NOTICE: This opinion is subject to formal revision before publication in the preliminary print of the United States Reports. Readers are requested to notify the Reporter of Decisions, Supreme Court of the United States, Washington, D. C. 20543, of any typographical or other formal errors, in order that corrections may be made before the preliminary print goes to press.

SUPREME COURT OF THE UNITED STATES

No. 01–188

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

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

[May 19, 2003]

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

[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).

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 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

---

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

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 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 authoriza-

---

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

[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.

tion 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 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

---

[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 for United States as *Amicus Curiae* 14–15.

[8] 104 Stat. 1388–143.

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 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-

---

[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).

[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).

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. 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

---

[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).

[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).

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 do "not have a comparable or superior prescription drug benefit plan."[14] The proposed rules also explain that

---

[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 regula-

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] 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

---

tions . . . 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.

[19] *Id.,* at 37 (Complaint ¶6).

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 Augmentin, 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

---

[20] *Id.*, at 50, 53, 76–77, 87.

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

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

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 "3 to 6 times as expensive" as amoxicillin.[25] Concannon's affidavit described the composition of a committee of physicians and

---

[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.

[25] *Id.*, at 154.

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

---

[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 a state program for highway and bridge construction or

fact that the 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.

---

school funding." *Ibid.*

[29] *Ibid.*

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

---

[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 would submit such a program for CMS review under the State plan process." App. to Brief 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").

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 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

---

[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).

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 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

---

[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

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 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.

---

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.

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 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.

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

---

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

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 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

---

[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).

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 follow 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 clas-

---

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

sic 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.