INTERNATIONAL

The ethics of industry support for professional education in medicine

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In the 1990s, academic leaders in internal medicine from the United States and Europe started a project to define medical professionalism. Their charter was published in the *Annals of Internal Medicine* and *Lancet* simultaneously in February 2002 (1). The first professional commitment the charter cites is a commitment to maintain lifelong professional competence, and not just for the individual physician; "...the profession as a whole must strive to see that all of its members are competent."(1) This requirement for lifelong learning by physicians was stressed by William Osler in the early 1900s (2). Most state licensing bodies in the US arbitrarily mandate 40-60 hours of continuing medical education (CME) every year for renewing medical licenses. Doctors are not the only professionals required to demonstrate continuing competence. Lawyers, nurses, and most other professionals also have similar continuing education requirements.

Medical education in the US today is largely guided by principles laid down almost 100 years ago by Abraham Flexner (3). In 1908, the Carnegie institute, concerned for the safety of the public at the mercy of poorly trained doctors and the welfare of medical students who may not be getting what they paid for, had appointed Flexner, a respected educationist working at the Rockefeller Center, to study medical education in the US and Canada. After two years of visiting and evaluating all 150 medical schools in existence at that time, Flexner, who had never stepped inside a medical school or in a hospital before this appointment, reported that too many private medical schools, to maximise profits, relied exclusively on didactic lectures, totally ignoring teaching of laboratory science and bedside clinical medicine. Lectures cost little while laboratories and bedside teaching are expensive!

Flexner's report revolutionised the teaching of medicine in the United States: most private medical schools were forced to close their doors unless they established a relationship with a university and a teaching hospital to provide the necessary training in anatomy, physiology, laboratory science, and bedside clinical medicine.

Continuing medical education

The two major problems in CME today are the format and the funding. It has been estimated that more than 95% of formal CME is conducted as PowerPoint presentations or in a didactic lecture format; a format frowned upon by Flexner a hundred years ago. Studies have shown that this format is not effective as a tool for teaching adults. Moreover, the subject matter invariably is based on drug therapy at the expense of other forms of treatment. And yet, either the information is not reaching the rank-and-file practitioners or they are ignoring the information under intense industry advertising. As the *New York Times* reported on September 1, 2008, months after ezetimibe (Vytorin), a new class of drug to reduce cholesterol, was shown not to prevent heart attacks or prolong life and may actually carry a risk of cancer, the sales of ezetimibe containing drugs exceeded $5 billion in the previous year (4).

While most of the CME in the US is organised under the aegis of local medical societies and the universities, over the last three years, a new player has appeared on the scene-the medical education and communication company (MECC). More and more physicians in private practice are getting their CME from these organisations. "Educational" grants from the pharmaceutical and medical equipment companies provide the bulk of MECC funding, and in turn about 34% of the income of MECCs goes to provide CME.

The commercial support for CME amounted to $1.5 billion in 2006. Most of this support came from the pharmaceutical industry. Industry support for CME quadrupled from 1998 to 2006; increasing from $302 million in 1998 to $1.2 billion in 2006. As has been pointed out frequently, the industry has a fiscal responsibility to its shareholders to maximise profit. Healthcare providers have a responsibility to their patients to provide evidence-based, cost-effective care. One study quoted by the AMA's Council on Ethical and Judicial Affairs (CEJA) contends that for every $1.00 spent by the pharmaceutical industry on CME, the industry enjoys a return of $3.54. "This ROI [return on investment] is higher than what has been estimated for pharmaceutical detail visits and direct-to-consumer advertising. Based on these estimates, industry support for professional education is unlikely to fall; more likely it will continue to grow for the foreseeable future unless steps are taken to intervene."(5) The ever increasing financial involvement of pharmaceutical corporations and medical device makers with doctors' education raises concerns about biased treatment and undermines the public's confidence in the profession. Such concerns led the United States Senate Finance Committee to conduct hearings on the subject. The committee, after a two-year-long hearing, concluded that, "It seems unlikely that (a) sophisticated industry would spend such large sums on an enterprise but for the expectation that

the expenditures will be recouped by increased sales." The Senate Committee recommended that organised medicine establish mechanisms to assure that the pharmaceutical industry interests did not unduly influence continuing education programmes. The Accreditation Council for Continuing Medical Education (ACCME), the official body that certifies and oversees CME activities, has established rigorous rules to limit commercial content in CME activities. The current efforts are mainly directed at increasing transparency by requiring full financial disclosure by the sponsors as well as the physicians conducting the education sessions. Also, the sponsors are required to assure that the funders have no control over the objectives, the content, the format and the selection of speakers.

The AMA and ethics: role of the Council on Ethical and Judicial Affairs

The Council on Ethical and Judicial Affairs (CEJA), a standing committee of the American Medical Association, is responsible for maintaining and updating the 160-year-old comprehensive AMA Code of Medical Ethics. CEJA is a composed of seven practising physicians, a physician in training, and a medical student. CEJA carries out timely evaluations of ethical concerns and reports the results of its analyses and its recommendations to the AMA House of Delegates.

