

Pharma Marketing News

Special Supplement

**Physician Education:
Key Opinion Leaders,
Medical Science
Liaisons, & CME**



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Each issue of Pharma Marketing News is packed with facts, opinions, and case studies based upon interviews with experts in the field of pharmaceutical marketing. Highlights of presentations from industry conferences, contact lists for experts consulted, and links to references help subscribers keep up to date on best practices and network with their peers.

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Introduction

It's a new era for pharmaceutical company support of physician education. First, the rules have changed dramatically. I'm referring, of course, to CME guidelines from the Accreditation Council for Continuing Medical Education (ACCME®), Department of Health and Human Services' Office of the Inspector General's (OIG's) Compliance Program Guidance for Pharmaceutical Manufacturers, and PhRMA's Code on Interactions with Healthcare Professionals, as well as the American Medical Association's Ethical Guidelines on Gifts to Physicians from Industry.

In order to understand pharma support for physician education and the roles of key opinion leader physicians (KOLs) and medical science liaisons (MSLs) in the process, it is necessary to understand the new rules. Consequently, the first section of this Special Supplement is a review of these rules.

Experts within the industry such as corporate counsels Cecilia Burke (Wyeth) and Marc Wilenzick (Pfizer) reveal which ACCME rules need special attention when designing compliant CME programs and working with key opinion leader consultants (see "Compliance with (Some) ACCME Rules Not So Easy").

The second event that has changed how the pharmaceutical industry interacts with physicians was the withdrawal of Vioxx from the market in 2004 and the subsequent re-emergence of the importance of physicians as "learned intermediaries."

More than ever, it is important to educate physicians about new drugs and to keep this education separate from the marketing function of the company. To that end, Jeffrey Spears, Executive Director of Medical Services at Bertek Pharmaceuticals, discusses how the PhRMA Code has redefined the roles of Medical Affairs and Marketing.

At the front line of Pharma's commitment to physician education is the recruitment and proper use of KOLs. As Elio Evangelista, a senior analyst at Cutting Edge Information, sees it, pharma companies that excel at building relationships with KOLs open doors that enable them to better disseminate product information (see "Developing Win-Win Key Opinion Leader Relationships").

Managing KOLs, however, requires good use of technology as well as adherence to effective standard operating procedures. John Estafanous, President of Estco Medical, describes his company's Web-based solution to KOL management in "Thought Leader Management: A Challenge Met."

The Medical Science Liaison (MSL) operates between the commercial and educational sides of the pharmaceutical company and plays a key role in the management of KOLs. Several articles in this Supplement examine the roles of the MSL in the new regulatory environment and discuss techniques for motivating and retaining MSLs. See, for example, "Medical Science Liaisons: Working between Two Worlds."

The last section of this Supplement addresses accredited CME programs as a component of the overall physician education process. MSLs and KOLs, of course, are often involved in pharma-sponsored CME programs. The articles in this section discuss that, but also focus on how to measure the effectiveness of CME programs (see, for example, "A Strategic Approach to CME Offers High Return on Educational Investment").

I hope that you find the selection of articles in this Special Supplement helpful in giving you a better understanding of the issues relating to physician education and how to improve the deployment and management of your physician education resources.



John Mack, Publisher & Editor
Pharma Marketing News

Compliance with (Some) ACCME Rules Not So Easy

By John Mack

PMN Reprint #46-01

At the end of September 2004, the seven member organizations of the Accreditation Council for Continuing Medical Education (ACCME®) unanimously approved the 2004 Updated ACCME Standards for Commercial Support: Standards to Ensure the Independence of CME. When these rules went into effect in July 2005, it was unclear how they would affect industry participation and support of CME or how the rules would change the status quo for CME providers soliciting CME support from industry.

A panel of experts at CBI's 5th Annual Continuing Medical Education conference in Princeton, NJ tackled these and other issues raised by the new ACCME rules.

OIG Oversight

According to the panel moderator, Marc Wilenzick, Senior Corporate Counsel, Pfizer Inc., "Violating [ACCME] rules by seeking to influence the content of independent CME can subject a program to challenge by the Department of Health and Human Services' Office of the Inspector General (OIG) and other governmental agencies, and could result in civil or criminal prosecution if the conduct constituted off-label promotion or a false claim scheme." Consequently, pharma CME supporters and CME providers that depend upon commercial support are concerned about compliance with the rules as well as what impact the rules may have on the quality of CME.

Disclosure is Hard to Do Right

Several panel members and other presenters at the conference acknowledged that the most troublesome ACCME rule is the one regarding conflict of interest (COI) disclosure.

There is broad agreement that disclosure of financial conflicts of interest is critical to the integrity of CME and a lack of compliance with disclosure rules could affect physicians' perception of whether a CME program is biased. It is very important, therefore, to get disclosure right.

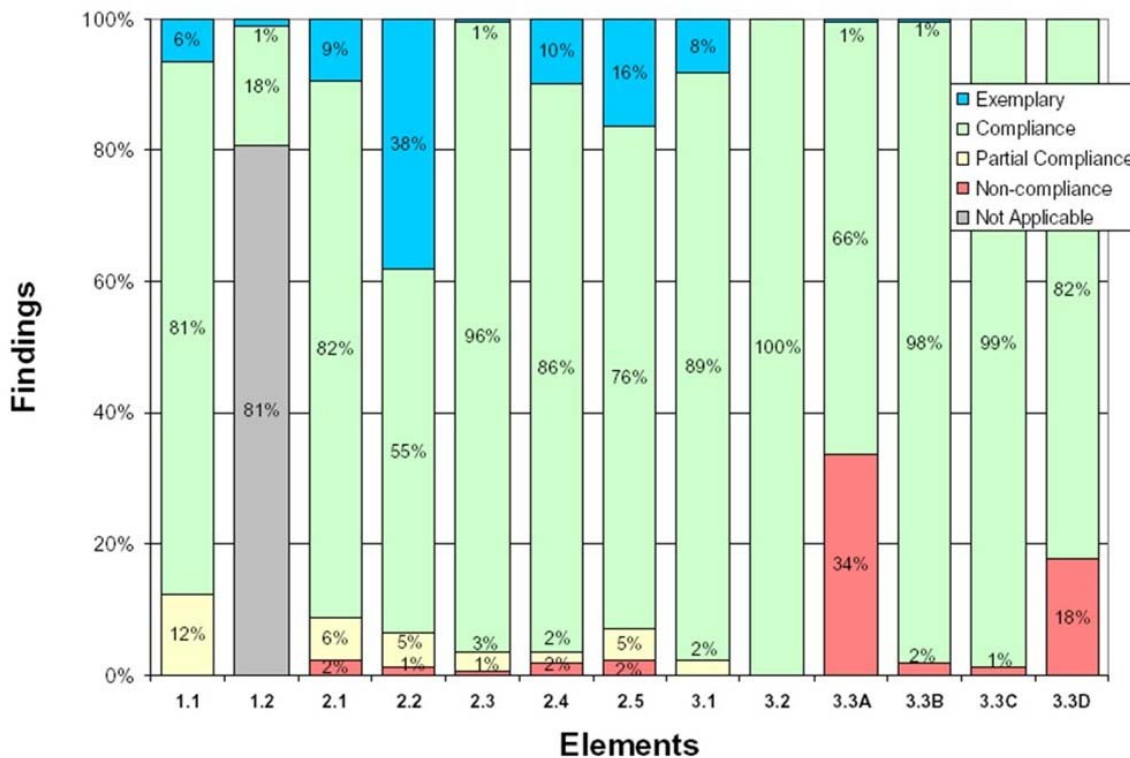


FIGURE 1: Compliance with the Essential Areas and Elements. Element 3.3A is "Consistently discloses required information and relationships." Source: ACCME 2004 Annual Report.

"I think it is hard to do disclosure right," said John Kamp, Executive Director, Coalition for Healthcare Communication. Indeed, the 2004 ACCME Annual Report and audit revealed that 34% of CME providers were non-compliant with the old disclosure rule (see Figure 1, pg. 2).

An audience member suggested that "a fairly large portion of the non-compliance percentage deals with off-label disclosures rather than disclosure of financial interests." That is, many CME providers may not instruct faculty to disclose off-label investigational content. This requirement is not part of the new ACCME rules.

Nevertheless, the new standard for disclosure is far more rigorous than the old standard (see Figure 2). If CME providers had trouble with the old standard, there may be more problems complying with the new standards. For example, ACCME's rules extend to conflicts of interest that a CME participant's "partner" may have. Wilenzick said he wasn't sure if a partner referred to a business partner or a social partner, or both and regarding the latter, what sort of relationship constituted "partnership." "There are still many questions to get clarification on," he noted.

STANDARD 6. Disclosures Relevant to Potential Commercial Bias

Relevant financial relationships of those with control over CME content

6.1 An individual must disclose to learners any relevant financial relationship(s), to include the following information:

- The name of the individual;
- The name of the commercial interest(s);
- The nature of the relationship the person has with each commercial interest.

6.2 For an individual with no relevant financial relationship(s) the learners must be informed that no relevant financial relationship(s) exist.

Commercial support for the CME activity.

6.3 The source of all support from commercial interests must be disclosed to learners. When commercial support is 'in-kind' the nature of the support must be disclosed to learners.

6.4 'Disclosure' must never include the use of a trade name or a product-group message.

Timing of disclosure

6.5 A provider must disclose the above information to learners prior to the beginning of the educational activity. ☞

FIGURE 2: New ACCME Rules Relating to Disclosure.

Conflict of Interest—Confusion Reigns

It's not just CME providers that are grappling with disclosure—faculty and speakers are also affected.

CME providers must implement a mechanism to identify and resolve all conflicts of interest (COIs) prior to the CME activity being delivered (see Figure 3, below). Consequently, faculty and speakers are being asked to disclose conflicts of interest and, if a conflict exists, they could be barred from participating in planning or delivering CME unless the accredited provider chooses to manage the conflict through another mechanism, such as peer-review.

STANDARD 2: Resolution of Personal Conflicts of Interest

2.1 The provider must be able to show that everyone who is in a position to control the content of an education activity has disclosed all relevant financial relationships with any commercial interest to the provider. The ACCME defines "'relevant' financial relationships" as financial relationships in any amount occurring within the past 12 months that create a conflict of interest.

2.2 An individual who refuses to disclose relevant financial relationships will be disqualified from being a planning committee member, a teacher, or an author of CME, and cannot have control of, or responsibility for, the development, management, presentation or evaluation of the CME activity.

2.3 The provider must have implemented a mechanism to identify and resolve all conflicts of interest prior to the education activity being delivered to learners. ☞

FIGURE 3: New ACCME Rules Relating to Personal Conflict of Interest.

As a result, physicians who make presentations at CME events or help plan them can count on tighter controls over what they can speak about. "I suspect we are going to see a lot more peer-review of CME," Wilenzick predicted. "It's important that whatever mechanisms are used to manage conflicts of interest are sensible, well thought out, and pragmatic—and that CME providers are held responsible for following them," he added.

The new rule on COI has been criticized by medical societies such as the American Society of Cataract and Refractive Surgery (ASCRS), which is "concerned because the guidance requires censorship and other measures for dealing with potential conflicts of interest, which would undermine the value of CME programs."

