No. 01-188

IN THE
SUPREME COURT OF THE UNITED STATES

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,

Petitioner,

v.

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

Respondents.

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

BRIEF AMICUS CURIAE OF THE CHAMBER OF COMMERCE OF THE UNITED STATES IN SUPPORT OF THE PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Can a state, consistent with the Supremacy Clause, deny participation in a federally funded program as a means of coercing participation in an unrelated state program?

2. Can a state, consistent with the Commerce Clause, regulate the prices charged in sales transactions taking place outside its borders, by requiring an out-of-state manufacturer to pay a rebate to the state whenever its products are re-sold by a retailer in the state?

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INTERESTS OF AMICUS CURIAE

The Chamber of Commerce of the United States of America (the 'Chamber") is the world's largest federation of businesses, representing an underlying membership of nearly 3,000,000 businesses and organizations, with direct members of every size, in every sector of the economy, and every region of the country. While most of the country's largest companies belong to the Chamber, the vast majority of its members are small businesses with fewer than 100 employees. Chamber members transact business in all or nearly all of the United States, as well as in a large number of countries around the world. An important function of the Chamber is to represent the interests of its members in important matters before the courts, Congress, and the Executive Branch. To that end, the Chamber has filed amicus curiae briefs in numerous cases that have raised issues of vital concern to the nation's business community.

Many of the Chamber's members engage in multi-state operations, and the question whether one state can regulate transactions or other conduct taking place entirely in another state is therefore of direct interest and concern to Chamber members. Equally important to Chamber members is any sanctioning of a state's use of its power over federal funding to force private parties to make financial or other contributions to unrelated state programs. The Maine statute at issue here implicates both of these concerns. The Chamber files this brief with the consent of all parties. [1]

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[1] No counsel for any party authored this brief in whole or in part. No person or entity other than the Chamber, its (...continued)

SUMMARY OF ARGUMENT

The salient facts presented by this petition are straightforward and uncontroverted: A manufacturer ("Manufacturer") sells and ships its product to a wholesaler ("Wholesaler"). The sale is made entirely outside Maine. Wholesaler then sells and ships the products to retailers in a number of states, including Maine, and the retailers in turn sells the products to consumers. The price for which Manufacturer sells its products to Wholesaler is the foundation of the price for which Wholesaler sells the products to retailers. That price, in turn, is the foundation of the price for which retailers sell the products to consumers.

The prices that Manufacturer is charging to Wholesaler result in retail prices that Maine deems too high. Maine, therefore, enacted legislation that: (1) forces Manufacturer to pay "rebates" to the State to subsidize discounts on the retail prices consumers pay, and (2) curtails Manufacturer's participation in unrelated federal programs if it refuses to make such payments. The legislation is thus the functional equivalent of a command to Manufacturer to reduce its prices to Wholesaler. As the district court in this case observed, "whatever price the manufacturer originally received for that out-of-state transaction is automatically reduced [by the mandatory rebate] when the drug comes to Maine." (App. 66).

The district court correctly held that, under the Supremacy Clause, a state cannot use the threat of limiting a private party's participation in a federal program to coerce its participation in an unrelated state program; and that, under

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members, or its counsel made a monetary contribution to the preparation or submission of this brief.

the Commerce Clause, a state lacks power to regulate the terms of a transaction that takes place entirely outside its borders. The appellate court's reversal of those holdings conflicts with precedents from other circuits, and would permit states both to hijack federal programs in order to serve their own parochial ends and to assert regulatory powers far beyond their borders.

REASONS FOR GRANTING THE WRIT

I. THE FIRST CIRCUIT DECISION WOULD ALLOW STATES TO HIJACK FEDERAL PROGRAMS FOR UNRELATED PURPOSES, AND CONFLICTS WITH A DECISION OF THE D.C. CIRCUIT.

The Medicaid program provides prescription drugs and other medical services to those with medical needs who meet the statute's eligibility requirements. 42 U.S.C. § 1396 (2001). These eligibility requirements are spelled out in great detail in the federal statute, *see* 42 U.S.C. § 1396a(a)(10) (2001), and are met by approximately 170,000 Maine residents. (JA 89). The federal government pays two-thirds of Maine Medicaid expenses. *See* 65 Fed. Reg. 8979-80, 69560-61 (2001).

