

REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS*

CEJA Report 1-I-09

Subject: Financial Relationships with Industry in Continuing Medical Education

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Referred to: Reference Committee on Amendments to Constitution and Bylaws
(John W. Spurlock, MD, Chair)

1 The practice of medicine is inherently a moral activity, founded in a “covenant of trust” between
2 patient and physician.^{1,2,3} The respect and autonomy that medicine enjoys rest on the profession’s
3 commitment to fidelity and service in the patient-physician relationship. To sustain that
4 commitment, medicine must ensure that physicians acquire and maintain the knowledge, skills, and
5 values that are central to the healing profession. In return, society grants medicine considerable
6 authority to set the ethical and professional standards of practice and the autonomy to educate
7 practitioners.^{4,5}

8
9 In recent decades, relationships between medicine and industry—by which we mean
10 pharmaceutical, biotechnology, and medical device companies—have driven innovation in patient
11 care, contributed to the economic well-being of the community, and provided significant resources,
12 financial and otherwise, for professional education, to the ultimate benefit of patients and the
13 public. In the end, however, the interests and obligations of medicine and industry diverge in
14 important ways, rendering these relationships double edged. Where medicine’s overriding
15 responsibility is to put the needs of patients first, commercial entities must serve their shareholders
16 and other vested stakeholders even as they engage in efforts to improve health and health care.

17
18 An increasingly urgent challenge for both medicine and industry is to devise ways to preserve
19 strong, productive collaborations for the benefit of patients and the public at the same time they
20 take clear, effective action to prevent relationships that damage public trust and tarnish the
21 reputations of both parties. Medicine must address growing concern that financial ties to industry,
22 in particular, carry ethical risks for the independence and integrity of professional education.

23
24 Medicine-industry relationships occur in research, clinical care, and beyond, not just in education,
25 of course. The Council also recognizes that pharmaceutical, biotechnology, and medical device
26 companies are not the only entities—commercial or otherwise—with which financial relationships
27 can raise concerns. Yet to attempt to address the range of ethical questions that can arise across all
28 of these different domains and among all of the different stakeholders is too ambitious a goal for a
29 single analysis. Thus this report focuses on issues raised by financial relationships with industry for
30 continuing medical education (CME). This allows us to explore the complex considerations at
31 stake in a manageable context and to provide practical ethical guidance on issues that increasingly
32 challenge medicine as a profession. It can lay the foundation for future analyses that address
33 similar concerns as they arise in other domains and among other stakeholders.

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1 LIFELONG LEARNING & MEDICINE’S DUTY TO EDUCATE

2
3 *Publicly in his oath and privately in his encounter with the patient, the physician professes*
4 *two things—to be competent to help and to help with the patient’s best interests in mind.*
5 —Edmund Pellegrino
6

7 The special moral character of the interaction between patient and physician arises from the need—
8 illness—that brings the patient into the relationship. Physicians are granted extraordinary privileges
9 to intervene in patients’ lives, to impose harm in the service of healing, to gain access to sensitive
10 information, and to engage in intimate contact with patients that would otherwise be prohibited.
11 Educating current and future generations of physicians to fulfill the responsibilities that flow from
12 the patient-physician relationship is the foundation of medicine’s status as a caring and competent
13 profession. Therefore, medicine’s ethical duty to educate cannot be delegated to others.
14

15 Individual physicians have an ethical obligation to dedicate themselves to “continue to study,
16 apply, and advance scientific knowledge” and to “maintain a commitment to medical education.”⁶
17 As professionals, practicing physicians are expected to commit themselves to lifelong learning and
18 to maintain their clinical knowledge and skills through CME and other professional development
19 activities.⁷ That commitment is reflected not only in ethical expectations and standards, but also in
20 requirements for licensure and specialty certification, as well as hospital credentialing.
21

22 Given the wide array of diagnostic and therapeutic options available today, physicians and the
23 patients who rely on them must be confident that treatment recommendations and clinical decisions
24 are well informed and reflect up-to-date knowledge and practice. CME activities that are
25 pedagogically sound, scientifically grounded, and clinically relevant are essential to ensure that
26 physicians can provide the high quality of care their patients deserve. To achieve these goals,
27 medicine has an ethical obligation to ensure that the profession itself sets the agenda and defines
28 the goals of physician education; controls what subject matter is taught; determines physicians’
29 educational needs; and takes steps to ensure the objectivity of educational content and of those who
30 teach it.
31

32 Despite the clear potential for benefit from strong working relationships with industry, there is
33 concern that medicine’s reliance on industry support to CME providers, as well as individual
34 financial ties between content developers or faculty and industry, undermines this independence
35 and objectivity. The implications may extend well beyond continuing education—as one recent
36 commentary noted, “[w]hat is at stake is nothing less than the privilege of autonomy in our
37 interactions with patients, self-regulation, public esteem, and a rewarding and well-compensated
38 career.”⁸
39

