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PRESS RELEASE

WRF Client Washington Legal Foundation Wins Decision in First Amendment Challenge to FDA Regulations

September 16, 2000

Washington, DC—A recent federal court ruling makes clear that a key First Amendment victory for WRF client Washington Legal Foundation applies to new regulations implementing the Food and Drug Administration Modernization Act ("FDAMA"). In an order issued February 16, 1999, in the case of Washington Legal Foundation v. Friedman, U.S. District Judge Royce C. Lamberth rejected the U.S. Food and Drug Administration's request to limit the judge's 1998 decision striking down the agency's restrictions on certain communications concerning the "off-label" use of drugs and medical devices. For a link to Judge Lamberth's Memorandum Opinion and Redline Amended Order,

The term "off-label" derives from FDA's authority to review and approve the labeling of prescription drugs and medical devices as safe and effective for particular ailments or conditions. However, physicians may—and frequently do—lawfully prescribe drugs or use devices for conditions other than those set forth on the label. Such off-label uses are both widespread and beneficial, particularly in fields such as oncology (where medical advancements routinely outpace the FDA approval process) and pediatrics (where the ability to conduct the controlled studies necessary for FDA approval is limited).

But FDA rules restricted some speech about these off-label uses, even though the uses themselves were not restricted. Specifically, FDA prohibited drug and device manufacturers from disseminating to doctors or other health care professional any information about the off-label uses of their products, even when the speech at issue—such as articles published in a peer-reviewed medical journal—originated

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with a speaker independent of the manufacturer.

In 1994, WLF challenged these restrictions as impermissibly tramping upon the First Amendment rights of pharmaceutical and medical device manufacturers to disseminate, and of physicians and other health care professionals to receive, medical and scientific information and data concerning lawfully marketed drugs and medical devices. Judge Lamberth in July 1998 ruled in favor of WLF.

During briefing on WLF's challenge, however, Congress enacted FDAMA. The new statute rejects FDA's old blanket prohibition against manufacturer distribution of independently generated speech about off-label uses. However, Section 401 of FDAMA still places numerous—and onerous—conditions and burdens on the exercise of First Amendment rights. For example, a manufacturer may circulate articles and textbooks discussing off-label uses only if it has submitted to FDA a supplemental application for approval of a new use or certifies that it will do so within a specified period.

In moving to implement FDAMA, FDA asked Judge Lamberth to limit the effect of his July 1998 ruling to the agency's old (and now superceded) rules. The Judge declined to do so, stating that

Clearly, it was not the Court's intention that the implementation of the new legislation would render its decision moot. On the contrary, the Court was aware that the [FDA's 1996 "Guidance Documents"] represented only the latest articulation of the FDA's ongoing policies toward dissemination of scientific and educational information to health care providers. Consequently, while focusing on the Guidance Documents as the most recent available articulation of the policies, the Court considered the underlying policies in evaluating the constitutionality of FDA's position on manufacturer-sponsored dissemination of medical information.

Judge Lamberth has now asked the parties to submit supplemental briefs addressing "the extent to which FDAMA and its implementing regulations perpetuate [FDA's previous] policies."

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