

Conflict of Interest Policy Guide for Academic Medical Centers and Medical Schools



COI Toolkit on Continuing Medical Education

I. Introduction

Support from the pharmaceutical and medical device manufacturing industries has decreased from its peak in 2007 when 48 percent of the revenue of accredited Continuing Medical Education (CME) providers—\$1.25 billion—derived from industry support.¹ In 2011, total support from industry was \$752 million, or 32 percent of the total. The majority of CME activities (79 percent) did not receive commercial support, accounting for 80 percent of physician participants and 75 percent of non-physician participants.²

Despite this decrease in industry support for CME, concerns remain about the effects that such support have on the information that clinicians receive through accredited CME programs and the influence that has on their prescribing behavior. A systematic review of the literature noted that only a limited number of studies of CME's effects on prescribing behavior have been published and those are more than 20 years old, but they do indicate that CME does influence prescribing behavior.³ The U.S. Senate Finance Committee expressed this concern by noting that physicians are aware of potential bias when they are presented with marketing materials, but when the same information is presented in the context of education, “there is an imprimatur of credibility and independence” that can lead to unquestioning acceptance of the messaging.⁴

Such concerns are not merely hypothetical. Cases cited by the Senate Finance Committee in which pharmaceutical companies used educational grants to fund purportedly independent educational programs but which actually served to promote off-label use of its products included the \$430 million settlement with Warner-Lambert (Neurontin) and the \$704 million settlement with Serono (Serostim) in 2005. More recently, Pfizer (which acquired Wyeth) settled a case for \$55 million for illegally promoting Protonix for off-label use. In that case, the government alleged that the company used CME to promote Protonix for unapproved uses. According to the complaint, the Protonix “brand team” influenced virtually every aspect of these CME programs: program topics, speaker selection, organization and content. In addition, the government alleges that Wyeth even insisted that the CME program materials use the same color and appearance as Protonix promotional materials—a tactic that Wyeth and the vendor called “branducation.”⁵

Continuing Medical Education

*“Industry funding for CME
can influence physician
behavior...That should not
happen in a profession whose
goal is to use the best
knowledge to guide treatment
for one’s patients.”*
— Philip Pizzo, MD, Former Dean,
Stanford School of Medicine

The Accreditation Council for Continuing Medical Education (ACCME) adopted stricter criteria for accrediting CME providers to mitigate the influence that commercial sponsors of CME might have on the integrity of the educational program. Nevertheless, authoritative independent bodies such as the Institute of Medicine called for a new system of funding accredited CME that would be free of commercial influence, enhance public trust in the integrity of the system, and provide high-quality education.⁶ A 2008 report from the Josiah Macy Jr. Foundation recommended that all commercial support for CME activities be eliminated within 5 years. The report concluded that “no amount of strengthening of the ‘firewall’ between commercial entities and the content and processes of CE [continuing education] can eliminate the potential for bias.”⁷

II. Arguments For and Against Commercial Support for CME

The concerns raised above notwithstanding, those in favor of continuing to permit commercial support for CME argue that loss of support will result in CME being less available, lower quality, and higher cost. Content experts in the best position to discuss emerging treatments and therapies will be lost due to conflict-of-interest issues. Ultimately, the patient benefits when physicians are well-informed about the latest therapeutic advances. Furthermore, the argument goes, CME programs are governed by regulations that maintain independence and minimize the influence of sponsors. Additional steps are being taken to reduce the influence of sponsors such as requiring more than one commercial sponsor.

Proponents of commercial support point out that most physicians are unwilling to pay higher registration fees for CME, which would happen without industry support.⁸ Pharmaceutical and medical device companies would simply shift their financial resources to non-accredited programs at restaurants that are even more blatantly aimed at marketing if they are barred from supporting accredited CME.

Opponents of commercial support for CME argue that CME would have a more balanced mix of content. This argument is supported by a study that demonstrated that the content of a symposia designed by a medical education communications company with support from multiple pharmaceutical companies had a narrower range of topics included than a CME course run concomitantly that was planned by a medical school without industry support. The industry-sponsored symposium focused more on recently approved new therapeutic products manufactured by the funders.⁹

Those opposed to industry support counter the argument about higher costs by pointing to the University of Michigan and Stanford University medical schools and the Memorial Sloan Kettering Cancer Center, which have banned industry support for CME. The institutions have restrained CME costs by utilizing their own conference space instead of renting expensive hotel facilities, avoiding lavish meals, and using local faculty as teachers whenever possible.

