No. 01-188

IN THE

Supreme Court of the United States

PHARMACEUTICAL RESEARCH AND MANUFACTURES 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 Writ of Certiorari to the United States Court of Appeals for the First Circuit

BRIEF *AMICUS CURIAE* OF THE LONG TERM CARE PHARMACY ALLIANCE IN SUPPORT OF PETITIONER

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QUESTION PRESENTED

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

CORPORATE DISCLOSURE STATEMENT

The Long Term Care Pharmacy Alliance (LTCPA) is a limited liability corporation representing five national long-term care pharmacy companies—Omnicare, Inc., PharMerica, Inc., NeighborCare, Inc., Kindred Pharmacy Services, Inc. and NCS Healthcare, Inc. LTCPA has neither a parent nor stockholders.

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INTEREST OF *AMICUS CURIAE*[1]

The Long Term Care Pharmacy Alliance (LTCPA) consists of five long-term care pharmacy companies that collectively dispense prescription drugs and provide consultant pharmacist services to more than 1.5 million patients. The patients served by LTCPA members include approximately two-thirds

[1] Pursuant to Sup. Ct. R. 37(3)(a), the Parties have consented to the submission of this brief, and their letters of consent have been filed with the Clerk of this Court. Pursuant to Sup. Ct. R. 37(6), none of the parties or their counsel authored this brief in whole or in part. No person other than the LTCPA, its members, or its counsel made a monetary contribution to the preparation or submission of this brief.

of the nation's nursing home residents. The LTCPA members' pharmacies are very different than retail pharmacies; LTCPA members dispense drugs to nursing home residents and others in specialized "unit dose" packaging. As consultant pharmacists, they conduct patient drug regimen reviews, visit and consult with patients, and work with doctors to ensure that patients are prescribed optimal drug therapies. Because the majority of nursing home residents are Medicaid beneficiaries, LTCPA members are directly affected by restrictions placed on the dispensing of drugs under Medicaid programs such as those at issue here.

LTCPA members' ability to serve their Maine nursing home customers is directly and adversely affected by the Maine Rx Program. Subjecting Medicaid drugs to "prior authorization" to coerce drug manufacturers to participate in state rebate programs for the benefit of Maine residents will impede LTCPA members' ability to serve Maine Medicaid beneficiaries. The program also violates the letter, spirit, and Congressional intent of the Medicaid statute. The Court should scrutinize Maine's use of Medicaid's "prior authorization" provisions in terms of its impact on the quality of care provided to Medicaid beneficiaries.

SUMMARY OF ARGUMENT

One of the questions before the Court is whether the Maine Rx Program's prior authorization requirement is inconsistent with the Medicaid statute, thereby requiring the preemption of the Maine law. The underlying facts are not in dispute: Maine, through its "Maine Rx Program," will require prescription drug manufacturers to submit to a "rebate agreement" which will, in turn, allow the State to fund the reduction of drug prices for all Maine residents. The drugs of any manufacturer failing to participate in the "rebate" program will be placed on the state Medicaid program's "prior authorization" list, requiring doctors and/or

pharmacists to obtain specific state approval each time the drug is dispensed to a Medicaid beneficiary. Maine's sole purpose is to reduce the State's costs in subsidizing Maine citizens' prescription drug purchases, without regard to the effects of the program on Medicaid beneficiaries.

Amicus contends that the Maine Rx Program and State's ability to impose prior authorization requirements for the benefit of non-Medicaid patients is inconsistent with the Medicaid statute's text and underlying purpose. Specifically, the Maine Rx Program violates the Supremacy Clause because it imposes an obstacle to Congress' purpose in enacting the Medicaid Act. Arbitrarily subjecting drugs to prior authorization as Maine proposes will harm nursing home patients, the majority of whom are Medicaid beneficiaries, thus contravening the very purpose of the Medicaid statute.

Nursing home residents today are among the nation's most elderly and frail. Residents often require significantly more drug therapy than non-institutional Medicaid beneficiaries. Under the Maine Rx Program, however, doctors and long term care pharmacists will not have access to the prescription drugs that residents need. Thus, the nursing home residents will bear the brunt of the Maine Rx Program's arbitrary and illegal misuse of the prior authorization mechanism. While Maine may choose to subsidize its citizen's prescription drug purchases, it may not do so at the expense of Medicaid beneficiaries. Maine's prior authorization program must be consistent with the goals and objectives of the Medicaid Act. *Amicus*, thus, urges the Court to reverse the Court of Appeals' decision and to find that the Medicaid Act preempts the Maine Rx Program under the Supremacy Clause.

