United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 02–5110 **September Term, 2002**
01cv01453

Filed On: March 5, 2003

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,
APPELLANT

v.

TOMMY G. THOMPSON, IN HIS OFFICIAL CAPACITY AS, SECRETARY,
UNITED STATES DEPARTMENT OF HEALTH AND
HUMAN SERVICES, ET AL.,
APPELLEES

BEFORE: Edwards, Henderson, and Randolph, Circuit Judges

O R D E R

Upon consideration of federal appellees' petition for rehearing filed February 7, 2003, it is

ORDERED that the petition be granted. It is

FURTHER ORDERED that the opinion in *Pharmaceutical Research and Manufacturers of America v. Thompson*, 313 F.3d 600 (D.C. Cir. 2002), be amended as follows:

Delete the last sentence of the second paragraph, "We therefore reverse the judgment of the District Court and enter judgment for PhRMA."

Insert in lieu thereof:

The judgment is reversed and the case is remanded for entry of an appropriate judgment by the District Court.

Delete the last clause of the last paragraph of the opinion. The last paragraph of the opinion now reads:

For the aforementioned reasons, the judgment of the District Court is hereby reversed and the case remanded for entry of an appropriate judgment.

Per Curiam

FOR THE COURT:
Mark J. Langer, Clerk

BY:

Michael C. McGrail
Deputy Clerk

United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued December 5, 2002 Decided December 24, 2002

No. 02-5110

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,
APPELLANT

v.

TOMMY G. THOMPSON, IN HIS OFFICIAL CAPACITY AS,
SECRETARY, UNITED STATES DEPARTMENT OF HEALTH
AND HUMAN SERVICES, ET AL.,
APPELLEES

Appeal from the United States District Court
for the District of Columbia
(No. 01cv01453)

John G. Roberts, Jr. argued the cause for appellant. With him on the briefs were *Jeffrey Pariser* and *Darrel J. Grinstead.*

Bills of costs must be filed within 14 days after entry of judgment. The court looks with disfavor upon motions to file bills of costs out of time.

Daniel J. Popeo and *Richard A. Samp* were on the brief for *amici curiae* Washington Legal Foundation, et al., in support of appellant.

Sushma Soni, Attorney, U.S. Department of Justice, argued the cause for federal appellees. With her on the brief were *Roscoe C. Howard, Jr.*, U.S. Attorney, and *Scott R. McIntosh*, Attorney, U.S. Department of Justice.

John R. Brautigam, Assistant Attorney General, State of Maine, argued the cause for intervenor Kevin W. Concannon in his capacity as Commissioner of the Maine Department of Human Services. With him on the brief were *G. Steven Rowe*, Attorney General, and *Paul Stern*, Deputy Attorney General.

Sarah Lenz Lock, *Dorothy Siemon*, *Bruce Vignery*, and *Michael Schuster* were on the brief for *amicus curiae* American Association of Retired Persons, in support of appellee.

Before: EDWARDS, HENDERSON, and RANDOLPH, *Circuit Judges*.

Opinion for the Court filed by *Circuit Judge* EDWARDS.

EDWARDS, *Circuit Judge*: Appellant Pharmaceutical Research and Manufacturers of America ("PhRMA"), an association of drug manufacturing and research firms, challenges a Medicaid demonstration project administered by the State of Maine under the auspices of the Secretary of Health and Human Services ("Secretary" or "HHS"). Maine's program offers low-income citizens a discount on prescription drugs, which is funded in part by manufacturer rebates and in part by a 2% state subsidy. PhRMA claims that the Maine program mirrors a demonstration project that was implemented by the State of Vermont, approved by HHS, but then declared unlawful under the Social Security Act ("Act") by this court in *Pharmaceutical Research and Manufacturers of America v. Thompson*, 251 F.3d 219 (D.C. Cir. 2001) ("*PhRMA I*"). The District Court rejected PhRMA's challenge and granted summary judgment for the Secretary. *See*

Pharm. Research and Mfrs. of Am. v. Thompson, 191 F. Supp. 2d 48 (D.D.C. 2002) (Mem. Op.) ("*PhRMA II*").

