

FINAL REPORT

The Relationship between Commercial
Support and Bias in
Continuing Medical Education Activities:
A Review of the Literature

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BACKGROUND AND PURPOSE

As the foundations for modern approaches to medical education were being built in the early years of the 20th century, William Osler fretted about the encroachment of pharmaceutical companies. He was concerned that physicians may come to rely on the “specious and seductive pamphlets issued by pharmaceutical houses, the bastard literature which floods the mail” and the salesmen who “are ready to express the most emphatic opinions on questions about which the greatest masters of our art are doubtful” (Osler, 1906, pp. 300-301). What was once a minor distraction in the early part of the last century has turned into a full-blown issue in the past two decades as attention has focused on how commercial interests impact medical practice, research, and education (Angell, 2005; Blumenthal, 2004; Brenann et al., 2006; DeAngelis, & Fontanarosa, 2008). This has become a much more serious issue now because: “Interactions between drug companies and doctors are pervasive. Relationships begin in medical school, continue during residency training, and persist throughout physicians’ careers. The pervasiveness of these interactions results in part from a huge investment by the pharmaceutical industry in marketing” (Blumenthal, 2004, p. 1885). The concern raised in the literature is that industry support of research, education, and practice creates potential “conflicts of interests between physicians’ commitment to patient care and the desire of pharmaceutical companies and their representatives to sell their products” (Brennan, et. al., 2006). This concern has gained a great deal of traction because of the argument’s face validity that pharmaceutical companies and device manufacturers would make such marketing investments precisely because there was a demonstrable positive impact on product sales. For example, a recent study (Steinman et al., 2006) showed how Parke-Davis’s marketing plan used many avenues, including research, publication, and educational activities, to promote the use of Gabapentin.

Within the larger discussion in the medical profession, the literature also shows a strong and persistent debate about the impact of the pharmaceutical industry on the development and delivery of continuing education designed to improve physician’s practice and patient care (DeSignore, 2003; Harrison, 2003; Holmer, 2001; Moynihan, 2003a, 2003b; Relman, 2001; Schaeffer, 2000; Steinbrook, 2005, 2008). Concerns specifically about the potential for bias in CME have been raised by a several influential national bodies (AAMC, 2007; Committee on Finance, U.S. Senate, 2007; Fletcher, 2008). As in the medical profession more generally, this concern arises because commercial support for accredited CME has increased dramatically in the past decade. In 2006, commercial support for CME totaled \$1.2 billion, or 60% of total revenues for accredited providers. The profession recognized this potential for bias and produced accreditation policies and procedures to assure that CME is not biased due to commercial support. The Accreditation Council on Continuing Medical Education (ACCME) issued its first set of “Standards for Commercial Support” in 1992. New “Standards for Commercial Support” were issued in 2004 to insure that CME activities are independent, free of commercial bias and beyond the control of persons or organizations with an economic interest in influencing the content of CME. In addition to ACCME guidelines, the AAMC has recently proposed principles to “guide the AAMC and the leaders of medical schools and teaching hospitals in developing policies and procedures to manage industry gifting practices and financial support of their activities

of medical education for students, trainees, faculty, and community physicians” (AAMC Task Force Report, 2008, p. iii).

There is a widespread belief that the safeguards the profession has erected to assure that CME is free of commercial bias have not been successful (Brenann et al., 2006; DeAngelis, & Fontanarosa, 2008; Macy, 2007; Steinbrook, 2008; Blumenthal, 2004). For example, one commentator concludes that: “Continuing medical education has become so heavily dependent on support from pharmaceutical and medical device companies that the medical profession may have lost control over its own continuing medical education. Commercial funding may inherently distort education and practice to the detriment of physicians and patients, regardless of the various safeguards to protect the integrity of the enterprise” (Steinbrook, 2008, p. 1060). In spite of the firmly held belief that commercial support produces CME that is biased toward the products of the sponsor, there has not been a comprehensive review of the literature to support or refute that claim. The purpose of this study was to analyze the research literature about relationship between commercial support and bias in CME.

METHODS

We searched Medline, LexisNexis, and Business Source Complete databases with very general terms of “education” and “industry or commercial” and “influence or support”. Our literature search identified more than 2,000 article titles. We then narrowed down the search to “continuing medical education” to reduce to 165 articles. These articles then were sorted into evidence-based studies and commentaries or conceptual articles on the topic. We ended with 10 evidence-based articles that addressed the relationship between commercial support and CME, which are listed in Table 1 and annotated in the Appendix.

RESULTS

We found no studies that directly addressed the question of whether commercial support produces bias in accredited CME activities. The 10 studies were then grouped into three categories: 1) four studies that examined the impact of commercially supported CME on prescribing practices, 2) four studies that examined physician opinions about bias in commercially supported CME, and 3) two studies about instruments to measure bias in commercially supported CME.

