ACRE Association of Clinical Researchers and Educators

ACRE Response to AMA CEJA Financial Relationships with Industry in Continuing Medical Education 1-A-10

The American Medical Association Council on Judicial and Ethical Affairs (CEJA) Report 1-A-10 entitled “Financial Relationships with Industry in Continuing Medical Education” is CEJA’s fourth attempt to ask individual physicians and institutions of medicine to not accept industry funding to support professional educational activities. The Report and its recommendations parrot its predecessors and, ultimately, rest on the claim that industry support of professional education threatens the integrity of medicine's educational function, a claim which is false and further discredited by 3 studies published in the past year (discussed below).

The Association of Clinical Researchers and Educators (ACRE) is an organization of physicians and colleagues engaged in promoting excellence in medical service, education, and innovation. Our members have records of achievement in these endeavors. ACRE recommends that the CEJA Report 1-A-10 and its recommendations **be rejected by the AMA House of Delegates** for the following reasons:

- CME is already highly regulated to prevent undue influence from industry
- Reducing resources in CME will result in less education of physicians
- With the adoption of Health Care Reform and the subsequent addition of 30 million new patients to the healthcare system, additional financial resources will be needed to educate a greater number of physicians and other healthcare providers not less
    - CME plays a vital role in promoting evidence-based medicine (EMB)
    - Failure to understand and adopt EMB is estimated to cost hundreds of millions of dollars
    - CME is also the best means of disseminating comparative effectiveness research, the cornerstone of any sensible health policy
- The CEJA report ignores 3 recently published studies, involving very large study populations, which are directly relevant to the Report's subject matter but "contra" to the report's recommendations. By an overwhelming margin, doctors who actually attend commercially sponsored CME do not perceive bias.
- For the CEJA report to ignore this evidence is tendentious and contrary to "evidence-based professional ethics"
- The best evidence of the perceived value of CME events is that doctors attend voluntarily, giving up Saturdays or evenings to do so
- Passage of the Physician Payment Sunshine Provisions in Health Care Reform eliminates the need for more detailed disclosure as recommended in the CEJA report

- CEJA's report is virtually the exact same report that has been rejected three times previously by the House of Delegates
    - It is identical to the December 2009 rejected report up to page 5
    - The exact same 57 references are utilized in the exact same order
- CEJA uses arbitrary methodology and relatively little evidence to support their claims
- CEJA defines all financial interests with industry as conflicts yet ignores all other financial interests
- CEJA ignores that CME participation is voluntary
- There is no discussion in the CEJA report of the following issues:
    - The risk to patients because of reduced financial support of CME
    - The effects of their restrictions on rural and inner-city physicians
    - The effects on medical societies
    - The progress made from education on medical innovation
    - That diversity of funding leads to competition for better CME
    - That industry has a social responsibility to support education
    - Americans are confident in the FDA and biomedical research
    - There are significant costs associated with increased regulation
- CEJA needs to recognize that according to the US courts, suppressing CME support is equivalent to suppressing freedom of speech

A detailed explanation of the reasons why CEJA Report 1-A-10 should be rejected is outlined below.

CME and Regulation

CME is highly regulated. The ACCME Standards for Commercial Support and the FDA Guidance already enforce much of what CEJA considers changes and need for a code of conduct. There is no compelling reason or evidence to support their proposed changes.

The existing guidelines include the following recommendations:

a. the educational activity is planned by the provider based on needs identified independent of and prior to solicitation or acceptance of the commercial support; and
b. the CME provider can articulate a compelling reason(s) to accept industry support for the educational activity or activities; and

c. the CME provider declines industry support that is conditioned on the provider's acceptance of advice or services concerning educational content, faculty or content developers, or other educational matters; and

All of these recommendations are already addressed in the current standards and practices.

The additional recommendations of justifying every incidence of interest, along with auditing programs and asking for magnitude of disclosure would result in enormous undue administrative burdens on specialty societies and state accredited organizations running thousands of CME programs each year.

