

COALITION FOR
Healthcare
Communication

**Statement of the Coalition for Healthcare Communication
On CEJA Study of Issues Related to Ethical Considerations on
Physician Participation in Certified CME Activities**

February 25, 2008

The Coalition for Healthcare Communication (Coalition), a coalition of associations and companies with significant medical education membership, appreciates this opportunity to participate in this dialogue and the February 25 public discussion on “Ethical and Practical Issues in Commercial Support of Continuing Medical Education” hosted by the Council on Ethical and Judicial Affairs (CEJA) and the Council of Medical Education (Council). This is an important and timely topic, and we share the interest of the councils and AMA members in addressing the practical and ethical challenges in meeting the educational needs of physicians. As many of our fellow participants know, Coalition member companies offer both certified CME and FDA regulated promotional education and marketing services that provide quality information and education to thousands of physicians each year, ultimately affecting millions of patients.

It is clear to objective observers that clinicians participate in commercially funded activities to learn about new and better ways to diagnose and manage disease, and then return to their practices better prepared to treat their patients. While many of these professional activities are provided or supported by industry, patients are the primary beneficiaries.

While the Coalition shares the goals and concerns that are the focus of this inquiry, we recommend that the CEJA Committee forgo most of the discussion on the previously circulated questions suggested as the focus of this meeting, and focus instead on more potent and productive discussions.

As this comment details below, although the Coalition agrees that conflict of interest issues created by commercial support of CME are important, these are mostly rear view mirror issues, largely settled over the last ten years by FDA, HHS-IG, ACCME as well as by AMA and industry guidelines.

If AMA chooses to take a leadership role at this point, the Coalition recommends that AMA create an information campaign for physician learners that publicizes its existing ethical guidance plus related laws, policy and accreditation standards, including the clear differences between certified CME and FDA regulated education and promotion. While other leading CME institutions have launched a significant education initiative for physician faculty, it may be that physician learners currently are least aware of the fundamental changes in CME over the last ten years, a situation which may be the source of much of the public confusion and consternation. An aggressive education program by AMA could well address this issue to the benefit of the public, the profession and policy makers who, themselves, may not fully grasp the present situation.

At the same time, the Coalition believes that the overarching challenge for AMA members and CME professionals in the next decade likely will be preparing physicians and other health care professionals (HCPs) for the increase in the number of US patients with access to healthcare. As never before, the public and our political leaders now are focused on adopting reform proposals that will enable greater access to care, including, especially, better primary care, chronic care and prevention. Without huge increases in primary care education, there simply will not be enough primary care professionals to bring expanded care to underserved Americans.

Accordingly, the CME and physician communities must ensure that the existing commercial funders of CME continue to fund at robust levels, and that additional funding sources can be found. In this light, continued focus on potential industry conflict of interest issues represent a major distraction and diversion of attention from these even more serious challenges.

Given that potential conflicts of interest and bias are the topics of this inquiry, we address them seriously below. But while we agree that conflicts and bias may exist in CME and must be managed throughout the healthcare enterprise, we do not believe that effective management requires new AMA ethical principles. Indeed, new ethical guides focused exclusively on conflicts related to commercial support risks a serious reduction of the very support that enables over half of the certified CME that informs today's professionals.

New guides might:

- Hamstring the capacity of academic institutions, hospitals, medical education companies, and professional societies to provide certified CME.
- Diminish education quantity and quality, potentially resulting in increased clinical mistakes and misjudgments that could compromise patient care.
- Adversely affect AMA members and its major constituencies.

While mistakes have been made in the past, the certified CME enterprise has and continues to make significant progress on bias and conflict of interest issues. The current heightened sensitivity to regulatory and public scrutiny and evolving guidelines—as well as a deep and genuine desire to create effective, practice-based learning and clinical improvements—are enabling both providers and supporters to create education that better informs practicing clinicians and their patients. Respect current progress and participate in it. Do not risk creating new rules that might impede the enterprise rather than improve it.

