A CME WHITEPAPER

CME CROSSROADS

A SURVEY OF CONTINUING MEDICAL EDUCATION
ANALYSIS, CRITICISM, RESEARCH AND POLICY PROPOSALS

global® EDUCATION GROUP

Disclosure

In developing this white paper, Global Education Group relied on publicly available and privately funded industry analysis and surveys; more than 100 published articles regarding the CME enterprise, CME standards and findings, including those from the Accreditation Council for CME (ACCME), the American Medical Association (AMA), U.S. Department of Health and Human Services, and the Food and Drug Administration; Congressional testimony, letters of inquiry, and other published reports. While the American Academy of Family Physicians and American Osteopathic Association have developed CME credit systems complementary to the AMA credit system, this document focuses on CME generally associated with the AMA system.

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Reviewers

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CME Crossroads:
A Survey of Continuing Medical Education Analysis, Criticism, Research and Policy Proposals

Summary

The continuing medical education (CME) enterprise and its stakeholders took action amid a perfect storm of criticism, analyses, and policy proposals between 2005 and 2010. Reports and committees called for everything from a restructuring of the CME system to regulatory and accreditation enforcement reform, to elimination of commercial support representing more than 50% of the funding for CME activities.[1-4] Dialog that includes contrasting opinions and ongoing self-examination based on an objective review of the available scientific evidence is essential to healthy growth. In the past five years, however, much of the discussion and analysis has been charged with emotions, peppered with anecdotal information and plagued by confusion. The damage to the CME enterprise is difficult to assess, but there are concerning trends found in the Accreditation Council for CME (ACCME) Annual Report data. Specifically, when comparing the recently published 2009 annual report to that from 2007, we find that the number of accredited providers of CME fell by 174. There are now fewer accredited providers in seven of the eight provider categories identified by the ACCME, including: 1) the government or military; 2) hospital/health care delivery systems; 3) insurance company/managed care company; 4) non-profit (other); 5) non-profit (physician membership organization); 6) not classified; and 7) publishing/education company.[5] Schools of medicine were the only provider type posting an increase between 2007 and 2009, with a growth of one accredited organization.

During this same period, the ACCME reported equally troubling data on the number of certified CME activities. The number of CME activities decreased by 17,941 (-15.8%) between 2007 and 2009. Despite claims that CME funding was "approaching $3 billion" in 2008, actual ACCME report data show that it decreased to a total of less than $2.2 billion, of which 39% ($856 million) was comprised of industry grant funding to support CME activities.[6] Despite the rally cry for alternative funding, the 29.3% decrease in industry grant funding was not offset by government or other sources.

It is difficult to fully determine the impact of these trends on stakeholders in the CME enterprise, practicing physicians, and patient care. One commentator characterized the current CME environment as follows: "If one were to take the vital signs on most continuing medical education (CME) providers, planners, and faculty today, one would likely find that the patient is febrile, hypertensive, and tachypneic – that is, the patient has signs and symptoms consistent with systemic inflammatory response syndrome (SIRS)."[7] One also has to question how many seasoned CME professionals have been lost in the process that led to the presentation of these signs and symptoms.

Interest in CME issues and policies has surged. More than 100 articles have been published on assessing and sharing educational outcomes for CME activities and curricular initiatives (rarely addressed prior to 2005), and a peer-reviewed journal devoted solely to continuing education out-

comes analysis has been published since 2006.[8] The CME enterprise also embraced general practice standards, including the development of a "Certified CME Professional" (CCMEP) exam and designation in 2008.[9] Further, the ACCME produced updated criteria for assessing all accredited CME providers in 2006, followed by 2007 policy updates and several calls for comment regarding regulatory proposals between 2008 and 2010, including those focusing on the Standards for Commercial Support, a rapid response system to address non-compliance, and blueprints for a future CME monitoring and compliance enforcement mechanism.[10-13]

In short, the CME enterprise has reached a crossroads. The purpose of this paper is to examine the available evidence, provide clarification of the analysis, criticism, research, and policy proposals regarding CME. An analysis of developments during the past five years will allow stakeholders to appropriately assess and project future direction. In a survey of more than 100 published articles, studies, consensus statements, and reports addressing the state of CME between 2005 and 2010, a set of four important "CME policy and scrutiny trends" emerged and is identified below. A collective analysis of these comments and findings produces a set of recommendations that will assist in shaping the CME debate and developments for the next five years.

Conflicts of Interest: CME, Non-Certified "Education" and Promotion

One of the complicating factors associated with identifying trends in articles, arguments and proposals regarding CME in the past five years is the fact that authors do not consistently define CME or separate it from other forms of "education." This phenomenon particularly occurs in studies and articles addressing either real or potential conflicts of interest.[14-17] The potential conflicts of interest cited in these publications stem from ties between medical school students and/or practicing physicians and the pharmaceutical and medical device industries. The possible conflicts vary, depending on the type of "education" being analyzed. Some reports and editorials address undergraduate medical education, while others are concerned with a combination of graduate medical education (GME), certified CME, and even non-CME activities developed for promotional purposes.[16-18]

While several older federal government reports note the significant differences between certified CME and industry programs for marketing and promotional purposes, less than 6% of the reports and policy papers examined during the past five years identified the distinction between certified and promotional activities.[19,20] Most published reports on "medical education" comingle discussion of CME, GME, and promotional programs designed to combine promotion with educational data.[16,4,17] The result is that criticism and policy papers addressing, for example, industry support of medical schools and teaching hospitals, have little connection to those addressing industry grants to ACCME-accredited providers of certified CME.[21]

The conflict of interest concerns for medical schools, teaching hospitals, and societies go well beyond CME. For example, a widely cited article on "pharmaceutical promotion and physician education" addresses problems with "journal advertising and direct mail" as well as physician office visits by "pharmaceutical representatives."[22] In addition, the American Medical Association (AMA)

Council on Ethical and Judicial Affairs (CEJA) identified conflicts of interest that occurred when industry financially supported "professional education"[16] such as:

- "industry marketing and promotional activities"
- "personal expenses associated with attendance at meetings"
- "educational travel grants for medical students"
- "free lunches"
- "residency positions"
- "company speakers' bureaus"
- "free or subsidized travel"
- "residency or fellowship training"

The real and potential conflicts associated with these industry-funded promotional programs are worthy of consideration but are outside the realm and guidelines governing certified CME. In fact, none of the "educational" programs cited above meet the definition of certified CME. The confusion between some promotional programs with educational content and certified CME programs even pervaded the original AMA CEJA ethical opinion on CME. This opinion addressing CME participants and faculty includes a recommendation regarding "[A]ttending promotional activities put on by industry…."[23] It should be noted that the most recent iteration of the AMA CEJA report on CME distinguished the difference between "promotional" activities and "certified and other (non-promotional) educational activities," including CME and other worthy industry funded educational activities that are neither certified nor promotional.[24]

In its report addressing "Industry Funding of Medical Education," the Association of American Medical Colleges (AAMC) sought to "minimize the risks" for conflict of interest that occurred when industry supported and collaborated with academic institutions. The AAMC developed guidelines on pharmaceutical samples, industry gifts to physicians and faculty, and access by pharmaceutical and medical device sales representatives to patient care and other academic medical center areas.[21] Despite the considerable thought that went into these guidelines, they are not directly connected to a discussion of CME. The AAMC, however, included CME in the same report and advocated that medical schools adopt audit mechanisms to comply with ACCME standards and strongly discourage faculty participation in industry-funded speaker bureaus and other funded promotional activities that could create a conflict of interest.

