Syllabus

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 affirma-

tion 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. 668–670.

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

(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. 660–662.

(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. 670.

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, 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. 662–668.

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. 670–674.

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. 674–675.

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. 675–683.

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 respect to Part V, in which SOUTER and GINSBURG, JJ., joined. BREYER, J., filed an opinion concurring in part and concurring in the judgment, *post*, p. 670. SCALIA, J., *post*, p. 674, and THOMAS, J., *post*, p. 675, 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, *post,* p. 684.

Carter G. Phillips argued the cause for petitioner. With him on the briefs were *Kathleen M. Sullivan*, *Daniel M. Price*, *Marinn F. Carlson*, *Bruce C. Gerrity*, and *Ann R. Robinson.*

Deputy Solicitor General Kneedler argued the cause for the United States as *amicus curiae* urging reversal. With him on the brief were *Solicitor General Olson*, *Assistant Attorney General McCallum*, *Lisa Schiavo Blatt*, *Mark B. Stern*, *Mark S. Davies*, *Alex M. Azar II*, *Sheree R. Kanner*, *Henry R. Goldberg*, and *Janice L. Hoffman.*

Andrew S. Hagler, Assistant Attorney General of Maine, argued the cause for respondents. With him on the brief were *G. Steven Rowe*, Attorney General, *Paul Stern*, Deputy Attorney General, *John R. Brautigam*, Assistant Attorney General, and *Cabanne Howard.**

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*Briefs of *amici curiae* urging reversal were filed for the Chamber of Commerce of the United States of America by *John G. Roberts, Jr.*, *Catherine E. Stetson*, and *Robin S. Conrad;* for the International Patient Advocacy Association et al. by *Bert W. Rein;* for the Long Term Care Pharmacy Alliance by *David C. Todd;* for the Pacific Legal Foundation by *Deborah J. La Fetra;* and for the Washington Legal Foundation et al. by *Daniel J. Popeo* and *Richard A. Samp.*

Briefs of *amici curiae* urging affirmance were filed for the State of Massachusetts et al. by *Thomas F. Reilly*, Attorney General of Massachusetts, and *Linda A. Tomaselli* and *Peter Leight*, Assistant Attorneys General, and by the Attorneys General for their respective jurisdictions as follows: *Bruce M. Botelho* of Alaska, *Janet Napolitano* of Arizona, *Mark Pryor* of Arkansas, *Bill Lockyer* of California, *Earl I. Anzai* of Hawaii, *Steve Carter* of Indiana, *Thomas J. Miller* of Iowa, *Albert B. Chandler III* of Kentucky, *Richard P. Ieyoub* of Louisiana, *J. Joseph Curran, Jr.*, of Maryland, *Jennifer M. Granholm* of Michigan, *Mike Hatch* of Minnesota, *Mike Moore* of Mississippi, *Jeremiah W. (Jay) Nixon* of Missouri, *Mike McGrath* of Montana, *Philip T. McLaughlin* of New Hampshire, *Patricia A. Madrid* of New Mexico, *Eliot Spitzer* of New York, *W. A. Drew Edmondson* of Oklahoma, *Hardy Myers* of Oregon, *D. Michael Fisher* of

JUSTICE STEVENS announced the judgment of the Court and delivered the opinion of the Court with respect to Parts I, II, III, and VI, an opinion with respect to Parts IV and VII, in which JUSTICE SOUTER, JUSTICE GINSBURG, and JUSTICE BREYER join, and an opinion with respect to Part V, in which JUSTICE SOUTER and JUSTICE GINSBURG join.

In response to increasing Medicaid expenditures for prescription drugs,[1] Congress enacted a cost-saving measure in 1990 that requires drug companies to pay rebates to States on their Medicaid purchases. Over the last several years, state legislatures have enacted supplemental rebate programs to achieve additional cost savings on Medicaid purchases as well as for purchases made by other needy citizens. The "Maine Rx" program, enacted in 2000, is primarily intended to provide discounted prescription drugs to Maine's uninsured citizens but its coverage is open to all residents of the State. Under the program, Maine will attempt to negotiate rebates with drug manufacturers to fund the reduced price for drugs offered to Maine Rx participants. If a drug company does not enter into a rebate agreement, its

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Pennsylvania, *Sheldon Whitehouse* of Rhode Island, *Charlie M. Condon* of South Carolina, *Mark Barnett* of South Dakota, *John Cornyn* of Texas, *William H. Sorrell* of Vermont, *Christine O. Gregoire* of Washington, *Darrell V. McGraw, Jr.*, of West Virginia, and *Anabelle Rodríguez* of Puerto Rico; for AARP et al. by *Sarah Lenz Lock, Bruce Vignery, Michael Schuster,* and *Robert M. Hayes;* for the Maine Council of Senior Citizens et al. by *Arn H. Pearson* and *Thomas C. Bradley;* and for the National Conference of State Legislatures et al. by *Richard Ruda* and *James I. Crowley.*

Sheldon V. Toubman filed a brief for Legal Services Organizations Representing Medicaid Beneficiaries as *amicus curiae.*

[1] From 1980 to 1989, payments for Medicaid prescription drugs increased 179% while Medicaid expenditures for all services increased by only 134%. Between 1982 and 1988, prescription drug costs "increased at an average annual rate of 9.5 percent . . . , more than any other component of the health care sector." M. Ford, Congressional Research Service Report to Congress, Medicaid: Reimbursement for Outpatient Prescription Drugs, CRS–15 (Mar. 7, 1991) (hereinafter Ford).

Medicaid sales will be subjected to a "prior authorization" procedure.

In this case, an association of nonresident drug manufacturers has challenged the constitutionality of the Maine Rx Program, claiming that the program is pre-empted by the federal Medicaid statute and that it violates the negative Commerce Clause. The association has not alleged that the program denies Medicaid patients meaningful access to prescription drugs or that it has excluded any drugs from access to the market in Maine. Instead, it contends that the program imposes a significant burden on Medicaid recipients by requiring prior authorization in certain circumstances without serving any valid Medicaid purpose, and that the program effectively regulates out-of-state commerce. The District Court sustained both challenges and entered a preliminary injunction preventing implementation of the statute. The Court of Appeals reversed, and we granted certiorari because the questions presented are of national importance. 536 U. S. 956 (2002).

I

Congress created the Medicaid program in 1965 by adding Title XIX to the Social Security Act.[2] The program authorizes federal financial assistance to States that choose to reimburse certain costs of medical treatment for needy persons. In order to participate in the Medicaid program, a State must have a plan for medical assistance approved by the Secretary of Health and Human Services (Secretary). 42 U. S. C. § 1396a(b).[3] A state plan defines the categories of individuals eligible for benefits and the specific kinds of medical services that are covered. §§ 1396a(a)(10), (17). The plan must

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[2] 79 Stat. 343, as amended, 42 U. S. C. § 1396 *et seq.*

[3] The Centers for Medicare & Medicaid Services (CMS) is the agency administering the Medicaid program on behalf of the Secretary.

provide coverage for the "categorically needy"[4] and, at the State's option, may also cover the "medically needy."[5]

Prior to 1990, the Medicaid statute did not specifically address outpatient prescription drug coverage. The Secretary's regulations and guidelines "set upper limits on each State's aggregate expenditures for drugs."[6] Under plans approved by the Secretary, some States designed and administered their own formularies, listing the drugs that they would cover. States also employed "prior authorization programs" that required approval by a state agency to qualify a doctor's prescription for reimbursement. See, *e. g.*, *Dodson* v. *Parham*, 427 F. Supp. 97, 100–101 (ND Ga. 1977) ("Georgia has historically administered its prescription drug program on the basis of a drug 'formulary' or, in other words, a restricted list of drugs for which Medicaid will reimburse provider pharmacists. Thus, any drug not specifically included on the list will not be reimbursed unless prior approval is granted by [the administrator of Georgia Medicaid program]"); *Cowan* v. *Myers*, 187 Cal. App. 3d 968, 974–975, 232 Cal. Rptr. 299, 301–303 (1986) (describing 1982 California law providing that certain drugs would be covered under

[4] The "categorically needy" groups include individuals eligible for cash benefits under the Aid to Families with Dependent Children (AFDC) program, the aged, blind, or disabled individuals who qualify for supplemental security income (SSI) benefits, and other low-income groups such as pregnant women and children entitled to poverty-related coverage. § 1396a(a)(10)(A)(i).

[5] The "medically needy" are individuals who meet the nonfinancial eligibility requirements for inclusion in one of the groups covered under Medicaid, but whose income or resources exceed the financial eligibility requirements for categorically needy eligibility. § 1396a(a)(10)(C). Individuals are typically "entitled to medically needy protection when their income and resources, after deducting incurred medical expenses, falls *[sic]* below the medically needy standards." House Subcommittee on Health and the Environment of the Committee on Energy and Commerce, Medicaid Source Book: Background Data and Analysis, 103d Cong., 1st Sess., 167 (Comm. Print 1993).

[6] Ford, at CRS–1.

