

Feature Article Reprint # 56-01

Trends in Commercial Support of CME

By John Mack

Pharmaceutical companies continue to provide financial support and funding for CME programs. Recently, these programs have come under scrutiny from numerous sources, including the commercial supporter organizations themselves, in the quest to ensure high quality, compliant and effective CME that results in tangible levels of "educational outcomes." A fundamental shift is occurring with regard to commercial entities' demands on CME programs.

However, being able to provide metrics about the effectiveness and impact of CME on physician performance and patient health is proving difficult. With the tightening of budgets and the need to demonstrate that CME programs are adding value to physicians and patients, commercial supporters are examining ways to determine effectiveness.

In recent years, a number of guidelines have emerged that influence how pharmaceutical manufacturers support independent educational activities. At the same time, the government has increased its scrutiny and enforcement in this area. Determining how to interpret FDA and OIG guidance documents in an evolving legal and regulatory environment can cause confusion and angst. It is imperative that organizations develop and implement activities that comply with the regulations and ethical codes promulgated by the agencies and policies that govern the CME enterprise, while meeting the needs of healthcare professionals. This is particularly important given that OIG imposed approximately \$11 billion in fines in 2005.

On 8 June 2006, members and guests of the **Pharma Marketing Roundtable** (see sidebar) met via conference call to discuss trends in commercial support of CME. The Roundtable discussion touched on the following and other questions related to this topic:

- Will commercial (for-profit) CME providers and producers increasingly give way to academic center networks? Are the days of the large CME companies numbered?
- Which technological and media approaches for CME delivery are gaining favor...and which are losing ground?

- What role should CME play in strengthening the communicative skills of MDs in their interactions with patients? Why aren't we seeing more of this with the advent (peaks and valleys) of DTC?

Regulation By Raised Eyebrows

John Mack: John Kamp, you've probably been keeping a close watch on CME developments. Would you like to start us off with a summary of what's going on with CME these days?

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Pharma Marketing Roundtable

www.pharmamarketingroundtable.com

Date: Thursday, 8 June 2006

This Roundtable discussion will be devoted to exploring the issues and trends in commercial support for continuing medical education (CME).

Moderator: John Mack

Participants:

1. **Jack Barrette**, Category Development Officer for Lifestyles, Health and Medicine, Yahoo!
2. **Mario Cavallini**, Manager of Competitive Intelligence, Simstar
3. **Joe DeBelle**, Senior Director of Marketing, Lathian Systems
4. **Neil Gray**, Managing Director, Healthcare Trends & Strategies, LLC
5. **Venkat Gullapalli**, MD, Chief Medical Officer/CEO, MaxMD/Gullapalli and Associates
6. **Jan Heybroek**, Executive Vice President, Imedex
7. **John Kamp**, Executive Director, Coalition for Healthcare Communication
8. **Robert Nauman**, Principal, BioPharma Advisors
9. **Harry Sweeney**, CEO/Chief Creative Officer, Dorland Global Health Communications

John Kamp: Lately in the CME area we've been seeing "regulation by raised eyebrows," by which I mean the chilling effect of such things as letters from Senator Grassley to pharmaceutical CEOs questioning a whole range of pharmaceutical marketing activities, including CME. Virtually everything he's been asking about is clearly illegal and not done by companies—at least not anymore—or are covered by PhRMA guidelines for gifts to physicians. Some practices he's questioning are clearly legal and he seems to be setting the stage for making them illegal or threatening to do so.

I think this is a very serious threat because government regulation by raised eyebrows causes companies to avoid CME while this uncertainty prevails. The risk-of-censure game is just not worth the candle.

Mack: It appears that Grassley is aware that some practices he's questioning are no longer going on. The letter from the Senate Finance Committee to J&J, for example, states:

"We recognize that the information described above represents past practices and might not continue under current policies and procedures. In reviewing documentation submitted in response to our initial request, our Committee staff found that many manufacturers have modified their grant policies and procedures in response to the PhRMA Code, issued in 2002, and the Department of Health and Human Services Office of Inspector General's OIG Compliance Program Guidance for Pharmaceutical Manu-

