UNITED STATES DISTRICT COURT

DISTRICT OF MAINE

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,	)	
PLAINTIFF	)	
v.	)	**Civil No. 00-157-B-H**
COMMISSIONER, MAINE DEPARTMENT OF HUMAN SERVICES, ET AL.,	)	
DEFENDANTS	)	

ORDER ON MOTION FOR PRELIMINARY INJUNCTION[1]

When prescription drugs are covered by insurance or Medicaid, volume buying produces substantially lower prices. But when a private citizen purchases on his or her own, the price is much higher.[2] The Maine Legislature has become concerned over these high prescription prices for Maine citizens. It decided that by using Maine's leverage as a large scale purchaser of drugs in the Medicaid market, it could help these people by requiring manufacturers to provide lower

[1] The Motion by Maine Council of Senior Citizens and Viola Quirion for Leave to File a Brief of Amicus Curiae in Opposition to Plaintiff's Motion for a Preliminary Injunction is **GRANTED** by agreement.

[2] A minority staff report for the U.S. House Committee on Government Reform and Oversight says that the average retail price is 86 percent higher for the elderly than the price charged to the federal government and most favored customers like HMOs. Minority Staff Report, Prescription Drug Pricing in the 1st Congressional District of Maine: Drug Companies Profit at the Expense of Older Americans, Committee on Government Reform and Oversight, U.S. House of Representatives, prepared for Rep. Thomas H. Allen, Oct. 9, 1998, at 8.

prices for them as well. To that end, the Legislature passed L.D. 2599 and the Governor signed it on May 11, 2000.

The Maine legislation does three things that are challenged in this case: (1) it prohibits profiteering and excessive pricing by drug manufacturers, and creates extensive civil penalties to enforce the prohibition; (2) it prohibits manufacturers from altering their distribution schemes so as to escape the Maine law; and (3) it orders the Commissioner of Human Services to negotiate with the drug manufacturers (all of whom are out-of-state) to provide a rebate every time an uninsured Maine citizen buys a prescription at a pharmacy in Maine. Any manufacturers' rebates go into a new state fund, the Rx Fund. Qualifying Maine citizens purchase their prescription medications from Maine pharmacies at a mandated discount; and the manufacturers' rebates in the Rx Fund reimburse the pharmacies for what they have lost. The incentive to make the manufacturers cooperate is the following: the names of those manufacturers who do not participate are to be made public; and their drugs are to be put on a special listing in Maine's Medicaid program, such that prior authorization will be required before those drugs will be approved for any Medicaid reimbursement.[3]

The plaintiff, an association representing drug manufacturers that account for over 75% of brand name drug sales in the United States, has challenged the

[3] The Commissioner has proposed a regulation by which the Maine Medicaid Drug Utilization Committee would review any drug slated to go on such a listing. The Committee could then exempt, for medical reasons, specified drugs from the prior authorization requirement. See Proposed Rule: Rules of the Dep't of Human Servs., § 15, Maine Rx Program (2000).

Maine legislation on the grounds that it violates the interstate Commerce Clause and is preempted by the federal Medicaid statute.[4] On October 19, 2000, I heard a motion for a preliminary injunction.

My conclusion: The Maine Legislature has sound reasons for wanting to assist its uninsured citizens who must cope with astronomical prescription drug prices. But in our country, under our Constitution, states cannot legislate outside their boundaries. Whatever power Maine may have over in-state pharmacies, it cannot legislate the amounts that out-of-state manufacturers obtain when they sell to pharmaceutical wholesalers or distributors out-of-state. That is what Maine has tried to do here, in a roundabout way, but the interstate Commerce Clause will not permit it. As for the small proportion of transactions where the manufacturers sell directly into Maine, the rebate program conflicts with the federal Medicaid program and is therefore preempted. As a result, I find that the plaintiff is entitled to a preliminary injunction preventing the enforcement of essential parts of the Maine legislation.