Moreover, the Standards for Commercial Support, coupled with the Office of Inspector General Compliance Program Guidance, have set clear boundaries between education and marketing. What is needed now is solid research on the effects of these regulatory changes. Continued rehashing of old rhetoric does a disservice to both accredited CME providers and the medical profession.[1]

In addition, with the passage of the Physician Payment Sunshine provision in the Affordable Care Act of 2010, there is no reasonable need for additional reporting of interests by CME faculty as recommended by CEJA.

Methodology and Evidence

CEJA's Report 1-A-10 relies on the same fifty seven (57) references in the same order as the previously rejected CEJA reports. In addition, as in previous iterations, it claims: "To date, there is no empirical evidence to support or refute the hypothesis that CME activities are biased" (p. 3 48-49). However, there now are substantial data that demonstrate a lack of commercial bias in industry-sponsored CME.

Three studies completed this year, and provided to CEJA by ACRE, each conclude that commercial support of CME is not associated with perceived bias by physicians who actually attend. Specifically, CEJA ignores a Cleveland Clinic study of almost 100,000 CME participants, which found no evidence that commercial support results in perceived bias in CME activities, that bias levels were quite low for all types of CME activities, and that commercial support made no significant difference in the degree of commercial bias.[2]

Report 1-A-10 also ignored a study by Medscape of over 1.6 million physicians who participated in online CME activities. Results showed that 93% of physician participants perceived no commercial bias.[3]

[1] Colburn, Lois. Dorman, Todd. Continuing Medical Education — Limiting Industry's Influence. *New England Journal of Medicine*. 362;11. March 18, 2010. Commentary.

[2] Kawczak S, Carey W, Lopez R, Jackman D. The effect of industry support on participants' perceptions of bias in continuing medical education. *Acad Med.* 2010;85(1):80-84.

[3] Ellison JA, Hennekens CH, Wang J, et al. Low rates of reporting commercial bias by physicians following online continuing medical education activities. *Am J Med.* 2009;122(9):875-878.

Lastly, Report 1-A-10 ignored a study from the University of California, San Francisco, which collected data from 213 directly sponsored live CME activities. The study found that rates of perceived bias were low for the vast majority of CME activities in the sample and did not differ by the degree of industry support or other event characteristics.[4] The study concluded that CME activities in general are perceived by physicians as free of commercial bias.

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 (50) sources used in the CEJA report and recommendations, there is very little reliance on systematically acquired data. The overwhelming majority of these sources are opinion pieces and policies. Many of the papers are written by non-physicians who chant the mantra of "financial conflicts of interest" and have advanced their own careers writing anti-industry papers.

There is no proof that industry support for CME causes bad patient care decisions. In fact, 1-A-10 acknowledges that to date, it "has not been clearly demonstrated to what extent the amount of a financial interest may influence perception and judgment" (p.4 31-32). Instead, CEJA declares that "clear evidence is lacking" and acknowledges that most policies on "conflict of interest" at least tacitly assume that the greater the financial interest, the more problematic that interest is, but without any evidence (p. 4 32-24).

While CEJA mentions a "growing concern within and outside medicine that industry funding can have undesired effects on CME," it completely ignores the reassuring findings of the three recently published on-point studies.

Industry-sponsored product updates typically concern medicines and devices that have been vetted by an agonizingly long and expensive (albeit imperfect) approval process. One source the CEJA Report cited as evidence is a commentary from Brennan et al (*JAMA.* 2006;295:429-433). This opinion piece falsely represents a study performed by Ashley Wazana (*JAMA.* 2000;283:373-380) as having documented "negative effects" of industry marketing on patient care. The Wazana paper explicitly stated that none of the studies reviewed used patient outcome data as a measure. Therefore, we have no evidence whatsoever that commercial influence adversely affects clinical care, the Brennan report's claim to the contrary notwithstanding. In fact, Wazana's literature survey found that product marketing enables "improved ability to identify the treatment for complicated illnesses," an outcome with potential for clearly desirable clinical effect.

