge or skills; that the individual discloses the source, nature, and magnitude of the specific financial interest at stake; that there is demonstrated, compelling need for the specific CME activity; that all feasible steps are taken to mitigate influence; and that this expert's participation in dissemination will, eventually, enable those without such financial interests to take on the educational role. An individual might be considered "uniquely qualified" when he or she is the only expert (or one of a few) who has significant knowledge about or experience in treating a rare disease or was involved in the early development or testing of a new treatment, device, or technology. A "compelling need" for a particular educational activity may be present when a new therapy becomes available to treat a disease present in the local community for which the new treatment represents a substantial improvement.
The need to rely on "conflicted expertise" can be affected by local conditions—CME in small or rural communities, for example, may not always have ready access to experts who are free of problematic ties to industry. In any event, when a substantial body of peer-reviewed evidence has evolved in a given subject area, or when a cohort of individuals without direct, substantial interests has become experienced in using a new medication, device, or technology and is available to teach, using a "uniquely qualified" expert becomes less justifiable.

As the professional community gains experience, it is to be expected that consensus will coalesce around core interpretations. As Harvard Medical School notes in its conflict of interest policy:

> These classifications are not intended to serve as a rigid or comprehensive code of conduct or to define "black letter" rules with respect to conflict of interest. It is expected that the guidelines will be applied in accordance with the spirit of the mission of Harvard Medical School in education, research and patient care. By this process, it is expected that a common institutional experience in the application of these guidelines will gradually evolve.[47]

We expect that a similar shared understanding of how principles of transparency, independence, and accountability should apply to financial relationships with industry in continuing medical education will evolve for the medical profession.

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RECOMMENDATION

The Council on Ethical and Judicial Affairs recommends that the following be adopted and the remainder of this report be filed:

In an environment of rapidly changing information and emerging technology, physicians must maintain the knowledge, skills, and values central to a healing profession. They must protect the independence and commitment to fidelity and service that define the medical profession.

Financial or in-kind support from pharmaceutical, biotechnology or medical device companies that have a direct interest in physicians' recommendations creates conditions in which external interests could influence the availability and/or content of continuing medical education (CME). Financial relationships between such sources and individual physicians who organize CME, teach in CME, or have other roles in continuing professional education can carry similar potential to influence CME in undesired ways.

CME that is independent of funding or in-kind support from sources that have financial interests in physicians' recommendations promotes confidence in the independence and integrity of professional education, as does CME in which organizers, teachers, and others involved in educating physicians do not have financial relationships with industry that could influence their participation. When possible, CME should be provided without such support or the participation of individuals who have financial interests in the educational subject matter.

In some circumstances, support from industry or participation by individuals who have financial interests in the subject matter may be needed to enable access to appropriate, high-quality CME. In these circumstances, physician-learners should be confident that that vigorous efforts will be made to maintain the independence and integrity of educational activities.

Individually and collectively physicians must ensure that the profession independently defines the goals of physician education, determines educational needs, and sets its own priorities for CME. Physicians who attend CME activities should expect that, in addition to complying with all applicable professional standards for accreditation and certification, their colleagues who organize, teach, or have other roles in CME will:

(a) be transparent about financial relationships that could potentially influence educational activities.

(b) provide the information physician-learners need to make critical judgments about an educational activity, including:

  (i) the source(s) and nature of commercial support for the activity; and/or

  (ii) the source(s) and nature of any individual financial relationships with industry related to the subject matter of the activity; and

  (iii) what steps have been taken to mitigate the potential influence of financial relationships.

(c) protect the independence of educational activities by:

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(i) ensuring independent, prospective assessment of educational needs and priorities;

(ii) adhering to a transparent process for prospectively determining when industry support is needed;

(iii) giving preference in selecting faculty or content developers to similarly qualified experts who do not have financial interests in the educational subject matter;

(iv) ensuring a transparent process for making decisions about participation by physicians who may have a financial interest in the educational subject matter;

(v) permitting individuals who have a substantial financial interest in the educational subject matter to participate in CME only when their participation is central to the success of the educational activity; the activity meets a demonstrated need in the professional community; and the source, nature, and magnitude of the individual's specific financial interest is disclosed; and

(vi) taking steps to mitigate potential influence commensurate with the nature of the financial interest(s) at issue, such as prospective peer review.

(New HOD/CEJA Policy)

Fiscal Note: Staff cost estimated at less than $500 to implement.

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