ANALYSIS

1. Maine's Prohibition on Unconscionable Prices and Unreasonable Profits. The statute makes it "illegal profiteering" for a manufacturer to "exact[] or demand[] an unconscionable price" or to "exact[] or demand[] prices or terms that lead to any unjust or unreasonable profit." An Act to Establish Fairer Pricing

[4] The defendants have not challenged the plaintiff's standing to bring this constitutional challenge.

for Prescription Drugs, § 2697(2), 2000 Me. Legis. Serv. 786 (S.P. 1026) (L.D. 2599) (West) (to be codified at 22 M.R.S.A. § 2697(2)). It is undisputed on the record before me that all the drug manufacturers represented by the plaintiff are located outside the State of Maine, Bantham Decl. ¶ 6, and that by far the greater bulk of their customers—wholesalers and distributors—are likewise outside Maine. There are limited exceptions. Hannaford Bros. Co., located in Maine, buys directly from Roxane Laboratories, Inc. and Boehringer Ingelheim Pharmaceuticals, Inc.; Bindley Western Drug Company, a distributor, has a subsidiary, J.E. Goold, that is located in Maine; and Progressive Distributors, Inc., another distributor, has a facility in Maine. Bilyk Decl. ¶ 5; Feldman Decl. ¶ 8. Under the contracts with these companies, however, the sale from the manufacturer always occurs at the place of business outside Maine—with the exception of Hannaford Bros. Co.[5] In other words, Bindley Western and Progressive Distributors go to other states to buy their products, then import them into Maine.

Where the manufacturers' sales occur outside of Maine, Maine has no authority to regulate the revenues obtained by the manufacturers. Maine's statutory prohibition on profiteering or excess pricing in such transactions is simply unenforceable. I set forth the caselaw concerning extraterritorial legislation in section (3) below.

[5] It appears that title passes in Maine in the case of Roxane and Boehringer sales to Hannaford Bros., Feldman Decl. ¶ 7, and Pfizer, Inc. sales pursuant to the Federal Supply Schedule. McPhillips Decl. ¶ 7. The record does not disclose whether any Pfizer sales under the Federal Supply Schedule would be subject to the Maine Rx rebate program.

2. The Prohibition on Retaliation. The statute makes it "illegal profiteering" for a manufacturer to "[i]ntentionally prevent[], limit[], lessen[] or restrict[] the sale or distribution of prescription drugs in this State in retaliation for the provisions" of the law. Act, § 2697(2)(D), 2000 Me. Legis. Serv. 786 (West) (to be codified at 22 M.R.S.A. § 2697(2)(D)). Obviously, manufacturers might enter Maine and undertake activities that would fall under this provision. The plaintiff wants me to declare, however, that if the manufacturers merely alter their distribution channels out-of-state, they cannot be held liable under this provision. Although that seems to be a reasonable conclusion, it is unnecessary and inappropriate for me to rule at this time. See Ernst & Young v. Depositors Econ. Protection Corp., 45 F.3d 530, 538 (1st Cir 1995) (noting that courts should avoid answering hypothetical questions); National Conference of Catholic Bishops v. Smith, 635 F.3d 535, 540 (1st Cir. 1981) (observing that court will not speculate and will not decide dispute without sufficient facts). I have no specific actions by manufacturers on which to base such a ruling, and a Maine court might construe this portion of the statute in a narrow way that would avoid any constitutional issue.

3. The Rebate Program.

(a) The Commerce Clause.

Under the United States Constitution, Article I, section 8, Congress has the power "[t]o regulate commerce with foreign nations, and among the several states, and with the Indian tribes." U.S. Const. art. I, § 8, cl. 3. The question is

whether Maine has intruded on this Congressional power.

