



Using Research, Professional Opinions, and Organizational Practices to Help Validate ACCME's Standards for Commercial Support: A Teaching Tool

The ACCME recognizes that an important component of recognized state medical societies and accredited providers' educational efforts with staff and physician volunteers on new Elements within the ACCME's Standards for Commercial Support will be the validity of these requirements. This reference list was developed to offer research, professional opinions, and organizational practices that support face validity of ACCME's Standards for Commercial Support and concurrent validity of ACCME's approach to resolving conflicts of interest.

Commercial Bias in CME Activities

"When commercial interests¹ contribute funds and services for the development of CME activities, it is considered commercial support. Commercial support has significantly enhanced the ability of the CME enterprise to fulfill its purpose. However, commercial support has the potential to introduce commercial bias that threatens the integrity of the CME enterprise. When individuals have financial relationships with commercial interests and are in a position to control the content of CME, there is also the potential for commercial bias. The Accreditation Council for Continuing Medical Education (ACCME) believes that CME must be free of the control of commercial interests. The ACCME believes that this independence from commercial interests will help ensure that CME is free of commercial bias" (*Excerpted from Preamble to ACCME's Updated Standards for Commercial Support, September 2004*).

Issue #1:

Why is it necessary to have requirements to guard against commercial bias in CME Activities... aren't physicians able to detect and guard against commercial bias themselves?

Research has shown that while physicians do not believe their behavior can be modified by interactions with commercial interests, these interactions actually DO change physician performance in favor of the commercial interest. These interactions include attendance at conferences.

References:

- Chren, M.M., & Landefeld, C.S. (1994). Pharmaceutical promotion and physician requests to hospital formularies. *Journal of the American Medical Association*, 271, 684-9.
- Lurie, N., et al. (1990). Pharmaceutical representatives in academic medical centers: Interaction with faculty and housestaff. *Journal of General Internal Medicine*, 5, 240-3.
- Orlowski, J.P., & Wateska, L. (1992). The effects of pharmaceutical firm enticements on physician prescribing patterns. There's no such thing as a free lunch. *Chest*, 102, 270-3.
- Steinman, M.A., Shlipak, M.G., & McPhee, S.J. (2001). Of principles and pens: Attitudes and practices of medicine housestaff toward pharmaceutical industry promotions. *American Journal of Medicine*, 110, 551-7.
- Wazana, A., (2000). Physicians and the pharmaceutical industry: Is a gift ever just a gift? *Journal of the American Medical Association*, 283, 373-380.

Issue #2:

Is commercial support of CME activities really threatening the integrity of the CME enterprise?

Published commentary from physicians and news reports indicate that elements of the medical profession and the public are concerned about industry's support of the medical profession and physicians' educational pursuits.

References:

- Adams, C. (2001, May 14). Doctors on the run can dine 'n' dash in style in New Orleans. *Wall Street Journal*. pp. A1, A6.
- Blumenthal, D, (2004). Doctors and drug companies. *The New England Journal of Medicine*, 351, 1885-1900.

¹ ACCME Definition: A commercial interest is any proprietary entity producing health care goods or services, with the exemption of non-profit or government organizations and non-health care related companies. (from 2004 Updated Standards for Commercial Support, Standard 1.1)

Eichenwald, K., & Kolata, G. (1999, November 30). Hidden interests: A special report. When physicians double as businessmen. *The New York Times*. p. C16.

McKinney, W.P., et al. (1990). Attitudes of internal medicine faculty and residents toward professional interaction with pharmaceutical sales representatives. *Journal of the American Medical Association*, 264, 1693-7.

Packer, S., & Parke, D.W. (2004). Ethical concerns in industry support of continuing medical education. *Archives of Ophthalmology*, 122, 773-776.

Relman, A.S., & Angell, M. (2002). America's other drug problem. *The New Republic*. 227(25). 27-41.

Issue #3:

For the past 12 years, accredited organizations have been disclosing financial relationships between teachers and commercial interests to physician learners before an activity begins. Who has said disclosure isn't enough? Why does the disclosure practice in CME need to change to "resolve conflicts of interest"? Is the ACCME asking teachers in CME to go above and beyond what other parts of the medical profession ask of physicians?

ACCME's updated Standards underscore continued voluntary self-regulation by the CME community. The ACCME recognized the importance of responding to concerns from the elements of the public and the profession. At the same time, there was a need to update the Standards for Commercial Support to keep up with today's legal and regulatory environment that includes litigation under the anti-kickback and false claims statutes and investigations by the Office of the Inspector General. In this environment, it was critical for the CME community to make explicit its commitment to improvements or quality in healthcare and not specific proprietary business interests. "Resolving Conflicts of Interest," in conjunction with disclosure to the physician learners, serves as a mechanism to ensure public trust in the validity of CME.

The ACCME's expectation that conflicts of interest in CME activities be managed is consistent with other components of medicine such as research and publishing. A number of academic institutions and physician membership organizations have developed their own policies on resolving conflicts of interest. In this sense, CME practices to manage conflicts of interest support the medical field's move to respond to concerns over commercial influence in the profession.

References:

Studdert, D. M., Mello M. M., Brennan T. A., (2004). Financial conflicts of interest in physicians' relationships with the pharmaceutical industry — Self-regulation in the shadow of federal prosecution. *New England Journal of Medicine*, 351, 1891-1900.

American Society of Clinical Oncology. (2003). American society of clinical oncology: Background for update of conflict of interest policy. *Journal of Clinical Oncology*, 21, 2387-2393.

