Is continuing medical education a drug-promotion tool?

YES

Michael A. Steinman MD Robert B. Baron MD MS

In recent years, industry sponsorship of continuing medical education (CME) has grown rapidly and now accounts for up to 65% of the total revenue of CME programs in the United States.[1,2] In Canada and the United States, national guidelines state that "independent" programs should maintain scientific objectivity and independence of content and receive commercial support only through unrestricted funding mechanisms.[3-5] Despite the technically unrestricted nature of such industry-funded programs, however, substantial conflicts of interest and the potential for undue commercial influence persist.[6]

Problems

Chief among these conflicts is the financial incentive for CME organizers to create educational programs that present companies' products favourably. These conflicts affect medical education and communications companies (MECCs), many of which are for-profit and are funded almost exclusively by drug and device manufacturers. Such MECCs host accredited educational programs and many also service a variety of other industry activities, including hosting company-sponsored advisory boards and advising industry on marketing strategies and tactics.[7] This presents a clear conflict, since the survival and success of both the educational and marketing arms of these companies depend on satisfying those who fund them to encourage their support of future programs.

Unfortunately, similar incentives affect academic providers of CME. Some specialty societies and university-based CME providers have assisted in potentially promotional activities, such as organizing industry-supported dinner lecture series and satellite symposia. Even university providers of CME who forego such relationships are not immune to financial conflicts. These universities often receive substantial industry support for their CME activities: in 2005, CME activities originating in US schools of medicine received 60% of their total income from industry, up from 43% 5 years earlier.[2] These universities also rely heavily on industry grants for research funding and other educational initiatives.[8]

These connections create a web of relationships and financial dependency that can have subtle yet strong

NO

Bernard Marlow MD CCFP FCFP

The College of Family Physicians of Canada (CFPC) has been accrediting continuing medical education (CME) programs for several decades. Since the inception of our Maintenance of Proficiency (Mainpro®) accreditation system in 1998, our CME and continuing professional development (CPD) standards have undergone a steady and continuous process of rigorous upgrading, revision, and improvement.

For family physicians to obtain and maintain their designations with the College, they must comply with the very detailed and strict regulations governing the many components of Mainpro. Similarly, CME and CPD organizations, including pharmaceutical companies, must adhere to fastidious criteria in order to have their programs recognized and accredited by the College.

Accreditation

The CFPC accredits programs rather than providers. Granting of accreditation is restricted to the College (and its Chapters) and university CME offices. We do not have for-profit accredited CME and CPD providers in Canada.

Every CME and CPD program seeking accreditation from the College must have at least 1 CFPC member on its planning committee right from the initiation of the design of the program. The CFPC member is responsible for ensuring "quality control" of the program and maintaining the standards of the College. National programs must have CFPC representatives from each of our 5 national regions on their planning committees.

All CME and CPD program applications are subjected to a rigorous review by up to 3 experienced, CFPC-trained reviewers, who check programs specifically for balance, lack of bias, and lack of overt commercial support. There must be objective evidence confirming the need for the educational intervention, and budgets must be submitted for review. Conflicts of interest must be declared. The content of all commercially sponsored programs is submitted for peer review. In some cases, specialist content experts are also consulted.

After initial review and approval, each time a CME and CPD program is conducted, further details must be submitted for ethical review before the program is finally accredited. This review includes assessment of the

YES

effects on the objectivity of "independent," accredited CME. Event organizers can choose to present topics likely to favourably highlight sponsors' products or discuss emerging clinical areas that sponsors are trying to penetrate. In addition, among a range of qualified experts on a given topic, event organizers can select speakers known to have attitudes favourable to sponsoring companies' products. The commercial influence that results from these decisions is not necessarily acknowledged or even conscious, but might well reflect the cumulative effect of subtle influences and financial dependency that can affect even the best-intentioned CME providers.

In addition to institutional conflicts, speakers face their own conflicts of interest that arise from receiving educational or research grants from industry, from attendance at company-sponsored events, and from paid service on advisory boards and speakers bureaus.[7] Although the great majority of these speakers do not intentionally teach in a biased manner, research suggests that the expectation of reciprocity, personal relationships, and fear of disrupting relationships with companies can dissuade lecturers from speaking ill of companies' products and thus "biting the hand that feeds them."[9,10]

Few published studies have evaluated directly the extent to which industry sponsorship of CME biases program content and in turn affects physicians' behaviour.[11] Corroborating data and a recent US government inquiry suggest, however, that industry uses CME for promotional purposes—with success.[12] Several prominent investigations have revealed industry efforts to use educational activities to increase drug sales.[7,13] In addition, drug companies track the effectiveness of marketing activities through the purchase of physician-specific prescribing data from pharmacies.[14] It is unlikely that industry would contribute substantial resources to CME (approximately $1 billion [US] per year in the United States) if there were little return on that investment. Finally, some providers of CME have advertised their own educational services as having promotional benefits. For example, one MECC declared, "Medical education is a powerful tool that can deliver your message to key audiences and get those audiences to take action that benefits your product."[6]

Solutions

These problems require both short- and long-term solutions. In the long-term, commercial influence on CME could be minimized by eliminating industry sponsorship of educational programs or by funding CME programs from a general pool of industry support within each academic medical centre.[15] In the absence of such sweeping changes, however, CME providers and doctors can take other steps to mitigate potential bias. Providers of CME

NO

appropriateness of venue, speakers, invitations, media releases, and honoraria.

