COMMENTS

of

WASHINGTON LEGAL FOUNDATION

to the

ACCREDITATION COUNCIL FOR CONTINUING MEDICAL EDUCATION

Concerning

REQUEST FOR COMMENTS ON THE JANUARY 14, 2003 DRAFT "STANDARDS TO ENSURE THE SEPARATION OF PROMOTION FROM EDUCATION WITHIN THE CME ACTIVITIES OF ACCME ACCREDITED PROVIDERS"

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Submitted Electronically: scs@accme.org
Standards for Commercial Support Task Force
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Re: Request for Comments on January 14, 2003 Draft ACCME Standards for Commercial Support

Dear Task Force Members:

The Washington Legal Foundation (WLF) is submitting these comments to express its strong dismay regarding the draft "Standards to Ensure the Separation of Promotion from Education Within the CME Activities of ACCME Accredited Providers." Whether or not it was the Task Force's intent, the inevitable result of adoption of the proposed standards by CME providers would be the suppression of significant amounts of accurate information needed by physicians to provided optimal medical care to their patients. The proposed standards would prevent many of the most knowledgeable medical authorities from participating in ACCME-accredited activities.

WLF finds it particularly disturbing that the Task Force is proposing a radical revision of existing standards in the absence of any significant evidence that the current standards are not sufficient to prevent the dissemination of biased information. Before making such a proposal, one would think that the Task Force would at least attempt to outline the evidence it deemed sufficient to warrant scrapping the existing standards; but the draft is silent on that point.

In light of the proposed standards' likely chilling effect on truthful speech, WLF will recommend (if the standards are adopted in a form resembling the draft) that CME providers seek alternatives to ACCME accreditation for their programs; adherence to the standards as the cost of ACCME accreditation is too high a price to pay in terms of reduced levels of health care for the American public. As a private entity, the ACCME is, of course, free from First Amendment constraints so long as it does not adopt standards in concert with the Food and Drug Administration (FDA) and/or state medical authorities. But to the extent that any standards ultimately adopted contain an element of "state action" (either in their development or as a result of government reliance on ACCME accreditation), the proposed standards are a clear violation of First Amendment rights because of their content-based restrictions on truthful speech. WLF strongly urges the Task Force 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 (both on and off-label) 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 dism'd,* 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. In September and October 2002, WLF filed extensive comments with FDA in response to FDA's request for input regarding First Amendment constraints on FDA's power to regulate manufacturer speech. *See* FDA Docket No. 02N-0209, 67 Fed. Reg. 34932 (May 16, 2002).

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, WLF believes, there is no justification for suppressing speech unless there is good reason to believe that the

speech is false. If a CME provider believes that doctors can better evaluate what they are being told by a speaker if the speaker discloses all potential sources of bias, then by all means the provider should require such disclosure. But WLF does not believe that there can be any justification for suppressing truthful speech altogether based solely on a fear of potential sources of bias; indeed, "it is precisely this kind of choice, between the dangers of suppressing information and the dangers of misuse if it is freely available, that the First Amendment makes for us." *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.,* 425 U.S. 748, 770 (1976).

II. Current CME Regulation

The Task Force's proposed re-write of its standards for commercial support is particularly mystifying in light of the widespread satisfaction with the current standards. Those standards, adopted in March 1992, take into account that CME speakers being compensated by a drug company may be tempted to bias their presentation in favor of products manufactured by that company, and that the company itself may seek to influence the presentation in return for commercial support of the CME activity. The 1992 standards attempt to minimize the effect of any such bias by, among other things: (1) preventing the company from "control[ling] 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 with the manufacturer of a product to be discussed. WLF is unaware of any evidence that any significant number of CME providers have not complied fully with these 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.[1] Rather, FDA has let it be known that it is satisfied with ACCME's regulation of CME; *i.e.,* so long as a CME activity has been accredited by ACCME, FDA is unlikely to closely examine the activity to determine whether a manufacturer may have engaged in improper promotion of one of its products.

One of the authors of these comments, Richard Samp, attended (as a speaker) the

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[1] 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.

AMA's Annual Conference of the National Task Force on Provider/Industry Collaboration in Baltimore in September 2002. A sentiment universally expressed at the conference was that current ACCME accreditation standards were working well to ensure that doctors received valuable and relatively unbiased information at CME activities. At a panel on potential FDA regulation in the area, participants were unanimous in their view that FDA regulation was unnecessary because the ACCME accreditation standards provided all the regulation that was necessary.

