



Education or Promotion?: Industry-Sponsored Continuing Medical Education (CME) as a Center for the Core/Commercial Speech Debate

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**Education or Promotion?:
Industry-Sponsored Continuing Medical Education (CME) as a
Center for the Core/Commercial Speech Debate**

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Abstract

Because of its importance to determining drug usage, information has always been an important part of the regulation of prescription drugs. The Food and Drug Administration (FDA) and the pharmaceutical industry are in a continuous battle over the dissemination of product information. This paper focuses on one of the battlegrounds on the speech issue, industry sponsorship of continuing medical education (CME). The FDA's guidance on regulating industry-sponsored CME bans speech about off-label uses at CME and requires that other speech presented be truthful, non-misleading and fairly balanced. This guidance raises First Amendment issues, in particular because the speech presented at CME, although arguably commercial speech, appears at first glance to be core scientific speech meriting the highest constitutional protection. This paper first provides a background on the FDA's regulatory authority over promotional activities, looking at the FDA's authority to approve drugs, to declare drugs misbranded due to lack of adequate directions for use, and to regulate the labeling and advertising of drugs. Next, it discusses the *Washington Legal Foundation* cases, brought to challenge the CME guidance as an unconstitutional restriction on speech because it bans speech about off-label uses. It examines the district court's holdings that industry-sponsored CME speech is commercial speech, and that the regulation is an unconstitutional regulation of commercial speech because it is considerably more extensive than necessary to further the government's interest in getting new uses on-label. Lastly, it examines the problem of representational speech that arises when speech is tied to financial sponsorship, which is that the speech of the funded speaker cannot always be attributed to the financial sponsor. It finds that the guidance factors fail to establish a representative connection between the CME speaker and the pharmaceutical manufacturer necessary to hold the pharmaceutical manufacturer responsible for the speaker's speech. Therefore, the CME guidance sweeps into its regulatory scheme not only commercial speech, but also core speech that deserves the highest First Amendment protection.

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I. Introduction

It is after all, only within a particular information context that a drug really exists. Without all of the information on the indications, dosage, and proper use contained in the labeling, coupled with the information and knowledge physicians possess about the use of drugs from their training and experience, a drug is not, in any practical sense, a drug. It's just a useless and probably dangerous chemical. But with the right information, a drug can be a therapeutic tool of enormous and often lifesaving value to patients.¹

Because of its importance, drug information is the focus of many struggles between the Food and Drug Administration (FDA) and the pharmaceutical industry. Who may provide this information and who may receive it are questions constantly being debated in the area of drug law. While commentators on all sides seem to agree that a free flow of accurate information is ideal, the FDA remains suspicious of allowing pharmaceutical manufacturers, who have an interest in casting their own products in a favorable light and thereby increasing sales, to provide this information.

The FDA has traditionally monitored manufacturer advertising to doctors who – as the prescribers of drugs – are arguably the most important recipients of this information. But while the FDA has jurisdiction over the pharmaceutical industry, it does not over the medical profession² and thus claims not to interfere with the exchange of purely *scientific* information between pharmaceutical manufacturers and doctors.³ But in recent years, the FDA has expanded its jurisdiction to reach forms of speech outside of the traditionally regulated areas of labeling and advertising; among the recent expansions was the FDA's assertion of jurisdiction over pharmaceutical industry-sponsored continuing medical education seminars and symposia (collectively

²See 21 U.S.C. § 396 (2000) (stating that the Food Drug and Cosmetic Act (FDCA) “[shall not] be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship.”).

³See Final Guidance on Industry-Supported Scientific and Educational Activities, 62 FED. REG. 64,074 (Dec. 3, 1997) [hereinafter Final CME Guidance] (noting that “FDA traditionally has not sought to regulate industry-supported scientific and educational activities that are otherwise independent and non-promotional.”). In addition, the FDA does not typically interfere with exchanges of information between physicians and the research departments of pharmaceutical manufacturers – for example, requests for information from physicians to manufacturers.

“CME”)⁴ in its “Guidance on Industry-Supported Scientific and Educational Activities.”⁵ This document declared the FDA’s intention to subject CME seminars that it found were not independent of a pharmaceutical sponsor (a determination that FDA would make based on 12 factors of independence) to its regulations governing labeling and advertising.⁶ Notably, the effect of regulation would be to prevent any discussion of off-label uses⁷ and to require that all other speech about products be truthful, non-misleading and provide a fair balance of information.⁸

The rules set out in the guidance were challenged in a suit brought by the Washington Legal Foundation (WLF), a free speech public interest group claiming to represent member physicians’ interests in receiving the information, which alleged that this guidance, plus a separate guidance on distribution of reprints of scientific articles and textbook excerpts,⁹ created a restriction on speech about off-label uses unconstitutional under the First Amendment.¹⁰ In its decision on the merits of the constitutional issue in *Washington Legal*

⁴The AMA defines CME as “educational activities that serve to maintain, develop, or increase the knowledge, skills, and professional performance and relationships a physician uses to provide services for patients, the public, or the profession.” See The AMA Definition of CME, available at <http://www.ama-assn.org/ama/pub/category/2937.html> (last visited April 15, 2003).

⁵62 FED. REG. 64,074.

⁶See *id.* The guidance document does not have a legal independent effect, but does “describe the agency’s interpretation of or policy on a regulatory issue. . .

. . . Guidance documents include, but are not limited to, documents that relate to: The design, production, labeling, promotion, manufacturing, and testing of regulated products; the processing, content, and evaluation or approval of submissions; and inspection and enforcement policies.

. . . Guidance documents do not include: Documents relating to internal FDA procedures, agency reports, general information documents provided to consumers or health professionals, speeches, journal articles and editorials, media interviews, press materials, warning letters, memoranda of understanding, or other communications directed to individual persons or firms.”

21 C.F.R. § 10.115(a)(1)-(3). “Although guidance documents do not legally bind FDA, they represent the agency’s current thinking. Therefore, FDA employees may depart from guidance documents only with appropriate justification and supervisory concurrence.” 21 C.F.R. § 10.115(d)(3).

⁷See Draft Policy Statement on Industry-Supported Scientific and Education Activities, 57 FED. REG. 56,412, 56,412 (Nov. 27, 1992) [hereinafter Draft CME Guidance]. Off-label uses are uses the FDA has not reviewed and approved for its label and therefore have not received a rigorous review by the agency as to the safety and efficacy for this use. See Steven R. Salbu, *Off-Label Use, Prescription, and Marketing of FDA-Approved Drugs: An Assessment of Legislative and Regulatory Policy*, 51 FLA. L. REV. 181, 187-88 (1999) (defining off-label use). They are also termed “unapproved,” “unlabeled,” or “extra-label” uses. See Citizen Petition Regarding the Food and Drug Administration’s Policy on Promotion of Unapproved Uses of Approved Drugs and Devices; Request for Comments, 59 FED. REG. 59,820, 59,820 (Nov. 18, 1994) [hereinafter Request for Comment on Citizen Petition].

⁸See *id.* at 57,412 at note 1.

⁹See Guidance to Industry on Dissemination of Reprints of Certain Published, Original Data, 61 FED. REG. 52,800 (Oct. 8, 1996); Guidance for Industry Funded Dissemination of Reference Texts, 61 FED. REG. 52,800 (Oct. 8, 1996).

¹⁰The court first considered the suit in *Washington Legal Found. v. Kessler*, 880 F. Supp. 26 (D.D.C. 1995) (denying FDA’s motion to dismiss). The court finally reached the merits of the case in *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998) [hereinafter WLF I], *amended*, 36 F. Supp. 2d 16 (D.D.C. 1999), 56 F. Supp.2d 81 (D.D.C. 1999), *appeal*

Foundation v. Friedman (*WLF I*), the Federal District Court for the District of Columbia ruled the guidance, insofar as it banned speech about off-label uses by pharmaceutical manufacturers, unconstitutional.¹¹ While this speech was commercial speech, the court found, the restriction was not narrowly tailored to meet the government’s interest in encouraging companies to apply for new drug indications.¹²

Despite this initial loss, the FDA’s position still remains at odds with the court’s view of CME speech. On appeal, the FDA reversed its position that the guidance set forth its enforcement authority, claiming instead that it merely established a safe harbor for promotional CME that the FDA would not regulate.¹³ Finding no constitutional question remaining, the D.C. Circuit vacated the district court’s holdings, though it did not reach the merits of the case.¹⁴ Following the decision, the FDA maintained that the “CME guidance document details how the agency intends to exercise its enforcement discretion”¹⁵ only acknowledging that, “if the agency brings an enforcement action, a manufacturer may raise a First Amendment defense.”¹⁶ This continued policy was upheld against a final challenge by the WLF back in the district court.¹⁷ The District Court confirmed that the Appeals Court decision had vacated the entire injunction it had ordered in *WLF I*.¹⁸ This leaves pharmaceutical companies back where they started; although the only court to pass on the merits of the case found the guidance unconstitutional, the procedural disposition of the case still has not freed pharmaceutical companies to engage in this type of speech.

There are still important unsettled issues regarding the FDA’s regulation of CME. *WLF I* was only the first

dismissed, judgment vacated in part, Washington Legal Found. v. Henney, 202 F.3d 331 (D.C. Cir. 2000) [hereinafter *WLF II*] (finding no constitutional question after FDA proposed guidance document to be merely a “safe harbor”), *remanded* 128 F. Supp. 2d 11 (D.D.C. 2000) [hereinafter *WLF III*].

¹¹See *WLF I*, 13 F. Supp. 2d 51.

¹²See *id.* at 73.

¹³See *WLF II*, 202 F.3d 331.

¹⁴See *id.*

¹⁵Notice; Decision in *Washington Legal Foundation v. Henney*, 65 FED. REG. 14,286 (Mar. 16, 2000) [hereinafter *WLF II Notice*] (notifying the regulated community how the court’s recent decision in *WLF II* will affect the FDA’s enforcement policy on CME).

¹⁶*Id.*

¹⁷*WLF III*, 128 F. Supp. 2d 11.

¹⁸*Id.*

of a series of important court cases that have struck down FDA attempts to regulate speech, suggesting a turning point in the courts' view on speech in the area of drug regulation.¹⁹ Far from supporting the FDA's regulation of modern pharmaceutical promotion, courts have looked disapprovingly on the FDA's aggressive approach, even stating that "FDA exaggerates its overall place in the universe."²⁰ The stance taken by the courts was so contrary to the FDA's approach to the First Amendment that it caused the FDA to reassess its First Amendment policies. In May of 2002, the FDA asked for comments in order to reassess its First Amendment policy.²¹ In its request, FDA recognized that "there may be tension between some aspects of FDA's authority and judicial developments"²²:

The Supreme Court has increasingly recognized the value of speech proposing a commercial transaction, which it calls commercial speech and which is entitled to First Amendment protection so long as it is truthful and not misleading. This case law presents a challenge to FDA. FDA must balance the need and right of Americans to speak and hear information vital to their every day lives against the need to ensure that people are not misled. . . .

FDA must continue to pursue regulation of products for purposes of protecting the public with a full recognition of the evolving judicial landscape in areas that directly affect its ability to regulate words. To be sure, FDA will continue to regulate commercial speech as part of its mandate. In particular, FDA intends to defend the act against any constitutional challenges, as it did in the *Western States* case. FDA seeks to ensure, however, that its regulations, guidances, policies, and practices comply with the First Amendment. FDA also wishes to learn what empirical evidence exists concerning the effect of commercial speech on the public health, and whether its regulations in this field in fact advance public health.²³

¹⁹Other recent significant cases include *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999) (holding that the FDA's regulation of health claims on dietary supplement labeling was an unconstitutional regulation of speech) and *Thompson v. Western States Med. Ctr.*, 535 U.S. 357 (2002) (holding that the FDA's ban on pharmacies' advertising of compounding was an unconstitutional regulation of speech). In addition, First Amendment scholars have found that we are now generally in a period of increasing recognition of new First Amendment rights. "[One explanation] for the emerging salience of [First Amendment] challenges . . . is the recognition of new forms of First Amendment claims: rights to receive information; rights not to speak; rights of corporations and organizations to speak; rights to speak (or not to speak) that arise out of a message attributed to an individual or group." Randall P. Bezanson and William G. Buss, *The Many Faces of Government Speech*, 86 IOWA L. REV. 1377, 1381 (2001).

²⁰*Friedman*, 13 F. Supp. 2d at 67. See also *Kessler*, 880 F. Supp. at 32-33 (criticizing the FDA's approach to First Amendment issues: "[T]he FDA's handling of WLF's Citizen Petition, as well as the statements in its filings and at oral argument, evidence a somewhat less vigilant concern for the doctors' First Amendment rights than this court would hope to see.").

²¹See Request for Comment on First Amendment Issues, 67 FED. REG. 34,942 (May 16, 2002) [hereinafter Request for First Amendment Comment]. Previously, the FDA had taken a "until we are told not to" approach in considering the legal consequences of its regulation, stating at one point, "how expansive the FDA's reach is remains an unsettled question. . . . Until further judicial decisions or congressional action clarifies the FDA's specific authority in the area of promotion, the FDA will continue to assert broad jurisdiction." David A. Kessler and Wayne L. Pines, *The Federal Regulation of Prescription Drug Advertising and Promotion*, 264 JAMA 2411 (1990). This stance changed both with the departure of Kessler (known to be a particularly aggressive Commissioner) and with the decisions in the First Amendment cases mentioned *supra*, note 19.

²²Request for First Amendment Comment, 67 FED. REG. 34,942.

More than 750 comments regarding the FDA's compliance with the First Amendment were filed by the time the docket closed on October 28, 2002.²⁴

This request for comments on First Amendment compliance could be an opportunity for the FDA to reconsider its entire approach to scientific speech, particularly in the CME context. Questions that deserve consideration include: Are the factors used by the FDA to determine which CME are promotional the proper ones? Do they comport with current First Amendment jurisprudence? Do they delineate a proper line between commercial and non-commercial speech that the FDA can use generally for regulation? Part II of this paper briefly sets out the FDA's regulatory scheme and how it was used in the CME guidance document. It also examines the various arguments put forth for and against the regulations. Part III describes *WLF I*'s analysis of the speech issues affected in CME. It examines the court's two-part holding that first, the CME speech was commercial speech and second, the FDA's regulation did not meet the test for commercial speech, and places the case in the context of First Amendment case law. Part IV analyzes the guidance document and the *WLF I* decision according to current First Amendment law, taking the position that the guidance fails to establish a representative connection between the CME speaker and the pharmaceutical manufacturer necessary to hold the pharmaceutical manufacturer responsible for the speaker's speech. This part looks at representative speech theory and case law from other situations where institutions have sponsored speech to support this conclusion. It shows that, as a result of the lack of a representative connection necessary to render the speech promotional, the CME guidance sweeps in speech that is not commercial in nature, but rather core speech that deserves the highest First Amendment protection.

²⁴See FDA's First Amendment comment docket, available at <http://www.fda.gov/ohrms/dockets/dockets/02n0209/02n0209.htm> (last visited March 24, 2003).

II. The FDA’s asserted authority over CME

With respect to CME, the effect of the FDA’s regulations can be grouped into two major categories: (1) restrictions on what can be said (*i.e.* the ban on promoting off-label uses) and (2) restrictions on how it can be portrayed (*i.e.* the requirement for objective treatment in the presentation of uses).

