
COMMENTS

of

WASHINGTON LEGAL FOUNDATION

to the

**ACCREDITATION COUNCIL FOR
CONTINUING MEDICAL EDUCATION**

Concerning

**June 11, 2008 Calls for Comment on
“Limiting the Interactions Between Accredited Providers
and Commercial Interests Over Commercial Support,” and
“The ACCME Believes that Due Consideration be Given
to the Elimination of Commercial Support
of Continuing Medical Education Activities”**

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Submitted Electronically:

<https://accme.wufoo.com/forms/call-for-comment-1> and **[call-for-comment-2](#)**

ACCME
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Re: June 11, 2008 Calls for Comments on “Limiting the Interactions Between Accredited Providers and Commercial Interests Over Commercial Support” and “The ACCME Believes that Due Consideration be Given to the Elimination of Commercial Support of Continuing Medical Education Activities”

Dear ACCME Members:

The Washington Legal Foundation (WLF) appreciates the opportunity to comment on the ACCME’s June 11, 2008 proposal to define appropriate interactions between Accredited Providers of CME and commercial entities that provide them with support, as well as on ACCME’s “new paradigm” for commercial support of CME activities. WLF is not commenting on ACCME’s August 8, 2008 proposal regarding “Additional Features of Independence” in accredited CME; WLF does not have sufficient expertise regarding the promotional activities of medical professionals to provide useful comments in that area.

WLF is quite dismayed by the June 8 proposals. Both entail wholesale revisions regarding the manner in which CME is provided in this country. One would think that anyone proposing such major revisions would set forth substantial evidence providing justification for the changes. Yet, the ACCME provides virtually no such evidence and only minimal

explanations for its rationales. Basic notions of due process require the ACCME to give a better account of its intent and why its proposed changes are justified. Moreover, because the proposed changes, if adopted, are likely to have massive changes on the industry, fairness requires that those affected be provided a greater opportunity to respond and to suggest alternatives. Finally, WLF believes that the proposed ban on interactions between CME providers and commercial interests raise serious First Amendment concerns. WLF strongly urges the ACCME to re-examine its commitment to constitutionally problematical speech regulation.

I. Interests of WLF

WLF is a public interest law and policy center with members and supporters in all 50 states. It devotes a substantial portion of its resources to defending the rights of individuals and businesses to go about their affairs without undue interference from government regulators. Among WLF's members are doctors and medical patients who wish to receive information about uses of FDA-approved drugs and medical devices, as well as medical patients who wish their doctors to receive such information.

WLF has for many years been actively involved in efforts to decrease FDA restrictions on the flow of truthful information about FDA-approved products. For example, WLF successfully challenged FDA restrictions on commercial speech by pharmaceutical manufacturers. *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998) [*“WLF I”*], *injunction modified*, 56 F. Supp. 2d 81 (D.D.C. 1999) [*“WLF II”*], *appeal dismissed*,

202 F.3d 331 (D.C. Cir. 2000) [“*WLF III*”]. The district court’s ruling included a holding that FDA violated the First Amendment when it attempted to restrict manufacturer support of CME activities at which the manufacturer’s products were discussed. *WLF I*, 13 F. Supp. 2d at 73. The court enjoined FDA from “prohibit[ing], restrict[ing], sanction[ing], or otherwise seek[ing] to limit any pharmaceutical company or medical device manufacturer or any other person . . . from suggesting content or speakers to an independent program provider in connection with a continuing medical education seminar program or other symposium . . .” *Id.* at 73-74.¹ On January 29, 2003, WLF filed comments with the ACCME regarding constitutionally objectionable features of proposed revisions to the ACCME Standards for Commercial Support of CME activities.

WLF agrees with the United States Supreme Court that it is “[t]he premise of our system that there is no such thing as too much speech – that the people are not foolish but intelligent, and will separate the wheat from the chaff.” *Austin v. Michigan State Chamber of Commerce*, 494 U.S. 652, 695 (1990) (Scalia, J., dissenting). Accordingly, provided that a CME provider maintains its independence, WLF believes that there is no justification for suppressing truthful speech by commercial interests to that provider.