40 CONTINUING MEDICAL EDUCATION

41
42 Continuing medical education today takes place in a complex, dynamic environment that hosts a
43 mix of “promotional,” “certified,” and other activities. As defined by the Food and Drug
44 Administration (FDA), promotional activities are those developed by or on behalf of a commercial
45 entity and under the substantive influence of that entity that are designed to market health care
46 products or services. Promotional activities, which provide information on the therapeutic use of a
47 product or service, are governed by the labeling and advertising provisions of the Food, Drug, and
48 Cosmetic Act.^{9,10} Promotional activities may constitute protected commercial speech. These
49 industry-developed, FDA-regulated activities lie outside the scope of the present analysis and
50 recommendations. Our immediate concern is with certified and other (nonpromotional) educational
51 activities.

1 “Certified CME” refers to educational activities developed and implemented in compliance with
2 the certification requirements of the American Medical Association Physician Recognition Award
3 (PRA) CME Credit System, or the accrediting policies of the American Academy of Family
4 Physicians or American Osteopathic Association.¹¹ Certified CME meets the requirements for
5 Category 1 credit under AMA’s PRA program, including compliance with Accreditation Council
6 for Continuing Medical Education (ACCME) standards and with relevant AMA ethics policy.¹²

7
8 Beyond these formal categories lie activities designed to inform and educate practicing physicians
9 that are neither certified CME nor “industry-developed, FDA-regulated activities.” These other
10 activities may or may not be commercially supported, may or may not voluntarily adhere to AMA
11 policy or ACCME Standards for Commercial SupportSM despite not being formally certified or
12 accredited, and may or may not be recognized by licensing bodies or credentialing boards as
13 fulfilling local CME requirements.

14 *Industry Support of CME Providers*

15
16
17 Over the past decade, medicine has come to rely significantly on commercial funding to support
18 professional education across the learning continuum. With respect to CME, industry support now
19 accounts for more than half of all income to CME providers accredited by ACCME. Between 1998
20 and 2006, commercial support of providers accredited by ACCME increased by 300 percent to
21 \$1.2 billion.¹³ There is some evidence that the rate of growth in industry support of CME may be
22 leveling off, or even declining slightly.^{14,15}

23
24 Commercial funding is not uniformly distributed across the community of diverse CME providers,
25 which includes medical professional groups (such as state and local medical associations, as well as
26 national specialty societies), hospitals, academic medical centers, and commercial providers (such
27 as medical publishing/communication companies). In 2007 (the most recent year for which data are
28 publicly available), medical schools, which accounted for 46 percent of all certified CME hours,
29 received 20 percent of the overall total of commercial funding; publishing/education companies,
30 which accounted for nine percent of overall certified CME hours, received 49 percent of all
31 commercial funding.¹⁶ Because ACCME has not yet established a uniform reporting protocol for
32 nationally accredited providers, it is impossible to know with any real accuracy what proportion of
33 CME providers’ annual budgets derive from commercial entities.

34
35 Industry support for CME helps to meet the costs of programs and activities in the face of uncertain
36 funding from other sources.¹⁷ By helping to reduce costs to individual attendees industry support
37 may make CME more accessible, especially for physicians in resource poor communities. Along
38 with lower costs, by providing amenities that make participation attractive, industry support may
39 encourage greater participation than would otherwise be the case, although there is no evidence
40 either to support or to refute this hypothesis.¹⁸ For some medical specialties that rely on high cost,
41 sophisticated, rapidly evolving technology or devices, industry engagement in and support of CME
42 may be essential. At the same time, however, there is growing concern within and outside medicine
43 that industry funding can have undesired effects on CME.

44
45 At present there is no clear evidence to settle the question whether such concerns are borne out
46 empirically. Studies suggesting a link between industry-funded educational activities and
47 prescribing practices predate the ACCME Standards for Commercial SupportSM. Cervero and He
48 concluded from their review of the relevant literature that “to date there is no empirical evidence to
49 support or refute the hypothesis that CME activities are biased.”¹⁹ They note that while there is
50 ample evidence that CME affects physicians’ prescribing practices, no studies have looked

1 specifically at the impact of prescribing changes on patient outcomes and thus cannot answer the
2 important question of whether observed changes in practice were or were not in patients' interest.

3
4 However, there is evidence to suggest that industry support can influence the overall topics,
5 speakers, and educational content of CME. Companies make educational grants consistent with
6 their business strategies and therapeutic areas of interest,^{20,21} which may tend to shift education
7 toward benefiting funders and away from serving patient interests.²² Industry-supported CME
8 programs tend to address a narrower range of topics,²³ focus more on drug therapies,²⁴ and give
9 more favorable treatment to company products²⁵ than do programs that are not funded by industry.