The FDA’s jurisdiction to regulate speech about drugs²⁵ normally derives from its authority to regulate prescription drug labeling²⁶ and prescription drug advertising.²⁷ In the CME guidance, the FDA also asserted a third basis: regulation of misbranded drugs based on the lack of adequate directions for their intended uses.²⁸ The bases asserted shape the form of the FDA’s regulation over speech and accordingly, over CME.

A. Authority to approve drugs

The FDA’s authority over labeling is closely tied to its authority over drug approvals.²⁹ Before a manufacturer can distribute a drug in interstate commerce, it must obtain approval from the FDA through a new drug

²⁵For simplicity’s sake, I will discuss only the FDA’s regulation of information about human prescription drugs, though each of the rules discussed can also generally be applied to animal drugs, biological products and medical devices – therapeutic products also within the FDA’s jurisdiction.

²⁶The FDA has had authority to regulate labeling since its inception. See Food, Drug and Cosmetic Act of 1938 (FDCA), 21 U.S.C. § 301 et seq. (2000) (creating the FDA and giving it authority to regulate drug labeling.)

²⁷The FDA was later given authority to regulate prescription drug labeling in the Kefauver-Harris Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (Oct. 10, 1962). The jurisdiction over advertising gave the FDA more power in the prescription drug area than it has in other industries it regulates (food, cosmetics, over-the-counter drugs), as the Federal Trade Commission (FTC) assumes jurisdiction over advertising in those industries. See FDA-FTC Memorandum of Understanding, 36 Fed. Reg. 18,539 (Sept. 16, 1971) (delineating the respective jurisdictional lines between labeling and advertising in the areas of food, cosmetics, and over-the counter drugs). The authority to regulate both prescription drug labeling and advertising gives the FDA the most power over this industry.

²⁸See Final CME Guidance, 62 Fed. Reg. 64,074.

²⁹Both are integral to the fulfillment of the FDA’s two general functions under the FDCA: “(1) the review and approval of important new products that can improve the public health, such as life-saving drugs, biological products, and medical devices; and (2) the prevention of harm to the public from marketed products that are unsafe or ineffective.” Food and Drug Administration Performance and Accountability Act of 1995, S. RPT. No. 104-284 (1996) [hereinafter FDA Accountability Report].

application (NDA) that demonstrates, through a series of preclinical and clinical trials, that the drug is safe and “will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.”³⁰ The approved labeling governs the uses for which the drug can be marketed,³¹ hence the term “on-label” uses. Any divergence from the approved labeling – an “off-label” use³² – in dosage, indications, method of administration or mixture with another drug, renders the drug a new drug. The manufacturer would be required to resubmit another drug approval form, and demonstrate, similar to the initial application, that it is “safe and effective” for this new use.³³

While pharmaceutical companies are forbidden from promoting any off-label uses, doctors are not forbidden from prescribing off-label uses. It is, in fact, an established and even mandated part of the practice of medicine, because medical knowledge almost always outpaces the FDA approval process,³⁴ and because drug companies often do not seek FDA approval for all the possible uses of the drug, due to the time and cost of filing NDAs.³⁵ It is often stated in the medical community that “if you didn’t use the drug in the

³⁰21 U.S.C. § 355(d) (2000). The FDA uses the substantial evidence test for safety and efficacy of a drug. This includes data from “adequate and well-controlled clinical investigations...by experts qualified by scientific training and experience to evaluate the safety and effectiveness of the drug involved, on the basis of which it can fairly and responsibly be concluded by such experts that the drug is safe and effective for such uses” (21 C.F.R. § 202.1(e)(4)(ii)(b) (2000)) and data from “substantial clinical experience...on the basis of which it can fairly and responsibly be concluded by qualified experts that the drug is safe and effective for such uses”. 21 C.F.R. § 202.1(e)(4)(ii)(c).

³¹21 U.S.C. § 352 (2000) (stating that manufacturer promotion of off-label uses constitutes misbranding).

³²See definition, *supra* note 7.

³³See 21 U.S.C. § 321(p) (2000) (stating that the term “new drug” means... “any drug...not generally recognized...as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof.”) and 21 C.F.R. § 314.54 (stating that the manufacturer must submit an NDA for each intended new use of a drug which has been approved for a different use).

³⁴In the 1990s, of the major complaints about the FDA leading to the passage of the Food and Drug Administration Modernization Act (FDAMA, PUB. L. NO. 105-115, 111 STAT. 2296 (1997) *amending* 21 U.S.C. §§ 201 *et seq.* (1994)) was the long delay in approval times for new drugs, at one point, averaging 570 days to approve a new drug. See FDA Accountability Report, *supra* note 29. One of the objectives of the FDAMA was to decrease approve time by providing more resources to the FDA through prescription drug user fees. Recently, the review time has decreased to less than a year for about 80 percent of NDAs. See Linda A. Suydam and Milan J. Kubic, *FDA’s Implementation of FDAMA: An Interim Balance Sheet*, 56 FOOD & DRUG L.J. 131, 133 (2001).

Clinical trial time also contribute to the lag time. For a new drug, clinical trials often take up to 6 years. See FDA Accountability Report, *supra* note 29. During this time, researchers and clinicians are continuing to investigate and publish new findings about drug uses.

³⁵According to a recent published study, from the beginning of the process to the end, it takes an average of 15 years and \$500 million dollars to bring a new drug to market. See J.A. DiMasi, *Trends in Drug Development Cost, Times, and Risks*, 29 DRUG INFO. J. 375, 382 (1995), *quoted in* FDA Accountability Report, *supra* note 29. Pharmaceutical manufacturers often

off-label way, you'd be guilty of malpractice.”³⁶ The FDA has tolerated and at times, recognized the value of off-label prescribing.³⁷ It has emphasized that it does not purport to regulate the practice of medicine – *i.e.*, doctors’ prescribing judgment.³⁸

This asymmetry in what can be marketed versus what can be prescribed has resulted in conflict over the dissemination of information about off-label uses. Critics of the ban on manufacturer speech on off-label uses argue that if doctors are allowed to prescribe off-label, they should have the most information about its off-label effects, and that manufacturers should be allowed to provide this information, given that they have the most information about the drug.³⁹ Restrictions on the discussion of off-label uses have an enormous impact on many specialties. According to Donald R. Bennett, one-time director of the American Medical Association’s Division of Drugs and Toxicology, 40 to 50 percent of all drugs are prescribed for off-label uses.⁴⁰ In some treatment areas, the percentage is even higher: 60 to 70 percent in oncology and 80 to 90 percent in pediatrics.⁴¹

The FDA and its supporters, on the other hand, argue that manufacturers’ commercial self-interest will result in an increase of uses that have not been proven safe and effective according to proper scientific testing procedures, but are based on incomplete and perhaps biased evidence.⁴² Initially promising treatments are

are unwilling to pay the cost to apply for another indication until that indication will pay for itself in increased profits. That means that valid additional uses that simply do not have a large patient base will often not get put on-label. *See* J. Howard Beales III, *Economic Analysis and the Regulation of Pharmaceutical Advertising*, 24 SETON HALL L. REV. 1370, 1387, 1392-93 (1994).

³⁶ *See* Fran Kritz, *FDA Seeks to Add Drugs’ Use to Labels*, WASH. POST., Mar. 29, 1997, at 11.

³⁷ *See* Request for Comment on Citizen Petition, 59 FED. REG. at 59,821 (stating that: “Unapproved, or more precisely, unlabeled uses may be appropriate and rational in certain circumstances, and may, in fact reflect approaches to drug therapy that have been extensively reported in medical literature. . . Valid new uses for drugs already on the market are often first discovered through serendipitous observations and therapeutic innovations, subsequently confirmed by well-planned and executed clinical investigations.”).

³⁸ The FDCA expressly prohibits the FDA from regulating physicians’ prescribing practice. *See* 21 U.S.C. § 396 (stating that the FDCA shall not be construed to “limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship.”).

³⁹ *See e.g.* Charles J. Walsh and Alissa Pyrich, *FDA Efforts to Control the Flow of Information at Pharmaceutical Industry-Sponsored Medical Education Programs: A Regulatory Overdose*, 24 SETON HALL L. REV. 1325 (1994).

⁴⁰ *See* Andrew A. Skolnick, *Pro-Free Enterprise Group Challenges FDA’s Authority to Regulate Drug Companies’ Speech*, 271(5) JAMA 332 (Feb 2, 1994).

⁴¹ *See id.*

⁴² *See* Request for Comment on Citizen Petition, 59 Fed. Reg. at 59,822 (“Promotion of unapproved uses can encourage physicians and patients to make decisions based on statements or claims that are, in many cases, supported by little or no

often later shown to be unsafe or ineffective after more extensive testing is done.⁴³

B. Authority to regulate misbranding for intended uses

In its final guidance on CME, the FDA asserted, in addition to its long-established power to regulate labeling and advertising, a justification not raised in the draft guidance⁴⁴: that “a drug or device shall be deemed misbranded unless its labeling bears adequate directions for use.”⁴⁵ This justification allows the FDA to regulate speech about off-label uses made at CME because “[o]ral statements and materials presented at industry-supported scientific and educational activities may provide evidence of a product’s intended use. If these statements or materials promote a use that is inconsistent with the product’s approved labeling, the product is misbranded under section 502(f)(1) of the [FDCA] for failure to bear labeling with adequate directions for all intended uses.”⁴⁶ This regulates speech by placing pharmaceutical manufacturers in a “Catch-22” bind: if they want to discuss a new “intended use,” then they must provide adequate directions

data.”).

⁴³See *id.* at 59,824-59,826 (describing several real-life examples). For example, the FDA cites an example where physicians began using anti-arrhythmic agents on post-heart-attack patients, on the theory that lowering the rate of ventricular premature beats will increase chances of survival. More extensive controlled studies were conducted showed this theory to be unsubstantiated and that use of anti-arrhythmic agents in fact increased the mortality rate. It is important to note that no manufacturer ever attempted to promote this use; the FDA uses this example to highlight the consequences if a manufacturer had to demonstrate “the potential power of plausible, but under-documented claims”. *Id.* at 59,824.

⁴⁴The Draft CME Guidance only cited the FDA’s authority to regulate labeling and advertising. See Draft CME Guidance, 57 FED. REG. 56,412.

⁴⁵Final CME Guidance, at 64,075, referring to 21 U.S.C. 352(f)(1).

⁴⁶*Id.* “Adequate directions for use”, as defined in a regulation interpreting 21 U.S.C. § 352(f), means “directions under which the layman can use a drug safely and for the purposes for which it is intended. . . Directions for use may be inadequate because, among other reasons, of omission, in whole or in part, or incorrect specification of:

a) statements of all conditions, purposes, or uses for which such drug is intended, including conditions, purposes or uses for which it is prescribed, recommended, or suggested in its oral, written, printed, or graphic advertising, and conditions, purposes or uses for which the drug is commonly used; except that such statements shall not refer to conditions, uses, or purposes for which the drug can be safely used under the supervision of a practice licensed by law and for which it is advertised solely to such practitioner. . . .”

21 C.F.R. § 201.5.

for use on the label. But they are not allowed to put any other uses on the label other than what the FDA has approved.⁴⁷ In this rather indirect way, the FDA bans speech on off-label uses at CME.

C. Authority over labeling and advertising

The ban on promotion of off-label uses (for lack of adequate directions for use) is only one, though perhaps the most restrictive, of the FDA’s regulation of information about pharmaceutical drugs. The FDA can also regulate the substance of labels and advertisements discussing approved uses, generally to “curb overstatement in product claims and encourage balanced disclosure of side effects, contraindications,⁴⁸ and warnings.”⁴⁹

Labeling is defined in the Federal Food, Drug, and Cosmetic Act (FDCA), the FDA’s organic statute and the source of most of its regulatory authority, as “all labels and other written, printed, or graphic material (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.”⁵⁰ “Accompanying” has been interpreted broadly by the courts to encompass not only materials traveling with the article, but can also include materials in any location that “supplements or explains” the product.⁵¹ Thus almost any written, or “enduring” material⁵² describing the product could be deemed “labeling.” Although this cannot

⁴⁷See 21 U.S.C. § 352.

⁴⁸“A ‘contraindication’ is some condition that makes use of a drug undesirable. For example, if a drug should not be taken by a pregnant woman, then pregnancy is a contraindication for that drug.” Paul H. Rubin, *From Bad to Worse: Recent FDA Initiatives and Consumer Health*, in *BAD PRESCRIPTION FOR THE FIRST AMENDMENT* at 104 n.4

⁴⁹See Peter Barton Hutt & Richard T. Merrill, *FOOD AND DRUG LAW* 459 (2d ed. 1991) (describing the general effect of 21 U.S.C. § 352(n)).

⁵⁰21 U.S.C. § 321(m).

⁵¹*Kordel v. United States*, 335 U.S. 345, 350 (1948).

⁵²“Enduring materials” is a term often used in the relevant literature to describe reprints of scientific journal articles and medical textbooks. See Glenn C. Smith, *Avoiding Awkward Alchemy in the Off-Label Drug Context and Beyond: Fully-Protected Independent Research Should Not Transmogrify into Mere Commercial Speech Just Because Product Manufacturers Distribute It*, 34 *WAKE FOREST L. REV.* 963, 973 at n.41 (1999).

be extended to encompass the oral speech of CME speakers, it could be used to regulate written materials distributed in conjunction with a presentation.⁵³ In addition, the approved content for the label governs promotion in other channels, as Part B above, describing misbranding, demonstrated.

Advertising, if one accepts the expansive definition provided by the FDA, could cover the speech at CME. “Advertising” is not defined in the FDCA, but in the Final CME Guidance, the FDA “[interpreted] the term . . . to include information (other than labeling) that originates from the same source as the product and that is intended to supplement or explain the product.”⁵⁴ FDA did not cite a source for this definition, however, and CME speech does not seem to be of the same kind as other items declared to be advertisements in the FDA regulations: “advertisements in published journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems.”⁵⁵ Critics have asserted that the FDA has never asserted such an expansive definition for advertising until this guidance.⁵⁶ Although an agency has discretion to define terms in its own regulations,⁵⁷ it would be a new addition to the items included as advertising.⁵⁸

Advertisements promoting approved uses must be balanced, by including a “true statement” in “brief sum-

⁵³ But see cases stating that even labeling does not include every written statement about a product, such as *United States v. 24 Bottles “Sterling Vinegar & Honey, Etc.”*, 338 F.2d 157, 158-59 (2d Cir. 1964) (stating that “[t]he distinguishing characteristic of a label is that, in some manner or another, it is presented to the customer in immediate connection with his view and his purchase of a product”); *United States v. Guardian Chem. Corp.*, 410 F.2d 157, 161 (2d Cir. 1969) (stating that “[i]t seems to stretch the meaning beyond the limit of elasticity” to say that literature disseminated at a medical convention accompanies the sale of a product).

⁵⁴ Final CME Guidance at 64,076.

⁵⁵ 21 C.F.R. § 202.1(1)(1).

⁵⁶ See Mark E. Boulding, *The Statutory Basis for FDA Regulation of Scientific and Educational Information*, 4 J. PHARMACY & L. 123, 141 (1995) (“FDA has very little statutory support for claiming that everything a manufacturer says that is not labeling is advertising.”).

