

## ACRE Response to AMA CEJA Financial Relationships with Industry in Continuing Medical Education 1-A-11

The American Medical Association Council on Judicial and Ethical Affairs (CEJA) Report 1-A-11 entitled “Financial Relationships with Industry in Continuing Medical Education” is CEJA’s fifth attempt to ask individual physicians and institutions of medicine to reject industry funding to support professional educational activities.

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.

We affirm CEJA’s dedication to excellence in medical education, clinical research and patient care. However, ACRE disagrees with, cannot support, and indeed, emphatically rejects the self-defeating, misguided, harmful strategy CEJA repeatedly has recommended to the AMA House of Delegates (HOD). CEJA’s continued use of a framing bias that is defined by “conflicts of interest”—whether real, potential or imagined—and their fixation on subjective, ill-defined “perceptions,” cannot advance the goals that unite the house of medicine, namely, professionalism, excellence and a commitment to base policy on objective evidence. Therefore, ACRE recommends that the House of Delegates **reject** CEJA Report 1-A-11 and its recommendations for the following reasons:

- Physicians overwhelmingly value industry grants to support CME and attendees overwhelmingly assert that commercially supported CME programs provide up-to-date, timely, useful, and reliable information about medications to treat particular conditions, and knowledge or skills helpful in their practice
- CME is already highly regulated to prevent undue influence from any sponsor
- CME already has in place adequate provisions for transparency and independence
- Three very large studies conclusively show there is little perception of bias in CME by participants in CME events
- Commercially supported CME has been documented to improve outcomes in a number of subjects including COPD, Hypertension, ICU patients, Sepsis, and hospital acquired infections
- A large number of professional organizations and specialty groups find value in commercially supported CME
- CME is critical to educating doctors about new drugs and treatments
- The report relies on references and research that do not differentiate CME and commercial education

- The report too vaguely describes under what circumstances commercial support of CME would be acceptable by using the term “significantly undermine”
- Attempts to change CME to a system similar to continuing legal education (CLE) are unrealistic because (1) the volume of information in medicine is vastly greater than law, (2) changes to practice in medicine occur at a much faster rate than law, and (3) mistakes in medicine can lead to death, whereas mistakes in law can be corrected through other, less life threatening processes
- 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 (EBM)
  - Failure to adopt EBM 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 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
- 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 by medical innovation from education
  - That diversity of funding leads to competition for better CME
  - That the medical products industry has a social responsibility to support continually updating physicians in the safe and effective use of its products

## Executive Summary

The funding of CME through commercial support is not an “ethics” matter as CEJA has repeatedly suggested over the years. Commercial support of CME is about practical access to high quality health care education. Industry makes life saving treatments, devices, and tools to help improve the health of people each day. Through research and development, companies are finding ways to diagnose, treat and prevent serious, chronic, and rare diseases at a faster rate than ever before. Accordingly, industry support of CME is one of the most effective ways to distribute this new information, to ensure that healthcare practitioners are aware of the benefits, risks, and uses of these new tools and treatments. Research has shown that there is little bias in such programs.

The CEJA report explicitly recognizes that, “relationships between medicine and industry—such as pharmaceutical, biotechnology, and medical device companies—have driven innovation in patient care, contributed to the economic well-being of the community, and provided significant resources for professional education, to the ultimate benefit of patients and the public.” Despite this recognition, CEJA asserts however that the “interests and obligations of medicine and industry diverge in important ways.” (*Id.*).

How industry’s obligation to support medical education diverges from that of medicine is unapparent. The opposite holds true: there is convergence of interests and obligations between industry and medicine, especially considering that the standard of care leads doctors to use the treatments and tools industry provides to them to improve the health of patients.

CEJA’s report clearly ignores the proven benefits and outcomes that commercially supported CME have caused in subjects including COPD, Hypertension, ICU patients, Sepsis, and hospital acquired infections. CEJA’s report is led to a biased conclusion that does not reflect the actual data currently available on the subject. The list of references in the CEJA report has not been updated to reflect evidence based research on this subject. It uses similar references from previous reports to support the bias of the authors. As a result, all CEJA’s report does is state opinions numerous times, without any evidence or factual support.