Indeed, the Coalition believes that collaboration with industry is a fundamental part of modern medicine and that physician interactions with the commercial sector are neither inherently, nor universally, bad. At the same time, market advantage and profitability are not incompatible with state-of-the-art, evidence-based health care. Here are the facts:

- Financial relationships with industry (both personal and institutional) are ubiquitous and have both positive and negative outcomes.
- Bias in its many forms (e.g., intellectual, scientific, commercial) cannot be entirely prevented.
- There are no credible published data documenting that industry support leads to commercial bias in CME.

Bias and Conflict of Interest

Underlying this dialogue is the assumption and rhetorical argument of critics that commercial support of certified CME introduces inappropriate bias. There is also the implicit assumption that physicians are incapable of detecting and managing bias when it occurs. The Coalition begins with different assumptions. We begin by recognizing 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.

Bias often describes a tendency or preference towards a particular perspective, ideology or result, especially when the tendency interferes with the ability to be impartial, unprejudiced, or objective. Bias is ubiquitous and influences clinical trial designs, formulary decisions, the content of peer-reviewed journals, editorial commentary, the FDA approval process, news coverage, and participation in both professional and political activities. *It is not possible to eliminate bias, only to recognize it, disclose it when appropriate, and manage it as well as possible.*

Physicians encounter and manage bias every day when listening to patients, reviewing medical literature, speaking with payers, experiencing drug detailing, selecting practice guidelines, and even when participating in CME activities. The management of bias has improved significantly in the past decade, thanks not only to AMA and other professional and accreditation guidelines, but also through adherence to FDA and other government policy and law. Thus, certified CME provides a tremendous service to physicians, and is a relatively safe haven for quality education.

The Coalition believes that most certified CME activities are aggressively managed to limit and disclose sources of commercial bias, and that physicians are well-equipped to manage whatever bias occurs. Notably, ACCME and others have recently released research that undermines the arguments of those critics who profess that commercial bias pervades the education universe. ACCME's recently commissioned report, *The Relationship between Commercial Support and Bias In Continuing Education Activities: A Review of the Literature*, failed to find "any objective evidence or studies documenting that commercially supported CME activities are biased." That report recommends that further "rigorous scientific studies" be conducted before conclusions are drawn.

The Coalition fears that proposals to limit the participation of physicians in commercially supported CME could well lead to further cutbacks in such support by industry, and reduced choices for clinicians seeking CME. While some believe that government programs can replace commercial support, this approach simply is not realistic in the near term and introduces a new source and level of potential bias. Consider, for example, the current debate in Congress around adequate funding for FDA, clearly a critical public priority. While most agree that the FDA has a current budget shortfall of at least a billion dollars a year, in 2008 Congress could only find one fourth of that for fiscal year 2009 and has not developed a consensus plan for fully funding this shortfall in subsequent years. If adequate funds cannot be found for a billion dollar shortfall at FDA, it is clearly unrealistic to expect that a similar amount of government support could be found to substitute for commercial support for CME.

Even if adequate government funding were available, it may not be optimal. Government funded CME often introduces a dangerous bias in favor of adoption of the immediately-least-expensive therapeutic or diagnostic practice. This bias is not always consistent with either the long term best interest of patients or even the government, and would require serious management and professional oversight.

Discussions of bias should consider other 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 focus for conflict and bias analysis. If AMA chooses to develop new guidance on conflicts and bias, it should also address the financial and other conflicts faced by physicians and other HCPs. As noted above, government sponsored CME raises its own conflict and bias issues. Similarly, doctors working in medical centers and private practice must manage conflicts presented by the demands of insurers, managed care providers, government programs, and increasingly litigious public.

Advances in Management of Commercial Support

It is important for AMA to recognize that much of the current criticism of commercial support is based on past unacceptable practices and incidents that have been addressed by industry, provider and ACCME reforms. The CME community has taken significant steps over the past decade to insure both independence and quality for CME. These steps not only help insure independence from commercial influence, they also have elevated both the scientific standards for content and improved measurement of physician change and patient outcomes.

