

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

WASHINGTON LEGAL FOUNDATION,)
)
Plaintiff,)
)
v.) Civil Action No. 94-1306
) (RCL)
JANE E. HENNEY, M.D., in her)
official capacity as Commissioner,)
Food and Drug Administration,)
)
and)
)
DONNA SHALALA, in her official)
capacity as Secretary, United)
States Department of Health and)
Human Services,)
)
Defendants.)
)
_____)

MEMORANDUM AND ORDER

Now before the Court is a motion by the plaintiff to confirm and enforce a permanent injunction issued by this Court on July 28, 1999. See *Washington Legal Found. v. Henney*, 56 F. Supp. 2d 81, 88-89 (D.D.C. 1999) ("WLF III"). The defendants claim that they are not in violation of the injunction, and therefore oppose the plaintiff's motion. After considering the parties' memoranda of points and authorities, and for the following reasons, the Court DENIES the plaintiff's motion.

BACKGROUND

This matter is yet another episode in a six-year controversy.¹ Beginning as far back as 1994, these two parties have sparred over the extent to which the federal government can regulate speech regarding the "off-label" uses of prescription drugs. The most recent dispute concerns two commands from the federal government: the Food and Drug Administration Modernization Act passed by Congress (the "FDAMA"), and the "Guidance for Industry: Industry-Supported Scientific and Educational Activities" issued by the FDA (the "CME Guidelines"). See Pub. L. No. 105-115, 111 Stat. 2296; 62 Fed. Reg. 64,093 (1997).

On July 28, 1999, this Court concluded that the FDAMA and CME Guidelines were "contrary to the rights secured by the United States Constitution," specifically the First Amendment. *Washington Legal Foundation v. Henney*, 56 F. Supp. 2d 81, 87 (D.D.C. 1999) ("WLF III"). The government appealed. According to the Court of Appeals, the government's briefs were "quite confusing as to the meaning of the [FDAMA] and the CME Guidance." *Washington Legal Found. v. Henney*, 202 F.3d 331, 335 (D.C. Cir.

¹ This opinion only summarizes the facts relevant to the instant matter. A fuller explanation of the facts, as well as the procedural history of this case are recounted in *Washington Legal Found. v. Henney*, 202 F.3d 331 (D.C. Cir. 2000) ("WLF IV"); *Washington Legal Found. v. Henney*, 56 F. Supp. 2d 81 (D.D.C. 1999) ("WLF III"); *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998) ("WLF II"); *In re Kessler*, 100 F.3d 1015 (D.C. Cir. 1996); *Washington Legal Found. v. Kessler*, 880 F. Supp. 26 (D.D.C. 1995) ("WLF I").

2000) ("WLF IV"). The confusion however--as well as the controversy itself--abated at oral argument.

During oral argument, the government clarified its interpretation of the FDAMA and the CME Guidance. With respect to the FDAMA, the government explained that, although the FDAMA seeks to restrict the dissemination of information in certain ways, it does *not* grant the FDA authority to prosecute those who transgress the restrictions. *Id.* According to the government, the FDAMA creates a "safe harbor" for manufacturers who follow its provisions; i.e., manufacturers who disseminate information in accordance with the FDAMA will not be prosecuted under the FDA's misbranding authority *using the information disseminated as evidence.* *Id.* Of course, a misbranding suit might still continue and succeed using other forms of evidence, but as long as a manufacturer complies with the FDAMA provisions, it can be confident that the dissemination will not be held against it at a later date.

On the other side of the coin, drug manufacturers who disseminate information in ways contrary to the FDAMA take themselves out of the safe harbor, and open themselves up to the possibility that, if the FDA should bring a suit under its misbranding authority, the dissemination could be used against them. The key distinction to note in this situation, as well as in the previous one, is that the FDA's prosecutorial power flows

from its long-established authority to prosecute manufacturers for misbranding, *not* from the newly created FDAMA. As the Court of Appeals summarized the government's position: "nothing in [the FDAMA] provides the FDA with independent authority to regulate manufacturer speech."

A similar interpretation applies to the CME Guidelines. The CME Guidelines order manufacturers to follow certain procedures in planning and promoting medical seminars. Although a manufacturer who violates these provisions might be prosecuted by the FDA, the prosecution will be pursuant to its misbranding enforcement power, and not some independent power created in the CME Guidelines. *Id.* at 335-36

With the revelation of the government's interpretation at oral argument, WLF admitted that it no longer had a constitutional objection to the FDAMA or CME Guidelines. *Id.* Seeing this, the Court of Appeals found there to be no case or controversy and declined to issue what would amount to an advisory opinion on the constitutionality of the FDAMA and CME Guidelines. *Id.* The Court then went a step further and vacated the district court's previous holdings and injunctions "insofar as they declared the FDAMA and the CME Guidelines unconstitutional." *Id.* at 337.

What brings the parties back to court is the FDA's March 16, 2000 Notice printed in the Federal Register. See 65 Fed. Reg.

14286 (Mar. 16, 2000). The Notice explains--from the FDA's perspective--the parameters of its regulatory authority in light of the Court of Appeals' opinion vacating this Court's July 28, 1999 injunction. According to the Notice, the FDA may, when appropriate, "proceed, in the context of case-by-case enforcement, to determine from a manufacturer's written materials and activities how it intends that its products be used." *Id.* A drug manufacturer's intent to promote an unapproved use, together with certain predicate acts, may in turn be used to make out a misbranding case. The WLF argues that such a practice is exactly what this Court prohibited in its July 16, 2000 injunction. Although the Court of Appeals vacated a portion of this injunction, WLF argues that the Court of Appeals expressly recognized that "part of [the] injunction still stands." *WLF IV*, 202 F.3d at 337.

