Wither CME?
New Rules for Industry Support

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Wither CME? 
New Rules for Industry Support 
By John Mack

“\text{The clock is ticking for industry-funded medical education,}’’ declared Daniel Carlat, M.D., author of the Carlat Blog and outspoken critic of pharma-sponsored continuing medical education (CME). Dr. Carlat was a guest on a recent Pharma Marketing Talk podcast—‘‘Welcome to the CME Laundromat!’’—which you can listen to \url{here}.

“The latest body blow,” says Carlat, “comes in the form of a report on medical education issued by the influential Josiah Macy, Jr. Foundation.” The report points out that the “majority of financial support for accredited CME, and increasingly for CNE (Continuing Nurse Education), derives directly or indirectly from commercial entities.”

In 2007, for example, the pharmaceutical industry provided $1.19 billion to sponsor CME programs ($1.44 billion if you include advertising and exhibits at CME events). That’s about 60% of all sources of funding for CME reported by the Accreditation Council on Continuing Medical Education (ACCME). The trend is shown in Figure 1.

A task force of the American Psychological Association (APA) recently recommended that its 148,000 members “turn their nose up at pharma funds; limit the role industry plays at professional conferences, meetings and CME sessions; and adopt strict guidelines on conflict-of-interest disclosure.”

Congress—specifically the Senate Committee on Finance—continues to examine pharma industry support of CME and reached conclusions that were echoed in the Macy Foundation report. In a letter to ACCME, the Committee posited that the retrospective, self-reported ACCME review process may not be sensitive enough to pick up the negative impact of influence by industry; that there is no explicit ACCME process for directly looking for commercial bias; and that the accreditation consequences of noncompliance are weak and do not force change in a timely manner.

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Pharma Marketing News
**Impact on MECCs**

As a consequence of this attention, the ACCME amended the definition of “commercial interest” in its bylaws. Previously, only FDA-regulated entities were included in that definition. Now, the ACCME “will consider advertising agencies and journal publishers as commercial entities, requiring those that own CME units to spin them off as separate companies, and providing an extra layer of independence to firewalls that may already exist between the two” (see “ACCME to providers: build higher firewalls,” MM&M, 9/4/2007).

Regarding medical education and communication companies (MECCs), Murray Kopelow, MD, ACCME chief executive, wrote “ACCME does not intend for this rule to exclude [MECCs] from being accredited providers. ACCME expects that if the ‘ad agency or publishing company’ is an ACCME-defined commercial interest, its owners will set up the two ‘companies’ as two separate and independent companies.” He enumerated the following criteria for independence:

- not owned or controlled by a commercial interest
- separate management
- employer of record is not a commercial interest
- separate governance where the majority cannot represent a commercial interest
- receives funds from a commercial interest only as commercial support.

Onerous though the new regulations—scheduled to take effect in August 2008—may be for MECCs, the Macy Foundation report doesn’t believe it is enough. “No amount of strengthening of the ‘firewall’ between commercial entities and the content and processes of CE can eliminate the potential for bias,” contends the report.

Dr. Carlat, agrees, and contends that the new ACCME guidelines are merely causing advertising and marketing agencies behind the curtains of MECCs to “spend a lot of money consulting with their attorneys and running Xerox machines to churn out a new layer of paperwork to demonstrate the existence of new firewalls.”

MECCs account for 34% of all CME income (see Figure 2, pg. 15) and approximately 76% of MECC-produced CME is sponsored by pharmaceutical companies (not including advertising income; see Figure 3, pg. 15). Pharma support of MECC-produced CME has decreased somewhat since 2003 when 87% of MECC CME income originated with pharmaceutical companies.

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**Social Media Marketing**

**Damned If You Do, Damned If You Don’t!**

It is generally agreed that the return on investments (ROI) for traditional media like print and TV is declining. A new approach to the way forward in pharma marketing is needed and is actively being pursued by pharmaceutical marketers and their ad agencies.

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Pharma Marketing News
Influence Within Medical Schools
Recently, more pharma CME funds have poured into medical schools, which account for 18% of all CME income. In 2006, about 62% of medical school CME programs were funded by pharma. If MECCs cannot comply with new ACCME guidelines, pharmaceutical companies are likely to continue to court medical schools.

Interestingly, a recent study published in JAMA found that 60 percent of department chairs at medical schools had some form of financial relationship with the drug industry. Such financial ties include serving as paid consultants, members of a scientific advisory boards, and paid speakers. This leads to questions about bias in CME programs developed by medical schools. Recent news reports also suggest that CME funding can be in jeopardy when professors speak out against the industry (see "How Pharma Uses CME Funding as a Weapon").

What About Physician Societies?
The third leg of the CME stool is comprised of physician societies, which accounted for 33% of the total CME income in 2006. Only 23% of that income, however, originated from direct pharmaceutical company grants. Another 26% came from advertising; ie, exhibits at society meetings.

