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Regulated Warnings and Manufacturer Liability: *Conte, Schrock* and the Extension of Liability Beyond the "Chain of Distribution"

Two recent decisions (*Conte v. Wyeth, Inc.*, 168 Cal. App. 4th 89 (2008) and *Schrock v. Wyeth, Inc.*, 2009 WL 635415 (W.D.Okla. March 11, 2009)) addressed pharmaceutical manufacturer liability involving regulated warnings. *Conte* held one manufacturer (Wyeth) liable for another manufacturer's product because it was foreseeable that consumers would rely on Wyeth's federally regulated warning label in using another manufacturer's product. *Schrock*, following a long line of precedent, rejected extending liability beyond entities that manufactured, sold, or supplied (i.e., in the "chain of distribution") the allegedly defective product. To our knowledge, the *Schrock* decision is the first time a court has addressed a manufacturer's liability for a product it did not manufacture, sell, or supply since the California Supreme Court declined to review the *Conte* decision on January 21, 2009.

The Plaintiffs' bar has recently pressed numerous theories, most notably conspiracy and misrepresentation, to extend product liability beyond entities in the allegedly defective product's chain of distribution. These theories have focused on the publication of allegedly insufficient warnings by one manufacturer which a customer or consumer relies upon when using another manufacturer's product. We expect Plaintiffs' bar to rely on *Conte* in its effort to expand tort liability to entities that disseminate information concerning an allegedly defective product. Although the *Conte* and *Schrock* decisions concerned federally regulated prescription drug warnings, the rationales in the two cases apply equally to any situation involving regulated warnings (e.g., Material Safety Data Sheets, food labels).

The *Conte* Decision

On November 7, 2008, the Court of Appeals of California, First Appellate District, Division Three, held that a name-brand drug manufacturer's duty of care to provide 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." *Conte v. Wyeth, Inc.*, 168 Cal. App. 4th 89, 94-95 (2008). Simultaneously, the *Conte* court held that the generic manufacturers were not liable because there was no evidence produced that the prescribing doctor relied upon the generic manufacturers' warning labels. *Id*. at 95.

Plaintiff Conte alleges she developed a neurological condition due to her long-term use of Metoclopramide to treat gastroesophageal reflux. Wyeth originally developed Metoclopramide and sold it under the name-brand Reglan. Plaintiff Conte did not use Reglan. She used generic Metoclopramide. However, the *Conte* court found that because Wyeth could reasonably foresee doctors relying upon the Reglan warnings when prescribing generic Metoclopramide, Wyeth owed a duty of care not only to users of its Reglan, but also to users of generic Metoclopramide manufactured by others. *Id*. at 111. According to *Conte*, name-brand drug manufacturers are now potentially liable in California for generic manufacturer's drugs – even though the name-brand manufacturer was not involved in the manufacture, sale, or distribution of the generic drug(s), did not profit from the sale of the generic drug(s), and had no control over the generic drug manufacturers or their products.

Fundamentally, the *Conte* court has disassociated product liability from the historic basis for imposing liability on product manufacturers – the manufacture, sale, and distribution of the allegedly defective product. Instead, the *Conte* court imposed liability solely on a third party's dissemination of information related to another manufacturer's allegedly defective product because it was foreseeable that product users will rely on this information. The *Conte* court broke ranks with prior California decisions that refused to impose liability based on the dissemination of (or failure to disseminate) information concerning another manufacturer's product,[1] as well as with numerous courts around the country that refused to impose liability on product manufacturers if the manufacturer was not in the allegedly defective product's chain of distribution.[2] To date, other courts have not followed *Conte's* rationale of decoupling liability for an allegedly defective product from the manufacture, sale, and distribution of that product. *See*, *e.g.*, *Simonetta v. Viad Corporation*, 165 Wash.2d 341, 197 P.3d 127 (2008); *Taylor v. Elliott Turbomachinery Co., Inc.*, 2009 WL 458543 (Cal. App. 1st Dist. Feb. 25, 2009) (upholding "bright line" rule of imposing product liability on only those entities in the product's "chain of distribution").

The *Schrock* Decision

In *Schrock v. Wyeth, Inc.*, the United States District Court for the Western District of Oklahoma held that Wyeth is not liable for alleged injuries caused by generic Metoclopramide. Plaintiff Schrock only ingested generic Metoclopramide, which allegedly caused her neurological disorder. *Schrock v. Wyeth, Inc.,* 2009 WL 635415 at *1. Plaintiffs claimed that Wyeth, along with the generic manufacturers, should be liable for failing to provide the medical community sufficient warnings and failing to update FDA-approved labeling. *Id.* In effect, the *Schrock* court came to a conclusion opposite that of *Conte*: generic manufacturers *could* potentially be liable for their generic drugs and the name-brand manufacturer

could not. *Id.* at *5.

