

Reprint

When Is Commercial Support Appropriate for CME Activities?

By Caren Spinner

On April 1, 2004, the Board of Directors of the Accreditation Council for Continuing Medical Education (ACCME), by unanimous vote, adopted the updated ACCME Standards for Commercial Support of Continuing Medical Education.

John Ukropec, PhD, Sr. Manager at Wyeth Pharmaceuticals, agreed that the thrust and purpose of CME is nicely summarized in the preamble to the ACCME guidelines, namely "The purpose of CME is to enhance the physician's ability to care for patients. It is the responsibility of the accredited provider of the CME activity is designed primarily for that purpose."

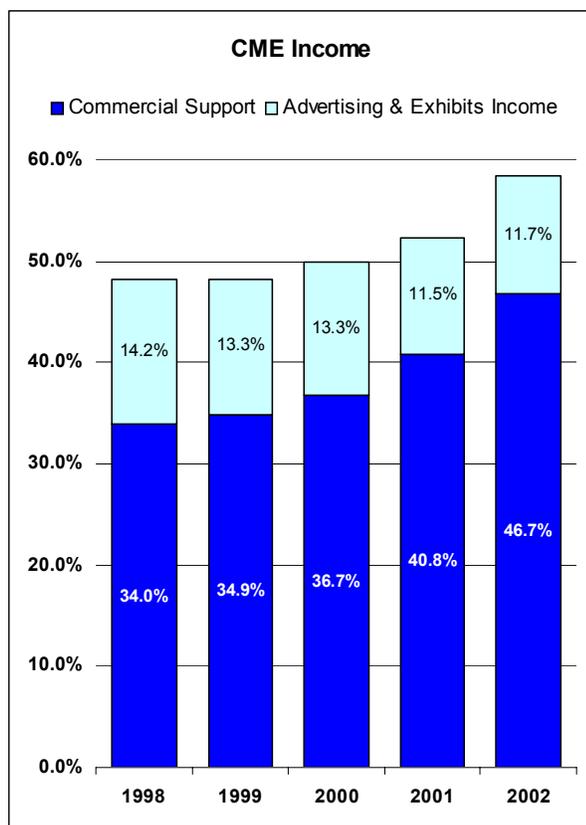
He was speaking at the Barnett International conference, "Defining the Value of Continuing Medical Education" held on March 15th and 16th 2004 in Philadelphia.

Ukropec cited the ACCME 2002 annual report data as saying that there is a decided increase in both the demand for CME and commercial support of CME. According to that data, between 2001 and 2002, physician participants increased from 5.1 million to 5.4 million. Likewise, during the same period of time, industry funding increased from \$539 million to \$720 million.

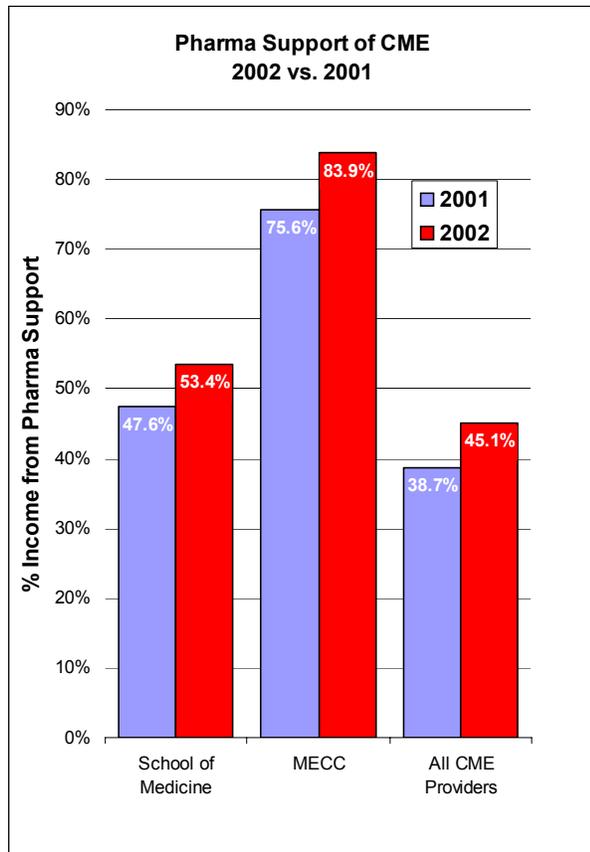
The increase of physician participation of CME programs combined with greater CME program availability gives rise to the question, "when is it appropriate to support independent CME programs?"