ANALYSIS

I. The Nature of the Plaintiff's Claim

By the title of its motion, the plaintiff asks to the Court to "confirm and enforce [its] continuing injunction." Although this appears relatively straightforward, it is instructive to notice what the plaintiff is *not* claiming. The plaintiff is not claiming that the defendant's Notice violates the First Amendment, either facially or as applied. The plaintiff is also

not claiming that the Notice is contrary to the FDA's official interpretation of the FDAMA and the CME Guidelines announced at the oral argument on appeal. Rather, the plaintiff is only claiming that the defendant's Notice is facially violative of the Court's July 28, 1999 injunction as modified by the Court of Appeals. Thus, to resolve this matter, the Court must analyze the exact scope of its injunction as well the exact nature of the FDA's Notice.

II. The Scope of the Modified Injunction

The proper place to start is with the text of the injunction as it was originally issued. On July 28, 1999, this Court ordered 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:

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.

WLF III, 56 F. Supp. 2d at 88. The Court supplemented these orders with definitions for "bona fide peer-reviewed journal", "bona fide independent publisher", and "independent program provider." *Id.* The Court concluded the injunction by clarifying that

Nothing herein shall be construed to limit Defendants' application or enforcement of any rules, regulations, guidances, statutes or other provisions of law that sanction the dissemination or redistribution of any material that is false or misleading. In addition, Defendants may require any pharmaceutical or medical device manufacturer that sponsors or provides financial support for the dissemination or redistribution of articles or reference textbooks or for seminars that include references to unapproved uses for drugs or medical devices that are approved by FDA for other uses to disclose (i) its interest in such drugs or devices, and (ii) the fact that the use discussed has not been approved by FDA.

Id.

On February 11, 2000, the Court of Appeals vacated this injunction "insofar as [it] declare[s] the FDAMA and the CME Guidance unconstitutional." *WLF IV*, 202 F.3d at 337. The pertinent question is thus: what portion of the injunction was grounded in law other than the federal constitution?

The answer, quite simply, is none. A thorough review of the Court's July 28, 1999 opinion reveals only one source of law: the United States Constitution. The opinion's discussion section begins with a declaration that the *Central Hudson* commercial speech doctrine applies to the case. *WLF III*, 56 F. Supp. 2d at 84-85. The opinion then proceeds to apply the constitutional doctrine to the relevant facts of the case, concluding that the FDAMA and the CME Guidelines were facially unconstitutional. *Id.* at 85-87. No other law was ever discussed, much less referenced.

Thus, as the injunction was completely based on constitutional law, and the Court of Appeals vacated the "injunction[] insofar as [it] declared the [disputed provisions] unconstitutional," this Court has choice but to declare the injunction wholly vacated as to the FDAMA and the CME Guidelines.²

² One sentence in the Court of Appeals' opinion might suggest to the contrary. In a footnote on the final page of its opinion, the Court of Appeals stated: "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." *WLF*, 202 F.3d at 337 n.7. One might construe this statement as implying that part of the injunction was, in the Court of Appeals view, not constitutionally based, not therefore vacated, and thus, "still stands."

Such a construction would be unreasonable. It is illogical to conclude that the court--without any review of the injunction--would declare that part of it still stands. It is much more logical to think that the court, in a measure of prudence considering that it had not reviewed the text of the injunction, sought to clarify that, if the injunction was in any way not constitutionally based, that part of the injunction would still stand. Thus, the best reading of the footnote is that Court of Appeals found the injunction to "still stand[] [to the extent it is not constitutionally based]."

III. The FDA's March 16, 2000 Notice

Given the above discussion, it makes little difference what the FDA's March 16, 2000 Notice contained. Since the injunction has been wholly vacated by the Court of Appeals, there is nothing for the Notice to violate. Therefore, the Court finds that the FDA's notice is not in violation of any order issued by this Court.

CONCLUSION

Today, the Court adds another order to this case's voluminous file; yet the order will do little to resolve the issue that lies at the heart of this dispute: whether the FDA violates the First Amendment by penalizing drug manufacturers for sending scientific literature to physicians regarding off-label uses. After six years' worth of briefs, motions, opinions, Congressional acts, and more opinions, the issue remains 100% unresolved, and the country's drug manufacturers are still without clear guidance as to their permissible conduct. 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.

This year, the Court of Appeals was poised to finally

galvanize a rule of law in this area. Yet, for whatever reason, the opportunity was spent debating not the U.S. Constitution's First Amendment, but its Article III case or controversy requirement. Thus, we have a little more law on advisory opinions, and nothing at all to say about our citizenry's First Amendment rights. In fact, after the Court of Appeals' opinion, we have even less First Amendment law than before; this is because the Court vacated all of this Court's previous constitutional rulings on the matter.

As for this Court's part in the controversy, the Court is confident that it has done its best at every step of the process. It has decided the underlying issue at least twice, and senses that it will be called on to do so again before the controversy is concluded. For now, however, the issue must be given a temporary rest.

For the foregoing reasons, it is hereby

ORDERED that the plaintiff's motion to confirm and enforce the July 28, 1999 injunction [75-1] is DENIED.

SO ORDERED.

Date: _____

ROYCE C. LAMBERTH
UNITED STATES DISTRICT JUDGE