Legal Backgrounder

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202.588.0302

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DRUG MANUFACTURERS' DEFENSES: EVERYTHING IS OLD AGAIN[1]

by

Gene M. Williams and Kathleen Frazier

In recent years, pharmaceutical manufacturers have become the target of plaintiffs' attorneys across the country. Reasons for the focus on the pharmaceutical industry can be attributed, at least in part, to tort reform. As state legislatures have begun to impose caps on the amount of damages a plaintiff can recover from a defendant, it has become more worthwhile for plaintiffs' attorneys to resort to a volume model in which they sue a single defendant on behalf of many plaintiffs. This increases the attorneys' potential award exponentially by the number of plaintiffs that can be identified.

The pharmaceutical industry is an ideal market for this mass litigation. Their products are often widely distributed, resulting in a multitude of potential plaintiffs that have been exposed to the same "defective" product. This also allows mass duplication of pleadings and discovery by the plaintiffs' firm, thereby reducing expenditures. And finally, large numbers of plaintiffs (called "inventory" by plaintiffs' lawyers) provide more leverage for a quick settlement. Combined, these factors encourage members of the plaintiffs' bar to rush to advertise on television and the new source of all knowledge, the Internet, soliciting potential clients as soon as any advisory or recall regarding a pharmaceutical product emerges.

Given this litigious atmosphere, pharmaceutical manufacturers placed high hopes on Wyeth Laboratories' federal preemption defense in *Wyeth v. Levine*, 129 S. Ct. 1187 (2009), a much anticipated case decided by the U.S. Supreme Court last March. There, Diana Levine filed suit against Wyeth alleging that Wyeth failed to adequately warn of the risk of directly injecting Wyeth's anti-nausea medication, Phenergan, into a patient's vein. Given that failure to adequately warn claims often comprise the heart of a product liability lawsuit against a pharmaceutical manufacturer, *Levine* garnered much attention when the U.S. Supreme Court granted certiorari on Wyeth's theory.

Levine. Volumes have been written about this case, but in brief, Wyeth's defense, federal preemption, is a principle grounded in the Supremacy Clause of the Constitution, which provides that federal law is the supreme law of the land and supersedes state law where inconsistencies exist. If decided in Wyeth's favor, preemption would have provided a complete defense to Levine's claims. Wyeth argued that

[1]Everything Old is New Again," from the musical "All That Jazz," lyrics by Carole Bayer Sager.

Gene M. Williams is the managing partner of, and **Kathleen Frazier** is an associate at, the Houston office of Shook Hardy & Bacon L.L.P.

it could not comply with both Vermont law (tort common law) and with federal law (regulations promulgated by the Federal Drug Administration ("FDA")) with regard to the warnings contained in Phenergan's labeling. Further complicating matters, the FDA supported Wyeth in endorsing the view that state tort law was inconsistent with the FDA findings that Phenergan was safe and effective. In the end, Wyeth's case turned on how much control the FDA maintained over the warnings provided by Wyeth.

The Supreme Court held that there was no direct conflict between FDA regulations and Levine's state law claims because Wyeth could have strengthened its warnings without FDA approval. In short, Levine's claims were not preempted and the trial court verdict in Levine's favor was affirmed. While preemption defenses certainly remain viable in some cases, the broad hopes of pharmaceutical manufacturers were not to be.

Learned Intermediary. So where does that leave the pharmaceutical industry in terms of defenses? One attractive possibility is the learned intermediary doctrine, which lends new meaning to the phrase "everything old is new again." The learned intermediary doctrine was first clearly defined in the mid-1960s. *See Sterling Drug v. Cornish*, 370 F.2d 82 (10th Cir. 1966). This doctrine, as applied to prescription pharmaceutical products, provides that when a drug manufacturer owes any warnings, it must give them to a patient's healthcare provider rather than directly to the patient. The logic behind this doctrine was succinctly stated by the Fifth Circuit:

> Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative.

Reyes v. Wyeth Labs., 498 F.2d 1264, 1276 (5th Cir. 1974). Every state high court to have addressed application of the learned intermediary doctrine to prescription pharmaceutical products, with the exception of West Virginia, has adopted it. *See West Va. ex rel. Johnson & Johnson Corp. v. Hon. Mark A. Karl*, No. 33211, slip op. (W.Va. June 27, 2007).[2]

In practice, application of the learned intermediary doctrine focuses solely on the warnings that the pharmaceutical manufacturer provides to the healthcare provider. Just as in any failure to warn case, the plaintiff must prove that the manufacturer owed a duty to warn, that the manufacturer breached that duty (i.e., the warning was inadequate), and that the breach caused of the plaintiff's injuries.

The duty to warn is a purely legal issue which must be determined by the judge rather than a jury. A pharmaceutical manufacturer may establish that it owed no duty to warn in circumstances such as where the plaintiff's complained-of injury had never previously been reported. Where the manufacturer did provide a warning, the adequacy of that warning often becomes a question of fact for the jury. They will have to consider the testimony of the plaintiff's and the manufacturer's labeling experts, as well as weigh factors such as whether the warning was prominent enough, whether it was placed in the appropriate location in the

[2]A few states following the doctrine have carved out certain exceptions in which the learned intermediary doctrine is purportedly inapplicable, such as when direct-to-consumer advertising has occurred. *See, e.g., Perez v. Wyeth Labs.*, 734 A.2d 1245, 1247 (N.J. 1999) ("[W]hen mass marketing of prescription drugs seeks to influence a patient's choice of a drug, a pharmaceutical manufacturer that makes direct claims to consumers for the efficacy of its product should not be unqualifiedly relieved of a duty to provide proper warnings of the dangers or side effects of the product").

