

## Testimony to the Senate Committee on Aging

My name is Steven E. Nissen, M.D. I am Chairman of the Department of Cardiovascular Medicine at Cleveland Clinic and a Past President of the American College of Cardiology (ACC). My testimony does not reflect the views of either Cleveland Clinic or the American College of Cardiology.

Continuing Medical Education, commonly known as or CME, was originally intended to serve as the principal means by which physicians maintain professional competence and acquire new medical knowledge. In fact, most states require a minimum number of CME credits as a condition for continued medical or nursing licensure. In recent years, CME has grown into an enormous industry with extraordinary influence over the practice of medicine. In 1998, the total income for CME was \$888 million. By 2007, this expenditure had grown to more than \$2.5 billion annually.

Ideally, CME should provide balanced and scientifically based education designed to improve the quality of health care. Instead, CME has become an insidious vehicle for the aggressive promotion of drugs and medical devices. Amazingly, 50% of CME funding, about \$1.2 billion, comes from companies who market pharmaceuticals and medical devices. Essentially, the marketing divisions of drug and device manufacturers now dominate a substantial proportion of physician education. CME has largely evolved into marketing, cleverly disguised as education.

An entirely new industry has been created, medical communications companies, often located in close proximity to the headquarters of major pharmaceutical and device companies. These communications companies solicit funds from industry to conduct a wide variety of “educational” offerings, providing a veneer of independence that camouflages the promotional nature of educational programs. Often the brochures state that the program was funded via an “unrestricted educational grant” from the sponsoring company. However, with a “wink and a nod”, the communications companies select speakers and topics that they know will please the sponsors. When I get these brochures, I often engage in an interesting sport. I try to guess the sponsoring company by examining the list of speakers and topics. My guesses are nearly always correct.

At major scientific meetings, there are often dozens of “satellite” symposia sponsored by industry, advertised via slick, multi-color, glossy promotional brochures. These meetings offer a sit-down dinner, followed by a series of lectures by high profile and well-paid academic physicians. The content is artfully organized by the communications company to subtly and not so subtly promote the sponsoring company’s products. If you don’t attend national meetings, you can obtain the same content via web-based education, which is professionally produced and skillfully displayed. The communications companies that produce these materials often charge industry hundreds of thousands of dollars for a single event or webcast.

Companies readily pay hundreds of millions of dollars annually to support CME for one very simple reason - it sells their products. Industry-funded CME is not philanthropy, it is marketing. In fact, the funds for CME are derived from marketing budgets of companies. The flow of money is so enticing that large academic medical centers now commonly administer CME organizations that compete with communications companies for management of industry-funded educational programs.

Not to be left out, many scientific journals accept reimbursement to publish the proceedings of industry-funded CME via “special editions” of the journal.

The lucrative CME process also has undermined the independence of professional medical societies, which may derive more than 50% of their income from the pharmaceutical and device industry. Industry-sponsored CME offered through medical societies carries the risk that the imprimatur of a prestigious medical organization will be misused for promotional purposes. In one of the worst examples, a very prominent heart organization has created a “pharmaceutical roundtable” where companies that provide huge donations to the organization are afforded special private access to medical leaders.

Professional societies play critical roles in the practice of medicine. They author the guidelines and practice standards used by physicians to select the most appropriate therapies for our patients. The co-mingling of industry funding with professional society dues potentially jeopardizes the integrity and independence of these professional organizations and raises major questions about the objectivity of the guidelines they produce. Recently, a group of current and former professional society leaders published the attached statement in the Journal of the American Medical Association, recommending that medical societies adopt a policy of zero industry funding over the next several years.

There remain a few examples where industry funding of CME appears to meet a somewhat higher standard of independence, but they are relatively rare. In these cases, a major medical center or professional society conducts a CME program sponsored by several commercial entities, each of whom provide a modest amount of funding.

With the billions of dollars of industry money flowing into CME, who is guarding the integrity of the CME process? Current oversight by the Accreditation Council for Continuing Medical Education (ACCME) is largely ineffective. The ACCME has strict rules governing educational activities, but appears uninterested or incapable of enforcing them. I am unaware of any communications companies that have lost their accreditation because of biased CME.

In fact, on several occasions I have written to ACCME to complain about inappropriate CME-accredited activities. My letters were never even acknowledged. In the worst of these cases, I received a document via mail that was titled “Cardiology Consensus Report” and formatted to mimic a professional society guideline. In fact, it was designed to promote a specific product and the authors were paid by the communications company to “write” the “consensus report.” The ACCME never acknowledged my complaint.

In recent years, CME has been increasingly used to conceal payments to physicians that would otherwise be disclosed by transparency rules at hospitals and medical schools. Since the honorarium comes from a third party and is used to support CME, recipients are shielded from disclosure. Essentially, communications companies are used to “launder” money to avoid disclosure.

As a nation, we spend nearly double the expenditures of other industrialized country on health care. We use more expensive drugs and medical devices than other countries, even when adjusted for our national wealth. I am convinced that the multi-billion marketing machine known as CME directly contributes to this excess in healthcare expenditures.

How can the Congress help?

- 1) Congress should pass the Physician Sunshine Act, introduced by Senators Grassley and Kohl, that requires pharmaceutical and device companies to disclose all payments to physicians. This law should require disclosure of payments routed through CME providers, not just direct payments.
- 2) Congress should consider legislation requiring the drug and device companies paying for CME to assume legal responsibility for content. If false and misleading statements are offered during a funded CME presentation, the funding organization should be held liable by the FDA for misbranding.
- 3) The medical profession needs an independent oversight board to replace ACCME, perhaps established by the Institute of Medicine. The current fees charged for CME accreditation are more than adequate to fund such an effort. No taxpayer dollars are needed.
- 4) For non-profit professional societies, Congress should consider designating industry funding of CME as taxable income rather than a charitable contribution.