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COURT UPHOLDS LEARNED INTERMEDIARY RULE, DECLINES TO CREATE EXCEPTIONS

(Centocor, Inc. v. Hamilton)

The Supreme Court of Texas this week issued a decision upholding the “learned intermediary rule,” which limits the liability of pharmaceutical companies in product liability lawsuits, and declined to create an exception for companies that engage in direct-to-consumer advertising.

The decision was a victory for the Washington Legal Foundation (WLF), which filed a brief in *Centocor, Inc. v. Hamilton*, urging the court to uphold the learned intermediary rule. The 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. Agreeing with WLF that the manufacturer had no duty to warn the drug user under the facts of this case, the Texas Supreme Court reversed. 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 Richard Samp following the Court’s decision. “If drug companies were required to begin providing warnings directly to consumers, the doctor-patient relationship would be undermined; and often it would not be possible for drug companies to identify and contact the users of their drugs,” Samp said.

The case involved 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. Her

doctor testified that Centocor (the manufacturer) had fully informed him about the risk of lupus and that he had told Hamilton about those risks (a claim she denied). Hamilton 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.

Agreeing with WLF that the learned intermediary rule appropriately places on doctors the primary responsibility for conveying warnings to patients, the Texas Supreme Court 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. The court's decision relied heavily on a point stressed by WLF: 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.

The Texas Supreme Court also rejected the lower court's exception to the learned intermediary rule for manufacturers who engage in direct-to-consumer advertising. The court noted that virtually all prescription drug makers engage in some advertising, so that the appeals court's "exception" would likely swallow the rule. The court also agreed with WLF 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, the court held, the DTC advertising exception relied on by the appeals court was 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.