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On behalf of Inspector General Levinson and the Office of Inspector General (OIG) for the U.S. Department of Health and Human Services (HHS), I thank you for the opportunity to discuss commercial sponsorship of continuing medical education (CME). Physicians must keep abreast of advances in medicine, and access to objective, unbiased CME is essential to the quality of medicine practiced in this country. However, the integrity of medical practice and the quality of patient care may be compromised if biased or inaccurate CME influences the physician's clinical practice, including the prescription of drugs, biologics, and medical devices. Preserving the independence and integrity of continuing medical education requires enhanced safeguards to preserve the boundaries separating education from marketing.

Background

Graduation from medical school and completion of residency training are the first steps in a career-long educational process for physicians. To take advantage of the growing array of diagnostic and treatment options, physicians must continually update their technical knowledge and practice skills. CME is a mainstay for such learning. Most State licensing authorities require physicians to complete a certain number of hours of accredited CME within prescribed timeframes to maintain their medical licenses. Hospitals and other institutions may impose additional CME requirements upon physicians who practice at their facilities.

Although some physicians pay the full expense of this additional education, more often the programs are either fully or partially subsidized by sponsors that provide educational grants and other funding to CME providers. Frequently, these sponsors are manufacturers of drugs, biologics, or medical devices related to the topic of the CME program. According to the Accreditation Council for Continuing Medical Education (ACCME), in 2007, the pharmaceutical industry spent more than a billion dollars to cover more than half the costs for CME activities conducted in the United States that year. Moreover, industry funding of accredited CME increased by more than 300 percent between 1998 and 2007.[1]

[1] ACCREDITATION COUNCIL FOR CONTINUING MEDICAL EDUCATION, ACCME ANNUAL REPORT DATA 2007 (2008). Available online at http://www.accme.org/dir_docs/doc_upload/207fa8e2-bdbe-47f8-9b65-52477f9faade_uploaddocument.pdf. Accessed July 15, 2009.

A productive collaboration between medicine and commercial interests can expand knowledge, drive innovation, and improve quality of care. However, the relationship also contains a potential divergence of interests. Physicians should make the welfare of the patient their first priority and pursue continuing education as a means to assist them to provide the best care possible. However, commercial sponsors, including pharmaceutical and medical device companies, strive to increase market share and maximize the shareholders' return on investment. Industry-sponsored medical education can be an effective means to accomplish those business objectives.

One study of the return on investment for pharmaceutical promotional strategies indicates that spending $1 on physician events and meetings, including CME, generated an average of $3.56 in increased revenue.[2] According to a report by the American Medical Association Council on Ethical and Judicial Affairs, industry-supported CME programs tend to focus on drug therapies and give more favorable treatment to sponsors' products than do programs that are not funded by commercial sponsors.[3] Given the mixed motivations of industry-sponsored education, it is essential that effective safeguards be in place to ensure that CME is free from commercial bias.

The Oversight of CME

ACCME, the principal CME accrediting authority in the United States, plays a pivotal role in ensuring the integrity of CME by determining whether providers qualify to offer accredited CME programs and by providing ongoing oversight of the CME industry. Once a CME provider gains ACCME accreditation, the provider may offer programs as accredited CME activities without seeking ACCME review or approval of the topic, content, faculty, or format of the individual activity. Generally, physicians can use only accredited CME to satisfy licensure and hospital privileging requirements. ACCME has accredited 736 CME providers, 150 of which are for-profit medical education and communication companies (MECCs).[4]

ACCME allows accredited CME providers to offer CME activities that are directly funded by commercial interests in the health care industry. The Institute of Medicine has reported that funding from industry provides almost three-quarters of the total income for MECCs.[5] In its "Standards for Commercial Support," ACCME imposes some requirements designed

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[2] SCOTT NESLIN, ROI ANALYSIS OF PHARMACEUTICAL PROMOTION (RAPP): AN INDEPENDENT STUDY (May 22, 2001). Available online at http://www.rxpromoroi.org/rapp/media/slides_speakernotes.pdf. Accessed on July 27, 2009.