*“The University of Michigan
Medical School has proved
that high-quality CME doesn’t
depend on industry support.”*

*— James Woolliscroft
MD Dean
UMMS*

Analyzing these arguments leads to the conclusion that the only way to guarantee the integrity of CME is to eliminate commercial support. As the Council on Ethical and Judicial Affairs of the American Medical Association states: “The ethical aspiration should be to avoid the potential for bias or the chance that confidence in the integrity and independence of professional education could be diminished.”¹⁰ The accreditation standards and procedures of the ACCME are too weak to prevent industry sponsors from influencing CME. The standards do not preclude those who have a financial interest with industry from participating in CME activities as members of the planning committee, as teachers or authors so long as the financial interest is disclosed and the conflict “managed.” However, the ACCME does not specify the methods of resolving the conflict or the standards that would be applied to judge if the conflict of interest was, indeed, resolved. Likewise, commercial interests are free to offer advice and services to the CME provider. While explicit quid pro quos have all but vanished, implicit understandings between funders and providers of CME undermine the effectiveness of “firewalls” between the two.

While financial constraints may be real, these are not valid reasons to abrogate our professional responsibilities to our patients and the public at large to provide balanced and unbiased information.

III. Policy Considerations

Prohibit commercial support of CME

Prohibition of commercial support of CME will assure that the program is free of commercial influence, thus enhancing the public’s trust in the integrity of the system of continuing education for clinicians and providing high-quality instruction.

Reduce the costs of CME

Seek ways to reduce the cost of CME while maintaining the quality of the instruction. Use internal conference space instead of renting expensive hotel facilities, avoid lavish meals and utilize local faculty.

Offer alternative forms of CME from traditional lectures

Alternative approaches to CME may be at least as effective as lecture-style CME and a better choice, so long as they are not funded by industry. For instance, point-of-care CME allows clinicians to ask questions immediately relevant to the care of their patients, utilize online sources of information at times convenient to themselves, apply what they’ve learned to their patients, and receive CME credit for the time expended. Some specialty boards offer low-cost CME credits without commercial support for maintenance-of-certification (MOC) learning activities for board-certified physicians.

Extend policies to all clinical providers

Advanced practice nurses, physicians assistants, and pharmacists have increasingly become the targets of pharmaceutical company marketing.

*“Developing local capacity
and networking with other
local stakeholders enabled us
to become free of industry
funding.”*

*— Donald Hess, MD, MPH
Susquehanna Health*

Health center policies should be applied to any clinician who can write a prescription.

Strengthen policies if commercial support is not prohibited

If the academic medical center (AMC) does not prohibit commercial support of CME, then the following policies could help to minimize the potential for bias:

- prohibiting those with a financial conflict of interest with the company sponsoring the event from participating in the planning or delivery of instruction for that event
- requiring multiple commercial sponsors. (Example: Harvard Medical School and Partners HealthCare)
- directing all commercial support to a pooled central account without earmarking for any specific event, department, or program that allows the AMC to decide how it can be used. (Example: Stanford Medical School)
- omitting the names of speakers in proposals for funding submitted to industry
- prohibiting any communication from the commercial sponsors on the program topics, content, or selection of speakers
- limiting the amount of the honorarium to modest levels and limiting food and social events to preset modest dollar amounts per attendee
- constituting a compliance committee separate and independent from the CME provider to review the proposed program and the steps taken to minimize industry influence before the program takes place and empowering the committee to monitor the event in real time and to audit the event after its conclusion at its discretion (Example: Partners HealthCare)

IV. Model Policies

Strict Prohibition

UNIVERSITY OF MICHIGAN MEDICAL SCHOOL POLICY ON INDUSTRY FUNDING FOR UMMS-OFFERED CME

Purpose

This policy states the position of the University of Michigan Medical School (UMMS) with regard to commercial entity support of UMMS-offered continuing medical education (CME), and to prohibit the practice of accepting such funding to support CME activities offered by UMMS.

