

THEME ARTICLE

Can Industry-Funded CE/CME Be Unbiased? Current Insights on an Old Question

Eve J. Wilson, PhD, FACEHP / Medical Director, PlatformQ Health, Needham, MA

ABSTRACT

Over the years, multiple reports and editorials have asserted that continuing education/continuing medical education (CE/CME) that is funded by the pharmaceutical or device industry is biased in favor of the funder’s product(s). But starting in the early 2000’s, several stakeholder organizations began establishing guidance to prevent such bias, and currently there are many protections in place. In particular, the Accrediting Council for Continuing Medical Education (ACCME), the accrediting body for all national organizations that provide CE/CME, established and continues to update specific standards to prevent bias, and all ACCME-accredited organizations must comply with these and other standards to maintain their accreditation in good standing. A careful review of the literature has identified just a few studies that explore the question of bias in CE/CME, all published from 2010 – 2012. None of these studies found evidence of bias in CE/CME, and no empirical studies on the topic have since been published. Thus it seems that the protections in place are working, although more rigorous and definitive research is needed. Nevertheless, continued vigilance is paramount, and medical writers play an important role in providing oversight of CE/CME by ensuring that content they develop is fair and unbiased, as well as accurate and intended to promote optimal patient care.

There is a widespread and persistent assumption that continuing education/continuing medical education (CE/CME) that is supported via educational grants from pharmaceutical or device companies is biased toward the supporter’s product or products. But is the assumption fair, and is there evidence to support it? What do clinician learners have to say? This article explores requirements intended to prevent industry bias in CE/CME, published research on bias in CE/CME activities, and practical steps medical writers can take to ensure that CE/CME content is accurate and objective.

CURRENT ACCREDITATION REQUIREMENTS FOR PREVENTING COMMERCIAL BIAS

For many years there have been layers of protections to prevent commercial bias in CE/CME from various stakeholders in CE/CME. Protections currently in place include codes of ethics (from the Pharmaceutical Researchers and Manufacturers of America, the Advanced Medical Technology Association, and the American Medical Association),¹⁻³ compliance guidance from the Department of Health and Human Services’ Office of Inspector General,⁴ and accreditation requirements from the Accrediting Council for Continuing Medical Education (ACCME).⁵ With regard to CE/CME content, ACCME’s *Standards for Integrity and Independence in Accredited Continuing Education* offers the most detailed guidance.⁵

The ACCME is the accrediting body for all national organizations that provide CE/CME. It has a long history of concern about commercial influence in CE/CME. The first ACCME standards were released in 1992;⁶ major revisions were released in 2004 and again in 2020. The revisions have (among other priorities) progressively better defined and further restricted industry influence. The most current standards focus on 5 aspects of CE/CME funding, development, and delivery (Table 1); the most relevant for development of CE/CME content are standards 1 and 2.

Table 1. The Accreditation Council for Continuing Medical Education’s Standards for Integrity and Independence in Accredited Continuing Medical Education⁵

Standard 1	Ensure content is valid.
Standard 2	Prevent commercial bias and marketing in continuing medical education.
Standard 3	Identify, mitigate, and disclose relevant financial relationships.
Standard 4	Manage commercial support appropriately.
Standard 5	Manage ancillary activities offered in conjunction with commercial support.

The content validity standard (Standard 1) holds accredited providers responsible for ensuring their education is fair and balanced and supports safe and effective patient care. Standard 1 specifies that research discussed in CE/CME must “adhere to generally accepted standards of experimental design, data collection, analysis, and interpretation” and that recommendations for patient care must be “based on current science, evidence, and clinical reasoning.”⁵

Standard 2 requires that all decisions regarding planning, delivery, and evaluation of CE/CME be made free of influence or involvement from “ineligible companies” (formerly called “commercial interests”). Ineligible companies are defined as those “whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used on or by patients.” Importantly, ineligible companies also cannot recommend, or even suggest, names of faculty for CE/CME programs.⁵

PERCEPTIONS OF BIAS AMONG CLINICIAN LEARNERS: WHAT DOES THE RESEARCH SHOW?

