

February 5, 2002

FDA REFUSES WLF DEMAND TO COMPLY WITH COURT ORDER

The Food and Drug Administration (FDA) this week refused the Washington Legal Foundation's (WLF) demand that it comply with a court order that prohibits FDA from interfering with the First Amendment rights of those who seek to speak truthfully about off-label uses of FDA-approved products.

In a 10-page letter to WLF, FDA rejected WLF's May 23, 2001 Citizen Petition, in which WLF pointed out that recent FDA pronouncements on off-label speech violate the terms of a court order issued against FDA in 1998. FDA stated in its letter that it no longer deems itself bound by the terms of the order, issued by U.S. District Judge Royce Lamberth in *Washington Legal Found. v. Friedman*.

"We are disappointed that FDA feels itself at liberty to ignore federal court orders," said WLF Chief Counsel Richard Samp after receiving FDA's letter. "We are exploring all options for reversing FDA's decision, including the possibility of renewed litigation," Samp said.

In its letter, FDA argues that it is no longer bound by Judge Lamberth's 1998 decision because it appealed that decision to the U.S. Court of Appeals for the District of Columbia Circuit. During the course of that appeal, FDA abandoned many of the arguments it had asserted in the district court; in particular, it abandoned its position that the Food and Drug Administration Modernization Act (FDAMA), adopted by Congress in 1997, granted FDA authority to punish manufacturers for disseminating off-label information about their approved products. As a result of that concession, the appeals court deemed that FDA had abandoned its appeal; the appeals court dismissed the appeal and simultaneously vacated a portion of Judge Lamberth's injunction as moot. *Washington Legal Found. v. Henney*, 202 F.3d 331 (D.C. Cir. 2000).

Almost immediately after its loss in the federal courts, FDA announced a new enforcement policy indicating that FDA deems itself free -- despite the court decision -- to prosecute manufacturers who engage in off-label speech. FDA's enforcement policy was contained in a Notice it published in the Federal Register on March 16, 2000.

WLF's May 23, 2001 Citizen Petition argued that the Federal Register notice was a thinly-veiled threat by FDA to bring enforcement actions against manufacturers who disseminate medical texts or peer-reviewed journal articles that discuss off-label uses of the manufacturers' products. Although the Federal Register notice adhered to FDA's position that FDAMA does not provide FDA with any powers to control off-label speech, the notice insisted that FDA is free to use *other* enforcement tools to impose identical speech restrictions on manufacturers. The notice states, "If a manufacturer does not comply with FDAMA, FDA may bring an enforcement action under the [Food, Drug, and Cosmetic Act], 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.'"

In rejecting WLF's Citizen Petition, FDA continues to adhere to that position. FDA nonetheless indicated that it may choose, in its discretion, not to bring enforcement action against a manufacturer that disseminates truthful, peer-reviewed journal articles that include off-label information about the manufacturer's approved products. FDA's letter stated, "Because 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 intended use is the distribution of enduring materials or sponsorship of CME."

WLF's attorneys expressed disappointment with FDA's response. "The clear intent of FDA's various statements is to browbeat manufacturers to the point that they will refrain from disseminating off-label information. Such action violates the First Amendment and the terms of Judge Lamberth's court order," said WLF's Samp. "We will continue to work to bring an end to FDA's unconstitutional activity," he said.

FDA's letter also denied WLF's request that it adopt some sort of guidelines for manufacturer support of Continuing Medical Education (CME). Although FDA has issued a "safe harbor" document that lists certain types of manufacturer support of CME that will *not* lead to FDA sanction, FDA continues to provide no guidance regarding what it believes constitutes improper support of CME. Indeed, it was FDA insistence that it no longer had any such policy that convinced the appeals court in *Washington Legal Found. v. Henney* that WLF's challenge to FDA's CME policy was moot. "FDA's refusal to provide guidance in this area means that much speech protected by the First Amendment is being chilled; but we will have to wait until FDA renews its enforcement activity in this area before going back to court on CME issues," said WLF's Samp.

WLF is a public interest law and policy center with supporters in all 50 states. It devotes a significant portion of its resources to efforts designed to protect the economic and civil liberties of individuals and businesses.

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