Litigation Update

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COURT DECLINES TO STRIKE DOWN MICHIGAN DRUG PRICE CONTROL LAW

(PhRMA v. Thompson)

The U.S. Court of Appeals for the District of Columbia Circuit this week declined to strike down a Michigan statute that imposes price controls on pharmaceuticals sold to Medicaid recipients in the State.

The decision in *Pharmaceutical Research and Manufacturers of America v. Thompson* was a setback for the Washington Legal Foundation (WLF), which filed a brief challenging the law. WLF argued that the Michigan program is invalid because it conflicts with federal Medicaid law. The appeals court agreed that WLF's argument was based on a reasonable interpretation of federal Medicaid law. Nonetheless, it upheld the Michigan program on the ground that the federal government's contrary interpretation was also reasonable and that in such instances it should defer to the government's interpretation.

WLF also argued that the program 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. WLF argued that the U.S. Department of Health and Human Services abused its discretion in approving the Michigan program. WLF filed its brief on behalf of itself and the Kidney Cancer Association, the 60 Plus Association, and the Allied Educational Foundation.

"If Michigan 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 court decision. "Regardless whether the Michigan program violates federal law and regardless whether it ultimately produces cost savings, it is poor health care policy," Samp said.

The Michigan program 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 explains 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 Michigan Medicaid patients have plunged since the Michigan program took effect in 2002.

For a manufacturer to have its drugs included in the formulary, it must agree to pay a substantial rebate to the State; this rebate is in addition to the rebate already required under federal law. 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.

Drug manufacturers filed suit against the program in 2002. A federal district court upheld the program in March 2003, and the manufacturers appealed to the District of Columbia Circuit. This week's decision affirmed the district court's decision.

In its brief, WLF argued that a Medicaid federal statute, 42 U.S.C. § 1396r-8(d)(4), prohibits programs such as Michigan'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 Michigan has excluded drugs based solely on cost concerns, and not based on any findings that the drugs had no therapeutic advantages over alternative drugs, Michigan's program violates federal law. While acknowledging that the federal government's contrary reading of Medicaid law creates "tension, if not actual inconsistency" with § 1396r-8(d)(4)'s intent "to broaden drug availability," the appeals court nonetheless decided to defer to the government's reading of the statute.

WLF argued that there are sound medical reasons underlying the federal statutory 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 Michigan. WLF devotes a significant portion of its resources to defending the rights of individuals and businesses faced with excessive government regulation.

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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.