Only in California: Name Brand Drug Manufacturer Owes Duty to Generic Drug User

by Christopher Wright
Column Editor: James R. Lance

Two years ago, a California appellate court rejected a national trend and extended a name-brand pharmaceutical manufacturer's duty of care to individuals using the generic version of the drug. *Conte v. Wyeth, Inc.* (2008) 168 Cal.App.4th 89 (cert. denied). It was the first time such a duty of care had been imposed. Today, *Conte* remains the outlier among the jurisdictions that have addressed the issue.

The *Conte v. Wyeth, Inc.* Case

Elizabeth Conte alleged she developed a permanent neurological condition — tardive dyskenisia. She claimed her condition was caused by metoclopramide, a medication commonly used to treat heartburn, nausea and vomiting. Wyeth, Inc. developed, manufactured and marketed the name-brand version of the drug, Reglan. In addition to naming Wyeth, Ms. Conte sued several generic manufacturers of the product and the physician that prescribed the medication.

Ms. Conte alleged that Wyeth disseminated false, misleading and incomplete warnings about the side effects. Specifically, she claimed Wyeth knew or should have known of the tendency among physicians to prescribe metoclopramide for periods of 12 months or more, even though the medication was only approved for a maximum usage of 12 weeks. Ms. Conte alleged that the labeling substantially understated the risks of serious side effects from extended use.

It was undisputed that Conte had only used generic versions of the medication. No California case had addressed the issue of whether a name brand drug manufacturer owed a duty to users of generic versions of its product which were produced by other manufacturers.

As a brief regulatory background, the Federal Drug and Cosmetic Act (21 U.S.C. §§355, *et seq*.) requires that drug manufacturers obtain approval from the Food and Drug Administration before they can distribute drugs. Name-brand drug manufacturers must demonstrate that the drug is safe and effective for its stated purpose and that the proposed labeling is not false or misleading. FDA approval for generic manufacturers is not as rigorous. The generic manufacturer is only required to demonstrate that its product is the bioequivalent (same active ingredients and rate and extent of absorption) of the name-brand product and the labeling and warnings are identical to those accompanying the approved name-brand drug.

In addition, in California, pharmacists are permitted to fill prescriptions for name brand medications with generic equivalents unless the prescribing physician specifically indicates otherwise. Bus. & Prof. Code §4073.

Wyeth, as the pioneering manufacturer, was responsible for developing the drug and drafting the warning labels as well as the literature included in the Physicians' Desk Reference. Per law, the generic products are Reglan's bioequivalent and contain the same labels and warnings.

The appellate court held that Wyeth owed a duty to Conte even though she did not use its product. The court relied on the California Supreme Court's rulings in *Randi W. v. Muroc Joint Unified School Dist.* (1997) 14 Cal.4th 1066, and *Garcia v. Superior Court* (1990) 50 Cal.3d 728, adopting the Restatement Second of Torts, §§310 and 311, that one owes a duty not to make a misrepresentation when there is a foreseeable risk of personal harm to a third party.

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Christopher Wright is an associate at Kirby Noonan Lance & Hoge LLP, where he practices civil litigation with emphasis in professional liability, commercial business disputes and class actions. He received his undergraduate degree in business administration from the University of Southern California in 1999 and received his Juris Doctor from Loyola Law School in 2003. He is admitted to practice in all courts of the State of California, the U.S. District Court, Central and Southern Districts of California and the 9th Circuit Court of Appeal. He may be reached at: cwright@knlh.com.

The court found it foreseeable that a physician would rely on Wyeth's product information when prescribing metoclopramide, that the patient would receive a generic version, and that misinformation could result in injury. Accordingly, Wyeth owed a duty to Conte.

Conte is Recognized as California Law by U.S. District Court

Conte was recognized and followed by the U.S. District Court, Central District, in *Dorsett v. Sandoz, Inc.* (C.D. Cal. 2009) 2009 WL 3633874. The *Dorsett* case, a similar action involving the medication Prozac, was pending at the time *Conte* was decided. Thereafter, the plaintiff amended her complaint to add the name-brand manufacturer, Eli Lilly and Company, in place of Doe 1. Eli Lilly moved for judgment on the pleadings on the ground that the action was time-barred.

The court found that the plaintiff could not have known that the cause of action existed against Eli Lilly because the *Conte* court was the first court in California, indeed anywhere, to extend such a duty to a pioneering manufacturer. Accordingly, it held that the amendment related back to the date of the original filing and denied Eli Lilly's motion.

No Support in Other Jurisdictions

The *Conte* reasoning has failed to gain traction outside of California. In reaching its decision, the *Conte* court expressly rejected a decision of the U.S. Court of Appeals for the Fourth Circuit in *Foster v. American Home Products Court* (4th Cir. 1994) 29 F.3d 165. Presented with an identical set of facts, the *Foster* court declined to "stretch the concept of foreseeability too far" and held that the name-brand manufacturer owed no duty to users of products it did not manufacture. *Id*. at 170-171. The *Foster* view prevails in other jurisdictions that have addressed the issue.

Conte has been described as "the lone outlier against the overwhelming weight of majority on this point." *Dietrich v. Wyeth, Inc.* (Fl. Cir. Ct. 2009) 2009 WL 4924722. The *Dietrich* court noted that 20 states do not impose the duty on name brand manufacturers. *Id.* at 10-11. Several recent decisions outside of California have adopted the reasoning in *Foster* and specifically rejected *Conte*. These include *Fisher v. Pelstring* (D. So.Car. 2010) 2010 WL 2998474; *Mensing v. Wyeth, Inc*. (8th Cir.2009) 588 F.3d 603; *Levine v. Wyeth, Inc.* (M.D.Fla.2010) 684 F.Supp.2d 1338; *Moretti v. Wyeth, Inc.* (D.Nev.2009) 2009 WL 749532; *Burke v. Wyeth, Inc.* (S.D.Tex.2009) 2009 WL 3698480; *Phelps v. Wyeth, Inc.*(D. Ore. 2010) 2010 WL 25553619; *Craig v. Pfizer, Inc.* (W.D. La. 2010) 2010 WL 2649545; and *Gross v. Pfizer, Inc.* (D. Md. 2010) 2010 WL 4485774. A common thread is that these federal courts found their forum state's products liability and/or negligence law differed from California's common law.

CONCLUSION

Bucking the trend, the *Conte* court reasoned that California's negligence body of law extended a name-brand drug manufacturer's duty of care to users of generic versions. The issue has not been addressed in the majority of states and it remains to be seen how long California will stand alone. **TBN**