The Agenda for Continuing Medical Education —
Limiting Industry’s Influence
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Most physicians must complete accredited continuing medical education (CME) programs to maintain their medical licenses, hospital privileges, and specialty board certifications. Data from the Accreditation Council for Continuing Medical Education (ACCME) show that CME is a $2 billion per year business in the United States that earns less than half its revenue from physician learners themselves.¹ CME is increasingly underwritten by commercial sponsors — primarily manufacturers of drugs, biologic therapies, or medical devices — that spend more than $1 billion per year in educational grants and other funding to cover more than half the costs for CME activities.¹ Industry funding of accredited CME increased by more than 300% between 1998 and 2007.¹ Since the marketing goals of pharmaceutical and device companies can influence CME funding, preservation of the academic integrity of CME requires clear boundaries separating education and marketing.

In 2007, there were 736 ACCME-accredited CME providers, including 270 physician membership organizations, 150 for-profit medical-education and communication companies, 123 medical schools, 93 hospitals and health care systems, 38 other nonprofit organizations, 14 insurance and managed-care companies, and 33 providers that were not classified.¹ Medical-education and communication companies sponsor more than 30,000 CME activities each year and receive more than half a billion dollars in commercial funding.¹ The ACCME allows accredited CME providers to accept industry funding, but it imposes “Standards for Commercial Support” designed to temper potential industry influence.² The ACCME’s standards require CME providers to identify CME needs and set program content that is “free of the control of a commercial interest.”²

In practice, however, CME providers can easily pitch topics designed to attract commercial sponsors, and commercial sponsors can preferentially award grants to programs that complement the marketing strategies of manufacturers. The Institute of Medicine noted that “CME has become far too reliant on industry funding and that such funding tends to promote a narrow focus on products and to neglect the provision of a broader education on alternative strategies for managing health conditions and other important issues, such as communication and prevention.”³

The government has an interest in protecting the integrity of CME to ensure that physicians have the knowledge and skills necessary to render high-quality care. Industry-sponsored CME can also implicate several federal statutes. For example, the criminal anti-kickback statute prohibits the knowing and willful offer or payment of anything of value to induce referrals to the federal health care programs.⁴ Cash or paid vacations offered in return for patient referrals are obvious kickbacks. Other kickbacks are more cleverly disguised, such as when a pharmaceutical manufacturer rewards high-prescribing physicians by directing a CME provider to pay (or overpay) them as CME faculty, consultants, or members of a speakers bureau. Manufacturers must not use kickbacks to increase sales, nor may they market or promote to increase sales for off-label uses, which is a violation of the federal Food, Drug, and Cosmetic Act⁵ (FDCA). The temptation to promote on an off-label basis is powerful, since off-label sales offer substantial revenue. One study estimated that off-label sales account for 21% of the prescription-drug market.⁶ Off-label promotion and kickbacks may also implicate the False Claims Act when these illegal activities cause
the submission of claims for payment from Medicare, Medicaid, or other federal health care programs. Manufacturers are permitted to sponsor an accredited CME program that, by the independent decision of the CME provider, compensates a physician to favorably discuss a product’s off-label use before an audience of targeted prescribers as they enjoy a gourmet meal. When the manufacturer stumbles on such good fortune honestly, no laws are violated. However, when a manufacturer intentionally corrupts CME, prosecution may ensue.