⁵⁷ A court will give great deference to an agency’s interpretation of its own rules. This deference is even greater than that afforded an agency’s interpretations of the statutes it enforces. See *Udall v. Tallman*, 380 U.S. 1, 16-17 (1965) (“Since this involves an interpretation of an administrative regulation a court must necessarily look to the administrative construction of the regulation if the meaning of the words used is in doubt. . . . [T]he ultimate criterion is the administrative interpretation, which becomes of controlling weight unless it is plainly erroneous or inconsistent with the regulation.”) quoting *Bowles v. Seminole Rock Co.*, 325 U.S. 410, 413-414 (1945). See also John Manning, *Constitutional Structure and Judicial Deference to Agency Interpretation of Agency Rules*, 96 COLUM. L. REV. 612 (1996).

⁵⁸ See Boulding, *supra* note 56, at 141 (“Any attempt to sweep in bona fide scientific or educational meetings or materials into the category of ‘advertising’ would likely meet with resistance in the courts.”).

mary relating to side effects, contraindications, and effectiveness.”⁵⁹ What the brief statement must present is often very restrictive:

An advertisement does not satisfy the requirement that it present a “true statement” of information in brief summary relating to side effects, contraindications, and effectiveness if. . . [i]t fails to present a fair balance between information relating to side effects and contraindications and information relating to effectiveness of the drug in that the information relating to effectiveness is presented in greater scope, depth, or detail than is required by section 502(n) of the act and this information is not fairly balanced by a presentation of a summary of true information relating to side effects and contraindications of the drug.⁶⁰

Applied to CME, the labeling and advertising provisions “require [companies] to ensure that . . . discussions of [their] products are not false or misleading in content and do not lack fair balance.”⁶¹ “In particular, discussions of unapproved uses, which can be an important component of scientific and educational activities, are not permissible in programs that are or can be (because the provider is not functionally independent) subject to substantive influence by companies that market products related to the discussion.”⁶²

D. The CME Guidance document

1. The development of the guidance

The FDA first began investigating the issue of industry involvement in CME in the early 1990s. The FDA turned its regulatory eye to CME because “[t]he agency’s experience over the years in regulating drug and device safety and effectiveness has demonstrated that regulatory control over package inserts, user manuals, and traditional advertising formats may be rendered meaningless if the company is free to engage in aggressive promotion outside of these formats.”⁶³ The FDA feared that pharmaceutical manufacturers were using CME

⁵⁹21 U.S.C. § 352(n)(3) (2000).

⁶¹Draft CME Guidance, 57 FED. REG. at 56,413 n.1.

⁶²*Id.* at 56,412.

⁶³Request for Comment on Citizen Petition, 59 FED. REG. 59,820.

as a way to get around the advertising and labeling regulations by funding others to say what they cannot say directly.

CME sponsorship has potential as a powerful promotional tool, because of the authority associated with ostensibly scientific information and because CMEs have a ready-made audience of professionals looking to fulfill continuing education requirements.⁶⁴ Manufacturer sponsorship had been on the rise, as providers look for sources to allay the cost of providing CME. Data gathered by the Accreditation Council for Continuing Medical Education (ACCME), an organization that oversees and sets voluntary standards for CME, show that industry support represented about half of the \$1.1 billion spent on CME in 1999,⁶⁵ usually in the form of general course grants or speaker funds.⁶⁶ Industry support doubled from 1996-99.⁶⁷ Total CME expenditures have increased 71 percent.⁶⁸ Studies have shown that company-supported CME activities are often slanted in favor of the supporting company's products, and that physicians who attend these seminars later prescribe the company's drugs more often than competing drugs.⁶⁹

Before it had developed any formal guidance documents, the FDA took case-by-case enforcement actions against pharmaceutical manufacturers it found to be using CME inappropriately.⁷⁰ For example, one medical device manufacturer received a warning letter from the FDA after allegedly sponsoring a program where an individual "associated with" the company had provided information and devices used for hands-on training for an off-label use.⁷¹ The letter stated that "[s]upporting such programs and providing devices for

⁶⁴All state medical licensing boards require licensed physicians to complete yearly CME. The requirements vary widely from state to state, ranging from 12 credit hours per year to 50 credit hours per year. See State Medical Licensure Requirements and Statistics, 2003, available at http://www.ama-assn.org/ama1/pub/upload/mm/40/table14_03.pdf (last visited April 15, 2003).

⁶⁵Susan L. Coyle, *Physician-Industry Relations. Part 2: Organizational Issues*, 136(5) ANNALS OF INTERNAL MED. 403-406 (Mar. 5, 2002).

⁶⁶*Id.*

⁶⁷See *id.*

⁶⁸See *id.*

⁶⁹See A. Wazana, *Physicians and the Pharmaceutical Industry*, 283 JAMA 373-380 (2000).

⁷⁰See *Kessler*, 880 F. Supp. at 28 (describing, in the discussion of facts, several enforcement actions taken by the FDA).

⁷¹See *id.*

the purposes of hands-on training in the use of devices for this unapproved use constitutes promotion of the device for such use.”⁷² It then asked the company for a “written response detailing your plans to correct these violations, and your intentions to comply with this Warning Letter.”⁷³ According to the complaint submitted by the Washington Legal Foundation in its case, this was representative of several enforcement actions taken even before the FDA instituted a formal policy.⁷⁴

Informal, case-by-case enforcement actions were later articulated in a limited-release draft document (the “Drug Company Supported Activities In Scientific or Educational Contexts: Draft Concept Paper”) and then more formally in the “Draft Policy Statement on Industry-Supported Scientific and Educational Activities”⁷⁵ on which the FDA requested comment. The Draft CME Guidance focused on distinguishing promotional from non-promotional sponsorship based on a written agreement between the pharmaceutical manufacturer and the CME provider. The written agreement would set out the limits on the pharmaceutical manufacturer’s role,⁷⁶ and include provisions about:

- 1)
statement of purpose
- 2) control of content and selection of presenters and moderators
- 3) disclosure of financial relationships
- 4) supporting company involvement in content

⁷² *Id.*

⁷³ *Id.*

⁷⁴ *See id.*

⁷⁵ Draft CME Guidance, 57 FED. REG. 56,412.

⁷⁶ *Id.*

- 5) ancillary promotional activities
- 6) objectivity and balance
- 7) limitations on data
- 8) discussion of unapproved uses
- 9) opportunities for debate
- 10) schedule of activities

The written agreement would provide that on all factors, the company would “take steps to ensure that it has no role in the design or conduct of the program that might bias the treatment of the topic.”⁷⁷ After considering comments on the draft policy, the Final Guidance was issued on December 3, 1997.⁷⁸

The Final CME Guidance places less emphasis on a written agreement.⁷⁹ Instead, it focuses on evaluating promotion based on 12 factors, most of which derive from the provisions for the written agreement it used in the Draft CME Guidance. Generally, the Final CME Guidance declares the FDA’s intention to regulate pharmaceutical company sponsorship of CME seminars on each of these grounds if the FDA finds the seminar promotional in nature, based on a consideration of these factors.⁸⁰ This position was the same as the Draft CME Guidance. In addition, it maintains the same regulatory position prohibiting off-label uses and requiring fair balance in the discussion of off-label uses. The 12 factors it identifies as relevant to the issue of promotion are:

⁷⁷*Id.*

⁷⁸Final CME Guidance, 62 FED. REG. 64,074.

⁷⁹*See id.* at 64,084.

⁸⁰*Id.*

- 1) control of content and selection of presenters and moderators
- 2) disclosures
- 3) focus of the program
- 4) relationship between provider and supporting company
- 5) providers involvement in sales or marketing
- 6) provider's demonstrated failure to meet standards
- 7) multiple presentations
- 8) audience selection
- 9) opportunities for discussion
- 10) dissemination
- 11) ancillary promotional activities
- 12) complaints.⁸¹

The guidance also notes that this is not an exhaustive list; "other factors may be appropriate for consideration

⁸¹ *Id.*

in a particular case.”⁸²

Thus the critical issue for pharmaceutical companies sponsoring CME is whether the FDA considers its sponsorship promotional. If it does, the program will have to conform to the FDA’s extensive regulations on labeling and advertising, including the prohibition of discussion of off-label uses. Although a guidance document is not legally binding,⁸³ the FDA has a policy of adhering to them in its enforcement decisions.⁸⁴

2. The Guidance Document’s effect on CME

The guidance document has two major effects.⁸⁵ First, it results in a flat ban on all mention of off-label uses at CME deemed promotional. Secondly, it requires the presentations at CME to present the drugs in a way that does not lack “fair balance,”⁸⁶ as evidenced by the approved labeling and advertising requirements. One can imagine several ways in which CME activities could violate the labeling and advertising provisions governing on-label uses. For example, a violation could occur if a speaker voiced an opinion, perhaps with some new clinical evidence, that the drug’s side effects were more negligible than the FDA has said and approved of its use despite the side effects. Portraying the drug in a more positive light could be “misleading,” according to the FDA, if the FDA takes a more negative view of its side effects and contraindications. For another example, CME presentations could run afoul of the FDA’s advertising regulations if comparative discussions

⁸²*Id.*

⁸³*See* 21 U.S.C. § 371(h). *See also* Final CME Guidance, 62 FED. REG. 64,074-01 (acknowledging that the guidance document has no legal effect).

⁸⁴*See* Administrative Practices and Procedures; Good Guidance Practices, 65 FED. REG. 56468, 56,477 (Sept. 19, 2000) (stating that “[although guidance documents do not legally bind FDA, they represent the agency’s current thinking. Therefore, FDA employees may depart from guidance documents only with appropriate justification and supervisory concurrence.”).

⁸⁵For analytical purposes, I assume a situation where the manufacturer would feel compelled to follow the guidance, because the guidance document describes how the FDA will use its enforcement power, although “[a]ctivities that fail to fall within this traditional safe harbor are not per se illegal, but... are subject to regulation.” Draft CME Guidance, 57 FED. REG. at 56,412.

⁸⁶*Id.* at 56,413 n.1.

(of the relative merits of two or more drugs) were not based on substantial evidence (typically two adequate and well-controlled clinical trials).⁸⁷ Fewer or less rigorous studies would not suffice. Some say this high bar of substantial evidence is not a standard that should be used in a scientific forum meant to promote free scientific discussion.⁸⁸

3. Arguments for and against regulation

The controversy over the FDA's decision to debate about whether CME needs to be regulated rages on because there is no conclusive evidence on how well physicians are able to critically evaluate information presented in CME. Cognitive studies on whether physicians are able to discount promotional biases in information show conflicting results.⁸⁹

The FDA argues that CME is dangerously exploitable because doctors are more inclined to trust more the information provided in CME than information provided in an advertisement or other clearly promotional literature. Thus the impact of misleading information could be far greater. Physicians value highly the information presented in CME, citing CME, along with medical journal reading, as the most significant influence on their practice.⁹⁰ In contrast, studies have shown that labeling, though tightly controlled by the FDA, has minimal impact on physicians' prescribing decisions.⁹¹ Anecdotes from these studies reveal that some doctors never read the label, depending instead on their training, information from journals and

⁸⁷See Comments of Pfizer, Inc. in the Matter of Request for Comments on First Amendment Issues 125 (Sept. 13, 2002) [hereinafter Pfizer First Amendment Comments], available at <http://www.fda.gov/ohrms/dockets/dailys/02/Sep02/091602/80027f2d.pdf> (last visited April 15, 2003).

⁸⁸See *id.*

⁸⁹See discussion of several studies generally in Lars Noah, *Medicine's Epistemology: Mapping the Haphazard Diffusion of Knowledge in the Biomedical Community*, 44 ARIZ. L. REV. 373, 379-387 (2002).

⁹⁰See E. Ray Stinson & Dorothy A. Mueller, *Survey of Health Professionals' Information Habits and Needs*, 243 JAMA 140, 140 (1980). However, other studies show CME as having a more minimal impact. See Dave Davis et al., *Impact of Formal Continuing Medical Education: Do Conferences, Workshops, Rounds and Other Traditional Continuing Education Activities Change Physician Behavior or Health Care Outcomes?*, 282 JAMA 867, 867 (1999).

⁹¹See Noah, *supra* note 89, at 438.

other scientific sources, and their formulary committee, to make prescribing decisions.⁹² Physicians are also required to attend a certain number of CME in order to maintain board certification,⁹³ providing a ready-made audience for promotion.

In addition, while physicians do have the training necessary to evaluate the information presented at CME, they do not always have the time. The amount of medical literature has increased exponentially; many doctors say they must struggle to keep up with the amount of new literature.⁹⁴ There is growing fragmentation among expert communities, leading to fewer consensus and more confusion about appropriate treatments.⁹⁵ Some studies have shown that, for whatever reason, physicians do not discount the information in promotional literature as much as they should.⁹⁶

But the guidance's critics oppose the regulations because they feel that the benefits of pharmaceutical sponsorship outweigh the dangers of biased information. Industry-supported CME fills an important need in disseminating information about new treatments quickly, because pharmaceutical companies have incentives to publicize their own advances.⁹⁷ This helps speed up new medical care, because "physicians have sometimes been slow to adopt efficacious new therapies into routine clinical practice and therefore to improve patient care."⁹⁸ In addition, critics say, the very purpose of CME is to discuss the uses and views about drugs that conflict with the labeling and the advertising. Said one CME provider: "If you prevent the discussion of off-label use of medications, there would be little point in holding CME programs. One could just read the package insert and one would know all one needs to know about the drug."⁹⁹

⁹²See *id.*

⁹³See discussion of CME requirements, *supra*, note 64.

⁹⁴See Noah, *supra* note 89, at 382.

⁹⁵See *id.*

⁹⁶See *id.* at 409.

⁹⁷See Coyle, *supra* note 65, at 403-406.

⁹⁸*Id.*

⁹⁹See Skolnick, *supra* note 40, at 332. The FDA has also conceded that CME serves an important purpose in advancing scientific knowledge about drugs that has not yet been fully accepted to be included in the labeling. "Labeling is not intended to be a dispositive treatise of all possible medical opinion. . . . The opinions of individual physicians on such matters can be, and are, thoroughly and adequately discussed through medical journals, treatises, meetings of professional associations, and other similar events." 40 FED. REG. 28,582, 28,583 (July 7, 1975), *quoted in* Noah, *supra* note 89, at 436.

They also discount the danger that is presented by allegedly promotional information.¹⁰⁰ Trained physicians are capable of “[taking] the interests of speakers, economic or otherwise, into account in evaluating for themselves the merit of the information and ideas being exchanged” and critically analyzing such information.¹⁰¹ After all, they say, if the FDA has enough confidence in physicians’ discretion to support their authority to prescribe off-label, they should have enough confidence in their ability to process the data about off-label uses.¹⁰²

In addition, there is little danger of physicians falling under the promotional sway of pharmaceutical manufacturers because other sources of information are available to provide opposing views.¹⁰³ The world of pharmaceutical information is one of “myriad speakers – from medical journals to patient advocacy groups to HMO benefits managers to dietary supplement manufacturers – each of whom has differing motivations in initiating public debate concerning various prescription drugs and different messages that they would like to convey.”¹⁰⁴ Thus, no source of information is objective; each source has its own interest it would like to further. Some of these interests are against the manufacturers’ interests and would serve the purpose of balancing the manufacturers’ speech. Because these interests are at times in opposition to the pharmaceutical manufacturers’ interest, the better policy choice would be to allow the manufacturers’ positions to

¹⁰⁰In addition, pharmaceutical manufacturers have denied that the primary reason they sponsor CME is to generate sales; “their main goal is to exchange information to promote better patient care,” said the president of the Pharmaceutical Research and Manufacturers of America (PhRMA), adding that “pharmaceutical companies generate considerable ‘goodwill’ through their support of CME and, to the extent that physicians become more knowledgeable about the benefits of their products, they may also generate increased sales.” Alan F. Holmer, Editorial, *Industry Strong Supports Continuing Medical Education*, 285(15) JAMA 2014 (2001).