Association of American Medical Colleges. (2001). Protecting subjects, preserving trust, promoting progress—Policy and guidelines for the oversight of individual financial interests in human subjects. Report from AAMC Task Force on Financial Conflicts of Interest in Clinical Research.

Davidoff, F, DeAngelis, C.D., Drazen, J.M, et al. (2001). Sponsorship, authorship, and accountability. *Canadian Medical Association Journal*, 165, 786-788.

International Committee of Medical Journal Editors. (2004). Uniform requirements for manuscripts submitted to biomedical journals: writing and editing for biomedical publication. Retrieved January 19, 2005, from <http://www.icmje.org/icmje.pdf>.

U.S. Food and Drug Administration. (2000). FDA Guidance on conflict of interest for advisory committee members, consultants and experts. Retrieved January 19, 2005, from <http://www.fda.gov/oc/advisory/conflictinterest/guidance.html>

Yale University. (2005). Yale University Conflict of Interest/Commitment Disclosure Form. Retrieved January 19, 2005, from http://www.yale.edu/provost/html/disclosure_combined.pdf

SELECTED ABSTRACTS:

Physicians' behavior and their interactions with drug companies. A controlled study of physicians who requested additions to a hospital drug formulary.

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OBJECTIVE--It is controversial whether physicians' interactions with drug companies affect their behavior. To test the null hypothesis, that such interactions are not associated with physician behavior, we studied one behavior: requesting that a drug be added to a hospital formulary. **DESIGN**--Nested case-control study. **SETTING**--University hospital. **PARTICIPANTS**--Full-time attending physicians. Case physicians were all 40 physicians who requested a formulary addition from January 1989 through October 1990. Control physicians were 80 randomly selected physicians who had not made requests. **MAIN EXPOSURE MEASURE**--Physician interactions with drug companies, as determined by survey of physicians (response rate, 88% [105/120]). **RESULTS**--Physicians who had requested that drugs be added to the formulary interacted with drug companies more often than other physicians; for example, they were more likely to have accepted money from companies to attend or speak at educational symposia or to perform research (odds ratio [OR], 5.1; 95% confidence interval [CI], 2.0 to 13.2). Furthermore, physicians were more likely than other physicians to have requested that drugs manufactured by specific companies be added to the formulary if they had met with pharmaceutical representatives from those companies (OR, 13.2; 95% CI, 4.8 to 36.3) or had accepted money from those companies (OR, 19.2; 95% CI, 2.3 to 156.9). These associations were consistent in multivariable analyses controlling for potentially confounding factors. Moreover, physicians were more likely to have requested formulary additions made by the companies whose pharmaceutical representatives they had met (OR, 4.9; 95% CI, 3.2 to 7.4) or from whom they had accepted money (OR, 1.7; 95% CI, 1.0 to 2.7) than they were to have requested drugs made by other companies. **CONCLUSION**--Requests by physicians that drugs be added to a hospital formulary were strongly and specifically associated with the physicians' interactions with the companies manufacturing the drugs.

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Of principles and pens: attitudes and practices of medicine housestaff toward pharmaceutical industry promotions.

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PURPOSE: Little is known about the factors that influence housestaff attitudes toward pharmaceutical industry promotions or, how such attitudes correlate with physician behaviors. We studied these attitudes and practices among internal medicine housestaff. **SUBJECTS AND METHODS:** Confidential surveys about attitudes and behaviors toward industry gifts were distributed to 1st- and 2nd-year residents at a university-based internal medicine residency program. **RESULTS:** Ninety percent of the residents (105 of 117) completed the survey. A majority of respondents considered seven of nine types of promotions appropriate. Residents judged the appropriateness of promotions on the basis of their cost (median percentage of items considered appropriate 100% for inexpensive items vs. 60% for expensive ones) more than on the basis of their educational value (80% for educational items vs. 75% for noneducational ones; $P < .001$ for comparison of appropriateness based on cost vs. educational value). Behaviors were often inconsistent with attitudes; every resident who considered conference lunches ($n = 13$) and pens ($n = 18$) inappropriate had accepted these gifts. Most respondents (61%) stated that industry promotions and contacts did not influence their own prescribing, but only 16% believed other physicians were similarly unaffected ($P < .0001$). Nonetheless, more than two thirds of residents agreed that it is appropriate for a medical institution to have rules on industry interactions with residents and faculty. **CONCLUSIONS:** Residents hold generally positive attitudes toward gifts from industry, believe they are not influenced by them, and report behaviors that are often inconsistent with their attitudes. Thoughtful education and policy programs may help residents learn to critically appraise these gifts.

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We surveyed faculty and residents from seven hospitals affiliated with three academic internal medicine training programs about their perceptions of the informational and service benefits vs the risks of ethical compromise involved in interactions with pharmaceutical sales representatives. Questionnaires were returned by 467 (81%) of 575 physicians surveyed. Residents and faculty generally had somewhat negative attitudes toward the educational and informational value of detailing activities at their institutions but indicated that representatives supported important conferences and speakers. Residents were more likely than faculty to perceive contacts with sales representatives as potentially influencing physician decision making. Sixty-seven percent of faculty and 77% of residents indicated that physicians could be compromised by accepting gifts. More than half of the physicians who suggested that such compromise was possible indicated that acceptance of gifts worth more than +100 from drug companies would be likely to compromise a physician's independence and objectivity. A majority of both faculty and house staff favored eliminating presentations by pharmaceutical representatives at their hospitals. Only 10% thought they had had sufficient training during medical school and residency regarding professional interaction with sales representatives.

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The effects of pharmaceutical firm enticements on physician prescribing patterns. There's no such thing as a free lunch.

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

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