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IS THERE A RELATIONSHIP BETWEEN COMMERCIAL SUPPORT AND  
BIAS IN CONTINUING MEDICAL EDUCATION ACTIVITIES?  
AN UPDATED LITERATURE REVIEW

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## EXECUTIVE SUMMARY

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### IS THERE A RELATIONSHIP BETWEEN COMMERCIAL SUPPORT AND BIAS IN CONTINUING MEDICAL EDUCATION ACTIVITIES? AN UPDATED LITERATURE REVIEW

RONALD M. CERVERO AND JULIE K. GAINES

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The **ACCME® Standards for Commercial Support: Standards to Ensure Independence in CME Activities**<sup>SM</sup> are designed to assure that CME activities are not biased toward the commercial interest supporting the activity. Although these standards have been in place since 1991 and updated in 2004, there continues to be a line of argument in medical education claiming that commercially supported CME is biased in favor of products of ACCME–defined commercial interests.

It is critically important for the delivery of high-quality patient care to understand the nature and type of evidence supporting or refuting this view. To this end, Cervero and He (2008) analyzed the data based literature about commercial support and bias in accredited CME. Of the 10 data based articles that addressed the relationship between commercial support and CME, no studies included a direct measurement of bias in an accredited CME program or found negative consequences of commercial support. The purpose of this study was to identify and summarize the data-based and the “viewpoint” literature on commercial support and bias in accredited continuing medical education (CME) that has been published since Cervero and He’s 2008 report.

Extensive searches produced 11 data-based articles that addressed the relationship between commercial support and bias in accredited CME. All articles were included that: 1) were published since 2008, 2) studied CME activities that were accredited by ACCME, and 3) presented empirical evidence collected through established research methods. The paper also presents an analysis of four major national reports published between 2008 and 2013 and six “viewpoint” articles in *JAMA*, *BMJ*, and the *New England Journal of Medicine*.

We did not identify any data-based articles to support or refute the assertion that commercial support produces bias in accredited CME. The evidence from the literature leads to the following conclusions: 1) Commercially-supported CME can provide clinically accurate medical content; 2) Physicians perceive very low levels of commercial bias (3-5% on average) in post-program course evaluations; and 3) This same level of perceived bias is reported for programs that were commercially supported and those that were free of commercial support.

The four national reports and six articles show a range of engagement and alignment with the evidence base in this paper and the 2008 paper (Cervero & He, 2008) related to the issue of commercial support and bias in CME. Each report and article proposes policy solutions based on the assumption that commercial support biases accredited CME, although the evidence-base reviewed in this paper shows that no study has been published that supports or refutes this hypothesis.

As in the previous report (Cervero & He, 2008), we recommend that rigorous scientific studies should be initiated to address important questions about the relationship between commercial support and bias in accredited CME. The findings of multiple studies derived from this research agenda would allow leaders and policy makers to understand if commercial support produces biased CME and propose evidence-based policy solutions if this hypothesis were supported.

## BACKGROUND AND PURPOSE

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The **ACCME® Standards for Commercial Support: Standards to Ensure Independence in CME Activities**<sup>SM</sup> are designed to assure that CME activities are not biased toward the commercial interest supporting the activity. Although these standards have been in place since 1991 and updated in 2004, there continues to be a line of argument in medical education claiming that commercially supported CME is biased in favor of products of ACCME –defined commercial interests (Hager, Russell, & Fletcher, 2008; The Pew Charitable Trusts, 2013). It is critically important for the delivery of high-quality patient care to understand the nature and type of evidence supporting or refuting this view (Goold & Campbell, 2008; Mazmanian, 2009).

Cervero and He (2008) analyzed the data-based literature about commercial support and bias in accredited CME. Of the 10 data-based articles that addressed the relationship between commercial support and CME, no studies included a direct measurement of bias in an accredited CME program or found negative consequences of commercial support. Thus, they concluded that: “to date there is no empirical evidence to support or refute the hypothesis that CME activities are biased” (p. 8).

They did find limited evidence showing that CME activities funded by commercial interests can be effective in changing physicians’ prescribing practices. This finding is consistent with the literature showing that CME can change physician practice and improve patient care (Forsetlund et al., 2009; Mansouri & Lockyear, 2007; Marinopoulos et al., 2009; Robertson, Umble, & Cervero, 2003). However, with no studies addressing the impact of these prescribing changes on patient care, they could not determine if the changes were or were not in the best interests of the patient. Although this is a critically important question, there was no evidence to answer it.

They found that the evidence from physicians’ opinions about the impact of commercial support on CME lends important support for future research in this area. The studies showed that while the majority of physicians do not believe that CME activities are biased by commercial support, there is substantial concern that CME activities can be biased toward the industry sponsor. This research is important because it shows that the vast majority of physicians believe they are capable of making clinical decisions for optimal patient care, and are not influenced by commercial interests. However, some 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 (Association of American Medical Colleges, 2007).

Cervero and He (2008) called for rigorous scientific studies to address the relationship between commercial support and bias in accredited CME. Thus, the purpose of this study was to identify and summarize the literature on commercial support and bias in accredited continuing medical education (CME) that has been published since Cervero and He’s 2008 report. The first section provides an analysis of the evidence that addresses the hypothesis that, “Commercial support biases accredited CME.” The second section provides an analysis of the evidence used for national reports and for published viewpoints on commercial bias in accredited CME.

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## METHODS

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In order to identify the published articles that offer evidence about commercial support and bias in CME, we searched MEDLINE, CINAHL, Academic Search Complete, and Education Research Complete. Appendix D describes the search process that we used to search these reference bases. We included all articles that were: 1) published since 2008, 2) studied CME activities that were accredited by ACCME, and 3) presented empirical evidence collected through established research methods. We found 11 data-based articles that addressed the relationship between commercial support and bias in accredited CME, which are listed in Table 1 and annotated in Appendix A.

Since 2008 there have been numerous viewpoints published in major medical journals as well as in national reports focused on the impact of commercial support on bias in accredited CME. We undertook an analysis of how the evidence used in these publications aligned with the data-based literature discussed in this report. Four major reports published between 2008 and 2013 were included in our analysis (Hager, Russell, & Fletcher, 2008; Institute of Medicine, 2009; Institute of Medicine, 2010; The Pew Charitable Trusts, 2013). Given the extensive body of viewpoint articles published since 2008, we used those from three of the most influential medical journals as representative of the literature: *JAMA: The Journal of the American Medical Association* (N=2), *BMJ* (N=2), and the *New England Journal of Medicine* (N=2).

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### COMMERCIAL SUPPORT AND BIAS IN CME: DATA-BASED ARTICLES

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The 11 data-based articles were grouped into the four categories used in the 2008 report and a new category of studies on the relationship between conflict of interest and bias in CME. The results are organized into five categories: 1) five studies that provided indirect evidence about whether commercial support produces biased CME, 2) one study that examined the impact of commercially supported CME on prescribing practices, 3) one study that examined physician opinions about bias in commercially supported CME, 4) one study about measuring bias in commercially supported CME, and 5) three studies that examined the relationship between conflict of interest and bias in CME.