¹⁰¹See Brief of Amici Curiae Pfizer, Inc. at 16, *Nike v. Kasky*, (No. 02-575) (U.S. 2003) [hereinafter Pfizer Brief], citing *Peel v. Attorney Registration and Disciplinary Comm’n*, 496 U.S. 91, 105 (1990) (rejecting notion that recipients of commercial speech “are no more discriminating than the audience for children’s television”). Courts have also supported this position. See *WLF I*, 13 F. Supp. 2d at 70 (“A physician’s livelihood depends upon the ability to make accurate, life-and-death decisions based on the scientific evidence before them.”).

¹⁰²See Glenn C. Smith, *Off-Label Research Ruling Missteps*, NAT’L L.J. A19, col. 1, Aug. 31, 1998 (“The agency freely allows, and has, in written statements, favored physician off-label prescribing. Yet these same discerning physicians need, in the FDA’s eyes, aggressive action to protect them against being deceived by off-label research once drug companies call the doctors’ attention to the data.”).

¹⁰³See Pfizer Brief, *supra* note 101, at 3a (“The agency’s regulations appear to be premised on the concept that the manufacturer is the only speaker concerning its drug product and that regulating manufacturer speech is the sole means of ensuring that physicians and consumers are fully advised about drug benefits and risks. This is largely not the case.”).

¹⁰⁴See *id.*

be tested “in the crucible of debate through the clash of informed but opposing scientific and technological viewpoints.”¹⁰⁵

The rigorous testing of scientific speech through the dissemination of multiple viewpoints is even more important in an informational environment where truth is elusive and ever-changing, as new scientific discoveries are made. The FDA justifies its constraints upon expressing certain opinions about the effect or approval or disapproval of certain treatments by a rule that labeling and advertising must be “truthful and non-misleading.” But in practice, this rule is hard to implement because of the nature of scientific truth, as the FDA has acknowledged:

However, FDA’s broad experience reviewing promotional materials and scientific data suggests that determining whether information is “truthful” may depend on a variety of factors. . . For example, a preliminary study may suggest a result that appears “truthful” at the time the preliminary study is first announced, but subsequent studies may fail to reproduce those results, disprove the preliminary result, or even show that the preliminary study was flawed. Given the wide variety of factors, how should one determine whether the information in question is, indeed, “truthful”?¹⁰⁶

By promulgating the guidance document, the FDA is in effect appointing itself the arbiter of what is truthful at industry-supported CME. The idea that truth is what the FDA says it is, and that pharmaceutical manufacturers are not allowed to challenge its version of truth by presenting conflicting information that it may have, has alarmed members of the pharmaceutical and medical communities because of its potential to hinder scientific debate. As two scholars succinctly stated, “The FDA is not a peer review mechanism for the scientific community.”¹⁰⁷ This opposition to FDA regulation of allegedly scientific debate led to the following litigation.

¹⁰⁵*Int’l Harvester Co. v. Ruckelshaus*, 478 F.2d 615, 652 (D.C. Cir. 1973).

¹⁰⁷Lars Noah and Barbara A. Noah, *Liberating Commercial Speech: Product Labeling Controls and the First Amendment*, 47 FLA. L. REV. 63, 96 (1995).

III. The WLF Decisions

A. The case in the district court

The Federal District Court for the District of Columbia first reached the substance of the controversy in its decision in *Washington Legal Foundation v. Friedman*.¹⁰⁸ This suit was first filed in 1994¹⁰⁹ by the WLF on behalf of its physician members to vindicate their rights as listeners to receive the speech on off-label uses, not to vindicate the rights of pharmaceutical manufacturers to speak, as might be expected.¹¹⁰ It is also important to note that this litigation concerned only the CME guidance’s effect on promotion of off-label uses, but not its effect on promotion of on-label uses – that they must provide an FDA-dictated “fair balance” of information. In this case, the WLF’s challenge was to both the ban on off-label speech in the dissemination of enduring materials (reprints of scientific articles and medical reference books)¹¹¹ and on off-label speech at CME.¹¹² The court considered these two regulations together.

The court held the FDA’s ban on discussion of off-label uses at CME unconstitutional because the restrictions “are considerably more extensive than necessary to further the substantial government interest in encouraging

¹⁰⁸ *WLF I*, 13 F. Supp. 2d 51 (D.D.C. 1998). A previous opinion was issued in *Washington Legal Found. v. Kessler*, 880 F. Supp. 26 (D.D.C. 1995) (denying FDA’s motion to dismiss).

¹⁰⁹ See *Washington Legal Found. v. Kessler*, No. CIV 1:94CV01306 (RCL) (D.D.C. filed Jun. 13, 1994), cited in Richard M. Cooper, *The WLF Case Thus Far: Not With a Bang, but a Whimper*, 55 FOOD & DRUG L.J. 477 (2000). This complaint followed the citizen petition filed by the WLF on Oct. 22, 1993, on which the FDA sought comment. See Request for Comment on Citizen Petition, 59 FED. REG. 59,820. The complaint and petition were filed before the final guidance was published, based instead on the draft guidance and a series of FDA enforcement actions that the WLF contended constituted final agency policy. See *Washington Legal Found. v. Kessler*, 880 F.Supp. 26. The court rejected FDA’s motion to dismiss on the ground that the case was not yet ripe because the agency had not yet finalized its policy, and held that the enforcement actions were representative of a final agency policy. See *id.* at 35. The final guidance was published during the course of the litigation.

¹¹⁰ The Supreme Court has held that listeners, as well as speakers, have a First Amendment right in speech. See e.g. *Red Lion Broad. Co. v. FCC*, 395 U.S. 367, 390 (1969); *Va. Board of Pharmacy v. Va. Citizens Consumer Council*, 425 U.S. 748, 757 (1976). The right of the listener is most often cited to justify commercial speech, and has particular applicability to speech about drugs, because of the importance of information to drugs to listeners like doctors. “Such speech typically conveys essential information about the drug product itself. . . Prescribing and purchasing decisions about pharmaceuticals are likely to be based on factors such as indications, contraindications, and side effects as much or more than on price alone.” See Kaplar, *supra* note 1, at 57.

¹¹¹ The constitutional issues dealing with the dissemination of enduring materials are not covered in the scope of this paper.

¹¹² *WLF I*, 13 F. Supp. 2d at 54.

manufacturers to get new uses on-label.”¹¹³ The court arrived at this holding after a two-step analysis. First, it decided how the speech involved in the regulation should be classified and second, after deciding that the speech was properly characterized as commercial speech, it analyzed the regulation under the four-part test for commercial speech. These two issues each merit further discussion.

1. The classification of CME sponsorship

There were three choices the court had of characterizing pharmaceutical sponsorship of CME: conduct, fully-protected “core” speech, or commercial speech. The court first decided it was speech, not conduct.¹¹⁴ The FDA had first attempted to characterize the activity as conduct (which would then be subject only to the expressive conduct law of the First Amendment – a much lower standard), but the court dispensed quickly with the issue, saying while “the relevant ‘conduct’ is the off-label prescription of drugs by physicians[,] [t]he distribution of enduring materials and sponsorship of CME seminars addressing and encouraging this conduct is speech. . . . There may certainly be a ‘line’ between education and promotion as regards a drug manufacturer’s marketing activities, but that is the line between pure speech and commercial speech, not between speech and conduct.”¹¹⁵

The court also considered whether this was speech that fell outside the ambit of the First Amendment because of the FDA’s extensive power to regulate the pharmaceutical industry.¹¹⁶ The court rejected the FDA’s argument that the pharmaceutical industry was a “separate area of extensive regulation”¹¹⁷ and so the greater power to prohibit an activity entirely includes the lesser power to prohibit speech about it,

¹¹³*Id.* at 73.

¹¹⁴*Id.* at 59.

¹¹⁵*Id.*

¹¹⁶*Id.* at 61.

¹¹⁷*Id.*

an argument which had been similarly rejected by the Supreme Court in *44 Liquormart, Inc. v. Rhode Island*.¹¹⁸ The Supreme Court’s oft-quoted statement in the *Liquormart* case presages many of the issues touched upon by FDA regulation of CME. Regarding Rhode Island’s ban on advertising alcohol content in advertising, a matter in which the state had power to regulate the sale of alcohol generally, the Court said:

The text of the First Amendment makes clear that the Constitution presumes that attempts to regulate speech are more dangerous than attempts to regulate conduct. That presumption accords with the essential role that the free flow of information plays in a democratic society. As a result, the First Amendment directs that the government may not suppress speech as easily as it may suppress conduct.¹¹⁹

In contrast to the FDA’s oft-asserted claim that regulation of drugs and information go hand in hand,¹²⁰ the Court makes a sharp distinction between regulation of activity and regulation of information. This is the first example from this case of how the FDA’s approach to speech has diverged from the judicial approach.

The final choice the court considered was one between fully-protected “core” speech¹²¹ and commercial speech. “Core speech” is speech that has traditionally been protected by the First Amendment, and until *Bigelow v. Virginia* in 1975,¹²² when the Supreme Court acknowledged qualified First Amendment protection for commercial speech, was the only kind of speech meriting First Amendment protection.¹²³ Political speech is the paradigmatic example of core speech meriting protection, because of its importance to the “free exchange of ideas,” and concern about its particular vulnerability because of its use in criticizing the government, but courts have also consistently included scientific and educational speech within this core.¹²⁴ What falls in the category of commercial is still subject to debate, but the paradigmatic example

¹¹⁸517 U.S. 484 (1996).

¹²⁰See note 1, *supra*.

¹²¹Fully-protected speech, core speech, and pure speech are all terms that courts and commentators have used to refer to speech that is not commercial. For uniformity’s sake, I will refer to it as core speech hereinafter.

¹²²421 U.S. 809 (1975).

¹²³See *e.g.*, *Valentine v. Chrestensen*, 316 U.S. 52 (1942) (holding that commercial advertising did not have as much value as core speech and so did not merit First Amendment protection).

¹²⁴See *Keyishian v. Bd. of Regents of Univ. of State of N. Y.*, 385 U.S. 589, 603 (1967) (holding that academic speech is at

of commercial speech is “speech that does no more than propose a commercial transaction.”¹²⁵ It is at the boundaries of core and commercial speech – when speech allegedly proposes a commercial transaction but includes other informative elements as well – where the most debate has occurred.

The court found the core/commercial issue to be the most difficult issue,¹²⁶ as “the communications present one of those ‘complex mixtures of commercial and non-commercial elements.’”¹²⁷ In addition, the dual character of the speech only arises because of the identity of the speaker; if a pharmaceutical sponsor were not involved, then the speech would certainly be characterized as scientific speech meriting core First Amendment protection.¹²⁸

The court applied the three-part test of core/commercial speech set out in *Bolger v. Youngs Drug Products Co.*,¹²⁹ the most definitive test the Supreme Court has announced for determining whether something is core or commercial speech. The factors that *Bolger* directs a court to examine are:

1)

whether the speech is concededly an advertisement;

2) whether the speech refers to a specific product;

the core of the First Amendment); *Bd. of Trustees of Leland Stanford Junior Univ. v. Sullivan*, 773 F. Supp. 472, 474 (D.D.C. 1991) (“It is equally settled...though less commonly the subject of litigation, that the First Amendment protects scientific expression and debate just as it protects political and artistic expression.”).

¹²⁵ *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n*, 447 U.S. 557, 566 (1980).

¹²⁶ See *WLF I*, 13 F. Supp. 2d at 62.

¹²⁷ *Id.*, quoting *Bolger v. Young*, 463 U.S. 60, 81 (1983) (Stevens, J., concurring).

¹²⁸ See *id.* (“It is beyond dispute that when considered outside of the context of manufacturer promotion of their drug products, CME seminars... merit the highest degree of constitutional protection.”).

¹²⁹ *Bolger*, 463 U.S. 60.

3) whether the speech has an economic motivation for disseminating the speech.¹³⁰

On the first factor, the court found that sponsorship of CME are “advertisements as that term is commonly understood.”¹³¹ It reached this conclusion by assuming that the purpose of drug manufacturers in sponsoring CME was to publicize the drug to physicians in hopes that they would prescribe the drug. Said the court, “the fact that an effective means for accomplishing that goal is through providing the academic research results generated by others does not mean that the activity is not an ‘advertisement.’”¹³² On the second factor, the court easily found that the CME “presumptively refer to a specific product – the drug that is the subject of the off-label use.”¹³³ On the third prong, the court found that the “pharmaceutical companies clearly have an economic motivation for providing the information; . . . the promotional efforts at issue have a positive effect on a physician’s prescription practices and therefore on sales.”¹³⁴ Concluding that the facts of this case satisfied the three factors of *Bolger*, the court concluded that the speech at issue was commercial speech. The finding of commercial speech is important because it means that governmental restrictions undergo a lower level of scrutiny – most particularly that “content-based restrictions on commercial speech may be permissible”¹³⁵ “[i]n light of the greater potential for deception or confusion in the context of certain advertising messages”.¹³⁶

¹³⁰*Id.* at 66.

¹³¹*WLF I*, 13 F. Supp. 2d at 64.

¹³²*Id.*

¹³³*Id.*

¹³⁴*Id.*

¹³⁵*Bolger*, 463 U.S. at 65 (citations omitted).

¹³⁶*Id.*

2. The commercial speech test applied

Once the court determined that CME and the distribution of enduring materials was commercial speech, it then analyzed the FDA's restriction on the speech in the guidance documents according to the four-part *Central Hudson* test of commercial speech. *Central Hudson Gas & Electric Corporation v. Public Service Commission of New York*, a leading Supreme Court case on commercial speech, held that commercial speech had a lower level of constitutional protection than did core speech. A governmental restriction on commercial speech was not unconstitutional if:

1)

the speech “[concerns] a lawful activity and [is not] misleading”;

2) the “asserted government’s interest is substantial”;

3) “the regulation directly advances the governmental interest asserted”;

4) the restriction “is not more extensive than is necessary to serve that interest.”¹³⁷

On the first factor, the court first found that “[t]he proper inquiry is not whether the speech violates a law or a regulation, but rather whether the conduct that the speech promotes violates the law.”¹³⁸ It determined this conduct was doctors’ off-label prescriptions, not manufacturers’ off-label promotion; since doctors were allowed to prescribe off-label, the activity was lawful.¹³⁹ On the issue of whether the speech is misleading, the court first rejected the FDA’s argument that misleading could mean “potentially misleading” – “[i]n order

¹³⁷ *Central Hudson*, 447 U.S. at 566.

¹³⁸ *WLF I*, 13 F. Supp. 2d at 66.

