

Officers 2008-2009

February 20, 2009

President

Melinda Steele, M.Ed.
Texas Tech University
Health Sciences Center

American Medical Association

Regina M. Benjamin, MD, MBA
Chair, Council on Ethical and Judicial Affairs

Past-President

Jocelyn Lockyer, Ph.D.
University of Calgary
Faculty of Medicine

Claudette C. Dalton, MD
Chair, Council on Medical Education

Dear Dr. Benjamin and Dr. Dalton,

President-Elect

Lois Colburn
University of Nebraska
Medical Center

The Society for Academic Continuing Medical Education is pleased to respond to the request for input from the AMA Council on Ethical and Judicial Affairs and the Council on Medical Education on the issues of bias and conflict of interest in CME. Attached you will find our response as well as two documents in addendum that will provide the feedback you have requested. Please feel free to contact me should you require clarification or additional information about the contents of the documents.

Vice President

Todd Dorman, M.D.
Johns Hopkins School of
Medicine

I look forward to the dialogue at the stakeholders meeting on February 25, 2009 in Chicago.

Sincerely,



Treasurer

Deborah Sutherland, Ph.D.
University of South Florida
Continuing Professional
Development

Melinda Steele, M.Ed., CCMEP
President, Society for Academic Continuing Medical Education (SACME)

Secretary

Susan Tyler, M.Ed., C.M.P.
University of Cincinnati College
of Medicine

Director, Continuing Medical Education
Texas Tech University Health Sciences Center
3601 4th Street, Stop 7113
Lubbock, Texas 79430
(806) 743-2226



**Response of the Society for Academic Continuing Medical Education to
the Council on Ethical and Judicial Affairs and the Council on Medical Education
of the American Medical Association**

The Society for Academic Continuing Medical Education (SACME) is pleased at this opportunity to respond to the request for input on the topics of bias and conflict of interest. We appreciate that the Council on Judicial and Ethical Affairs and the Council on Medical Education have reached out to various stakeholders to gather information and seek opinions on the approach to these critically important issues.

SACME is the professional organization for educators and physicians in medical schools, academic health science centers, and professional/specialty organizations, as well as other academically based professionals interested in academic continuing medical education (CME). SACME's mission is to promote research, scholarship, evaluation and development in CME to enhance the performance of physicians and other healthcare professionals. SACME is pleased to respond to the request for input to the critical issues facing the CME enterprise today.

Academic institutions are an essential component of the CME enterprise, with medical schools alone providing approximately one-third of all nationally accredited activities, and almost half of the hours of instruction. At the same time, academic institutions, through their faculty, provide most of the teaching in CME across all settings. While many potential conflicts of interest (COIs) apply to the continuum of medical education, some are particularly important to continuing medical education and its direct links with practicing physicians. Given the critical role of academic institutions in CME, SACME would like to provide feedback about how this community of CME professionals thinks about conflicts of interest and bias.

CEJA has put forth these broad ethical considerations:

1. Ethically preferable practice with respect to commercial funding for CME.
2. Ethically permissible practice, including strategies for managing or mitigating potential conflict of interest or bias.
3. Ethically permissible practice in situations involving uniquely qualified but unavoidably conflicted parties.

The questions we have been asked to focus our input to CEJA are:

- When is conflicted expertise essential in CME? How can we tell when it is no longer needed?
- What unique challenges do you as a stakeholder face regarding CME?
- How can we ensure that medicine sets the agenda for CME overall so that it meets the needs of patients and physicians rather than the interests of commercial supporters?

Much discussion has taken place among CME leaders regarding the framing of the agenda and the questions posed for this response. We are not certain that these are the questions that should be focal in the discussion nor are the answers to these questions as straightforward or simple as

one might like for them to be. In reflecting on how to approach this response, SACME leadership believes that many issues impact the discussion.

In formulating this response, we have drawn on documents and surveys of SACME membership prepared for response to at least three other recent inquiries: The Institute of Medicine COI Task Force (May 2008), the ACCME Calls for Comment (July and August 2008) and the original CEJA documents put forth in June 2008.

To adequately understand all the issues impacting the questions above, many considerations need to be made. One consideration is that bias will always exist and can never be eliminated. In fact, there are times when there can be “good” bias. Consideration might then be centered on how to effectively “manage” conflict or interest or bias and maintain the best interest of patients and physicians in meeting continuing education practice performance gaps and needs. As a part of that consideration, one must examine the funding issues as well. Funding exists for hospitals, institutions and research. Conflict and bias may exist in those arenas and there is no call for removal of funding. There is no reason to single education out, much less CME. Though some may advocate for the elimination of commercial support of CME, the effects on academic CME providers could be devastating. Perhaps the focus should shift to how to effectively manage and monitor the relationships presented by the commercial support of CME.

SACME and the Alliance for CME collaboratively developed a *National Faculty Education Initiative* to provide education on the difference between independent CME and promotional education. The initiative was launched in October of 2008 and in a few short months over 800 had viewed the content with 500+ completing the activity and receiving a certificate of completion. The numbers continue to increase. This initiative is an example of a process that might be considered by CEJA and the Council as an alternative to putting forth new positions. Many other organizations and institutions are already effectively taking measures to address the issue of bias and conflict of interest. One might ask what more another position statement might add to this dialogue. Alternatively, what powerful tools and education might be produced if the Council were to collaborate with other organizations to produce toolkits and educational modules to address the issues? CEJA has experience and a track record in a very productive educational campaign with the *Ethical Opinion on Gifts to Physicians*. Following this successful effort, expanding to collaborate with partners from various organizations could effectively add currently missing elements to the approaches to address *proactively* the issues of bias and conflict of interest for both the medical community and the public.