“Although many of us had this concern after the initial announcement of the COI rules,” said Kamp, “subsequent clarification by ACCME Chief Executive Murray Kopelow and others has addressed it.” Specifically, ACCME issued guidance and clarification regarding resolution of “conflicts of interest,” including “peer review” and reference to the “best available evidence,” among other mechanisms. ACCME does not intend to require “censorship” in any but the clearest instances of a speaker either not disclosing conflicts or not willing to have the content reviewed and include balanced references. These assurances may have mollified the concerns of ASCRS as well as other CME providers.

CME speakers may have financial conflicts of interest other than “commercial” conflicts of interest. The new ACCME rules, however, only mandate management of the latter and not the former according to Wilenzick. He suggested that CME providers should focus on all conflicts of interest, not just on commercial relationships.

Honoraria Also an Issue

“Pharma industry supporters of CME,” said Cecilia H. Burke, Senior Attorney, Wyeth Pharmaceuticals, “are also interested in the process providers have for determining honoraria.” The question arose as to what the appropriate role of the supporter should be in negotiating honoraria. Burke suggested that supporters can have a dialogue with the provider about the rationale for the honoraria proposed, but “negotiation is not appropriate. At the end of the day the provider makes the final decision regarding honoraria as well as all other aspects of the CME program,” Burke said.

What about fair market value? Often a specialist will demand and get a much higher honorarium than a family physician, for example. A speaker making a presentation in a later session at the conference suggested that the honoraria paid to industry speaker bureau members—an unregulated area—drives higher fees paid to CME faculty because many of the same physicians participate in both activities.

Kamp pointed out that while “you get what you pay for and you have to pay market value,” the OIG is going to be concerned about how much money might flow to somebody and whether or not that creates bias. “Providers,” Kamp said, “must be sure to have a very good reason for paying what they pay to faculty.”

Continued on next page...

Return on Physician Education

Pharmaceutical meetings and events have become an integral component of the drug industry's promotional efforts used to gain face time with physicians. According to a Verispan Sales Force Effectiveness audit in 2004, 63% of physicians surveyed considered rep-arranged meetings and events to be more or much more effective than a traditional detail (see [Versipan Press Release](#)).

According to internal Merck documents cited in a *Wall Street Journal* article (“To Sell Their Drugs, Companies Increasingly Rely on Doctors”; July 15, 2005), the “return on investment” (ROI) of doctor-led discussion groups is 3.66, versus 1.96 for a meeting with a sales representative.

According to the document, doctors who attended a lecture by another doctor wrote an additional \$623.55 worth of prescriptions for the painkiller Vioxx over a 12-month period compared with doctors who didn't attend. That compared to an increase of only \$165.87 in Vioxx prescriptions by doctors who attended a meeting with a salesperson.

Vioxx, a painkiller sold by Merck, was pulled from the market in 2004 over concerns about cardiovascular side effects.

Return on Education

Measuring ROI of educational meetings is considered unacceptable by continuing medical education (CME) standards and may indicate a breakdown in the “firewall” that many pharmaceutical companies have erected between promotion and education.

If the budget for education no longer comes from the marketing team but from professional services, then there should be no measurement of “return on investment” in the traditional sense: i.e., in which new prescriptions written are tracked after physicians receive education.

Some physician education professionals prefer to talk about ROE or return on education (see, for example, “A Strategic Approach to CME Offers High Return on Education Investment” in this Supplement).

“However, many pharma companies lack interest in the return on education investment or ROE data,” says Jan Heybroek, Vice President at Imedex, Inc., an accredited worldwide CME provider located in Alpharetta, Georgia.

Excerpt from a July 15, 2005 post to [Pharma Marketing Blog](#)

The future of CME

"I'm concerned about the future of CME," Kamp said. "The ACCME has created a system that requires providers to be editors and make peer-review judgments. That puts a tremendous burden on CME providers." Kamp was especially concerned with "shoe-string" providers such as community hospitals that may not have the resources to comply.

An audience member proclaimed that "you cannot legislate ethics" and the panel moderator also wondered if better compliance with ACCME rules will make CME better.

Whether the new ACCME rules will improve the quality of CME or public trust in CME remains to be seen, but it's clear the CME providers will have to live with the rules and comply with them as best they can.

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Experts Consulted and/or Cited In This Article

- **Cecilia H. Burke**, Senior Attorney, Wyeth Pharmaceuticals
- **John Kamp**, Executive Director, Coalition for Healthcare Communication, 202-719-7216, jkamp@wrf.com
- **Marc Wilenzick**, Senior Corporate Counsel, Pfizer Inc., 212-733-4210, wilenm@pfizer.com

Resources

ACCME 2004 Annual Report,
http://www.accme.org/dir_docs/doc_upload/2130a818-1c9f-400b-9d54-56b3f8f9a2f6_uploaddocument.pdf

ACCME Standards for Commercial Support,
http://www.accme.org/dir_docs/doc_upload/68b2902a-fb73-44d1-8725-80a1504e520c_uploaddocument.pdf



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PhRMA Code Helps Re-define Roles of Medical Affairs and Marketing

By **John Mack**

PMN Reprint #24-01

Medical affairs and marketing divisions in pharmaceutical companies have historically functioned as two separate entities, rarely relying upon one another to perform their jobs. Some might go so far to say that the relationship between the two functions has been strained. Marketers may feel that medical affairs is a "threat" to their effectiveness, holding them back from employing effective communication programs to extol the benefits of their products. Medical affairs people, on the other hand, sometimes wince at the envelope pushing tactics of their marketing colleagues, claiming that product managers view FDA warning letters as rites of passage, often framing them for display.

Can't We All Just Get Along?

Experts at a pharmaceutical industry conference on aligning medical affairs and marketing claimed that "a harmonious partnership between the two areas is critical." Yet, I came away from the meeting with the feeling that medical affairs people have achieved, in their own minds, a sense of much-deserved vindication. A harmonious partnership may actually require a power shift from marketing to medical affairs, at least when it comes to using field-based medical programs—or what some might call physician "edutainment"—for marketing purposes.

What may aid in this power shift is the 2002 "PhRMA Code on Interactions with Healthcare Professionals" as well as the final Compliance Program Guidance for Pharmaceutical Manufacturers issued on April 28, 2003, by the HHS Office of Inspector General (OIG). These two guidelines for best practices are related in that the OIG draft guidance states that with respect to arrangements such as entertainment, sponsorship of third-party educational conferences, scholarships, and grants, "a good starting point for compliance purposes" is the PhRMA Code, "which provides useful and practical advice for reviewing and structuring these relationships." The OIG states that compliance with the Code "will

substantially reduce the risk of fraud and abuse and help demonstrate a good faith effort to comply with the applicable federal health care program requirements.”

Why Now?

Critics have often said that pharmaceutical marketing practices often “push the edge” and these practices have come under increasing scrutiny in the press as the debate over drug prices goes on and as the drug industry reports robust annual earnings and record profits.

A few of the physician marketing tactics that have been “exposed” by the press include “Gas ‘n’ Go,” “Dine and Dash,” and clinical presentations made at expensive dinners preceding sports events or theatre productions or at lavish resorts. Of course, golf outings have been a staple of sales reps for a long time.

Jeffrey B. Spears, PharmD, Executive Director, Medical Services at Bertek Pharmaceuticals, mentioned these practices in his presentation at a Medical Affairs conference entitled “Impact of the PhRMA Code on Interactions with Healthcare Professionals.” Dr. Spears conceded that these practices evolved over many years and physicians, not just the industry, bear some responsibility for responding to the criticisms. Indeed, many physicians have benefited from gifts, free lunches, junkets, and honoraria paid for by pharmaceutical companies.

According to Spears, an important goal of the PhRMA Code is to “reinforce the intention that PhRMA’s members’ efforts are to benefit patients and enhance the practice of medicine.” The Code also provides a level playing field for the industry and helps to mitigate the consequences of questionable pharma giveaways to physicians, including:

- bad press
- escalating costs
- unwanted attention from prosecutors, Congress and the HHS Inspector General
- perception of adding to price concerns
- whistle-blower scenarios

Provisions of the Code

The Code addresses informational presentations, third-party educational meetings, using physicians as consultants, speaker training meetings, and practice related items as giveaways.

Informational Presentations

Informational presentations by or on behalf of a pharmaceutical company must provide valuable scientific and educational benefits and meals, if provided, must be modest by local standards.

Spears pointed out that the cost of a meal provided in Peoria, IL should not be “modest” by Manhattan, NY standards, but by Peoria standards. No entertainment or recreational events can be offered in connection with the presentation, and inclusion of spouse or other guest is inappropriate. Offering meals to be eaten without a company representative being present (often referred to as “dine and dash” programs) is not appropriate.

Consultants

Perhaps the most lucrative arrangement some physicians enjoy with pharmaceutical companies is that of a “consultant.” Physician consultants often are invited to all-expenses-paid social events, vacation getaways, and golf outings. Sometimes very little “consulting” actually takes place. The Code, which aims to change all that, states: “token consulting or advisory arrangements should not be used to justify compensating health care professionals for their time or their travel, lodging and other out-of-pocket expenses” and “the venue and circumstances of any meeting with consultants are conducive to the consulting services and activities related to the services are the primary focus of the meeting, and any social or entertainment events are clearly subordinate in terms of time and emphasis.” Spears stated, “I think, as a rule, entertainment is probably gone.”

Third-Party Educational Meetings (CME)

Pharmaceutical companies have long sponsored continuing medical education (CME) for physicians. The PhRMA Code won’t change that, but it does put limits on activities, like meals, associated with sponsored CME events. Meals or receptions should be modest and be conducive to discussion among faculty and attendees, and the amount of time at the meals or receptions should be clearly subordinate to the amount of time spent at the educational activities of the meeting. Spears cautions, “although the guidelines do not prevent meals being served at these events, we must be careful to use meals appropriately.”

Under the OIG Guidance it is important that all parties to the CME process train employees in the existing guidances, require strict compliance, and have a mechanism in place to address violations.

The Accreditation Council for Continuing Medical Education (ACCME) Standards for Commercial Support of CME has drawn criticism from several quarters. The document states that some relationships that ‘commercial interests’ have with persons and organizations create conflicts of interest that cannot be addressed only by disclosure. Now, a conflict of interest will exclude a person or firm from controlling the content of CME. According to a February 10, 2003, article in

Medical Meetings, "...while the PhRMA code and the Office of the Inspector General's guidance for pharmaceutical manufacturers would lead to more money for CME, the revised Standards of Commercial Support might result in a reduction of CME funding."

Practice-Related Items

many physicians' offices are littered with items supplied by pharmaceutical companies. Some of these, such as pens and clocks, are purely promotional and are enhanced with product logos. Some are related to the physician's practice such as anatomical charts and models.

The PhRMA Code limits promotional giveaways to items of minimal value if they are primarily associated with a healthcare professional's practice (such as pens, notepads, and similar "reminder" items with company or product logos). Items intended for the personal benefit of healthcare professionals (such as floral arrangements, artwork, music CDs or tickets to a sporting event) should not be offered. Also, no more golf balls!