WLF also believes that CME providers are doing a commendable job of supplying

¹ That portion of the district court’s injunction was later vacated by the D.C. Circuit as moot, after FDA provided assurances to the appeals court that had absolutely no intention of restricting manufacturer speech with respect to CME, and that its existing guidance documents on manufacturer support of CME were intended to be advisory only.

doctors with valuable medical information. In the absence of evidence that there are serious problems with the industry's integrity – and the ACCME has supplied none – WLF does not believe that there is any justification for a major paradigm shift that could significantly impair the industry's ability to continue to provide first-rate information.

II. ACCME Concern Over Commercial Support Is of Quite Recent Origin

The ACCME's proposals are a continuation of a heightened concern over commercial support of CME, a concern that is of quite recent origin. Indeed, until at least 2003, there was widespread satisfaction with the ACCME standards governing such support. Those prior standards, adopted in March 1992, sought to prevent any bias in CME presentations by, among other things: (1) preventing the manufacturer from "control[ing] the planning, content or execution of the activity"; (2) barring a company from conditioning the provision of financial support on "acceptance . . . of advice or services concerning speakers, invitees or other educational matters, including content"; (3) requiring that any commercial support "be acknowledged in print announcement and brochures" without making any reference to specific products; and (4) requiring all speakers to disclose "the existence of any significant financial relationship or other relationship" they may have had with the manufacturer of a product to be discussed. While evidence of occasional violations of those standards have surfaced, WLF is unaware of any evidence that a significant number of CME providers did not comply fully with the standards.

In the early 1990s, FDA proposed adoption of its own standards for manufacturer

support of CME, and also brought enforcement actions against several manufacturers whose support of CME was viewed as constituting promotion of an unapproved new use of an FDA-approved product. These FDA activities were widely criticized and led directly to the WLF lawsuit cited above. After the district court's 1998 decision in *WLF I*, FDA backed off of its efforts to regulate CME.² Rather, FDA let it be known that it was satisfied with the ACCME's regulation of CME; *i.e.*, so long as a CME activity was accredited by the ACCME, FDA was unlikely to closely examine the activity to determine whether a manufacturer may have engaged in improper promotion of one of its products.

In January 2003, an ACCME task force proposed significant revisions to the ACCME commercial support standards, calling for the exclusion from CME activities of anyone who was (due to financial arrangements) potentially biased in favor of a particular manufacturer's products; full disclosures of those biases was no longer deemed sufficient. The January 2003 proposal was similar to the latest proposal in one very significant respect: the task force made no effort to explain why its proposed major revisions were necessary. After opposition to the proposal was expressed by WLF and others, some of the more draconian features of the

² Indeed, in its appeal to the U.S. Court of Appeals for the District of Columbia Circuit, FDA explicitly denied that it had any policy whatsoever on manufacturer support of CME. FDA told the appeals court that it viewed its CME Guidance (*see* 62 Fed. Reg. 64093-64100 (Dec. 3, 1997)) as a mere "safe harbor"; *i.e.*, manufacturers who complied with the Guidance could rest assured that they would not be targeted for enforcement action, but failure to adhere to the Guidance could not by itself form the basis for enforcement action. Solely on the basis of FDA's assurance that it would never invoke the CME Guidance in an enforcement action, the appeals court dismissed FDA's appeal and vacated as moot the district court injunction with respect to the CME Guidance. *WLF III*, 202 F.3d at 335-337.

proposal were modified before the current *ACCME Standards for Commercial Support* were adopted in 2004.

The ACCME's June 2008 proposal once again threatens major changes in the way that the industry operates. But once again, the ACCME provides virtually no evidence suggesting that there is a need for such major changes. WLF respectfully suggests that the latest proposal is based on a naive misunderstanding of how CME operates and a misguided faith that reliance on supposed alternative sources of funding would lead to superior educational results.