ARGUMENT

The Maine Rx Program on its face violates the Supremacy Clause by establishing prior authorization requirements that impose "an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" in the federal Medicaid Act. *See Gade v. National Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 98 (1992) (quoting *Hines v. Davidowitz*, 312 U.S. 52 (1941)). Specifically, the Maine Rx Program's prior authorization requirement conflicts with the purpose of the federal Medicaid Act to provide health care to needy Americans. The Medicaid Act allows prior authorization programs, but not if such programs harm beneficiaries. The Maine Rx Program cannot be implemented without undermining "the full purposes and objectives of Congress" expressed in the Medicaid Act and its legislative history. *See Hines*, 312 U.S. at 67. Therefore, the Maine Rx Program's prior authorization requirements should be invalidated.

I. THE MAINE RX PROGRAM CONFLICTS WITH FEDERAL LAW BECAUSE IT WILL HARM THE FRAIL AND ELDERLY WHOM MEDICAID WAS CREATED TO SERVE.

In 1965, Congress enacted the federal Medicaid Act to allow States to provide "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.[2] Congress required participating states to

[2] The Centers for Medicare and Medicaid Services ("CMS," formerly "HCFA"), which oversees the Medicaid program, clearly notes this purpose in its regulations: "Title XIX of the Social Security Act, enacted in 1965, authorizes Federal grants to States for medical assistance to low-income persons who are age 65 or over, blind, disabled, or members of families with dependent children or qualified pregnant women or children." 42 C.F.R. § 430.0.

"provide such safeguards as may be necessary to assure that eligibility for care and services under the plan will be determined, and such care and services will be provided, in a manner consistent with simplicity of administration and the best interests of the recipients." 42 U.S.C. § 1396a(a)(19). The Maine Rx program's prior authorization requirement, however, will harm, rather than serve, the "best interests" of Medicaid recipients.

Recent studies document the cause and effect relationship between restrictive cost-containment programs (*e.g.,* formularies, prior authorization) and reductions in patients' access to drugs. *See, e.g.,* Neil J. MacKinnon & Ritu Kumar, *Prior Authorization Programs: A Critical Review of the Literature,* 7 J. Managed Care Pharmacy 297 (2001) (noting physicians' belief that prior authorization programs prevent patients from timely obtaining needed medications); Mental Health Assoc. in Mich. & Mich. Psychiatric Soc'y, *A Survey of Community Mental Health Services Programs Regarding Medications for Recipients Also Enrolled in Qualified Health Plans* (1999) (documenting providers' problems with prior authorization programs); Mark Schiller, *A Prescription for Medi-Cal,* Action Alert, Pacific Research Institute (1998) (concluding that the Medi-Cal drug treatment authorization request system prevents patients from obtaining "the most appropriate medications"); Stephen B. Soumerai *et al.*, *A Critical Analysis of Studies of State Drug Reimbursement Policies: Research in Need of Discipline,* 71 The Millbank Q. 217, 247 (1993) (citing study demonstrating decline in use of drug without substitute due to prior authorization requirement).[3]

[3] *See also* National Mental Health Association, *Penny-wise & Pound-Foolish: Restricting Access to Psychotropic Medications* (2002) (noting extensive paperwork associated with restricted medications can result in a loss of access of such medications to patients); The Lewin Group, *SAMHSA Managed Care Tracking System* 6 (1998) (finding mechanisms used to control access "may have negative consequences on consumer health status or overall behavioral health expenditures"); Henry G.

