

Financial Support of Continuing Medical Education

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CONTINUING MEDICAL EDUCATION (CME) IS A MULTI-billion-dollar industry. In 2006, the CME providers accredited by the Accreditation Council for Continuing Medical Education (ACCME) had a total income of \$2.38 billion.¹ In 1998, the income was \$889 million, and most had come from the registration fees of participants or sponsoring organizations. Since 2003, however, most of the income for CME providers has come from industry.²

Commercial support for CME accredited by the ACCME quadrupled between 1998 and 2006—from \$302 million to \$1.2 billion—and doubled from other sources.¹ In 2006, the combined for-profit support (commercial support and advertising and exhibit income) represented 60.6% of total income. An industry magazine stated in its annual medical education report: “For continuing education to continue, commercial funding must remain healthy. The future of CME depends on it.”³

The profit margin for ACCME-accredited providers increased from 5.5% in 1998 to 31.0% in 2006.¹ The 3 main types of CME providers are physician member organizations, publishing and education companies, and medical schools. In 2006, their margins were 46.3%, 34.7%, and 20.7%, respectively.¹ Nonprofit organizations often use CME revenue to subsidize other activities.

Continuing medical education has become so heavily dependent on support from pharmaceutical and medical device companies that the medical profession may have lost control over its own continuing education.⁴ Commercial funding may inherently distort education and practice to the detriment of physicians and patients, regardless of the various safeguards to protect the integrity of the enterprise. Problems associated with commercial support of CME, current safeguards, and other approaches to funding are discussed below.

Funding for Different Types of CME Organizations

In 2006, there were 729 accredited CME providers.¹ Of the \$2.38 billion of CME income, publishing and education companies received 34.3%, physician member organizations received 32.8%, and medical schools received 17.6%. The rest went to other CME providers, such as hospitals. Publishing and education com-

panies and medical schools received 75.8% and 61.8%, respectively, of their CME income from commercial support. Physician member organizations received 23.0% of their CME income from commercial support and 25.5% from advertising and exhibits; this represented about three-quarters of all advertising and exhibit income for CME.¹

In 2006, the 1684 CME providers accredited by state medical societies had an income of \$134.5 million and expenses of \$136.5 million; 29.3% of their income was from commercial support.¹ These CME providers were responsible for 349 696 hours of instruction (including jointly sponsored activities); medical schools for 331 298 hours; physician member organizations for 147 308 hours; and publishing and education companies for 61 404 hours.¹

Continuing Education and Marketing

Although commercial support for CME increases available funds, it may promote sales of new medications, including their off-label use, notwithstanding the various measures to prevent conflict of interest and commercial bias.^{2,5,6} The CME activities supported by industry are often free or subsidized for physicians. Patients and payers, however, may ultimately pay the bill.

Physicians who are invited to speak at industry-supported CME events or to organize them may have extensive financial relationships with companies, and pharmaceutical companies may have paid them to give other presentations.⁶ There may be overlap between the material presented at promotional events such as dinner lectures and satellite symposia and CME courses.² Industry sponsorship also may lead to overemphasis on medicines, medical devices, and diagnostic tests, thereby biasing “the overall curriculum of topics,”⁵ regardless of their importance to improving care.⁷

The accreditation of medical education and communication companies raises additional concerns.⁸ Medical education and communication companies may organize and manage meetings, develop written educational materials, provide public relations services, or prepare advertising and marketing campaigns, among other activities. In 2006, publishing and education companies, a category that includes medical education and communication companies, re-

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See also p 1003.

ceived a higher percentage of their CME income from commercial support than any other type of organization, and had more income than any other CME provider group.¹ A related issue is the financial associations between industry and other CME providers; independence may be difficult.

The Senate Finance Committee Report

In April 2007, the Senate Finance Committee, after studying drug company grants to fund continuing education, concluded:

It seems unlikely that this sophisticated industry would spend such large sums on an enterprise but for the expectation that the expenditures will be recouped by increased sales. Press reports and documents exposed in litigation and enforcement actions confirm these suspicions in some instances. There is also evidence from ACCME that some accredited CME providers still allow commercial sponsors to exert improper influence on educational activities that are supposed to be independent from commercial interests.⁹

The report noted that although “major drug companies have adopted corporate policies that, on their face, do not allow educational grants to be awarded for unlawful purposes,” the policies “still allow this industry to walk a fine line between violating rules prohibiting off-label promotion and awarding grant money in a manner likely to increase sales of their products, including sales for off-label uses.”

According to the Senate Finance Committee, much of the industry funding for CME follows this pattern. A for-profit medical education or communication company submits a grant proposal. The drug company funds

“a program on a general topic (eg, treatment of a specific condition—and the condition is one for which at least one of the sponsoring drug company’s products is used), but the specifics of the content are determined by the medical education and communications company.”

