Legal Backgrounder

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HEALTH AND SPEECH RIGHTS AT RISK FROM ATTACKS ON MEDICAL EDUCATION

By

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Continuing Medical Education (CME) plays a critical role in the healthcare system. Medical school is merely the start of a physician's education; however, physicians need to remain current in the decades following completion of their formal education. With the rapid growth in medical information, the importance of CME is increasing, not diminishing.

Providing CME is a costly endeavor. There are a number of funding sources, including physicians, professional societies, academic institutions, and manufacturers of healthcare products. This latter source has recently come under direct attack from the Senate Finance Committee. Through a series of letters to pharmaceutical companies, the Committee has probed and challenged industry's sponsorship of CME programs. The committee appears to fear that this sponsorship will bias physician prescribing practices, particularly if any marketing personnel in the company play any role in evaluating whether the company should support the program. The Committee's attack on corporate sponsorship of CMEs ignores both the First Amendment and the well-established existing mechanisms that are designed to protect the integrity of CME programs.

Controversy surrounding company-supported CME programs is not a new phenomenon. In the early 1990s, Food and Drug Administration (FDA) Commissioner David Kessler criticized pharmaceutical industry support of CME programs. As a result, FDA drafted a "Concept Paper" which would have severely restricted industry-sponsored programs. Under this document, CME programs that discussed off-label uses of drugs would be considered violative of the Federal Food, Drug, and Cosmetic Act (FDC Act). However, the program also needed to be entirely independent of the sponsor, precluding the sponsor from trying to ensure that all discussions were on-label. The Concept Paper was criticized for this inherent contradiction of prohibiting sponsor input into the program, but holding companies accountable for what was said, as well as for being unworkable and unwieldy in other ways.

FDA then proposed new, less onerous restrictions on corporate sponsorship. These limitations, along with an almost complete ban on the distribution by drug and device companies to doctors of scientifically valid, peer-reviewed journal articles discussing off-label uses of approved drugs and devices, was challenged by the Washington Legal Foundation (WLF). WLF filed a lawsuit in U.S. District Court for the District of Columbia alleging that FDA had violated the First Amendment.

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The court agreed. Judge Lamberth held that FDA's restrictions were incompatible with the First Amendment. In his conclusion, Judge Lamberth states "the court finds that the restrictions in the Guidance Documents are more extensive than necessary to serve the asserted government interest and that they *unduly burden important speech*."[1]

During the ongoing litigation, FDA issued a new policy for company-sponsored educational programs.[2] FDA took the position that all statements made by speakers at company-sponsored CME programs could be used as evidence of the "intended use" of the device; thus, FDA established a regulatory framework under which many company-sponsored CME programs would be deemed illegal because a speaker chose to discuss an off-label use.

At the same time, FDA recognized the importance of CME, and said that it would not take enforcement action if the CME program was independent of the company. The guidance document laid out twelve indices of independence. These included a written contract between the sponsor and the entity actually running the program; conferring the exclusive power to choose speakers upon the provider (although it can ask the sponsor for recommendations); giving the power to set content to the provider; and ensuring an adequate opportunity for the audience to ask questions.

Subsequently, the U.S. Court of Appeals for the D.C. Circuit struck down the district court injunction.[3] The court did so because statements made at oral argument suggested that the dispute between the parties had largely been bridged; the court did not question the merits of the district court's First Amendment analysis or its decision.

As a practical matter, the FDA guidance document, while perhaps not wholly consonant with the First Amendment, has worked fairly well. It has given industry sponsors and CME providers relatively clear guidance on how to establish independent CME programs. Many drug and device companies have used the FDA's criteria as the framework for entering into contracts with CME providers. For its part, FDA has not taken enforcement action against drug or device companies for sponsoring these programs.

Other organizations have also focused on the independence of the provider as being the paramount consideration. For example, the American Council on Continuing Medical Education (ACCME) issued its own detailed guidelines. More recently, on June 6, 2005, ACCME issued an amended guidance. This document retained its emphasis on provider independence, and tightened the requirement for speakers to be independent.[4] Significantly, even this more restrictive ACCME guidance document does not challenge the validity of company-sponsored CME programs that comply with the ACCME's criteria. Nor does this document address or limit the process by which companies decide to support CME programs.