With these points in mind, we offer the following attachments from responses to similar inquiry as thoughts worth pondering as CEJA and the Council on Medical Education formulates their positions and strategies.

- ***SACME Response to the Institute of Medicine COI Committee***
- ***SACME Response to the Accreditation Council for CME (ACCME) Call for Comments on the Elimination of Commercial Support of Continuing Medical Education***
- ***SACME Response to ACCME Call for Comment on Additional Features of Independence in Accredited Continuing Medical Education***

Excerpts from Summary Comments and Survey Results of SACME members regarding the Original CEJA Statements

In a survey of SACME Members in June 2008, the statement was posed: “The CEJA report accurately represents the current environment in academic CME” 57%+ either strongly disagreed or disagreed with the statement. Following are selected comments received from the survey respondents:

“The CEJA report does not adequately distinguish between promo and certified CME activities. There are many certified CME providers that strictly follow the ACCME Standards for Commercial Support and maintain adequate separation between educational activities and commercial influence. Many CME providers have identified ways to maintain an appropriate association with industry while avoiding influence in certified CME activities; not all associations with industry are harmful. Therefore, to imply that industry influence is currently a strong influential force in education is incorrect. If commercial support is eliminated from certified activities, commercial supporter funds may be “channeled” to other promotional educational activities for physicians, which may not be managed by existing standards or guidelines in place (ACCME, PhRMA, Advamed, etc.). It is clear that regulations about interacting with industry may need to be tightened, and CME providers must be part of the solution to identify acceptable strategies when working with commercial supporters to ensure public trust and commercially unbiased certified CME activities.”

“I find the report poorly written and poorly supported if the goal was to craft an evidence-based guideline. Let me clarify just a few: 1) The word CME is used to mean both accredited and non-accredited activities. This adds to the confusion that already exists and is a bit surprising for an AMA document. 2) CME and promotion activities are confused in several places. An example is the data presented on ROI that came from the RAPP study. That study did not ask about CME but did a ROI for money given to “meetings and events” defined very broadly. 3) Almost all of the data presented is from studies prior to the “new” era in CME. Thus it is unclear if the data is still pertinent and it is unclear if the new approaches have worked or not. 4) No evidence grades are provided. In fact in several places they quote published literature but literature that is from a single author and are opinion pieces. Unfortunately the referenced material is presented as though it is scientific information. Even if the goal was to produce a “Value” document and not an “evidence” document these sorts of references are not appropriate. 5) The first recommendation calls for a prohibition on funding to organized medicines and explicitly names medical schools, states, and societies. This means that funding to the MECCs could not only continue but in fact all funding (~\$1.1billion) WOULD be shifted to MECCs. How does this achieve the stated goals they espouse? 6) The document presents single sided arguments and thus is not fair and balanced. For instance, the argument around disclosure. There is very good data that it has Pros and Cons, but only the cons are presented. 7) Remedies are not presented. If all direct and indirect funding were eliminated how would an academic center know if a foundation providing a grant was really a source of indirect funding. What legal rights would we have to investigate a 501(c) 3 entity that is not required to do public reporting? If only direct eliminated then would the money not all move to become indirect? If all for-profits money were addressed how would a for-profit hospital educate its staff. It’s nice to say no, but how will no be enacted, managed and monitored and by whom? There is more, but that’s a start.....”

“People need to recognize the difference between perception and reality. The literature is anything but evidence-based, and the examples often cited by the media are old practices that are rarely, if ever, used today. We are all being placed in a “Catch 22” -- those opposed to any pharmaceutical support claim (using the old, misquoted, poorly constructed literature) that all doctors are influenced, even by insignificant gifts such as pens and note pads. Thus, any doctor who says, “I am not influenced,” is labeled “Exhibit A.” The fact that studies have shown that doctors say they are not personally influenced but believe other doctors are influenced, is a major misinterpretation of statistical reporting. If someone asks one doctor if he/she is influenced, most will say (truthfully in my opinion) “No.” If he/she is then asked, “Do you believe other doctors are influenced,” the denominator just jumped from one to thousands. Of course the answer is going to be yes; everyone agrees that some physicians are influenced. The better question would be, “What percent of your colleagues do you believe are influenced?”

Summary comments to CEJA and the Council on Medical Education of the AMA

Taking a position on bias and conflict of interest in continuing medical education is a difficult task. With many varying facets to consider and opinions to sort out, the best one can hope to achieve is to neutralize or manage the conflict and bias without compromising the integrity of evidence based content or the financial stability of the CME enterprise. Whatever position may be put forth, careful consideration of all facets of this controversial subject must be weighed. In the end, what is best for the improvement of patient outcomes must be paramount. What is best for the medical profession and what is best for the CME enterprise, hopefully, will also be aligned with that goal. SACME encourages CEJA and the Council on Medical Education to consider alternative approaches to simply stating yet another opinion or position on bias and conflict of interest and rather take a proactive approach. Consider focusing on the ethical aspects of interactions with outside interests. Partner with other organizations to create toolkits and educational modules for both physicians and the public to take an affirmative stance using existing policies and documents, as well as the work of others, to form the foundation of the strategies. SACME would be pleased to partner on an initiative such as this and we are sure other organizations would as well.

