

The Effect of Industry Support on Participants' Perceptions of Bias in Continuing Medical Education

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Abstract

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 level seem quite low for all types of CME activities and is not significantly higher when commercial support is present.

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The role of industry—pharmaceutical companies and device makers—in underwriting the costs of certified continuing medical education (CME) for physicians, although firmly established, is increasingly controversial. The Accreditation Council for Continuing Medical Education (ACCME) reported that support of CME providers by industry reached \$1.2 billion, or more than 47% of total revenue to CME providers offering education certified for American Medical Association (AMA) Physician's Recognition Award Category 1 credits, in 2007.¹ The integrity of

professional medical education may be sacrificed if the content of educational activities is controlled or influenced by industry. Some argue that *any* industry support corrupts content, whereas others maintain that the alliance between industry and medicine, if properly managed, benefits both the education of physicians and their care of patients. In large measure, the lines are drawn between those who think that the risks of industry support of education can be managed and those who do not.

No published studies have addressed the relationship between commercial support and perceived bias in accredited CME activities.² Some research has explored the changes in physicians' prescribing behavior that are related to commercial funding.³ Limited attention has been given to the impact of commercially funded CME on prescribing behavior and on physicians' opinions about bias, but no evidence exists for a link between commercial funding and issues of bias that may result from such funding.² To help narrow this gap in the research by analyzing one institution's CME activities since 2004—the same year in which the ACCME updated its Standards for

Commercial Support—we sought to explore physicians' perceptions of the presence of bias in CME activities. We hypothesized that CME activities with industry support would be judged to have more commercial bias than those without such support and that activities with a single funding source could be particularly susceptible to bias.

Method

We analyzed the experiences at the Cleveland Clinic, an urban academic medical center with a large (>86,000 CME certificates in 2007) and diverse (live courses, enduring materials [e.g., a certified journal supplement, monograph, or DVD], Web-based programs, and other offerings for multiple specialties) CME curriculum that is operated by the Cleveland Clinic's Center for Continuing Education (CCE). In the most recent reaccreditation evaluation, the ACCME awarded the Cleveland Clinic's CME program "accreditation with commendation."

Data collection

The CCE maintains an electronic database that includes information

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about CME activity attendees' perceptions of bias, which are obtained from evaluations collected after CME activities are concluded. We analyzed the database to determine whether any relationship existed between perceived bias in CME activities and industry support. We also sought to determine whether activities with a single source of industry funding were at greater risk of perceived bias than those with no industry funding or funding from multiple sources. We analyzed all administratively completed activities certified in 2007 ($n = 346$): live courses, regularly scheduled series, journal-based activities, online activities, and enduring materials.

In their evaluations of CME activities, each participant is asked to respond to the following: (1) Please rate the degree (excellent, good, fair, or poor) to which this activity met the ACCME requirement that CME activities must be free of commercial bias for or against a specific product, and (2) Overall, was this activity satisfactorily free (yes/no) from commercial bias?

The CCE fully adheres to all ACCME requirements, including the Standards for Commercial Support. Additional oversight that is provided when a proposal calls for commercial support from a single funding source includes the requirement that a content expert with no connection to either the proposed activity or the proposed funding source review all content (slides, syllabus, and other material) to ensure that it is fair and balanced, that brand names are not used, and that no bias exists in the selection of subject matter. Moreover, a specific review evaluates the colors used in CME promotional materials and the general appearance of educational activity packaging to ensure that no color schemes or design formatting might be perceived as reflecting product branding. For CME activities with multiple funding sources, educational grants must support the entire CME activity, rather than a single speaker, presentation, or social event within the program.