[3] AMERICAN MEDICAL ASSOCIATION, COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS, CEJA REPORT 1-A-09 FINANCIAL RELATIONSHIPS WITH INDUSTRY IN CONTINUING MEDICAL EDUCATION (June 5, 2009). Available online at http://www.cohealthcom.org/content/library/cc/CEJA/CEJA_Recommendation_Jun09.pdf. Accessed on July 18, 2009.

[4] ACCREDITATION COUNCIL FOR CONTINUING MEDICAL EDUCATION, ACCME ANNUAL REPORT DATA 2007 (2008). Available online at http://www.accme.org/dir_docs/doc_upload/207fa8e2-bdbe-47f8-9b65-52477f9faade_uploaddocument.pdf. Accessed July 15, 2009.

[5] INSTITUTE OF MEDICINE. CONFLICT OF INTEREST IN MEDICAL RESEARCH, EDUCATION, AND PRACTICE 5-17 (Bernard Lo & Marilyn J. Field eds., Nat'l Academies Press 2009).

to temper the potential influence of the industry sponsor on the content of the CME program. For example, CME content must not promote a specific proprietary interest of a commercial interest and decisions regarding identification of CME needs and content must be made "free of the control of a commercial interest."[6] Notwithstanding these standards, ACCME's role in mitigating commercial bias is limited because it does not pre-approve CME content and does not routinely monitor CME programs. Furthermore, oversight is complaint-driven and occurs after the fact, and in practice, up to 9 years may elapse between the identification of a noncompliant CME activity and ACCME's revocation of that provider's accreditation.[7]

The current environment tolerates industry sponsors' preferential funding of programs that serve the business needs of the funders. As the Senate Finance Committee observed in its study of industry-sponsored medical education, developing CME curricula biased to favor the funders' economic interests is a logical outgrowth of CME providers seeking commercial financial support. Industry's influence on CME content can be overt or more subtle. Some manufacturers publicize general topics they are willing to fund and invite CME providers to submit grant applications that propose programs in topic areas or disease states. CME providers are aware of the therapeutic areas and product lines of the potential industry sponsor. Many grant applications identify proposed faculty and other course details that indicate whether the program will favor the sponsor's products. CME providers can easily pitch topics designed to attract commercial sponsors, who in turn award grants to programs that complement the manufacturers' marketing strategies.[8] As a result, industry sponsored CME almost exclusively covers topics related to commercial products, instead of broader discussions of patient care.[9]

The Role of Federal Law Enforcement in CME

Various Federal laws may be implicated by industry sponsorship of CME. Under the provisions of the Federal Food, Drug, and Cosmetic Act (FDCA), a company is prohibited from introducing a new drug, biologic, or medical device into interstate commerce unless that product and its label have been approved, licensed, or cleared by the Food and Drug Administration (FDA). FDA restricts the promotion of the product to only the approved indications and prohibits marketing or promoting an unapproved or so-called "off-label" use. Although pharmaceutical and device manufacturers may not advertise or promote their products for unapproved uses, physicians may prescribe drugs, biologics, and devices

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[6] ACCREDITATION COUNCIL FOR CONTINUING MEDICAL EDUCATION, ACCME STANDARDS FOR COMMERCIAL SUPPORT: STANDARDS TO ENSURE THE INDEPENDENCE OF CME ACTIVITIES (2007). Available online at http://www.accme.org/dir_docs/doc_upload/68b2902a-fb73-44d1-8725-80a1504e520c_uploaddocument.pdf. Accessed on July 14, 2009.

[7] STAFF OF S. FINANCE COMM., 110TH CONG., USE OF EDUCATIONAL GRANTS BY PHARMACEUTICAL MANUFACTURERS. (Comm. Print 2007). Available online at http://www.senate.gov/~finance/press/Bpress/2007press/prb042507a.pdf. Accessed on July 27, 2009.

[8] *Id*.

