

Virtual Mentor

American Medical Association Journal of Ethics
July 2003, Volume 5, Number 7: 255-259.

MEDICAL EDUCATION

Commercial Support for Continuing Medical Education

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Virtual Mentor interviewed Murray Kopelow about some of the ethical issues involved with the growing levels of commercial support for CME. Dr. Kopelow oversees the Accreditation Council for Continuing Medical Education (ACCME). The council's new draft standards for commercial support (SCS) are under discussion as part of the ongoing debate over the relationships between physicians and manufacturers of pharmaceuticals and medical devices.

Q. How do the new draft standards set the stage for better continuing medical education?

A. It is important that the standards for commercial support that we eventually adopt reflect the needs of the physicians and the CME enterprise for the 21st Century.

One important factor present in 2003 that was not as prominent in 1992 is the prevalence of professionals and CME providers with financial relationships with FDA regulated industry. (Editor's note: http://www.accme.org/dir_docs/doc_upload/dcd182a-bf21-49da-933f-d6c13409b011_uploaddocument.pdf—Link to "new ACCME standards for commercial support." The current standards date from March 1992.).

Q. What is the evidence of that growing relationship?

A. The amount of disclosure that's required by people at Continuing Medical Education activities. It seems that virtually everyone who is speaking has a relationship with industry. The data show that 60 to 80 percent of research is now funded directly by FDA-regulated firms. In association with this, researchers have been recognized by industry as "influentials" and change agents. Many researchers have been recruited to a new role involved in the education and promotion activities done by regulated industry. In this capacity they can effectively become the "agents" of FDA-regulated industry with the concomitant duties of loyalty and care.

These investigators could then be put in the position of controlling the content of the CME developed by an ACCME accredited provider.

Now, at that point a conflict of interest could exist. A conflict between the interest of the public and the interests of the FDA-regulated industry.

Simply telling the learner that the relationship exists does nothing in itself to resolve or reconcile the conflict. It simply reveals it. It might even go unrecognized by the learner.

Q. The learner has to sleuth out whether there's a subtle promotional bias in each particular CME event?

A. Yes. The existing 1992 ACCME standards for commercial support only demand disclosure. The responsibility for detecting bias is formally on the shoulders of the learners. Realistically, however, a great many providers already are "managing" conflict of interest intuitively. For example, salespeople from FDA-regulated industry are not invited speakers at CME events.

Q. Who *should* have that responsibility for detecting bias, according to the new standards?

A. The teachers and the CME providers have a role in reconciling those conflicts—*before* the education activity is developed and presented to the learner. (Editor's note: The list of ACCME-accredited CME providers includes institutions and organizations such as professional societies, medical schools, and hospitals as well as physician- and non-physician-owned medical education companies or MECCs—see Table 7 at <http://www.accme.org/find-cme-provider>) That's new.

When people come to learn, asking them to be expert enough to decide whether this is biased or not—we shouldn't depend on that.

Q. How can industry participate in CME without overstepping the bounds of propriety?

A. From the point of view of the kind of CME I am talking about, continuing medical education is by physicians for physicians. The *content* is created by them for them. It is separate from promotion in time and place. The pharmaceutical industry has no role in CME content at all, unless they are invited.

Industry knows best about the pharmacotherapeutics of their drugs—for example, what the complications are. The physicians need access to that. The drug company speakers have a role. But it needs to be controlled, monitored, and regulated by the physicians.

Q. Could physicians afford the same CME without the current subsidies from the pharmaceutical industry?

A. It seems to us that there could be a substantial reduction in the amount of money spent on CME without a loss of quality in CME activity, if less money were spent on meals and amenities--and objects—pens, books, brief cases—and documents, expensive handout materials, for example. There's a billion dollars spent, half of that comes from commercial sources. Do we need to spend a billion dollars? That question needs to be very, very carefully examined. Even if people say that the new ACCME standards for commercial support are going to decrease the amount of industry support, that does not mean there is going to be a decrease in the amount of education.

There are many funding sources, potentially. Clearly the two choices are the profession or someone beyond the profession. And that issue has not been debated very strongly yet. There's a movement among the medical students who believe that doctors have a professional responsibility to pay for their continuing medical education. (See www.nofreelunch.org.) So there's an important debate that needs to occur. There's quite a range of beliefs in the profession as to what should be paid for; it's a complicated issue.

Q. Can any one group resolve that?

A. Well, the physicians can. The doctors can say this is how we want to be. We don't want to take funds, or we do want to take funds.

Q. In some of the published articles on the subject, you made an estimate that 30 percent of CME providers did not disclose all conflicts of interest. Would these new requirements help with that?

A. While we are working on reducing that number through education and clarifying instructions, its existence does beg the question, "Is there anything else that can be done to mitigate against commercial bias?"

Q. Have you seen a drop-off in funding?

A. It's too early to say. Our data is 6 months late when we get it. It would be 2004 before we could tell. We don't see any reason for anything we've published to have any effect on the commercial support or the total amount of CME.

Q. Do you think physicians could pay for medical education themselves if companies reduce their support for CME? Could physicians pay for it themselves?

A. I'm not sure. That's not for me to postulate. If you take the billion-plus dollars a year, and divide by the 750,000 doctors who may be practicing, that's about \$1333 a year right? If it's 400,000 practicing doctors, it is closer to \$2400. Is that too much? Doctors have to answer that.

Q. Would the new standards or any anticipated policy of the Office of Inspector General at the U.S. Department of Health and Human Services make it impossible to have the kind of meetings we've had in the past?

A. The Office of the Inspector General made some important observations when they said it was possible to perceive the commercial support of continuing medical education as a kickback. And that funds coming into a health care institution that makes decisions on Medicare could be designed to influence those decisions. If CME is viewed as a kickback, that's dramatic and that's serious.

What our standards say is that no one who has a relationship with a pharmaceutical firm can be in a position to control *content* in CME. So CME becomes a safe harbor, not in the legal sense, but a safe harbor conceptually.

That's why drug companies have taken a role. Merck was the first to say "We are giving our money to ACCME-accredited providers because they manage money properly. We're not giving our money to a person, where the intent of our money could be misconstrued."

Q. How many CME providers are there?

A. Over 700 accredited by us. About 1700 including those accredited by state licensing authorities.

Q. Will there be enough CME providers?

A. The system can accommodate the delivery of CME, absolutely.

Q. What was the ethical thinking that went into the new SCS draft guidelines?

A. The fact that the people who are part of the profession today have relationships with industry that need to be accommodated and accounted for in our standards of commercial support. That was reflected in the draft and will be in further iterations.

Q. The five themes in the draft were the linchpins of connecting ethics to the real world? (Editor's note: The five themes are independence, absence of commercial bias, disclosure of required information and relationships, appropriate management of funds from commercial interests, and appropriate management of advertising and exhibits.)

A. Yes, right. Those were in the old standards too. Those aren't really new. Those are different ways to articulate what we now felt.

Q. What is the timeline for debating the new standards?

A. There are two major elements dictating the time line. One is that ACCME is a thoughtful and reflective organization and will take some time to develop a final document. The task force is working on it now. The council has not yet seen or heard it. So if the council can hear a report in November—a report that may or may not have attached to it a recommendation for action—the council could take action to adopt a document. The second element is that action is subject to review by our member organizations, and they could take 90 days for review to say yea or nay. So if it is adopted on that time line, it could be in the middle of 2004, and after that there would be an implementation time, when we'd give CME providers time to come into compliance.

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