Prior authorization requires prescribing doctors (and/or dispensing pharmacists) to obtain specific state permission before dispensing drugs that are subject to the program. This additional procedural hurdle, appearing to some to be seemingly minor, in reality significantly impedes doctors' willingness to prescribe certain drugs. The Lewin Group, *SAMHSA Managed Care Tracking System* 6 (1998) (noting that the administrative requirements are "unduly burdensome"); Carl E. Hopkins *et al.*, *Cost-Sharing and Prior Authorization Effects on Medicaid Services in California: Part II: The Providers' Reactions*, 13 Med. Care 643 (1975) (documenting providers' feelings of harassment and inference from prior authorization requirements); *see also* Art Haymes, *Letters: Prior Authorization a Threat to Doctor-Patient Bond*, 90 Wis. Med. J. 506 (1991) (explaining disruptiveness of prior authorization programs on provider-patient relationship). Given the proliferation of paperwork that medical professionals must endure under today's managed care programs, doctors will switch drugs rather than endure the burden of obtaining authorization for a particular drug and waiting twenty-four hours before obtaining permission to prescribe a necessary medication. The result will be that patients will not get their doctor's "first choice" drugs simply because the manufacturer at some earlier point decided not to pay Maine a supplemental rebate for non-Medicaid purposes.

The adverse effects of Maine's prior authorization program will be borne principally by Maine's nursing home Medicaid

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Grabowski *et al.*, *The Effect of Medicaid Formularies on the Availability of New Drugs*, 1 (Supp. 1) PharmacoEconomics 32-40 (1992) (noting prior authorization creates strong incentives against prescribing drugs); Stephen B. Soumerai *et al.*, *Effects of Medicaid Drug-Payment Limits on Admission to Hospitals and Nursing Homes*, 325 New Eng. J. Med. 1072 (1991) (documenting adverse impact of New Hampshire's cost-containment Medicaid requirement limiting the number of prescription drug reimbursements per month).

beneficiaries to whom LTCPA members dispense drugs. The average nursing home patient is 83.1 years old [4] and requires six prescription medications (with forty-five percent requiring seven and twenty percent needing ten or more drugs). The numbers of prescriptions are not due to over-medication, but, rather, are necessary because of nursing home residents' poorer health as compared with that of ambulatory seniors living at home or in assisted living facilities.[5] Studies indicate that nursing home patients have multiple medical conditions, often accompanied by impaired or abnormal cognitive function.[6] These residents' serious medical conditions make unobstructed access to the appropriate medications critical. Mark Monane *et al., Pharmacotherapy: Strategies to Control Drug Costs in Managed Care,* 53

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[4] Roberto Bernabei *et al., Characteristics of the SAGE Database: A New Resource for Research on Outcomes in Long-term Care,* 54 J. Gerontology: Med. Sci. M25 (1999). Sixty-six percent of those entering nursing homes are already on Medicaid, and those residents who are not eligible upon admission are very likely to become Medicaid eligible (through the process known as "spending down") within their first year of residing in a skilled nursing facility.

[5] J. Lyle Bootman *et al., The Health Care Cost of Drug-Related Morbidity and Mortality in Nursing Facilities,* 157 Archives of Internal Med. 2089 (1997).

[6] A recent HCFA-sponsored analysis suggests that nursing home patients have on average 7.8 medical conditions. *See* Thomas Bodenheimer, *Long Term Care for Elderly People, The On-Lok Model,* 341 New Eng. J. Med. 1324, 1326 (1999) (analyzing 1995 data indicating average patient was eighty years old, has 7.8 medical conditions, and had impairments impeding performance of two to three activities of daily living). In addition, changes in bodily function capacity mean that the elderly process prescriptions different than younger patients. As a result, the elderly require specific geriatric formularies. *See* Mark Monane *et al., Pharmacotherapy: Strategies to Control Drug Costs in Managed Care,* 53 Geriatrics 51 (1998). Understanding the specifics of geriatric care and ensuring that the right drugs are available to be dispensed are critical to providing appropriate treatment and avoiding inappropriate medication interaction.

Geriatrics 51 (1998) (finding that cost-containment strategies must be adopted with care because many elderly patients have multiple diseases that require physicians to maximize the appropriate use of drugs, while avoiding duplicative or interacting medications). The advanced medicines now available permit significant improvements in quality of life to long term care residents who previously had little hope of recuperation from serious illnesses.

The Maine Rx Program's prior authorization requirement, however, will have the practical effect of preventing long term care pharmacies from dispensing the necessary drugs to nursing home residents. Pharmacies forced to dispense a second choice drug will find it difficult, if not impossible in certain instances to find a medication that treats the patient effectively, avoids dangerous side effects, and does not interact inappropriately with a patient's other medications.[7] No matter how noble Maine's motivation in enacting the Maine Rx Program might be, imposing prior authorization on the drugs of certain manufacturers for reasons unrelated to treatment will harm the interests of Maine Medicaid patients in violation of statute and Congress's purposes and objectives in enacting the Medicaid program.

