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IN THIS ISSUE

In the year subsequent to Conte v. Wyeth, 168 Cal.App.4th 89 (2008) (holding a name-brand manufacturer liable despite plaintiff only taking the generic equivalent), courts across the county have analyzed and overwhelmingly rejected the Conte decision. This article will examine those cases evaluating and commenting on the Conte decision and analyze whether Conte has any staying power beyond California and its scope within California.

Name-Brand Manufacturers Liable for Ingestion of Generic Products?: An Analysis of The Nation's Response to California's *Conte v. Wyeth* Decision

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Introduction

Prior to November 7, 2009, every single court to address the issue of brand-name-manufacturer liability for conduct arising out of the generic version of a drug had concluded that the brand-name manufacturer was not liable.[1] However, on that date, the California Court of Appeal was the first court to hold that "the common law duty to use due care owed by a name-brand prescription drug manufacturer when providing product warnings extends not only to consumers of its own product, but also to those whose doctors foreseeably rely on the name-brand manufacturer's product information when prescribing a medication, even if the prescription is filled with the generic version of the prescribed drug."[2]

The *Conte* decision was an unfortunate decision of the California Court of Appeal which subjected name-brand pharmaceutical manufacturers to potential liability for the action or inaction of generic manufacturers over which they had no control and to additional potential litigation and liability costs to defend actions in which they had not even provided the medication used. The rationale of the Court was that "it is eminently foreseeable that a physician might prescribe generic metoclopramide in reliance on [the name-brand pharmaceutical manufacturer's] representations about Reglan. In this context, we have no difficulty concluding that [the name-brand pharmaceutical manufacturer's] should reasonably perceive that there could be injurious reliance on its product information by a patient taking generic metoclopramide."[3] Now, a year after the decision, it is appropriate to evaluate the effect of *Conte* on other courts' decisions in similar circumstances.

In the year subsequent to *Conte*, plaintiffs across the country have relied on the case in opposing motions for summary judgment when undisputed evidence showed that the plaintiff never used the name-brand prescription medication while defense counsel assert it is inconsistent with settled law with no bearing in other jurisdictions.[4] To date, courts across the country have overwhelmingly rejected the *Conte* decision and it appears to be an anomaly. This article will examine those cases evaluating and commenting on the *Conte* decision and analyze whether *Conte* has any significant effect beyond California.

Conte v. Wyeth

Between 2000 and 2004, Elizabeth Conte took generic metoclopramide, a prescription drug used to treat gastroesophageal reflux disease.[5] Subsequently, Conte developed tardive dyskinesia, a neurological disorder, and alleged she developed her condition as a result of taking metoclopramide.[6] It was undisputed that Conte *never* took Reglan®; the name-brand version of the drug. Consequently, the name-brand manufacturer, Wyeth, moved for summary judgment

[1] *See Foster v. American Home Products Corp.*, 29 F.3d 165, 171 (4th Cir. 1994); *Colacicco v. Apotex, Inc.*, 432 F.Supp.2d 514, 540-541 (E.D.Pa. 2006) (compiling all ten court rulings to-date addressing brand-name manufacturer liability for a generic product and finding that every court had either adopted the *Foster* reasoning or cited *Foster* with approval); *see also, Dorsett v. Sandoz, Inc.*, 2009 WL 3633874, *2 (C.D.Cal. 2009).
[2] *Conte v. Wyeth*, 168 Cal.App.4th 89, 94 (2008).
[3] *Id.* at 105.
[4] The *Conte* decision has even spawned its own on-line "scorecard", *see Drug and Device Law: http://druganddevicelaw.blogspot.com/2009/11/scorecard-non-manufacturer-name-brand.html.*
[5] *Conte, supra*, 168 Cal.App.4th at 95.
[6] *Id.*

arguing its product information had no causal relationship to Conte's injuries and it owed no duty to warn consumers who use its competitors' products.[7] The trial court agreed and granted the motion.

However, the Court of Appeal reversed.[8] First, it held that Conte's action against Wyeth was not based on products liability, but instead on "misrepresentation."[9] Then relying on what it said were well-settled principles of misrepresentation law, the Court imposed an unprecedented duty on a product manufacturer for injury allegedly caused by a competitor's product—even though the manufacturer was not involved in that product's sale and made no representations and derived no benefit in connection with that sale. Specifically, the court held that the manufacturer of a name-brand prescription drug owed a duty to warn those consumers who might foreseeably be injured while using generic drugs produced by its competitors – a duty, the court acknowledged, that products liability law precludes. [10]

In other words, the Court determined that liability could be imposed on a name brand manufacturer despite the plaintiff allegedly being injured while using a generic drug sold by a name-brand's competitors. Because of the presumed equivalence of the name-brand product and the generic, the court found it "eminently foreseeable" that prescribing physicians might rely on the name-brand manufacturer's product labeling information when prescribing either the name brand or the generic.[11] As a result, it held that the name-brand manufacturer could be held liable for injuries to a plaintiff who never used its drug, but only used the products of its generic competitors. The court also held that its duty was warranted under *Rowland v. Christian*, 69 Cal.2d 108 (1968).[12]

The Aftermath of *Conte*

Not surprisingly, name-brand manufacturers have had to address *Conte* and its foreseeability analysis in a number of

[7] *Id.* at 96.
[8] *Id.* at 95.
[9] *Id.* at 102 ("We perceive no logical or legal inconsistency between allowing the suit for negligence [misrepresentation] and disallowing the suit for strict products liability.").
[10] *Id.* at 105.

