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California Appellate Court Holds That Innovator Drug Manufacturers Can Be Liable for Injuries Suffered by Patients Who Take Generic Equivalents

In a recent decision, the California Court of Appeals for the First Appellate District reversed a grant of summary judgment in favor of Wyeth, Inc. in a personal injury action brought by an individual claiming injuries caused by her ingestion of a generic equivalent to Wyeth's product Reglan. In *Conte v. Wyeth, Inc.*, the court held that the company could be found liable for the patient's injuries even though she did not take the Wyeth's product under a theory of negligent misrepresentation.[1] The court concluded that Wyeth could anticipate that doctors would review and rely on the labeling for Reglan but that doctors would prescribe a generic equivalent or that pharmacies would fill Reglan prescriptions with generic substitutes.[2] Therefore, it was foreseeable in the court's view that Wyeth's labeling could start a chain of events leading to the patient's injury.[3]

Conte's holding is virtually unprecedented — no appellate court had accepted such a theory before.[4] While it is one case against a backdrop of numerous contrary precedents, if adopted more broadly, *Conte* will expose innovator companies to significant new liability. Further, the case adds to a trend in state courts rethinking well-established product liability doctrines that had served to limit the circumstances in which pharmaceutical manufacturers can be held liable.[5]

Conte involves a common set of facts.[6] Over a period of time, a physician prescribed a name-brand drug and its generic equivalents to a patient. Because California has a generic substitution law, the plaintiff did not ever receive Wyeth's product. The patient filed her suit against the generic manufacturers and Wyeth asserting claims for fraud, fraud by concealment, and negligent misrepresentation against Wyeth, and negligence, strict products liability negligence *per se*, and breach of express and implied warranties against the generic manufacturers. All of the defendants moved for summary judgment on various grounds including a motion by Wyeth arguing a lack of causation because the plaintiff had not taken Wyeth's product. The trial court, following established product liability law, granted Wyeth's motion concluding that the company owed no duty to patients who did not ingest its product.[7]

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1 *Conte v. Wyeth, Inc.*, Nos. A116707 & A117353, slip op. at 8-22 (Cal. Ct. App. Nov. 7, 2008).

2 *Id.*

3 *Id.*

4 A Pennsylvania trial court has also suggested that a company's off-label promotion of a branded product could make the company liable for refunds to users of both the branded product and generic equivalents. *Clark v. Pfizer, Inc.*, No. 1819 (Ct. Comm. Pleas Mar. 12, 2008).

5 *See State ex rel. Johnson & Johnson Corp. v. Karl*, 647 S.E.2d 899 (W.Va., 2007) (rejecting the learned intermediary doctrine).

6 Facts described below can be found at *Conte*, slip op. at 2-3.

7 The trial court also granted the motion of Wyeth and one of the generic manufacturers arguing that there was insufficient evidence that plaintiff's prescribing physician had read and relied on the labeling for their products. *Conte*, slip op. at 3. The court of appeals reversed that holding as to Wyeth but affirmed as to the generic manufacturer and extended that holding to the other generic manufacturers. *Id.* at 8; 22-25. Thus the case will proceed to trial against Wyeth alone unless the California Supreme Court hears the case.

The court of appeals, however, concluded that the traditional product law did not apply in a case in which plaintiff alleges negligent misrepresentation. To make out such a claim, the court concluded that plaintiff did not need to show that plaintiff actually ingested Wyeth's product to show that the existence of a duty — the rule in product liability cases. Rather, relying on two California Supreme Court decisions that did not involve the use of products, and the *Restatement Second of Torts* sections 310 and 311, the court concluded that Wyeth owed a patient who ingested a generic product a duty if it was foreseeable that a physician would rely on the company's labeling for its product and then prescribe a generic equivalent, or have a pharmacy fill the prescription with a generic.[8] As the court explained "a defendant who authors and disseminates information about a product manufactured by another may be liable for negligent misrepresentation where the defendant should reasonably expect others to rely on that information and the product causes injury, even though the defendant would not be liable in strict products liability because it did not sell the product."[9]

Conte stands in contrast to a large body of case law requiring that a patient must have used a product to have a claim against a drug manufacturer. For example, the United States Court of Appeals for the Fourth Circuit addressed the exact issue in *Foster v. American Home Products*, 29 F.3d 165 (4th Cir. 1994). Plaintiffs, parents of an infant who died after using a generic equivalent of a product manufactured by American Home Products, brought suit against the company claiming, *inter alia*, negligent misrepresentation. The Fourth Circuit affirmed a grant of summary judgment — concluding that whatever type of legal theory a plaintiff employs, she must show that she used a company's product to have a valid claim.[10] Numerous other federal and state courts have reached a similar conclusion.[11] The California court simply rejects these cases because they are products cases and negligent misrepresentation is doctrinally different.[12]

Wyeth can seek *certiorari* from the California Supreme Court in *Conte*. Because the decision places California law at variance with every federal and state appellate court to have considered the issue, *Conte* would appear to be a strong candidate for review by the court.[13] Review by that court will offer an opportunity to explore fully the policy consequences of shifting some portion of the risk of personal injury liability from generic manufacturers to innovator companies.

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8 *Conte*, slip op. at 11. The court relied on *Garcia v. Superior Court*, 789 P.2d 960 (Cal. 1990), in which the court concluded that a parole officer owed a woman a duty when he represented to her that a criminal who had victimized her before would "not come looking for her" (he kidnapped and shot her in the event) and *Randi W. v. Muroc Joint Unified School Dist.*, 929 P.2d 582 (Cal. 1997), in which the court found a school board had a duty to a victim of sexual abuse at the hands of teacher when that school district had given the teacher a job recommendation.

9 *Conte*, slip op. at 11.

10 *Foster*, 29 F.3d at 168-69.

11 *See Colacicco v. Apotex, Inc.*, 432 F.Supp.2d 514, 540-41 (E.D. Pa. 2006) (collecting cases), *aff'd on other grounds*, 521 F.3d 253 (3d Cir. 2008).

12 *Conte*, slip op. at 18. The California court also rejected policy arguments that imposing liability on innovator companies for the use of generic drugs, though it noted that it had a limited record on these points. Id. at 19-21.

13 *See* California Rules of Court Rule 8.5000 (Supreme Court will review case "[w]hen necessary to secure uniformity of decision or settle an important area of law.").