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label, and whether it was clear enough for a prescriber to understand the risk involved. However, the adequacy of the warning can sometimes be determined by the judge as a matter of law if the manufacturer's warning specifically addresses the plaintiff's complained-of injury, or if the physician was already familiar with the risk based on training or experience. Similarly, a plaintiff's failure to establish that he has or had any injury can dispose of plaintiff's failure to warn claims before the case ever reaches a jury.

A Learned Intermediary Trumps Causation. The final focus of a warnings case is causation. To succeed on a failure-to-warn claim, the plaintiff must prove that the failure to adequately warn the healthcare provider *legally caused* the plaintiff's injuries. Thus, even if the warning was inadequate and even if the plaintiff sustained injuries that were the result of ingesting the pharmaceutical manufacturer defendant's product, the manufacturer cannot be found liable unless there was a causal connection between the inadequate warning given to the prescribing physician and the injury.

To this end, the testimony of the prescribing physician is critical to the case. A pharmaceutical manufacturer can negate causation by establishing certain facts relevant to the physician's prescription of the pharmaceutical agent at issue. One way to break the chain of causation is through testimony from the prescribing physician that the labeling for the product at issue was provided to him, but he did not read it at any time prior to prescribing the product to the plaintiff. Most healthcare providers will be reluctant to testify that they did not review the literature for a pharmaceutical product before prescribing it, so this type of testimony is somewhat unlikely.

The more likely scenario is testimony from the prescribing physician that he was aware of the potential for the adverse event of which the plaintiff complains, either through the labeling or through some other source, but prescribed the product anyway. This scenario is, in fact, quite common. Because every prescription medication has associated risks, a prescribing physician must weigh those risks as well as the potential benefits to his patient and conclude that the potential benefits outweigh the risks every time he prescribes a medication. Thus, it is a rare situation where a physician is not aware of certain risks associated with a medication before prescribing it.

The question then becomes whether the physician was aware of the specific risk of which the plaintiff complains at the time he prescribed the medication to the plaintiff. If so, then any inadequacy in the warnings provided could not have caused the plaintiff's injury. This is further bolstered by testimony from the prescriber that even if the warning had been worded differently, placed in a different location in the labeling, or some other aspect of the warning had been different, it would not have changed his decision to prescribe the medication.

A recent U.S. Court of Appeals for the Fifth Circuit decision confirmed that the learned intermediary doctrine is alive and well. In *Ebel v. Eli Lilly and Co*., the family of a man who committed suicide sued Lilly, claiming that ingestion of Zyprexa, a pharmaceutical agent manufactured by Lilly, caused the decedent to commit suicide. 321 F. App'x 350, 2009 WL 837325 (5th Cir. 2009). While the decedent had an extensive history of unremitting, disabling headaches and a prior suicide attempt, a defense verdict was by no means a sure thing given the emotional aspects of the case.

Prior to trial, Lilly filed a motion for summary judgment, requesting that the court dismiss the case based on the learned intermediary doctrine. During the discovery process, the physician who prescribed Zyprexa to the decedent had testified that he was aware of some association between the class of medications of which Zyprexa is a member and suicide. The fact that the prescriber could not remember exactly how he

learned this information or that the information may not be correct did not matter—the only thing that mattered was that the prescriber was aware of the potential for the exact adverse effect of which the plaintiff complained. Given this unequivocal testimony, the trial court granted Lilly's summary judgment motion for lack of causation, thereby dismissing all of the plaintiff's claims against Lilly and avoiding trial. The Fifth Circuit agreed with the trial court's assessment and affirmed the trial court's decision, thereby reaffirming the learned intermediary doctrine's place in Texas law.

In an earlier case with similar operative facts to those in *Ebel*, the Fifth Circuit not only affirmed summary judgment for the pharmaceutical manufacturer defendant based on the learned intermediary doctrine, but recognized another important caveat to the learned intermediary doctrine. *See Ackermann v. Wyeth Pharms.*, 526 F.3d 203 (5th Cir. 2008). The court noted that the so-called "read and heed presumption" does not apply to cases involving a learned intermediary. The "read and heed" presumption is a rebuttable presumption, typically applied to product manufacturers, which provides that had adequate warnings been provided, the plaintiff would have heeded them. The effect of this presumption is to shift the burden of producing evidence on this issue to the defendant. The inapplicability of this doctrine to learned intermediary cases is a significant factor in reducing the pharmaceutical manufacturer's burden in a warnings case.

Besides the Fifth Circuit, other federal circuit courts have also recently issued decisions disposing of claims through application of the learned intermediary doctrine. The Eleventh Circuit affirmed a trial court's holding that the pharmaceutical manufacturer defendant's allegedly inadequate warnings could not have caused the plaintiff's injuries where the prescribing physician testified that he was aware of the potential for the side effect from which the plaintiff complained and that he had chosen to prescribe the product independent of the warnings. *See Bodie v. Purdue Pharma Co.*, 236 F. App'x 511, 2007 WL 1577964 (11th Cir. 2007). *See also Latiolais v. Merck & Co.*, 302 F. App'x 756, 2008 WL 5157705 (9th Cir. 2008) (affirming trial court's finding that the defendant was not liable for failure to warn where the prescribing physician testified that the product labeling did not play a role in his decision to prescribe the product to the plaintiff).

Conclusion. Pharmaceutical manufacturers have worked to develop novel defenses to combat the litigation they now face. Some of these defenses will prevail and some will fail. The cost of advancing these defenses can be high. Consequently, it may be more cost effective and may result in a better outcome for pharmaceutical manufacturers to rely on that old friend, the learned intermediary doctrine, in battling failure-to-warn claims.

With sincere apologies to Broadway and the late Bob Fosse, "Get out your white suit, your tap shoes and tails. Let's go backward when forward fails." Everything old is new again.

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