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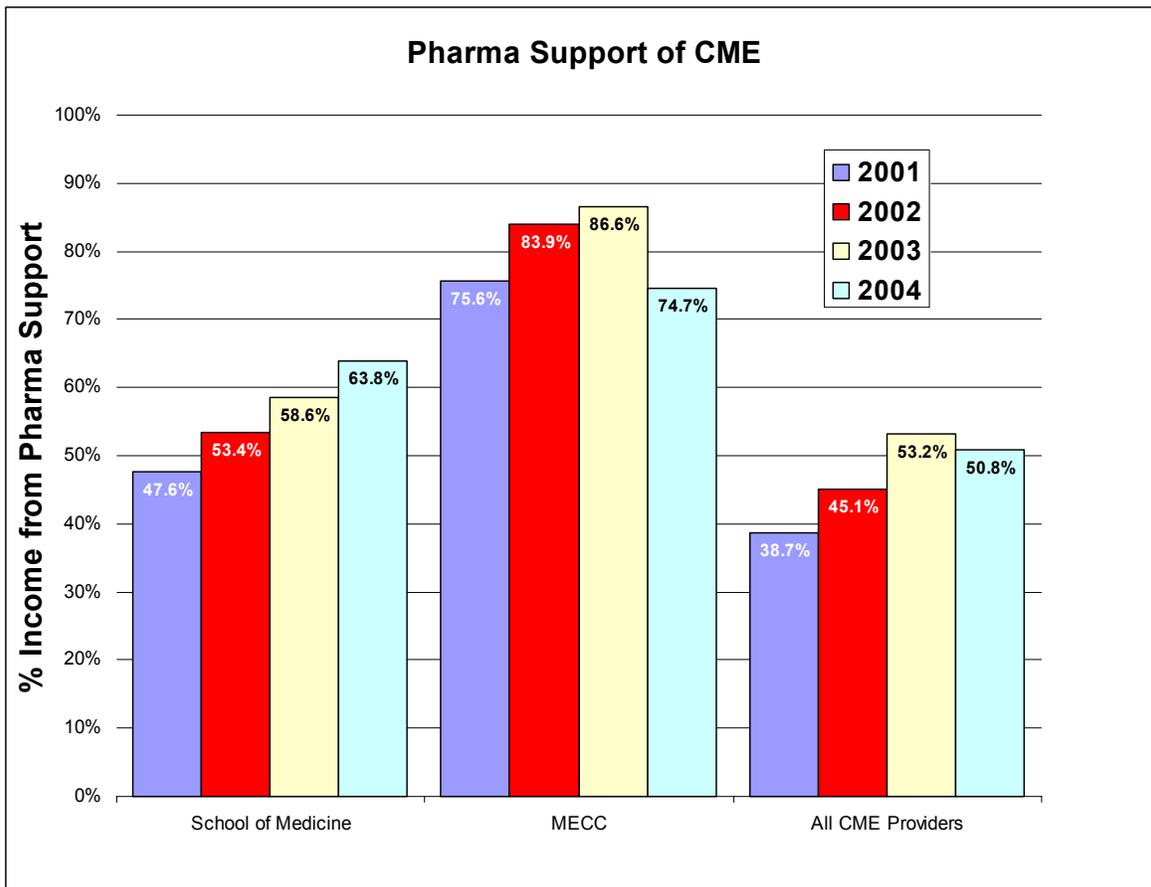


Figure 1: Shifting Pharma Support of CME. Although the total amount of pharma support for CME increased in 2004 compared with 2003 (\$1,071,064,979 vs \$971,100,098, respectively, not considering advertising), the percent of CME income attributable to pharma has decreased and shifted away from MECCs to Schools of Medicine. The 2005 ACCME data—due to be released soon—is expected to reveal that the absolute amount of pharmaceutical CME dollars has decreased somewhat.

Manufacturers, issued in 2003. However, it appears that many manufacturers', sales and/or marketing personnel still have a role in originating or evaluating grant requests, and, consequently, the potential for abuse remains. In addition, it appears that most manufacturers continue to provide funding to professional societies and patient advocacy organizations, but the information received by the Committee shows that only one drug manufacturer considers the portion of funding provided to such organizations when evaluating grant requests. Accordingly, we remain concerned about both the direct and indirect influence that manufacturers may have on such organizations."