[9] Harvey P. Katz, Stephen E. Goldfinger, & Suzanne W. Fletcher, *Academia-Industry Collaboration in Continuing Medical Education: Description of Two Approaches*, 22 J. CONTINUING EDUC. HEALTH PROF'L 43-54 (2002).

for unapproved uses and manufacturers can reap substantial profits from resulting off-label sales. It is not known exactly how much revenue is attributable to off-label uses, but at least one researcher has estimated that off-label uses account for about 21 percent of prescription drug sales.[10] Simply put, increased off-label use of a product benefits its manufacturer financially.

Although it is illegal for a manufacturer to promote a product for an off-label use, there is no express prohibition against a manufacturer sponsoring a CME program that discusses an off-label use of the product. Thus, a CME forum funded by a pharmaceutical company can deliver messages about a drug that the law forbids the drug's manufacturer from delivering directly. When a manufacturer misuses CME for the purpose of off-label promotion, the FDCA may be implicated. A violation of the FDCA is inherently a fact-based determination, but the greater the manufacturer's involvement in the delivery of the off-label message, the greater the risk.

A number of recent cases highlight the nexus between industry-sponsored CME and the enforcement of FDCA. In 2004, Pfizer/Warner-Lambert paid $430 million to resolve charges relating to the off-label promotion of Neurontin, an anti-seizure drug used by epilepsy patients. The government alleged in part that the company engaged in an illegal promotion scheme that corrupted the physician education process by fraudulently sponsoring "independent medical education" events on off-label Neurontin uses with extensive input from Warner-Lambert regarding topics, speakers, content, and participants.

In 2007, Jazz Pharmaceuticals' subsidiary, Orphan Medical Inc., agreed to pay $20 million to settle charges that it had illegally marketed the prescription drug Xyrem for off-label uses. Xyrem, also known as "GHB," has been subject to abuse as a recreational drug and is classified by the Federal Government as a "date rape" drug. The government alleged that the company engaged in a scheme to expand the market for Xyrem by promoting the drug to physicians for off-label indications. As part of the scheme, the government alleged that the company paid a psychiatrist tens of thousands of dollars for speaking engagements that promoted a wide range of off-label indications. Some of these speaking engagements were characterized as independent CME programs, when in fact they were promotional events approved by Orphan's marketing department.

In both of these cases, the companies entered into corporate integrity agreements (CIA) with the OIG as a condition of their continued participation in the Federal health care programs. The CIAs require, among other provisions, that the companies implement written policies and procedures designed to ensure that the funding of medical educational activities, including CME, conform to Federal Government requirements. Those policies must also address the disclosure of financial support of CME and financial relationships

[10] David C. Radley, Stan N. Finkelstein & Randall S. Stafford, *Off-Label Prescribing Among Office-Based Physicians*, 166 ARCHIVES OF INTERNAL MED. 1021-1026 (2006).

with faculty and speakers and ensure sponsored CME programs are independent and balanced.

Other laws may be implicated when commercial sponsors use CME to market drugs or devices for which reimbursement is sought from the Federal health care programs. Generally, Federal law and regulations governing Medicare and Medicaid do not provide for reimbursement for off-label prescriptions where the use is not medically accepted. The False Claims Act (FCA) imposes civil penalties (in the amount of treble damages plus $5,500 to $11,000 per claim filed) on any person who "knowingly presents, or causes to be presented … a false or fraudulent claim for payment or approval" to the United States government.[11] The FCA may be implicated when a pharmaceutical manufacturer engages in a scheme to promote the off-label use of its drugs and the illegal marketing campaign results in the submission of claims for payment from Federal health care programs. In addition, the FCA sanctions a conspiracy to submit false claims.[12] If a manufacturer and a CME provider knowingly collaborate in the promotion of an off-label use, the resulting submission of claims for that drug to the Federal health care programs could establish a cause of action against both co-conspirators.

Industry-sponsored CME can also implicate the criminal anti-kickback statute.[13] In general, the anti-kickback statute prohibits the knowing and willful offer or payment of anything of value to induce referrals to the Federal health care programs. Offering doctors or others money or other benefits to induce them to change a current prescription to the manufacturer's product is illegal if the drugs are reimbursable by Federal health care programs. When the reward is a cash payment, the kickback is blatant. Sometimes, however, the kickback is more cleverly disguised. For example, when a pharmaceutical manufacturer rewards a high-prescribing physician by directing a CME provider to pay (or overpay) that physician to be CME faculty, that payment may be a kickback.

