

The logo consists of the letters 'GJF' in a bold, white, serif font, set against a solid black rectangular background.

SUBSIDY LITIGATION **WATCH**

Vol. 1, No. 6

DRUG MANUFACTURERS LOSE CHALLENGE TO STRIKE DOWN MAINE'S

LOW-COST PRESCRIPTION DRUG PLAN

Pharmaceutical Research and Manufacturers of America v. Walsh, 2003 U.S. LEXIS 4056 (United States Supreme Court, 5/19/03)

The United States Supreme Court has rejected a challenge by an association of nonresident drug manufacturers to stop a Maine program that reduces prescription drug prices for state residents. The decision recognizes the right of states to reject public programs that may be profitable for certain corporations, but are costly for government.

Maine's Rx Program was enacted in response to a federal law passed in 1990 to curb increasing Medicaid costs for prescription drugs. The federal law requires drug manufacturers to pay rebates to states on their Medicaid purchases. In the past several years, states have enacted supplemental rebate programs to obtain additional cost savings for purchases by Medicaid recipients, as well by other uninsured citizens.

Maine's program requires a drug manufacturer to enter into an agreement with the state to provide rebates on prescription drugs provided to Medicaid recipients and others in need of medical services. If the company refuses, the state can require prior authorization of the drug by a medical committee. The rebates are deposited into a fund to pay pharmacists for the discounted Medicaid drugs they sell. The provisions of the Maine program are authorized under the federal Medicaid law.

An association representing manufacturers that account for more than 75% of the country's brand name drug sales sued to have the Maine program declared unconstitutional. The association claimed that Maine's program violates the Commerce Clause because it discriminates against interstate commerce by subsidizing in-state retail sales. The Court rejected this claim and found no discrimination since the program applies to in-state and out-of-state drug manufacturers alike. In-state drug companies receive no benefit from the rebates, and the payments to local pharmacists provide no special benefit to competitors of rebate-paying companies.

Second, the association claimed that Maine's law was pre-empted by the federal Medicaid law. The Association argued that the Maine Rx program imposes a significant burden on Medicaid recipients by requiring prior authorization without serving any valid Medicaid purpose. The State claimed that the program reduces Medicaid costs, as well as potential costs by helping uninsured citizens from having to resort to Medicaid.

The Court agreed with the State and determined that Maine's program did serve Medicaid-related interests. First, the Court found that prior authorization reduces unnecessary administrative costs, which serves the interests of both the federal and state governments that pay for providing prescription drugs to Medicaid patients. Further, giving uninsured persons better access to prescription drugs helps to prevent their conditions from worsening and eventually having to rely on Medicaid. Also, the Court found that the association presented no convincing proof that the prior authorization procedure harms Medicaid patients.

Impact of the Decision:

The Maine Rx Program may still need the approval of the Secretary of Health and Human Services since the program amends Maine's Medicaid plan which the Secretary previously approved. That outcome remains to be seen. The Supreme Court decision, however, is important because it upholds the constitutionality of such cost reducing programs by the states. Drug manufacturers have been urging states to include brand name drugs in their Medicaid plans. Last year, a similar challenge by nonresident drug manufacturers to invalidate Michigan's pre-authorization procedure was rejected by the Michigan Court of Appeals. Pharmaceutical Research & Manufacturers of America v. Department of Community Health, 254 Mich. App. 397 (Ct. of App., 2002).

The defeat of these legal challenges have led some drug manufacturers to try a new tactic to get states to include their drugs in a state's Medicaid plan. In places such as Michigan, a major drug manufacturer has threatened to reduce jobs at its Michigan facilities if the state refuses to include the company's drugs on its preferred drug list for Medicaid. So far, these efforts have been unsuccessful.