(i) Market Participation. The State argues that I need not reach the constitutional issue concerning its rebate program. It says that it is not really legislating or regulating, but simply exercising its market power as a volume purchaser of prescription medicines in the Medicaid program.[6] The Supreme Court has held that when a state participates in the market as a buyer or seller rather than as a regulator, it is not subject to the restrictions of the interstate Commerce Clause. Instead, as it said in a case that originated in Maine, Supreme Court cases "stand for the proposition that . . . 'under the dormant Commerce Clause, a State acting in its proprietary capacity as a purchaser or seller may "favor its own citizens over others."'" Camps Newfound/Owatonna, Inc. v. Town of Harrison, Maine, 520 U.S. 564, 592-93 (1997); accord National Foreign Trade Council v. Natsios, 181 F.3d 38, 64 (1st Cir. 1999).[7]

But the "citizen favoring" the Supreme Court has allowed states to indulge in, when they are market participants, has always been in the actual transaction—

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[6] Under 42 U.S.C. § 1396r-8(a)(1), manufacturers must enter into a rebate agreement with the federal government or individual states in order for their drugs to be covered under the Medicaid program. See 42 U.S.C.A. § 1396(b) (West 1992). According to the agreement, a manufacturer provides a rebate to the states each quarter based on information submitted by the states for the amount of drugs paid for under Medicaid. 42 U.S.C.A. § 1396r-8(1)(A). The amount of the rebate is calculated by a formula in the statute, which incorporates the manufacturer's submission of its average manufacturer price and best price for the covered drugs. 42 U.S.C.A. § 1396r-8(c). In addition, the drug rebate program allows states to require that certain drugs be approved before physicians may dispense them, see n.12 infra, and requires states to conduct drug review prospectively and retrospectively. 42 U.S.C.A. § 1396r-8(d), (g).

[7] This unfortunate terminology—"dormant Commerce Clause"—refers to Supreme Court cases holding that even where Congress has not used its interstate commerce power to legislate on a particular subject (hence, "dormant" or "negative"), states are not free to intrude in ways that burden commerce. Justice Scalia has noted his disagreement with the principle, General Motors Corp. v. Tracy, 519 U.S. 278, *(continued on next page)*

Boston limiting its construction projects to firms that employ 50% Boston residents on those projects, White v. Massachusetts, 460 U.S. 204, 206, 215 (1983); South Dakota selling its cement only to South Dakota residents, Reeves, Inc. v. Stakes, 447 U.S. 429, 440 (1980); Maryland purchasing junked cars from its residents with less paper documentation than from out-of-staters, Hughes v. Alexandria Scrap Corp., 426 U.S. 794, 809-10 (1976). None of the cases supports extending this market power to other activities. Here, Maine is not favoring its citizens in the actual transaction when it buys prescription drugs in the Medicaid program. (An example of permitted favoritism would be buying only from Maine manufacturers, if there were any.) Instead, it is trying to use its leverage there to achieve a social, regulatory goal elsewhere—to reduce the price of prescription medications for Maine citizens who do not participate in Medicaid and who do not have private insurance.[8] That is a worthy legislative goal, but it is not the kind of market participation that the Supreme Court has freed from interstate commerce power limits. In fact, the Supreme Court struck down Alaska's attempt to sell its timber only to customers who would also agree to process the purchased timber in Alaska, South-Central Timber Dev., Inc. v. Wunnicke, 467 U.S. 82, 96-98 (1984), finding the program to be tantamount to regulation.[9] The

312-14 (1997), but it remains good law.

[8] According to the statute, "the State shall serve as a pharmacy benefit manager. . . ." Act, § 2681, 2000 Me. Legis. Serv. 786 (West) (to be codified at 22 M.R.S.A. § 2681). The State does not, however, buy the drugs. If it did, the analysis and result might be different.

[9] The Court also struck down Wisconsin's refusal to make any state purchases from repeat labor law violators, Wisconsin Dep't of Industry, Labor & Human Relations v. Gould, Inc., 475 U.S. 282, 289 (1986), on the same ground, that it was in fact a regulatory measure.