The Maine "Act to Establish Fairer Pricing for Prescription Drugs," 2000 Me. Legis. Ch. 786 (the "Maine Rx Act"), purports to require drug companies to enter into "rebate agreements" in order to reduce the price of prescription drugs purchased by at least 325,000 Maine citizens who do not qualify for the Medicaid program, and potentially all Maine residents. Me. Rev. Stat. Ann. tit. 22 § 2681 (West 2000); JA 144; App. 3. These rebate agreements are required for any drug company that participates in any publicly supported pharmaceutical assistance program, such as the federal Medicaid program. Me. Rev. Stat. Ann. tit. 22

§ 2681(3). These rebates are collected by the state and provided to pharmacists in order to reimburse them for price discounts funded entirely by the rebates. *Id.* at § 2681(9); *see also* App. 3.

The Maine Rx Act provides that the State will restrict patient access under the federal Medicaid program to the drugs of any manufacturer that fails to enter into a rebate agreement. Me. Rev. Stat. Ann. tit. 22 § 2681(7). The Act accomplishes this goal by requiring "prior authorization" by the state Medicaid administrator for Medicaid prescriptions of drugs made by manufacturers that have refused to enter into rebate agreements. *Id.*; *see also* App. 4. As the district court found (App. 71) and the Court of Appeals did not dispute (App. 15), prior authorization often reduces access to drugs subject to this requirement, either because doctors will simply substitute other drugs not subject to prior authorization, or the state will not provide the requisite authorization. [2]

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[2] The Maine Rx Act also contains additional enforcement mechanisms. The Act provides that non-cooperating drug companies may be charged with "profiteering," which is defined to include "unconscionable" pricing and which exposes the company to a panoply of sanctions: treble damages, punitive damages if the violation was determined to have been willful or repeated, civil penalties of up to $100,000 per violation, and injunctive relief. Me. Rev. Stat. Ann. tit. 22 § 2697(1)(2)(3)(4) (West 2000). A violation of the anti-profiteering prohibition is automatically also a violation of the Maine Unfair Trade Practices Act, *id* at. § 2697(5), which itself provides for civil penalties of up to $10,000 per violation, private actions for actual damages, and injunctive relief. Me. Rev. Stat. Ann. tit. 5, §§ 209, 213 (West 2000). Respondent did not appeal the district court's
(...continued)

A. *Conflict with federal law*. There is no question that Congress intended to permit states, under appropriate circumstances, to impose a "prior authorization" requirement on prescription drugs reimbursed under the federal Medicaid program *in order to benefit that program or its beneficiaries,* for example, to ensure cost-effective Medicaid operations by preventing the over prescription to Medicaid recipients of popular but expensive drugs. *See* 42 U.S.C. § 1396r-8(d)(1). But here the state is doing something radically different. It is purporting to use its power to impose a Medicaid "prior authorization" requirement in order to punish a drug company's refusal to participate in the unrelated state "rebate" program for hundreds of thousands of citizens who do not qualify for the Medicaid program, Me. Rev. Stat. Ann. tit. 22, § 2681(7); JA 144.

That action, by its very nature, interferes with the purposes of the Medicaid program. Prescription drugs that had previously been freely available to Medicaid patients suddenly will not be, for reasons having nothing to do with the interests of the Medicaid program or Medicaid beneficiaries. *See* App. 71 ("The State makes no argument that the new condition of prior approval serves any purpose of the Medicaid program."). Yet the Medicaid statute explicitly provides that a state cannot design its Medicaid program to serve other interests, but must instead "provide such safeguards as may be necessary to assure that...care and services will be provided, in a manner consistent with...the best interest of *the recipients*." 42 U.S.C. § 1396a(a)(19) (emphasis added).

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ruling enjoining enforcement of these provisions. *See* App. 5 n.2.

This state conduct runs afoul of the Supremacy Clause, U.S. Const. art. VI, § 2. A state may not take action that imposes an "obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Crosby v. National Foreign Trade Council*, 530 U.S. 363, 373 (2000)(citation omitted). Maine inevitably does that when it burdens access to drugs under the Medicaid program to serve non-Medicaid ends. Indeed, as the district court noted, the Maine Rx Act flouts the principle of federal supremacy not merely because it "might conflict with the objectives of a federal law," but because it "has actually taken the federal Medicaid program and altered it to serve Maine's local purposes." (App. 68); *see also id.* at 69 n.12 ("the Medicaid program [has been] hijacked to provide leverage for other purposes.").

The First Circuit erred in holding that proof of a conflict would have to await evidence that the health of a Medicaid patient had actually been harmed by the denial of necessary drugs. (App. 16). Respondent concedes that the state "will not authorize payment for [a] first-choice drug manufactured by a non-participant where there is another drug for the ailment manufactured by a participant...." (App. 15). So long as the Maine statute serves its intended function of causing a doctor to prescribe for a Medicaid patient a drug different than the drug he would otherwise have preferred—an effect the First Circuit did not deny—the Medicaid program has been negatively impacted for purposes unrelated to that program.