Studies of the relationship between commercial support and bias in accredited CME

There is no published study that addresses the relationship between commercial support and bias in accredited CME activities. Although it has been speculated that commercial support produces bias in CME activities, there is no evidence to support or refute this assertion. The ACCME’s Standards for Commercial Support have been in place since 1992 and a new set of Standards were initiated in 2004. The efficacy of these Standards in preventing bias has not been evaluated by a published research study.

Studies of the impact of commercially supported CME on prescribing practices

Very limited attention has been given in the research literature to the impact of commercially supported CME on prescribing practices and no studies have been conducted of the impact on patient care. Four publications have addressed the impact of commercially supported CME on physicians' prescribing practices, including a comprehensive literature review (Wazana, 2000), two original research articles (Bowman & Pearle, 1988; Orłowski & Wateska, 1992), and one research letter (Dieprink, & Drogemuller, 2001).

Table 1. Empirical Studies of the Relationship between Commercial Support and Bias in CME

Categories	Study Citations	Conclusions
Studies of the Relationship between Commercial Support and Bias in Accredited CME	None	There is no published study that addresses the link between commercial support and bias in accredited CME activities.
Studies of the Impact of Commercially Supported CME on Prescribing Practices	Wazana, A. (2000). Physicians and the pharmaceutical industry: Is a gift ever just a gift? Bowman, M. A., & Pearle, D.L. (1988). Changes in drug prescribing patterns related to commercial company funding of continuing medical education. Orłowski, J. P., & Wateska, L. (1992). The effects of pharmaceutical firm enticements on physician prescribing patterns. Dieprink, M. E., & Drogemuller, L. (2001). Research letter, Industry-sponsored grand rounds and prescribing behavior.	There has been very limited attention given to the impact of commercially supported CME on prescribing practices and no studies of the impact on patient care.
Studies of Physician Opinions about Bias in Commercially Supported CME	Mueller, P. S. et al. (2007). Physician preferences and attitudes regarding industry support of CME activities. Rutledge, P. et al. (2003). Do doctors rely on pharmaceutical industry funding to attend conferences and do they perceive that this creates a bias in their drug selection? Results from a questionnaire survey. Katz, H. P. (2002). Academia-industry collaboration in Continuing Medical Education: Description of two approaches. Cornish, J. K., & Leist, J. C. (2006). What constitutes commercial bias compared with the personal.	Most physicians do not believe that commercially supported CME is biased or creates bias in their prescribing behaviors.
Studies of How to Measure Bias in Commercially Supported CME	Barnes, B.E. et al. (2007). A risk stratification tool to assess commercial influences on continuing medical. Takhar, J. et al. (2007). Developing an instrument to measure bias in CME.	Recently developed instruments could be used to address some dimensions of the issue of commercial support producing bias in CME activities.

Wazana (2000) conducted a comprehensive review of all interactions between physicians and the pharmaceutical industry to determine the extent of these interactions, physicians' attitudes towards these interactions and the impact on physicians' knowledge, attitude, and behavior. A MEDLINE search and interviews with 5 key informants produced 538 studies, of which 29 were included in the comprehensive analysis. Only 2 of the 29 studies were focused on CME activities and these are discussed below (Bowman & Pearle, 1988; Orłowski & Wateska, 1992). Wazana reports that these two CME studies found "an increase in the physician prescribing rate of the CME sponsor's drug" (Bowman & Pearle, 1988) and "an increase in the hospital prescribing rate of the conference travel sponsor's drug" (Orłowski & Wateska, 1992). At the most general level of all interactions, Wazana concluded that "the present extent of physician-industry interactions appears to affect prescribing and professional behavior and should be further addressed at the level of policy and education." An important point is that none of the 29 studies used patient outcome measures, and therefore there is no evidence about the positive or negative impact of the prescribing practice changes.

As reported above, two studies examined the impact of commercial company funding of CME on drug prescribing practices. The Bowman and Pearle study (1988) used a pre-post self-report design in which physicians were surveyed by mail for three courses they had attended on either beta blockers or calcium channel blockers. The courses met three criteria: 1) a single drug company financially supported the course, 2) the course topic was directly related to a single set of at least 3 possible drugs, and 3) the drugs in the set were basically similar with no major advantage over each other. For the first two courses, pre-and post respondents were not matched, although they were matched for the third course. In course 1, physicians' prescriptions for the sponsor's drug increased but the increase was less than for a drug that was not produced by the sponsor. In course 2, the sponsor's drug increased although the number of physicians prescribing the drug for new prescriptions was not statistically significant. In course 3, the sponsor's drug went from second to the most frequently prescribed for new prescriptions as the other 2 drugs decreased. Thus, this study shows that CME activities can influence physicians "to change their prescribing practices for the drug sets in question" (p. 19), with mixed results for the drugs of the sponsoring company. The activity was not accredited under the Standards of Commercial Support since the publication date of the article (1988) predated the first set of guidelines in 1992. Some of the reasons that the authors offer for why prescriptions increased are not allowed under current guidelines. A final question asked, but left unanswered, by the authors is whether it is "inappropriate for the prescription rates for the company drug to have increased?"