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#### *IMPACT OF COMMERCIAL SUPPORT ON BIAS IN ACCREDITED CME*

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We did not identify any data-based articles to support or refute the assertion that commercial support produces bias in accredited CME. Unlike the previous study (Cervero & He, 2008) that did not find any published studies that address this link, we identified five articles that sought to provide evidence about this issue (Ellison, et al., 2009; Goldfarb, et al., 2012; Kawczak, Carey, Lopez, & Jackman, 2010; Roland, et al., 2010; Steinman, Boscardin, Aguayo, & Baron, 2010). One reviewed whether commercial support influences the content of online activities (Roland, et al., 2010) and the other four studied the impact of commercial support on learner-perceived bias in CME activities (Ellison, et al., 2009; Goldfarb, et al., 2012; Kawczak, Carey, Lopez, & Jackman, 2010; Steinman, Boscardin, Aguayo, & Baron, 2010).

Table 1. Commercial Support and Bias in Accredited CME: Data-Based Articles (2008-13)

Category	Study Citation	Conclusions
<p><b>Impact of Commercial Support on Bias in Accredited CME</b></p>	<p>Ellison, et al. (2009). Low rates of reporting commercial bias by physicians following online continuing medical education activities.</p> <hr/> <p>Goldfarb, et al. (2012). Attendees' perceptions of commercial influence in noncommercially funded CME programs.</p> <hr/> <p>Kawczak, et al., (2010). The effect of industry support on participants' perceptions of bias in continuing medical education.</p> <hr/> <p>Roland, et al. (2010). Content analysis of continuing medical education for cervical cancer screening.</p> <hr/> <p>Steinman, et al. (2010). Commercial support and learner-perceived bias in continuing medical education.</p>	<p>There is no published study that addresses the link between commercial support and bias in accredited CME activities.</p> <p>Commercially-supported CME can provide clinically accurate medical content.</p> <p>Physicians report very low levels of commercial bias (3-5% on average) in post-program course evaluations.</p> <p>This same level of perceived bias due to commercial support is reported for programs that were commercially supported and those that were free of commercial support.</p>
<p><b>Impact of Commercially Supported, Accredited CME on Prescribing Practices</b></p>	<p>Fugh-Berman, et al. (2010). Why lunch matters: Assessing physicians' perceptions about industry relationships.</p>	<p>A presentation on industry influence can influence physicians' intention to change prescribing practices.</p>
<p><b>Physician Opinions about Bias in Commercially Supported, Accredited CME</b></p>	<p>Tabas, et al. (2011). Clinician attitudes about commercial support of continuing medical education.</p>	<p>Most physicians believe that commercially supported CME has the potential to be biased, but do not want to eliminate that support.</p>

<b>Measuring Bias in Commercially Supported, Accredited CME</b>	Dixon, et al. (2011). Controlling quality in CME/CPD by measuring and illuminating bias.	Psychometrically-sound instruments are available to study commercial support and bias in accredited CME activities.
<b>Conflicts of Interest and Commercial Bias in Accredited CME</b>	Birkhan, et al. (2011). Self-reported financial conflicts of interest during scientific presentations in emergency medicine.	There is a lack of consistent and accurate reporting of potential COI at accredited CME activities.
	Davis, et al. (2008). Evaluating conflicts of interest in research presented in CME venues.	
	Okike, et al. (2009). Accuracy of conflict-of-interest disclosures reported by physicians.	

Roland, et al. (2010) reviewed whether web-based CME activities reflected updated guidelines for cervical cancer screening and HPV testing issued by the American Cancer Society and the American College of Obstetricians and Gynecologists. Among the 20 CME activities from April 2006 to June 2008 were 7 research articles, 3 online modules, 2 audiocasts, and 8 webinars. The authors identified 41 messages in the content of the activities. The majority of the activities were active for 12 months and credited for at least 1.0 hours of CME. Eight of the activities disclosed relationships or support from industry. Of the 8 activities that had commercial support, 7 “contained clinically accurate messages about extension of screening intervals for the HPV co-test” (p. 656). In comparison, 9 of the 12 activities without commercial support contained clinically accurate messages. As the authors note, this study was limited to an analysis of the content and did not address “how access to and context of CME activities are translated into clinical practice” (p. 656).

Ellison, et al. (2009) collected data on a post-activity evaluation survey from 1,064,642 participants who completed an online course on [www.medscape.com](http://www.medscape.com). There were 3,137 CME activities, with 887 (28.3%) commercially supported. The question used to assess bias, “The activity was presented objectively and free of commercial bias,” had 5 response options: Strongly agree, agree, no opinion, disagree, and strongly disagree. The disagree/strongly disagree responses were aggregated to provide an overall rate of participants who disagreed with the item statement of “no bias.” The results showed a very low percentage (N=6674; 0.63%) of respondents perceived that the CME activity was biased. The breakdown showed that commercially supported activities had statistically higher perception of bias (N=3553; 0.84%) than non-commercially supported activities (N=3121; 0.48%). The authors note that any small observed difference in a sample size this large is likely to reach the threshold for statistical significance, but is not of practical significance.

Goldfarb, et al. (2012) collected data on a post-activity evaluation survey from 1,544 attendees at 14 live non-commercially funded CME programs in 2006, 2007, and 2010 that focused on psychiatry. Attendees were asked to evaluate each lecture and the entire program for perceived sources as well as manifestations of commercial influence. The bias question, “Did you think that

commercial support influenced course content,” had three response options: No, somewhat, and yes. The assessment of bias (yes or somewhat) ranged from 6% to 9.3% across the programs. Of this percentage who rated the program as biased, 74.6% also rated 1 or more lectures as biased. The major sources of bias were funding of the speakers’ research or other research referenced. The major manifestations of bias were speakers’ mentions of specific pharmaceuticals or products and speakers’ expression of personal opinions about specific pharmaceuticals or products. The study concludes that: “attendees comprehend a great deal more in the term *commercial influence* than simply the impact of industry support on a CME program” and suggest that further research should “distinguish sources and manifestations of commercial influence in both commercial and noncommercially supported CME programs” (p. 211).

Kawczak, Carey, Lopez, and Jackman (2010) analyzed all administratively completed activities offered by the Cleveland Clinic in 2007. The 346 activities included live courses, regularly scheduled series, journal-based activities, online activities, and enduring materials. The activities were classified by industry funding source, with 149 (52,044 participants) receiving no funding, 79 (10,753 participants) funded by one source, and 118 (32,632 participants) funded by multiple sources. Each activity was evaluated in two ways: 1) percentage of participants who perceived that the activity was free of commercial bias using a yes/no question, and 2) degree to which it was free of commercial bias by using a four point scale of excellent, good, fair, and poor (excellent means free from bias). Overall, 97.3% to 99.2% of participants (depending on type of activity) said that the activity was free of commercial bias and the differences in perceived bias were not statistically related to the source of industry funding. On the second measure, a range of 1.0% to 6.8% of participants gave a response of “poor” or “fair” (depending on type of activity) indicating very few perceived commercial bias and the differences were not statistically related to the source of funding. The study concludes that: 1) physicians perceive very low levels of bias in accredited CME, 2) level of commercial support does not influence perceived bias, and 3) a small percentage of physicians perceive bias even when there is not commercial support for the CME activity.