Statistical methods

We computed the descriptive statistics for all factors, including the means and percentiles for the number of participants and the credits and frequencies for the type of activity and

Table 1
Industry Support of Certified CME Activities, Cleveland Clinic, 2007*

Variable	Industry funding sources		
	None: No. (%)	Single: No. (%)	Multiple: No. (%)
Activities	149 (43.1)	79 (22.8)	118 (34.1)
Credits	1,987 (53)	124 (3.3)	1,638 (43.7)
Participants	52,044 (54.5)	10,753 (11.3)	32,632 (34.2)

* CME indicates continuing medical education.

funding support. For each activity, we measured the percentage of participants who perceived that the activity was free of commercial bias by using a yes/no question, and we measured the degree to which it was free of commercial bias by using a four-point scale of excellent, good, fair, and poor. This scale offers participants a range within which to report their perceptions: An "excellent" rating is given when there is no commercial bias, and a "poor" rating is given when commercial bias is unacceptably high. Values are reported as means and 95% confidence limits. We used analysis of variance to evaluate whether there was any difference in the percentages of participants who considered the activity to be bias-free (answer of "yes" or "excellent") when they compared the different types of activities and funding support. We considered a value of $P < .05$ to be statistically significant. We used SAS software (version 9.1; SAS Institute Inc., Cary, North Carolina) for all analyses.

Results

The activity evaluations of a total of 95,429 participants in 346 separate activities formed the basis for this analysis. The number of participants per activity ranged from 1 to 3,080 (median: 276); on average, the response rate for participants completing the evaluation was approximately 70% for all activities. Participants were from all regions of the United States and from around the world. Although those from the U.S. Midwest predominated, we found no difference in perceptions of bias according to the location of the participants (data not shown). We divided the CME activities between those that did (56.9%) and did not (43.1%) have commercial support. Of the 197 activities with commercial support, 118 (60%) had funding from

more than one source (Table 1). The 79 activities (40% of those with commercial funding) with single-source funding were developed and implemented entirely with the use of funds provided by a single commercial interest in industry. The CME courses presented and evaluated were of several types, as shown in Table 2.

Overall, 97.3% to 99.2% of the participants (depending on type of activity) responded "yes" to question 2 ("Overall, was this activity satisfactorily free from commercial bias?"). The difference in perceived bias between different types of activities or different types of support was not statistically significant ($P > .05$; Table 3). Activities with no commercial support rated a "yes" response no more often than did those with funding from one or more commercial sources.

When participants were asked about the degree to which the activity was free of commercial bias (question 1: "Please rate the degree to which this activity met the ACCME requirement that CME activities must be free of commercial bias for or against a specific product."), a range of 0% to 0.7% of respondents (depending on the type of activity) gave

Table 2
Type of Certified CME Activities, Cleveland Clinic, 2007*

CME activity	Number (%)
Regularly scheduled series	64 (18.5)
Dinner meeting	37 (10.7)
Short live course (half-day or less)	24 (6.9)
Live course (all others)	89 (25.7)
Journal-related CME	17 (4.9)
Web-based CME	99 (28.6)
Other enduring materials	16 (4.6)

* CME indicates continuing medical education.

Table 3
CME Activity Participants' Perceptions of the Absence of Commercial Bias, Cleveland Clinic, 2007*

Factor	Responses that activity was free of commercial bias: Mean % (95% CL) [†]	
	Mean %	95% CL
Type of certified CME activity		
• Regularly scheduled series	97.3	(96.2, 98.4)
• Dinner meeting	99.0	(97.6, 100.0)
• Short live course	97.6	(95.7, 99.5)
• Live course	98.0	(97.0, 98.9)
• Journal-related CME	99.2	(97.0, 100.0)
• Web-based CME	98.5	(97.7, 99.4)
• Other enduring materials	99.2	(96.9, 100.0)
Type of industry support		
• None	98.0	(97.3, 98.8)
• Single source	98.5	(97.5, 99.5)
• Multiple sources	98.3	(97.4, 99.1)

* CME indicates continuing medical education; CL, confidence limits.
[†] Results correspond to ANOVA.

a response of “poor,” the lowest rating on the four-point scale (Table 4). Between 1.0% and 6.8% of respondents (again, depending on the type of activity) assigned the two lowest scores (“fair” or “poor”) to the CME activities in which they participated. Here, too, participants were no more likely to judge activities with no commercial funding than to judge those with funding from one or more sources as being relatively free of commercial bias.

