

Learned Intermediary Doctrine: Pharmaceutical Company Loses the Adequate Warning Battle But Wins the War on Causation

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In *Pustejovsky v. PLIVA, Inc.*, ___ F.3d ___, 2010 WL 3928770 (Oct. 8, 2010), the U.S. Court of Appeals for the Fifth Circuit affirmed summary judgment against a plaintiff alleging that inadequate drug labeling caused her to suffer a neurological disorder. Plaintiff Martha Pustejovsky brought suit against PLIVA, Inc., manufacturer of metoclopramide (MCP), a generic drug for gastroesophageal reflux disease, alleging that PLIVA failed to adequately warn of the true magnitude of the risks associated with long-term MCP use. Pustejovsky claimed that, but for inadequate warning of the risk of tardive dyskinesia (TD), which causes involuntary facial spasms, her doctor never would have prescribed Pustejovsky MCP for a three-year period.

As a federal court sitting in diversity, the Fifth Circuit applied Texas' learned intermediary doctrine, which states that a drug manufacturer is not liable for failing to adequately warn of a prescription drug's side effects when the manufacturer "properly warns a prescribing physician of the dangerous propensities of its products . . ." *Id.* at *3. Additionally, manufacturer liability will not exist unless the inadequate warning was a "producing cause" of the plaintiff's injuries—that is, a proper label would have stopped the doctor from prescribing the drug in a way that caused the patient's injuries.

On appeal, the Fifth Circuit addressed two issues regarding the doctrine. On the first issue, the Fifth Circuit held that, contrary to the district court's opinion, the evidence showed that Dr. Wendi Collini was never aware of the fact that long-term MCP use resulted in TD in 1 out of 5 cases, instead believing the rate to be "one in a million." Accordingly, the court held PLIVA failed to support a defense under the first element of the learned intermediary doctrine because Dr. Collini "was not fully aware of the risk of TD" and thus couldn't be a *learned* intermediary. *Id.* at *4.

But on the second issue, the court held that Pustejovsky failed to present sufficient summary judgment evidence to prove that PLIVA's inadequate warning was the producing cause of her injury. Dr. Collini could not testify to having read the MCP warning insert or consulting the *Physician's Desk Reference* about MCP's risks. Although Pustejovsky surmised that perhaps Dr. Collini had talked about MCP's risks with other doctors or discussed it at continuing-education seminars, the court held that "[w]hile Pustejovsky can imagine any number of scenarios to fill the gaps in Dr. Collini's memory, she has provided evidentiary support for none of them." Accordingly, the court held that the second element of the learned intermediary doctrine barred Pustejovsky's recovery because the inadequate label was not a producing cause of her injury and affirmed summary judgment in PLIVA's favor.

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