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May 23, 2001

Dockets Management Branch (HFA-305)
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Citizen Petition Regarding Manufacturer Dissemination of Non-Misleading Information Concerning Off-Label Uses of FDA-Approved Products

CITIZEN PETITION

The Washington Legal Foundation (WLF) hereby submits this petition under 21 C.F.R. § 10.30 to request that the Commissioner of Food and Drug withdraw the Federal Register Notice it published on March 16, 2000 entitled, "Decision in Washington Legal Foundation v. Henney." The notice purports to provide guidance to manufacturers regarding their rights to disseminate non-misleading information concerning off-label uses of FDA-approved products. By raising the threat of enforcement action against manufacturers that exercise their free-speech rights, the notice violates the First Amendment rights of manufacturers who wish to speak in a non-misleading manner about off-label uses of their products and the rights of WLF, its members, and others who wish to hear such speech. Subsequent letters sent by FDA to manufacturers indicate that FDA continues to adhere to its unconstitutional enforcement policy. WLF requests that FDA withdraw the March 16, 2000 Federal Register notice.

In its place, WLF requests that FDA issue a policy statement indicating its adherence to the decision of the U.S. District Court for the District of Columbia in *Washington Legal*

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Found. v. Friedman, 13 F. Supp. 2d 51 (D.D.C. 1998), *motion to alter or amend judgment denied,* 36 F. Supp. 2d 16 (D.D.C. 1999), *inj. modified,* 56 F. Supp. 2d 81 (D.D.C. 1999), *appeal dism'd,* 202 F.3d 331 (D.C. Cir. 2000). The district court decision could not be clearer that the policies enunciated in the March 16, 2000 Federal Register notice violate the First Amendment because they suppress far more speech than is necessary to serve FDA's legitimate policy interests. In particular, the district court held that the First Amendment protects the right of manufacturers to disseminate so-called "enduring materials" (medical textbooks and reprints of peer-reviewed medical journal articles) that discuss off-label uses of FDA-approved products. Although FDA appealed from the district court decision, it later abandoned the great majority of its appeal. *Washington Legal Found. v. Henney*, 202 F.3d 331 (D.D.C. 2000). Accordingly, the district court decision stands as a clear statement of First Amendment limitations on FDA's authority to restrict truthful speech. WLF requests that FDA issue a policy guidance indicating its willingness to abide by the district court's decision. A proposed policy statement is attached hereto as Exhibit A.

In light of the March 16, 2000 Federal Register notice and subsequent letters sent by FDA to manufacturers on this issue, WLF believes that its First Amendment rights are continuing to be violated. In the absence of FDA action to correct its violations, WLF will take appropriate legal action. Accordingly, WLF also requests that relevant FDA personnel be made aware of the district court's holdings regarding First Amendment issues. Such personnel need to be made aware that violation of constitutional rights spelled out in authoritative court rulings may render them personally liable for payment of monetary damages, including punitive damages.

A. ACTION REQUESTED

FDA published a Federal Register Notice on March 16, 2000 entitled, "Decision in Washington Legal Foundation v. Henney." *See* 65 Fed. Reg. 12486 (Mar. 16, 2000) (attached hereto as Exhibit B). WLF requests that FDA withdraw that Notice.

In its place, WLF requests that FDA issue a policy statement that indicates FDA's willingness to adhere to the decision of the district court in *WLF v. Friedman*. The statement should indicate that manufacturers will not be subject to enforcement action for disseminating enduring materials that contain truthful information about off-label uses of FDA-approved products. The statement should also indicate that manufacturers will not be subject to enforcement action for providing support to scientific and educational activities (hereinafter "Continuing Medical Education activities" or "CME") along the lines outlined by the district court as constituting protected First Amendment activities.

B. INTERESTS OF PETITIONER

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

WLF has for many years been actively involved in efforts to decrease FDA restrictions on the flow of truthful information about such off-label uses. For example, WLF filed a Citizen Petition on October 22, 1993, requesting much the same relief requested

herein. *See* Docket No. 92N-0434/CP1 (attached hereto as Exhibit C). After FDA's denial of the 1993 Citizen Petition, WLF filed suit against FDA in 1994 in U.S. District Court for the District of Columbia; the suit sought a determination that FDA's policies regarding manufacturer dissemination of enduring material containing off-label information, and regarding manufacturer support of CME, violated the First Amendment. The district court ruled in WLF's favor on those issues in 1998 and 1999.

C. STATEMENT OF GROUNDS

Congress adopted the Federal Food, Drug, and Cosmetic Act (the "FDCA"), 21 U.S.C. §§ 301 *et seq.*, in 1938 to regulate the sale of drugs and medical devices to the public. In 1976, Congress adopted the Medical Device Amendments of 1976 (the "MDA"), 21 U.S.C. § 360c *et seq.*, to give it greater regulatory authority over medical devices.

Section 505(a) of the FDCA, 21 U.S.C. § 355(a), provides that no "new drugs" may be introduced into interstate commerce unless they are approved by FDA. The MDA imposes similar restrictions on new medical devices. Once FDA has approved a drug or device for introduction into interstate commerce, it has only limited statutory authority to control dissemination of information regarding the product. For example, FDA is authorized by statute to restrict what manufacturers have to say about their drugs and medical devices to the extent that such materials constitute "labeling" of those products within the meaning of § 201(m) of the FDCA, 21 U.S.C. § 321(m). FDA's statutory authority also extends to "advertisements" of prescription drugs (21 U.S.C. § 352(n)) and a small subset of medical devices referred to as "restricted" devices, *i.e.*, hearing aids (21 U.S.C. § 352(q)). The FDCA grants FDA no authority to control what those other than manufacturers and distrib-

utors say about the proper uses of FDA-approved drugs and medical devices.

The Importance of Off-Label Uses. When it approves a drug or medical device for introduction into interstate commerce, FDA reviews the product labeling. The labeling sets forth the indications approved by FDA. FDA requires all such drugs or devices to bear labeling which list their approved uses, and prohibits such labeling from listing any use that has not been approved by FDA.

The medical community's knowledge regarding the safety and efficacy of FDA-approved drugs and devices inevitably outpaces FDA-approved labeling. Physicians who regularly work with such drugs and devices learn of safe and efficacious uses for the drugs/devices that are not included within the labeling (generally referred to as "off-label" uses). In some fields such as oncology (the study and treatment of cancer in humans), the great majority of medically-accepted treatments involves off-label uses of FDA-approved drugs and medical devices. Accordingly, were doctors limited to using therapeutic products only as labeled, doctors would be providing sub-optimal care to their patients. In many cases, doctors simply could not treat their patients properly without resort to off-label uses. Indeed, just this year, the U.S. Supreme Court officially recognized off-label treatments as an important part of medical care in this country. *See Buckman Co. v. Plaintiffs' Legal Committee*, 121 S. Ct. 1012, 1018, 1019 n.5 (2001) ("'[O]ff-label' usage of medical devices (use of a device for some other purpose than that for which it has been approved by the FDA) is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine. . . . Off-label use is widespread in the medical community and often is essential to giving patients optimal medical care, both of

which medical ethics, FDA, and most courts recognize."). WLF's 1993 Citizen Petition provides more detail regarding the particular importance of off-label uses in certain medical fields, such as oncology and orthopedic surgery.

