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COURT SPLITS 4-4 ON WHETHER TO PERMIT SECOND-GUESSING OF FDA APPROVALS

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

The U.S. Supreme Court announced this week that it was evenly divided on whether 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. The result of the 4-4 decision is that the appeals court decision is affirmed; but the decision has no precedential value, and the Supreme Court issues no opinion.

The decision was a disappointment for the Washington Legal Foundation (WLF), which filed a brief in the case, *Warner-Lambert Co. v. Kent*, urging that the appeals court decision be overturned. 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 throws a monkey wrench into the entire FDA product-approval regime," said WLF Chief Counsel Richard Samp after learning of the High Court's ruling. "Among other things, allowing state courts to adjudicate fraud-on-the-FDA claims conflicts 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.

Only eight justices participated in the case because Chief Justice John Roberts was recused -- he is a stockholder in the defendant drug manufacturer. It is likely that the issue will return to the Supreme Court within the next several years; assuming that none of the justices are recused from that case, the preemption issue could be decided at that time. In the meantime, the split among the lower courts will persist, and whether the claims of a plaintiff asserting fraud on the FDA are preempted will depend on which federal circuit the plaintiff files suit in.

The case involved 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 Supreme Court's 4-4 vote leaves the appeals court decision in place.

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 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 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.