The letters from Grassley et al (see <http://www.senate.gov/~finance/press/Gpress/2005/prg011106.pdf>) are seeking specific information as this excerpt demonstrates:

"After reviewing information provided by drug manufacturers in response to the Committee's initial request and from other sources, the Committee seeks additional information about certain practices. Most notably, as Chairman and Ranking member of the Committee we seek to better understand the role(s) of sales and marketing personnel in initiating and/or evaluating grants, and the use of grants to provide funding to professional societies or associations and patient advocacy organizations. With respect to the role of sales and marketing personnel in the grant approval process, we are concerned that sales and marketing personnel may influence the awarding of grants in a way that favors those individuals or organizations that are known to advocate use of specific product(s). With respect to the use of educational grants to fund professional and patient advocacy organizations, we are concerned that such organizations, many of which develop treatment or practice guidelines, may come to rely on such funding to an extent that may compromise their independence. The Committee is also interested in funding provided to academic institutions or state agencies to support the development of practice guidelines or treatment algorithms."

Kamp: At the same time, the HHS Inspector General is continuing to investigate all kinds of marketing activities and looking directly at CME. The most significant case resulted in a corporate integrity agreement by Serono, which, if the government's case is true, was engaged in some

questionable activities, including controlling content in CME that the company sponsored.

Could Chill Kill CME?

Kamp: Between Senator Grassley asking questions in a very threatening way and virtually every pharma company's marketing practices under investigation by the OIG and DOJ lawyers, I think there's a very clear chill, generally, on communications from the pharmaceutical industry, including CME. Many pharma people think it's just not worth the criticism, even though they may be doing it correctly.

Mack: Can you clarify what practices are clearly legal that Grassley is threatening to make illegal? In other words, where do you see the threat?

Kamp: He's not directly accusing anyone of anything, but when you get a letter from a senator asking you to "back up the truck" and drop off all relevant documents in support of any commercial activities you've done over the past couple of years, that's pretty threatening. He's essentially questioning the legitimacy of all CME that is supported by pharmaceutical companies or executed by commercial providers or by groups that get funded by them (eg, patient advocacy groups). In other words, he's looking under every rock for illegalities. Like pornography, if you look for it everywhere, you'll liable to find it in a few places.

Mack: Has this "chilling effect" resulted in less support for CME by pharmaceutical companies?

Jan Heybroek: One of the things we are seeing is a tendency of pharmaceutical companies to somewhat limit their support of complimentary programs or look for ways that complimentary programs can be done in a multi-supported rather than a single-supported manner. We have not seen a big change in the amount of money pharmaceutical companies have given in support of CME.

Mario Cavallini: Are you saying that there is a shift from supporting individuals to funding a pool that is then distributed by a third party provider?

Heybroek: Pharma clearly cannot support individuals in the US. What I am saying is that a number of events we provide are single-supported—one company provides all the funding for these events. We do see a trend, however, towards programs that are supported by multiple companies, not just one.

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Venkat Gullapalli: We also have noted that multi-sponsored events are becoming more popular as a means to counteract the negative aspects of single-sponsorship and to mitigate potential conflicts of interest.

Piper Paid, But Wants to Play Own Tune

Mack: To reform CME, the authors of a recent JAMA article suggest that “manufacturers wishing to support education for medical students, residents, and/or practicing physicians should contribute to a central repository (eg, a designated office at an academic medical center), which, in turn, would disburse funds to ACCME-approved programs.” (JAMA, January 29, 2006. Vol. 295, No 4). Any comments on that?

Kamp: Only academicians could think that companies would essentially give them money with no control over how it was going to be spent. I’m hoping this is just a shot across the bow, designed to get our attention rather than something they actually expect to happen.

Cavallini: There definitely is a perception problem. The University of Pennsylvania recently announced that they weren’t going to allow drug reps to drop off “trinkets” and such but they still accept grants. In other words, don’t give me junk jewelry, just send money.

Mack: I guess the real issue is who controls the money.

Neil Gray: I think that commercial entities (pharma, biotech, device companies) will always control the money. The question is, can it be administered and executed ethically and without conflict of interest? In the 80s and 90s, the environment was clearly different. Pathways to CME budgets were 100% through the product teams with very little medical affairs involvement or activity. That, of course, has changed. The guidances have played a role. Associations such as ACCME have reinforced the fact that conflict of interest doesn’t help generate unbiased content, which is what is needed to improve health care.