California Medicaid program only after prior authorization). These programs were not specifically governed by any federal law or regulations, but rather were made part of the State Medicaid plans and approved by the Secretary because they aided in controlling Medicaid costs.[7]

Congress effectively ratified the Secretary's practice of approving state plans containing prior authorization requirements when it created its rebate program in an amendment contained in the Omnibus Budget Reconciliation Act of 1990 (OBRA 1990).[8] The new program had two basic parts. First, it imposed a general requirement that, in order to qualify for Medicaid payments, drug companies must enter into agreements either with the Secretary or, if authorized by the Secretary, with individual States, to provide rebates on their Medicaid sales of outpatient prescription drugs.[9] The rebate on a "single source drug" or an "innovator multiple source drug" is the difference between the manufacturer's average price and its "best price," or 15.1% of the average manufacturer price, whichever is greater. 42 U. S. C. §§ 1396r–8(c)(1), (2). The rebate for other drugs is 11.1% of the average manufacturer price. See § 1396r–8(c)(3).

Second, once a drug manufacturer enters into a rebate agreement, the law requires the State to provide coverage for that drug under its plan unless the State complies with one of the exclusion or restriction provisions in the Medicaid Act. See § 1396r–8(d). For example, a State may exclude

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[7] "Before 1990, States had routinely required prior authorization for prescription or dispensing of drugs in order to control Medicaid costs . . . . In enacting the drug rebate provisions of Section 1396r–8 in 1990, Congress did not intend to upset that practice." Brief in Opposition for United States as *Amicus Curiae* 14–15.

[8] 104 Stat. 1388–143.

[9] The statute authorizes payment for some drugs not covered by rebate agreements if a State determines that their availability is essential to the health of beneficiaries, if they have been given a special rating by the Federal Food and Drug Administration, and if a doctor has obtained prior authorization for their use. See 42 U. S. C. § 1396r–8(a)(3).

coverage of drugs such as "[a]gents . . . used for cosmetic purposes or hair growth." § 1396r–8(d)(2)(C).

Most relevant to this case, Congress allowed States, "as a condition of coverage or payment for a covered outpatient drug," § 1396r–8(d)(5), to require approval of the drug before it is dispensed. Thus, under OBRA 1990, except for a narrow category of new drugs,[10] "[a] State may subject to prior authorization any covered outpatient drug," § 1396r–8(d)(1)(A), so long as the State's prior authorization program (1) provides a response by telephone or other telecommunication device within 24 hours of a request for prior authorization, and, (2) except for the listed excludable drugs, provides for the dispensing of at least a 72-hour supply of a covered drug in an emergency situation, see § 1396r–8(d)(5).

In the Omnibus Budget Reconciliation Act of 1993,[11] Congress further amended the Act to allow the States to use formularies subject to strict limitations. That amendment expressly stated that a prior authorization program that complies with the 24-hour and 72-hour conditions is not subject to the limitations imposed on formularies.[12] The 1993 amendment reenacted the provisions for state prior authorization programs that had been included in OBRA 1990, omitting, however, the narrow exception for new drugs.

II

In 2000, the Maine Legislature established the Maine Rx Program "to reduce prescription drug prices for residents of the State." Me. Rev. Stat. Ann., Tit. 22, § 2681 (West Supp.

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[10] "A State may not exclude for coverage, subject to prior authorization, or otherwise restrict any new biological or drug approved by the Food and Drug Administration after the date of enactment of this section, for a period of 6 months after such approval." 104 Stat. 1388–150, § 1927(d)(6).

[11] 107 Stat. 613.

[12] "A prior authorization program established by a State under paragraph (5) is not a formulary subject to the requirements of this paragraph." § 1396r–8(d)(4).

2002). The statute provides that "the State [shall] act as a pharmacy benefit manager in order to make prescription drugs more affordable for qualified Maine residents, thereby increasing the overall health of Maine residents, promoting healthy communities and protecting the public health and welfare." § 2681(1). The program is intended to enable individuals to buy drugs from retail pharmacies at a discount roughly equal to the rebate on Medicaid purchases. See § 2681(4).

The statute provides that any manufacturer or "labeler"[13] selling drugs in Maine through any publicly supported financial assistance program "shall enter into a rebate agreement" with the State Commissioner of Human Services (Commissioner). § 2681(3). The Commissioner is directed to use his best efforts to obtain a rebate that is at least equal to the rebate calculated under the federal program created pursuant to OBRA 1990. See § 2681(4). Rebates are to be paid into a fund administered by the Commissioner, and then distributed to participating pharmacies to compensate them for selling at discounted prices. § 2681(6).

For those manufacturers that do not enter into rebate agreements, there are two consequences: First, their nonparticipation is information that the Department of Human Services must release "to health care providers and the public." § 2681(7). Second, and more importantly for our purposes, the "department shall impose prior authorization requirements in the Medicaid program under this Title, as permitted by law, for the dispensing of prescription drugs provided by those [nonparticipating] manufacturers and labelers." *Ibid.*

The statute authorizes the department to adopt implementing rules. § 2681(14). The rules that have been proposed would limit access to the program to individuals who

[13] A "labeler" is a person who receives prescription drugs from a manufacturer or wholesaler and repackages them for later retail sale. § 2681(2)(C).

do "not have a comparable or superior prescription drug benefit plan."[14] The proposed rules also explain that Maine intends to appoint a "Drug Utilization Review Committee," composed of physicians and pharmacists who will evaluate each drug manufactured by a company that has declined to enter into a rebate agreement to decide whether it is clinically appropriate to subject the drug to prior authorization.[15] The State represents that it "certainly will not subject any single-source drug that fulfills a unique therapeutic function to the prior authorization process" even if its manufacturer does not enter into a rebate agreement.[16] The determination "whether a particular drug should be subjected to a prior authorization requirement will be based firmly upon considerations of medical necessity, and in compliance with the State's responsibilities as the administrator of the Maine Medicaid Program."[17]

III

Several months before January 1, 2001, the intended commencement date of the Maine Rx Program, the Commissioner, then Kevin Concannon, sent a form letter to drug manufacturers enclosing a proposed rebate agreement.[18]

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[14] App. 317. The statute authorizes coverage for all "qualified Maine residents," Me. Rev. Stat. Ann., Tit. 22, §2681(1) (West Supp. 2002), and defines a qualified resident as one "who has obtained from the department a Maine Rx enrollment card," §2681(2)(F). In describing program goals, it provides: "It is not the intention of the State to discourage employers from offering or paying for prescription drug benefits for their employees or to replace employer-sponsored prescription drug benefit plans that provide benefits comparable to those made available to qualified Maine residents under this subchapter." §2681(1). In their brief, respondents state: "It would be economically irrational for a person with prescription drug coverage to use Maine Rx, but if any patient mistakenly attempts to do so, [the] proposed regulations . . . will not allow it." Brief for Respondents 7.

[15] See App. 268, 278.

[16] *Id.*, at 149.

[17] *Ibid.*

[18] See *id.*, at 62–74.

Although 27 individual manufacturers elected to participate by executing the proposed agreement, petitioner, the Pharmaceutical Research and Manufacturers of America, an association representing manufacturers that "account for more than 75 percent of brand name drug sales in the United States,"[19] responded by bringing this action challenging the validity of the statute. Its complaint was accompanied by a motion for a preliminary injunction, supported by seven affidavits.

Four of the affidavits describe the nature of the association and the companies' methods of distribution, emphasizing the fact that, with the exception of sales to two resident distributors, all of their prescription drug sales occur outside of Maine.[20] Three of them comment on the operation of prior authorization programs administered by private managed care organizations, describing their actual and potential adverse impact on both manufacturers and patients. Thus, one executive stated: "Imposition of a prior authorization [(PA)] requirement with respect to a particular drug severely curtails access to the drug for covered patients and sharply reduces the drug's market share and sales, as the PA causes a shift of patients to competing drugs of other manufacturers that are not subject to a PA. Because a PA imposes additional procedural burdens on physicians prescribing the manufacturer's drug and retail pharmacies dispensing it, the effect of a PA is to diminish the manufacturer's goodwill that helped foster demand for its drug over competing drugs produced by other manufacturers, and to shift physician and patient loyalty to those competing drugs, perhaps permanently."[21] Another affidavit described how prior authorization by a managed care organization in Nevada had sharply reduced the market share of four of SmithKline's drugs. For example, the market share of Aug-

[19] *Id.*, at 37 (Complaint ¶ 6).

[20] *Id.*, at 50, 53, 76–77, 87.

[21] *Id.*, at 57 (affidavit of George Bilyk of Janssen Pharmaceutica, Inc.).

mentin, a drug used to treat bacterial infections, declined from 49% to 18% in the six months after the program was imposed.[22] In the third affidavit, Dr. Howell of SmithKline Beecham Corporation expressed the opinion that prior authorization had never been required in one program "for the purpose of influencing the manufacturer's pricing behavior in another program," and that such use, "without regard to safety or efficacy, will lead to drugs being prescribed that are less safe and efficacious."[23]

Respondents' opposition to the motion was supported by Concannon's own affidavit and the affidavits of two doctors. They do not dispute the factual assertions concerning the impact of prior authorization on the drug companies' market shares, but instead comment on the benefits of prior authorization for patients. The State's Medicaid Medical Director, Dr. Clifford, explained that "[p]hysicians in Maine are already well acquainted with the extensive prior authorization programs of the four HMO/Insurance programs which collectively cover nearly half the state's residents" and that the State had taken steps to "ensure that physicians will always be able to prescribe the safest and most efficacious drugs for their Medicaid patients."[24] The second doctor, Dr. Richardson, stated that he prescribed Augmentin as a second line drug, that the drug amoxicillin was effective in treating ear infections 80%–85% of the time, and that Augmentin was

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[22] *Id.*, at 112 (affidavit of David Moules of SmithKline Beecham Corp.).

