

## **ACRE Response to AMA CEJA Financial Relationships with Industry in Continuing Medical Education 1-I-09**

The American Medical Association Council on Judicial and Ethical Affairs (CEJA) report 1-I-09 titled Financial Relationships with Industry in Continuing Medical Education is their third attempt to ask individual physicians and institutions of medicine to not accept industry funding to support professional educational activities. This proposal and its recommendations, which claim that industry support of professional education threatens the integrity of medicine's educational function, are unfounded and lacking basis in fact.

The Association of Clinical Researchers and Educators (ACRE), an organization of physicians and colleagues recommend that the CEJA Report 1-I-09 and its recommendations be referred back to committee for the reasons outlined below. ACRE members are engaged in promoting excellence in medical service, education, and innovation and have substantive track records in these endeavors.

### **Methodology and Evidence**

The recent report from CEJA about Continuing Medical Education (CME) states: “To date, there is no empirical evidence to support or refute the hypothesis that CME activities are biased” (p. 3 48-49), and the available data by no means demonstrate conclusively that commercial funding unduly biases continuing professional education (p. 4 11-12). Such an absence of data makes claims to eliminate industry funding of CME (“Continuing Medical Education”) misguided from the start.

The “arbitrary” methodology of the report to define criteria that would be used to eliminate industry-funded CME is even more problematic considering the evidence CEJA uses to advance its claims. For example, of over fifty sources used in the CEJA report and recommendations, there is very little evidence presented based on systematically acquired data, the overwhelming majority of sources are opinion pieces, surveys and policies. Many of the papers are written by non-physicians who view financial conflicts of interest as damaging and have established their careers writing anti-industry papers. In an era of evidenced based medicine and comparative effectiveness research, the reports lack of evidence fails to support their claims of the need for signification changes in the already highly regulated CME system.

There is little empirical evidence cited by the report and no proof that industry support for CME causes bad patient care decisions. This lack of evidence is especially obvious when considering that such industry-sponsored product updates concern medicines and devices that have been vetted by an agonizingly long, expensive albeit imperfect approval process.

One source the CEJA report cites as evidence includes commentary from Brennan (JAMA 2006;295:439-433) on a study done by Ashley Wazana, who also explicitly stated that no patient care data existed to show how interactions with industry hurt patients. In fact, according to Wazana's literature survey, product marketing enables the *"improved ability to identify the treatment for complicated illnesses"* -- a clearly desirable effect.

In another indirect argument, Brennan embraced the conclusion, derived from psychological experiments and embellished by neuro-imaging studies, that physicians lack discriminatory

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powers to resist subtle persuasion tactics skillfully embedded in educational activities by commercial marketers. The research behind these ideas is limited to the extent of questionable relevance or validity.

All of the references that Brennan and colleagues cited were to books, medical journal articles, and newspaper reports supportive of the authors' claims. These references were compilations of anecdotes, purportedly exemplifying industrial corruption of medical research, rather than evidenced based reports.

### **Ignoring Relevant Evidence**

CEJA's reliance upon the Brennan paper violates a major requirement of serious scholarship by not citing research that shows the many benefits of commercial contributions to medicine. Instead, Brennan exercised confirmation bias by referring only to publications critical of industry influences on medicine, although others refuting these criticisms existed when the Brennan paper appeared.

Like the Brennan paper, the CEJA Report only cited literature supportive of its conclusions and treated the benefits of commercialism in medicine cursorily. Today, there is evidence that public trust in doctors is high and stable, according to a series of Harris polls on "most trusted professions." There is evidence that the public worries about incentivizing physicians to economize on resources, and that the public associates more resource use with better care. We do not judge whether such views are appropriate, but there is no evidence that the public worries about doctors prescribing too much patent-protected medicine. There is also current and emerging evidence to show that "supporter bias" in content is not evident to the physicians who take CME courses.

### **CME Participation is Voluntary**

Participation at industry sponsored CME is always a voluntary activity. If doctors choose to go it's because they find it to be of value. They do not have to go. And when physicians do go, they know the nature of the content being presented from the disclosure and the rules governing industry sponsored CME (through the Accreditation Council for Continuing Medical Education ("ACCME")).

Physicians have no incentive to learn about what's new in medicine unless what they currently work with is limited or ineffective, so that they desire to get their hands on something better. Indeed, the "clinical inertia" literature says that physicians resist change to better therapy even when they know and have reason to know that it is better. The idea that physicians mindlessly hanker after novelty and innovation and that industry panders to this longing is not consistent with the facts.

