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COURT DECLINES TO LIMIT LIABILITY TO FIRMS WHOSE PRODUCT CAUSED INJURY

(*Conte v. Wyeth, Inc.*)

The California Supreme Court this week declined to review an appeals court decision that extends liability in a products liability tort suit to a manufacturer that played no role in making the product that caused the plaintiff's injury. The one-sentence order declining review was a setback for the Washington Legal Foundation (WLF), which filed a brief urging that review be granted.

In its brief filed in *Conte v. Wyeth, Inc.*, WLF argued that a pharmaceutical manufacturer should not be held liable for injuries sustained by the user of a drug that was produced by a different manufacturer. In this case, the defendant initially developed the formula for the drug in question, but the drug taken by the plaintiff was manufactured by a generic drug company, not the defendant. WLF argued that the defendant cannot be held liable under a "failure to warn" theory, because a manufacturer owes no duty to provide warnings to those that do not use its products. The California Court of Appeal ruled last fall, however, that the plaintiff can recover if she can show that her doctor relied on warnings given years ago by the defendant in connection with its sale of a brand-name version of the drug.

WLF filed its brief with the *pro bono* assistance of Thomas P. Hanrahan, Mark E. Haddad, and Alycia A. Degan of the Los Angeles office of the law firm Sidley Austin LLP. The case now returns to the trial court, where the plaintiff will attempt to prove its case. WLF anticipates that other California plaintiffs will begin pursuing similar liability theories, and it has pledged to seek out other cases that may present an opportunity to overturn the appeals court decision.

"The appeals court decision is a radical and unsound departure from traditional principles of tort law that will have a profound impact on legal liability and business decision-making not only for innovator drug companies but potentially for manufacturers of vast numbers of other products as well," said WLF Chief Counsel Richard Samp after the California Supreme Court issued its order declining to review the case. "We are aware of no other decision in the history of product liability litigation in which a manufacturer has been held liable for injuries caused by a product which it had no role in placing on the market," Samp said.

The defendant in the case is Wyeth, a pharmaceutical company that developed Reglan, a drug approved for treating acid reflux. Wyeth's patent for Reglan expired many years ago, so the majority of sales consists of generic versions of the drug. Based on her doctor's prescription, the plaintiff used a generic form of Reglan for four years, even though the FDA-approved labeling states that use of Reglan is not indicated for more than 12 weeks at a time. The plaintiff contends that she was injured due to her use of the drug.

The plaintiff filed suit against Wyeth, alleging that Wyeth was negligent in failing to provide sufficient warnings regarding potential side-effects from taking Reglan (or its generic equivalents) for an extended period of time. The plaintiff's doctor stated that he had relied on his memory of the Wyeth labeling when he prescribed generic Reglan to his patient and that he would not have renewed the prescription for a four-year period had Wyeth included stronger warnings.

The trial court dismissed the claims against Wyeth on the grounds that Wyeth could not be held responsible for injuries caused by another manufacturer's drug, but the California Court of Appeal reversed. The appeals court held that it was reasonable that a doctor would rely on an innovator drug company's labeling when prescribing a generic drug, and thus the innovator owes a duty of reasonable care to individuals who take a generic version of its drug.

In its brief in support of Wyeth's petition for review, WLF argued that the Court of Appeal decision is unprecedented and significantly expands potential manufacturer liability. WLF argued that it is the manufacturer of a product that is in the best position to provide appropriate warnings regarding use of its product. If new information becomes available regarding potential side effects after generic sales of a drug have begun, the innovator company has no power to require generic companies to change their labeling to take account of the new information, WLF noted. WLF argued that imposing failure-to-warn liability on companies other than the manufacturer of the offending product exposes all manufacturers to open-ended liability and decreases incentives for the actual manufacturer to ensure that its labeling is adequate.

WLF is a public interest law and policy center with supporters in all 50 states. WLF devotes a substantial portion of its resources to defending free enterprise, individual rights, and a limited and accountable government. To that end, WLF has frequently appeared in the federal and state courts to support tort reform efforts.

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For further information, contact WLF Chief Counsel Richard A. Samp, (202) 588-0302. A copy of WLF's brief is posted on its web site, www.wlf.org.