

**BEFORE THE ACCREDITATION COUNCIL FOR
CONTINUING MEDICAL EDUCATION**

In the matter of:)

June 11, 2008 ACCME Policy Announcements)
and Calls-for-Comment; August 6, 2008)
Further Call-for-Comment)

**COMMENTS OF THE NORTH AMERICAN ASSOCIATION OF MEDICAL
EDUCATION AND COMMUNICATION COMPANIES, INC.**

September 12, 2008

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EXECUTIVE SUMMARY

The North American Association of Medical Education and Communication Companies, Inc. (“the Association”) strongly supports the enablement of quality continuing medical education (CME) in the United States. We commend the Accreditation Council for Continuing Medical Education (ACCME) for providing all CME stakeholders with this forum for discussion and debate about issues central to the on-going viability of the CME enterprise and consequently to post-graduate education of licensed physicians and the resultant health and well-being of patients across the country. At the same time, the Association is concerned that the ACCME’s proposals will work at cross-purposes with these laudable objectives. For example, the ACCME’s proposal to categorically ban commercial support for CME is seriously flawed and, if adopted, may well cripple the ongoing viability of the CME enterprise. The ACCME’s alternative “new paradigm” for commercial support is ambiguous and unworkable and, in any event, beyond the ACCME’s authority. Proposals of this magnitude should be adopted, if at all, by bodies more representative of the entire stakeholder community. Likewise, the ACCME’s proposed new

“independence” standards, including the categorical prohibition on (a) suggestion of topics, (b) provision of requests for proposals (RFPs), and (c) CME faculty members speaking at promotional meetings that are subject to regulation by the U.S. Food and Drug Administration (FDA), are equally unnecessary. The ACCME’s *Standards for Commercial Support: Standards to Ensure the Independence of CME Activities*, as currently formulated, adequately address concerns about bias occasioned by commercial support. If problems persist, they should be addressed through more aggressive monitoring and enforcement by the ACCME. Moreover, the ACCME is a “state actor” subject to norms established under the U.S. Constitution. Many of the procedural steps and substantive criteria embodied in the proposals violate these standards.

For these reasons, and the others recounted here, we urge the ACCME to reconsider its proposals and to withdraw them. In their stead, we propose that the ACCME create an operational framework that follows the practices of other well-respected regulatory and oversight bodies. The ACCME should also reach out to leading organizations in each provider group and work at grass-roots levels to engage in issues identification and consensus building around needed changes. In this way, the ACCME can ultimately put forth guidance, together with any related regulatory changes, that is fair and addresses the needs of all stakeholders, while at the same time building a platform for growth and development fundamental to the effective maturation of the CME enterprise. The Association is prepared to work closely and collaboratively with the ACCME in such an endeavor.

I. INTRODUCTION.

The Association appreciates this opportunity to provide comments in response to the ACCME's June 11, 2008 Policy Announcements and Calls-for-Comment¹, and the ACCME's August 6, 2008 further Call-For-Comment² on a proposed new policy regarding the independence of CME³ from commercial influence (collectively, "the Package"). The Association represents, advocates for, and educates medical education and communication companies ("MedEd companies") in order to foster important learning, public policy, and commercial objectives.⁴ We support the enablement of quality CME in the United States and we share fully the ACCME's objective to preserve the value of and to improve CME, even though we may disagree on how best to accomplish these goals. The Association appreciates the discussion stimulated by the Package and commends the ACCME for providing a forum in which these issues can be meaningfully debated. In itself, this is an important contribution to the public health.

In addition to submitting these written comments, the Association requests an opportunity to make an oral presentation to the ACCME Board of Directors before any final action is taken by the Board on any element of the Package. Such an oral presentation by the Association—and other stakeholders recognized to represent a majority of ACCME-accredited providers, and others—is particularly called for here given the multiplicity and complexity of the fact, public health policy, and related legal questions raised by the Package, the numerous stakeholders that are potentially affected by the ACCME's proposals, and the far-ranging potential impact of the

¹ Available at http://www.accme.org/index.cfm/fa/news.detail/news_id/c7b2d7ee-854d-4440-9b87-265746af2495.cfm.

² Available at http://www.accme.org/index.cfm/fa/news.detail/News/.cfm/news_id/ac4a519e-a2d3-4cd7-80d8-9695ce98179f.cfm.

³ In these Comments, we generally use the term "CME" to refer to certified CME provided by an ACCME-accredited provider.

⁴ See *By-Laws of the Association* (Amended as of May 24, 2005), §1, available at http://www.naamecc.org/Portals/0/NAAMECC_Policy_Procedure.pdf (at 29).

Package, if adopted as proposed, on CME in the United States and, consequently, on the health and well-being of the American public.

Moreover, and in addition to the points raised below, the Association reiterates the concerns it voiced in letters to the ACCME dated July 30, 2008⁵ and August 12, 2008⁶, respectively, as well as in verbal communications between the Association and ACCME leadership, about problematic aspects of the process employed by the ACCME in initiating and pursuing this rulemaking proceeding, particularly its lack of transparency. The Association renews its call that the ACCME provide greater transparency to this process, including, particularly, disclosure of *all* comments received on the Package in their entirety and without summarization or extraction of the kind the ACCME has said it intends to employ in lieu of full disclosure.⁷ Surely, given the self-evident possibility that implementation of the Package may well have a serious impact on the CME enterprise generally, and will disproportionately affect one ACCME provider category—MedEd companies—it does not seem like not too much to ask that we (and everyone else) know what is being said, by whom, and based on what evidence. This elementary kind of fairness and transparency—“due process”, if you will—which is required in this rulemaking as a matter of law in any event because of the ACCME’s status as a “state actor”⁸, at least provides

⁵ Available at http://www.naamecc.org/downloads/public_disclosure.pdf. See also ACCME’s Undated [August 6, 2008] Response Letter (to the Association’s July 30, 2008 Letter), available at <http://www.naamecc.org/downloads/ACCME%20Response%20to%20NAAMECC%20July%2030.pdf>.

⁶ Available at <http://www.naamecc.org/downloads/NAAMECC%20Response%20to%20ACCME%20August%206.pdf>.

⁷ See ACCME’s August 6, 2008 Response Letter.

⁸ Despite the fact that the ACCME “does not accept” the view that it is the “functional equivalent of the government” and asserts that it is merely “a private organization established to conduct professional self regulation” (*see id.*), there are strong grounds on which to conclude that the ACCME is a “state actor” subject to constitutional norms. See Section VI. There is no incompatibility between the ACCME’s status as a private organization, on the one hand, and its status as a “state actor” for constitutional purposes in certain circumstances, on the other. See *e.g.* *Brentwood Acad. v. Tenn. Sec. Sch. Athletic Assoc.*, 531 U.S. 288, 295 (2001) (“[T]he deed of an ostensibly private organization or individual is to be treated sometimes as if a State had caused it to be performed.”); *US v. Stein*, No. 07-3042-cr, Slip Op. at 36, *et seq.* (2nd Cir. Aug. 28, 2008) (KPMG, a private accounting firm, nevertheless a “state actor” in the circumstances presented).

an opportunity for the public, including the Association, to review, evaluate, and directly assess all of the evidence and arguments being advanced in response to the Package. Only this kind of “sunshine” can provide the degree of public confidence and legitimacy that the ACCME’s ultimate conclusion here, whatever it is, represents a valid and validly supported outcome or conversely, and somewhat ironically, is the product of preexisting bias and predetermined beliefs.

II. THE ASSOCIATION STRONGLY SUPPORTS CME AND UNDERSTANDS AND APPRECIATES ITS IMPORTANCE TO THE PUBLIC HEALTH.

We do not address here the importance and value of CME to the medical profession and the public at large, as there appears to be absolute agreement on all sides of the debate about this foundational premise. The Association strongly supports the goal of promoting continuous improvement in physician competence and clinical knowledge through life long learning with the ultimate aim of helping patients obtain the best possible medical care. MedEd companies understand the critical role that we and other CME providers play in this process. The current controversy is not about whether to retain CME, which we all agree should and must be preserved, but about how best to optimize its value. Accordingly, we do not address here the substantial body of evidence that establishes the value of life long learning for physicians and its profound consequent impact on the health and well-being of the American public.⁹ Rather, we address here aspects of the Package that, in our view, undercut that laudable objective without adequate justification. As a result, and if adopted as proposed by the ACCME, the Package

⁹ See e.g. “*CME As a Bridge to Quality: Leadership, Learning, and Change Within The ACCME® System*”, at 2, available at http://www.accme.org/dir_docs/doc_upload/e2843247-7cae-40fe-a0eb-27a982b8fcc0_uploaddocument.pdf (“IN THIS FRAMEWORK, ACCREDITED CME IS ONE OF OUR NATION’S STRATEGIC ASSETS FOR IMPROVING CARE.”) (“*Bridge to Quality*”).

would have a serious adverse impact on the public health, on the CME enterprise generally, and on the more than 80 generally small businesses that comprise the Association.

