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COURT UPHOLDS FLORIDA DRUG PRICE CONTROL LAW (*PhRMA v. Medows*)

The U.S. Court of Appeals for the Eleventh Circuit in Atlanta this week upheld a Florida statute that seeks to impose price controls on pharmaceuticals sold to Medicaid recipients in the State. The decision was a setback for the Washington Legal Foundation (WLF), which filed a brief in the case, *Pharmaceutical Research and Manufacturers of America v. Medows*, urging that the law be struck down.

The appeals court rejected WLF's argument 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.

The case turned on the court's interpretation of a federal statute, 42 U.S.C. § 1396r-8(d). In holding that that statute did not preempt the Florida statute, the appeals court relied in part on a decision of the U.S. Court of Appeals for the First Circuit in Boston, in the case of *PhRMA v. Concannon*. The U.S. Supreme Court recently agreed to review *Concannon*. Accordingly, the final outcome of the Florida case is likely to depend on how the Supreme Court rules in *Concannon* -- a decision not expected until next spring.

"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 reviewing the Eleventh Circuit's decision. "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. WLF has pledged to support any further appeals in the Florida case.

The Florida price control scheme 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, he may do so only if he goes through a "prior authorization" procedure and explains to state officials why he 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 in July 2001.

For a manufacturer to have its drugs included in the formulary, it must agree to pay a 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 2001. A federal district court upheld the program in December, and the manufacturers appealed to the Eleventh Circuit. This week's decision upheld the district court's ruling.

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. The appeals court rejected that argument, finding that the Florida program did not constitute a "formulary" but rather was a permissible "prior authorization program."

WLF also 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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