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

BRIEF OF WASHINGTON LEGAL FOUNDATION, ALLIED EDUCATIONAL FOUNDATION, KIDNEY CANCER ASSOCIATION, THE SENIORS COALITION, and THE 60 PLUS ASSOCIATION AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

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Date: August 30, 2001

QUESTIONS PRESENTED

1. Does the federal Medicaid statute, 42 U.S.C. § 1396, *et seq.*, allow a state to use authority under that statute to compel drug manufacturers to subsidize price discounts on prescription drugs for non-Medicaid populations?

2. May a State circumvent the Commerce Clause prohibition against regulating or taxing wholly out-of-state transactions by requiring an out-of-state manufacturer, which sells its products to wholesalers outside the State, to pay the State each time one of its products is subsequently sold by a retailer within the State?

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INTERESTS OF *AMICI CURIAE*

The Washington Legal Foundation (WLF)[1] is a non-profit public interest law and policy center with supporters in all 50 states, including many in Maine. WLF devotes a substantial portion of its resources to defending and promoting free enterprise, individual rights, and a limited and accountable government. To that end, WLF has appeared before numerous federal and state courts in cases raising issues arising under the dormant Commerce Clause. *See, e.g., National Foreign Trade Council v. Natsios*, 181 F.3d 38 (1st Cir. 1999), *aff'd*, 530 U.S. 363 (2000). WLF recently successfully challenged the constitutionality of Food and Drug Administration restrictions on commercial speech by pharmaceutical manufacturers. *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998), *appeal dism'd*, 202 F.3d 331 (D.C. Cir. 2000).

The Allied Educational Foundation (AEF) is a non-profit charitable and educational foundation based in Englewood, New Jersey. Founded in 1964, AEF is dedicated to promoting education in diverse areas of study, such as law and public policy, and has appeared as *amicus curiae* in this Court on a number of occasions.

The Kidney Cancer Association is a patient and survivor-led voluntary health agency pursuing the goal of a world without kidney cancer through research, education, and advocacy.

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[1] Pursuant to Supreme Court Rule 37.6, *amici curiae* state that no counsel for a party authored this brief in whole or in part; and that no person or entity, other than *amici* and their counsel, contributed monetarily to the preparation and submission of this brief.

The Seniors Coalition (TSC) is a non-profit, non-partisan education and issue advocacy organization that represents the interests and concerns of America's senior citizens at both the state and local levels. TSC's mission is to give America's seniors a real voice in government to enact public policies that promote and protect their quality of life and economic security. Founded in 1989, TSC has grown to nearly 4 million members; its advocacy includes a wide range of issues important to seniors, including Social Security, Medicare, long-term care, generic drug access, and tax reform.

The 60 Plus Association is a Virginia-based seniors' advocacy group devoted to the free market, free enterprise system. 60 Plus is opposed to price controls on prescription drugs because: (1) they stifle pharmaceutical research leading to the medical miracles enabling seniors to live longer and better and stay out of hospitals; and (2) they result in shortages, as evidenced by the shortcomings of the Canadian health care system.

Amici are concerned that the Maine Rx Program, if allowed to take effect, will have long-term adverse effects on health care in this country. By interfering with the free market in pharmaceutical sales, the Program threatens to discourage research and development of new, life-saving drugs and to Balkanize what is now an efficient national market.

Amici also filed a brief in this case when it was before the appeals court. *Amici* are filing this brief with the consent of all parties. The written consents are on file with the Clerk of the Court.

STATEMENT OF THE CASE

In the interests of brevity, WLF hereby adopts by reference the Statement of the Case contained in the Petition.

In brief, the Pharmaceutical Research and Manufacturers of America ("PhRMA") challenges a Maine law that requires drug manufacturers to subsidize retail drug discounts to Maine residents under a new program called the "Maine Rx Program." Payment of the subsidies is (from a practical standpoint) mandatory, because the State of Maine administers the federal Medicaid program within the State (a program in which all major drug manufacturers participate), and the Maine Rx Program prescribes severe retaliation in connection with Medicaid against any manufacturer that refuses to pay the mandated subsidy. *See* Petition Appendix ("Pet. App.") 70-71.