Items primarily for the benefit of patients may be offered to healthcare professionals if they are not of substantial value (\$100 or less). Payments in cash or cash equivalents (such as gift certificates) should not be offered to healthcare professionals either directly or indirectly.

To comply with the PhRMA Code and OIG Guidance, pharmaceutical companies will have to update their standard operating procedures and ensure that sales reps are knowledgeable about the new guidelines.

Challenges Ahead

The PhRMA Code is a self-regulatory set of guidelines and, as such, critics may claim it has "no teeth." Nevertheless, according to John T. Kelly, MD, PhD, senior vice president of scientific and regulatory affairs at PhRMA, "there is overwhelming support for the guidelines within the pharmaceutical industry" at the highest levels—the PhRMA Board of Directors, which approved the Code, consists of the chief executive officers of the major pharmaceutical companies in the U.S.

The Code also has its loopholes. For example, it uses the phrase "modest" without further definition.

Despite all good intentions of the industry, the medical community isn't united in its view on what is appropriate behavior. "Our challenge," as Kelly sees it, "is to inform all physicians of the code and encourage them to consider the upside of not continuing to receive benefits to which some physicians and their office staffs may have become accustomed. My belief is that most physicians will embrace it and few physicians will criticize it."

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Resources

PhRMA Code on Interactions with Healthcare Professionals, PhRMA,

<http://www.phrma.org/publications/policy//2002-04-19.391.pdf>

Compliance Program Guidance for Pharmaceutical Manufacturers, Office of the HHS Inspector General,

<http://oig.hhs.gov/fraud/docs/complianceguidance/042803pharmacymfgnonfr.pdf>

Free Gifts to Physicians: What's the Big Deal?

Authors of a January 25, 2006 *Journal of the American Medical Association* article recommend a ban on "gifts" from pharmaceutical companies to doctors. The authors—"a group of influential doctors" from major academic medical centers—claim that gifts pose challenges to the principles of medical professionalism. *Pharma Marketing News* hosted an online survey and a [Pharma Marketing Expert Roundtable](#) discussion on the topic of gifts to physicians. This article summarizes the findings of that survey and includes comments and insights from survey respondents and Roundtable members. Topics covered include:

- JAMA Article Calls for Ban on Gifts
- Time to Ask the Experts -- Results from the Pharma Gifts to Physicians Survey
- Gifts with High Conflict Potential
- Ghosts in the Machine
- Speakers Bureaus Are on the Cusp
- Gifts with Low Conflict Potential
- Educational vs. Promotional Grants
- Drug Samples: The "Mere Ownership Effect"
- Greasing Access
- Culpability on the Other Side
- Suggestions for Change: Ethics and Best Practices

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Responding to the Challenges of Evolving Regulation

By John Mack

PMN Reprint #26-04

Dennis D. Elliott, SVP and Managing Director of S.G. Madison & the CBCE, an accredited CME/CE provider, suggested in a presentation at an industry forum on CME that the ongoing public scrutiny of pharmaceutical support for CME and the various CME guidelines and standards may be having a chilling effect on the business of commercial CME providers.



Dennis D. Elliott

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.

When pharmaceutical 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.

“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 OIG Guidance, ACCME guidelines, and the PhRMA voluntary code by pharmaceutical

companies. Some have changed little, others have complied sporadically with 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.

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Experts Consulted and/or Cited In This Article

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Developing Win-Win Key Opinion Leader Relationships

By John Mack

PMN Reprint #210-01

In today's health care industry, the competition for the most respected, experienced physicians is heating up. This is true not only for health care delivery organizations, it is also a challenge for pharmaceutical companies seeking key opinion leaders (KOLs) to help them in researching, launching, and marketing new drugs. KOLs offer valuable insights into disease states and patient treatment regimens, in addition to new product exposure through medical literature and their professional circles.

Pharma companies that excel at building relationships with key opinion leading physicians open doors that enable them to disseminate new product information and clinical trial results to the medical community through trusted sources.

"At the global, national, regional and local levels, drug companies not only contend with their competitors for doctors' time," says Elio Evangelista, Senior Analyst at Cutting Edge Information, "but they often compete against themselves when they fail to manage key opinion leader (KOL) relationships from a united, coordinated front."

Thought leader relationships are built upon a single, core characteristic. They must be mutually beneficial to both drug companies and physicians. Pharmaceutical companies wish to gain insight into their markets from a unique perspective—through the eyes of general practitioners, researchers, and medical specialists. On the other hand, physicians seek to expand their expertise and gain respect among their peers as they work with innovative, exciting new therapies. "Linking oneself with a medical breakthrough can skyrocket a thought leader's career," says Evangelista.

Winning Practices

Cutting Edge Information, a pharmaceutical business intelligence firm in Durham, North Carolina, studies winning practices in thought leader management and has worked closely with more than a dozen KOL management executives

from industry leaders, such as Pfizer, AstraZeneca and GlaxoSmithKline.

Their research reveals five principles for drug companies to live by:

- Build KOL relationships early in the drug development lifecycle
- Establish win-win relationships between medical science liaisons (pharma companies' relationship-builders) and key opinion leading physicians
- Engage local thought leaders to establish a broader sphere of influence
- Define unique strategies for working with each KOL segment (global, national, regional and local)
- Support KOL management efforts with adequate funding

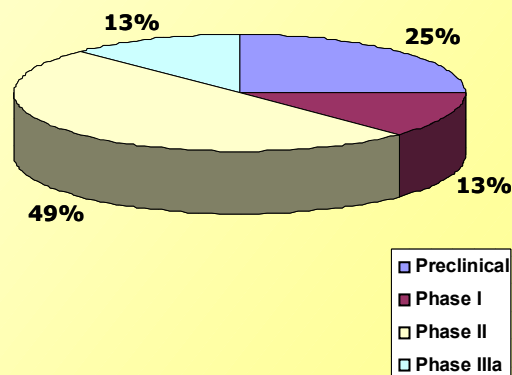
"While no one company has perfected its practices in each of these five areas," says Evangelista, "those that come close stand the greatest chance of winning the support of a key industry segment."

Early Involvement

Most brand teams want to know early those thought leaders they can turn to for critical advice on marketing communications and messages. Brand managers also desire feedback from key opinion leaders on market trends and therapeutic area advancements. "The earlier the brand team has critical market information," Evangelista suggests, "the more it can incorporate thought leader feedback into its marketing strategy."

Thought Leaders' Early Involvement

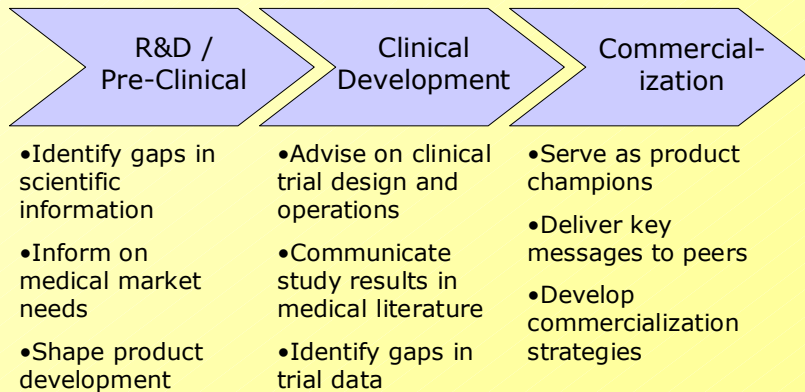
Pharmaceutical companies generally engage key opinion leaders early in the drug development process to provide advocacy activity and key marketing feedback.



n = 8

Involve Key Opinion Leaders Throughout the Product Lifecycle

Opinion leaders provide input and spread the word about new drugs throughout the product development lifecycle.



MSLs are integral to advancing new research within a therapeutic area, growing market awareness prior to launch, and discovering new indications and market needs for a product. To do so, however, MSLs must focus on developing win-win relationships with key opinion leaders (KOLs). Often, MSLs will work with 25 to 50 thought leaders within a region at any given time—a challenging task, no doubt.

Cutting Edge Information's research found that MSLs who remain scientifically focused and offer thought leaders the opportunity to advance research within their respective therapeutic areas help their companies benefit greatly from increased product awareness.

Medical Science Liaisons

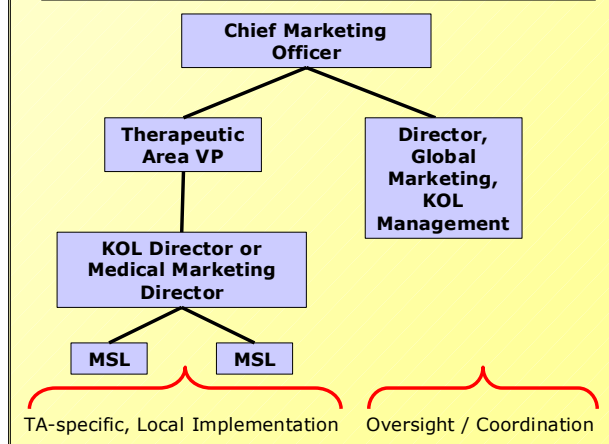
Over the past decade, pharmaceutical companies have increasingly implemented medical science liaison (MSL) programs as part of their ongoing marketing initiatives. But simply deploying liaisons to interact with thought leaders does not guarantee market success. It is critical that MSLs remain committed to the science behind a product. Otherwise, thought leaders who listen to MSLs' marketing pitches will be permanently turned off from working with them.

Pharmaceutical companies must also provide thought leaders with research opportunities that could lead to increased influence within the medical community.

For example, Cutting Edge Information studied one company whose liaisons monitor opinion leaders' research progress and help plan a post-research publication strategy. As the relationship develops over time, liaisons provide valuable insights on new research within their therapeutic areas, which, when applied, helps build thought leaders' status within the medical community.

Company E's KOL Program Structure

Company E's KOL organizational structure combines centralized oversight/coordination with localized/therapeutic area-specific implementation.



“Win-win relationships between opinion leaders and medical science liaisons develop over time and require an open, honest exchange of ideas,” suggests Evangelista. According to one interviewed executive, it is important to always “do it right” when working with medical professionals. By this he means things should not be done “half-way.”

Commercial vs. R&D Oversight

Lasting relationships draw on win-win scenarios for both the company and thought leaders. Company liaisons that act with clear commercial motivation—only working with thought leaders to benefit a drug during launch, for example—tend to isolate most thought leaders. As such, some pharmaceutical companies' medical education groups position themselves as service organizations providing meaningful scientific aid to thought leader contacts. Some also build a “wall” between R&D

and commercial management of KOLs (see Figure, right).

MSLs continue this relationship by acting as a resource in the field. They may set up meetings for local thought leaders with a respected national-level investigator, for example, or provide information on new research into specific disease states.

Providing such services helps MSLs forge bonds with the company in the long-term. MSLs find physicians interested in clinical investigations through its thought leader relationships. At the next level, MSLs identify candidates for speaker programs and approach these individuals about increasing their involvement in product development and advocacy.

