News Release

Washington Legal Foundation
Advocate for freedom and justice®
2009 Massachusetts Avenue, NW
Washington, DC 20036
202.588.0302

FOR IMMEDIATE RELEASE **June 4, 2008**

COURT URGED TO UPHOLD PREEMPTION OF FAILURE-TO-WARN SUITS INVOLVING DRUGS

(Wyeth v. Levine)

The Washington Legal Foundation (WLF) yesterday urged the U.S. Supreme Court to rule that federal law preempts state-law product liability suits challenging the adequacy of safety warnings provided by drug manufacturers, where the drug has been determined to be safe and effective by the Food and Drug Administration (FDA), and FDA has mandated the warnings that appear on product labeling.

In a brief filed in *Wyeth v. Levine*, WLF argued that such torts suits are impliedly preempted by federal law because they stand as an obstacle to the accomplishment of the goals of Congress and FDA. WLF argued that state court judgments against a pharmaceutical manufacturer that are based on a determination that the drug's label did not provide adequate safety warnings would undermine the new-drug approval process by calling into question FDA's decisions mandating specific product labels. WLF filed its brief on behalf of itself and the American College of Emergency Physicians. WLF drafted its brief with the pro bono assistance of Eric G. Lasker, an attorney with the Washington, D.C. law firm of Spriggs & Hollingsworth.

"WLF agrees with the majority of federal courts that have held that Congress intended to preempt suits that challenge the adequacy of FDA-approved labeling," said WLF Chief Counsel Richard Samp after filing WLF's brief. "Federal law impliedly preempts such common law causes of action because they stand as an obstacle to the accomplishment of Congress's purposes in establishing the new-drug approval process in 1962," Samp said.

WLF's brief focused on the adverse health consequences of permitting the plaintiff's lawsuit to go forward. If the plaintiff were to prevail, the manufacturer would be required to include new safety warnings on its product label, beyond the warnings mandated by FDA. WLF's brief provided several examples of instances in which "overwarning" regarding potential health risks has been bad for public health. WLF cited numerous medical studies demonstrating that overwarning results in many individuals forgoing medical treatment that they should be receiving. The adverse health effects of underutilization of available drugs far exceeds the adverse health effects from use of FDA-approved drugs, WLF argued. Among the examples of overwarning cited by WLF were: (1) warnings that use of SSRI drugs by adolescents might lead to suicides led to a drop in use of such drugs, and to an *increase* in teen suicides; (2) warnings that pregnant women might want to reduce fish consumption due to high mercury concentrations in fish led to decreased fish consumption, and to lower child IQ scores; (3) increased warnings regarding the safety of oral contraceptives led European women to abandon contraceptives altogether and ultimately to a significantly increased abortion rate; and (4) controversial warnings regarding the dangers of vaccines led to increasing numbers of parents choosing to forgo childhood vaccinations and later to huge increases in outbreaks of measles.

The case before the court involves Diana Levine, a resident of Vermont who suffered from severe migraine headaches. Her doctor chose to treat her with Phenergan, a drug manufactured by Wyeth. FDA and Wyeth knew that Phenergan could cause major complications if accidentally injected into an artery, so over the course of 35 years they had agreed on extensive labeling that warned against such use. Nonetheless, Levine's doctor accidentally injected Phenergan into one of her arteries instead of into one of her veins, and Levine suffered a severe injury. She then filed suit against Wyeth, alleging that its labeling inadequately warned against the dangers of intravenous injection. A jury found for Levine, and the Vermont Supreme Court affirmed the judgment in her favor. The U.S. Supreme Court agreed in January to review the case.

In its brief, WLF argued that the Vermont judgment conflicts with FDA's labeling determinations. WLF said that FDA had determined that the benefits of intravenous injunction outweighed the risks (*i.e.,* the risk that a doctor or nurse might inject Phenergan into an artery, mistakenly believing it to be a vein). WLF argued that if Wyeth is required to change its labeling to discourage intravenous injection of Phenergan, health care will suffer because patients will be steered away from a treatment option that FDA has deemed safe and effective.

WLF noted that the position it espouses does not leave injured patients without remedies. For example, they are still free to pursue other, non-preempted remedies against the manufacturer, such as that the drug was manufactured negligently (*i.e.*, not in conformance with the FDA-approved design), or that the drug was defectively designed. Alternatively, they can pursue remedies against others who may be responsible for the injuries, such as their physicians, WLF argued.

The Washington Legal Foundation is a public interest law and policy center with supporters in all 50 States. WLF devotes a significant percentage of its resources to defending and promoting free enterprise, individual rights, and a limited and accountable government.

* * *

For further information, contact WLF Chief Counsel Richard Samp, (202) 588-0302. A copy of WLF's brief is posted on its web site, www.wlf.org.