

REPORT 1 OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS (A-09)  
Financial Relationships with Industry in Continuing Medical Education  
(Reference Committee on Amendments to Constitution and Bylaws)

EXECUTIVE SUMMARY

**Objective:** To provide ethical guidance for physicians and the profession with respect to industry support for continuing medical education pursuant to CEJA-CME Report 1 (A-08), “Industry Support for Professional Education in Medicine – Update.”

**Methods:** Literature review; ethical analysis of issues in professionalism raised by influence of financial relationships with industry in continuing medical education; and feedback from key stakeholders within and outside the AMA.

**Results:** Medicine’s autonomy and authority to regulate itself depends on its ability to ensure that physicians acquire, maintain, and apply the values, knowledge, skills, and judgment essential for quality patient care. To fulfill that obligation, the profession must safeguard the independence and integrity of continuing medical education by ensuring that control of the educational enterprise remains in the hands of the profession.

**Conclusions:** Relationships with industry—i.e., pharmaceutical, biotechnology, and medical device companies—can offer enormous benefit to the profession and the patients it serves. However, commercial funding for professional education can pose significant ethical challenges to medicine’s ability to focus primarily on the needs of patients and ensure quality education for physicians.

It is *ethically preferable* that CME providers accept funding only from sources that have no direct financial interest in a physician’s clinical recommendations and that those involved in CME have no current, recent or potential direct financial interest in the subject matter and are not currently/have not recently been involved in a compensated relationship with a commercial entity that has a financial interest in the educational subject matter.

It is *ethically permissible* that CME providers accept funding from industry sources *if* the educational activity is planned by the provider based on needs identified independent of and prior to solicitation or acceptance of the funding; the use of the funding is not restricted in any way; the source of the funding is clearly disclosed; and the CME provider is not overly reliant on funding from industry sources. CME providers may permit involvement of individuals with modest financial interests if the nature and magnitude of those interests are disclosed and steps are taken to eliminate or mitigate the potential influence of those interests. In rare circumstances, CME providers may permit involvement of a *uniquely qualified expert* who has a direct, substantial, unavoidable financial interest if the nature and magnitude of the specific interest are clearly disclosed; there is a demonstrated, compelling need for the specific CME activity in the professional community that cannot otherwise be met; and steps are taken to mitigate the potential influence of the unavoidable financial interest to the greatest extent possible. Every effort should be made to develop a pool of qualified, independent experts as quickly as possible

CME activities that involve financial relationships which cannot be addressed through any of these mechanisms are *ethically prohibited*.

# REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS\*

CEJA Report 1-A-09

Subject: Financial Relationships with Industry in Continuing Medical Education

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Referred to: Reference Committee on Amendments to Constitution and Bylaws  
(Daniel W. Van Heeckeren, MD, Chair)

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1 The practice of medicine is inherently a moral activity, founded in a “covenant of trust” between  
2 patient and physician.<sup>1, 2, 3</sup> 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 current and future generations of physicians acquire and  
5 maintain the knowledge, skills, and values that are central to the healing profession. In return,  
6 society grants medicine considerable authority to set the ethical and professional standards of  
7 practice and the autonomy to educate its practitioners.<sup>4, 5</sup>

8  
9 Today, medicine is engaged in multiple relationships with industry (by which we mean  
10 pharmaceutical, biotechnology, and medical device companies). Practitioners serve as physician-  
11 innovators; clinical investigators; consultants and advisors; members of speakers bureaus; and in  
12 other roles. Such relationships can drive innovations in patient care, contribute to the economic  
13 well-being of the community, and provide financial support for professional education, to the  
14 ultimate benefit of patients and the public.

15  
16 Medicine and industry share a common goal of benefiting patients and their interests align at many  
17 points. Ultimately, however, their interests and obligations diverge in important ways. Medicine  
18 has an overriding responsibility to put the needs of patients first. Commercial entities have a  
19 responsibility to their shareholders and other vested stakeholders to thrive as businesses and  
20 maximize returns on investment even as they engage in efforts to improve health and health care.  
21 As financial relationships between medicine and industry expand, concern grows that such  
22 relationships carry ethical risks for the independence and integrity of education in medicine and  
23 can have important implications for public confidence in the profession.

24  
25 An increasingly urgent challenge for both medicine and industry is to devise ways to preserve  
26 strong, productive collaborations for the benefit of patients and the public at the same time they  
27 take clear, effective action to prevent relationships that damage public trust and tarnish the  
28 reputations of both parties.