[11] A name-brand manufacturer's labeling and Physician Desk Reference requirements stem from its obligations under the Federal Food, Drug and Cosmetic Act ("FDCA"). After a New Drug Application is submitted, the FDA will deny approval if clinical testing data and other information do not show that the drug is safe and effective "for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof …" 21 U.S.C. § 355(d). Conversely, a generic manufacturer may submit an Abbreviated New Drug Application whereby it need only certify that the generic product is a bioequivalent of the name-brand drug and that the labeling and warnings for the generic drug are identical to those for the approved name-brand drug. 21 U.S.C. § 355(j)(2)(A). Because of this difference, it is the name-brand manufacturer's labeling upon which physicians rely when referencing the PDR.

[12] *Id.* 105-106. *Rowland* is the seminal California Supreme Court case used to determine whether a duty of care exists in a novel situation. The "*Rowland* factors" are: (1) the foreseeability of harm to the plaintiff; (2) the degree of certainty that the plaintiff suffered injury; (3) the closeness of the connection between the defendant's conduct and the plaintiff's injury; (4) the moral blame attached to the defendant's conduct; (5) the policy goal of preventing future harm; (6) the burden to the defendant and consequences to the community of imposing a duty of care; and (7) the broader consequences including the availability, cost, and prevalence of insurance for the risk involved. *See Rowland, surpa*, 69 Cal.2d at 112; *Randi W. v. Muroc Joint Unified School Dist.*, 14 Cal.4th 1066, 1077 (1997). Analyzing these factors, the *Conte* court held, "We are not persuaded that the application of these factors supports a departure in this case from the general rule that all persons have a duty to use ordinary care to prevent harming others." *Conte, supra*, at 106.

instances since its publication. The first court to scrutinize *Conte* was the U.S. District Court for the District of Nevada. In *Moretti v. Wyeth*, 2009 WL 749532 (D.Nev. 2009), a plaintiff again ingested the generic form of metoclopramide and alleged developing tardive dyskinesia as a result.[13] Based on the *Conte* decision, plaintiff asserted misrepresentation and fraud claims against the name-brand manufacturer who once again brought a motion for summary judgment on the basis that it did not manufacturer or sell the generic drug that allegedly caused plaintiff's injuries.[14] Rejecting *Conte*, the *Moretti* court first noted that name-brand manufacturers "do not owe a duty to warn or otherwise disseminate information about the risks associated with their generic competitor's drugs."[15] Second, the *Moretti* court could not be clearer in its dismissal of *Conte*: "[T]he Court rejects Plaintiff's argument that this Court should create a duty in light of a recent California intermediate appellate decision, *Conte* (citation omitted). The *Conte* decision, including its foreseeability analysis, is contrary to well-established Nevada law. Moreover, with the exception of *Conte*, every other court that has considered this issue has rejected Plaintiff's arguments. Those courts have correctly held that name-brand manufacturers do not have a legal duty to warn about the risks associated with their competitors' generic drugs. Simply put, *Conte* stands alone and is contrary to Nevada law and public policy."[16] Based on this rejection, the Nevada District Court granted the name-brand manufacturer's motion for summary judgment.[17]

In October of last year, the same issue was before the U.S. District Court for the Southern District of Texas in *Burke v. Wyeth*, 2009 WL 3698480 (S.D.Tex. 2009). Again, the plaintiff conceded that she only ingested the generic metoclopramide, which was neither manufactured nor distributed by the name-brand manufacturer.[18] Nevertheless, the plaintiff pursued her claims for negligence, strict liability, misrepresentation and fraud claiming that the name-brand manufacturer owed her and/or her physician a duty to warn about the dangers associated with using metoclopramide.[19] Defendant brought a motion for summary judgment insisting that the law imposes no such legal duty. The *Burke* Court agreed and ordered summary judgment. In reaching its conclusion, the Court first noted that "federal district courts have determined that a name brand drug manufacturer did not owe a legal duty to consumers of a generic equivalent arising out of the content of product labeling and descriptions formulated for the name brand drug."[20] Despite the seemingly settled law, plaintiffs advocated for the Court to adopt the *Conte* analysis:

> While the Burkes urge the Court to follow a decision reached by a state appellate court in California, *Conte v. Wyeth* (citation omitted), the Court declines to do so. The California court's holding in *Conte* is anomalous. Moreover, the Court is not persuaded that it comports with the applicable Texas law for two reasons. First, under Texas law all claims for personal injury allegedly caused by a defective product are, regardless of the theory alleged, "products liability actions." [citations] Second, while the court in *Conte* imposed a duty of care

[13] *Moretti* at *2.
[14] *Id.*
[15] *Id.* at *3.
[16] *Id.* at *4.
[17] *Id.* at *5.
[18] *Burke v. Wyeth, supra* at *1.
[19] *Id.* at *2.
[20] *Id.*

> based on foreseeability, this Court is of the opinion that a Texas court, persuaded by the reasoning in *Foster*, would similarly conclude that "to impose a duty in the circumstances of this case would be to stretch the concept of foreseeability too far."[21]

Again, a Court addressing *Conte* not only refused to follow its reasoning but noted that it is out of step with the rest of the country's jurisprudence.

