

November 8, 1999

**ACLU, PhARMA SUPPORT WLF'S
FIRST AMENDMENT SUIT AGAINST FDA**
(Washington Legal Foundation v. Henney)

Both the American Civil Liberties Union of the National Capital Area ("ACLU") and the Pharmaceutical Research and Manufacturers of America ("PhARMA") have urged a federal appeals court to uphold the Washington Legal Foundation's (WLF) First Amendment challenge to Food and Drug Administration (FDA) speech restrictions. The ACLU and PhARMA filed *amicus curiae* ("friend of the court") briefs this week in support of WLF's precedent-setting challenge to FDA policy, *Washington Legal Foundation v. Henney*.

The two *amicus* briefs were in addition to WLF's own brief, which it filed today with the U.S. Court of Appeals for the District of Columbia Circuit. WLF urged the court to uphold a district court decision striking down FDA policies that severely restrict the free flow of truthful information regarding off-label uses of FDA-approved drugs and medical devices.

"We are extremely honored that both the ACLU and the pharmaceutical industry's trade group have chosen to support our efforts to uphold free-speech rights," said WLF Chief Counsel Richard Samp after filing WLF's brief. "That support indicates that individuals and groups across a wide political spectrum are unhappy with FDA's overregulation," Samp said.

The case is in the appeals court following U.S. District Judge Royce Lamberth's decision last July that FDA restrictions on dissemination of off-label information violated the First Amendment. Judge Lamberth also held that a provision of the Food and Drug Administration Modernization Act (FDAMA), a law adopted by Congress in 1997 that sanctioned a portion of those restrictions, was similarly unconstitutional. FDA filed its appellate brief on October 8, 1999. The case will be argued before a three-judge panel -- consisting of Judges Silberman, Williams, and Tatel -- on January 10, 2000.

FDA continues to press an argument it raised in the district court -- that its restrictions are not subject to First Amendment limitation because it is regulating not speech but conduct (i.e., the sale of drugs for off-label purposes). The district court rejected that argument, stating that FDA's argument that its restrictions were not subject to First Amendment limitation was "of course, preposterous." "The First Amendment is

premised upon the idea that people do not need the government's permission to engage in truthful, nonmisleading speech about lawful activity," the court ruled.

WLF argues in its brief that the FDA restrictions violate the First Amendment rights of both providers and recipients of information about off-label drug uses. WLF is suing on behalf of doctors and medical patients who wish to receive information about off-label uses of FDA-approved drugs and medical devices.

"Off-label" uses of a drug or device are uses of an FDA-approved product that have not received explicit FDA approval. Although federal law prohibits the manufacturer from specifying on the label any uses of the product other than the precise use approved by FDA, doctors are free to prescribe FDA-approved products for uses other than those specified on the product label. Judge Lamberth noted in his decision that off-label uses are in widespread use, and, in some areas of medical practice, doctors "consider off-label use to constitute the standard of good medical care."

WLF emphasized in its brief before the appeals court that it does not challenge FDA's right to control what manufacturers may place on product labels, or to regulate advertising. But, WLF asserted, FDA should not be permitted to regulate manufacturers' truthful speech about their products when the speech is not directly tied to marketing of the products.

The FDA policies challenged by WLF seek to prevent manufacturers from disseminating information about off-label uses of their products by prohibiting them, in most instances, from sending to doctors medical textbooks and reprints of articles from peer-reviewed medical journals that mention off-label uses of their products; and from providing funding for CME programs at which off-label uses of their products are to be discussed.

WLF is a nationwide public interest law and policy center. 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. WLF filed its brief with the pro bono assistance of Bert Rein, Andrew Krulwich, Thomas Queen, Daniel Troy, Michael Sturm, and Rosemary Harold of the law firm of Wiley, Rein & Fielding. Attorneys from the law firms of Pepper Hamilton LLP; Fox, Bennett & Turner; and Hyman, Phelps & McNamara also provided invaluable assistance in preparing WLF's case.

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