Upon conclusion of all CME and CPD programs, attendees are asked to complete evaluations. These evaluations must include a question asking attendees whether they perceived any bias in the program. The CFPC is developing processes for auditing these responses. We are also developing a new tool to detect and measure bias that will be used in the accreditation review and program audit.

In addition, the College is in the process of developing a policy of cosponsorship wherein programs will no longer be submitted by individual companies, but rather by physician organizations. These organizations will be responsible for quality control as well as for payment of all expenses associated with CME and CPD programs. Many other new safeguards are also in development.

Not foolproof

While the CFPC has accredited CME programs for many decades, we know that our landscape has changed dramatically in the last 10 years. All CME and CPD programs accredited by the College are unquestionably balanced, free of bias, and not being used by pharmaceutical companies to market their products.

That is not to say that there are not companies who do, or try to, abuse or misuse our Mainpro process for their own ends. No system is completely foolproof so that those "in the know" cannot get around it. The College, however, prides itself on the experience and acumen of its reviewers and has confidence that they will "catch" those who try to misuse our system.

Additional measures

In addition to the measures put in place by the College, the Canadian Medical Association in 2001 established guidelines for "Physicians and the Pharmaceutical Industry."[1] These guidelines clearly defined the distinction between CME or CPD activities and promotion and included guidelines related to sponsorship, advisory boards, samples, gifts, and relations with medical students and residents.

Industry itself, led by Canada's Research-Based Pharmaceutical Companies, established a strict code of conduct.[2] The latest edition of this code of conduct became effective in July 2007 and features financial penalties and public censure for those who violate the code.

We believe these measures can and will prevent our accredited CME and CPD programs from being used for marketing[3] in the manner described by Steinman.

Dr Marlow *is an Assistant Professor in the Department of Family and Community Medicine at the University of Toronto in Ontario, a Certificant and Fellow of the College*

YES

can go beyond minimum accreditation requirements to institute quality-control mechanisms, such as declining to host events sponsored by a single company, using risk assessment tools to prospectively identify activities at higher risk of bias, and assessing potential bias through attendee questionnaires and direct observation of higher-risk courses.[16] Individual doctors can minimize their exposure to potentially biased information by avoiding programs that are heavily subsidized by one company. These programs can often be identified by low or no registration fees. Physicians can also be mindful of other risk factors for bias, such as the presence of course faculty who are representatives of or closely allied with industry, including members of companies' speakers bureaus.

Continuing medical education is critical for disseminating new advances in medicine and improving the quality of care that physicians provide to their patients. Commercial intrusion into CME threatens the reality and perception of scientific objectivity and best practice. Substantial changes in the structure and regulation of CME activities are needed to correct these problems. In the meantime, individual physicians need to be aware of and to minimize commercial intrusion into their CME.

Dr Steinman *is an Assistant Professor of Medicine in the Division of Geriatrics at the San Francisco VA Medical Center and the University of California, San Francisco.* **Dr Baron** *is a Professor of Medicine and Associate Dean of Graduate Medical Education and Continuing Medical Education at the University of California, San Francisco.*

Acknowledgment

This work was supported by a Research Career Development Award from the United States Department of Veterans Affairs, Health Services Research and Development Service.

CLOSING ARGUMENTS

- Medical education is an important part of drug companies' promotional strategy to increase sales of their products.
- Many continuing medical education (CME) programs are funded wholly or in part by drug and device manufacturers.
- Despite various mechanisms to protect against commercial influence, financial conflicts of interest faced by CME providers and speakers can affect course content in favour of sponsors' products.
- To minimize commercial bias, physicians should seek CME programs with less industry sponsorship and with rigorous mechanisms to mitigate conflicts of interest.

NO

of Family Physicians of Canada, President-elect of the Canadian Association of Continuing Health Education, and Director of Continuing Professional Development at the College of Family Physicians of Canada.

Competing interests

None declared

Correspondence to: **Dr Bernard Marlow,** *Director of Continuing Professional Development, College of Family Physicians of Canada, 2630 Skymark Ave, Mississauga, ON L4W 5A4; telephone 905 629-0900, extension 304; fax 905 629-0893; e-mail* **bm@cfpc.ca**

References

1. Canadian Medical Association. *Physicians and the pharmaceutical industry (update 2001).* Ottawa, ON: Canadian Medical Association; 2001. Available from: **http://policybase.cma.ca/dbtw-wpd/PolicyPDF/PD01-10.pdf**. Accessed 2007 September 5.
2. Canada's Research-Based Pharmaceutical Companies. *Code of conduct.* Ottawa, ON: Canada's Research-Based Pharmaceutical Companies; 2006. Available from: **http://www.canadapharma.org/Pharm_comm/Code/0701-Code_EN.pdf**. Accessed 2007 August 21.
3. Marlow B. The future sponsorship of CME in Canada: industry, government, physicians or a blend? *CMAJ* 2004;171:150-1.

