CME and Bias

elimination vs. illumination

Suzette Tomaska, MBA
Associate Director, Medical Education
Purdue Pharma L.P.

Disclosures

Currently employed at Purdue Pharma L.P.

The information, opinions and views expressed here are my own and do not necessarily reflect those of Purdue Pharma L.P. or of this organization.

I have no interests in selling a technology, program, product, and/or service to CME professionals.

Educational Objectives

- **Define bias related to commercial support including the challenges in today's CME environment**

- **Explain findings from studies surrounding perceptions of bias in CME among faculty and learners**

- **Identify practical recommendations for industry, CME Providers and partnering organizations to avoid bias in CME**

The Current State

- Industry currently funds over 60% of CME (Takhar, 2007)
  - With this increase in commercial support and decrease in institutional support since 1990's then there is natural **increasing bias potential** (Harrison, 2003)
- Reorganization of the U.S. health care system – reorganization of infrastructure of CME?
- While there are current measures to identify and resolve conflict of interest relevant to potential commercial bias per the ACCME, there is no guideline for an acceptable **level of bias**
- Achieving no bias is argued to be difficult to attain

Harrison, V. 2003. "The Uncertain Future of Continuing Medical Education: Commercialism and Shifts in Funding" The Journal of Continuing Education in the Health Professions. 23. 198-209.

Takhar, J. 2007. "Developing an Instrument to Measure Bias in CME" The Journal of Continuing Education in the Health Professions. 27 (2): 118-123.

Definition of Bias

- "An unfair influence or distortion of facts" (Takhar, 2007,119).

- Merriam-Webster defines bias as:
  - "an inclination of temperament or outlook; especially a personal and sometimes unreasoned judgment and systematic error introduced into the sampling or testing by selecting or encouraging one outcome or answer over others."

Takhar, J. 2007. "Developing an Instrument to Measure Bias in CME" The Journal of Continuing Education in the Health Professions. 27 (2): 118-123.

Why is Defining Bias Important?

- Relevance and significance to the ACCME Standards for Commercial Support 1,2 and 6 (independence, resolution of personal conflict of interest, and disclosures relevant to potential commercial bias)(Lichti, 2007).
- Audiences may not be able to detect bias reliably or consistently (Price et al, 2009)
- No common definition of bias so audience responses may vary greatly (Price et al, 2009)
- "CME Providers should define commercial bias for **participants, faculty, and planners** and **provide education** about that definition." (Cornish et al, 2006).

Cornish et al. 2006. *"What Constitutes Commercial Bias Compared with the Personal Opinion of Experts".*The Journal of Continuing Education in the Health Professions (26).

Lichti, A.C. 2007 "CME in Practice: Evaluating Commercial Bias". Accessed July 22, 2009.

Price, D., Carol Havens, Philip Bellman. 2009. "Audience Assessment of Bias in Continuing Medical Education Programs" Journal of Continuing Education of the Health Professions. 29.

Physician's Perception of Bias

Based on the 2008 *Medical Meetings* annual Physician's Preferences in CME Survey (Hosansky, 2008) (N=127)

- When asked if physicians have observed commercial bias in CME activities:
  - 17% - never
  - 39% - rarely
  - 38% - occasionally
  - 5% - frequently

Hosansky, T. 2008. "Bias in the Hot Seat". Medical Meetings (January/February). 18-23.

Summary of Studies-
Commercial Support and Bias

Categories	Study Citations	Conclusions
Studies of the Relationship between Commercial Support and Bias in Accredited CME	None	There is no published study that addresses the link between commercial support and bias in accredited CME activities.
Studies of the Impact of Commercially Supported CME on Prescribing Practices	Wazana, A. (2000). Physicians and the pharmaceutical industry: Is a gift ever just a gift?	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.	

Cervero, R. and Jiang He. 2008. The Relationship between Commercial Support and Bias in Continuing Medical Education c Activities: Review of the Literature.

Summary of Studies-
Commercial Support and Bias

Studies of Physician Opinions about Bias in Commercially Supported CME	Mueller, P. S. et al. (2007). Physician preferences and attitudes regarding industry support of CME activities.	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. (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.	

Studies of How to Measure Bias in Commercially Supported CME	Barnes, B.E. et al. (2007). A risk stratification tool to assess commercial influences on continuing medical.	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.	

Cervero, R. and Jiang He. 2008. "The Relationship between Commercial Support and Bias in Continuing Medical Education Activities: Review of the Literature."

The Review of the Literature Shows:

- “There is no empirical evidence to support or refute the hypothesis that CME activities are biased” (Cervero and He, 2008, 8).
- However, the evidence does show that CME activities funded by commercial interests **can change** prescribing practices of physicians.
- Although the literature shows that this can improve patient care there are no **studies** on the impact of these prescribing changes on patient care and if they were in the best interest of the patient.
- Recent research does show judgment of the physician can be influenced in unconscious ways but they may not be aware of it.