The Orłowski and Wateska (1992) study differed in two significant ways from Bowman and Pearle. First, the CME activity was an "all-expenses-paid trip to an attractive resort for the physician and a significant other to attend a symposium on one of the company's drugs. The actual scientific or educational component of the trip typically consumes only 3 or 4 hours on each of the three or four days of the trip." (p. 270). The activity for Drug A (a new intravenous antibiotic) was held a resort on the

West Coast and the activity for Drug B (a new intravenous cardiovascular drug). This CME activity was a much purer marketing activity than the ones in the Bowman and Pearle study, which were organized and offered at a medical center and featured multiple drugs at each activity. This activity also pre-dated the 1992 Standards of Commercial Support, although it would not be eligible under current guidelines given how it was organized. The second difference is that Orlowski and Wateska used a much stronger research design with usage data from the hospital pharmacy where the physicians practiced. Usage data was obtained retrospectively for approximately 22 months before and 17 months after the activities with a timeframe from 1987 to 1989. National usage data on the drugs was also collected. The study concludes that: "We have demonstrated that one elaborate promotional technique, the expense-paid seminar at a resort, was associated with a significant increase in the prescribing of the promoted drugs at one institution" (p. 273). Significantly, the changes occurred "in spite of the [physicians'] belief that such inducements would not affect their prescribing patterns" (p. 273).

The Dieprink and Drogmuller (2001) research letter discusses the potential impact of a grand rounds activity sponsored by a pharmaceutical company. The letter describes finding an increase in prescriptions for "quetiapine fumarate, an atypical antipsychotic agent, at the Minneapolis Veterans Affairs Medical Center (VAMC)" (p. 1443). The data collection was similar to the Orlowski and Wateska design in that the authors collected data on prescribing behavior at the individual behavior because VAMC has a closed panel of prescribers. There is no doubt that the use of the drug went up but there are a number of alternative explanations that can not be ruled out since this was not designed as a research study. First, there is no description of the educational activity so we don't know the activity content. Without this, the issue of whether the activity was biased toward the sponsor is unknown. Although it is likely that this activity was approved for credit under the 1992 Guidelines for Commercial Support, we cannot determine whether the guidelines were followed without an activity description. Second, no evidence is presented about whether the new prescribers attended the rounds, in contrast to the Bowman and Pearle and Orlowski and Wateska studies. Third, with the drug having been on the formulary for 5 months, perhaps those attending the rounds just learned of that addition. Finally, as asked by Bowman and Pearle, is it inappropriate that the prescription rate should increase? While the research letter shows an increase, perhaps there had been an under treatment for the condition or this may be a more effective drug.

Studies of physician opinions about bias in commercially supported CME

There is very little research on physicians' opinions of whether commercially supported CME is biased or creates bias in their prescribing practices. There are 3 studies conducted with US physicians (Cornish & Leist, 2006; Katz, Goldfinger, & Fletcher, 2002; Mueller, Hook, & Litin, 2007) and 1 study conducted in Scotland (2003). Although most physicians don't believe there is a problem with commercially supported CME, an appreciable number of physicians are aware of the potential bias problems raised by the funding source.

The Mueller, Hook, and Litin study (2007) surveyed participants in 4 accredited Mayo Clinic courses in 2004. Two activities were supported by pharmaceutical companies and 2 were not supported by industry. Of the 1603 physicians attending the CME activities, 1103 (70.5%) completed the survey. One question on the survey asked: "Is it your impression that the content of CME courses supported by industry tend to be biased in favor of the supporting companies?" Overall, 53% answered "no", 36% answered "yes", and 11% had "no opinion." However, there was a statistically significant difference in responses by whether they completed the survey in an industry supported course (64% "no") or a non-industry supported course (38% "no"). Thus, physicians attending industry supported activities are less likely to believe that the course content is biased in favor of the sponsor's product. The study of physicians in Scotland (Rutledge, Crookes, McKinstry, & Maxwell, 2003) was conducted as a mailed survey to 622 hospital physicians and 515 general practitioners. The response rates, respectively, were 46% and 38% resulting in 487 usable surveys. One question asked: "Do you believe that the involvement of the Pharmaceutical Industry in CME creates a conflict of interest?" The response was very similar to the Mayo Clinic results with 51% "no" from both the hospital-based and the primary care physicians. A second question asked was: "Do you think that your current level of involvement with the Pharmaceutical Industry creates a bias in your drug selection?" Similar to the Orłowski and Wateska study, there was a "no" response from 87% of hospital-based physicians and 85% of the primary care physicians. The authors raise the concern about this latter finding: "We believe that it is of concern that nearly 90% think they are not influenced. Several studies have shown that financial benefit will make doctors more likely to refer patients for tests, operations or hospital admission or to ask for specific drugs to be stocked by the hospital pharmacy" (p. 666).