Why include analysis and policy proposals about both promotional activities and non-promotional CME activities in the same document? Universities with medical schools have to juggle management of undergraduate education, graduate medical education, CME, and promotional activities supported by industry. Collaboration with industry has proven benefits for medical centers, students, practicing faculty, and patients.[24] But the mix of programs on a medical school campus requires management of gifting practices and industry financial support/collaboration on a wide range of promotional activities (distribution of drug samples), general education-related activities (industry-sponsored research and scholarships), as well as non-promotional CME activities. Medical schools, as well as professional societies, have varied interests and missions; CME units, however, typically focus exclusively on CME. In some medical schools, however, the CME office impacts education across the continuum. 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.

Confusion over critical non-CME and CME issues also stems from the fact that institutions manage broad conflicts much differently from how the ACCME requires accredited providers to manage financial conflicts of interest related to CME activities. Support for academic freedom and a diverse medical society and graduate education system has enabled each medical school or society to act autonomously from others when managing the broad range of issues that create potential conflicts. The result: rules and guidelines governing conflicts of interests for academic centers and medical societies vary widely.[15] Management of conflicts for medical societies and universities is generally decentralized; each organization decides for itself. Management of accredited CME providers, however, is highly centralized under the ACCME. As a result, the University of Colorado develops its rules regarding, for example, industry access to faculty and distribution of drug samples, independent from the rules set forth by Emory, Stanford, and other universities. But all ACCME accredited providers of CME – be they medical societies, hospitals, education companies, or academic institutions – must demonstrate compliance with a unified set of ACCME, Food and Drug Administration (FDA), and other rules governing CME practices (see Figure 1: Unified Guidelines for CME).

More than 81% of the reviewed reports, policy proposals, and consensus documents comingled analysis or discussion of CME with non-CME activities. Some of the analyses published between 2005 and 2010 actually note this confusion. In 2008, the AMA Reference Committee stated that testimony regarding the AMA CEJA report on Industry Support of Professional Education in Medicine "emphasized that the report lacked clarity with respect to distinguishing certified continuing medical education and uncertified promotional education…."[26]

Figure 1: Unified Guidelines for CME

In addition to guidance documents from the U.S. FDA in 1997 and U.S. Department of Health and Human Services (Office of Inspector General) in 2003, all accredited CME organizations must develop certified CME activities in compliance with a uniform set of policies, guidelines, and standards set forth by the ACCME and AMA, including the following[19,20]:

- ACCME Accreditation Criteria 1 through 15 (setting forth the minimum requirements to ensure educational rigor and independence) and 16-22 (accreditation with commendation)
- ACCME Standards for Commercial Support requiring 1) Independence, 2) Resolution of Conflicts of Interest, 3) Appropriate Use of Commercial Support Grant Funding, 4) Appropriate Management of CME grants, 5) Development of Content and Format without Commercial Bias, and 6) Disclosures to ensure transparency
- ACCME Content Validation Value Statements requiring all CME content to 1) include evidence-based clinical recommendations, 2) rely on research that conforms to generally accepted standards of experimental design, data collection and analysis, and 3) meet the AMA definition of CME and avoid patient care recommendations in which risks outweigh the benefits.
- ACCME audits of accredited education providers to ensure they fully comply with all criteria and policies
- AMA Definition of Continuing Medical Education, requiring that CME activities "maintain, develop or increase the knowledge, skills, and professional performance" of physicians[25]
- AMA PRA Credit System requirements[25]
- ACCME rapid response measures (announced in 2008) to identify compliance infractions, place accredited providers on probation, and work with these organizations to bring them back into compliance
- ACCME audits of actual CME activities

The National Task Force on CME Provider/Industry Collaboration supported by the AMA later noted this confusion over CME and non-CME activities and sought to clarify the distinction. In October 2008, the Task Force developed statements and a fact sheet campaign to distinguish CME from both promotional activities and a host of education-related activities that do not qualify as certified CME. The Task Force produced the "Get The Facts" campaign in order to clarify what CME is and what it is not.[27]

The first four AMA CME Fact Sheets addressed the following:

1. CME: Providing Valid and Independent Evidence for Clinical Decisions
2. Addressing Conflict of Interest through Disclosure and Resolution
3. Commercial Support of CME and Compliance with Guidelines
4. Appropriate Discussion of Off-Label Drug Use within CME

In its announcement of the Get the Facts campaign, the Task Force plainly stated the perception problem faced by the CME enterprise:

"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. This has led to increased regulatory scrutiny and critical public opinion regarding CME practices."

While the confusion about CME and conflicting arguments can be analyzed, mis-identifying certified and promotional activities hinders the ability of the enterprise to clarify analysis or help achieve consensus on critical topics. Several studies have shown that confusion about policies and processes can invite scrutiny and lead to unproductive debate.[28] As we set forth the four CME policy and scrutiny trends below, it is important to note that confusion between CME and non-CME issues has blurred our collective vision and hindered the ability of stakeholders to agree.

For example, articles and opinion statements in the Journal of the American Medical Association (JAMA) regularly support industry marketing to underwrite scientific publishing but do not support industry education grants to underwrite independent CME.[6,18] Several articles published in JAMA, including one co-authored by the editor of JAMA, articulate the need for continued industry advertising to underwrite journal publishing.[15] But JAMA articles have uniformly called for a decrease or end to industry CME grants. On the other hand, the AAMC published analysis supporting an effective program to accept and manage CME grants from industry while arguing for a complete ban on industry marketing and promotion within the medical school learning environment.[21]

Stakeholders in the CME enterprise may never achieve complete consensus on matters of policy. On matters of definition, however, achieving consistency regarding CME terminology will allow those within and outside of CME to make a more accurate assessment of the field.

CME Policy and Scrutiny Trends

The analysis of dozens of articles, policy proposals, consensus statements, and other documents addressing CME demonstrated a clear set of trends in the literature. Each of these trends is set forth below, with additional information regarding the response from the CME enterprise to each trend.