In sum, subjecting drugs to prior authorization only because the manufacturer is unwilling to engage in a separate

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[7] Avoiding inappropriate drug interactions and medication errors is particularly important for nursing home residents. *See* Bootman, *supra*, at 2089 (positively correlating number of prescriptions and increased risk of medication errors and estimating that every dollar spent on prescription drugs generates an additional cost of $ 1.33 in health care costs associated with medication errors). Dr. Bootman was able to estimate that consultant pharmacist intervention saved the health care system $3.6 billion (in 1997 dollars) by avoiding drug related problems. Maine's prior authorization scheme, however, will hinder consultant pharmacists' ability to prevent medication errors through drug substitution, which ironically will lead to greater, rather than lower, Maine health care costs.

state rebate program for non-Medicaid patients is not in the best interests of Medicaid nursing home residents. The real-world effect will be to limit access to drugs based upon financial concerns for non-Medicaid patients, rather than based upon the medical and health requirements of Medicaid patients.[8] Ultimately, the Maine Rx Program will have the unintended consequence of preventing LTCPA members from dispensing those medically necessary drugs to the patients who need them most—nursing home Medicaid beneficiaries.

II. THE MAINE RX PROGRAM CONTRADICTS MEDICAID'S GOAL OF BENEFITING A TARGETED POPULATION.

The Maine Rx Program's misuse of Medicaid's prior authorization program also is inconsistent with the Medicaid Act as a whole. Medicaid is intended to serve needy individuals, not *all* individuals. In contrast, the Maine Rx Program targets *all* individuals within Maine purchasing prescription drugs—both rich and poor. *See* Me. Rev. Stat. Ann. tit. 22, §2681. The Maine legislature enacted the Maine Rx Program "to make prescription drugs more affordable for qualified[9] Maine residents, thereby increasing the overall

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[8] Maine has argued below that the provision is not inconsistent because it authorizes the use of prior authorizations only "as permitted by law." Me. Rev. Stat. Ann. tit. 22, § 2681(7). However, for Maine's statutory provision to have some meaning, as it must, at least some drugs will be subject to prior authorization on the basis of manufacturer identity, rather than medical necessity. What Maine ignores is the reality that different drugs have different effects on different people and that it is the doctor's prescription, in conjunction with the consultant pharmacist's review and consultation, that the law dictates must guide the dispensing of drugs to Medicaid beneficiaries.

[9] A "qualified resident" is "a resident of the State who has obtained from the department a Maine Rx enrollment card." Me. Rev. Stat. Ann. tit. 22, § 2681(2)(F) (footnote added).

health of Maine residents, promoting healthy communities and protecting the public health and welfare." *Id.* at § 2681(1). While perhaps serving an important state purpose, this law, as the Solicitor General has noted, has "no Medicaid purpose [that] appears to be served by a state program focusing on that population." Brief for the United States as *Amicus Curiae* at 13.

The Maine statute's conflict with the Medicaid Act's purpose creates an obstacle to achieving the federal goal of providing health care to needy individuals. By adopting programs that benefit non-Medicaid beneficiaries, Maine has diverted valuable resources that inevitably will harm the population Medicaid is intended to protect.

III. THE MAINE RX PROGRAM ALSO CONFLICTS WITH MEDICAID'S EQUAL ACCESS REQUIREMENT.

The Maine Rx Program's prior authorization provision also conflicts with 42 U.S.C. § 1396a(a)(30)(A), the Medicaid Act's equal access provision. That provision requires that Maine's Medicaid program be implemented to "assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area." Federal courts analyzing the requirement have concluded that under this provision "budgetary considerations cannot be the conclusive factor in decisions regarding Medicaid." *Arkansas Med. Soc'y v. Reynolds*, 6 F.3d 519, 531 (8th Cir. 1993); *see also Orthopaedic Hosp. v. Belshe*, 103 F.3d 1491, 1500 n.3 (9th Cir. 1997) (rejecting Medicaid changes made "for purely budgetary reasons"); *Ohio Hosp. Ass'n v. Ohio Dep't of Human Servs.*, 579 N.E.2d 695, 698 (Ohio 1991) (same); *cf. Methodist Hosps. v. Sullivan*, 91 F.3d 1026, 1030 (7th Cir.