III. THE PROPOSAL TO CATEGORICALLY BAN COMMERCIAL SUPPORT SHOULD NOT BE ADOPTED.

The centerpiece of the Package is the ACCME's proposal that commercial support for CME end.¹⁰ This proposed ban would apply even to CME whose content is free from commercial bias and which otherwise meets the laudable and widely accepted independence criteria established under the ACCME's 2004 *Standards for Commercial Support: Standards to Ensure the Independence of CME Activities*.¹¹ As an alternative to the complete elimination of commercial support for CME, the ACCME proposes a four-part test for determining when "commercial support of individual activities would be in the public interest and could continue to be allowed."¹² We address the proposed categorical ban on commercial support first as implementation of such a ban, as the ACCME itself acknowledges, may have the practical effect of deconstructing a system without identification of alternatives and "nothing would be worse" than that.¹³ In fact, the *Standards for Commercial Support*, which the Association strongly endorses, are working as intended to address any legitimate concerns about the independence of CME content, and the requisite absence of commercial bias in CME, and the ACCME has said so repeatedly. If problems persist, the answer lies in additional monitoring and enforcement of the existing requirements by the ACCME and not in adding yet additional layers of regulatory prohibitions.

¹⁰ See "The ACCME Believes that Due Consideration be Given to the Elimination of Commercial Support of Continuing Medical Education Activities", fn. 1 above at 6-7.

¹¹ Available at http://www.accme.org/dir_docs/doc_upload/68b2902a-fb73-44d1-8725-80a1504e520c_uploaddocument.pdf ("*Standards for Commercial Support*").

¹² See fn. 10 above.

¹³ *Id.*

A. There is No Empirical Evidence to Support the Proposed Categorical Ban.

On several recent occasions, the ACCME has explicitly acknowledged the absence of any empirical evidence to support the proposition that commercial support, in and of itself, creates a high risk of commercial bias in CME.¹⁴ Most recently for example, in its letter regarding the Special Inquiry on so-called “high risk” providers, the ACCME stated that “[t]here is no evidence to support [the] belief” that commercial support unilaterally compromises the independence of CME, particularly because “we are not operating in an unregulated system” and because the current system, “based on the ACCME Standards for Commercial Support™”, has “an effective set of internal controls”.¹⁵ Accordingly, the ACCME itself has publicly and unequivocally concluded that the current system “ensure[s] learners and the public of the high quality, the independence and the scientific integrity of accredited continuing medical education.”¹⁶ As the Society for Academic Continuing Medical Education (SACME) stated in

¹⁴ See e.g. July 11, 2008 ACCME Letter (transmitting “Information from the Accreditation Council for Continuing Medical Education (ACCME) for the Special Committee on Aging of the United States Senate”, at 17), available at http://www.accme.org/dir_docs/doc_upload/6d4d0864-2f45-4185-975c-cd8954feb966_uploaddocument.pdf (“No data demonstrating commercial content bias is found in the medical education or regulatory literature.”) (“ACCME Senate Committee Submission”); see also June 11, 2008 “Statement from the Accreditation Council for Continuing Medical Education (ACCME) to the Institute of Medicine Committee on Conflict of Interest in Medical Research, Education and Practice”, at 11, available at http://www.accme.org/dir_docs/doc_upload/151305e9-cb64-4bac-8539-fe010b640527_uploaddocument.pdf. (“The ACCME does not have data from its own direct measurements or from measurements made by Providers on the prevalence or incidence of commercial bias in today’s CME. No data demonstrating commercial content bias is found in the medical education or regulatory literature.”) (“ACCME IOM Submission”); June 11, 2008 ACCME Funded Final Report by Ronald M. Cervero, Ph.D., and Jiang He, MPA, titled “The Relationship between Commercial Support and Bias in Continuing Medical Education Activities: A Review of the Literature” at 3, available at http://www.accme.org/dir_docs/doc_upload/aae6ecc3-ae64-40c0-99c6-4c4c0c3b23ec_uploaddocument.pdf. (“Although it has been speculated that commercial support produces bias in CME activities, there is no evidence to support or refute this assertion.”).

¹⁵ See ACCME August 5, 2008 “Dear CME Colleagues” Letter, available at http://www.accme.org/dir_docs/doc_upload/d2bc4716-6e9a-41bb-a289-9b7fe4d7b1b5_uploaddocument.pdf.

¹⁶ *Id.*

its comments on this rulemaking: “We fully reject the premise that merely receiving a grant creates an inherent conflict *as there is no evidence that this is true.*”¹⁷

Inasmuch as CME providers are required by the ACCME to use an evidence-based approach when developing CME content, it seems only reasonable for the ACCME itself to utilize a similar evidence-based approach when determining if sufficient *evidence* exists to demonstrate that commercial support for CME that otherwise meets all applicable indicia of independence in and of itself results in commercial bias that somehow undercuts the integrity of the ensuing CME. There is no such *evidence* and the ACCME has repeatedly acknowledged as much. The absence of any empirical evidence to support the proposed ban on commercial support would itself render any ensuing adoption of the proposal purely arbitrary and hence not sustainable either as a legal or policy matter.¹⁸

In fact, any neutral review of the many ACCME pronouncements and policies, and extensive documentation, evaluations, audits, reports and the like required by the ACCME to substantiate the “independence” from commercial bias of CME¹⁹, including additional proposals on the subject that are included in the Package, reveal a profoundly robust system of ACCME monitoring and enforcement capable of ensuring the independence from commercial bias of CME. In the absence of any *evidence* on which to conclude that commercial support in and of itself is *per se* biasing, there appears to be no factual predicate for the ACCME’s proposal to categorically ban commercial support. In fact, the first principle of medicine is to “do no

¹⁷ See “SACME Response to ACCME Calls for Comment” at 3 of attachment to SACME September 5, 2008 Letter (emphasis supplied), available at http://www.accme.org/dir_docs/doc_upload/68b2902a-fb73-44d1-8725-80a1504e520c_uploaddocument.pdf.

¹⁸ See e.g. *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (agency factual determination not based on *evidence* is arbitrary and capricious and therefore unlawful). This is also a “due process” principle that is applicable to the ACCME as a legal matter in view of ACCME’s status as a “state actor”.

¹⁹ See e.g. Items Listed in ACCME “Documents and Forms Library”, available at <http://www.accme.org/index.cfm/fa/home.library/home.cfm>.

harm”²⁰. The ACCME has already acknowledged the potentiality for harm that is likely to ensue from a categorical ban on commercial support given the absence of documented evidence of its inherently biasing characteristics, and particularly in the absence of any validated regime to take its place—in the ACCME’s own words, “nothing would be worse” than that. SACME put it this way: “[E]liminating all commercial support from CME programs poses a very real threat to the viability of CME within the current academic environment.”

B. There Is No Stakeholder Consensus To Support The Proposed Categorical Ban.

Moreover, the absence of a stakeholder consensus on the wisdom of categorically eliminating commercial support for CME likewise reveals the imprudence and impropriety of the ACCME unilaterally adopting such an outright ban at this time. For example, the American Medical Association’s (AMA’s) Reference Committee on Constitution and Bylaws recently rejected a proposal from the AMA’s own Council for Ethical and Judicial Affairs proposing that the AMA adopt a resolution categorically banning all commercial support of CME.²¹ In fact, the Council of Medical Specialty Societies (CMSS), which is an ACCME-member organization²², voiced its own strong objections to CEJA’s proposal.²³ CMSS identified a number of existing conflicts management tools that serve to ensure that the educational content of CME is “clearly and completely separate from commercial support”.²⁴ These management tools include the ACCME’s *Standards for Commercial Support*, which the Package proposes to modify further

²⁰ *Primum non nocere* (“First, do no harm.”), available at http://en.wikipedia.org/wiki/Primum_non_nocere. (“Since at least 1860, the phrase has been for physicians a hallowed expression of hope, intention, humility, and recognition that human acts with good intentions may have unwanted consequences.”)

²¹ AMA 2008 Annual Meeting.

²² See ACCME Board of Directors and Member Organizations, available at <http://www.accme.org/index.cfm/fa/about.directors.cfm>.

²³ See CMSS June 5, 2008 Letter to CEJA, available at <http://www.cmss.org/index.cfm?p=readmore&itemID=1335&detail=News%20Items>.

²⁴ *Id.*

in several respects; the pharmaceutical and device industries' own guidelines on the subject that affirmatively require such separation²⁵; enforcement action by the Office of the Inspector General of the Department of Health and Human Services, which "has put teeth into compliance by industry, as the penalties for non-compliance include very large fines and potential incarceration"²⁶; Congressional oversight by the Senate Finance Committee²⁷; and the U.S. Food and Drug Administration's (FDA's) standards for ensuring the independence of CME, which, while adopted by the agency primarily to address the use of CME as a subterfuge for "off-label" promotion, nevertheless establishes standards for ensuring the independence of CME from commercial influence.²⁸ CMSS concluded that, collectively, these tools provide the requisite assurance of independence of CME from bias created by commercial support and that a categorical ban on commercial support is not warranted.