10
11 The available data by no means demonstrate conclusively that commercial funding unduly biases
12 continuing professional education. They do suggest, however, that in addition to its primary *ethical*
13 commitments, medicine has reason to be concerned about possible unintended and undesirable
14 effects of industry support and should take steps to address the potential for industry funding to
15 undermine—or be perceived to undermine—the quality and credibility of CME.

16 17 *Individual Relationships with Industry*

18
19 In addition to concerns about the effects of industry funding for CME providers, there are concerns
20 about how financial ties with industry may affect the objectivity of individual physicians and others
21 who develop content for or teach in CME activities. We must be clear: Our concern is not with
22 egregious lapses of judgment or with corruption, but with the subtle bias that financial ties create.
23 Research indicates that relationships in which benefits—financial compensation, gifts, favors, or
24 other perceived benevolent gestures—are bestowed on one party by another introduce unconscious
25 bias favoring the giver. This occurs independent of the magnitude of the perceived benefit and even
26 when individuals are alert to the possibility of bias and strive to be objective.^{26,27,28} Emerging
27 neurobiological data confirm that such influence operates below the level of conscious awareness.²⁹
28 As Cervero and He note, the majority of physicians “may not be aware of how industry support of
29 a CME activity may influence their clinical decisions.”³⁰

30
31 What has not been as clearly demonstrated is to what extent the amount of a financial interest may
32 influence perception and judgment. Although clear evidence is lacking, most policies on conflict of
33 interest at least tacitly assume that the greater the financial interest, the more problematic that
34 interest is. Yet different institutions set the threshold of concern at significantly different amounts.
35 For example, the University of Massachusetts–Worcester requires faculty members involved in
36 nonclinical research to disclose financial interests in commercial entity of more than 5 percent
37 equity or \$100,000, while faculty involved in clinical research must disclose all equity interests and
38 nonequity interests over \$1,000.³¹ Northwestern University, meanwhile, requires reporting of
39 external income above \$10,000 a year.³² Trying to define any specific threshold is essentially an
40 arbitrary exercise.

41 42 *New Trends in Institutional Policy*

43
44 As relationships between medicine and industry have come under greater public scrutiny in recent
45 years, many academic medical centers, state and medical specialty societies, and health care
46 organizations have moved toward policies that more vigorously address the potential for conflict of
47 interest and bias with respect to physicians' interactions with industry. While many of these
48 policies focus particularly on gifts, consulting arrangements, and other specific physician-industry
49 relationships, several also address CME. For example, since September 2008 Stanford School of
50 Medicine has prohibited direct commercial support for individual CME activities, requiring that
51 (unrestricted) support from commercial funders be made to its Center for CME for broadly defined

1 areas of interest.³³ The University of Pittsburgh similarly requires that industry support of CME be
 2 negotiated through the university's Center for Continuing Education in the Health Sciences.³⁴

3
 4 State medical societies have begun adopting similar policies with respect to industry support for
 5 their CME activities. The nonprofit Physicians' Institute for Excellence in Medicine, affiliated with
 6 the Medical Association of Georgia (MAG) serves as an intermediary between state CME
 7 providers and industry funders not only for the MAG, but for 11 other state medical societies as
 8 well.³⁵ The Wisconsin Medical Society's newly updated policy on conflict of interest maintains
 9 that a CME provider should not accept industry support directly, but should create a fund to which
 10 commercial supporters may make unrestricted donations, with funding subsequently dispersed to
 11 CME programs according to publicly disclosed policies adopted by the fund.³⁶

12
 13 Medical specialty societies at the local and national level are also taking a new stance toward
 14 commercial supporters of their educational programming. Under policy adopted in 2006, the North
 15 American Spine Society (NASS) requires disclosure not only by speakers, faculty, and moderators
 16 in NASS educational activities, but also by audience members who offer comments or questions.
 17 NASS members are expected to encourage disclosure when they believe there has been a lapse and
 18 report ongoing failure to disclose. Members who fail to disclose their financial interests are subject
 19 to discipline through the organization's Professional Conduct and Ethics Committee.³⁷ In
 20 November 2007, the Oregon Academy of Family Physicians (OAFP) discontinued accepting
 21 industry support for OAFP-sponsored CME activities.³⁸ The Academy also seeks to evaluate
 22 industry's role in developing third-party programs it considers offering to its membership.

23 24 ENSURING THE INDEPENDENCE, OBJECTIVITY & INTEGRITY OF CME

25
 26 Financial relationships inevitably create conditions for conflict of interests that can undermine—or,
 27 just as important, *appear* to undermine—independence and objectivity. There are three options to
 28 address such undesired consequences: avoid the possibility altogether by not permitting conditions
 29 that give rise to potential bias or influence; implement strategies to mitigate actual or perceived
 30 bias or influence; or both. Each option has ethical and practical advantages and disadvantages.

