



October 2, 2007

COURT AGREES TO CONSIDER WHETHER STATES MAY SECOND-GUESS FDA APPROVAL

(Warner-Lambert Co. v. Kent, No. 06-1498)

The U.S. Supreme Court this week agreed to review an appeals court decision that permits plaintiffs' lawyers to bring state-law tort suits against drug companies, even when those suits have the effect of second-guessing decisions of the Food and Drug Administration (FDA) to approve the marketing of a new drug. The Court's decision was a victory for the Washington Legal Foundation (WLF), which filed a brief in the case, *Warner-Lambert Co. v. Kent*, urging the Court to grant review.

WLF's brief argued that any product liability suit that requires a court to litigate claims that a manufacturer obtained marketing approval by defrauding the FDA is preempted by federal law. WLF argued that Congress intended to prohibit such suits because they interfere with FDA's ability to regulate the marketing of drugs and to police fraud on the agency. Now that the Court has agreed to review the case, WLF has pledged to file a second brief, urging that the lower-court decision be reversed.

"The decision below, if allowed to stand, will throw a monkey wrench into the entire FDA product-approval regime," said WLF Chief Counsel Richard Samp in response to the Supreme Court's decision to review the case. "Among other things, allowing state-courts to adjudicate fraud-on-the-FDA claims would conflict with FDA's responsibility to address fraud allegations in a flexible manner, so as not to interfere (for example) with the right of physicians to prescribe FDA-approved products for uses not approved by FDA; would discourage manufacturers from seeking approval of medical products with potentially beneficial off-label uses; and would cause applicants seeking product approval to submit a deluge of information to FDA that it neither wants nor needs, thereby delaying approval of new products," Samp said.

The case involves suits filed against the manufacturer of the diabetes drug Rezulin by several Michigan residents. Michigan has adopted a law that bars product liability suits against a drug manufacturer, if the manufacturer can demonstrate that the drug has been approved for marketing by FDA and is, in fact, being marketed in accordance with that FDA approval. The Michigan statute includes an exception: the bar to liability is lifted if the plaintiff can demonstrate that the manufacturer obtained FDA product approval by defrauding the agency.

FDA itself has never questioned the process by which Rezulin was approved for marketing. Although the plaintiffs in these lawsuits alleged that Rezulin was approved for marketing based on fraud, the district court dismissed the lawsuits, finding that Michigan's fraud-on-the-FDA exception was preempted by federal law. It based its ruling on a recent Supreme Court decision, *Buckman v. Plaintiffs Legal Comm.*, which held that lawsuits are preempted by federal law if they allege that the plaintiff was injured by a medical product that would never have been on the market but for the manufacturer's fraud on the FDA. The U.S. Court of Appeals for the Second Circuit in New York reversed, finding that *Buckman* was distinguishable. The appeals court held that *Buckman* does not apply where, as here, the plaintiffs' cause of action is a traditional common-law negligence claim and the issue of fraud on the FDA arises only in the context of determining the applicability of a state tort reform statute that cuts back on traditional common-law claims. The Supreme Court agreed to review that decision.

In its brief, WLF argued that *Buckman* is fully applicable and bars the plaintiffs' effort to avoid application of the Michigan tort reform statute. WLF argued that the context within which a fraud-on-the-FDA claim arises is irrelevant to the issue of whether the claim is preempted. WLF argued that preemption applies whenever (as here) the state-law tort suit has the negative impacts on the FDA product-approval system described by the Supreme Court in *Buckman*. WLF noted that the Second Circuit decision directly conflicts with a decision of the U.S. Court of Appeals for the Sixth Circuit in Cincinnati, which relied on *Buckman* in holding that the fraud-on-the-FDA exception to the Michigan tort reform law was preempted by federal law.

WLF also noted that at least seven other states have adopted tort reform laws akin to Michigan's, and that other states are considering adopting such laws. WLF argued that Supreme Court review was particularly important as a means of providing States with guidance regarding how to write such laws in a manner that avoids federal preemption pitfalls.

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 and promoting free enterprise, individual rights, and a limited and accountable government. In particular, WLF has appeared in numerous federal and state courts in cases raising issues regarding federal preemption of state tort law.

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