C. There Are Unintended Negative Consequences From the Proposed Categorical Ban.

Perhaps the predominant unintended consequence of the proposed categorical ban on commercial support is its likely effect in diminishing the quantity and quality of CME. If that happens, then this would likely result in increased clinical mistakes and misjudgments that may well compromise patient care substantially. Such a result would indeed be a sad and unfortunate byproduct of the proposed categorical ban on commercial support. In fact, and as the Coalition

²⁵ See Pharmaceutical Research and Manufacturers Association "Code on Interactions with Healthcare Professionals" (revised July 10, 2008), available at <http://www.phrma.org/files/PhRMA%20Marketing%20Code%202008.pdf>; Advanced Medical Technology Association, "Code of Ethics on Interactions with Healthcare Professionals", available at <http://www.advamed.org/NR/rdonlyres/D96644D9-7FA9-4DCC-B944-F00A8351FE57/0/AdvaMedCodeofEthicswithFAQ.pdf>.

²⁶ See also e.g. "OIG Compliance Program Guidance for Pharmaceutical Manufacturers", 68 Fed. Reg. 23731 (May 5, 2003) ("OIG Compliance Guidance").

²⁷ See e.g. "Committee Staff Report to the Chairman and Ranking Member: Use of Educational Grants By Pharmaceutical Manufacturers", S. Rept. 110-21, 110th Cong., 1st Sess. (April 2007), available at <http://www.senate.gov/~finance/press/Bpress/2007press/prb042507a.pdf>.

for Healthcare Communication (“the Coalition”) observes in its September 12, 2008 Comments²⁹: “Commercial funding accounts for a far greater portion of innovative CME activity that is focused on improvement in patient care . . . Commercial support often funds new designs for educational programs to address practice gaps and has been a driver in creating non-traditional learning venues such as e-learning and other Internet-based activities.” In fact, the ACCME’s Annual Report Data 2007³⁰ support this conclusion. They show that MedEd companies, which rely to a greater extent on commercial support than other provider types, have funded and created the revolution on how CME is made available, accessed, and used by an overwhelming majority of clinicians in the United States and around the world. MedEd companies have created innovative, interactive multimedia programs that are engaging, that clearly fill an educational need, and that support life long learning.

In its submission to the AMA³¹, and harkening to the underlying rationale for the “do no harm” first principle of medicine, CMSS expressed profound concern about another “potential unintended consequence” of a categorical prohibition of commercial support for otherwise “independent” CME:

“The elimination of commercial support for certified CME will significantly reduce the availability of certified CME, produced by accredited CME providers, such as medical specialty societies. We expect the funds previously devoted to this support will be channeled by industry to promotional activities, including promotional educational activities for physicians . . . [T]hese activities [are] not governed by standards to separate promotional bias from education . . . [T]he

²⁸ See “Guidance for Industry: Industry-Supported Scientific and Educational Activities”, 62 Fed. Reg. 64094 (Dec. 3, 1997).

²⁹ At 8.

result of adoption and implementation of CEJA[‘s] recommendation . . . will likely be a rebalancing of education for physicians, with significantly less unbiased certified CME and significantly more biased promotional education.” In its August 15, 2008 comments to the ACCME on the Package, CMSS reiterated the point in the following terms: “If the goal is to eliminate product bias from the education of physicians, it will be critical to avoid an unintended consequence of stimulating significantly increased product biased education through the mechanism of promotional education.”³²

The ACCME’s proposal to ban commercial support for CME does not analyze or even address *any* “unintended consequences” from its adoption.³³ Indeed, it does not specifically address or even consider the straightforward proposition advanced by CMSS in its recent AMA submission and ACCME comments that such an outright ban would have the inevitable counterproductive effect of shifting industry support from independent CME to promotional activities that by their nature are not intended or required to be independent. After all, they are *promotional*. In fact, in its August 15, 2008 comments to the ACCME on the Package³⁴, CMSS reiterated what it previously said to the AMA—“*The Council of Medical Specialty Societies does not support the [ACCME] proposal that commercial support of continuing medical education end.*” The absence of a consensus on the subject among the ACCME’s own membership should be sufficient reason, in and of itself, for the ACCME not to adopt the proposed ban. Moreover, CMSS’s views should be accorded especially significant weight not only because of its status as

³⁰ Available at http://www.accme.org/index.cfm/fa/home.popular/popular_id/127a1c6f-462d-476b-a33a-6b67e131ef1a.cfm. If requested, we can provide the ACCME with a written explanation for how we derived this conclusion from the Annual Report Data 2007.

³¹ At 7.

³² Available at <http://www.cmss.org/index.cfm?p=readmore&itemID=1341&detail=News%20Items>, at 7.

³³ In its comments in this proceeding, SACME identified a number of unintended consequences from the proposed ban, including a decrease in the number and scope of CME activities and consequent reduction in the number of clinicians educated.

an ACCME member organization, but also because its constituent medical specialty societies, and hence CMSS itself, represent a substantial segment of non-commercial providers of CME in the United States.

Further, there are additional collateral implications from the ACCME's adoption of a ban on commercial support beyond those identified by CMSS that likewise deserve consideration. If all conflicts in medical education must be eliminated rather than managed, is the same prophylactic standard to be applied to a variety of other interactions that society tolerates—indeed encourages—where the potential for bias exists yet is deemed to be managed through disclosure and other techniques? For example, does it mean that any physician who receives industry funding for biomedical research should resign from all medical school faculty appointments lest the commercial relationship be deemed categorically to bias the content of her curriculum? If so, how will this affect the quality of medical education going forward, as some of the best and brightest minds withdraw from teaching medical students? Conversely, what does this do to the quality of biomedical innovation if all medical faculty terminate all paid relationships with industry instead of resigning their faculty appointments?

Examples from contexts that relate directly to personal physical health and well-being and personal financial health and well-being are also relevant. Under the Federal Food, Drug, and Cosmetic Act, the government permits advertising of prescription drugs to physicians subject to a variety of statutory and regulatory disclosure obligations intended to ensure that the communication is truthful, not misleading, fully substantiated and fairly balanced. If commercial support is inherently biasing, then it might reasonably be argued that the law should be modified to categorically prohibit all-but-government-sponsored advertising for medical products.

³⁴ At 3 (emphasis in original).

Likewise, under the Securities Laws, commercial financial instruments are permitted subject to detailed disclosure and filing requirements designed to ensure that the selling materials are truthful and not misleading. If commercial support is inherently biasing, and could not be addressed through conflicts management tools, then it might be argued that the Securities Laws should be modified categorically to prohibit all-but-government-sponsored communications about financial instruments. Other examples abound. The point is simply that in a variety of conflicts contexts that are arguably analogous to, and at least equally as important as, the CME context, we as a society have concluded that conflicts management tools, not categorical prohibitions, are the better way of achieving socially desirable objectives. If someone violates these conflicts management rules, we punish them. But we do not simply discard conflicts management principles in favor of outright prohibitions simply because of the *possibility* that there will be rule-violators. Otherwise, we would have a governmental and regulatory regime of total suppression, as opposed to one that favors the open, but regulated, exchange of information and ideas. As former U.S. Supreme Court Justice Sandra Day O'Connor recently stated in discussing commercial free speech rights in *Thompson v. W. States Med. Ctr.*³⁵: “If the First Amendment means anything, it means that regulating speech must be a last—not first—resort.”

D. Conflicts Management Tools Are More Appropriate Than Categorical Prohibitions, And The ACCME Has Said So Itself.

It is important to observe that the ACCME's proposal to ban commercial support for CME represents a conclusion that potential conflicts cannot be managed and must be eliminated entirely that is at odds with other thoughtful recent recommendations from highly respected organizations in analogous contexts. Indeed, it is directly at odds with FDA's and NIH's conclusions that management tools, such as disclosure, are better suited to address potential

³⁵ 535 U.S. 357, 373 (2002).

conflicts in clinical research rather than are outright prohibitions.³⁶ In fact, several recent ACCME public presentations to the CME provider community endorse the proposition that conflicts of interest can and should be managed through conflicts management tools and should not be categorically prohibited.³⁷ What has changed, empirically, over the last few months that would justify such a dramatic shift in the ACCME's position? The ACCME's overall credibility is seriously eroded when, unexpectedly and without any evidence in the interim to support the change, the ACCME reverses course 180 degrees and announces that due consideration be given to banning commercial support altogether because, now, conflicts of interest can no longer be managed. Such an abrupt change of position also compromises the ACCME's credibility and effectiveness and suggests that it is acting in response to political pressures. Reactions of this kind are viewed by many in the CME stakeholder community as a distraction from what the ACCME has tasked us to do—conducting CME that matters to doctors and hence matters to patient care.

Moreover, for example, in February 2008, a Joint Advisory Committee of the American Association of Medical Colleges (AAMC) and the American Association of Universities (AAU) issued general guidelines on conflicts of interest that utilize conflicts management tools to address problems of bias without creating the total elimination of commercial support that the ACCME here proposes. Likewise, in June 2008, the AAMC adopted a Task Force Report on medical education that does not seek a total ban on industry funding of CME and that looks to conflicts management tools, such as the ACCME's preexisting standards on commercial support,

³⁶ See 21 CFR Part 54 (FDA); 42 CFR Part 40 (NIH).