¹³⁹ *See id.*

to end the *Central Hudson* analysis on the first prong, the speech must be inherently misleading, which is defined in *Central Hudson* as more likely to deceive the public than to inform it.”¹⁴⁰ Because the FDA did not object to the distribution of enduring materials when physicians requested it from the manufacturer, nor to CME presenting the same off-label findings if the seminar was not sponsored by a manufacturer, the court determined that it was not inherently misleading.¹⁴¹ Here, the court rejected the FDA’s approach in rejecting its position as the arbiter of truth, noting that “the findings presented by a physician at a CME seminar are not ‘untruthful’ or ‘inherently misleading merely because the FDA has not yet had the opportunity to evaluate the claim.”¹⁴²

For the second factor, the FDA asserted two governmental interests: 1) the government’s interest in ensuring that physicians receive accurate and unbiased information so that they may make informed prescription choices and 2) providing manufacturers with incentive to get unapproved uses on label.¹⁴³ The court found the first illegitimate, the second legitimate.¹⁴⁴

¹⁴⁰*Id.* at 66-67.

¹⁴¹*Id.* at 67.

¹⁴²*Id.*

¹⁴³*Id.* at 69.

¹⁴⁴*See id.*

The first ruling would seem to upset the whole regulatory approach the FDA has brought to CME and promotion through presentation of scientific information; most of the justifications and discussions in the guidance documents have dealt with the FDA's concern about the promotional use of CME that would deceive physicians. However, the court dismissed this concern, saying that "[a] physician's livelihood depends upon the ability to make accurate, life-and-death decisions based upon the scientific evidence before them. They are certainly capable of critically evaluating journal articles or textbook reprints that are mailed to them or the findings presented at CME seminars."¹⁴⁵ The court expressed sharp disapproval for what it perceived to be the FDA's paternalistic attitude toward doctors, and cited case law that stood for the general proposition that courts normally disapprove of restrictions on speech "for the good of the recipient."¹⁴⁶

The court found the second asserted interest to be substantial, however, "[i]n light of the fact that Congress has declared that *all* uses must be proven safe and effective by the FDA, and has recently affirmed that position through the 1997 Food and Drug Amendments [FDAMA]."¹⁴⁷ It also found that the guidance documents directly advanced the government interest in getting uses on-label, which satisfied the third

Central Hudson factor.¹⁴⁸

¹⁴⁵Id. at 70.

¹⁴⁶Id. Courts have consistently struck down paternalistic "protection of the listener" interests as legitimate government interests. See *Va. State Bd. of Pharmacy*, 425 U.S. at 771 (stating that while the state is free to set professional standards for its pharmacists, "it may not do so by keeping the public in ignorance of the entirely lawful terms that competing pharmacists are offering."); *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 497 (1995) (J. Stevens, concurring) ("In my opinion, the Government's asserted interest, that consumers should be misled or uninformed for their own protection, does not suffice to justify restrictions on protected speech in any context, whether under 'exacting scrutiny' or some other standard.").

¹⁴⁷*WLF I*, 13 F. Supp. 2d at 71. For this provision of the FDAMA, see Pub. L. No. 105-115, 111 Stat. 2296, § 551(b) (to be codified at 21 U.S.C. § 360aaa *et seq.*).

¹⁴⁸*WLF I*, 13 F. Supp. 2d at 71.

It was on the fourth and final *Central Hudson* factor that the court found the CME guidance unconstitutional; it found that they were “considerably more extensive than necessary to further the substantial government interest in encouraging manufacturers to get new uses on-label.”¹⁴⁹ It based this finding on the “fact that there exists less-burdensome alternatives to this restriction on commercial speech”¹⁵⁰ – for example, full disclosure of sponsorship by the manufacturer. The court felt that full disclosure would address many of the FDA’s concerns – physicians would not be misled if they knew that manufacturers were the providers of the information, and many regulations still exist for manufacturers to get uses on-label.¹⁵¹ Once finding that the CME guidance document violated the First Amendment, the court enjoined the FDA from applying such regulations, ordering, *inter alia*, that the FDA “shall not in any way prohibit, restrict, sanction or otherwise seek to limit any pharmaceutical or medical device manufacturer or any other person... from suggesting content or speakers to an independent program providers in connection with a continuing medical education seminar program or other symposium, regardless of whether uses of drugs and medical devices other than those approved by the FDA are to be discussed.”¹⁵²

B. The case on appeal and beyond

However, the district court’s decision was not the last word on the issue. Several more developments on the case followed. The FDAMA¹⁵³ had changed the law on the dissemination of reprints of enduring materials on off-label uses in its provision that a manufacturer may distribute such materials if it complies with several requirements. The manufacturer must submit an application for approval of the off-label use,¹⁵⁴ provide

¹⁴⁹ *Id.*

¹⁵⁰ *Id.*

¹⁵¹ See discussion of other incentives, Part III.C.2, *infra*.

¹⁵² *Id.* at 74-75.

¹⁵³ Pub. L. No. 105-115, 111 Stat. 2296.

¹⁵⁴ See 21 U.S.C. § 360aaa(b)(1) (2000).

the materials to the FDA prior to dissemination,¹⁵⁵ provide the materials in an unedited form,¹⁵⁶ include disclosures that the materials refer to an off-label use,¹⁵⁷ and, if the FDA deems it appropriate, include “additional objective and scientifically sound information... necessary to provide objectivity and balance.”¹⁵⁸ Once the FDAMA became effective, shortly after *WLF I* was decided, the FDA then moved to have its injunction confined to express provisions of the guidance documents, given that the enduring materials guidance was superseded by the FDAMA.¹⁵⁹ The FDA wanted to be certain that it could implement the FDAMA provisions without violating the injunction, which was expressed in general terms not necessarily confined to the documents at issue in the litigation.¹⁶⁰ The District Court denied the FDA’s motion and held that the FDAMA provisions and the guidance documents all violated the First Amendment.¹⁶¹ The FDA appealed this ruling.¹⁶²

The appeal went before the Circuit Court for the District of Columbia. During oral argument, the FDA changed its position, now asserting that the guidance documents were simply a safe harbor for manufacturers

¹⁵⁵ See *id.* at 360aaa(b)(4).

¹⁵⁶ See *id.* at 360aaa-1.

¹⁵⁷ See *id.* at 360aaa(b)(6).

¹⁵⁸ *Id.* at 360aaa(c).

¹⁵⁹ 13 F. Supp. 2d 16.

¹⁶⁰ The amended injunction stated that the guidance documents on CME, on enduring materials and the applicable FDAMA provisions were “contrary to rights secured by the United States Constitution and therefore must be set aside pursuant to 5 U.S.C. § 706(2)(B) except insofar as they are consistent with the injunctive provisions below.” Final Amended Order Granting Summary Judgment and Permanent Injunction, *Friedman*, 56 F. Supp. 2d at 88. The injunction then goes on to prohibit the FDA:

a) from disseminating or redistributing to physicians or other medical professionals any article concerning prescription drugs or medical devices previously published in a bona fide peer-reviewed professional journal, regardless of whether such article includes a significant or exclusive focus on unapproved uses for drugs or medical devices that are approved by FDA for other uses and regardless of whether such article reports the original study on which FDA approval of the drug or device in question was based;

b) from disseminating or redistributing to physicians or other medical professionals any reference textbook (including any medical textbook or compendium) or any portion thereof published by a bona fide independent publisher and otherwise generally available for sale in bookstores or other distribution channels where similar books are normally available, regardless of whether such reference textbook or portion thereof includes a significant or exclusive focus on unapproved uses for drugs or medical devices that are approved by FDA for other uses;

c) from suggesting content or speakers to an independent program provider in connection with a continuing medical education seminar program or other symposium regardless of whether unapproved uses for drugs or medical devices that are approved by FDA for other uses are to be discussed.

Id. at 88-89.

¹⁶¹ 56 F. Supp. 2d 81.

¹⁶² *WLF II*, 202 F.2d 331.

under which certain forms of conduct are protected.¹⁶³ Upon questioning by the court, for example, the FDA said that “[i]f a drug manufacturer wishes to suggest content to a CME program provider in a manner that runs afoul of all the Guidance’s twelve ‘factors’ that, by itself, is not a violation of law” but the FDA would retain the prerogative to use the promotional conduct in an misbranding or “intended use” enforcement action.¹⁶⁴ At argument, the WLF agreed with this interpretation.¹⁶⁵ Therefore, the D.C. Circuit found that because the parties agreed that the statute and guidance document do not “facially violate the First Amendment,” there was “no constitutional controversy between the parties that remains to be resolved.”¹⁶⁶ Accordingly, it “[vacated] the district court’s decisions and injunctions insofar as they declare the FDAMA and the CME Guidance unconstitutional.”¹⁶⁷ Because it found that there was no longer a constitutional question in dispute, the D.C. Circuit did not reach the merits of the constitutional question, and expressly stated that did not intend to “criticize the reasoning or the conclusions of the district court.”¹⁶⁸

Despite the signs of judicial disapproval of its First Amendment approach from *WLF I*, after the Appeals Court’s decision, the FDA issued a notice of the “Decision in *Washington Legal Foundation v. Henney*” declaring that it would continue to use the CME Guidance to guide its enforcement, but that “if the agency brings an enforcement action, a manufacturer may raise a First Amendment defense.”¹⁶⁹ It took no further steps to conform the CME guidance to the First Amendment.

That the guidance document is still in effect and that the FDA intends to follow its policy is clear from the last disposition of the case. After the appellate decision, the WLF moved to confirm and enforce the

¹⁶³ *Id.* at 335. The FDA’s change in position even confused the court, which stated that “the FDA’s view of the Act and the CME Guidance was somewhat unclear: At times the FDA appeared to share WLF’s assessment that these provisions provide legal authorization to restrict manufacturer speech, but more frequently the FDA asserted that they established nothing more than a “safe harbor” ensuring that certain forms of conduct would not be used against manufacturers in misbranding and “intended use” enforcement actions based on pre-existing legislative authority.” *Id.*

¹⁶⁴ *Id.* at 335-36.

¹⁶⁵ *See id.* at 336.

¹⁶⁶ *Id.*

¹⁶⁷ *Id.* at 337.

¹⁶⁸ *Id.* at 337 n.7.

¹⁶⁹ *See* WLF II Notice, 65 FED. REG. 14,286.

injunction previously issued, based on the D.C. Circuit’s comment that it “did not reach the merits of the district court’s First Amendment holdings and part of its injunction still stands.”¹⁷⁰ Because the D.C. Circuit vacated the injunction “insofar as [it] declare[s] the FDAMA and the CME Guidance unconstitutional”, the District Court interpreted the issue to be “what portion of the injunction was grounded in law other than the federal constitution?”¹⁷¹ It found that all parts of the injunction were based on its constitutional holdings, and thus all were vacated by the appellate decision.¹⁷² However, it sharply criticized the FDA’s decision to continue using the CME guidance, stating that:

To say that the FDA’s March 16, 2000 Notice finally clarifies the situation is a farce; the Notice specifically invites a constitutional challenge to each and every one of its enforcement actions. That is no way to establish policy on an issue that both sides argue is of – quite literally – life and death proportions.¹⁷³

The CME Guidance has a chilling effect on CME sponsorship. Although a First Amendment defense is available, many manufacturers are loathe to try such a strategy because the FDA wields enormous power over manufacturers; it has the power to seize the entire product line at issue during litigation and to hold up new approvals, among other things. It is unlikely that a manufacturer would risk such devastating consequences, but rather would refrain from such speech from the start.

C. Analysis of the WLF I Decision

Because *WLF I* has been vacated, its importance lies mostly in its use as a blueprint for future courts considering issues of free speech in the pharmaceutical industry. In this area, unfortunately, despite its ultimate finding on unconstitutionality, *WLF I* presents a weak case for future pharmaceutical sponsorship

¹⁷⁰ *Id.*

¹⁷¹ *WLF III*, 128 F. Supp. 2d at 14-15.

¹⁷² *See id.* at 15.

of CME, for the following reasons. First, it uses the *Bolger* test of commercial speech in a way that will sweep too much speech into the commercial category, because of its emphasis on the intent of the manufacturer in making the determination. Secondly, it is under-inclusive in its effect on CME regulation because it hangs its unconstitutional ruling on the thin thread of an interest in getting drugs on label, and rejecting the government interest in protecting physicians for fear that they will misuse it.

1. The *Bolger* core v. commercial speech issue

Whether the speech was core speech or commercial speech is important because while the state cannot generally regulate core speech based on its content, it can regulate commercial speech based on its content.¹⁷⁴ The FDA would have to meet a much higher bar in order to restrict non-commercial speech. It would have to show that “the government’s interest in preserving regulatory incentives [was] among the most ‘compelling’ of interests – not merely a ‘substantial’ one.”¹⁷⁵ This would necessitate an entirely different analysis than the *Central Hudson* test actually used.

WLF I highlights the weaknesses of *Bolger* as a test of commercial speech. The *Bolger* test has already been criticized in the scholarly literature because of its vagueness and difficulty of application,¹⁷⁶ and the

¹⁷⁴See *Central Hudson*, 447 U.S. at 564 n.6 (“In most other contexts, the First Amendment prohibits regulation based on the content of the message. Two features of commercial speech permit regulation of its contents. First, commercial speakers have extensive knowledge of both the market and their products. Thus, they are well situated to evaluate the accuracy of their messages and the lawfulness of the underlying activity. In addition, commercial speech, the offspring of economic self-interest, is a hardy breed of expression that is not particularly susceptible to being crushed by overbroad regulation.”). (internal citations and quotations omitted).

¹⁷⁵See Smith, *supra* note 52, at 983.

¹⁷⁶See e.g., Arlen W. Langvardt and Eric L. Richards, *The Death of Posadas and the Birth of Change in Commercial Speech Doctrine: Implications of 44 Liquormart*, 34 AM. BUS. L.J. 483 (stating that “[*Bolger*] created uncertainty, however, by noting that the commercial speech label could be appropriate even if not all of the characteristics were present, and by implying that the presence of all three characteristics would not always mandate the commercial speech classification. Besides being unclear about how to apply its “test” for what constitutes commercial speech, *Bolger* arguably created the danger of undervaluing

Supreme Court has pulled away from its use in later cases.¹⁷⁷ The difficulties the *WLF I* court had in using the test exposes its weaknesses as an appropriate test of commercial speech and can lead to suggestions for reform.

Even in *Bolger*, the court was not in agreement on the factors for the test or even that it was a test.¹⁷⁸ In a cryptic footnote, the majority first noted that the three-factor test was not definitive, stating that “[we do not] mean to suggest that each of the characteristics present in this case must necessarily be present in order for speech to be commercial. For example, we express no opinion as to whether reference to any particular product or service is a necessary element of commercial speech.”¹⁷⁹

How the Supreme Court came to use these factors in *Bolger* itself deserves some elaboration. In *Bolger*, the speech at issue also concerned a healthcare products manufacturer’s right to engage in scientific and commercial speech about its products. Specifically, Youngs sought to distribute one type of brochure that advertised the manufacturer’s contraceptives and a second type of brochure that provided information about venereal disease and the benefits of using contraceptives. The latter did not discuss any of the manufacturer’s products specifically in the main text, and were marked with only a small notation of the manufacturer’s name at the end of the pamphlet: “Youngs, the distributor of Trojan-brand prophylactics.”¹⁸⁰ The court easily found the former to be advertisements but had a more difficult time deciding on the latter because they appeared to be scientific and educational speech:

certain expression that should merit more than an intermediate level of protection.”).