29  
30 Medicine-industry relationships can occur in research, clinical care, education, and beyond. The  
31 Council also recognizes that pharmaceutical, biotechnology, and medical device companies are not  
32 the only entities—commercial or otherwise—with which financial relationships can raise concerns.  
33 To address the range of ethical questions that can arise across all of these different domains and

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\* Reports of the Council on Ethical and Judicial Affairs are assigned to the reference committee on 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.

1 among all of the different stakeholders is too ambitious a goal for a single analysis. Thus this report  
 2 focuses on issues raised by financial relationships with industry for continuing medical education  
 3 (CME). This allows us to explore the complex considerations at stake in a manageable context and  
 4 to provide practical ethical guidance on issues that increasingly challenge medicine as a profession.  
 5 It can lay the foundation for future analyses that address similar concerns as they arise in other  
 6 domains and among other stakeholders.

## 8 LIFELONG LEARNING & MEDICINE'S DUTY TO EDUCATE

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

12 —Edmund Pellegrino

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

22 Individual physicians have an ethical obligation to dedicate themselves to “continue to study,  
 23 apply, and advance scientific knowledge” and to “maintain a commitment to medical education.”<sup>6</sup>  
 24 As professionals, practicing physicians are expected to commit themselves to lifelong learning and  
 25 to maintain their clinical knowledge and skills through CME and other professional development  
 26 activities.<sup>7</sup> That commitment is reflected not only in ethical expectations and standards, but also in  
 27 requirements for licensure and specialty certification, as well as hospital credentialing.

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

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

## 46 CONTINUING MEDICAL EDUCATION

48 Continuing medical education today takes place in a complex, dynamic environment that hosts a  
 49 mix of “promotional,” “certified,” and other activities. As defined by the Food and Drug  
 50 Administration (FDA), promotional activities are those developed by or on behalf of a commercial  
 51 entity and under the substantive influence of that entity which are designed to market health care

1 products or services. Promotional activities, which provide information on the therapeutic use of a  
2 product or service, are governed by the labeling and advertising provisions of the Food, Drug, and  
3 Cosmetic Act.<sup>9, 10</sup> Promotional activities may constitute protected commercial speech. These  
4 industry-developed, FDA-regulated activities lie outside the scope of the present analysis and  
5 recommendations. Our immediate concern is with certified and other (nonpromotional) educational  
6 activities.

7  
8 “Certified CME” refers to educational activities developed and implemented in compliance with  
9 the certification requirements of the American Medical Association Physician Recognition Award  
10 (PRA) CME Credit System, or the accrediting policies of the American Academy of Family  
11 Physicians or American Osteopathic Association.<sup>11</sup> Certified CME meets the requirements for  
12 Category 1 credit under AMA’s PRA program, including compliance with Accreditation Council  
13 for Continuing Medical Education (ACCME) standards and with relevant AMA ethics policy.<sup>12</sup>

14  
15 Beyond these formal categories lie educational activities designed for practicing physicians that are  
16 neither of certified CME nor of “industry-developed, FDA-regulated activities.” These other  
17 educational activities may or may not be commercially supported, may or may not adhere to AMA  
18 policy or ACCME Standard for Commercial Support<sup>SM</sup> (despite not being formally certified or  
19 accredited), and may or may not be recognized by licensing bodies or credentialing boards as  
20 fulfilling local CME requirements.

#### 21 22 *Industry Support for CME*

23  
24 Over the past decade, medicine has come to rely significantly on commercial funding to support  
25 professional education across the learning continuum. With respect to CME, industry support now  
26 accounts for more than half of all income to CME providers accredited by ACCME.<sup>13</sup> Between  
27 1998 and 2006, commercial support of providers accredited by ACCME increased by 300 percent  
28 to \$1.2 billion.<sup>13</sup>

29  
30 However, not all CME providers are heavily supported by industry. For example, in 2007 medical  
31 schools represented some 17 percent of nationally accredited CME providers, accounted for 46  
32 percent of all (directly sponsored) certified CME hours, and received 20 percent of all commercial  
33 funding.<sup>13</sup> Nonprofit physician professional organizations represented 37 percent of nationally  
34 accredited providers, accounted for 23 percent of certified CME hours, and received 18 percent of  
35 all commercial funding, while hospitals comprise 13 percent of accredited providers, accounted for  
36 12 percent of certified CME hours, and received just under four percent of all commercial  
37 support.<sup>13</sup> Publication and communication companies represented 20 percent of accredited  
38 providers, offered nine percent of all certified CME hours, and received 49 percent of all  
39 commercial funding.<sup>13</sup>