Measuring Success

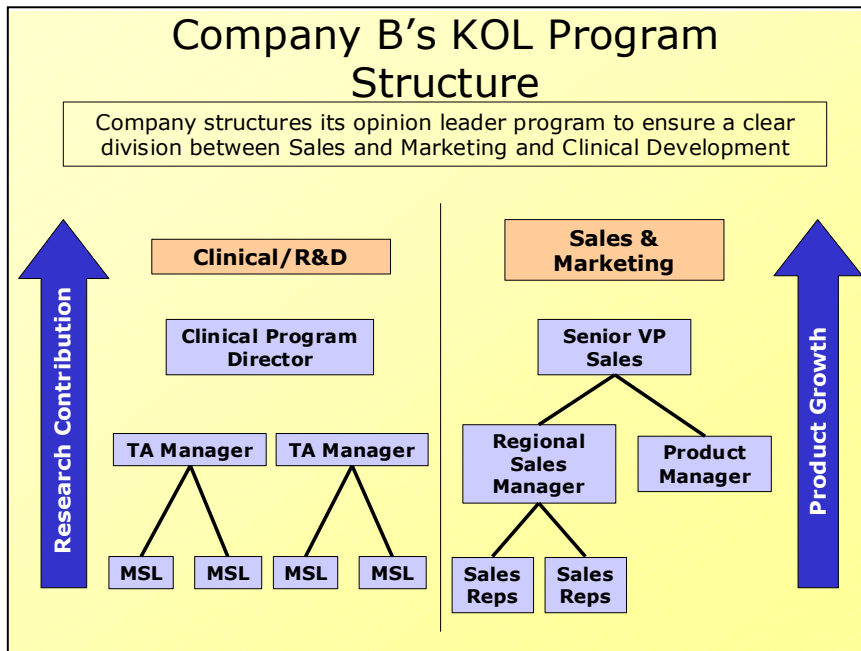
The results of thought leader management often prove intangible or difficult to isolate. Sales success, development progress and marketing impact all require strong opinion leader support—but they also involve a range of company functions whose contributions blend cause-and-effect measurement.

Accurately tracking opinion leader program effectiveness requires creativity. Veteran team leaders craft innovative measurements that reflect the “soft” nature of their employees’ activities.

One company may monitor relationship progress to gauge its thought leader managers’ effectiveness. Another may use unique criteria to build a matrix of thought leader effectiveness:

- Educational impact
- Product advocacy and knowledge
- Publications presence
- Company research
- Public relations

Looking across a doctor’s contributions in these categories provides a snapshot of her role in company success.



One pharmaco interviewed by Cutting Edge has many teams communicating with thought leaders. To record the many interactions between the company and key opinion leaders, the thought leader relations group created a customer communication database. The database houses information on all the company’s interactions and people can determine the current state of each thought leader relationship and what activities they have engaged in with the organization.

The thought leader management database is a subsection of the company’s customer database, which is driven by sales data and used by many groups. The thought leader relations group is developing a limited access portion of the database restricted to opinion leader managers.

Experts Consulted and/or Cited In This Article

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Resources

“Managing Key Opinion Leader Relationships,” Cutting Edge Information, Inc., <http://www.pharmathoughtleaders.com>

Thought-Leader Management

A Challenge Met

By John Mack

PMN Reprint #45-02

Pharmaceutical companies are continually working to establish and maintain relationships with thought leaders—influential physicians who play an important role in communicating a new therapy's benefits for other physicians. Thought Leaders—also known as Key Opinion Leaders, or KOLs—help pharmaceutical companies identify unmet medical needs, shape clinical studies, launch products, and understand critical lifecycle issues.

However, across the pharmaceutical industry, thought leader management programs have not been as effective as internal management would like, particularly in the age of the Internet, when the dissemination of information should be easier than ever, according to John Estafanous, President of Bethesda, Maryland-based Estco Medical.

Indeed, in a recent report from Cutting Edge Information, a business intelligence firm, research found that “[many companies] suffer from industry-wide challenges in thought leader management—challenges that create missed opportunities and result in lackluster performance.”

Principles for Managing KOLs

“There are a few important principles a drug company should follow to manage KOLs,” says Estafanous, whose company recently launched a Web-based software solution for managing KOLs called Medigent® Thought Leader.

These basic principles include:

- Research and recruit early. Carefully research the appropriate physicians and experts who can act as product advocates, and understand that they must be recruited early in the drug development lifecycle.
- Keep track of the activity of your KOLs within the program and ensure that all are active participants.
- Provide valuable, current, and relevant information targeted to the needs of each KOL segment (global, national, regional and local).
- Provide physicians with easy, fast and appealing web-based programs that advocate your brand.

- Empower physicians to control the frequency with which they can access information, giving them necessary clinical data on the spot.

Use a specialized Web environment centered on your brand to provide discussions about your product in a centralized location, as well as to keep the facts and feedback up-to-date.

Recruit Early

Pharmaceutical companies view KOL advisory boards as the first and most influential activity in thought leader development, and companies that assemble KOL advisory boards early in the product development phase stand to benefit by forging long-term ties with these experts. The recruitment of physicians and medical experts may begin as early as several years before the launch of a product.

Advisory boards, once established, usually meet on average four to six times per year leading up to the launch of a new drug. It is important within this phase to keep the entire community updated on current best practices and to keep discussions going between face-to-face meetings. The Internet is ideally suited to do this.

But the climate for recruiting, building credibility and maintaining relationships with thought leaders has become more difficult as pharma companies host more clinical trials, thus creating a competitive environment for knowledgeable and influential advisors.

What is needed is an efficient and effective system to manage KOLs. It should be easily deployable, capable of delivering targeted information on demand, and able to attract physicians to your product. Today, that means using the Internet as the channel and Web-based software as the solution.

Medigent Thought Leader

“Managing relationships and building credibility with key opinion leaders are the driving forces behind Medigent Thought Leader, which can keep physicians engaged and increase their productivity,” says Estco’s Estafanous. The Web-based software is designed to dramatically improve a pharma company’s communications with Key Opinion Leaders.

Using Medigent Thought Leader, influential key decision makers can join brand-focused online communities to obtain product education, articles, meeting information, speaker materials, video and interactive libraries, best practices forums, newsletters and FAQs. Members of Medigent Thought Leader communities are recruited either internally among existing customers or through

Estco's panel of more than 12,000 cooperating physicians.

The Medigent Thought Leader software suite is comprised of:

- **Medigent Imprint**, which manages online focus groups;
- **Medigent CMS**, which is a web site content management system; and
- **Medigent Course Builder**, which manages and delivers eDetailing programs.

Imprint is not a replacement for in-person contact, but a valuable addition that provides a more effective method for gaining insight into product development and marketing efforts.

Knowledge Management

With Medigent CMS, pharma marketers can efficiently update web site content and online marketing messages and disseminate the information to multiple audiences through a single user-interface. This gives marketers the control that enables them to apply segmented strategies directed to a wide variety of audiences and issues.



FIGURE: Medigent® Thought Leader provides easy-to-use administrative tools, left, for product managers and Medigent® Imprint software, right, uses avatars—or visual representations of people—in an online focus group.

Focus Groups & Online Meetings

Traditional focus groups and in-depth interviews (IDIs) are staples of market research. By combining proven traditional research methodologies with an innovative interactive interface, Medigent Imprint replicates the real-world focus group and IDI setting, while offering features and benefits not available with in-person groups.

Imprint replicates the setting of traditional focus groups and interviews by providing a variety of avatars (visual representations of people) and interfaces that demonstrate emotion in order to increase participation levels and elicit better conversation threads.

Imprint provides a comprehensive set of moderation tools to guarantee the discussion is guided appropriately. Group moderators also control the content that is available to the group. Whether the content is provided in text or multimedia format, moderators regulate the exposure of the right information to the right audience.

Thought leaders can be managed globally and targeted locally so that specific regional markets receive the appropriate regulatory-approved information. Whatever the format, be it text, audio, video, imagery, archival documents or any other form, custom content can be sent to the right audience and web site areas at the click of a button. Built-in user and group management tools maintain centralized control, and workflow management tools allow for content to be edited, tracked and approved by a number of administrators before publication. All published data is archived and traceable for auditing purposes to meet FDA compliance requirements.

KOL online community members can choose what information they would like to receive—clinical studies, published articles, key slide data, speaking events calendar, and more—through a “subscription management” feature of the software.

“Physicians sit in the driver’s seat,” says Estafanous. “They own and control how the

pharma company communicates with them.” This is the essence of a permission-based communication program.

Brand Managers' Perspective

Product and brand managers should view Medigent Thought Leader as a marketing and educational tool designed to support specific conferences, or serve as an ongoing resource for thought leaders throughout the lifecycle of a brand. Among a range of administrator tools, the software allows managers to measure usage, track program success, and enables multiple brand managers to moderate and track group members.

This technology allows for a comprehensive, central database of KOL profiling information, which is an invaluable resource. Likewise, by using the latest web-based program to deliver key data to thought leaders and speakers, pharmaceutical companies can save time and money, and set the standard for innovative relationship management.

Pharma Marketing News

Experts Consulted and/or Cited In This Article

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Medical Science Liaisons Working between Two Worlds

By **Mark Schmukler**

PMN Reprint #33-02

Since their inception in 1967, Medical Science Liaisons (MSLs) have assumed a pivotal role interfacing between pharmaceutical and biotechnology companies and the opinion and thought leaders (OTLs) who influence how medicine is routinely practiced. Today's MSL navigates between the unbiased, evidence-driven world of hands-on patient care and the business imperatives of pharmaceutical and biotechnology companies.

These professionals—most with advanced medical, pharmacy or science degrees—offer the OTL the credibility and objectivity of a peer, but also provide an insider's knowledge of their companies and products. Their ability to coordinate

the flow of clinical information and manage important relationships can be critical to a product's success at any stage of its life cycle. At the same time, the current regulatory climate puts MSLs and their activities under greater scrutiny than ever before.

Presenters at a Best Practices for Medical Science Liaisons seminar highlighted how MSLs can maximize their unique position to help improve medical care while they enhance their companies' bottom lines.

Diverse Responsibilities

According to Kyle Kennedy, Senior Vice President of MSL Programs at SOS, a contract medical organization, many companies give MSLs titles that emphasize their research and educational function, such as AstraZeneca's "Medical Information Scientist" and Aventis' "Professional Education Specialist." Traditional MSL responsibilities span field-based research and educational activities, but their emphasis is fluid, generally shifting from research to education along a product's life cycle's time line. Prior to product launch, MSLs increase awareness and expand use through clinical research activities. Post-launch, MSLs help drive approved label use through education. Kennedy notes that while there is no "typical" MSL, the "true" MSL is likely to be an outstanding multitasker.

That multitasking requires a broad set of skills. Walter Tatarowicz, Ph.D., of EMD Pharmaceuticals, describes the "ultimate new-hire MSL" as someone who:

- has previous MSL experience,
- is well-published and well-respected in their field,
- is able to handle 75% overnight travel,
- has excellent communications and interpersonal skills, and
- is a really nice person.

He also points out that a hire's skills alone are not enough. The company should provide a structured training and mentoring program and continuing education, and management should add reasonable expectations and timely feedback.

