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New California Appellate Decision Makes Brand Name Drug Manufacturers Potentially Liable for Injuries Suffered by Consumers of Generic Drugs

In *Conte v. Wyeth, Inc.*1, a case of first impression in California, the Court of Appeal reversed the entry of summary judgment in favor of a brand name drug manufacturer that, along with other defendants, was sued by a consumer who alleged injuries from having been administered a generic form of the drug. In both its conclusion and its reasoning, the court has departed from what had seemed to be relatively settled case law. While the effect of the decision may ultimately be limited, either because of further review by the California Supreme Court or because other courts decline to follow the precedent, for now the decision has opened a very large door to litigation in an area of ongoing concern to branded drug companies.

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The plaintiff in *Conte* alleged that she developed a "debilitating and incurable" neurological condition as a result of her use over a four-year period of generic versions of the Wyeth drug, Reglan®.2 The labeling for Reglan® indicated use for only a twelve-week period, but the plaintiff alleged that Wyeth and the three companies that manufactured generic versions of Reglan® "knew or should have known" of a "widespread tendency" of physicians to prescribe the drug for a year or more.3 The labeling of Reglan®, as well as a monograph on the drug that was prepared by Wyeth for inclusion in the *Physician's Desk Reference* ("PDR"), were alleged to have substantially understated the risks of long-term use. The generics' labeling was identical to that of the branded drug.

As most relevant here, the plaintiff sued Wyeth for fraud and negligent misrepresentation, the three manufacturers of the generics for negligence and strict products liability, and her physician for negligence.4 Following discovery, the trial court granted summary judgment in favor of Wyeth and one of the generics manufacturers. The judgment for Wyeth was based upon the trial court's conclusion that the plaintiff's physician had not relied upon drug information provided by Wyeth, and that Wyeth owed no duty of care to people who, like plaintiff, consumed generic copies of Wyeth drugs. The court dismissed the three generics manufacturers on the ground that claims based upon alleged deficiencies in prescription drug labeling were preempted by the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq*.

On appeal, the ruling in favor of Wyeth was reversed on both theories advanced by the trial court. Importantly, the Court of Appeal found that a factual dispute existed as to the reliance of the plaintiff's physician on materials prepared by Wyeth. The physician had submitted a declaration to the effect that he had not relied upon representations made in the PDR or Wyeth labeling in order to formulate his course of care and treatment of the plaintiff, and the court observed that, without more, this fact would support the entry of judgment for the manufacturer on a theory of nonreliance. But the physician had also testified in his deposition that he "probably" read the PDR entry for Reglan® during his residency, "generally" used the PDR in his practice, and believed statements in the PDR to be true.5 The court concluded that these statements, amounting to little more than an admission of access by doctors to information prepared by Wyeth, created a question of fact as to the physician's actual reliance upon that information in treating the plaintiff, precluding the entry of summary judgment.

Describing the question as one of first impression under California law, the Court of Appeal also

disagreed that Wyeth owed no duty of care to consumers who did not take its product. In this regard the court drew a sharp distinction between product liability claims, which had not been brought against Wyeth, and negligence and intentional misrepresentation claims, which had. It agreed with the large body of law that limited product liability claims to plaintiffs who had been injured by the defendant's products. But, noting that Wyeth had not been sued on a product liability theory, the court disagreed that such limitation applied in general to injuries resulting from negligent and intentional misrepresentations. Rather, citing authority to the effect that the scope of a defendant's duty of care principally was limited to the universe of injuries that were foreseeable, the court concluded that liability could attach to injuries irrespective of source. Because the use of generic drugs is commonplace, and generic drug labeling is required to be based on that which is approved for the branded pioneer drug, the court found that it was "eminently foreseeable" that a physician prescribing a generic copy of Reglan® would do so based upon representations made by Wyeth.[6] "In this context, we have no difficulty concluding that Wyeth should reasonably perceive that there could be injurious reliance on its product information by a patient taking generic [Reglan®]."[7]

California law also requires that a court deciding whether to extend a duty of care in a "novel situation" also consider various policy factors, including:

> The foreseeability of harm to the plaintiff; the degree of certainty that the plaintiff suffered injury; the closeness of the connection between the defendant's conduct and the plaintiff's injury; the moral blame attached to the defendant's conduct; the policy goal of preventing future harm; the burden to the defendant and consequences to the community of imposing a duty of care; and broader consequences including the availability, cost, and prevalence of insurance for the risk involved.[8]

As to these, the court largely demurred:

> While there is much that could and will be said in various fora about the burdens, social consequences, cost, and insurance implications of Wyeth's potential liability, the limited record on summary judgment does not provide the information necessary to inform such a debate. These broader consequences of the duty we identify today cannot be considered on the limited facts in the record.[9]

Wyeth had argued that the case was governed by a line of cases, beginning with *Foster v. American Home Products Corp.*,[10] which held that no such duty exists, irrespective of the theory used as a basis for recovery. The *Foster* case was itself one that alleged a negligent misrepresentation, and it rejected claims that liability for a generic drug's labeling could attach to the brand name manufacturer that may have originated the labeling.[11] Moreover, the Fourth Circuit, largely on policy grounds, rejected the claim that the brand name manufacturer owed a duty to consumers of generic products.