Notably, the Brennan commentary embraced the conclusion, derived from limited psychological experiments and embellished by neuroimaging studies, that physicians lack insight to detect and sufficient self-control to resist subtle persuasion tactics skillfully embedded in educational activities by commercial marketers. The study populations involved in the research behind these ideas did not involve physicians, so it is of questionable relevance or validity.

All of the references that CEJA, Brennan, and other critics have cited are to books, medical journal articles, and newspaper reports supportive of their claims. These references were

[4] Steinman MA, Boscardin CK, Aguayo L, Baron RB. Commercial influence and learner-perceived bias in continuing medical education. *Acad Med.* 2010;85(1):74-79.

compilations of anecdotes, purportedly exemplifying industrial corruption of medical research, rather than evidence-based reports. The Brennan paper authors have introduced *their* bias, and CEJA has blindly followed this path. As an AMA council, CEJA cannot, and must not, be manipulated by opinions. CEJA has the ethical and moral duty to provide reports that are based in science, provide fair balance, and respect the will of the membership to do what is best for medicine.

Framing Bias

It is well-established that risk-framing influences judgment. For example, when British women were informed that taking "the pill" doubled the risk of thromboembolism, many stopped taking it, and there was an increase in unwanted pregnancies and abortions. Had the report avoided the risk-hyping framing bias (by reporting that the pill increases risk from 1 to 2 in 14,000 women), fewer women would have been frightened and fewer untoward events would have occurred.[5]

Using "conflict of interest" to frame physicians' relationships with industry is an example of a "framing bias," specifically "risk framing."

Framing a physician's relationships with industry by using the term "conflict of interest" insinuates that in order to receive the commercial funding to do research, CME, or consulting, etc., the physician behaved (or appeared to behave) unprofessionally, putting patients at increased risk of harm. "Conflict" carries an inherently negative connotation, insinuating that the physician has questionable motives based solely on an association with industry.

As a result, the COI framing bias has rhetorically reconstructed what were once termed "relationships" between physicians and industry into something malignant – "conflicts." The COI framing bias dictates a conclusion by linguistic fiat – the only appropriate response to a "conflict" is to eliminate, manage, or reduce it. The framing bias cuts off from appreciation that the complex relationships between industry and the medical profession are almost always positive and are perceived as such by most physicians.

CEJA Ignores 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. Brennan et al indulged in confirmation bias by referring only to publications critical of industry, supportive of their position that industry influences medicine. These authors ignored the fact that others refuted these criticisms when the Brennan paper appeared.[6]

Like the Brennan paper, the CEJA Report only cites literature supportive of its conclusions and treats 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 ration 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

[5] Gigenrenzer G. Why does framing influence judgment? *J Gen Intern Med*. 2003;18:960-961.

[6] Stossel TP. Regulating academic-industry research relationships—solving problems or stifling progress? *N Engl J Med.* 2005;353:1060-1065.

doctors prescribing too much patent-protected medicine. To the contrary, in some states, like Minnesota, there is growing concern about the harm done to patients by the over-prescription of generic medications. [7]

CME Participation Is Voluntary

Participation at industry-sponsored CME is always voluntary. Insofar as 1-A-10 proposes that physicians avoid the potential for bias or the chance that confidence in CME is diminished, this change is unnecessary. If doctors choose to attend it is because they find CME 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 disclosures and the rules governing industry-sponsored CME (through the Accreditation Council for Continuing Medical Education [ACCME]).

Physicians have no incentive to learn about what is new in medicine. That is, unless what they currently work with is limited or ineffective, so that there is a desire to get renewed knowledge. Indeed, literature on "clinical inertia" reports 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 example, the vast majority of patients with atherosclerotic disease and common, lethal syndromes (e.g., hypertension, hyperlipidemia) are undertreated and *not* at goal. Attendance at industry-sponsored lectures is one of a very few methods to address this systematic undertreatment of patients.

