

Press Release



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Arkansas Supreme Court Sides with WLF, Overturns \$1.2 Billion Judgment that Drug Label Was Improper

(*Ortho-McNeil-Janssen Pharmaceuticals v. State of Arkansas*)

“Today’s decision vindicated First Amendment rights by eliminating a penalty that was imposed without a showing that the defendants had said anything false.”
—Richard Samp, WLF Chief Counsel

WASHINGTON, DC—The Arkansas Supreme Court today overturned a \$1.2 billion civil penalty the State of Arkansas had sought claiming a drug manufacturer included inadequate risk information on a product label for Risperdal, a widely-prescribed “second-generation” antipsychotic medication. The Court agreed with the Washington Legal Foundation (WLF) that the manufacturer did not violate Arkansas’s Medicaid Fraud and False Claims Act by distributing a drug whose labeling FDA later amended to require additional health warnings.

The Court also overturned the trial court’s finding that the manufacturer, Janssen Pharmaceutica, Inc. (a Johnson & Johnson subsidiary), violated the Arkansas Deceptive Trade Practices Act (DTPA) when it sent Arkansas doctors a letter expressing views about Risperdal’s safety. The Court held the trial judge improperly admitted into evidence a “warning letter” FDA had sent to Janssen. The Court held the warning letter, which the FDA sent after Janssen distributed its “Dear Doctor” letter, was inadmissible hearsay evidence and noted it did not represent any official determination by FDA that Janssen violated any federal law.

In light of its determination that the improper evidentiary ruling required overturning the DTPA judgment, the Court declined to rule on other grounds for overturning it—including WLF’s arguments that federal law preempted the DTPA claim and that the First Amendment barred Arkansas from imposing liability for statements included in the “Dear Doctor” letter. As WLF has noted, the plaintiffs’ bar has played an outsized role in bringing about lawsuits of this sort. Both here and in Risperdal claims filed by a half-dozen other States, private attorneys hired by States on a contingency-fee basis filed the suits—an arrangement that often prods plaintiffs to make unreasonably high damages claims.

After the Court’s decision, WLF released the following statement by Chief Counsel Rich Samp: “The judgment below imposed massive liability based on nothing more than good-faith disagreements regarding regulatory requirements. Today’s decision overturning that judgment vindicated First Amendment rights by eliminating a penalty that was imposed without a showing that the defendants had said anything false. The judgment’s size was particularly unwarranted given that Arkansas introduced no evidence that any of its citizens was injured.”

WLF is a public interest law firm and policy center that regularly litigates in support of civil justice reform, to ensure that unwarranted lawsuits do not drive up costs for all consumers.

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