Supreme Court reasoned that Alaska was impermissibly trying to use its leverage in the timber market, where it was a participant, in order "to exert a regulatory effect in the processing market, in which it is not a participant." 467 U.S. at 98. Likewise here, Maine is using its leverage in the Medicaid market, where it is a participant, to exert a regulatory effect in the uninsured market for prescription drugs, in which it is not a participant. As the First Circuit has observed (quoting approvingly from the Wunnicke plurality decision): "the market participant 'doctrine is not carte blanche to impose any conditions that the State has the economic power to dictate, and does not validate any requirement merely because the State imposes it upon someone with whom it is in contractual privity.'" National Foreign Trade Council, 181 F.3d at 63. As a result, Maine's Rx program cannot escape interstate Commerce Clause limitations.

(ii) Constitutionality. Treating the rebate program as an exercise of Maine's regulatory or police power, then, I must decide whether it is constitutional. First, the State is correct that this is not the typical attempt to favor in-state businesses over out-of-state businesses. There are no Maine drug manufacturers, and no suggestion on this record that Maine is in the process of trying to establish a favorable environment to bring them here. Instead, the rebate program applies to any manufacturer, whether or not it is from Maine. Maine is trying to benefit its residents, specifically those who are uninsured, in the purchase of prescription

medicines; but it is not trying to better their lot over out-of-staters.[10] So the question is not whether Maine is discriminating against out-of-staters, but simply whether it has the power to extend its authority to out-of-state manufacturers. I conclude that the answer for most transactions is "no," on bedrock principles concerning the territorial limits of a state's power established by the Supreme Court at least as far back as 1935.

In Baldwin v. G.A.F. Seelig, Justice Cardozo wrote:

> 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 at low ones. This again is not disputed.

294 U.S. 511, 521 (1935). If we change the names of the states, and substitute prescription medications for milk, the statements are equally applicable here to distributors that acquire prescription drugs outside the state of Maine before they bring them here. Maine may have power over what pharmacists later do here in Maine, or over the few distributors who transact business in Maine, but it has no power to regulate the prices paid earlier in transactions in other states. The Supreme Court reiterated these principles as recently as 1989:

> Taken together, our cases concerning the extraterritorial effects of state economic regulation stand at a minimum for the following propositions: First, the "Commerce

[10] Of course, if the drug manufacturers are unwilling just to give up their profits, any lowering of prices to uninsured Maine consumers will have to result in an increase somewhere else—prices to out-of-state buyers, or in Maine's Medicaid program, or in insured purchases.

> 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,". . . . Second, 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.

Healy v. Beer Institute, 491 U.S. 324, 336 (1989) (internal citations omitted). It is undisputable that the practical effect of what Maine has done here is to limit the revenue an out-of-state manufacturer can obtain when it sells drugs to out-of-state distributors that ultimately send or bring the drugs to Maine. Under the Maine rebate program, whatever price the manufacturer originally received for that out-of-state transaction is automatically reduced when the drug comes to Maine. Because Maine has no power thus to extend its power extraterritorially and to impose this burden on interstate commerce, it is irrelevant whether its program actually discriminates against out-of-staters. Brown-Forman Distillers Corp. v. New York State Liquor Auth., 476 U.S. 573, 579 (1986) (stating that state statutes are struck down if they favor in-state economic interests over out-of-state, *or* if they discriminate against interstate commerce *or* if they simply regulate interstate commerce directly, whether or not they discriminate). Accord Edgar v. MITE Corp., 457 U.S. 624, 644 ("Insofar as the Illinois law burdens out-of-state transactions, there is nothing to be weighed in the balance to sustain the law."); Laurence H. Tribe, American Constitutional Law § 6-8 (3d ed. 2000).