[23] *Id.*, at 103–104. Dr. Howell further stated: "Prior authorization is often employed by managed care organizations ('MCOs') to enforce a drug formulary and is usually intended to limit the drugs to be prescribed by health care professionals. MCOs typically require health care professionals to obtain prior authorization from the MCO before prescribing a drug (1) to ensure proper use of prescription drugs with a high potential for inappropriate use, (2) to limit the use of prescription drugs with severe or life threatening side effects and/or drug interactions; and (3) to encourage the use of cost-effective medications without diminishing safety or efficacy." *Id.*, at 102–103.

[24] *Id.*, at 149–150.

"3 to 6 times as expensive" as amoxicillin.[25] Concannon's affidavit described the composition of a committee of physicians and pharmacists that would "make the final determination of the clinical appropriateness of any recommendation that a prior authorization requirement be imposed with respect to a particular prescription drug manufactured by a manufacturer which has not entered into a Maine Rx Rebate Agreement."[26]

Without resolving any factual issues, the District Court granted petitioner's motion for a preliminary injunction. Relying on *Healy* v. *Beer Institute*, 491 U. S. 324, 336 (1989), the court first held that Maine had no power to regulate the prices paid to drug manufacturers in transactions that occur out of the State. Recognizing that some of their sales were made to two distributors in Maine, the court further held that the Medicaid Act pre-empted Maine's Rx Program insofar as it threatened to impose a prior authorization requirement on nonparticipating manufacturers. In so holding, the court assumed for the purpose of the decision that the " 'Department of Human Services will not deny a single Medicaid recipient access to the safest and most efficacious prescription drug therapy indicated for their individual medical circumstances.' "[27] In that court's view, pre-emption was nevertheless required because "Maine can point to no *Medicaid* purpose in this new prior authorization requirement that Maine has added for Medicaid prescription drugs. Maine has not just passed a law that might conflict with the objectives of a federal law. It has actually taken the federal Medicaid program and altered it to serve Maine's local purposes."[28] In the District Court's view, the fact that the

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[25] *Id.*, at 154.

[26] *Id.*, at 167.

[27] Civ. No. 00–157–B–H (D. Me., Oct. 26, 2000), App. to Pet. for Cert. 68.

[28] *Ibid.* The court further observed: "If Maine can use its authority over Medicaid authorization to leverage drug manufacturer rebates for the benefit of uninsured citizens, then it can just as easily put the rebates into

alteration served purposes outside the scope of the Medicaid program and created an obstacle to the administration of the federal program was sufficient to establish pre-emption: "No matter how modest an obstacle the new prior authorization amounts to (the parties disagree on the severity of the obstacle), it is an obstacle—drugs on the list must be approved by the state Medicaid Medical Director before they can be dispensed . . . ."[29]

The Court of Appeals disagreed with the District Court's analysis of the pre-emption issue for three reasons. First, since the federal statute expressly authorizes use of prior authorization, it found "no conflict between the Maine Act and Medicaid's structure and purpose." 249 F. 3d 66, 75 (CA1 2001). In its view, as long as there is compliance with the federal 24- and 72-hour conditions, the State's motivation for imposing the requirement is irrelevant. Second, given the absence of an actual conflict, the court found that the mere fact that Maine Rx "fails to directly advance the purpose of the federal program" is an insufficient basis for "inflicting the 'strong medicine' of preemption" on a state statute. *Id.*, at 76. Third, the court further stated that, assuming the relevance of the State's motivation, "the Maine Rx Program furthers Medicaid's aim of providing medical services to those whose 'income and resources are insufficient to meet the costs of necessary medical services,' 42 U. S. C. § 1396, even if the individuals covered by the Maine Rx Program are not poor enough to qualify for Medicaid." *Ibid.* Moreover, the court held that there is evidence that making prescription drugs more accessible to the uninsured may keep some of them off Medicaid thereby minimizing the State's Medicaid expenditures.

The Court of Appeals also reviewed the affidavits and concluded that they "fall short of establishing that the Act will

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a state program for highway and bridge construction or school funding." *Ibid.*

[29] *Ibid.*

inflict inevitable or even probable harm" on Medicaid patients, and thus were insufficient to support a pre-emption-based facial challenge. *Id.*, at 78. The court did, however, express concern that the prior authorization requirement might affect the quality of medical care for Medicaid recipients in subtle ways, such as inconveniencing prescribing physicians. It therefore expressly preserved petitioner's right to renew its pre-emption challenge after implementation of the program "should there be evidence that Medicaid recipients are harmed by the prior authorization requirement 'as applied.'" *Ibid.* The Court also found no violation of the dormant Commerce Clause and vacated the temporary injunction, but stayed its mandate pending our review of the case.

IV

The question before us is whether the District Court abused its discretion when it entered the preliminary injunction. See *Doran* v. *Salem Inn, Inc.*, 422 U. S. 922, 931–932 (1975). By no means will our answer to that question finally determine the validity of Maine's Rx Program. The District Court did not conduct an evidentiary hearing and did not resolve any factual disputes raised by the affidavits filed by the parties. Accordingly, no matter how we answer the question whether petitioner's showing was sufficient to support the injunction, further proceedings in this case may lead to a contrary result.

Moreover, there is also a possibility that the Secretary may view the Maine Rx Program as an amendment to its Medicaid Plan that requires his approval before it becomes effective.[30] While the petition for certiorari was pending,

[30] We note that CMS, acting on behalf of the Secretary, see n. 3, *supra*, sent a letter on September 18, 2002, to all of the state Medicaid directors. In that letter, the CMS Director indicated that "the establishment of a prior authorization program for Medicaid covered drugs to secure drug benefits, rebates, or discounts for non-Medicaid populations is a significant component of a State plan and we would therefore expect that a State

the United States filed a brief recommending that we deny review, in part because further proceedings may clarify the issues. Its brief cautioned against the adoption of a rule prohibiting prior authorization programs whenever they operate in part to benefit a non-Medicaid population, and suggested that a program tailored to benefit needy persons who are not Medicaid-eligible might advance Medicaid-related goals.[31] That brief, however, as well as the Federal Government's brief filed after we granted review, expressed the opinion that, because Maine's program was adopted without the Secretary's approval and was open to all Maine residents regardless of financial need, it was not tailored to achieve Medicaid-related goals and was therefore invalid. Like the interlocutory judicial rulings in this case, we assume that a more complete understanding of all the relevant facts might lead to a modification of the views expressed in those briefs. In all events, we must confront the issues without the benefit of either a complete record or any dispositive ruling by the Secretary.

The issue we confront is, of course, quite different from the question that would be presented if the Secretary, after a hearing, had held that the Maine Rx Program was an impermissible amendment of its Medicaid Plan. In such event, the Secretary's ruling would be presumptively valid. As the case comes to us, however, the question is whether there is a probability that Maine's program was pre-empted by the mere existence of the federal statute. We start therefore with a presumption that the state statute is valid, see *Davies Warehouse Co.* v. *Bowles*, 321 U. S. 144, 153 (1944), and ask

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would submit such a program for CMS review under the State plan process." App. to Brief in Opposition for United States as *Amicus Curiae* 48a.

[31] Brief in Opposition for United States as *Amicus Curiae* 9, 12 ("A prescription drug discount, made possible by encouraging manufacturers to give rebates to the State, may significantly decrease the chance that such individuals will become Medicaid-eligible").

whether petitioner has shouldered the burden of overcoming that presumption.

V

The centerpiece of petitioner's attack on Maine's Rx Program is its allegedly unique use of a threat to impose a prior authorization requirement on Medicaid sales to coerce manufacturers into reducing their prices on sales to non-Medicaid recipients. Petitioner argues, and the District Court held, that the potential interference with the delivery of Medicaid benefits without any benefit to the federal program is prohibited by the federal statute. In accepting this argument, the District Court relied heavily on the fact that Maine had failed to identify any "*Medicaid* purpose" in its new authorization requirement. It appears that Maine had argued before the District Court that such a purpose was unnecessary because the federal statute expressly authorizes what it has done.

In this Court, petitioner argues that it could not have been an abuse of discretion for the District Court to decide the case on the assumption that the program will serve no Medicaid purpose, even if that assumption is erroneous, given that the State, insisting that no such purpose was necessary, offered no Medicaid purpose in its opposition to the motion for a temporary injunction. To the extent that petitioner is relying on a waiver theory, such reliance is inappropriate because the State never represented that there was no Medicaid purpose served by its program; it simply argued that it did not need to offer one. Regardless of the legal position taken by the State, petitioner bore the burden of establishing, by a clear showing, a probability of success on the merits. See *Mazurek* v. *Armstrong,* 520 U. S. 968, 972 (1997) *(per curiam);* cf. *Benten* v. *Kessler,* 505 U. S. 1084, 1085 (1992) *(per curiam)* (requiring movant to demonstrate a substantial likelihood of success on the merits). Accordingly, it was petitioner's burden to show that there was no Medicaid-related goal or purpose served by Maine Rx. Given that

burden, if the program on its face clearly serves some Medicaid-related goals, it would follow that the District Court's evaluation rested on an erroneous predicate. We are persuaded that there are three such goals plainly present in the Maine Rx Program.