The Maine RX Program was adopted by the state legislature in May 2000. The law, entitled "An Act to Establish Fairer Pricing for Prescription Drugs" (the "Act"), 2000 Me. Legis. Ch. 786 (S.P. 1026), is codified at 22 M.R.S.A. § 2681. The Act provides that drug manufacturers "shall enter into a rebate agreement" with the Maine Department of Human Services (the "Department") and that the agreement "must require" manufacturers to "make rebate payments to the State each calendar quarter or according to a schedule established by the department." 22 M.R.S.A. § 2681(3). The Act further requires the Department to use "best efforts" to establish rebates at a level equal to or greater than discounts obtained by the federal government in connection with its bulk purchases of prescription drugs. 22 M.R.S.A. § 2681(4). The Act further provides that pharmacists in Maine are to sell prescription drugs to Maine residents at substantially discounted prices and that money collected by the State from drug manufacturers under the Maine Rx Program is to be paid to the pharmacists in order to reimburse them for those discounts. 22 M.R.S.A. §§ 2681(5), (6).

The subsidies are required of all drug manufacturers whose products are sold in Maine, even though no drug manufacturers are based in Maine and even though very few of them sell their products to Maine wholesalers. Rather, virtually all prescription drugs that end up in Maine are sold to wholesalers or distributors in transactions that occur outside the State; the wholesalers and distributors make their own arrangements for shipment into Maine. Pet. App. 60. Moreover, as the district court recognized, the rebate program results in a reduction in the wholesale price obtained by manufacturers for each drug that is later sold in Maine, because the amount of a manufacturer's rebate is determined by the quantity of that manufacturer's products sold in Maine. *Id.* at 66.

PhRMA filed suit against the Maine Rx Program in U.S. District Court for the District of Maine. The Complaint alleged that the Program violated the Commerce Clause of the U.S. Constitution by attempting to regulate transactions occurring outside of Maine, and violated the Supremacy Clause by requiring Maine to administer the Medicaid program in a manner that conflicts with federal law.

On October 26, 2000, the district court granted PhRMA's motion for a preliminary injunction against any efforts by Maine to enforce the payment of rebates under the Program. Pet. App. 57-72. Initially, the court rejected Maine's argument that the Maine Rx Program entailed nothing more than the exercise of power derived from Maine's role as a participant in the prescription drug market, and thus that the Program should be exempt from Commerce Clause scrutiny under the "market participation" exception. The court said that that exception does not immunize State efforts to leverage power derived from one market in which it participates (in this case, the purchase of drugs under the Medicaid program) in order to regulate a

market in which it does not participate (in this case, the market for prescription drugs purchased outside of Medicaid). *Id.* at 61-64.

The court went on to find that the Program violated the Commerce Clause because it attempted to regulate transactions taking place solely outside the State. *Id.* at 64-66. "Maine may have power over what pharmacies later do here in Maine, or over the few distributors who transact business in Maine, but it has no power to regulate the price paid in earlier transactions in other states." *Id.* at 65. The court held that the Program was invalid without regard to whether the Program could be said to discriminate against out-of-staters in favor of in-staters. *Id.* at 66.

The court also held that the Program was invalid under the Supremacy Clause because it was impliedly preempted by federal Medicaid law. *Id.* at 66-70. The court found that the Program stood "as an obstacle to the accomplishment and execution of the Congressional objectives of federal Medicaid," because it made it more difficult for certain drugs to be prescribed to Medicaid recipients. *Id.* at 68.

Having found that PhRMA was "overwhelming[ly]" likely to prevail on the merits and that the other relevant factors also favored PhRMA, the court granted a preliminary injunction against enforcement of the Program's rebate scheme. *Id.* at 72.

