News Release

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Court Urged To Overturn $1.2 Billion Judgment For Improper Drug Label

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

The Washington Legal Foundation (WLF) this week urged the Arkansas Supreme Court to overturn a $1.2 billion civil penalty imposed by the State of Arkansas based on claims that a drug manufacturer included inadequate risk information on the label for one of its products.

In a brief filed in Ortho-McNeil-Janssen Pharmaceuticals v. State of Arkansas, WLF argued that when the federal Food and Drug Administration (FDA) has approved the label for a prescription drug, States have no business second-guessing labeling decisions. It argued that civil penalties are particularly inappropriate when, as here, the State does not allege that it suffered any injury as a result of the allegedly inadequate risk disclosure on the product label. It also argued that the State law under which the penalties were imposed was never intended to apply to product labeling issues and provided no notice that violators could be held liable for massive damages.

"We are concerned that the judgment below, if affirmed on appeal, will create tremendous uncertainty among regulated entities in the healthcare field and will make it extremely difficult for them to remain in business in Arkansas without exposing themselves to massive liabilities based on nothing more than good-faith disagreements or misunderstandings regarding regulatory requirements," said WLF Chief Counsel Richard Samp after filing WLF's brief. "The judgment also violates free speech rights because it penalizes speech without any showing that the defendants said anything that was false," Samp said.

The case involves the labeling of Risperdal, an anti-psychotic medication manufactured by Ortho-McNeil-Janssen (Janssen) and widely prescribed in Arkansas and throughout the United States. A lawsuit filed by the State of Arkansas (represented by private plaintiffs' attorneys hired on a contingency fee basis) alleged that between 2002 and 2006 the "Warnings" section of the Risperdal label failed to include sufficient information regarding the risks of Risperdal use, including diabetes and weight gain. Information about the risks at issue were included in other sections of the label, but Arkansas contended that the failure to include the risk information in the Warnings section rendered the label "false." Although FDA had approved the 2002-2006 labels, Arkansas contended that Janssen violated state law by failing to update the label as soon as it became aware of additional health concerns associated with use of Risperdal.

The state law that Janssen was alleged to have violated was the Medicaid Fraud False Claims Act (MFFCA), a statute adopted in 1993 to combat Medicaid fraud. Janssen defended by pointing out that Arkansas did not contend that anyone had been defrauded and that product labeling is not an area that is regulated by Medicaid officials. An Arkansas jury nonetheless found that Janssen had violated the MFFCA, and the trial court entered a $1.2 billion judgment – a $5,000 penalty for

each of the 239,000 Risperdal prescriptions that were filled by Arkansas Medicaid patients between 2002 and 2006.

In its brief urging that the judgment be reversed, WLF argued that the MFFCA was never intended to regulate product labeling but rather focused solely on combating the submission of fraudulent Medicaid claims by patients and healthcare providers. It argued further that if the MFFCA were interpreted as applying to Risperdal labels, then it violated Janssen's due process rights – because Janssen was not given fair warning that its actions were prohibited and could lead to the imposition of massive penalties.

WLF also argued that the $1.2 billion judgment violated Janssen's First Amendment rights because Arkansas failed to demonstrate that its severe regulation of Janssen's speech served any compelling state interest. Arkansas argues that the First Amendment does not protect "false" speech such as Janssen's. WLF responded that the failure to fully disclose all risk information in one section of a product label (and to instead disclose the information elsewhere on the label) cannot be deemed "false" speech for First Amendment purposes. Nondisclosure could only be deemed "false" if the Warning section of the Risperdal label had stated that all available risk information was included therein when Janssen knew of other risk information that was not included.

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.

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.