The record shows that Maine's initial version of the disputed demonstration program was explicitly patterned after Vermont's program. Eugene Gessow Deposition ("Gessow Dep.") at 8, *reprinted in* Joint Appendix ("J.A.") 58. After the decision in *PhRMA I*, officials in Maine decided to modify that state's program, adding a 2% state contribution to the manufacturer rebates to avoid the fate of Vermont's program. However, this modification was never approved by the Secretary. Therefore, to the extent that the modified Maine program purports to be different from the flawed Vermont program, it has yet to be considered or approved by the federal government. The only program from Maine that the Secretary has endorsed is one identical to the Vermont program that was found unlawful by the court in *PhRMA I*. The judgment is reversed and the case is remanded for entry of an appropriate judgment by the District Court.

We have no need to consider questions about the extent to which the Secretary has authority to "regard" a state payment as a Medicaid payment; whether the 2% subsidy is sufficient to trigger the rebate obligations under the Act; or whether the Act requires that all Medicaid "payments" include federal matching funds. Until the Secretary has made clear his views on these questions, we decline to address these matters.

I. Background

Under the Social Security Act, states can develop Medicaid "pilot" or "demonstration" projects that experiment with new methods of providing health care to low-income citizens. The Secretary may approve such projects if they will "assist in promoting the objectives" of the Medicaid system. 42 U.S.C. § 1315(a) (2000). Upon granting such approval, the Secretary can waive certain federal requirements that would normally apply to traditional Medicaid programs. *Id.* § 1315(a)(1). The Secretary also has authority to "regard"

costs for a demonstration project as an "expenditure" pursuant to that state's Medicaid plan. *Id.* § 1315(a)(2).

In January 2001, the State of Maine received the Secretary's authorization to create a demonstration project for a prescription drug benefit. *See* Secretary's Approval Letter to Maine Department of Human Services (Jan. 18, 2001) ("HHS Letter"), *reprinted in* J.A. 101-03; Health Care Financing Administration Special Terms & Conditions ("Terms and Conditions"), *reprinted in* J.A. 105-21. Through its Prescription Drug Discount Program ("PDDP"), Maine gives a discount on drug purchases to a specified category of people who are not otherwise eligible for Medicaid assistance. HHS Letter at 1, J.A. 101. The State's administrators expressly patterned this demonstration project after one administered by the State of Vermont. *See* Maine Department of Human Services Proposal Letter to HHS (Jan. 5, 2001) ("Maine Proposal"), *reprinted in* J.A. 75-104 at 76; Gessow Dep. at 8, J.A. 58. A central goal of Maine's project design was to provide a prescription drug benefit without creating net costs for the State. Gessow Dep. at 8, J.A. 58; Maine Proposal, J.A. 76-77, 98. Maine thus proposed that the funding for PDDP would come from special rebates paid by drug companies. *See* Healthy Maine Prescriptions Operational Protocol ("Operational Protocol"), *reprinted in* J.A. 125-60. As a condition of participating in Medicaid, the drug companies have a duty under the Social Security Act to offer rebates so that state purchasers pay the best available rates for pharmaceutical products. *See* 42 U.S.C. § 1396r-8(b)(1)(A). Maine sought to piggyback on this requirement to fund its PDDP. Operational Protocol at 126.

On June 8, 2001, soon after Maine implemented PDDP, this court issued *PhRMA I*. The court held that Vermont's program was impermissible under the Act, because there was no "net expenditure of funds for Medicaid purposes in an amount determined independently of the amount of the rebates." *PhRMA I*, 251 F.3d at 225. The court found that the State merely acted as a "conduit" in the discount pro-

gram, recouping all of its spending from drug company rebates. *See id.* at 223.

Maine reacted to *PhRMA I* by adopting several revisions to PDDP (renamed the Healthy Maine Prescription Program). Eugene Gessow Declaration at 4-5, J.A. 68-69. The change most relevant to this appeal is the State's decision to contribute 2% of the annual costs of PDDP. Gessow Dep. at 41, J.A. 63. Maine's so-called "two-percent solution" comes from state appropriations that are not matched by federal dollars. The contribution is not mandated by state law and the amount and frequency of state contributions are not otherwise guaranteed. And, most significantly, Maine's revised program was never submitted to the Secretary for consideration or approval. *See id.* at 59-60.

PhRMA filed suit in the District Court, charging that Maine's program was illegal under the Social Security Act and, consequently, the Secretary's approval of the program was unreasonable under the Administrative Procedure Act ("APA"). *See PhRMA II*, 191 F. Supp. 2d at 51-52. Appellant first argued that because the Secretary had never approved the "two-percent solution," Maine's program was identical to the rebate scheme rejected in *PhRMA I*. Second, PhRMA claimed that even if the revisions had been authorized, the State expenditure did not qualify as a Medicaid "payment," because the amount was *de minimis* and the money was not matched by federal funding. Third, appellant claimed that the program exceeded the Social Security Act's "nominal" limits for all co-payments in state Medicaid programs. *See* 42 U.S.C. § 1396o(b)(3). Finally, PhRMA claimed that, by allowing an illegal demonstration program to proceed, the Secretary violated the terms of the APA.