[The charts reproduced in this article are based upon data obtained from ACCME Annual Reports.]

According to Dr. Ukropec there are many appropriate situations to support CME, first and foremost being that which is cited in the ACCME preamble--when the program would benefit patient care. However, other reasons also include situations when new information/data or new topics emerge that are of interest to the medical community or when there is a well-defined need within the medical community for specific information. He also pointed out that apart from any specific "need" it is also good business to provide information to healthcare providers and that continuing medical education endeavors can compliment a company's commercial interests. Despite all of these various reasons for CME, Dr. Ukropec emphasized that policies and guidelines governing independent education should be adhered to and followed.



Continues on next page...



Any involvement between the CME provider and the company's sales and marketing departments should be avoided. He referred to the FDA's "Final Guidance" communication document (December 1997) that listed 12 factors for "independence" and explained that while none are "critical", all would be considered thereby creating a situation whereby as the number of factors violated increases, so does the sponsoring company's risk and potential liability.

Referring to the fact that CME has now come under scrutiny, and citing that commercial support in the form of grants to health care providers has elevated anti-kickback concerns of the OIG, Dr. Ukrepec again stressed that commercial influence over programs (including the presenters/faculty) is not an appropriate marketing function. He further cautioned that "following the dollar" would be one method used to determine if educational activities were used to exert any sort of influence or to promote off-label use of a product.

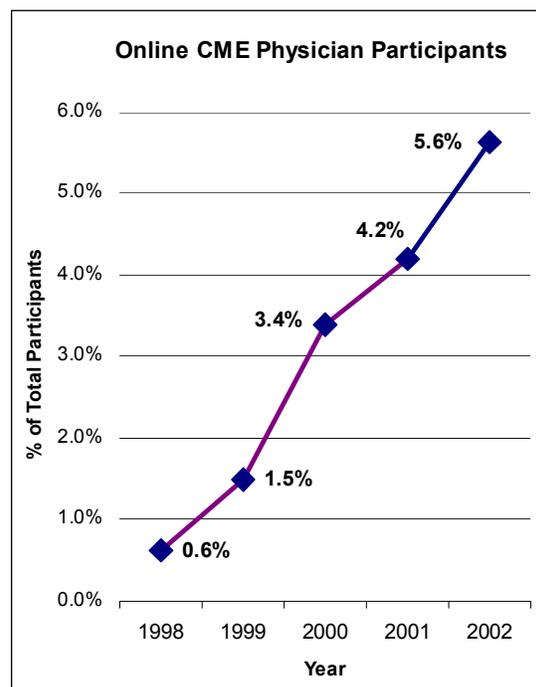
Dr. Ukrepec encouraged the audience that going forward, everyone needs to learn how to engage and work together to better serve the needs of the healthcare professionals and improve patient care. One way this can be accomplished is by understanding all the various stakeholders and their roles while appreciating the various laws, guidelines and policies of the individual stakeholders and how they drive behavior.

Continues on next page...

Conversely, he illustrated some situations when it would not be appropriate to support independent CME. The primary situation would be when the need for the specific information does not exist. Likewise, it would also not be appropriate to commercially support programs or educational activities that only serve a company's commercial interests without improving or enhancing patient care, or those programs that have an extremely narrow (single-product/therapy) focus. Other situations that would qualify as inappropriate would be when the program is not consistent with a company's business strategy or when various policies and guidelines governing independent CME activities cannot be met.

Compliance with Guidelines Crucial

Citing recent fines and penalties within the pharmaceutical industry that have ranged from \$30 to \$875 million, he stated that compliance with the various guidelines of the FDA, OIG, ACCME, PhRMA, AMA etc., as well as any treatment guidelines that may exist, is crucial. Especially important is full disclosure of any and all financial relationships that may exist between the sponsoring company, the CME provider and the "thought leaders" or speakers and other participants. It is mandatory that the CME provider controls all elements within the program--especially as it applies to content and planning.



Evidence-based CME

Dr. Ukropec pointed out that one of the barriers to successful collaboration amongst various stakeholders could be the lack of understanding of all relevant guidelines, both in their letter and their spirit, and how they apply to all parties. The diverse views of commercial supporters as well as the traditional "preferred vendor" status or "agency" of record relationship were also cited as possible barriers. Lastly he encouraged the adoption of methods and/or metrics to evaluate and demonstrate the ROE (return

on education) and suggested that "evidence-based CME" may emerge as an important metric.

