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NOTE: Where it is feasible, a syllabus (headnote) will be released, as is being done in connection with this case, at the time the opinion is issued. The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States* v. *Detroit Timber & Lumber Co.*, 200 U. S. 321, 337.

SUPREME COURT OF THE UNITED STATES

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PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA *v.* WALSH, ACTING COMMISSIONER, MAINE DEPARTMENT OF HUMAN SERVICES, ET AL.

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

No. 01–188. Argued January 22, 2003—Decided May 19, 2003

A State participating in Medicaid must have a medical assistance plan approved by the Secretary of Health and Human Services (HHS). In response to increasing Medicaid expenditures for prescription drugs, Congress enacted a cost-saving measure in 1990 that requires drug companies to pay rebates to States on their Medicaid purchases. States have since enacted supplemental rebate programs to achieve additional cost savings on Medicaid purchases and purchases for other needy citizens. The purpose of the "Maine Rx" Program is to reduce prescription drug prices for state residents. Under the program, Maine will attempt to negotiate rebates with drug manufacturers. If a company does not enter into a rebate agreement, its Medicaid sales will be subjected to a "prior authorization" procedure that requires state agency approval to qualify a doctor's prescription for reimbursement. Petitioner, an association of nonresident drug manufacturers, challenged the program before its commencement date, claiming that it is pre-empted by the Medicaid Act and violates the negative Commerce Clause. Without resolving any factual issues, the District Court entered a preliminary injunction preventing the statute's implementation, concluding, *inter alia,* that any obstacle, no matter how modest, to the federal program's administration is sufficient to establish pre-emption. The First Circuit reversed.

Held: The judgment is affirmed.

249 F. 3d 66, affirmed.

JUSTICE STEVENS delivered the opinion of the Court with respect to

Parts I, II, III, and VI, concluding that petitioner has not carried its burden of showing a probability of success on the merits of its Commerce Clause claims. Its arguments—that the rebate requirement constitutes impermissible extraterritorial regulation and that it discriminates against interstate commerce in order to subsidize in-state retail sales—are unpersuasive. Unlike the price control statute invalidated in *Baldwin* v. *G. A. F. Seelig, Inc.,* 294 U. S. 511, and the price affirmation statute struck down in *Healy* v. *Beer Institute,* 491 U. S. 324, Maine Rx does not regulate the price of any out-of-state transaction by its express terms or its inevitable effect. Nor does Maine Rx impose a disparate burden on out-of-state competitors. A manufacturer cannot avoid its rebate obligation by opening production facilities in Maine and would receive no benefit from the rebates even if it did so; the payments to local pharmacists provide no special benefit to competitors of rebate-paying manufacturers. *West Lynn Creamery, Inc.* v. *Healy,* 512 U. S. 186, distinguished. Pp. 22–24.

JUSTICE STEVENS, joined by JUSTICE SOUTER, JUSTICE GINSBURG, and JUSTICE BREYER, concluded in Parts IV and VII that:

(a) The answer to the question before the Court—whether petitioner' s showing was sufficient to support the District Court's injunction—will not determine the validity of Maine's Rx Program since further proceedings may lead to another result. Moreover, the Secretary may view Maine Rx as an amendment to its Medicaid Plan that requires his approval before becoming effective. As the case comes to this Court, the question is whether there is a probability that Maine's program was pre-empted by the federal statute's mere existence. Therefore, there is a presumption that the state statute is valid, and the question asked is whether petitioner has shouldered the burden of overcoming that presumption. Pp. 13–14.

(b) At this stage of the litigation, petitioner has not carried its burden of showing a probability of success on the merits of its claims. P. 24.

JUSTICE STEVENS, joined by JUSTICE SOUTER and JUSTICE GINSBURG, concluded in Part V that petitioner's showing is insufficient to support a finding that the Medicaid Act pre-empts Maine's Rx Program insofar as it threatens to coerce manufacturers into reducing their prices on non-Medicaid sales. Petitioner claims that the potential interference with Medicaid benefits without serving any Medicaid purpose is prohibited by the federal statute. However, petitioner must show that Maine Rx serves no such goal. In fact, Maine Rx may serve the Medicaid-related purposes of providing benefits to needy persons and curtailing the State's Medicaid costs. While these purposes would not provide a sufficient basis for upholding the program if it severely curtailed Medicaid recipients' prescription drug access,

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the District Court erred in assuming that even a modest impediment to such access would invalidate the program. The Medicaid Act gives States substantial discretion to choose the proper mix of amount, scope, and duration limitations on coverage as long as care and services are provided in the recipients' best interests. *Alexander* v. *Choate,* 469 U. S. 287, 303. That a State's decision to curtail Medicaid benefits may have been motivated by a state policy unrelated to the Medicaid Act does not limit the scope of its broad discretion to define the benefits package it will finance. See *Beal* v. *Doe,* 432 U. S. 438. The presumption against federal pre-emption of a state statute designed to foster public health has special force when it appears, and the Secretary has not decided to the contrary, that the two governments are pursuing common purposes. At this stage of the proceeding, the severity of any impediment that Maine's program may impose on a Medicaid patient's access to the drug of her choice is a matter of conjecture. Thus, the First Circuit correctly resolved the pre-emption issue. Pp. 15–22.