III. Commercial Interests Supply CME Funding Because They Believe it is in Their Financial Interest to Do So

Underlying much of what the ACCME has written regarding commercial support of CME is its apparent belief that such support is appropriate only if provided solely for charitable reasons. It apparently believes that if, in fact, commercial entities provide such support out of self-interest, then any CME provider that accepts such support is irreparably tainted and the integrity of its CME activity is compromised.

WLF wishes to state the obvious: no medical product manufacturer subsidizes CME based on a philanthropic desire to subsidize the education of underpaid physicians. Instead, they provide support because they believe that doing so will result in increased dissemination of information about their products, and that the increased information dissemination will result in increased sales of their products.³ Accordingly, if the ACCME succeeds in preventing

³ Some government officials are wary of manufacturer support of CME for precisely that same reason. They realize that increased product sales may well translate into increased

manufacturers from having any opportunities to suggest topics and content for CME, manufacturers will quickly lose much of their interest in providing financial support. WLF sees much to be gained and little potential harm if manufacturers continue to use their financial leverage to gain some voice in CME programs, so long as the accredited providers continue to exercise ultimate control over program content. Some at the ACCME seem to believe that loss of that funding stream would be a net plus for CME; for reasons set forth below, WLF respectfully submits that the results would be disastrous.

IV. The ACCME Should Continue Its Focus on Independence

Standard 1.1 of the *ACCME Standards for Commercial Support* provides as follows:

A CME provider must ensure that the following decision were made free of the control of a commercial interest:

- (a) Identification of CME needs;
- (b) Determination of educational objectives;
- (c) Selection and presentation of content;
- (d) Selection of all persons and organizations that will be in a position to control the content of the CME;
- (e) Selection of educational methods; and
- (f) Evaluation of the activity.

WLF fully supports Standard 1.1. We believe it is important that a manufacturer not be permitted to turn a CME activity into a one-sided promotion of its product by providing funding for the activity in return for control over how the activity is conducted. The whole

government expenditures for Medicare and Medicaid. Such officials often focus almost exclusively on the bottom line, with very little heed to whether increased product sales will lead to improved health care.

point of the ACCME accreditation process is to ensure that it is accredited CME providers who makes the final determinations regarding how CME activities are to be conducted. Evidence that an accredited provider is abdicating its responsibility to exercise such control is grounds for revoking that accreditation.

The ACCME now proposes taking the position that an accredited provider is not maintaining independence if it either: (1) receives communications from commercial interests announcing or prescribing any specific content that would be a preferred, or sought-after, topic for commercially supported CME; or (2) receives communications from commercial interests regarding a commercial interest's internal criteria for providing commercial support. That position is not even a plausible interpretation of Standard 1, which focuses on *independence* not *communication*. For the ACCME to state otherwise suggests a bad-faith attempt to disguise the drastic nature of the revision being proposed. Clearly, if evidence indicates that a manufacturer regularly gives a provider "suggestions" regarding preferred content and if in each instance the provider adopts those suggestions without further deliberation, that would be strong evidence that the manufacturer is not operating independently. But there are any number of internal controls that a provider can install to maintain independence, and thereby ensure that no manufacturer suggestions regarding CME content are adopted without first conducting an independent confirmation that the content both meets a perceived educational need and is medically sound. The concept of independent verification is sufficiently established within the medical profession to put the lie to the ACCME's contention that a

provider can never exercise independence if it receives both funding and suggested content from a commercial entity.

Thus, what the ACCME's position really comes down to is a preference that manufacturers provide no input whatsoever in formulating CME content. Precisely why one would have such a preference is difficult to understand, particularly when one considers that a manufacturer's employees and consultants are likely to be among those most knowledgeable regarding the latest medical advances in the fields in which the manufacturer operates. They are also likely to be aware of the topics regarding which doctors are most likely to desire additional information. If manufacturers are not permitted to suggest content, CME programs are less likely to cover as wide a range of cutting edge issues.