EMD's Mary Ann Watson, PharmD, goes on to explain that the MSL's role is not easily defined. Depending on the company, the MSL may report to Sales or Medical Affairs and perform a function that is primarily educational, clinical/research-oriented, or a hybrid of the two. Corporate expectations of the MSL differ with respect to working with sales representatives, with the most

effective relationships benefiting both the rep and the MSL (however, see “It’s All about Perception and Intent”, bottom right).

Lessons Learned

Navigating corporate culture can be a major challenge for MSLs says Jane Chin, Ph.D., former senior MSL at Aventis and now publisher of an MSL newsletter. Cultivating strong relationships on the inside can be just as important as developing them in the field. Chin applies marketing wisdom, encouraging MSLs to create and manage their own “brand”—the image their colleagues have of them—and to speak the company’s language or business jargon. At the same time, she warns against losing sight of the need to maintain a fair balance. “Your responsibility as a scientific professional,” says Chin, “is critical discernment of scientific information and accurate presentation of information to clients.”

When that balance is lost, the results can be devastating. Chin cites the case of one company where a whistleblower exposed a pattern of misrepresentation among MSLs—of data, of their credentials, and of their roles. She counters that sad tale with simple, practical advice:

- Know the regulatory rules and don’t break them.
- Don’t promise what you can’t deliver.
- Exercise integrity.
- Communicate with internal customers, too.
- Keep all customers informed.
- Handle change in personal and professional life.
- Focus on science AND business.

Field Trials

One key activity of MSLs is coordinating investigator-initiated trials (IITs). EMD’s Director of Medical Information and Science Liaisons and Global Head of Field Medical Affairs, W. David Dawson, sees the uniform goals of any IIT program as:

- Adding to the base of knowledge for a product
- Generating abstracts and publications to be shared with the medical community at congresses or meetings
- Increasing familiarity of key physicians with the use of a product in specific disease states
- Producing advocates for the use of a product in specific disease states

Beyond those goals there are important differences. For example, before product registration,

the reporting of adverse events must go into the integrated safety report. This might raise questions from the FDA or jeopardize time lines. Post-launch, additional goals are to expand the potential patient population and possibly explore higher-risk patient populations.

The ITT process itself, which derives from the Clinical Development Plan, should be timed carefully. For pre-launch trials results and publications should come forward within 6 months of the anticipated launch. Dawson breaks the process into specific stages with clearly defined flows and projects a timeline of 12 to 16 weeks from the time an investigator indicates interest in an ITT to the beginning of patient enrollment.

The Key to Opinion Leaders

To Kennedy, a key opinion leader (KOL) is one who drives a therapeutic area, has conducted significant research, is regarded by peers as an expert and is actively treating or advising on the

It’s All about Perception and Intent

A post to the *Medical Science Liaison Quarterly* newsletter (www.mslquarterly.com) online forum spoke about the FDA’s opinion of MSL “call quotas.”

“During an audit of some of my company’s sales and marketing materials, the FDA inspector reamed the group director and the marketing/sales people up one side and down the other,” said the poster, “and told them in no uncertain terms that call quotas or anything of the kind were not only seen as sales-type activities, but were also worthy of a cease and desist letter.”

“The FDA said that all MSL activity was to be unsolicited, spontaneous and in valid response to a clinically relevant scientific, medical or clinical question and therefore imposing call quotas were a violation because they looked like the company was soliciting off-label questions that by definition were to be unsolicited and therefore unanticipated and could not be reliably predicted or acted upon otherwise. That is the language from their report to management, and they dropped the call quota for fear the FDA would put them under a consent decree.”

“It’s all about perception and intent,” said another poster. “If the MSL program is but one facet of a concerted off-label selling effort, then no matter how you separate it—even if you take the MSL program and put it under R&D—it is still illegal.”

treatment of patients. KOLs can be identified through a wide variety of sources from within the company and in the healthcare community as a whole. Once KOLs are identified, the MSL must build relationships to develop advocacy. Kennedy recommends:

- Building relationships with top-tier national KOLs, regional KOLs and local high-volume prescriber KOLs
- Engaging in scientific dialogue with KOLs influential to the business and lacking in awareness of key scientific data
- Conveying complete medical/scientific knowledge to KOLs
- Identifying KOLs' unmet needs that can be fulfilled by the MSL.

Kennedy emphasizes that relationships are at the heart of any KOL advocacy initiative. The "successful MSL pyramid" is built on a base of technical expertise, KOL relationships, field-based relationships and internal corporate relationships. From these, influential activities flow, such as managed markets support, scientific convention support, training and research facilitation.

Day-to-day Matters

MSLs have no "set" weekly schedule, points out Tatarowicz. The nature of the job and the life cycle stage of the product vary, and MSLs should be realistic about what they can accomplish in a week. He underscores the need to be realistic about how long travel takes, which is often longer than we think, and plan accordingly.

In any given week a wide range of activities may occur, including appointments with KOLs, presentations, sales meetings, Medical Affairs meetings, conventions, symposia and training meetings. In addition, MSLs need office time to prepare for meetings and presentations, respond to email, fill out expense reports, pay bills and file. Tatarowicz calls office days "your good friend" and prescribes them for those tasks, plus catching up on reading, returning phone calls and conferencing with management.

Mary Ann Watson, PharmD, an EMD MSL, advises care in maintaining a balance between work and family. The MSL's family has to understand how much travel is involved. She recommends keeping an up-to-date calendar available with all travel plans. Including the family in travel whenever possible can also help. Those important "office days" should be spent in a dedicated area complete with basic equipment. She notes that breaks are important, too.

New directions

Today's successful MSL has developed a rich network of deep internal and external relationships. Now is the time for companies to leverage those relationships to maximize their return on investment. Dawson points out that the scope of MSL activities touches on virtually every aspect of the healthcare system.

Clinician advisories impact healthcare organizations through advisory boards, investigator meetings and consumer advocacy groups. IITs yield abstracts and publications, resulting in increased physician awareness. Clinician sciences lead to new product search and discovery and business development. Clinical operations such as site selection for studies lead to more efficient use of company resources. MSL activities provide resources for medical information, writing and publications planning.

All this leads to better health—for the pharmaceutical and biotech companies, and for the patients they serve.

Pharma Marketing News

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- **W. David Dawson**, Director of Medical Information and Science Liaisons, EMD Pharmaceuticals, (919) 401-7196, David.dawson@emdpharmaceuticals.com

Resources

Medical Science Liaison Quarterly newsletter and website forum. <http://www.mslquarterly.com>. The *Medical Science Liaison Quarterly Newsletter* ("MSLQ" - The Voice of Medical Science Liaisons™) is the first online publication for medical liaisons.

MSL Role in Educational Development

By Douglas L. Wicks

PMN Reprint #41-03

Armed with a strategic blend of advanced clinical training, an intrigue for data and its role in disease management, and a penchant for cultivating and advancing scientific dialogue, Medical Science Liaisons (MSLs) are in an optimal position to lead pharma-sponsored CE planning. MSLs, moreover, can provide educational strategy to improve patient care by furthering effective medical educational activities.

Regulations Create an Opportunity

"While we must not underplay the regulatory environment in which we currently operate," states Bob Reina, MS, MBA, Vice President of the Veritas Institute for Medical Education, "it creates increased opportunity for MSLs to assume a greater role as the educational 'eyes and ears' for in-house pharma medical education departments, and provide clarity in an organization's understanding for the dynamic nature of clinicians' educational needs and practices."

Reina, along with Sharon Schneider, PsyD, MBA, Program Director, Medical Education, Ortho-McNeil Pharmaceuticals Inc., presented their views on the MSL role in the medical education setting at a Pharmaceutical Educational Associates conference entitled "Maximizing the Effectiveness of Medical Liaison Team Capabilities."

Adult Learning

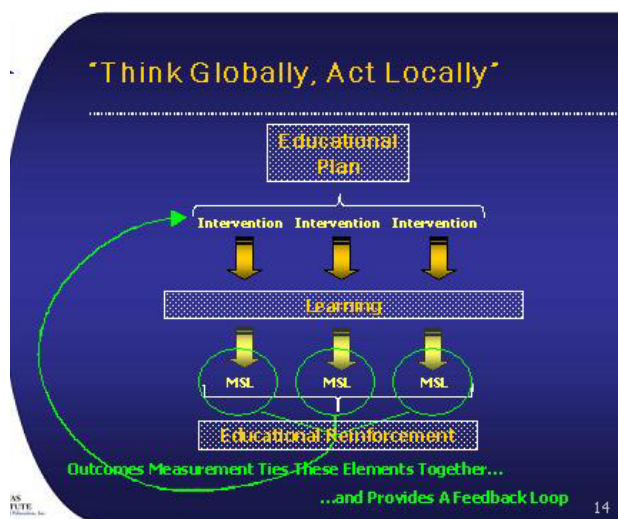
Creating quality pharma-sponsored educational programming requires an ability and responsibility of both CME providers and educators to embrace adult education as a "science." This implies, according to Dr. Schneider, "fostering balance between educational sponsors (pharma) and providers (CE accreditors) that allows for operational transparencies, yet at the same time, maintains regulatory strictures and guidelines."

MSLs, in their field roles, may be able to facilitate this relationship by offering their in-house medical education counterparts feedback regarding clinical trends that may predict levels of acceptance and translation of new scientific data into clinical practice and learning.

Unharvested Thought Leader Findings

"At times," states Schneider, "regional developments and thought leader findings remain unharvested," and lag behind observations in published scientific literature. By availing their teams of real-time environmental conditions (i.e. medical, demographic, psychosocial, epidemiological trends), MSLs provide feedback at a local level that is invaluable in assessing educational strategies and new concepts. This feedback is invaluable in the allocation of limited annual resources for educational programming.

"Adults learn in response to need—if everything is 'okay,' little learning takes place," affirms Schneider. By treating MSLs as extensions of a pharmaceutical company's medical education departments this improves an organization's ability to provide educational programming that addresses practitioners' specific educational gaps. It also may positively influence MSL career paths and overall job satisfaction by fully utilizing their skills and integrating them into the educational process.



Reina furthers the medical education department role of MSLs through what he refers to as a "Think Globally, Act Locally mindset" (see Figure above).

In this approach, MSLs act as educational agents in the feedback loop in determining the unmet medical needs that drive medical education planning and enhance the learning that has occurred in the educational activity.

Lack of Objective Outcomes Evidence

Despite the millions of dollars spent on medical education little is known regarding how health care providers use the information obtained from continuing education activities in the care of their patients.

Continued on next page...

Without objective evidence of efficacy in learning and improvement in patient care, Reina believes there is little incentive for pharmaceutical companies to continue to support educational programming at its current level.

Schneider and Reina assert that MSLs can bridge the “communication chasm” and deliver crucial information to decision makers each time an educational gap analysis is conducted. This allows them to develop effective medical education strategies.

In this way MSLs become members of the public health team and active educators. Schneider and Reina feel that this is the role for which MSLs are ideally trained, educated, and eager to participate in.

Pharma Marketing News

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Motivating & Retaining the MSL

What Makes MSLs Tick?

