

May 15, 2009

Murray Kopelow, MD, MSC, FRCPC
Chief Executive
Accreditation Council for Continuing Medical Education (ACCME)
515 N. State Street, Suite 1801
Chicago, IL 60654

Re: April 22, 2009 Call for Comments

Dear Dr. Kopelow:

The Biotechnology Industry Organization (BIO) appreciates the opportunity to comment on the CME issues raised by the ACCME in your April 22, 2009 call for comments.

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.

BIO's biopharmaceutical company members are committed to supporting quality CME and we appreciate the ACCME's continuing efforts to maintain standards for CME programs that are unbiased, independent and help to advance medical care. In September 2008, we commented in response to the ACCME's Summer 2008 calls for comments in regard to commercial support of CME, and BIO is pleased that the ACCME has recently decided not to end commercial support of accredited CME at this time. We continue to believe that the primary goal should be supporting high quality independent CME programs for the medical community, intended to improve patient care, and that efforts to address unfounded perceptions of bias may be a distraction from this goal.

BIO has comments on the following issues now being raised by the ACCME:

Notice and Comment Procedure within the Rulemaking Process at ACCME

The ACCME proposes to employ notice and comment procedures in the adoption of rules and policies that directly impact members and ACCME-accredited providers. The proposal states that issues for comment will be posted on the ACCME website and that at least 30 days will be provided for comment and input.

BIO supports the use of notice and comment procedures in matters that will affect accredited providers, CME participants and commercial sponsors. We suggest that a time frame of 60 days is

preferable to enable stakeholders to fully assess the issues presented by the ACCME and provide meaningful input. Further, it would be helpful to stakeholders if calls for comment are publicized more widely. For example, perhaps the ACCME could employ a mechanism to notify organizations who have previously submitted comments to alert them to a new call for comment. It would also be helpful if the ACCME would publicize the ability to sign up for email updates on new postings on the site, including calls for comments.

Commercial-Support Free™ Accredited CME

The ACCME requests comment on a proposal to create a new designation and review process for programs that would not utilize funding from commercial sources.

Creating a separate category of CME without commercial support could appear to imply that there is something less independent with respect to the content of commercially supported CME. As stated in BIO's previous comments, there currently are sufficient controls and oversight to assure that accredited CME is independent, non-biased, objective and educational. BIO has also commented that, absent any evidence that commercial support for CME compromises the independence or scientific quality of supported activities, there is no basis for proposing or adopting changes to CME accreditation. As we also recognized in our prior comments, a report commissioned by the ACCME in 2008 concluded that there was no empirical scientific evidence that industry support of CME results in any bias.¹ Accordingly, it is unclear what concern a new category of CME would seek to address. If the ACCME is concerned about a perception of bias (rather than actual bias), it seems that creating a distinct CME category without commercial support would serve only to perpetuate unfounded assumptions. It would perhaps be more fruitful to further study the issue, and/or further publicize the results of studies addressing commercial support of CME and any associated bias.

Additionally, BIO is concerned that a stratification of CME programs could impact the overall quality and availability of programs. A designation process, suggesting that there is an unsubstantiated problem with these activities, could reduce learner participation, resulting in reduced interest in commercial support for CME, and a decrease in overall activities. In 2007, the Agency for Healthcare Research and Quality (AHRQ) published findings on the effectiveness of CME (which includes CME supported by commercial interests) and concluded that "CME appears to be effective at the acquisition and retention of knowledge, attitudes, skills, behaviors and clinical outcomes."² BIO is concerned that the current proposed change could impact and undermine the overall effectiveness of CME, ultimately harming physician education and potentially affecting patient care. BIO agrees with the ACCME's belief that CME is a strategic asset and a bridge to quality and therefore we encourage the ACCME to focus on how to meet this goal through the current accreditation process.

¹ Ronald M. Cervero PhD and Jiang He, MPA, "The Relationship Between Commercial Support and Bias in Continuing Medical Education Activities: A review of the Literature" (June 2008)
http://www.accme.org/dir_docs/doc_upload/aae6ecc3-ae64-40c0-99c6-4c4c0c3b23ec_uploaddocument.pdf

²Marinopoulos SS et al. Effectiveness of Continuing Medical Education. Evidence Report/Technology Assessment Number 149, AHRQ Publication No.07-E006 January 2009.
<http://www.ahrq.gov/downloads/pub/evidence/pdf/cme/cme.pdf>

Promotional Teacher and Author-Free™ Accredited CME

As discussed above, BIO is concerned about the implications and perceptions of creating a separate category of CME. We believe that the existing controls on accredited CME, including oversight of content and disclosure of financial relationships of speakers, are adequate to ensure independence and objectivity. Again, we do not know of evidence from the ACCME that CME conducted with teachers and/or authors who have financial relationships with commercial entities has compromised quality, objectivity or independence.

As we have stated in previous comments, physicians involved in the development of innovative therapies are generally the most knowledgeable about important therapeutic advances, by virtue of both their expertise and participation in research. These same experts are often considered to be the most informed and proficient to conduct training and educational sessions, as consultants to individual companies, regulators, patient groups, and others. They are also likely to be the most qualified to present at a CME program, and the most sought after by potential attendees of these programs, particularly in a niche therapeutic area. Such experts are also likely to be the most effective in communicating new information regarding a particular therapy, as related to safety, effectiveness, and labeling changes, as well as providing product information mandated by an FDA-mandated Risk Evaluation and Mitigation Strategy (REMS). Speaker programs are an important mechanism for companies to provide education to physicians about the appropriate utilization of a product in accordance with its label, including as part of a REMS commitment or for rapid dissemination of new safety information. Eliminating these experts from a category of CME could have a significant impact on quality of both CME activities and speaker programs.

Independent CME Funding Entity

The ACCME requests comment on the creation of a granting entity, independent of the ACCME, that would accept unrestricted donations for the purpose of funding medical education.

BIO seeks clarification on how such a fund would be implemented. For example, would this create another separate category of CME that would be funded through unrestricted grants?

Our primary concern remains: would such a measure enhance the ability to provide quality, independent CME to medical providers? If not, it would seem that the creation of a separate entity would be an expensive and inefficient vehicle.

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BIO appreciates your consideration of these comments and looks forward to ACCME's clarifications on the issues we have raised. If you have any questions, please contact me at 202-962-6673.

Sincerely,



Sandra J.P. Dennis
Deputy General Counsel for Healthcare