STATEMENT OF SUBJECT MATTER AND APPELLATE JURISDICTION

This appeal is from an interlocutory order entered on October 26, 2000 (the "Order"), granting preliminary injunctive relief in an action challenging a State statute which establishes a pharmaceutical benefit program (the "Maine Rx Program"). Jurisdiction in the district court is pursuant to 28 U.S.C. §§ 1331 and 1343. Jurisdiction on appeal is pursuant to 28 U.S.C. § 1292(a)(1). Notice of Appeal was filed on November 8, 2000.

STATEMENT OF ISSUES PRESENTED

1) Whether the plaintiffs have standing to mount a Supremacy Clause challenge to the Act.

2) Whether the district court erred in holding that plaintiff is likely to succeed on the merits of its claim that the rebate provision of the Act violates the dormant Commerce Clause.

3) Whether the district court erred in holding that plaintiff is likely to succeed on the merits of its claim that the "prior authorization" provision of the Act is preempted by federal law.

4) Whether the district court erred in finding that the plaintiff will suffer irreparable harm without a preliminary injunction, and that the "balance of equities" and "public interest" prongs of the preliminary injunction test weigh in favor of granting preliminary injunctive relief.

STATEMENT OF THE CASE

Plaintiff, Pharmaceutical Research and Manufacturers of America ("PhRMA") commenced this action in the District Court for the District of Maine on August 11, 2000, challenging the constitutionality of certain provisions of the newly adopted "Act to Establish Fairer Pricing for Prescription Drugs," 2000 Me. Legis. Ch. (S.P. 1026) (L.D. 2599) (West) (the "Act"). Plaintiff also moved for an order preliminarily enjoining enforcement of the provisions of the Act which it claims violate the Commerce Clause and Supremacy Clauses of the United States Constitution.

On October 26, 2000, the district court entered an order preliminarily enjoining the Commissioner of the Department of Human Services from implementing the prior authorization provision of the Act, 22 M.R.S.A. § 2681(7) (Add. 21).[1] The district court also preliminarily enjoined the Attorney General from enforcing another portion of the Act which prohibits profiteering in prescription drugs in transactions occurring outside of the State of Maine. 22 M.R.S.A. § 2697 (App. A-032).

[1] References to the Addendum are abbreviated as "Add"; references to the Appendix as "App."

Defendants appeal from the district court's Order only insofar as it enjoins the Commissioner from implementing the prior authorization provision of the Act.[2]

STATEMENT OF FACTS

The Problem Addressed By The Act

The Maine Rx Program was created to promote and protect the overall health of Maine's citizens. 22 M.R.S.A. § 2681(1) (Add. 18). The legislative impetus for creating this program was the high price of prescription medication in Maine and the disproportionate price charged to citizens without insurance as compared to the price charged for the very same medication when purchased by other Maine residents through private or public insurance plans. An estimated 325,000 Maine residents lack prescription drug coverage. *Concannon Aff.* ¶ 3 (App. A-144). Out-of-pocket sales of medicine accounted for 48.1 percent of all drug expenditures in Maine in 1996. Amanda McCloskey, *Cost Overdose: Growth in Drug Spending for the Elderly,* Families USA Foundation, July 2000, at 10. Persons who pay cash for prescription drugs pay the highest per-unit price because they do not have the market power to negotiate a lower price with manufacturers. *Order* at 1 (Add. 1). A few examples are both revealing and disturbing.

[2] By doing so, the State does not waive its right to defend the profiteering provisions of the Act in the district court.

Faced with the highest prescription drug prices in the market, the uninsured respond in a variety of ways. Many travel to Canada, where drug prices are, on average, 37 percent less than in Maine. Alan Sager, Deborah Socolar*, Cutting Prescription Drug Spending By Paying Federal Supply Schedule Prices,* Northeast Legislative Association on Prescription Drug Pricing, Boston University School of Public Health, August 5, 2000, at 10; Diana Graettinger, *Border doctors offer prescription relief – Seniors go to great lengths for less expensive medications*, Bangor Daily News, Sept. 5, 2000, at A1. Others choose between buying food and buying medicine. Congressional Report, *supra,* at 4, *citing Worthless Promises, Drug Companies Keep Boosting Prices,* Families USA Foundation, Mar. 1995, at 6, *and also citing A Status Report – Accessibility and Affordability of Prescription Drugs For Older Americans,* Senate Special Committee on Aging, 102d Congress., 2d Sess. 2(1992) (S. Rpt. 100). Some patients skip doses or split pills; others do not fill their prescriptions at all. *Id. at 16. See also* Soumerai, *supra*, 340 NEJM at 723.

Confronted with these disturbing truths, Maine established the Maine Rx Program "to make prescription drugs more affordable for qualified Maine residents, thereby increasing the overall health of Maine residents, promoting healthy communities and protecting the health and welfare." 22

M.R.S.A. § 2681(1) (Add. 18). The examples noted above amply support the legislative findings that:

> Many Maine citizens are admitted to or treated at hospitals each year because they can not afford the drugs prescribed for them that could have prevented the need for hospitalization. Many others must enter expensive institutional care settings because they can not afford their necessary prescription drugs that could have supported them outside of an institution. All Maine citizens are threatened by the possibility that when they need medically necessary prescription drugs most they may be unable to afford their doctor's recommended treatment.

1999 Me. Laws, ch. 786, § A-5 (App. A-034).

The Maine Rx Program

Under the Maine Rx Program, participating pharmacies will offer discounted prices for drugs purchased by Maine residents who are not covered by private insurance or Medicaid, the joint federal-state health insurance program for the poor. The discount offered by these pharmacies will be reimbursed by the State, and will be funded on a continuing basis through the collection of rebate payments from participating drug manufacturers. 22 M.R.S.A. § 2681 (Add. 18).

The Act directs the Commissioner of the Department of Human Services (the "Department") to negotiate rebate agreements similar to those required of manufacturers participating in the Maine Medicaid outpatient drug program. 22 M.R.S.A. § 2681(4) (Add. 19). Under these agreements, the rebate is triggered by the retail sale of the manufacturer's drugs through a participating

pharmacy to an enrollee in the Maine Rx Program. Actual rebate payments are made quarterly on the basis of retail sales records for that quarter. 22 M.R.S.A. § 2681(3) (Add. 19). The first rebate payments for drugs dispensed through the new program will be due after September 30, 2001. *Concannon Aff.,* ¶ *5* (App. A-144; A-150).

The Act instructs the Department to publicly identify those manufacturers that refuse to participate in the Maine Rx Program, and to "impose prior authorization requirements in the Medicaid program…as permitted by law, for the dispensing of prescription drugs provided by those manufacturers." 22. M.R.S.A. § 2681(7) (Add. 21). If a drug is subjected to a "prior authorization requirement," the Medicaid administrator must give its approval before that drug may be dispensed to a Medicaid recipient. Medicaid specifically authorizes States to impose prior authorization requirements.[3] 42 U.S.C. § 1396r-8(d)(1)(5). Indeed, any and all drugs offered through a State's Medicaid outpatient drug program may be subjected to a prior authorization requirement. *Id.*

[3] A state is not required to offer an outpatient drug benefit as part of its general Medicaid program. 42 U.S.C. § 1396a(a)(54).

Plaintiff's Claims

PhRMA is a trade "association representing drug manufacturers that account for over 75 percent of brand name drug sales in the United States." *Order* at 2 (Add. 2). PhRMA's manufacturer members are located outside of Maine, and, with limited exceptions, apparently sell their drugs to out-of- state distributors which, in turn, transport the drugs into Maine. *Id.* at 4 (Add. 4).

PhRMA challenged the provision of the Act which requires that the drugs of a manufacturer that fails to enter into a rebate agreement shall be placed on a Medicaid prior authorization list "as permitted by law." 22 M.R.S.A. § 2681(7) (Add. 21). Plaintiff claims that placing a drug on a prior authorization list is generally detrimental to the sales of that drug. *Bilyk Aff.,* ¶¶ 6-8 (App. A-058,59). This is so because other comparable drugs manufactured by competing companies are often available within the same therapeutic class, and physicians shift their prescribing behavior towards equivalent drugs not subject to prior authorization. *Id.* According to the plaintiff, the prior authorization provision of the Act conflicts with the purposes of, and is preempted by, the federal Medicaid statute.

