News Release

Washington Legal Foundation
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# COURT URGED TO UPHOLD PREEMPTION OF DESIGN DEFECT SUITS INVOLVING DRUGS

**(*Mutual Pharmaceutical Co. v. Bartlett*)**

The Washington Legal Foundation (WLF) this week urged the U.S. Supreme Court to rule that federal law preempts state-law product liability suits alleging that a prescription drug is defectively designed, where the drug has been determined to be safe and effective by the Food and Drug Administration (FDA).

In a brief filed in *Mutual Pharmaceutical Co. v. Bartlett*, WLF argued that such tort suits are impliedly preempted by federal law because they make it impossible for manufacturers to comply with both federal and state law and because they stand as an obstacle to the accomplishment of the goals of Congress and FDA. WLF argued that state law judgments against a pharmaceutical manufacturer that are based on a determination that the drug is defectively designed undermine the new-drug approval process by calling into question FDA's decision that a drug's benefits outweigh its risks.

"WLF agrees with the majority of federal courts that have held that Congress intended to preempt suits that allege that a drug is unreasonably dangerous and thus defectively designed," said WLF Chief Counsel Richard Samp after filing WLF's brief. "Federal law impliedly preempts such common law causes of action because Congress has made clear that it looks solely to FDA to make those sorts of determinations," Samp said.

The case before the Court involves a generic drug—that is, a drug approved for marketing based solely on the fact that it is bioequivalent to a drug that has previously been approved by FDA. WLF nonetheless urged the Court to rule that preemption of design defect claims applies not only to the generic drug manufacturers but also to manufacturers of brand-name drugs.

The case involves a New Hampshire woman who suffered serious and permanently disabling injuries after taking sulindac, an FDA-approved drug manufactured by Mutual Pharmaceutical Co. Sulindac has been widely used to treat arthritis since 1978. Mutual began marketing its generic form of sulindac in 1991 after the patent held by the brand-name pharmaceutical company expired. In order to keep down the costs of generic drugs, federal law prohibits FDA from requiring generic manufacturers to do their own safety testing; rather, they are entitled to rely on FDA's prior determination (following extensive safety testing by the brand-name manufacturer) that the drug is safe and effective.

A jury applying New Hampshire law awarded the plaintiff $21 million in damages, including $16.5 million in non-economic damages. A federal appeals court upheld the judgment, rejecting Mutual's argument that federal law preempted the jury's determination that sulindac was defectively designed because its risks outweighed its benefits. The Supreme Court later agreed to review the preemption issue.

In its brief urging that the judgment be overturned, WLF argued that the tort suit is preempted by federal law because it is impossible for Mutual to comply with both federal law and New Hampshire law (*i.e.*, the jury's determination that sulindac is defectively designed as a matter of New Hampshire law). WLF noted that FDA does not permit drug companies to change the design (*i.e.*, the chemical composition) of their drugs in order to eliminate a design defect perceived by a State. Thus, Mutual could comply with both sets of requirements only by going out of business. WLF asserted that, under the Court's established case law, "impossibility" preemption is established if the only way for a company to comply with both federal and state law is to stop manufacturing the product in question.

WLF further argued that preemption applies regardless whether the defendant is a brand-name manufacturer or (as here) a generic manufacturer. It noted that a brand-name manufacturer has no more rights under federal law than does a generic manufacturer to alter the design of an FDA-approved drug in order to comply with a determination under state law that the current design is defective.

WLF noted that the position it espouses does not leave injured patients without remedies. For example, they are still free to pursue other, non-preempted remedies against the manufacturer, such as that the drug was manufactured negligently (*i.e.*, not in conformance with the FDA-approved design), or (in the case of a brand-name manufacturer) that the drug labeling contained inadequate health warnings. Alternatively, they can pursue remedies against others who may be responsible for the injuries, such as their physicians.

The Washington Legal Foundation is a public interest law and policy center with supporters in all 50 States. WLF devotes a significant percentage of its resources to defending and promoting free enterprise, individual rights, and a limited and accountable government.

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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.