



February 23, 2009

Regina M. Benjamin, MD, MBA
Chair, Council on Ethical and Judicial Affairs

Claudette C. Dalton, MD
Chair, Council on Medical Education
American Medical Association
515 N. State St.
Chicago, IL 60654

Re: Request for comments regarding ethical and practical issues in commercial support of continuing medical education (CME)

Dear Drs. Benjamin and Dalton:

The Biotechnology Industry Organization (BIO) appreciates the opportunity to comment in response to your letter of February 3, 2009 raising issues specific to commercial funding of CME. BIO represents more than 1,200 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology technologies, thereby expanding the boundaries of science to benefit humanity by providing better healthcare, enhanced agriculture, and a cleaner and safer environment.

As an organization whose biopharmaceutical company members are committed to supporting quality CME, BIO appreciates the American Medical Association's (AMA's) interest in this issue and initiation of this exchange on appropriate relationships between physicians and industry in CME. In September 2008, we commented to the Accreditation Council for Continuing Medical Education (ACCME) on CME issues, and as stated in those comments, available on our website at <http://bio.org/letters/20080912.pdf>, BIO encourages the continuing dialogue on what factors and characteristics create CME that is unbiased, independent and contributes to advancing medical care.

Our responses to each of the three questions in your letter are set forth below.

Question 1: When is conflicted expertise essential in CME? How can we tell when it is no longer needed?

BIO believes that experts should not be excluded from presenting CME content solely because of a relationship with a commercial interest in that content area. BIO member companies are engaged in cutting edge research that seeks to develop treatments for a wide variety of conditions, but often focuses on rare diseases and therapies for unmet needs. Physicians involved in research, clinical trials and peer-reviewed scientific publications on these innovative therapies are generally the most knowledgeable about important scientific and medical advances, by virtue of their background in a therapeutic area, clinical involvement, and participation in the research. Biopharmaceutical companies often engage these expert physicians to consult with them regarding and to directly participate in research because of their specific expertise. Similarly, when a CME provider is seeking experts to present at a CME program, these same physician experts may be the most qualified, particularly in a niche therapeutic area where the number of experts or specialists may be very limited. If a potential presenter is deemed by an objective CME provider to be the primary choice for a program, participation may be considered essential to a high-quality educational program, regardless of industry relationships.

The question above uses the term “conflicted” but does not define it. In our view, participation in research funded in whole or in part by industry does not necessarily present a conflict of interest that is likely to interfere with a physician’s ability to present unbiased educational content. Physicians with recognized expertise in a specialty area should not be presumed incapable of presenting unbiased scientific/medical information when there is a relationship with a commercial interest. Exclusion of such experts could deprive CME program attendees of hearing from and learning from the best and the brightest in particular therapeutic areas. In terms of the AMA’s question regarding when a presenter’s expertise may no longer be needed, we cannot draw any bright lines; we would defer to the CME provider to assess who the best experts are, keeping in mind the content, environment, and other relevant factors.

Further, there are well-established protections against potential bias in these situations. In addition to guidelines issued by the Food and Drug Administration (FDA) and the Department of Health and Human Services Office of Inspector General (HHS OIG), and the PhRMA Code on Interactions with Healthcare Professionals (PhRMA Code), the ACCME requirements govern accredited CME programs, employing extensive criteria to assure that these programs are educationally rigorous and independent. BIO believes that transparency is key, and these existing guidelines and standards -- which require the disclosure of all relevant financial relationships with a commercial interest, and that each program provide a balanced view of therapeutic options -- are sufficient to produce CME programs that are independent and unbiased. Further, physicians who would attend such CME programs are sufficiently educated and sophisticated to assess the nature of the information presented and the relevant disclosures.

It is also important to note that the framework for composition of other expert bodies, such as FDA Advisory panels, takes into account that financial or other conflicts of interest may exist. FDA advisory panel members are required to disclose financial interests prior to a particular meeting. Such disclosure can result in prohibition on participation for a particular meeting, or the HHS Secretary can issue a waiver if deemed necessary to enable participation if the member has essential expertise. Accordingly, even in decision-making bodies (i.e. a committee that makes recommendations to FDA on product approvals), it is recognized that a “conflict” does not always result in a “bias”, and that the contributions of experts with a financial interest in a matter can be essential. BIO urges the AMA to consider that exclusion of certain persons from CME participation may serve only to address a *perception* of bias, and would not serve the primary goal of providing high quality independent CME.

Question 2: What unique challenges do you as a stakeholder face regarding CME?

As supporters of independent education, BIO members want to support high-quality educational programs that address true unmet needs and improve patient outcomes. To do so, accredited providers must conduct valid needs assessments that both identify the need and appropriately identify the educational approach to improve outcomes. BIO is concerned that the current overall quality of educational needs assessments, and the quality of processes for pairing those assessments with appropriately designed programs, may not be consistently robust. We believe these are areas that should be addressed by accredited providers.