The Katz, Goldfinger, and Fletcher (2002) study reports on 19 primary care-conferences offered from 1995 to 2001. These conferences were an academia-industry collaboration that offer commercial-free activities organized by Harvard Medical School on "Current Clinical Issues in Primary Care" and industry sponsored symposia at the same site. All of the activities offered in this activity meet ACCME standards. The authors found that: "When the titles of the talks were categorized according to clinical activities, content varied substantially in the two venues: drug therapy was the central topic in 27% of the HMS talks and 66% of symposia" (p. 52). They report that: "Not surprisingly, we found that symposia focus primarily on medical conditions for which there are new therapeutic products; compared to the HMS courses, a narrower breadth of topics is covered" (p. 52). In reference to the issue of bias, the participant evaluations of the industry-sponsored symposia found that: "At least 85% of respondents for each symposium stated that they felt the presentations were balanced and free of commercial bias" (p. 48). The authors conclude based on this 6-year experiment that: "An important unanswered question is the extent to which medical education and communication companies and CME sponsors function free from commercial influence" (p. 53).

The Cornish and Leist (2006) study sought to identify the ways in which participants in educational activities distinguished between actions that represented bias and actions that represented the presenters' personal opinions. The research design

involved distributing questionnaires to participants in 7 accredited CME activities in 2003. Respondents were asked about CME activities in general and not about the CME in which they were participating. A total of 212 questionnaires (92% response rate) were completed, 65% of which were physician responders. The authors found that: "The learner perceives a difference between commercial bias and personal opinion in CME activities" (p. 166). They found 10 specific actions that were perceived as commercial bias, with the highest rated one being "Focusing on 1 agent, device or procedure when others exist." Of those respondents who believe commercial bias exists in CME, 53% attribute their perception to an overall impression rather than 1 or 2 specific actions. There were no findings reported, however, that indicate the percentage of the sample that believes that CME activities are affected by commercial bias.

Studies of how to measure bias in commercially supported CME

With the increasing interest on the topic of the relationship between industry and physicians and the potential for bias in CME, two instruments have recently been developed. These instruments (Barnes, et al., 2007; Takhar, et. al., 2007) could be useful in studying some dimensions of the relationship between commercial support and bias in CME. A primary difference between the instruments is that one (Barnes, et. al., 2007) is a risk stratification tool that is used prospectively and the other (Takhar, et. al., 2007) is used retrospectively at the completion of a CME activity to measure participants' perception of bias.

The Barnes, et al (2007) 12-item instrument was developed by the Consortium for Academic Continuing Medical Education and its validity and reliability were shown in this follow-up study. The numerical weighting of the items are used to calculate an overall risk score grouped into categories of low, moderate, high, and very high. The authors recommend that the instrument can be used to both *predict* risk by collecting evidence about a activity prospectively and to *manage* risk by addressing the risk factors identified. The Takhar, et al (2007) 14-item instrument was developed by a committee comprised of representatives from industry, suppliers, and CME professionals from academia. The authors defined bias as "unfair influence or distortion of facts" (p. 119) and conclude that the "CME bias assessment tool is valid and reliable for illuminating bias in CME events" (p. 122). Although the instrument is best used to collect information about bias by participants or raters at the conclusion of a activity, the authors recommend that it can be used prospectively to train CME providers, speakers, and participants to identify bias and to screen CME activities prior to approval.

DISCUSSION

With the widespread concern about the impact of industry support on medical research, practice, and education, the question of whether this support produces bias in accredited CME activities is critically important. The ACCME Standards for Commercial Support are designed to assure that CME activities are not biased toward the commercial interest supporting the activity. However, to date there is no empirical evidence to support or refute the hypothesis that CME activities are biased.

The limited evidence that does exist shows that CME activities funded by commercial interests can be effective in changing physicians' prescribing practices. This is consistent with the extensive literature showing that CME changes physician practice and improves patient care (Mansouri & Lockyear, 2007; Robertson, Umble, & Cervero, 2003). However, with no studies about the impact of these prescribing changes on patient care, we cannot determine if the changes were or were not in the best interests of the patient. Although this is a critically important question, there is no evidence to answer it.

The evidence from physicians' opinions about the impact of commercial support on CME lends important support for future research in this area. The studies show that while the majority of physicians do not believe the CME activities are biased by commercial support, there is substantial concern that CME activities can be biased toward the industry sponsor. This research is especially important because it shows that the vast majority of physicians believe that they are capable of making clinical decisions that are in the best interests of the patient, and are not influenced by commercial interests. However, recent research shows that there are many ways that independent judgment can be influenced in unconscious ways and thus physicians may not be aware of how industry support of a CME activity may influence their clinical decisions (AAMC, 2007).

