

Opinion of O'CONNOR, J.

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 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 16. 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 5. 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]

Opinion of O'CONNOR, J.

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 16.

Opinion of O'CONNOR, J.

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 appellate 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 16. 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 AFDC or SSI 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 17–18. Asserting that these “Medicaid-related goals” are “plainly present in the Maine Rx Program,” the

plurality concludes that District Court's failure *sua sponte* to recognize them constituted "an erroneous predicate" for the preliminary injunction. *Ante*, at 16.

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 15–19. 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

Opinion of O'CONNOR, J.

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.