Policy

Effective January 1, 2011, UMMS-offered activities for which CME credit is designated may not receive financial funding (e.g.,

A Case Study in Good Practice

Susquehanna Health, a four-hospital integrated health system in north central Pennsylvania, no longer needs any commercial funding for CME. Using an approach he calls “creative stewardship”, CME coordinator Donald Hess, MD, MPH, gradually reduced the dependency of a program that had relied on commercial grants and pharmaceutical displays. Dr. Hess adopted a multi-modal strategy that included:

- offering lower honoraria to outside speakers
- reducing travel and hosting expenses
- discontinuing poorly attended, expensive CME programs and developing well attended, inexpensive CME programs
- building mutually beneficial relationships with community human service stakeholders and inviting more local physicians to serve as speakers
- improving internal cost center processes and increasing registration fees.

grant, gift, subsidy, or exhibit fee) from commercial entities that produce, market, re-sell, or distribute health care goods or services consumed by, or used on, patients or biomedical research subjects.

Tightly restricted

STANFORD UNIVERSITY SCHOOL OF MEDICINE POLICY ON COMMERCIAL SUPPORT OF CONTINUING MEDICAL EDUCATION (CME)

Commercial Funding for Specific CME Activities Is Not Permitted

This includes both on campus and off site venues and all functions that propose to use the Stanford name. This also includes payments from third party sources or for-profit course organizers that have received industry support. Donations from individuals, foundations, and charitable organizations that are not commercial interests may be used for support of a specific CME activity.

Undesignated Commercial Support

The School recognizes that industry may wish to provide support for CME that is not designated to a specific subject, course, speaker, or program but is intended for use in a broadly defined field of study. Support from industry for CME will be considered in the following general categories:

- Medical, pediatric and surgical specialties
- Diagnostic and imaging technologies and disciplines
- Health policy and disease prevention
- Other broadly defined topic areas

Commercial Support Funds Must Be Contributed to a Central Pool

Industry support for CME activities must be directed to the Stanford Center for CME. The only commercial funds eligible for use in support of CME activities are those that have been specifically donated to the Stanford CME central pool.

Exemption for Training on Medical Equipment

GEORGETOWN UNIVERSITY SCHOOL OF MEDICINE

However, reimbursement for, or payment of, the reasonable and necessary expenses associated with modest travel, meals, and lodging for bona-fide purchasing, training, education are permitted if they are primarily for:

- a. learning how to properly and safely use medical devices, equipment and other technologies, or compliance with legal, regulatory or accreditation requirements; and
- b. the payment is pursuant to the terms of a written agreement with the Industry Company, or is related to the review of capital equipment GUH is considering purchasing or acquiring which cannot be transported to the GUH facility.

Requiring More than One Commercial Sponsor

PARTNERS HEALTHCARE

Industry monetary support for a specific Partners Educational Activity must come from more than one Industry entity. ...Generally, no one Industry entity can provide more than 70% of the total commercial support.

HARVARD MEDICAL SCHOOL

Sponsorship of CME by a single healthcare corporation (pharmaceutical, medical/dental device or supply, or other biomedical company) is strictly prohibited. Support by more than one company is permitted, provided that (i) no single company accounts for more than 50 percent of the activity's budget (i.e. not more than 50 percent of the budgeted expenses) and (ii) support among the commercial interests is relatively equitable, with no one company accounting for more than 70 percent of the commercially supported portion of the activity's overall budget (i.e. not more than 70 percent of the commercial support obtained). Support includes both cash and in-kind support.

V. References

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This Toolkit is one of a series in Community Catalyst's Policy Guide for Academic Medical Centers and Medical Schools, available online at:

<http://tinyurl.com/AmcModelCoiPolicy>

The Toolkit is a publication of Community Catalyst, a national, nonprofit consumer advocacy organization dedicated to making quality affordable health care accessible to everyone. Among its prescription drug initiatives, Community Catalyst combats pharmaceutical marketing that creates conflicts-of-interest and threatens the safety and quality of patient care. We provide strategic assistance to medical schools and teaching hospitals seeking to improve their conflict-of-interest policies as part of the Partnership to Advance Conflict-Free Medical Education (PACME), a collaboration of Community Catalyst, The Pew Charitable Trusts, the American Medical Student Association and the National Physicians Alliance. PACME is supported by a grant from the Attorney General Consumer and Prescriber Grant Program, which was funded by the multi-state settlement of consumer fraud claims regarding the marketing of the prescription drug Neurontin.