

**Statement of the Coalition for Healthcare
Communication
IOM Committee on Conflict of Interest
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The Coalition for Healthcare Communication (Coalition) hereby offers this statement for the record in this proceeding. While we are interested in other conflict issues considered by this committee, our comments today focus only on conflict of interest in continuing medical education (CME), a primary topic for this session.

By way of introduction, the Coalition is composed of trade associations and companies engaged in publishing and professional communication related to medical treatments focused largely on the products and services of drug, biologic and device companies. The Coalition for Healthcare Communication defends the right of health professionals and consumers to receive truthful information regarding pharmaceuticals and medical products, as safeguarded by the Constitution of the United States. Founded in 1991, the Coalition represents organizations, rather than individuals, dedicated to assuring the free exchange of scientific information without undue government interference.

Our members are principle players in the existing health care system. Many are accredited providers of CME; many others partner with accredited providers at medical schools, medical specialty societies and with accredited medical education and communication companies (MECCs).

Although we are disappointed that the Coalition was denied the opportunity to speak today, we trust we will be allowed to participate fully in subsequent meetings. Meanwhile, we offer the following short comments summarizing our position and point you to other relevant recent statements by us. Further, we recommend that you also carefully attend to today's comments by Karen Overstreet on behalf of the North American Association of Medical Education and Communication Companies (NAAMECC), and its more detailed written comment in this proceeding.

We offer four basic points today for your consideration.

1. **IOM Must Reject Calls to Eliminate Commercial Support and MECCs.**

The Coalition is alarmed that well meaning but misguided organizations, such as the Macy Foundation, are calling for the elimination of commercial support and of MECCs in certified CME as the *key* solutions for eliminating bias. Commercial support enables nearly half of CME today. Meanwhile, MECCs are the compliance leaders in CME, exceeding the performance of other providers in virtually every standard of regulatory compliance.

Systematically eliminating the private sector from medical education would eliminate the competition and plurality of competitors that are a hallmark of our democratic and economic system. Moreover, it would stifle the innovations, efficiencies and quality education they have brought to medical education.

If academics, utopians and socialists are embarrassed that for-profit companies offer education that clinicians find compelling, let them compete more effectively for the attention and attendance of medical professionals. It is clear to objective observers that clinicians continue to participate in commercially funded activities about new and better ways to diagnose and manage disease and return to their practices better prepared to treat their patients. While supported by industry, the content is independently created by accredited providers and it is also clear that patients are the primary beneficiaries.

Proposals that begin with unrealistic notions that half of certified CME can be eliminated without a plausible plan for filling that gap have no place in a serious public policy discussion on how to improve patient care in America.

2. Commercial funding and MECCs provide crucial support for patient care.

Commercial supporters and providers have been leaders in studies and research on the value of CME to patient care in America. While counting hours of instruction is easy and enables efficient certification standardization, the community fully understands that this surrogate marker must be superseded by real measures of patient care. Commercial supporters and providers are among the leaders in this process, as evidenced in their participation in related programs at the Alliance for CME as well as in the academic journals and elsewhere where the advances in measurement are progressing.

3. Discussions of Bias in CME Must Consider All Sources of Bias.

While the Coalition agrees that all CME must be of superior quality and based on the best available science, we reject the idea that commercial bias is the only appropriate criterion for conflict analysis. Indeed, we begin with the widely accepted notion that bias is inherent in the human condition – all individuals and institutions are a product of the communication and other realities within which they are formed, operate and are immersed every day. It is not possible to eliminate bias, only to recognize it, disclose it when appropriate, and manage it as well as possible.

Over the past decade, the ACCME has created a rigorous set of accreditation criteria to ensure management of commercial bias by providers. Indeed, as you have heard from ACCME, these continue to evolve, and MECCs are moving swiftly to comply with another new set of guidelines established by ACCME this past summer.

For a summary of the advances over the past 10 years, we recommend that you read the letter to the editor of the British Medical Journal published earlier this week. The letter outlines those advances and suggests the US systems for the management of commercial bias provide a model for the rest of the world. This letter and other related documents can be found on the homepage of the Coalition website: www.cohealthcom.org.

Meanwhile, the Coalition and NAAMECC are urging the ACCME to expand its requirements for the management of bias by providers to include the well-recognized forms of bias often faced by non-commercial CME providers, including medical schools. Most of the currently exempted providers have done little or nothing to separate the medical education activities they conduct as accredited providers from the influence of commercial and other interests within their organizations. Recent papers in both the *New England Journal of Medicine* and *JAMA* have pointed to this risk among physicians in practice, medical schools and major teaching hospitals. An October 17, 2007, publication in *JAMA* reported that, in a survey of 125 medical schools and the 15 largest teaching hospitals, 27% of department heads were founders, officers or board directors of drug or device companies. This is a particularly important finding that can be used by the critics of CME because of the direct and indirect influence department heads have within their organizations. The Coalition and NAAMECC has urged ACCME address this widespread risk with a unified approach toward all its accredited providers.

4. IOM Must Avoid Overlooking Significant Advances in the Management of Commercial Bias by FDA, HHS, Industry and ACCME.

IOM must recognize that the government, the professions and industry have taken significant steps over the past decade to ensure both independence and quality in “certified CME.” Since 1997 when a U.S. Food and Drug Association guidance document called for clear separation between promotion and education in the US, the CME community has made consistent improvements. Changes in the organization, structure and oversight of CME activities have all been directed toward ensuring independence from commercial influence, the highest scientific standards for content and measurable improvements in patient outcomes. The initiative has been embraced and supported by industry and commercial providers, and moved forward by the leading US accrediting organization, the Accreditation Council for Continuing Medical Education (ACCME).

Also recognize that the now famous cases brought by federal and state enforcers and much of the current criticism are based on historical events, not recent transgressions. Six major documents have had a profound effect in the past decade: the FDA’s 1997 Guidance on Industry-Supported Activities; the OIG Compliance Program Guidance; the ethical codes from PhRMA, AdvaMed, and the AMA; and the 2004 Standards for Commercial Support from the ACCME. Quite simply, the world has changed for the vast majority of players in this industry. And, for those who have not yet gotten the message, the HHS-IG, ACCME and other enforcement groups continue to evolve and act.

Furthermore, the Coalition and NAAMECC agree with the Senate Finance Committee Report of last year that called for swifter, more public enforcement of current ACCME policies. Indeed, as the ACCME considers these criticisms, NAAMECC has begun a private effort to do so. In the meantime, we ask anyone who sees continued violations of the current standards to avoid press and policy hype but to participate in legitimate enforcement efforts by reporting them to ACCME, the providers and grantors, or proper government enforcement agents. It's time for all stakeholders to participate in solutions, rather than attempt to destroy educational systems that work for doctors and patients.

Summary

The CME community recognizes that conflict of interest is a legitimate concern for all in medical education and has taken significant steps over the past decade to address legitimate issues of commercial conflicts. While we urge the IOM to be a participant in the ongoing development of these policies, we also urge full recognition of the government, industry and self regulatory systems already in place. We recommend you build on them rather than seek to supplant them.

At the same time, we recommend you reject some of the most dramatic and destructive proposals made by some organizations and individuals. We also suggest that the IOM study conflicts of interest that have not been recognized and addressed thus far, particularly in the academic community. While progress is apparent in the commercial sector, little recognition – much less progress – is apparent elsewhere.

Thank you for allowing this statement. We look forward to full participation as these proceedings progress.

Respectfully submitted,

John F. Kamp
Executive Director
Coalition for Healthcare Communication