Respectfully submitted,



Melinda Steele, M.Ed., CCMEP
President, Society for Academic Continuing Medical Education (SACME)

Director, Continuing Medical Education
Texas Tech University Health Sciences Center
3601 4th Street, Stop 7113
Lubbock, Texas 79430
(806) 743-2226

Response of the Society for Academic Continuing Medical Education to the Institute of Medicine Request for Input About Conflict of Interest

The Society for Academic Continuing Medical Education (SACME) is the professional organization for educators and physicians in medical schools, academic health science centers, professional/specialty organizations, and other interested academically based professionals. SACME's mission is to promote research, scholarship, evaluation and development in continuing medical education (CME) to enhance the performance of physicians and other healthcare professionals.

Academic institutions are an essential component of the CME enterprise, with medical schools alone providing approximately one-third of all nationally accredited activities, and almost half of the hours of instruction. At the same time, academic institutions, through their faculty, provide most of the teaching in CME across all settings. While many potential conflicts of interest (COIs) apply to the continuum of medical education, some are particularly important to CME and its direct links with practicing physicians. Given the critical role of academic institutions in CME, SACME would like to provide feedback to the IOM about how this community of CME professionals thinks about conflicts of interest.

Background

While discussion about conflicts of interest often centers on ties that individual faculty have with pharmaceutical or device companies, there are many types of relationships that present the potential for real or perceived conflicts of interest. Individuals or their

institutions develop relationships with a variety of entities or other individuals, some of which may conflict with providing the highest quality CME program. That conflict may be in terms of personal or institutional financial gain, competing commitments, or contradictory strategies to provide learning intended to improve the health of the public.

Few faculty only teach; they are clinicians, researchers, administrators, and scholars, and are role models for students, residents, patients and fellow faculty in each role. In addition, they often fill important roles in their communities. The relationships among all of the pieces are complex, sometimes complimentary and sometimes contradictory, routinely creating the potential for conflicts of interest that impact CME.

Basic premise

The work of faculty in academic institutions, with multiple roles in a variety of settings, routinely presents the potential for COIs. Academic institutions and their members share a responsibility to create and support a system to manage conflicts to support the highest quality programs for the education continuum, including CME, with policies and systems that clearly define and facilitate management of COIs. COIs related to the education continuum are common; failure to manage them may affect the quality and integrity of CME.¹

We assume:

1. Academic institutions and their members are committed to providing the highest quality CME.
2. Academic institutions and their members are obligated to support the dissemination of new knowledge and clinical management approaches to practicing physicians. At the same time, physicians have a professional

obligation to maintain and enhance their competence to continually improve the care they provide.

3. Academic institutions and their members routinely face conflicts of interest. A system to manage those conflicts is essential to providing effective CME.

Relationships Presenting Conflicts

Many types of relationships may present the potential for a conflict of interest that impacts CME. Not all relationships present a conflict, and no single definition of COIs is adequate. The kinds of relationships listed below may result in effective CME that improves patient care, or may result in bias that interferes with high quality and cost effective care. CME faculty are often chosen for their experience in difficult clinical management issues. The lack of available evidence for complex issues forces physicians to look for alternatives for their patients with problems that do not respond to traditional strategies. New applications and innovative management strategies may present new approaches and thinking that may be perceived as biased since they are not supported by current evidence. The range of relationships also potentially presents varying goals for administrators and faculty. Faculty involved with commercial interests may categorize their work differently than faculty not involved with commercial interests.

Administrators may approach the work of their institutions differently than faculty.

There are varying ideas about intellectual property and the value of entrepreneurship. To make decisions about the impact of COIs in CME, we must have a system that accounts for the range of ways our faculty and institutions work.

Types of relationships with examples:

1. Healthcare Business/Industry Relationships Involving CME

- a. Medical industry – pharmaceutical and device manufacturers, medical supply companies, speakers bureaus, funding/grants for CME
- b. Biotech industry – local “start-ups” and entrepreneurial efforts, some efforts encouraged by the academic center
- c. Practice management/Quality of care tools – development of data bases that generate patient care data, IT options that reflect practitioners work, educational support involved with patient care
- d. Consumer industries – educational programs that promote products/services of an institution, faculty involvement with industries advocating products that may be inconsistent with evidence based health goals such as tobacco, nutrition, unproven natural products, etc.

2. Other Commercial/Business/For-Profit Relationships Involving CME

- a. Educational materials – For-profit technology companies involved with retrieval and dissemination of information, software, hardware, textbook or other publishers, educational supply companies
- b. Educational-support activities – board/exam preparation companies and products, tutoring options, activities to prepare to meet requirements in medicine; distance learning including intra-institutional sites
- c. Economic development – projects fostered by the institution, especially in technology transfer

3. Outside Funding Relationships That Include CME Activities

- a. Government – grants, other projects/guidelines, disease specific projects, project requirements/mandates for educational activities
- b. Commercially funded research/projects – Research/projects may include restrictions on publication of research, other mandates to shape results may be included, requirements for outcomes measurement