Steinman, Boscardin, Aguayo, and Baron (2010) analyzed 213 accredited live educational programs organized by the University of California, San Francisco from 2005 to 2007. The study was designed to assess whether CME activity characteristics relating to potential commercial influence were associated with perceived bias at the activity. The outcome measure was percentage of respondents who perceived the activity was free of commercial bias, with 100% meaning that it was bias-free. The first predictor variable was a prospective rating of each activity’s potential for commercial bias as “lowest,” “intermediate,” or highest.” The second predictor variable was a standardized rating instrument (Barnes, et al., 2007) that prospectively measures activity characteristics that are at high risk for commercial bias, such as basis of funding source and responsibility for course logistics. Of the 213 programs, about 33% had no commercial support and the remaining courses had varying levels of support. The study found that most participants rated the programs as free of commercial bias (median of 97%). There was no association between perceived bias and CME activities classified as lowest, intermediate, and highest risk and no association between level of commercial support and perceived commercial bias. With the exception of the course director being a first-time chair, none of the individual risk factors were associated with perceived commercial bias. The study concludes that “rates of perceived bias were consistently low regardless of the presence or absence of risk factors for commercial bias” (p. 77).



Although there are no data-based articles to support or refute the hypothesis that commercial support produces bias in accredited CME, the evidence from these five studies leads to the following conclusions:

1. Commercially-supported CME can provide clinically accurate medical content;
2. Physicians perceive very low levels of commercial bias (3-5% on average) in post-program course evaluations; and
3. This same level of perceived bias is reported for programs that were commercially supported and those that were free of commercial support.

### *IMPACT OF COMMERCIALLY SUPPORTED, ACCREDITED CME ON PRESCRIBING PRACTICES*

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As in the previous study (Cervero & He, 2008), very limited attention has been given to the impact of commercially supported, accredited CME on prescribing practices and no studies have been published of the impact of these practices on patient care. One study (Fugh-Berman, Scialli, & Bell, 2010) assessed the short-term effects of an educational intervention about industry influence that was developed by physicians associated with PharmedOut for grand rounds presentations. This is a university-based, physician run project to educate physicians about inappropriate pharmaceutical promotion. Two versions of the presentation were used, with “Physician-Pharma Relationship” at 9 venues (with 266 participant evaluations) and “Why Lunch Matters” at 5 venues (with 107 participant evaluations). In response to the question, “Will you change your prescribing behavior as a result of the talk,” 20% of respondents indicated an intention to increase the use of generic drugs and/or decrease the use of sample drugs. The study noted that changes of attitudes “does not necessarily mean they changed their actions” (p. 203) and that “there remained a large number of attendees whose responses suggested lack of agreement with the presentation message” (p. 203).

### *PHYSICIAN OPINIONS ABOUT BIAS IN COMMERCIALLY SUPPORTED, ACCREDITED CME*

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There continues to be some interest in understanding physicians’ opinions about whether commercially supported CME is biased, with one study being published since the previous review (Cervero & He, 2008). Tabas, et al. (2011) collected data at 5 live CME programs for physicians and other clinicians who provide medical care for people with HIV/AIDS from January to June 2009. The survey asked whether commercial support for live CME should be eliminated and whether raising registration fees is an effective way to decrease commercial support. There were 770 respondents of which 55% were physicians. Physicians believe that the likelihood of substantial potential bias increases based on the level of commercial support. They believe that there is more potential for bias when there is a single commercial supporter (86%) or 2 or more commercial supporters (70%) as compared to programs with no commercial support (7%). Although many physicians perceived bias from commercial support, only 46% believed that increasing registration costs would be an effective way to decrease that support. With 77% of physicians responding that registration costs are an important factor in deciding to attend programs, 56% agreed or strongly agreed that commercial support should not be eliminated. The authors conclude that: “although many participants perceived that commercial support poses a risk for bias in CME activities, and greater amounts pose a greater risk, many did not seem willing to offset those costs by paying more for the activity or decreasing what was offered” (p. 843).

## *MEASURING BIAS IN COMMERCIALY SUPPORTED, ACCREDITED CME*

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With the continuing interest in measuring commercial bias in accredited CME, researchers have continued to refine a standardized instrument that was designed to be used retrospectively at the completion of a CME program and was shown to be valid and reliable (Takhar, et al., 2007). This effort is important in that it seeks to develop a psychometrically-sound approach to the measurement of bias as opposed to using single items to assess physicians' subjective opinions. The current study (Dixon, et al., 2011) involved CME/CPD events in 5 centers across Canada as part of a Bias Management Process. The 14-item instrument showed moderate inter-rater reliability and the live reviews showed poor overall inter-rater reliability, suggesting the need for high quality training in using the instrument to assess bias. The study concludes that "the process appears to be less effective at preventing bias than at facilitating a process to provide feedback to organizations seeking accreditation and the speaker after the completion of the event" (p. 115).

## *CONFLICTS OF INTEREST AND COMMERCIAL BIAS IN ACCREDITED CME*

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Given that the ACCME's guidelines require resolution of any potential conflicts of interest (COI) prior to presentations at CME activities, it is important to understand how the COI process is working and its' potential impact on commercial bias in CME activities. Three studies have been published since the previous review (Cervero & He, 2008) that address different dimensions of the issue (Birkhahn, Fromm, Larabee, & Dierks, 2011; Davis, et al., 2008; Okike, et al., 2009).

Birkhahn, Fromm, Larabee, and Dierks (2011) reviewed scientific abstracts presented at the 2010 annual meeting of the Society for Academic Emergency Medicine for the required COI disclosure both before the meeting and during presentation. 382 posters were reviewed for presence of the required COI disclosure statement and compared to the submitted CME disclosure form. Sixty-nine (18%) abstracts reported a COI, but only 26 (38%) were reported on the CME disclosure form; the remaining 62% were found only on the poster. COI reported on the CME disclosure form were found on only 46% of the posters. The authors recognize that the limitation to this audit study is that the financial COI were self-reported and conclude that: "The current system for reporting and relaying conflicts of interest in original research is inconsistent and suffers from a lack of transparency and oversight" (p. 980).

Davis, et al. (2008) reviewed the oral and printed content of 236 research abstract presentations made at the 2005 annual meetings of the American Academy of Family Physicians and the North American Primary Care Research Group. Nineteen abstracts were selected that were evidence-based and disclosed a potential COI or indicated commercial support for the research. Two reviews were made of these 19 papers: 1) monitoring of the presentations by blinded (BM) and unblinded monitors (UBM), and 2) blinded and unblinded review of the paper copies of the slides. The study found that 9 of 19 presentations reviewed by BMs and UBMs resulted in disagreement about whether commercial products limited to a single vendor were mentioned in the presentation, with the primary pattern being the blinded reviewers responding "no" and the unblinded reviewers responding "yes." The study concludes that: "This suggests that knowledge of the presenter's COI increases awareness of a single product in the presentation" (p. 223).

Okike, et al. (2009) conducted an observational study of actual payments made to physicians by five manufacturers of total hip and knee prostheses in 2007 and compared these payments to self-

reported COI disclosure by presenters and board members or committee members attending the 2008 annual meeting of the American Academy of Orthopaedic Surgeons. The overall rate of disclosure was 71.2% (245 of 344 payments), with higher rates for payments directly related to the presentation topic (79%) compared with indirectly related (50%) and unrelated (49%). Payments were also more likely to be disclosed if they exceeded \$10,000, were directed to an individual, or included an in-kind contribution. The primary reason provided for nondisclosure was that the payment was unrelated to the presentation topic. The study concludes that the most notable finding “was the high rate of nondisclosure” (p. 1471).