Maine was not obligated to participate in the Medicaid program, but having chosen to do so, must comply with the requirements of the federal Medicaid law. *See Wilder v. Virginia Hosp. Ass'n*, 496 U.S. 498, 502 (1990); *Alexander v. Choate,* 469 U.S. 287, 289 n.1 (1985). Maine fails to meet that obligation when it subverts the Medicaid

program and the interest of Medicaid beneficiaries in order to serve other purposes.

B. *Conflict with D.C. Circuit.* Maine seeks to impose through its administration of the Medicaid program the very regime that the D.C. Circuit recently held the Medicaid statute does not permit—one in which "pharmaceutical manufacturers [must] provide substantial discounts to individuals not otherwise covered by state Medicaid programs." *PhRMA v. Thompson*, 251 F.3d 219, 226 (D.C. Cir. 2001). That court struck down as beyond Medicaid's statutory authority a federal waiver allowing Vermont to require rebates from manufacturers in order to reduce the cost of pharmaceutical drugs to persons not meeting Medicaid's eligibility requirements. If, as the D.C. Circuit held, such a regime is beyond that permitted by Medicaid's express terms, then *a fortiori* it is impermissible for a state to restrict benefits otherwise available to Medicaid participants in order to achieve precisely the same result. The circuit decisions are in conflict and merit this Court's review.

The implications of Maine's conduct go well beyond the specifics of this case. Other states are now considering similar legislation. *See* Pet. for a Writ of Cert. at 21-23. Furthermore, as the district court noted, Maine could just as easily have used its authority over Medicaid authorization to coerce drug companies to make contributions to highway or bridge construction or to school funding. (App. 68). The First Circuit's speculation that the Maine statute may serve a "Medicaid purpose" by warding off impoverishment and thus keeping some Maine residents off the Medicaid rolls (App. 13) could just as readily be used by a state to justify conditioning participation in any federal program upon coerced payments to virtually any social program.

Medicaid is only one of numerous federal programs that match federal funding and oversight with state administration and eligibility determination. *E.g.,* Aid to Families with Dependent Children, 42 U.S.C. § 601 (2001); Community Development Block Grants, 42 U.S.C. § 5301 (2001); Community Services Block Grants 42 U.S.C. § 9901 (2001); Social Services Block Grants, 42 U.S.C. § 1397 (2001); Maternal and Child Health Services Block Grants, 42 U.S.C. § 701 (2001); Alcohol and Drug Abuse and Mental Health Block Grants, 42 U.S.C. § 290cc-21 to cc-35 (2001). It is inconceivable that Congress intends that states shall have license to condition participation in such federal programs on a company's or individual's willingness to make substantial financial contributions to unconnected state programs. Yet states would be free to impose precisely such conditions if Maine is permitted to do so here with respect to the Medicaid program.

II. THE FIRST CIRCUIT DECISION WOULD ALLOW STATES TO ENGAGE IN EXTRATERRITORIAL REGULATION, AND CONFLICTS WITH A DECISION OF THE SEVENTH CIRCUIT AND OTHER PRECEDENTS.

The Commerce Clause, U.S. Const. art. I, § 8, cl. 3, both evidences a grant of power to Congress directly limits the powers of the states. *Wyoming v. Oklahoma*, 502 U.S. 437, 454 (1992) (citing authorities). From the earliest days of the Republic, it has been understood that the Commerce Clause encompassed *territorial* limitations on a State's powers. Thus, Chief Justice Marshall in *Gibbons v. Ogden*, 22 U.S. 1, 194 (1824), distinguished between commerce consigned to federal authority by the Commerce Clause and "commerce, which is completely internal [to a state], which is carried on between man and man in a State, or between different parts of the same State." *See also Mayor of New*

York v. Miln, 36 U.S. 102, 133 (1837) ("If we look at the place of [the challenged New York statute's] operation, we find it to be within the territory, and therefore, within the jurisdiction of New York."); *Thurlow v. Commonwealth of Massachusetts*, 46 U.S. 504, 583 (1847) (*The License Cases)*, ("a State [may] regulate commerce within its own limits.")(separate opinion of Chief Justice Taney).