40  
41 Industry support for CME helps to meet the costs of programs and activities in the face of uncertain  
42 funding from other sources.<sup>14</sup> By helping to reduce costs to individual attendees industry support  
43 may make CME more accessible, especially for physicians in resource poor communities. Along  
44 with lower costs, by providing amenities that make participation attractive, industry support may  
45 encourage greater participation than would otherwise be the case, although there is no evidence  
46 either to support or to refute this hypothesis.<sup>15</sup> At the same time, however, industry funding can  
47 have undesired consequences, such as encouraging questionable prescribing and narrowing the  
48 range of topics and faculty in CME.

49  
50 Although the only studies that specifically examine the relationship between industry-funded  
51 educational activities and inappropriate prescribing predate the ACCME Standards for Commercial

1 Support<sup>SM</sup>, they do offer some insight. One quasi-experimental study evaluated whether industry-  
2 funded CME led to increased prescribing of the company drug compared to noncompany drugs in  
3 the same therapeutic class. Results revealed that the company drug was prescribed more often by  
4 physicians after attending a company-supported CME event compared to other drugs in the same  
5 class.<sup>16</sup> Another study examined physicians' prescribing patterns of two drugs before and after they  
6 attended symposia sponsored by the manufacturers. Participants' usage of both drugs increased  
7 significantly following the symposia and differed significantly from national prescribing patterns of  
8 the same drugs for the same time period in comparable clinical settings.<sup>17</sup>

9  
10 Evidence also indicates that industry support can influence the overall topics, speakers, and  
11 educational content of CME. Companies make educational grants consistent with their business  
12 strategies and therapeutic areas of interest,<sup>18, 19</sup> which may tend to shift education toward  
13 benefiting funders and away from serving patient interests.<sup>19</sup> Industry-supported CME programs  
14 tend to address a narrower range of topics,<sup>20</sup> focus more on drug therapies,<sup>18</sup> and give more  
15 favorable treatment to company products<sup>21</sup> than do programs that are not funded by industry.

16  
17 Although these data by no means demonstrate conclusively that commercial funding unduly biases  
18 continuing professional education, they suggest that medicine has reason to be concerned about the  
19 possibility and should take steps to address the potential for industry funding to undermine—or be  
20 perceived to undermine—the quality and credibility of CME.

#### 21 22 *Individual Relationships with Industry*

23  
24 In addition to concerns about the effects of industry funding for CME providers, there are concerns  
25 about how financial ties with industry may affect the objectivity of physicians and others who  
26 develop content for or teach in CME activities. We must be clear: Our concern is not with lapses of  
27 judgment or with corruption, but with the subtle bias that financial ties create. Research indicates  
28 that relationships in which benefits—financial compensation, gifts, favors, or other perceived  
29 benevolent gestures—are bestowed on one party by another introduce unconscious bias favoring  
30 the giver. This occurs independent of the magnitude of the perceived benefit and even when  
31 individuals are alert to the possibility of bias and strive to be objective.<sup>22, 23, 24</sup> Emerging  
32 neurobiological data confirm that such influence operates below the level of conscious awareness.<sup>25</sup>

33  
34 What has not been as clearly demonstrated is to what extent the amount of a financial interest may  
35 influence perception and judgment. Nonetheless, most policies on conflict of interest at least tacitly  
36 assume that the greater the financial interest, the more problematic that interest is. Yet different  
37 institutions set the threshold of concern as significantly different amounts. For example, Stanford  
38 University requires faculty members to disclose financial interests of more than 0.5% equity or  
39 \$100,000, while Northwestern and Vanderbilt Universities require reporting of income above  
40 \$10,000 a year.<sup>26</sup> Trying to define any specific threshold is essentially an arbitrary exercise.

#### 41 42 ENSURING THE INDEPENDENCE & OBJECTIVITY OF CME

43  
44 There are three options to address the potential of industry funding to compromise the integrity of  
45 professional education. Medicine could avoid the potential altogether by not permitting conditions  
46 that give rise to potential bias or influence; it could implement strategies to mitigate actual or  
47 perceived bias or influence; or both. Each option has ethical and practical advantages and  
48 disadvantages.