Since the 1997 U.S. Food and Drug Administration guidance document calling for clear separation between promotion and education in the US, the CME community has made consistent improvements. Pharmaceutical manufacturers have done their part as well: hiring compliance officers and instituting strict compliance policies; creating education groups and grant review committees that are independent of sales and marketing; removing all CME activity from their sales organizations; and other practices to insure the independence of the CME programs they fund. While it may be impossible to eliminate all bias, these reforms have led to aggressive and competent management of bias from commercial support.

Physician Awareness Campaign on CME Practical and Ethical Issues

The Coalition suggests that the AMA, CEJA, and CME councils consider initiating a physician education campaign, perhaps patterned after the campaign initiated in 2000 by the working group of CEJA and CME councils on the communication of ethical guidelines on gifts to physicians from industry. According to AMA, that effort was commenced nearly 10 years after AMA adopted a major ethical opinion on gifts to physicians that still was not well recognized and understood in the physician community. Much like the situation faced in the education community today, even while the ethical and other standards existed, professional and public attention was focusing on the gift issue and medical professionals and their organizations were often the target of adverse publicity.

The AMA councils created this Working Group to increase awareness of and compliance with CEJA's ethical guidelines. The target audiences included practicing physicians, industry personnel, medical students and undergraduate medical education faculty, residents and graduate medical education faculty, supporting organizations and industry. The Working Group included representatives from major medical societies, accreditation councils, the public, pharmaceutical and medical device firms, and the Pharmaceutical Research and Manufacturers of America (PhRMA).

Four years later, in June of 2004, the Working Group declared that the goals of the project had been achieved. Self-study and class room materials were made available on line at no cost in order to insure their continued use and the Working Group was disbanded. The Coalition urges the AMA to revisit that experience and develop a similar program that would similarly increase awareness of existing ethical and accreditation guidelines as well as applicable government policy and law.

In doing so, the AMA will wish to coordinate its activities with industry organizations, including NAAMECC and the Coalition. In this regard, we recognize and salute the leaders of the National Faculty Education Initiative launched in October last year by the Alliance for CME (Alliance) and the Society for Academic Continuing Medical Education (SACME), in collaboration with the Association of American Medical Colleges (AAMC). We are certain that the representatives from the Alliance, SACME and AAMC would be delighted to share with you the details of the program, their success to date, and to collaborate with the AMA on efforts to compliment this excellent initiative. Those groups can offer more detail, but you should note that the goal of this initiative is to help medical education faculty understand the differences between certified CME activities and FDA regulated marketing and promotional programs, and thus comply with federal regulations, accreditation codes as well as professional standards.

Although we trust that the AMA will not wish to duplicate this initiative, it is clear that despite the promise of its success, much more education needs to be done in this area, including education of clinical physicians who routinely attend these programs. The Coalition would be delighted to be among the groups that collaborates with AMA on any such education effort.

Summary

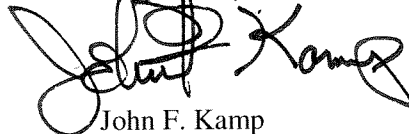
The CME community recognizes that bias and conflict of interest is a legitimate concern for all in medical education and has taken significant steps over the past decade to address legitimate issues of commercial conflicts. While we urge the AMA to be a participant in the ongoing development of these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

At the same time, we also suggest that if AMA launches a new study conflicts of interest, it focus on issues that have not been recognized and addressed thus far, particularly conflicts and bias inherent in medical institutions, government, insurance and managed care, and physician concern over possible litigation. While progress is apparent in the commercial sector, little recognition – much less progress – is apparent elsewhere.

Further, we suggest that if AMA chooses to participate in current issues related to industry conflicts of interests, it begin by creating an education campaign for physicians on existing AMA ethical codes, related accreditation standards, and applicable law and public policy.

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

Respectfully submitted,

A handwritten signature in black ink, appearing to read "John F. Kamp". The signature is stylized with large, sweeping loops and a prominent "K".

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