The Court of Appeals identified two Medicaid-related interests that will be served if the program is successful and rebates become available on sales to uninsured individuals. First, the program will provide medical benefits to persons who can be described as "medically needy" even if they do not qualify for AFDC or SSI benefits. There is some factual dispute concerning the extent to which the program will also benefit nonneedy persons, but even if the program is more inclusive than the Secretary thinks it should be, the potential benefits for nonneedy persons would not nullify the benefits that would be provided to the neediest segment of the uninsured population.[32] Second, there is the possibility that, by enabling some borderline aged and infirm persons better access to prescription drugs earlier, Medicaid expenses will be reduced. If members of this borderline group are not able to purchase necessary prescription medicine, their conditions may worsen, causing further financial hardship and thus making it more likely that they will end up in the Medicaid program and require more expensive treatment.

A third rather obvious Medicaid purpose will be fostered whenever it is necessary to impose the prior authorization requirement on a manufacturer that refuses to participate. As the record demonstrates, private managed care organizations typically require prior authorization both to protect patients from inappropriate prescriptions and "to encourage the use of cost-effective medications without diminishing

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[32] We note in this regard that it is estimated that almost two-thirds of the nonelderly uninsured are low-income individuals or come from low-income families making less than 200% of the federal poverty level. See Kaiser Commission on Medicaid and the Uninsured, The Uninsured: A Primer 2 (Mar. 2001).

safety or efficacy."[33] No doubt that is why Congress expressly preserved the States' ability to adopt that practice when it passed the Medicaid amendments in 1990.[34] The fact that prior authorization actually does produce substantial cost savings for organizations purchasing large volumes of drugs is apparent both from the affidavits in the record describing the impact of such programs on manufacturers' market shares and from the results of a program adopted in Florida. See *Pharmaceutical Research and Manufacturers of America* v. *Meadows*, 304 F. 3d 1197 (CA11 2002).[35] Avoiding unnecessary costs in the administration of a State's Medicaid program obviously serves the interests of both the Federal Government and the States that pay the cost of providing prescription drugs to Medicaid patients.

The fact that the Maine Rx Program may serve Medicaid-related purposes, both by providing benefits to needy persons and by curtailing the State's Medicaid costs, would not

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[33] See n. 23, *supra*.

[34] "As under current law, States would have the option of imposing prior authorization requirements with respect to covered prescription drugs in order to safeguard against unnecessary utilization and assure that payments are consistent with efficiency, economy, and quality of care." H. R. Rep. No. 101–881, p. 98 (1990).

[35] "The new Florida law . . . exempts certain Medicaid-eligible drugs from a 'prior authorization' requirement. If a drug is not on the preferred list, the prescribing doctor must call a state pharmacist to obtain approval of its use. In the course of this procedure, the pharmacist informs the doctor of the availability of other drugs (usually on the preferred drug list) that allegedly have comparable therapeutic value but are less expensive. The actual phone calls tend to be relatively brief (usually less than 10 minutes in length), and approval of the prescribing doctor's first-choice drug is guaranteed in 100 percent of all cases, provided only that he or she make the telephone call. During the first three months of the program, approximately 55 percent of all these calls have resulted in a change of the prescription to a drug on the preferred drug list. Naturally, because this procedure may tend to promote less profitable drugs at the expense of more profitable ones, it is not favored by the pharmaceutical manufacturers that brought this lawsuit." 304 F. 3d, at 1198.

provide a sufficient basis for upholding the program if it severely curtailed Medicaid recipients' access to prescription drugs. Cf. 42 U. S. C. § 1396a(a)(19) (State Medicaid plan must assure that care and services are to be provided "in a manner consistent with . . . the best interests of the recipients"). It was, however, incorrect for the District Court to assume that any impediment, "[n]o matter how modest," to a patient's ability to obtain the drug of her choice at state expense would invalidate the Maine Rx Program. Civ. No. 00–157–B–H, App. to Pet. for Cert. 68.

We have made it clear that the Medicaid Act "gives the 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 best interest of the recipients.'" *Alexander* v. *Choate*, 469 U. S. 287, 303 (1985). In that case, we rejected a challenge brought by a class of handicapped persons to a Tennessee cost-saving measure that reduced the number of annual days of inpatient hospital care for Medicaid patients from 20 to 14, emphasizing that the change did not deny beneficiaries "meaningful access" to medical services. *Id.*, at 302, 306. The District Court's finding that the 14-day limitation would fully serve 95% of handicapped individuals eligible for Medicaid satisfied the statutory standard.

In this case, the District Court made no comparable finding, but assumed that Maine would fully comply with all federal requirements and "not deny a single Medicaid recipient access to the safest and most efficacious prescription drug therapy indicated for their *[sic]* individual medical circumstances."[36] The District Court's assumption gave appropriate credence to the affidavits filed on behalf of the State, and, under our reasoning in *Alexander*, reflects compliance with the statutory standard.

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[36] Civ. No. 00–157–B–H, App. to Pet. for Cert. 68 (internal quotation marks omitted).

The fact 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 package of benefits it will finance. In *Beal* v. *Doe*, 432 U. S. 438 (1977), despite accepting the plaintiffs' submission that nontherapeutic abortions are both less dangerous and less expensive than childbirth, we held that Pennsylvania's interest in encouraging normal childbirth provided an adequate justification for its decision to exclude the abortion procedure from its Medicaid program. Maine's interest in protecting the health of its uninsured residents also provides a plainly permissible justification for a prior authorization requirement that is assumed to have only a minimal impact on Medicaid recipients' access to prescription drugs. The Medicaid Act contains no categorical prohibition against reliance on state interests unrelated to the Medicaid program itself when a State is fashioning the particular contours of its own program. It retains the "considerable latitude" that characterizes optional participation in a jointly financed benefit program.[37]

The presumption against federal pre-emption of a state statute designed to foster public health, *Hillsborough County* v. *Automated Medical Laboratories, Inc.*, 471 U. S. 707, 715–718 (1985), has special force when it appears, and the Secretary has not decided to the contrary, that the two governments are pursuing "common purposes," *New York State Dept. of Social Servs.* v. *Dublino*, 413 U. S. 405, 421 (1973). In *Dublino*, we rejected a pre-emption challenge to a state statute that imposed employment requirements as conditions for continued eligibility for AFDC benefits that went beyond the federal requirements. Commenting on

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[37] "There is no question that States have considerable latitude in allocating their AFDC resources, since each State is free to set its own standard of need and to determine the level of benefits by the amount of funds it devotes to the program." *King* v. *Smith*, 392 U. S. 309, 318–319 (1968) (footnotes omitted).

New York's interest in encouraging employment of its citizens, we wrote:

> "To the extent that the Work Rules embody New York's attempt to promote self-reliance and civic responsibility, to assure that limited state welfare funds be spent on behalf of those genuinely incapacitated and most in need, and to cope with the fiscal hardships enveloping many state and local governments, this Court should not lightly interfere. The problems confronting our society in these areas are severe, and state governments, in cooperation with the Federal Government, must be allowed considerable latitude in attempting their resolution." *Id.*, at 413.

The mere fact that the New York program imposed a nonfederal obstacle to continued eligibility for benefits did not provide a sufficient basis for pre-emption, but we left open questions concerning possible conflicts with the federal program for resolution in further proceedings. *Id.*, at 422–423. Similarly, in this case, the mere fact that prior authorization may impose a modest impediment to access to prescription drugs provided at government expense does not provide a sufficient basis for pre-emption of the entire Maine Rx Program.

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. To the extent that drug manufacturers agree to participate in the program, there will be no impediment. To the extent that the manufacturers refuse, the Drug Utilization Review Committee will determine whether it is clinically appropriate to subject those drugs to prior authorization. If the committee determines prior authorization is required, that requirement may result in the delivery of a less expensive drug than a physician first prescribed, but on the present record we cannot conclude that a significant

number of patients' medical needs—indeed, any patient's medical needs—will be adversely affected.

The record does demonstrate that prior authorization may well have a significant adverse impact on the manufacturers of brand name prescription drugs and that it will impose some administrative costs on physicians. The impact on manufacturers is not relevant because any transfer of business to less expensive products will produce savings for the Medicaid program. The impact on doctors may be significant if it produces an administrative burden that affects the quality of their treatment of patients, but no such effect has been proved. Moreover, given doctors' familiarity with the extensive use of prior authorization in the private sector, any such effect seems unlikely.

We therefore agree with the Court of Appeals' resolution of the pre-emption issue based on the record before us. We again reiterate that the question whether the Secretary's approval must be sought before Maine Rx Program may go into effect is not before us. Along these same lines, we offer no view as to whether it would be appropriate for the Secretary to disapprove this program if Maine had asked the Secretary to review it. We also offer no view as to whether it would be proper for the Secretary to disallow funding for the Maine Medicaid program if Maine fails to seek approval from the Secretary of its Maine Rx Program. Based on the CMS letter of September 18, 2002,[38] it appears that the Secretary is likely to take some action with respect to this program. Until the Secretary does, however, we cannot predict at this preliminary stage the ultimate fate of the Maine Rx Program, and we limit our holding accordingly.