Moreover, CEJA ignores recent research that shows both Americans and physicians want industry-physician collaboration. For example, a recent poll showed that 81 % of Americans support developing public-private partnerships between government, industry and universities to maximize resources and expertise in medical innovation and research in the U.S.<sup>1</sup>

In addition, a recent survey found that 89% of physicians valued industry grants to support CME because such programs provide knowledge or skills helpful in their practice and information about medications to treat particular conditions that is up-to-date, timely, useful, and reliable.<sup>2</sup> Additionally, a large number of professional organizations and specialty groups find value in commercially supported CME. These physicians recognize that commercially supported CME is critical to educating doctors about new drugs and treatments.

CEJA's report fails to acknowledge that for over five years, CME has been highly regulated to prevent undue influence from industry. CME already has in place adequate provisions for transparency and independence. Accordingly, to ensure that physicians continue to have access to appropriate, high-quality CME, ACRE recommends that the AMA House of Delegates reject the CEJA Report 1-A-11.

### **Current Regulation of CME**

The 2011 CEJA report asserts that, "CME providers, content developers, faculty, and physicians should strive to avoid financial relationships with industry." (p. 4, 47-48). However, the report offers no evidence as to why CME providers should "strive to avoid" such relationships. Despite its lack of objective reasoning and evidence to support this claim, CEJA recommends a number of specific measures that CME providers should adopt such as transparency, disclosure and protecting the independence of educational activities (p. 9, 4-44).

These recommendations however, are obsolete. They fail to realize that the overwhelming majority of CME providers have been doing what CEJA 1-A-11 recommends for several years now. As recognized by a 2010 report published by the Global Education Group<sup>3</sup>, CME providers have been following 2005 ACCME guidelines and rules regarding commercial support of CME. Specifically, the 2005 ACCME Standards for Commercial Support requires:

- Independence and Resolution of "Conflicts of Interest"
- Appropriate Use and Management of Commercial Support Grant Funding
- Development of Content and Format without Commercial Bias, and
- Disclosures to ensure transparency

In addition to these measures, the Global Education Group Crossroads report recognized a number of other initiatives currently in place that account for exactly the type of recommendations CEJA proposes, including but not limited to:

- 2006 ACCME Accreditation Criteria 1 through 22 (setting forth requirements to ensure educational rigor and independence)
- 2006 ACCME Elements addressing appropriate educational Purpose/Mission, Planning, and Evaluation/Improvement
- 2007 updated definition of "commercial interest" requiring all accredited CME providers to sever any relationships to pharmaceutical and medical device marketing/promotion
- 2008 and 2009 policy updates and calls for comment to ensure CME's independence from promotional influences
- 2009 ACCME statement to the IOM referencing ACCME Content Validation Value Statements requiring CME content to:
  - Include evidence-based clinical recommendations,
  - Rely on research that conforms to generally accepted standards of experimental design, data collection and analysis, and

- Meet the definition of CME and avoid patient care recommendations in which risks outweigh the benefits
- Ongoing ACCME audits of accredited education providers to ensure they fully comply with all criteria and policies
- 2009 ACCME rapid response measures to identify compliance infractions, place accredited providers on probation, and work with these organizations to bring them back into compliance
- 2010 and future ACCME on-site audits of CME activities and Program Activity Reporting System

In addition to the regulations and changes noted above, CME stakeholders have also reduced and managed any potential for bias through:

- The National Faculty Education Initiative
- Monitoring and enforcement of Standards for Commercial Support for CME independence from promotional influence
- The development of separate CME/IME departments within commercial interest organizations, ensuring CME is managed outside of sales/marketing departments
- ACCME rules prohibiting control over faculty selection and CME content by potential/current funding organizations, ensuring independence of accredited providers that develop certified CME
- Dramatic increases in the number of accredited CME providers on probation or working with the ACCME on progress reports for quality improvement
- Increased transparency of ACCME reporting on accredited provider compliance
- Increased transparency among pharmaceutical and medical device companies regarding CME grants issued

CEJA 1-A-11 recognizes that the ACCME Standards for Commercial Support “have been established to address concerns about possible influence in CME.” (p. 4, 8-9). However, they believe that, “the efficacy of those standards or other processes to address the potential for industry influence on content or the overall range of CME topics is difficult to determine.” (*Id.*, 9-10). This comment clearly contradicts CEJA’s own recognition that, “several recent studies have suggested that the great majority of physicians attending CME activities do not perceive bias in the content of those activities.” (*Id.*, 11-13).<sup>456</sup> Given the large amount of well established regulations already in place to address CEJA’s concerns, coupled with the results from these very large studies, it should be clear to CEJA that these standards are in fact working, and therefore additional regulations from CEJA are unnecessary, repetitive, and burdensome.