¹⁷⁷In *Bd. of Trustees of State Univ. of N.Y. v. Fox*, the next Supreme Court case considering the core/commercial issue, the Court narrowed its definition by characterizing the proposal of a commercial transaction as “the test for identifying commercial speech.” 492 U.S. 469 at 473-474 ((1989). See also *City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 423 (1993) (agreeing with the narrower test of *Fox*).

¹⁷⁸See *Bolger*, 463 U.S. at 76 (Rehnquist, J. concurring; *id.* at 80 (Stevens, J. concurring).

¹⁷⁹*Id.* at 68.

¹⁸⁰*Id.* at note 4.

Youngs' informational pamphlets, however, cannot be characterized merely as proposals to engage in commercial transactions. Their proper classification as commercial or non-commercial speech thus presents a closer question. The mere fact that these pamphlets are conceded to be advertisements clearly does not compel the conclusion that they are commercial speech. . . .The reference to a specific product does not by itself render the pamphlets commercial speech. Finally, the fact that Youngs has an economic motivation for mailing the pamphlets would clearly be insufficient by itself to turn the materials into commercial speech.¹⁸¹

However, the court found that “[t]he combination of all these characteristics, however, provide strong support for the District Court’s conclusion that the informational pamphlets are properly characterized as commercial speech.”¹⁸² Although the facts in this case met the test, the refusal to plainly declare the three factors to be a test leaves its usefulness as a practical test of commercial speech open to question.

Given that the court did not explain how the test should be used, it presents problems when the facts differ from those in *Bolger*. For example, in *Bolger*, the manufacturer conceded that the informational pamphlets were advertising.¹⁸³ The court therefore did not instruct future courts in how to determine if something was an advertisement if this was not stipulated.

In *WLF I*, the district court seemed to base its finding that it was an advertisement on the fact of commercial motivation, but this interpretation conflates the first and third factors. On the first factor, it determined that the activity is an advertisement because of the manufacturer’s economic motivation for distributing enduring materials and sponsoring CME, which is the same as the third factor.¹⁸⁴ In addition, unlike *Bolger*, the plaintiff did not concede that the activities at issue were advertisements.¹⁸⁵ The court instead determined that it was an advertisement based on the fact that the manufacturer undertakes these activities to “call a physician’s attention to the subject drug product, show that the drug effectively treats a certain condition (emphasize a desirable quality) in the hopes that the drug will prescribe (buy or patronize) the drug.”¹⁸⁶

¹⁸²*Id.* at 67.

¹⁸³*See id.* at 66.

¹⁸⁴*See WLF I*, 13 F. Supp. 2d at 64.

¹⁸⁵*See id.*

¹⁸⁶*Id.*

This determines the finding of commercial speech based on the motivation of the speaker, which is the third factor: “whether the speaker has an economic motivation for disseminating the speech.”¹⁸⁷ Because it uses practically the same analysis for both the first and third factors, the *Bolger* test, as demonstrated by this court, seemed to base its finding of commercial speech almost exclusively on motivation.

It weakens the argument that the CME sponsorship was commercial speech if the test is reduced to a two-factor test, given that the Supreme Court found *Bolger* a close issue. The *Bolger* court only decided it was commercial speech after finding that it was the “combination of *all* these characteristics,”¹⁸⁸ one of them being that the manufacturer *conceded* the pamphlets to be advertising.¹⁸⁹ That fact had a significant effect on the court. If core and commercial speech are ends of a spectrum with “mixed” speech in the middle, sponsorship of CME is arguably closer to the core end than the informational pamphlets.

It seems that the *Bolger* court’s objective was to block advertisers from distributing what they clearly admit to be advertisements while still enjoying core speech protection “simply by including references to public issues.”¹⁹⁰ “[A]dvertising which ‘links a product to a current public debate’ is not thereby entitled to the constitutional protection afforded noncommercial speech.”¹⁹¹ Therefore, the more precise holding of *Bolger* is that advertising which also mentions public issues cannot be boot-strapped into core speech. However, it still fails to define what is advertising, leaving courts which must decide closer questions, like the *WLF I* court, without a clear guide.

¹⁸⁷ *Bolger*, 463 U.S. at 66, *quoted in WLF I*, 13 F. Supp. 2d at 64.

¹⁸⁸ *Id.* at 67. (emphasis original).

¹⁸⁹ *See id.* at 66.

¹⁹⁰ *Id.* at 68.

¹⁹¹ *Id.*, *quoting Central Hudson*, 447 U.S. at 563.

2. The government interest issue

The biggest blow to the FDA's regulatory scheme was the finding that the protection of physicians from off-label speech was not a legitimate interest. The FDA's entire approach to CME regulation has been premised on this concern. The governmental interest in getting drugs on-label has always been a secondary justification in the FDA's guidance documents.¹⁹² As precedent for future decisions to be made about FDA regulation of scientific speech, the better method would be to ground the judgment on the interest in non-misleading speech. Instead, the narrower ground leaves future regulation of scientific speech far more vulnerable now that a court has disapproved of the FDA's interest in protecting the listener from speech. It casts into doubt the other parts of the CME guidance that do not address off-label uses, but instead allow the FDA to regulate on-label speech that is false, misleading, or lacks fair balance.

Although there is strong judicial dislike for bans on information to protect the listener, in my view, the court erred in striking down the governmental interest in "ensuring that physicians receive accurate and unbiased information."¹⁹³ It did not sufficiently weigh the government's interest in ensuring that accurate information about drugs is given to doctors. The court simply concludes, without support, that trained physicians are "certainly capable of critically evaluating journal articles or textbook reprints that are mailed to them, or the findings presented at CME seminars."¹⁹⁴ However, the court did not adequately consider the nature of the information at issue. Studies on the nature of information have shown that scientific information is the least conducive to easy evaluation.¹⁹⁵ Although it is true that physicians must evaluate scientific information when they read scientific journals, journals already have a built-in screening mechanism through

¹⁹²The Final CME Guidance discusses the protection justification in far more detail than the on-label interest. See Final CME Guidance, 62 FED. REG. at 64,080.

¹⁹³Friedman, 13 F. Supp. 2d at 69.

¹⁹⁴*Id.* at 70.

¹⁹⁵See Noah, *supra* note 89, at 379.

the peer-review system.¹⁹⁶ CME have no such screening mechanism, therefore the danger that undetectable, misleading information will be presented should have been given more weight. Thus, when in fact the pharmaceutical manufacturers are using CME for promotional purposes,¹⁹⁷ the FDA should be able to ensure that it is truthful, non-misleading and fairly balanced.

This does not mean that I disagree with the court's ruling that the ban of speech about off-label uses is unconstitutional. I agree with the court that this regulation is not narrowly tailored to either the interest in accurate and unbiased information or the interest in getting drugs on-label. The interests that this regulation serves can be taken care of by disclaimers as the *WLF I* court noted. "Full disclosure not only addresses all of the concerns advanced by the FDA, but addresses them more effectively. It is less restrictive on speech, while at the same time deals more precisely with concerns of the FDA and Congress."¹⁹⁸ But without affirming the interest in accurate and unbiased information, the second effect of the guidance – the regulation of the presentation of on-label uses – is left in doubt, as this relies solely on an interest in protecting doctors. The regulation of content is one that can pass constitutional muster, given that the same regulations are already applied to other forms of advertising and labeling. Courts have looked more favorably on content regulation than on flat bans on speech.

In addition, there is no substitute for this interest in regulation. In contrast, there are already adequate incentives for pharmaceutical manufacturers to get uses on label. Many insurance plans will only reimburse for on-label prescriptions.¹⁹⁹ Speech at CME is also a very narrow forum for discussion of off-label uses;

¹⁹⁶A peer review system is the editorial screening process by which medical journals evaluate articles submitted for publication. In the system, experts in the field evaluate submitted articles before they are approved for publication. See *id.* at 379-402.

¹⁹⁷This issue, when speakers are actually representing the pharmaceutical manufacturer, thus making their speech promotional, will be discussed in depth in Part IV, *infra*.

¹⁹⁸See *WLF I*, 13 F. Supp. 2d at 73. The standard that disclosure requirements must meet to regulate speech is lower than the standard that bans on speech must meet. The Supreme Court has applied a three-part test: 1) the disclosure requirements are reasonably related to the state's interest in preventing deception of consumers, and 2) there is no problem of vagueness and 3) they are not "unjustified or unduly burdensome." See *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985).

¹⁹⁹See 42 U.S.C. § 1395y(a)(1)(A) (2000) (Medicare does not cover treatments which are "not reasonable and necessary."). This is often interpreted to mean exclude treatments which have not been judged safe and effective by the FDA, i.e., an off-label

pharmaceutical manufacturers must still get uses on-label if they want to engage in more traditional advertising, such as print and television advertising, or to use their sales force to promote the use.²⁰⁰ These methods reach a far broader audience than CME. Lastly, FDA approval is still a factor in tort liability for pharmaceutical manufacturers and physicians. For manufacturers, FDA approval can sometimes provide a defense to product liability actions.²⁰¹ Conversely, overpromotion of drugs that dilute otherwise adequate warnings can give rise to liability.²⁰² For physicians, prescribing off-label involves a higher risk of medical malpractice because the FDA-approved use can be evidence of the appropriate standard of care.²⁰³ Although physicians will not be liable if the off-label use comports with the currently accepted medical practice in the community or reliable medical research, the threat of liability means that physicians will not take a manufacturer's word about the safety and efficacy of off-label use at face value, but instead will check that it is backed up by other reliable evidence. Therefore a manufacturer will always have more physician support for their on-label uses of products, when physicians no longer have to worry about whether an off-label use comports with currently accepted medical practice. These incentives to get new uses on-label still exist when speech about off-label uses at CME is allowed.

use.

²⁰⁰ *WLF I*, 13 F. Supp. 2d at 73.

²⁰¹ See Richard C. Ashcroft, *The Impact of the Washington Legal Foundation Cases on Pharmaceutical Manufacturer Practices in the United States*, 34 IND. L. REV. 95, 109 (2000) (noting that several states have enacted statutes that bar punitive damages when the manufacturer has complied with FDA regulations in bringing a product to market, including complying with packaging and labeling provisions. FDA approval is a factor considered by other jurisdictions that do not have a statutory defense.).

²⁰² See Restatement (Third) of Torts: Products Liability § 6d (1997) (manufacturers have a duty to warn prescribers); *Stevens v. Parke, Davis & Co.*, 507 P.2d 653, 661 (Cal. 1973) (“Although the manufacturer or supplier of a prescription drug has a duty to adequately warn the medical profession of its dangerous properties or of facts which make it likely to be dangerous, an adequate warning to the profession may be eroded or even nullified by overpromotion of the drug through a vigorous sales program which may have the effect of persuading the prescribing doctor to disregard the warnings given.”).

²⁰³ See *e.g., Ramon v. Farr*, 770 P.2d 131, 135 (Utah 1989) (holding that package inserts are one of several factors for consideration of whether the physician used the appropriate standard of care).

IV. Analysis: First Amendment Issues

In my view, neither the guidance document nor the *WLF I* decision is entirely correct because the entire scheme to regulate CME set out in the guidance document (and not contested in the WLF cases) does not conform to current First Amendment law governing speech. Specifically, the line the FDA drew to determine what was promotional and what was not does not conform to current First Amendment law on speech attribution because CME speakers do not always speak for the sponsoring pharmaceutical company and therefore their independent speech is not subject to regulation by the FDA. For this reason, the guidance document is over-inclusive in its classification of speech subject to regulation.

The issue of speech attribution, or representation, was not raised by either party or the court. All parties accepted without question the FDA's assertion that these 12 factors delineated promotional speech from non-promotional speech. But because the "speech" of the pharmaceutical company is expressed through financial sponsorship, one question that must be asked is "who is the speaker?". This is always a question where there is more than one potential speaker, a situation that is becoming more and more prevalent as institutions are "speaking" more and more often.

There may have been [...] a time when institutions did not often speak; when technology was less pervasive; when the question "who is the speaker?" seemed to be, and usually was, redundant; and when the question, "Is there a speaker?" seemed facetious. But that was another era for the First Amendment. Now much, if not most speech is institutional. Money and speech have become deeply intertwined because the medium of speech has become as central to its force as the message.²⁰⁴

The *WLF I* court assumed that the CME speaker *spoke for* the sponsoring pharmaceutical manufacturer. The court's assumption is clear from its statements when it decided whether the speech was conduct, commercial speech or core speech. First, it said "[the] sponsorship of CME seminars addressing and encouraging

that conduct is speech.”²⁰⁵ It goes on to say “the activities at issue are only ‘conduct’ to the extent that moving one’s lips is ‘conduct.’”²⁰⁶ Thus it seems that in the court’s thinking, the two form parts of the same activity.

The *WLF I* court was simply picking up the FDA’s own assumption when it devised the CME guidance document. The guidance states that:

the “intended use” of a drug or device refers to the objective intent of the persons legally responsible for the labeling of the product. This intent is determined by labeling claims, advertising matter, or oral or written statements by such persons or their *representatives*.²⁰⁷

Speakers at CME are not necessarily representatives of the pharmaceutical manufacturers. Indeed, many CME speakers – almost always unaffiliated doctors and researchers – would be surprised to find themselves representatives of the pharmaceutical company, according to the FDA, simply because they happen to accept a speaking engagement that a company funds. This forms the ground for several commentators’ unease at the regulation of CME; it seems counterintuitive to accept that a speaker at a CME seminar run by an independent CME provider should suddenly be positioned as the speaker for the pharmaceutical company because the pharmaceutical company has provided funding or suggested him as a potential presenter for the seminar.²⁰⁸

Attribution of speech makes more sense when considered in the context of the company distributing reprints of scientific articles; in that situation, the company has chosen to distribute that already-written, specific

²⁰⁵ *WLF I*, 13 F. Supp. 2d at 59.

²⁰⁶ *Id.*

²⁰⁸ In this section, when I consider CME activities that the guidance considers as factors of promotion (and therefore representation), I will use the example of when a pharmaceutical manufacturer suggests a speaker to a CME provider. Of course there are other activities included in the 12 factors and arguably these are most mild of any of them, but I choose the mildest in order to show how the guidance is over-inclusive in sweeping these things in. In Part B, I will look at more of the factors and try to establish which ones count as “representative speech” and which do not.

article and *adopted* the speech within it. But in the CME context, in many cases, the speaker enjoys a degree of autonomy from the sponsoring company; he or she, not the company, has ultimate control over the content of the speech. Although there could be situations where the pharmaceutical company sponsor is so involved in directing the CME conference that it does dictate exactly what the speaker says, the CME regulations at issue also sweep in situations where the pharmaceutical company merely suggests speakers or topics for presentation. In these situations, the connection between the speaker and the funding company is too tenuous to consider the speaker to be speaking for the pharmaceutical company. The fact that the manufacturer provided the means for the CME speaker to speak is not dispositive of representation; “subsidization is only one factor that must be considered when making judgments about the characterization of speech.”²⁰⁹

This issue is *a priori* to any consideration of the FDA’s regulation of CME. While it can regulate what pharmaceutical companies say, it cannot regulate what independent third parties say; thus if the speech cannot be attributed to the pharmaceutical company, the FDA has no authority to regulate it.²¹⁰ Because the line that the CME guidance document draws is over-inclusive in terms of the speech that can be attributed to the sponsoring pharmaceutical manufacturer, it thus results in restriction of some core as well as commercial speech. For example, if a pharmaceutical company suggests speakers or content, the speech presented at the CME will have to comply with the advertising, labeling and promotional regulations applicable only to pharmaceutical companies – regulations banning off-label speech, and comparative claims and claims not presenting the drugs with an FDA-approved “fair balance” of information.²¹¹ This restricts the speech of independent, third-party speakers – the CME speakers – who must now comply with even though they do not represent the pharmaceutical company.

