



May 17, 2001

COURT DECLINES TO STRIKE DOWN PRESCRIPTION DRUG PRICE CONTROLS

(Pharmaceutical Research and Mfrs. of America v. Concannon)

The U.S. Court of Appeals for the First Circuit in Boston yesterday declined to strike down a Maine law that imposes strict controls on the price of all prescription drugs sold in the State. The court reversed a district court decision that had preliminarily enjoined enforcement of the law; but the court also left open the possibility that the law could be struck down after a full trial.

The decision was a setback for the Washington Legal Foundation (WLF), which had filed a brief in the case, *PhRMA v. Concannon*, urging that the price-control law be struck down. WLF argued that the Maine price control scheme violates the Constitution's Commerce Clause because it imposes an unreasonable burden on interstate commerce. WLF also argued that the Maine law is void because it conflicts with federal laws regulating the sale of prescription drugs.

The First Circuit rejected both arguments. The court agreed with WLF that Maine could not claim an exemption from Commerce Clause limitations by virtue of its alleged status as a "market participant" in the prescription drug market. But the court held that Maine is not violating the Commerce Clause because its law should not be deemed an effort to regulate commerce occurring in other states.

WLF filed its brief 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.

"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 First Circuit's decision. "Health-care policy 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 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. WLF argued that Maine's effort to give extraterritorial effect to its laws by regulating sales taking place outside of the State constitutes a *per se* violation of the Takings Clause.

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 First Circuit directly cited WLF's arguments but ultimately rejected them. The court said that the plaintiff faced an especially stringent burden of proof, because it was mounting a "facial challenge" to the Maine law -- meaning that the plaintiff was asserting that the law is unconstitutional in all conceivable applications. The court held that the plaintiff had failed to make that showing; noting that Maine officials have not yet implemented the law, the court said that it was possible that Maine would administer the law in a way that does not attempt to regulate wholesale drug transactions taking place entirely outside the state. The court said that opponents of the law were free to renew their challenge if Maine administers the law in a manner that unduly burdens interstate commerce.

While expressing disappointment with yesterday's ruling, WLF attorneys pledged to provide support for any further appeals in the case.

WLF is a public interest law and policy center with supporters in all 50 states, including many in Maine. 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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For further information, contact WLF Chief Counsel Richard Samp, (202) 588-0302.