### **Certified CME Has Adequate Transparency, Independence**

The 2011 CEJA report recognizes that the ACCME Standards for Commercial Support include provisions for transparency—i.e., disclosing the existence of a financial relationship. (p. 6, 6-8). However, CEJA believes that disclosure is not sufficient because it places the burden on learners themselves to determine how skeptical they should be about possible bias in an educational activity. (*Id.* at 8-10). Yet, CEJA cites no evidence to support this assertion, and thus only

expresses their opinion. Instead, CEJA believes that bias is so hard to detect, that the only way to eliminate bias is to avoid industry support altogether.

Such reasoning is misguided because physicians are highly trained, and can easily spot bias. Physicians know when they are being marketed and when they are being educated because they deal with both on a regular basis. Accordingly, CEJA's assertion that disclosure is insufficient again is contrary to the findings of the three very large studies noted above, which showed that physicians can detect bias, but did not find any in the CME programs surveyed.

### **There is Little Bias in Certified CME**

The practice of making strong claims regarding alleged CME problems without providing evidence to support the accusations was widespread in the literature reviewed in the Crossroads report. For example, "in addition to making specific accusations without evidence, several articles make inferences about certified CME without citing evidence. These authors often utilize statements incorporating the words "may" or "might" or "growing concern." However, there is strong evidence showing there is no bias in certified CME.

CEJA's report claims that CME grants from industry lead to bias in educational activities based on several recent studies. However, the 2008 Cervero and He survey used to back up this position clearly stated: "there is no evidence to support or refute" speculation that commercial support produces bias in CME activities. On the other hand, the three very large studies produced last year, showed substantial data that demonstrate a lack of commercial bias in industry-sponsored CME. Based on this evidence, CEJA's comment that physicians "should aspire to avoid the potential for influence" is misplaced.

Today's CME professionals have the experience, expertise, and long-term commitment to manage the challenges posed by an increasingly complex healthcare environment. Additionally, many stakeholders that comprise the CME enterprise have taken significant steps toward quality improvement. In addition, CEJA itself recognized that "industry support helps to meet the costs of CME activities in the face of uncertain funding from other sources and may help make CME more accessible, especially for physicians in resource-poor communities." (p. 4, 33-35).

CME programs with commercial support are no different from other CME programs because the audiences are the same. CME programs are not provided to "naïve audiences."<sup>7</sup> Commercially supported CME programs speak to "physicians who face their own reputational and liability risks when they prescribe drugs." In most of these sessions, physician questioning plays a prominent role, and there is little reason to think that a commercially supported CME program would push improper risk-making claims given the risk the provider could have of losing its accreditation or other legal sanctions from the FDA, HHS OIG, or DOJ.

Moreover, CEJA recognized that, "industry engagement and support can be especially helpful in ensuring affordable CME when educational activities need high cost, sophisticated, rapidly evolving technology or devices." (p.3, 3-37). Along with lower costs, CEJA also noted that

“industry support may encourage greater participation than would otherwise be the case by providing amenities.” (*Id.* at 35-40).

In the end, CEJA’s recommendations deny society the benefits of the knowledge that highly regarded and well motivated professionals possess. Since 1945, “we have had the benefit of these collaborations without having seen any sign of the systematic abuse that could justify the tough bans that have been put into place today.” By continuing to create and uphold intrusive and unwise policies and injunctions on physician-industry collaboration, such as those recommended by CEJA, we will only be “throwing sand into the gears of progress at every stage of the drug production cycle, from basic research through final sale.”

Because there is strong evidence that shows no bias in commercially supported CME, and CEJA itself recognizes the important value in commercially supported CME, 1-A-11 should be rejected.