JUSTICE BREYER concluded that petitioner cannot obtain a preliminary injunction simply by showing minimal or quite modest harm even though Maine offered no evidence of countervailing Medicaid-related benefit. Proper determination of the pre-emption question will demand a more careful balancing of Medicaid-related harms and benefits than the District Court undertook. Thus, its technical misstatement of the proper legal standard should not be overlooked. Vacating the injunction will also help ensure that the District Court takes account of the Secretary's views in further proceedings, which is important since HHS administers Medicaid and is better able than a court to assemble relevant facts and to make relevant predictions, and since the law grants significant weight to the Secretary's legal conclusions about whether Maine's program is consistent with Medicaid's objectives. Under the Medicaid Act, Maine may obtain those views when it files its plan with HHS for approval. In addition, a court may "refer" a question to the Secretary under the legal doctrine of "primary jurisdiction," which seeks to produce better informed and uniform legal rulings by allowing courts to take advantage of an agency's specialized knowledge, expertise, and central position within a regulatory regime. Where, as here, certain conditions are satisfied, see *Far East Conference* v. *United States,* 342 U. S. 570, 574–575, a court may raise the doctrine on its own motion. A court may then stay its proceedings to allow a party to initiate agency review. Even if Maine chooses not to obtain the Secretary's views on its own, the desirability of the District Court's having those views to consider is relevant to the "public interest" determination that often factors into whether a preliminary injunction should issue. Pp. 1–5.

JUSTICE SCALIA concluded that petitioner's statutory claim should

be rejected on the ground that the remedy for the State's failure to comply with its Medicaid Act obligations is set forth in the Act itself: termination of funding by the Secretary. Petitioner must seek enforcement of Medicaid conditions by that authority and may obtain relief in the courts only when a denial of enforcement is arbitrary, capricious, an abuse of discretion, or otherwise unlawful. 5 U. S. C. §706(2)(A). Pp. 1–2.

JUSTICE THOMAS concluded that Maine Rx is not pre-empted by the Medicaid Act. The premise of petitioner's pre-emption claim is that Maine Rx is "an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines* v. *Davidowitz,* 312 U. S. 52, 67. The Medicaid Act represents a delicate balance between competing interests, *e.g.,* care and cost. It grants States broad discretion to impose prior authorization, and proper consideration of the Secretary's role in administering the Act forecloses petitioner's pre-emption claim. The Act provides a complete list of the restrictions participating States may place on prescription drug coverage. 42 U. S. C. §1396r–8(d)(1). The only stricture on a prior authorization program is compliance with certain procedures, §1396r–8(d)(5). The purpose of §1396r–8(d)(1) is its effect—to grant participating States authority to subject drugs to prior authorization subject only to §1396r–8(d)(5)'s express limitations. In light of the broad grant of discretion to States to impose prior authorization, petitioner cannot produce a credible conflict between Maine Rx and the Medicaid Act. Given the Secretary's authority to administer and interpret the Medicaid Act, petitioner can prevail on its view that the Medicaid Act pre-empts Maine Rx and renders it void under the Supremacy Clause only by showing that the Medicaid Act is unambiguous or that Congress has directly addressed the issue. See *Chevron U. S. A. Inc.* v. *Natural Resources Defense Council, Inc.,* 467 U. S. 837, 842. However, the Act's text cannot be read in such a way. Indeed, the Secretary has adopted an interpretation of the Act that does not preclude States from negotiating prices for non-Medicaid drug purchases. Obstacle pre-emption's very premise is that Congress has not expressly displaced state law and therefore not directly spoken to the pre-emption question. Therefore, where an agency is charged with administering a federal statute, as the Secretary is here, *Chevron* imposes a perhaps-insurmountable barrier to an obstacle pre-emption claim. Pp. 1–9.

STEVENS, J., announced the judgment of the Court and delivered the opinion of the Court with respect to Parts I, II, III, and VI, in which REHNQUIST, C. J., and O'CONNOR, KENNEDY, SOUTER, GINSBURG, and BREYER, JJ., joined, an opinion with respect to Parts IV and VII, in which SOUTER, GINSBURG, and BREYER, JJ., joined, and an opinion with

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respect to Part V, in which SOUTER and GINSBURG, JJ., joined. BREYER, J., filed an opinion concurring in part and concurring in the judgment. SCALIA, J., and THOMAS, J., filed opinions concurring in the judgment. O'CONNOR, J., filed an opinion concurring in part and dissenting in part, in which REHNQUIST, C. J., and KENNEDY, J., joined.