III. The Task Force's Proposal

In its January 14, 2003 proposed revision of the ACCME commercial support standards, the Task Force makes no effort to critique the current standards or to suggest that speaker bias is adversely affecting the quality of CME presentations. Rather, the proposed standards simply decree that henceforth speakers who are (due to financial arrangements) potentially biased in favor of a particularly manufacturer's products must be *excluded* from CME activities; full disclosures of those biases will no longer be sufficient:

> Persons will be excluded from the roles of planning committee member, manager, teacher, and author when disclosure of a relationship reveals a conflict between the interests of the individual and the interests of the public or learners.

Proposed Standards, Theme I (Independence), Item 4. The proposed standards do not explain why the Task Force deemed this radical change necessary or the precise circumstances under which exclusion would be mandated, except to state that exclusion is to be the norm rather than the exception:

> Normally, when a relationship is a conflict, it can *only* be managed by recusal from one of the roles creating the conflict. The context created by the content of the education activity will be very important. For example, drug company executives could deliver CME on the mechanism of action of their firm's drugs. Their staff relationship would not necessarily be considered a conflict of interest. However, a conflict of interest might exist if the same person was asked to synthesize the uncertain literature into a set of clinical indications for the drug's use.

Id., Item 4, Note 4 (emphasis added).

IV. Adverse Effects on Health Care

Because the Task Force's description of what constitutes an exclusion-worthy conflict is left vague, it is difficult to predict the precise level of impact that the proposed standards would have on the quality of CME presentations. Nonetheless, one can predict with some assurance that quality would suffer significantly if the proposed standards were adopted.

It is widely acknowledged that most of the top medical authorities in this country, and virtually all of the top speakers on medical topics, are employed in some capacity by one or more of the country's pharmaceutical companies. That is how it should be: the nation's health care system benefits greatly when companies in the business of developing innovative life-saving products have access to the best minds in the field. The success of the American pharmaceutical industry in developing such products is unparalleled, in no small part because of the assistance the industry receives from leading doctors.

As WLF reads Theme I of the proposed standards, any medical authorities receiving compensation from a pharmaceutical company in their field of expertise would be barred from

providing anything more than the most rudimentary information regarding the safety and effectiveness of that company's products. WLF does not pretend to have special expertise in the operation of CME activities; but one need not possess such expertise to realize that excluding the top medical professionals from CME will lead to a decline in the quality of CME presentations. Indeed, it is difficult to understand how the Task Force believes that CME providers will be able to locate speakers knowledgeable regarding the latest compounds in development -- except among those medical professionals being compensated by the company that is financing the development.

The proposed standards appear to be premised on the assumption that medical professionals are incapable of giving an unbiased scientific information solely because of some separate association they may have with a pharmaceutical manufacturer. In the absence of evidence to support that assumption, it is an insult to our nation's leading medical professionals. It is also an insult to those doctors who attend CME activities to suggest that they are incapable, after being informed of any remuneration the speaker may have received from a product manufacturer, of evaluating the weight to be assigned to the speaker's opinions in light of that disclosure.

While WLF has concerns about some of the provisions of the proposed standards as they apply to specific situations, we do not deem it necessary to detail those concerns here. It is sufficient to note that WLF objects to the Task Force's entire premise (that new standards are needed) in the absence of any effort to demonstrate that the current "full disclosure" system

is not working.

V. Constitutional Infirmities

To the extent that CME providers and doctors are free to ignore ACCME accreditation standards, the harm that can arise from the proposed standards is minimized. Once CME providers realize that they cannot both comply with the proposed standards and provide the high quality programs that doctors have come to expect, they are likely simply to forgo seeking ACCME accreditation if there are no regulatory impediments to doing so.

Unfortunately, while WLF would recommend to CME providers that they ignore the proposed standards even if adopted, those providers may not feel at liberty to do so. For one thing, in many States doctors may be unable to obtain necessary continuing education credits from State medical authorities if the CME activity they attend has not been accredited by the ACCME. Accordingly, unless those States can be convinced of the folly of the proposed standards and thus to drop accreditation requirements, doctors may be reluctant to attend CME activities that are not ACCME-accredited -- regardless how valuable the doctors may deem the information being imparted at those activities.

Moreover, many CME providers (with considerable justification) suspect that FDA will once again seek to impose CME regulation if the ACCME accreditation system falls apart. That fear of FDA regulation is an additional reason why CME providers may not feel free to eschew ACCME accreditation.

Because the ACCME derives much of its authority over CME content due to its

perceived ties to government agencies at both the federal and state level, a good case can be made that any action taken by ACCME in this area should be deemed "state action" by a reviewing court. That would undoubtedly be true if the Task Force developed its proposed standards at the prodding of FDA officials. If "state action" is present, ACCME's actions would be subject to First Amendment constraints. 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 proposed standards 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 "full disclosure" 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 by medical authorities who have been employed by pharmaceutical companies. ACCME would be well advised to consider the First Amendment ramifications of its actions before adopting the proposed standards.

CONCLUSION

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

Respectfully submitted,

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