Furthermore, audience attendance at commercial CME–sponsored events, which is voluntary and uncompensated, usually occurs in the evening or on weekends — in time away from a busy practice or family. Given that many alternatives exist for CME certification (e.g., online, journal-associated), attendees must find value in these sessions beyond that of the accompanying meals. Several physician groups have started to reject the notion that industry sponsorship of CME should end. The Institute of Medicine could not find objective evidence of harm. A recent peer-reviewed study by Ellison et al., funded by a CME company, shows that the vast majority of physicians in the audience at such events do not perceive undue influence. Therefore, the value of CME should be gauged on content, not provenance, because limiting CME (a sure consequence of no industry funding) carries the real risk of limiting the transmission of knowledge and of being deleterious to patients.[8]

Industry-funded CME and Healthcare Reform

With the passage of the Affordable Care Act (ACA – Health Care Reform), over 30 million Americans, a population the size of Canada, will now have access to insured medical care. The addition of these patients will create an enormous need to educate physicians on medical and surgical treatments. There will be a greater need for CME resources to help educate physicians. Constricting the supply of resources is not a viable solution, and we should be focused on expansion of resources to improve access to medical education.

[7] Gonzalez-Campoy JM. The physician-industry relationship: lessons from the Minnesota experience. *Endocr Pract.* 2009;15(4):292-297.

[8] Fonseca, Rafael. Continuing Medical Education — Limiting Industry's Influence. *New England Journal of Medicine*. 362;11. March 18, 2010. Commentary.

For healthcare reform to be successful, the conversation needs to change from limiting to expanding resources. CME plays a vital role in promoting evidence-based medicine (EBM), Failure to understand EBM is estimated to cost hundreds of millions of dollars and results in substandard care for thousands of patients. Also CME is by far the best means of disseminating comparative effectiveness research (CER). The Federal government is spending over ten billion dollars on this research.

Industry support of CME provides a valuable resource for promoting both EBM and CER.

With over 50% of CME being funded by industry, who is going to pick-up the bill if physicians are told to "avoid" industry-sponsored education? For the most part, the federal government does not see supporting CME as part of its mission, and states are broke. Insurance companies and academic medical centers have received reduced funding for CME over the last ten years. Additionally, there is some evidence that the rate of growth in industry support of CME may be leveling off, or even declining slightly (p.3 21-22).

If industry funding of CME is removed or continues to decline, physicians will lose critical access to programs that teach them how to use new medicines, treatments, devices, and technology, the majority of which is created by the same industry that supports 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 commercial interests who have the most knowledge about emerging therapeutic areas, as well as 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, especially those that develop and produce the highest quality education.

Interestingly, the 1-A-10 proposal recognizes the potential harm to patients that could result from complete restriction of commercially funded CME, and consequently creates a new section to address "exceptional cases" (p.7 28) where CME can be funded by industry. Specifically, CEJA recognizes that industry support is "vital to the professional community," and proposes in 1-A-10 that "some essential educational activities may not be feasible without financial or in-kind support from industry—for example, the provision of cadavers or high-cost, sophisticated equipment to train physicians in new surgical procedures or the use of new technologies" (p. 7 42-45).

Equally important, the new proposal recognizes that frequently "the only individuals truly qualified to train physicians in the earliest stage of adoption of a new medical device, technique, or technology, are often those who developed the innovation" (p.7 35-37).

In some circumstances, however, access to appropriate, high-quality, independent CME may be seriously impaired if support from industry is refused. For example, when expensive equipment is needed, accepting funds or in-kind support from multiple, competing firms might result in more independence than refusing such support (p.9 28-31).

Despite acknowledging the important and essential role industry plays in CME, the fourth proposal makes the same mischaracterizations as its predecessors by adding to its language that

"even minor conflicts of interest can undermine confidence" (p.5 27-28) and that "physicians should avoid the potential for bias" (p.5 37-38).

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 in 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, and generics are now overutilized in some states. CEJA should also consider the benefit of using branded products (i.e. new to market drug categories such as antiretroviral therapy, new insulins, etc).

Rural and Inner-city Physicians Benefit from CME

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

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 1-A-10 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.