A corollary to the need for doctors to employ off-label uses of therapeutic products is that they must be able to learn which such uses are medically recognized. The need for knowledge does not stop with graduation from medical school; new drugs and devices are constantly entering the market, and new uses for these products are constantly being discovered. The discovery that an approved product is beneficial in treating an off-label condition is of no help to a patient unless his/her physician knows about that use. Accordingly, it is highly important (both to the nation and (presumably) to FDA) that information about new uses be widely disseminated within the medical community. Disseminating this information takes both effort and resources. Manufacturers -- who have both the necessary resources and the incentive to exert the necessary effort -- have traditionally played a large and beneficial role in supporting the dissemination of information about new uses of marketed products. For example, they have arranged for the distribution of textbooks and reprints from medical journals. They have helped support continuing medical education (CME) programs. They have helped sponsor scientific seminars and symposia at which peers discuss their cutting-edge research.

FDA Crackdown on Dissemination of Off-Label Information. Despite its endorsement of off-label uses as an important part of medical care, FDA for the past decade has been openly hostile to manufacturer dissemination of off-label information. Beginning no later than 1992, FDA adopted a policy designed to restrict manufacturer distribution of

enduring materials. The policy declared that any such unsolicited distribution constituted unauthorized "labeling" of the products discussed and rendered the manufacturer's entire stock of the drug or device "misbranded" and therefore subject to seizure. FDA took that position regardless of the independence of the publisher of the enduring materials, regardless whether the materials were accompanied by a sales solicitation, and regardless whether the manufacturer made any effort to highlight discussion of its products within the materials distributed.

Initially, the FDA policy was not set forth in any formal fashion. Rather, FDA set forth its policy through a series of letters and telephone calls to drug manufacturers in which FDA warned the manufacturers against distributing enduring materials in which off-label uses of their products were discussed. Examples of such FDA actions were set forth in the 1993 Citizen Petition. Later, the FDA policy was formalized through issuance of two guidance documents. *See* "Guidance to Industry on Dissemination of Reprints of Certain Published, Original Data," 61 Fed. Reg. 52800 (Oct. 8, 1996) (the "Reprint Guidance"); "Guidance for Industry Funded Dissemination of Reference Texts," 61 Fed. Reg. 52800 (Oct. 8, 1996) (the "Textbook Guidance").[1] Enforcement of the Reprint Guidance and the Textbook Guidance was formally enjoined by the district court in connection with its 1998 decision in *WLF v.*

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[1] Congress signaled its displeasure with the Reprint Guidance and the Textbook Guidance when in 1997 it adopted a somewhat more relaxed policy on manufacturer dissemination of enduring materials containing discussion of off-label uses of FDA-approved products. *See* § 401 of the Food and Drug Administration Modernization Act of 1997 ("FDAMA"), 21 U.S.C. §§ 331(z) and 360aaa, *et seq.* Section 401 of FDAMA took effect in 1998, after FDA adopted implementing regulations. 21 C.F.R. Part 99. Although the Reprint Guidance and the Textbook Guidance have never formally been withdrawn, FDA has subsequently asserted that the adoption of the regulations implementing FDAMA § 401 "superseded" the Reprint and Textbook guidances.

Friedman.

Similarly, FDA became openly hostile to manufacturer support of CME activities. In 1991, it issued a preliminary draft of a policy (the "Draft Concept Paper") that would have severely limited the ability of manufacturers to provide financial support for CME activities at which the manufacturer's product was to be discussed. That preliminary draft engendered such a firestorm of criticism that in 1992 FDA issued a somewhat relaxed version of that policy entitled, "Draft Policy Statement on Industry-Supported Scientific and Educational Activities" (the "Draft Policy"). *See* 57 Fed. Reg. 56412 (Nov. 27, 1992). Although the 1992 policy remained in draft form for many years and although it purported to be merely a "safe harbor" document,[2] FDA made clear through its enforcement activity that it expected manufacturers to comply fully with the terms of the Draft Policy. Indeed, enforcement activity demonstrated that FDA deemed itself free to go beyond the terms of the Draft Policy in restricting manufacturer support of CME, and that FDA policy in this area was more restrictive than as set forth in the Draft Policy. For example, FDA has sent out numerous Warning Letters to manufacturers who supplied samples of their medical devices for use at CME activities at which off-label uses of those devices was demonstrated. Details of that enforcement activity were set forth in the 1993 Citizen Petition. The Draft Guidance was adopted as final by FDA in December 1997 with minor modifications (the "CME Guidance"). *See* 62 Fed. Reg. 64,093-64,100 (Dec. 3, 1997). Enforcement of the CME

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[2] The Draft Policy explained that FDA was creating a "safe harbor" policy whereby manufacturers who complied with the terms of the policy would not be subject to FDA enforcement action based on their support of CME activities. FDA further explained that compliance with the Draft Policy was voluntary in the sense that failure to comply would not by itself be deemed evidence of violation of FDA requirements.

Guidance was enjoined by the district court in 1998 in connection with its 1998 decision in *WLF v. Friedman,* to the extent that it could be interpreted as prohibiting a manufacturer from "suggesting content or speakers" to a CME provider in connection with a CME activity for which the manufacturer was providing financial support. On appeal, FDA insisted that it had no such policy, that its history of enforcement activity should not be construed as establishing any policy whatsoever in this area, and that the CME Guidance was nothing more than a "safe harbor" document -- meaning that manufacturer non-compliance with the CME Guidance could never be the basis for FDA enforcement action. The court of appeals accepted that representation from FDA; accordingly, it held that the controversy over the CME Guidance was moot, dismissed FDA's appeal, and vacated the district court's injunction with respect to the CME Guidance. *WLF v. Henney,* 202 F.3d at 335-37.[3]

WLF Litigation. Following FDA's denial of its 1993 Citizen Petition, WLF filed suit against FDA in 1994 in U.S. District Court for the District of Columbia. *Washington Legal Found. v. Kessler,* No. 1:94CV01306 (RCL). The complaint alleged that FDA was violating the First Amendment rights of WLF and its members by restricting manufacturer dissemination of enduring materials and manufacturer support of CME activities. In 1995, the district court denied FDA's motion to dismiss the case, finding that WLF was a proper plaintiff and that the case was ripe for review. *Washington Legal Found. v. Kessler,* 880 F.

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[3] The result, of course, is to leave manufacturers with virtually no guidance regarding FDA's views on the extent to which manufacturers may support CME activities. While the CME Guidance provides manufacturers with some guidance regarding limited steps they can take to support CME without fear of FDA objection, the CME Guidance says absolutely *nothing* regarding steps that manufacturers may *not* take to support CME activities.

Supp. 26 (D.D.C. 1995). After extensive discovery, the parties filed cross motions for summary judgment in 1997.

