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THE SUPREME COURT'S FIRST WORD IN THE LATEST PRICING CONFLICT

In May 2003, the U.S. Supreme Court rendered a decision of significant interest to pharmaceutical manufacturers in Pharmaceutical Research and Mfrs. of Am. v. Walsh, 538 U.S. 644, 123 S.Ct. 1855 (2003). Although the full impact of the Walsh decision will not be known until the case is decided on the merits, the Supreme Court's May 2003 ruling merely affirmed that a district-court injunction was improper and returned the case to the lower courts for merits determination, the Walsh litigation may materially impact how prescription drugs are priced.

THE BACKGROUND

Under Medicaid statutes and regulations, states may control Medicaid costs by requiring drug manufacturers to provide rebates on Medicaid sales of prescription drugs. If a manufacturer refuses to provide rebates, states may impose prior authorization requirements, which can significantly limit market share, for that manufacturer's drugs. A new Maine law seeks to force drug manufacturers to sell their products at the Medicaid price in non-Medicaid transactions. Under the "Maine Rx" program, if a manufacturer refuses to provide a rebate on any particular drug, its sales are subjected to a prior authorization procedure in order to qualify that drug for reimbursement by the state.

THE LAWSUIT, THE DISTRICT COURT'S INJUNCTION, AND THE COURT OF APPEALS' RULING

Pharmaceutical Research and Manufacturers of America (PhRMA) filed a federal-court lawsuit challenging the validity of the Maine program before it could take effect. PhRMA argued that the prior authorization procedure would unfairly limit drugs' market share (i.e., if a particular drug is subject to the procedure, there is a major shift of patients to a competitor's drug that is not subject to the procedure). PhRMA also contended that the Maine program presented a federal, rather than a purely state, issue because the program would have a significant effect on sales outside Maine and could impact the federal Medicaid pricing system.

The district court issued a preliminary injunction agreeing with PhRMA, ruling that Maine had no power to regulate prices paid to drug manufacturers in transactions that occur outside Maine. With respect to sales occurring inside Maine, the district court further held that the federal Medicaid Act preempted the Maine program insofar as it threatened to impose a prior authorization procedure in non-Medicaid transactions.

The First Circuit Court of Appeals vacated the injunction. The court of appeals found no conflict between the Maine program and the Medicaid Act, as they had the same goals. The court of appeals also found that the industry affidavits submitted as evidence by PhRMA did not establish the type of harm that would warrant the extraordinary remedy of an injunction.

THE SUPREME COURT'S DECISION

The Supreme Court affirmed the appellate determination that the injunction should not have been issued. In doing so, the Supreme Court took care to point out that its answer to the procedural question of whether the district improperly granted the injunction would not finally determine the substantive validity of Maine's Rx Program. The court, however, was openly skeptical of PhRMA's concerns, stating that the Maine Act did not regulate the price of any out-of-state transaction (either by its express terms or by its inevitable effect), that Maine did not insist that manufacturers sell their drugs to a wholesaler for a certain price, and that Maine was not tying the price of its in-state products to out-of-state prices.

The court also rejected PhRMA's argument that Maine's Rx fund was similar to an unconstitutional protectionist local subsidy funded by out-of-state businesses, created entirely from rebates paid by out-of-state manufacturers, which would be used to subsidize sales by local pharmacists to local consumers.

The court indicated that, unlike such programs that courts have struck down, the Maine Rx Program did not impose a disparate burden on any competitors.

WHAT THE DECISION MEANS

The final effects of Walsh are unknown at this time, since the lower courts have not passed on the merits of the Maine Rx program following the Supreme Court's decision. But the Walsh litigation likely will have a nationwide impact because the issue is of nationwide interest. The attorneys general of 29 states signed a joint brief in support of the Maine program when the matter was pending before the Supreme Court. Several states have passed or are considering legislation similar to Maine's, and if Maine Rx is upheld by the federal courts, additional states may follow. Moreover, even if Maine Rx does not ultimately pass court muster in its current form, other states may craft plans testing the limits of the court rejection of the Maine program. In this era of state budget deficits, the temptation to attempt to cut drug costs any way possible will likely be too strong for state legislators to pass up.

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