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Court Urged To Find Preemption Of Punitive Damages Awards In Failure-To-Warn Suits Involving Prescription Drugs

Novartis Pharmaceuticals Corp. v. Fussman

The Washington Legal Foundation (WLF) today urged the U.S. Supreme Court to review (and ultimately overturn) an appeals court decision that permits a private plaintiff suing under state law to impose punishment, in the form of punitive damages, on a prescription drug manufacturer who has fully satisfied the FDA's rigorous approval and labeling requirements.

In a brief filed in *Novartis Pharmaceuticals Corp. v. Fussman*, WLF argued that such punitive damages claims are impliedly preempted by federal law because they stand as an obstacle to the accomplishment of the goals of Congress and the FDA. WLF argued that a punitive damages award under North Carolina law against a pharmaceutical manufacturer based on a determination that the drug's label did not provide adequate warnings undermines the Food, Drug, and Cosmetic Act (FDCA) by calling into question FDA's decisions enforcement specific product labels.

"North Carolina law is free to determine that the defendant failed to provide adequate warnings, and even to require the defendant to pay compensation for damages actually caused by that failure" said WLF Senior Litigation Counsel Cory Andrews after filing WLF's brief. "But punitive damages awards impermissibly conflict with the FDCA's federal scheme by effectively removing enforcement discretion from the FDA and placing it in the hands of the jury," Andrews said.

WLF's brief sought to distinguish the instant case from *Wyeth v. Levine*, an earlier Supreme Court case decided in 2009. That case involved an award of compensatory damages, which serve vastly different purposes than the punitive damages imposed by the jury in this case. Whereas compensatory damages are solely intended to make the plaintiff whole for any loss actually caused by the defendant, WLF explained, punitive damages go much further and are designed to punish the defendant's wrongdoing in much the same way as criminal penalties. WLF argued that this is a critical distinction in the context of the FDCA, and the Fourth Circuit's failure to carefully consider Petitioner's preemption argument warrants review by the Court.

WLF also argued that the appeals court's holding below conflicts with the Court's 2001 decision in *Buckman v. Plaintiffs' Legal Committee*, where a unanimous Court held that federal law preempted all state-law claims that the defendant misled the FDA for the purpose of obtaining FDA approval for its device. Because the FDCA has established a "comprehensive scheme" of disclosure requirements as part of the approval process for any prescription drug, WLF argued that Fussman's punitive damages claim presents precisely the same sort of obstacle to federal policy identified by the Court in *Buckman*. If plaintiffs are allowed to manipulate state-law duties as a backdoor way to enforce federal regulatory requirements, WLF argued, *Buckman* will be rendered a dead letter.

WLF is a public interest law and policy center with supporters in all 50 States. WLF routinely litigates in state and federal courts to promote free enterprise, individual rights, and a limited and accountable government. In particular, WLF devotes a substantial portion of its resources to promoting tort reform and reining in excessive litigation.

For further information, contact WLF Senior Litigation Counsel Cory Andrews, (202) 588-0302. A copy of WLF's brief is posted on its web site, www.wlf.org.