NAAMECC
North American Association of Medical Education and Communication Companies, Inc.

COALITION FOR
Healthcare
Communication

DATE: May 22, 2008

TO: Mark A. Levine, MD, Chair
The Council on Ethical and Judicial Affairs (CEJA)
American Medical Association

Raymond G. Christensen, MD, Chair
Reference Committee on Amendments to Constitution and Bylaws
American Medical Association

FROM: North American Association of Medical Education and Communications Companies (NAAMECC)

And

Coalition for Healthcare Communication

RE: Critical Concerns with Accuracy and Validity of "Report 1 of The Council on Ethical and Judicial Affairs: Industry Support of Professional Education in Medicine"

Many in the CME community, including the North American Association of Medical Education and Communication Companies, Inc. (NAAMECC), the trade organization for medical education and communication companies, and the Coalition for Healthcare Communication (CHC) take significant interest in all initiatives designed to promote continuous improvement of certified continuing medical education (CME) activities. The over 100 NAAMECC and CHC member education companies and publishers represent more than 1,000 physicians, nurses, adult learning experts, and other professionals that are dedicated to the advancement of clinically relevant and scientifically sound CME that promotes lifelong learning and healthcare improvement.

We read with great interest the recent *Report 1 of The Council on Ethical and Judicial Affairs: Industry Support of Professional Education in Medicine*. We appreciate and support several of the report's summary statements regarding education, including:

- The need for physicians to "maintain their clinical knowledge and skills through continuing medical education and other professional development activities."
- The need to "sustain ongoing, productive relationships with the pharmaceutical, biotechnology, and medical device companies" in order to "promote continued innovation and improvement in patient care," and
- The requirement to "provide clinical training which ensures that current and future generations of physicians are competent and caring."

While the Council, NAAMECC and the Coalition share several mutual goals, we are writing today to respectfully request that the report and its specific amendments and recommended changes be referred back to CEJA for significant modification, because of critical concerns with accuracy and validity in three main areas, as follows.

Concern #1:

The report findings promote a significant misunderstanding and confusion regarding the dramatic differences between certified CME and other non-certified "education" cited.

First and foremost, the report lumps certified CME developed according to the guidelines, standards, and policies of the Accreditation Council for Continuing Medical Education (ACCME), under a broad banner of multiple types of activities called "professional education."

According to the report, "professional education" includes:

- "CME"
- "industry marketing and promotional activities"
- "personal expenses associated with attendance at meetings"
- "educational travel grants for medical students"
- "free lunches"
- "residency positions"
- "company speakers' bureaus"
- "free or subsidized travel"
- "residency or fellowship training"
- "considerable funds in support of the educational mission of medical schools and teaching hospitals"

The report dismisses the fact that commercially supported, certified CME is managed by professionals whose organizations must comply with the ACCME Standards for Commercial Support. Organizations that do not abide by these requirements place their accreditation – their earned right to certify CME activities – at risk. The ACCME has taken significant steps to update Standards, Policies, and requirements. These changes, especially those since 2004, expressly require the identification and resolution of personal conflicts of interest in CME and eliminate the ability for commercial interests to provide input on faculty selection or education content/clinical validation.

The egregious "professional education" practices at which the report takes aim (e.g., free travel to attend meetings and "detail visits to physician offices" related to the drug OxyContin™) are either specifically prohibited under ACCME guidelines or have no relationship to a certified CME activity. By combining CME with other so-called "professional education" practices and recommending elimination of commercial funding in its entirety, the CEJA report appears to throw the baby out with the bathwater. Certified CME is very different from the majority of practices cited in the report. Any changes to the CME funding structure require a thorough analysis of current CME requirements, along with evidence showing why or how current certified CME activities should be in the same class of "professional education" activities as "industry marketing." Both industry and accredited providers have made significant structural and quality improvements that have enhanced certified CME during the past five years, and these changes deserve full evaluation, not accusation. In short, in swinging wildly at some of

the problems associated with industry marketing and promotion, the CEJA report unfairly gives certified CME a black eye.

Concern #2:

The report includes possible misinterpretation and/or misuse of data and conclusions, especially regarding the few instances of data that specifically address certified CME.