By **Douglas L. Wicks**

PMN Reprint #43-02

If every medical science liaison (MSL) job is a self-portrait of the person doing it, Erin Albert, RPh, MBA, is autographing her work with excellence. Albert is an experienced and successful MSL for Sepracor in the Indianapolis, IN

area. In addition, she has spent a considerable amount of time researching and gathering psychometric data about her peers' job satisfaction in their current MSL roles. Her findings appear in venues such as The Medical Science Liaison Quarterly (MSL Quarterly) (www.mslquarterly.com) and her annual Medical Liaison Job Satisfaction Survey. This survey continues to be a growing benchmark within pharma for overall evaluation of the many drivers that motivate, frustrate, inhibit, but most importantly, fulfill MSLs from an overall career vantage point.

Retention, Retention, Retention

The overall cost of losing highly specialized field talent dips into all areas of a company's bottom line no matter what the economic landscape. MSL retention and the pharma industry's ability to foster “corporate allegiance” among MSLs, therefore, are top of mind these days.

More and more pharmaceutical companies are vying for a limited pool of candidates possessing very desirable skills sets. MSLs combine credentialed scientific training with clinical application and business savvy. It's no wonder that they are continually approached by recruiters, pharma-direct contacts and, at times, their peers, for job opportunities. In many instances, offers are for considerably more pay and maybe in more clinically innovative fields. Finding a new job for MSLs has never been easier.

Who's Responsible?

Where does responsibility lie for motivating and retaining MSLs? The answer, according to Albert, is multifactorial. While 50% of work life satisfaction is determined by the relationship an employee has with his/her immediate manager, the balance of MSL job satisfaction can be found within MSLs themselves according to Albert. Corporate culture, individual aptitude and willingness to assume risk, intellectual challenge and flexible scheduling are top drivers that motivate and influence MSL satisfaction.

Survey Results

“It's not always about the money,” says Albert. Only 11% of those MSLs surveyed in 2004 indicated that financial compensation was a key contributor to overall job dissatisfaction.

Perhaps the most critical element in fostering a positive working environment, and ultimately job satisfaction, lies in establishing clear lines of opportunity for career advancement and development.

When polled as to where each would like to further themselves within each of their respective organizations, only about one third of MSLs

responded that they would like to stay in the same area and in the same therapeutic discipline. Another 18% of MSLs responded, "I don't know" according to Albert's survey results.

It is incumbent therefore upon MSL management to create a challenging and foreseeable career path for MSLs. Short term assignments, special in-house management projects and geographical repositioning (AKA 'repotting') are various methods of providing MSLs an ability to explore additional career pathways and gain networking opportunities access across organizational lines.

MSL retention and overall job satisfaction hinges on a variety of interpersonal and organizational factors. Providing MSLs every opportunity to gain exposure within a pharma organization will encourage better understanding of the options open to them. MSLs should be more fulfilled and less inclined to leave their current positions and organizations along the way.

Companies that retain valued field-based MSL talent will "continue to possess a competitive advantage" according to Albert, and furthermore set themselves apart from others as valued healthcare organizations fully committed to maximizing human resources and motivation to improving patient care.

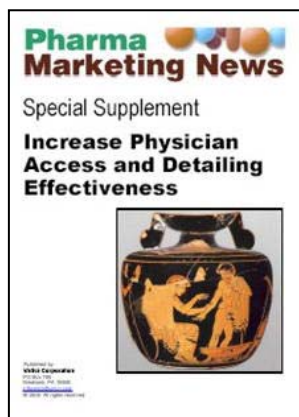
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Managing Medical Science Liaisons from Afar

By **Douglas L. Wicks**

PMN Reprint #41-05

Managing a winning team of Medical Science Liaisons (MSLs) from afar demands proper selection of highly driven, self-motivated and scientifically-fluent professionals. It also requires a manager's recognition and vision of "top-down-bottom-up" leadership style, which includes consistency, rapid long distance communication, a team-shared vision of goals and responsibilities, and a working foundation of trust for overall success and MSL job satisfaction.

Effective MSL managers, according to Mario Sylvestri, PharmD, PhD, Senior Director Medical Informatics and Communications, Amylin Pharmaceuticals, create team "character." They do this, according to Sylvestri, by developing team decision making-processes and operational procedures that are clearly understood, are mutually agreed upon, and also foster proactive professional development.

Just as critical to a MSL manager's success is selecting MSL candidates that have an aptitude for and an ability to mentor new MSL hires.

The majority of MSLs function as regionally based medical scientists and Key Opinion Leader (KOL) clinical information specialists. Managers must constantly monitor and respond to field-prompted subtleties, daily KOL nuances and clinical updates from their team, and act upon requests and suggestions promptly.

Rapid Communication

"MSLs need to know that their thoughts are valued, their needs are immediately addressed and their views are communicated up the corporate ladder," states Sylvestri. Furthermore, feedback and communication must occur rapidly "at a staccato level."

Effective field communication fosters an ability to ensure that MSLs working in remote locations relay attitudes and field conditions as "in-house extensions" of their colleagues for consideration, and that their opinions and attitudes become an integral part of the "whole" corporate structure of

www.pharma-mkting.com/news/PMNSupplementSFE.htm

daily operations. This type of interaction will make the field-based team feel part of the whole corporate organization they represent and the corporate organization will feel a part of the field as well.

Personal, One-to-One Interaction

Even though rapid field communication these days is accomplished without hitch through state-of-the-art technology, i.e. cell phones, email, pagers, the technology should never replace direct one-on-one manager-MSL interaction. Manager-MSL field time together and informal communication, Dr. Sylvestri emphasizes, is critical for overall MSL job satisfaction and productivity.

By spending one-on-one field time with regional MSLs, managers are able to take into account the personalities and culture of their team members and enforce or amend “best practice” daily operational procedures and requirements. Daily encounters with KOLs and clinical peers may require different regional, geographic, and at times, cultural approaches by MSLs. One-on-one interaction allows MSL managers the ability to compare and contrast regional approaches and “best practices” among their team members.

Direct one-on-one interaction is also essential when MSL performance development plans need to be established. Managers should request the MSL to develop an action plan during a one-on-one meeting and, through subsequent encounters, stimulate a sense of ownership and responsibility within the MSL to perform job improvements and increase productivity.

Mutual Trust

Because MSLs require an ability to work in an autonomous field environment, mutual trust between MSLs and a manager is the hallmark of MSL management success. Managers must not only trust team members to perform their jobs well, but also live up to the team’s expectations and deliver on promises. Sensitivity to trust within all areas and in all encounters, particularly when communicating rapidly and responsively (via voice-mail, telephone, email, etc.) remains critical for MSLs to thrive and succeed.

By blending the tenets of consistent and rapid communication, direct and ongoing MSL field contact, and earned manager/MSL trust, managers and MSLs can thrive in an environment where geographical distance will not impede overall productivity, MSL job satisfaction and success.

Pharma Marketing News

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Give Docs What They Want

Physicians participating in a keynote panel at a recent pharmaceutical industry conference emphasized that they value a pharmaceutical sales rep’s product knowledge over the relationship with the rep. Perhaps pharmaceutical companies need to provide more access to the kind of representative physicians seem to want—the medical science liaison or MSL.

Traditionally, there’s been a rivalry between sales, marketing and the medical sciences departments at pharmaceutical companies. MSLs often play second fiddle to the commercial side of the business. That situation should be turned on its head. The MSL should be the primary contact and call in the rep when the physician asks for samples. After all, sample delivery is the primary reason sales reps gain access to physicians anyway.

Docs would be more eager to see MSLs and not make them wait in the office or turn them away as they do sales reps. Less time would be spent on unproductive calls and each MSL could service many more docs than a sales rep. The sales rep’s time would also be better managed because the docs would request a rep visit to obtain the samples. At that time, the rep can still make the pitch without having to explain the value of the product—the MSL would have already done that.

Adapted from a March 21, 2005 post tp [Pharma Marketing Blog](#)

Provider- Pharmaceutical Partnerships Are They Possible Without Conflict of Interest?

By John Mack

PMN Reprint #26-02

Pharmaceutical companies can partner with academic CME providers if both parties respect mutual core values, suggested Jann Torrance Balmer, RN, PhD, Director of Continuing Medical Education at the University of Virginia School of Medicine.

A mutually successful CME program begins when both parties bring something to the table and agree to the desired outcomes of the educational activity. Pharma can bring research data to the table and the academic CME provider brings the faculty. Although pharma supporters may know who the thought leaders of today are, “an academic provider can tell you who the thought leaders of tomorrow are,” says Balmer.

As for outcomes, the academic center wants to improve patient care, while the pharmaceutical supporter also may want changes in prescribing patterns. The two are not mutually exclusive and Dr. Balmer suggests that a change in prescribing can be one of several “reasonable outcomes.” Some other experts, however, have suggested that it is not permissible for a pharma supporter to track prescribing patterns as an ROI measure for CME.

There are several codes, guidelines, opinions, and guidances that are relevant to all parties concerned. Balmer emphasizes that she “lives and breathes by” ACCME’s accreditation system and Standards for Commercial Support of CME and that she expects her pharma CME partners to respect this. For her part, she needs to understand the PhRMA Code on Interactions with Healthcare Professionals if she is going to be a good partner. Physician faculty members need to pay attention to the AMA ethical opinion on gifts to physicians and pharmaceutical companies certainly need to be wary of the OIG guidance, which says that there should be a bright line between sales and marketing and educational programs.

“I love parameters,” says Balmer. “Just tell me where the line is. I want our physician faculty to know that the content will be fair and balanced.”

Balmer suggests several strategies for successful academic/pharma CME partner-ships:

- Look for projects that highlight the goals and objectives that are mutually beneficial to both partners—the proposed CME program must relate to the core values of the institution and be tied to the mission of the medical school.
 - Get the involvement of the CME provider at the beginning of the plan, especially when determining the desired outcomes.
- Some red flags for Dr. Balmer as a CME provider working with pharma are:
- Short time frames of less than 3-4 months
 - Lack of responsibility and control—“If I don’t have control, I don’t do it,” warns Balmer. “I am the one who is held accountable by ACCME.”
 - Not being involved in planning—the CME provider, who is most knowledgeable about the ACCME guidelines, must be involved. “Without

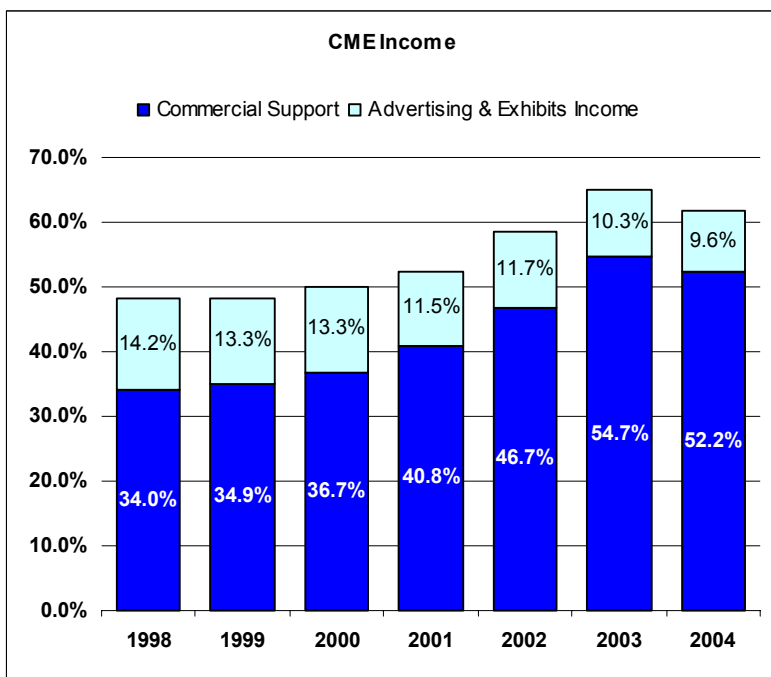


FIGURE: Portion of CME income from commercial support, advertising, and exhibits. Source: ACCME

this involvement," cautions Balmer, "there is a risk of conflict of interest."