On cross-motions for summary judgment, the District Court ruled against PhRMA on all counts and granted summary judgment for appellees. *PhRMA II*, 191 F. Supp. 2d at 51. The court rejected each of appellant's claims that PDDP was impermissible. The judge found *PhRMA I* distinguishable because of Maine's 2% contribution toward the prescription discount costs. *Id.* at 63. The court also determined that the Secretary had reasonably exercised his authority to approve Maine's payments "as Medicaid expenditures," which were also sufficient to trigger the manufacturer rebate re-

quirement in the statute. *Id.* at 64-66. Finally, the court found that PhRMA did not have standing to assert claims that the co-payments in Maine's program exceed the "nominal" limits set forth in the Social Security Act. *Id.* at 59-61.

PhRMA appeals the decision below and renews each of these claims.

II. Analysis

We limit our discussion to PhRMA's first argument – that the demonstration project is illegal under the Social Security Act in light of *PhRMA I*. This issue is dispositive, so we reach no other.

The District Court's decision hinges on its finding that a 2% subsidy is a part of Maine's demonstration project. This finding cannot carry the day. Under the original proposal that the Secretary approved in January 2001, the single source of revenue for the program was to be the rebate from drug companies. As *PhRMA I* holds, Maine cannot impose a rebate obligation on drug companies where neither the State nor the federal government makes a Medicaid "payment." 251 F.3d at 224-25.

Maine insists that the revised program cures the flaws uncovered in the Vermont program. This is far from clear on the record before us. Under the revised program, although Maine presently has volunteered to contribute 2% of the project's costs, this contribution is not guaranteed by state law. In other words, it is not an official component of PDDP. The amount can be changed and the contribution can be discontinued at any time. This does not appear to be meaningfully different from the Vermont program.

We need not reach this issue, however. The Social Security Act requires HHS to approve all Medicaid demonstration projects, *see* 42 U.S.C. § 1315(a). However, all parties agree that the Secretary has never formally considered or endorsed Maine's revised program that includes the 2% contribution. Therefore, the revised program is not properly before this court for review.

Appellees nonetheless claim that the "two percent solution" is consistent with the original terms that the Secretary did

approve. But the record simply does not support this argument. In reviewing Maine's program, the Secretary merely indicated that the State could not look to the federal government to cover funding shortfalls:

> If, in any quarter, the State believes subsidies are likely to exceed rebates collected, the State will not request [federal money] for the estimated difference between subsidies paid and anticipated rebates collected. The state will perform an annual reconciliation of subsidies paid and rebates received 180 days after the end of each demonstration year. The state will return to [HHS] the Federal share of any subsidies claimed in excess of applicable rebates. Rebates collected in excess of subsidies paid to pharmacies in any given year will be considered in the calculation of the pharmacy subsidy percentage for the next demonstration year.

Terms and Conditions at 11, J.A. 115. This language, which is repeated in the State's Operational Protocol, *see* Operational Protocol at 10, J.A. 134, merely affirms Maine's duty to reconcile any budgetary shortfalls if they occur in PDDP. There is nothing in the record to indicate that HHS considered and approved Maine's revised program which is founded on an unguaranteed 2% contribution.

Appellees also suggest that federal approval is implied in a June 1 letter from the Secretary that acknowledges a modification to PDDP. But the only programmatic change discussed in that document pertains to the project's scope and not its source of funding. *See* HHS Letter to Maine Dep't of Human Services (June 1, 2001), *reprinted in* J.A. 299-300 (approving a modification "to include coverage for all individuals under 300 percent of the [poverty line] – rather than for adults only – as was inadvertently approved."). This communication occurred before *PhRMA I* and Maine's revisions, and its language does not endorse a limited state contribution to assist in the funding of PDDP.

Maine's only federally approved version of PDDP mirrors Vermont's legally flawed program, *i.e.*, one in which all costs

are covered by drug discount rebates, with no required state or federal "payments" under Medicaid. This approach is clearly forbidden under the Social Security Act for the reasons stated in *PhRMA I*.

III. Conclusion

For the aforementioned reasons, the judgment of the District Court is hereby reversed and the case remanded for entry of an appropriate judgment.