On July 30, 1998, the district court granted WLF's motion for summary judgment and denied FDA's cross-motion for summary judgment. *Washington Legal Found. v. Friedman*, 13 F. Supp. 51 (D.D.C. 1998) ("*WLF I*"). The court rejected FDA's initial argument that the challenged policies regulated conduct instead of speech and thus were not subject to First Amendment review. The court explained, "[T]he activities at issue in this case are only 'conduct' to the extent that moving one's lips is 'conduct,' or to the extent that affixing a stamp and distributing information through the mails is 'conduct.' . . . This court is hard-pressed to believe that the agency is seriously contending that 'promotion' of an activity is conduct and not speech, or that 'promotion' is entitled to no First Amendment protection." *Id.* at 59. The court then determined that the speech at issue should be deemed "commercial speech" and thus that its regulation should be subject to review under the standards set forth in *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n,* 447 U.S. 557 (1980).[4] *Id.* at 62-66. The court rejected FDA's contention that the speech for which WLF sought dissemination (peer-reviewed enduring materials) could be deemed inherently misleading (and thus not subject to commercial speech protection) simply because FDA had not approved it; the court explained:

[I]n asserting that any and all scientific claims about the safety, effectiveness,

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[4] Under *Central Hudson*, the government may regulate commercial speech that is neither inherently misleading nor related to an unlawful activity only upon a showing that: (1) the government has a substantial interest that it seeks to achieve; (2) the regulation directly advances the asserted interest; and (3) the regulation serves that interest in a narrowly tailored manner. *Id.* at 566.

> contraindications, side effects, and the like regarding prescription drugs are presumptively untruthful or misleading until FDA has had the opportunity to evaluate them, FDA exaggerates its overall place in the universe.

Id. at 67. The Court explained that, notwithstanding the absence of FDA evaluation, there are sound reasons for believing that peer-reviewed journal articles and medical texts contain accurate information.

Applying *Central Hudson*, the court determined that although FDA had a substantial interest in encouraging manufacturers to bring new uses for a product "on label," and although the FDA speech restrictions directly advanced that interest (by providing manufacturers with strong incentives to apply for new labeling authority in order to increase what they could say about the new uses), *id.* at 70-72, the FDA speech restrictions violated the First Amendment because they were more extensive than necessary to achieve the agency's permissible goals. *Id.* at 72-74. The court determined that FDA's goals could be fully achieved were it to require "full, complete, and unambiguous disclosure by the manufacturer" that the enduring materials being disseminated (or the CME activities being financed) contained discussion of off-label product uses not approved by FDA. *Id.* at 73. The court entered an injunction that provided in pertinent part:

> Defendants SHALL NOT in any way prohibit, restrict, sanction or otherwise seek to limit any pharmaceutical or medical device manufacturer or any other person:
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> a) from disseminating or distributing 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 uses of drugs or medical devices other than those approved by FDA and regardless of whether such article reports the original study on which FDA approval of the drug or device in question was based;
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> 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 uses of drugs or medical devices other than those approved by FDA; or

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 uses of drugs and medical devices other than those approved by FDA are to be discussed.

Id. at 73-74.

FDA thereafter filed a motion to alter or amend the judgment. FDA's motion noted that between the time that WLF had filed its motion for summary judgment (in November 1997) and the time that the court granted that motion, Congress had passed FDAMA and FDA had issued regulations implementing § 401 of FDAMA (relating to manufacturer dissemination of enduring materials that discuss off-label uses). Noting that § 401 of FDAMA came within the literal terms of the court's injunction, FDA asked the court to modify its injunction so as to: (1) limit its scope to the Reprint Guidance, the Textbook Guidance, and the CME Guidance; and (2) state explicitly that the injunction was inapplicable to § 401.

On February 16, 1999, the court denied FDA's motion. *Washington Legal Found. v. Friedman*, 36 F. Supp. 2d 16 (D.D.C. 1999) ("*WLF II*"). The court stated that FDA was "mistaken about the intended scope of the Court's opinion and injunction." *Id.* at 18. The court explained that it had not intended merely to address the validity of the three guidance documents -- which, after all, had not even existed at the time that WLF filed suit in 1994 -- but rather to address the validity of "the policies underlying the Guidance Documents,"

policies which had pre-existed the issuance of those documents. *Id.* Thus, it concluded, "The Court's decision and injunction must be read to apply to the underlying policies of the FDA, and not merely to the express provisions of the Guidance Documents." *Id.* The court concluded, nonetheless, that an additional round of briefing was warranted before it determined whether § 401 of FDAMA fell within the terms of the existing injunction, because the parties' previous briefs -- filed before FDAMA took effect -- had not addressed that issue. *Id.* at 20.

Following additional briefing, the court on July 28, 1999 once again denied FDA's motion to amend the judgment and issued a "final amended order granting summary judgment and permanent injunction." *Washington Legal Found. v. Henney,* 56 F. Supp. 81 (D.D.C. 1999) ("*WLF III*").[5] The court made clear that § 401 of FDAMA and its implementing regulations fell within the terms of the prior injunction, and thus it enjoined enforcement of those provisions. *Id.* at 88. The court repeated its *Central Hudson* analysis from *WLF I* and concluded that FDAMA was not sufficiently narrowly tailored to survive scrutiny under that analysis. *Id.* at 87. The court concluded that § 401 of FDAMA amounted to an unconstitutional condition because it required manufacturers unwilling to subject themselves to an onerous supplemental application process to waive their First Amendment rights to speak truthfully regarding their products: "The supplemental application requirement of [FDAMA] amounts to a kind of constitutional blackmail -- comply

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[5] The wording of the final injunction was altered slightly, with WLF's consent, from the July 1998 wording, in order to allay FDA's concern that the injunction might be read as permitting manufacturer dissemination of information about products that had never been approved by FDA for *any* use.

with the statute or sacrifice your First Amendment rights. It should go without saying that this tactic cannot survive judicial scrutiny." *Id.*[6] The court doubted the sincerity of FDA's claims that unsolicited manufacturer dissemination of enduring materials relating to off-label use raised serious health concerns, stating:

> [FDA's] true perception of the speech at issue here is revealed by their attitude toward the same speech disseminated under other circumstances. For example, [FDA has] no concern over the exchange of article reprints and reference texts among physicians; more telling, defendants do not even object to a manufacturer providing such information to a health care provider upon such person's request. Only when the manufacturer initiates the exchange does the FDA choose to label the speech false or inherently misleading. The Supreme Court has recently addressed this situation with the following observation: "Even under the degree of scrutiny that we have applied in commercial speech cases, decisions that select among speakers conveying virtually identical messages are in serious tension with the principles undergirding the First Amendment." *Greater New Orleans Broad. Assoc. v. United States,* 527 U.S. 173 (1999).

Id. at 86-87.

