

December 5, 2000

CONSTITUTIONALITY OF FDA SPEECH RESTRICTIONS REMAINS UNCLEAR FOLLOWING DISTRICT COURT DECISION (*Washington Legal Foundation v. Henney*)

A decision this week from the U.S. District Court for the District of Columbia has added considerably to the confusion regarding the constitutionality of Food and Drug Administration (FDA) policies that purport to restrict the First Amendment rights of those who seek to speak truthfully about off-label uses of FDA-approved products.

Judge Royce Lamberth issued an order denying a motion by the Washington Legal Foundation (WLF) for a ruling that FDA -- in a March 16, 2000 Federal Register notice -- had violated the Court's injunction against speech restrictions. The court concluded that there was no injunction that FDA could be found to have violated because the court's prior injunction was no longer in place.

At the same time, the Court was highly critical of FDA's actions. The Court termed FDA's Federal Register notice a "farce." The Court said, "[T]he country's drug manufacturers are still without clear guidance as to their permissible conduct," and charged, "That is no way to establish policy on an issue that both sides argue is of -- quite literally -- life and death proportions." In a related order issued the same day, Judge Lamberth reiterated his belief that he "does not agree with the government's position on the merits of the case," and that the government's arguments are "wrong, in the Court's view."

While disappointed that Judge Lamberth did not rule that FDA had violated an existing injunction, WLF attorneys expressed optimism that FDA will not now dare to attempt to enforce the speech-suppression policies threatened in its Federal Register notice. WLF pledged that the first time FDA so much as hints that it contemplates such an enforcement policy, WLF will be back in front of Judge Lamberth seeking an order that FDA is in violation of the First Amendment.

"Given Judge Lamberth's statement that he disagrees with FDA's interpretation of the First Amendment, it is hard to believe that FDA would risk the Court's wrath by adhering to its discredited policies," WLF Chief Counsel Richard Samp said after reviewing the Court's order.

WLF's challenge to FDA's speech suppression policies has had a long and tortuous history. WLF filed suit in 1994, arguing that FDA -- by attempting to prohibit manufacturer dissemination of truthful medical texts and medical journal reprints if those materials contained any information about off-label uses of the manufacturer's products -- was violating the First Amendment. The district court agreed, and granted an injunction against the FDA policy in July 1998. In November 1998, a new federal law known as FDAMA took effect; it included a provision that purported to codify much of FDA's prior policy. As a result, the district court issued a new injunction in July 1999 that enjoined enforcement of the FDAMA provision as well.

FDA appealed that decision to the U.S. Court of Appeals for the District of Columbia Circuit. In its argument before the appeals court, FDA disavowed its prior interpretation (and the most obvious reading) of FDAMA; FDA argued for the first time that FDAMA imposed no restrictions on manufacturer speech whatsoever. Based on that concession, the appeals court in February 2000 dismissed FDA's appeal and vacated most of the district court's injunction. But almost immediately thereafter, FDA seemingly backtracked and (in its March 16 Federal Register notice) appeared to once again threaten to seek sanctions against manufacturers who disseminate truthful off-label information. That notice led WLF to file its motion to enforce the injunction. The district court's order this week denied the motion based on the court's belief (erroneous, in WLF's view) that the appeals court's decision had vacated the entire injunction.

WLF noted that although Judge Lamberth refused to enjoin FDA's actions at this time, he all but invited WLF to return to court when and if FDA seeks to bring an enforcement action based on truthful manufacturer speech about off-label uses. The judge stated, "[The Court] has decided the underlying issues at least twice and senses that it will be called on again to do so before the controversy is concluded."

In its lawsuit, WLF has made clear its view that the protections afforded by the First Amendment are limited in scope. The constitution does not, for example, prohibit FDA from bringing enforcement actions against a manufacturer disseminating off-label information that is false or misleading, or that is written by the manufacturer itself. But, as Judge Lamberth held and is poised to hold again, the First Amendment prohibits FDA from initiating enforcement actions based *solely* on the dissemination of truthful, peer-reviewed journal articles or medical texts.

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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