1 *Avoiding Conditions that Can Compromise the Integrity of Medical Education*

2  
3 Avoiding the potential for influence entirely has the virtue of ethical clarity and practical  
4 simplicity. In the context of CME, avoiding conditions that can give rise to bias means declining to  
5 accept or seek commercial support for professional education activities from funders who have  
6 significant financial interests in physicians' clinical decisions. Avoiding such support would  
7 strongly underscore medicine's defining professional commitment to independence, objectivity,  
8 and fidelity to patients. Eliminating industry funding would have the further practical advantage of  
9 avoiding the administrative and resource costs that must otherwise be devoted to mitigating  
10 influence.<sup>27</sup>

11  
12 Funding for CME that does not originate from a source that has a direct financial interest in  
13 physicians' clinical recommendations is ethically preferable.

14  
15 In keeping with this ethical ideal, CME providers and participants should strive to avoid relying  
16 overly on industry funding—e.g., by cultivating alternative sources of support and designing and  
17 conducting educational activities to reduce costs. Medicine as a profession should work to develop  
18 and disseminate educational programming that best meets physicians' needs and is accessible and  
19 affordable for all practitioners.

20  
21 The Council recognizes that this ethical ideal cannot feasibly be implemented for all professional  
22 education. Thus we must also define when funding from a commercial source that may create  
23 actual or perceived bias or influence is ethically permissible.

24  
25 *Mitigating Potential Influence*

26  
27 Not all financial relationships in CME are equally problematic. Financial relationships that are only  
28 indirectly related to an educational activity, modest in scope, or distant in time are unlikely to  
29 adversely affect—or be perceived to affect—the activity in question. For example, having once  
30 conducted sponsored research or accepted a modest honorarium for speaking on behalf of a  
31 company would not necessarily create such clear potential for bias as to make it inappropriate for  
32 an individual with the appropriate expertise to serve as a faculty member for a given CME activity.  
33 (In its analysis of conflict of interest in research, the Association of American Medical Colleges  
34 (AAMC) suggested that very modest financial relationships might be exempt from consideration  
35 under an institution's policies regarding financial relationships.<sup>28</sup>)

36  
37 Financial relationships of a more direct or substantial nature, however, must be managed if they  
38 cannot be eliminated. Examples of direct and/or substantial financial interests include ownership or  
39 equity interest in the industry funder, royalties, ongoing compensated relationships (e.g., consulting  
40 arrangements or service on scientific advisory bodies or speakers bureaus),<sup>29</sup> or relationships that  
41 involve fiduciary responsibilities on behalf of the funder (such as service on a corporate board of  
42 directors) or decision-making authority in financial matters.<sup>30</sup>

43  
44 Mechanisms to mitigate the potential influence of these relationships: disclosure, “firewalls,” and  
45 changing the terms of financial relationships in specific circumstances.

46  
47 Disclosure

48  
49 The disclosure of relationships that have the potential to create bias (or give the appearance of  
50 bias), must be implemented in all CME activities and indeed is mandated by the ACCME  
51 Standards for Commercial Support<sup>SM 31</sup> (AAMC guidelines on financial relationships in research

1 similarly mandate disclosure.<sup>29, 32</sup>) However, evidence suggests that disclosure is an imperfect tool  
2 and may even have perverse effects. Disclosure places the burden of mitigating the effect of the  
3 financial relationship on those to whom the disclosure is made. It requires that they determine how  
4 skeptical to be about the objectivity of the educational content.<sup>33</sup> For the presenter, confidence that  
5 the potential for influence has been mitigated by disclosing the existence of a financial relationship  
6 may lead him or her to feel less need to strive for objectivity, potentially encouraging self-  
7 interested behavior.<sup>34</sup> For the learner, disclosure can convey the impression that the presenter is  
8 particularly honest and trustworthy, thereby encouraging false confidence in the objectivity of the  
9 educational content.<sup>34</sup> Disclosure thus is a necessary but not sufficient component of efforts to  
10 mitigate the potential influence of direct, substantial financial interests. Disclosing not just the  
11 existence of a financial interest but also its magnitude may enhance the value of disclosure as a  
12 means of mitigating the influence of financial relationships.<sup>35</sup>