VI

Whereas petitioner's pre-emption challenge focused on the effects of the prior authorization requirement that would fol-

[38] See n. 30, *supra*.

low a manufacturer's refusal to participate in the Rx Program, its Commerce Clause challenge focuses on the effects of the rebate agreements that will follow manufacturer compliance with the program. As we understand the challenge, the alleged harm to interstate commerce would be the same regardless of whether manufacturer compliance is completely voluntary or the product of coercion. Petitioner argues, first, that the rebate requirement constitutes impermissible extraterritorial regulation, and second, that it discriminates against interstate commerce in order to subsidize in-state retail sales. Neither argument is persuasive.

Writing for the Court in *Baldwin* v. *G. A. F. Seelig, Inc.*, 294 U. S. 511, 521 (1935), Justice Cardozo made the classic observation that "New York has no power to project its legislation into Vermont by regulating the price to be paid in that state for milk acquired there." That proposition provided the basis for the majority's conclusion in *Healy* v. *Beer Institute*, 491 U. S. 324 (1989), that a Massachusetts price affirmation statute had the impermissible effect of regulating the price of beer sold in neighboring States. Petitioner argues that the reasoning in those cases applies to what it characterizes as Maine's regulation of the terms of transactions that occur elsewhere. But, as the Court of Appeals correctly stated, unlike price control or price affirmation statutes, "the Maine Act does not regulate the price of any out-of-state transaction, either by its express terms or by its inevitable effect. Maine does not insist that manufacturers sell their drugs to a wholesaler for a certain price. Similarly, Maine is not tying the price of its in-state products to out-of-state prices." 249 F. 3d, at 81–82 (footnote omitted). The rule that was applied in *Baldwin* and *Healy* accordingly is not applicable to this case.

In *West Lynn Creamery, Inc.* v. *Healy*, 512 U. S. 186 (1994), we reviewed the constitutionality of a Massachusetts pricing order that imposed an assessment on all fluid milk sold by dealers to Massachusetts retailers and distributed

the proceeds to Massachusetts dairy farmers. Because two-thirds of the assessed milk was produced by out-of-state farmers while the entire fund was used to benefit in-state farmers, the order effectively imposed a tax on out-of-state producers to subsidize production by their in-state competitors. We concluded that the program was invalid because it had a discriminatory effect analogous to a protective tariff that taxes goods imported from neighboring States but does not tax similar products produced locally.

Petitioner argues that Maine's Rx fund is similar because it would be created entirely from rebates paid by out-of-state manufacturers and would be used to subsidize sales by local pharmacists to local consumers. Unlike the situation in *West Lynn*, however, the Maine Rx Program will not impose a disparate burden on any competitors. A manufacturer could not 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 the local pharmacists provide no special benefit to competitors of rebate-paying manufacturers. The rule that was applied in *West Lynn* is thus not applicable to this case.

VII

At this stage of the litigation, petitioner has not carried its burden of showing a probability of success on the merits of its claims. And petitioner has not argued that the Court of Appeals was incorrect in holding that other factors—such as the risk of irreparable harm, the balance of the equities, and the public interest—do not alter the analysis of its injunction request. The judgment of the Court of Appeals is affirmed.

It is so ordered.

JUSTICE BREYER, concurring in part and concurring in the judgment.

I join Parts I–III and Part VI of the Court's opinion and Parts IV and VII of the plurality's opinion. I also agree

with Part V's conclusion. The District Court's entry of a preliminary injunction rested upon a determination that federal Medicaid law pre-empted the Maine Rx Program as long as Maine's prior authorization program posed some obstacle, "*'[n]o matter how modest,'*" to realizing federal Medicaid goals. *Ante*, at 659 (majority opinion) (emphasis added). Like the plurality, I believe that the italicized phrase understates the strength of the showing that the law required petitioner to make. *Ante*, at 667.

To prevail, petitioner ultimately must demonstrate that Maine's program would "seriously compromise important federal interests." *Arkansas Elec. Cooperative Corp.* v. *Arkansas Pub. Serv. Comm'n*, 461 U. S. 375, 389 (1983). Cf. *Rosado* v. *Wyman*, 397 U. S. 397, 422–423 (1970). Petitioner consequently cannot obtain a preliminary injunction simply by showing minimal or quite "modest" harm—even though Maine offered no evidence of countervailing Medicaid-related benefit, *post*, at 687–688 (O'CONNOR, J., concurring in part and dissenting in part). The relevant statutory language, after all, expressly permits prior authorization programs, 42 U. S. C. § 1396r–8(d)(1), and Congress may well have believed that such programs, in general, help Medicaid by generating savings. See *ante*, at 651–653, and n. 7 (majority opinion). That being so, Congress would not have intended to forbid prior authorization programs virtually *per se*—*i. e.*, on the showing of slight harm—even if no specific Medicaid-related benefit is apparent in a particular case.

I recognize that petitioner presented evidence to the District Court that could have justified a stronger conclusion. *E. g.*, App. 57, 103–104. Cf. Brief for Legal Services Organizations Representing Medicaid Beneficiaries as *Amici Curiae* 14. Yet the District Court's preliminary injunction nonetheless rests upon premises that subsequent developments have made clear are unrealistic. For one thing, despite Maine's initial failure to argue the matter, Maine's program may further certain Medicaid-related objectives, at

least to some degree. *Ante*, at 663–665 (plurality opinion). For another, the Secretary of Health and Human Services (whose views are highly relevant to the question before us, *infra* this page) has indicated that state programs somewhat similar to Maine's may prove consistent with Medicaid objectives, and the Secretary has approved at least one such program. *Ante*, at 660–661, n. 30 (plurality opinion); Letter from Theodore B. Olson, Solicitor General, to William K. Suter, Clerk of the Court (Jan. 10, 2003). As a result, it is now apparent that proper determination of the pre-emption question will demand a more careful balancing of Medicaid-related harms and benefits than the District Court undertook. Cf. *California* v. *FERC*, 495 U. S. 490, 506 (1990) (finding a state law pre-empted where it "would disturb and conflict with the balance embodied in [a] considered federal agency determination"). These postentry considerations, along with the general importance of the pre-emption question, convince me that we should not overlook the District Court's technical misstatement of the proper legal standard, and that we should therefore affirm the Court of Appeals' judgment vacating the injunction.

By vacating the injunction, we shall also help ensure that the District Court takes account of the Secretary's views in further proceedings that may involve a renewed motion for a preliminary injunction. It is important that the District Court do so. The Department of Health and Human Services (HHS) administers the Medicaid program. Institutionally speaking, 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). And the law grants significant weight to any legal conclusion by the Secretary as to whether a program such as Maine's is consistent with Medicaid's objectives. See, *e. g.*, *Chevron U. S. A. Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U. S.

837 (1984); *Skidmore* v. *Swift & Co.*, 323 U. S. 134 (1944). Cf. *post*, at 680–681 (THOMAS, J., concurring in judgment).

The Medicaid statute sets forth a method through which Maine may obtain those views. A participating State must file a Medicaid plan with HHS and obtain HHS approval. 42 U. S. C. § 1396. A State must also promptly file a plan amendment to reflect any "[m]aterial changes in State law, organization, or policy, or in the State's operation of the Medicaid program." 42 CFR § 430.12(c) (2002). And the Secretary has said that a statute like Maine's is a "significant component of a state plan" with respect to which Maine is expected to file an amendment. App. to Brief for United States as *Amicus Curiae* 48a.

In addition, the legal doctrine of "primary jurisdiction" permits a court itself to "refer" a question to the Secretary. That doctrine 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. *United States* v. *Western Pacific R. Co.*, 352 U. S. 59, 63–65 (1956). "No fixed formula exists" for the doctrine's application. *Id.*, at 64. Rather, the question in each instance is whether a case raises "issues of fact not within the conventional experience of judges," but within the purview of an agency's responsibilities; whether the "limited functions of review by the judiciary are more rationally exercised, by preliminary resort" to an agency "better equipped than courts" to resolve an issue in the first instance; or, in a word, whether preliminary reference of issues to the agency will promote that proper working relationship between court and agency that the primary jurisdiction doctrine seeks to facilitate. *Far East Conference* v. *United States*, 342 U. S. 570, 574–575 (1952); see also *Western Pacific R. Co.*, *supra*, at 63–65. Cf. 2 R. Pierce, Administrative Law § 14.4, p. 944 (2002) (relatively frequent application of the doctrine in pre-emption cases).

Where such conditions are satisfied—and I have little doubt that they are satisfied here—courts may raise the doctrine on their own motion. *E. g.*, *Williams Pipe Line Co.* v. *Empire Gas Corp.*, 76 F. 3d 1491, 1496 (CA10 1996). See also 5 J. Stein, G. Mitchell, & B. Mezines, Administrative Law § 47.01[1], pp. 47–5 to 47–6 (2002); 2 Federal Procedure: Lawyers Edition § 2:337, p. 373 (2003). A court may then stay its proceedings—for a limited time, if appropriate—to allow a party to initiate agency review. *Western Pacific R. Co.*, *supra*, at 64; see also *Wagner & Brown* v. *ANR Pipeline Co.*, 837 F. 2d 199, 206 (CA5 1988) (stay of limited duration). Lower courts have sometimes accompanied a stay with an injunction designed to preserve the status quo. *E. g.*, *Wheelabrator Corp.* v. *Chafee*, 455 F. 2d 1306, 1316 (CADC 1971). And, in my view, even if Maine should choose not to obtain the Secretary's views on its own, the desirability of the District Court's having those views to consider, *supra*, at 672, is relevant to the "public interest" determination that often factors into whether a preliminary injunction should issue, see, *e. g.*, *MacDonald* v. *Chicago Park District*, 132 F. 3d 355, 357 (CA7 1997); 11A C. Wright, A. Miller, & M. Kane, Federal Practice and Procedure § 2948, pp. 131–133 (1995). But cf. *Rosado*, 397 U. S., at 406.