4. Institutional Goals Linked with CME Goals

- a. Experts reflecting the institution – Experts charged with expanding a given patient care program, or commenting in newspapers/TV that viewers may assume institutional stance or endorsement, faculty reflecting the institution in industry or professional activities through participation in panels, programs
- b. Organizational self-interest – favoring or providing differential training or benefits to some with expectations for future considerations, expansion of a given area for income or increased share of “business”
- c. Intra-institutional competing goals – one component of an institution involved in a project, funding, activity that conflicts with the standards of another part of the institution

5. Institutional Members' Conflicts of Commitment Involving CME

- a. Academic roles vs. healthcare obligations – healthcare professionals seek to fulfill their teaching and service roles with inadequate time or resources.
- b. Academic roles vs. professional obligations - participation in one's professional association or attendance at national meetings that compete with teaching obligations or institutional committees.
- c. Academic scholarship - Fulfilling scholarship roles may include input or results from learners, with completion of surveys, test scores, matched groups "at student expense".

Consensus Principles

Given our basic assumptions and examples of the types of relationships that involve CME, the following principles represent a summary of ideas from the SACME membership. A total of 113 (58%) of the 195 members responded; at least 85% agreed with each principle. (See Appendix 1)

1. Academic institutions, with their faculty and staff, contribute to improving the health of the public through effective CME.
2. Effective CME incorporates the best available evidence and professional standards about teaching and learning strategies. (Evidence points toward effective strategies such as content based on identified gaps in practice, learning over time, content in multiple formats, interaction among colleagues, and feedback.)
3. A system to identify and manage COIs is an essential basic component of all CME programs. Institutions, with their faculty and staff, routinely face real or perceived conflicts of interest in providing the highest quality education program across the continuum of medical education. Academic institutions' COI policies and systems must include the range of issues that arise in CME.
4. There is lack of agreement about the role of funding from outside sources such as pharmaceutical/device companies for CME.
5. Systems must be in place so that no source of funding influences the balance or objectivity of CME activities, and measurement of its outcomes.
6. Changes in funding sources require new institutional approaches to supporting CME.
7. Changes in funding sources require changes in physician expectations for their role in CME.
8. Closely aligning quality initiatives and CME contributes to improving healthcare quality.

9. Academic institutions must provide research and measures to understand the impact of CME on the care physicians provide, and share information among institutions.
10. Regulatory systems (e.g. MOC, licensing, accreditation) must support implementation of effective CME to improve health care outcomes.

Emerging Principles

The group was asked questions representing new approaches to conflict of interest principles; there were 91 responses (47% of the membership). There is strong agreement that CME professionals have the skills to design effective CME activities that eliminate bias, but there is less confidence in physicians' ability to distinguish between biased and evidence-based CME activities. There is no consensus that the current funding system leads to content bias, or that funding from commercial interests is essential to CME, but there is agreement that removing funding in support of CME from commercial sources is not essential. Government funding may be one new funding source among many other options. The majority are in favor of eliminating all gifts, including free lunches, at activities with CME credit as part of managing conflicts of interest. Respondents agreed that faculty with industry relationships were eligible to teach in academic CME, but that faculty should not serve on speakers' bureaus. The majority noted that current regulatory requirements do not eliminate bias from CME. The exploration of areas without consensus points to a strong call for change with principles that result in a new funding model, new regulatory approaches, and a new form of academic/industry partnership. (See Appendix 2)

Challenges/Barriers

The current CME system is large, readily available, with many points of access. Options for free or low cost CME credit are easily found, with widely varying quality. To reconfigure our understanding about conflicts of interest, changes to the system require removing barriers to funding, shifting the culture, and providing needed expertise.

- **Funding models**
Many academic institutions provide little or no funding to CME, but rely on units to fund themselves or raise funds for the institution. Loss of current funding from commercial interests may result in fewer educational activities with increased cost to the institution. Decreasing outside funds may mean fewer CME professionals supporting a program, and fewer types of activities.
- **Institutional role**
Although we talk about the continuum of medical education, continuing education is often not a focus of the educational system. Expectations point more to CME's marketing role in representing the institution, presenting new findings/research, supporting hospital activities. Increasing referrals, showcasing new clinical facilities, or highlighting new research findings often have a role in CME, rather than a foundation of partnering in quality initiatives. Linking CME to core institutional goals to improve quality of care requires new thinking.
- **Cultural change**
In addition to the issue of CME as a support for hospital activities, most physicians have been trained in an environment in which lectures and conferences are provided at no cost. Asking physicians to bear more of the cost of their professional development comes with the challenge of developing activities that are more effective. Though changing, many learning opportunities demand little of participants. Many physicians lack practice in learning using different modalities, and experience a level of discomfort.
- **Faculty relationships**
Academic faculty provide the content expertise essential to CME. At the same time, they often have a wide range of relationships with commercial and non-commercial interests that may result in conflicts, many of them unintended. Unintended bias in CME evolving through relationships that involve faculty or planners and commercial interests decreases the value of CME, distorting balance and objectivity

- **CME Professionals**
Lectures are a cost effective way to present information, requiring relatively little of planners and participants. Using approaches that have been shown to be more effective, and linking CME to quality initiatives, requires expertise on the part of planners as well as faculty. CME professionals with skills in instructional design, evaluation, and teaching/learning to support faculty are essential, but require more time and money.