To date, numerous reports and editorials have asserted that commercial support introduces bias in CE/CME; some have even called for a total ban.⁷⁻⁹ But none cite empirical evidence to support bias due to commercial support—perhaps because so few studies have systematically examined the issue. A careful literature search turned up only 4 studies conducted after 2004 (when ACCME first released more rigorous standards) that relied specifically on feedback from clinicians participating in CE/CME.

One study examined 95,000 evaluation responses across 346 CE/CME activities held in 2007 by the Cleveland Clinic Center For Continuing Education.¹⁰ The analysis found that a mean of 98.4% participants responded “yes” (vs “no”) to a question about whether the activity was “satisfactorily free” of commercial bias, and a mean of 97.2% participants responded with “excellent” or “good” to the question about the degree to which the activity was free of commercial bias. When analyzed based on commercial support, activities were considered free of commercial bias by 98.5% of respondents for activities with a single support source, 98.3% of respondents for activities with multiple support sources, and 98.0% of respondents for activities with no commercial support.

A second study examined evaluation responses for 213 accredited, live educational courses offered by the University of California at San Francisco from 2005 to 2007.¹¹ About 33% of courses had no commercial support; the others had varying levels of support. This study found that a median 97% of participants perceived no commercial bias (median number of participants per program was 132). Moreover, no associations were observed between the

degree of perceived bias and the extent or absence of commercial support.

A third study looked at perceived bias in evaluations from 1,064,642 physician participants in 3,137 Medscape online CME activities, of which 28% were supported by industry.¹² Evaluations asked whether the activity was “presented objectively and free of commercial bias,” with these answer choices: strongly agree, agree, no opinion, disagree, or strongly disagree. Overall, just 0.63% of respondents disagreed or strongly disagreed with the statement; that rate was slightly higher (0.84%) for commercially supported activities and slightly lower (0.48%) for those with no commercial support.

Interestingly, the fourth study examined perceptions of bias in live CME programs that received *no* commercial support, held in 2006, 2007, and 2010.¹³ More than 1,500 attendees were asked whether they thought commercial support influenced content selection for the overall program and for individual lectures. From 6% to 9% responded “yes” or “somewhat” across programs; of those who rated a program as biased, about 75% also rated one or more lecture as biased. These findings speak to a nuance well beyond the scope of this article—specifically, that clinicians may perceive commercial influence as something beyond just commercial support.

Based on these findings, it seems fair to conclude that at least from clinicians’ point of view, commercial bias in CME is quite low and independent of commercial support. However, more—and more definitive—research is needed. In the meantime, it remains crucial to safeguard against bias. All those involved in content development, including medical writers, must be aware of that potential and work to mitigate the risk.

PRACTICAL STEPS FOR MEDICAL WRITERS

Perhaps the 2 most important (and interrelated) concepts for medical writers to uphold, vis-à-vis the ACCME standards, are *ensuring content validity* and *ensuring that content is fair and balanced*.

Often medical writers work closely with faculty to develop CME content. A common approach is for faculty to send a set of slides that the writer then organizes, carefully fact-checks, and frequently develops further. Another approach is for medical writers to craft content that faculty then review. Either way, the medical writer must provide oversight to ensure the content is accurate and free from marketing messages or other commercial influence.

Regarding content validity, use of appropriate source material is key. Sources should include peer-reviewed clinical and scientific articles, published preferably in high impact factor journals. Published abstracts outlining

research to be presented at medical meetings are often peer reviewed and can serve as acceptable references. Posters based off these abstracts are generally not peer reviewed, but often present the most current information available and so may require a judgment call. Other valid resources include guidelines or special reports published by government sources or medical societies, or textbooks—although textbooks may not have the most current information. Many medical writers like UpToDate as comprehensive resource for clinical care, but it is not suitable as an original source.

Sources to avoid include blogs, Wikipedia, or other non-scholarly websites; other CE/CME programs; ineligible companies' websites or press releases; and of course, outdated or obsolete references.

Ensuring that content is fair and balanced means that, by ACCME's definition, information and recommendations or emphases in CE/CME "fairly represent" and are "based on a reasonable and valid interpretation" of information available on the topic.⁵ The box provides a checklist to help medical writers to develop CE/CME content that is fair and balanced.