Plaintiff also challenged the rebate mechanism of the Maine Rx Program, alleging that the requirement to pay rebates runs afoul the "dormant" Commerce Clause.

The District Court's Decision

The district court preliminarily enjoined enforcement of the prior authorization provision of the Act. The court's decision is based almost exclusively on its consideration of the likelihood of success of plaintiff's constitutional challenge.

The district court rejected the State's argument that the rebate program is not subject to Commerce Clause scrutiny because it relies on market power rather than the State's regulatory authority. While the court recognized that the Maine Rx Program relies only upon Maine's power as the administrator of the State's Medicaid Program, it disagreed that this is an exercise of the "kind of market participation that the Supreme Court has freed from interstate commerce power limits." Order at 7 (Add. 7).

Turning to the merits of the Commerce Clause argument, the district court held that the Act runs afoul of the "dormant" Commerce Clause, even though it does not discriminate against interstate commerce. Order at 8 (Add. 8). In the court's view, the rebate scheme directly regulates out-of-state transactions between manufacturers and wholesalers. Order at 10 (Add. 10).

The district court also held that plaintiff will likely succeed on the merits of its claim that the prior authorization provision of the Act is preempted by Medicaid. Finding no express preemption language precluding what Maine has

here attempted, the court nonetheless determined that imposing prior authorization requirements on nonparticipating manufacturers conflicts with the goals of Medicaid. Order at 12 (Add. 12). This is so, said the court, because no Medicaid purpose is advanced by requiring approval of the Medicaid administrator before a drug is dispensed to a Medicaid recipient. *Id* (Add. 10).

The district court relegated its discussion of the "irreparable harm," "balance of equities," and "public interest" prongs of the preliminary injunction test to the conclusion section of its Order. The court simply noted that without a preliminary injunction, "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." Order at 15 (Add. 15).

The lower court plainly agreed that there is a strong public interest in helping "economically and medically needy" citizens obtain relief from high drug prices. Order at 15 (Add. 15). However, the court declined to separately weigh this interest against those of the plaintiff. Instead, it simply folded its merits analysis into its consideration of the other prongs of the preliminary injunction test, noting merely that the State can have no interest in advancing its legitimate goals "through unconstitutional legislation." Order at 15 (Add. 15).

STANDARD OF REVIEW

On appeal from an order granting a preliminary injunction, "pure issues of law (e.g., the construction of a statute) are reviewed *de novo*, findings of fact for clear error, and 'judgment calls' with considerable deference depending upon the issue." *Langlois v. Abington Housing Authority*, 207 F.3d 43, 47 (1st Cir. 2000) (internal citations omitted). Here, the district court's merits analysis raises pure issues of constitutional law and is reviewed de novo. Likewise, the court's finding that plaintiff will suffer irreparable harm because a Maine Rx Program rebate agreement would be enforceable even if the statute is ultimately struck down, is a matter of contracts law and is reviewed *de novo*. The district court's manipulation of the balance of equities and public interest prongs of the criteria is reviewed for an abuse of discretion.

SUMMARY OF ARGUMENT

Plaintiff lacks standing to bring its challenge to the prior authorization provision of the Act. Medicaid was intended to advance the interests of medically and financially needy persons, not the financial interests of drug manufacturers. Plaintiff's members therefore stand outside of the zone of interests the federal statute was intended to protect. Without a protected interest of its own, plaintiff lacks standing to assert that the Act will deprive Medicaid recipients of medically necessary drugs.

Even if plaintiff has standing, the district court erred in concluding that the prior authorization provision of the Act conflicts with the purposes of Medicaid in violation of the Supremacy Clause. The Medicaid statute itself provides the states with broad discretion to subject any drug to a prior authorization requirement. The Act is merely an exercise of that discretion. By failing to properly construe the statutory language of the Act, and to give deference to the Department's interpretation of it, the district court found conflict instead of harmony between the Act and Medicaid. The court also incorrectly read into Medicaid a requirement that would prohibit the Department from imposing prior authorizations if the motivation for doing do were based solely on the refusal of a manufacturer to participate in the Maine Rx Program. No motivation test exists in Medicaid. Moreover, the Act as written, and the Department's interpretation set forth in its proposed administrative rules, simply do not permit the imposition of prior authorization if to do so would deprive Medicaid recipients of the drugs they need. The court's finding of conflict with the goals of Medicaid are therefore purely conjectural.

Second, although the Maine Rx Program relies entirely on the state's purchasing power, and although plaintiff has not alleged any actual effect on interstate commerce resulting from the Program, the district court decided that it regulates interstate commerce in violation of the Commerce Clause. The court

ignored the firmly established principle that legislation that does not discriminate against other states' commerce must be upheld unless it creates an actual burden on interstate commerce which exceeds the benefits to the State.

Third, the Maine Rx Program should not have been preliminarily enjoined because manufacturers make no rebate payments before September 2001, giving sufficient time to conclude a trial before any threat of irreparable harm. And the district court's perfunctory application of the preliminary injunction balancing test ignored the overwhelming and uncontroverted state interest served by the program and now thwarted by the injunction.

I. PLAINTIFF LACKS STANDING TO CHALLENGE THE PRIOR AUTHORIZATION PROVISION OF THE ACT BECAUSE ITS INTERESTS DO NOT FALL WITHIN THE ZONE OF INTERESTS PROTECTED BY MEDICAID.

To the extent the lower court's preliminary injunction rests upon the validity of 22 M.R.S.A. § 2681(7), the "prior authorization" provision of the Act, it should be vacated because plaintiff lacks standing to challenge it.[4] According to plaintiff, implementation of this provision will deprive State Medicaid recipients of access

[4] Although we expressed doubt about whether plaintiff has standing in the district court, it was related only in a footnote in our brief below. However, the question of standing goes to the jurisdiction of the federal courts to decide a matter, and therefore may not be waived, even if entirely ignored below. *FW/PBS, Inc. v. City of Dallas*, 493 U.S. 215, 230-31 (1990). A federal court is obligated to satisfy itself that it has jurisdiction to hear a particular case, and may itself raise the issue of standing, even where the parties have not. *Id.*

to medically necessary prescription drugs. *Complaint* at ¶ 76 (App. A-019). Plaintiff lacks standing to rest its challenge on this claim because it is a pharmaceutical industry association and not a Medicaid recipient, and thus outside the zone of interests protected by Medicaid.

The prudential standing doctrine known as the "zone of interests" test is meant to ensure that a party challenging a state action on the grounds that it violates a federal statutory provision is asserting one of the interests protected by the statutory provision at issue. *National Credit Union Administration v. First National Bank & Trust Co*., 522 U.S. 479, 492 (1998); *see also Air Courier Conference of America v. American Postal Workers Union, AFL-CIO*, 498 U.S. 517 (1991). The first step in applying the doctrine here is to determine what interests are protected by Medicaid. The next step is to determine whether the interests of the plaintiff which might be affected by the prior authorization provision of the Act are among those interests. *TAP Pharmaceuticals v. U.S. Department of Health & Human Services*, 163 F.3d 199, 203-4 (4th Cir. 1998).

No one can dispute that Medicaid protects the interest of *recipients* to receive drugs necessary to their medical treatment. Medicaid, however, does not acknowledge any interest on the part of recipients in one particular drug over a clinically appropriate alternative. Indeed, States are granted broad discretion to substitute one drug for another and otherwise regulate access to drugs through

implementation of a prior authorization program. 42 U.S.C. § 1396r-8(d)(1)(A). A Medicaid recipient's purchase of a drug subjected to prior authorization will be reimbursed only after the Medicaid administrator has specifically approved the physician's request to dispense that medication.

Plaintiff's interests plainly do not fall within the zone of interests protected by Medicaid. Plaintiff's members are drug manufacturers. A drug manufacturer's only interest here is a financial one -- seeing that its drug, and not the drug of a competitor, is widely dispensed. Nothing in Medicaid suggests that Congress intended to ensure sales of any manufacturers' product. Any doubt on this point is dispelled by Medicaid itself which affirmatively grants to States the discretion to subject any and all outpatient drugs to prior authorization requirements. 42 U.S.C. § 1396r-8(d)(1)(A).