For common, lethal syndromes (*e.g.*, hypertension, hyperlipidemia) in patients with atherosclerotic disease, etc., the vast majority of patients are undertreated and NOT at goal. Attendance at sponsored lectures are one of a very few methods to address this systematic undertreatment of our patients.

### **Industry-Funded CME**

With over 50% of CME being funded by industry, who is going to pick-up the bill if industry is banned? For the most part, the federal government does not see supporting CME as part of its

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mission and states are broke. Insurance companies and academic medical centers have reduced funding for CME over the last ten years.

If industry funding of CME is removed, physicians will lose critical access to programs that teach them how to use new medicine, treatments, devices and technology, the majority of which is created by the same industry that support such programs. In CEJA's perfect world commercial interests would be able to provide only philanthropic/charitable funding (which would decrease support substantially); it would remove from grant evaluation those commercial interests who have the most knowledge about emerging therapeutic areas and the most knowledge about educational and clinical practice gaps.

If providers are routinely audited as CEJA suggests for the level of industry support they receive to ensure that they "maintain the independence" and integrity of their educational mission and programs, the consequences will hurt patients. Medical associations and many other organizations will cease to exist, decreasing the number and quality of providers, and most especially those that develop and produce the highest quality education.

### **Delayed Implementation**

The CEJA recommendation on elimination of commercial support, chooses to ignore the potential for patient harm by delaying treatment if new procedures and therapies are not discussed and explored in CME activities or those activities fail to take place due to lack of support.

To delay a physician's participation for an industry funded CME program for 12 months following termination of that relationship will cause fewer true thought leaders to participate in advising industry on drug development, and remove from on-label education some of the brightest and most engaging educators. Physicians need the freedom to strive to become thought leaders and leading researchers in their field of expertise. Trying to mitigate the potential influence of conflict under these circumstances will only hurt patients and medicine by restricting the experience and training doctors need to become such leaders and researchers.

If it is necessary for there to be a demonstrated and compelling need for the specific CME activity that cannot otherwise be met, this further imposes administrative and research hurdles for providers, which may increase the cost of creating educational activities.

### **Industry vs. Generics**

While industry funded CME probably does result in more prescribing of branded products, why should CEJA care about that? Suppose CEJA members prefer makers of generics rather than makers of patent-protected, branded products. Why should that preference prevail under the aegis of ethics? A substantial majority of prescriptions today are generics.

### **Rural and Inner-City Physicians benefit from CME**

In these areas, it is unlikely that any outside expert would come on their own to teach other providers the management of diabetes or complex cancers without commercial support helping to cover expenses of these experts.

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The justification criteria in the recommendations will be administratively over burdensome, further restricting small CME providers from soliciting commercial support to help fund their activities.

### **Medical Societies**

Medical Societies will also suffer from recommendation 2, in that a vast majority of new science is presented by faculty who are currently involved in compensated relationships with a commercial entity. The exception criteria will be tremendously burdensome on smaller societies who will be forced to dedicate resources to justify the use of the most knowledgeable speakers and presenters.

### **Healthcare Reform: More CME, Not Less**

With healthcare reform around the corner, we need to consider that adding an additional 30–60 million patients to the system will force a need for additional training by physicians especially primary care physicians. Reducing the sources of funding for education of physicians will only further strain the already overburdened physician healthcare providers.

### **Other Stakeholders**

The problem is not the need to restrict commercial support of CME but to chastise the other medical stakeholders who have withdrawn from support for CME. This includes insurance companies (who should be supporting physician education instead of complaining and denying coverage), managed care organizations, governments (state and national), and hospitals (large chains spend little on CME).

### **CME Progress**

The commercial support which helps pay for CME enhances patient care. Wouldn't you rather have a physician trained in an area of medicine and able to interact with other professionals as opposed to just reading about a new therapy? CME creates communities of interest, opportunities for physicians to ask questions to dig deeper into complex medical issues providing venues for discussion and/or online courses that allow the physician to learn about medications and breakthrough science in real time, offering hope to patients.

Since the 1960's, longevity and quality of life have steadily improved as medicine began to become increasingly "commercial," including industry funded CME. The death rate from cardiovascular disease, for example, the number one killer, has steadily decreased and is currently half of what it was at that time. Death rates for cancer have also decreased.

Many factors have contributed to these trends, but economic analyses have concluded that the principal reason for them has been the introduction and marketing of new technologies by private companies -- drugs, biologics, devices, and information systems. Publicly-funded mechanistic-focused research, primarily from the National Institutes of Health (NIH), has been essential for medical innovation, but the investments of private companies are the major mechanisms for the development and delivery of useful products on the basis of such innovation to patients.