For these reasons, I concur in the Court's judgment and in major part in the plurality's opinion.

JUSTICE SCALIA, concurring in the judgment.

I would reject petitioner's negative-Commerce-Clause claim because the Maine statute under challenge is neither facially discriminatory against interstate commerce nor (as the Court explains, *ante*, at 668–670) similar to other state action that we have hitherto found invalid on negative-Commerce-Clause grounds; and because, as I have explained elsewhere, the negative Commerce Clause, having no foundation in the text of the Constitution and not lending itself to judicial application except in the invalidation of facially

discriminatory action, should not be extended beyond such action and nondiscriminatory action of the precise sort hitherto invalidated. See *West Lynn Creamery, Inc.* v. *Healy*, 512 U. S. 186, 209–210 (1994) (opinion concurring in judgment).

I would reject petitioner's statutory claim on the ground that the remedy for the State's failure to comply with the obligations it has agreed to undertake under the Medicaid Act, see *Blessing* v. *Freestone*, 520 U. S. 329, 349 (1997) (SCALIA, J., concurring); *Pennhurst State School and Hospital* v. *Halderman*, 451 U. S. 1, 17 (1981), is set forth in the Act itself: termination of funding by the Secretary of the Department of Health and Human Services, see 42 U. S. C. § 1396c. Petitioner must seek enforcement of the Medicaid conditions by that authority—and may seek and obtain relief in the courts only when the denial of enforcement is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U. S. C. § 706(2)(A).

JUSTICE THOMAS, concurring in the judgment.

I agree with the plurality that petitioner was not entitled to a preliminary injunction against the enforcement of the Maine Rx Program. I write separately because I do not believe that "further proceedings in this case may lead to a contrary result," *ante*, at 660, and because I do not agree with the plurality's reasoning. It is clear from the text of the Medicaid Act and the Constitution that petitioner's pre-emption and negative Commerce Clause claims are without merit. I therefore concur in the judgment of the Court.

I

The premise of petitioner's pre-emption claim is that Maine Rx "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines* v. *Davidowitz*, 312 U. S. 52, 67 (1941). The plurality agrees that to succeed petitioner must demonstrate "that

there was no Medicaid-related goal or purpose served by Maine Rx." *Ante*, at 662. Both JUSTICE STEVENS and JUSTICE O'CONNOR treat the Medicaid Act as embodying an abstract and highly generalized purpose that is inconsistent with the Act's depth. The text of this complex statute belies their efforts to distill from it a single purpose.

The Medicaid Act represents a delicate balance Congress struck between competing interests—care and cost, mandates and flexibility, oversight and discretion. While petitioner principally relies on 42 U. S. C. § 1396a(a)(19), which requires the Secretary of the Department of Health and Human Services to ensure that state plans "provide such safeguards as may be necessary to assure that . . . care and services will be provided, in a manner consistent with . . . the best interests of the recipients," the Medicaid Act also pursues arguably competing interests such as cost control, see § 1396a(a)(30), and affording States broad discretion to control access to prescription drugs, see *Pharmaceutical Research and Mfrs. of America* v. *Thompson*, 259 F. Supp. 2d 39, 72 (DC 2003) (hereinafter *Pharmaceutical Research*) (noting that prior authorization may be in tension with the "'best interests'" of Medicaid recipients).

The plurality's conclusion that § 1396a(a)(19) imposes a silent prohibition on prior authorization programs that "severely curtai[l] Medicaid recipients' access to prescription drugs," *ante*, at 665, ignores this complexity. In my view, the Medicaid Act grants States broad discretion to impose prior authorization and proper consideration of the Secretary of the Department of Health and Human Services' role in administering the Medicaid Act forecloses petitioner's pre-emption claim.

A

I begin with an analysis of the relevant provisions of the Medicaid Act. Title 42 U. S. C. § 1396r–8(d)(1) provides a complete list of the restrictions participating States may

place on prescription drug coverage under Medicaid. Importantly, it says that "[a] State may subject to prior authorization any covered outpatient drug." § 1396r–8(d)(1)(A). The only stricture placed on a prior authorization program is compliance with certain enumerated procedures, § 1396r–8(d)(5). Undoubtedly, the "purpose" of § 1396r–8(d)(1) is its effect—to grant participating States the authority to subject drugs to prior authorization subject only to the express limitations in § 1396r–8(d)(5).

This reading of the Medicaid Act's prior authorization provisions is confirmed by its near-neighbors. Section 1396r–8(d) allows States to exclude or further restrict coverage (beyond prior authorization) of a "covered outpatient drug" if "the prescribed use is not for a medically accepted indication," § 1396r–8(d)(1)(B)(i), or if the drug or use is on a list specified in § 1396r–8(d)(2). That list includes, for example, prescriptions for "anorexia . . . or weight gain," § 1396r–8(d)(2)(A), and "cosmetic purposes or hair growth," § 1396r–8(d)(2)(C), as well as all barbiturates, § 1396r–8(d)(2)(I). Furthermore, under § 1396r–8(d)(6), "[a] State may impose limitations, with respect to all such drugs in a therapeutic class, on the minimum or maximum quantities per prescription . . . if such limitations are necessary to discourage waste . . . ." This fine-tuning of a State's ability to restrict drug coverage beyond prior authorization stands in stark contrast to the broad authority granted to States to impose prior authorization. Indeed, these provisions confirm that when Congress meant to impose limitations on state authority in this area it did so explicitly.

The authority to entirely exclude coverage of certain drugs or uses, for any reason,[1] again illustrates the futility

[1] Neither the plurality nor the opinion concurring in part and dissenting in part (hereinafter dissent) suggests that there is any purpose-based limitation on a State's authority under § 1396r–8(d)(2). Nor can they. The restrictions enable States to make value, rather than cost or care, judg-

of discerning one "purpose" from the Medicaid Act. If, as the plurality reasons, the "'best interests'" of Medicaid beneficiaries require that access to prescription drugs not be "severely curtailed," then § 1396r–8(d)(2) empowers States to do what the plurality believes is precisely opposed to the best interests of Medicaid beneficiaries. This is just a further illustration of the compromises embodied in the Medicaid Act and demonstrates the impossibility of defining "purposes" in complex statutes at such a high level of abstraction and the concomitant danger of invoking obstacle pre-emption based on the arbitrary selection of one purpose to the exclusion of others.

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. Both the plurality and the dissent fail to explain how a State's purpose (and there may be many) in enacting a prior authorization program makes any difference in determining whether that program is in the "best interests" of Medicaid beneficiaries. The mere existence of a prior authorization procedure, as contemplated by § 1396r–8(d)(5), cannot "severely curtai[l]" access to prescription drugs (the Court's touchstone for a "conflict" with § 1396a(a)(19), *ante*, at 665). Otherwise the plurality has rendered an interpretation of the Medicaid Act that leaves it with an internal conflict.

The dissent reasons that prior authorization programs must "safeguar[d] against unnecessary utilization," *post*, at 685 (O'CONNOR, J., concurring in part and dissenting in part) (internal quotation marks omitted), of prescription drugs and

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ments as to whether a drug should be covered. See, *e. g.*, § 1396r–8(d)(2)(B) (fertility drugs), § 1396r–8(d)(2)(C) (cosmetic purposes). Again, this begs the question of why, for example, Congress would give States greater authority over the decision whether or not to cover a prescription hair growth drug than whether or not to subject the same hair growth drug to prior authorization.

control costs, but also never explains how the motivation for imposing prior authorization affects whether it furthers these ends.[2] The dissent points to nothing in the record that suggests that Maine Rx will not limit unnecessary use of the covered drugs or control costs associated with prescription drug expenditures under Medicaid. Rather, the dissent merely asserts that because Maine Rx conditions prior authorization on nonparticipation in the rebate program it follows *ipse dixit* that Maine Rx does not further these objectives. *Post*, at 688–689 (O'CONNOR, J., concurring in part and dissenting in part). Obstacle pre-emption turns on whether the goals of the federal statute are frustrated by the effect of the state law. The dissent's focus on the subjective intent of the state legislature enacting the law targeted for pre-emption asks an irrelevant question.

B

The plurality and dissent also fail to consider the necessary implications of the Secretary's role in approving state Medicaid plans and otherwise administering the Act. The Secretary is delegated a type of pre-emptive authority—he must approve state plans that comply with § 1396a, § 1396a(b), but is given the authority to withhold funds if he deems a State to be noncompliant, § 1396c.[3] While acknowledging the pos-

[2] These requirements, of course, have no basis in the text of the Medicaid Act. I discuss the dissent's reasoning only because its reliance on Maine Rx's express "purpose" turns the presumption against pre-emption on its head. If Maine Rx also stated that its purpose was to control prescription drug costs under Medicaid would it be safe from pre-emption? I find it odd that application of federal statutory pre-emption under the Supremacy Clause should turn on whether a state legislature has recited what this Court deems to be the proper rationale.