On February 17, 2008, CEJA released a report on industry's support for medical education and provided guidelines on how physicians and the medical profession should address these issues (5). The report asserts that "medicine must control the subject matter that is taught and ... ensure the objectivity of educational content and of those who teach it. ... There is growing concern that medicine's increasing reliance on industry financial support of professional education has undermined its status in society." Furthermore, the report states that "... Professional education in medicine must be free of all bias. Since it is not humanly possible to be free of bias ... whenever the priorities of medicine and industry are misaligned, and industry promotes its priorities by supporting educational activities, the integrity of professional education is undermined." The report cites a study showing that physicians who attended an industry- supported CME activity prescribed the company's drug more often. In another study, prescribing practices of physicians who attended symposia organised by manufacturers of two drugs showed that usage of both drugs increased after attending the symposia.

CEJA, by stressing that its concern with commercial support of CME is not about corruption but about subtle bias, feels that current practices of assuring transparency through disclosure of potential financial conflicts of interest place the burden of managing the conflict on the recipients, who have to decide how skeptical they should be regarding the material being presented. Moreover, presenters may believe that once they have made a disclosure, they need not be very objective. Learners may believe that presenters are being honest having made the disclosure of their conflict of interest. "In other words, disclosure can create a false sense of security about the objectivity of the educational content." CEJA believes that the ACCME standards for assuring independence of CME activities from commercial bias are ineffective. "Commercially supported CME programs tend to address a narrower range of topics, focus more on drug therapies, and give more favorable treatment to company products than do programs that are not commercially funded."

As the CEJA report states, "... We are not convinced that attempting to manage industry influence in professional education is a prudent use of resources. Rather, avoiding the influence altogether is essential to ensuring the integrity of professional education." Its recommendations are:

Medicine's autonomy and authority to regulate itself depends on its ability to ensure that current and future generations of physicians acquire, maintain, and apply the values, knowledge, skills, and judgment essential for quality patient care. To fulfil this obligation, medicine must ensure that the values and core commitments of the profession protect the integrity of professional education. It must strive to deliver scientifically objective and clinically relevant information to individuals across the learning continuum-from medical school, into residency and fellowship training, and throughout continuing medical education.

To promote continued innovation and improvement in patient care, medicine must sustain ongoing, productive relationships with the pharmaceutical, biotechnology, and medical device companies. However, industry support of professional education has raised concerns that threaten the integrity of medicine's educational function. Existing mechanisms to manage potential conflicts and influences are not sufficient to address these concerns.

Given medicine's current reliance on industry funding of professional education, implementing the following recommendations will take time. Yet we must recognize the profession-defining importance of ultimately achieving these goals. To that end:

(1) Individual physicians and institutions of medicine, such as medical schools, teaching hospitals, and professional organizations (including state and medical specialty societies) must not accept industry funding to support professional education activities. Examples of such activities include, but are not limited to, industry funding for:

(a) residency positions and clinical fellowships;

(b) didactic educational programs, such as live or web-based continuing medical education activities:

(c) physician speakers' bureaus; and

(d) travel, lodging, and amenities for participants of clinically relevant educational programming.

(2) One exception to no industry support of professional education is when new diagnostic or therapeutic devices and techniques are introduced. Given the requirement for technical training on how to use new devices, industry

representatives may have to play an educational role because they could be the only available teachers. But once expertise in the use of previously new devices has developed within the professional community, continuing industry involvement in educating practitioners is no longer warranted. Technical assistance or support that industry representatives may provide physicians in the context of patient care (e.g., helping a surgeon in the operating room select the appropriately sized prosthesis components) is not considered professional education and is not ethically inappropriate.

(3) Medical schools and teaching hospitals are learning environments for future physicians at a critical, formative phase in their careers. These institutions have special responsibilities to create and foster learning and work environments that instill professional values, norms, and expectations. They must limit, to the greatest extent possible, industry marketing and promotional activities on their campuses. Examples of such activities include, but are not limited to:

(a) free food and other industry gifts for trainees and faculty, and

(b) detailing visits by industry representatives.

Medical schools and teaching hospitals have a further responsibility to educate trainees about how to interact with industry and their representatives, especially if and when trainees choose to engage industry in varying capacities after residency and fellowship training.

(4) The medical profession must work together to:

(a) identify the most effective modes of instruction and evaluation for physician learners, then;

(b) more efficiently develop and disseminate educational programming that serves the educational needs of all physicians, especially for those who have difficulty accessing continuing medical education (such as those who practice in rural areas); and

(c) obtain more noncommercial funding of professional education activities.

Reaction to the CEJA report

As one may expect, the report received international media attention. Most medical specialty societies, while agreeing with the basic objective of the report, felt that the report went too far in recommending the elimination of all commercial funding for CME: How can you eliminate $1 billion in funding without having a significant negative impact? The American Association of Medical Society Executives felt that CEJA had not taken full account of the recent revisions in the ACCME guidelines, both in terms of handling conflict of interest and in refashioning CME content (6).

