CLIENT ALERT

Recent California Appeals Court Ruling May Lead To Direct Liability For Pioneer Manufacturers In Suits Involving Generic Drugs: *Conte v. Wyeth, Inc., et al.*

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On November 7, 2008, California's First District Court of Appeal set a remarkable precedent in pharmaceutical product liability law in *Conte v. Wyeth, Inc. et al.*, when it reversed a lower court ruling in favor of Wyeth and held that the prescription drug manufacturer could be liable for injuries caused by generic versions of its product if it had failed to disclose foreseeable side effects in its product labeling. (Link to opinion: *Conte v. Wyeth, Inc. et al.*) The court's reversal was based, in large part, on evidence that the plaintiff's physician may have relied on Wyeth's labeling, not the generics' labeling, when determining the plaintiff's course of care.

In *Conte v. Wyeth*, the plaintiff alleged that she developed tardive dyskinesia, an incurable and debilitating neurological disorder, as the result of taking metoclopramide for a period of four years. Metoclopramide is the generic version of Wyeth's brand name product, Reglan®. Ms. Conte claimed that Wyeth knew or should have known that physicians prescribe Reglan and its generic equivalents for periods exceeding the twelve-week period approved by the Food and Drug Administration (FDA). She claimed that this practice is prevalent because Reglan's product labeling minimizes the risk of serious injury that could result from extended use.

Section 505 of the federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355 (FDCA), prohibits the marketing of new drugs that have not received FDA approval. To obtain approval to market a new drug, a manufacturer must file a new drug application (NDA) and submit extensive data establishing the safety and efficacy of the product. The FDA also approves product labeling as part of this process. In 1984, Congress created a mechanism enabling generic drug manufacturers to obtain approval through an abbreviated new drug application (ANDA) process. Under the provisions of the Drug Price Competition and Patent Restoration Act of 1984, PL 98-417, more commonly known as the "Hatch-Waxman Act," a generic manufacturer is not required to prove that its product is safe and effective, only that the product is "bioequivalent" to the brand name, or "listed" product. Generally speaking, a drug is considered "bioequivalent" if the rate and extent of absorption of the generic product is not significantly different from that of the brand product. 21 U.S.C. § 355(j)(8)(B). The conditions of use and warnings for the generic versions of the product must be identical to those for the brand-name product. 21 U.S.C. § 355(j)(2)(A).

Court Concludes That Foreseeable Risk Of Physical Harm Runs To Users Of Both Name-Brand And Generic Drugs

The court's reversal hinges on the testimony of Dr. Elsen, Ms. Conte's physician. Ms. Conte claimed that Dr. Elsen relied on information contained in the Physician's Desk Reference (PDR) monograph on Reglan, written by Wyeth. Wyeth argued that that Dr. Elsen did not rely on the PDR monograph, Wyeth's package insert or other labeling in determining Ms. Conte's course of care. In his deposition, however, Dr. Elsen testified that he "probably" read Wyeth's monograph during his residency; that the PDR was one of the sources he would use in making prescribing decisions about Reglan and that he believed the PDR information to be accurate. The court reasoned that because the facts regarding Dr. Elsen's recollections are in dispute, Wyeth was not entitled to summary judgment.

The court went on to state that brand name companies such as Wyeth owe a duty of care to a patient for whom a generic drug is prescribed if the physician relies upon the brand-name product information in determining the patient's course of care. In the court's opinion, brand-name drug companies should realize that physicians will rely on their product information, even when prescribing a generic equivalent. Thus, the court concluded, if Wyeth intentionally or negligently excluded from its labeling warnings of reasonably foreseeable injury, the company would be liable to a patient injured by the generic product where the prescriber relied on Wyeth's product information.

The court rejected Wyeth's argument that imposing liability would deter innovation in the pharmaceutical industry, stating that Wyeth had produced no evidence on summary judgment to support this argument. The court also noted that there was insufficient evidence on the record to inform a discussion about possible injury to Wyeth. The court refused to reconsider the lower court's ruling that Ms. Conte's claims against the three generic companies were preempted by the FDCA. Wyeth did not assert that federal law preempted Ms. Conte's claims. Wyeth is involved in another lawsuit regarding federal preemption, *Wyeth v. Levine*, which is pending before the Supreme Court. (***See*** **Crowell & Moring Life Sciences and Torts Alert:** Supreme Court Asked To Consider Congressional Staff Report on Eve of Oral Argument in *Wyeth v. Levine*)

Generic Manufacturers Dismissed Because No Evidence of Reliance on Their Label

The plaintiff also named three generic manufacturers as defendants in this case. The court affirmed the lower court's grant of summary judgment as to these three defendants because there was no evidence that Dr. Elsen relied on the generic manufacturers' labeling.

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