The U.S. Court of Appeals for the First Circuit reversed and vacated the preliminary injunction. *Id.* at 1-53. The appeals court initially determined that the Program was not preempted by federal law, finding "no conflict between the Maine Act and Medicaid's structure and purpose." *Id.* at 11. While noting that the Program threatens imposition of a "prior authorization" requirement on manufacturers that do not

participate in the Act's price control program, the court held that the Medicaid statute does not concern itself with a State's motivation in choosing to impose such a requirement -- and thus that Maine's use of its "prior authorization" power as a club to ensure manufacturer participation does not conflict with any purpose of the Medicaid law. *Id.* at 12-13. The court said that the Program actually "furthers Medicaid's aim of providing medical services to those" otherwise unable to meet the costs of necessary medical services but who are not poor enough to qualify for Medicaid. *Id.* at 13.

The appeals court also held that the Program did not violate the Commerce Clause. *Id.* at 17-27. As did the district court, the appeals court rejected Maine's argument that it was exempt from Commerce Clause restraints by virtue of its status as a "market participant." *Id.* at 20. The court nonetheless rejected PhRMA's Commerce Clause challenge, finding that "the Maine Act does not impose direct controls on a transaction that occurs wholly out-of-state," *Id.* at 23. The court reasoned, "Simply because the manufacturers' profits might be negatively affected by the Maine Act . . . does not necessarily mean that the Maine Act is regulating those profits." *Id.* The court held that whatever burdens the Program imposed on interstate commerce were not "clearly excessive" in relation to the benefits derived by Maine. *Id.* at 25-27.

REASONS FOR GRANTING THE PETITION

Amici curiae fully support the arguments put forth by PhRMA regarding why grant of the Petition is warranted. They write separately in order to emphasize the significant public importance of the issues raised by this case. The price of prescription drugs is of great importance to virtually all Americans; high prices may deprive some consumers of the ability to afford proper medical care, but artificially low prices

may deprive *all* citizens of optimal care by reducing the financial incentives necessary to ensure that new, life-saving medical products continue to be developed.

Numerous States either have already enacted or are on the verge of enacting legislation designed to control the price of prescription drugs. That legislation has spawned numerous lawsuits challenging various aspects of these price control schemes. In light of those challenges -- which have led to conflicting court decisions -- guidance from the Court is urgently needed. In particular, guidance is needed regarding whether price controls are appropriately imposed on an *ad hoc*, state-by-state basis or whether, in light of the Commerce Clause and relevant federal statutes, the issue is more appropriately addressed on a nationwide basis.

I. REVIEW IS WARRANTED IN LIGHT OF THE MAJOR IMPORTANCE OF THE QUESTIONS PRESENTED TO THE DELIVERY OF HEALTH CARE IN THIS COUNTRY

Rising use of prescription drugs by consumers has led in recent years to a significant increase in total expenditures for prescription drugs in this country. That increase in turn has led to efforts in numerous States to control prescription drug prices.

According to the National Conference of State Legislatures (NCSL), 30 states have now adopted some type of program designed to control prescription drug prices. *See* NCSL, *2001 Prescription Drug Discount, Bulk Purchasing, and Price-Related Legislation, at* http://www.ncsl.org/programs/health/drugdisc01.htm (updated August 24, 2001). New legislation mandating discount programs, bulk purchasing programs, expanded manufacturer rebates, and/or price controls "are being considered in at least

40 states." *Id.* The pace at which such legislation is being considered has quickened following the First Circuit's rejection of PhRMA's facial challenge to the Maine price control Program. The Center for Policy Alternatives ("CPA") reports that the First Circuit's decision has "reignited efforts to lower prescription drug prices at the state level," with legislation modeled after the Maine Rx Program pending in 27 states. CPA, *States Poised to Lower Prescription Drug Prices as First Circuit Court of Appeals Rules Against PhRMA,* (Summer 2001) *at* www.stateaction.org/alternatives/altbody2.cfm?volume=v9no3&artnumber=4 (visited August 27, 2001).