In response to a questionnaire sent out by The American Society for Academic Continuing Medical Education (SACME) to its members, the majority felt that the CEJA report did not adequately separate out industry-supported, not-for-credit, promotional activities from accredited CME. While the majority of responses favoured sending the report back to CEJA for its failure to take into account the recent ACCME changes, one respondent pointed out that the CEJA report addresses ethics: organisations that provide CME and rely heavily on financial support from the industry should not be discrediting the report because they feel threatened from the proposed ban on funding from the pharmaceutical industry. "To say that the quality of CME will decline because industry does not pay for it doesn't really speak well for CME."(7)

Like other institutions mentioned here, the North American Association of Medical Education and Communications Companies (NAAMECC), rejects the CEJA report on the basis of its failure to take into account the recent changes in the ACCME rules governing corporate funding; failure to adequately distinguish between non-CME and accredited CME activities; "... possible misinterpretation and/or misuse of data and conclusions..."; and its failure to provide evidence to support the contention that the loss of funding of approximately $ 1 billion will improve CME (8).

Medscape, a subsidiary of WebMD, a prominent MECC, published an article by a Thomas Stossel (9) in their on-line journal, challenging most of the arguments put forward by the CEJA. Stossel argues that the changes proposed in the report would profoundly change medical education as it exists today. He does not see any conflict of interest in accepting payments and other incentives from pharmaceutical companies. He questions the validity and interpretation of the numerous studies since the 1980s that have shown that a real or a potential conflict does exist. He cites multiple studies to argue that the tremendous improvement in longevity in the second half of the last century came from industry research and innovation in health care. He argues that the report failed to take into account the many studies that showed that patients often fail to get the most appropriate treatment because the treating physician was unaware of them; "potentially curtailing information transfer by constraining its funding will increase this deficiency." He argues that a risk-benefit analysis of industry support for medical education has not been performed and, in the absence of such an analysis, the CEJA report has no validity. He rejects the definition of professionalism adopted by the CEJA (and the society for internal medicine, and other professional organisations). He questions the sanity of rejecting a major source of funding for medical education when government support is dwindling. Unlike the government, judges, or news reporters, he does not consider physicians bound by the same requirements of impartiality or bias. He points out that academic medical centres and medical journals behave in the same competitive manner as many corporations, often engaging in promotional practices that may be considered abhorrent in corporations. He urges his readers not to accept altruism at face value: "...good intentions disguise self-dealing and tyranny ... The moral life of a practicing physician is a balancing act between multiple competing values and incentives -- not the abstract worship of absolute altruism."

SACME, in a response to the Institute of Medicine request for a comment on conflict of interest (COI), recognised the need for developing a system to manage actual or apparent COI. SACME posited that no single definition of COI is adequate. Academic physicians play a complex role as teachers, researchers, clinicians, administrators, etc. Their involvement in CME teaching may have multifarious potential conflicts extending far beyond any relationship with a pharmaceutical company. Academicians do not necessarily see CME as a natural extension of the undergraduate and graduate medical education system. "Expectations point more to CME's marketing role in representing the institution, presenting new findings/ research, supporting hospital activities. Increasing referrals, showcasing new clinical facilities, or highlighting new research findings...". SACME stressed that "Systems must be in place so that no source of funding influences the balance or objectivity of CME activities, and measurement of its outcomes." SACME membership did not agree that the current system of funding CME "leads to content bias". They, however, did agree that the current regulatory system does not eliminate bias. They did stress that there is no necessity to eliminate commercial support for CME. That said, "The majority would eliminate all gifts, including free lunches," in association with any CME activities to manage bias. CME planners and faculty need to develop expertise in using teaching approaches that are more effective as well as linking CME to quality improvement initiatives (10)

Stanford University, one of a handful of medical institutions, has announced that they will no longer accept any pharmaceutical industry support for specific CME activities as of September 1, 2008. The American Medical Students' Association, for some time now, requires its members to take a pledge not to accept any gift, however small, from a pharmaceutical industry representative.

Outcome

On June 15, 2008, the AMA's Reference Committee on Amendments to Constitution and Bylaws met to consider the CEJA report. While only two spoke in favour of the report, more than 40 participants representing various organisations involved in providing CME (and receiving sizable financial support from industry), spoke against the report. Siding with the opposition, the committee voted against the report, citing many of the same reasons listed above, and referred it back to CEJA. There will be no further consideration by the full AMA House of Delegates. As the Reference Committee did not recommend "Not for adoption", CEJA can rework the report and resubmit its recommendations (11).

While it appears that big money has won the day, there is some merit to their objections. CEJA's evaluation of the influence of funding on CME does appear biased. Also, CEJA does not seem to have taken into account the full impact of the recent changes in the ACCME regulations on industry funding of CME and its efforts at transparency.

It is a pity that ethics has once again been pushed aside. The then chair of the CEJA has since retired and a new chair is to be selected. It is important that the CEJA soon revisits commercial support for CME and takes a closer look at the subject.

(Those involved in medical education in India would benefit from reading the Flexner report. Anyone interested in learning more about the problems of CME in the United States should download the Macy Foundation conference on the subject. The proceedings are available as a monograph at www.josiahmacyfoundation.org)

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