A number of significant cases have involved allegations that funding for "educational support" was a pretext for the payment of kickbacks. The following cases are illustrative.

- As part of the illegal promotion of Neurontin, Pfizer/Warner-Lambert allegedly made kickbacks to doctors in the form of payments to doctors to "author" medical journal articles that were actually written by a medical marketing firm.
- In a case against TAP Pharmaceuticals, sales representatives allegedly offered kickbacks disguised as "educational grants" that were intended to be used for everything from office Christmas parties to influencing placement on a health plan's drug formulary. To settle these and other charges, in 2001 TAP pled guilty to criminal charges, paid $875 million in fines and penalties, and entered into a CIA.

[11] 31 U.S.C. § 3729.
[12] 31 U.S.C. § 3729(a)(3).
[13] 42 U.S.C. § 1320a-7b(b).

- In 2006, Medtronic paid $40 million and entered into a CIA to settle a range of allegations that it illegally paid physicians to promote and use its spinal devices. The improper payments allegedly included free travel and lodging of physicians and their families at lavish locations, such as Hawaii, Cancun, and Malaysia, for "discussion groups" of no or limited substance.

Preserving the Integrity of Continuing Medical Education

In light of the risks posed by commercial sponsorship of medical education, the question becomes how best to ensure that CME serves a *bona fide* educational purpose, the programs are not co-opted as marketing tools, and industry support does not conflict with relevant Federal law. The surest way to eliminate commercial bias in CME is to eliminate industry sponsorship by funders who have a significant financial interest in physicians' clinical decisions. As the American Medical Association's Council on Ethical and Judicial Affairs recently concluded, "it is ethically preferable that CME providers accept funds only from sources that have no direct financial interest in a physician's clinical recommendations…."[14] Commercial interests can deliver promotional messages to physicians through advertising and marketing.

Eliminating industry sponsorship is appealing for its purity and simplicity. However, CME providers would need to identify alternative sources of funds to maintain the availability of CME. In the interim, the following approaches would allow continued access to industry funding for CME, but limit industry's ability to influence how that money is used and what messages physicians receive.

In our Compliance Program Guidance for Pharmaceutical Manufacturers (CPG)[15], we recommended that pharmaceutical manufacturers should take steps to ensure that neither they, nor their representatives, are using CME to channel improper remuneration to physicians or others in a position to generate business for the manufacturer or to influence or control the content of the program. OIG identified several measures that manufacturers can take to enhance the integrity of industry-sponsored educational grants. Comparable safeguards would also promote the integrity of grants to CME providers.

We suggest that companies:

(1) Separate grant making functions from sales and marketing. Effective separation of these functions helps insure that grant funding is not influenced by sales or marketing motivations and that the grant is for legitimate educational purposes.

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[14] AMERICAN MEDICAL ASSOCIATION, COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS, CEJA REPORT 1-A-09 FINANCIAL RELATIONSHIPS WITH INDUSTRY IN CONTINUING MEDICAL EDUCATION (June 5, 2009). Available online at http://www.cohealthcom.org/content/library/cc/CEJA/CEJA_Recommendation_Jun09.pdf. Accessed on July 18, 2009.

[15] OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731 (May 5, 2003).

(2) Establish objective criteria for making educational grants to the CME provider. This also would help ensure that funded activities are for legitimate educational programs.

(3) Eliminate any control over the speakers or content of the educational activity. This would help reduce the risk that the payment is for the speaker's referrals or to promote "off-label" uses.

When OIG issued the CPG in 2003, several pharmaceutical companies asserted that our suggestions were impractical and it would be difficult to separate educational grants from sales and marketing. However, since that time, we have been pleased to hear that many companies have adopted some of our recommendations. In addition, the Pharmaceutical Research and Manufacturers of America (PhRMA) recently updated its voluntary "Code on Interactions with Healthcare Professionals" to address industry support for CME.[16] Among its recommendations are the separation of CME grant-making functions for sales and marketing departments, the adoption of objective criteria for making grants, and adherence to the ACCME standards for commercial support. The Advanced Medical Technology Association ("AdvaMed") has also recently updated its code of ethics. In contrast to the PhRMA code and OIG's CPG, the AdvaMed code provides that sales personnel may provide input about the suitability of a grant or donation recipient or program, but should not "control or unduly influence" the decision whether a health care provider will receive a grant.[17] The AdvaMed code also permits a company to make recommendations for CME faculty, although suggests that the ultimate selection should be made by the CME sponsor.