³⁷ See e.g. ACCME IOM Submission at 12 (ACCME “manages” interactions between commercial supporters and CME providers); ACCME Presentation at the AMA National CME Task Force Conference, “*Accredited Continuing Medical Education as a Strategic Asset: The value-added of CME from within the ACCME system*” at

(continued...)

as a way of ameliorating concerns about commercial bias.³⁸ While the Macy Report³⁹ admittedly recommended an end to commercial support for CME, the ACCME itself, together with two other accrediting organizations, took issue in very strong terms with virtually every aspect of that report, including, notably, the absence of an evidentiary basis for any of the Report's conclusions and recommendations.⁴⁰ Relatedly, the Institute of Medicine of the National Institutes of Health (NIH) is considering a broad array of questions concerning CME, including whether and to what extent commercial support for CME that is otherwise "independent" should continue to be permitted and the ACCME itself has likewise responded in that proceeding.⁴¹ It seems entirely appropriate and important for the ACCME and others to await the conclusion of that process before moving forward with proposals to eliminate commercial support that, while sounding high-minded, may have a serious adverse impact on the overall CME enterprise if adopted.

E. The ACCME Lacks the Authority to Adopt a Categorical Ban.

The involvement of so many other thoughtful organizations in the debate about conflicts of interest generally, and conflicts of interest in CME potentially created by commercial support *per se*, suggests yet an additional reason why the ACCME should not adopt the categorical prohibition it has proposed. This has to do with the serious question that exists about whether the ACCME has, or should have, the authority unilaterally to pronounce National policy in this

printed page 10 of slide deck (October 2007) (describing management tools used by ACCME, including independence, transparency, and separation of promotion from CME).

³⁸ Available at <http://www.aamc.org/research/coi/start.htm>. On the use of management tools to address conflicts of interest in lieu of outright prohibitions, *see generally* Bernadette M. Broccolo and Jennifer S. Geetter, "Today's Conflict of Interest Compliance Challenge: How Do We Balance the Commitment to Integrity with the Demand for Innovation?", *American Health Lawyers Association Journal of Health & Sciences Law*, Vol. 1, No. 4 (July 2008) at *1 et seq.*

³⁹ See "Continuing Education in the Health Professions, Proceedings of a Conference [Sponsored by the Josiah Macy, Jr. Foundation in November 2007]", published 2008, available at http://www.josiahmacyfoundation.org/documents/pub_ContEd_inHealthProf.pdf.

⁴⁰ See generally "Chief Executives of the ANCC [American Nurses Credentialing Center], ACPE [Accreditation Council for Pharmacy Education], and ACCME Respond to the Josiah Macy, Jr. Foundation" (June 19, 2008), available at http://www.accme.org/index.cfm/fa/news.detail/news_id/5834283e-b17e-487f-8b4a-4e32cfdb5a67.cfm.

area. We submit that the ACCME’s institutional mandate is only to provide a mechanism for monitoring and enforcement of criteria for accredited providers that develop valid CME, but was never intended to, and does not, encompass profound questions of National policy about whether and to what extent commercial support *per se* should be deemed to be a categorically disqualifying factor for CME. In analogous contexts, and no matter what their own view of the policy justifications for the underlying proposals, courts will compare a regulatory agency’s actions against its underlying statutory mandate and will overturn them if found to exceed the scope of the agency’s authority.⁴² Analogous principles apply to so-called *ultra vires* acts of corporate Boards of Directors when they take action in excess of the underlying rights conferred in the corporation’s charter or by-laws.⁴³ We believe that National policy on conflicts of interest with such profound ramifications should be undertaken, if at all, by a representative body able to determine a National consensus on the subject, and not by the ACCME. Such a radical change is unquestionably beyond what anyone ever conceived to be the scope of the ACCME’s authority in this area. Indeed, Congress is now considering legislation that would effectively codify the categorical disqualification of any recipient of commercial support from developing educational materials for physicians.⁴⁴ Whatever one believes about the wisdom or constitutionality of this kind of prohibition, the fact remains that it is a matter far better suited for Congressional

⁴¹ See ACCME IOM Submission.

⁴² See *e.g. Assoc. Am. Physicians & Surgeons, Inc. v. FDA*, 226 F. Supp. 204, 222 (D.D.C. 2002) (“This court does not pass judgment on the merits of the FDA’s regulatory scheme. The Pediatric Rule may well be a better policy tool than the one enacted by Congress; it might reflect the most thoughtful, reasoned, balanced solution to a public health problem. The issue here is not the Rule’s wisdom . . . The issue is the Rule’s statutory authority, and it is this that the court finds lacking.”)

⁴³ See *e.g.* §3.15, Illinois Business Corporation Act of 1983 (“Defense of *Ultra Vires*”), 805 ILCS 5/3.15.

⁴⁴ See S. 3396, 110th Cong., 2nd Sess., July 31, 2008, proposed “Independent Drug Education and Outreach Act of 2008”, available at <http://www.thomas.gov/cgi-bin/query/D?c110:2:/temp/~c11013NgID::> (proposing, among other things, to add new §904(b)(2)(B) of the Social Security Act to provide for grants or contracts to “eligible entities” for “the development and production of educational materials” for healthcare providers, and requiring that in order to be so “eligible” an “entity shall . . . receive no support from any entity that manufactures products . . . or from any organization funded by such entities . . .”) (Emphasis supplied).

determination by a representative National assembly than it is for determination by the ACCME in this rulemaking proceeding.

In fact, CMSS makes an analogous point in its August 15, 2008 comments on the Package.⁴⁵ It proposes a “national solution” that would be developed under the aegis of the Conjoint Committee on Continuing Medical Education (CCCME), which is a multi-organizational committee consisting of key stakeholders across the continuum of medical education. Whatever the merits of this specific proposal by CMSS that CCCME, which includes only select representation from the CME stakeholder community and notably fails to include any representation of MedEd companies of the kind who are members of the Association, CMSS could equally well have framed its proposal as a fundamental lack of authority on the part of the ACCME to legislate unilaterally a categorical ban on commercial support of CME. However framed, the primary point that CMSS is making is the same as ours—the ACCME lacks any underlying institutional mandate to pursue such a profound policy change on its own, and the ACCME’s suggestion that it may do so is not appropriate.

F. The Proposed Categorical Ban Violates The First Amendment And Is Otherwise Problematic.

Moreover, and in view of the ACCME’s status as a “state actor”⁴⁶, a categorical prohibition on commercial support for CME that is otherwise independent and unbiased raises “free speech” concerns under the First Amendment to the U.S. Constitution. These concerns are analogous to those dealing with discrimination against disfavored speakers based merely on their identity and without regard to whether the underlying speech is truthful and not misleading.⁴⁷ The

⁴⁵ At 3-4, 7.

⁴⁶ See Section VI. below.

⁴⁷ See e.g. *First Nat’l Bank of Boston v. Belotti*, 435 U.S. 765, 777 (1978) (“The inherent worth of the speech in terms of its capacity for informing the public does not depend upon the identity of its source, whether corporate,

(continued...)

categorical prohibition on commercial support for CME, in the absence of any evidence of actual commercial bias, further amounts to a kind of viewpoint discrimination that also raises serious First Amendment questions.⁴⁸ In fact, the proposed ban on industry funding may even be less justifiable than discrimination based on a particular viewpoint or against particular speakers, such as commercial speakers, inasmuch as it represents a categorical prohibition on *all* commercial support no matter what the underlying content of the CME communication and no matter how independent and free from bias that content can be proved to be. Hence, and even if not technically required to comply with the First Amendment as such, the principle of access to all voices in the marketplace of ideas, that animates First Amendment jurisprudence, should nevertheless quite clearly apply here as a matter of policy.

Moreover, and ironically, the categorical exclusion of commercial funding for CME, even if it otherwise meets all applicable criteria on independence, amounts to the kind of blanket censorship that is at odds with the principle of academic freedom. After all, the ACCME sees CME, as we all do, as a form of academic learning. We can all agree that academic discourse of this kind should be open to all manner of ideas, even those that are currently out of favor politically and even those supported by commercial interests, assuming they are independent and

association, union or individual.”) While we agree that the ACCME’s definition of “commercial interest” properly includes companies that produce, market, resell, or distribute health care goods or services consumed by or used on patients (*see* ACCME August 2007 “*Policies and Definitions To Supplement 2004 Standards for Commercial Support*”, available at http://www.accme.org/index.cfm/fa/Policy.policy/Policy_id/9456ae6f-61b5-4e80-a330-7d85d5e68421.cfm), other entities not deemed by the ACCME to be “commercial interests”, such as for example, health insurance providers and others, may well introduce “bias” into CME comparable to or even more problematic than the “bias” that the ACCME is concerned about in the case of defined “commercial interests”. If potential “bias” in CME is the concern, then the justification for such disparate treatment of different organizations is not readily apparent and may raise “equal protection” concerns that are beyond the scope of these Comments but that the ACCME as a “state actor” should nevertheless be sensitive to.

⁴⁸ *See e.g. Rosenberger v. Rector & Visitors Univ. of Va.*, 515 U.S. 819, 829 (1995) (“When the government targets not subject matter, but particular views taken by speakers on a subject, the violation of the First Amendment is all the more blatant.”).

otherwise lack bias.⁴⁹ It is also fair to observe that there is simply no need for the ACCME to promulgate categorical rules banning commercial support, as the marketplace itself will adapt to the changing environment and as organizations adopt policies and procedures that they believe are best suited to their own particularized needs.⁵⁰

IV. THE PROPOSED “NEW PARADIGM” IS A PARADIGM OF AMBIGUITY. COMMERCIAL SUPPORT SHOULD NOT BE CONDITIONED ON ADOPTION OF THE “NEW PARADIGM”.

