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Justices Allow Drug-Cost Plan to Go Forward

By LINDA GREENHOUSE

WASHINGTON, May 19 — Maine's innovative effort to reduce prescription drug costs for uninsured state residents by pressuring manufacturers to grant price rebates received the Supreme Court's qualified approval today.

The 6-to-3 decision lifted an injunction that has kept the Maine Rx Program from taking effect since the state's Legislature enacted it in 2000. The court's action is likely to shift the drug pricing debate away from the courts and back to the executive branch and the states.

The Federal District Court in Portland, ruling in a suit brought by the pharmaceutical industry, had found that the program violated both the federal Medicaid statute and the constitutional proscription against state interference with interstate commerce. The federal appeals court in Boston disagreed and found the program valid, but kept its decision on hold until the Supreme Court could rule.

Other states have been following the Maine case closely, with 29 states filing a Supreme Court brief on Maine's behalf. As prescription drug legislation has remained stalled in Congress, about half the states have started experimenting with ways to hold down costs for various groups of consumers.

Among these efforts, the Maine program was not only one of the earliest but also one of the broadest. While the program was intended primarily for the state's 325,000 residents who lack medical insurance, it set no income ceiling or other description of financial need. The program is theoretically open to anyone, although the state has proposed regulations to disqualify those who have prescription drug coverage.

Under Maine Rx, the state assumes the role of a pharmacy benefit manager and requires drug manufacturers who want to sell their products in Maine to negotiate rebates similar to those the manufacturers have accepted on drugs they sell through the Medicaid program, which provides medical assistance for the poor.

Since a state cannot directly impose price regulation, Maine gave the drug companies a powerful incentive to go along: manufacturers that did not cooperate faced having their products subject to a "prior authorization" procedure, under which the state's Department of Human Services would have to approve prescriptions case by case before pharmacies could dispense them.

For drugs prescribed through Medicaid, federal law permits states to use this pre-authorization procedure, which manufacturers, doctors, and patients all regard as onerous. Doctors and patients tend to seek alternatives to drugs for which pre-authorization is required. The industry argued in its lawsuit that by using the procedure for a purpose not directly linked to Medicaid, Maine had gone beyond its legal authority.

The state had not sought federal approval for its program, a fact the Bush administration stressed in urging the justices to invalidate it.

The court today declined to take that step, instead leaving the next move up to the state and the administration. "We cannot predict at this preliminary stage the ultimate fate of the Maine Rx Program," Justice John Paul Stevens wrote in a portion of the opinion that was joined by Justices David H. Souter and Ruth Bader Ginsburg.

In fact, the justices in the majority were united only in the result — to permit the program to go into effect, at least provisionally — while splintering into four separate opinions that did not produce a majority for a rationale. There was general agreement that the Federal District Court had acted prematurely in granting the injunction in the absence of factual development on what the impact of Maine Rx would be on consumers, both those covered by Medicaid and those who, while "medically needy," were not poor enough to be covered by the federal program.

In a clear setback to the industry, a solid majority rejected the argument that the program amounted to unconstitutional discrimination against interstate commerce. That aspect of the decision meant that further developments will occur in the realm of statutory interpretation and administrative action.

Of the justices in the majority, Justice Stephen G. Breyer was most explicit, in a separate opinion, about the need for the Department of Health and Human Services to make its position clear and for the district court, in any further proceedings, to take that position into account.

"That agency is better able than a court to assemble relevant facts (e.g. regarding harm caused to present Medicaid patients) and to make relevant predictions (e.g. regarding furtherance of Medicaid-related goals)," Justice Breyer said.

Justice Stevens, who spoke for a majority of the court in some portions of his opinion and sometimes only for two or three other justices, also expressed frustration with a lack of clarity from the administration. "We must confront the issues without the benefit of either a complete record or any dispositive ruling by the secretary," he said, referring to the secretary of Health and Human Services. If the department formally reviewed the Maine plan, "the secretary's ruling would be presumptively valid," he said.

Justices Breyer, Souter and Ginsburg joined all or part of his opinion. Justices Antonin Scalia and Clarence Thomas each wrote separately and were the strongest in upholding the program.

Justice Sandra Day O'Connor, in a dissenting opinion joined by Chief Justice William H. Rehnquist and Justice Anthony M. Kennedy, said that the district court had correctly blocked the program because the new pre-authorization requirement imposed a burden on Medicaid recipients while not accomplishing any additional goal of the Medicaid program. A brief filed on behalf of Medicaid recipients in Connecticut and Florida warned the court of the tendency of pre-authorization requirements to limit access to many drugs.

Addressing that issue, Justice Stevens said the record in this case, *Pharmaceutical Research and Manufacturers of America v. Walsh*, No. 01-188, was insufficient at this point to draw conclusions about who would be helped or hurt by the program.