In *Tap Pharmaceuticals v. U.S. Department of Health and Human Services,* 163 F.3d 199 (4th Cir. 1998), the Fourth Circuit held that pharmaceutical manufacturers lack standing to challenge Medicare rules restricting the availability of their products through that program. In *TAP Pharmaceuticals,* a manufacturer alleged that a reimbursement policy affecting the dispensing of its drug ran afoul of the requirements of the Medicare statute. The court held that the manufacturer lacked standing to challenge the reimbursement policy because its financial interests were not within the zone of interests protected by Medicare. *Id.* at 208.

According to the court, Congress did not "express an interest in making different treatments for the same condition available on the same basis." *Id.* at 205.

The same conclusion applies here. The whole purpose of the Medicaid prior authorization provision is to enable states to differentiate between drug treatments. Indeed, the very nature of a prior authorization requirement is that one manufacturer's drug will be substituted for that of another. Thus, as in the Medicare program at issue in *Tap Pharmaceuticals*, it is plain that Congress did not intend to confer a right on pharmaceutical companies to object to prior authorization policies which might reduce the volume of their drugs dispensed through Medicaid.

This is consistent with the view that Medicaid is a contract between the federal government and the States that may not be enforced by an entity which is neither a party thereto nor an intended third-party beneficiary. Medicaid was promulgated pursuant to Congress' "spending power" as conferred by Article I, section 8, of the Constitution. Art. I, § 8, cl. 1. Medicaid is thus a "cooperative federal-state program through which the Federal Government provides financial assistance to States so that they may furnish medical care to needy individuals." *Wilder v. Virginia Hospital Association*, 496 U.S. 498, (1990). Medicaid, like all "legislation enacted pursuant to the spending power is much in the nature of a

contract;" *Pennhurst State Sch. & Hosp. V. Halderman*, 451 U.S. 1, 17 (1981); *see also South Dakota v. Dole,* 483 U.S. 203 (1987).

The conditions which Congress may impose upon states through "spending power" contracts may be enforced in two ways. *See Brogdon v. National Healthcare Corp.*, 103 F.Supp.2d 1322, 1339 (N.D. Ga. 2000) (suggesting that it is contracts principles rather than the Supremacy Clause which gives primacy to the conditions Congress imposes through its spending power). First, Congress may authorize the withholding of federal payments where a breach of the contract is found. The Medicaid statute provides precisely such a remedy. Specifically, 42 U.S.C. § 1396c permits the Secretary of the Department of Health and Human Services to withhold payment of federal Medicaid funds where a State is found to have violated Medicaid's requirements. 42 U.S.C. § 1396c.

The second class of plaintiffs who may seek to enforce the conditions Congress imposes when it exercises its "spending power" is those individuals on whose behalf those conditions were imposed. This sort of "intended third-party beneficiary" action may be brought when Congress intended the conditions it attached to the funds to create an enforceable statutory right in a particular class of beneficiaries. *Pennhurst State School and Hospital v. Halderman*, 451 U.S. 1 (1981); *Maine v. Thiboutot,* 448 U.S. 1 (1980); *also Suter v. Artist M.*, 503 U.S.

347 (1992); *Wilder v. Virginia Hosp. Ass'n*, 496 U.S. 498 (1990); *Golden State Transit Corp. v. City of Los Angeles*, 493 U.S. 103 (1989).

Plaintiff can point to no provision in Medicaid intended to benefit its members' interest in avoiding the imposition of prior authorization requirements on their drugs. Indeed, the Complaint identifies not a single statutory right which the Medicaid statute confers upon its members, let alone one violated by the Act. Because plaintiff's members are not an "intended third-party beneficiary" of the Medicaid contract with an enforceable right to have their drugs dispensed through Medicaid without prior authorization, it has no standing to challenge the prior authorization provision of the Act.

II. 22 M.R.S.A. § 2681(7) IS NOT PREEMPTED BY FEDERAL LAW.

The district court found that the federal Medicaid statute preempts the prior authorization review requirement of § 2681(7) applicable to any manufacturer that does not negotiate a Maine Rx Program rebate agreement. The court based its preemption conclusion on two factors. First, the court found that the Act does nothing to advance the purposes of Medicaid. Order at 12. (Add. 12) ("Maine can point to no *Medicaid* purpose in this new prior authorization requirement") (emphasis in original). Second, the district court found that § 2681(7) constitutes

an "'an obstacle to the accomplishment and execution of the Congressional objectives of federal Medicaid.'" *Id.* at 13.

Neither factor relied upon by the district court justifies the "strong medicine" of preemption. *Grant's Dairy Maine, LLC v. Commisioner of Maine Department of Agriculture, Food & Rural Resources*, 2000 WL 1677985, *9 (1st Cir. 2000). First, whether or not the state statute actually advances the purposes of the federal statute is utterly irrelevant to preemption analysis. Rather, the proper inquiry only considers the very different question of whether the state statute actually *conflicts* with the federal program. Second, the prior authorization review process triggered by §2681(7) cannot be considered an "obstacle" to the objectives of Medicaid because Medicaid expressly authorizes such review.

A. The Prior Authorization Provision Of The Act Does Not Conflict With Any Clearly Expressed Intent Of Congress.

The fundamental error of the district court's preemption analysis is its assumption that whether or not the Act advances the purposes of Medicaid is somehow relevant. This is not preemption analysis at all. The proper question is whether the Act conflicts with the purposes of Medicaid.[5] For the reasons which follow, the answer to the appropriate question is no.

[5] The district court also suggests that it may never have occurred to Congress that a state might adopt a statute like 22 M.R.S.A. § 2681(7). Assuming the correctness of this observation, it hardly supports a finding of preemption. Certainly Congress could not have intended to preempt something it never considered.

"Preemption is strong medicine, not casually to be dispensed." *Grant's Dairy Maine, supra,* 2000 WL 1677985 at *9. Courts must apply a strong presumption against federal preemption of state statutes, especially where, as here, a state has acted to protect the health and safety of its citizens. *Medtronic v. Lohr*, 518 U.S. 470 (1996) ("States traditionally have had great latitude under their police powers legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons") (quoting *Metropolitan Life Ins. Co. v. Massachusetts,* 471 U.S. 724, 756 (1985)). When this presumption against preemption is properly applied, a court will declare that these historic powers of the States have been superceded by federal law only where that is "the clear and manifest purpose of Congress." *Rice v. Santa Fe Elevator Corp.* 331 U.S. 218, 230 (1947).

The first question in any preemption analysis is whether Congress has expressly stated an intention to preempt state action. *Pacific Gas & Electric Co. v. State Energy Resources Conservation & Development Comm'm*, 461 U.S. 190, 203 (1983). Medicaid contains no such language. The district court appropriately found that "[t]here is no question that Congress has legislated an extensive and detailed federal Medicaid program. But nowhere has it expressly forbidden what Maine has done" through the Maine Rx Program. *Order* at 11 (Add. 11).

Where Congress has not expressly preempted state action, an intent to preempt may be implied, but only in certain well established circumstances.

Implied preemption comes in two flavors, only one of which is at issue here. "Conflict preemption takes place either when compliance with both state and federal regulations is impossible or when state law interposes an obstacle to the achievement of Congress's discernible objectives." *Grant's Dairy*, 2000 WL 1677985 at *3. The lower court relied on this "obstacle conflict" preemption.

The Supreme Court's decisions in this area "establish that a high threshold must be met if a state law is to be pre-empted for conflicting with the purposes of a federal Act. Any conflict must be irreconcilable….The existence of a hypothetical or potential conflict is insufficient." *Gade v. National Solid Waste Management Association*, 505 U.S. 88, 110 (1992) (Kennedy, J., concurring) (internal quotations and citations omitted). Moreover, "obstacle" conflict preemption is "limited to state laws which impose prohibitions or obligations which are in direct contradiction to Congress' primary objectives, as conveyed with clarity in the federal legislation." *Id.* Had the district court applied these standards, it could not have found it likely that plaintiff will succeed in its challenge to the Act on preemption grounds.