In lieu of banning commercial support altogether, the ACCME proposes as an alternative what it characterizes as a “new paradigm”. This proposed “new paradigm” consists of demonstrating compliance with a four-part test for determining the acceptability of commercial support; if all conditions are met, “then the commercial support of individual activities would be in the public interest and could continue to be allowed.” But the contours of the new paradigm relate primarily to the criteria for determining the validity of CME *content* and do not relate directly to determining its *independence* from commercial support. Accordingly, there is a threshold question that needs to be asked and answered about the nexus between the problem that the ACCME is purporting to address—*independence from commercial support*—and the solution it is proposing in the new paradigm. The absence of a direct nexus between the problem and the solution is highlighted by the fact that, in addition to proposing a new paradigm governing CME content, the ACCME is separately proposing a variety of additional modifications to the independence criteria in its *Standards for Commercial Support*.⁵¹ Even assuming, *arguendo*, that

⁴⁹ “Scientific and academic speech reside at the core of the First Amendment.” *Washington Legal Foundation v. Friedman*, 13 F. Supp. 2d 51, 62 (D.D.C. 1998), *appeal dismissed and judgment vacated in part by, Washington Legal Foundation v. Henney*, 202 F. 2d 331 (D.C. Cir. 2000) (citation to U.S. Supreme Court authority omitted).

⁵⁰ See e.g. Stanford University School of Medicine, “*A New Policy on the Use of Industry Support for Continuing Medical Education (CME)*”, The Dean’s Newsletter (August 25, 2008), available at <http://deansnewsletter.stanford.edu/#1>. The Association’s citation to this new policy at Stanford should not be understood or interpreted as our endorsement of it.

⁵¹ See Section V below.

the proposal for a new paradigm in lieu of a total ban on commercial support is not entirely incompatible with the ACCME's proposal to establish additional standards for determining independence, it nevertheless represents a kind of duplicative "piling on", particularly given, as we demonstrate above, the absence of any empirical evidence to establish the bias inherent in commercial support for CME.

As a further threshold matter, and as the Association observed in its July 30, 2008 letter, there is a fundamental lack of clarity about the substantive standards and procedural steps that would apply in assessing each of the proposed criteria in the new paradigm. Nor has the ACCME been helpful in that regard as, in response to our request for greater clarity, the ACCME, in its August 5, 2008 letter, asked the Association for additional details and examples of what we wish to have clarified. As we said in our letter of August 12, 2008, the ACCME's unwillingness or inability to provide additional detail absent more information from us places the burden of clarity on the wrong party and itself speaks volumes about the ambiguity of the proposal.

Put differently, the ACCME is poised to adopt a new paradigm for commercial support for CME in response to comments on the Package, and perhaps to eliminate commercial support entirely, yet the ACCME's notice fails to provide sufficient detail to allow for the submission of meaningful comments on the "new paradigm". This process is fundamentally unfair. It departs from well-settled principles that apply to agencies that engage in comparable rulemaking. In other words, a notice of proposed rulemaking must provide adequate "notice" of the terms of the proposed rule and how it will operate in practice in order, in turn, to provide affected parties and the public at large with a meaningful opportunity to comment on the proposal.⁵² Absent such

⁵² See e.g. *Ethyl Corp. v. EPA*, 541 F. 2d 1, 48 (D.C. Cir. 1976) (Under Administrative Procedure Act, notice of proposed rulemaking must be "sufficiently descriptive" so that "interested parties may offer *informed* criticism and comments" (emphasis supplied)).

specificity, the Association is effectively shooting at an unidentified target. Whether these principles of administrative “due process” apply directly to the ACCME, which they do because the ACCME is a “state actor”⁵³, or whether instead they are applicable only by analogy, the fundamental point is the same—we cannot be expected to provide meaningful comments absent the requisite level of specificity from the ACCME.

A. The Requirement for Third Party Identification and Verification of Educational Needs Is Ambiguous.

For example, Part 1 of the “new paradigm” would condition commercial support on, among other things, identification and verification of educational needs by organizations, such as U.S. Government agencies, that do not receive commercial support and that are themselves free of financial relationships with industry. What criteria would be applied to the identification and verification of these educational needs? How if at all would these criteria be the same as or different from the needs assessment criteria that apply under the ACCME’s current validation paradigm? Why is the current paradigm inadequate to establish the validity of the educational needs, especially in light of the recent statement by the ACCME that it “. . . believes that our system has an effective set of internal controls, based on the ACCME Standards for Commercial Support, that ensure learners and the public of the high quality, the independence and the scientific integrity of accredited continuing medical education.”⁵⁴ What agencies of the U.S. Government would be involved? Are there any such agencies that, in fact, are free of any financial relationships with industry by way of grants, contracts, and the like? What are the standards and procedures for seeking identification and verification of educational needs by any such agency? Will these be established by notice-and-comment rulemaking by the agency? Will

⁵³ See Section VI below.

⁵⁴ See ACCME August 5, 2008 “Dear CME Colleagues” Letter, fn. 15 above.

there be a case-by-case adjudication to identify and verify educational needs? How would that process work? What impact would either rulemaking or case-by-case identification and verification of educational needs have on the commercial support approval or grant process? Would commercial supporters remain willing to contribute to CME in this new paradigm of delay? What does the ACCME propose to do about the serious economic impact that the resultant delay will unquestionably have on the commercial viability of the CME operations of medical education providers, including MedEd companies, academic medical centers, specialty medical societies, and others? And perhaps most importantly, how will this delay impact the creation and delivery of CME addressing new models of care and medical innovation generally and what will be the impact of such a delay on the public health?

Moreover, and as CMSS observes in its August 15, 2008 comments on the Package⁵⁵, the CME provider is in the best position to determine needs and in fact is responsible for designing the CME to meet those needs. Accordingly, “[i]t does not seem logical to separate” the two, and “[d]ivorcing the CME provider . . . from needs assessment appears to be ‘throwing the baby out with the bathwater.’”⁵⁶

B. The Requirement for Third Party Corroboration of Practice Gaps Is Ambiguous.

Likewise, Part 2 of the “new paradigm” would condition commercial support on corroboration of a professional practice gap of a particular group of learners by *bona fide* performance measurements (e.g. National Quality Forum) of the learners’ own practice. It is not apparent why or how this corroboration relates in any way to the propriety in the first instance of commercial support for CME. Nor is it apparent what are the universe of sources for

⁵⁵ At 7.

⁵⁶ Id.

determining professional practice gaps and who determines their *bona fides* and on what basis. On what basis does the ACCME conclude that CME should be used exclusively to fill practice “gaps”? How if at all can this be harmonized with the proposition that CME is about life long learning? How can the proposed requirement for independent corroboration of practice gaps be reconciled with the American Medical Association’s (AMA’s) Physician Recognition Award (PRA) and Credit System that awards so-called PRA Category 1 credit for internet point-of-care or other physician CME “lookup” or self-directed study options?⁵⁷ Assuming *arguendo* that CME is only about learning “gaps”, what role if any would the views of the highly motivated prospective physician learners have in determining the validity of a learning “gap”? If a group of physician learners wants information on a particular topic is that, in itself, inadequate to establish a *bona fide* learning gap? If so, why? Will the ACCME adopt social utility criteria in assessing whether professional practice gaps have been adequately corroborated in order to justify commercial support? For example, will a professional practice gap for dermatologists be deemed to have been adequately corroborated only if it relates to treatment, say, of diseases such as skin cancer, whereas, by contrast, and even if there is a need and desire on the part of dermatologists to learn about dermal fillers for cosmetic use, will that be deemed categorically inadequate to corroborate a gap as determined by *bona fide* performance measurements? If so, why?

Moreover, and as CMSS observes in its August 15, 2008 Comments on the Package⁵⁸, “divorcing the CME provider” from identifying practice gaps amounts to “abrogating the CME provider from its educational responsibility”, which seems entirely inappropriate. Likewise, and given the fact that many conditions do not yet have established practice standards as the data

⁵⁷ See e.g. 2006 Revision at 11, available at <http://www.ama-assn.org/ama1/pub/upload/mm/455/pr2006.pdf>.

required to create them are still being developed, foreclosing commercial support for CME for such conditions “would arbitrarily eliminate CME for many conditions for which needs assessment demonstrates a need, which would ultimately have a negative impact on patient care.”⁵⁹

C. The Requirement For Third Party Establishment of CME Curricula Is Ambiguous.

Part 3 of the “new paradigm” suffers from similar ambiguity. It fails to articulate, for example, how the CME curricula are going to be established by the so-called *bona fide* organization or entity and whether and how that curriculum setting process will be open and transparent, or, like much of this ACCME proceeding, will be conducted out of the sunshine and behind closed doors. Moreover, the design of educational curricula, as CMSS observes, is “part of the responsibility inherent in professionalism”, which should not be removed from the purview of CME providers. While CMSS admittedly makes this point in the context of medical specialty societies serving as CME providers, the same principle is equally applicable to other provider types. So long as the provider is “ACCME accredited”, it is neither logical nor appropriate to distinguish the “responsibilities inherent in professionalism” as between the differing categories. Again, to quote CMSS’s thoughtful comments in the broader context of all CME providers: “Divorcing [CME providers] from designing curricula for the education of its members appears to be a Solomonian solution of cutting a whole entity in half, resulting in non-viable educational programming.” We agree.