The flip side is the notion that academicians are as pure as the driven snow. To answer the question of whether academic centers will become more dominant CME providers, I would say only “partially” because I don’t think they will be able to execute with the same efficiency and with the historic “product championing” attitude of commercial providers.

Can We All Just Get Along?

Mack: Can you expand on what you mean by commercial providers as “product champions?”

Gray: Over the years, a lot of the reason commercial providers were retained was not only their capacity to execute well and timely live events and enduring materials, but that they really appreciated both sides of the equation. That is, they understood the science, but they were also very conscious—overtly or sub rosa—of what the proper messaging needed to be to support the brands that ultimately were underwriting the activities 100%.

Mack: Prior to OIG guidelines, many commercial providers were not truly independent, but were divisions or departments set up within advertising agencies. Perhaps there still are ties between the spun-off commercial CME providers and their parent ad agencies. Could this be the kind of problem Grassley is looking at?

Gray: In many instances, I think this is more a perception problem. I’m sure there are bad apples out there.

Mack: Looking at data from ACCME and comparing 2004 with 2003, a smaller portion of pharma’s CME support is going to MECCs, while a larger proportion is going to schools of medicine (see Figure 1, pg. 4). Does anyone know if this trend is likely to continue in 2005 and 2006?

Kamp: Anecdotally, I’d say yes. CME managers of pharmaceutical companies tell me that doing CME through academic providers gives them a certain amount of public relations benefit that they wouldn’t get otherwise.

Mack: Given this trend and the fact that academic centers may not execute CME as well as MECCs, do you see a blending of these two types of providers or more cooperation?

Gray: I do think that’s where this is heading. If we had this Roundtable discussion a year from now, I think we would definitely see more partnerships and collaboration activities that build good, strong networks of CME providers that exhibit the best features of both academia and commercial entities. Commercial providers will, in other words, collaborate with schools of CME to provide these activities.

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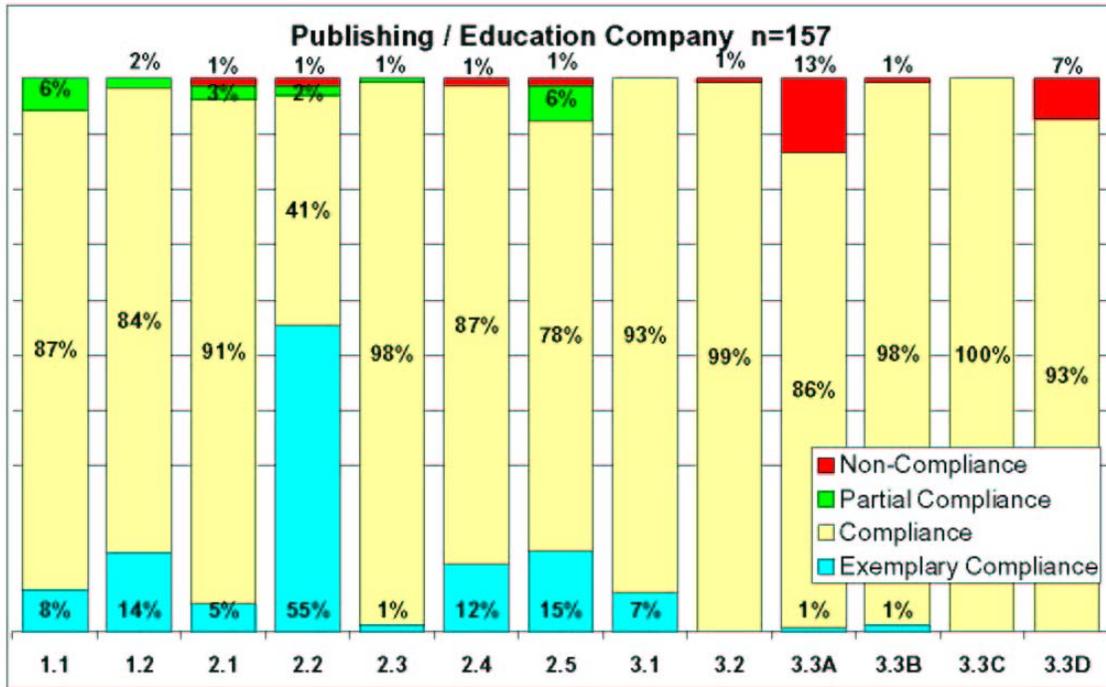


