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COURT URGED TO PREVENT STATES FROM SECOND-GUESSING FDA PRODUCT APPROVAL

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

The Washington Legal Foundation (WLF) yesterday urged the U.S. Supreme Court to overturn 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.

In a brief filed in *Warner-Lambert Co. v. Kent*, WLF 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. WLF filed its brief with the pro bono assistance of Eric G. Lasker and James M. Sullivan, attorneys with the Washington, D.C. office of Spriggs & Hollingsworth.

"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 after filing WLF's brief. "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 in September 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 took particular issue with the Second Circuit's invocation of a "presumption against preemption" as the principal basis for allowing the plaintiffs' claims to go forward. WLF argued that the so-called "presumption against preemption" is wholly inapplicable to cases, as here, in which state law is alleged to conflict with federal law. WLF noted that the Court declined to apply a presumption against preemption in *Buckman*, even though the extent of federal control over the marketing of new drugs is far more extensive than the federal control over the marketing of the § 510(k) medical devices at issue in the *Buckman* case.

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.