FDA appealed from that decision. In its appellate briefs, FDA challenged the merits of the district court's decision, arguing that it had every right to restrict manufacturers' activities in the manner that WLF alleged. At oral argument before the appeals court, however, FDA radically shifted its position. FDA attorneys argued: (1) the Reprint Guidance and the Textbook Guidance had been "superseded" by FDAMA and therefore the validity of those documents was no longer at issue; (2) § 401 of FDAMA was a mere "safe harbor" provision that imposed no new obligations on manufacturers but rather merely

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[6] At no time in connection with its motion to amend did FDA suggest to the district court that FDAMA § 401 was a mere "safe harbor" provision that did not prohibit any speech. Rather, the thrust of FDA's entire argument was that § 401 imposed restrictions that were fully justified when analyzed under First Amendment case law. It was only later, during oral argument in the court of appeals, that FDA adopted the fanciful "safe harbor" interpretation of § 401.

provided them with a blueprint for avoiding sanctions that might otherwise be imposed on them based on other provisions of the FDC Act; and (3) the CME Guidance was similarly a mere "safe harbor" document that imposed no obligations on manufacturers.[7]

The appeals court responded with a decision that dismissed FDA's appeal without reaching the merits of the First Amendment issues raised by the case. *Washington Legal Foundation v. Henney,* 202 F.3d 331 (D.C. Cir. 2000) ("*WLF IV*"). The court said that it would accept FDA's limiting construction of § 401, even though (as the court noted) the result of that "safe harbor" construction was to deprive § 401 of all teeth.[8] *Id.* at 335 ("Were a pharmaceutical company to send out reprints of an article devoted to its drug's off-label uses to thousands of physicians tomorrow, the government agreed -- indeed stipulated -- that the agency would draw no independent prosecutorial authority from FDAMA to buttress

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[7] In fairness to the FDA attorneys, it should be noted that they had consistently taken the position that the CME Guidance was a mere "safe harbor" document. However, the "safe harbor" argument did not address WLF's argument that FDA had adopted a policy categorically prohibiting certain types of manufacturer support of CME and that that policy had long preceded adoption of the CME Guidance in 1997.

[8] That construction appears to be at odds with the plain language of one portion of § 401 (codified at 21 U.S.C. § 331(z)), which specifically prohibits manufacturer "dissemination of information in violation of" § 401. The appeals court was nonetheless willing to defer to FDA's interpretation of its own statute, given that the result was to reduce FDA's enforcement powers. But the court explicitly warned that FDA would be bound by that limiting construction in the future, regardless whether FDA still perceived a tactical litigation advantage in sticking with that construction:

> The government has announced here nothing less than an official interpretation of the FDAMA which the agency may not change unless it provides a reasoned explanation for doing so. . . . It goes without saying that an attempt to evade judicial review in this case would hardly be a legitimate basis.

Id. at 336-37 (citations omitted).

any enforcement proceeding.") The appeals court also accepted FDA's contention that the CME Guidance was nothing more than a "safe harbor" document and 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 the law." *Id.* at 335-36. Thus, the appeals court determined, there was no longer a live controversy between the parties regarding "whether the statute and [CME] guidance document facially violate the First Amendment." *Id.* at 336.[9] In light of that mootness determination, the appeals court "vacate[d] the district court's decisions and injunctions insofar as they declare the FDAMA and the CME Guidance unconstitutional." *Id.* at 337.

All that remained for decision was the district court's July 1998 determination (in *WLF I*) that the Reprint Guidance and the Textbook Guidance violated the First Amendment and its February 1999 determination that the injunction against FDA extended not just to those two documents but to "the policies underlying the Guidance Documents," which policies had pre-existed the issuance of those documents. *WLF II,* 36 F. Supp. 2d at 18. In light of FDA's extraordinary about-face at oral argument and its position that the validity of the Reprint Guidance and the Textbook Guidance was no longer at issue, the appeals court determined that FDA had abandoned its appeal on those issues; in other words, the appeals court determined that the district court's ruling on those issues remained intact. The court held that it was irrelevant that FDA was contending that FDAMA § 401 had "superseded"

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[9] In disposing of the CME issue on mootness grounds, the court focused exclusively on the CME Guidance and did not address WLF's claim that the actual enforcement policy that FDA had in place at the time that suit was filed in 1994 (more than three years before the CME Guidance was adopted) violated the First Amendment.

the Reprint Guidance and the Textbook Guidance because:

> [E]ven if they were not superseded, they would be unenforceable, since the FDA does not challenge on appeal the district court's decision and injunction insofar as they pertain to the Enduring Materials Guidances. *See WLF I,* 13 F. Supp. at 74.

WLF IV, 202 F.3d at 334 n.4. To drive home its conclusion that, by dismissing the appeal and vacating portions of the district court's decisions and injunction, it was not disturbing those portions of the district court opinion from which FDA had abandoned its appeal, the court of appeals concluded its decision by stating:

> [W]e certainly do not criticize the reasoning or conclusions of the district court. As we have made clear, we do not reach the merits of the district court's First Amendment holdings and part of its injunction still stands.

Id. at 337 n.7. The appeals court thus could not have been clearer that while a portion of the district court's decisions had been vacated, left intact was that portion of the decisions that had struck down the Enduring Materials Guidances and had held that the FDA policies underlying those guidance documents were unconstitutional because they violated WLF's First Amendment rights. FDA did not seek review of the appeals court's decision, and its mandate is now final.

FDA's Response To Its Appeals Court Defeat. Almost immediately after the appeals court issued its decision in February 2000, FDA began backtracking from the concessions that it had made in the appeals court and tried to characterize the appeals court decision as an FDA victory. FDA officials told the press that the federal court determinations that it had violated the First Amendment were inconsequential because the specific policies that had been struck down (the Enduring Materials Guidances) were no longer policies enforced by FDA.

FDA's effort at "spin" culminated in issuance of the March 16, 2000 Federal Register notice, "Decision in Washington Legal Foundation v. Henney" (the "Notice"). The Notice indicated that FDA felt at liberty to suppress manufacturer dissemination of enduring materials to the same extent as it had been doing prior to WLF's lawsuit; the Notice mischaracterized the appeals court's decision as having essentially wiped the slate clean. The Notice stated:

> [T]he District of Columbia Circuit vacated the district court's decisions and injunctions insofar as they declared section 401 and the CME guidance document unconstitutional. See slip op. at 10. (The other two guidance documents [*i.e.*, the Enduring Materials Guidances], pertaining to the dissemination of certain written materials about "new uses," had been superseded by FDAMA and its implementing regulations and were not at issue in the Court of Appeals.) The D.C. Circuit's decision was based on its conclusion that there is no case or controversy to provide a basis for WLF's facial First Amendment challenge.

65 Fed. Reg. at 14287.

As is readily apparent from the preceding discussion, that statement in the Notice mischaracterizes the appeals court's decision in several significant respects. First, the Notice is incorrect in stating that Enduring Materials Guidances were not "at issue" before the appeals court because they "had been superseded by FDAMA." Rather, the appeals court explicitly held that the Enduring Materials Guidances were "unenforceable" because they had been struck down by the district court on First Amendment grounds and "the FDA does not challenge on appeal the district court's decision." *WLF IV,* 202 F.3d at 334 n.4. Second, FDA indicated that the only issues before the appeals court were the validity of the Enduring Materials Guidances, the CME Guidance, and § 401 of FDAMA. That is clearly incorrect, as even a cursory reading of *WLF II* makes clear. The district court stated in *WLF II* that its injunction covered not only the Enduring Materials Guidances but also "the policies

underlying the Guidance Documents." *WLF II,* 36 F. Supp. 2d at 18. Thus, the decision striking down "the policies underlying" the Enduring Materials Guidances was before the appeals court; because FDA ended up not challenging that decision, it remains intact today. The Notice was highly misleading in suggesting otherwise. Third, the Notice mischaracterized the decision in stating that it "was based on" the absence of a case or controversy regarding "WLF's facial First Amendment challenge." While a portion of the decision "was based on" that ground, the remainder of the decision sustained in large measure the district court's decision upholding WLF's facial challenge.