The *Schrock* court followed *Wyeth v. Levine*, No. 06-1249, --- S.Ct. --- 2009 WL 529172 (Mar. 4, 2009), and found that generic manufacturers could be liable because "a central premise of federal drug regulation [is] that the manufacturer bears responsibility for the content of its label at all times" and "regardless of the theory of recovery advanced, the responsibility for the defect must still be traced to the proper defendant." *Schrock v. Wyeth, Inc.,* 2009 WL 635415 at *4; *Wyeth v. Levine*, 2009 WL 529172 at *8. Therefore, the *Schrock* court denied the generic manufacturers' motion to dismiss and allowed Plaintiffs' claims against them to proceed.[3]

The *Schrock* court granted summary judgment in favor of name-brand manufacturer Wyeth because "[t]he imposition of liability on brand name manufacturers for injuries caused by competitor generic manufacturers is inconsistent with Oklahoma law, precedents from other jurisdictions and sound public policy." *Schrock v. Wyeth, Inc.*, 2009 WL 635415 at *4. The court noted that twenty-four courts in fourteen different states "rejected the assertion that defendants have a duty to warn about products they did not manufacture." *Id.* at *5. The *Schrock* court declined to follow *Conte* and did not reference the decision in its opinion, even though Plaintiffs relied heavily on *Conte* in their brief.

The *Schrock* decision is the first time a court addressed the precise issue raised by *Conte* after the California Supreme Court declined to review the decision. The future of expanding product liability to third parties outside the chain of distribution remains in doubt. The *Conte* decision will undoubtedly embolden Plaintiffs to continue to press theories of liability against third parties outside the chain of distribution. The *Schrock* court's rejection of third-party liability bodes well, but this issue warrants continued monitoring.

The *Conte* court specifically declined to address various public policy arguments implicit in finding one manufacturer liable for another manufacturer's product, because there was "no evidence" in the record concerning these public policy issues. *Conte v. Wyeth*, 168 Cal. App. 4th at 106-107. Fortunately, other courts continue to apply "logic, common sense, justice, policy, and precedent," whether or not it is found in the appellate record, in rejecting the extension of product liability beyond the chain of distribution. *Simonetta v. Viad Corporation*, 165 Wash.2d 341, 349 (2008) (Supreme Court of Washington, *en banc*, rejects the extension of tort duties to entities outside the chain of distribution). *Conte* remains an anomaly, for now.

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[1] In *Ferris v. Gatke Corp.*, 101 Cal. App. 4th 1211 (2003) and *Chavers v. Gatke Corp.*, 107 Cal. App. 4th 606 (2003), the California Court of Appeals First District, Fourth Division, held that Gatke Corp. owed no duty to the plaintiff for failing to disclose information about other manufacturers' asbestos products if Gatke was not in the product's chain of distribution.

[2] *See, e.g., Foster v. American Home Products Corp.*, 29 F.3d 165, 171 (4th Cir. 1994) (name-brand manufacturer owes no tort duty to users of generic manufacturer's products); *Colacicco v. Apotex, Inc.*, 432 F.Supp.2d 514, 539-43 (E.D. Pa. 2006) (same, relying on similar, unpublished holdings from a number of other jurisdictions); *Swicegood v. Pliva, Inc.*, 543 F.Supp.2d 1351, 1355-58 (N.D. Ga. 2008) (same); *Carrier v. Riddell, Inc.*, 721 F.2d 867, 869 (1st Cir. 1983) (manufacturer does not owe a duty to warn users of another manufacturer's product); *Barnes v. The Kerr Corp.*, 418 F.3d 583, 590 (6th Cir. 2005) (same); *Firestone v. Barajas*, 927 S.W.2d 608, 615-16 (Tex. 1996) (same); *Ford Motor Co. v. Wood*, 119 Md. App. 1, 37, *cert. denied,* 349 Md. 494 (1998), *abrogated on other grounds John Crane v. Scribner,* 369 Md. 369 (2002) (same).

[3] It remains to be seen whether the *Schrock* Plaintiffs will be able to maintain a cause of action against the generic manufacturers for failure to warn and whether that failure to warn proximately caused Plaintiffs' alleged injuries.