Almost exactly a year after *Conte*, the U.S. District Court for the Southern District of West Virginia also had an opportunity to approve its analysis and deny summary judgment for a name-brand manufacturer. In *Meade v. Parsely, D.O, et al.*, 2009 WL 3806716 (S.D.W.Va. 2009), the plaintiffs once more sought to impose liability on the name-brand manufacturer despite admitting that the plaintiff never ingested its drug.[22] Plaintiffs based this assertion on the argument that, as the original manufacturers, the name-brand manufacturer had a duty to "ensure their warnings to the medical community [were] accurate and adequate."[23] In making this contention, plaintiffs relied on *Conte*. Nevertheless, the name-brand manufacturer brought a motion for summary judgment arguing that based on well-settled law, because plaintiff never ingested its product, it was not liable to plaintiff for the claims alleged.[24] The Court agreed with the manufacturer, first noting that it is "not responsible for the damage resulting from a product that they did not manufacture, distribute or sell.[25] The Court further noted that "[p]roduct liability law in West Virginia allows for recovery when the plaintiff can prove that a product was defective when it left the manufacturer and the defective product was the proximate cause of the plaintiff's injuries. [citations omitted] Because neither Wyeth nor Schwarz manufactured the product that injured plaintiffs, there is no proximate cause."[26]

Plaintiffs nonetheless relied on *Conte* and the Court did acknowledge that "[t]he facts of *Conte* are identical to those of this case."[27] However, the Court rejected *Conte's* reasoning, holding, "So far, *Conte*, which recognized but declined to follow *Foster*, is the only decision in several like actions that has allowed the plaintiff to proceed against Wyeth when only the generic version of the drug was ingested. Our court of appeals in *Foster* has addressed this issue, making the negligent misrepresentation theory of liability unavailable to plaintiffs seeking damages against name-brand defendants when their injuries resulted from another manufacturer's product."[28] Accordingly, the Court granted the name-brand manufacturer's motion for summary judgment.[29,30]

[21] *Id.* at *3, citing *Foster*, *supra*¸ 29 F.3d at 171.
[22] *Meade*, *supra* at *1.
[23] *Id* at *2.
[24] *Id.*
[25] *Id.*
[26] *Id.* at *3.
[27] *Id.*
[28] *Id.*
[29] *Id.* at *4.
[30] Despite the overwhelming rejection of the Conte decision, a September 2009 opinion from the U.S. District Court for the District of New Hampshire should at least be noted. The Court expressed sympathy for plaintiffs who could be left without recourse if generic manufacturers were immune from challenges to their labeling based on the doctrine of preemption as generics depend on the name-brand warnings and name-brand manufacturers are immune as their drugs were not ingested. While the Court in *Bartlett v. Mutual Pharmaceutical Company*, 2009 WL 3126305 (D.N.H. 2009) did not specifically decide whether *Conte's* reasoning would be followed in New Hampshire, it did note that "its widespread rejection supports the view that, if failure-to-warn claims against generic drug makers are indeed preempted, those

Conclusion

The potential impact of *Conte* on pharmaceutical and medical device litigation could have been (and still may be) substantial. Not only could it seemingly expand the liability of manufacturers of name-brand, innovative prescription drugs well beyond accepted limits of manufacturers' liability, but also has the potential to pit name-brand manufacturers and generic manufacturers against each other. One can easily see the tension between a name-brand manufacturer's defense that the plaintiff did not even ingest its drug (but rather ingested the generic drug) whereas the generic manufacturer could claim that it is without liability for failure to warn as a prescribing physician did not depend on the generic's warnings (but rather depended on the original warnings of the name-brand manufacturer).

Fortunately, based on the subsequent cases addressing *Conte* over the past year, the California Court of Appeal's decision must be seen for what it is—a radical departure that is out of step with settled product liability law. Simply put, not a single court has adopted the *Conte* foreseeability analysis or approved its reasoning. A fundamental principal of product liability has always held that a defendant is not liable to a consumer who allegedly is injured while using a product manufactured and sold by the defendant's competitors. It is clear that despite the *Conte* decision, courts across the country will continue to adhere to that fundamental tenant and it will remain a compelling argument for name-brand manufacturers when moving for summary judgment.

injured as a result of deficient warnings on those products have no recourse. The defendants did not dispute this point at oral argument, suggesting instead that consumers who opt for generic drugs over name-brand equivalents may have effectively lost their right to recompense for injuries suffered from inadequate warnings in the bargain. That suggestion is not only distasteful but also contrary to fundamental principles of tort law." *Id.* at *25, fn. 40.

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