Largely ignoring these well-developed frameworks, the Senate Finance Committee has initiated an investigation into company-sponsored CME programs. In 2005, the Committee issued letters to a

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[1] *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 74 (D.D.C. 1998).

[2] 62 Fed. Reg. 64,074 (Dec. 3, 1997).

[3] 202 F.3d 331 (D.C. Cir. 2000).

[4] Standards for Commercial Support: Standards to Ensure the Independence of CME activities, *available at http://www.accme.org* (last visited Mar. 2, 2006).

number of drug companies requesting a wide range of information. These requests included, among other items, the total number and dollar amount of educational grants in a two-year period, and asked the companies to "indicate the source of the funds for educational grants," such as the supporting product line.[5] Then, in January 2006, the Committee issued follow-up letters requesting *more* information about CME programs. (As part of its far-ranging inquiry, the Committee also requested various other documents, including ones relating to company support of patient advocacy groups.)

The Committee's investigation is alarming on several levels. First, there is no acknowledgment that a federal court had held that corporate-support of CME programs is constitutionally protected. Rather, the letters from the Committee apparently assume that this is a routine commercial transaction that can freely be probed by Congress, rather than one implicating the First Amendment.

Second, the letters appear to rest on a very different view of CME programs than adopted by FDA or ACCME. These guidelines are designed to protect the independence of the program, *i.e.*, establishing the provider's ability to run the program as it sees fit. The Committee seems to give no weight to this, but instead focuses on whether anyone from the company's marketing department played any role in evaluating the program. A letter issued January 9, 2006, stated, "[I]t appears that many manufacturers', [sic] sales and/or marketing personnel still have a role in originating or evaluating grant requests, and, consequently, the potential for abuse remains."[6]

This assertion makes little to no sense. Sponsors routinely review proposals for CME support from a variety of perspectives, including clinical, regulatory, legal, commercial, and marketing. It is unrealistic to expect companies to expend significant sums of money on programs which may be educationally worthwhile, but bear no relationship whatsoever to the company's business objectives. More important, the participation of marketing personnel in reviewing a proposal in no way diminishes the independence of the program. A speaker's independence is not compromised because someone from the sponsor's marketing department participated in an internal meeting to review the proposal.

The Finance Committee also ignores some key attributes of CME programs: attendance is voluntary and the audience is comprised of trained health care professionals. And, as Judge Lamberth found in *WLF*, physicians "are certainly capable of critically evaluating . . . the findings presented at CME seminars."[7] Attendees also receive information from a wide variety of sources, not just CME programs.

There may well be company-sponsored CME programs that fail to meet accepted norms for independence and scientific rigor, and are therefore inappropriate. The overly broad inquiry by the Senate Finance Committee, however, appears to be attacking CME programs that meet FDA and ACCME standards and are constitutionally protected. Nor is there any recognition in these inquisitional letters of the value of these programs in educating doctors about developments in medicine.

There appears to be a certain amount of hypocrisy in this investigation. A fundamental objection is that marketing employees of drug companies may play a role in evaluating candidate CME programs.

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[5]Letter from Senate Committee on Finance, June 9, 2005.

[6]Letter from Senate Finance Committee, Jan. 9, 2006.

[7]*WLF v. Freidman*, 13 F.Supp. 2d at 70 (footnote omitted).

The Committee seems concerned that speakers or the audience might be influenced by a purely internal function performed by marketing staff, even though under FDA and ACCME guidelines the company itself is to have no control over program content and the program is conducted by third party. Yet members of Congress who receive money directly from lobbyists and constituents repeatedly and predictably deny that the money has any impact on their conduct.

There are ways that CME programs can be improved. Unfortunately, this overly broad inquiry by the Senate Finance Committee is likely to inhibit corporate support of worthwhile programs, rather than yield useful, constructive suggestions.