It is necessary at this time to initiate rigorous scientific studies to address important questions about the relationship between commercial support and bias in CME. The research could focus on several questions:

- Does commercial support produce bias in CME activities?
- What are the mechanisms by which bias is produced?
- Are accreditation guidelines or other strategies effective in preventing bias?
- In what ways does commercial support of CME contribute to physicians' adoption of the sponsor's product in the context of the other influences on their clinical decision-making?
- As a result of commercially-supported CME, does physicians' adoption of the sponsor's product lead to better patient care?

REFERENCES

Angell, M. (2005). *The truth about the drug companies: How they deceive us and what to do about it*. New York: Random House.

Association of American Medical Colleges (AAMC). (2008). *Report of the AAMC task force on industry funding of medical education to the AAMC executive council*. Washington, D.C.: Author.

Association of American Medical Colleges (AAMC). (2007). *The scientific basis of influence and reciprocity: A symposium*. Washington, D.C.: Author.

- Barnes, B.E., Cole, J.G., King, C. T., Zukowski, R., Allgier-Baker, T., Rubio, D. M., & Thorndyke, L. E. (2007). A risk stratification tool to assess commercial influences on continuing medical. *The Journal of Continuing Education in the Health Professions*, 27(4), 234-240.
- Blumenthal, D. (2004). Doctors and drug companies. *The New England Journal of Medicine*, 351(18), 1885-1890.
- Bowman, M. A., & Pearle, D.L. (1988). Changes in drug prescribing patterns related to commercial company funding of continuing medical education. *The Journal of Continuing Education in the Health Professions*, 8(1), 13-20.
- Brennan, T. A., Rothman, D. J., Blank, L., Blumenthal, D., Chimonas, S. C., Cohen, J. J., Goldman, J., Kassirer, J. P., Kimball, H., Naughton, J., & Smelser, N. (2006). Health industry practices that create conflicts of interest: A policy proposal for academic medical centers. *JAMA*, 295(4), 429-433.
- Committee on Finance, United State Senate. (2007). *Committee staff report to the chairman and ranking member, use of educational grants by pharmaceutical manufacturers*. Washington, D.C.: Government Printing Office.
- Cornish, J. K., & Leist, J. C. (2006). What constitutes commercial bias compared with the personal. *The Journal of Continuing Education in the Health Professions*, 26, 161-167.
- DeAngelis, C. D., & Fontanarosa, P. B. (2008). Impugning the integrity of medical science: The adverse effects of industry influence. *JAMA*, 299(15), 1833-1835.
- DelSignore, J. L. (2003). Current guidelines regarding industry-sponsored continuing medical education. *Clinical Orthopaedics and Related Research*, 412, 21–27.
- Dieprink, M. E., & Drogemuller, L. (2001). Research letter, Industry-sponsored grand rounds and prescribing behavior. *JAMA*, 285, 1443-1444.
- Fletcher, S. W. (2008). Chairman's summary of the conference. In M. Hager (Ed.), *Continuing education in the health professions: Improving healthcare through lifelong learning*; 2007 November 28- December 1, Bermuda. New York: Josiah Macy, Jr. Foundation.
- Harrison, R. V. (2003). The uncertain future of continuing medical education: Commercialism and shifts in funding. *The Journal of Continuing Education in the Health Professions*, 23, 198–209.
- Holmer, A. F. (2001). Industry strongly supports continuing medical education. *JAMA*, 285(15), 2012–2014 [erratum published in *JAMA* 2001; 285(19):2451].

- Katz, H. P. (2002). Academia-industry collaboration in continuing medical education: Description of two approaches. *The Journal of Continuing Education in the Health Professions*, 22, 43-54.
- Mansouri, M., & Lockyear, J. (2007). A meta-analysis of continuing medical education effectiveness. *The Journal of Continuing Education in the Health Professions*, 27, 6-15.
- Moynihan, R. (2003a). Drug company sponsorship of education could be replaced at a fraction of the cost. *British Medical Journal*, 326, 1163.
- Moynihan, R. (2003b). Who pays for the pizza? Redefining the relationships between doctors and drug companies. 1: Entanglement. *British Medical Journal*, 326, 1189–1192.
- Moynihan, R. (2003c). Who pays for the pizza? Redefining the relationships between doctors and drug companies. 2: Disentanglement. *British Medical Journal*, 326, 1193–1196.
- Mueller, P. S., Hook, C. C., & Litin, S. C. (2007). Physician preferences and attitudes regarding industry support of CME programs. *The American Journal of Medicine*, 120(3), 281-285.
- Orlowski, J. P., & Wateska, L. (1992). The effects of pharmaceutical firm enticements on physician prescribing patterns. *Chest*, 102, 270-273.
- Osler, W. (1906). *Aequanimitas*. London: Lewis.
- Relman, A. S. (2001). Separating continuing medical education from pharmaceutical marketing. *JAMA*, 285(15), 2009–2012.
- Robertson, M. K., Umble, K. E., Cervero, R. M. (2003). Impact studies in continuing education for health professions: Update. *The Journal of Continuing Education in the Health Professions*, 23, 146-156.
- Rutledge, P., Crookes, D., McKinstry, B., & Maxwell, S. R. (2003). Do doctors rely on pharmaceutical industry funding to attend conferences and do they perceive that this creates a bias in their drug selection? Results from a questionnaire survey. *Pharmacoepidemiol Drug Saf*, 12(8), 663-667.
- Schaffer, M. H. (2000). Commercial support and the quandary of continuing medical education. *The Journal of Continuing Education in the Health Professions*, 20, 120–126.
- Steinbrook, R. (2005). Commercial support and continuing medical education. *The New England Journal of Medicine*, 352(6), 534–535.