Summary

Academic CME is an essential part of the healthcare system, and there are many types of academic institutions with varying goals. As partners in the system, faculty and planners routinely face a wide range of conflicts that may interfere with providing the highest quality education. CME activities must be unbiased, and rely on balance and objectivity, but the resources to meet those goals are not readily available in the current system.

Funding from commercial interests is not essential to CME, but need not necessarily be eliminated if a new funding model is designed with clear principles and goals.

Addressing gifts such as lunches, changing the regulatory requirements, and defining management strategies for faculty relationships are essential steps. Broadening the sources of funding for CME, including a culture change where physicians bear more of the cost, are options for discussion.

Changes to the system may result in fewer CME opportunities for physicians that contribute to improving the patient care they provide, as well as fewer CME professionals and faculty to create high quality CME. Decreasing the number of CME activities changes the current system, but is not necessarily a barrier. One result could be higher quality in terms of careful assessment of practice needs and effective learning strategies



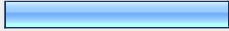
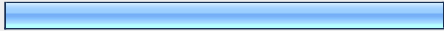
among those remaining. Improving the quality of CME demands a clear understanding and management of the sources of potential conflicts of interest, institutional support for the role of CME in physicians' continued development, and expanded expertise from faculty and planners. By including academic CME with its range of conflicts in its report, The IOM will provide an opportunity to move the discussion forward with changes to the system. These changes will require creativity and innovation, with results that are important to all aspects of healthcare. (Report prepared April 2008.)




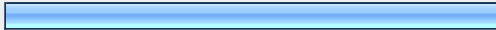
References

1. Cosgrove E, Arnold L, Bennett NL. Defining Faculty Conflicts of Interest in Medical Education: 2006 Draft paper, not distributed. (Some of the discussion including the types of relationships above is adapted from this paper.)
2. Brennan, T. A., Rothman, D. J., Blank, L., Blumenthal, D., Chimonas, S. C., Cohen, J. J., Goldman, J., Kassirer, J. P., Kimball, H., Naughton, J., Smelser, N. Health Industry Practices That Create Conflicts of Interest: A Policy Proposal for Academic Medical Centers. *JAMA* 2006 295: 429-433
3. Campbell, E. G., Weissman, J. S., Ehringhaus, S., Rao, S. R., Moy, B., Feibelmann, S., Goold, S. D. Institutional Academic Industry Relationships. *JAMA* 2007 298: 1779-1786
4. Campbell, E. G., Gruen, R. L., Mountford, J., Miller, L. G., Cleary, P. D., Blumenthal, D). A National Survey of Physician-Industry Relationships. *NEJM* 2007 356: 1742-1750
5. Ehringhaus SH, Weissman JS, Sears JL, Goold SD, Feibelmann S, Campbell EG. Responses of medical schools to institutional conflicts of interest. *JAMA* 2008 Feb 13;299(6):665-71
6. Fletcher SW. Chairman's summary of the conference: continuing education in the health professions: improving healthcare through lifelong learning. <http://www.josiahmacyfoundation.org/>. Accessed March 7, 2008



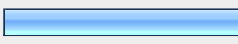
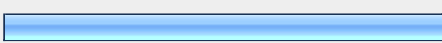
7. Ratanawongsa N, Thomas PA, Marinopoulos SS, Dorman T, Wilson LM, Ashar BH, Magaziner JL, Miller RG, Prokopowicz GP, Qayyum R, Bass EB. The reported validity and reliability of methods for evaluating continuing medical education: A systematic review. *Acad Med* 2008; 83(3):274-283.
8. Studdert DM, Mello MM, Brennan TA. Financial conflict of interest in physician relationships with the pharmaceutical industry: self-regulation in the shadow of federal prosecution. *N Engl J Med*. 2004;351:1891-1900
9. Wazana A. Physicians and the pharmaceutical industry: is a gift ever just a gift? *JAMA*. 2000;283:373-380.
10. The Scientific Basis of Influence and Reciprocity: A Symposium. AAMC June 12, 2007, Washington DC. <http://www.aamc.org/publications>. Accessed March 7, 2008.
11. Protecting Patients, Preserving Integrity, Advancing Health: Accelerating the Implementation of COI Policies in Human Subjects Research A Report of the AAMC-AAU Advisory Committee on Financial Conflicts of Interest in Human Subjects Research. February 2008. <http://www.aamc.org/publications>. Accessed March 7, 2008

Appendix 1: IOM SACME RESPONSE




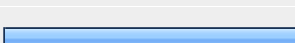
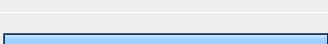
1. Academic institutions, with their faculty and staff, contribute to improving the health of the public through effective CME			Response Percent	Response Count
Strongly disagree			1.8%	2
Disagree			0.0%	0
Neutral			3.5%	4
Agree			31.9%	36
Strongly agree			62.8%	71
			<i>answered question</i>	113
			<i>skipped question</i>	0

2. Effective CME incorporates the best available evidence and professional standards about teaching and learning strategies. (Evidence points toward effective strategies such as content based on identified gaps in practice, learning over time, content in multiple formats, interaction among colleagues, and feedback.)			Response Percent	Response Count
Strongly disagree			2.7%	3
Disagree			0.0%	0
Neutral			0.9%	1
Agree			25.9%	29
Strongly agree			70.5%	79
			<i>answered question</i>	112
			<i>skipped question</i>	1



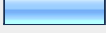
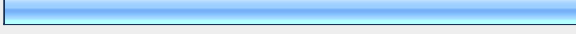
3. A system to identify and manage COIs is an essential basic component of all CME programs. Institutions, with their faculty and staff, routinely face real or perceived conflicts of interest in providing the highest quality education program across the continuum of medical education. Academic institutions' conflict of interest policies and systems must include the range of issues that arise in CME.