After badly mischaracterizing the appeals court decision, The Notice asserted that FDA felt itself free to proceed as it had before WLF first filed suit. For example, the Notice described § 401, noting that that section provides a "safe harbor" whereby under very limited conditions manufacturers may disseminate enduring materials that outline off-label uses of their products without fear of FDA enforcement action. 65 Fed. Reg. at 14287. The Notice then asserted, "If section 401 did not exist, the government could use such dissemination as evidence in establishing a manufacturer illegal distribution of a new drug or device for a 'new use,' and in establishing that the product is misbranded or, in the case of a device, adulterated as well as misbranded." *Id.* Later and to the same effect, the Notice asserted, "If a manufacturer dos not comply [with § 401], FDA may bring an enforcement action under the FDCA, and seek to use journal articles and reference texts disseminated by the manufacturer as evidence that an approved product is intended for a 'new use.'" *Id.* Those assertions are legally incorrect in light of *WLF I* and *WLF II,* which hold that the First Amendment bars FDA from sanctioning or otherwise seeking to limit manufacturers from

disseminating enduring materials to doctors. Indeed, in striking down previous FDA policies that had sought to suppress manufacturer dissemination of enduring materials, the district court explicitly rejected FDA's arguments that it ought to be permitted to use such dissemination as evidence of illegal distribution of a product for an unapproved "new use" or as evidence that the product is misbranded or adulterated.

The Notice also marked FDA's apparent abandonment of its position (argued vociferously in the appeals court) that the CME Guidance is a mere "safe harbor" document. While previously, FDA had insisted that the CME Guidance established no minimum standards and that no negative inference would be drawn based merely on a CME provider's failure to adhere to one or more of the Guidance's 12 "factors" (*WLF IV*, 202 F.3d at 335-36), the Notice takes a contrary position: "FDA intends to take [the 12 factors] into account in exercising its enforcement discretion in relation to industry-supported scientific and educational activities." 65 Fed. Reg. at 14287.[10]

The effect of FDA's publication of the Notice has been dramatic. Following the district court's rulings, manufacturers had generally felt at liberty to disseminate truthful enduring materials in the manner outlined in those rulings. The court of appeals's decision did not materially alter the district court ruling with respect to dissemination of enduring materials. However, after FDA issued the Notice on March 16, 2000 and indicated that it no

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[10] In an apparent effort to square that statement with its prior position, FDA added, "The CME guidance document, however, does not itself have the force and effect of law." *Id.* Such semantic quibbling misses the point. Regardless whether the CME Guidance has "the force and effect of law," the relevant question is whether FDA has in place a policy that failure to adhere to one or more of the 12 factors can be the basis for an FDA enforcement action. If the answer to that question is now "yes," then FDA's position is not now as it was represented to the appeals court.

longer felt bound to comply with the district court's rulings with respect to enduring materials, many manufacturers were understandably reluctant to continue to disseminate enduring materials that discussed off-label uses of their products. The result was a precipitous decrease in such dissemination, to the detriment of doctors and patients across the nation.

FDA's disregard of the district court's First Amendment rulings has not been confined to the Notice. That disregard has also found its way into enforcement letters sent by FDA directly to manufacturers. For example, on November 27, 2000, FDA's Center for Devices and Radiological Health (CDER) sent a letter to New Star Lasers, Inc. (the manufacturer of a medical device used in dermatology) regarding a peer-reviewed medical journal article that New Star had distributed to doctors. A copy of the letter is attached as Exhibit D. The letter stated:

> Item 2 of your letter indicates that you are distributing journal articles with a label that reads, "Wrinkle Treatment Indication Pending FDA Clearance." We object to the use of this language on your journal reprints because your device has not been cleared by the agency for wrinkle treatment. Dissemination of journal articles with this kind of language is considered by the agency to be promotion of your laser for an uncleared use and causes your device to be misbranded and adulterated. It would, however, be acceptable to distribute such journal reprints in accordance with the agency's unsolicited request policy i.e., you may distribute journal articles that discuss an off-label use of your device if specifically requested by a consumer, physician, or other third party. New Star however, may not initiate the distribution of its own accord.
>
> Additionally, the FDA Modernization Act of 1997, section 401, as well as 21 CFR Part 99 describes certain circumstances when the dissemination of information regarding unapproved/uncleared uses may be distributed to health care practitioners. We suggest you become familiar with these regulations which may be found on FDA's home page.

The journal reprint distributed by New Star was a peer-reviewed journal article. FDA makes

no allegation that any information contained in the article is in any way false or misleading. Indeed, FDA indicates that dissemination of the article by New Star would have been just fine if it had come in response to a request for information about New Star's approved medical device. Accordingly, FDA's threat to sanction New Star for its dissemination of the article is a clear violation of the First Amendment, as set forth by the district court in *WLF I* and *WLF II*. Moreover, FDA's citation to § 401 of FDAMA is highly misleading. The letter states that § 401 "describes certain circumstances when the dissemination of information regarding unapproved/uncleared uses may be distributed to health care practitioners." As so phrased, the clear implication of the letter is that disseminating such information under circumstances not described in § 401 violates FDA regulations. Given the limiting construction of § 401 to which FDA has committed itself, the letter's implication is absolutely false. It is inexcusable that FDA allows such lawless and false letters to be sent out in its name.

Should FDA continue to disregard the clear mandate of the district court's decisions in *WLF I* and *WLF II,* WLF will feel compelled to initiate legal action against FDA and/or appropriate agency officials to prevent further restrictions on manufacturer dissemination of truthful enduring materials. For the following reasons, WLF believes it extremely likely that it would once again prevail in such litigation.

FDA Will Be Collaterally Estopped from Denying Liability in Any Subsequent WLF Lawsuit. After FDA denied WLF's 1993 Citizen Petition that complained about FDA restrictions on manufacturer dissemination of enduring materials, WLF filed a First Amendment challenge to those restrictions. After seven years of litigation, WLF won its

case; in particular, several crucial legal disputes between the parties were decided in WLF's favor. Given FDA's current posture, it appears that those same legal issues would be in dispute in any subsequent litigation between WLF and FDA. But the law does not permit a party that has litigated and lost on an issue of law in one lawsuit to continue to contest that issue in a subsequent lawsuit with the same opposing party. Rather, under the doctrine of collateral estoppel, a party gets only one bite at the apple; if it loses, it is barred from re-raising that same issue in subsequent litigation. That doctrine will be applicable to any challenge that WLF may bring to FDA's current restrictions on enduring materials; accordingly, in any such challenge, FDA in large measure would be barred from resisting WLF's First Amendment claims.