"Long-term academic/industry CME relationships play a huge role in physician education and improved healthcare," says Balmer. "When pursuing these relationships, pharma companies should pursue strategies that keep both partners well within their respective regulatory and accreditation requirements."

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When Is Commercial Support Appropriate for CME Activities?

By **Caren Spinner**

PMN Reprint #34-03

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 a recent Barnett International conference, "Defining the Value of Continuing Medical Education" held 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 in CME programs combined with greater CME program availability gives rise to the question, "when is it appropriate to support independent CME programs?"

According to Ukropec there are many appropriate situations to support CME, first and foremost being that which is cited in the ACCME preamble—ie, 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, Ukropec emphasized that policies and guidelines governing independent education should be adhered to and followed.

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, Ukropec 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.

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Any involvement between the CME provider and the company's sales and marketing departments should be avoided. Ukropec 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 by regulators. 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, Ukropec 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.

Ukropec encouraged the audience that going forward, everyone needs to learn how to engage and work together to better serve the needs of 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.

Evidence-based CME

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

ACCME Board Adopts Updated Standards for Commercial Support

At the end of September 2004, the seven member organizations of the Accreditation Council for Continuing Medical Education (ACCME®) unanimously approved the 2004 Updated ACCME Standards for Commercial Support: Standards to Ensure the Independence of CME. 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.

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.

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

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Return on CME Are Pharma Companies Getting Desired Outcomes?

By **Lisa S. Berger**

PMN Reprint #45-04

Measuring the outcomes of medical education is increasingly important in Continuing Medical Education (CME) and cannot be ignored by the CME provider or industry sponsor.

The Accreditation Council for Continuing Medical Education (ACCME), which develops standards for CME through voluntary self-regulated system, requires the provider to evaluate the effectiveness of its CME activities in meeting identified educational needs. In addition, measuring the effectiveness of a particular program is crucial to matching the right program to participant needs and to future program design for the provider, and evaluating the money spent for the sponsor.

Sharyn Lee, CEO and cofounder of Medical Educational Broadcast Network (MEBN), a division of CEU-Online, a leading medical education communications and publishing company, spoke on outcomes-based CME and the importance of selecting the best assessment tool at a recent Medical Education Congress.

Adult Learning

Adults do not learn as efficiently as children or adolescents do in standard classroom teaching formats. According to Lee, current educational research indicates adult learners are self-directed, bring a reservoir of experience to learning, prefer immediate application of learned principles, and prefer a performance-centered, rather than subject-centered orientation to learning. These principles are essential in designing effective educational activities for continuing professional education.

Outcomes-based CME

In a model described by the American Medical Association, there are six levels of outcomes-based measurements that can be used to evaluate the effectiveness of a continuing professional development program, including CME—the higher the level, the broader the impact of change on a physician.

These measurement levels are:

1. **Participation:** the number of participants?
2. **Satisfaction:** how satisfied were the participants?
3. **Learning:** changes in knowledge, skills, and or/attitudes of participants; increased competency
4. **Performance:** changes in practice performance as result of activity
5. **Patient health:** changes in health status of patients due to changes in practice behavior
6. **Population health:** changes in health status of population due to changes in practice behavior

Traditionally, CME providers have used measurements that fall into the first three categories, such as number of participants, how satisfied they were with the program, and what specific content, attitudes, and skills have been acquired from the program content. Sharyn Lee suggests that the outcome measurement tools of performance, patient health, and population health may better assess the value of the educational program intended for continuing professional medical education.

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Outcomes Based on Needs

All good CME begins with needs assessment, which generally comes from thought leaders and learners in a particular therapeutic field. The most effective outcomes measurements come from the need itself.

An example of this tight relationship would be if primary care docs miss depression in 20% of their patients, they need education on diagnosing depression. So an effective outcome measurement might be: Are you better able to diagnosis depression in your patients based on the program you just attended?

This kind of metric would be of interest to a sponsor that markets a drug to treat depression—obviously, the better a physician can properly diagnose depression, the more scripts will be written for the appropriate patients.

Selecting an Appropriate Assessment Measure

Other questions to consider in selecting an appropriate assessment measure are the objectives of the CME program. Specifically, is the measure appropriate to the design of the program? Will the outcome measure validate your hypothesis? What motivations for learning are in play during your event? Will your evaluation measurement support or disrupt learning? What are the skills of your faculty?

Commitment to Change (CTC)

Clinician's intent and commitment to change behavior comprise a powerful vehicle to measure the impact of a particular educational intervention or CME program. According to Lee, "assessing CTC is a measure by which we determine what you think you will do. ...and then measure it."

The purpose of measuring commitment to change is to assess and document actual change in physician behavior provoked by a CME program or other type of educational intervention. Upon completion of a CME event, participants are asked to "write in" their intent to change behavior as a result of the content of the course. At specified intervals, a select number of attendees are contacted by email and asked if they have made the changes they indicated. If they hadn't already done so, they were asked if they intended to make changes in the future, and if so, for permission to contact them again.

As an example, Lee described an MEBN diabetes program that presented evidence of the importance of encouraging patients to self-monitor blood sugar levels. After the program, and using a "free-text" approach, attendees were asked what behavioral changes they would implement in their medical practice to encourage their patients to self-

test their blood glucose levels. At the conclusion of the program, 44% of attendees listed specific behavioral changes they intended to make in the management of their diabetic patients, and listed their intended specific changes. In this case, measurement of CTC was used to evaluate how effective a CME program had been in changing physician behavior.

CTC and Effective Learning Methods

CTC data can also be used to assess the effectiveness of various CME formats—or combinations of formats on the same topic—on specific physician behavior. The resulting information can then be used to design, or re-design, the most effective CME program for accomplishing a specific goal.

Follow-up email surveys can be used to assess the impact of a single CME or series of CME programs, to determine the instructional format that best effects a change in the clinician's behavior. MEBN offered a series of programs on treating diabetes for MDs, NPs, and PAs in a variety of formats, including interactive CD, print journal, audio CD, and live web event. An email survey was sent to 650 people who completed at least 1 credit hour of the possible 6 credits of CME/CE. Sixty-six percent and 33%, respectively, of the participants indicated

Sharyn Lee's Top Ten List for Redesigning CME to Improve Desired Outcomes!

Utilize principles of adult learning:

1. Mix it up—use a variety of CME formats. For example, add internet Q&As with remote thought leaders during live sessions.
2. Employ laptop problem-solving.
3. Promote peer-to peer learning at the office.
4. Use interactive techniques such as audio, gaming, and video technology to engage learners.
5. Employ a post-program internet event with faculty discussion to reinforce learning.
6. Design handouts that have workbook study and self-testing questions.

Entertain to sustain behavioral change:

7. Design curriculum with small intimate discussions rather than text based.
8. Use color, graphics, animation, and illustrations to pique interest.
9. Provide complex and multifaceted, problem-oriented, and case-based programs.
10. Assimilate context-based education to promote behavior change.

definite or some intentions to change their behavior based on the CME material, reported Lee. The survey revealed that although the CD format was the most used by the participants, the CD format alone did not change behavior. The greatest change in behavior, as measured by CTC, was a using a combination of multimedia format, i.e., an interactive CD, journal, or live web event. Audio programs were also effective in changing physician behavior but were chosen by a smaller percentage of participants. This information can then be used for future program design.

Thinking Differently about the Future

Key to achieving desired outcomes of continuing professional medical education is the incorporation of principles of adult learning, choosing outcome assessment tools that measure effectiveness at more meaningful levels, and redesigning your programs based on your results. This continuous cycle of assessment, measurement and redesign leads to competency on the part of the participant as well as of the CME provider.

The selection/design of the best assessment tool is critical. The better the tool, the better the results will answer the question: Was this program effective in meeting the needs of the learner? The better you are able to answer that question, the better you will be able to answer the ultimate question: Were my educational dollars spent on an effective program?

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A Strategic Approach to CME Offers High Return on Education Investment

By **John Mack**

PMN Reprint #46-05

Commercial support from pharmaceutical companies for continuing medical education (CME) accounted for 51.1% of the \$2.042 billion income received by CME providers in 2004 (see Figure 1, next page). Although this represents a decrease from 53.2% in 2003, the absolute amount of money that pharmaceutical companies invest in CME is considerable. As a famous US Senator once said, "A billion here, a billion there, and pretty soon you're talking about real money."

Jan Heybroek, Vice President at Imedex®, Inc., an accredited worldwide CME provider located in Alpharetta, Georgia, estimates that pharmaceutical companies spend about 7% of their marketing budget (excluding samples) on educational activities. "However, many pharma companies lack interest in the return on education investment or ROEI data our programs are able to provide," says Heybroek.

More Effective Than Sales Reps

The data that Heybroek speaks of relate to changing physician behavior and adopting the therapeutic options discussed by the learned faculty of CME programs. When compared with many other techniques for changing physician behavior—such as detailing by sales reps—CME is very effective in educating physicians on patient management approaches.

Sixty percent (60%) of physicians surveyed immediately after taking an Imedex CME program, for example, say they intend to change their patient management practice based on the information provided. One year later nearly the same percent (56%) indicate they actually have changed the way they treat patients. Over 90% also share the information they learned with colleagues. See Figure 2 (pg. 28) for more data on the impact of Imedex programs on disease management decisions of physician attendees.

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“Compared to the effectiveness of sales reps, which is about 8%,” says Heybroek, “our CME programs offer incredible return on investment.” He was citing the McKinsey Consulting 2002 Quarterly Report, which claimed that out of 100 sales reps calling on physicians, only 8 actually speak to a physician and are remembered. Each call, by the way, cost \$142 (in 2002) regardless of the outcome.

“We believe our high ROEI is due to the fact that our programs are developed independently based on scientific evidence and are recognized as being unbiased (more than 90% of surveyed physicians perceive no bias),” says Heybroek, “even though the programs are supported by pharmaceutical companies.”

Unbiased Proprietary CME Programs

The three major sources of CME—medical schools, publishing/ education companies, and non-profit physician societies—accounted for 87% of the income generated by CME in 2004. The publishing/education company grouping includes medical education and communication companies (MECCs), which develop advertising communication programs as well as CME programs, and purely medical education companies like Imedex, which only produce CME programs.

