News Release

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2009 Massachusetts Avenue, NW
Washington, DC 20036
202.588.0302

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COURT URGED TO UPHOLD THE LEARNED INTERMEDIARY RULE

(*Centocor, Inc. v. Hamilton*)

The Washington Legal Foundation (WLF) this week urged the Supreme Court of Texas to uphold the "learned intermediary rule," which limits the liability of pharmaceutical companies in product liability lawsuits.

In a brief filed in *Centocor, Inc. v. Hamilton*, WLF noted that the rule has been upheld by 48 of the 49 states in which courts have addressed it, and it urged the Texas courts to do so as well. The learned intermediary rule holds that a product manufacturer has no duty to provide safety warnings directly to consumers, so long as the manufacturer has supplied warnings to an appropriate intermediary who can be expected to pass warnings directly on to consumers. In the case of prescription drugs, the learned intermediary rule provides that drug manufacturers fulfill their duty to warn by providing complete warnings to the prescribing physicians.

In this case, the Texas Court of Appeals adopted a highly restricted version of the learned intermediary rule and thereby upheld a multi-million dollar tort judgment against a drug manufacturer. WLF's brief urged the Texas Supreme Court to reverse. WLF's brief was drafted with the pro bono assistance of Daniel R. Volkmuth and Richard D. Salgado of the Jones Day law firm.

"Patients can receive prescription drugs only with the permission of a doctor; accordingly, it makes sense that they should receive warnings regarding potential safety issues from their own doctors, who are best acquainted with their patients' medical needs," said WLF Chief Counsel after filing WLF's brief. "If drug companies are required to begin providing warnings directly to consumers, the result will be an undermining of the doctor-patient relationship; and often it will not even be possible for drug companies to identify and contact the users of their drugs," Samp said.

The case involves the prescription drug Remicade, approved by FDA to treat Crohn's disease and rheumatoid arthritis. In rare cases, Remicade can cause the development of a lupus-like syndrome; Remicade's product labeling provides doctors with detailed warnings regarding that risk. The plaintiff, Patricia Hamilton, developed lupus after taking repeated infusions of Remicade to treat her Crohn's disease. She does not challenge the sufficiency of the warning provided by Centocor (the manufacturer) to her doctor, but she denies her doctors' claims that they told her about the danger of lupus. She also claims that she would not have used Remicade had she been aware of the risk of developing lupus. She sued Centocor for

failing to provide her an adequate warning and won a multi-million dollar judgment. The appeals court affirmed the judgment; it held that the learned intermediary doctrine should never be applied when a drug company (as here) engages in direct-to-consumer advertising.

WLF's brief urged that the judgment below be reversed. WLF devoted much of its brief to responding to a brief submitted by a group of Texas doctors who urged the Texas Supreme Court to abolish the learned intermediary rule entirely. WLF argued that the rule serves important functions and that doctors are in by far the best position to provide all appropriate warnings. WLF noted that the learned intermediary rule does not absolve manufacturers of all responsibilities; they can still be held liable for any injuries caused by their failure to provide an adequate warning to doctors.

WLF also urged the Texas Supreme Court to reject the lower court's exception to the learned intermediary rule for manufacturers who engage in direct-to-consumer advertising. WLF pointed out that virtually all prescription drug makers engage in some DTC advertising, so that the appeals court's "exception" would likely swallow the rule. WLF also argued that the exception makes little sense, given that DTC advertising has never been intended to displace the doctor-patient relationship and the pivotal role of doctors in advising their patients regarding appropriate medications. Moreover, WLF asserted, the DTC advertising exception relied on by the appeals court is not actually applicable here because the manufacturer never directed any advertising to the plaintiff. Rather, the only material produced by Centocor and seen by the plaintiff was an explanatory video tape that Centocor supplied to the treating physician and which the treating physician later decided to show to the plaintiff *after* she had agreed to take Remicade.

WLF is a public interest law and policy center with supporters in all 50 States. WLF devotes a substantial portion of its resources to defending and promoting free enterprise, individual rights, and a limited and accountable government. In particular, WLF has appeared in numerous federal and state courts in cases raising tort reform issues.

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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.