31 32 *Avoiding Conditions that Can Compromise the Integrity of CME*

33
 34 The ethical aspiration should be to avoid potential bias altogether. In the context of CME, this
 35 would mean declining to accept or seek support for professional education activities from
 36 commercial funders who have significant financial interests in physicians' clinical decisions.
 37 Avoiding the potential for influence entirely has the virtue of ethical clarity and practical
 38 simplicity. Doing so would strongly underscore medicine's defining professional commitment to
 39 independence, objectivity, and fidelity to patients. Eliminating industry funding would have the
 40 further practical advantage of eliminating the administrative and resource costs that must otherwise
 41 be devoted to mitigating influence.³⁹ These costs may be particularly challenging for smaller CME
 42 providers, notably at the state and local level.⁴⁰

43
 44 CME providers, content developers, and faculty should strive to avoid financial relationships with
 45 industry. In testimony to the U.S. Senate Special Committee on Aging, ACCME indicated that as
 46 of July 2009 some 20 percent of nationally accredited CME providers no longer accept commercial
 47 support.⁴¹ The Institute of Medicine has called for development of a new system of funding CME
 48 that is free of industry influence.⁴² Medicine should cultivate alternative sources of support, should
 49 design and conduct educational activities so as to reduce costs, and should identify content
 50 developers and faculty members who do not have problematic ties with industry, to ensure

1 independent, unbiased, high quality educational programming that best meets physicians' needs
2 and is accessible and affordable for all practitioners.

3
4 Yet it is not always feasible, or necessarily desirable, for professional education to disengage from
5 industry completely. Thus we must also define conditions under which maintaining financial
6 relationships with industry can be ethically justifiable. Such conditions involve implementing
7 strategies to mitigate the potential for bias or influence when not accepting support from a
8 commercial source would significantly undermine medicine's capacity to ensure that physicians
9 have access to appropriate, high quality CME.

10 11 *Mitigating Potential Influence That Cannot Be Avoided*

12
13 While there should be a strong presumption that CME providers, content developers, and faculty
14 members should not have concurrent financial ties to industry, it is important to recognize that not
15 all relationships with industry are equally problematic. A relationship that is only indirectly related
16 to an educational activity, modest in scope, or distant in time is not likely to adversely affect—or
17 be perceived to affect—the activity in question. For example, having once conducted sponsored
18 research or accepted a modest honorarium for speaking on behalf of a company would not
19 necessarily create such clear potential for bias as to preclude an individual with the appropriate
20 expertise developing content or serving as a faculty member for a given CME activity.⁴³

21
22 Financial relationships that are direct or substantial, however, have significant potential to
23 undermine the independence and objectivity of educational activities. Examples of direct and/or
24 substantial financial interests include ownership or equity interest in the industry funder, royalties,
25 ongoing compensated relationships (e.g., consulting arrangements or service on scientific advisory
26 bodies or speakers bureaus),⁴⁴ or relationships that involve fiduciary responsibilities on behalf of
27 the funder (such as service on a corporate board of directors) or decision-making authority in
28 financial matters.⁴⁵ Similarly, some essential educational activities may not be feasible without
29 financial or in-kind support from industry—for example the provision of cadavers or high-cost,
30 sophisticated equipment to train physicians in new surgical procedures or the use of new
31 technologies. Such support may be vital to the professional community, but, like individual
32 financial ties, also creates potential for bias. When commercial funding, in-kind support, or
33 participation in CME by individuals or organizations that have direct, substantial financial ties with
34 an industry funder cannot reasonably be avoided, ethically strong practice requires that strategies
35 be implemented to mitigate the possible influence of such ties on educational activities.

36
37 Transparency is essential in mitigating the potential of financial relationships to create bias (or the
38 appearance of bias). As the ACCME Standards for Commercial SupportSM recognize, disclosing
39 the existence of a financial relationship is a necessary first step,⁴⁶ but it is not sufficient and may
40 even have perverse effects. Disclosure places the burden on those to whom it is made—in our
41 context, it requires learners themselves to determine how skeptical they should be about the
42 objectivity of an educational activity.⁴⁷ To the extent that disclosure fosters the impression that the
43 presenter is particularly honest and trustworthy, it can encourage false confidence in the objectivity
44 of the activity.⁴⁸ To the extent that the presenter believes disclosing a financial relationship is
45 adequate to mitigate its potential influence, the individual may not strive as hard to ensure
46 objectivity.⁴⁹ Disclosure plays an important role in mitigating the potential influence of financial
47 relationships, one whose value may be enhanced when both the existence and the magnitude of a
48 financial relationship is disclosed,⁵⁰ but it cannot be the only strategy relied on.