(b) Supremacy Clause. The plaintiff manufacturers concede that the Commerce Clause limitations on Maine's power to legislate outside its borders do not prevent Maine from regulating sales to Maine-based distributors (*e.g.*, Hannaford Bros., J.E. Goold, Progressive Distributors). Instead, I must decide whether the federal Medicaid program invalidates Maine law as to such transactions by virtue of the Supremacy Clause.

Under Article VI of the United States Constitution,

> This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land, and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

U.S. Const. art. VI. There is no question that Congress has legislated an extensive and detailed federal Medicaid program. But nowhere has it expressly forbidden what Maine has done.[11] The Supremacy Clause issue, therefore, is whether there is "implied" preemption on the basis that Maine's legislation is inconsistent with Medicaid's objectives. This inquiry boils down to a question of Congressional intent. See Pacific Gas v. State Energy Resources Conserv. & Dev. Comm'n, 461 U.S. 190, 203-04 (1983); Massachusetts Ass'n of HMOs v. Ruthhardt, 194 F.3d 176, 178 (1st Cir. 1999); O'Brien v. Massachusetts Bay Trans. Auth., 162 F.3d 40, 43 (1st Cir. 1998).

[11] Congress recognizes the existence of prior authorization programs for prescription drugs and specifies two requirements: (1) a 24-hour response to any request for authorization; (2) a 72-hour emergency supply where authorization is unavailable. 42 U.S.C.A. § 1396r-8(d)(5) (West 1992). Maine *(continued on next page)*

"Preemption may, of course, be inferred from the goals of a federal statute." French v. Pan Am Express, Inc., 869 F.2d 1, 5 (1st Cir. 1989). The purposes of the federal Medicaid program are straightforward: to provide medical services, including prescription drugs, 42 C.F.R. §§ 456.702-3 (West 2000), to those with medical needs who qualify under Medicaid's eligibility standards. 42 U.S.C.A. § 1396 (West 1992); Mayburg v. Secretary of Health & Human Servs., 740 F.2d 100, 103 (1st Cir. 1984) (noting the general principle that the Social Security Act should be broadly construed "to carry out Congress's intent to provide medical expense coverage for all qualifying individuals"). To that end, Congress has demanded that any state restriction on drug distribution "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 Medicaid's requirements.*" 42 U.S.C.A. § 1396c(a)(19) (West 1992) (emphasis added). Nowhere has Congress suggested that the federal Medicaid program can be used to further the interests of *non*-Medicaid recipients. Maine asserts that under its proposed regulations Maine will comply with federal requirements; that the "Department of Human Services will not deny a single Medicaid recipient access to the safest and most efficacious prescription drug therapy indicated for their individual medical circumstances." Def. Mem. in Opp'n to Mot. for Prelim. Inj. at 29. But Maine can point to no *Medicaid* purpose in this new prior authorization requirement that Maine has added for Medicaid prescription drugs. Maine has not just passed a law that

satisfies both requirements. See Code Me. R. §§ 80.07-3-80.07-4 (1979).

might conflict with the objectives of a federal law. It has actually taken the federal Medicaid program and altered it to serve Maine's local purposes. If Maine can use its authority over Medicaid authorization to leverage drug manufacturer rebates for the benefit of uninsured citizens, then it can just as easily put the rebates into a state program for highway and bridge construction or school funding. All these purposes are outside the scope of the federal Medicaid program. No matter how modest an obstacle the new prior authorization amounts to (the parties disagree on the severity of the obstacle), it is an obstacle—drugs on the list must be approved by the state Medicaid Medical Director before they can be dispensed or prescribed—and therefore "an obstacle to the accomplishment and execution of the Congressional objectives of federal Medicaid." See Pacific Gas, 461 U.S. at 402-03; Ruthhardt, 194 F.3d at 178; Beckley Capital Ltd. P'ship v. DiGeronimo, 184 F.3d 52, 56 (1st Cir. 1999); O'Brien, 162 F.3d at 43.[12] The Supremacy Clause prevents Maine from diverting the Medicaid