Recent ACCME, OIG, and FDA guidelines have tremendously impacted how publishing/education

companies produce CME and how pharmaceutical companies fund CME. All accredited MECCs and most pharma CME supporters have erected “firewalls” between their educational and promotional activities to prevent conflicts of interest. Imedex does not need a firewall because it does not also produce promotional programs. It’s only focus is accredited CME programs.

Another difference between Imedex and other commercial CME providers is that Imedex provides significantly more CME hours per live event, which provides excellent value for supporters and attendees (see Figure 3, pg. 28). “We believe that this is one of several factors contributing to the success of Imedex programs,” says Heybroek.

Deep Reach Into Multiple Therapy Areas

Another reason is the high quality of the faculty and scientific programs devoted to current and relevant topics. Imedex can produce unbiased CME programs with a high ROEI because its programs are similar to the kinds of programs developed by non-profit medical associations. However, Imedex does not focus on just one or two therapeutic areas as is the case with medical societies. It has developed CME programs in oncology, infectious diseases, gastroenterology, urology, psychiatry, cardiology, and endocrinology.

With over 200,000 physicians in its database, Imedex’s reach into these therapy areas is deep. For example, Imedex can reach about 80% of

oncologists by direct mail and survey them regarding trends and issues critical to them. This helps Imedex develop appropriate educational programs and draw more physicians to their live events than their competitors do (see Figure 4, pg. 28).

Multiple Supporters

As with medical association programs, most of the programs Imedex offers are supported by multiple pharma companies. “We had over 100 supporting companies for our CME programs last year,” says Heybroek. “Our top 20 supporters represent about 60% of our total revenue. None of them is so critical to our income that they cloud our focus or unduly influence our decisions.”

Continued on pg. 29. See Figures on next page...

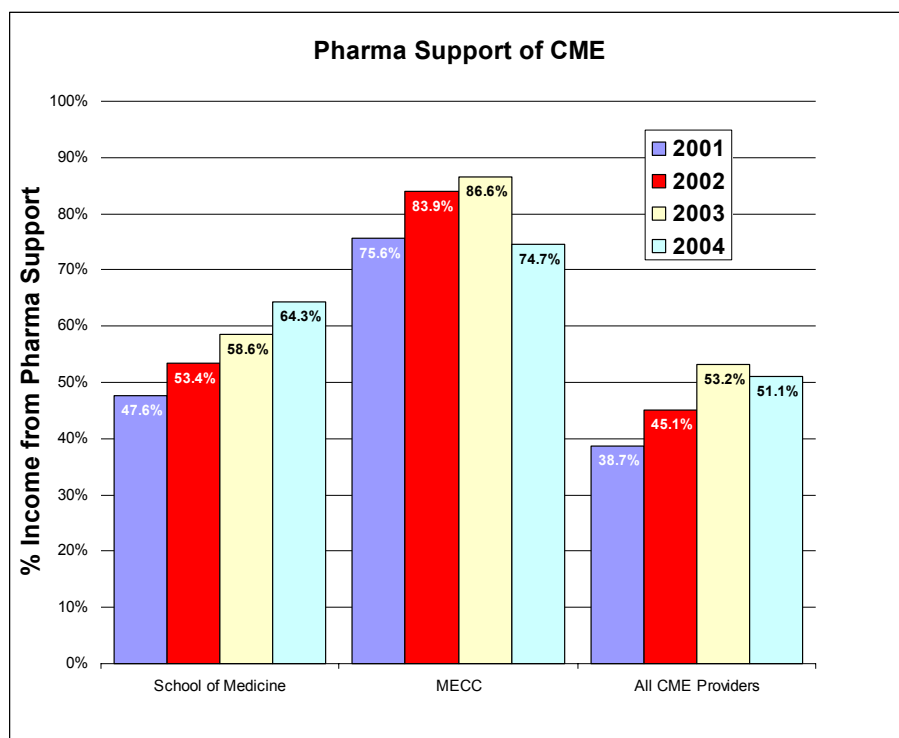


FIGURE 1: Pharma Support of CME. Source: ACCME Annual Reports.

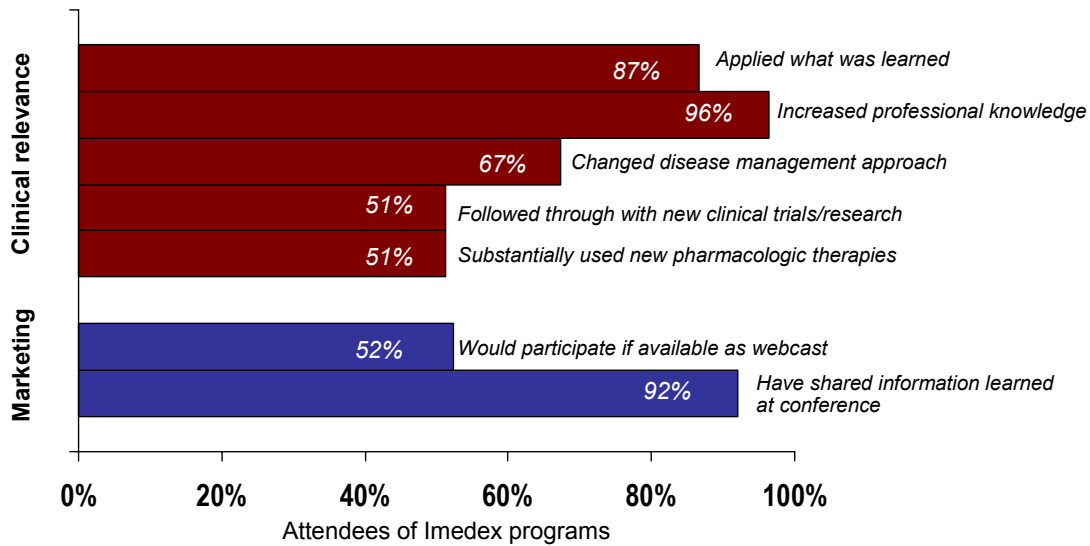


FIGURE 2: Three-month post-conference survey of 27 Imedex conferences with total of 722 respondents. Source: Internal data. Number of respondents varies per question from 448 to 722.

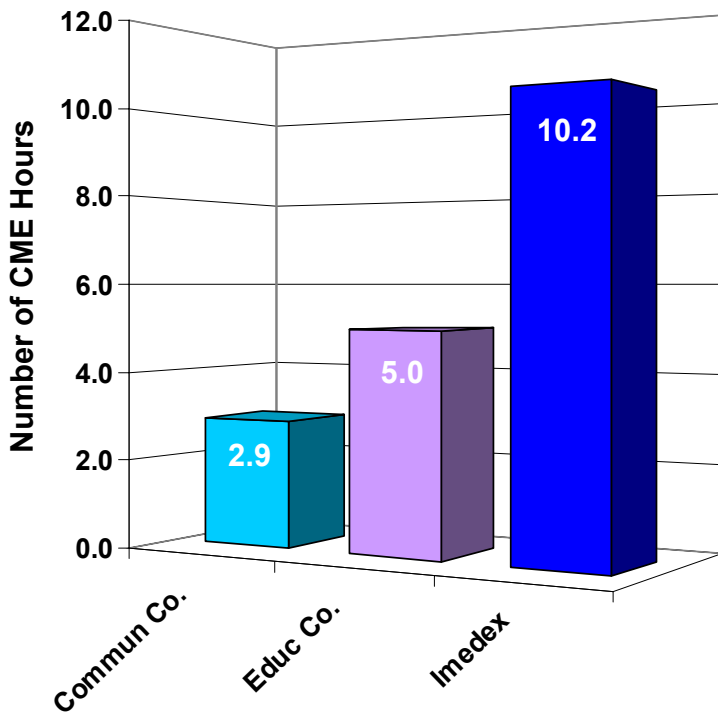


FIGURE 3: Average Number of CME Hours per Live Event. Source: Internal data and ACCME 2003 annual report.

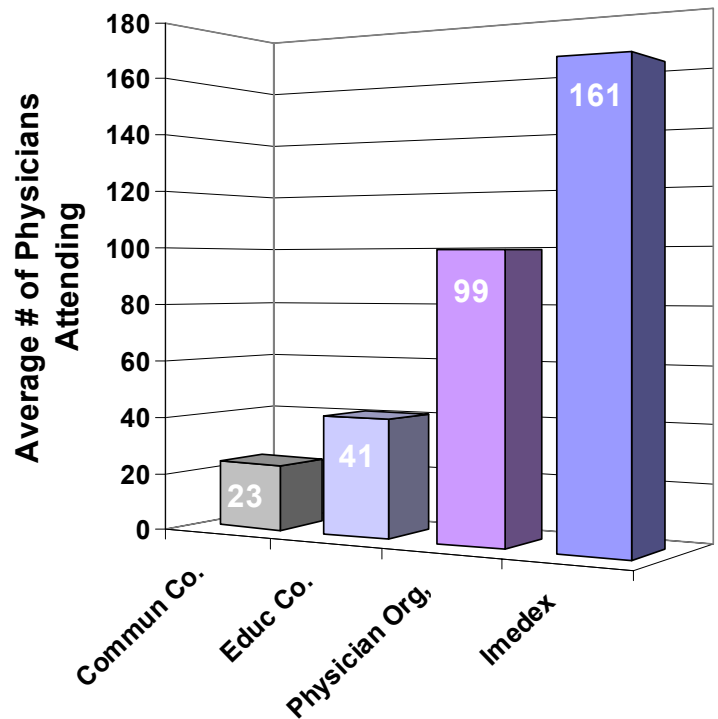


FIGURE 4: Average Number of Physicians Attending CME Events. Imedex draws 4 times more physicians than competitors and 62% more physicians than specialty physician organizations. Source: Internal data and ACCME 2003 annual report.

"We seek support from pharma only after we have determined that there is a need for a program and we have established our own internal scientific committee," says Heybroek. "We then draft a program based on the need and we identify a chairperson who we believe is a thought leader in the field who comments on the program and supports its execution."

Trend Towards More CME

A trend noticed by Imedex is that more pharma-supported educational programs are being offered as CME events. Proverbial dinner meetings, in which physicians are invited to hear speakers over dinner at restaurants, are now becoming CME dinner meetings. In one case, Imedex organized twenty single-supported dinner meeting programs, supported with teleconferences and a webcast about the impact of the Medicare Modernization Act on oncology practice. Approximately 600 physicians, coding specialists, and nurses attended.

Given that the return on CME is comparable or greater than that for sales reps or even DTC, Heybroek is surprised that more pharmaceutical companies are not using physician education as a strategic tool for communicating educational messages that fit the scientific profile of their products. "The science, along with reimbursement considerations," says Heybroek, "are the two biggest influencers of physician prescribing behavior that ultimately benefit patient care."

Although decisions regarding CME are now often made by an independent committee at pharmaceutical companies rather than marketers, Heybroek says it is not harder to get support from pharma, at least not for Imedex programs. Often, however, it is not clear how these decisions are being made. Heybroek suggests that pharma companies adopt a consistent strategic approach to supporting CME. "Some companies recognize the value of CME better than others," says Heybroek.

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