News Release

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WLF HAILS FDA POLICY STATEMENT ON PREEMPTION OF FAILURE-TO-WARN SUITS

The Washington Legal Foundation praised the Food and Drug Administration (FDA) for issuing a policy statement indicating that manufacturers who label their drugs in accordance with FDA policy cannot be sued under state law for failure to include additional safety warnings in their product labeling.

FDA published the policy statement yesterday in the Federal Register, in connection with its release of new regulations setting forth requirements on the content and format of product labeling. *See* 71 Fed. Reg. 3921-3997 (Jan. 24, 2006). FDA's statements concerning preemption of failure-to-warn claims appear at pp. 3933-36 and 3967-69.

"WLF has been calling on FDA to issue such a policy statement for several years," WLF Chief Counsel Richard Samp said. "We are gratified that FDA has now seen fit to do so. The policy statement does not represent a shift in FDA's views; FDA has taken the same position in litigation for several years. Nonetheless, issuing the policy statement is an important step, because it significantly increases the likelihood that courts will heed FDA's views," Samp said.

The plaintiffs' bar has criticized FDA's pro-preemption position and is likely to continue to file failure-to-warn claims against manufacturers whose drugs are labeled in accordance with FDA standards. WLF has pledged to litigate actively in support of FDA's position. "We expect trial lawyers to renew their challenge to FDA's authority in this area; WLF is committed to do all it can to beat back their challenge. Effective health care in this country requires that medical product labeling be subject to a single, federal standard," Samp said.

Some courts have permitted failure-to-warn actions to go forward against drug manufacturers, on the theory that FDA labeling requirements represent only *minimum* safety standards and that States are free to exceed those standards. FDA's policy statement explicitly rejects that approach. "FDA interprets [federal law] to establish both a 'floor' and a 'ceiling,' such that additional disclosures of risk information can expose a manufacturer to liability under the act if the additional statement is unsubstantiated or otherwise false or misleading," the policy statement says. 71 Fed. Reg. at 3935. When state laws (including court judgments) purport to require a manufacturer to include in labeling or advertising additional warning statements not mandated by FDA, the state laws are preempted because they "stand as an obstacle to achievement of the full objectives and purposes of Federal law." *Id.* FDA opposes

State efforts to impose additional warning requirements because "[e]xaggeration of risk could discourage appropriate use of a beneficial drug." *Id.* Failure-to-warn suits against doctors are also barred, so long as they provide warnings to their patients consistent with FDA labeling. *Id.* at 3936.

FDA's policy statement said that failure-to-warn suits are *not* preempted if FDA *has made a finding* that the manufacturer withheld material information related to the proposed warning at the time it sought FDA approval for its labeling. *Id.* Plaintiffs' lawyers can be expected to challenge FDA's conclusion that the "withhold[ing] material information" exception applies only if FDA has made a finding to that effect. They will insist -- and WLF will contest -- that individual courts should be competent to determine for themselves whether a manufacturer defrauded FDA in this manner.

WLF stated that one must recognize important limitations on FDA's pro-preemption position. In particular, it applies only to failure-to-warn claims, not to claims that a medical product is unreasonably unsafe or was manufactured defectively in a particular instance, WLF stated. Thus, FDA's policy statement comes no where near absolving manufacturers from product liability concerns so long as they properly label their FDA-approved drugs. For example, WLF noted, the many suits pending against the manufacturer of Vioxx, which claim that Vioxx is defective due to an association with heart failure, are unaffected by FDA's policy statement.

WLF stated that FDA's policy statement is critically important because courts are now required to give deference to FDA's views. Some courts, most notably the California Supreme Court in *Dowhal v. SmithKline Beecham Consumer Healthcare*, have heeded FDA's considered view -- expressed in the past few years in friend-of-the-court briefs -- that failure-to-warn claims against medical products manufacturers are preempted by federal law. But because views expressed in the course of litigation are not deemed official positions of a federal agency, courts were not required to defer to FDA's views. WLF argued that because those views have been incorporated into an official policy statement, courts are now required to give deference to FDA's interpretation of 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.

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