		Response Percent	Response Count
Strongly disagree		1.8%	2
Disagree		0.0%	0
Neutral		1.8%	2
Agree		33.6%	38
Strongly agree		62.8%	71
		<i>answered question</i>	113
		<i>skipped question</i>	0




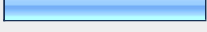
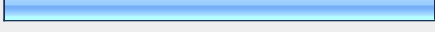
4. There is lack of agreement about the role of funding from outside sources such as pharmaceutical/device companies for CME.

		Response Percent	Response Count
Strongly disagree		1.8%	2
Disagree		3.6%	4
Neutral		6.3%	7
Agree		42.0%	47
Strongly agree		46.4%	52
		<i>answered question</i>	112
		<i>skipped question</i>	1






5. Systems must be in place so that no source of funding influences the balance or objectivity of CME activities, and measurement of its outcomes.

		Response Percent	Response Count
Strongly disagree		2.7%	3
Disagree		0.9%	1
Neutral		0.0%	0
Agree		14.3%	16
Strongly agree		82.1%	92
		<i>answered question</i>	112
		<i>skipped question</i>	1





6. Changes in funding sources require new institutional approaches to supporting CME.

		Response Percent	Response Count
Strongly disagree		2.7%	3
Disagree		1.8%	2
Neutral		5.4%	6
Agree		28.6%	32
Strongly agree		61.6%	69
		<i>answered question</i>	112
		<i>skipped question</i>	1




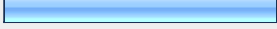
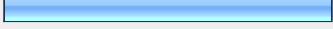
7. Changes in funding sources require changes in physician expectations for their role in CME.

		Response Percent	Response Count
Strongly disagree		2.7%	3
Disagree		2.7%	3
Neutral		4.5%	5
Agree		34.8%	39
Strongly agree		55.4%	62
		<i>answered question</i>	112
		<i>skipped question</i>	1






8. Closely aligning quality initiatives and CME contributes to improving healthcare quality.

		Response Percent	Response Count
Strongly disagree		1.8%	2
Disagree		0.0%	0
Neutral		5.5%	6
Agree		39.1%	43
Strongly agree		53.6%	59
		<i>answered question</i>	110
		<i>skipped question</i>	3






9. Academic institutions must provide research and measures to understand the impact of CME on the care physicians provide, and share information among institutions.






		Response Percent	Response Count
Strongly disagree		1.8%	2
Disagree		0.9%	1
Neutral		11.5%	13
Agree		38.9%	44
Strongly agree		46.9%	53
		<i>answered question</i>	113
		<i>skipped question</i>	0

10. Regulatory systems (e.g. MOC, licensing, accreditation) must support implementation of effective CME to improve health care outcomes.


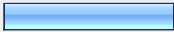
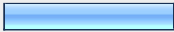


		Response Percent	Response Count
Strongly disagree		0.9%	1
Disagree		1.8%	2
Neutral		2.7%	3
Agree		35.7%	40
Strongly agree		58.9%	66
		<i>answered question</i>	112
		<i>skipped question</i>	1

Appendix 2: SACME ROUND II SURVEY

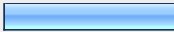




1. CME professionals know how to design effective CME to eliminate bias			
		Response Percent	Response Count
Strong disagree		2.2%	2
Disagree		8.8%	8
Neutral		9.9%	9
Agree		53.8%	49
Strongly agree		25.3%	23
		<i>answered question</i>	91
		<i>skipped question</i>	0


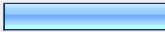
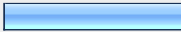


2. Physicians know how to distinguish biased CME from evidence-based CME			
		Response Percent	Response Count
Strong disagree		5.5%	5
Disagree		29.7%	27
Neutral		17.6%	16
Agree		33.0%	30
Strongly agree		14.3%	13
		<i>answered question</i>	91
		<i>skipped question</i>	0


3. Current funding approaches lead to bias in academic CME.

		Response Percent	Response Count
Strong disagree		12.1%	11
Disagree		24.2%	22
Neutral		24.2%	22
Agree		26.4%	24
Strongly agree		13.2%	12
		<i>answered question</i>	91
		<i>skipped question</i>	0


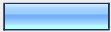
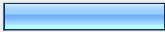


4. Funding from commercial interests must be eliminated from academic CME.

		Response Percent	Response Count
Strongly disagree		24.4%	22
Disagree		36.7%	33
Neutral		14.4%	13
Agree		12.2%	11
Strongly agree		12.2%	11
		<i>answered question</i>	90
		<i>skipped question</i>	1

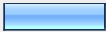




5. Funding from commercial interests is essential for academic CME			Response Percent	Response Count
Strong disagree			11.1%	10
Disagree			23.3%	21
Neutral			25.6%	23
Agree			31.1%	28
Strongly agree			8.9%	8
			<i>answered question</i>	90
			<i>skipped question</i>	1



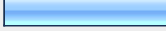

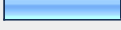
6. A new model for funding from commercial interests must be developed			Response Percent	Response Count
Strong disagree			4.4%	4
Disagree			15.6%	14
Neutral			17.8%	16
Agree			35.6%	32
Strongly agree			26.7%	24
			<i>answered question</i>	90
			<i>skipped question</i>	1


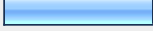

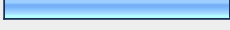
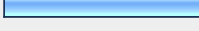
7. Government funding for academic CME must increase.