In light of the large number of state statutes being adopted in this area, the need for the Court's guidance regarding the constitutionality of such legislation is readily apparent. The challenges raised by PhRMA are substantial; it prevailed in the district court, and the First Circuit conceded that this was a "close case." Pet. App. 28.

Nor are the issues raised by PhRMA ones that would benefit from additional "percolation" in the lower courts. As the district court recognized, the record in this case "is essentially undisputed." *Id.* at 72. Accordingly, although the case is before the Court in connection with a motion for a preliminary injunction, there is little reason to believe that delaying consideration of the case until after entry of a final judgment would sharpen the issues by providing the Court with a more complete factual record. Moreover, the Court is well-experienced in dealing with claims that States are violating the Commerce Clause by regulating commerce extraterritorially, and thus would benefit little by awaiting additional court of appeals review before taking up the issue.

Amici are particularly concerned that additional delays in the Court's consideration of PhRMA's claims will lead to massive disruptions of the American health care system. The experience in Canada and elsewhere is that price controls inevitably lead to shortages both in drugs and medical services -- without having any significant effect on costs. *See* "Prescription Drug Costs: Has Canada Found the Answer?," National Center for Policy Analysis, Brief Analysis No. 323 (May 19, 2000). That study found:

> While some drugs do cost less in Canada, others don't. Furthermore, large numbers of Canadians come to the United States to buy drugs because so many drugs are not available at any cost in Canada. The Canadian government purposely restricts the overall availability of prescription drugs through a combination of lengthy drug approval process and oppressive price controls. The result is that patients are often harmed.
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> Through limiting the availability of prescription drugs and controlling prices of those that are available, Canada has succeeded only in preventing Canadians from obtaining drugs that might have reduced hospital stays and expensive medical procedures. Despite prices on some individual drugs that are lower than in the United States, Canada has been unable to hold down the overall cost of either prescription drugs or other health care. The result is a lower standard of health care at a higher cost than Canadian patients and taxpayers have a right to expect.

Id.

Delays in consideration of PhRMA's claims could also disrupt health care delivery if, as is likely, new price control legislation leads to diminished research and development ("R&D") and, ultimately, to decreased development of new, life-saving drugs. On average, it costs anywhere from $500 million to $1 billion in R&D costs to get a drug approved for use in the United States. *Drug Price Controls: A "Cure" Worse Than the Disease,* The Independent Institute (2000). Basic economics dictate that pharmaceutical companies must recover all their costs, plus a reasonable profit, in order to spur them to continue to develop new medicines. As one expert has noted:

> Any attempt to regulate pharmaceutical prices on the basis of cost. . . will be imprecise and arbitrary. Regulators are tempted to set prices to cover only those costs that are clearly attributable to the delivery of particular drugs to particular market segments. That narrow focus tends to result in prices that are too low to cover R&D, therefore stifling innovation and competition.

Patricia M. Danzon, "Making Sense of Drug Prices," 23 REGULATION at 62-63 (2000).

Whether prescription drug price controls are good public policy is not, of course, the issue before the Court. Nonetheless, in light of the very significant potential impact on health care delivery of the Maine Rx Program and similar laws proposed in other States, immediate review of the issues raised by PhRMA is warranted.

II. THE FIRST CIRCUIT'S DECISION CONFLICTS WITH THIS COURT'S "DORMANT" COMMERCE CLAUSE CASE LAW

The Court should grant review for the additional reason that the First Circuit's decision so clearly conflicts with this Court's "dormant" Commerce Clause case law.

The record is uncontested that virtually all prescription drugs sold in Maine were initially sold by drug companies to wholesalers in connection with transactions that took place wholly outside the State of Maine. Yet, the Maine Rx Program attempts to regulate such wholesale transactions by reducing the wholesale price by the amount of the rebate that manufacturers are required to pay to the State. The Court has held on numerous occasions that such State efforts to exert extraterritorial control over sales transactions lacking any significant nexus with the State constitute a *per se* violation of the Commerce Clause.