The report boldly states that "industry support for professional education is unlikely to fall," and this support "will grow unless steps are taken to intervene." Because CME is included in the same category with other forms of "professional education," these statements fail to recognize two important CME developments. First, virtually all certified CME experts expect ACCME annual reports to show a decline in commercial funding of CME between 2006 and 2007. Second, if the expected decline in funding for certified CME is shown in the ACCME annual report data, this supports the conclusion that appropriate steps were, in fact, "taken to intervene" by the ACCME. If so, the additional proposals targeting CME in the report could be rendered moot.

In order to support its conclusions, the CEJA report must produce evidence-based data showing that adherence to current ACCME guidelines produces biased or poor quality certified CME. In fact, the report produces so called "evidence" about negative CME impacts from a time period *prior* to the development of the 2003 Health and Human Services (HHS) Office of Inspector General (OIG) Compliance Guidance and the 2004 ACCME Standards for Commercial Support of CME activities. While the initial Standards for Commercial Support were developed in 1992, the report cites a 1988 study stating that physicians prescribe a company drug more often "after attending a company-supported CME event." Even worse, the report cites a 1986 study stating that CME activities "give more favorable treatment to company products" than other "education" and marketing activities.

Prior to the development of ACCME Standards, guidelines, and policies to address commercially supported, certified CME, these claims should surprise no one. Citing studies that pre-date the ACCME Standards for Commercial Support begs the question: Why would a report with the objective of providing "ethical guidance for physicians…with respect to industry support" include data and conclusions about industry supported CME from a time period that pre-dates standards and guidelines for delivering such industry supported, certified CME? The CEJA report ignores the significant progress over the past decade by ACCME and the industry to ensure the independence of accredited providers of CME from industry funders. The report fails to address its own bias, including failure to demonstrate fair balance in the reference articles it selected and arguments that it makes.

Last, the report actually misinterprets a key study cited to equate CME with marketing. The report claims that industry funding puts the integrity of "professional education" at risk. Using data regarding "return on investment" for "education," the report states: "One study estimated that for every $1.00 industry spent on CME programs and other meetings yielded on average $3.56 in increased revenue." The study cited has very little to do with certified CME. In fact, the figures quoted in the study cover "Physician Meetings & Events," which include such non-CME promotional meetings as the following:

- Teleconference
- Videoconference
- Third Party: conducted by a moderator
- Focus groups or personal interviews
- Small Rep: led by a pharmaceutical representative

In addition, it is worth noting that the study cited never mentions the term "CME" in any of the "Physician Meetings & Events" listed. The study objectives are to "measure the ROIs for detailing (DET), direct-to-consumer advertising (DTC), medical journal advertising (JAD), and physician meeting & events (PME)." It is clear from the list of PME's that these include marketing meeting and promotional education activities that are not, in fact, certified CME activities.

The validity of the CEJA report is in question. By relying on studies more than 20 years old, as well as footnoting an internet blog, the report does not meet the AMA's own standard for evidence-based decision making. The CEJA proposal calls for wholesale elimination of industry funding and other sweeping changes that undermine the ability of academic institutions, hospitals, medical education companies, and professional societies to develop certified CME. The quality of data and arguments presented in the CEJA report do not meet the tests of evidence required to warrant the grave changes proposed.

Concern #3:

The report lacks a detailed proposal or plan to ensure that the proposed elimination of $1 billion in certified CME funding would improve the quality of certified CME amid an increasingly complex healthcare environment. In addition, the report does not address the potential negative consequences of elimination of commercial funding of certified CME, including the probability that elimination of funding would lead to diminished education quantity and quality, which could result in increased healthcare mistakes and misjudgments that actually increase harm to patients.

If approved, this proposal will adversely affect major constituencies of the AMA, including specialty societies, hospitals and state societies. Adoption of the report would put the AMA in direct conflict with the most significant recommendations of the American Association of Medical College's (AAMC's) similar recent report on conflict of interest. While we support improved enforcement of standards and policies to ensure that certified CME is balanced, relevant, and accurate, we can not support a report that does not consider the negative implications of the actions it proposes.

The CEJA report cites sporadic examples in which individual organizations have developed certified CME without industry funding. While some CME can and should be developed in the absence of industry funding, and while organizations should be encouraged to seek CME funding outside of traditional industry mechanisms, the reality is that industry funding is both valid and needed in order to improve physician competence, performance, and patient outcomes.