		Response Percent	Response Count
Strong disagree		5.7%	5
Disagree		14.8%	13
Neutral		22.7%	20
Agree		31.8%	28
Strongly agree		25.0%	22
		<i>answered question</i>	88
		<i>skipped question</i>	3

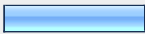
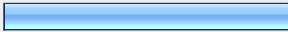
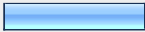


8. Faculty must not teach in academic CME if they have relationships with commercial interests.

		Response Percent	Response Count
Strong disagree		14.3%	13
Disagree		47.3%	43
Neutral		18.7%	17
Agree		13.2%	12
Strongly agree		6.6%	6
		<i>answered question</i>	91
		<i>skipped question</i>	0

9. Faculty should not serve on speakers bureaus.			Response Percent	Response Count
Strong disagree			5.5%	5
Disagree			22.0%	20
Neutral			23.1%	21
Agree			33.0%	30
Strongly agree			16.5%	15
			<i>answered question</i>	91
			<i>skipped question</i>	0

10. All gifts, including free lunches, must be eliminated from activities with CME credit.			Response Percent	Response Count
Strong disagree			5.6%	5
Disagree			21.1%	19
Neutral			13.3%	12
Agree			32.2%	29
Strongly agree			27.8%	25
			<i>answered question</i>	90
			<i>skipped question</i>	1

11. Current regulatory requirements eliminate bias in CME activities.

		Response Percent	Response Count
Strong disagree		19.8%	18
Disagree		40.7%	37
Neutral		19.8%	18
Agree		17.6%	16
Strongly agree		2.2%	2
		<i>answered question</i>	91
		<i>skipped question</i>	0

SACME Response to ACCME Call for Comment on the Elimination of Commercial Support of Continuing Medical Education Activities

On June 11, 2008, the Accreditation Council for CME (ACCME) released several announcements and two documents with a call for comment on items that have the potential for seriously impacting academic CME. The following is SACME's response to the call for "Elimination of Commercial Support of Continuing Medical Education Activities" and is based on the responses of 86 SACME members who comprise 40% of SACME voting members.

Over the last several years, considerable national debate has focused on the role of commercial support in all aspects of medical education, with a special emphasis on its role in continuing medical education for physicians. The underlying assumption of this debate is that CME supported by industry is inherently biased regardless of safeguards put into place by the ACCME, its accredited providers, and industry. We fully reject the premise that merely receiving a grant creates an inherent conflict as there is no evidence that this is true. We do acknowledge that there have been abuses within the system, but also believe that the entire CME community should not bear the burden of those abuses.

The reality of academic CME is that only a handful of academic institutions do not take commercial support for their CME activities. Most institutions provide minimal or no funding to CME programs and require these programs to be self-supporting. Therefore, eliminating all commercial support from CME programs poses a very real threat to the viability of CME within the current academic environment.

Since the call for Comment on Elimination of Commercial Support of CME Activities contained several different elements, we asked SACME membership to respond to each element.

Commercial support of continuing medical education should end

Overwhelmingly, SACME members who responded to the survey disagreed with the ACCME proposal to eliminate commercial support in continuing medical education. Less than 20% were in agreement with this proposal, and fewer than 10% indicated a neutral position.

When asked about the impact to their CME programs, 77% of the respondents indicated that ending commercial support for CME would have a significant negative impact on their overall CME program. These impacts include:

- a decrease in the number and scope of CME activities
- fewer external speakers used for RSS's
- reduction in the number of clinicians educated
- less CME research
- reduction in staff, or
- complete elimination of the CME program itself.

As one respondent noted, "opportunities to pursue the development of innovative educational and QI applications and rigorous assessment of the resultant outcomes would be severely curtailed."

Elimination of commercial support is a complex issue. Even those respondents who agreed that commercial support should be eliminated felt there would be negative impact to their CME such as a reduction in external programs or an increase in registration fees.

Within the call for comments, ACCME proposed the following three scenarios:

- continuation of the status quo with commercial support,
- complete elimination of commercial support, and
- a new paradigm for CME support.

Less than 10% supported eliminating commercial support entirely, with approximately 30% retaining the status quo, and 60% in favor of a new funding paradigm for CME.

Of those who responded that a new paradigm was needed, there was no consensus on any single model. Examples of two suggested paradigms follow.

- A simple arrangement that allows commercial support to CME programs, but prohibits them from being designated for specific activities. For example, five commercial companies each contribute \$10,000 to a hospital's (or medical school's) CME program.
- CME credits should be awarded by accredited degree granting centers of higher education. This would consolidate the accredited provider process to monitoring and management of < 200 providers nationwide.

Given the lack of consensus of those surveyed, any future CME funding paradigm must be well thought out and not put forth as a reaction to pressure from the external environment. The CME system could/should be improved but only if a systematic approach is taken that is responsive to the educational needs of our healthcare provider community and not those who would seek to vilify it.