Trend 1: Incorporate adult learning principles/expertise into CME

Even prior to the 2005-10 upsurge of CME scrutiny and policy proposals, several national organizations called for greater incorporation of adult learning principles and professional expertise in the CME field. The 2002 Conjoint Committee on CME (CCCME) report called CME the "cornerstone" of physician professional development, but recommended a "restructuring and strengthening of the existing system."[1] The report called for "directed self learning" of physicians and greater reliance on adult learning expertise in planning, implementation and assessment. Scott advocated for activities that combine "non-traditional" educational approaches with CME to achieve improved results with "self directed/experientially oriented" learners."[29] In addition, the AMA credit system for CME imbedded adult learning principles within CME formats.

More recent reports supported the call for greater adult learning expertise from various types of accredited providers. Davis and others lamented that CME was not part of the core mission for academic medical centers and pushed these organizations to move beyond basic CME programs and consider development of activities that fostered performance improvement and better patient outcomes.[30] Miller called for "multifaceted" CME interventions that include non-CME education in order to demonstrate patient care improvements.[31] Hampton noted in a 2008 article that CME activities developed by all accredited providers "should do better at addressing the many needs of clinicians across a wide spectrum" and quoted one CME conference chair as saying, "More effort should be made to get [continuing education] closer to daily practice."[32]

The manager of the CME credit system, the AMA, stated that CME should advance to "impart clinical knowledge and skills" to the profession and "advance the science of adult learning in medicine."[16] The Alliance for CME identified key competencies and associated skill sets for CME professionals in 2005. The first competency identified by the Alliance was "Adult/Organizational Learning Principles."[33] Several CME leaders argued for a future in which practice-focused CME replaced "seat-time" requirements of previous years.[34] Established in 2006, the National Commission for Certification of CME Professionals (NC-CME) discussed the need to "raise the bar in CME," further stating, "The public deserves assurance that CME is being managed by persons who understand principles of adult learning and professional development…."[9]

The ACCME called for incorporation of adult learning expertise in its 2006 updated accreditation criteria, as well as its 2008 "CME as a Bridge to Quality" publication and June 2008 policy announcements and calls for comment. The accreditation criteria convinced providers to re-assess their mission statements and incorporate improvements in physician competence, performance, and/or patient outcomes across their CME programs.[10] The Bridge to Quality document outlined a pathway to improve CME quality based on adult learning fundamentals. The organization stated that "ACCME accreditation requirements are evolving CME so that it is more effectively address-

ing current and emerging public health concerns."[10] ACCME policy announcements stated that an understanding of physician learners and associated adult learning techniques would now provide "the basis for CME professionals to design interventions that effectively address" physician learning/gap issues.[12]

Trend 1 was readily identified and appears to be borne out of a need to demonstrate professionalism and specific expertise within the CME enterprise. Prior to 2005, CME staff teams were dominated by generalists, such as administrative assistants or coordinators who worked in a variety of areas, as well as individuals who split their time between educational and promotional projects. Following the implementation of the 2003 Department of Health and Human Services Office of Inspector General Compliance Guidance and ACCME policies and definitions that no longer allowed those working on behalf of commercial interests to have any control over certified CME content, the push for CME-specific professional roles and expertise seems to have increased. Early calls for increased expertise and better incorporation of adult learning theory in CME culminated in a chorus of voices for improvement in this area of practice. An analysis of the response to this scrutiny follows.

CME Enterprise Response to Trend 1: Incorporate adult learning principles/expertise into CME

CME stakeholders appear to have embraced the call for greater incorporation of adult learning expertise. The NC-CME developed a Certified CME Professional (CCMEP) exam and designation in 2008; within two years, more than 250 individuals earned the credential for expertise across five core competency areas.

The Society for Academic CME (SACME) and Alliance for CME developed and produced a national CME faculty training initiative to improve CME faculty management/expertise, especially in recognizing the differences between independent and promotional education. This physician training also sought to teach faculty to be better educators by understanding and applying adult learning principles. The North American Association of Medical Education and Communication Companies (NAAMEC) and SACME collaborated on a vetting form to ensure development of independent, quality-focused CME partnerships. In addition, CME that was specifically developed to assess and improve physician performance (PI CME) was regularly being incorporated into CME curricula by 2010.[34] To date, however, there is little data to demonstrate that PI CME is either cost effective or successful in achieving lasting performance improvement.

The following are quality improvement indicators related to Trend 1:

- Updated ACCME Accreditation Criteria (2006)
- ACCME published the "CME as a Bridge to Quality" document and associated live workshops
- AMA published a handbook identifying performance improvement and internet point of care learning as eligible for AMA credit
- New, experiential educational formats incorporated a blend of self-directed and hands-on assessment/mentoring
- NC-CME developed the CCMEP exam addressing adult learning fundamentals

- Accredited providers moved beyond participant satisfaction to measure, at a minimum, improved physician competence resulting from CME
- Several new training programs and online tools were launched to support growth in performance improvement (PI) CME
- Increased standards for and improved practices related to CME grant evaluators were developed within pharmaceutical and medical device manufacturers
- The development of the Pharmaceutical Alliance for CME within the Alliance for CME and its efforts to share best practices and improve CME outcomes and professionalism
- 2010 updates to the AMA Physician's Recognition Award credit system requiring assessment of learner performance and new format requirements

Trend 2: Produce Better CME Outcomes

The call for more adult learning expertise coincided in the literature with demand for better outcomes design, analysis, and reporting. Building on recommendations from the Conjoint Committee regarding its vision for CME to deliver measurable outcomes, several individual authors and organizations recommended significant improvements in this area. Two of the seven Conjoint Committee recommendations focused on improving outcomes analysis and reporting.[1] Recommendation 5 sought to develop performance and continuous improvement by documenting evidence of changes in physician knowledge, competence and practice performance along with outcomes in patient care. Recommendation 6 focused on the metrics used to measure and recognize physician learning and practice changes: the evolution of CME programs should identify innovative ways for implementing education and measuring learning and change in physicians. Davis and others called for higher level outcomes based on analysis showing that didactic CME sessions in some therapeutic areas were less effective at producing behavior change than interactive sessions.[35]

Acting on these recommendations, stakeholders called for improvements to CME outcomes methodologies and results. The AMA and the Alliance for CME published documents outlining educational formats and measurement approaches to achieve higher outcomes levels.[25,36] Fordis and others tested the effectiveness of online CME versus live, interactive CME and advocated for "appropriately designed, evidence-based online CME" that could produce comparable or better results than some live CME sessions.[37] In a meta-analysis of studies regarding 61 CME interventions, Mansouri and Lockyer concluded that CME was still not meeting its outcomes goals to change physician behavior and improve patient results.[38]

Along with continuous development of innovative programs to engage physicians and lead to changes in competence and performance, the CCCME described the importance of documenting the effectiveness of these CME programs and the changes associated with physician knowledge, competence or practice behavior. The CCCME noted that this evaluation methodology should not only validate improvement related to physician scope of practice, goals and practice gaps but also identify areas where improvement could be made in future initiatives. The ability to produce better outcomes was further recognized by the CCCME in its national priorities for 2010, including integrating performance improvement into CME. Stressing outcomes, this report called CME the "target system in which to intervene to improve health system performance."[39]