⁵⁸ At 6.

⁵⁹ Id.

D. The Proposed Requirement That CME Be Verified As Free From Commercial Bias, While Valid, Is Circular.

This brings us to Part 4 of the “new paradigm” which, on examination, shows the apparent circularity of the ACCME’s reasoning here and why the absence of detail is fatal to the proposal. This criterion would permit commercial support if Parts 1 through 3 of the “new paradigm” had been satisfied, *and* “the CME is verified as free of commercial bias”. Of course, the freedom from commercial bias criterion is part of the existing ACCME validation paradigm and is the *sine qua non* of “independent” CME. But, presumably, under the new paradigm, the CME would not be verified as free of commercial bias, unless Parts 1 through 3 of the “new paradigm” had also been satisfied. The ACCME has failed to explain or even to address the interplay between the respective elements of the “new paradigm” and whether and how the proposals in the August 6, 2008 further call-for-comment do or do not impact the “new paradigm” which, after all, was proposed in June and, apparently, without regard to the concepts in the August 6 notice. Like CMSS, we “do not believe the proposed extreme solution to the problem of the perception of commercial bias in commercially supported CME, as outlined in the proposed ‘new paradigm’, is appropriate or necessary, as it removes the responsibilities of CME providers . . . from the design and implementation of CME which is free from commercial bias.”

E. The Adoption Of A New Paradigm For CME Is Beyond The ACCME’s Authority.

Several points deserve emphasis. The kind of profound change represented by the “new paradigm”, whatever its specific contours and however it works in actual practice (which, as we demonstrate above, are not apparent in the proposal) again represents a fundamental shift in National policy on CME. This kind of shift—“new paradigm”, in the ACCME’s own terminology—seems well beyond the scope of the ACCME’s underlying remit for all of the same reasons, and others, that establish why unilateral elimination of commercial support is

beyond the scope of the ACCME’s authority. Indeed, one can speculate, with a high degree of certainty, that the practical effect of conditioning commercial support on compliance with the “new paradigm” would be the elimination of commercial support altogether, which may well be its intended purpose. But the point is simply that such an outcome should be accomplished, if at all, through a much more representative National consensus process than the seriously flawed rulemaking process initiated here by the ACCME. Whatever the merits of the “new paradigm”, and they are few, these should be determined by institutions such as the U.S. Congress or, as proposed by CMSS by the CCCME. Moreover, an examination of the ACCME’s own recent statements about the integrity and comprehensiveness of the current regime in establishing the independence of CME themselves belie the need for a “new paradigm” as an additional constraint on commercial support.

* * *

In sum, we believe, as did many SACME members⁶⁰, that adoption of the “new paradigm” would be time consuming and burdensome and create needless additional bureaucracy and that it suffers—ironically—from the flaw that many of the third party validators that would be accorded special status themselves have their own biases and may not even know or understand the CME needs of individual physician learners. We believe that the current ACCME *Standards for Commercial Support*, if properly monitored and enforced by the ACCME, fully and completely preserve the independence of CME and that no demonstrable need exists for adoption of the “new paradigm” as a condition for commercial support of CME.

⁶⁰ See SACME Comments at 4-5.

V. THE PROPOSED NEW INDEPENDENCE STANDARDS SHOULD NOT BE ADOPTED.

The Package includes several proposals intended to eliminate “influence” by industry on CME on the theory, presumably, that any commercial “influence” necessarily erodes the “independence” of the ensuing CME. For example, the ACCME proposes that commercial interests cannot communicate with accredited providers about any “sought-after topic” for commercially supported CME, including not only suggestions of CME topics about a particular “product line” but also suggestions about topics such as “therapeutic areas” or “pathophysiology” of disease. Likewise, the ACCME proposes that commercial interests may not communicate with CME providers about their “internal criteria for providing commercial support”, as this would be deemed to be the receipt of “guidance, either nuanced or direct, on the content of the activity or on who should deliver that content” and hence prohibited by the ACCME’s *Standards for Commercial Support*. Relatedly, all parties are admonished by the ACCME “to pay close attention to what are known as ‘requests for proposals’ [RFPs] for CME activities as they may be a point for insertion of influence by industry.”

Further, the ACCME, in its August 6, 2008 call-for-comment is proposing to establish what amounts to a categorical ban that would exclude any “thought leader” in any field of medicine or science, or any medical writer, or anyone else for that matter, from being paid to participate in the creation or presentation of promotional information on behalf of a commercial interest and, at the same time, creating or presenting information for CME on the same content, even if the CME content is otherwise independent and free of commercial bias. In other words, thought leaders and others who wish to participate in the development and presentation of CME content will have to declare in advance whether they are on the “side” of promotion or on the “side” of education. If they pick the promotional side of the line, then, under the ACCME’s proposal, they

would be categorically prohibited from crossing the line to the other side, apparently forever, at least with respect to particular content.

These proposed new independence standards are not in the public interest and should not be adopted.

A. The Proposed Prohibition on Suggestion of CME Topics and Provision of RFPs By Commercial Interests Should Not Be Adopted.

It is revealing that ACCME cites no evidence to support the proposition that “influence” and “bias” are functionally equivalent concepts. Why is it inappropriate for a commercial interest to “influence” the topics to be presented in a CME activity that it funds, so long as it does not “bias” the content, and particularly if there is valid and independently derived evidence of clinical practice gaps and identified need? After all, if I am spending money to support something, then at a minimum I should at least be able to have a voice in what topics I am interested in funding without at the same time in any way trying to “control” what is said on the subject? The ACCME’s proposal is like telling someone they can contribute to charity, but then prohibiting them from deciding which charity to contribute to because, by designating the “topic” of my beneficence, I am somehow controlling the disposition of the funds. This makes little sense except as a kind of “absolute” vision of rectitude unencumbered by any concept of practical reality. It would convert commercial support for CME into sort of a charitable undertaking where the donor cannot decide what charity it should fund, even though the donor demonstrably refrains from attempting in any way to influence how the designated charity spends the donated funds. Further, directing commercial support into an anonymous fund of some kind to be awarded at the discretion of an oversight body such as the ACCME is simply not workable. This is likely to have the consequence of limiting the amount of commercial support for CME with an unknown present and future effect on the viability of the entire CME

enterprise. And equating a commercial interest's suggestion of a *topic* or equating a CME provider's knowledge of a commercial interest's RFP standards, to *control* of the ensuing CME *content* by the commercial supporter is an unjustified leap by any measure.

By way of analogy, if a professor teaches oncology at a medical school, adoption of an ACCME-like approach would mean that she may assign a mandatory research paper to her students but is foreclosed from telling them what topics are permissible subjects because, if she does, this would effectively amount to controlling the content of the research paper. Medical students would be left to guess whether a paper on breast cancer would count for course credit or whether only papers on lung cancer or some other form of the disease are acceptable. This charade seems quite unnecessary. So long as the professor does not control the content of the paper, the fact that she suggested the topic seems perfectly reasonable—indeed appropriate. Suggestion of the *topic* by the professor in no way demonstrably biases the *content* of the communication. Likewise here, the entities who provide the funding should have every right to suggest a topic, but without controlling the content. Otherwise, CME providers are left to scour a company's web site or the literature generally to divine what topics a company is and is not likely to fund, which seems like a large waste of everyone's time. Just because I tell you what is of interest to me does not mean that the content of my ensuing communication is necessarily biased. Where is the social science evidence to support that proposition? Certainly the new mandatory clinical trial posting regime under the Food and Drug Administration Amendments Act of 2007 and the greater transparency that commercial interests are now routinely providing about their areas of research interest will give CME providers more *clues* about what CME programs a company *might* be interested in funding. But why should everyone be spending their time on guesswork?

Rather, they should be spending their time on developing high quality CME activities that have the kind of rigor the ACCME, the Association, and most others in the CME enterprise seek.

Likewise, the use of RFPs, in and of itself, seems entirely appropriate and unproblematic. In fact, government agencies, such as the National Institutes of Health, routinely use RFPs to inform interested parties that funds are available to support education or research, to provide context about why the funds are available, and to explain how applications should be submitted and what information is required to be included. This use of an RFP-type process saves time and resources that are better spent on the development of the underlying CME content.

If the concern about suggestion of topics and about the use of RFPs is that they are points at which to insinuate commercial *bias* in the ensuing CME content, that concern is amply addressed by the current *Standards for Commercial Support*. If violations of these standards are taking place, then enhanced monitoring and enforcement by the ACCME is in order. Violators should be caught and punished. However, additional regulatory prohibitions that would foreclose suggestion of CME topics by commercial interests or the use of RFPs are unnecessary and potentially counterproductive. As SACME put it in its comments, “[A] lack of a transparent approach would likely lead to hidden agendas, a waste of time and resources and unnecessary increase in the cost associated with accredited CME to cover the inefficiencies created by such a policy.”⁶¹ We agree.