Moreover, there already exist self-correcting mechanisms that deter providers from offering biased programs that serve a particular manufacturer's interests but that offer little helpful information to doctors. In particular, doctors are all highly educated professionals who are likely to be able to detect a biased presentation that cannot be trusted. Once a provider develops a reputation for offering biased and untrustworthy CME activities, doctors will be very reluctant to attend that providers events in the future.⁴ Similarly, if a provider accepts on faith a manufacturer's suggestion and offers a course for which there is little demand within the medical profession, the provider is unlikely to attract many attendees. Accordingly,

⁴ Nor, for that matter, are they likely to prescribe drugs in the manner suggested by the biased presentation.

providers have a strong financial self-interest in maintaining their independence so as to continue to attract attendees.

IV. Adverse Effects on Health Care

WLF approaches this topic with the old adage, “if it ain't broken, don't fix it.” There is little to suggest that there are any serious bias problems today in the provision of CME. Moreover, the proliferation of programs means that CME activities cover a multitude of topics. The only sure result of the adoption of the ACCME proposals is a decrease in that variety.

The ACCME's proposed “new paradigm” makes plain, however, that the ACCME is intent on doing away with all commercial support for CME activity. By insisting that four stringent and ill-defined conditions be met before it will concede that commercial support is *ever* in the public interest and could continue to be allowed, the ACCME is attempting to stack the deck to require adoption the outcome it quite evidently prefers: the elimination of all commercial support.

WLF suggests that that outcome would be disastrous for health care. Nearly 50% of all CME is provided through commercial support. If that support is ended, there is no readily apparent source of alternative financing. One of the ACCME's suggested alternatives -- “industry donated, pooled funds” cannot be taken seriously. Manufacturers have no incentive to donate to a pooled CME fund when they have no assurance that the funds will be used to conduct programs that have any relevance to the products they produce.

Nor is there any reason to believe that the government would be an alternative source

of funds of that magnitude. Moreover, there is every reason to believe that funding coming from a single source (*i.e.*, the government) would result in content far less diverse than currently exists. Furthermore, the government has its own biases that it no doubt would bring into play. Governments have an interest in reducing health care expenditures in order to help balance their budgets. Such reduced expenditures, if evidenced-based, may in some cases be good for society as a whole, but it can often be bad for individual patients who are denied treatment based on cost-benefit determinations.

WLF points to the model of continuing legal education (CLE) as one that the medical profession ought not emulate. There are no industry groups with a strong interest in influencing the content of CLE, and thus with an interest in providing subsidies. The result is that most CLE is of very low quality, and lawyers attend when forced to by state licensing requirements -- not because they believe that the courses offer them any meaningful educational benefits. WLF submits that if the ACCME deprives CME of a significant portion of its funding by prohibiting commercial support, the quality of CME will fall to that of CLE. Such a loss in quality and quantity of CME would be a tragic loss to the quality of health care in this country.

V. First Amendment Considerations

WLF only briefly touches on its First Amendment concerns about the restrictions that the ACCME proposes be imposed on manufacturer speech. A number of other commentators have provided strong arguments regarding why the ACCME would be deemed a "state actor"

if its speech restrictions were challenged in court. If the ACCME were deemed a state actor, its restrictions would surely be struck down on First Amendment grounds.

As the U.S. District Court for the District of Columbia made clear in *WLF I*, the types of content-based speech regulations contemplated by the ACCME proposals could not withstand First Amendment scrutiny. As the Supreme Court has held in numerous First Amendment cases, “if the Government could achieve its interests in a manner that does not restrict speech, the Government must do so.” *Thompson v. Western States Medical Center*, 122 S. Ct. 1497, 1506 (2002). Because the current “independence” system has worked well to prevent CME attendees from being misled by potentially biased speakers, the First Amendment precludes the government -- or a government-affiliated organization -- from attempting to preclude all speech that is funded by commercial interests.

CONCLUSION

The Washington Legal Foundation respectfully requests that the ACCME withdraw its proposals, unless and until it provides a substantial basis for concluding that the current "independence" system is not working to ensure that doctors receive unbiased presentations at CME activities.

Respectfully submitted,

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