July 29, 1999

COURT EXPANDS DECISION STRIKING DOWN FDA SPEECH RESTRICTIONS

(Washington Legal Foundation v. Henney)

A federal judge in Washington yesterday expanded his landmark July 1998 decision striking down Food and Drug Administration restrictions on the free flow of truthful information regarding off-label uses of FDA-approved drugs and medical devices.

Yesterday's ruling, issued by Judge Royce Lamberth, was a major victory for the Washington Legal Foundation (WLF), which had filed suit against the FDA restrictions. WLF argued that the restrictions violated the First Amendment rights of both providers and recipients of information about off-label drug uses.

The July 1998 injunction held that then-existing FDA speech restrictions were invalid under the First Amendment. In November 1998, FDA adopted regulations reimposing the restrictions; FDA argued that the new regulations should not be subject to the judge's injunction because they were adopted pursuant to a new law adopted by Congress, the Food and Dug Administration Modernization Act of 1997 (FDAMA). Judge Lamberth's decision yesterday rejected that argument; it held that the new FDA regulations and the provision of FDAMA under which the new regulations were adopted were both unconstitutional.

The court said 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.

FDA is expected within the next 60 days to appeal Judge Lamberth's decision to the U.S. Court of Appeals for the District of Columbia Circuit. FDA may also ask the appeals court to stay the effect of Judge Lamberth's decision during the course of the appeal (which can take two years).

The July 1998 decision invalidated three FDA policy documents that imposed restrictions on what manufacturers could say regarding off-label uses of their products. Those three FDA policy documents are: (1) FDA's December 3, 1997 "Final Guidance" on financial support provided by drug and device manufacturers for Continuing Medical Education (CME); (2) FDA's October 8, 1996 "Guidance" on dissemination of medical texts; and (3) FDA's October 8, 1996 "Guidance" on dissemination of reprints

from medical journals.

"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 1998 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."

The three FDA policy documents struck down by Judge Lamberth in 1998 sought 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.

The November 1998 regulations issued by FDA pursuant to FDAMA imposed similar restrictions. The regulations did allow certain limited exceptions, including that manufacturers could disseminate information about off-label use of a product if the manufacturer promised to submit within 36 months a supplemental application seeking FDA approval for the use in question. Judge Lamberth held that even with this exception, the new regulations violated the First Amendment because they were far more extensive than necessary to advance FDA's interest in encouraging manufacturers to seek FDA approval of all known uses for a product.

While enjoining enforcement of FDA's restrictive policies, the court made clear that FDA was still free to take actions to suppress false and misleading speech, and to require manufacturers who seek to disseminate information about off-label product information to attach disclaimers making clear to doctors that FDA has not approved the use being described.

WLF prosecuted its suit with the pro bono assistance of Daniel Troy, Thomas Queen, Michael Sturm, and Rosemary Harold of the law firm of Wiley, Rein & Fielding. Attorneys from the law firms of Pepper, Hamilton & Sheetz; Fox, Bennett & Turner; and Hyman, Phelps & McNamara also provided invaluable assistance in preparing WLF's case. 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.

* * *

For further information, contact WLF Chief Counsel Richard Samp at (202) 588-0302.