

## **COURT DECLINES TO STRIKE DOWN PRESCRIPTION DRUG PRICE CONTROLS**

***(Pharmaceutical Research and Mfrs. of America v. Walsh, No. 01-188)***  
***(Pharmaceutical Research and Mfrs. of America v. Medows, No. 02-869)***

The U.S. Supreme Court this week issued a decision that declined to strike down a Maine law that imposes strict controls on the price of all prescription drugs sold in the State. The Court also declined to accept review over a case that challenged a similar Florida law.

The decisions were setbacks for the Washington Legal Foundation (WLF), which filed briefs with the Court in both the Maine case (*PhRMA v. Walsh*, formerly known as *PhRMA v. Concannon*) and the Florida case (*PhRMA v. Medows*). The Court rejected as premature WLF's argument that the Maine price control scheme is void because it conflicts with federal laws regulating the sale of prescription drugs.

WLF filed its briefs on behalf of itself and a coalition of groups that support expanded research toward development of new, life-saving drugs, including the Kidney Cancer Foundation, The Seniors Coalition, The 60 Plus Association, the International Patient Advocacy Association, and the Allied Educational Foundation. WLF explained that the coalition opposes price controls on drugs because such controls have been shown to lead to reduced research and development of new drugs and to product shortages. The coalition is particularly opposed to the Maine and Florida programs because those states use the threat of denying medications to its poorest, Medicaid-eligible citizens as its means of enforcing price controls on drug sales. WLF noted that Maine imposed price controls on sales to all of its citizens, even sales to higher-income residents.

The Supreme Court affirmed an appeals court's denial of a preliminary injunction against the Maine law. The Court held that the plaintiffs had not yet introduced sufficient evidence to demonstrate that Medicaid recipients would suffer significant harm if the law

were implemented. The Court remanded the case back to the federal district court in Maine for a trial on that issue. The Court also made clear that it was reluctant to strike down the Maine law in the absence of a ruling from Department of Health and Human Services (HHS) officials that the Maine law conflicts with federal law. Such a ruling from HHS is a distinct possibility, because the federal government filed a brief with the Supreme Court asking that the Maine law be struck down.

"Regardless whether the government has a role to play in reducing society's overall drug expenditures, any government oversight should be at the federal level," said WLF Chief Counsel Richard Samp after reviewing the Supreme Court's decisions in the *Walsh* and *Medows* cases. "While we are disappointed that the Court did not strike down the Maine law immediately, we are encouraged that the Court left open that possibility and that it openly invited HHS officials to step into the fray. Decisions of this magnitude and complexity ought to be made at the national level, where the interests of consumers around the nation can be taken into account, not simply the parochial interests of one State's consumers," Samp said.

WLF also argued in its brief that the Maine law violates the Commerce Clause by attempting to control the wholesale price of prescription drugs. WLF noted that no drug manufacturers are located in Maine and that virtually all drugs sold at the retail level in Maine were previously sold by drug manufacturers to distributors in wholesale transactions that took place outside the State. The Court rejected that argument, holding that there could be no Commerce Clause violation in the absence of evidence that the Maine law favors in-state manufacturers.

WLF fared better in its argument that the Maine law conflicts with federal law. Maine administers the sale of prescription drugs to Medicaid recipients within the State. Maine is attempting to enforce its controls on wholesale drug prices by threatening Medicaid sanctions against any drug manufacturer that fails to abide by the State's wholesale drug price controls. WLF argued that Maine's attempt to use its leverage within the Medicaid program to force manufacturers to comply with its separate drug price control scheme is a violation of federal Medicaid law. The Court agreed that, on remand, the law should be struck down unless Maine can demonstrate that its program in some way serves the Medicaid law's purposes.

The Florida law left standing by the Court's decision not to review *Medows* is not nearly as broad as the Maine law. Moreover, unlike the Maine price control program, the Florida program has been explicitly approved by HHS.

WLF is a public interest law and policy center with supporters in all 50 states,

including many in Maine and Florida. WLF devotes a significant portion of its resources to defending the rights of businesses that have become the target of unwarranted government regulation.

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