49
50 Creating a “firewall” between industry funders and decisions about educational goals, content,
51 faculty, pedagogical methods and materials, and other substantive dimensions of CME activities is

1 also an important strategy for mitigating the influence of financial relationships. Both ACCME and
2 the Inspector General of the Department of Health and Human Services have recommended clearly
3 separating decisions about funding from substantive decisions about CME activities. ACCME
4 standards require that a CME provider ensure the independence of key decisions, although the
5 standards do not provide specific guidance about how to do so.⁵¹ (HHS guidance for industry
6 requires that manufacturers clearly separate their sales and marketing functions from their grant-
7 making functions.⁵²) Emerging strategies to create strong firewalls include pooling monies from
8 multiple commercial sources and disbursing support to individual activities through a “blind trust”
9 model. In such models, funders have no knowledge of which programs their grants or gifts
10 supported,⁵³ nor are CME providers, content developers, or faculty aware of which funder
11 supported their activities. Where it is not feasible to create a blind trust to manage industry support,
12 one strategy to help protect the independence and integrity of CME would be to have activities
13 routinely supported by multiple, competing funders.

14
15 Another way to mitigate the influence of financial relationships when they cannot be eliminated is
16 to change the terms of those relationships. A CME provider, for example, could set an upper limit
17 on how great a proportion of its income derives from industry support to avoid becoming overly
18 reliant on commercial funding. Among individuals who develop content for or teach in CME
19 activities, strategies must be tailored to the nature and magnitude of their varying individual
20 relationships. For example, physicians participating as content developers or faculty in a CME
21 activity could be required to desist from speaking on behalf of the activity's industry supporter for a
22 defined period before and after the activity. Similarly, an individual could forgo royalties or other
23 compensation from the company for a defined interval following his or her participation (whether
24 as content developer or faculty) in an industry-funded CME activity. It will be important, of course,
25 that in seeking to change the terms of problematic relationships decisions be made fairly and
26 consistently across individual cases.

27 *Exceptional Cases: Conflicted But Essential Expertise*

28
29
30 Sometimes a financial interest cannot be avoided and is extraordinarily difficult or even impossible
31 to mitigate. In most cases, participation in CME by providers, content developers, or faculty
32 members who have direct, and unavoidable financial interests would not be ethically acceptable.
33 However, in certain compelling circumstances, it may be justifiable to allow such participation—
34 for example, when an individual who has a significant financial interest to participate in a CME
35 activity has unique expertise. In the earliest stage of adoption of a new medical device, technique,
36 or technology, the only individuals truly qualified to train physicians in its use are often those who
37 developed the innovation. Yet these are the very individuals who often have the most substantial
38 and direct interests at stake, whether through employment, ongoing relationships with
39 manufacturers, or other direct financial interests in the adoption and dissemination of the new
40 device, technique, or technology.

41
42 Criteria for determining when it is ethically justifiable to permit participation by someone who has
43 a direct, substantial, unavoidable, and irreducible financial interest in a CME activity might include
44 a variety of considerations. For example, that the dissemination of the device, technique or
45 technology will be of significant benefit to patients, and to the public and the professional
46 community; that the individual is uniquely qualified as an expert in the relevant body of knowledge
47 or skills; that disclosure includes the nature and magnitude of the specific financial interest at stake;
48 that there is demonstrated, compelling need for the specific CME activity; and that all feasible
49 steps are taken to mitigate influence.⁵⁴

1 *Understanding Key Ethical Criteria*

2
3 Current guidelines for CME do not distinguish among financial relationships based on their
4 different potential to undermine the independence and objectivity of educational activities. Nor do
5 they provide specific guidance for how to manage potential conflicts of interest when such
6 conflicts are disclosed. At present there are no specific, publicly agreed on understandings of key
7 criteria proposed above: “substantial interest,” “significant benefit,” “uniquely qualified,” or
8 “compelling need.” Attempting to provide specific, concrete delineations of these criteria would be
9 an essentially arbitrary exercise—what is a “substantial” interest for one practitioner may not be for
10 another. Inevitably, these criteria must be interpreted case by case, based on knowledge of the
11 particular circumstances and on the exercise of judgment. In other contexts, physicians routinely
12 make similar judgments under conditions of uncertainty.

13
14 Judgments about some criteria, such as “significant benefit,” will be reasonably familiar; others are
15 more challenging. While we cannot offer precise definitions, it is possible to suggest considerations
16 that might come into play. For example, current standards require CME providers to design
17 activities to address demonstrated educational needs,^{55,56} a “compelling need” for a particular
18 educational activity may be present when a new therapy becomes available to treat a disease that is
19 prevalent in the local community for which there is otherwise no satisfactory treatment.

20
21 Similarly, an individual might be considered “uniquely qualified” when he or she is the only expert
22 (or one of only a very few) who has significant knowledge about or experience in treating a rare
23 disease or who was involved in the early development or testing of a new treatment, device, or
24 technology. To some extent, the need to rely on conflicted expertise may be dictated by local
25 conditions—CME providers in small or rural communities, for example, may not always be able to
26 obtain the services of experts who do not have problematic ties to industry. In any event, it will no
27 longer be appropriate to speak of an expert being “uniquely qualified” when a substantial body of
28 peer-reviewed evidence has evolved in a given subject area, or when a cohort of individuals who
29 do not have direct, substantial, unavoidable, and irreducible financial interests have become
30 experienced in using a new medication, device, or technology and are available to teach others.