Congress' primary objective in the Medicaid outpatient prescription drug provisions is straightforward: to assist the states in providing medically necessary outpatient drugs to financially needy persons. 42 U.S.C. §1396a(a)(54). As part of the Medicaid scheme, Congress specifically granted to the States broad discretion

to limit access to drugs through prior authorization. Medicaid provides that "[a] State may subject to prior authorization *any* covered outpatient drug," and Congress imposed no limit on a State's discretion to place a drug on the prior authorization list. [6] 42 U.S.C. § 1396r-8(d)(1)(A) (emphasis added). Thus, it cannot be said that Congress believed that prior authorization requirements are an obstacle to the achievement of its primary goal.

The district court's decision does not rest upon the notion that imposition of a prior authorization requirement under any circumstances is preempted. Rather, the lower court reasoned that prior authorization is preempted only when motivated by the refusal of a manufacturer to enter into a Maine Rx Program rebate agreement. As discussed below, there are two equally compelling and independently sufficient ways to answer this concern. First, the Act as written and as interpreted by the Department simply does not permit the imposition of a prior authorization requirement based solely on the refusal of a manufacturer to participate in the Maine Rx Program. Second, Congress did not intend that the

[6] The only conditions Congress imposed in the area of prior authorizations concern the manner by which a state must respond to a physician's request to dispense a drug that has been placed on the prior authorization list. It must respond "by telephone or other telecommunication device within 24 hours of a request for prior authorization" and it must provide "for the dispensing of at least 72-hour supply of a covered outpatient prescription drug in an emergency situation." § 1396r-8(d)(5). "Maine satisfies both requirements." Order at 11, n.11 (Add. 11, n.11).

State's discretion to place a drug on the prior authorization list would in any way depend on its motivation for doing so. As long as Medicaid recipients receive the drug therapy they require, Medicaid's purposes are achieved.

B. The Act Does Not Permit Imposition Of A Prior Authorization Requirement Based Solely On The Refusal Of A Manufacturer To Participate In The Maine Rx Program.

The district court's Supremacy Clause holding assumed that the Act requires imposition of prior authorization even when to do so would conflict with the objectives of Medicaid. Order at 12 (Add. 12). That conclusion was based on an erroneous reading of the Act.

In ascertaining the constitutionality of state legislation, the court must reasonably construe the law, where possible, to uphold it. *See National Pharmacies, Inc. v. Feliciano-de-Melicio*, 221 F.3d 235, 241-42 (1st Cir. 2000), *citing K-S Pharmacies v. American Home Products,* 962 F.2d 728, 730 (7th Cir. 1992). Simply put, the lower court failed to do so. The provision of the Act at issue states that "[t]he Department shall impose prior authorization requirements in the Medicaid program…*as permitted by law*, for the dispensing of drugs provided by those manufacturers" which do not enter into Maine Rx Program rebate agreements. 22 M.R.S.A. § 2681(7) (emphasis added). If the words "as permitted by law," are to be given any meaning, they must be read to incorporate into § 2681(7) any pertinent federal or state statutory limits on the use of prior

authorization in Medicaid. *See Massachusetts Ass'n of Health Maintenance Organizations v. Ruthardt*, 194 F.3d 176, 181 (1st Cir. 1999) ("[a]ll words and provisions of statutes are intended to have meaning and are to be given effect, and no construction should be adopted which would render statutory words or phrases meaningless, redundant or superfluous.") (internal quotations and citations omitted). Thus, from the language of the Act itself, the Department is not permitted to place a drug on the Medicaid prior authorization list if to do so would somehow contravene federal Medicaid law.

The Department's own interpretation of the Act is consistent with this reading. Specifically, the Department proposed administrative rules governing the prior authorization listing process which ensure that Medicaid recipients will always have access to the drugs they need. *Concannon Aff.,* ¶¶ 10-11 (App. A-145,46). First, the decision to place a drug on the list can be made only by the State's Medicaid Drug Utilization Committee, a body which is comprised exclusively of physicians and pharmacists who are licensed to prescribe or dispense medications in Maine. *Concannon Aff.,* ¶¶ 10-11 (App. A-3); Ch. II, sec. 80.05-3, *Medical Assistance Manual* (App. A-171). Second, the standard for placing a drug on the prior authorization list is "clinical appropriateness." *Id.*

When this criteria is applied by physicians and pharmacists, it can only result in decisions which comport with the best interests of Medicaid recipients.[7]

The Act's prior authorization mechanism will work as follows. Prior authorization review will be triggered by the refusal of a manufacturer to participate in the Maine Rx Program. While the drugs of nonparticipating manufacturers will be brought up for consideration, the final drug-by-drug determination of whether a prior authorization requirement should be imposed will be made only on clinical criteria applied by health care professionals. It was therefore pure conjecture -- and clear error -- for the district court to find that the prior authorization mandate of the Act will harm Medicaid recipients. The Act simply cannot be said to conflict with Medicaid's goal of providing medically necessary drugs to recipients if the Act itself, and the Department's implementation of it, ensures that recipients will always receive the drugs they require.

[7] The rule provides: "Drugs of manufacturers that do not participate in a rebate agreement for the Maine Rx Program shall be reviewed by the Department as to the clinical appropriateness of prior authorization for those drugs under the Medicaid Program. Recommendations to prior authorize any of those drugs shall be referred to the Medicaid Drug Utilization Committee, for a final determination of whether those drugs should be prior authorized, in accordance with federal and state law. In all instances, Medicaid recipients shall be assured access to all medically necessary outpatient drugs." *Chapter II, section 80.05-3, Medical Assistance Manual* (App. A-171). Due to the imposition of the preliminary injunction, the Department has not yet formally adopted this rule.

By holding that the Act will require the Department to place drugs on the prior authorization list even when to do so would be inconsistent with the best interests of Medicaid recipients, the district court strained to find a potential, or hypothetical conflict. "[T]he existence of a hypothetical or potential conflict is insufficient," however, to overcome the strong presumption against the preemption of a state statute on the grounds that it conflicts with the objectives of a federal statute. *Gade v. National Solid Wastes Management Association*, 505 U.S. at 110. The need to avoid hypothetical or potential conflicts is especially strong here, where plaintiff has mounted only a facial challenge to the Act. "A facial challenge to a legislative Act is, of course, the most difficult challenge to mount successfully, since the challenger must establish that no set of circumstances exists under which the Act would be valid." *United States v. Salerno*, 481 U.S. 739, 745 (1987).

Moreover, deference should be afforded to the Department's interpretation of the Act, because it is the agency charged with administration of the Maine Rx Program. *Fireside Nissan Inc. v. Fanning*, 30 F.3d. 206 (1st Cir. 1994); *Massachusetts v. Lyng*, 893 F.2d 424 (1st Cir. 1990); *Swasey v. Whalen*, 562 F.2d 831 (1st Cir. 1977). Rather than granting deference to the Department's interpretation, the district court improperly relied upon an alternative interpretation of the Act which, in its view, could potentially lead to a conflict with the purposes of Medicaid. Because that alternative interpretation both ignores statutory

language and only results in a "potential" conflict, the conclusion that plaintiff is likely to prevail on the merits of its "conflict" preemption claim is error.

C. Congress Did Not Intend To Regulate The State's Motivation For Placing A Drug On The Prior Authorization List.

The district court apparently concluded that a decision to impose a prior authorization requirement on a drug conflicts with Medicaid if motivated solely by the refusal of the manufacturer of that drug to provide a Maine Rx rebate. Order at 12 (Add. 12). This conclusion is erroneous because Medicaid places no limits on the factors which a State may consider in placing a drug on the prior authorization list, and it certainly contemplates no motivational criteria. All that Medicaid requires is that recipients obtain medically necessary drugs in a timely fashion, which the Maine Act unquestionably ensures.