Several other individuals and organizations addressed the need for improved CME outcomes. Miller called for "learner-focused CME with measurable outcomes" in order to address core competencies in the medical profession.[31] In addition, AMA CEJA supported the notion that CME creates an "evidence base that will contribute to positive changes in how physicians learn to care for patients."[16] One author concluded that CME design, implementation, and analysis should focus around a singular objective: valid outcomes.[40]

Before the adoption of the updated accreditation criteria from the ACCME and the AMA's recognition of *AMA PRA Category 1 Credit™* for performance in practice, most CME activities did not provide physicians with an opportunity to develop new skills and competency but rather focused on physician participation and knowledge gains. Several articles called for CME to more actively lead to improved physician performance and patient outcomes.[41-44] While much of the response to the scrutiny over the effectiveness of CME has focused on providers developing strategies to assess the outcomes of their activities, Moore suggested building a CME activity with outcomes planned from the onset. Moore's revised levels of outcomes recognize seven levels within the CME framework, from participant attendance and satisfaction, (Levels 1 and 2) to improvements in community health (Level 7). Using a gap-analysis approach advocated by the ACCME, CME providers can develop a needs assessment that addresses outcomes levels 3-7 and track how their activities bridge the identified practice gaps.[45]

The CME enterprise was asked to become an integral tool in achieving improved physician and patient outcomes. As a topic for discussion and analysis, CME outcomes grew from side show to center stage between 2005 and 2010.

CME Enterprise Response to Trend 2: Produce Better CME Outcomes

In response to scrutiny regarding the effectiveness of CME and the necessity of providing better outcomes, the ACCME, the AMA and CME/adult learning professionals have taken a stand to improve the knowledge, competence and performance behaviors of the learners. The ACCME's 2006 updated accreditation criteria requires accredited providers to set forth outcomes in their mission statements and measure effectiveness in achieving these goals. More than half of the 22 ACCME accreditation criteria either directly or indirectly address CME outcomes-related issues/results.[10]

The American Board of Medical Specialties (ABMS) and the Federation of State Medical Boards (FSMB) have recognized the importance of continued education that strives to improve physician competence and practice behaviors and have implemented both the Maintenance of Certification (MoC) and Maintenance of Licensure (MoL) programs respectively.[46,47] These programs were both developed to establish physician life-long learning that leads to improved practice behaviors and patient outcomes. Many hospital systems are also utilizing competency-based credentialing that physicians will need to complete to obtain hospital privileges.[48]

The interest in CME outcomes led to the development of several outcomes-focused companies and new methodologies to assess outcomes based on adult learning theories, such as Prochaska's stages of change, and the incorporation of knowledge, attitude, and case-based competency testing. In

2006, the first issue of the journal *CE Measure* was published. This journal strives to provide an "intellectual platform for the exchange of information and to dialogue and debate concepts and issues important to the advancement of outcomes modeling and application in continuing professional education."[8] The development of a peer-reviewed journal specifically for healthcare-related educational outcomes measurement promotes controlled, evidence-based scrutiny of the effectiveness of educational interventions and the methodology for outcomes assessment.

While all stakeholders can recognize that CME is an important resource for physicians to maintain their desire and need for life-long learning, the CME enterprise has taken significant steps toward the development of reliable practices and systems to accurately measure the effectiveness of the interventions. Several CME organizations have implemented methodologies managed by biostatisticians to measure initial and retained competence, educational erosion, performance in practice, and patient/community outcomes. All accredited CME providers are now required to plan for and demonstrate their role in improving knowledge, competence, physician practice behaviors and/or patient health both at the activity level and more broadly.

The following are quality improvement indicators related to Trend 2:

- Formation of the peer-reviewed journal, *CE Measure*, focusing on outcomes measurements of continuing healthcare education
- Incorporation of performance improvement and internet point of care CME programs by the AMA
- Donald Moore's reevaluation and update of the levels of outcomes measurements, which was supported in part by industry
- The number of performance measurement posters and presentations at the Alliance for CME annual meetings doubled between 2005 and 2010
- Outcomes-specific organizations and service offerings led by biostatisticians were introduced and have grown in number in the CME field
- Outcomes measurements are now routine components of CME grant applications

Trend 3: Heighten CME Regulation/Enforcement

In the two decades leading up to 2005, the CME enterprise evolved in fits and starts. The ACCME was founded in the 1980s. The first Standards for Commercial Support were not developed until 1992. Collaboration between commercial interests and CME staff members on education were relatively common. Some CME professionals looked back on the period between 1984 and 2004 and labeled it the "wild west".[49] While this may be an overstatement, there were a number of unhealthy practices in need of reform, including but not limited to dialogues between CME funding organizations and accredited providers regarding faculty selection and content.

Calls for a more restrictive regulatory framework occurred immediately prior to and during the 2005-10 time period, resulting in what was to become a radical transformation of the way in which CME is managed. White papers and consensus documents questioned the "CME system's effectiveness in the ever-changing contemporary healthcare environment," and predicted the era of CME scrutiny to come.[1,50] Individual authors argued for a "professionally responsible system" for CME.[51]

As would be expected for an enterprise this large, there were egregious, albeit rare, examples of unethical behavior. It is difficult to fully discern to what degree today's concerns are rooted in current issues versus those from the pre-reform era. One article reiterated a belief that "many observers are talking about a CME system that they were part of a decade ago."[83] Additionally, as explained in the "Conflicts of Interest: CME, Non-Certified 'Education' and Promotion" section above, most cases of unethical or illegal practices involved marketing programs, not CME. Problems of 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. However, examples of certified CME activities that were considered "veiled marketing" were cited.[52] In the literature reviewed, there were no OIG settlements identified that related specifically to certified CME developed between 2005 and 2010.

At a 2007 conference sponsored by the Josiah Macy, Jr. Foundation—an organization significantly invested in the healthcare sector and opposed to industry grant support for CME—the Macy conference report blamed accrediting bodies, stating that they "have not found ways to promote teamwork or align CE with efforts to improve the quality of health systems."[4] Other critics argued that accrediting organizations had "not done enough" to enforce rules.[3] The 2007 Senate Finance Committee staff report on medical education and follow-up letters to the ACCME also requested increased regulatory vigilance. Senate Finance Committee Chairman Max Baucus (D-Mont.) asked the ACCME to take additional regulatory steps, saying, "This report shows some separation between medical education and marketing efforts, but this process still isn't clean enough."[53] In addition, the 2009 Institute of Medicine report on Conflict of Interest in Medical Education cited several articles questioning whether or not ACCME standards and guidelines were effective in managing some CME practices.[17] It should be noted that the IOM references to support these claims were from 2001 and 2003, prior to a series of more stringent ACCME policies implemented between 2004 and 2009 (see Unified Guidelines for CME above).