Steinbrook, R. (2008). Financial support of continuing medical education. *JAMA*, 299(9), 1060-1062.

Steinman, M. A., Bero, L. A., Chren, M. M., & Landefeld, C. S. (2006). Narrative review: The promotion of gabapentin: An analysis of internal industry documents. *Annals of Internal Medicine*, 145(4), 284–293.

Takhar, J., Dixon, D., Donahue, J., Marlow, B., Campbell, C., Silver, I., Eadie, J., Monette, C., Rohan, I., Sriharan, A., Raymond, K., & Macnab, J. (2007). Developing an instrument to measure bias in CME. *The Journal of Continuing Education in the Health Professions*, 27(2), 118-123.

Wazana, A. (2000). Physicians and the pharmaceutical industry: Is a gift ever just a gift? *Journal of the American Medical Association*, 283(3), 373-80.

Appendix A. Abstracts of the Final Ten Studies

Bowman, M. A., & Pearle, D.L. (1988). Changes in drug prescribing patterns related to commercial company funding of continuing medical education. *The Journal of Continuing Education in the Health Professions*, 8(1), 13-20.

In order to determine the impact of commercial company funding of continuing medical education (CME) courses, a survey was undertaken. Drug prescribing rates for drugs related to course content were determined by self-report survey of physician attendees (374 in number) for three different CME courses. The survey was performed immediately before and six months after the courses. A single, though different, drug company provided the majority of the funding for each course. Courses I and III were related to calcium channel blockers and Course II to beta blockers. The return rate before Course I was 73.0 percent; after, 54.0 percent (unmatched). The return rate for Course II was 49.4 percent before and 42.9 percent after (unmatched). There were 121 (61.4%) matched returns for Course III. While the rates for prescribing some of the related drugs increased after the courses, overall the sponsoring drug company's products were favored. Although physicians attending CME and accredited sponsors of CME need to be aware of this potential influence, the final burden of adequate evaluation of drugs remains with the physician prescriber. Further studies should be done to substantiate the findings and elucidate the mechanism(s) of the increase in sponsoring company's drug prescriptions.

Barnes, B.E., Cole, J.G., King, C. T., Zukowski, R., Allgier-Baker, T., Rubio, D. M., & Thorndyke, L. E. (2007). A risk stratification tool to assess commercial influences on continuing medical. *The Journal of Continuing Education in the Health Professions*, 27(4), 234-240.

Introduction: Heightened concerns about industry influence on continuing medical education (CME) have prompted tighter controls on the management of commercial funding and conflict of interest. As a result, CME providers must closely monitor their activities and intervene if bias or noncompliance with accreditation standards is likely. Potential for industry influence can be difficult to assess at a stage in the planning process when mitigation strategies can assure balance and content validity. Few tools exist to aid providers in this regard.

Methods: A 12-item instrument was designed to assess risk for commercial influence on CME. To determine reliability and validity, a cohort of experienced CME professionals applied the tool to standardized "cases" representing CME activities in the early stages of planning. Results were compared with the experts' assignment of the same cases to one of four risk categories. A survey of study participants was conducted to ascertain usefulness and potential applications of the tool.

Results: Analysis demonstrated strong intraclass correlation across cases (0.90), interrater reliability (94%), and correlation between assessment of risk with and without the tool (Spearman coefficient, 0.93, $p < 0.01$; weighted kappa, 0.59). Participants found the tool easy to use and of potential benefit to their CME office.

Discussion: The risk stratification tool can help CME providers identify activities that must be closely monitored for potential industry influence, remain aware of factors that place programming at risk for noncompliance with accreditation standards, and substantiate the allocation of resources by the CME office.

Cornish, J. K., & Leist, J. C. (2006). What constitutes commercial bias compared with the personal. *The Journal of Continuing Education in the Health Professions*, 26, 161-167.

Introduction: The presence of commercial messages in continuing medical education (CME) is an ongoing cause of concern. This study identifies actions perceived by CME participants to convey commercial bias from CME faculty.

Methods: A questionnaire listing actions associated with CME activities was distributed to 230 randomly selected participants from 7 CME activities designated for AMA PRA Category 1 Credit™. The activities were held over an 8-month period. Participants were asked to complete the questionnaire before participating in the live activity.

