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California Appeals Court Ruling May Lead to Direct Liability for Pioneer Drug Manufacturers in Suits Involving Generic Products

On Nov. 7, 2008, California's First District Court of Appeals set a remarkable precedent in pharmaceutical product liability law in *Conte v. Wyeth Inc. et al*. In this case, the court reversed the trial court's summary judgment ruling in favor of Wyeth, a manufacturer of prescription drugs, and held that the company could be liable for injuries caused by generic versions of its product under theories of fraud and negligent misrepresentation if Wyeth's own product information failed to disclose foreseeable side effects of its drugs. On Jan. 21, 2009, the Supreme Court of California denied Wyeth's petition for review of the appellate court's decision, clearing the way for the lawsuit against Wyeth to proceed and leaving in place what is now a state-wide precedent.

Inadequate Labeling

In *Conte v. Wyeth*, the plaintiff alleged that she had developed tardive dyskinesia, an incurable and debilitating neurological disorder, as a result of taking metoclopramide for a period of four years. Metoclopramide—the generic version of Wyeth's brand-name product, Reglan®—is used to treat gastroesophageal reflux. Conte claimed that Wyeth knew, or should have known, that physicians prescribe Reglan and its generic equivalents for periods exceeding the 12-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 of the drug.

Section 505 of the federal Food, Drug, and Cosmetics Act, 21 U.S.C. § 355, 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 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 that enabled generic drug manufacturers to obtain approval through an abbreviated new drug application 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 manufacturer of a generic drug is not required to prove that its product is safe and effective, only that the product is the "bioequivalent" of 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-name 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).

Critical to the appellate court's holding that Wyeth was not entitled to summary judgment was the fact that the plaintiff asserted fraud and negligent misrepresentation claims against Wyeth. The court noted that the plaintiff had alleged that Wyeth had failed to use due care when disseminating information about its product and had made intentional and/or negligent misrepresentations about the safety of metoclopramide, the risks of long-term use of the drug, and the likelihood of serious side effects. By contrast, the manufacturers of the generic product were sued on the traditional product liability grounds for claims of negligence, strict products liability, negligence per se, and breach of warranty. Thus, the court summarily rejected Wyeth's central argument, which was premised on product liability law, that it could not be liable to Conte, because it had not manufactured or sold the generic medication that allegedly had caused her medical condition. Instead, under a "fraudulent representation" liability theory, the court reasoned that, if a manufacturer disseminates misleading information about a product—even one that is produced by another company—the manufacturer should reasonably ex-

pect to be held liable if others rely on its information and that reliance leads to injury.

With regard to generic drugs, the court held that it was "eminently foreseeable" that a physician might prescribe a generic version of a drug based on representations made by the manufacturer of the pioneer drug. Thus, factually, the court's reversal of the trial court's ruling on Wyeth's summary judgment motion hinged on the disputed testimony of Dr. Elsen, Conte's physician. Conte claimed that Dr. Elsen had relied on information on Reglan, which was written by Wyeth and included in the *Physicians' Desk Reference* (*PDR*). Wyeth argued that that Dr. Elsen had not relied on the *PDR*, Wyeth's package insert, or other labeling in determining Conte's course of treatment. In his deposition, however, Dr. Elsen testified that he had "probably" read Wyeth's information in the *PDR* during his residency, that the *PDR* was one of the sources he would use in making decisions about prescribing Reglan, and that he believed the *PDR* information to be accurate. The court reasoned that, because the facts regarding Dr. Elsen's recollections remained in dispute, summary judgment in favor of Wyeth was not appropriate.

In reaching its decision, the court of appeals explicitly rejected a series of state and federal decisions holding that, under theories of misrepresentation, manufacturers of pioneer drugs are not liable for injuries caused by the generic equivalent. The court explained that the other courts (as well as the trial court) had misapplied the rule that no product liability exists if the defendant did not manufacture the drug. This decision was in error, because this rule does not apply to claims of fraud and negligent misrepresentation. The fact that Wyeth had not manufactured the drug did not relieve the company from a "general duty to use due care" in disseminating product information to those the manufacturer knows—*or should know*—are likely to be harmed as a result of a prescriber's reliance on that information.

The appellate court rejected as unpersuasive Wyeth's argument that the court's decision would deter innovation in the pharmaceutical industry and stated that Wyeth had produced no evidence to support this argument. The court also rejected the trial court's contention that allowing misrepresentation claims would make the manufacturer of pioneer drugs liable for the acts of its generic competitors. The court explained that a pioneer drug manufacturer would be held accountable only for any misleading information *it disseminated about the drug* and not for defects in the generic version of the product or for information disseminated by the manufacturer of the generic product.

Generic Drug Manufacturers Dismissed Because of No Evidence of Reliance on Their Label

The plaintiff also named three manufacturers of generic drugs as defendants in this case and, as noted above, alleged the typical suite of product liability claims against these companies: negligence, negligence per se, strict product liability, and breach of express and implied warranties. Unlike Wyeth, the generic manufacturers all moved for summary judgment on the grounds that the claims against them were preempted by the Food, Drug, and Cosmetics Act. Only one generic drug manufacturer joined in Wyeth's motion asserting a lack of causation. The court affirmed the lower court's grant of summary judgment as to these three defendants, because there was no evidence that Dr. Elsen had relied on anything beyond Wyeth's PDR statement. The court concluded that the plaintiff could not prove that any of the three generic drug manufacturers were responsible for her injury and dismissed the claims against them. Thus, the court determined that there was no need to address the generic drug defendants' argument that the plaintiff's claims were subject to federal pre-emption.

Uncertain Implications

The rationale for the *Conte* court's expansive view of pioneer drug manufacturers' liability in this context is based on the fact that federal law requires manufacturers of generic drugs to rely on the safety and efficacy data provided to the Food and Drug Administration by manufacturers of pioneer drugs and on the risk information contained in the pioneer drug manufacturer's FDA-approved labeling. Prior to the court's decision in *Conte*, manufacturers of pioneer drugs were, in a sense, protected by the application of traditional theories of product liability law. The *Conte* court introduced elements of FDA law into its decision, thus highlighting an issue that had not been previously considered in such cases. If other courts follow the decision in *Conte*, pioneer drug manufacturers who fail to include critical risk information in their labeling may might become unwilling parties to lawsuits for products manufactured by third-party manufacturers of generic drugs. **TFL**

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