### **Certified CME Has Proven Benefits, Outcomes**

Several recent CME programs supported by industry have shown positive outcomes, underlying the important role commercial support plays in making patients healthier and giving physicians the tools and training necessary for medical progress. For example, physicians who attended an industry-supported educational activity were 50% more likely to provide evidence-based care for COPD than nonparticipants were.<sup>8</sup> Another program showed that the patients of physicians who attended an industry supported educational activity were 52% more likely to receive evidence-based hypertension care than those seen by health care providers than nonparticipants were.<sup>9</sup>

Commercially supported CME has also improved patient outcomes in intensive care units at hospitals,<sup>10</sup> and has helped patients with sepsis (the unadjusted hospital mortality decreased from 37% to 30.8% over 2 years).<sup>11</sup> Industry supported CME programs are also helping physicians fight hospital acquired infections.<sup>12</sup> In addition, the results of a recent study showed that “heart disease patients whose general practitioners participated in an interactive, case-based CME program had a significantly reduced risk of death over 10 years compared with those whose doctors didn’t receive the education.”<sup>13</sup>

As a result, CEJA fails to recognize that removing commercial support from CME will erode the positive outcomes it produces and could lead to physicians failing to understand and adopt evidence-based medicine, which is estimated to cost hundreds of millions of dollars.

### **Professional Organizations and Specialty Groups Support Certified CME**

Many specialty groups, such as endocrinologists,<sup>14</sup> electrophysiologists,<sup>15</sup> experts in multiple myeloma,<sup>16</sup> and surgeons,<sup>17</sup> have expressed their deep appreciation and firm conviction that commercially supported CME is crucial to improving patient outcomes and keeping their education up to date on the latest treatments and breakthroughs.

For example, the American Association of Clinical Endocrinologists (AACE) recognized that endocrinologists have a greater responsibility than ever to educate physician colleagues, allied health professionals, and patients on the most up-to-date treatments and guidelines in endocrinology. This is in response to the worsening national epidemic of poorly controlled diabetes and metabolic diseases, the shortage of endocrinologists to treat these conditions, and the rapid expansion of therapeutic innovations that can improve patient outcomes.

Specifically, AACE recognized that ongoing education on new medications and devices is necessary for their safe and effective use, especially in complex diseases like diabetes. Educational presentations provide the scientific background, the data, and the reasoning to understand new treatment options and make better use of old ones. AACE acknowledged that to make this education accessible, it must take place in as many settings as possible, and when sponsored by industry, it operates under very strict rules of conduct.

In addition, AACE pointed out how new therapeutic options and guidelines to treat disease require education for safe and effective use and therefore, eliminating sources or stigmatizing sources of education because they are commercially supported will only result in less informed health care practitioners. Accordingly, AACE maintained that educational programs, including those sponsored by industry, must expand the number and types of health professionals who can effectively treat patients with diabetes and metabolic diseases.

Similarly, 60 oncologists noted that, “evolving institutional and national trends now in the public domain may seriously curtail the interactions between clinical educators and investigators, industry, and CME providers.” If such interactions are prohibited or hurt, it “will diminish clinical investigation and education alike, with a consequent negative effect on patient care.”

Moreover, these experts recognized that commercial support of CME, with independent review of content for fairness and balance, has resulted in the development and implementation of a variety of educational events directed toward physicians, patients, and allied health care personnel, which has improved their understanding of the disease, the benefits and risks of different treatment strategies, and the existence of additional resources to help in patient care. Through these educational events, the myeloma experts recognized that the quality of care delivered to patients with myeloma has improved and that by accelerating deployment of new therapies, lives have been prolonged and toxicities of treatment decreased.

As a result, CEJA’s report should be rejected because withdrawal of commercial support of CME would have a negative impact on specialists and physicians specializing in chronic and severe diseases.

### **Certified CME is Critical to Educating Doctors about New Drugs, Treatments**

When CME providers, academic institutions, and industry are not able to work together, physicians will lose a valuable source of information and scientific evidence about new treatments and therapies. CME is necessary because new drugs are complex chemical products that require a close understanding, and because research and development often involve the

creation of new products. However, the creation of new products will produce enduring social gains only if physicians are properly trained and educated about them.

The producers of pharmaceutical products and medical devices need the ability to collaborate with CME providers and academic medical institutions to offer objective and independent CME programs, which follow the ACCME guidelines for commercial support. CME also provides the function of making sure doctors are aware that new therapies, indications or treatments are actually on the market.