Additionally, the recently released Code of Interactions with Industry from the Council of Medical Specialty Societies (CMSS), which represents 32 leading medical professional societies with a collective membership of more than 650,000 US physicians, is comprehensive enough to render 1-A-10 repetitive and burdensome. Although this code is voluntary, it provides detailed

guidance to medical specialty societies on appropriate interactions with for-profit companies in the healthcare sector, allowing physicians to maintain the independence to critically evaluate information from all sources.

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

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 the government to enhance physicians' ability to provide the highest quality of medical care for patients.

In fact, when looking at drug advisory committees at the FDA, one study found that "excluding advisory committee members and voting consultants with "conflicts" would not have altered the overall vote outcome at any meeting studied."[9] In other words, industry involvement by members of a committee did not affect the outcome of the FDA drug advisory committee votes.

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

[9] Lurie P, Almeida CM, Stine N, et al. Financial conflict of interest disclosure and voting patterns at Food and Drug Administration Drug Advisory Committee meetings. *JAMA.* 2006;295(16):1921-1928.

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, and 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 reveals and eliminates them.

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 and 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.

The reason people claim that industry support of education is corrupt, according to a different group within the AMA, is that “the media, state and federal law and policy makers as well as regulators and other ‘collective/consensus opinions’ frequently use and disseminate information that can lead to incorrect assumptions and false perceptions about CME, which has led to increased regulatory scrutiny and critical public opinion regarding CME practices.”

In particular, the AMA’s National Task Force on CME Provider/Industry Collaboration, which is diametrically opposed to AMA CEJA, produced a “Get The Facts” campaign which sets the record straight with a toolkit and series of fact sheets that clarify what CME is and what it is not.

Moreover, CME providers with suitable oversight to ensure compliance with ACCME Standards for Commercial Support can ensure that commercial funding does not affect commercial bias in an activity.

Since the AMA and CEJA certainly do not question a physician's evaluative skills, their lack of evidence makes it unclear why the ability of a doctor to critically evaluate scientific findings is dependent upon how the article got into the physician's hands, or whether a manufacturer suggests speakers or content for a CME seminar.

Suppressing Free Speech

Over a decade ago, the United States District Court for the District of Columbia determined that FDA Guidance Documents pertaining to CME were unconstitutional because they restricted free speech and violated the First Amendment. In deciding the case, the Court declared that the “FDA had exaggerated its overall place in the universe.” With regard to 1-A-10, and for that matter all of their previous proposals, CEJA has done the same.

In particular, CEJA has ignored this legal precedent, and previous case law from the United States Supreme Court “that a state may not completely suppress the dissemination of truthful information about entirely lawful activity because of concern over the effect that the speech will have upon its disseminators and its recipients.” The Supreme Court reasoned that FDA Guidance Documents were too restrictive, given the fact that the FDA had more appropriate alternatives, such as disclosure.

As a result, the Supreme Court concluded that disclosure comports with the Supreme Court's preference for combating potentially problematic speech with more speech. Specifically, the Supreme Court recognizes that in choosing between the dissemination of more or less information "it is precisely this kind of choice, between the dangers of suppressing information, and the dangers of its misuse if it is freely available, that the First Amendment makes for us."

CEJA’s call for physicians to “avoid” hearing information from industry-funded CME is unconstitutional. Moreover, with the recent passage of the Sunshine Act, disclosure of physician payments will be more than enough to satisfy the Supreme Court’s reasoning that disclosure is adequate, rendering the attempt of 1-A-10 to prohibit commercially funded CME irrelevant. Despite the legal precedent, and research which shows that “disclosure plays an important role in mitigating the potential influence of financial relationships, one whose value may be enhanced when both the existence and the magnitude of a financial relationship is disclosed,” CEJA still feels that disclosure is not enough (p.6 46-48).

