

Commercial Support for Continuing Medical Education

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A thoughtprovoking American experience

I (MBM) recently gave a talk on sleep disorders at a small community hospital as part of their continuing medical education (CME) activity for their staff. I was offered a small honorarium for this. Prior to my talk, I received a letter from the hospital asking me if I had a significant financial interest in any company or any product that would be discussed in my presentation. In addition, the letter specifically requested that my talk be free from commercial bias and that I use generic names, rather than trade names, for drugs or equipment. The letter was accompanied by copies of standards for commercial support of continuing medical education set by the Accreditation Council for Continuing Medical Education, Code of Pharmaceutical Marketing Practices of the Pharmaceutical Manufacturers Association¹ and a *JAMA (Journal of the American Medical Association)* editorial regarding gifts to physicians from industry². This got me thinking about industry sponsorship of CME. What lessons can we learn from the American experience for the Indian situation?

Ethics in CME programmes

Continuing medical education keeps the practising physician in touch with the ever-changing field of medicine. Thus it improves the physician's ability to care for patients. Initially in the US such programmes were encouraged. Over the years state medical licensing bodies have mandated them. So how does ethics come into this eminently worthwhile activity?

Someone has to pay to produce CME programmes. Money is needed to pay for the lecture hall, the audio-visual equipment used, honoraria for speakers etc. Couldn't the physicians pay for this through registration fees for the programmes? After all, the physicians are required to attend a certain number of hours of CME every year in order to maintain their license to practice medicine. Yes, the physician should pay and they do. However, corporations, eager to influence the physician to use or prescribe their product, often pay the major cost of such programs in return for advertisement of their products. Often, corporations use CME as a pretext with the educational program forming a (optional) part of extravagant holidays and parties for physicians and their families and huge honoraria for the lecturing physicians.

Recognising these dangers, the Board of Regents of the

American College of Physicians stated their position on relationships between physicians and the pharmaceutical industry. These specifically state "A useful criterion to determine acceptable activities and relationships (between industry and physician) is 'Would you be willing to have these arrangements generally known?'" The Council on Ethical and Judicial Affairs of the American Medical Association approved the following guidelines on gifts to physicians from industry in 1990. In summary, they state: Any gifts accepted by physicians individually should primarily entail a benefit to patients and 'should not be of substantial value e.g. textbooks. Individual gifts of minimal value are acceptable as long as they are related to physician's work e.g. pens.

Permissible subsidies

Subsidies to underwrite costs of CME are permissible provided they are not given to an individual physician but to the conference sponsor who can use it to reduce registration fee for participants. Subsidies should not be accepted for travel, lodging or other personal expenses of physicians who will attend such conferences.

Hospitality should be no more than modest meals or social events that are part of a conference. Consultants or speakers can receive reasonable compensation. Scholarship for students and residents to attend conferences are permissible as long as the attendees are selected by the academic institution.

No gifts should be accepted if there are strings attached. The Pharmaceutical Manufacturers Association endorsed both and incorporated them in their Code of Pharmaceutical Marketing Practices¹. The Accreditation Council for CME which oversees all aspects of CME has published their *Standards for Commercial Support of Continuing Medical Education*³. The standards specify in detail appropriate behaviour for sponsors of CME programs that receive support from profit-making organisations.

There is ongoing debate among physicians about the conflict of interest issues and the advisability of accepting funds for CME. In "Acceptance of External Funds by Physician Organisations: Issues and Policy options", the authors discuss the benefits to the organisation from receiving such funds⁴. Such benefits include enhanced activity to promote the organisation's goals, improving the skills of its members which would benefit the patients indirectly, influencing public policy meant to improve patient care and so on. The authors point out that this is laudable provided the goal of the organisation itself is

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worthy and is not simply a promotion of the well being of its members. If industrial financial support leads to an improved relationship with other organisations that share common goals (education of its physician members), it helps develop a morally healthy relationship with industry.

Risks in accepting funds from companies

They acknowledge the many risks of accepting such funds. To begin with, there is the potential for undue influence. This has been shown to occur in speakers' presentations at conferences but more subtly may affect the organisation at the planning level and alter its focus. There is a potential for dependency by creating such an opulent meeting one year that organisations are unable to meet the expectations of its members for similar meetings in future without soliciting external funds which this time may not come without strings attached. An organisation receiving such support has to be concerned with the potential loss of reputation with the public and the government. This may decrease its effectiveness in promoting certain goals even if it remains uninfluenced by these funds. Also, the authors acknowledge that the money donated for such CME programs invariably gets passed on to patients as higher cost of drugs, making it imperative on the organisation to make the conference as clinically oriented as possible to justify the transfer of funds from the public to the physicians.