#### 13 14 “Firewalls”

15  
16 “Firewall” describes mechanisms intended to distance commercial funding from decisions about  
17 content, faculty, pedagogical methods and materials, and other substantive dimensions of CME  
18 activities. For example, pooling monies from multiple commercial sources and disbursing support  
19 to individual activities through a “blind trust” model creates circumstances in which funders have  
20 no knowledge of which programs their grants or gifts supported.<sup>36</sup> Nor are CME providers or  
21 faculty aware of which funder supported their activities. Both ACCME and the Inspector General  
22 of the Department of Health and Human Services have recommended clearly separating decisions  
23 about funding from substantive decisions about CME activities. ACCME standards require that a  
24 CME provider ensure the independence of key decisions—including needs identification,  
25 educational objectives, content, etc.—although the standards do not specify how a provider should  
26 do so.<sup>31</sup> HHS guidance for industry requires that manufacturers clearly separate their sales and  
27 marketing functions from their grant-making functions.<sup>37</sup>

#### 28 29 Changing the Terms of Financial Relationships that May Compromise Integrity

30  
31 Another way to mitigate the influence of financial relationships is to change the terms of those  
32 relationships to the extent feasible, without necessarily eliminating the relationship altogether. For  
33 a CME provider, setting an upper limit on how great a proportion of income derives from industry  
34 support is one way to accomplish that and to help safeguard the (actual and perceived) integrity and  
35 independence of its educational activities. For individuals, among whom the nature and magnitude  
36 of financial interests can vary considerably, strategies should be tailored to the specific  
37 circumstances. For example, physicians participating as content developers or faculty in a CME  
38 activity could be required to desist from speaking on behalf of the activity's industry supporter for a  
39 defined period before and after the activity. Similarly, an individual could forgo royalties or other  
40 compensation from the company for a defined interval following his or her participation (whether  
41 as content developer or faculty) in an industry-funded CME activity. It will be important, of course,  
42 that in seeking to change the terms of problematic relationships a CME provider ensure decisions  
43 are made fairly and consistently across individual cases.

44  
45 Sometimes a financial interest is extraordinarily difficult or impossible to distance or lessen. In  
46 almost all cases, these relationships would not be ethically permissible in CME. An exception  
47 would be “conflicted but necessary expertise.” In the earliest stage of adoption of a new medical  
48 device, technique, or technology, the only individuals truly qualified to train physicians in its use  
49 are often those who developed the innovation. Yet these are the very individuals who often have  
50 the most substantial and direct interests at stake, whether through employment, ongoing  
51 relationships with manufacturers, or other direct financial interests in the adoption and

1 dissemination of the new device, technique, or technology. In such situations, the expertise is  
2 unavailable from other sources. To mitigate influence on the educational activity, the expert's  
3 unavoidable interest should be minimized to the extent feasible.

4  
5 The analysis might take a cue from AAMC guidelines on financial interests in research. In  
6 "compelling circumstances" those guidelines permit an individual who has a direct, substantial  
7 financial interest to carry out proposed research with human participants provided that: the  
8 individual is uniquely qualified by virtue of experience or expertise; the research cannot be carried  
9 out as safely or effectively without the conflicted individual's participation; and it is feasible to  
10 credibly mitigate the likelihood that the relationship will influence the investigator's judgment or  
11 conduct of the research.<sup>29</sup> In the CME setting, similar criteria might be proposed for participation  
12 as content developer or faculty, by an individual who has a direct, substantial financial interest in  
13 the subject matter of an educational activity—for example, a physician-innovator who stands to  
14 benefit from the adoption or dissemination of a new device, technique, or technology. Criteria  
15 might include that: the dissemination of the device, technique or technology will be of significant  
16 benefit to patients, and to the public and the professional community; the individual is uniquely  
17 qualified as an expert in the relevant body of knowledge or skills; disclosure includes the nature  
18 and magnitude of the specific financial interest at stake; there is demonstrated, compelling need for  
19 the specific CME activity; and all possible steps are taken to mitigate influence.

20 Although there may not be specific, publicly agreed on criteria for determining when an individual  
21 is "uniquely qualified" with respect to a given body of knowledge or skills in medical education,  
22 CME providers should be transparent about what considerations led them to decide to permit an  
23 individual with a direct, substantial financial interest to participate as a content developer or faculty  
24 member in a particular CME program or activity. Among possible considerations might be the fact  
25 that an individual with a direct, substantial financial interest is the only expert (or one of only a  
26 very few) who has significant knowledge about or experience in treating a rare disease or who was  
27 involved in the early development or testing of a new treatment, device, or technology. The goal is  
28 to ensure that decisions are made objectively and are based on considerations the CME provider  
29 believes will be persuasive to the professional community at large.