In closing Ukropec stated that the commercial sponsor's focus should strive to be compliant within policies and guidelines, strategic within business objectives and that all parties involved in the creation of a CME activity be fiscally accountable and responsible.

Pharma Marketing News

ACCME Board Adopts Updated Standards for Commercial Support

On April 1, 2004, the Board of Directors of ACCME, by unanimous vote, adopted the updated ACCME Standards for Commercial Support of Continuing Medical Education.

The updated Standards focus on six core principles:

- STANDARD 1: Independence. Ensure that certain decisions are made free of the control of commercial interest, which is defined as any proprietary entity producing health care goods or services
- STANDARD 2: Resolution of Personal Conflicts of Interest. Ensure that proper disclosures are made.
- STANDARD 3: Appropriate Use of Commercial Support. Ensures the proper management of commercial support.
- STANDARD 4: Appropriate Management of Associated Commercial Promotion. Ensures the separation of promotion from education
- STANDARD 5: Content and Format without Commercial Bias. Ensures balance and improvement in quality of health care.
- STANDARD 6: Disclosures Relevant to Potential Commercial Bias. Ensures disclosure of relevant financial arrangements to learners.

Background on the Process of Review

This action follows a thorough process of review and input led by the ACCME's Task Force on the Standards for Commercial Support. Beginning with a "call for comment" to accredited providers and other interested parties in early 2001, the Task Force reviewed input from over 200 sources, held a live hearing, issued a first draft for comment and input in January 2003, and met numerous times over the course of two+ years in order to draft the revised document that was approved by the Board on April 1, 2004.

Next Steps in the Approval Process

The updated Standards for Commercial Support will now be transmitted to the seven ACCME member organizations* for their approval. As allowed by the ACCME's Bylaws, the member organizations have 180 days to consider the document. Therefore, the member organizations have until September 28, 2004 to make their decision about the updated ACCME Standards.

Providers and commercial supporters should note that the updated ACCME Standards for Commercial Support of Continuing Medical Education do not apply until approved by the ACCME's member organizations.

Pharma Marketing News

Pharma Marketing News—the First Forum for Pharmaceutical Marketing Experts—is published monthly by **VirSci Corporation** except for August. It is distributed electronically by email and the Web to members of the Pharma Marketing Network (www.pharmamarketing.com).

VirSci Corporation specializes in pharmaceutical marketing intelligence and best practices, development of sponsored newsletters and other educational programs, and consulting in privacy and HIPAA. Our goal is to help our clients gain access to *their* clients and do business via the Internet more effectively, with greater return on

Publisher & Executive Editor**John Mack**

VirSci Corporation

www.virsci.com

PO Box 760

Newtown, PA 18940

215-504-4164, 215-504-5739 FAX

<mailto:editor@pharmamarketingnews.com>**Advisory Board****Jack Pfister**

Director, Business Development, Bruce Leeb & Company

Mark Schmukler

Managing Partner, Sagefrog Marketing Group, LLC

Harry Sweeney

Chairman, CEO, Dorland Global Health Communications

Richard Vanderveer, PhD

Chairman & CEO, V2

Subscribe to Pharma Marketing News

Pharma Marketing News (PMN) is the FREE monthly e-newsletter of the **Pharma Marketing Network**. Highlights are delivered to subscribers by e-mail. The full pdf version is available at www.pharmamarketingnews.com. You also have the option to participate in 2-way, peer-to-peer e-mail discussions with your pharmaceutical marketing colleagues through the **PHARMA-MKTING list**. By subscribing to PMN, you agree to receive e-mail messages through this service as well as newsletter highlights. We do not sell or share your personal information with third parties.

RED=REQUIRED INFORMATION

FIRST NAME: _____ LAST NAME: _____

JOB TITLE: _____ COMPANY: _____

COUNTRY: _____

E-MAIL ADDRESS: _____

E-MAIL FORMAT PREFERENCE: ___ HTML ___ TEXT ___ NONE

 I also wish to join the PHARMA-MKTING list to participate in 2-way peer-to-peer discussions.

SUBSCRIPTION OPTION: ___ FULL DISCUSSION ___ "LURK & LEARN" (DIGEST MODE)

BLACK=OPTIONAL INFORMATION (For our internal use only. We don't sell or rent mailing lists/labels)

ADDRESS: _____

CITY: _____ STATE/PROV: _____ POSTAL CODE: _____

PHONE: _____ FAX: _____

 Mail or fax to: VirSci, PO Box 760, Newtown, PA 18940, 215-504-5739 (Fax)