Various options

Based on these considerations they recommended several policy options. One was to take no external funds at all, thus there is no chance of improper conduct. But this absolute ban was felt to be counterproductive as even government research or educational grants would be banned under it.

Another option was to accept grants based on the type of funding agency. One with little involvement in patient care activities (such as luxury car manufacturer or jewelry manufacturer) is preferred because these sources do not take money directly from patients and give it to physicians. Similarly, external funds would be acceptable if they came from an organisation that shared some of the goals of the association of physicians. Basing acceptance on the profit status of the organisation, preferring a non-profit status, was attractive but they pointed out that non-profit organisations could be a "front" for businesses wishing to hide their role in disbursement of funds.

Keeping the programme committee totally separate from the fund raising committee reduced the potential for donor influence on the content of the presentation. However, this recommendation assumed that the members of the two committees have no influence on each other, which is not true in practice.

To reduce the risk of becoming dependent on external funds, a physician organisation could set a limit on the amount of external funds accepted, as a percentage of its total budget, or it could set up its budget in such a way that it never needs external funds to meet its yearly expenses. Also, they emphasised that funds should always be

unrestricted, that is, not directed towards any particular topic or speaker.

In view of the potential pitfalls in any option chosen, the authors felt that it was crucial for an association of physicians to establish a mechanism to receive broad input from the organisation's members and to devise a process to review and modify policy on acceptance of external funds.

In "May the piper take the payment and still call the tune?"⁵, Dr. Perkins, editor of *Journal of General Internal Medicine* criticised the above article for offering a variety of options without specifically advocating a course of action. Dr. Perkins felt that there were only two options for the Society of General Internal Medicine (SGIM), taking no external funds and taking limited external funds. He recommended the latter with five guidelines: 1) SGIM officers must be notified about any gift received and be held responsible for decisions about it. 2) Gift must promise significant benefit to patients. 3) The gift must not allow the giver control over the program. 4) Gifts must not be more than 5-15% of SGIM's budget and must be a "bonus" and not a part of the budget. 5) Gifts accepted as well as refused must be announced at the SGIM business meeting and published in its newsletter.

Dr. Nina Bickell⁶, relating a personal experience of a donor trying to influence the content of her talk, suggested ways to curb the growing violations of these guidelines. The suggestions included a sheet from sponsor to presenter that would specify the identity of the supporter, the exact amount and type of support, and would offer the option of direct contact with supporter. Thereby, the presenter could choose either to receive or refuse supporter contact and funds. If the presenter chose to receive contact and support, this would be disclosed to the audience giving details of funds received for travel, honoraria, preparation of audiovisuals and so on. This could affect presenters' acceptance of support but it would certainly give adequate disclosure information to the audience. In addition, a task force to monitor violations of these guidelines and with the authority to rescind the award of CME credits in case of proved violations would be a strong deterrent for potential violators. Talley⁷ emphasised how nothing is really free, and that the pharmaceutical industry invariably passed on the cost of support of CME programs to patients in the form of higher prices for its drugs. In this scenario, pharmaceutical company support of worthless or dubious items, such as computer software programs dedicated to enhance use of one particular product, promotional rather than educational conferences and so on increased the cost of drugs without really benefiting the physicians or their organisation. He suggested that it would be far better to recognise up front that any support from pharmaceutical industry comes with a price tag and to make sure that what one gets in return for that price is a truly balanced and legitimate educational program.

Relevance in India

All this is well and good, one might say, but what relevance does it have to the situation in India? The State has delegated authority for medical licensure to the local (state) medical council. Monitoring of licensure is so lax that unlicensed practice is rampant. Where large number of practising physicians do not bother to renew their licenses, how can CME be mandated? Moreover, how can ethical standards be enforced? Where 'in our days we did' type of knowledge governs medical practice, is some CME better than none? We disagree. We believe that unethical education is worse than no education at all. We believe that, taking into account all of the problems, the responsibility for upholding very high ethical standards rests with the organisations offering CME. While discussion of the problems of regulating medical practice is beyond the scope of this article, we believe that in this scenario, the best option would be to not accept any commercial support of CME. Teaching institutions and hospitals must be encouraged to hold such programs with their own faculty as

speakers thus minimising expenditure and therefore the need for outside support. Such programmes should be made accessible to the rural practitioners also. The State should recognise its responsibility with supplemental support for such activities. As individual practitioners, the objects of CME, we must acknowledge our responsibility to promote ethical values in our society by publicly censuring organisations transgressing ethical expectations.

References

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