Figure 2: Compliance with ACCME “Essential Elements”—Publishing/Education Companies (MECCs)

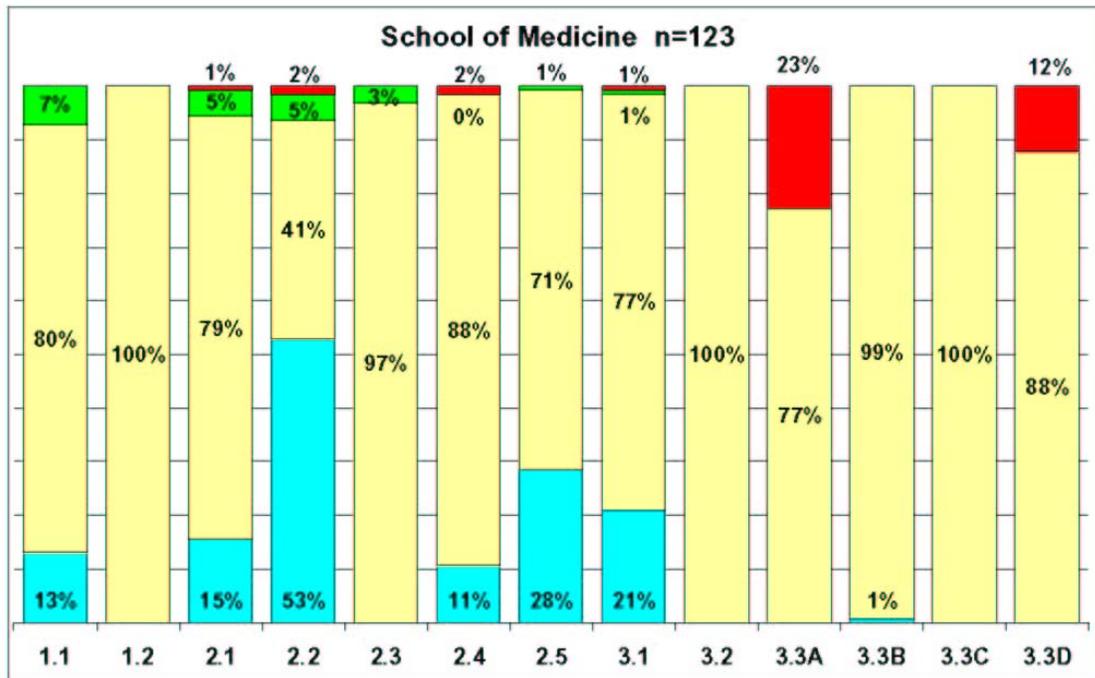


Figure 3: Compliance with ACCME “Essential Elements”—Schools of Medicine (SOMs)

<i>Provider Type</i>	<i>% Non-Compliance</i>
Publishing / Education Company	13%
School of Medicine	23%
Non-profit (Physician Membership Org)	37%

Table 1: Compliance findings for ACCME Essential Element 3.3A: The provider must disclose required information and relationships.

<i>Provider Type</i>	<i>Accredited with Commendation</i>	<i>%</i>
Publishing / Education Company	16 out of 157	10%
School of Medicine	28 out of 123	23%
Non-profit (Physician Membership Org)	21 out of 273	8%
All	90 out of 736	12%

Table 2.A: Provider Accreditation Status. Accreditation with Commendation.

<i>Provider Type</i>	<i>Provisional Accreditation</i>	<i>%</i>
Publishing / Education Company	26 out of 157	17%
School of Medicine	1 out of 123	<1%
Non-profit (Physician Membership Org)	11 out of 273	4%
All	49 out of 736	7%

Table 2.B: Provider Accreditation Status. Provisional Accreditation.