Cervero, R. and Jiang He. 2008. The Relationship between Commercial Support and Bias in Continuing Medical Education Activities: A Review of the Literature.

Bias vs. Personal Opinion

Commercial bias: "..information presented in a manner that attempts to sway participants' opinions in favor of a particular commercial product for the express purpose of furthering a commercial entity's business, **meaning a deliberate intent to mislead**"

Personal Opinion: "..a belief held by an individual based on his or her experiences in the practice of health care, **meaning no intent to mislead but rather to share knowledge formed from personal experiences**"

Cornish et al. 2006. *"What Constitutes Commercial Bias Compared with the Personal Opinion of Experts"*. The Journal of Continuing Education in the Health Professions (26).

Based on the study by Cornish et al (2006):

Five of the top 10 Actions Perceived by HCPs as Commercial Bias (N=212)

1. Only focusing on 1 agent, device or procedure when others exist
2. Not providing a balanced presentation
3. Faculty have relationships with grantor
4. References to inappropriate studies (promotional, bad design)
5. Inconsistent use of brand names

- **BUT More than ½ HCPs said that "overall impression" contributed to their perception of bias, rather than 1 or 2 items**
- **Overall, the HCPs in this study could separate bias from personal opinion but they still said there were indicators of bias, even for activities that were certified for AMA PRA Category 1 Credit**

Cornish et al. 2006. *"What Constitutes Commercial Bias Compared with the Personal Opinion of Experts".* The Journal of Continuing Education in the Health Professions (26).

Areas to Consider

- We do realize bias in CME does exist…but it is recommended to ***educate on bias*** upfront by:
  - **Encouraging** the faculty to express to the audience when they are stating their personal opinion
  - **Explaining the common actions that infer bias** to the planners, faculty and learners (Cornish et al. 2006).

Then we are approaching <u>identification</u> and <u>clarification</u> of bias from various approaches

Instruments to Measure Bias

- **Why Measure?**
  - Price et al (2009) - One standard response bias question vs. A 9-item questionnaire
  - **Results:** 89 % perceived no bias with "This presentation was free of commercial bias" question
  - However of responses to the 9 item questionnaire, "all sessions had a least some questions answered in a manner that would indicate possible bias" (2009, 76).

- **Bias Evaluation Tool** (Takhar et al, 2007)
  - 14 item instrument – retrospectively and prospectively used
  - Valid and reliable via Chronbach's alpha for "illuminating bias in CME events" (122).
  - Intended as multistaged process:
    - Expert review of materials prior to CME activity
    - Random evaluation of live events
    - Evaluation from participants
  - Can also be used prospectively
    - To train CME participants how to identify bias
    - To train speakers and providers to identify and avoid bias

- **Risk Stratification Tool** (Barnes et al, 2007)
  - 12 item instrument with numeric weighting
  - Prospectively used
  - To predict and manage risk

Price, D., Carol Havens, Philip Bellman. 2009. "Audience Assessment of Bias in Continuing Medical Education Programs" Journal of Continuing Education of the Health Professions. 29.

Takhar, J. 2007. "Developing an Instrument to Measure Bias in CME" The Journal of Continuing Education in the Health Professions. 27 (2): 118-123. Barnes et al. 2007

Recommendations to Control Bias

Providers

- **Address the Learner**
  - There is a level of unconscious influence - so be extra diligent
  - Many providers already use a basic tool to ask **if** the participant perceived bias, but are many following-up to ask the learner **what factors they observed contributed to the bias**? (Lichti, A. 2007).
    - Assess the percent of bias perceived after an activity
    - Re-review the content via internal steering committee and/or external, experts review (use 3 or more to get a mean average)
    - Follow up with participants to recognize their concern over bias – true dedication to learner needs

Lichti, A.C. 2007 "CME in Practice: Evaluating Commercial Bias"

Recommendations to Control Bias

Providers (Cont'd)

- **Address Industry:**
  - Include and share your processes that **identify and resolve** COI in your grant submission paperwork – along the interest of full disclosure
  - Utilize instruments to **measure bias** in commercially supported CME before and after an activity BUT **consistently** use these tools and report findings
- **Address faculty and contributors:**
  - Re-utilize instruments to train and educate on bias

Recommendations to Control Bias

- **Industry:**
  - Fund multi-supported programs as the standard
  - Rigorously review grant submissions to:
    - Ensure that resolution of conflicts of interest process/policy is in place
      - Include this in the LOA as an exhibit emphasizing attention to ACCME Guidelines
  - Closely review program evaluations for detail beyond whether bias was just detected, but what factors contributed to the learners' perception of this
  - Audit/attend supported programs as extra measure