As the district court held, "bedrock principles concerning the territorial limits of a state's power" prohibit a State from attempting to "extend its authority to out-of-state manufacturers" in this manner. Pet. App. 64-65. The Court has repeatedly held that a State's efforts to control commerce occurring wholly outside the boundaries of the State are *per se* invalid under the dormant Commerce Clause. The Court has explained:

> Taken together, our cases concerning the extraterritorial effects of state economic regulation stand at a minimum for the following propositions. First, the Commerce Clause precludes the application of a state statute to commerce that takes place outside of the State's borders, whether or not the commerce has effects within the State. [Citations omitted.] . . . Second, a statute that directly controls commerce 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.

Healy v. Beer Institute, 491 U.S. 324, 336 (1989). In *Healy*, the Court struck down a Connecticut law that required liquor wholesalers to affirm that their prices were no higher than the prices at which their products were sold in neighboring states, because the law had the inevitable impact of controlling wholesale prices in those neighboring States. *Id.* at 338.

Similarly, the Court struck down as a *per se* Commerce Clause violation a New York law that prohibited the sale in New York of milk which had been sold by milk producers in other states for less than New York's minimum producer price. *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511 (1935). Justice Brandeis wrote for the Court in that case:

> 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. So much is not disputed. New York is equally without power to prohibit the introduction within her territory of milk of wholesome quality acquired in Vermont, whether at high prices or low ones.

Id. at 522.

The First Circuit attempted to distinguish *Healy* and *Baldwin* by asserting that the Maine Rx Program does not operate extraterritorially. Pet. App. 22-23. That assertion cannot be squared with the uncontested facts. The parties agree that the amount of the rebate is tied directly to the volume of a manufacturer's drugs ultimately sold within Maine. Accordingly, each dollar of the rebate can be traced to a specific wholesale transaction that took place wholly outside Maine. The First Circuit is correct, of course, that Maine does

not dictate to manufacturers the precise wholesale price at which they must sell their drugs. But it cannot seriously be disputed that Maine is directly regulating those wholesale transaction: it is directing that the net wholesale price be reduced by the amount of the Maine Rx Program rebate.

The Commerce Clause does not, of course, constrain Maine's power to impose price controls on retail sales occurring within the State. But Maine has chosen not to pursue that path. Instead of imposing economic burdens on in-state pharmacists, it has attempted to impose those burdens on out-of-state drug manufacturers who, for the most part, have not engaged in any economic transactions within the State. Maine's efforts to regulate out-of-state drug sales are at least as "direct" as New York's efforts in *Baldwin* to regulate out-of-state milk sales, or Connecticut's efforts in *Healy* to regulate out-of-state liquor sales. Yet the First Circuit rejected the Commerce Clause challenge to the Maine Rx Program, while this Court struck down the factually indistinguishable programs in *Baldwin* and *Healy* as *per se* Commerce Clause violations. The Court should grant review in this case to address the conflict between the First Circuit's decision and this Court's Commerce Clause case law.

III. THE FIRST CIRCUIT'S DECISION CONFLICTS WITH A D.C. CIRCUIT DECISION REGARDING THE MEDICAID LAW'S PREEMPTIVE EFFECT

The Court should grant review for the additional reason that the First Circuit's decision conflicts with a decision from the U.S. Court of Appeals for the District of Columbia Circuit regarding the preemptive effective of federal Medicaid law.