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## COMMERCIAL SUPPORT AND BIAS IN CME: REPORTS & VIEWPOINTS

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In his 2009 editorial, “Commercial Support of Continuing Medical Education in the United States: The Politics of Doubt, the Value of Studies,” Mazmanian (2009) argues that there “are few reliable data to respond to careful criticism” (p. 81) that questions the integrity of the CME system in the United States related to the issues of commercial support and bias in CME. He indicates there is no evidence that supports or refutes the hypothesis that commercially supported CME is biased and calls for more studies to address this proposition because we “need to know who benefits from it and how” (p. 82). His argument that educational policy recommendations need to be evidence-based is consistent with the widespread agreement that evidence-based medicine is the foundation of optimal patient care.

Since 2008 there have been several national reports and numerous articles in prominent medical journals that provide policy recommendations to provide increased oversight over the influence of commercial support in accredited CME activities. We analyzed the evidence base used to discuss the issue of whether commercial support biases accredited CME in four major national reports and six articles from *JAMA*, *BMJ*, and the *New England Journal of Medicine*. These ten publications agree that: 1) there has been substantial, though decreasing, commercial support in CME, 2) commercial support has a possibility of biasing accredited CME, and 3) the ACCME Standards of Commercial Support are the primary policy tool used to prevent bias in CME.

### NATIONAL REPORTS

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The four major national reports addressing the issue of commercial support and bias in accredited CME (Hager, Russell, & Fletcher, 2008; Institute of Medicine, 2009; Institute of Medicine, 2010; The Pew Charitable Trusts, 2013) demonstrate a range of alignment with the evidence in this report and the 2008 report (Cervero & He, 2008) that concluded there are no published studies to support or refute the proposition that commercial support biases accredited CME.

Steinbrook’s (2008) chapter in Hager, Russell, and Fletcher (2008), asks “Does the commercial funding of continuing education distort medical practice away from what is best for health professionals and patients? Should changes be made to the funding and existing safeguards against financial bias and conflict of interest” (p. 104)? The chapter presents extensive data on the commercial support of CME and argues that “there is a long-standing concern that continuing education is often a marketing activity that promotes sales of newer and more lucrative medical products, including their off-label use, notwithstanding the various safeguards against conflict-of-interest and commercial bias...[and] there are multiple reasons for this concern about the

commercial aspects of CME” (p. 106). Although there is a case presented in the chapter arguing that commercial interests support and influence CME, no published studies are referenced demonstrating that commercial support biases accredited CME.

The Institute of Medicine (IOM) released two tandem reports on conflict of interest in medical research, education, and practice (Institute of Medicine, 2009) and redesigning continuing education in the health professions (Institute of Medicine, 2010) that addressed the issue of commercial support and CME. The chapter “The Learning Environment in Accredited Continuing Medical Education” in the 2009 report provides the most comprehensive review of the research of the four major reports reviewed in this paper. The report concludes that: “The committee found little systematic research on other consequences of industry-supported continuing medical education, for example, whether it promotes bias in individual programs or in overall educational offerings” (p. 147). The report discusses three studies covered in the Cervero and He (2008) review. Two studies (Bowman & Pearle, 1986; Orłowski & Wateski, 1992) investigated CME that is no longer permitted under ACCME guidelines. A third study (Katz, Goldfinger, & Fletcher, 2002) was conducted before the adoption of the 2004 Standards of Commercial Support, and thus cannot be generalized within the current CME policy environment. The report does agree with the promising directions of Takhar, et al.’s (2007) efforts to develop an objective instrument to assess bias in CME activities. The report concludes that: “Work is needed to validate this and other instruments that are intended to be used to assess bias in presentations retrospectively or identify presentations at risk of bias during the planning stage (see, e.g., Barnes et al., 2007)” (p. 148). These two studies (Barnes, et al., 2007; Takhar, et al., 2007) were also referenced in Cervero and He’s 2008 report as promising directions to understand the question of commercial bias in accredited CME.

The 2009 IOM report bases its overall recommendation that “a new system of funding accredited continuing medical education should be developed that is free of industry influence” (p. 161) using the rationale that although there is no evidence that commercial support produces biased CME, such funding may influence CME in other ways that are not conducive to optimal patient care:

**“Overall, there was general agreement that CME has become too reliant on industry funding and that such funding tends to promote a narrow focus on products and to neglect the provision of a broader education on alternative strategies for managing health conditions, and other important issues, such as communication and prevention. Given the lack of validated and efficient tools for preventing or detecting bias, industry funding creates a substantial risk of bias, to the extent that industry-reliant providers want to attract industry support for future programs. (p. 161)”**

The tandem IOM report on “Redesigning Continuing Education in the Health Professions” (2010) notes that:

**“ACCME has detailed regulations to ensure that commercial interests are kept separate from learning activities and course content. The regulations require CME providers to disclose conflicts of interest and resolve relevant financial relationships with any commercial interest among those in a position to control CME content. For example, the ACCME requires CME providers to give a balanced view of therapeutic options and encourages the**

**use of generic names of therapies, rather than promoting specific propriety names. (p. 72)”**

Nevertheless, without citing research that investigates the effectiveness of these guidelines, the IOM report raises the possibility that “such efforts *may not* [italics added] be sufficient to keep activities free from bias” (p. 72) and that “The availability of funding has the potential to influence types of CE programs offered” (p. 74). In summary, neither IOM report cites research that supports or refutes the hypothesis that commercial support biases accredited CME.

The fourth report was recently released by the Pew Charitable Trusts (2013) and recommended best practices about conflict of interest policies for academic medical centers. Like the other reports, this one notes that:

**“ACCME Standards for Commercial Support were promulgated to prevent industry’s promotional content from entering accredited continuing medical education. Key requirements include financial disclosure, confirmation that supporting companies have no influence over the content and choice of speakers, and a procedure for resolving conflicts of interest should they arise. (p. 9)”**

Suggesting that these guidelines may not be sufficient to prevent commercial support from biasing accredited CME, the report states:

**“However, studies suggest that industry funding of CME tends to bias topic choices and content in favor of the sponsors’ products and therapeutic areas. Of the three published studies that have examined whether industry sponsorship is associated with higher prescribing of the sponsors’ products, all three have shown a positive correlation...Another study found that industry support of primary care continuing medical education resulted in a narrow list of course topics related exclusively to products marketed by the sponsor. (p. 9)”**

The report asserts that Cervero and He’s review of these studies (Bowman & Pearle, 1988; Dieprink & Drogmeuler, 2001; Katz, Goldfinger, & Fletcher, 2002; Orłowski & Wateski, 1992) concluded that “industry supported continuing medical education activities were indeed effective in increasing attendees’ prescriptions of the sponsors’ products” (p. 9). However, the Pew report does not include our discussion that: 1) these studies were all completed before the current Standards of Commercial Support were in place and thus were in different policy context of acceptable CME, 2) had serious questions of research design, with plausible alternative explanations for the results, 3) did not include studies of the impact of these prescribing changes on patient care and thus could not determine if the changes did or did not produce optimal patient care.