If Congress intended that the State's motivation for placing a drug on the prior authorization list were somehow relevant, one would expect there to be some criteria spelled out in the Medicaid statute itself. But under Medicaid the state may "subject to prior authorization *any* outpatient drug," 42 U.S.C. § 1396r-8(d)(1)(A). Congress plainly was not concerned with how, or why, a drug gets placed on a prior authorization list. Rather, it intended to ensure that Medicaid recipients get the drugs they need in a timely fashion. Thus, the only statutory limitations on prior authorization programs, found in § 1396r-8(d)(5), concern the necessary timeframe in which a State Medicaid administrator must respond to a request to

dispense a listing drug, and an assurance that a 72-hour emergency supply of any drug always be available to recipients. 42 U.S.C. § 1396r-8(d)(5).

The district court was also incorrect to rely on 42 U.S.C. § 1396a(a)(19) as the textual hook for its conclusion that Maine may exercise its discretion to place a drug on the prior authorization list only if its primary motive for doing so is to advance the interests of Medicaid recipients. Order at 11-12 (Add. 111-12). Section 1396a(a)(19), which is one of sixty-five enumerated requirements for the states' Medicaid plans, has nothing at all to do with prior authorization programs or prescription drugs.[8] Instead, it sets forth the general requirement that a State Medicaid plan must provide "safeguards as may be necessary to assure…that care and services will be provided, in a manner consistent with…the best interests of the recipients. 42 U.S.C. § 1396a(a)(19). In any case, the provision is concerned with results, not motives, and if the results are that recipients receive the drugs they need, their best interests are met and Medicaid's goals are fully satisfied.

Use of the broad "best interests of the recipients" language of § 1396a(a)(19) to strike down Maine's statute is also suspect for the additional reason that this provision is so general and amorphous. Conflict preemption will

[8] In contrast, another of the enumerated State plan requirements, § 1396a(a)(54), speaks directly to prescription drug benefits and provides that if an outpatient drug benefit is offered to Medicaid recipients, it is the requirements of § 1396r-8 which govern. As shown above, § 1396r-8 is what gives the states broad discretion to impose prior authorization requirements in the first place.

only be found where Congress' primary objectives are "conveyed with clarity in the federal legislation." *Gade*, *supra,* 505 U.S. at 110*; see also Evelyn V. v. Kings County Hospital Center*, 819 F.Supp. 183, 196 (E.D.N.Y. 1993) (holding that the terms "safeguards as may be necessary" and "best interests of the recipients" of § 1396a(a)(19) "are too general and vague to permit judicial enforcement."); *see also Massachusetts Medical Society v. Dukakis,* 815 F.2d 790, 792 (1st Cir.) cert. denied 484 U.S. 896 (1987) (refusing to find that Medicare preempts a state statute prohibiting "balance billing" even though the practice was allowed by Congress as an option under Medicare, because Congress did not unmistakably intend "to create a legal right to balance bill, a right immune from significant state interference").

So long as Medicaid recipients receive the drugs they need in a timely fashion, it simply does not conflict with the purposes of Medicaid for the State to require that its permission be obtained before a particular drug, or any drug, is dispensed. Results, not motivations, are what matter. For these reasons, the district court's conclusion that plaintiff is likely to prevail on its claim that the Act is preempted by federal law should be reversed.

D. The District Court Erred In Concluding That The Act Does Not Advance The Objectives Of Medicaid.

As set forth above, it is irrelevant under preemption analysis whether the Act affirmatively advances Medicaid's goals. But even if that were an appropriate

factor to consider, the Maine Rx Program clearly passes muster. Medicaid is a program intended to provide healthcare, and prescription drugs, to uninsured citizens who are medically and financially needy. The Maine Rx Program advances these same goals by making prescription drugs more affordable to the uninsured. Prescription drugs are an increasingly important component of modern healthcare. Drug therapy can maintain the health of individuals with serious medical conditions such that they can continue to lead productive lives. By making prescription drugs more affordable to uninsured citizens, the Maine Rx Program will help prevent citizens who suffer from treatable medical conditions from becoming medically and financially needy in the first place, and thus keep them off the Medicaid rolls.

The Health Care Financing Administration ("HCFA"), through which the Secretary of the United States Department of Health and Human Services administers the federal government's Medicaid responsibilities, has itself recognized that, due to the high price of prescription drugs, many individuals are pressed against the gates of Medicaid itself. Accordingly, on November 3, 2000, HCFA approved a Vermont program which permits certain individuals who do not meet Medicaid's financial qualifying requirements to take advantage of the lower

price charged for drugs that are purchased through Medicaid.[9] The Maine Rx Program, like the Vermont program, advances both the goals of Medicaid and the State's Medicaid program itself by helping to preserve limited public funds for those who have become so medically and financially needy that they require the full range of medical benefits offered though Medicaid.

III. THE MAINE RX PROGRAM DOES NOT VIOLATE THE COMMERCE CLAUSE.

A. The Maine Rx Program Is Immune From Commerce Clause Scrutiny Because It Relies On Maine's Purchasing Power In The Prescription Drug Market Rather Than The Regulatory Power Of The State.

The Maine Rx Program adopts a novel approach to the problem of excessive retail drug prices, and the lower court failed to recognize that the statute is unlike any legislation previously considered by the courts. This led the court to base its Commerce Clause analysis on precedents that address statutory systems fundamentally different from that involved here. Proper application of the correct tests mandates the conclusion that the Maine Rx Program rebate provision is likely to pass muster under the Commerce Clause.

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[9] PhRMA has challenged the Vermont program in the United States District Court for the District of Columbia. *Pharmaceutical Research and Manufacturers of America v. Shalala*, Civ. Docket # 00-CV-2990. That district court's PACER docket entries, as of January 6, 2001, indicate that motions to dismiss, and for preliminary injunctive relief, are pending.

The "dormant" Commerce Clause doctrine has been recognized by the Supreme Court in order to limit the states' power to impinge on Congress' express Constitutional authority to regulate interstate commerce. U.S. Const. Art. I, § 8, cl. 3 ("Congress shall have the power . . . to regulate Commerce with foreign nations and among the several States.") The doctrine evolved to protect the national economy from "economic retaliation" between the separate States and to control their "mutual jealousies and aggressions." *Baldwin v. G.A.F. Seelig*, 294 U.S. 511, 522 (1935) (citation omitted); *see also Gibbons v. Ogden*, 22 U.S. (9 Wheat.) 1, 199-200 (Marshall, C.J.) (1824) ("when a State proceeds to regulate commerce . . . among the several States, it is . . . doing the very thing which Congress is authorized to do").

The court below found that the Maine Rx Program rebate provision violates the dormant Commerce Clause by regulating the price of out-of-state transactions between drug manufacturers and distributors. This court need not reach this issue, however, because Maine is acting as a "market participant" and is therefore excepted from Commerce Clause restrictions.

This well-recognized exception to the dormant Commerce Clause applies when a state seeks to obtain benefits for its citizens using its power as a buyer or seller rather than its regulatory authority. *White v. Massachusetts Council of Construction Employers, Inc*. 460 U.S. 204 (1983); *Reeves, Inc. v. Stake*, 447 U.S.

429 (1980)*; Hughes v. Alexandria Scrap Corp.*, 426 U.S. 794 (1976). The Maine Rx Program relies exclusively on the State's buying power in the market for prescription drugs and therefore is not subject to Commerce Clause scrutiny.

Maine spent over $135 million to purchase prescription drugs for its Medicaid program in 1999. *Concannan Aff.*, *exh. C* (App. A-159). The Maine Rx Program seeks to use that spending power to leverage benefits for residents who otherwise lack insurance coverage for prescription drugs. The lower court suggested that the relationship between the Maine Rx beneficiaries and Medicaid recipients was too attenuated to justify application of the market participant exception. Order at 5-8 (App. 5-8). Both Medicaid and the Maine Rx Program, however, serve individual Maine consumers who do not have private insurance coverage for prescription drugs. The fact that both programs benefit the same group of needy citizens makes an even more compelling case for the market participant exception than in *White*. In *White* the Supreme Court upheld a Boston regulation that relied on the city's purchasing power in the market for building construction to influence hiring decisions in a different market – the market for construction labor. The regulation prohibited the city from entering building contracts with contractors who would not agree to hire at least 50 percent of their workers from the local labor pool. The Court held that the Commerce Clause imposes no barrier to such an arrangement because Boston was simply using its

power as a purchaser. 460 U.S. at 210; *see also Hughes*, 426 U.S. at 808 ("[n]othing in the purposes animating the Commerce Clause prohibits a State . . . from participating in the market and exercising the right to favor its own citizens over others"). Here, Maine seeks to use its purchasing power in the prescription drug market just as Boston used its purchasing power in the construction market in *White*.