B. The Proposed Categorical Ban On CME Faculty Speaking at Promotional Meetings On The Same Content Should Not Be Adopted.

The ACCME’s proposal to categorically ban CME faculty from speaking at promotional meetings on the same content would effectively require thought leaders and any other CME faculty members to “take sides” on CME content. They would effectively be required to declare

in advance whether they are on the side of promotion or on the side of education, apparently forever, at least with respect to the same and closely related content. This “crossover” prohibition would apply even if the CME faculty members promotional presentation is truthful, not misleading, fully substantiated, fairly balanced, and “on label”, as required by FDA. It would presumably mean that a thought leader who makes such a promotional presentation could not thereafter teach at a CME activity about emerging data and innovative models of care on the same general content area. This seems like a profoundly misguided policy.

Oddly, in proposing a categorical crossover ban, the ACCME does not explain or even address why the ACCME’s *Standards for Commercial Support* are inadequate to address and resolve any conflicts of interest that might be created by these dual roles. In fact, Standard 6 currently requires disclosure to learners of potential conflicts of interest created by relevant financial relationships. And Standard 2 defines relevant financial relationships to include a financial relationship in “any” amount during the preceding 12 months. Coupled with the overarching requirement that CME be independent and free from commercial bias, such a disclosure regime appears to be adequate in itself to address the problem the ACCME seeks to remedy and the ACCME does not explain why it isn’t.

Moreover, the proposed crossover prohibition applicable to CME faculty appears to be just an indirect way of categorically prohibiting commercial support for CME even if the CME is otherwise independent and free from commercial bias. The proposition that one should not be able to accomplish indirectly what one may not accomplish directly, which is a relevant constitutional principle for example under the First Amendment⁶², seems applicable in this

⁶¹ At 2.

⁶² See e.g. *Grosjean v. Am. Press Co.*, 297 U.S. 233, 250 (indirect regulation of speech through taxation of newspapers unconstitutional).

context as well. All of the reasons discussed above why a categorical ban on commercial support for CME should not be adopted are equally applicable to the proposed CME faculty crossover ban. A policy with such profound National implications seems quite clearly beyond the purview of the ACCME and should be considered and adopted as National policy, if at all, as in the case of a proposed ban on commercial support for CME, by a more representative body.

Moreover, the “authority” cited by the ACCME fails to support the proposed crossover ban. First, the ACCME says that the ban is supported because a group of state attorneys general “won” a judgment against a major pharmaceutical company imposing a comparable prohibition. But this use by the ACCME of the term “won” suggests that a neutral third party, such as a judge, evaluated the evidence and arguments on all sides of the matter and concluded that a crossover prohibition should be ordered. In fact, the crossover prohibition in that case, which nevertheless applies only for a limited duration for any particular CME faculty member, is part of a government coerced settlement agreement, and was not “won” by the state attorneys general in a fully litigated proceeding. Indeed, as anyone involved in this kind of litigation knows, “fencing in” provisions like this are sometimes imposed as part of a settlement in a particular case based on the specific underlying facts of the matter and cannot and should not be interpreted as necessarily establishing policy in other, unrelated contexts.⁶³

Moreover, the ACCME’s citation to the June 2008 *AAMC Task Force Report* as support for the proposed crossover ban is incomplete and somewhat misleading. It is true of course, as the ACCME says, that the Task Force recommended that academic medical centers (AMCs) “strongly discourage” participation by faculty members as speakers at promotional events. At the same time, however, the Task Force specifically acknowledged that AMCs may “choose” to

allow participation of faculty members in “industry sponsored, FDA regulated programs”.⁶⁴ If they “choose” the latter, then the Task Force suggested that AMCs “require full transparency and disclosure by their personnel to the centers *and when participating in such programs*” and “require that payments to academic personnel be only at fair market value.”⁶⁵ In other words, and contrary to the impression created by the ACCME in the proposal, the AAMC Task Force did not recommend a categorical crossover prohibition of the kind the ACCME is proposing. Indeed, the Task Force acknowledged that this matter is best left to institutional “choice” and that if the choice is to permit such participation, then conflicts management tools, such as transparency and disclosure, are adequate to address the matter.

The ACCME’s proposed categorical crossover ban has the potential to seriously impair and weaken the quantity and quality of CME in the United States. It may well deter significant numbers of physicians, including some who are the most interested and qualified to participate as CME faculty, from engaging in promotional relationships with commercial interests, or, alternatively from participating in CME altogether.⁶⁶ Either result seems unfortunate, as it may well remove some of the most qualified individuals, including key “thought leaders”, from participation in one or another of these important activities.⁶⁷

⁶³ The ACCME’s proposed importation into its own criteria of standards mandated in a government coerced settlement agreement itself belies the ACCME’s assertion that it is not a “state actor”.

⁶⁴ See AAMC Task Force Report, *available at* https://services.aamc.org/Publications/showfile.cfm?file=version114.pdf&prd_id=232&prv_id=281&pdf_id=114 at 20.

⁶⁵ *Id.* (Emphasis supplied).

⁶⁶ See “*White Paper: Merck Settles Vioxx® Litigation with State Attorneys General: an Analysis*”, McDermott, Will & Emery (May 29, 2008), at 5, *available at* http://www.mwe.com/index.cfm/fuseaction/publications.nldetail/object_id/25354abe-4d4d-4f08-846c-55f05f96f1af.cfm.

⁶⁷ *Id.*

C. The Proposed Categorical Prohibition On Medical Writer Crossover Is Duplicative and Unnecessary.

The ACCME's proposed new independence standards, as applied to CME crossover by medical writers who work on promotional programs in connection with the same content, is duplicative and unnecessary for yet an additional reason beyond those articulated above in connection with crossover by CME faculty (e.g. disclosure and use of other conflicts management tools). This has to do with the ACCME's extant August 2009 deadline that already requires significant institutional firewalls between agencies that create promotional programs and accredited providers who produce CME activities. In itself, this will likely have the effect that the ACCME is seeking to achieve by the proposed CME crossover prohibition. It is unfortunate that the ACCME does not address or even identify the overlap between the forthcoming separation of functions requirements and the proposed crossover prohibition as applied to medical writers (and other staff and freelancers that work on content).

In fact, most commercial interests who provide CME grant funding already require that the provider not be working in both promotion and CME, and will refuse to provide CME grants to entities involved in promotional programming. Data from the most recent (2007) survey of MedEd companies⁶⁸ demonstrates that this provider sector is moving swiftly into a certified education-only model from the mixed promotional/certified CME model that was prevalent before the issuance of the OIG Compliance Guidance in 2003. A great deal has changed in the CME environment since then, and MedEd companies and other stakeholders have continued to adapt as rules and regulations, including the ACCME's own *Standards for Commercial Support*, new accreditation criteria, and recent policy revisions, have evolved. MedEd companies have

changed their internal organizational structure through separation of the unit involved in CME and through the erection of stringent internal firewalls. The data demonstrate for example that all MedEd companies who deliver certified CME have firewalls that separate education from promotion and that substantial progress is being to ensure the adequacy of these firewalls through an array of controls (e.g. separate project teams; separate communications systems; separate office space; etc.).⁶⁹ None of the organizations who responded to the survey reported sharing staff that controls content (e.g. writers, medical directors) between the education company that produces certified CME and the affiliate that produces promotional activities.

VI. THE ACCME IS A “STATE ACTOR” SUBJECT TO CONSTITUTIONAL NORMS.

There are strong grounds to conclude that the ACCME is a “state actor” and hence subject to constraints, such as due process and First Amendment free speech requirements imposed by the U.S. Constitution. We demonstrate above how a number of the ACCME’s proposals violate these constitutional norms. The ACCME should carefully analyze the “state actor” issue and how it affects the current rulemaking, as ACCME may well be called upon to do so later in any event, particularly given the highly charged current atmosphere. In the attached State Actor Appendix, we provide some thoughts for consideration by the ACCME on this exceptionally important question.

VII. CONCLUSION.

The ACCME has a fiduciary responsibility not only to all segments of the provider community, but also, and most importantly, to physicians and to the American people to consider well the

⁶⁸ See Peterson ED, Overstreet KM, Parochka JN, Lemon MR. “*Medical Education and Communication Companies Involved in CME: An Updated Profile.*” Journal of Continuing Education in the Health Professions (In Press).

⁶⁹ *Id.*

impact of its proposals, particularly the unintended consequences from their adoption that are likely to seriously and adversely affect the overall CME enterprise and consequently the public health. The first principle of medicine is to "do no harm". As we demonstrate above, promulgation of the Package as proposed by the ACCME is not in the public interest and may well do serious harm to post-graduate education of physicians in the United States.