Although the Maine Rx Program is independent of the State's administration of Medicaid, the Program uses a

provision of Medicaid as a club to ensure manufacturer participation in its rebate program, the "prior authorization" provision. When subjected to prior authorization, a drug may not be dispensed to a Medicaid beneficiary without the approval of the State Medicaid administrator. The Maine Rx Program threatens that all of a manufacturer's drugs will be subject to Medicaid prior authorization if the manufacturer fails to participate in the rebate program. Because all pharmaceutical manufacturers derive significant income from Medicaid and because it is well accepted that any company whose drugs are subjected to Medicaid prior authorization will suffer significant sales loss, manufacturers are, for all intents and purposes, forced to participate in the Maine Rx Program. As the district court found, the Maine Rx Program cannot realistically be deemed "voluntary."

Although it acknowledged that the Maine Rx Program does not serve Medicaid recipients, the First Circuit found nothing objectionable in this scheme. The court discerned nothing in federal Medicaid law to indicate that Congress frowned on States using the powers delegated to them as local Medicaid administrators in order to effectuate a prescription drug price control program for non-Medicaid recipients. Pet. App. 12-13. Accordingly, the appeals court rejected PhRMA's argument that the Maine Rx Program is preempted under the Supremacy Clause. *Id.*

The First Circuit decision directly conflicts with a decision from the U.S. Court of Appeals for the District of Columbia Circuit on this preemption issue. At issue in *Pharmaceutical Research and Manufacturers of America v. Thompson*, 251 F.3d 219 (D.C. Cir. 2001), was a State of Vermont program imposing price controls on pharmaceuticals sold to lower-income Vermonters who did not qualify to receive Medicaid. Similar to the Maine Rx Program, the

Vermont program relied on a Medicaid provision to force manufacturers to comply with the program.[2] The D.C. Circuit struck down the Vermont scheme, finding that Congress had not intended the Medicaid provision upon which Vermont and HHS relied (the rebate requirement) to be used to effectuate price controls for non-Medicaid purchasers. *Thompson*, 251 F.3d at 226. The D.C. Circuit did *not* suggest that any federal law explicitly prohibited the Vermont scheme; rather, the court reasoned that the scheme was unauthorized because it did not serve any purposes of the Medicaid laws. The court said that Congress added the rebate requirement to reduce the cost of the Medicaid program, not to permit price controls to be imposed on pharmaceutical sales to non-Medicaid recipients. *Id.*

The conflict between *Thompson* and the First Circuit decision could hardly be more direct. Both cases turned on whether, in the absence of an explicit statutory prohibition, a State may leverage its power derived from its status as the local Medicaid administrator to impose price controls on prescription drugs sold to those not covered by Medicaid. The First Circuit said yes; the D.C. Circuit said no. That the cases required analysis of different sections of the Medicaid laws does not make the conflict any less direct. In the final analysis, each appellate court based its decision on whether Congress intended

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[2] The provision used by Vermont is one that requires pharmaceutical manufacturers to rebate a portion of the price of their drugs sold to Medicaid recipients, as a condition for participating in Medicaid. *See* 42 U.S.C. § 1396r-8(a)(1). Vermont sought to extend the rebate requirement to cover drugs sold to 70,000 Vermont residents who were not eligible for Medicaid; indeed, the U.S. Department of Health and Human Services had approved Vermont's request to expand the rebate requirement.

to permit use of a Medicaid administrator's enforcement tools to serve non-Medicaid purposes; they arrived at opposite conclusions regarding that issue.[3] The Court should grant review in order to resolve the conflict.

CONCLUSION

Amici curiae respectfully request that the Court grant the Petition.

Respectfully submitted,

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[3] The First Circuit made a half-hearted assertion that the Maine Rx Program does, in fact, further Medicaid's aims. Pet. App. 13 (Program furthers the aim of "providing medical services to those whose income and resources are insufficient to meet the costs of necessary medical services" and, by making prescription drugs more accessible to the poor, it may reduce total Medicaid expenditures by preventing onset of more serious diseases). However, that assertion does nothing to distinguish the decision below from *Thompson.* Indeed, those same assertions could have been made even more plausibly in *Thompson* because the Vermont price control program (unlike the Maine Rx Program) imposed strict income limitations on eligibility.