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Other important examples of value derived from commercial medical technology include medications enabling prolonged symptom-free survival of HIV-infected patients and the introduction of diagnostic methods that render our blood supply increasingly safe.

### **Commonality of Interests**

There is no inherent “conflict” of interest in the working relationship of physicians with industry and government. Rather, there is a commonality of interest that is healthy, desirable, and beneficial. The collaborative and constructive relationship among physicians, government, and industry has resulted in many medical advancements and improved health outcomes. Various organizations have formulated policies and procedures to guide the conduct of the organizations and their members in cooperative interactions with industry and with government to enhance physicians’ ability to provide the highest quality of medical care for patients.

### **CME and Industry Promote Variety**

Since the purpose of medical "professionalism" is better patient care, positive outcomes of corporate investments in research, development, and promotion create a variety of knowledge and information to providers wishing to be competent to help with the patient's best interest in mind.

CEJA and Brennan’s paper fail to acknowledge the evidence that many patients frequently do not receive appropriate products, not because of access problems, but because their physicians do not recommend them. A major reason for deficient prescribing is the lack of physician awareness, potentially curtailing information transfer will constrain its funding increasing this deficiency.

Industry-funded CME is merely one of many options physicians use to address the well being of patients. Labeling such programs as wrong for the mere appearance of undue influence creates a problem for CME providers and the doctors who use their services because neither can afford to spend all their time explaining what they are doing, especially when there is no conclusive evidence to prove that it is bad.

### **Scientific Objectivity?**

Scientists passionately pursue their research driven by strong competing biases, but they subject their treasured ideas to rigorous tests designed to delineate their reproducibility and validity. From these tests, a consensus may evolve, but in the end, except in mathematics, subjective interpretations come into play. Ultimately, the track record of the science, not the motives -- or the profits -- of the scientists, determines the durability and utility of the scientific claims.

### **Commercial vs. Non-proprietary Information**

To believe that some repository of non-promotional or otherwise unbiased information exists that is superior to what physicians obtain from the competing universe of propriety, or in part, commercially supporting education, is unrealistic. Transparency in medicine helps eliminate bias and fraud, and it also ensures competition and inquiry that over time reveal and eliminate them.

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Companies maximize profitability by coming up with products that benefit patients, and to conclude that industry has no interest in social responsibility is an enormous, erroneous leap. If corporate support of educational activities enables physicians to sustain their patient care activities, it is in the interests of patients. At a time when public support of biomedical research is not meeting research opportunities, when medical students are laden with debts and when organized medicine must desperately fight to sustain physician reimbursement rates, the wisdom -- indeed the ethics -- of arbitrarily discarding a major source of revenue for medical education is questionable.

### **Industry Support of Education is Not Corrupt**

CEJA's use of the Brennan Report is oddly selective because it neglects the obvious fact that academic health centers and medical journals are also "commercial," are engaged in vigorous competition with rivals, and exhibit the same promotional behavior deemed unattractive when exhibited by private companies.

One needs only to listen to the radio in any major metropolitan area to hear (multiple times each day, if not each hour) academic medical centers promoting their prowess for cardiovascular interventions, cancer therapy, diabetes treatments, joint replacements, etc.

### **Conclusion**

The activities of ACRE's membership in the clinics, classrooms, and laboratories of medicine require it to base decisions on evidence and reasoned debate, not on the kind of abstract beliefs held by critics on the sidelines of medicine.

ACRE believes that the operation of medical education is, unless proven to create harm, a practical and not an "ethical" issue. ACRE strongly recommends that the AMA cease to accommodate the handling of CME as if it were a matter solely of ethics, or a perceived lack thereof. In addition, ACRE points out that in its repetitive advancement of its ideology, CEJA has consistently failed to cite a growing literature invoking both evidence and reasoned debate that contrasts with CEJA's opinions (**See attached**).

Indeed, the repetitive packaging of the same arguments by CEJA is wasting the time of working physicians, educators, and researchers to refute them. For example, no amount of repetition could legitimize the persistence of purging and bleeding or obviate their harm.

ACRE believes there is value to physicians, medicine, medical education, and patients from the working relationship between physicians and industry. There is no conflict in advancing science, and there is no conflict in providing the education that is required to do so.

By working together with industry colleagues, we can explain to the public that the contributions of corporations to medicine are, on balance, more beneficial than harmful and that both medicine and the industries that provide it with its technologies are worthy of public support. Cooperation, instead of antagonism, can help industry develop and market therapies with the highest integrity, by keeping physicians current on the best available evidence, and by providing excellent patient care.

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## Additional Sample References for Future CEJA Reports

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