[3] In fact, the Secretary's power to withhold funds from States that breach the Medicaid Act's terms indicates that the Act itself contemplates the existence of state plans that do not comply with the requirements of § 1396a(a). Title 42 U. S. C. § 1396c provides:

sibility that the Secretary "may view the Maine Rx Program as an amendment to its Medicaid Plan that requires . . . approval before it becomes effective," *ante,* at 660, and potentially withhold such approval, the plurality does not discuss the logical consequences of petitioner's view that Maine Rx is pre-empted by the Medicaid Act.

According to petitioner, the Secretary is forbidden by the Medicaid Act from approving Maine Rx because the Act itself pre-empts Maine Rx and renders it void under the Supremacy Clause. If the Secretary approved Maine Rx, his interpretation would necessarily, if petitioner is correct, be rejected by a reviewing court under the first step of the inquiry of *Chevron U. S. A. Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U. S. 837, 842–843 (1984), which asks whether the statute is unambiguous.[4] See, *e. g.*, *Smiley* v.

"If the Secretary, after reasonable notice and opportunity for hearing to the State agency administering or supervising the administration of the State plan approved under this subchapter, finds—

"(1) that the plan has been so changed that it no longer complies with the provisions of section 1396a of this title; or

"(2) that in the administration of the plan there is a failure to comply substantially with any such provision;

"the Secretary shall notify such State agency that further payments will not be made to the State . . . until the Secretary is satisfied that there will no longer be any such failure to comply."

The Medicaid Act cannot meaningfully be interpreted to invalidate state laws, such as Maine Rx, that do not comply with its express terms, much less state laws a court concludes pose an obstacle to the Act's "purpose." State plans that do not meet § 1396a(a)'s requirements are to be defunded by the Secretary—they are not void under the Supremacy Clause. It is not apparent to me where the plurality finds the congressional directive to pre-empt state plans that breach a contract between the Federal Government and the State. Cf. Part I–D, *infra.* In my view, no such directive exists, and States are free to deviate from the Medicaid Act's requirements, subject only to sanctions by the Secretary.

[4] If a federal statute is ambiguous with respect to whether it pre-empts state law, then the presumption against pre-emption should ordinarily prevent a court from concluding that the state law is pre-empted. Therefore, a court's conclusion that Maine Rx is pre-empted would require rejection

Citibank (South Dakota), N. A., 517 U. S. 735, 739 (1996). Petitioner must therefore show that the Medicaid Act is unambiguous or, in other words, that Congress "has directly spoken to the precise question at issue." *Chevron*, *supra*, at 842. However, given the foregoing discussion of the text of the Medicaid Act, it cannot be read to unambiguously prohibit Maine Rx, or indicate that Congress, in enacting § 1396a(a)(19), directly addressed this issue. Indeed, the Department of Health and Human Services has already adopted an interpretation of the Medicaid Act that "does not preclude States from negotiating prices, including manufacturer discounts and rebates for non-Medicaid drug purchases." Letter from D. Smith, Dir. of Center for Medicaid and State Operations, Centers for Medicare & Medical Services, to all State Medicaid Dirs. (Sept. 18, 2002), App. to Brief for United States as *Amicus Curiae* 48a.[5] Obstacle pre-emption's very premise is that Congress has not expressly displaced state law, and thus 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 a claim of obstacle pre-emption.

I note that the interpretation of the Medicaid Act I offer, unlike petitioner's, does not require the Secretary to reach a particular decision with respect to Maine Rx. The Secretary is expressly charged with determining whether state plans comply with the numerous requirements of 42 U. S. C. §§ 1396a(a), 1396a(b), 1396c. Among these, as discussed earlier, is the requirement that the plan serve "the best in-

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of the Secretary's contrary construction of the statute at *Chevron*'s first step, not its second, which asks whether the agency construction is reasonable. 467 U. S., at 843.

[5] This interpretation has been upheld by the District Court for the District of Columbia. *Pharmaceutical Research and Mfrs. of America* v. *Thompson*, 259 F. Supp. 2d 39, 69–72 (2003). Petitioner's arguments provide no answer to the careful analysis offered by that court.

terests of [Medicaid] recipients." § 1396a(a)(19). While I maintain that federal courts cannot use obstacle pre-emption to determine whether or not Maine Rx serves these interests, the Secretary must examine the entire state plan, not just Maine Rx in isolation. Moreover, the Secretary's mandate from Congress is to conduct, with greater expertise and resources than courts, the inquiry into whether Maine Rx upsets the balance contemplated by the Medicaid Act. Congress' delegation to the agency to perform this complex balancing task precludes federal-court intervention on the basis of obstacle pre-emption—it does not bar the Secretary from performing his duty to adjudge whether Maine Rx upsets the balance the Medicaid Act contemplates and withhold approval or funding if necessary. If petitioner or respondents disagree with the Secretary's decision, they may seek judicial review, as petitioner has already done for plans similar to Maine Rx that the Secretary has approved. See *Pharmaceutical Research and Mfrs. of America* v. *Thompson*, 259 F. Supp. 2d 39, 69–72 (DC 2003).

C

Maine Rx is not pre-empted by the Medicaid Act. This conclusion is easily reached without speculation about whether Maine Rx advances "Medicaid-related goals" or how much it does so. The disagreement between the plurality and dissent in this case aptly illustrates why "[a] freewheeling judicial inquiry into whether a state statute is in tension with federal objectives . . . undercut[s] the principle that it is Congress rather than the courts that pre-empts state law." *Gade* v. *National Solid Wastes Management Assn.*, 505 U. S. 88, 111 (1992) (KENNEDY, J., concurring in part and concurring in judgment).

D

I make one final observation with respect to petitioner's pre-emption claim. The Court has stated that Spending Clause legislation "is much in the nature of a contract."

Pennhurst State School and Hospital v. *Halderman*, 451 U. S. 1, 17 (1981). This contract analogy raises serious questions as to whether third parties may sue to enforce Spending Clause legislation—through pre-emption or otherwise. See *Blessing* v. *Freestone*, 520 U. S. 329, 349–350 (1997) (SCALIA, J., concurring). In contract law, a third party to the contract (as petitioner is here) may only sue for breach if he is the "intended beneficiary" of the contract. See, *e. g.*, Restatement (Second) of Contracts § 304 (1979) ("A promise in a contract creates a duty in the promisor to any intended beneficiary to perform the promise, and the intended beneficiary may enforce the duty"). When Congress wishes to allow private parties to sue to enforce federal law, it must clearly express this intent. Under this Court's precedents, private parties may employ 42 U. S. C. § 1983 or an implied private right of action only if they demonstrate an "unambiguously conferred right." *Gonzaga Univ.* v. *Doe*, 536 U. S. 273, 283 (2002). Petitioner quite obviously cannot satisfy this requirement and therefore arguably is not entitled to bring a pre-emption lawsuit as a third-party beneficiary to the Medicaid contract. Respondents have not advanced this argument in this case. However, were the issue to be raised, I would give careful consideration to whether Spending Clause legislation can be enforced by third parties in the absence of a private right of action.

II

Petitioner's Commerce Clause challenge is easily met, because "[t]he negative Commerce Clause has no basis in the text of the Constitution, makes little sense, and has proved virtually unworkable in application." *Camps Newfound/Owatonna, Inc.* v. *Town of Harrison*, 520 U. S. 564, 610 (1997) (THOMAS, J., dissenting). I therefore agree with the Court that petitioner cannot prevail on this claim.

JUSTICE O'CONNOR, with whom THE CHIEF JUSTICE and JUSTICE KENNEDY join, concurring in part and dissenting in part.

I join Parts I–III and VI of the Court's opinion, and I agree with the plurality's conclusion that States may not impose on Medicaid beneficiaries the burdens of prior authorization in the absence of a countervailing Medicaid purpose, *ante*, at 662. I part with the plurality because I do not agree that the District Court abused its discretion in enjoining respondents from imposing prior authorization under the Maine Rx Program. Before the District Court, respondents "point[ed] to no *Medicaid* purpose" served by Maine Rx's prior-authorization requirement. App. to Pet. for Cert. 68 (emphasis in original). This is not surprising. The program is open to all Maine residents, rich and poor. It does not purport to further a Medicaid-related purpose, and it is not tailored to have such an effect. By imposing prior authorization on Maine's Medicaid population to achieve wholly non-Medicaid related goals, Maine Rx "stands as an obstacle to the accomplishment and execution of the full purposes and objectives" of the federal Medicaid Act. *Hines* v. *Davidowitz*, 312 U. S. 52, 67 (1941). I would uphold the District Court's injunction on this basis, and I therefore respectfully dissent from Parts IV, V, and VII of the plurality's opinion.

I

Our ultimate task in analyzing a pre-emption claim is "to determine whether state regulation is consistent with the structure and purpose" of the federal statutory scheme "as a whole." *Gade* v. *National Solid Wastes Management Assn.*, 505 U. S. 88, 98 (1992) (plurality opinion of O'CONNOR, J.). We look to "'the provisions of the whole law, and to its object and policy.'" *Ibid.* (quoting *Pilot Life Ins. Co.* v. *Dedeaux*, 481 U. S. 41, 51 (1987)). Our touchstone is Congress' intent. *Gade* v. *National Solid Wastes Management Assn.*, *supra*, at 96. "The nature of the power exerted by

Congress, the object sought to be attained, and the character of the obligations imposed by the law, are all important in considering the question of whether supreme federal enactments preclude enforcement of state laws on the same subject." *Hines* v. *Davidowitz*, *supra*, at 70.