1996). Yet, the Maine Rx Program modifies the Medicaid requirements for precisely such budgetary reasons.

The inevitable result of the Maine statute is to create a conflict with the federal Medicaid Act's mandate to provide efficient, economical and a high level of health care to needy individuals. Maine Medicaid participants will be denied the access to drugs enjoyed by the general population, because doctors will avoid prescribing drugs on the prior authorization list. Hijacking the prior authorization process in the name of lowering the costs of prescription drugs for other Maine residents violates both the Medicaid statute's purpose and text.

IV. THE MAINE RX PROGRAM VIOLATES CONGRESS'S INTENT IN PERMITTING PRIOR AUTHORIZATION.

The Maine Rx Program's prior authorization provisions also conflict with the conditions under which Congress created prior authorization. The Medicaid Act permits prior authorization only if the state also provides: (1) a response to authorization requests within twenty-four hours; and (2) the dispensing of a seventy-two-hour supply of the covered drug in emergency situations. 42 U.S.C. § 1396r-8(d)(5)(A) & (B). Although the relevant statutory provisions do not explicitly speak to *when* states may use prior authorization,[10] Congress's intent is expressed in the Conference Report

[10]The First Circuit misread the Act to allow a prior authorization for "any" purpose, because the prior authorization provision applies to "any" drug. *See* 42 U.S.C. § 1396r-8(d)(5)(A); *Pharmaceutical Research & Manuf. of America v. Concannon*, 249 F.3d 66, 76 (1st Cir. 2001); *see also Pharmaceutical Research & Manuf. of America v. Meadows*, --- F.3d ---, 2002 WL 31000006 *9 (11th Cir. September 6, 2002) (using same rationale). Permission to apply prior authorization to "any drug," however, hardly supports allowing the program for "any purpose." Thus, reference to legislative history is necessary. *See Barnhill v. Johnson*, 503 U.S. 393,402 (1992) (noting appropriateness of using legislative history when statute's intent is unclear).

which explains that: "the option of imposing prior authorization requirements with respect to covered prescription drugs [is] in order to safeguard against unnecessary utilization and assure that payments are consistent with efficiency, economy and quality of care." H.R. Rep. No. 881, 101st Cong., 2d Sess. 98 (1990).[11] The Maine Rx Program, however, is indifferent to the efficiency and economy of the Medicaid program and presents a serious threat to the "quality of care" Maine currently provides to Medicaid beneficiaries. Thus, Maine's use of prior authorization as a lever to extract lower prices for non-Medicaid populations is directly contrary to Congress's intent.

Congress's goals of avoiding over-utilization and assuring appropriate treatment are, of course, consistent with the Medicaid Act itself. The legislative history mirrors the requirements of 42 U.S.C. § 1396a(a)(30)(a) ("efficiency, economy, and quality of care"). States may, thus, only use prior authorization for purposes consistent with these criteria. The Maine Rx Program's use of prior authorization, however, directly conflicts with them.

CONCLUSION

The Maine Rx program violates the overall purpose of the Medicaid Act, Congress's intent in allowing prior authorization programs, and the best interests of Medicaid beneficiaries. Prior authorization requirements have a devastating impact on the care of Medicaid beneficiaries, many of whom are nursing home residents. Congress provided for limited use of prior authorization programs, and then only to address the equally harmful problem of improper drug utilization.

The Maine Rx Program does not employ prior authorization to protect Medicaid beneficiaries from over-utilization

[11] For example, it may be appropriate for States to subject Oxycontin, a pain medication widely recognized as being abused, to prior authorization.

or to improve the efficiency, economy, or quality of care. Instead it adopts prior authorization as a means of forcing pharmaceutical manufacturers into submitting to supplemental state rebates. Maine's purpose conflicts with Congressional intent as expressed in Medicaid's statutory requirements and its legislative history. Therefore, it violates the Supremacy Clause and must be found unconstitutional. The First Circuit's decision should be reversed.

Respectfully submitted,

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