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 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 13, 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 15. 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*, 2003 WL 1701416, *27 (D. D. C., Mar. 28, 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 18, 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–

(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

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[1] Neither the plurality nor the dissent suggest 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, judgments 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

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 plurality's touchstone for a "conflict" with §1396a(a)(19), *ante,* at 9). 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 2 (O'CONNOR, J., concurring in part and dissenting in part) (internal quotation marks omitted), of prescription drugs and control costs, but also never explains how the

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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.

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 6–7 (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

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[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:

acknowledging the possibility 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 13, 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.,*

"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-

Smiley v. *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

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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 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,* 2003 WL 1701416, *24–27 (Mar. 28, 2003). Petitioner's arguments provide no answer to the careful analysis offered by that court.

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. Amongst these, as discussed earlier, is the requirement that the plan serve "the best interests 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,* 2003 WL 1701416 (D. D. C., Mar. 28, 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.