

ACCME Regulation Takes Affect— Changing the CME Industry For Better or For Worse



by Neil Canavan

According to the Accreditation Council for Continuing Medical Education (ACCME), continuing medical education (CME) providers raked in over \$2.5 billion in 2007, with 1.2 billion of that sum coming from commercial support. In a 2007 summary of an investigation into the promotional activities of 23 pharmaceutical companies, Senator Chuck Grassley, of the Senate Finance Committee was quoted as saying, “CME has developed into a multi-billion dollar a year industry, much of which is funded by pharmaceutical manufacturers. It seems unlikely that this sophisticated industry would spend such large sums on an enterprise but for the expectation that the expenditures will be recouped by increased sales.” With that in mind, the ACCME established in August 2007 a set deadline date of August 2009 for one of its most severe policies to date: Providers of CME cannot be owned by a commercial interest.

What This Means

Back in August 2007, the ACCME modified its definition of a commercial interest to any entity that produces, markets, re-sells, or distributes healthcare goods or services consumed by, or used on patients. Since 2004, commercial interests could not be accredited providers and could not be joint sponsors of CME material, and the new deadline date of August '09 is when the ACCME will start to hold accredited providers accountable to its revised definition of commercial interests. Accredited providers that might have been affected by this revised definition were given two years' time to modify existing structures so that the CME component of their organization would be an independent entity and not come under any undue corporate influence.

One Pharmaceutical Company Reacts

Prior to the ACCME new definition, but nonetheless concerned over the appearance of bias, Pfizer announced last year that it would no longer provide funds, or unrestricted

educational grants, to medical education communication companies (MECCs) to produce CME materials. Rather, they will only provide unrestricted educational grants to non-profit entities such as academic institutions, teaching hospitals, and medical societies. The idea is to correct the impression that corporate-funded, commercial CME is promotional and, therefore, inappropriate.

Lois Trench-Hines, CEO of Meniscus Limited, a holding company of three distinct businesses, of which Meniscus Educational Institute (MEI) is but one, first thought that maybe she should cut MEI off and become non-profit.

“Then I realized that’s not going to help. A number of companies have gone non-profit over the years,” she said, and the impression of undue corporate influence still persists.

Debu Tripathy, MD, Director of the Komen/UT Southwestern Breast Cancer Research Program at the University of Texas, and a frequent faculty member of CME activities, considers Pfizer’s move to be a knee-jerk reaction. “I think that was done for cosmetic reasons because there’s a

perception that for-profit companies may have bias, but the evidence actually speaks to the contrary.” According to him, the ACCME has for many years required all MECCs to keep track of the audience’s perception of bias; and most programs, he stated, score pretty high with “95% to 98% of attendees usually feeling that the information was fair balanced.”

Establishing a Code of Conduct...

Karen Overstreet, President of Indicia Medical Communications, and a pharmacist by training is deeply involved in the creation and adoption of CME guidelines, and testified before the Institute of Medicine regarding conflicts of interest in medical education. “It’s unfortunate that the misdeeds occurring when a different set of rules were in place keep bubbling up and getting a lot of attention,” she said. According to her, the majority of CME

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providers have updated their procedures, and are diligent in their compliance with existing guidelines, especially to those pertaining to fair balance or the promotion of off-label use.

Yet, there is still a sense of urgency, and she thinks that's the very reason a code of ethics was created last year, and why the Society for Academic Continuing Medical Education (SACME) has launched the faculty education initiative that's developing a code of conduct for providers and supporters in relation to commercially-supported CME. Overstreet herself is chairing a taskforce to develop a code of conduct for providers *and* supporters in relation to commercially-supported CME. "We would all prefer to be self regulating than have additional rules placed on us," she said.

...With an Eye on CME in Oncology

A clearer understanding of not only the mission, but the recommended CME guidelines will help protect a reasonably free flow of educational information—a source vital to oncology. "This is where the context bucket is really important. This is not about one product being better than another; this is about how do you get a late-stage patient the best quality of life while treating their terminal disease," said Jann Torrance Balmer, PhD, President, Alliance for CME—not an advocacy group per se, but a professional organization of constituencies from all aspects of the CME community.

Explicit in the new ACCME accreditation guidelines is that patient care must be the driver of CME activity, and inherent to this endpoint is interdisciplinary care. "The team focus has become a pivotal piece in terms of CME," says Balmer, who is a nurse by training. In practical terms this may be accomplished by the bundling of CME activities, ie, a comprehensive educational program involving a webcast, a live meeting, and/or enduring materials.

Despite the fact that all this attention has been placed on CME, Dr. Tripathy continues to believe that it has, for the most part, been quite a balanced system for obtaining the latest information in healthcare. Yet, if industry is cowed by all the attention, and pulls away from CME funding, the effect would be profound, says Jordan Berlin, MD, Clinical Director of Oncology, Vanderbilt-Ingram Cancer Center. "There will be significant reductions in CME activities. For instance, we run two courses reviewing ASCO

and ASH presentations and those will go away—that data is the newest information."

There will also be a shift to online content, which Berlin finds to be far less comprehensive, and too demanding of a physician's time. "And what happens when you can't get knowledge from [our program] or other CME programs? People will turn to their drug rep." And most feel this would not be a step in the direction of unbiased, patient-centric information.

As It Stands Now

Of those MECCs striving to remain in business in the face of the new ACCME definition, many attended the recently held annual meeting of the Alliance for CME to share systems information, and exchange ideas about those approaches that can best get the newest research out to the healthcare teams that are critical to improving

patient care. The Alliance has developed a set of core competencies for CME professionals—skills and abilities needed in order to be effective and unbiased communicators. These include partnering techniques with fellow CME stakeholders; systems thinking that recognizes the complexity of the healthcare system; and organizational self assessment. "There's a huge amount of confusion out there related to CME," says Balmer, "and the more

we are all on the same page, the better we can communicate with the regulators."

As far as the August '09 deadline, Balmer reports that there's been no mass exodus from the CME world as yet, and the main complaint to date is the effort and expense it takes to actually fill out all the necessary forms. As was heard at the Alliance meeting, "CME isn't going away, it is changing." And the companies that provide CME are changing too, making the process harder for providers, grant writers, and sponsors. While the full impact of all these changes remains to be seen, the invisible hand of economics will likely continue to impact the CME industry and may change it into a less vibrant industry with fewer products and innovations. **NC**

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>> OBR DAILY ASCO NEWS COVERAGE

At ASCO, mid-stage results from a PARP inhibitor developed by BiPar/Sanofi-Aventis showed that it improved survival by 60 percent compared with chemotherapy alone for women with "triple negative breast cancer." (*Reuters*, 5/31/09)