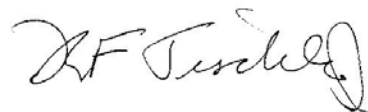
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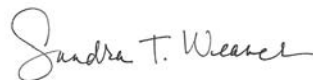
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Member organization liaison: Jan Simon, RN, MHSA (jsimon@abms.org)
American Hospital Association
Member organization liaison: John Supplitt, MPH, MBA
(jsupplitt@aha.org)
American Medical Association
Member organization liaison: Alejandro Aparicio, MD, FACP
(alejandro.aparicio@ama-assn.org)
Association for Hospital Medical Education
Member organization liaison: Charles Daschbach, MD, MPH
(cdaschb@chw.edu)
Association of American Medical Colleges
Member organization liaison: David Davis, MD (ddavis@aamc.org)
Council of Medical Specialty Societies
Member organization liaison: Norman Kahn, MD (nkahn@cmss.org;
also c/o jkersten@cmss.com)

Federation of State Medical Boards of the U.S., Inc.

Member organization liaison: Carol Clothier (cclothier@fsmb.org)

STATE ACTOR APPENDIX

The ACCME Is a “State Actor” Subject to Constitutional Norms

There are strong grounds to conclude that the ACCME is a “state actor” and hence subject to constraints, such as due process and commercial free speech, imposed by the U.S. Constitution. In our main comments, the Association demonstrates how a number of the proposals in the Package and the process employed in this proceeding violate these constitutional norms. Here we address some of the reasons why we believe that in the context of this rulemaking the ACCME is a “state actor”.

Most state medical regulatory authorities either directly or indirectly incorporate ACCME accreditation requirements into their CME regimes. The AMA’s PRA program, with its “Category 1” credit system, has been adopted by forty-three states and the District of Columbia as either the sole CME credit acceptable under state rules or as a significant feature of the mandatory CME regime.⁷⁰ For example, California requires an M.D. to secure 100 CME credits during a given four-year period, with all 100 of these consisting of AMA PRA Category 1 credits, and the state licensing board has the statutory authority to deem any courses that meet certain content standards and receive accreditation from either the ACCME or the California Medical Association to satisfy state CME requirements.⁷¹ Similarly, Florida, while requiring a varying number of CME credits for each license renewal based on a multiple-year cycle, mandates that the credits come either from AMA PRA Category 1 courses or from certain other sources, and the licensing board advises doctors that Category 1 providers “are either accredited

⁷⁰ A current table summarizing state requirements is *available at* http://www.aad.org/education/relicensure/_doc/StateLicensureRequirementsRevised.pdf.

⁷¹ Cal. Bus. & Prof. Code § 2190.1(e). *See also e.g. “The California Medical Board, Continuing Medical Education, Option Available to You”, available at* http://www.mbc.ca.gov/licensee/continuing_education_options.html.

by the [ACCME] or intra-state by the Florida Medical Association.”⁷² Likewise, Illinois requires 150 CME credits over a three-year cycle with at least 40 percent of the credits coming from Category 1 courses, and the licensing board notes that the ACCME is the organization responsible for accrediting CME providers.⁷³

There are other indicia of substantial entwinement between the ACCME and state medical licensing boards. For example, the Federation of State Medical Boards⁷⁴ is a member organization of the ACCME and has a seat on its Board of Directors.⁷⁵ “The FSMB is working to assure the pertinence of accreditation of CME as a trusted source *on behalf of its member boards* that require CME and utilize ACCME.”⁷⁶ (Emphasis supplied). In fact, the ACCME itself, in its *Bridge to Quality*, quite convincingly makes the “state action” case by demonstrating that CME is an essential requirement for maintenance of licensure and recouping, chapter and verse, the “pervasive entwinement”⁷⁷ among the ACCME, the FSMB, and individual state medical boards.

While it is true the states do not necessarily adopt the ACCME’s standards directly, many indirectly require ACCME-accredited coursework by mandating that physicians take courses under a CME regime that uses ACCME accreditation as a baseline. In this respect, therefore, the ACCME is serving as a surrogate for the state medical licensing boards in developing,

⁷² Fla. Dep’t of Health, *Continuing Medical Education (CME)*, available at http://www.doh.state.fl.us/mqa/medical/me_ceu.html (information updated for reporting period ending Jan. 31, 2008).

⁷³ Ill. State Medical Soc’y, *Medical Licensure & Relicensure in Illinois*, available at http://www.isms.org/physicians/licensure/licensure_a.html.

⁷⁴ The FSMB, although not in and of itself a government entity, represents the 70 medical licensing boards of the U.S. and its territories, and its mission is to improve the quality, safety, and integrity of health care through developing and promoting high standards for physician licensure and practice. See “*About FSMB*”, available at <http://www.fsmb.org/aboutFSMB.html>.

⁷⁵ See *ACCME Board of Directors*, available at <http://www.accme.org/index.cfm/fa/about.directors.cfm>.

⁷⁶ See *2008 Annual FSMB Meeting, Agenda Item 13A, Tab 2* (at page 6 of 6), available at http://www.fsmb.org/pdf/annualmeeting_2008/hod_agenda/item_13a_tab_i_accme.pdf.

⁷⁷ See *Brentwood Acad.* at fn. 8 above.

implementing, and policing its CME accreditation standards. This surrogacy, as well as other areas of pervasive entwinement among the ACCME, the FSMB, and the state medical licensing boards demonstrates that there are strong arguments for characterizing the ACCME as “state actor” subject to the same constitutional principles that would be applicable to the Government itself were it regulating CME directly. As the Coalition puts it in the comments it is filing in this rulemaking: “[T]he process, procedures and substance of the ACCME system of accreditation is inextricably tied to the official, governmental process of professional certification.”⁷⁸ And whether or not the ACCME is itself a “state actor”, there are substantial arguments that a state medical licensing board, by incorporating by reference ACCME standards (and the process used to develop those standards), which would be unconstitutional if adopted by a Government body itself, likewise is subject to a constitutional challenge as a consequence of the ACCME’s actions here. In other words, to the extent that a state medical licensing board indirectly incorporate the ACCME’s standards, which have been adopted using constitutionally flawed procedures, there is a compelling argument that they are subject to challenge as a result. This possibility is something to which the ACCME should likewise be attentive.

There is no clear single formula for determining whether and when a private or semi-private association, such as the ACCME, is nevertheless a “state actor” for constitutional purposes. The Supreme Court itself has noted that it is an “impossible task” to “fashion and apply a precise formula” to this question.⁷⁹ “What is fairly attributable [to the State] is a matter of judgment, and the criteria lack rigid simplicity.”⁸⁰ As a general matter, however, the Supreme Court has noted

⁷⁸ September 12, 2008 Comments at 2.

⁷⁹ *Burton v. Wilmington Parking Auth.*, 365 U.S. 722 (1961).

⁸⁰ *Brentwood Acad.* at 531 U.S. at 295.

a number of factors that may be relevant in any given case in deciding whether state action is present:

- Did the activity result from the state’s exercise of “coercive power”?
- Did the state provide “significant encouragement, either overt or covert”?
- Did the private actor operate as a “willful participant in joint activity with the State or its agents”?
- Is the nominally private actor controlled by an agency of the state, or is it exercising a public function delegated to it by the state?
- Is the private actor “entwined with governmental policies,” or is the government “entwined in its management or control”?⁸¹

Private actors will be held to constitutional standards if “there is a sufficiently close nexus between the State and the challenged action of the regulated entity”⁸² The determination of whether there is a “sufficiently close nexus” looks, among other things, to the standards listed above, and whether the state provided “a mantle of authority that enhanced the power of the harm-causing individual actor.”⁸³ Notably, the Supreme Court has suggested that a state agency, by “embracing” rules promulgated by an association, may well transform those rules into state rules such that the association itself, i.e. the ACCME in this case, becomes a “state actor.” Given the pervasive degree of entwinement between the state medical licensing boards, the FSMB, and the ACCME, among others, and given the extent to which the ACCME’s rules have been “embraced” by a panoply of government actors, including not only by state medical licensing boards but, as also, as the Coalition observes in its comments⁸⁴, by FDA and even by state legislatures in contexts that do not relate directly to medical licensing but relate to regulation of

⁸¹ *Id.* at 531 U.S. at 296.

⁸² *Id.*

⁸³ *NCAA v. Tarkanian*, 488 U.S. 179, 192 (1988).

⁸⁴ *Id.* at 194.

industry behavior⁸⁵, there is an unquestionably tight “embrace” between what the ACCME does and how it does it, and what the state does and how it does it.

For these reasons, and others not recounted here, the Association believes that strong grounds exist for concluding that the ACCME is a “state actor” subject to constitutional norms. Equally as important, state medical licensing boards, who unquestionably are state actors, may well also be liable for breaches of constitutional norms occasioned by the ACCME’s actions in this rulemaking.

⁸⁵ See e.g. §14 of Massachusetts S. 2863, adding Chapter 111N, and requiring, in new §2(3), that the State Department of Health adopt a marketing code of conduct for pharmaceutical and medical device companies that would prohibit, among other things, industry “sponsorship or payment” for CME “that does not meet the Accreditation Council for Continuing Medical Education Standards for Commercial Support.” Available at <http://advamed.org/NR/rdonlyres/AEAF3DC5-356E-49DF-BD69-5CA048624AB1/0/ma2863.pdf> (beginning at line 791). To the extent that the process employed by the ACCME in this rulemaking and the substantive standards that emerge are constitutionally flawed but are ultimately incorporated into the ACCME’s *Standards for Commercial Support* nevertheless, these flaws may well be imputed to the State in the context of legislation like this. The ACCME should be sensitive to this possibility.