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BY HAND DELIVERY; E-MAIL

Mark Levine, M.D., Chair
Council on Ethical and Judicial Affairs
Raymond Christensen, M.D., Chair
Reference Committee on Constitution and Bylaws
American Medical Association
515 State Street
Chicago, IL 60610

Dear Dr. Levine and Dr. Christensen

We urge the American Medical Association (AMA) Reference Committee on Amendments to Constitution and By-laws not to adopt the recent Report of the Council on Ethical and Judicial Affairs (CEJA) on "*Industry Support of Professional Education in Medicine*,"¹ and to refer the matter for further study.

We have a strong interest in the legal and ethical principles that govern conflicts of interest in a variety of health-care and other contexts and an active practice in the area. However, we do not represent a specific client in connection with the CEJA Report. We make the recommendation for rejection of the Report and reference for further study on our own initiative and because of our commitment to the development of workable standards on conflicts of interest that reflect the considered views of all relevant stakeholders. There are at least three overarching reasons why the Reference Committee should reject the CEJA Report and refer it for further study.

First, the procedures used by CEJA to develop the recommendations in the Report lacked due process. We understand of course that constitutional due process standards may not apply to CEJA or to the AMA for that matter. At the same time, and as a matter of fundamental fairness, an open and transparent process that provides an opportunity for input from all interested constituencies would provide a much more robust foundation for any ensuing recommendations. As it now stands, the CEJA Report lacks the significant credibility that would emerge from an open and collaborative process and can be criticized as reaching a predetermined conclusion based on a one-sided collection and assessment of the relevant "evidence."

¹ CEJA Report 1-A-08, available at <http://www.ama-assn.org/ama1/pub/upload/mm/471/ceja1.doc>

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Second, in concluding that conflicts cannot be managed and must be eliminated entirely, the CEJA Report is at odds with other thoughtful recent recommendations from organizations with comparable interests. For example, in April 2008, a Task Force of the American Association of Medical Colleges (AAMC) issued a report on the same subject that does not seek a total ban on industry funding of Continuing Medical Education (CME) and that looks to conflicts management tools as a way of ameliorating the concerns.² Similarly, in February 2008, a Joint Advisory Committee of the AAMC and the American Association of Universities (AAU) issued more general guidelines on conflicts of interest that likewise utilize conflicts management tools to address problems without creating the total separation that the CEJA Report recommends.³ It seems necessary and proper for AMA to consider the views of these other organizations before promulgating conflicting standards that leave key stakeholders uncertain as to which of them to follow.

Third, the CEJA Report fails to identify and consider the serious collateral implications of its recommendations. If all conflicts in medical education must be eliminated rather than managed, is the same prophylactic standard to be applied to a variety of other interactions that society tolerates—indeed encourages—where the potential for bias exists yet is deemed to be managed through disclosure and other techniques? For example, does it mean that any physician who receives industry funding for biomedical research must resign from all medical school faculty appointments? If so, how will that affect the quality of medical education going forward, as some of the best and brightest minds withdraw from teaching medical students? Conversely, what does this do to the quality of biomedical innovation if all medical faculty terminate all paid relationships with industry instead of resigning their faculty appointments? The first principle of medicine is to “do no harm”. Adoption of the CEJA Report without further study creates the very real potential of doing substantial harm to medical education and research and, in turn, to patients.

² See “*Report of the AAMC Task Force on Industry Funding of Medical Education to the AAMC Executive Council*” (April 27, 2008), available at <http://www.aamc.org/research/coi/industryfunding.pdf>.

³ See e.g., McDermott, Will & Emery “*On the Subject: AAMC/AAU Joint Advisory Committee Issues New Guidelines on Managing Conflicts of Interest*” (February 28, 2008, available at http://www.mwe.com/index.cfm/fuseaction/publications.nldetail/object_id/7a0c63ef-8eab-43a0-9c36-39c2a61d4773.cfm).

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For the reasons set forth above, we urge the Reference Committee not to adopt the CEJA Report and to refer it for further study through a process that is open to all stakeholders.

Sincerely,



Arnold I. Friede
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cc: Lee Black (By Hand Delivery; E-Mail)
American Medical Association Staff

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