30  
31 A further challenge will be to determine when the relevant expertise has become sufficiently  
32 widespread in the professional community that participation in CME activities by individuals with  
33 direct, substantial, unavoidable financial interest is no longer ethically warranted. For example, it is  
34 no longer appropriate to speak of there being a "uniquely qualified" expert when a substantial body  
35 of peer-reviewed evidence has evolved in a given subject area or when a cohort of individuals who  
36 do not have direct, substantial financial interests have become experienced in using a new  
37 medication, device, or technology and are available to teach others.

38  
39 Finally, CME activities that involve financial relationships which can compromise the integrity and  
40 objectivity of education that cannot be addressed through any of these mechanisms are ethically  
41 prohibited.

#### 42 43 RECOMMENDATION

44  
45 The Council on Ethical and Judicial Affairs recommends that the following be adopted and the  
46 remainder of this report be filed:

47  
48 Medicine's autonomy and authority to self-regulate depend on its ability to ensure that  
49 physicians acquire, maintain, and apply the values, knowledge, skills, and judgment essential  
50 for quality patient care. To fulfill that obligation, the profession must safeguard the

1 independence and integrity of continuing medical education by ensuring that control of the  
2 educational enterprise remains in the hands of the profession.

3 Relationships with industry—i.e., pharmaceutical, biotechnology, and medical device  
4 companies—can offer enormous benefit to the profession and the patients it serves. However,  
5 commercial funding for professional education can pose significant ethical challenges to  
6 medicine’s ability to focus primarily on the needs of patients and ensure quality education for  
7 physicians.

8  
9 The considerations below define an ethical framework to guide professional practice with  
10 respect to financial relationships in the context of continuing medical education. Physician-  
11 learners should seek out CME activities that indicate their adherence to the following  
12 guidelines:

13  
14 It is **ethically preferable** that:

- 15
- 16 1. CME providers accept funding only from sources that have no direct financial interest  
17 in a physician’s clinical recommendations; and that
  - 18 2. Individuals who program, develop content for, or teach in CME activities:
    - 19 a. have no current, recent (within the preceding 12 months), or potential direct  
20 financial interest (e.g., royalties or ownership interest) in the educational subject  
21 matter; and
    - 22 b. are not currently and have not recently been (within the preceding 12 months)  
23 involved in a compensated relationship (e.g., direct employment, service on a  
24 speakers bureau, service as a consultant or expert witness) with a commercial entity  
25 that has a financial interest in the educational subject matter.
- 26  
27  
28

29 It is **ethically permissible** that:

- 30
- 31 3. CME providers accept funding from industry sources if the following conditions are  
32 met:
    - 33 a. the educational activity is planned by the provider based on needs identified  
34 independent of and prior to solicitation or acceptance of the funding; and
    - 35 b. the use of the funding is not restricted in any way; and
    - 36 c. the source of the funding is clearly disclosed; and
    - 37 d. the CME provider is not overly reliant on funding from industry sources.
  - 38 4. CME providers permit individuals who have *modest* financial interests in the  
39 educational subject matter to program, develop content for, or teach in CME activities if  
40 the following conditions are met:
    - 41 a. the existence and magnitude of any financial interests are clearly disclosed; and
    - 42 b. steps are taken to eliminate or mitigate the potential influence of those interests.
  - 43 5. CME providers permit an individual who currently has a *direct, substantial, and*  
44 *unavoidable* financial interest in the educational subject matter (e.g., as the inventor of a  
45 new device) to program, develop content for, or teach in a CME activity **only** if the  
46 following conditions are met:
    - 47
    - 48
    - 49
    - 50

- 1 a. the individual is *demonstrably uniquely qualified* as an expert in the relevant body
- 2 of knowledge or skills; and
- 3 b. participants are clearly informed about the nature and magnitude of the individual's
- 4 specific financial interest in the subject matter; and
- 5 c. there is a demonstrated, compelling need for the specific CME activity in the
- 6 professional community that cannot otherwise be met; and
- 7 d. steps are taken to mitigate the potential influence of the unavoidable financial
- 8 interest to the greatest extent possible; and
- 9 e. every effort is made to develop a pool of qualified, independent experts as quickly
- 10 as possible.

11  
12 CME activities that involve financial relationships which cannot be addressed through any of  
13 these mechanisms are **ethically prohibited**.

14 (New HOD/CEJA Policy)

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

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