CME Enterprise Response to Trend 3: Heighten CME Regulation/Enforcement

The ACCME, accredited providers, planners, faculty, and others actively responded to calls for change related to CME regulation and enforcement. The ACCME produced a series of policy updates, new definitions, proposals, and standards that went into effect between 2005 and 2010. In testimony to the U.S. Senate, the ACCME stated that it was "willing to add additional layers of monitoring, surveillance, and support to the systems it oversees."[13] The AMA introduced new CME formats stressing performance in practice in 2005. During the same year, the ACCME required providers to begin implementing and demonstrating compliance with updated Standards for Commercial Support. As a result of this requirement, the ACCME produced several guides for the implementation of new rules, including those for "Identifying and Resolving Conflicts of Interest in Medical Education."[54]

Many more regulatory proposals and policy changes followed the introduction of updated accreditation criteria in 2006. Indicating room for quality growth in the CME enterprise, the ACCME introduced the 2006 criteria stating that "this revised model of accreditation and updated criteria will be a significant improvement for CME providers and learners."[10] In 2007, the ACCME required

all accredited providers to sever any financial connections to pharmaceutical and medical device promotional/marketing arms. By redefining the term "commercial interest," ACCME required accredited CME units of all types – hospitals, societies, medical education companies, and medical schools – to focus exclusively on certified CME.[55] This change forced some organizations to leave the CME enterprise, while others worked successfully with the ACCME to restructure their organizations to meet the new rule.[56]

A series of policy updates and proposals for new rules were contained in 2008 and 2009 ACCME calls for comment.[12,57] The 2008 calls included policy updates and proposals to ensure that certified CME was produced independent of promotional influence and met the AMA definition for evidence-based CME. The 2009 call for comment included a potential designation program for accredited providers, an idea for a centralized CME funding entity, and a notice and comment procedure for ACCME rulemaking.

Some organizations expressed frustration over the rapid pace of CME rule changes. Accredited medical education companies and societies, such as the American Society of Anesthesiologists, argued that the impact of changes already made required time for implementation and analysis of the success of the new policies and rules.[58] Other organizations echoed this sentiment and called for CME stakeholders to follow a well-documented method for engaging in policy debate known as the "stock issues" approach (see Figure 2).[59]

In addition to the examples of increased rules and CME requirements above, there are several important indicators demonstrating the rapid pace of CME rule changes between 2005 and 2010. The first is the number of policy and other announcements generated by the CME accreditation body. Between 2004 and 2006, the ACCME developed and distributed an average of nine press releases annually regarding policies, rules, and other issues. Between 2007 and 2009, the number of ACCME announcements actually doubled to an average of 18 releases per year.[60]

Figure 2:
Stock Issues for Productive CME Policy Debate

Amid the scrutiny, conflicting opinions, and policy proposals, CME stakeholders have not relied on a proven tool for methodically approaching policy debate: the Stock Issues. This set of issues was developed by academicians and refined by those involved in policy discussions. In short, the Stock Issues require those engaging in productive debate to prove the merits of new policy ideas. With respect to CME, there are two critical "stock issues" questions that must be answered in debate regarding changes to U.S. CME policy:

1. **Is the system for CME advancing and improving or harming physician education/patient care?** If the former, our debate should focus on adjustments that can continue the progress and improvement. If the latter, what can we do within the current system to make improvements before suggesting a completely new system?
2. **"What are the intended and possibly unintended consequences of any new recommended changes or proposals?"** Any new policy proposal faces a two-fold burden: it must successfully address the problems ("harms") proven to exist in the current system, and it must not create additional negative consequences that would harm stakeholders in the current system. As several organizations have noted, the last thing the CME field needs is to cripple potential progress or replace the current system with one that is either untested or that could harm physician practice improvement or patients.

The second indicator of increased rulemaking activity and enforcement is the number of accredited CME providers either choosing not to renew or becoming ineligible to renew their accreditations. Between 2007 and 2009, the number of nationally accredited CME providers declined by 29 (3.9%). During that same period, the number of providers accredited by state medical societies declined by 145 (8.7%).[61] A majority of intrastate accredited providers surveyed by AMA indicated that the current regulatory environment made it "somewhat difficult" or "very difficult" to achieve compliance with eight of the 22 updated ACCME accreditation criteria.[62]

Between 2005 and 2010, the calls for increased CME rulemaking and enforcement were answered with a series of compliance and quality improvement measures. Not only did the ACCME engage in a transparent rulemaking process, but CME stakeholders updated policies, implemented new practices, and restructured their organizations to ensure that certified CME was managed by organizations and individuals independent of promotional influence.

The following are quality improvement indicators related to Trend 3:

- 2005 Implementation of updated ACCME Standards for Commercial Support requiring 1) Independence, 2) Resolution of Conflicts of Interest, 3) Appropriate Use of Commercial Support Grant Funding, 4) Appropriate Management, 5) Development of Content and Format without Commercial Bias, and 6) Disclosures to ensure transparency
- 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 Institute of Medicine referencing ACCME Content Validation Value Statements requiring CME content to 1) include evidence-based clinical recommendations, 2) rely on research that conforms to generally accepted standards of experimental design, data collection and analysis, and 3) 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

Trend 4: Address Conflicts of Interest

Perhaps the most cited and debated issue regarding certified CME between 2005 and 2010 is that of "conflicts of interest." A 2007 report cited evidence showing that some accredited providers of CME did not comply with the requirement to "identify and resolve all conflicts of interest prior

to education activities."[2] Several articles and policy recommendations call for managing "both real and perceived conflict of interests."[15] Other articles reference conflicts by analyzing the intersection of "commercial and professional interests."[22]

The Institute of Medicine (IOM) defined conflict of interest as "a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest."[17] Most reports, rules, and policies concentrate on financial conflicts or connections between industry and physicians.

Several organizations, including the Federation of American Societies for Experimental Biology, National Institutes of Health, and American Council on Education, produced reports targeting conflicts of interest that have the potential to impact physician practices outside the arena of CME.[63-65] Virtually all the conflicts discussed in the literature fall within the IOM definition of conflict of interest. That is, a physician has a financial relationship with industry that creates a risk of undue influence.

Questions regarding professional integrity in medicine and conflicts stem from reports citing examples of illegal or unethical behavior. The 2009 IOM report cites several of these "disturbing situations," including:

- "physicians and researchers failing to disclose substantial payments from drug companies…
- companies and academic investigators not publishing negative results from industry-sponsored clinical trials…
- professional societies and other groups that develop clinical practice guidelines choosing not to disclose their industry funding…."