²⁰⁹See Robert C. Post, *Subsidized Speech*, 106 YALE L.J. 151,154 (1996).

²¹⁰See *WLF I*, 13 F. Supp. 2d at 67 (“FDA has no objection to . . . distribution [of speech] from any source *other than the drug manufacturer*.”) (emphasis original). See also Kessler and Pines, *supra* note 21, at 2401-11 (“A person with no ties to a drug manufacturer can say anything he or she wants about a drug, it is neither labeling nor advertising.”).

²¹¹See Draft CME Guidance, 57 FED. REG. at 56,413 n.1.

Even if the FDA did try to assert authority to regulate the speech of persons other than the pharmaceutical manufacturers, an additional consequence if the speech is not attributable is that the speech would remain core, rather than commercial speech, necessitating a different regulatory analysis.²¹² This fact was acknowledged by the *WLF I* court when it stated that “[i]t is beyond dispute that when considered outside of the manufacturer promotion of their drug products, CME seminars . . . merit the highest degree of constitutional protection . . . [residing] at the core of the First Amendment.”²¹³ The FDA would have to meet a much higher bar in order to restrict non-commercial speech: “the government’s interest in preserving regulatory incentives would have to be shown to be among the most ‘compelling’ of interests – not merely a ‘substantial’ one.”²¹⁴

It is also problematic because the guidance document is a guide to enforcement. Basing its enforcement decisions on 12 factors in this document, the FDA would be using its enforcement power against the pharmaceutical company based on the speech of an (in my view) independent third party. Liability arises from the CME speaker’s speech; but it is not necessary, according to the guidance document, that the pharmaceutical manufacturer have control over the speech.²¹⁵ However, the pharmaceutical manufacturer played its part before the CME seminar occurs when it decided to fund and perhaps suggested speakers or content. If that was all that the manufacturer did, it had no editorial control over what the CME speaker said and no other part in the planning by the independent CME provider. Therefore, the pharmaceutical company would be responsible for speech it exercised no control over.

Thus the question of who is the speaker is of the greatest importance. The constitutional speech issues that must be considered are:

²¹² See Post, *supra* note 209, at 154 (“[S]ubstantive First Amendment analysis will depend on whether the citizen who speaks is characterized as a [. . .] functionary or as an independent participant in public discourse.”).

²¹³ *WLF I*, 13 F. Supp. 2d at 62.

²¹⁴ See Smith, *supra* note 52, at 983.

²¹⁵ See Final CME Guidance, 62 FED. REG. 64,074.

1)

Can the speech of CME speaker always be attributed to the sponsoring pharmaceutical manufacturer based on the 12 factors used in the *CME Guidance*? In other words, is the CME speaker necessarily the representational speaker for the pharmaceutical manufacturer?

2)

If the 12 factors do not delineate the appropriate line to define representational speech, what factors should be used?

The answers will establish the line between core and commercial speech. It will also establish when the pharmaceutical company is responsible for the speech of speakers at the CME conference.

A. Sponsorship as speech: theory and cases

1. Representational speech theory

Attribution is a difficult question, particularly because corporate speech²¹⁶ is necessarily accomplished by the speech of individuals associated with it – its employees and agents. “Attribution is, almost by definition, an uncontrollable phenomenon, since it is a product of third party observers and interpreters of events in specific context.”²¹⁷ The fact that the pharmaceutical

²¹⁶Speech by corporations is protected by the First Amendment. See *First Nat’l Bank of Boston v. Bellotti*, 435 U.S. 765 (1978).

²¹⁷See Bezanson and Buss, *supra* note 19, 1484.

company's speech is speech accomplished by funding²¹⁸ and by editorial decision-making,²¹⁹ while also recognized as speech protected by the First Amendment, presents another layer of complexity.

Randall Bezanson has written about concepts of "representational speech" in the area of institutional (including corporate) speech.²²⁰ "Representational speech is speech that does not represent the speaker's free communicative will but instead represents the speech of another."²²¹ Some ways that representative speech can happen is "when the content of a person's speech is dictated by another, perhaps through coercion or payment, or the voluntary choice of a speaker to express the views of another as an agent."²²² According to Professor Bezanson, the question of when a speaker speaks for himself or another is determined by "whether the speech was an intentional and voluntary act expressing the speaker's own beliefs and communicative free will."²²³ This is particularly important as commercial speech becomes more prevalent:

In the commercial speech setting, the representational speech concept has particular relevance to the "official capacity" question. . . – the relationship between the formal capacity in which one speaks and the 'ownership' of the views one is expressing for purposes of the First Amendment. . . The question in the corporate speech setting, therefore is, "Who is the speaker speaking for?" The answer to the question should depend not on the post hoc claim of the speaker, but rather, as in *Rust v. Sullivan*²²⁴ on the formal capacity in which the speaker claims to speak or is reasonably understood to speak. For purposes of the First Amendment liberty to speak, it is the speaker's own ideas and communicative free will that count.²²⁵

This view is supported by speech jurisprudence. Although there is no case law exactly on point to the

²¹⁸See *Buckley v. Valeo*, 424 U.S. 1, 21 (1976) (holding that the act of financial contribution involved a limited element of protected speech). See also *Gerawan Farming, Inc. v. Lyons*, 101 Cal.Rptr.2d 470, 491-92 (2000) (The First Amendment "may also be implicated in the use of money" as well as in speaking itself.).

²¹⁹Editorial decision-making is also considered a kind of speech protected by the First Amendment. See *Miami Herald Publ'g Co. v. Tornillo*, 418 U.S. 241, 258 (1974).

²²⁰See Bezanson, *supra* note 204.

²²¹See *id.* at 766.

²²²*Id.*

²²³*Id.*

CME sponsorship issue, there are similar cases in the areas of campaign contributions and government-subsidized speech. The common factor between these cases and the CME situation is that the court must determine under what circumstances the speech of an otherwise independent speaker can be attributed to the financial sponsor. Generally, although the Supreme Court has not articulated a general test for when speech is representational, their analysis generally holds that speech is only attributable to a financial sponsor when the sponsor has such editorial control over the speech that it displaces the speaker's "own ideas and communicative free will."²²⁶ In those situations, the speaker is thus speaking for the sponsor because the sponsor has control over the content. Because the 12 factors in the CME guidance do not necessarily implicate editorial control, the CME guidance sweeps in more speech than can properly be attributed to the financial sponsor.

2. Campaign finance cases

The most similar cases are the campaign finance cases.²²⁷ These also concern representational speech and deal with the ambiguity in whether the speech of a political candidate or a political action committee (PAC) can be said to represent the speech of the contributor. CME funding cases are very similar. Instead of funding political speech, the pharmaceutical manufacturers are funding scientific speech.²²⁸ In the CME context, the speech is expressed through the act of funding plus the suggestion of content. In these acts, the pharmaceutical manufacturer sponsor chooses from among different candidates, which indicates a preference for the candidate's

²²⁶See campaign finance cases, *infra* Part IV.A.2 and subsidized speech cases, *infra* Part IV.A.3. See also *Southworth v. Grebe*, 157 F.3d 1124, 1140 (7th Cir. 1998) (stating that "speech rights are implicated only where their interest allows [a financial investor] to exercise editorial control, in which case attribution would be proper").

²²⁷See e.g., *Buckley v. Valeo*, 424 U.S. 1, *Cal. Med. Assoc. v. Fed. Elec. Comm'n*, 453 U.S. 182 (1981) [hereinafter "CMA"].

²²⁸Although the court finds that financial contributions are speech when they are used to fund *political* speech, I find no logical reason that contributions to scientific speech should not similarly be speech, given that political and scientific speech are both at the core of the First Amendment. See note 124, *supra*.

views, character, and other attributes. Funding CME generally is not enough if it does not also include any editorial preference of content or speaker. In such a case, it is just a contribution to education and implies no narrower preference. It would be equivalent to giving money to a general candidate fund.

When a company suggests speakers or content, its action is equivalent to when an organization chooses to fund a certain candidate or PAC – it is a contribution based on sympathy of interests. It seems reasonable to say that the pharmaceutical manufacturer is interested in disseminating information on that particular topic or that it supports the views of that particular speaker.²²⁹ It may even choose that speaker because it believes that he will give a favorable presentation of its products. But sympathy of interests is not enough to make the CME speaker the mouthpiece for the pharmaceutical manufacturer, as the next cases will show.

The original campaign finance case in which the Court articulated its view of campaign finance as speech is *Buckley v. Valeo*.²³⁰ In *Buckley*, the limitations on campaign contributions were challenged on the ground that they limited the ability of the contributor to express his political views through the speech of another. The Court in that case dismissed the “representational speech” claim in that case, stating: “While contributions may result in political expression if spent by a candidate or association to present views to the voters, the transformations of contributions into political debate involves *speech by someone other than the contributor*.”²³¹ The Supreme Court declined to say that the interests of a candidate and a contributor were so intertwined that the candidate can be said to speak for the contributor. This is because of the vague nature of contribution. It “serves as a general expression of support for a candidate and his views, but does

²²⁹ See e.g., Holmer, *supra* note 100 (describing some of the reasons why pharmaceutical manufacturers sponsor CME).

²³⁰ 424 U.S. 1.

²³¹ *Id.* at 21. (emphasis added).

not communicate the underlying basis for the support.”²³² The act of contributing is an “undifferentiated, symbolic act.”²³³

The Supreme Court’s view on representational speech in campaign finance was further detailed in *California Medical Association (CMA) v. Federal Election Commission*.²³⁴ In this case, the CMA alleged that CALPAC, a PAC it funded, spoke for it and so its contributions to CALPAC should not be limited because it would restrict CMA’s speech. The court rejected this argument, finding no connection close enough between the two groups to make CALPAC’s speech also CMA’s by “speech by proxy”²³⁵: “CALPAC instead is a separate legal entity that receives funds from multiple sources and that engages in independent political advocacy. Of course, CMA would probably not contribute to CALPAC unless it agreed with the views espoused by CALPAC, but this sympathy of interests alone does not convert CALPAC’s speech into that of the CMA.”²³⁶

The analysis in this case relevant to CME is the proposition that “sympathy of interests” alone is insufficient to make speech representational. This affects the FDA’s assumption that the pharmaceutical manufacturer is sponsoring the speech because it, in some degree, agrees with the speech and wants to encourage its dissemination. The pharmaceutical manufacturer could even desire to disseminate the speech because the speaker views its products favorably and will promote its off-label uses. But under the court’s analysis in CMA, this “sympathy of interests”, without additional connection between the speaker and pharmaceutical manufacturer, is not enough to make the CME speaker the “mouthpiece” for the pharmaceutical manufacturer. Campaign contributions fail the test of representation because “it is often difficult if not impossible to trace the resultant speech to the purposeful and free decision of the donor to express his or her own views

²³² *Id.*

²³³ *Id.*

²³⁴ *CMA*, 453 U.S. 182.

²³⁵ *Id.* at 196.

²³⁶ *Id.*

by the contribution.”²³⁷ That is, although they might share similar views, their views are not one and the same. Thus, each idea expressed by the speaker cannot be automatically attributed to the pharmaceutical manufacturer sponsor as well. To regulate speech at CME, the FDA would need this sort of identity of speech because CME enforcement action would be very speech specific. The FDA would have to prove a violation by reference to specific sentences and words that stated the off-label use or misleading characterization. Identity between the CME speaker and the sponsoring company will not normally be located at this level of specificity.

3. Subsidized speech cases

Of course, the biggest difference between campaign finance and CME sponsorship is that a pharmaceutical manufacturer is the sole contributor. The Supreme Court found it relevant in its non-speech analysis that campaign contributors were only one of many supporters of the candidates or PACs.²³⁸ It could be argued that, in the CME context, the CME speaker does speak for the sole sponsor, it is more likely to be aware and take account of its sponsor’s views. For this argument, the subsidized speech cases are illuminative.

Government subsidization cases are similar to CME cases in their consideration of the question: if an entity (whether it be the government or a private corporation) pays money to fund speech, can the speaker be said to speak for the financial sponsor? As First Amendment scholar Robert C. Post put it: “Subsidized speech challenges two fundamental assumptions of ordinary First Amendment doctrine. It renders uncertain the status of speakers, forcing us to determine whether speakers should be characterized as independent

²³⁷ See Bezanson, *supra* note 204, at 777.

²³⁸ See *CMA*, 453 U.S. at 196 (“CALPAC instead is a separate legal entity that receives funds from multiple sources and that engages in independent political advocacy.”).

participants in the formation of public opinion or instead as instrumentalities of the government.”²³⁹

In government-subsidized speech, the government funds certain activities and places conditions on what their recipients can say. The government can play many roles, and whether it “speaks” in a certain situation is a contextual issue: “Does [the government] speak when it acts as a distributor of funds? As a sponsor of research, a tenure committee, or a speakers’ committee?”²⁴⁰ Indeed, in certain cases, the government can play similar sponsorship roles. The only difference is that the government is a public sponsor, and CME speech involves a private sponsor. In determining conditions on speech in these cases, the court must determine whether the speaker represents the government (in which case it can constrain the speaker’s speech) or whether the speaker remains independent (in which case it cannot).

Rust v. Sullivan is one of the most significant cases on subsidized speech, where the Supreme Court passed on the question of “who is the speaker.”²⁴¹ *Rust* concerned federal funding for family-planning services under Title X of the Public Health Service Act.²⁴² The family-planning clinics were not operated by government employees, but by independent contractors, normally private health-care organizations. Part of the Act expressly provided that the funds may not be used to “provide counseling concerning the use of abortion as a method of family planning or provide referrals for abortion as a method of family planning,”²⁴³ and may not engage in activities that “encourage, promote or advocate abortion as a method of family planning.”²⁴⁴ Recipients of federal funds were not prohibited from engaging in abortion-supporting activities, but any such activities were required to be “physically and financially separate” from the Title X projects. In addition, recipients of Title X funds were expressly directed that one approved response to a question about abortion

²³⁹See Post, *supra* note 209, at 152.

²⁴⁰Bezanson, *supra* note 204, at 1383.

²⁴¹500 U.S. 173 (1991).

²⁴²*Id.* at 177.

²⁴³42 C.F.R. § 59.8(a)(1) (1989).

²⁴⁴42 C.F.R. § 59.10(a).

was that a Title X project “does not consider abortion an appropriate method of family planning.”²⁴⁵

The prohibition on abortion counsel and the direction to withhold information about abortions was claimed violate the freedom of speech rights of the Title X personnel and of the women obtaining services from Title X clinics.²⁴⁶ It was argued that the prohibitions discriminated against the pro-abortion point of view in violation of the First Amendment.²⁴⁷ However, the Court found that this regulation constitutional because it determined that the doctors were *speaking for* the government and the government, when it spoke, was allowed to favor one viewpoint over another.²⁴⁸ While employed by the government, they were expressing the government’s ideas, and so the restrictions “[did] not in any way restrict the activities of those persons acting as private individuals.”²⁴⁹ In a similar situation, the FDA should be able to regulate speech when the CME speaker speaks for the manufacturer. However, there are situations covered within the CME guidance document where the speaker is expressing ideas of her own communicative free will; these should have the highest First Amendment scrutiny.