Under the Medicaid Act, once a drug manufacturer enters into a Medicaid rebate agreement with respect to a particular outpatient drug, a State that has elected to offer prescription drug coverage must cover the drug under its state plan unless it complies with one of the Medicaid Act's provisions that permits a State to exclude or restrict coverage. 42 U. S. C. § 1396r–8(d); see *ante*, at 652. Prior authorization is one such restriction. Section 1396r–8(d)(5) provides that a state plan "may require, as a condition of coverage or payment for a covered outpatient drug . . . the approval of the drug before its dispensing for any medically accepted indication."

Prior authorization is, by definition, a procedural obstacle to Medicaid beneficiaries' access to medically necessary prescription drugs covered under the Medicaid program. It nevertheless may serve a Medicaid purpose by "safeguard-[ing] against unnecessary utilization and assur[ing] that payments are consistent with efficiency, economy and quality of care." H. R. Rep. No. 101–881, p. 98 (1990). A State accordingly may impose prior authorization to reduce Medicaid costs. Cf. *New York State Dept. of Social Servs.* v. *Dublino*, 413 U. S. 405, 421 (1973) ("Where coordinate state and federal efforts exist within a complementary administrative framework, *and in the pursuit of common purposes*, the case for federal pre-emption becomes a less persuasive one" (emphasis added)). A State may not, however, impose prior authorization to generate revenue for purposes wholly unrelated to its Medicaid program.

While the Medicaid Act does not expressly bar States from using prior authorization to accomplish goals unrelated to the Medicaid program, such a limit on States' authority is

inherent in the purpose and structure of the Medicaid Act. As the District Court recognized, a contrary rule would permit Maine to use prior authorization to raise funds for "highway and bridge construction or school funding," and presumably any other purpose, so long as the Secretary of Health and Human Services took no action to prevent it. App. to Pet. for Cert. 68. The purpose and structure of the Medicaid Act make clear that Congress did not intend such an absurd result.

Congress created the Medicaid program to "enabl[e] each State, as far as practicable under the conditions in such State, to furnish . . . medical assistance on behalf of families with dependent children and of aged, blind, or disabled individuals, whose income and resources are insufficient to meet the costs of necessary medical services." 42 U. S. C. § 1396. Consistent with that purpose, Congress has imposed income and resource limitations on many of the groups eligible for assistance under the Act. See, *e. g.*, §§ 1396a(a)(10)(A)(i)(IV), (VI), and (VII); § 1396b(f).

A requirement that prior authorization be used only where it furthers a Medicaid purpose is reinforced by the structure of the Medicaid Act. Congress has afforded States broad flexibility in tailoring the scope and coverage of their Medicaid programs, see *Alexander* v. *Choate*, 469 U. S. 287, 303 (1985), but the Act establishes a number of prerequisites for approval of a state plan by the Secretary. 42 U. S. C. §§ 1396a(a)(1)–(65). Two such requirements are of particular relevance here. First, a state plan must contain safeguards to ensure covered services are provided in a manner consistent with "the best interests of the [Medicaid] recipients." § 1396a(a)(19). Second, a state plan must "safeguard against unnecessary utilization" of services and ensure that "payments are consistent with efficiency, economy, and quality of care." § 1396a(a)(30)(A). These provisions confirm Congress' intent that state Medicaid initiatives not burden

Medicaid beneficiaries without serving a Medicaid goal such as stretching available resources to the greatest effect.

II

The District Court correctly concluded that the Maine Rx Program's prior-authorization provision is invalid because it burdens Medicaid recipients while advancing no Medicaid goals. Under the Maine Rx Program, the State "shall impose prior authorization requirements in the Medicaid program" on any "nonparticipating" drug manufacturer that does not enter into a rebate agreement with the State for drugs dispensed to non-Medicaid patients. Me. Rev. Stat. Ann., Tit. 22, § 2681(7) (West Supp. 2002). The rebate agreements are designed to reduce prescription drug prices for all residents of the State, regardless of financial or medical need. §§ 2681(1), (2)(F). The program thus serves the State's non-Medicaid population by threatening to erect an obstacle to Medicaid recipients' ability to receive covered outpatient drugs.

The plurality concedes that Maine Rx cannot survive a pre-emption challenge if it does not have as its purpose or effect a "Medicaid-related goal or purpose." *Ante*, at 662. Based on the record before the District Court, I would hold that the court did not abuse its discretion in concluding that petitioner demonstrated a likelihood of success on its pre-emption claim. Petitioner alleged that the Maine Rx Program does not serve a Medicaid purpose. The Maine Rx statute on its face bears this out. The program is designed "to reduce prescription drug prices for residents of the State," and it accomplishes this goal by threatening to impose prior authorization on otherwise covered outpatient drugs. Me. Rev. Stat. Ann., Tit. 22, §§ 2681(1), (2)(F), (7) (West Supp. 2002). In the District Court, Maine did not attempt to justify the program on the basis that it served a Medicaid purpose. Instead, Maine took the position that it was not required to demonstrate any such purpose. An ap-

pellate court reviewing a preliminary injunction is confined to the record before the District Court, and here, neither the record before the District Court nor the Maine Rx statute itself reveals a Medicaid purpose that will be served by the Maine Rx Program.

The plurality speculates about three "Medicaid-related interests that will be served if the [Maine Rx] program is successful." *Ante*, at 663. First, the plurality asserts that Maine Rx "will provide medical benefits to persons who can be described as 'medically needy' even if they do not qualify for [Aid to Families with Dependent Children] or [Supplemental Security Income] benefits." *Ibid.* Second, the plurality contends that "there is the possibility that, by enabling some borderline aged and infirm persons better access to prescription drugs earlier, Medicaid expenses will be reduced." *Ibid.* Third, the plurality posits that "whenever it is necessary to impose the prior authorization requirement on a manufacturer that refuses to participate," Maine Rx will promote the use of cost-effective medications and thereby "[a]voi[d] unnecessary costs in the administration of [the] State's Medicaid program." *Ante*, at 663, 664. Asserting that these "Medicaid-related goals" are "plainly present in the Maine Rx Program," the plurality concludes that the District Court's failure *sua sponte* to recognize them constituted "an erroneous predicate" for the preliminary injunction. *Ante*, at 663.

I disagree. I would not say it was an abuse of discretion for the District Court to conclude petitioner met its burden in showing that there was no Medicaid-related goal or purpose served by Maine Rx. Cf. *ante*, at 662–665. Each of the plurality's *post-hoc* justifications for the Maine Rx Program's burden on Medicaid beneficiaries rests on factual predicates that are not supported in the record. Even assuming the predicate assumptions behind the plurality's first and second justifications—that some of the potential beneficiaries of Maine Rx can be classified as "medically needy" or

"borderline aged and infirm"—it is impossible to discern based on the facts in the record whether the Medicaid program would reap a benefit from the discounts made available to such populations. The proposition that discounts on prescription drugs purchased out-of-pocket might produce Medicaid cost savings by preventing Maine residents from becoming eligible for Medicaid is not self-evident. With no party before it advocating such an attenuated causal chain, and with no facts in the record to support it, the District Court can hardly be said to have abused its discretion in divining no Medicaid purpose on the face of the Maine Rx statute.

The plurality's third rationale fails on similar grounds. The assertion that prior authorization under the Maine Rx Program will *necessarily* produce cost savings for Maine's Medicaid program is unsupportable. Under Maine Rx, the imposition of prior authorization is in no manner tied to the efficacy or cost-effectiveness of a particular drug. Rather, the sole trigger for prior authorization is the failure of a manufacturer or labeler to pay rebates for the benefit of non-Medicaid populations. Me. Rev. Stat. Ann., Tit. 22, §2681(7) (West Supp. 2002). It is thus entirely possible that only the most efficacious and cost-effective drugs will be subject to a prior-authorization requirement under Maine Rx. Maine Rx's prior-authorization requirement would, in that event, at best serve no purpose and at worst delay and inhibit Medicaid beneficiaries' access to necessary medication. In concluding that the District Court abused its discretion, the plurality essentially rejects, out of hand, this possibility. In so doing, the plurality distorts the limitations on the scope of our appellate review at this interlocutory stage of proceedings. See *Doran* v. *Salem Inn, Inc.*, 422 U. S. 922, 931–932 (1975) ("[W]hile the standard to be applied by the district court in deciding whether a plaintiff is entitled to a preliminary injunction is stringent, the standard of appellate review

is simply whether the issuance of the injunction . . . constituted an abuse of discretion").

The District Court had before it, on one hand, concrete evidence of the burdens that Maine Rx's prior-authorization requirement would impose on Medicaid beneficiaries. On the other hand, the District Court had no evidence or argument suggesting that Maine Rx would achieve cost savings or any other Medicaid-related goal. Finding that the District Court, under these circumstances, did not abuse its discretion by preliminarily enjoining Maine Rx's prior-authorization requirement, I would reverse the judgment of the Court of Appeals and remand for further proceedings.