

FEDERAL COURT REJECTS BRAND-NAME DRUG LIABILITY FOR GENERIC-CAUSED INJURY

by

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The Federal District Court for the Western District of Oklahoma recently refused to expand the California First District Court of Appeal's decision in *Conte v. Wyeth* and instead, like the majority of other jurisdictions having considered the issue, concluded that innovators can not be held liable for harm caused by a generic version of a brand-name product.

In *Schrock v. Wyeth*, Susan Schrock claimed she developed an irreversible neurological condition after long-term use of generic versions of Wyeth's Reglan, a drug used to treat acid reflux. Although she only took the generic version of the drug, Schrock argued that Wyeth should be held liable because the company: failed to warn of the serious risks associated with long-term use of the brand-name version of the drug; failed to request a labeling change revision with the Food and Drug Administration (FDA) under the Changes Being Effected (CBE) provisions of the federal Food, Drug, and Cosmetic Act (FDCA); and failed to report safety information directly to the medical community. Schrock filed a lawsuit against Wyeth, as well as the drug's distributor, Schwarz Pharm, Inc., and generic manufacturers Actavis, Inc., Actavis-Elizabeth, L.L.C., and Pliva U.S.A., Inc.

The district court granted summary judgment to Wyeth and Schwarz, ruling that the brand-name manufacturer and distributor should not be liable for harm allegedly caused by the generic manufacturers of the prescription drug. The court reasoned that Wyeth's product information had no causal relationship to Schrock's injuries, and that Wyeth owed no duty to her as a user of a generic version of its brand-name drug. The court stated that "twenty[-]four courts in fourteen different states have rejected the assertion that defendants have a duty to warn about products they did not manufacture." Absent a relationship with the plaintiffs, the court found that holding Wyeth and Schwartz liable under the circumstances would "extend the concept of duty beyond reason and good sense as a matter of public policy."

The generic manufacturers, however, were unsuccessful on their motions to dismiss based on federal preemption. Despite regulations to the contrary, the District Court, citing the United States Supreme Court's recent decision in *Wyeth v. Levine*, concluded that generic manufacturers have the same ability and duty to add and strengthen warnings as do brand-name manufacturers under the CBE provisions of the FDCA. The Court's reliance on *Levine* was misguided. The drug at issue in *Levine* was a brand-name drug, not a generic drug. As the FDA and several courts have recognized, generic manufacturers do not have the same duty to add and strengthen warnings as do brand-name manufacturers under the CBE procedure. The District Court also failed to address the United States Supreme Court's recent decision to accept certiorari in *Colacicco v. Apotex Inc.*

This decision will likely have little impact on claims brought against innovators in the near future. We believe that other courts across the country will also conclude that innovators are not the indemnitor for injuries caused by their generic competitors' products. Unfortunately, until the California Supreme Court addresses *Conte* and concludes that innovators should not be held liable for harm caused by their generic competitors' products, plaintiffs will continue venue-shopping in an attempt to get their cases into California state court. Fortunately, innovators can avail themselves of either motions to remove these cases to federal court, or motions to transfer these actions to more appropriate venues where *Conte* is not binding precedent.

However, the Oklahoma Court's ruling may support future claims against generic drug manufacturers in the meantime.

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