The ACCME proposed a four-part paradigm for funding CME that would permit commercial support only if all of the following conditions were met:

- A. When educational needs are identified and verified by organizations that do not receive commercial support and are free to financial relationships with industry (e.g., US Government agencies), **and**
- B. If the CME addresses a professional practice gap of a particular group or learners that is corroborated by *bona fide* performance measures (e.g., National Quality Forum) of the learners' practice, **and**
- C. When the CME content is from a continuing education curriculum specified by a *bona fide* organization, or entity (e.g., AMA, AHRQ, ABMS, FSMB), **and**
- D. When the CME is verified as free of commercial bias.

Fifty-eight percent of respondents did not believe all components of this model were necessary compared to 22% who did. Twenty-percent indicated they were uncertain about the paradigm presented by the ACCME.

Those who did not support the ACCME proposed paradigm indicated that

- would create more bureaucracy,

- the needs of national organizations differ from those at the provider-level,
- bona fide organizations have their own bias and may not know or understand what the individual healthcare provider needs,
- the model would be time consuming and burdensome, and
- the model suggests lack of provider competence in what the needs of its learners are.

Finally, one comment from a respondent who was uncertain about the ACCME proposed paradigm noted that even some *bona fide* organizations may, in fact, be biased. As noted in a recent article, even the NIH review and grant award process is subject to reader bias. (V.E. Johnson, *Proc.Natl Acad.Sci.USA* doi:10.1073/pnas.0804538105;2008)

Potential Consequences of Adopting the ACCME 4-Part Paradigm

When asked about what the consequences of adopting such a paradigm, there was a wide-range of responses ranging from negative to positive.

- increased bureaucracy and documentation
- limited the range of CME activities
- less innovative CME
- diminished value of local audience needs
- decreased number of activities
- decrease in the number of CME providers
- less commercial bias
- improved CME programs

SACME members who responded to the survey believe that CME providers are in the best position to identify their learner needs and organizations that receive commercial support do manage that support and possible conflicts of interest within the guidelines of the current ACCME Standards for Commercial Support.

Many of those surveyed questioned what a “bona fide” organization actually is and whether or not those organizations are truly free of bias. The reality is that even “mature” review systems such as those in place at the FDA, the NIH, JAMA and NEJM have missed commercial bias.

In summary, we believe:

- The total elimination of commercial support is unnecessary and unjustified.
- The CME system should be improved through an evidence-based approach as a component of a well thought through strategic plan.
- Elimination of commercial support will likely produce significant unintended consequences that have not yet been assessed or analyzed.
- The commercial component of today’s healthcare system supports institutions, organizations, research and education. Financial support for education should not be eliminated but managed by appropriate constraints consistent with the medical professionalism.

SACME Response to ACCME Call for Comment on Additional Features of Independence in Accredited Continuing Medical Education

The Society for Academic Continuing Medical Education welcomes the opportunity from ACCME to comment on its proposed policy to further define the independence of accredited continuing medical education. In the continued scrutiny of the CME enterprise we believe it is important to establish mechanisms to further define and ensure the separation of promotion from education and to ensure the independence of accredited CME from commercial interests. As such, SACME supports this proposed policy and agrees with the stipulation that those who are involved with the creation and presentation of content for commercial entities should not also be involved in the control of content of accredited CME. The inherent biases that exist in the involvement in promotional content present conflicts of interest that are not resolvable for accredited CME. We believe this policy will assist to clarify the issues of accredited CME vs. promotion for those who are currently examining CME for bias and conflict of interest.

We wonder, though, if the policy might benefit from clarification in a few areas. First, the policy does not specify any time reference for elimination of such conflicts. Is it intended to be that if one has *ever* produced or presented content of a promotional nature that one is thus banned forever from involvement in accredited CME? Or is the intention similar to other conflicts of interest that such a ban would only refer to relationships or promotional involvement in the past 12 months, allowing one to “cleanse” themselves of such relationships and move back into involvement in accredited CME only after a 12 month period?

Secondly, we believe that the policy when read in isolation and without the ACCME commentary might be strengthened by the addition of non-limiting examples. For instance, at the end of the current statement the addition of “e.g. participation on planning committees, development of content or presentation of content” might add further clarity and meaning when one reads or quotes the policy without benefit of the commentary.

Thirdly, the definition of “promotional” can have many and varied interpretations. The current definition is unclear and we recommend that the ACCME work with the academic community (SACME and AAMC) to define and clarify what the term “promotional” means in the context of this proposed policy.

Additionally, some comments received from our members question how a provider can *verify* whether or not a person has been “paid” to develop or present promotional content. Self report is often less than accurate and without some means of credible verification, this seems to be a critical portion of the policy that providers may not have the means to determine accurately. Would a provider be held accountable if a person did not disclose such information and it is later reported in some manner, for instance on a pharmaceutical web site listing such payments?

We applaud ACCME’s efforts to further define and ensure the independence of accredited CME in this particular area. SACME supports the spirit of the policy as stated: “Persons paid to create, or present, promotional materials on behalf of commercial interests cannot control the content of accredited continuing medical education on that same content.” We recommend that the policy be further refined with the addition of time frame, non-limiting examples, definition of

the term “promotional,” and verification methods for persons who have been paid for promotional content development or presentation as described above.