31
32 CME providers should be transparent about what considerations led them to decide to permit an
33 individual with a problematic financial interest to participate as a content developer or faculty
34 member in a particular CME program or activity. The goal is to ensure that decisions are made
35 objectively and are justifiable based on considerations the CME provider believes will be
36 persuasive to the professional community at large. As the community gains experience in working
37 with these criteria it is to be expected that consensus will coalesce around core interpretations. As
38 Harvard Medical School notes in its conflict of interest policy:

39
40 These classifications are not intended to serve as a rigid or comprehensive code of conduct or
41 to define "black letter" rules with respect to conflict of interest. It is expected that the
42 guidelines will be applied in accordance with the spirit of the mission of Harvard Medical
43 School in education, research and patient care. By this process, it is expected that a common
44 institutional experience in the application of these guidelines will gradually evolve.⁵⁷

1 RECOMMENDATION

2
3 The Council on Ethical and Judicial Affairs recommends that the following be adopted and the
4 remainder of this report be filed:

5
6 The respect and autonomy that medicine enjoys rest on the profession's commitment to fidelity
7 and service in the patient-physician relationship. To sustain that commitment, medicine must
8 ensure that physicians acquire and maintain the knowledge, skills, and values central to the
9 healing profession. With that comes an ethical obligation to ensure that the profession itself sets
10 the agenda and defines the goals of physician education, decides what subject matter is taught,
11 determines physicians' educational needs, and takes steps to ensure the objectivity of
12 educational content and of those who teach it.

13
14 Financial and in-kind support of continuing medical education (CME) by pharmaceutical,
15 biotechnology, and medical device companies puts that ethical obligation at risk by creating
16 conditions for conflict of interest. Medicine's ethical aspiration should be to avoid this potential
17 for bias.

18
19 In some circumstances, however, refusing support from industry entirely could significantly
20 undermine the profession's capacity to ensure that physicians have access to appropriate, high
21 quality CME. Medicine should seek to minimize such occasions; when they cannot be avoided,
22 medicine must act vigorously to protect the interests of patients and the integrity and
23 independence of the educational enterprise.

24
25 The following considerations define an ethical framework to guide professional practice with
26 respect to industry support for CME:

- 27
- 28 1. Funding or in-kind support should be provided only by sources that have no direct
29 financial interest in a physician's clinical recommendations; and
 - 30 2. Individuals who develop content for or teach in CME activities should:
 - 31 a. have no current, recent (within the preceding 12 months), or potential direct
32 financial interest (e.g., royalties or ownership interest) in the educational subject
33 matter; and
 - 34 b. not currently be and not recently have been (within the preceding 12 months)
35 involved in a compensated relationship (e.g., direct employment, service on a
36 speakers bureau, service as a consultant or expert witness) with a commercial entity
37 that has a financial interest in the educational subject matter.
 - 38 3. When adhering to guidelines (1) and (2) above would significantly undermine the
39 capacity to ensure that physicians have access to appropriate, high quality professional
40 education, funding or in-kind support may be provided by industry sources under the
41 following conditions:
 - 42 a. the educational activity is planned by the provider based on needs identified
43 independent of and prior to solicitation or acceptance of the commercial support;
44 and
 - 45 b. the CME provider can articulate a compelling reason(s) to accept industry support
46 for the educational activity or activities; and
- 47
48
49
50

- 1 c. the CME provider declines industry support that is conditioned on the provider's
2 acceptance of advice or services concerning educational content, faculty or content
3 developers, or other educational matters; and
- 4 d. the source and magnitude of the funding or in-kind support are clearly disclosed;
5 and
- 6 e. the CME provider routinely audits the level of industry support it receives to ensure
7 that it maintains the independence and integrity of its educational mission and
8 programs.
- 9
- 10 4. When necessary to ensure that physicians have access to appropriate, high quality
11 professional education, individuals who currently have *modest* financial interests in the
12 educational subject matter may develop content for or teach in CME activities if the
13 following conditions are met:
14
 - 15 a. the existence and magnitude of any financial interests are clearly disclosed; and
 - 16 b. steps are taken to eliminate or mitigate the potential influence of those interests.
- 17
- 18 5. It can be ethically justifiable for an individual who currently has a *direct, substantial,*
19 *and unavoidable* financial interest in the educational subject matter (e.g., as the inventor
20 of a new device) to develop content for or teach in a CME activity if the following
21 conditions are met:
22
 - 23 a. there is a demonstrated, compelling need for the specific CME activity in the
24 professional community that cannot otherwise be met; and
 - 25 b. the CME provider demonstrates that the individual is *uniquely qualified* in the
26 relevant body of knowledge or skills; and
 - 27 c. the CME provider takes steps to mitigate the potential influence of the unavoidable
28 financial interest; and
 - 29 d. participants are clearly informed about the nature and magnitude of the individual's
30 specific financial interest in the subject matter; and
 - 31 e. CME activities that use such experts contribute overall to the timely development of
32 a pool of qualified, independent experts in the relevant field.
- 33
- 34
- 35

