News Release

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COURT URGED TO UPHOLD STATUTE LIMITING DRUG COMPANY LIABILITY

(Taylor v. Medeva Pharmaceuticals, Inc.)

The Washington Legal Foundation (WLF) this week asked the Michigan Court of Appeals to uphold a Michigan statute that precludes design-defect tort actions against the manufacturer of a pharmaceutical that has been approved for sale by the federal Food and Drug Administration (FDA).

In a brief filed in *Taylor v. Medeva Pharmaceuticals, Inc.,* WLF argued that the Michigan legislature acted properly in adopting the statute and that it did not violate a state constitutional provision that prohibits the legislature from delegating its powers to a federal administrative agency.

"When FDA approves a product for sale, that signifies that FDA has determined -- after extensive testing -- that the product is both safe and effective for its intended use," said WLF Chief Counsel Richard Samp after filing WLF's brief. "It is entirely reasonable for a state legislature to determine that the FDA's seal-of-approval for a drug is not to be second-guessed by plaintiffs' lawyers who file tort suits challenging the drug's safety," Samp said.

This suit was brought against the manufacturers of the prescription drugs fenfluramine, phentermine, and dexfenfluramine. All three were approved by FDA as safe and effective. Some patients now claim that when they used those drugs in combination (the "fen-phen" combination), they suffered heart damage. The class-action suit alleges that the three drugs were defectively designed. The manufacturers raised the Michigan tort reform statute in defense, but the trial court held that the statute was unconstitutional. The manufacturers have appealed from that decision.

The plaintiffs argue that the Michigan Constitution prohibits the legislature from delegating to FDA the decision regarding which drugs are to be exempt from product liability suits in

Michigan courts. The plaintiffs argue that such decisions are legislative in nature and can only be made by the legislature itself.

In response, WLF argued in its brief that the legislature's actions were totally in compliance with the state constitution. WLF argued that the legislature did not delegate any of its power to FDA. Rather, the legislature (not FDA) has made the legislative determination regarding what significance to attach to FDA's scientific findings regarding safety and effectiveness.

WLF noted that the attack on the Michigan tort reform law is part of a series of challenges that plaintiffs' lawyers have mounted against state tort reform legislation. A significant number of those challenges have been successful, in large measure because many state supreme courts are populated with former trial lawyers who are generally hostile to any tort reform measures. WLF has played a major role in efforts to defend a large number of these tort reform measures. WLF views the fate of the Michigan statute -- the first of its kind in the nation -- as an important bellwether of whether significant tort reform measures can ever be upheld. WLF has argued repeatedly that such measures are necessary in order to hold down health care costs and to ensure that low-income Americans continue to have access to quality health care.

WLF is a public interest law and policy center with supporters in all 50 states, including many in Michigan. WLF filed its brief with the pro bono assistance of Scott Gorland, an attorney with the Detroit office of Pepper Hamilton LLP.

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For further information, contact WLF Chief Counsel Richard Samp, (202) 588-0302.