Moreover, CME must address complications of treatments and therapies. Through collaboration with industry, CME providers can ensure that the information being discussed at programs includes FDA labeling information and clinical trial data. CEJA's report should be rejected because their recommendations will "stifle the education of new drugs that outperform their rivals, and their tardy arrival could spell death or serious injury to the people who cannot obtain the desired relief from existing drugs."<sup>18</sup>

### **Certified CME and Commercial Education Must be Differentiated**

Much of the discussion and analysis of CME studies and reports over the past several years "has been charged with emotions, peppered with anecdotal information, and plagued by confusion."<sup>19</sup> Moreover, most reports on CME use a broad category of "education," which often includes certified CME activities under the same umbrella as promotional programs that are directly funded by industry." In fact, less than 6% of the reports and policy papers examined during the past five years identified the distinction between certified and promotional activities.<sup>20</sup> This is problematic because there is a huge distinction between activities that are directly funded by industry for promotional purposes and certified CME activities.

Most published reports on "medical education" coningle discussion of CME, GME, and promotional programs designed to combine promotion with educational data. As a result, criticism and policy papers addressing industry support of medical schools and teaching hospitals have little connection to those addressing industry grants to ACCME-accredited providers of certified CME.

Another instance of this problem happened in the Association of American Medical Colleges (AAMC) report on "Industry Funding of Medical Education," which is cited in 1-A-11. The AAMC developed guidelines that were not directly connected to a discussion of CME, but were nevertheless included CME in the same report, causing confusion. The report did not acknowledge that collaboration with industry has proven benefits for medical centers, students, practicing faculty, and patients. Accordingly, the "confusion between certified CME and non-CME activities seems partially to result from the fact that many organizations have not managed CME separately from other activities."

In reality, most of the cases of unethical or illegal practices involve commercial CME, not independent, certified CME. Problems caused by lack of disclosure at Emory University and Stanford were related to direct payments for marketing services or research from industry to

physicians, not CME grants to accredited providers. Additionally, a recent study found no OIG settlements that related specifically to certified CME developed between 2005 and 2010.<sup>21</sup> As a result, CEJA 1-A-11 should be rejected for including sources that do not differentiate between commercial education and CME.

### **When Commercially Supported CME is “Ethical” or Acceptable**

As in past reports, CEJA recognized that it is not always feasible, or necessarily desirable, for professional education to disengage from industry completely. (p.5, 15-16). For example, when accessible, high-quality CME cannot reasonably be carried out without support from sources that have a direct financial interest in physicians’ clinical recommendations, such as activities that require cadavers or high-cost, sophisticated equipment to train physicians in new procedures or the use of new technologies. Similarly, in the earliest stage of adoption of a new medical device, technique, or technology the only individuals truly qualified to train physicians in its use are often those who developed the innovation.

In some situations, CEJA asserts that, “financial relationships with industry can be ethically justifiable.” When not accepting support from a commercial source or not permitting participation by individuals who have financial interests in the educational subject matter would **significantly undermine medicine’s capacity to ensure that physicians have access to appropriate, high-quality CME**, it can be acceptable to permit such support or participation. (p.5, 17-21).

However, who will be in charge of deciding what would “significantly undermine” medicine’s capacity? Would a CME provider be responsible for submitting additional forms and having additional oversight to the AMA or ACCME in order to use industry support or a speaker who has a potential conflict of interest? Programs supported by industry are often of the highest quality because of the fact that they have the additional support to provide them with the resources, tools, experts, and incentive to produce the best quality program. Accordingly, the CEJA report should be rejected for providing vague terms in describing when financial relationships are ethical.

CEJA goes on to explain that an individual might be considered “uniquely qualified” when he or she is the only expert (or one of a few) who has significant knowledge about or experience in treating a rare disease or was involved in the early development or testing of a new treatment, device, or technology. The adoption of this definition by CEJA is also problematic because it is vague and uncertain. Who will decide and under what criteria whether someone is “uniquely qualified?” How much time would it take to get a CME program approved waiting for CEJA or ACCME to determine an individual is “uniquely qualified?”

In addition, a “compelling need” for a particular educational activity, according to CEJA, may be present when a new therapy becomes available to treat a disease present in the local community for which the new treatment represents a substantial improvement. But what exactly constitutes a “new treatment” and “substantial improvement?” Ultimately, CEJA’s report must be rejected because it uses vague and uncertain terms to govern physician-industry CME relationships.

## **CME is not CLE**

Frequently, proponents of removing commercial support of CME draw analogies to the legal profession. However, using this analogy is based on misperception and actually could be harmful to public health. Physicians, through their membership dues and registration fees paid to attend medical society meetings, already do help to underwrite the cost of a significant number of CME programs. Moreover, there are three specific reasons why CLE and CME are not comparable.