The government is not exempt from the collateral estoppel doctrine.[11] Indeed, the Supreme Court explicitly rejected the federal government's bid for such an exemption in *United States v. Stauffer Chemical Co.*, 464 U.S. 165 (1984). The Court held that the doctrine applied to the federal government, regardless whether the previously-decided issue was one of fact or law:

> [W]hen the claims in two separate actions between the same parties are the same or are closely related . . . it is not ordinarily necessary to characterize an issue as one of fact or of law for purposes of issue preclusion. . . . In such a case, it is unfair to the winning party and an unnecessary burden on the courts to allow repeated litigation of

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[11] Unlike private litigants, the federal government cannot be subject to collateral estoppel on a non-mutual basis; in other words, only a litigant that was a party to the prior litigation may seek to bind the federal government based on issues decided in the prior litigation. *United States v. Mendoza,* 464 U.S. 154, 158 (1984). Under *Parklane Hosiery Co. v. Shore,* 439 U.S. 322 (1979), mutuality is not always a prerequisite to application of collateral estoppel to a private litigant. Lack of mutuality will not be a concern in any future litigation between WLF and FDA, however, because WLF was a party to *WLF I, WLF II,* and *WLF III.*

> the same issue in what is essentially the same controversy, even if the issue is regarded as one of "law."

Stauffer Chemical, 464 U.S. at 171 (quoting Restatement (Second) of Judgments § 28, Comment *b* (1982)). The Court also rejected the government's claim that it could not be collaterally estopped unless the two cases raising the same legal issue "ar[o]se from the very same facts or transaction"; the Court said that that claim had no validity outside the context of tax cases. *Id.* at 173 n.5.

Under the doctrine of collateral estoppel, "once an issue is actually and necessarily determined by a court of competent jurisdiction, that determination is conclusive in subsequent suits based on a different cause of action involving a party to the prior litigation." *Montana v. United States,* 440 U.S. 147, 153 (1979). A party may rely on collateral estoppel to preclude relitigation of an issue if it can demonstrate:

> (1) the issue was identical to one in a prior adjudication; (2) there was a final judgment on the merits; (3) the estopped party was a party or in privity with a party to the prior adjudication; and (4) the estopped party was given a full and fair opportunity to be heard on the adjudicated issue.

United States v. Gurley, 43 F.3d 1188, 1198 (8th Cir. 1994), *cert. denied,* 516 U.S. 817 (1995).

The chief issue likely to be in dispute in any subsequent litigation between WLF and FDA is FDA's assertion, contained in its March 16, 2000 Notice, that "[i]f a manufacturer does not comply [with § 401 of FDAMA while disseminating enduring materials about 'new uses' of approved products], FDA may bring an enforcement under the FDCA, and seek to use journal articles and reference texts disseminated by the manufacturer as evidence that an approved product is intended for a 'new use.'" 65 Fed. Reg. at 14287. WLF disagrees with

that assertion, because it believes that any such enforcement action would constitute a violation of the First Amendment. More importantly, FDA would be estopped from defending the First Amendment validity of such enforcement actions, because FDA litigated and lost that precise First Amendment issue in *WLF I* and *WLF II*.

Following the appeals court's decision, FDA has attempted to re-write history in terms of what was actually litigated between the parties. FDA has asserted that WLF's only real objection was to government regulation that *directly* prohibited speech and that both sides at all times agreed that FDA was within its rights when it "merely" used speech as evidence of an intended use of a product, which then could lead to a finding that the product was adulterated, misbranded, or being distributed for an unapproved new use if the "intended use" inferred from the speech was not one previously approved by FDA. *See, e.g.,* FDA April 17, 2000 district court brief.[12] Thus, FDA now asserts, the prior litigation never

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[12] FDA has based its assertion regarding WLF's litigating position on out-of-context snippets from oral argument before the appeals court. Read in the context of WLF's entire oral presentation to the appeals court, those isolated statements cannot be interpreted as an abandonment by WLF of its First Amendment objection to FDA use of manufacturer dissemination of enduring materials as evidence of an intended new use of a product. Moreover, in order to ensure that there could be no doubt that it had not abandoned its position, WLF stated unequivocally in papers filed with the appeals court following oral argument:

> As WLF has argued consistently throughout this litigation, the First Amendment is violated just as much by a policy that uses the dissemination of truthful speech as the sole basis for threatening or bringing an enforcement action as it is by directly prohibiting speech. . . . [W]hen FDA announces that it will deem virtually any dissemination of off-label information outside the FDAMA "safe harbor" to establish improper distribution of an otherwise approved drug or device (as FDA has done both in its [Enduring Materials] Guidance Documents and now again in its letter [to the appeals court], FDA has suppressed truthful in violation of the First Amendment.

WLF February 2, 2000 letter to D.C. Circuit in *WLF IV*.

addressed whether the First Amendment imposes limitations on FDA's evidentiary use of manufacturer speech. That assertion is false, as FDA's attorneys well know. Indeed, the Enduring Materials Guidances did not attempt to impose any "direct" controls on manufacturer speech but rather warned that any such speech could be used as evidence of an intended "new use" of a product. Thus, by striking down those guidance documents on First Amendment grounds, *WLF I* and *WLF II* could not have been clearer that the First Amendment prohibits FDA from bringing an enforcement action based solely on manufacturer dissemination of non-misleading enduring materials, even if those materials include information about off-label uses of an approved product.

Thus, in any future litigation based on FDA's failure to abide by *WLF I* and *WLF II*, WLF will be able to show that the first prerequisite for application of collateral estoppel has been met: the First Amendment issue is identical to the issue previously decided in WLF's favor. The other three prerequisites set forth in *Gurley* for application of collateral estoppel would also easily be met: there was a final judgment on the merits in WLF's favor (and the final judgment was not overturned on appeal on relevant issues); the parties to the two lawsuits (WLF and FDA) would be the same; and FDA was given a full and fair opportunity to be heard on the First Amendment issue.

In sum, FDA almost certainly will not be permitted to relitigate the First Amendment issues it lost in its prior lawsuit with WLF. Accordingly, it would save everyone involved

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In light of WLF's numerous statements throughout its litigation with FDA that it did, in fact, object to FDA's use of manufacturer dissemination of enduring materials as evidence of an intended new use of a product, one can only conclude that FDA's repeated assertions that WLF had not raised such objections are not being made in good faith. WLF trusts that with the change in administrations, FDA will not continue to make such assertions.

considerable time and expense if FDA were to avoid a new round of litigation by granting this Citizen Petition.

First Amendment Case Law Strongly Supports WLF's Position. The district court cogently explained why FDA's efforts to suppress manufacturers dissemination of enduring materials that discuss off-label uses of FDA-approved products run afoul of the First Amendment. *See WLF I, WLF II,* and *WLF III. See also* WLF's October 1993 Citizen Petition (Exhibit C) at 12-15. WLF will not repeat all those arguments here.

Suffice to say that FDA has been on an extended losing streak in the courts in its efforts to resist First Amendment limitations on its enforcement activities. For example, the U.S. Court of Appeals for the District of Columbia Circuit held recently that the First Amendment imposes strict limitations on FDA's power to restrict health claims made by manufacturers of dietary supplements, even when the claims are made on the product label. *Pearson v. Shalala,* 164 F.3d 650 (D.C. Cir. 1999) ("*Pearson I*"). In overturning a district court decision that had upheld FDA's outright ban on such claims when use of disclaimers might have responded fully to FDA's concerns, the appeals court stated:

> The government insists that it is never obliged to utilize the disclaimer approach, because the commercial speech doctrine does not embody a preference for disclosure over outright suppression. Our understanding of the doctrine is different. . . . In more recent cases, the [Supreme] Court has . . . repeatedly point[ed] to disclaimers as constitutionally preferable to outright suppression.