This Court has long recognized that states lack authority to regulate transactions occurring outside their territorial limits. "Laws have no force of themselves beyond the jurisdiction of the state which enacts them, and can have extraterritorial effect only by the comity of other states." *Huntington v. Attrill*, 146 U.S. 657, 669 (1892); *accord New York Life Ins. Co. v. Head,* 234 U.S. 149, 161 (1914) ("[I]t would be impossible to permit the statutes of Missouri to operate beyond the jurisdiction of that state and in the state of New York . . . This is so obviously the necessary result of the Constitution that it has rarely been called into question . . .").

This Court's modern Commerce Clause jurisprudence has repeatedly recognized and applied these precepts to forbid state efforts to control the prices paid in out-of-state transactions. *E.g., Baldwin v. G.A.F. Seelig, Inc.* 294 U.S. 511, 521 (1935) (a state "has no power to project its legislation into [another state] by regulating the price to be paid in that state for [products] acquired there"); *Healy v. The Beer Institute,* 491 U.S. 324, 336 (1989) ("a statute that directly controls commerce occurring wholly outside the boundaries of a State exceeds the inherent limits of the enacting State's authority and is invalid regardless of whether the statute's extraterritorial reach was intended by the legislature. The critical inquiry is whether the practical effect of the regulation is to control conduct beyond the boundaries of the State."); *see generally* 1 Laurence H. Tribe, *American*

Constitutional Law, § 6-12 at 1098 (3d ed. 2000)(referencing "the *per se* principle against extraterritorial state regulation").

These bedrock principles are of great significance to the Chamber's members, which often conduct business in multiple states, and whose operations would be seriously impeded if states were permitted to impose regulatory requirements applicable outside their borders.

The district court was clearly correct that Maine "cannot legislate the amounts that out-of-state manufacturers obtain when they sell to pharmaceutical wholesalers or distributors out-of-state." (App. 59). Yet legislating the price received by the drug company for its out-of-state sales transaction is what "Maine has tried to do here." (*Id.)* As the district court aptly observed, "whatever price the manufacturer originally received for that out-of-state transaction is automatically reduced [by the mandatory rebate] when the drug comes to Maine." (App. 66). Maine is not buying or financing the purchase of the drugs (App. 20); it is instead dictating the price to be received in third-party transactions. Its use of "rebates" to achieve that end, while perhaps innovative, cannot mask the ultimate result.

The prices drug companies charge in their out-of-state sales to wholesalers and distributors likely do have an impact upon the Maine residents who ultimately purchase those drugs. But "[a] State does not acquire power or supervision over the internal affairs of another State merely because the welfare and health of its own citizens may be affected...." *Bigelow v. Virginia*, 421 U.S. 809, 824-25 (1975); *accord Seelig*, 294 U.S. at 523-24. Thus, irrespective of impact, a state may neither "proscribe[]" nor "regulate[]"activities in another state. *Bigelow*, 421 U.S. at 822-23. *Accord Edgar v. MITE Corp.*, 457 U.S. 624, 642-43 (1982) ("The Commerce Clause ... precludes the application of a state statute to

commerce that takes place wholly outside of the State's borders, whether or not the commerce has effects within the State.").

The rule could hardly be otherwise; while Maine is dissatisfied with the prices charged in out-of-state drug transactions, other states may be equally unhappy with the prices at which wheat is sold by farmers to grain depots in Kansas, or at which computers are sold to wholesalers in California. Yet surely these other states cannot dictate the price at which those out-of-state sales take place, nor require that a "rebate" be paid to them by the farmer or manufacturer if the products ultimately reach their citizens.

The Maine Rx Act is therefore unconstitutional, insofar as it attempts either to condemn as "unconscionable" the price charged in out-of-state transactions, or to require that a "rebate" be paid by the manufacturer in order to reduce that price. Indeed, Respondent did not even seek to appeal the district court's preliminary injunction against the former (*see* n.2 *supra*), and the latter is no less an effort to control out-of-state pricing. Review by this Court is necessary in order that this principle be clarified.

The appellate court was mistaken to treat the Maine Rx Act as one that regulates activities within the state. (App. 24). While an activity within the state—the sale by a retailer to a Maine resident—triggers the operation of the statute, no obligations are imposed upon either party to that transaction. The target of the regulation is the out-of-state manufacturer, and its purpose and effect is the extraction from that manufacturer of a rebate on the amount it received in an out-of-state transaction. If, as is surely the case, it would be unconstitutional for Maine to decree that Florida orange growers may not be paid more than fifty cents a pound by Florida juice processors, then it is no less unconstitutional for

Maine to demand that the Florida processor pay Maine citizens a "rebate" sufficient to lower that price to fifty cents on juice re-sold by a retailer in Maine.