First, the volume of information in medicine is vastly greater than law. More than 400,000 medical journal articles are published each year, making the practice of medicine much more dynamic than that of law. The sheer volume of new scientific data and changes in medicine requires as many appropriate avenues for funding certified CME as possible. If commercial support of CME was to evaporate or be severely restricted, how could our physicians learn about the findings and results from these 400,000 journal articles? There is not enough time in the day to read these articles let alone gain an insight into the implications of the results.

Second, the changes to practice in medicine occur at a much faster rate than law. The nature of medicine involves constant advancement, testing, and application. Medicine features landmark breakthroughs, such as the discovery and testing of a new therapeutic agent. The legal system is based on the tradition of *stare decisis*, or precedent. In short, changes in the law are evolutionary while changes in medicine often are revolutionary. Patients and society demand that our physicians receive information instantaneously, and that updates in treatment, diagnosis, and prevention are disseminated to physicians as soon as practically possible. Commercial support of CME enables a smooth process to ensure that health care practitioners get the most recent and up to date advances so that physicians can begin implementing new breakthroughs sooner and improve patient outcomes before it's too late.

Finally, mistakes in medicine can lead to death, whereas mistakes in law can be corrected through other, less life threatening processes. Continuing professional education is necessary for physicians, partially because a drug used incorrectly is a poison. A failure to diagnose or prevent a disease or illness can lead to further complications and spreading of the disease. A physician's inability to adopt new guidelines or practices can result in thousands of medical issues. When a lawyer makes a mistake in practice, parties can appeal to a higher court. A physician mistake with prescriptions or on the operating table can mean serious illness or even death, a situation for which no appeal process exists.

Accordingly, CEJA's report should be rejected because it fails to take into account the effect removing commercial support of CME would have on physicians and the very real and significant differences between CME and CLE.

## **Not All Relationships are Equal**

CEJA recognizes that "not all relationships with industry are equally problematic." (p. 6, 27-28). For example, having once conducted sponsored research or accepted a modest honorarium for

speaking on behalf of a company would not necessarily create such clear potential for bias as to preclude an individual with the appropriate expertise from developing content or serving as a faculty member for a given CME activity. (p. 6, 30-33)

However, CEJA noted that direct or substantial financial relationships have significant potential to undermine confidence in educational activities, even if they do not actually compromise those activities. Consequently, CEJA's report should be rejected because it does not adequately describe a process for how it will differentiate such relationships or whether it will consider the differences objectively to ensure that CME programs and education in medicine are not significantly undermined.

### **Overregulation of CME Will Hurt Patients, Physician-Industry Collaboration/Innovation**

Since the first academic-industry-physician collaboration helped produce insulin over eighty years ago, American's have enjoyed a "high standard of living, including their state of health and the medical discoveries and treatments that have steadily improved it." This "active partnership between science and commerce" has created a "wide-ranging and productive exchange of knowledge and information."<sup>22</sup>

The CEJA report quotes Edmund Pellegrino, who said that, "*Publicly in his oath and privately in his encounter with the patient, the physician professes two things—to be competent to help and to help with the patient's best interests in mind.*" (p.2, 3-5). For the last century, physicians have worked hand-in-hand with industry to create some of the most revolutionary advances in medicine and healthcare. Today, it would seem impossible for a physician to be competent in medicine without the information, tools, treatments, data, and other resources industry provides. As a result, commercially supported CME is an effective way to disseminate this information to doctors.

Separation of commercial support from CME "whenever possible" could easily prevent cooperation and collaboration. CME depends on collaboration to "encourage scientific interactions that facilitate the cross-pollination of ideas with colleagues. Ultimately, CEJA's recommendations should be rejected because they will only degrade the quality of education physicians receive and delay the provision of lifesaving medicines and treatments, mainly because such policies were created without carefully weighing the impact of such harms.

### **Conclusion**

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 language contained in 1-A-11 contradicts itself throughout the proposal, similar to the 2010 report. 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) commercial support provides access to appropriate, high-quality CME. Yet they still propose that physicians not use commercial support “whenever possible.”

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.” Their confusion also contradicts their own recognition that commercial support of CME reduces costs,” especially for physicians in resource poor communities, it encourages greater participation than would otherwise be the case by providing amenities,” and ensures “affordable CME when educational activities need high cost, sophisticated, rapidly evolving technology or devices.” (p. 4, 33-40).

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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