Another way to limit the influence of commercial sponsors is the creation of independent CME grant organizations. These entities could accept donations from industry and use an independent board of experts to distribute the funds to CME providers. Such a pooled funding mechanism could limit the influence of commercial support by establishing a firewall between sponsors and CME providers. For example, in 2008, the American Academy of Orthopaedic Surgeons (AAOS) established a separate grant organization to receive and distribute funds to support orthopaedic education.[18] The Center for Orthopaedic Advancement ("the Center") is structured to receive donations from industry and make grants based on objective criteria. The Center's board members may not have any personal or institutional relationships with an orthopaedic device or pharmaceutical manufacturer for the previous 3 years. OIG recently learned that five of the major

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[16] PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, CODE ON INTERACTIONS WITH HEALTHCARE PROFESSIONALS (effective Jan. 2009). Available online at http://www.phrma.org/files/PhRMA%20Marketing%20Code%202008.pdf. Accessed on Jul. 17, 2009.

[17] ADVANCED MEDICAL TECHNOLOGY ASSOCIATION, CODE OF ETHICS ON INTERACTIONS WITH HEALTHCARE PROFESSIONALS (effective July 1, 2009). Available online at http://www.advamed.org/NR/rdonlyres/61D30455-F7E9-4081-B219-12D6CE347585/0/AdvaMedCodeofEthicsRevisedandRestatedEffective20090701.pdf. Accessed on July 27, 2009.

[18] Mark Wieting, *AAOS Announces Center for Orthopaedic Advancement*, AAOS NOW, Sept. 2008. Available online at http://aaos.org/news/aaosnow/sep08/youraaos4.asp. Accessed on July 27, 2009.

manufacturers of artificial joints declined the Center's funding requests in favor of making grants directly to organizations. The future of the Center is uncertain.

Additional safeguards could include establishing broad educational categories for the allocation of industry donations. For example, an organization awarding grants for general topics, such as "orthopaedic education" or "oncology education," would operate with less influence from commercial interests than an organization awarding grants for education on specific topics, such as "injectable therapies for osteoarthritis of the knee" or "treating small cell lung cancer." Ensuring that the intermediary is not a potential customer of the commercial sponsors also reduces the risk of conflicts of interest. For example, if a hospital or group practice were to become a CME grant organization, there would be a risk that the organization might wield its purchasing power inappropriately. The integrity of the grant organization model would be impaired by efforts to make purchasing decisions dependent on a commercial entity's willingness to sponsor CME. An industry-sponsored CME pool might still favor CME activities that generally promote drug therapies or surgical intervention, but the risk of inappropriate influence would be lower than allowing sponsorship of individual programs.

While the use of independent grant organizations could limit the ability of industry sponsors to slant the content of the CME, companies may not be willing to fund CME under these terms. If this proves to be the case, physicians would have to pay for their own continuing education, as do lawyers, accountants, and other professionals. It is possible that the quality of CME would improve if physicians, acting as prudent consumers, demand more meaningful education for their training dollar. CME providers would no longer view industry sponsors as their customers and instead would address the needs of physician learners. Ideally, the CME providers would respond to this change by offering higher quality programs at lower cost.

Conclusion

There is growing concern about the integrity of medical education and the financial relationships between commercial sponsors and CME providers. Although restricting commercial sponsorship could shift some costs of CME onto physicians, such a shift could have positive impacts on the quality and value of CME. Commercial sponsorship could be maintained if the appropriate safeguards are implemented to prevent undue commercial influence and preserve the integrity and independence of CME. Whether the medical profession and health care industry are willing to embrace these measures remains to be seen.