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## **COURT URGED TO STRIKE DOWN FLORIDA DRUG PRICE CONTROL LAW (*PhRMA v. Medows*)**

The Washington Legal Foundation (WLF) this week urged the U.S. Court of Appeals for the Eleventh Circuit in Atlanta to strike down a Florida statute that seeks to impose price controls on pharmaceuticals sold to Medicaid recipients in the State.

In a brief filed in *Pharmaceutical Research and Manufacturers of America v. Medows*, WLF argued that the Florida statute is invalid because it conflicts with federal Medicaid law. WLF also argued that the statute will result in substandard medical care for the State's poorest citizens, because it will result in their being denied access to essential drugs that the State has deemed too expensive.

"If Florida seeks to hold down drug costs, it must do so in a way that does not sacrifice patient care," said WLF Chief Counsel Richard Samp after filing WLF's brief. "Regardless whether the Florida program ultimately produces cost savings, it is poor health-care policy and is precisely the type of program that Congress intended to prohibit," Samp said.

The Florida statute establishes a "formulary" – a list of preferred drugs that doctors may prescribe for Medicaid patients without seeking any advance approval. If a doctor wishes to prescribe a drug not included in the formulary, she may do so only if she goes through a "prior authorization" procedure and explain to state officials why she believes it is necessary to prescribe a non-listed drug. In practice, very few doctors will take the time to seek such prior authorization. The result is that sales of non-listed drugs to Florida Medicaid patients have plunged since the Florida statute took effect last July.

For a manufacturer to have its drugs included in the formulary, it must agree to pay a

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rebate to the State equal to 25% of the drug's normal retail price. Those manufacturers who have not agreed to pay the rebate have had their drugs excluded from the formulary, without regard to the effectiveness of those drugs and without regard to the availability of other drugs that provide equivalent benefits. Although the federal government has approved more than 1,800 drugs for use in the Medicaid program, the Florida formulary includes less than 1/2 of those drugs.

Drug manufacturers filed suit against the statute in August. A federal district court upheld the program in December, and the manufacturers have appealed to the Eleventh Circuit.

In its brief, WLF argued that a Medicaid federal statute, 42 U.S.C. § 1396r-8(d)(4), prohibits programs such as Florida's. WLF argued that federal law permits a drug to be excluded from state Medicaid formularies only after the State, after careful study, has concluded that the drug "does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome . . . over other drugs included in the formulary." WLF argued that because Florida had excluded drugs based solely on cost concerns, and not based on any findings that the drugs had no therapeutic advantages over alternative drugs, Florida's program violated federal law.

WLF argued that there are sound medical reasons underlying the federal policy. WLF cited to numerous studies that show that when States have attempted to limit prescription drug sales as a cost-saving measure, patient health has suffered. Indeed, WLF argued, States in those situations often end up paying more, because patients who formerly were being treated effectively through medication end up having to be hospitalized after being denied their normal medications.

WLF is a public interest law and policy center with supporters in all 50 States, including many in Florida. WLF devotes a significant portion of its resources to defending the rights of individuals and businesses faced with excessive government regulation. WLF filed its brief on behalf of itself and the Allied Educational Foundation.

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