The report’s overall recommendation about CME is that even though “the empirical research on bias in industry CME is limited and in some cases outdated, ...the task force recommends that, in general, academic medical centers should ban commercial funding of continuing medical education” (p. 9). As in the IOM’s conflict of interest report (2009), the Pew report explicitly recognizes the weak, at best, evidence base addressing the question of commercial support and biased CME. Nevertheless, like the other three reports, Pew recommends serious policy changes on

a research base that does not support or refute the hypothesis that commercial support biases accredited CME.

### *VIEWPOINTS IN MAJOR MEDICAL JOURNALS*

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The six articles in major medical journals since 2008 that address the issue of commercial support and bias in accredited CME demonstrate a range of alignment with the evidence in this report and the 2008 report (Cervero & He, 2008) that concluded there are no published studies to support or refute the proposition that commercial support biases accredited CME.

Morris and Taitsman (2009) explain that there is extensive commercial support for CME activities and that the ACCME imposes the Standards for Commercial Support to “temper potential industry influence” (p. 2478). Arguing that the Standards are not a sufficient safeguard against bias, they cite the 2009 IOM report that “CME has become far too reliant on industry funding and that such funding tends to promote a narrow focus on products” (p. 2478). The article then discusses the merits and drawbacks of several alternative approaches to the current accreditation system in order “to ensure that CME serves a bona fide educational purpose, is not co-opted as a marketing tool, and does not violate laws against fraud and abuse” (p. 2479).

Tabas and Baron (2012) argue that that commercial funding of CME is decreasing but that a greater reduction is needed. They point out that “several prominent organizations—including the Association of American Medical Colleges, the Institute of Medicine, and the Josiah Macy Jr. Foundation—have called for limits to the amounts and scope of commercial support for medical education” (p.1). Two of the organizations cited include the reports previously reviewed in this paper (Hager, Russell, & Fletcher, 2008; Institute of Medicine, 2010) that did not base their recommendations on an evidence base showing that commercial support biases accredited CME.

Steinman, Landefeld, and Baron (2012) argue that industry support has been declining since 2007 for several reasons including that the ACCME “progressively developed an aggressive system of identifying, disclosing, and resolving conflicts of interest” (p. 1069). During this time of declining support several “influential reports and policy papers have recommended major new restrictions on industry funding, with some proposing the complete elimination of industry support for CME” (p. 1069). Two of the organizations cited include reports previously reviewed in this paper (Hager, Russell, & Fletcher, 2008; Institute of Medicine, 2009) that did not base their recommendations on an evidence base showing that commercial support biases accredited CME. They conclude that: “We may have reached a tipping point: the slow uphill progress in limiting industry involvement appears to be accelerating, and further restrictions are likely to become more widespread” (p. 1070). This viewpoint uses the leverage of inevitability to recommend further changes: “The question for both supporters and opponents of greater restriction is not whether we should institute these changes—that train has left the station—but how to maximize the benefits of those changes and avoid unintended consequences in other aspects of physician-industry relations” (p. 1071).

Skolnik’s (2013) paper is unique among all of the reports and articles reviewed, with the paper title making his argument: “Don’t restrict funding from drug companies for doctors’ education.” He points out that: “Debate about potential conflicts of interest has led to proposals to stop drug companies funding continuing medical education and to diminish interactions between drug

companies and doctors” (p. 1). He believes this debate “ignores the fact that conflicts of interest are all around us” (p. 1), such as in running a small medical practice that needs to financially survive, “in which the practitioner has incentives to see more patients and do more procedures” (p. 1). His recommendation is that “Potential conflicts need to be managed, and the idea that they are best avoided by forbidding any interaction with industry undermines the free flow of ideas and information that is essential in any free society and is important for patient care” (p. 1). While recognizing that potential for bias exists, he argues for solutions to regulate the conflicts of interest that may produce biased CME.

Lo and Ott’s (2013) article, which most clearly engages the data-based literature on the topic, argues that CME has focused on managing conflicts of interest, specifically those involving commercial support, rather than focusing on reducing bias in accredited CME. Conflicts of interest only involve an unacceptable probability of bias, whereas bias in accredited CME is what actually leads to sub-optimal patient care. They argue that conflicts of interest and bias are distinctly different problems and that CME needs to “give greater attention to identifying and reducing bias, in addition to implementing sound COI policies” (p. 1019). The authors define bias as “presenting information, drawing conclusions, or making recommendations that are not scientifically valid or not supported by the weight of rigorous evidence” (p. 1019) and explain how COI and bias are related:

***“Many COIs do not result in bias. Conversely, bias may result from factors other than financial relationships with industry, including intellectual commitment to a therapeutic approach, limited expertise about a topic, methodological shortcomings, and poor judgment. Conflicts of interest resemble a screening test for bias, with imperfect sensitivity and specificity. (p. 1019)”***

The authors reference the evidence base reviewed in this paper, showing that learners report very little commercial influence and bias in post-program evaluations (Ellison, et al., 2009), but provide a variety of reasons that these studies “probably underestimate bias” (p. 1019). They recommend a solution to better address bias in CME, by asking “about specific manifestations of bias that can be readily and consistently identified” (p. 1020) and develop and validate scoring systems for bias based on the questions like:

- Does the presentation compare options for managing the condition, including generic drugs and lifestyle changes? Are their advantages and disadvantages compared?
- Does the presentation use a critical literature review or meta-analysis to summarize the totality of evidence?
- Are the limitations of data for new therapies discussed?
- What important pertinent topics are missing from the presentation or course?

They propose that physicians who are knowledgeable about the topic should review the slide decks before presentations using such an instrument. If bias is detected the course director should work with the presenter to eliminate biased information.

Korn and Carlat (2013), who were centrally involved in the Pew Charitable Trusts report, summarize its background and recommendations. They repeat the central argument of the report: “The task force, finding evidence that commercially funded CME unduly influences the choice of



topics offered, recommended that such funding be limited to specialized training, such as the use of medical training devices for which expertise may be very limited and costs of training high.” As discussed in the earlier section of this paper, this is a major policy recommendation based on a weak, at best, evidence base.

The four reports and six articles show a range of engagement and alignment with the evidence base related to the issue of commercial support and bias in CME. However, each one proposes policy solutions based on the assumption that commercial support biases accredited CME, although the evidence-base reviewed in the first section of this paper shows that no study has been published that supports or refutes this hypothesis.

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## SUMMARY AND CONCLUSIONS

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As was true for the previous review of the literature (Cervero & He, 2008), we did not identify any data-based research to support or refute the hypothesis that commercial support produces bias in accredited CME. However, we identified five published studies that sought to provide evidence about this issue, leading to the following conclusions:

- 1) Commercially-supported CME can provide clinically accurate medical content;
- 2) Physicians perceive very low levels of commercial bias (3-5% on average) in post-program course evaluations; and
- 3) This same level of perceived bias is reported for programs that were commercially supported and those that were free of commercial support.

As seen in the national reports and viewpoints published in the major medical journals that were reviewed in the paper, there continues to be a significant concern that commercial support produces bias in accredited CME, with significant policy recommendations being offered to address this concern. Consistent with the findings of this paper, however, the national reports and viewpoints do not present an evidence-base that supports or refutes the hypothesis that commercial support produces bias in CME.