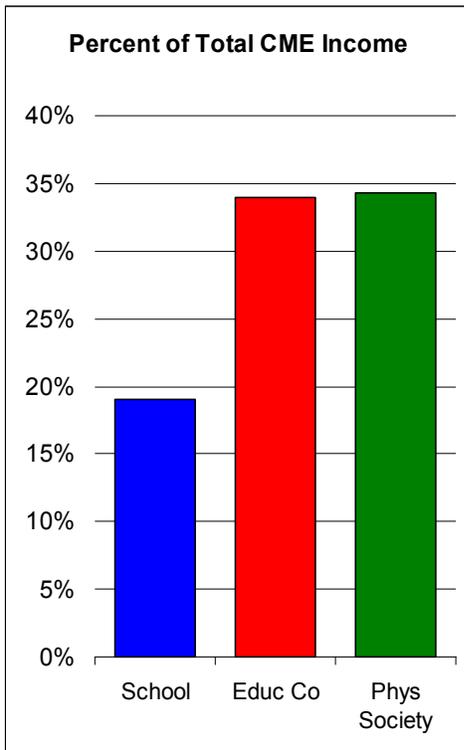


Figure 4: Percent of Total CME Income by Provider Type (2004).

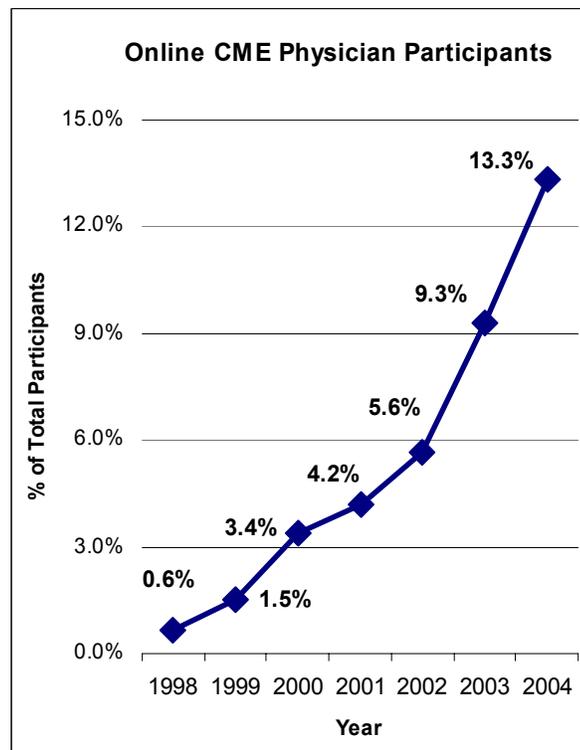


Figure 5: Physicians Participating in online CME (enduring materials only, not including live CME events). In 2004, 3.6% of all CME hours were delivered online and 20.7% of all CME activities were delivered online.

Comparing Providers' Skillsets

Harry Sweeney: Marty Cearnal of Jobson tells me that pharma industry sponsors are well aware of the skills and knowledge that commercial CME providers bring to the table. You only need to look at the violations of ACCME guidelines by commercial versus academic providers as reported by ACCME. Cearnal says that the violations are predominantly on the academic side. That may be because the commercial organizations understand the various liabilities and risks, follow the rules, and pay great attention to the bureaucratic burden of complying with the rules and guidelines.

Mack: The ACCME compliance findings show some differences in how well different provider types comply with ACCME's "Essential Elements" related to standards of commercial support. With regard to element 3.3A (disclosure), MECCs do better than schools of medicine (see Table 1 and Figures 2 and 3, pg. 5).

Aggregate compliance with the Elements overall (i.e. Elements 1.1 through 3.3), however, showed less variance among provider types. From this, one could say the commercial providers do as well as, if not better than, schools of medicine complying with the standards.

On the other hand, a smaller percentage of MECCs than schools of medicine (SOMs) have achieved accreditation with commendation and a larger percentage of MECCs than SOMs have received provisional accreditation (See Tables 2A and 2B, pg. 6).

Conflicts of Interest

Heybroek: Many schools of medicine receive pharma company funding to run clinical trials. I would like the group's view on a potential conflict of interest this may cause when these same schools seek CME funding from the same companies.

Sweeney: A bit of perspective might help here. The development of professional associations took place because the academic centers saw themselves as responsible for teaching and research but not for continuing education. Professional associations filled that gap. It's only been in recent years that CME in academic centers became an important function. Because of the money being spent on CME, you can easily see why this has happened. These schools are under significant budgetary pressure, so any income stream they can develop puts them that much ahead. There are many people in professional associations that are not happy about these new competitors! However, the easy targets to shoot at

are the commercial providers, not the academicians. As if the not-for-profit provider is holier than thou!