The Court of Appeal in *Conte* identified a number of potential distinctions between the case at bar and the *Foster* line, but frankly acknowledged that it was just breaking new ground: "We are aware that in declining to follow *Foster* we depart from the majority of courts to have wrestled with this particular issue."[12] It viewed the potential liability of third parties under a theory of negligent misrepresentation theory to be almost settled law, and appeared convinced that limitations on liability that exist in products liability cases could simply be ignored.

On this basis, the Court of Appeal reversed the entry of summary judgment against Wyeth and sent the case on a course to trial. The court affirmed the entry of summary judgment against the generic manufacturers upon the plaintiff's concession that her physician had not relied upon any statement the manufacturers may have made.[13] The trial court's determination that the claims against the generics were preempted by federal law was not reached on appeal.

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We have written a number of times on potential theories of recovery where injuries have arisen

from the ingestion of drugs not sold by the defendant for sale to the plaintiff – cases where drugs are counterfeit, illegally diverted, or, as here, generic. The *Foster* line of cases, followed in at least ten rulings,[14] did not seem to be a likely candidate for reevaluation. Despite the *Conte* ruling, the reevaluation of *Foster* still seems unlikely. Pending appeal, California seems to stand alone in extending a branded prescription drug manufacturer's duty to warn to remote users of generic copies of its products, to say nothing of the fact necessary to create a jury question or to actual reliance. In California as elsewhere, decisions in cases such as this in large measure are driven by policy concerns and notions of fundamental fairness. This panel of three judges, assessing that question for the first time under California law, has struck a balance in favor of expansive obligation that most other states have not made or appear unlikely to make. While it will no doubt be the basis for additional litigation—or at least litigation against additional defendants making additional claims—we are not persuaded that other states will use this opinion as a means to reevaluate their own law.

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1. A116707, 2008 Cal. App. LEXIS 1736 (Cal. Ct. App. Nov. 7, 2008).
2. See *id.* at *3.
3. See *id.* at *3-4.
4. Specifically, Wyeth was sued for fraud, fraud by concealment and negligent misrepresentation; the three manufacturers of generic copies of Reglan® were sued for negligence, strict products liability, negligence *per se*, and breach of express and implied warranties; and the plaintiff's prescribing physician was sued for medical negligence. See *id.* at *4.
5. See *id.* at *13-14.
6. See *id.* at *27.
7. *Id.*
8. *Id.* at *28-29 (citing *Randi W. v. Muroc Joint Unified School Dist.*, 14 Cal.4th 1066, 1077 (1997) [60 Cal. Rptr. 2d 263, 929 P.2d 582] and *Rowland v. Christian*, 69 Cal.2d 108, 112 (1968) [70 Cal. Rptr. 97, 443 P.2d 561]).
9. *Id.* at *32.
10. 29 F.3d 165 (4th Cir. 1994).
11. The Fourth Circuit observed that FDA regulations permitted generic drug manufacturers to add or strengthen warnings that they are required to incorporate from the brand name product's labeling. See *Foster*, 29 F.3d at 170.
12. *Conte*, 2008 Cal. App. LEXIS 1736, at *41.
13. Interestingly, for practical and understandable reasons, the court ordered that judgment be entered against all three generics manufacturers even though only one had moved on a theory of nonreliance. See *id.* at *46-49.
14. See, e.g., *Goldych v. Eli Lilly & Co.*, No. 5:04-CV-1477, 2006 U.S. Dist. LEXIS 49616 (N.D.N.Y. July 19, 2006); *Colacicco v. Apotex, Inc.*, 432 F.Supp.2d 514, 540 (noting that the *Foster* decision has encountered widespread acceptance, and listing the following cases as examples: *Tarver v. Wyeth, Inc.*, Civil Action No. 3-04-2036, slip. op. (W.D.La. Apr. 28, 2005) (applying Louisiana law); *Block v. Wyeth, Inc.*, 02-cv-1077, 2003 WL 203067 (N.D.Tex. Jan. 28, 2003); *DaCosta v. Novartis AG*, 01-cv-800, 2002 WL 31957424 (D.Or. Mar. 1, 2002); *Christian v. 3M*, 126 F.Supp.2d 951, 958 (D.Md. 2001); *Miller v. Bristol-Meyers Squibb Co.*, 121 F.Supp.2d 831, 836 (D. Md. 2000); *Sharp v. Leichus*, 2004-CA-0643, 2006 WL 515532 (Fla. Cir. Ct. Feb. 17, 2006); *Kelly v. Wyeth*, MICV 2003-03314-B, 2005 WL 4056740, slip. op. (Super. Ct. Mass. May 6, 2005); *Sheeks v. Am. Home Prods. Corp.*, No. 02CV337, slip. op. (Dist. Ct. Colo. Oct. 15, 2004); *Sloan v. Wyeth, Inc.*, No. MRS-L-1183-04, slip. op. (Super. Ct. N.J. Oct. 13, 2004); *Beutella v. A.H. Robins*, Civil No. 98052372, 2001 WL 35669202, slip. op. (Utah Dist. Ct. Nov. 7, 2001)).

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