Id. at 657. The court added, "[W]hen government chooses a policy of suppression over disclosure -- at least where there is no showing that disclosure would not suffice to cure misleadingness -- government disregards a 'far less restrictive' means" of achieving its policy interests. *Id.* at 658 (quoting *Bd. of Trustees of State Univ. of New York v. Fox,* 492 U.S.

469, 479 (1989)).

On remand, FDA's First Amendment arguments were again rejected. The district court granted a preliminary injunction against FDA's continued violation of First Amendment rights; the court required FDA to approve a health claim (for inclusion on product labeling for folic acid) regarding the positive relationship between consumption of folic acid and prevention of birth defects. *Pearson v. Shalala,* 130 F. Supp. 2d 105 (D.D.C. 2001) ("*Pearson II*"). The district court was harshly critical of FDA's continued resistance to court orders that it comply with the First Amendment; the court said:

> [I]t is clear that the FDA simply failed to comply with the constitutional guidelines outlined in *Pearson* [*I*]. Indeed, the agency appears to have at best, misunderstood, and at worst, deliberately ignored, highly relevant portions of the Court of Appeals Opinion.

Pearson II, 130 F. Supp. 2d at 112. The court held that under the First Amendment, FDA "must shoulder a very heavy burden if it seeks to totally ban a particular health claim." *Id.* at 118. The court held that FDA had failed to meet that burden; it held that "[t]he mere absence of significant affirmative evidence in support of a particular [health] claim . . . does not translate into negative evidence 'against' it." *Id.* at 115. In other words, the court held, any FDA efforts to regulate manufacturer dissemination of unapproved health claims must take the form of disclaimer requirements rather than outright bans on the claims, unless FDA can demonstrate that the claims are "against" the great weight of the scientific literature.[13]

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[13] Significantly, the district court simply ignored FDA's argument that its efforts to ban the folic acid health claims were not subject to First Amendment review because FDA was not banning speech *directly* but rather was simply using the speech as evidence that the manufacturer intended to market its product as a drug. (And, of course, FDA was asserting that dissemination of the health claims would render the folic acid subject to seizure as an unapproved new drug, because FDA has never approved the marketing of folic acid as a

On May 9, 2001, the district court denied FDA's motion for reconsideration of the preliminary injunction order. Noting that FDA's "arguments contained in the motion for reconsideration further demonstrate Defendants' reluctance to fully comply with *Pearson I,*" the court reiterated its conclusion:

> [T]he philosophy underlying *Pearson I* is perfectly clear: that the First Amendment analysis in *Central Hudson* . . . applies in this case, and that if a health claim is not inherently misleading, the balance tilts in favor of disclaimers rather than suppression. In its motion for reconsideration, the FDA has again refused to accept the reality and finality of that conclusion by the Court of Appeals.

Pearson v. Thompson, No. 00-2724 (GK), ___ F. Supp. 2d ___, slip op. at 4, 13 (D.D.C. May 9, 2001).

The Ninth Circuit has been equally dismissive of FDA's defenses to First Amendment claims. That court held that a FDAMA provision that restricts pharmacists from advertising the availability of compounded drugs cannot survive the final two prongs of the *Central Hudson* test and thus violates the First Amendment. *Western States Medical Center v. Shalala,* 238 F.3d 1090 (9th Cir. 2001). Noting the absence of evidence that the advertisements regarding the availability of compounded drugs were misleading, the appeals court stated, "Government prohibitions of truthful commercial speech are 'particularly dangerous' and deserve 'rigorous review.'" *Id.* at 1096 (quoting *44 Liquormart, Inc. v. Rhode Island,* 517 U.S. 484, 501 (1996).[14]

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drug.)

[14] Significantly, the appeals court found that FDA was violating the First Amendment even though the relevant legislation did not *directly* prohibit advertising but rather provided that pharmacists who advertised specific compounding services would not be eligible for 21 U.S.C. § 353a(a)'s exemption from FDA's NDA requirements. *See* 21 U.S.C. § 353a(c) ("A drug may be compounded under subsection (a) of this section only if the pharmacy,

Just this week, the U.S. Supreme Court reiterated its near-absolute disapproval of government efforts to suppress truthful speech. The Court held that the First Amendment prohibits the federal government from proscribing the dissemination of truthful noncommercial information of public concern, even if the information was initially obtained by illegally intercepting a private phone message and even if the government proscription is imposed in a content-neutral fashion. *Bartnicki v. Vopper,* No. 99-1687, ___ U.S. ___ (May 21, 2001). The Court explained, "As a general matter, 'state action to punish the publication of truthful information seldom can satisfy constitutional standards.'" *Bartnicki,* slip op. at 12 (quoting *Smith v. Daily Mail Publishing Co.,* 443 U.S. 97, 102 (1979)). The Court explicitly rejected the federal government's argument that First Amendment limitations were inapplicable because it was attempting to regulate conduct rather than speech. The Court explained that the wiretap statute's:

> [N]aked prohibition against disclosures is fairly characterized as a regulation of pure speech. Unlike the prohibition against the "use" of the contents of an illegal interception in [18 U.S.C.] § 2511(1)(d), subsection (c) is not a regulation of conduct. It is true that the delivery of a tape recording might be regarded as conduct, but given that the purpose of such a delivery is to provide the recipient with the text of the recorded statements, it is like the delivery of a handbill or a pamphlet, and as such, it is the kind of 'speech' that the First Amendment protects.

Id. at slip op. 11-12. Similarly, FDA is regulating "pure speech" when it uses manufacturer dissemination of enduring materials (without any further promotional activity on the

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licensed pharmacist, or licensed physician does not advertise or promote the compounding of any particular drug, class of drug, or type of drug."). In other words, the Ninth Circuit paid no heed to a distinction of the sort that FDA tried to draw in its March 16, 2000 Federal Register notice: a distinction between regulations that "directly" prohibit speech (which FDA admits are subject to First Amendment review) and regulations that use speech as evidence of manufacturer intent to market a product for a new use (which FDA contends is not subject to First Amendment review).

manufacturer's part) as evidence of a new intended use of the manufacturer's product. In such circumstances, there is no illegal conduct apart from the very speech FDA seeks to control.

In the commercial speech context, the Supreme Court has, of course, made clear that speech that proposes an illegal transaction is not entitled to any First Amendment protection. But that doctrine is of no avail to FDA in its effort to remove its regulation of enduring materials from the realm of First Amendment review. The Supreme Court held in *Pittsburgh Press Co. v. Human Relations Comm'n*, 413 U.S. 376 (1973), that gender-based employment ads could be prohibited because they directly aided and abetted illegal conduct: the hiring of employees on the basis of sex. But in those circumstances, the illegal conduct that the government is trying to prevent is separate and distinct from the speech to be regulated. The Supreme Court has never accepted the notion that truthful speech can be regulated in order to prevent a harm where the sole embodiment of that harm is the speech itself.[15] FDA's arguments to the contrary essentially rely on circular reasoning: truthful manufacturer