The previous literature review (Cervero & He, 2008) concluded that rigorous scientific studies should be initiated to address important questions about the relationship between commercial support and bias in accredited CME. Although there has been some progress made in approaches (Lo & Ott, 2013) and methods (Dixon, et al., 2011) for this research, the same questions as proposed in 2008 are relevant today:

- 1) Does commercial support produce bias in accredited CME activities?
- 2) What are the mechanisms by which bias is produced in these activities?
- 3) Are accreditation guidelines or other strategies effective in preventing bias?
- 4) 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?
- 5) As a result of commercially-supported CME, does physicians’ adoption of the sponsor’s product lead to better patient care?



The findings of multiple studies derived from this research agenda would allow leaders and policy makers to understand if commercial support produces biased CME and to propose evidence-based policy solutions if this hypothesis were supported.

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## APPENDICES

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### APPENDIX A. ABSTRACTS OF THE ELEVEN DATA-BASED ARTICLES IN THE 2014 REPORT

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Birkhahn, R.H., Fromm, C., Larabee, T., & Dierks, D.D. (2011). Self-reported financial conflicts of interest during scientific presentations in emergency medicine. *Academic Emergency Medicine*, 18(9), 977-980.

**Objectives:** This study was a review of the scientific abstracts presented at a national conference for the required conflict of interest (COI) disclosure both before the meeting and during presentation.

**Methods:** All presenters were given specific instructions regarding COI reporting at the time of abstract acceptance. All poster presentations were required to have a COI statement. Three physicians using standardized data abstraction forms reviewed abstracts accepted for poster presentation at the 2010 annual meeting of the Society for Academic Emergency Medicine (SAEM). Posters were reviewed for the presence of a required COI disclosure statement, and these results were compared to the mandatory continuing medical education (CME) disclosure form that was sent by the presenters to the SAEM central office before the meeting.

**Results:** There were 412 posters accepted for presentation at the 2010 SAEM annual meeting. The reviewers observed 382 (93%) of the total posters for the conference. Sixty-nine abstracts (18%) reported a COI. Only 26 (38%) of these were actually reported to the SAEM office on the CME disclosure form before the meeting; the remaining 62% were found on the poster alone. COI that were reported on the CME disclosure form were found on the poster 46% of the time. The remaining posters without a COI actually displayed the mandatory disclosure statement only 14% of the time.

**Conclusions:** This review of presentations at a national meeting found a lack of compliance with printed guidelines for COI disclosure during scientific presentation

Davis, N.L., Galliher, J.M., Spann, M.S., Main, D.S., Brannigan, M., & Pace, W.D. (2008). Evaluating conflicts of interest in research presented in CME venues. *The Journal of Continuing Education in the Health Professions*, 28(4), 220-227.

**Introduction:** There is much in the literature regarding the potential for commercial bias in clinical research and in continuing medical education (CME), but no studies were found regarding the potential for bias in reporting original research in CME venues. This pilot study investigated the presence of perceived bias in oral and print content of research findings presented in certified CME activities.

**Methods:** Research presentations at two national primary care CME activities, where authors had self-reported potential conflicts of interest, were peer reviewed and monitored for perceived commercial bias. Blinded and unblinded peer reviewers' and monitors' analyses of bias were compared to assess whether knowledge of potential conflicts of interest affected perceptions of bias.

**Results:** Knowledge of potential conflicts of interest appeared to increase awareness of potential commercial bias with regard to use of a single product in care and assurance that there was reasonable evidence to support the practice recommendation. A perception of the presenter's strong opinion regarding care did not appear to be influenced by knowledge of a potential conflict of interest.

**Discussion:** While limited by study design, this research detected subjectivity and variability in perceiving commercial bias within research findings presented in CME venues. Further study of these questions is required to guide the resolution of conflicts of interest in research and CME.

Dixon, D., Takhar, J., Macnab, J., Eadie, J., Lockyer, J., Stenerson, H., François, J., Bell, M., Monette, C., Campbell, C., & Marlow, B. (2011). Controlling quality in CME/CPD by measuring and illuminating bias. *The Journal of Continuing Education in the Health Professions*, 31(2), 109-116.

**Introduction:** There has been a surge of interest in the area of bias in industry-supported continuing medical education/continuing professional development (CME/CPD) activities. In 2007, we published our first study on measuring bias in CME, demonstrating that our assessment tool was valid and reliable. In light of the increasing interest in this area, and building on our experience, we wanted to further understand the application of this tool in different environments. We invited other CME/CPD providers from multiple sites in Canada to participate in a second CME bias study.

**Methods:** A new steering committee was established with representatives from 5 academic CME/CPD offices nationally, the Royal College of Physicians and Surgeons, and the College of Family Physicians of Canada to outline the project in terms of review of the literature, refining items on the tool, updating the training guide for implementation, and establishing a resource Web site for reviewers. Training involved a train-the-trainer session with the event coordinators at each of the 5 participating centers via videoconferencing.

**Results:** The content reviews from the study showed moderate inter-rater reliability (ICC = 0.54), and the live reviews showed poor overall inter-rater reliability; however, one center achieved substantial inter-rater reliability (ICC = 0.68).

**Discussion:** The analysis from this study suggests that the tool can be used as a part of a multistage process to introduce quality control mechanisms to help raise standards for CME/CPD. It is imperative to develop a cost-effective standardized training protocol that can be implemented at all sites to maximize the reliability of the tool.

Ellison, J.A., Hennekens, C.H., Wang, J., Lundberg, G.D., & Sulkes, D. (2009). Low rates of reporting commercial bias by physicians following online continuing medical education activities. *The American Journal of Medicine*, 122(9), 875-878.

**Background:** Concerns have been raised about bias in commercially supported continuing medical education (CME) activities, although the data are sparse about whether such bias exists, or if so, its extent.

**Methods:** Postactivity CME evaluation surveys were analyzed to quantitate reporting rates of bias, overall and by funding source.

**Results:** Of 1,621,647 physicians who participated in online CME activities, 1,064,642 (65.7%) completed the evaluation surveys and 5.9% reported no opinion. The affirmative rates of physician perception of bias were 0.63% overall, a weighted average of 0.84% for activities developed with and 0.48% for those developed without commercial support, a difference of 0.36% ( $P < .001$ , 95% confidence interval, 0.33-0.39). Among the subgroup who strongly disagreed that there is no bias, the difference between commercial (0.17%) and noncommercial (0.11%) funding was 0.06% ( $P < .001$ , 95% confidence interval, 0.05-0.08,  $P < .05$ ), smaller than the overall difference.

**Conclusions:** These data demonstrate that about 93% of physician participants affirmatively claim to perceive no commercial bias following online CME activities, over 99% if no opinion is included, overall and regardless of funding source.

Fugh-Berman, A.J., Scialli, A.R., & Bell, A.M. (2010). Why lunch matters: Assessing physicians' perceptions about industry relationships. *The Journal of Continuing Education in the Health Professions*, 30(3), 197-204.

**Introduction:** Many studies have shown that pharmaceutical marketing affects prescribing choices. Studies that have assessed the effects of educational interventions on perceptions of pharmaceutical promotion have found mixed results. This study assesses the short-term effects of an educational intervention about marketing tactics on the attitudes and fund of knowledge of residents, medical students, and attending physicians.