[12] It may never have occurred to Congress that the Medicaid program could be hijacked to provide leverage for other purposes. Instead, the legislative history reveals that Congress contemplated prior authorization only in narrow circumstances: "As under current law, States would have the option of imposing prior authorization requirements with respect to covered prescription drugs in order to safeguard against unnecessary utilization and assure that payments are consistent with efficiency, economy, and quality of care." H. Rep. No. 101-881 at 98 (Oct. 16, 1990), reprinted in 1990 U.S.C.C.A.N. 2016-1, 2110. Maine's Rx rebate program has nothing to do with these concerns of unnecessary use of prescription drugs or with safeguarding Medicaid payments.

The Secretary (here, HCFA) has not promulgated a final regulation on prior authorization, see 65 Fed. Reg. 22802, 22805 (Apr. 24, 2000), and therefore I do not apply Chevron analysis under Visiting Nurses Ass'n of North Shore, Inc. v. Bullen, 93 F.3d 997, 1006-09 (1st Cir. 1996). See Goodlin v. Medtronic, Inc., 167 F.3d 1367, 1375 n.15 (11th Cir. 1999) (refusing to give the FDA's proposed rule any authoritative weight or deference); Public Citizen, Inc. v. Shalala, 923 F. Supp. 13, 18 n.6 (D.D.C. 1996) (noting that "tentative conclusion articulated in a nonfinal proposed rules does not command deference from the Court nor is it binding on the agency"). But see Vanscoter v. Sullivan, 920 F.2d 1441, 1445 (9th Cir. 1990) (deferring to agency interpretation expressed in a proposed rule). A comment (comments are

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program to this other objective, however worthy an objective it may be.

(c) Voluntariness. The State has not argued directly that its rebate/Rx program is voluntary and therefore not to be considered a forbidden exercise of state power. But there is the flavor of such an argument—that this is all just a matter of negotiation with the Commissioner—and I therefore address it. Is negotiation and participation in the rebate program simply a voluntary decision that out-of-state manufacturers make for the greater good? If public listing of those refusing to negotiate with the Commissioner were the only incentive, I would find no serious constitutional issue. Nothing prevents a state from seeking voluntary largess from companies, even out-of-state companies, and then publicly recognizing them for their civic-mindedness or publicly stigmatizing those who do not participate for their lack of civic-mindedness. There is likewise no prohibition on the Commissioner merely negotiating with companies to try to persuade them to take action that will lower the prices to Maine citizens. Instead, the bite here—if there is any—is the new condition that drugs of an uncooperative manufacturer require prior approval before they can qualify for Medicaid reimbursement. Indeed, the statute says that manufacturers "shall enter" into rebate agreements and speaks of negotiating the "rebate *required* from a manufacturer." Act, § 2681(3), (4), 2000 Me. Legis. Serv. 786 (2000) (to be

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not entitled to deference, Visiting Nurses Ass'n, 93 F.3d at 1007) concerning the proposed regulation does support the proposition that prior authorization can be used for clinical or economic purposes and refers approvingly to a state seeking a larger rebate. Medicaid Program: Payment for Covered Outpatient Drugs Under Drug Rebate Agreements with Manufacturers, 60 Fed. Reg. 48442, 48473 (Sept. 19, 1995). But there is *no* suggestion that HCFA was discussing anything other than a larger rebate that would *(continued on next page)*

codified at 22 M.R.S.A. § 2681(3), (4)) (emphasis added).[13] It is only common sense to conclude that the requirement has been put in the legislation because the Legislature thought it would create *some* bite to give the Commissioner negotiating leverage for the Rx rebate program. The State makes no argument that the new condition of prior approval serves any purpose of the Medicaid program.[14] And the State has not contested the plaintiff's affidavits that a prior authorization listing often results in substantially reduced market share for a manufacturer. See e.g., Moules Aff. ¶¶ 7, 9-14; Bilyk Decl. ¶ 6. It is, therefore, not a voluntary program.