Pharmaceutical funding of CME and non-CME activities at medical society meetings is becoming so pervasive that a few associations are beginning to call upon their members to wean themselves from pharma-supported CME. A task force of the American Psychological Association (APA) recently published a report that listed more than half a dozen ways the pharmaceutical industry exerts "enormous financial and political influence" that enables it to "assume a significant role in directing medical treatment, clinical research, and physician education" (see "Corporate Funding and Conflicts of Interest - A Primer for Psychologists").

The report also recommended that its 148,000 members "turn their nose up at pharma funds; limit the role industry plays at professional conferences, meetings and CME sessions; and adopt strict guidelines on conflict-of-interest disclosure" (see "Psychologists Urged To Upgrade Ethics Rules").

According to the APA, "pharmaceutical industry money is so crucial to the funding of university medical centers that no threats or offers need to be made for a company to exert its influence" (see, however, "How Pharma Uses CME Funding as a Weapon").

What caused the APA to set up its Task Force on External Funding that issued this report? It was the industry itself, of course. Philip Zimbardo, former president of the APA, was appalled by the extravagant exhibits sponsored by pharmaceutical companies at the 2002 annual APA convention. Zimbardo described the exhibit scene at the 2002 American Psychiatric Association convention (see box, pg. 17).

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Fixing the “Problem”
If overarching pharmaceutical sponsorship of accredited CME is a problem and firewalls don’t work, what's the solution? "The solution could hardly be simpler," says Carlat: "any continuing medical education that is paid for by the drug industry should not be accredited. Drug companies could still pay for any educational event, article or pamphlet they choose, but their courses and materials would no longer bear the imprimatur and implied credibility of accreditation."

But not everyone believes there’s a problem; at least not anything that couldn't be fixed with a little more transparency. “Regarding concerns about conflicts of interest in CME funded by pharma,” said Cavallini, “I would suggest that pharma will wind up funding CME in some way or other, so the closer it is to the surface, the better for all concerned. While current firewalls on content and faculty selection are not perfect, they DO well define the intent. The consumers of the service learn fairly quickly which CME providers carry through on the intent well, and which are hounds after pharma honey.”

“The alternative—completely banning pharma from CME sponsor—would really not ban pharma, but just push the influence further away from the surface,” said Mario Cavallini, Director of Competitive Intelligence at Rosetta (public profile). “Institutions and individual researchers will continue to need funding; pharma will always be willing to provide; and those who see pandering as a way to influence funders will pander.”

Jan Heybroek, President, The Arcas Group, LLC, and Pharma Marketing Roundtable member (public profile), is of the of the opinion that “the current CME system including funding by pharma isn't completely broke and doesn’t require tearing down. Rather—like most of the homes we live in—it is structurally sound, and in need of some serious upgrading. The implementation of CME grant systems has been one of these upgrades... One of the pending (and overdue) upgrades is the addition of active oversight by ACCME of CME-accredited programs at the time of their implementation; instead of the current spot-check approach as part of the reaccreditation process.”

Virtually Free CME?
Meanwhile, the number of physicians participating in online CME “events” has increased dramatically, especially in 2006 when there were recorded over 8 million physician online participants (see Figure 4). Obviously, many physicians participate in online CME more than once per year. Approximately one quarter of physician participants in CME activities occur via the Internet. However, only about 5% of the total hours of instruction are delivered via the Internet.

The delivery of CME via the Internet on demand where and when physicians want has got to be much more convenient and a lot cheaper than attending live CME events. Could technology commoditize CME and make it cheap enough to give away? If CME were “virtually” free, it could even happen that physicians would pay for it themselves and the whole issue of bias caused by the drug industry support would go away.

Heybroek quoted some results of a physician CME preference survey published in Medical Meetings. “The results support previous analyses I have completed on the same subject," said Heybroek, "that an overwhelming majority (92%) of physicians find CME activities effective in meeting their educational needs (38% extremely effective, 54% somewhat effective). In addition, respondents earned 60% of all CME credits in live programs (41% in out-of-town meetings, 19% earned locally). Interestingly, the 41% was the highest percentage reported in a decade; this means that physicians are seeing more benefit coming from live meetings.”

“Benefiting from the introduction of new educational formats and continuous improvement of existing ones, physicians will continue to select..."
CME programs first and foremost based on the quality of the educational content,” said Heybroek. “Subsequent to this decision, they will opt for the CME program that delivers the desired content in the most appropriate format for that moment. While we will continue to see transition from one CME-format (live, online, paper-based) to another, I don't see any format replacing another one, now or any time soon.”

The CME Evolutionary Horizon

Neil Gray, Managing Director, Healthcare Trends & Strategies, LLC and Roundtable member (public profile), summed it up nicely: “As it is completely impossible to envision healthcare providers

rejecting all industry sponsored education and embracing self-funding of same, two evolutions are (perhaps) on the horizon:

1. Continued federal and academic bluster about the need for change in and strengthening of ACCME’s capacity to audit programs and content producers for actual commercial bias, or

2. A new FDA bureaucracy that will (painfully) seek to ensure that all educational programs are bias free (as if), funded by (you guessed it) more industry tithes.