(New HOD/CEJA Policy)

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

REFERENCES

1. Pellegrino ED. Professionalism, profession and the virtues of the good physician. *Mt. Sinai Journal of Medicine*. 2002;69(6):378–384.
2. Inui TS. *Flag in the Wind: Educating for Professionalism in Medicine*. Washington, DC: Association of American Medical Colleges;2003.
3. Swick HM. Toward a normative definition of medical professionalism. *Academic Medicine*. 2000;75:612–616.
4. Sullivan WM. Medicine under threat: professionalism and professional identity. *CMAJ*. 2000;162(5):673–6.
5. 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;295:429–433.
6. American Medical Association. Principles of Medical Ethics: Principle V. *AMA Code of Medical Ethics*. Chicago, IL: American Medical Association;2008.
7. American Medical Association. Opinion E-9.011, Continuing Medical Education. *AMA Code of Medical Ethics*. Chicago, IL: American Medical Association;2008.
8. Stern DT, Papadakis M The developing physician — becoming a professional. *NEJM*. 2006;355:1794–1799.
9. U.S. Food and Drug Administration. Guidance for industry: Industry-supported scientific and educational activities. *Federal Register*. 1997;62(232):64093–64100.
10. Cf. Office of Inspector General. *Compliance Program Guidance for Pharmaceutical Manufacturers*. Washington, DC: Department of Health and Human Services;2003.
11. Alliance for CME. Letter to Mark Levine, MD, Chair, Council on Ethical and Judicial Affairs, and Raymond Christensen, MD, Chair, Reference Committee on Amendments to Constitution and Bylaws, June 9, 2008.
12. American Medical Association. *The Physicians Recognition Award and Credit System: Information for Accredited Providers and Physicians*. Chicago: American Medical Association; 2006.
13. Accreditation Council on Continuing Medical Education. Accreditation Council for Continuing Medical Education. ACCME™ Annual Report Data, 2007. Available at http://www.accme.org/dir_docs/doc_upload/f51ed7d8-e3b4-479a-a9d8-57b6efedc27a_uploaddocument.pdf. Accessed March 3, 2009.
14. Accreditation Council on Continuing Medical Education. See Reference 13.
15. Kopelow M. Testimony to the U.S. Senate Special Committee on Aging. July 29, 2009. Available at http://www.accme.org/dir_docs/doc_upload/0e7fba7d-9d68-4414-901b-aebb44c60dda_uploaddocument.pdf. Accessed September 4, 2009.
16. Accreditation Council on Continuing Medical Education. See Reference 13.
17. Holmer AF. Industry strongly supports continuing medical education. *JAMA*. 2001; 285(15):2012.
18. Goold SD, Campbell EG. Industry support of continuing medical education: Evidence and arguments. *Hastings Center Report*. 2008;38(6):34–37.
19. Cervero RM, He J. The relationship between commercial support and bias in continuing medical education: a review of the literature. Available at http://www.accme.org/dir_docs/doc_upload/aae6ecc3-ae64-40c0-99c6-4c4c0c3b23ec_uploaddocument.pdf. Accessed September 4, 2009.
20. Steinbrook R. Financial support of continuing medical education. *JAMA* 2008;299:1060–1062.
21. Harrison RV. The uncertain future of continuing medical education: commercialism and shifts in funding. *J Cont Ed Health Professions*. 2003;23:198–209.
22. Harrison RV. See Reference 21.
23. Steinbrook R. See Reference 20.