Gray: It's a great illustration of how the academic environment is consistently able to fly under the radar of the legislators like Grassley. There's definitely going to be more competition for grants in this marketplace and it's not all going to go to commercial providers, who perhaps have pushed the envelope too far in support of their grantors.

Mack: It appears that physician societies receive the same portion of the CME income pie as do the commercial providers (see Figure 3, pg. 5). Whether or not the commercial providers are the easier targets, they certainly appear to be the main competitors of the societies and therefore deserve most of the arrows aimed at them.

Sweeney: The schools also are targeting commercial providers. Rather than going to "professional war" by attacking "colleagues" in the medical societies, they have chosen to go to "commercial war" and attack the commercial providers.

Kamp: Some academic centers are getting their acts together and teaming up with commercial vendors, who might be ad agencies, to carry out the implementation of CME. The sponsor is still the academic center, however. The agencies are the agents of the academic centers. What is positive about this is the academic centers know how to find good people to implement their programs. The commercial providers have been doing it longer, are better organized, and are more focused on communications, and are much better at analyzing the effectiveness of the program.

Gray: It's a result of the distinction between the culture of for-profit and non-profit employees in my view.

Mack: Is this collaboration strategy actively being pursued by commercial providers? In my experience as a commercial physician education provider working under pharmaceutical educational grants, I often sought out the medical society as a partner and brokered the kind of collaboration you mention. Often the grant went to the society which hired my company to provide the program.

Gullapalli: Actually, that still happens today. I've seen academic centers contract with consultants to seek out grant opportunities from pharmaceutical companies.

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The Economic Facts of CME Life

Mack: Putting a layer between the pharma company and the for-profit company would be a good thing, wouldn't it?

Sweeney: Let's look at the economics of this kind of structure. If a commercial provider received a \$100,000 grant to do the program on its own and now must work with an academic center, up to 20% of that grant would have to be shared with the academic center. In the real world, the commercial provider is not going to "eat" that expense, but pass it along. In that scenario, the program that once cost the sponsor \$100,000 would cost \$120,000.

Rob Nauman: Today, pharmaceutical marketers are under pressure to keep costs down. Wall Street analysts and brokers are saying that pharma companies need to get their costs from 35% of sales down to 22% of sales in the next five years in order to maintain growth. In this environment, the \$120,000 proposal is likely to get dismissed quicker. Regardless of who owns the biggest piece of the CME pie, there's a shrinking pie overall. Perhaps some money is coming out of DTC, but I don't see it going to CME. It's going right to the bottom line.

Sweeney: The commercial objective of pharmaceutical companies is to sell more products. Companies have 25 alternative ways to get their messages out. CME is only one of those options. According to ACCME numbers, about \$1.2 billion is being spent by the commercial sector on CME. It's a significant number as a raw number. It's a fractional percentage of the total.

ROI vs ROE

Mack: Are pharmaceutical companies getting a good return on CME investment? Wouldn't that determine how much of the mix should be devoted to CME?

Sweeney: That's not politically correct to ask, John. You have to talk about return on education.

Kamp: The OIG has said that if there's an ROI, there's no education. So every pharmaceutical company has to pretend that it's ROE they are focusing on. It's really goofy. Categorizing CME that makes money as illegitimate is bad for the public interest.

Mack: CME can no longer come out of marketing budgets, correct?

Kamp: That's right. It can't come from the marketing pot. It's moved into the "charity pot" and who's going to pay attention to that? When

executives look into ways of cutting costs, they're going to go after items in the charity pot first!

Gray: Moving the CME budget from the brand team to the medical affairs group is tantamount to giving a kid a pile of money without the experience about how best to use it. A lot of medical affairs teams are learning as they go. I am not convinced that they have had great dialogue with brand teams.

Mack: Some experts maintain that it is completely feasible—ie, within OIG guidelines—to have brand team input into CME decisions. For example, CME committees can be set up with brand team participants as long as marketers don't have a majority vote.

Kamp: The problem is that OIG investigators are making up the rules as they go and no-one knows how much of that can be done. What you do know is that they can demand all your records and your emails and decide that what somebody said in retrospect was inappropriate.