**Methods:** A 1-hour slide show that covered detailing, prescription tracking, drug samples, medical meetings, and journals was developed by PharmedOut and presented at a total of 14 grand rounds and seminars at departments of family medicine, internal medicine, pediatrics, psychiatry, cardiology, and neurology. Pre- and posttests included attitudinal and fact questions addressing the influence of drug reps, gifts, pharmaceutical advertising and drug samples on prescribing behavior. The posttest asked whether attendees intended to change their prescribing behavior. The Mann-Whitney U test was used for Likert-scale questions and the Fisher exact test was used to compare the number of pre- and posttest correct answers for the multiple choice and true/false questions.

**Results:** Three hundred seventy-three participants completed pre- and posttests. Significant attitudinal shifts were seen overall, particularly in questions addressing influence of salespeople on physicians in general and on the respondent individually. Some participants commented that they intended to stop seeing drug reps or stop attending industry-funded meals.

**Conclusions:** A new educational presentation can substantially shift attitudes toward perceived susceptibility to pharmaceutical marketing activities. Further research is needed to see if attitude change persists.

Goldfarb, E., Baer, L., Fromson, J.A., Gorrindo, T., Iodice, K.E., & Birnbaum, R.J. (2012). Attendees' perceptions of commercial influence in noncommercially funded CME programs. *The Journal of Continuing Education in the Health Professions*, 32(3), 205-211.

**Introduction:** The controversy surrounding commercial support for continuing medical education (CME) programs has led to policy changes, but data show no significant difference in perceived bias between commercial and noncommercial CME. Indeed, what attendees perceive as commercial influence is not fully understood. We sought to clarify what sources contribute to attendees' perceptions of commercial influence in non-industry-supported CME programs, and how attendees perceive that this influence manifests itself on both speaker and program levels.

**Methods:** Evaluation forms were received from 1544 attendees at 14 live non-commercially supported CME programs in 2006, 2007, and 2010. Attendees rated perceived commercial influence for each lecture and the entire program. Using open-ended and "check all that apply" questions, participants specified perceived sources and manifestations of commercial influence.

**Results:** Attendees rating individual lectures but not the entire program as commercially influenced accounted for 59.9% of those who identified bias. The most frequently endorsed source of commercial influence was individual speakers' funding, and the most listed manifestations were speakers' mentions of pharmaceuticals and expressions of personal opinions. Rating the entire program commercially influenced correlated with whether attendees considered the funding of referenced research a source of influence.

**Discussion:** CME attendees consider a broad spectrum of factors when reporting commercial influence. Evaluation forms should include bias questions per lecture as well as items to clarify perceived sources and manifestations of commercial influence.

Kawczak, S., Carey, W., Lopez, R., & Jackman, D. (2010). The effect of industry support on participants' perceptions of bias in continuing medical education. *Academic Medicine*, 85(1), 80-84.

**Purpose:** To obtain prospective evidence of whether industry support of continuing medical education (CME) affects perceptions of commercial bias in CME activities.

**Method:** The authors analyzed information from the CME activity database (346 CME activities of numerous types; 95,429 participants in 2007) of a large, multispecialty academic medical center to determine whether a relationship existed among the degree of perceived bias, the type of CME activity, and the presence or absence of commercial support.

**Results:** Participants per activity ranged from 1 to 3,080 (median: 276). When asked the yes/no question, "Overall, was this activity satisfactorily free from commercial bias?" 97.3% to 99.2% (mean: 98.4%) of participants answered "yes." In responding on a four-point scale to the request, "Please rate the degree to which this activity met the Accreditation Council for Continuing Medical Education requirement that CME activities must be free of commercial bias for or against a specific product," 95.8% to 99.3% (mean: 97.2%) of participants answered "excellent" or "good." When analyzed by type of funding relative to commercial support--none (149), single source (79), or multiple source (118)--activities were deemed to be free of commercial bias by 98% (95% CI: 97.3,

98.8), 98.5% (97.5, 99.5), and 98.3% (97.4, 99.1) of participants, respectively. None of the comparisons showed statistically significant differences.

**Conclusions:** This large, prospective analysis found no evidence that commercial support results in perceived bias in CME activities. Bias levels seem quite low for all types of CME activities and is not significantly higher when commercial support is present.

Okike, K., Kocher, M.S., Wei, E.X., Mehlman, C.T., & Bhandari, M. (2009). Accuracy of conflict-of-interest disclosures reported by physicians. *New England Journal of Medicine*, 361(15), 1466-1474.

**Background:** The recent public reporting of payments made to physicians by manufacturers of orthopedic devices provides an opportunity to assess the accuracy of physicians' conflict-of-interest disclosures.

**Methods:** We analyzed the reports of payments made to physicians by five manufacturers of total hip and knee prostheses in 2007. For each payment recipient who was an author of a presentation or served as a committee member or board member at the 2008 annual meeting of the American Academy of Orthopaedic Surgeons, the disclosure statement was reviewed to determine whether the payment had been disclosed. To ascertain the reasons for nondisclosure, a survey was administered to physicians who had received payments that were not disclosed.

**Results:** The overall rate of disclosure was 71.2% (245 of 344 payments). For payments that were directly related to the topic of the presentation at the meeting, the rate was 79.3% (165 of 208); for payments that were indirectly related, the rate was 50.0% (16 of 32); and for payments that were unrelated, the rate was 49.2% (29 of 59) ( $P=0.008$ ). In the multivariate analysis, payments were also more likely to have been disclosed if they exceeded \$10,000 ( $P<0.001$ ), were directed toward an individual physician rather than a company or organization ( $P=0.04$ ), or included an in-kind component ( $P=0.002$ ). Among the 36 physicians who responded to the survey regarding reasons for nondisclosure (response rate, 39.6%), the reasons most commonly given for nondisclosure were that the payment was unrelated to the topic of presentation at the annual meeting (38.9% of respondents) and that the physician had misunderstood the disclosure requirements (13.9%); 11.1% reported that the payment had been disclosed but was mistakenly omitted from the program.

**Conclusions:** In this study of self-reported conflict-of-interest disclosure by physicians at a large annual meeting, the rate of disclosure was 79.3% for directly related payments and 50.0% for indirectly related payments.

Roland, K.B., Larkins, T.L., Benard, V.B., Berkowitz, Z., & Saraiya, M. (2010). Content analysis of continuing medical education for cervical cancer screening. *Journal of Women's Health*, 19(4), 651-657.

**Background:** Since 2003, newer cervical cancer screening guidelines that include human papillomavirus (HPV) testing with cytology (HPV co-testing) call for extension of screening intervals in women who are cytology normal and HPV negative. Continuing medical education (CME) may



help increase knowledge and appropriate adoption of new technologies and guidelines. However, there are concerns that industry support of CME may bias messages favoring newer technologies without emphasizing the updated guidelines, especially less frequent testing recommendations. Our objectives were to assess availability and accuracy of web-based CME activities describing cervical cancer screening guidelines, screening intervals, and HPV testing.

**Methods:** We identified 20 web-based CME activities available between 2006 and

2008 and evaluated the content for messages related to HPV and natural history, cervical cancer screening guidelines, management of HPV abnormalities, and counseling tips for patients. In addition to content, we noted funding source, credit offered, and dates available.

**Results:** Most activities (80%) discussed the updated screening guidelines with

HPV co-testing for eligible women. Twelve activities (60%) referenced professional organization support of the extended screening interval with the HPV co-test, and three (15%) discussed the justification for extension of intervals for eligible women. Eight activities (40%) were funded by industry, seven of which included accurate, updated screening guidelines about extension of screening intervals.