The literature generally advocated a two-step process for addressing conflicts of interest: 1) disclosure, and 2) resolution or management of conflicts. Several papers noted the lack of systematic data and studies addressing conflicts and the potential for bias in both university settings and in CME.[17,66] Several articles with validated analysis regarding potential bias or negative perceptions of actual CME activities were published in 2009 and 2010.[67,68]

As noted in the "Conflicts of Interest: CME, Non-Certified 'Education' and Promotion" section above, confusion abounds among analysts and authors. Activities that are directly funded by industry for promotional purposes are regularly included within analysis or proposals regarding certified CME activities. Most reports comingle discussion of conflicts under a broad category of "education," which often includes certified CME activities under the same umbrella as promotional programs that are directly funded by industry.[17,24] As indicated by the title of the 2009 IOM report, it addresses conflicts in medical research, education, and practice. The report discusses a range of situations that create conflicts, ranging from "gifts from drug companies" to faculty member "research support" to "provision of drug samples."

The consensus in the literature is that all financial relationships between industry and physicians create a potential for conflict of interest. The confusion appears to occur when authors and editorialists consider all forms of so-called "education" as certified CME. The CME enterprise often

is impugned based on the fact that authors do not acknowledge the separate rules that govern accredited CME providers.[69] In the absence of evidence, recommendations can be partially drawn from a reference to negative "personal experience" with an "education" session, which may or may not be related to actual practices or even the arena of certified CME.[17] In addition, some published reports make the mistake of classifying CME with GME or even promotional programs managed by industry.

The 2009 IOM report addresses CME conflicts under the banner of "Conflicts of Interest in Undergraduate, Graduate, and Continuing Medical Education." Within the analysis, however, the report cites an example of a promotional activity in which industry directly "paid some physicians large but generally undisclosed amounts to give talks to other physicians…."[17] No doubt, this constitutes a potential conflict. But it is clearly not a certified CME activity, nor does it appear to qualify as undergraduate or graduate medical education.

The volume of reports and recommendations addressing conflicts of interest sparked some disagreement. As an expected result, there arose cases of "conflict" regarding the discussion of conflicts of interest. The first example occurred after several reports and a letter from U.S. Sen. Charles Grassley (R-Iowa) addressed the need to manage even "the appearance of influence."[70] It should be noted that the letter from Sen. Grassley expressed concern about conflicts related to a connection between payments the American College of Cardiology received from industry and a press release it issued regarding a clinical trial. As cited above, this analysis was not related to certified CME, but it was included in an article about CME. An additional article quotes a chairperson of a CME policy conference as saying, "We are very concerned about the need to minimize bias, in both reality and appearance."[32]

The 2009 IOM report argued against dealing with the vague notion of "appearance" of conflict, stating, "Some conflict of interest policies refer to actual or perceived conflicts of interest and state that professionals should avoid even 'the appearance of influence.' That requirement may lead to confusion."

A second area of conflict regarding conflicts focused on the financial support provided to the IOM to underwrite development of its 2009 report. Because the IOM is a government-sanctioned body, the article questioned the appropriateness of IOM accepting funding to develop conflict of interest recommendations from private organizations that may want to "advance their own agendas."[71] In addition to partially funding the 2009 IOM report, the Josiah Macy Jr. Foundation was criticized for underwriting a 2007 conference in Bermuda that condemned industry CME grants without citing evidence to support the claim.[72]

While a majority of reports and articles combined discussion of industry promotion with certified CME activities, several were very specific about the need to identify, resolve, and monitor for the effect of conflicts (e.g., bias) in CME. When CME was specifically addressed and analyzed related to conflicts of interest, the literature could be categorized within four conflict-related sub-topics.

Sub-Topic A:
Conflicts differ among accredited providers

Despite a common set of accreditation criteria and rules for managing certified CME, several authors indicated that conflicts could be traced to a particular type of provider. Some articles and documents claimed that accredited medical education companies were more apt to develop CME activities that were biased or less compliant than other providers. Relman claimed in 2008 that education companies "act as agents for the pharmaceutical manufacturers."[6] In the same year, Steinbrook concluded that accredited CME companies may "provide public relations services, or prepare advertising" for industry.[14] These articles seem to be based upon misperception or outdated information rather than the facts. For example, in addition to citing his own articles from 2001 and 2003, Relman cites findings from a widely discredited Josiah Macy Jr. Foundation conference on continuing education as evidence for his claims (see "Sub-Topic D: Conclusions in the Absence of Evidence" section below). Steinbrook cites several editorials, including one from 2000 addressing "promotional and non-promotional/educational services" provided by organizations. While companies were allowed to have promotional and CME arms prior to 2007, accredited CME providers of all types were mandated to sever ties to industry marketing activities since that time.

Other articles and papers focused on the potential for bias at academic medical centers, hospitals, and other organizations that may have "institutional conflicts of interest."[17] One statement cited ACCME Annual Report data showing that hospitals, schools of medicine, and physician membership organizations were less compliant with ACCME rules than education companies.[73] Elsewhere, authors have argued about the pros and cons of the "for-profit" versus "not-for-profit" status of hospitals, education companies, universities, and other accredited corporations.[40,74] Very few reports or testimony note the fact that all accredited providers – hospitals, schools of medicine, publishing/education companies, and physician membership organizations – must demonstrate compliance with the same rules for independence and appropriate management or risk losing their accreditation.[72]

Sub-Topic B:
Eliminate Conflicts/Bias by Eliminating Industry Grants to Support CME

A group of reports recommend the elimination of industry grants to accredited CME providers.[4] Others do not cite evidence but conclude that certified CME "may promote sales of new medications" or that there "may be overlap between the material presented at promotional events…and CME courses."[14] In some cases, authors support the notion of continued industry funding but recommend that steps be taken to ensure that the system ensures that funding is "free of industry influence."[72] As one of the editors of a report summarized, "Our goal is to eliminate industry influence, not funding."[3]

Several organizations and individuals have promoted proposals for physicians to directly pay for all of their continuing medical education.[32] The theme of these arguments, made in print and via testimony before Congress, is that physician CME should be treated similarly to continuing legal education. That is, since lawyers typically pay for their own continuing education, physicians should follow suit. Even groups that promote the idea of physician-funded CME, such as the IOM, conclude that the proposal may not work as planned.[32] Other authors who propose to eliminate indirect funding and require physicians to pay for their own education do not address the differences between physicians and lawyers (See Figure 3).

Figure 3: Lawyers And Physicians: Differences Related to Continuing Education

In its 2009 report on *Conflict of Interest in Medical Research, Education, and Practice*, the Institute of Medicine supported the idea that physicians could pay for Certified CME in the same manner that attorneys pay for their continuing education.

The IOM report echoed Congress and others when it stated, "Although legal continuing education cannot be seen as an exact model for medicine, it does suggest that alternatives to the major role of industry funding for continuing medical education may exist."

The comparison between lawyers and physicians may be based on misperception. Taking action in CME based on this analogy actually could be harmful to public health.[32] It should be noted that 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.

While there is a rationale supporting physician payment of a portion of their certified CME, the legal-medical continuing education analogy appears to be a *non-sequitur* on several fronts.

- Volume of information: 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.
- Changes to practice: 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.
- Mistakes make a difference: Continuing professional education is a must for physicians, partially because a drug used incorrectly is a poison. 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.