Results: Nine actions identified by over 50% of all respondents were perceived to convey commercial bias. The most critical ones reflecting commercial bias were speaking about only one agent, not providing a balanced presentation of all agents, and faculty relationships with commercial supporters. Ten actions identified by over 50% of the respondents were perceived to convey personal opinion of the faculty. The most prevalent actions were the influence of mentors or teachers, relating general practice habits from the faculty member's own experience, and cultural differences among patient populations. More than half the respondents who indicated they perceived commercial bias in certified activities attributed this perception to an overall impression, instead of 1 or 2 specific actions.

Dieprink, M. E., & Drogemuller, L. (2001). Research letter, Industry-sponsored grand rounds and prescribing behavior. *JAMA*, 285, 1443-1444.

To the Editor: We recently discovered a sudden and sustained 3-fold increase in the pharmacy expenditures for quetiapine fumarate, an atypical antipsychotic agent, at the Minneapolis Veterans Affairs Medical Center (VAMC). This occurred in April 2000, which was 28 months after the drug became available in the United States and 5 months after it was placed on the hospital formulary. We investigated this sudden and dramatic increase in prescription costs for this drug at our institution.

Katz, H. P. (2002). Academia-industry collaboration in continuing medical education: Description of two approaches. *The Journal of Continuing Education in the Health Professions*, 22, 43-54.

Introduction: Although concerns have been raised about industry support of continuing medical education (CME), there are few published reports of academia-industry collaboration in the field. We describe and evaluate Pri-Med, a CME experience for

primary care clinicians developed jointly by the Harvard Medical School (HMS) and M/C Communications.

Methods: Since 1995, 19 Pri-Med conferences have been held in four cities, drawing more than 100,000 primary care clinicians. The educational core of each Pri-Med conference is a 3-day Harvard course, "Current Clinical Issues in Primary Care." Course content is determined by a faculty committee independent of any commercial influence. Revenues from multiple industry sources flow through M/C Communications to the medical school as an educational grant to support primary care education. Pri-Med also offers separate pharmaceutical company—funded symposia.

Results: Comparing the two educational approaches during four conferences, 221 HMS talks and 103 symposia were presented. The HMS course covered a wide range with 133 topics; the symposia focused on 30 topics, most of which were linked to recently approved new therapeutic products manufactured by the funders. Both the course and the symposia were highly rated by attendees.

Discussion: When CME presentations for primary care physicians receive direct support from industry, the range of offered topics is narrower than when activities are developed independently of such support. There appear to be no differences in the perceived quality of presentations delivered with and without such support. Our experience suggests that a firewall between activity planners and providers of financial support will result in a broader array of educational subjects relevant to the field of primary care.

Mueller, P. S., Hook, C. C., & Litin, S. C. (2007). Physician preferences and attitudes regarding industry support of CME programs. *The American Journal of Medicine*, 120(3), 281-285.

First two paragraphs

Pharmaceutical and other health care-related companies spend approximately \$12 to \$15 billion per year (\$8000-\$15 000 per year, per physician) on marketing. One marketing approach used by many pharmaceutical companies is to provide financial support of continuing medical education (CME) activities. In recent years, this support has increased. Ten years ago, 17% of CME funding came from industry; today, that number is 40%. Between 1992 and 2001, industry support of medical school-sponsored CME quintupled. Organizations that conduct CME activities claim that without financial support from industry, activities must rely on registration fees, which, when combined with travel expenses, would make the activities unaffordable for many participants.

Physicians attend CME activities for many reasons, including fulfilling state medical licensure requirements, maintaining hospital privileges and specialty society memberships, and obtaining new knowledge and skills. Many physicians also regard CME courses as their most valuable source for clinical information. However, evidence suggests that CME activities sponsored by industry not only may be more biased (in favor of the sponsoring companies' products) than activities not sponsored by industry but also may influence physicians' professional behavior (eg, increased prescriptions of the sponsor's medication). These findings raise the ethical concern of industry influence on physicians who participate in CME activities.

Orlowski, J. P., & Wateska, L. (1992). The effects of pharmaceutical firm enticements on physician prescribing patterns. *Chest*, 102, 270-273.

We examined the impact on physician prescribing patterns of pharmaceutical firms offering all-expenses-paid trips to popular sunbelt vacation sites to attend symposia sponsored by a pharmaceutical company. The impact was assessed by tracking the pharmacy inventory usage reports for two drugs before and after the symposia. Both drugs were available only as intravenous preparations and could be used only on hospitalized patients. The usage patterns were tracked for 22 months preceding each symposium and for 17 months after each symposium. Ten physicians invited to each symposium were interviewed about the likelihood that such an enticement would affect their prescribing patterns. A significant increase in the prescribing pattern of both drugs occurred following the symposia. The usage of drug A increased from a mean of 81 ± 44 units before the symposium to a mean of 272 ± 117 after the symposium ($p < 0.001$). The usage of drug B changed from 34 ± 30 units before the symposium to 87 ± 24 units ($p < 0.001$) after the symposium. These changed prescribing patterns were also significantly different from the national usage patterns of the two drugs by hospitals with more than 500 beds and major medical centers over the same period of time. These alterations in prescribing patterns occurred even though the majority of physicians who attended the symposia believed that such enticements would not alter their prescribing patterns.