**Conclusions:** Web-based CME activities generally support updated guidance for HPV co-testing and extended screening intervals but need more information on counseling patients and acceptability of extending screening intervals.

Steinman, M.A., Boscardin, C.K., Aguayo, L., & Baron, R.B. (2010). Commercial influence and learner-perceived bias in continuing medical education. *Academic Medicine*, 85(1), 74-79.

**Purpose:** To directly examine the relationship between commercial support of continuing medical education (CME) and perceived bias in the content of these activities.

**Method:** Cross-sectional study of 213 accredited live educational programs organized by a university provider of CME from 2005 to 2007. A standard question from course evaluations was used to determine the degree to which attendees believed commercial bias was present. Binomial regression models were used to determine the association between course features that may introduce commercial bias and the extent of perceived bias at those CME activities.

**Results:** Mean response rate for attendee evaluations was 56% (SD 15%). Commercial support covered 20%-49% of costs for 45 (21%) educational activities, and  $\geq 50\%$  of costs for 46 activities (22%). Few course participants perceived commercial bias, with a median of 97% (interquartile range 95%-99%) of respondents stating that the activity they attended was free of commercial bias. There was no association between extent of commercial support and the degree of perceived bias in CME activities. Similarly, perceived bias did not vary for 11 of 12 event characteristics evaluated as potential sources of commercial bias, or by score on a risk index designed to prospectively assess risk of commercial bias.

**Conclusions:** Rates of perceived bias were low for the vast majority of CME activities in the sample and did not differ by the degree of industry support or other event characteristics. Further study is

needed to determine whether commercial influence persisted in more subtle forms that were difficult for participants to detect.

Tabas, J.A., Boscardin, C., Jacobson, D.M., Steinman, M.A., Volberding, P.A., & Baron, R.B. (2011). Clinician attitudes about commercial support of continuing medical education: Results of a detailed survey. *Archives of Internal Medicine*, 171(9), 840-846.

**Background:** Pharmaceutical and medical device company funding supports up to 60% of accredited continuing medical education (CME) costs in the United States. Some have proposed measures to limit the size, scope, and potential influence of commercial support for CME activities. We sought to determine whether participants at CME activities perceive that commercial support introduces bias, whether this is affected by the amount or type of support, and whether they would be willing to accept higher fees or fewer amenities to decrease the need for such funding.

**Methods:** We delivered a structured questionnaire to 1347 participants at a series of 5 live CME activities about the impact of commercial support on bias and their willingness to pay additional amounts to eliminate the need for commercial support.

**Results:** Of the 770 respondents (a 57% response rate), most (88%) believed that commercial support introduces bias, with greater amounts of support introducing greater risk of bias. Only 15%, however, supported elimination of commercial support from CME activities, and less than half (42%) were willing to pay increased registration fees to decrease or eliminate commercial support. Participants who perceived bias from commercial support more frequently agreed to increase registration fees to decrease such support (2- to 3-fold odds ratio). Participants greatly underestimated the costs of ancillary activities, such as food, as well as the degree of support actually provided by commercial funding.

**Conclusion:** Although the medical professionals responding to this survey were concerned about bias introduced from commercial funding of CME, many were not willing to pay higher fees to offset or eliminate such funding sources.

*APPENDIX B. SUMMARY OF THE TEN DATA-BASED ARTICLES IN THE 2008 REPORT*

Table 2. Commercial Support and Bias in Accredited CME: Data-Based Articles (1988-2007)

Category	Study Citation	Conclusion
<b>Studies of the Relationship between Commercial Support and Bias in Accredited CME</b>	None	There is no published study that addresses the link between commercial support and bias in accredited CME activities.
<b>Studies of the Impact of Commercially Supported CME on Prescribing Practices</b>	Wazana, A. (2000). Physicians and the pharmaceutical industry: Is a gift ever just a gift?	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.
Bowman, M. A., & Pearle, D.L. (1988). Changes in drug prescribing patterns related to commercial company funding of continuing medical education.		
Orlowski, 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.		
<b>Studies of Physician Opinions about Bias in Commercially Supported CME</b>	Mueller, P. S. et al. (2007). Physician preferences and attitudes regarding industry support of CME activities.	Most physicians do not believe that commercially supported CME is biased or creates bias in their prescribing behaviors.
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., et al. (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 opinion of experts?	
<b>Studies of How to Measure Bias in Commercially Supported CME</b>	Barnes, B.E. et al. (2007). A risk stratification tool to assess commercial influences on continuing medical education.	Recently developed instruments could be used to address some dimensions of the issue of commercial support producing bias in CME activities.
	Takhar, J. et al. (2007). Developing an instrument to measure bias in CME.	

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 education. *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.

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.

Cornish, J.K., & Leist, J.C. (2006). What constitutes commercial bias compared with the personal opinion of experts? *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. *Journal of the American Medical Association*, 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., Goldfinger, S.E., & Fletcher, S.W. (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.

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 (e.g., 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  $81 \pm 44$  units before the symposium to a mean of  $272 \pm 117$  after the symposium ( $p < .001$ ). The usage of drug B changed from  $34 \pm 30$  units before the symposium to  $87 \pm 24$  units ( $p < .001$ ) 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. *Pharmacoepidemiology and Drug Safety*, 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? *Journal of the American Medical Association*, 283(3), 373-80.

**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.

## APPENDIX D. SEARCH PROCESS FOR ARTICLES IN THE 2014 REPORT

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### MEDLINE

#### Data-Based Articles

Two separate searches were performed in MEDLINE using the PubMed interface. The following terms/strategies were used:

["Education, Medical, Continuing"[Mesh] OR CME OR "continuing medical education"] AND [("Bias (Epidemiology)"[Mesh]) OR "Conflict of Interest"[Mesh]) OR (bias OR "conflict of interest" OR "commercial support")]. Used the Filters: 2007 – 2014; English Language

["Education, Medical, Continuing"[MAJR]] AND (commercial OR industr\* OR influence OR economics OR financ\* OR support). Used the Filters: 2007-2014; English Language

#### Viewpoint Articles

("JAMA: the journal of the American Medical Association"[Jour]) AND ("Education, Medical, Continuing"[Mesh] OR CME OR "continuing medical education"). Used the Filters: 2007 - 2014; English

("The New England journal of medicine"[Jour]) AND ("Education, Medical, Continuing"[Mesh] OR CME OR "continuing medical education"). Used the Filters: 2007-2014; English

("BMJ"[Jour]) AND ("Education, Medical, Continuing"[Mesh] OR CME OR "continuing medical education"). Used the Filters: 2007-2014; English

### CINAHL

[MH "Education, Medical, Continuing" OR continuing medical education OR CME] AND [commercial OR TX industr\* OR TX influence OR TX econom\* OR TX financ\* OR TX support]. Limits: 2007-2014; English

#### Academic Research Complete and Education Search Complete

The same search strategy was used in Academic Research Complete and Education Search Complete.

[SU medicine -- study & teaching (continuing education) OR continuing medical education OR CME] AND [commercial OR TX industr\* OR TX influence OR TX econom\* OR TX financ\* OR TX support]. Limits: 2007-2014; English