Contrary to the decision below, it is irrelevant that the Maine Rx beneficiaries are not "in the [Medicaid] transaction," Order at 6 (App. 6), because it was of no import in *White* that the workers were not a party to Boston's construction contracts. Nothing in the leading cases limits the exception to benefits sought "in the transaction." Indeed, *White* makes clear that the market participant exception may be broadly applied even when the state uses its market power to do much more than simply get better terms in the purchase transaction. A state may "impose restrictions that reach beyond the immediate parties with which the government transacts business 'because' the Commerce Clause does not require the [State] to stop at the boundary of formal privity of contract." *White*, 460 U.S. at 211 n.7. As the Court later explained, it did not place a formalistic boundary on the exception in *White* because everyone affected by Boston's regulation was, "in a substantial if informal sense," working for the city. *South-*

Central Timber Dev., Inc. v. Wunnicke, 467 U.S. 82, 95 (1984) (internal quotation marks and bracketing omitted).

Here, all the prescription drugs consumed through the Maine Rx program and Medicaid are "in a substantial but informal sense" for the benefit of the same population – Maine residents without private insurance. Maine Rx beneficiaries will acquire the same prescription drugs, produced by the same manufacturers and sold by the same pharmacists, as their fellow residents on Medicaid. That Maine does not purchase the drugs in the Maine Rx program is no more significant than the fact that Boston did not hire the laborers in *White*. Nothing in any Supreme Court precedent compelled the district court to diminish the market participant exception as it did.

South-Central Timber Dev., cited by the district court, does not require a different result. That case entailed a challenge to an Alaska requirement that purchasers of state-owned timber must further process the timber before shipping it out of state. A plurality of the Court determined that the market participant exception did not apply when the state, acting as a seller of goods, attempts to restrict the purchaser's further handling of those goods in its subsequent business dealings. *Id.* at 96-98. The Court refused to apply the exception in part because restrictions on resale "have a greater regulatory effect" than restrictions in effect only "during the course of an ongoing commercial relationship." *Id.* at 99.

Here, the rebate payment requirement only exists in connection with the "ongoing relationship" between the manufacturer and the Maine Medicaid Program. Moreover, the payment requirement is not a "resale" restriction but a condition tied to Maine's Medicaid purchases. For these reasons, *White* is the controlling precedent. Accordingly, the district court should have found that Maine is acting as a market participant and that the Maine Rx Program is not subject to Commerce Clause scrutiny.[10]

B. The Maine Rx Program Easily Satisfies The Dormant Commerce Clause Analysis Established By The Supreme Court.

1. The Maine Rx Program Does Not Affect Interstate Commerce And Therefore Does Not Require Commerce Clause Scrutiny.

Assuming that the Maine Rx Program is deemed a regulation rather than an exempt exercise of the state's purchasing power as argued above, it is not likely to be found to violate the Commerce Clause. The crux of plaintiff's challenge is that the Program infringes Congress' express Constitutional power under Article I, Sec. 8 to "regulate Commerce" among the states. At the most fundamental level,

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[10] *National Foreign Trade Council v. Natsios*, 181 F.3d 38, 64 (1st Cir. 1999) *aff'd Crosby v. National Foreign Trade Council*, 530 U.S. 363 (2000), also relied on by the district court, is readily distinguished. Unlike the Maine law at issue here, Massachusetts was using its market power to stop companies from engaging in activities "not even remotely connected to such companies' interactions with Massachusetts," in order to achieve objectives "not even remotely linked to Massachusetts" and unrelated to "local economic well-being." *Id.* at 63-64.

however, if the Program does not "regulate interstate Commerce," it does not run afoul of the Commerce Clause.

Unlike a wide variety of price affirmation and control statutes tried by other states, the Maine Rx Program simply does not "regulate" commerce. The rebate requirement is utterly indifferent to manufacturers' decisions to increase or decrease prices charged to their customers. Manufacturers in the program may charge whatever they wish, to whatever customers they wish, without any consequences whatsoever. The Program only seeks to obtain a rebate, the amount of which is fixed (though renegotiated each year). Plaintiff fails to identify any transaction that will be affected by the rebate requirement, let alone substantiate what that effect is.

There is no argument presented in this case that the Program dictates the terms at which products are sold in interstate commerce. In this regard one must observe a sharp distinction between the effect the Program might have on *manufacturers* an any speculative effect it may have on *commerce*. "The Commerce Clause protects the interstate market, not the particular interstate firms, from . . . burdensome regulations." *Exxon Corp. v. Governor of Maryland*, 437 U.S. 117, 127 reh. denied sub nom., *Shell Oil Co. v. Governor of Maryland*, 439 U.S. 884 (1978). Plaintiff's objection to the rebate requirement therefore is not cognizable under the dormant Commerce Clause theory.

The Maine Rx Program only requires drug manufacturers participating in state-supported pharmaceutical assistance programs to make payments each year on the basis of the sales of their products to Maine residents participating in the Program. *See* 22 M.R.S.A. § 2681(3). Most significant is what the Maine Rx Program does *not* do. The Program does not prohibit sales in Maine, impose a tariff on imports into Maine, or tie prices in Maine to out-of-state prices. The statute simply does not violate the Commerce Clause doctrine because its only extraterritorial aspect is that rebates are required of manufacturers who happen to be located out-of-state. The rebate requirement would apply on the same terms to any in-state manufacturer.[11] Because a rebate payment does not constitute "regulating" the actual terms of commerce, dormant Commerce Clause scrutiny is not appropriate.

2. The District Court Erroneously Applied The Price-Control Line Of Cases To Strike Down The Maine Rx Program.

The first and most glaring error of law in the district court's Commerce Clause analysis was its application of the Supreme Court's price-control line of cases. For the following reasons, those cases are fundamentally distinguished and do not control this analysis.

[11] The record does not indicate whether any prescription drug manufacturers are located within Maine.

Each case cited by the court below involved a state statute explicitly tying the prices charged in one state to those in other states in order to leverage lower prices in the first state at the expense of the buyers and sellers in the other states and the market advantages they enjoyed. In *Baldwin v. G.A.F. Seelig*, 294 U.S. 511 (1935), the New York Milk Control Act prohibited the sale in New York of "*milk produced outside of the state*" if that milk was purchased at a price lower than that of milk produced within the state. *Id.* at 499 n.1 (quoting New York statute) (emphasis added).[12] More recently, in *Brown-Forman Distillers Corp. v. New York State Liquor Auth.*, 476 U.S. 573 (1986), the Supreme Court struck a provision of the New York Alcoholic Beverage Control Law that required distillers to affirm that prices to wholesalers within New York would be no higher than their prices to wholesalers "*in any other state*." *Id.* at 574. (quoting New York statute). The New York law would have required distillers to post their prices in New York and then affirm that they will make no sales anywhere at lower prices during the following month. Three years later, in *Healy v. Beer Institute*, 491 U.S. 324 (1989), the Supreme Court invalidated Connecticut's contemporaneous price

[12] One commentator suggested that the statute at issue in *Baldwin* might have been upheld if, instead of banning the sale of such milk in New York, it had merely required a payment in connection with each lower-priced out-of-state milk transaction. *See* Lawrence Tribe, *American Constitutional Law*, 3rd Ed. 2000, § 6-8 n. 6. And just two years later the Court made clear that *Baldwin* does not apply to state statutes that simply require payments rather than establish prices. *See Henneford v. Silas Mason Co.*, 300 U.S. 577, 585-86 (1937).

affirmation statute which tied beer prices in that state to the lowest price at which beer is currently offered for sale "to any wholesaler in *any state bordering this state*." *Id.* at 329 n.7 (quoting Connecticut statute) (emphasis added).