Rutledge, P., Crookes, D., McKinstry, B., & Maxwell, S. R. (2003). Do doctors rely on pharmaceutical industry funding to attend conferences and do they perceive that this creates a bias in their drug selection? Results from a questionnaire survey. *Pharmacoepidemiol Drug Saf*, 12(8), 663-667.

Purpose To determine the sources of funding for doctors attending conferences and meetings and the doctors' perception on whether their involvement with the pharmaceutical industry created a conflict of interest or bias in their drug selection.

Method A postal questionnaire was distributed to 622 hospital doctors and 515 general practitioners (GPs) working in the Edinburgh area in Scotland, UK.

Results The pharmaceutical industry funded approximately half of the meetings and conferences attended by doctors. Less than 20% of the doctors funded themselves. One-third of the meetings would not have been attended if funding from the industry had not been available. Hospital doctors and GPs had similar views on conflict of interest and bias. A minority of doctors (40%) thought that industry involvement created a conflict of interest but the majority of doctors (86%) thought that it did not create a bias in their own drug selection.

Conclusions If continuing medical education (CME) for doctors is going to rely on pharmaceutical industry funding in the future, then we need more explicit codes of conduct. It is of concern that while many doctors recognize the potential for the industry to influence their prescribing habits, few recognize that they themselves are susceptible.

Takhar, J., Dixon, D., Donahue, J., Marlow, B., Campbell, C., Silver, I., Eadie, J., Monette, C., Rohan, I., Sriharan, A., Raymond, K., & Macnab, J. (2007). Developing an instrument to measure bias in CME. *The Journal of Continuing Education in the Health Professions*, 27(2), 118-123.

Introduction: The pharmaceutical industry, by funding over 60% of activities in the United States and Canada, plays a major role in continuing medical education (CME), but there are concerns about bias in such CME activities. Bias is difficult to define, and currently no tool is available to measure it.

Methods: Representatives from industry and academia collaborated to develop a tool to illuminate and measure bias in CME. The tool involved the rating of 14 statements (1 = strongly disagree, 4 = strongly agree) and was used to evaluate 17 live CME events. Cronbach's alpha was used to assess the internal consistency of the scale.

Results: Cronbach's alpha for the total score was 0.82, indicating excellent internal consistency. Incomplete or biased data, data presented in an unbalanced manner, and experience not integrated with evidence-based medicine were found to correlate strongly with the total score. Use of trade names showed a low correlation with the total, and nondeclaration of conflict of interest correlated negatively with the total. These associations suggest that whereas sponsor companies may declare conflicts of interest, such a declaration may not ensure an unbiased presentation.

Discussion: The tool and the data from this study can be used to raise awareness about bias in CME. Policymakers can use this tool to ensure that CME providers meet the standards for education, and CME providers can use the tool for conducting random audits of events they have accredited.

Wazana, A. (2000). Physicians and the pharmaceutical industry: Is a gift ever just a gift? (3), 373-80. *Journal of the American Medical Association*, 283

Context Controversy exists over the fact that physicians have regular contact with the pharmaceutical industry and its sales representatives, who spend a large sum of money each year promoting to them by way of gifts, free meals, travel subsidies, sponsored teachings, and symposia.

Objective To identify the extent of and attitudes toward the relationship between physicians and the pharmaceutical industry and its representatives and its impact on the knowledge, attitudes, and behavior of physicians.

Data Sources A MEDLINE search was conducted for English-language articles published from 1994 to present, with review of reference lists from retrieved articles; in addition, an Internet database was searched and 5 key informants were interviewed.

Study Selection A total of 538 studies that provided data on any of the study questions were targeted for retrieval, 29 of which were included in the analysis.

Data Extraction Data were extracted by 1 author. Articles using an analytic design were considered to be of higher methodological quality.

Data Synthesis Physician interactions with pharmaceutical representatives were generally endorsed, began in medical school, and continued at a rate of about 4 times per month. Meetings with pharmaceutical representatives were associated with requests by physicians for adding the drugs to the hospital formulary and changes in prescribing practice. Drug company–sponsored continuing medical education (CME) preferentially highlighted the sponsor’s drug(s) compared with other CME activities. Attending sponsored CME events and accepting funding for travel or lodging for educational symposia were associated with increased prescription rates of the sponsor’s medication. Attending presentations given by pharmaceutical representative speakers was also associated with nonrational prescribing.

Conclusion The present extent of physician-industry interactions appears to affect prescribing and professional behavior and should be further addressed at the level of policy and education