CME: Continuing Medical Education or Commercial Marketing Efforts?

Testimony submitted to the Senate Committee on Aging

Adriane Fugh-Berman MD
Director, PharmedOut
Department of Physiology and Biophysics
Georgetown University Medical Center
Box 571460
Washington DC 20057-1460
Ajf29@georgetown.edu

Disclosure: Dr. Fugh-Berman has been a paid expert witness on behalf of plaintiffs in litigation regarding pharmaceutical marketing practices.

Continuing medical education (CME) is the pharmaceutical industry's most important marketing tool. The development of marketing messages for a drug starts seven to ten years before a drug is submitted for FDA approval. Many of the marketing messages that are developed for each product do not mention the drug at all. A 'pre-launch' marketing message might emphasize the importance of a specific physiologic process in order to set the stage for acceptance of a drug that affects that mechanism, or might create an unnecessary diagnostic distinction in order to establish a niche for a drug entering a crowded market.

Selling disease

CME is used to sell drugs by selling diseases. As a marketing article called "Proving the case for investing in CME," states:*"The most significant benefits for industry may include creating disease-state awareness and disease state significance."*[i][1] Another marketing article notes that:*"CME activities are most valuable in introducing products early in their life cycles or for promoting mature brands with new indications and new clinical data."*[2]

Industry-funded CME often emphasizes the severity or prevalence of specific conditions in order to prepare, or expand, a market.[3] Manipulating physicians' understanding of the prevalence or severity of medical conditions can lead to overtreatment, and expose patients to the adverse effects of drugs without significant benefit.

The marketing messages imbedded in CME lectures, articles, on-line modules, and tests are never advertisements for a specific therapy because physicians will reject speakers or articles that obviously favor a specific drug. One marketing message might emphasize the risks of competing therapies; another the lack of evidence regarding an over-the-counter remedy.

CME is often used to promote unproven uses of a drug. While it is illegal for a drug company to promote off-label use of a drug, CME is not considered promotion and is not regulated by the FDA. Physicians can say whatever they want, so are used as mouthpieces for marketing messages that would be illegal coming from a company rep.

The academic physicians involved in industry-funded CME may protest, quite honestly, that they are expressing their independent opinions. However, they are chosen because what they are saying aligns with a product's marketing messages, and are supported only as long as they do so.[4] A physician who expresses doubts about a

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[1] Raichle L. Proving the case for investing in CME. *Medical Marketing & Media*. Jun 1998; 33(6): 84.

[2] Bottiglieri D. Crowd Pleaser. *Pharmaceutical Executive.* Sep 2001; 21(9): 122.

[3] Fugh-Berman A, Melnick D. Off-Label Promotion, On-Target Sales. **PLoS Medicine** 2008;5 (10): e210 http://medicine.plosjournals.org/perlserv/?request=get-document&doi=10.1371/journal.pmed.0050210

[4] Fugh-Berman A. Key opinion leaders: Thus are our medical meetings monitored. **BMJ** 2008;337:a789 http://www.bmj.com/cgi/content/full/337/jul15_1/a789

product's efficacy, concerns about its risks, or enthusiasm for a competing therapy will be unceremoniously dropped from a company's speaker's bureau.

Vetting bias in CME modules

There is little incentive for medical education and communication (MEC) companies or academic medical centers to attempt to ferret out bias in CME modules, because both depend on industry for survival. In 2007, about half of the $2.5 billion spent on CME came from pharmaceutical manufacturers. Seventy-two percent of the income from events sponsored by medical education companies is from firms that manufacture FDA-regulated products. Academic medical centers are only a little better; 57% of CME income to medical schools comes from industry.

Although academic CME providers do their best to vet industry-funded modules for bias, such review focuses on the detection of obvious advertising, the use of brand rather than generic names, of drugs, and adequate disclosure of conflict of interest. No matter how vigilant they are, CME providers are not trained in recognizing marketing messages and cannot adequately assess industry-funded materials for bias.

As previously noted, marketing begins years before a drug reaches the market. Adequate vetting of CME modules would require knowledge of every drug, biologic, device, and diagnostic test that every company is marketing, developing, or considering. The task becomes even more daunting when mergers, acquisitions, co-marketing agreements and collaborative marketing arrangements for example, among companies selling drugs in the same class) are taken into account. Similarly, disclosures of financial conflicts of interest are impossible to interpret without knowing every company's marketing plan for every drug on the market or in the pipeline.