Rust has come to stand for the proposition that “for purposes of the First Amendment, . . .that even when individuals speak, their act of speaking is not protected by the First Amendment unless the ideas they express are the product of their own communicative free will.”²⁵⁰ **In *Rust***, the court found that the speaker was the government, not the individual. Because there were no individual speech rights implicated, the speech could be regulated.

²⁴⁵42 C.F.R. § 59.8(b)(5).

²⁴⁶*Rust*, 500 U.S. at 181.

²⁴⁷*Id.*

²⁴⁸*Id.* at 198-99 (“The regulations, which govern solely the scope of the Title X project’s activities, do not in any way restrict the activities of those persons acting as private individuals. The employees’ freedom of expression is limited during the time that they actually work for the project; but this limitation is a consequence of their decision to accept employment in a project, the scope of which is permissibly restricted by the funding authority.”).

²⁴⁹*Id.*

²⁵⁰Bezanson, *supra* note 204, at 767.

The Court elaborated further on the subsidized speech question when it decided *Legal Services Corporation v. Velazquez*.²⁵¹ **This case concerned the Legal Services Corporation (LSC)’s receipt of federal money for the legal representation of indigent persons. Congress enacted a statute that prohibited LSC representation in cases that “involve an effort to amend or otherwise challenge existing law in effect on the date of the initiation of the representation” – meant to address concerns that federal funds would be used to litigate welfare reform issues.**²⁵² **This statute was challenged on the ground that it violated free speech rights.**²⁵³

Distinguishing the case from *Rust v. Sullivan*, the Court found that the statute did infringe the rights of lawyers to speak and the clients to receive their speech.²⁵⁴ The *Velazquez* Court distinguished the case from *Rust* on a factual finding of whom the speaker represented. It found that in *Rust*, the “counseling activities of the doctors... amounted to governmental speech” and thus the government could restrict the speech to its favored viewpoint.²⁵⁵ In contrast, it found that the LSC program was designed “to facilitate private speech, not to promote a governmental message.”²⁵⁶ That is, the court said that an LSC-funded lawyer “speaks on the behalf of the client,” and “is not the government’s speaker.” It determined this based on the characteristics of a lawyer – a lawyer’s duty to is to *speak for* his client. The court clearly felt some discomfort in allowing a restriction on speech by the government that would interfere with a lawyer’s traditional relationship to his client. In addition, the adversarial nature of legal advocacy made it clear that it could not be government speech; an LSC-funded lawyer had to speak for his client because the government’s message would be conveyed by the prosecutor or government lawyer opposing him.²⁵⁷ The fact that the

²⁵¹ 531 U.S. 533 (2001).

²⁵² *Id.* at 538.

²⁵³ *Id.* at 536-37.

²⁵⁴ *Id.* at 537.

²⁵⁵ *Id.*

²⁵⁶ *Id.* at 542.

²⁵⁷ *Id.*

government regulation would have “distorted [the speech’s] usual functioning” was another indication that the speech was of a “private nature.”²⁵⁸ Based on the characteristics of the speaker and the fact that the control would have distorted the speech’s usual function, the Court found that the government subsidization funded private speech.

The Court worked very hard to distinguish the case from *Rust*, as the principles articulated here would seem to apply to *Rust* as well. The restrictions in *Rust* apply to restrict doctors’ professional judgment and advice in the same way that the *Velazquez* restriction restricted lawyers’ professional judgments. *Rust* has been criticized for that reason, and many commentators still feel that *Rust* and *Velazquez* are irreconcilable.²⁵⁹ However, given that *Velazquez* is the more recent case, it is the better indicator of the Court’s current position on representational speech.

B. A new standard for the CME Guidance

These cases demonstrate that whether speech is representational is “a very specific, context-bound judgment.”²⁶⁰ It depends on analysis into the exact circumstances at issue: the relationship between the sponsor and its fund recipient, the relationship between the fund recipient and the audience for its speech, and the norms generally associated with the role of the fund recipient. Because of this, it is difficult to devise clear

²⁵⁸ *Velazquez*, 531 U.S. at 543 (“The private nature of the speech involved here, and the extent of LSC’s regulation of private expression, are indicated further by the circumstance that the Government seeks to use an existing medium of expression and to control it, in a class of cases, in ways which distort its usual functioning.”).

²⁵⁹ See e.g., Jessica Russak Sharpe, *Legal Services Corp. v. Velazquez: Tightening the Noose on Patients’ Rights*, 81 N.C. L. REV. 1312 (2003).

²⁶⁰ See Post, *supra* note 209, at 156.

rules for classifying speech as representational.

Nonetheless, a few principles can be derived from these cases. First, from the campaign finance cases, “sympathy of interests” is not sufficient to make the speech representational. Some causal relationship between the funding and the speech is required. In CME, the fact that a pharmaceutical manufacturer favors a certain speaker because his views are in line with the manufacturers, and the fact that the manufacturer suggests him to speak at a particular seminar, without more, is not sufficient to make the speaker’s speech representative of the sponsoring manufacturer. However, the speech could be representational if the manufacturer not only favors a certain speaker, but a certain presentation as well, based on the adoption theory of representation. For example, if the CME speaker had a “canned” presentation that he regularly used, and the pharmaceutical company, knowing this, asked him to give this presentation at its CME, the pharmaceutical company can be considered to have adopted the speech of the speaker, because it knew of and approved of the speech beforehand. This is similar to why the speech in reprints of articles can be attributed back to the company. The company and the speaker are at a more specific level of identification; the pharmaceutical company has pre-approved the speech and thus established a traceable connection between it and the resulting speech.²⁶¹ But this is clearly a very contextual determination to be made on a case-by-case-basis.

Second, whether a speech is representational can also be examined on whether the sponsor’s conditions interfere with the speech’s “usual functioning.”²⁶² This is a corollary of the idea that a non-representative speaker must speak for himself – based on his “general ideas and own free will.” This is determined on a factual basis, whether the manufacturer has affected the *speech*, not the speaker. For example, I would not classify the manufacturer’s suggestion of a speaker as an interference with a speaker’s usual functioning – which at CME is to “offer expert teaching and best evidence information.”²⁶³ In the CME situation,

²⁶¹See Bezanson comment, *supra* note 237.

²⁶²*Velazquez*, 531 U.S. at 543.

²⁶³*See* Coyle, *supra* note 65, at 403. *See also* ACCME Standards for Commercial Support of Continuing Medical Education,

the speaker often still has control of the views he presents and is free to decide what his views are based on his expert opinion of the evidence. However, I would characterize a manufacturer's attempt to control the content (by scripting the speech or providing final editing of the speech) to be an interference with the speaker's usual functioning because it interferes with a speaker's ability to fulfill his function, much as the restrictions in *Velazquez* interfered with a lawyer's function.

Thus, I believe that all the factors considered in the guidance document²⁶⁴ should be factors that address the issue of whether the speaker was speaking from his "own beliefs and communicative free will."²⁶⁵ The focus of the document should be on the relationship between the CME speaker and the manufacturer, the first factor – "control of content and selection of presenters and moderators" – listed in the guidance. The other factors, such as whether the audience was chosen from sales and marketing lists, are irrelevant if the CME speaker did not transmit the pharmaceutical manufacturer's promotional message. These factors should be considered by the FDA perhaps as warning signs suggesting a need for further investigation, but should not be considered as evidence of promotion.

available at http://www.accme.org/accreditation/sec_acc_sta.asp (last visited March 29, 2003) ("The purpose of continuing medical education (CME) is to enhance the physician's ability to care for patients. It is the responsibility of the accredited provider of a CME activity to assure that the activity is designed primarily for that purpose.").

²⁶⁴Again, the 12 factors for consideration are:

- 1) control of content and selection of presenters and moderators
- 2) disclosures
- 3) focus of the program
- 4) relationship between provider and supporting company
- 5) providers involvement in sales or marketing
- 6) provider's demonstrated failure to meet standards
- 7) multiple presentations
- 8) audience selection
- 9) opportunities for discussion
- 10) dissemination
- 11) ancillary promotional activities
- 12) complaints.

Final CME Guidance, 64 FED REG. 64,074.. The guidance also notes that this is not an exhaustive list; "other factors may be appropriate for consideration in a particular case." *Id.*

²⁶⁵Bezanson, *supra* note 204, at 793.

The line that I propose still allows for FDA regulation of speech that is made on behalf of the pharmaceutical company. Other commentators take a more extreme view: that speaker-based distinctions should not be made at all.²⁶⁶ For example, Glenn C. Smith argues that to do so would be to “transmogrify” scientific speech into commercial speech, simply because the speaker is the pharmaceutical company rather than an independent scientist.²⁶⁷ In his view, this makes an arbitrary distinction between speakers even if the speech is exactly the same.

The problem is when commercial speech and non-commercial speech is indistinguishable in content. The line that the FDA draws is what the motivation behind the speech is, or who the speaker is. As one commentator put it, the regulation seems ill-fitting because “given the initial fully-protected status of off-label research, it seems unnatural that the same scientific work delivered to the same audience without any change of content should undergo a fundamental status change and default to lesser protection just because one additional speaker (the drug’s manufacturer) disseminates it.”²⁶⁸

Indeed, some courts have at times expressed a distaste for regulating speech based on the identity of the speaker, noting that “[t]he inherent worth of the speech in terms of its capacity for informing the public does not depend upon the identity of its source, whether corporation, association, union, or individual.”²⁶⁹

However, in the CME context, this view fails to take into account the changed inherent nature of the speech when promotion is injected into the speech’s creation. As one CME provider put it, “there [is] a difference between commercial speech and educational speech, and this boundary is worth protecting.”²⁷⁰ The com-

²⁶⁶This was the position taken by the WLF during the *WLF I* litigation. See *WLF I*, 13 F. Supp. 2d at 62 (“Plaintiff claims that because this speech merits full protection when uttered by a scientist or academic, the level of constitutional scrutiny should not change merely because a corporation wishes to enhance the distribution of that message.”) See also Pfizer First Amendment Comments, *supra* note 87, at 110-111 (“FDA’s current regulations single out drug manufacturers as the only class of speakers who cannot join freely in this public debate. Instead, manufacturers are governed by ‘pervasive, extensive regulations that tightly control what manufacturers may say about their products and attempt to transmogrify advertising and other promotional communications into comprehensive instructional messages.”); Scott Bass et al., *Off-Label Promotion: Is FDA’s Final Guidance on Industry-Supported Scientific and Educational Programs Enforceable?*, 53 FOOD & DRUG L.J. 193, 202 (1998).

²⁶⁷See Smith, *supra* note 52, at 966; Bass, *supra* note 266, at 202 (noting that “[t]he content of an independent, non-promotional program might be identical to one influenced or sought to be influenced by a manufacturer, yet FDA recognizes that it has no regulatory authority whatsoever over the former type of activity. Thus the net effect of FDA’s rules, if upheld, would be to prevent a particular class of speakers from expressing ideas that the agency itself acknowledges are beyond the scope of its regulatory power.”).

²⁶⁹*Bellotti*, 435 U.S. at 777..

²⁷⁰See Skolnick, *supra* note 40.

mentators and the courts suppose the existence of a seminar prior to the involvement of the manufacturer sponsor. While this must be true of reprints of scientific articles already published in a peer-reviewed journal before it came into the hands of the pharmaceutical manufacturers, the same cannot necessarily be said of CME. CME seminars are usually not ready-made before sponsoring company enters into the picture; it is speech that will always occur after the decision to sponsor is made.²⁷¹ Therefore, one can never guarantee that the CME will be the “same scientific work delivered to the same audience without any change of content”²⁷² whether the CME sponsor was involved or not. Given the complexity of scientific speech, whether promotional influence had an effect or not will be difficult to discern.²⁷³ The CME sponsor can always potentially control the speech. If it interferes to control the content of the speech, the FDA should be able to regulate the speech.

On the other hand, it could be argued that focusing only on actual editorial control will still allow some speech that has been influenced by the pharmaceutical industry. The FDA took this position in the Final CME Guidance.²⁷⁴ In its response to comments, the FDA rejected suggestions from commentators who “contended that the correct inquiry is whether a company has actually influenced a presentation,” and maintained its position that “the agency will examine whether and to what extent the company ‘is in a position to influence’ the presentation.”²⁷⁵ But problems of proof are not reason enough to sweep in activity that legally, according to principles derived from existing case law, cannot be attributed to the pharmaceutical company. When an entity is being held responsible, both civilly and criminally,²⁷⁶ for speech, it must be proven that it was its ideas and will behind the speech. The possibility of influence is not sufficient. Given the high value the Constitution and the courts put on scientific speech, it is better to leave out some speech

²⁷¹This excepts of course, where there is a canned speech that the pharmaceutical company agrees to fund. In that case, the pharmaceutical company will have adopted the speech and it would be subject to regulation as discussed above.

²⁷²See Smith, *supra* note 52, at 966.

²⁷³See discussion of the nature of scientific speech, *supra*, Part II.D.3.

²⁷⁴See 64 FED. REG. at 64,083.

²⁷⁵*Id.*

²⁷⁶The FDA has the power to enforce violations of acts under its jurisdiction criminally as well as civilly. See 21 U.S.C. § 352(f).

than to include too much.

V. Conclusion

Some might say that the exact line that the CME guidance draws does not matter because the FDA will not enforce minor violations and we can trust in the FDA for a more common sense determination of what is promotional. The FDA has admitted that it will use discretion in enforcing the CME Guidance.²⁷⁷ But if that is true, if the guidance is not a reflection of what the FDA will do, then it is no guidance at all. Given the consequences, this leaves pharmaceutical manufacturers in a state of uncertainty and chills their speech. If the FDA intends for its policies to comply with First Amendment law, as it claims in its request for comments, it should revise the factors to reflect First Amendment law, thus ensuring that valuable scientific speech is maximized.

This will not be the last time that the FDA will have to deal with First Amendment issues in formulating its policies and regulations. The FDA has a unique regulatory jurisdiction in that it occupies an area that concerns the commercial side of science and medicine. That means it will often find itself straddling the core/commercial speech line. In addition, as corporate speech becomes more common and as corporations increasingly assert their rights to speak, the FDA will particularly have to deal with more complex speech issues involving multiple speakers and speech by entities instead of individuals, as this example demonstrates. As corporations become more creative in using media, the FDA will have to deal with various new modes of speech, such as speech on the Internet, speech by virtual press releases, and speech by sponsorship in various configurations. In order to fulfill its regulatory goals of protecting the public health and further the development of life-saving new drugs, the FDA must develop a clear First Amendment compliance that

²⁷⁷In a letter to WLF responding to its citizen petition, the FDA stated that “[b]ecause the FDA must choose carefully where to deploy its limited resources, FDA is unlikely to initiate an enforcement action where the only evidence of an unapproved use is the distribution of enduring materials or sponsorship of CME” *quoted in Drug Makers Struggle With Evolving FDA Off-Label Policy*, FOOD AND DRUG LETTER, Mar. 15, 2002.

comports with representational speech doctrine in order to establish a workable division between commercial speech that it can regulate and core speech it cannot.