24. Katz HP, Goldfinger SE, Fletcher SW. Academia-industry collaboration in continuing medical education: Description of two approaches. *Journal of Continuing Education in the Health Professions*. 2002;22:43–54.
25. Bowman MA. Impact of drug company funding on the content of continuing medical education. *Moebius*. 1986;6(1):66–69.
26. Dana J, Lowenstein G. A social science perspective on gifts to physicians from industry. *JAMA*. 2003;290(2):252–255.
27. Weber LJ, Wayland MT, Holton B. Health care professionals and industry: reducing conflicts of interest and established best practices. *Archives of Physical Medicine & Rehabilitation*. 2001;82Suppl 2:S20–S24.
28. Bazerman MH, Lowenstein G, Moore DA. Why good accountants go bad. *Harvard Business Review*. 2002; 80(11):96–102, 134.
29. Korn D, Ehringhaus SH. *The Scientific Basis of Influence and Reciprocity: A Symposium*. Washington, DC: Association of American Medical Colleges;2007.
30. Cervero RM, He J. See Reference xx
31. University of Massachusetts. *Policy on Conflicts of Interest Relating to Intellectual Property and Commercial Ventures*;1996. Available at <http://www.umassmed.edu/uploadedFiles/ConfInterUMW.pdf>. Accessed September 4, 2009.
32. National Ethics Committee, Veterans Health Administration. *Compensation to Health Care Professionals from the Pharmaceutical Industry*. Washington, DC: National Center for Ethics in Health Care;2006. Available at http://www1.va.gov/VHAPUBLICATIONS/ViewPublication.asp?pub_ID=1384. Accessed April 20, 2009.
33. Stanford University School of Medicine. *Policy and Guidelines for Interactions between the Stanford University School of Medicine, the Stanford Hospital and Clinics, and Lucile Packard Children's Hospital with the Pharmaceutical, Biotech, Medical Device, and Hospital and Research Equipment and Supplies Industries ("Industry")*; Revised May 2009. Available at <http://www.ncfh.org/pdfs/PIRT4.pdf>. Accessed September 4, 2009.
34. University of Pittsburgh. *Policy on Conflicts of Interest and Interactions between Representatives of Certain Industries and Faculty, Staff and Students of the Schools of the Health Sciences and Personnel Employed by UPMC at all Domestic Locations*; 2007. Available at <http://www.ogc.pitt.edu/publications/IndustryRelationshipsPolicy.pdf>. Accessed September 4, 2009.
35. Physicians' Institute for Excellence in Medicine. <http://www.physiciansinstitute.org/about/>. Accessed September 4, 2009.
36. Wisconsin Medical Society. *ETH-004: The Relationship of the Profession to the Health Product Industry*; 2009. Available at <http://www.wisconsinmedicalsociety.org/files/ETH-004.pdf>. Accessed September 8, 2009.
37. North American Spine Society. *NASS Disclosure Policy*; 2009. Available at <http://www.spine.org/Pages/PracticePolicy/EthicsProfConduct/NASSDisclosurePolicy.aspx>. Accessed April 8, 2009.
38. Oregon Academy of Family Physicians. *Pharmaceutical Funding of the OAFP*; 2007. Available at <http://www.oafp.org/about.php>. Accessed September 17, 2009.
39. E.g. Harrison RV, Davis DA, Fordis M, et al. Society for Academic Continuing Medical Education Survey for 2006: Descriptive Results. Available at http://www.sacme.org/site/sacme/assets/pdf/BS_results_2006.pdf. Accessed April 11, 2008.
40. Observations made by participants during the stakeholder conversation sponsored by the American Medical Association Council on Ethical and Judicial Affairs and Council on Medical Education. Chicago, Illinois, February 25, 2009.
41. Kopelow M. See Reference 15.

42. Lo B, Field MJ. *Conflict of Interest in Medical Research, Education, and Practice*. Washington, DC: Institute of Medicine; 2009.
43. Cp. AAMC-AAU Advisory Committee on Financial Conflicts of Interest in Human Subjects Research. *Protecting Patients, Preserving Integrity, Advancing Health: Accelerating the Implementation of COI Policies in Human Subjects Research*. Washington, DC: Association of American Medical Colleges;2008.
44. Association of American Medical Colleges. *Protecting Subjects, Preserving Trust, Promoting Progress—Policy and Guidelines for the Oversight of Individual Financial Interests in Human Subjects Research*. Washington, DC: AAMC;2001.
45. Cp. National Ethics Committee, VHA. See Reference 32.
46. Accreditation Council on Continuing Medical Education. *Standards for Commercial Support*. Chicago, IL: ACCME;2004.
47. Cp. Cain DM, Lowenstein G, Moore DA. The dirt on coming clean: Perverse effects of disclosing conflicts of interest. *Journal of Legal Studies*. 2005;34:1–25.
48. Cain DM. See Reference 47.
49. Cain DM. See Reference 47.
50. North American Spine Society. See Reference 37.
51. Accreditation Council on Continuing Medical Education. See Reference 40.
51. Office of Inspector General. See Reference 10.
53. Joshi N. Med school restricts industry funding. *Stanford Daily Online* 2008; September 9.
54. Association of American Medical Colleges. See Reference 38.
55. American Medical Association. See Reference 12.
56. Accreditation Council for Continuing Medical Education. *Essential Areas and Their Elements*. Available at http://www.accme.org/dir_docs/doc_upload/f4ee5075-9574-4231-8876-5e21723c0c82_uploaddocument.pdf. Accessed September 4, 2009.
57. Harvard University Medical School. *Policy on Conflicts of Interest and Commitment*; 2004. Available at <http://www.hms.harvard.edu/integrity/conf.html>. Accessed September 4, 2009.