The Neurontin case exemplifies the government’s use of the False Claims Act, the anti-kickback statute, and the FDCA to combat improper use of CME as a marketing tool. Neurontin (gabapentin), which was manufactured by Warner-Lambert, was approved for adjunctive therapy in epilepsy, but the lion’s share of the profit from Neurontin derived from sales for pain management, bipolar disorder, monotherapy for epilepsy, and other off-label uses. Among other alleged misconduct, Warner-Lambert sponsored CME activities that encouraged the use of Neurontin for these off-label indications. The Office of Inspector General in the Department of Health and Human Services and the Department of Justice pursued criminal and civil charges against Warner-Lambert for a range of abuses, including allegations that the CME activities, although nominally independent, were actually influenced by the manufacturer, which gave extensive input on topics, speakers, content, and participants. In addition to the allegations of off-label promotion, the government alleged that Warner-Lambert paid kickbacks to doctors in the form of lavish trips to attend presentations about off-label uses of Neurontin. In 2004, Warner-Lambert and Pfizer, which had purchased Warner-Lambert, paid $430 million to settle criminal and civil charges.8

The first approach, and the surest way to eliminate commercial bias in CME, is to eliminate commercial sponsorship. Physicians would then have to pay for their own continuing education. Acting as prudent purchasers, physicians might demand more meaningful education for their training dollars. Ideally, CME providers would respond by offering higher-quality programs at lower cost.

The downside of this option is that it risks the loss of the subgroup of commercially sponsored CME programs that objectively serve a true educational need. Given pressing financial demands and a prevalent perception of diminishing reimbursements, hospitals and physicians may not be willing to dip into their own pockets to replace the approximately $1,500 currently funded by the pharmaceutical and device industry for each of the 633,000 physicians working in the United States.9

Even if individual CME sessions are accurate and balanced, a problem persists when the pharmaceutical and device industry, rather than the medical profession, controls the CME curriculum that is available to physicians. Invitations to complimentary CME dinner sessions on pharmacotherapy for type 2 diabetes arrive in the mail far more frequently than invitations to sessions addressing disease prevention. This discrepancy is easily explained. CME programs that discuss drugs and devices attract industry sponsors more easily than programs that do not. The second approach is thus to allow commercial organizations to sponsor accredited CME programs but not to control the educational agenda.

Even if commercial interests and physicians, researchers, and others who participate in CME; these relationships raise additional issues that are beyond the scope of this article.

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award grants to support educational programs. Such grant organizations could collect donations from commercial interests, and then, via an objective and transparent process, award funding based on the educational merit of the CME programs, without allowing the donors to specify which programs their donations will fund. The use of decision makers who are free from industry ties also would help these organizations block commercial interests from influencing the content of CME. Many industry sponsors have established firewalls within their companies to separate grants from marketing, and this pooled-funding mechanism would further detach CME funding from marketing. Also, the broader the educational category, the better. For example, an organization awarding grants for general topics (e.g., education in orthopedics or oncology) is less easily controlled by particular donors than an organization awarding grants for education on specific topics (e.g., injectable therapies for osteoarthritis of the knee or treating small-cell lung cancer). Any industry-sponsored CME pool might still favor CME activities that generally promote interventions involving pharmaceuticals or devices, but the risk is dramatically reduced.

The American Academy of Orthopaedic Surgeons announced its plans for, but has not yet put into operation, a grant organization to receive and distribute funds to support orthopedic education. To date, several device companies have declined the request by the academy to fund the CME grant organization, explaining that they prefer existing CME funding vehicles. The current funding guidelines may serve the interests of manufacturers, but pooled funding may gain appeal if direct funding from manufacturers is no longer permitted for accredited CME. Manufacturers might reduce funding for CME in favor of product marketing, but marketing is an appropriate venue for industry spending that is designed to increase sales. Even if the total industry funding for CME decreased, the medical profession could still be better served if the remaining funds supported unbiased education. Pharmaceutical companies have shown some willingness to fund patient-assistance programs that help financially needy Medicare beneficiaries afford Part D drugs, including drugs marketed by other manufacturers; a mechanism of pooled funding for CME might have similar success.

**MENU OF CME TOPICS**

The ACCME has proposed tasking a respected third party with identifying educational needs and requiring that accredited CME cover a topic from this menu. This approach promises to eliminate the most blatant abuses of CME by ensuring that CME programs address real educational needs and not just the marketing goals of commercial sponsors.