The common thread running through *Baldwin*, *Brown-Forman* and *Healy* is that each statute expressly tied in-state prices to out-of-state prices. In each case one state was attempting to co-opt the market advantages enjoyed by purchasers or producers in another state. In each case a manufacturer could not legally change its prices in transactions that had no relationship whatsoever to the enacting state. In each case the linkage between in-state and out-of-state prices was the necessary core of the statutory system. And in each case the challenged statutes warped and therefore burdened a stream of commerce unconnected to the state in which the statute was enacted.

Unlike those New York and Connecticut laws, the Maine Rx Program has not "establish[ed] a . . . scale of prices for use in other states," directly or indirectly. *Baldwin*, 294 U.S. at 528. Nor is that the law's intent. The problem Maine sought to address was *not* that consumers in other states enjoy lower prices, but that Maine residents without insurance cannot afford medications upon which their health depends. The Act seeks to reduce the out-of-pocket cost for prescription drugs for uninsured citizens by a system of negotiated rebate payments, not by leveraging another state's stream of commerce. The manifest

difference between the effects on interstate commerce of the rebate approach adopted by the Maine Rx Program and the price control approach in *Baldwin*, *Brown-Forman*, and *Healy* deprives those cases of any precedential force here.

Equally important, the rationale articulated in those decisions does not apply. Each case relied heavily on the core dormant Commerce Clause value of an open competitive market. The *Baldwin* court was concerned that the "avowed purpose of the [statute], as well as its necessary tendency, [was] to suppress or mitigate the consequences of competition between the states." 294 U.S. at 522. The *Brown-Forman* ruling was based on the principle that a State "may not insist that producers or consumers in other States surrender whatever competitive advantages they may possess." 476 U.S. at 580. And the *Healy* Court struck the Connecticut law because it threatened to create "competing and interlocking local economic regulation" and "clearly discriminate[d] against interstate commerce." 491 U.S. at 337, 340. But, as the court below held, the Maine Rx Program has no protectionist intent or effect.

The district court's reliance on the *Baldwin*, *Healy*, *Brown-Forman* line of cases no doubt results from its uncritical acceptance of plaintiff's characterization of the Act -- that it "effectively regulates [sic] the prices received by drug manufacturers from their customers in transactions occurring outside of Maine." Complaint at ¶ 61; Order at 9 (Add. 9) (equating Maine Rx Program with New

York's extraterritorial price regulation in *Baldwin*). There may or may not be effects of a rebate requirement on the manufacturer's "bottom line," just as a price control may or may not effect the bottom line. But rough "[e]conomic equivalence alone has . . . not been (and should not be) the touchstone of Commerce Clause jurisprudence." *Oklahoma Tax Commission v. Jefferson Lines, Inc.*, 514 U.S. 175, 196 n. 7 (1995). Maine simply has not "prescribe[d] the rule by which commerce is to be governed." *Gibbons v. Ogden*, 22 U.S. 1 (9 Wheat.) (1824). The practical, economic effect of requiring a rebate payment cannot be equated to that of mandating actual out-of-state prices, and plaintiff presents no evidentiary support for such a proposition.[13]

Maine has crafted a unique approach to the problem of unaffordable prescription drugs – one that avoids the error of price control laws because it

[13] The district court's failure to analyze the "practical effects" is significant. For example, the court acknowledged that it would find no Commerce Clause problem if the Maine Rx Program only imposed a rebate requirement on drug manufacturers that ship their products directly into Maine. Order at 3 (Add. 3). The district court therefore implied that the dormant Commerce Clause is violated only insofar as the Program applies to manufacturers that use out-of-state wholesalers to access the Maine market. Yet nothing in common sense – or the record of this case – explains how the "practical effects" on commerce of a rebate on sales originally sold directly into the state are any different from the "practical effects" of a rebate on sales made through an intermediary. In fact, at least one court has warned of the dangers that manufacturers might establish "dummy" firms as intermediaries to evade legitimate state regulations under dormant Commerce Clause pretenses. *See New York v. Brown*, 721 F.Supp. 629, 640 n.11 (D.N.J. 1989)

operates independently of the stream of commerce into any other state. The district court's conclusion that the Act regulates out-of-state wholesale prices, and in this way violates the dormant Commerce Clause, is simply incorrect. That fundamental error lead the court to rely exclusively on the wrong line of cases. *Baldwin*, *Healy*, and *Brown Forman* are not controlling here.

3. Only Protectionist Measures May Be Invalidated On A *Per Se* Basis.

The district court also erred when it invalidated the Act on a *per se* basis. Only protectionist or discriminatory legislation is subjected to the *per se* analysis and the Act is not even alleged to be protectionist or discriminatory. The district court's fundamental departure from established precedent is fatal to its conclusion that plaintiff had shown a likelihood of success on the merits of its Commerce Clause argument.

The Supreme Court has established a two-tiered analysis of state laws under the dormant Commerce Clause. Statutes that discriminate against interstate commerce or favor in-state economic interests over out-of-state interests are generally struck down as *per* se unconstitutional without further analysis. *Brown-Forman,* 476 U.S. at 578-79. On the other hand, statutes that regulate evenhandedly are upheld unless the incidental effects on interstate commerce clearly outweigh the putative local benefits. *Pike v. Bruce Church, Inc.,* 397 U.S. 137 (1970).

The *per se* test is reserved for discriminatory statutes because they alone violate the essential purpose of the dormant Commerce Clause, which is to "prevent States and their political subdivisions from promulgating protectionist policies." *Houlton Citizens' Coalition v. Town of Houlton*, 175 F.3d 178 (1st Cir. 1999); *see also CTS Corp. v. Dynamics Corp. of America*, 481 U.S. 69, 87 (1987) ("[t]he principal objects of dormant Commerce Clause scrutiny are statutes that discriminate against interstate commerce"); Donald Regan, *The Supreme Court and Economic Protectionism: Making Sense of the Dormant Commerce Clause*, 84 Mich. L. Rev. 1091, 1092 (1986) (in dormant Commerce Clause cases "the Court has been concerned exclusively with preventing states from engaging in purposeful economic protectionism"). Any statute with "the aim and effect of establishing an economic barrier against competition" will be automatically invalidated in order to protect the economic functioning of the national market. *Baldwin*, 294 U.S. at 527; *see also Hughes v. Alexandria Scrap Corp.,* 426 U.S. 794, 803 (1976) (dormant Commerce Clause is meant to protect "the free flow of both raw materials and finished goods in response to the economic laws of supply and demand.") [14]

[14] Other purposes of the dormant Commerce Clause include preventing "price gridlock," *Healy*, 491 U.S. at 340, and "inconsistent obligations," *Brown-Forman,* 476 U.S. at 583, that may result when more than one state attempts to regulate the same stream of commerce. The Maine statute implicates neither concern.

Courts must carefully adhere to the anti-protectionist purpose of the dormant Commerce Clause because otherwise the doctrine, which is not expressly limited by the text of the Constitution, might expand without limit and intrude upon the proper role of the states in our federal system.[15] For this reason, the threshold question in analyzing any law subject to judicial scrutiny under the dormant Commerce Clause must be whether it "regulates evenhandedly with only 'incidental' effects on interstate commerce, or discriminates against interstate commerce." *Hughes*, 441 U.S. at 336. In this context, "'discrimination' . . . means differential treatment of in-state and out-of-state economic interests that benefits the former and burdens the latter." *Oregon Waste Systems, Inc. v. Department of Environmental Quality,* 511 U.S. 93, 99 (1994); *see also Cotto Waxo*, 46 F.3d 790, 794 (8th Cir. 1995) ("[n]egatively affecting interstate commerce is not the same as discriminating against interstate commerce"). Where a regulation "clearly" or "affirmatively" discriminates against interstate commerce on its face or in practical effect, it violates the Constitution unless the discrimination is demonstrably justified by a valid factor unrelated to protectionism. *See Wyoming v. Oklahoma*, 502 U.S. 437, 454 (1992); *Maine v. Taylor*, 477 U.S. 131, 138 (1986). The Maine

[15] Justices Thomas and Scalia have consistently criticized dormant Commerce Clause doctrine and would not invoke it to invalidate state legislation unless required by principles of *stare decisis*. *See, e.g., West Lynn Creamery, Inc. v. Healy,* 512 U.S. 186, 209-10 (1994) (Scalia, J, concurring).

statute, of course, regulates "evenhandedly" and is not alleged to be discriminatory.

a. Regulations Which Have Extraterritorial Effects On Out-Of-State Commerce Are Not, Per Se, Violations Of The Dormant Commerce Clause.