The First Circuit also erred in concluding that no Commerce Clause violation was present because the amount of the rebate is purportedly the subject of "negotiation".[3] The mandatory nature of the rebate,[4] coupled with the coercive threat of prior authorization, belie any notion that this is a voluntary program. Simply stated, drug companies have no leverage: If they do not agree to pay the rebates requested by Respondent, their drugs become subject to prior authorization within the Medicaid program. And, even assuming that the Commissioner would be flexible as to the exact amount of the rebate, conduct otherwise violative of the Commerce Clause cannot not salvaged by arguments as to the precise dollar amount of the impact. *Cf. Camps Newfound/Owatonna, Inc., v. Town Of Harrison, Maine*, 520 U.S. 564, 581 n.15 (1997) ("there is no 'de minimis' defense to a charge of discriminatory taxation under the Commerce Clause")(*citing Fulton Corp. v. Faulkner*, 516 U.S. 325, 333 n.3 (1996)).

The First Circuit decision is in direct conflict with *Dean Foods Co. v. Brancel*, 187 F.3d 609 (7th Cir. 1999). That case involved a Wisconsin statute that forbade the payment of "volume premiums" to Wisconsin dairy farmers supplying purchasers with large quantities of milk. While the

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[3] The Maine Commissioner of Human Services is directed to use his "best efforts" to achieve a rebate payment at least as great as that required by Medicaid. Me. Rev. Stat. Ann. tit. 22, § 2681(3)(4).

[4] The Maine Rx Act provides that a drug manufacturer "*shall* enter into a rebate agreement with the department for this program." Id. at § 2681(3)(emphasis added).

First Circuit upheld the Maine Rx Act on grounds that it was not an obstacle to the programs of other states, discriminatory, or protectionist (App. 24-25), the same was true for the Wisconsin statute. That statute did not interfere with any other state's dairy pricing regimes; it did not treat differently in-state and out-of-state purchasers; and it did not protect Wisconsin farmers from out-of-state competition.[5]

Nonetheless, the Seventh Circuit struck down the statute insofar as it purported to apply to sales transactions by Wisconsin farmers that took place outside Wisconsin. In so doing the court relied upon the "long line of cases holding that states violate the Commerce Clause by regulating or controlling commerce occurring wholly outside their own borders," and "the long-established core principle that a statute or regulation that violates the extraterritoriality ban is per se invalid." *Dean Foods*, 187 F.3d at 615-16 (citations omitted). [6]

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[5] Indeed, the Wisconsin statute actually made Wisconsin farmers *less* competitive *vis-à-vis* farmers in neighboring states; the statute made Wisconsin milk *less* attractive to purchasers who "[f]or efficiency reasons . . . prefer[] to purchase from milk producers with large herds." *Dean Foods Co. v. Brancel*, 187 F.3d 609, 611 (7th Cir. 1999).

[6] To be sure, the Commerce Clause is *also* concerned with protectionism and discrimination and forbids state regulation so aimed irrespective of whether its foci are within the state. *E.g., West Lynn Creamery, Inc. v. Healy*, 512 U.S. 186 (1994) (striking down state law imposing an assessment on all milk sold in the state and its distribution to in-state farmers only); *Philadelphia v. New Jersey*, 437 U.S. 617 (1978) (striking down state law forbidding the disposal of out-of-state waste in New Jersey landfills). But the mere fact that the dormant Commerce Clause also serves these
(...continued)

Because the purchases of milk at issue were found to have transpired outside Wisconsin—as is the case with the drug sales at issue here (App. 60)—they were beyond that state's regulatory reach. *See also Louisiana Dairy Stabilization Board v. Dairy Fresh Corp.*, 631 F.2d 67 (5th Cir. 1980) (out-of-state sales of products ultimately consumed in Louisiana could not, consistent with the Commerce Clause, be subjected to Louisiana's three-cent assessment on milk). At that point, it is not a question of balancing of interests (*cf.* App. 25-27); once it is determined that the statute "burdens out-of-state transactions, there is nothing to be weighed . . ." *Edgar v. MITE Corp.*, 457 U.S. at 644.

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functions in no way limits its role as a bar to extraterritorial state regulation.

CONCLUSION

The First Circuit, which itself described this as a "close case" (App. 28), erred in its decision and in so doing put itself in conflict with other circuits and caused damage to important Supremacy and Commerce Clause principles. The petition for certiorari should be granted.

Respectfully submitted,

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