The field of healthcare is becoming more – not less – complex. New drugs, combination therapies, and off-label treatments enter into practice each week. Industry has an ethical and perhaps legal responsibility to provide grants to accredited organizations that

can deliver scientifically sound and clinically relevant education under specific guidelines and standards. In addition, industry has a First Amendment right to do so.

The debate over appropriate amounts of and mechanisms for certified CME funding should always remind the CME enterprise of what it can do to foster continuous improvement. This debate helped create significant changes in grant review and approval within industry. As noted in the recent U.S. Senate Finance Committee Staff Report, the pharmaceutical industry has made radical improvements to the CME grant funding and approval structure since the issuance of the 2003 HHS OIG Compliance Guidance. The OIG guidance distinguished CME from "other education" and required industry to separate CME "grant making functions from their sales and marketing functions" in order to ensure that CME grants are not "used improperly to induce or reward product purchases or to market product inappropriately." Industry is not allowed any control over speakers or content of a certified CME activity, and most pharmaceutical organizations are spearheading transparency efforts by posting CME grant data on the internet.

Since 2004, healthy debate also led to positive changes in ACCME policies and standards and improvements to adult education practices and delivery structure among accredited providers. Debate is critical for continuous improvement. But when calls are made for physicians to bear the burden of paying for all their continuing education, such as the case with attorneys, we need to remember three critical differences between physicians and attorneys:

- When an attorney makes a mistake in the practice of law, it causes problems and potential costs within the legal system. But when a physician makes a mistake in the practice of medicine, it can cause the loss of a human life.
- Second, the amount of changes to case law each year pales in comparison to the number of journal articles, scientific advancements and treatment changes occurring in the field of medicine each week.
- Last, attorneys have the ability to charge for every hour they spend in their practice of law. Physicians are limited in the amount they can charge by government and others, regardless of the time they spend. Placing the full financial burden of continuing education upon physicians will only reduce the quality and quantity of CME.

In order to successfully argue for elimination of industry funding of certified CME, CEJA advocates must show that this funding currently results in education that is not clinically relevant or scientifically objective. These advocates also have the burden to prove that any new system being proposed will improve the quality of education and not lead to greater harms within the healthcare system. To date, no evidence-based study has shown that industry funding causes bias within certified CME. More important, the CEJA report has not identified a plan or proposal that will improve the quality and breadth of certified CME offerings to the medical community.

The report actually cites information in conflict with its proposal to eliminate industry funding. On one hand, the report calls for medical schools, hospitals, professional societies and others to conduct more education without industry support – in order to develop education devoid of "bias." On the other hand, the report produces information stating that "it is not humanly possible to be free of bias." If this latter statement is true, then no education developed – in the presence or absence of industry funding – is free

of bias. Again, while tertiary data is provided to support claims about information bias in general, no evidence-based study has assessed levels of bias specifically within certified CME activities.

Last, we take issue with the report's claim about the inability of physicians to recognize bias in certified CME. Accredited providers are required to monitor, evaluate, and respond to any complaints about bias. The CEJA report does not support its claim, "It is not reasonable to expect physician learners who are attending an educational event to acquire new knowledge to be in a position to fully discern what 'information' provided by the presenter is objective or biased." With due respect to the report's author(s), physicians are not naïve schoolchildren taking the teacher's word as gospel.

Summary

The CEJA report begins with the laudable goal of ensuring "that current and future generations of physicians acquire, maintain, and apply the values, knowledge, skills, and judgment essential for quality patient care." While the goal deserves support, the CEJA report's data and conclusions require significant modification.

The report mistakenly combines certified CME with "marketing" and other information included under the umbrella of "professional education." Certified CME is not addressed specifically, and the report calls for elimination of industry funding of CME based on 22-year-old data that pre-dates the ACCME Standards for Commercial Support and federal government guidance requirements for producing high quality, industry supported education. In addition to blending CME with non-CME activities, the report misinterprets critical data in support of its recommendation, and it does not provide a tenable plan or evidence-based support for the transition it proposes. In short, this report's conclusions and proposals demand substantial modification in order to garner support.