No. 01-188

IN THE

Supreme Court of the United States

PHARMACEUTICAL RESEARCH & MANUFACTURERS OF AMERICA,

Petitioner,

v.

KEVIN CONCANNON, COMMISSIONER, MAINE DEPARTMENT OF HUMAN SERVICES, AND G. STEVEN ROWE, ATTORNEY GENERAL OF MAINE,

Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the First Circuit

SUPPLEMENTAL BRIEF

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SUPPLEMENTAL BRIEF OF PETITIONER

Pursuant to Rule 15.8, Petitioner Pharmaceutical Research and Manufacturers of America ("PhRMA") files this supplemental brief in response to the Brief of the United States as *Amicus Curiae*, which was filed on May 30, 2002 pursuant to this Court's order of October 9, 2001.

I. THE SOLICITOR GENERAL AGREES THAT THE FIRST CIRCUIT'S DECISION ON THE SUPREMACY CLAUSE ISSUE WAS IN ERROR.

The Solicitor General agrees with Petitioner that the Maine Rx program's use of Medicaid prior authorization to benefit non-Medicaid patients conflicts with the federal Medicaid statute, and that the court of appeals erred on the Supremacy Clause issue (first question presented, Pet. at i).

The Solicitor General notes without qualification that prior authorization "burden[s] the ability of Medicaid recipients to receive covered drugs." U.S. Br. at 11.[1] Because prior authorization imposes that burden on Congress's intended beneficiaries, the Solicitor General also concludes that its use must further at least *some* Medicaid purpose. *Id.* In the view of the United States, Maine cannot use Medicaid prior authorization for any purpose it desires; the First Circuit, however, doubted that any such constraint exists, Pet. App. at 12. Most important, the Solicitor General states clearly that "no Medicaid purpose appears to be served" by the Maine Rx program. U.S. Br. at 13. In sum, the only conclusion to be drawn from the Solicitor General's brief is that the Maine Rx program conflicts on its face with the Medicaid statute – a straightforward rejection of the First Circuit's holding that no such conflict exists, Pet. App. at 13-14.

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[1] The First Circuit, in contrast, held that that burden is not evident on its face, and must be proven by evidence of harm to Medicaid recipients. Pet. App. at 16-17.

II. THE SOLICITOR GENERAL'S REASONS FOR RECOMMENDING AGAINST REVIEW DO NOT WITHSTAND SCRUTINY.

If this Court declines review, it is the First Circuit's flawed reading of the federal Medicaid statute, and not the Solicitor General's contrary interpretation, that will be law. Curiously, the Solicitor General nevertheless recommends against granting certiorari. But none of the reasons offered for denying review – that the decision below is interlocutory, that no other appellate court has yet addressed the statutory issue, or that the U.S. Department of Health and Human Services should be left to deal with the states on issues of expanded prescription drug coverage – justifies allowing the decision below to stand unreviewed.

Although this case was decided on a motion for a preliminary injunction, no further development of the record would contribute to or alter the relevant legal analysis. The Solicitor General has already shown how the Maine Rx program facially conflicts with the federal Medicaid statute, because it burdens Medicaid prescription drug benefits for ends unrelated to those of the Medicaid statute. U.S. Br. at 11, 13, 15. No additional factual development is required to complete that legal analysis, and none is suggested by the government.

For similar reasons, the Court should not await review by other courts of appeals of other "State Rx" programs to come.[2] As noted in the Petition, states around the country are

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[2] The Solicitor General is mistaken that the First Circuit's decision is "the first appellate decision to address the validity of such a law." U.S. Br. at 9, 13. The D.C. Circuit has also considered (and rejected) a state effort to leverage Medicaid authority to benefit non-Medicaid populations. Specifically, it rejected a state's effort to "require pharmaceutical manufacturers to provide substantial discounts to individuals not otherwise covered by state Medicaid programs" in *PhRMA v. Thompson*, 251 F.3d 219, 226 (D.C. Cir. 2001). Notwithstanding the different

poised to act on the basis of this Court's guidance.[3] The conflict issue – whether states may leverage federal Medicaid powers for non-Medicaid purposes – is clear now, and consideration by other courts of appeal will not further illuminate it. With no prospect of legal clarification, all that will be furthered by delaying this Court's intervention is litigation and administrative confusion as programs are tied up in court.

Finally, the Court should not be dissuaded from review by the Solicitor General's plea to leave to HHS the job of policing states to ensure that their prescription drug programs are consistent with the Medicaid statute. The First Circuit's decision is a legal green light for other states to copy Maine's program, and, other than chastising Maine in the Solicitor General's brief, neither HHS nor any other executive authority has taken action to stop the Maine Rx program or prevent other states from adopting similar programs. Indeed, HHS has already approved[4] state programs that have the very features – such as wide availability to persons many of whom are in no danger of becoming Medicaid patients – that the

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statutory texts at issue, the D.C. Circuit decision conflicts with the First Circuit's holding that such leveraging is compatible with the Medicaid statute. Pet. at 11-13.

