

www.pharmamarketingnews.com

June 2003

Vol. 2, No. 6

Published by **VirSci Corp.**

www.virsci.com

Reprint Highlight from 2nd Annual Forum on Continuing Medical Education, June 2003 **RESPONDING TO THE CHALLENGES OF EVOLVING REGULATION**By John Mack



Dennis D. Elliott

Dennis D. Elliott, SVP and Managing Director of S.G. Madison & the CBCE, an accredited CME/CE provider, suggested in this presentation that the recent public scrutiny of pharmaceutical support for CME and the various new guidelines and standards may be having a chilling effect on the busi-

ness of commercial CME providers.

Although Elliott does not believe that commercial support of CME is an inherent conflict of interest and automatically biases the content, he did point out several legitimate concerns in his presentation.

With regard to **inappropriate bias**, Elliott suggested that CME providers must self-police their programs in order to maintain their

credibility and their accreditation. "An offending provider would soon lose its accreditation and cease to exist," said Elliott.

Survey

Do CME activities that accept commercial support have more bias that activities that don't?

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"Many times," Elliott said, "there is a lack of diligence in separating promotion from education by potential commercial supporters." Unfortunately, there is little the CME provider can do to control this other than to walk away from a program when the commercial supporter tries to have too much influence over the content (usually to make it too product-specific).

It is Elliott's experience that there is a varied response to the new OIG Guidance, draft ACCME guidelines, and the PhRMA voluntary code by pharmaceutical companies. Some have changed little, others have complied sporadically to the guidelines, and others have implemented significant changes in policy such as demanding a line item grant reconciliation and a return of excess funds. A few companies have changed their organizational structure so that CME grants are handled by non-marketing/sales departments. Compliance officers and oversight committees manage the

process and legal departments perform risk assessments.

In conclusion, Elliott suggested three keys for industry success as a commercial supporter of

CME activities: (1) trust your product; if you have a good story; you don't need to attempt to "bend the rules...but instead trust the balanced CME activity;" (2) pick the right type of educational activities to support; and (3) more and more medical communications companies have become accredited – carefully consider the quality and credibility of past activities before agreeing to provide educational grants.

When pharma sales representatives get involved in CME, there is a danger of **overt promotional activities being disguised as CME**. Elliott suggested that the only legitimate involvement of the pharma supporter's sales force is the distribution of announcements to increase awareness of the activity. Sales reps should not view the activity as a promotional opportunity or discuss the content with potential physician participants.

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