Sweeney: The elephant in the room that we are not talking about is an attempt by Senator Grassley and others to censorship speech coming out of the pharmaceutical industry. Pure and simple. It's an attempt to shove the pharmaceutical industry out of the communications business and somehow force it to lower prices.

Jack Barrette: We are giving politicians too much credit for long-term goals as opposed to gathering public support and votes in the short term. This criticism of CME is another attempt to pander to social interests about the big, bad pharmaceutical industry. These are great sound bites and CME is going to be held up besides other issues such as sales rep behavior, etc.

Kamp: Senator Grassley does not have a sophisticated understanding of CME. That's not what this is about for him. It's about sound bites critical of the pharma industry getting picked up by media in his district.

Novel Idea: Physicians paying for CME

Mack: Considering that even some physicians see a problem with commercial support for CME, do you see any movement afoot requiring physicians to pay for CME?

Heybroek: We offer accredited CME programs in the US and in other countries. Some are complimentary and some require registration fees to be paid by physicians.

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Kamp: I don't know if there's a movement among physicians, but I know that lawyers pay for their own CME and I can't understand why doctors shouldn't as well.

Sweeney: That could happen with the stroke of the pen. If mandatory recertification went into ascendancy, physicians would have to deal with CME as a cost of doing business. They would reach into their pockets and pay for it, because that would be their ticket to the dance.

Gullapalli: The way things are going, physicians may not have a choice. There are publishers out there doing very well that cater to physicians who on an annual basis pay about \$300-\$400 for CME. This is without any commercial support at all. So, it's possible.

Cavallini: I've met too many physicians that have moved from one state to another, become jazz musicians, caterers, etc. Paying for CME could be the last straw that breaks the camel's back for a good number of physicians.

CME via the Internet

Mack: I thought paying for IT was the last straw! Speaking of which, what about using the Internet to deliver CME more cost-effectively?

Gullapalli: Not all physicians go to annual conferences for CME. While the rate of adoption is growing, I think the overall numbers of physicians using the Internet for CME is still low, especially among primary care physicians.

Joe DeBelle: What we have found is that there has been a dramatic increase in online CME to where about 14% of physicians get their CME online (see Figure 5, pg. 6).

Sweeney: I think 14% is a significant number given human nature and physicians' desire to get hands-on demonstrations. There's no single silver-bullet method for delivering CME. The on-demand aspect is what's driving online CME. It works well for physicians who are insomniacs or who get up early in the morning and want to spend an hour or two running through online CME. For them, online CME is perfect.

Gullapalli: I agree. Physicians will always use a variety of media—live meetings, print, online—for CME activities.

CME for Communications Skills

Sweeney: One of your questions, John, that we have not talked about yet is whether the communications skills of physicians should be addressed in CME. There's an awareness in the academic medical community that their graduates' bedside manner is terrible! Several of them have inaugurated bedside manner courses.

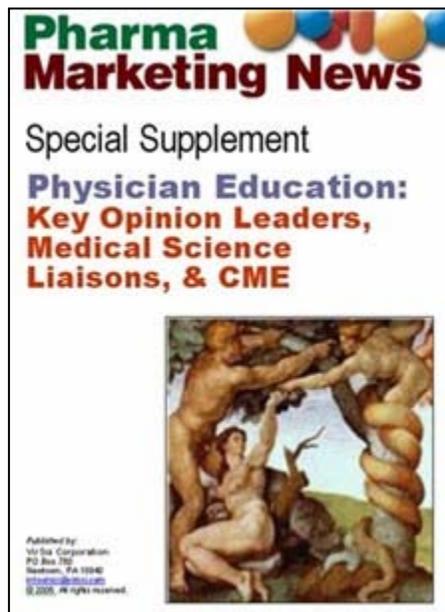
Gray: This is a huge issue. The ability of physicians to communicate well with patients is one of best skills they could have for treating patients. They are taught much science, but very little communicative skills. A lot of times physicians don't treat as well as they could because they are not listening or communicating as well as they could be. CME rarely touches this problem.

Cavallini: I'm skeptical that CME can address this. Much individual attention and practice is necessary and just getting a lecture with a few Powerpoint slides isn't going to get the point across.

Kamp: It's important, but I don't know if pharmaceutical companies will be paying a lot of attention to it.

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