Item	Lawyers	Physicians
Work	For People	On People
Mistakes Lead to	Appeals	Death/Harm to Human Health
Change is	Evolutionary (*stare decisis*)	Revolutionary (medical breakthroughs)
Decisions in hands of	Judge, Jury	Physician

Sub-Topic C: Address Possible Bias in Certified CME

Several reports debate or attempt to define the meaning of bias.[26] These proposals and critiques make the argument that industry funding of certified CME grants leads to bias in the educational activities. One report claims that commercial support "invites bias," although it does not provide evidence for this claim.[4]

In one case, arguments that both support and refute the concept of funding-related bias are contained within the same CME report.[76] The AMA CEJA argued both for and against the idea that industry CME grants result in bias. Despite the statement, "there is concern that medicine's reliance on industry support to CME providers…undermines this independence and objectivity," the CEJA report stated, "The available data by no means demonstrate conclusively that commercial funding unduly biases continuing professional education." In addition, the CEJA report states that

funding may have positive results: "it is not always feasible, or necessarily desirable, for professional education to disengage from industry completely." Later in the report, CEJA further states that "refusing support from industry entirely could significantly undermine the profession's capacity to ensure that physicians have access to appropriate, high quality CME."[75]

The concepts of "subtle bias" or "unconscious bias" can be found in several reports.[17,24] These reports draw on psychological studies from 1986 and 1988 indicating that bias can enter into a discussion or educational presentation sometimes unnoticed.[23] One report claimed that industry funding may create "subtle bias," but the report did not offer evidence to support this claim. Instead, it cited the 2008 ACCME-sponsored survey of literature stating that physicians "may not be aware of how industry support of a CME activity may influence their clinical decisions." In fact, the specific 2008 Cervero and He survey cited by the authors to support the claim of "subtle bias" actually concluded that "there is no evidence to support or refute" speculation that commercial support produces bias in CME activities.[66] In addition, the IOM report cites "subtle bias" as a potential problem but concludes that "the empirical evidence relevant to financial relationships and conflicts of interest is limited in many ways. On many topics related to conflicts of interest, no systematic studies are available."[17]

The claim of "subtle" or "unconscious" bias contradicts an existing AMA ethical opinion that physicians can detect bias and, therefore, should avoid or report CME activities that are not independent of promotional influence. Because physicians voluntarily attend CME activities of their interest, the AMA CEJA guides them to "select only those activities which are of high quality and appropriate for the physician's educational needs."[23]

On the topic of bias, emotions run high. Commenting on the authors who promote the concept of "subtle bias," one columnist asked the pointed question: "[I]f CME bias is so subtle that physicians can't detect it, how is it that the authors of these reports can do so?"[77] Testifying on bias in 2009, the chair of the Cleveland Clinic Department of Cardiovascular Medicine told the U.S. Senate that "CME has become an insidious vehicle for the aggressive promotion of drugs and medical devices."[78] Passionate claims arouse audiences, but as JAMA editor Catherine DeAngelis once noted, "A rush to judgment may spark heat and controversy, but rarely sheds light or advances medical discourse."[79] As found in the majority of the literature, the 2008 Cervero and He survey cited the need for more valid, bias-related studies in the CME field.

Sub-Topic D: Conclusions in the Absence of Evidence

In the world of medicine, decisions are made on the basis of objective, fair-balanced, scientific evidence. Yet it appears a different standard for analysis and criticism was accepted when addressing the CME enterprise. The Macy conference on "Continuing Education in the Health Professions" in November 2007 provided an example of a practice that was repeated throughout the CME literature between 2005 and 2010: strong claims in the absence of solid evidence, garnering a mixture of attention and consternation. The report from that conference was discussed in a special session at the Alliance for CME annual conference in 2008. The Macy report's call for elimination of industry grant funding for CME earned headlines and gave rise to many articles and other reports.[80,16] A following for the report's conclusions grew on the basis of the foundation's clout and

the list of conference attendees without credible evidence regarding the alleged conflicts in CME activities. Some future conferences were held partially in order to address the findings of the Macy report.[81] Despite the attention the Macy conference report received, several authors questioned the legitimacy of the original claims made.

Shortly after the Macy report was published, the Alliance for CME stated, "[T]he report includes broad generalizations of divisive issues that have not been vetted and we believe may not be in the best interests of the CME community at large."[82] Several months later, the executives of the ACCME, American Nursing Credentialing Center and Accreditation Council for Pharmacy Education discussed the Macy conference report and concluded, ". . . neither the conference, its observations, its assumptions, it conclusions, nor its recommendations seem to be based on the facts..."[71]

The practice of making strong claims regarding alleged CME problems without providing evidence to support the accusations was widespread in the literature.[68,83,84] 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." For example, one article states that industry grants for CME "may promote sales of new medications."[14] Another report made it known that "[c]oncerns were expressed about the structural soundness and stability of the (CME) enterprise."[81]

Discovering multiple examples of accusations without evidence was somewhat unexpected in an enterprise that otherwise strongly promotes development of "evidence-based" CME and a reliance on principles of "sound science."

CME Enterprise Response to Trend 4: Address Conflicts of Interest

Many of the reports cited above encourage development of policies to assess and address conflicts prior to allowing a healthcare professional to work on a particular project. Very few published reports focus on assessing how well these conflict of interest policies actually work in practice. Fortunately, the CME enterprise requires both. Accredited CME providers now must manage a system for detecting, disclosing, and addressing conflicts of interest. In addition, these providers also must monitor for perceived bias. This examination and management prior to and following a CME activity requires accredited CME providers to actively manage CME content during its development and survey the physician audience members regarding any possible bias during the presentation of the certified CME content.

Evidence-Based Studies

Partly in response to the call for more evidence and valid studies, and especially in the area of potential bias, the CME enterprise devoted significant resources to analyzing the potential impacts of industry grant funding. Published in 2009, a Medscape study of more than one million physician participants analyzed responses to bias questions from two categories of CME activities: those that were supported via industry CME grants and those that were not funded via "commercial support." Regarding the question of bias, less than 1% of physicians indicated any bias in either activities that were underwritten with industry funds or those without industry funding. [66]

A second valid study of more than 95,000 physician participants in 346 separate CME activities showed that 98% of these respondents indicated no bias in CME activities that were either commercially supported or developed without industry grant funding.[67] The authors reporting on this second study concluded that there was "no evidence that commercial support results in perceived bias…."

All accredited providers now work in the CME planning and implementation phases to identify and manage conflicts. In addition, CME activities include surveys addressing potential bias of the CME faculty and content. Conflicts of interest are inherent in any profession, especially one as large as medicine. While the risks that conflicts create will never cease, the CME enterprise responded to the risks with new practices, rules, and evidence demonstrating significant improvements and high ratings from the profession regarding CME quality.