Although this approach offers considerable improvements, it still allows the preferences of industry sponsors to shape which CME programs are developed. If industry sponsors are permitted to select which CME programs to support, a respected third party could designate important issues from which no commercial sponsor stands to benefit financially (e.g., identifying domestic violence or counseling on exercise and nutrition) as “orphan CME topics.” The ACCME could then require commercial sponsors to fund at least one orphan CME topic for every few topics discussing commercial products. Logistical issues may arise regarding how specific the topics must be and who should serve as the respected third party. Perhaps several overseers would be required to determine the educational needs for physicians practicing in various specialties or serving particular communities.

**ACREDITATION OF SPECIFIC CME ACTIVITIES INSTEAD OF CME PROVIDERS**

Currently, the ACCME neither preapproves CME content nor routinely monitors CME programs. Bias or inaccuracy in CME activities is detected only retrospectively, after complaints or during re-accreditation reviews that may occur years later. Thus, a third approach involves accrediting specific CME programs, after verifying their accuracy, balance, and educational value.

Activity-level accreditation would be more resource-intensive than provider-level accreditation and may require additional user fees, but it is feasible, at least on a small scale. The College of Family Physicians of Canada established an activity-level accreditation process that, among other content requirements, certifies approved CME programs as fostering improved patient care. If respected professional societies were to review individual CME programs, they could of-
fer a stamp of approval that physician learners could rely on when selecting CME activities.

We recognize that unscripted aspects of live events, such as question-and-answer sessions, defy advance review. Anecdotal reports abound of CME providers or sponsors planting audience members to ask questions that set the stage for planned discussions of off-label uses of the products of a commercial sponsor, and only real-time monitoring can combat this devious practice. CME providers, hoping to attract commercial sponsors, might still disproportionately pitch topics related to drugs or devices marketed by potential sponsors. However, accreditation based on a review of program content would go a long way toward ensuring that accredited CME serves the educational needs of the medical profession and not the business goals of the commercial sponsors.

Limitation of the Types of Entities Allowed to Function as Accredited CME Providers

One major pharmaceutical company, for the stated reason of improving the quality of CME, has prohibited for-profit medical-education and communication companies from directly receiving CME grants, and other companies have discussed following suit. Since commercial support accounts for so much of the income of medical-education and communication companies, they may be especially susceptible to commercial influence. Some of the alleged misconduct by Warner-Lambert regarding Neurontin marketing was orchestrated by obliging medical-education and communication companies.

Designating these companies as being ineligible to receive commercial support eliminates one type of risk, but creates and increases others. Other types of CME providers must also manage interests that potentially conflict with serving the educational needs of the medical profession. For example, professional societies not only rely on commercial funding to support their CME programs, but also to support core operations such as their annual meetings, so they could face similar pressures to tailor CME activities to please their industry benefactors. Or, a hospital soliciting commercial funding might seek a financial reward for favorable formulary placement of the company’s product or lucrative CME faculty opportunities for the hospital’s physician rainmakers. Simply eliminating medical-education and communication companies does not ensure CME quality and independence.

Conclusions

CME is important to quality of care, but there are serious concerns about the overlap between education and marketing. We hope the medical profession will one day eschew commercial support for CME. Until then, we do not know which approaches will prove most palatable to the medical profession, industry sponsors, or CME providers. However, the pooled-funding mechanism, using safeguards to ensure that CME programs serve an educational need and that industry donors cannot influence CME content, offers a promising compromise solution that may allow the medical profession to enjoy subsidized CME that is designed to improve patient care.

The views expressed in this article are those of the authors and do not necessarily reflect the official view of the Office of Inspector General in the Department of Health and Human Services.

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4. 42 U.S.C. § 1320a-7(b).

5. 21 U.S.C. § 301 et seq.


7. 31 U.S.C. § 3729 et seq.


10. Porucznik MA. Board members named for Center for Ortho-