Further, due in part to the limited communication that is permitted between commercial supporters and accredited CME providers, it has become extremely difficult for manufacturers to provide constructive feedback to accredited providers on program quality issues. Without an established mechanism to provide quality feedback, commercial supporters are only able to approve or deny programs and are not able to assist in the assessment or improvement in quality of CME activities overall.

BIO members want to support CME and other public health initiatives and be considered welcome participants. However, disparaging statements regarding the role of commercial supporters have suggested that funding from industry is inherently bad for the quality, objectivity, and integrity of CME. This is not necessarily the case, as much of the very best CME has been produced with support from industry and in collaboration with physician-investigators, and educational experts, working in partnership with academic physicians and other non-industry experts

BIO members would welcome the opportunity to work with medical professional societies, academic medical centers and medical education leadership to identify shared objectives and goals, and to establish metrics for ensuring that CME improves healthcare and addresses areas of unmet educational need, as well as physician interest. By establishing such metrics for assessing the quality of CME we can help to assure the effectiveness of CME programs in accomplishing their stated educational objectives and improving the delivery of healthcare.

Additionally, we would like to see greater transparency in the CME process, including consideration of a system where potential CME supporters could be matched with CME providers. This type of moderated transparency may help address concerns about the interactions between CME supporters and CME providers in a way that would foster collaboration, while maintaining the independence of content that is critical to the integrity of accredited CME.

Industry is also faced with several new challenges, one of which is the potential for requests from FDA exploring the use of CME as a component of Risk Evaluation and Mitigation Strategies (REMS). Generally, the responsibility for fulfillment of REMS obligations is imposed on the manufacturer and not directly on a third party. Although such a request by FDA might be an effective method of communicating safety issues and an appropriate element of REMS if it could be executed, given the limited role that manufacturers are permitted to have in CME programming, they would not currently have a clear path to fulfill such requests.

Another challenge we face is in evaluating the capabilities of multiple accredited providers seeking support for educational activities. In many cases, manufacturers have limited or no prior history with an accredited provider requesting support for a CME program. As such, it is difficult to assess the quality of the content validation process employed by the specific accredited provider. Increasing transparency of accredited providers, such as posting evaluations of recent educational activities by attendees, would help provide increased transparency around the quality of accredited providers' work and contribute to higher quality CME.

Question 3: How can we ensure that medicine sets the agenda for CME overall, so that it meets the needs of patients and physicians rather than the interests of commercial supporters?

As noted above, there are numerous controls in place to assure that CME activities remain independent, objective and educational. Accredited CME providers must ensure that decisions regarding the identification of CME needs, determination of educational objectives, selection and presentation of content, and other aspects of a program are not controlled by a commercial interest. The adoption of more rigorous guidelines and standards has further ensured that commercial support does not bias the agenda for CME.

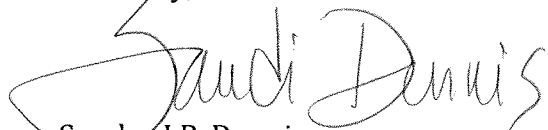
BIO also believes that the medical profession should be fundamentally involved in setting its own educational agenda. Medical professional societies and academic medical centers are well-positioned to help to identify education needs in particular therapeutic areas. In working to define that agenda, it is also important to take into account variations based upon geography, type and size of practice, and other factors, as medical education may not be "one size fits all". Individual physicians know what is critical in their clinical practice and can be involved in communicating that to develop their own long-term professional development. If physicians are empowered to evaluate their own educational needs and seek out specific education to fill their individual needs, they and their patients will be

better served in the long run, rather than “consuming” CME that may or may not be meeting those needs. Understanding the individual needs can further the overall agenda for CME while also validating potential opportunities for specific CME. Performance improvement CME linked to individual physician performance is a positive step, but other methods to achieve the goal of high quality CME is goal are needed. Broader involvement can be significant in helping to assure that medical education meets the needs of physicians and their patients, and ultimately improves health care.

As a final point, and as we mentioned in our comments to the ACCME, BIO remains concerned that assumptions and perceptions of bias may lead to changes in standards for industry involvement with CME regardless of whether a true problem or bias exists. Without any evidence that commercial support for CME results in programming that is inherently biased, a change in commercial support for CME may be unwarranted. BIO urges the AMA to fully consider not just all views, but data and evidence that may exist, showing whether there are indeed concerns to be addressed.

BIO appreciates your consideration of these comments and looks forward to the AMA’s efforts on these issues. If you have any questions, please contact me at 202-962-6673.

Sincerely,

A handwritten signature in cursive script that reads "Sandra J.P. Dennis". The signature is written in black ink and is positioned above the printed name.

Sandra J.P. Dennis

Deputy General Counsel for Healthcare