Not Just Financial Conflicts

The focus of commercially funded CME has always centered on financial conflicts of interest, and the potential for bias. The new proposal does not acknowledge other sources of bias, such as intellectual bias, which includes authorship of original studies, participation in guideline panels, and peer-reviewed grant funding by institutions such as the government or nonprofit organizations that directly relate to a recommendation. Accordingly, since 1-A-10 notes that "not all conflicts are equally problematic ethically" (p.5 27), CEJA must reevaluate their proposal to acknowledge that financial conflicts are not the only potential affecting bias in CME.

Institutions

The fourth proposal is also unnecessary and burdensome because institutions and academic medical centers have responded to the potential for bias adequately. As 1-A-10 asserts, "in recent years, many academic medical centers, state and medical specialty societies and health care organizations have moved toward policies that more vigorously address the potential for conflict of interest and bias with respect to physicians' interactions with industry" (p.4 44-47). Consequently, introducing the need to "avoid" commercially funded CME will create confusion among institutional policies, as well as overlap that will result in an administrative burden that drains valuable resources and staff away from more important projects like research and clinical care.

America Is Confident in the FDA and Biomedical Research

In February 2010, an online survey of 1,000 adults conducted by ResearchAmerica! An Alliance for Discoveries in Health showed that Americans overwhelmingly support and trust the interactions and relationships the government and medical institutions have with the pharmaceutical industry. In fact, the poll found very strong support (94%) for the idea that institutions conducting medical and health research — the government, universities, and private industry — should work together. Moreover, almost 75% of participants felt the pharmaceutical industry creates products that save lives and improve people's quality of life very well or somewhat well.

The survey also showed that over 51% of participants felt that the pharmaceutical industry has a very positive or somewhat positive impact on improving American healthcare, and 56% believed that industry positively improved the health of themselves and their family.

Another important indicator about trust for the pharmaceutical industry was that 64% of Americans polled believed that accurate information about the risks and side effects of their products are done very well or somewhat well. Also, almost 50% believed the pharmaceutical industry conducts clinical trials responsibly somewhat well.

Additionally, with regard to safety, 64% of Americans polled believed that the pharmaceutical industry does a very well or somewhat well job making sure their products are safe and effective before bringing them to market, and 63% responded that the pharmaceutical industry provides general medical safety information very well or somewhat well.

The results of this survey clearly show that "Americans see such collaboration as leading to greater knowledge, better success rates and faster development of cures and treatments, as well as avoiding duplication and maximizing resources devoted to research and development." As a result, recommending that doctors avoid these relationships will go against what patients want, and will only slow progress and success rates.

The Cost of Transparency

With a broad and sweeping proposal like 1-A-10, the AMA will need to find the right part of the bureaucracy to specialize in drug industry spending on CME. This will likely require new staff, training, rules, procedures, testing, and oversight, among other things — all of which will cost money and take time. While CEJA and the AMA may end up with a lot of names and data, this information will not be relatively useful, something already being seen with the size of the initial grant/payment reports on corporate websites like Eli Lilly & Co. and Pfizer Inc.

In addition, since current company disclosures tend to co-mingle expenditures for a range of functions, from speakers bureaus to consulting to clinical research grants, CEJA will force institutions to use additional staff and resources to handle this task.

At a time when resources, staff, and funding are scarce, and there is a need for new treatments and trials, the AMA cannot afford to enforce their proposal, and neither can patients.

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. To vote in favor of this report results in a tacit consent of the logic behind the report and the references, which are basically opinion papers.

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.

Furthermore, the new language contained in 1-A-10 contradicts itself throughout the proposal. On the one hand, CEJA acknowledges that 1) CME in some cases may not be feasible without industry support; 2) individuals who develop an innovation are the only ones truly qualified to train physicians; and 3) access to appropriate, high-quality CME may be impaired if support from industry is refused. Yet while asserting that without industry funding CME will be impaired, they still propose that physicians avoid potential bias. This confusion clearly ignores the proposal's own acknowledgement that "industry support for CME helps to meet the costs of programs and activities in the face of uncertain funding from other sources." It also reduces "costs to individual attendees and makes CME more accessible, especially for physicians in resource poor communities" (p.3 35-37).

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.

Additional Sample References for Future CEJA Reports

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