The following are quality improvement indicators related to Trend 4:

- National Faculty Education Initiative to train CME faculty on the difference between certified CME content and presentations and promotional/other content
- Comprehensive bias study of more than a million physician CME participants
- Comprehensive hospital network bias study of more than 95,000 physician CME participants
- ACCME requirement to both identify (via financial disclosures for all faculty and CME content developers) conflicts and resolve them through mechanisms including elimination of the faculty member, altering the conflicted faculty member's role, etc.
- 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 that 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 issues
- Increased transparency among pharmaceutical and medical device companies regarding CME grants issued

Recommendations: Where Do We Go From Here?

According to one reporter, the CME enterprise went through a period of "seismic" changes between 2005 and 2010. Some applauded the changes to the landscape. Some worried the enterprise went too far too quickly. Still others said we haven't gone far enough to improve quality. We will never achieve unanimity in the CME enterprise (nor would that necessarily be a good outcome), but we can learn from our experience and the experiences of other fields (see Figure 4).

Figure 4 CME: Lessons Learned from the Automotive Industry

Akin to the period of reaction amid scrutiny faced by the CME enterprise, the lessons learned from Toyota's response to automotive recalls and safety problems in 2010 may provide a case study highlighting areas for growth.

Toyota recalled over 9 million Toyota and Lexus vehicles after braking and acceleration problems were reported on several models in late 2009 and early 2010.[85] At first, the recalls were heralded as disastrous for Toyota, which faced steep $16.4 million fines from the U.S. government and a falling stock price, but the company rebounded due to what analysts said was a serious commitment to addressing the errors.[86]

Toyota addressed the recall problems in several ways, from the top down: pay was reduced and bonuses were withheld from head officers to reinforce the serious nature of the recalls.[87] The company president initiated a quality control committee with himself as the chief, recruited the former Transportation Secretary to lead an independent quality control panel, and put six quality control representatives in place for Toyota's global regions.[88] Toyota voluntarily launched investigations into the quality of two other vehicles and stopped sales of its Lexus GX 460.[87]

Following the recalls and initial financial losses, Toyota posted a significant rebound in the first eight months of 2010.[89] Takahiro Fujimoto, a professor specializing in Toyota's production systems, attributed the comeback to a saying at Toyota that "a problem is a treasure. You want to find problems because each problem provides an opportunity for improvement."[90]

What can CME providers learn from Toyota's response to the recalls?

While critics accused Toyota of acting too slowly or even ignoring early safety data that led to the problems, the ultimate response offers important lessons for the CME enterprise.

- Self-correction restores public perception by showing a willingness to adapt and improve.
- A commitment to transparency and full disclosure--going beyond the minimum requirements for compliance and engaging in serious reviews of practices—can restore confidence in the quality of educational activities.
- Strong leaders who take responsibility for mistakes can reduce negative perceptions and restore faith in the efficacy of CME industry guidelines without additional government regulation.

Recommendations for Future

To improve the quality of discourse and results within the CME enterprise during the next five years, we offer the following recommendations.

1. Widen the National Discussion

The CME enterprise is made up of varied stakeholders, including:

- Patients
- Physician attendees
- Faculty
- Accredited CME Providers
- Non-Accredited Education Partners (e.g. publishers, companies, societies)
- The ACCME, AMA, and regulators
- Funders (non-industry and industry)

Critics of CME have dominated the discussion and discounted or ignored the participation of many stakeholders, especially accredited providers, physician faculty, and patient groups. At the same time, major improvements in programs and self-regulatory processes have not been fully addressed, researched, and assessed. Some of these stakeholders have been more vocal and involved in CME discussions than others during the past five years. Indeed, some have taken aim and accused individuals or even types of organizations as being responsible for problems in the field. We should be guided by quality, not stereotypes. As an enterprise, we need to embrace the calls for continued improvement and convene transparent, honest discussions about where we have been, our progress, and our plan for the future. These individual voices, representing all stakeholder groups, then need to be harnessed into a national discussion that identifies areas for growth, improvement, and collaboration ahead.

2. Rely on Evidence-Based Debate; Reject Unproven CME Accusations

The CME enterprise often paid more attention to passionate accusations than evidence-based debate during the past five years. We recommend relying on proven rules of inductive and deductive logic, and asking all those making an accusation about CME to provide evidence to support the claim. We expect CME to advance science and adhere to "generally accepted standards of experimental design, data collection, and analysis." CME analysis, criticism, and policy proposals should meet the same standard. Articles or papers without supporting evidence should continue to be publicly rejected. In the absence of evidence, claims about the CME enterprise are at best a distraction and at worst a turn in the wrong direction.

3. Track Regulatory System Progress

A significant portion of the flurry of CME rules, policy proposals, and increased enforcement has only recently been implemented. Management of certified CME left a period of incremental change and entered a period of accelerated change starting in 2005. We recommend following the "stock issues" model for policy discussions and tracking the success and progress of the ACCME, AMA and other existing rules and guidance reports before considering any aggressive restructuring. An article quoting ACCME Chief Executive Murray Kopelow, MD, appropriately summed up the path the CME enterprise has taken:

"We're in a different regulatory and operational environment now. It's clear where the boundaries are. The commercial supporters see them and are respectful of them. The providers see them and know how to manage them. We need this to play out over some years, and ACCME needs to produce data on compliance, and we're going to."[84]

4. Self-Monitor and Regulate Via the Current System

The CME enterprise is a niche area among multiple forms of professional education. It has its own rules, many of its own acronyms, and, as some would argue, its own language. We have seen the confusion and deleterious effects on the enterprise when legislators and others either confuse CME practices with marketing or promotional activities that clearly violate the rules for certified CME, or they confuse the past environment with the highly regulated and evolved environment of today. Clearly there exists much room for growth. Today's CME professionals have the experience, expertise, and long-term commitment to manage the challenges posed by an increasingly complex healthcare environment. When confusion over definitions and stakeholders exists, so does the opportunity for misguided or inappropriate regulation. We will better manage the success and quality improvement of certified CME by engaging in meaningful debate from within while educating the periphery (those not aware of the policies and practices of the CME enterprise). We must chart our course based on a clear set of definitions, goals, and an uncompromising plan for CME quality.

Conclusion

The literature surveyed demonstrated clear trends in criticism and a clear reaction from the CME enterprise. It included genuine evidence-based debate as well as unproven CME accusations. These rational and irrational concerns accelerated CME changes starting in 2005. Clearly, the many stakeholders that comprise the CME enterprise have taken significant steps toward quality improvement. The challenge lies within the CME community to speak with one voice when defining certified CME. While it is certainly worthwhile to continue to hold robust debate around *how* to improve the CME enterprise, we need to communicate clearly to groups outside of our industry exactly *what* the CME enterprise is, and perhaps more important, *what it is not*. As managers of CME, our movement toward quality will continue to improve healthcare through physician performance improvement. Genuine fidelity to that vision will ultimately lead to improved patient care, the goal of certified CME.

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