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[15] Thus, for example, *Wisconsin v. Mitchell*, 508 U.S. 476 (1993), is of no help to FDA. *Mitchell* involved the prosecution of individuals who had engaged in criminal activity: a vicious assault. The issue was whether the defendants' First Amendment rights were violated because the State introduced evidence regarding the defendants' statements in order to demonstrate that the defendants' actions were racially motivated (and thus that the defendants were subject to a sentence enhancement for having committed a "hate crime"). The Court held that the First Amendment did not prohibit such evidentiary use of speech to demonstrate motivation for the illegal conduct. *Mitchell,* 508 U.S. at 489. But that holding is a far cry from FDA's efforts to free itself from First Amendment limitations. FDA seeks to use manufacturer speech not to demonstrate the motivation for conduct that is independently illegal, or even to demonstrate that the conduct is illegal. Rather, FDA is seeking to use truthful speech as the *sole* basis for transforming what FDA admits is an otherwise unobjectionable activity (the sale of an FDA-approved product) into an illegal activity. Any such evidentiary use of speech can only be described as a speech regulation to which First Amendment analysis is fully applicable.

speech demonstrates that the manufacturer is intending to distribute its product for an unapproved new use; and because such distribution is illegal, the truthful speech is not protected commercial speech (per *Pittsburgh Press*). The courts have never accepted such circular reasoning, which would allow the government to sidestep First Amendment constraints with little difficulty.

A strong argument can be made that manufacturer dissemination of enduring materials should not be deemed commercial speech at all but rather is noncommercial speech entitled to the highest level of First Amendment protection. *See, e.g.*, 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 (1999). But even if analyzed under a commercial speech standard, FDA's enduring material's policy cannot withstand First Amendment scrutiny.[16] The evidence is overwhelming that FDA's policy objectives could be achieved in a much more narrowly tailored manner. As the district court found in *WLF I, WLF II*, and *WLF III*, a regime based on disclaimers and a continued ban on *labeling* for uses not approved by FDA would ensure that: (1) doctors would not be misled into believing that off-label uses described in a journal reprint had been approved by FDA; and (2) manufacturers would continue to have an incentive to seek supplemental labeling authority for the most popular off-label uses.

WLF notes that between the time of the district court's initial 1998 injunction barring

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[16] The existence of such a policy is evidenced both by the March 16, 2000 Federal Register notice and by letters to manufacturers, such as the November 27, 2000 letter to New Star Lasers, Inc.

enforcement of FDA's enduring materials policy and FDA's publication of the Notice in March 2000, manufacturers disseminated an extraordinarily large quantity of enduring materials to doctors. Yet, WLF is unaware of a single instance in which a doctor later came to believe that (s)he had been misled by any of this medical literature. That history suggests that FDA's fears of the dangers created by dissemination of enduring materials are overwrought. In the absence of evidence that allowing truthful speech will cause any harm, and in light of the Constitution's preference for more speech rather than speech suppression, FDA's enduring materials policy cannot withstand First Amendment analysis.

Adoption of WLF's Proposal Represents Sound Public Health Policy. Quite apart from its First Amendment objections to FDA's current policies, WLF believes that FDA ought to adopt the proposal set forth herein because it represents sound public health policy.

As noted above and as both the Supreme Court and FDA have recognized, off-label use of FDA-approved products plays an important role in health care delivery in this country. Given the importance of off-label uses, it stands to reasons that FDA would want doctors and patients to learn as much as possible about which off-label uses are medically recognized. Because they have both the necessary resources and incentives to become involved, manufacturers are the most logical group to be supplying doctors and patients with the necessary information.

There is always a danger that manufacturers will provide biased information about their products, or will fail to inform doctors adequately regarding side-effects and contra-indications. WLF is not asking FDA to permit manufacturers to say *anything* they choose about off-label uses; without question, FDA should continue to guard against manufacturer

dissemination of false or misleading information. But "enduring materials" come with strong indicia of reliability (based on their pedigree), so there is little reason for concern that the information being conveyed has no acceptance within the medical community. Furthermore, because "enduring materials" by definition are not prepared by the disseminating manufacturer, there is no danger that the materials have been biased by financial self-interest. Finally, because the information is being disseminated to a highly educated audience -- medical professionals -- there is little danger that readers will misunderstand the materials.

Manufacturer support of CME is another effective method by which doctors can learn about off-label uses that have won widespread medical acceptance. FDA is correct to be concerned that manufacturer support of CME can turn into manufacturer control in the absence of some degree of oversight. But the watchword ought to be independence; if the CME activity can legitimately claim independence from manufacturer control, then manufacturer support of the activity should not be cause for concern even when off-label uses are to be discussed. WLF believes that so long as CME activities are subject to an accreditation requirement from an independent accrediting group, independence can be assured.[17] Once that assurance is achieved, there is no reason to attempt (as FDA has done frequently in the past) to prohibit manufacturers from engaging in such activities as: (1) suggesting topics to CME providers; or (2) providing samples of their medical devices for use in training sessions at the CME activity.

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[17] Indeed, when the district court in *WLF I, WLF II,* and *WLF III* issued an injunction prohibiting full enforcement of the CME Guidance, it did so on the condition that all CME providers seeking to invoke the benefits of the injunction obtain accreditation from an independent accrediting body.

More importantly, FDA ought to develop *some* comprehensive policy on manufacturer support of CME. As a result of *WLF IV,* FDA has placed an extremely limited interpretation on the CME Guidance. FDA insisted to the court of appeals that the CME Guidance is nothing more than a "safe harbor" document, meaning that it tells manufacturers what they *can* do but tells them nothing about what they *cannot* do. Unless FDA provides clearer guidance regarding what it believes constitutes improper manufacturer support of CME, manufacturers are less likely to provide such support and medical care will suffer as a result. Of course, one potential down side is that FDA might open itself up to lawsuits (by those who believe their First Amendment rights have been impaired) if it begins to place limits on manufacturer support; but presumably FDA policy is being guided by what it believes will best promote the public welfare, not by what FDA believes is necessary to avoid litigation.[18]

D. ENVIRONMENTAL IMPACT

Petitioner claims a categorical exclusion under 21 C.F.R. § 25.24(a)(1).

E. ECONOMIC IMPACT

Petitioner will submit information upon request of the Commissioner. Petitioner believes that FDA's failure to rescind the March 16, 2000 Federal Register notice and its maintenance of a policy that suppresses manufacturer dissemination of truthful information

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[18] The worst of all possible worlds is for FDA to deny publicly that it has a policy of imposing specific restrictions on manufacturer support of CME activities but then attempting to impose "secret" limitations through the *in terrorem* effect of occasional threatening FDA statements. A statement in the March 16, 2000 Notice suggests just such a scenario: while denying in one breath that it has any policy imposing specific restrictions on CME activities, the FDA stated with the next breath (in the Notice) that the CME Guidance Document "details the factors FDA intends to take into account in exercising its enforcement discretion in relation to industry-supported scientific and educational activity." 65 Fed. Reg. at 14287. Such *sub rosa* implementation of an enforcement policy smacks of bad faith.

about off-label uses of FDA-approved products is raising health care costs and having harmful economic impact on patients and their doctors. Conversely, granting this Petition, Petitioner believes, will result in the more effective use of available therapies and therefore have a favorable economic impact.

F. CERTIFICATION

The undersigned certify that, to the best of the knowledge and belief of the undersigned, this Petition includes all information and views on which this Petition relies, and that it includes all representative data and information known to the Petitioner which are unfavorable to the Petition.

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