Legal Opinion Letter

Washington Legal Foundation
Advocate for freedom and justice®
2009 Massachusetts Ave., NW
Washington, D.C. 20036
202.588.0302

Vol. 13 No. 12 June 6, 2003

NEW CME BIAS STANDARDS WILL REDUCE QUALITY OF MEDICAL EDUCATION

by
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The 2003 draft new ACCME (Accreditation Council for Continuing Medical Education) Standards for Commercial Support of Continuing Medical Education both overreach and underachieve at once. The new Standards, which were released in January, were intended to reform continuing medical education (CME) by reducing the risk of bias resulting from commercial support of programs. But instead of achieving that goal — assuming there is a problem with bias under the current standards, which ACCME has *not* shown — the new standards, if adopted in their current form, would likely reduce the quality of CME programs without addressing all sources of potential bias.

ACCME is the private organization that oversees CME for physicians. Through its Accreditation Policies, the group seeks to ensure that accredited CME programs are balanced and based on accepted science. ACCME recognizes that commercial support can "contribute significantly to the quality" of CME programs, and created separate standards — the Standards for Commercial Support for Continuing Medical Education — in 1992 to protect against bias in commercially supported CME programs. Many of the concepts from the 1992 Standards are reflected in the proposed 2003 version. However, the new version proposes significant changes involving: (a) pharmaceutical company consultants' and speakers' participation in CME; (b) CME subsidiaries of pharmaceutical companies; and (c) distribution of enduring CME materials by pharmaceutical sales representatives. These changes are discussed below.

Industry Consultants and Speakers. While the 1992 Standards require speakers at CME events to disclose significant financial relationships they have with the manufacturers of drugs they are discussing, the 2003 version would completely *exclude* health care professionals from planning or presenting CME in therapeutic areas for which they are paid by a drug manufacturer to speak, provide advice, or perform research. This provision would allow those with such "conflicts of interests" to present the most basic information about a drug product, but it would not allow them to make clinical recommendations on the use of the product.

This new provision will effectively bar leading physicians, many of whom have relationships with drug manufacturers, from significant participation in the planning and presentation of CME programs. It is no surprise that the pharmaceutical industry seeks out the best minds in healthcare to assist them in researching, developing, and promoting their products. This is as it should be. When the top physicians and clinicians work together with industry, the best products can be produced, and patients receive the benefit. Why, then, would we prohibit those physicians from presenting what they know to the rest of the health care community?

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Excluding providers with industry connections would remove the risk of bias resulting from a company compensating a CME planner or teacher for his services in another context. However, there is no evidence that the current standards requiring that CME planners and teachers disclose all relevant financial relationships — thus allowing learners to properly weigh the information they are receiving — do not adequately manage any risk of bias. Further, the new provision does nothing to affect the risk of bias from teachers and planners whose bias might result from a non-financial source. Those with relationships with drug companies will be completely barred from CME while those with, for example, ardent consumer-protection ties or a preference for physical therapy over medication would remain free to present their views as impartial with no disclosure requirement.

Drug Companies with CME Subsidiaries. Superceding the existing "Firewall Policy," the 2003 Standards would prohibit drug companies with accredited CME subsidiaries from offering education courses in the same therapeutic areas in which they sell products. This is a change of course for ACCME. As it deals with speakers, ACCME again excessively scrutinizes commercial industry bias, while ignoring other possible sources of bias.

The literature recently has focused on institutional bias in the world of academia. *See*, *e.g.*, Johns MM, Barnes M, Florencio PS, *Restoring Balance to Industry-Academia Relationships in an Era of Institutional Financial Conflicts of Interest: Promoting Research While Maintaining Trust*, J. OF THE AM. MED. ASSOC. 2003; 289 741-746. Research institutions have intellectual property offices that patent inventions and license them to commercial producers, often retaining stock options in the licensee. They may even start their own companies to develop the inventions. These economic incentives are good — they help patients by encouraging innovation. But the incentives can create bias at academic medical centers that produce and receive accreditation for CME programs. If an institution owns stock in a company that is manufacturing a product developed onsite, certainly it stands to benefit if an auditorium full of CME learners receive position information about that product.

Under the 2003 Standards, it is not clear that the situation described above would constitute a "conflict of interest." In introducing the new Standards, ACCME comments that the "interests of hospitals, medical schools and academic medical centers in delivering health care and education will not be considered "commercial interests" that would result in a bar. However, there is no further explanation. Absent any rationale, it is unclear that intellectual-property or product-based issues were contemplated by ACCME when reaching its conclusion. ACCME should not treat pharmaceutical companies and academic institutions differently, for they may have similar financial interests in developing products, and as a result, they present similar potential for bias.

Dissemination of Enduring CME Materials. The 2003 Standards would also prohibit a drug company from distributing, through its representatives, enduring CME materials in the therapeutic areas in which it sells its products. This includes journal CME, monographs, CD-ROMs, and even passwords to web sites that physicians would choose to visit on their own.

ACCME has provided no reason for restricting this source of information. Consider the physician in a rural area that may have limited local access to academic medical centers or other sources of continuing learning. It is quite obvious to the physician that the *accredited* CME has been delivered by a pharmaceutical industry representative. It seems overly paternalistic for ACCME to assume that a highly trained provider is incapable of assessing and weighing the information provided when the source is apparent and the proper disclosures are made, as the current standards mandate.

Conclusion. The draft 2003 Standards unnecessarily restrict those with industry ties from participating in CME while generally ignoring other potential sources of bias. This problem is compounded by the fact that government actors, including the FDA and state medical boards, rely on ACCME accreditation in place of their own evaluation of education opportunities for healthcare professionals. If government actors were involved in the development of the new Standards, or rely on the standards to meet their responsibilities, state action is involved and there are obvious First Amendment implications in the resulting restriction of speech. ACCME should rethink the lengths to which these new standards go, and should not adopt the new Standards in their current form. The current requirements that *all* relevant financial interests be disclosed by all parties should suffice. Learners can certainly be trusted to use their own judgment when presented with relevant information.

ISBN 1056 3059