Litigation Update

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Tennessee Court Declines To Revisit The Learned Intermediary Doctrine

(Jones v. Abbott Laboratories)

Supreme Court of Tennessee

The Supreme Court of Tennessee has rejected a request by plaintiffs' attorneys that it reconsider its adherence to the "learned intermediary doctrine," which limits the liability of pharmaceutical companies in product liability lawsuits. At the request of those attorneys, a federal district court had addressed "certified questions" to the Tennessee court in an effort to ascertain whether Tennessee still adhered to the doctrine; in late August, the Tennessee court issued an order declining to respond to the certified questions.

The decision not to hear the case, *Jones v. Abbott Laboratories*, was a victory for WLF, which filed a brief urging that the learned intermediary doctrine not be reconsidered. WLF's brief noted that the doctrine has been upheld by 48 of the 49 states in which courts have addressed it (including Tennessee), and it urged the Tennessee Supreme Court to adhere to the doctrine. The learned intermediary doctrine 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 U.S. District Court for the Western District of Tennessee, which is hearing a failure-to-warn suit against a drug manufacturer, sent two certified questions to the Tennessee Supreme Court, asking whether Tennessee recognizes any exceptions to the doctrine. Noting the large increase in direct-to-consumer (DTC) advertising of pharmaceutical products in the 20 years since the Tennessee courts first recognized the learned intermediary doctrine, the district court asked whether Tennessee deems the doctrine inapplicable whenever a manufacturer's promotion of its product includes DTC advertising. The case before the district court involves Humira, a drug that its manufacturer, Abbott Labs, promotes through DTC advertising. The patient alleges that she developed lymphoma after being prescribed Humira to treat her severe rheumatoid arthritis. Although her doctor was aware that lymphoma is among the potential (albeit very uncommon) risks of Humira, she alleges that Abbott breached its duty of care by failing to provide warnings directly to her.

"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 Tennessee Supreme Court's decision not to reconsider the learned intermediary doctrine. "If drug companies were required to begin providing warnings directly to consumers, the doctor-patient relationship would be undermined; and often it is not possible for drug companies to identify and contact the users of their drugs," Samp said.

In urging the Tennessee court not to address the certified questions, WLF's brief argued that the learned intermediary doctrine serves important functions and that doctors are in by far the best position to provide all appropriate warnings. WLF noted that the learned intermediary doctrine 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.

In the event that the court agreed to address the certified questions, WLF argued in the alternative that the court should decline to create an exception to the learned intermediary doctrine 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 plaintiffs' proposed "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 espoused by the plaintiffs was not actually applicable in the case before the district court, because the patient neither read nor relied on any of the DTC advertisements issued by Abbott Labs.

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.

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.