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Survey Results

Is It Time to End Industry Sponsored CME?
Preliminary Results from an Ongoing Survey

By John Mack

Since 17 December 2007, Pharma Marketing News has hosted an online survey (access it here) asking respondents their views regarding industry sponsorship of accredited CME, including views on value, bias, ACCME firewalls, and alternative means of CME support. We present some preliminary results here based on 59 responses.

About Respondents

Figure 1 shows the affiliation of respondents. Grouped in “Agency/Pub” are ad agencies, marketing/PR agencies, and publishing/media companies; “Other” includes medical schools, professional societies, and patients.

Approximately 25% of respondents reported that their organization is accredited by ACCME, whereas about two-thirds were not. The remaining 9% were unsure. Eighty-eight percent (88%) of respondents were based in the U.S.

Seventy-six percent (76%) of respondents indicated they were very or somewhat supportive of the pharmaceutical industry (42% were very supportive). Only 12% were very or somewhat unsupportive of the industry (5% were very unsupportive).

Figure 1: Respondent Affiliation

Views on Industry-Sponsored CME

Respondents were asked to rate their level of agreement with the following statements:

1. Referring to single-company sponsored CME, I believe it is strongly biased in favor of the sponsor's product(s). [BIAS]
2. ACCME guidelines regarding “firewalls” between the commercial and educational interests of a CME provider are effective in preventing bias in pharma-sponsored CME. [FIREWALL]
3. Pharma-sponsored CME should be eliminated or greatly reduced and other means found for paying to develop CME (eg, direct payment by physicians, government grants, private foundation grants, etc.) [NO INDUSTRY]
4. Industry sponsorship of CME is vital to the improvement of medical outcomes. [VITAL]
5. The best way for pharmaceutical companies to sponsor CME is through block grants made to medical schools and/or professional societies. [GRANTS]

Figure 2 (pg. 19) summarizes the results.

Views of Segments

Accredited Organizations: Of the 25% of respondents from ACCME-accredited organizations, 73% disagreed that single-company sponsorship of accredited CME was biased (compared to 40% overall). The same percentage disagreed that pharma-sponsored CME should be eliminated (versus 40% overall). Eighty percent (80%) agreed that industry sponsorship of CME is vital (versus 61 %) overall.

Some comments from respondents in this segment:

“For many professional medical societies, the major source of revenue to allow the implementation of CME programs comes from the pharma industry. To cut off this funding resource would result in many fewer CME activities and perhaps the extinction of many smaller professional societies who truly impact physician and researcher knowledge in a very positive way.” — Anonymous

Continues...
“Universities and medical societies can be very academic and ivory tower plus are rife with politics. But they often have KOLs and expertise. Private providers are innovative and cost conscious. A combination of the two can be the best deliver vehicle while pharma can provide the firewalled funding.” -- David Hoo, VP Marketing, Advanstar

“It is the obligation of the CME provider to establish the educational need prior to pursuing grant support from industry. Upon grant receipt, the pharmaceutical company has no input as to the content or faculty selection. It is the obligation of the CME provider/MECC to ensure that the content is fair-balanced and current.” -- Anonymous

Pharmacos: Of the 25% of respondents from pharmaceutical/biotech/medical device companies, 43% disagreed that single-company sponsorship of accredited CME was biased (compared to 40% overall). A somewhat higher percentage (50%) disagreed that pharma-sponsored CME should be eliminated (versus 40% overall). Eighty-six percent (86%) agreed that industry sponsorship of CME is vital (versus 61 %) overall.

Some comments from respondents in this segment:

“I think it is important that pharma sponsor programs, but it should be totally independent from the company e.g. a third party should make the determination from pharma where the funding will go, not a department in pharma.” -- Anonymous

“Pharma has money. Pharma has interest in interacting with physicians. Sponsoring CME is one way for pharma to spend money as a way of interacting with physicians. It is up to the regulators to create frameworks to ensure the CME modules offered stay product and company neutral (as far as possible).” -- Anonymous

“It can be done right but most companies aren’t doing it right.” -- Anonymous

“The credibility of the accrediting agencies are at risk. Typically even CME programs will show benefits to the sponsor’s products, but the vetting done by the accrediting group should man that the material presented is unbiased. My personal experience is that these programs do provide unbiased education and create forums for genuine scientific discussion.” -- Anonymous

“I think that pharma companies can effectively support CME without biasing the content. Within my organization, the entire process is completely divorced from Marketing and is managed solely by Medical. Grant requests must come from outside organizations; if they meet general guidelines with regards to the objectives that we have, they are approved. Once a grant is made, my company allows the content to be developed independently. Moreover, we have no approval sayso whatsoever.” -- Anonymous

If you have taken the survey, thanks very much. If not, you can take the survey here. To review the de-identified results to date, click here.
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