[3] "State Rx" copycat proposals have proliferated in state legislatures, *see* Pet. at 21-23, and the flurry of Medicaid waiver applications mentioned in the Solicitor General's brief further evidences that states are bent on pursuing all options available to them. Unless this Court intervenes, the Maine Rx program – which the United States recognizes will burden Medicaid yet serve no Medicaid purpose – will stand as the court-endorsed model for their efforts.

[4] In addition to the demonstration programs discussed in the Solicitor General's brief, U.S. Br. at 3-4, 13, the Secretary of HHS can also consider requests from states to amend directly the state plans under which they administer Medicaid benefits. Maine never pursued, and HHS has not required, any such amendment for the Maine Rx program – omissions that cast further doubt on HHS's putative ability to rein in state programs.

Solicitor General now condemns as incompatible with Medicaid.[5]

The Solicitor General rightly condemns Maine for "unilaterally" using Medicaid authority in Maine Rx "to achieve ends unrelated to the Medicaid program itself." U.S. Br. at 14-15. But, if states are free to enact Maine Rx-style programs, they will have no reason to seek federal approval for the more tailored Medicaid waiver programs and state plan amendments that the Solicitor General endorses in his brief. *See id.* at 13, 15. A state will have little incentive to create and negotiate federal approval for a more limited program if it believes it can unilaterally obtain comparable benefits for all its citizens at no cost to the state under a program like Maine Rx.

III. THE SOLICITOR GENERAL MISAPPREHENDS THE COMMERCE CLAUSE VIOLATIONS INHERENT IN THE MAINE RX PROGRAM.

As the Solicitor General notes, this Court's Commerce Clause precedents prohibit extraterritorial state regulation "even if, in a narrow sense, it addresses conduct that occurs within the State. The critical inquiry is whether 'the practical effect of the regulation is to control conduct beyond the boundaries of the State.'" *Id.* at 16 (quoting *Healy v. Beer Inst., Inc.*, 491 U.S. 324, 336 (1989)). Yet the Solicitor General fails to appreciate that the Maine Rx program – in which a state demands payment from out of state manufacturers based on third parties' in-state sales of their products – fails this very inquiry.

The Solicitor General falls victim to the same fallacy that led the First Circuit's Commerce Clause analysis astray – the

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[5] On January 28, 2002, for example, the Secretary approved a Michigan state plan amendment under which the state will use the threat of Medicaid prior authorization to obtain, *inter alia*, manufacturer rebates for residents enrolled in the state's non-Medicaid health programs.

notion that the Maine Rx rebate requirement regulates "the sale, in Maine, of the manufacturers' products." U.S. Br. at 17. But, as the Petition demonstrates, in-state sales are not what are regulated; they are only the trigger for Maine's regulation of sales transactions between manufacturers and wholesalers in other states. Pet. at 14-17. The rebate required by Maine has the same effect as a duty imposed at the state's border: it reduces the price received by the manufacturer outside Maine on the units of its drugs that are eventually sold in Maine. While the government suggests that "the Maine Rx Program does not regulate the terms of those out-of-state transactions," U.S. Br. at 17, it has no adequate answer to the question "what *else* could a demand for payment be regulating, when it is directed to entities that engage in no other transactions involving the drugs that trigger the demand?"

The Solicitor General warns that invalidating Maine's rebate demands as extraterritorial would also condemn state tort and product safety laws as Commerce Clause violations. The analogy is inapt. Maine is demanding money from out-of-state manufacturers based solely on the fact that their products reach the state. This direct regulation of out-of-state manufacturers' revenue is a far cry from health and safety regulation of the products themselves that only incidentally affect companies' costs of doing business. The difference is between direct regulation of out-of-state commerce on the one hand, and in-state regulation with incidental out-of-state effects on the other. Maine Rx rebates are in the former category, and thus violate the Commerce Clause.

Finally, the Solicitor General repeats the error of the First Circuit in supposing that Maine has not engaged in impermissible price tying because the statute directs the commissioner to use his best efforts to "negotiate" rebates as large as those charged around the country. As explained in PhRMA's prior filings, the Maine Rx program leaves nothing to "negotiate." *See* Pet. at 19; Reply at 2-3. Clever drafting

cannot obscure the Maine Rx program's mandatory nature, or excuse its use of price tying in violation of the Commerce Clause. The Commerce Clause boundaries of states' legislative authority are clearly at issue in the petition, and warrant this Court's clarification.

CONCLUSION

For the foregoing reasons and those set forth in Petitioner's previous filings, the petition for certiorari should be granted.

Respectfully submitted,

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