Ensuring CE/CME Content Is Fair and Balanced

- Use the best available source materials.
- Avoid focus on any one treatment.
- Give equal time to benefits and risks of treatment.
- Avoid brand names for agents, devices, or procedures; if it is necessary to use a brand name for one intervention, then provide brand names for all interventions.
- Be transparent about emerging therapies, including what clinical trial phase they are in.

CONCLUSION

There are many protections against bias in CME; prominent among them are the current ACCME Standards. On review of published studies, these protections would seem to be working, however, more rigorous and definitive research is warranted. In the meantime, medical writers can play an important role in oversight of CE/CME by ensuring that content they develop is fair, balanced, unbiased, and accurate, with a goal of promoting safe and effective patient care.

Author declaration and disclosures: *The author notes no commercial associations that may pose a conflict of interest in relation to this article. Statements and opinions presented in this article are the author's own and do not necessarily reflect those of current or past employers or contractors.*

Author contact: *evejwilson1@gmail.com*

References

1. Pharmaceutical Researchers and Manufacturers of America (PhRMA). Code on interactions with health care professionals. PhRMA; 2021. Accessed August 25, 2023. <https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/P-R/PhRMA-Code---Final.pdf>
2. Advanced Medical Technology Association. AdvaMed code of ethics on interactions with U.S. health care professionals. Advanced Medical Technology Association; 2023. Accessed August 25, 2023. <https://www.advamed.org/wp-content/uploads/2023/06/2023-AdvaMed-Code-of-Ethics.pdf>
3. Ethics opinions. American Medical Association. <https://code-medical-ethics.ama-assn.org/opinions?search=medical+education>
4. Department of Health and Human Services, Food and Drug Administration. Guidance for industry: industry-supported scientific and educational activities. *Fed Regist.* 1997; 62(232):64074-64092. Accessed August 25, 2023. <https://www.fda.gov/media/70844/download>
5. Accreditation Council for Continuing Medical Education. Standards for integrity and independence in accredited continuing education. 2020. Accessed August 25, 2023. <https://www.accme.org/accreditation-rules/standards-for-integrity-independence-accredited-ce>
6. McMahon GT. Changes to the standards for integrity and independence in continuing medical education. *JAMA.* 2021;325(18):1833-1834. doi: 10.1001/jama.2021.0213
7. Fletcher SW. Chairman's summary of the conference. Bermuda, 2007. In: Hager M, ed. *Continuing Education in the Health Professions: Improving Healthcare Through Lifelong Learning.* Josiah Macy, Jr. Foundation; 2008. Accessed August 25, 2023. https://macyfoundation.org/assets/reports/publications/macy_conted_1_7_08.pdf
8. The Pew Charitable Trusts. Conflict-of-interest policies for academic medical centers: recommendations for best practices. Pew Trusts. Published December 18, 2013. Accessed August 25, 2023. <https://www.pewtrusts.org/en/research-and-analysis/reports/0001/01/01/conflictsofinterest-policies-for-academic-medical-centers>
9. Fugh-Berman A. Industry-funded medical education is always promotion—an essay by Adriane Fugh-Berman. *BMJ.* 2021;373:n1273. doi: 10.1136/bmj.n1273
10. Kawczak S, Carey W, Lopez R, Jackman D. The effect of industry support on participants' perceptions of bias in continuing medical education. *Acad Med.* 2010;85(1):80-84. doi: 10.1097/ACM.0b013e3181c42f80
11. Steinman MA, Boscardin CK, Aguayo L, Baron RB. Commercial influence and learner-perceived bias in continuing medical education. *Acad Med.* 2010;85(1):74-79. doi: 10.1097/ACM.0b013e3181c51d3f
12. Ellison JA, Hennekens CH, Wang J, Lundberg GD, Sulkes D. Low rates of reporting commercial bias by physicians following online continuing medical education activities. *Am J Med.* 2009;122(9):875-878. doi: 10.1016/j.amjmed.2009.02.026
13. Goldfarb E, Baer L, Fromson JA, Gorrindo T, Iodice KE, Birnbaum RJ. Attendees' perceptions of commercial influence in noncommercially funded CME programs. *J Contin Educ Health Prof.* 2012;32(3):205-211. doi: 10.1002/chp.21146