'Unrestricted' grants

Unrestricted educational grants to academic medical centers or MECs are no solution. Although the new PhRMA Code of Ethics does not allow sponsors (companies that fund the event) to suggest speakers, sponsors may indicate which topics they are interested in funding. "Unrestricted" grants provided for grand rounds and lunch conferences depend on a sense of obligation rather than a quid pro quo. When lists of recommended speakers are supplied to organizers, it is unstated, but nonetheless understood, that company-paid speakers will be included in the lecture series.

The organizing board of the CME program may include speakers selected and paid by the sponsor. The desired messages about particular products or diseases may be made clear. Organizers understand that sponsors or exhibitors may withdraw if they don't like the content. Not every speaker in a lecture series or conference is chosen by industry. Pharmaceutical companies refer to presentations with marketing messages as "message talks," and sponsored CME programs usually include talks that are not connected with the sponsor's product. Although these camouflage talks may involve independent speakers, organizers know that they must avoid inviting speakers who might criticize a sponsor's products or oppose a sponsor's marketing messages[3].

Physicians will never hear about how a targeted disease is overdiagnosed or overtreated at a sponsored event. And rarely will they hear positive recommendations

for a competitor's product, a generic product, or a non-pharmacologic therapy at a sponsored program.

ACCME

The ACCME Standards for Commercial Support[5] to discourage potential conflicts of interest are both weak and ignored. A 2007 annual report by the ACCME, however, showed that 29% of providers failed to comply with Standard 2, which requires that any individuals that control content of a CME activity disclose and resolve conflicts of interest.[6] 27% of the providers did not comply with Standard 3, which includes guidelines to prevent those with commercial interest from dictating the content of a CME activity. And 36% of providers were noncompliant with Standard 6, which requires that all commercial support and financial relationships of authors be disclosed to CME participants before the activity. [6]

The ACCME does not screen CME activities, and does not encourage audience members to report commercial bas. Although written complaints are accepted, the process is burdensome The ACCME would not tell us whether or not any providers have lost accreditation status due to commercial bias. Losing accreditation for any reason is rare; according to the annual reports published by the ACCME only one provider lost accreditation in 2005.

Conclusion

If sponsoring CME events did not increase product sales, drug companies would not do it. The large amount of commercial support poured into CME is in itself testimony that industry believes supporting CME is cost-effective. Industry influence on medical discourse limits the discussion to the most profitable therapies, which may not be best for patients. Industry-funded medical education is a contradiction in terms.

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About PharmedOut

PharmedOut, a project based at Georgetown University Medical Center, uses academic research and drug industry insider perspectives to educate prescribers about how covert marketing techniques affect prescribing behavior. PharmedOut was launched through a grant from the Attorney General Consumer and Prescriber Grant Program.

Our latest free, web-based, 3-CME credit educational module is called The Pharmalyzer: Are you prescribing under the influence? Our unique approach draws on academic and marketing materials

[5] ACCME. Essential Areas and Elements; 2008 Available via the Internet: http://www.accme.org/dir_docs/doc_upload/f4ee5075-9574-4231-8876-5e21723c0c82_uploaddocument.pdf. Accessed June 30, 2009

[6] ACCME [Standards for Commercial Support; 2008 Available via the Internet: http://www.accme.org/dir_docs/doc_upload/68b2902a-fb73-44d1-8725-80a1504e520c_uploaddocument.pdf. Accessed June 30, 2009.

combined with original interviews with industry insiders to create novel articles, videos, and educational materials. Our goal is to foster evidence-based, cost-effective prescribing and to decrease the adverse public health effects of inappropriate pharmaceutical promotion.

We provide original web-based CME modules and links to more than 150 free, non-industry-funded, web-based continuing medical education (CME) courses – enough for any physician, nurse, or pharmacist to complete annual continuing education requirements. Educational resources include our slideshows, Drug Ad Bingo (a teaching exercise), *Fast Facts on Generic Drugs* (a factsheet for patients), and seven original videos, featuring industry insiders. Our publications include *Off-Label Promotion, On-Target Sales*,*Following the Script: How Drug Reps Make Friends and Influence Doctors*, *Do New Drugs Increase Life Expectancy?*, *Ethical Considerations of Publication Planning in the Pharmaceutical Industry*, *Prescription Tracking and Public Health*, *Key Opinion Leaders: Thus Are Our Medical Meetings Managed*, and *Smoke and Mirrors*.

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[i] Raichle L. Proving the case for investing in CME. *Medical Marketing & Media*. Jun 1998; 33(6): 84.