It was surprising to us that there was a small numeric inferiority in performance of activities with no commercial funding as compared with activities with single- and multisource funding (“poor” ratings for 0.4% versus 0.1% and 0.2%, respectively). Activities that might be considered to be at greatest risk of bias—those with single sources of commercial funding—actually had the smallest proportion (0.1%) of “poor” ratings. These

differences between the ratings for all of the activities evaluated were not statistically significant.

Discussion

Our data support the supposition that a CME provider with suitable oversight to ensure compliance with ACCME Standards for Commercial Support can ensure that commercial funding does not affect commercial bias in an activity. Across a wide range of types of CME activities, no difference in commercial bias is apparent between those programs with and without commercial support.

The issue of industry-supported medical education is complicated and controversial, and opinions are strongly held. The ACCME has been sensitive to the risks and benefits of industry support for CME, and yet the U.S. Senate Finance Committee recently concluded that ACCME guidelines may be insufficient to prevent commercial bias within CME.⁴ The Macy Foundation recently issued a report⁵ with similar implications, in which it asserted that the presence of commercial support in continuing education risks distortion of content, may compromise evidence-based decision making, upholds a mindset among health professionals that CME should be paid for by others, and even impedes the adoption of effective modes

Table 4
Degree to Which CME Participants Perceived the CME Activities to Be Free of Commercial Bias, Cleveland Clinic, 2007*

Factor	Participants' perceptions of the degree of absence of commercial bias: Mean % (95% CL) [†]			
	Excellent	Good	Fair	Poor
Type of activity				
• Regularly scheduled series	73.3 (68.9, 77.7)	22.5 (19.1, 26.0)	3.5 (1.0, 5.9)	0.7 (0.2, 1.2)
• Dinner meeting	78.2 (72.2, 84.1)	20.6 (15.0, 26.1)	1.3 (0.0, 2.7)	0
• Short live course	73.5 (64.5, 82.5)	24.7 (16.2, 33.1)	1.7 (0.2, 3.2)	0.1 (0.0, 0.3)
• Live course	69.5 (66.1, 72.9)	27.6 (24.6, 30.6)	2.8 (1.5, 4.1)	0.1 (0.0, 0.2)
• Journal-related CME	78.3 (76.7, 79.8)	21.0 (19.5, 22.5)	0.6 (0.4, 0.8)	0.2 (0.1, 0.2)
• Web-based CME	74.3 (72.5, 76.1)	24.5 (22.7, 26.3)	0.9 (0.7, 1.2)	0.1 (0.0, 0.3)
• Other enduring materials	70.0 (56.2, 83.9)	23.2 (13.0, 33.3)	6.7 (0.0, 20.0)	0.1 (0.0, 0.3)
Type of support				
• None	73.6 (71.0, 76.3)	23.5 (21.3, 25.7)	2.5 (0.8, 4.2)	0.4 (0.1, 0.6)
• Single source	73.0 (69.4, 76.7)	25.5 (22.1, 29.0)	1.3 (0.6, 2.0)	0.1 (0.0, 0.2)
• Multiple sources	72.9 (70.2, 75.6)	24.5 (22.1, 26.9)	2.4 (1.4, 3.4)	0.2 (0.1, 0.2)

* CME indicates continuing medical education; CL, confidence limits.
[†] Rankings on a four-point scale were given in response to the statement, “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.”

of learning. The participants in the Macy Foundation’s effort felt that even a “firewall,” regardless of its strength, could not properly mitigate bias and that a new structure for the funding of CME should be sought.⁵

At the 2008 Annual Meeting of the AMA, its Council on Ethical and Judicial Affairs (CEJA) proposed a new model for medical education,⁶ quoted here:

- (1) Individual physicians and institutions of medicine, such as medical schools, teaching hospitals, and professional organizations (including state and medical specialty societies), must not accept industry funding to support professional education activities. Examples of such activities include, but are not limited to, industry funding for
 - (a) residency positions and clinical fellowships;
 - (b) didactic educational programs, such as live or Web-based continuing medical education activities;
 - (c) physician speakers’ bureaus; and
 - (d) travel, lodging, and amenities for participants of clinically relevant educational programming.
- (2) One exception to no industry support of professional education is when new diagnostic or therapeutic devices and techniques are introduced.