But only the prior approval requirement creates the coercion that makes the rebate/Rx program unconstitutional. If the State wants to continue the program as a voluntary program with public stigma being the only incentive, it may do so.

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benefit the *Medicaid* program.

[13] The L.D. that was ultimately enacted came from Senate Amendment A of May 11, 2000, to S.P. 1026, L.D. 2599. According to the Senate Amendment "A" Summary, the amendment "directs the department to require prior authorization for the dispensing of drugs in the Medicaid program that are provided from manufacturers and labelers who do not enter into rebate agreements with the State under the Maine Rx Program." ¶ 6.

[14] Instead, the Medical Director for the Maine Bureau of Medicaid Services, which administers Maine's Medicaid Program, states that the "primary purpose of a prior authorization requirement is to ensure that a drug is not being used inappropriately" and is not designed "to limit the use of that drug." Clifford Aff. ¶¶ 6, 7. Indeed, the Commissioner has recently proposed a regulation to make clear that medically necessary drugs will still be approved and in some instances may even escape the prior authorization requirement despite a manufacturer's failure to negotiate a rebate. See Proposed Rule: Rules of the Dep't of Human Servs., § 15, Maine Rx Program (2000) (to be codified at Code Me. R. § 15). The reason for this narrowing of the program is apparently to forestall Medicaid challenges and, according to the Assistant Attorney General at oral argument, to recognize that the Department is directed to "impose prior authorization requirements in the Medicaid program under this title, *as permitted by law* . . . ." Act, § 2681(7), 2000 Me. Legis. Serv. 786 (West) (to be codified at 22 M.R.S.A. § 2681(7)) (emphasis added).

CONCLUSION

For purposes of the preliminary injunction motion, the record is essentially undisputed. On that record, I find the plaintiff's likelihood of success on the merits of most of its constitutional challenges to be overwhelming. That being so, the State's interest in forestalling the preliminary injunction is weak. The State has a strong interest in assisting its economically and medically needy citizens, but not through unconstitutional legislation. The public interest is the same. The plaintiff's interest is strong because, under the Eleventh Amendment manufacturers would be unable to recover payments they made to the State, and by entering the rebate agreements, may be submitting themselves contractually to an obligation, regardless. Accordingly, the plaintiff is entitled to a preliminary injunction, see Philip Morris, Inc. v. Harshbarger, 159 F.3d 670, 673-74 (1st Cir. 1998); Ross-Simons of Warwick, Inc. v. Baccaral, Inc., 102 F.3d 12, 15 (1st Cir. 1991). No security is appropriate under Fed. R. Civ. P. 65(c), and the State has not requested security.

The Commissioner is hereby **PRELIMINARILY ENJOINED** from penalizing manufacturers, by placing their drugs on prior listing status, for refusing to negotiate or to pay a rebate to Maine's Rx program.

The Attorney General is hereby **PRELIMINARILY ENJOINED** from seeking to enforce the illegal profiteering portion of the statute against transactions that occur outside the State of Maine, even if the prescription drugs eventually end up and are ultimately purchased in Maine.

SO ORDERED.

DATED THIS 26TH DAY OF OCTOBER, 2000.

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D. BROCK HORNBY
UNITED STATES DISTRICT JUDGE

U.S. District Court
District of Maine (Bangor)
Civil Docket For Case #: 00-CV-157

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v.	
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ATTORNEY GENERAL, MAINE defendant	PAUL STERN, ESQ. ANDREW S HAGLER (See above)

MAINE COUNCIL OF SENIOR CITIZENS Interested Party	ARN H. PEARSON, ESQ. MAINE CITIZEN LEADERSHIP FUND ONE PLEASANT STREET PORTLAND, ME 04101 (207) 780-8657
VIOLA QUIRION Interested Party	ARN H. PEARSON, ESQ. (See above)