Pharmaceutical company documents reveal no “explicit agreement that the CME program will favorably discuss a company product or an off-label use of a company product. However, it is possible that both parties reasonably expect that to be the result.”⁹

ACCME Standards

The ACCME has a staff equivalent of 12 full-time employees and an annual budget of about \$3.5 million according to the council. Its “Standards for Commercial Support” specify the relationships between CME providers and commercial interests.¹⁰ The council will not accredit commercial interests or entities they own or control.¹¹ Entities that provide clinical service directly to patients, including physician organizations, medical groups, and academic medical centers, are not considered commercial interests. Previously, the ACCME had not classified medical education and communication companies as commercial interests. However, under the definition adopted in August 2007, a commercial interest is “any entity producing, marketing, reselling or distributing health care goods or services consumed by, or used on, patients.”¹¹ Some medical education and communication companies may be considered commercial interests. For example, advertising agen-

cies that do promotional work for pharmaceutical companies and companies that resell drugs or devices are now considered commercial interests. If such firms have divisions that are accredited CME providers, they must spin their CME units off as separate companies by August 2009 or withdraw from accreditation.

For CME planners, speakers, or authors, relevant financial relationships in any amount within the past 12 months must be disclosed and conflicts of interest resolved before the educational activity occurs.¹⁰ Conflicts can be resolved by finding another planner, speaker, or author, assigning a different topic, having an effective peer review of the content so that unsubstantiated or promotional claims are eliminated, or changing the overall activity. They are usually resolved through peer review or by changing the activity.

In August 2007, the ACCME stated its commitment to “ensuring the validity of the CME enterprise” and announced new policies.^{11,12} The ACCME indicates that “CME can receive commercial support from industry without receiving any advice or guidance, either nuanced or direct, on the content of the activity or on who should deliver that content.”¹¹ Under consideration are enhanced data collection, such as establishing a monitoring system that would allow independent decisions about compliance with the council’s requirements, changes in the administration of the standards, such as procedures for more rapid responses to serious problems, and expanded education and outreach programs.¹² The council’s review also includes

“the management of commercial support across the CME enterprise including funding models and the role of industry in CME. Alternate funding models will be considered (eg, pooled funding, limits, sources) including discussions on the value, or impact, of no commercial support.”¹²

The effect of these initiatives—and the sufficiency of the council’s standards—remains to be seen.

Federal Laws and Regulations

The Pharmaceutical Research and Manufacturers of America¹³ and the American Medical Association¹⁴ have voluntary policies with regard to commercial sponsorship of CME. Eli Lilly & Co posts online all of its educational grants and charitable contributions to health care–related organizations in the United States.¹⁵ Other companies are considering similar disclosures.

Programs and materials about therapeutic products regulated by the US Food and Drug Administration that are prepared by, or on behalf of, the companies that market the products are subject to the labeling or advertising provisions of the Food, Drug, and Cosmetic Act. However, “truly independent and nonpromotional industry–supported activities” are not regulated.¹⁶ The agency, however, has been criticized for doing “little to ensure that educational grants are used for bona fide educational purposes.”⁹

The Departments of Justice and Health and Human Services enforce the antikickback statute and the False Claims

Act.¹⁷ Educational grants from drug companies are a risk area for fraud and abuse. Risk-reduction measures include separating grant making from sales and marketing within pharmaceutical companies, establishing objective criteria for awarding grants that do not take into account recipients' purchases, and funding only bona fide activities.¹⁸ The manufacturer should have no control over the speaker or the content; organizers should not improperly compensate physicians, such as by paying them to attend. Many pharmaceutical manufacturers have voluntarily adopted this guidance, and implemented internal "firewalls" to separate grants from marketing and sales. Sales and marketing personnel may no longer have authority to solicit grant requests or award funds.^{3,17}

Pharmaceutical and medical device companies decide how to spend their money and usually choose the CME provider. The effectiveness of firewalls and other measures is unknown. The Senate Finance Committee found that it is

"difficult to quantify the risk of kickbacks related to industry-sponsored education where companies overpay high-prescribing physicians as 'consultants' or 'speakers' for minimal work to develop educational material or teach at educational programs."¹⁹

Policy Considerations

Other approaches to temper industry funding of CME include (1) allowing no direct or indirect commercial support; (2) limiting the percentage of commercial support that is permitted for a provider or activity and not accrediting activities that are supported by a single company; (3) not accrediting providers, such as medical education and communication companies, that are dependent on commercial support; (4) eliminating direct or indirect commercial support of programs but allowing contributions to a central repository of funds, which, in turn, would disburse funds to approved programs¹⁹; (5) further tightening the ACCME's standards for commercial support and procedures for monitoring compliance; and (6) increasing disclosure about the funding of CME through a comprehensive searchable online registry of support for providers, activities, speakers, authors, and event planners. Proposed legislation would require manufacturers of drugs and medical devices to report publicly nearly all payments and gifts to physicians, including those for CME. The federal government would make the information available on "an Internet website that is easily searchable, downloadable, and understandable."²⁰ In addition, expenses could be decreased, for example by holding meetings and events at less expensive facilities and locations, or reducing speaker honoraria. Continuing medical education providers can stop accepting commercial support, as Memorial Sloan-Kettering Cancer Center in New York has recently done. A related issue is whether changes to policy should also apply to advertising and exhibit income.

Some, if not all, of these approaches would decrease CME funding—in which case physicians or their employers would pay more of the true costs. Some CME providers would

change their operations or go out of business, and many of those remaining would make less money. Although eliminating support from pharmaceutical and medical device companies would involve more change than the alternatives, this approach will likely allow the medical profession to control its own continuing education. The current situation is at best very troubling.

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