The AMA House of Delegates voted to return this report to the CEJA for reconsideration and specifically requested further consideration of the implications of such an action on all stakeholders. Many who read the CEJA’s recommendation, including us, felt that the lack of contemporaneous data on CME activities with industry funding that were conducted under current ACCME standards and guidelines was glaring.

The Association of American Medical Colleges (AAMC) recently published a report⁷ from its Task Force on Industry Funding of Medical Education, which called for the adaptation of policies to better manage industry involvement that creates conflicts of interest and that may undermine physician professionalism.⁷ The AAMC believes that medicine itself can, and should, effectively regulate all real or perceived conflicts of interest.

Creation of content for CME activities should be based on independent research identifying educational gaps in physician

performance or issues in patient care. One argument against industry involvement in CME is based on the potential risk of bias in an educational activity that is supported by industry, including the bias toward developing CME content that is of interest to commercial supporters.⁸ Safeguards that have been in effect for many years were recently enhanced to create a more secure firewall between industry and educational content. The ACCME’s updated Standards for Commercial Support,⁹ adopted in September 2004, require accredited CME providers to show “that everyone who is in a position to control the content of an education activity has disclosed all relevant financial relationships with any commercial interest to the provider” (Element 2.1) and that there is “a mechanism to identify and resolve all conflicts of interest prior to the education activity being delivered to learners” (Element 2.3). CME providers often augment these external standards with additional guidelines and requirements.

There may be particular concerns regarding commercial bias when a CME activity has a single (rather than multiple) industry funding source, because the topics of such activities may be more aligned with the business interests of the sole commercial source of support. To address this potential risk of bias, we developed special safeguards for the review process for activities with single-source funding. Our data reveal that the characteristics of an activity with single-source funding did not produce a significant variation in perceived commercial bias among participants, and such activities even showed an increase, albeit nominal, in the degree to which participants felt activities were free of bias.

The development of multiple lines of systematically collected, scientifically valid data may help to advance the discussion about commercial support for CME. The current study indicates that the risk of participants’ perceptions of bias in CME activities that receive industry funding is low. It seems unlikely that the rate of perceived bias will be reduced to zero. Participants detected some bias even in activities with no funding. It is up to the stakeholders in CME to determine the acceptable rate of bias. The CEJA recognizes that, although the goal of professional medical education is to be free of all bias, “this

ideal is never fully realized.”⁶ Evidence from the current study does not support the notion that industry support of CME undermines the integrity of professional education.

It seems reasonable to consider the degree to which CME participants perceive bias in CME activities. The current study provides limited data. Although the sample size is large and the types of CME activities surveyed range widely, the data represent the experience of a single, large academic medical center with robust resources from which to administer its CME programs. Similar data are needed from other types of CME providers, including commercial CME providers, small, community-based providers, and others. Nevertheless, it is reasonable to conclude that the perception of commercial bias does not have a strong correlation to the presence of commercial funding.

The more subtle ways in which commercial support for CME creates bias cannot be easily measured, but every effort should be made to maintain and monitor scientific integrity. There can be little question that industry desires to establish and maintain personal rapport with physicians and that industry’s ultimate goal is commercial in nature. However, it is clear from our experience, although largely unsupported by contemporaneous studies, that such a goal is not inimical to the goal of unbiased, high-quality medical education. It is apparent from the current study that the effect of industry support on participants’ perceptions of bias within CME activities is minimal. We believe that this study lends credence to our contention that accredited CME providers with suitable oversight to ensure compliance with ACCME Standards for Commercial Support are proven to be successful and that the prohibition of commercial support for CME is not needed.

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