CLOSING ARGUMENTS

- Industry practices in relation to continuing medical education and continuing professional development have changed dramatically in the last 10 years.
- Accrediting bodies, such as the College of Family Physicians of Canada, have introduced measures in their accreditation standards that prevent promotion in accredited educational activities.
- Physician organizations and industry leaders have established guidelines and codes that have been adopted widely and that clearly define the relationship between industry and physicians. These guidelines and codes ensure that accredited medical education and continuing professional development programs are balanced and unbiased.

YES

Competing interests

Dr Steinman *served as an unpaid expert witness in United States of America ex rel. David Franklin v. Pfizer, Inc, and Parke-Davis, Division of Warner-Lambert Company, litigation that in part alleged that Parke-Davis used educational activities to promote gabapentin (Neurontin).* **Dr Steinman** *also participated in the creation and development of an online, searchable archive of documents from the gabapentin litigation (***http://dida.library.ucsf.edu***). Seed funding for this archive was provided by a gift from* **Thomas Greene***, lawyer for the whistle-blower plaintiff in this litigation, to the University of California Board of Regents.* **Drs Steinman and Baron** *are coinvestigators on an educational grant administered through the Attorney General of Oregon that was funded through a settlement fund from the aforementioned litigation.* **Dr Baron** *is Associate Dean of Graduate Medical Education and Continuing Medical Education at the University of California in San Francisco and in this role has participated in the organization of CME courses that have received educational grants from industry.*

Correspondence to: **Dr Michael Steinman,** *San Francisco VA Medical Center, 4150 Clement St, Box 181G, San Francisco, CA 94121 USA; fax 415 750-6641; e-mail* **mike.steinman@ucsf.edu**

References

1. Steinbrook R. Commercial support and continuing medical education. *N Engl J Med* 2005;352:534-5.
2. Accreditation Council for Continuing Medical Education. *ACCME annual report data 2005*. Chicago, IL: Accreditation Council for Continuing Medical Education; 2006. Available from: **http://www.accme.org/dir_docs/doc_upload/9c795f02-c470-4ba3-a491-d288be965eff_uploaddocument.pdf**. Accessed 2007 August 27.
3. Canadian Medical Association. *Physicians and the pharmaceutical industry (update 2001).* Ottawa, ON: Canadian Medical Association; 2001. Available from: **http://policybase.cma.ca/dbtw-wpd/PolicyPDF/PD01-10.pdf**. Accessed 2007 April 2.
4. What's wrong with CME? *CMAJ* 2004;170:917, 919.
5. Accreditation Council for Continuing Medical Education. *Standards for commercial support.* Chicago, IL: Accreditation Council for Continuing Medical Education; 2006. Available from: **http://www.accme.org/dir_docs/doc_upload/68b2902a-fb73-44d1-8725-80a1504e520c_uploaddocument.pdf**. Accessed 2006 July 13.
6. Relman AS. Separating continuing medical education from pharmaceutical marketing. *JAMA* 2001;285:2009-12.
7. Steinman MA, Bero LA, Chren MM, Landefeld CS. The promotion of gabapentin: an analysis of internal industry documents. *Ann Intern Med* 2006;145:284-93.
8. Angell M. Is academic medicine for sale? *N Engl J Med* 2000;342:1516-8.
9. Chren MM, Landefeld CS. Physicians' behavior and their interactions with drug companies. A controlled study of physicians who requested additions to a hospital drug formulary. *JAMA* 1994;271:684-9.
10. Chren MM, Landefeld CS, Murray TH. Doctors, drug companies, and gifts. *JAMA* 1989;262:3448-51.
11. Bowman MA, Pearle DL. Changes in drug prescribing patterns related to commercial company funding of continuing medical education. *J Contin Educ Health Prof* 1988;8:13-20.
12. US Senate Finance Committee. *Committee staff report to the chairman and ranking member: use of educational grants by pharmaceutical manufacturers.* Washington, DC: US Government Printing Office; 2007. Available from: **http://www.finance.senate.gov/press/Bpress/2007press/prb042507a.pdf**. Accessed 2007 May 8.
13. Prakash S; National Public Radio. *Part 1: Documents suggest Merck tried to censor Vioxx critics.* Washington, DC: National Public Radio; 2007. Available from: **http://www.npr.org/templates/story/story.php?storyId=4696609**. Accessed 2007 March 28.
14. Steinbrook R. For sale: physicians' prescribing data. *N Engl J Med* 2006;354:2745-7.
15. Brennan TA, Rothman DJ, Blank L, Blumenthal D, Chimonas SC, Cohen JJ, et al. Health industry practices that create conflicts of interest: a policy proposal for academic medical centers. *JAMA* 2006;295:429-33.
16. Marlow B. The future sponsorship of CME in Canada: industry, government, physicians or a blend? *CMAJ* 2004;171:150-1.