The Maine Rx rebate is only triggered by retail sales of the manufacturers' products within Maine, by Maine pharmacists, to uninsured Maine residents. If none of a manufacturer's products are sold in Maine, the manufacturer has no obligation under the law. The only "extraterritorial" aspect of the Maine Rx Program is that it does not exempt products originating in other states from the rebate requirement.

The district court determined that the only question in the case was "whether [a state] has the power to extend its authority to out-of-state manufacturers." Order at 9 (App. at 9); *see also id.* at 2 (App. at 2) ("In our country, under our Constitution, States cannot legislate outside their boundaries.") Finding that such authority would contravene the dormant Commerce Clause, the court summarily enjoined the statute. In doing so, it unjustifiably expanded the dormant Commerce Clause beyond its intended purpose of ensuring competitive markets, into a categorical ban on extraterritorial effects.

The Supreme Court, however, has repeatedly recognized the States' constitutional authority to regulate and otherwise burden out-of-state entities on

account of the flow of their products into the State, and dormant Commerce Clause jurisprudence simply does not support a *per se* ban on all state legislation with any extraterritorial effect. *See Maine v. Taylor,* 477 U.S. 131, 138 (1986) ("The limitation imposed by the Commerce Clause on state regulatory power 'is by no means absolute.'") For example, in *Exxon Corp.*, 437 U.S. 117, the Supreme Court upheld a state law prohibiting vertical ownership in the gasoline industry even though the law would have eliminated a profitable portion of the out-of-state parent companies' business. The Supreme Court has frequently upheld other state statutes despite obvious and substantial extraterritorial effects. *See, e.g., Standard Oil Co. of Kentucky v. Tennessee*, 217 U.S. 413 (1910) (antitrust); *International Shoe Co. v. Washington*, 326 U.S. 310 (1945) (unemployment compensation law); *see also e.g., Cotto Waxo Company*, 46 F.3d 790 (toxic substances control law); *K-S Pharmacies, Inc. v. American Home Products Corp.* 962 F.2d 728 (7th Cir. 1992) (Easterbrook, J.) (law prohibiting price discrimination in wholesale drug transactions). The Supreme Court "has never suggested that the dormant Commerce Clause requires Balkanization, with each state's law stopping at the border." *Instructional Systems, Inc. v. Computer Curriculum Corporation,* 35 F.3d 813, 825 (3d Cir. 1994) (franchise law).

A proper reading of the extraterritorial regulation cases relied upon by the district court does not establish that the Constitution limits state legislative

jurisdiction to those policies without effects beyond the state's borders. To the contrary, the Seventh Circuit understood that it was only the *combination* of the "extraterritoriality" and "price control" factors in *Baldwin, Brown-Forman* and *Healy* that offended the Constitution, not "extraterritoriality" alone. "Any statute of the form 'charge in this state the same price you charge outside it' carries the implied command: 'Charge outside this state the same price you charge inside it.' This latter, implied (but inseparable) command . . . is a forbidden attempt to exercise extraterritorial power." *K-S Pharmacies, Inc.,* 962 F.2d at 730. It was forbidden because of its effects on commerce, not because of its reach across state lines alone. And in *Cotto Waxo* the Eighth Circuit determined that "extraterritorial reach" in *Brown-Forman* and *Healy* is limited to statutes which "necessarily require[] out-of-state commerce to be conducted according to in-state terms." 46 F.3d at 794. A statute "does not suffer from an unconstitutional extraterritorial reach" if it does not *regulate* sales occurring out of state, even if it *affects* them to some extent. *Id.*

This court's recent decision in *Consolidated Cigar Corp. v. Reilly*, 218 F.3d 30 (1st Cir. 2000) suggests how a statute may have an extraterritorial effect yet not burden interstate commerce. That case involved, *inter alia,* a Massachusetts regulation requiring warning labels on all packages of tobacco products sold in the state. This Court invalidated the warning label regulation because of its burden on

out-of-state manufacturers, who had no way to control whether their products might eventually be sold in Massachusetts. They could avoid liability only by labeling *all* their packages nationwide. *Id.* at 57. This Court suggested, however, that the burden on interstate commerce might have been viewed quite differently had there been some way for the manufacturer to easily label only those packages that would ultimately enter Massachusetts. *Id.* That is essentially what the Maine law achieves. Linking the rebate only to retail sales reported by Maine pharmacies effectively satisfies the interstate commerce concerns identified in *Consolidated Cigar Corp.* because it removes all possibility that the law would be applied to retail sales not occurring in Maine.

The district court therefore erred in its determination that Maine lacks constitutional authority to seek rebates from out-of-state manufacturers in connection with the consumption of their products by Maine consumers.[16]

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[16] Even if the rebate requirement did actually burden extraterritorial commerce, it is not at all clear that the Supreme Court follows the *per se* rule applied by the district court. The district court cited a passage in *Edgar v. MITE Corp*., 457 U.S. 524 (1981) for the proposition that "'[I]nsofar as the Illinois law burdens out-of-state transactions, there is nothing to be weighed in the balance to sustain the law.'" Order at 10, quoting *Edgar*, 457 U.S. at 644. But six years after *Edgar* the Supreme Court declined to apply that aspect of its holding to a more narrowly-drawn anti-takeover statute in *CTS Corp. v. Dynamics Corp. of America*, 481 U.S. 69 (1987), even though the statute in *CTS Corp.* had indisputable (though limited) extraterritorial effects. Accordingly, notwithstanding the sentence quoted by the district court, it is far from clear that the *Edgar* Court would automatically regard a statute's extraterritorial reach, without more, as an impermissible burden on interstate commerce. *See also K-S Pharmacies,* 962 F.2d at 731 ("states may

b. Regulations With "Direct" Extraterritorial Effects On Out-Of-State Commerce Are Also Not Per Se Violations Of The Dormant Commerce Clause

The district court incorrectly held that the Act is a *per se* violation of the dormant commerce clause by virtue of its supposed "direct" effects on out-of-state wholesale transactions. Order at 10 (Add. 10). The court's reliance on the distinction between direct and indirect effects on interstate commerce has been discredited by this Court, and should not have formed the basis for deciding that plaintiffs would likely succeed on the merits of their claims.

This Court's recent decision in *Grant's Dairy* flatly rejected the direct/indirect dictum of *Brown-Forman. Grant's Dairy Maine v. Commissioner of Maine Department of Agriculture, Food & Rural Resource,* 2000 WL 1677985, *9 (1st Cir.) (November 13, 2000). This Court observed that the Supreme Court has not repeated the "direct regulation" factor as a basis for invalidating a state law since *Brown-Forman. Id.* at *10. Instead, as set forth above, the "critical consideration" is "the overall effect of the statute on both local and interstate activity," and the direct/indirect distinction has no place in that analytical framework. *Id.*, citing *Brown-Forman,* 476 U.S. at 579. It bears repeating that

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regulate transactions that wind up within their borders.") (citing *Michelin Tire Corp. v. Wages,* 423 U.S. 276 (1976)).

plaintiff has not even alleged an overall effect on interstate commerce resulting from the statute.

4. The Maine Rx Program Easily Satisfies The *Pike* Balancing Test Which Governs Dormant Commerce Clause Analysis Of Non-Discriminatory State Legislation.

As discussed above, the *per se* standard should not have been applied to the Maine Rx Program. Rather, this non-discriminatory statute should have been analyzed under the balancing test set forth in *Pike v. Bruce Church, Inc.,* 397 U.S. 137, 142 (1970). If the correct *Pike* standard had been applied the lower court would not have found that plaintiff was likely to succeed on the merits of its Commerce Clause claim.

The "critical consideration" in dormant Commerce Clause review is "the overall effect of the statute on both local and interstate activity." *Brown-Forman,* 476 U.S. at 579; s*ee also Healy*, 491 U.S. at 337 (considering statute's "practical effect"); *Complete Auto Transit, Inc. v. Brady*, 430 U.S. 274, 279 (1977)(warning of the dangers of a formalistic approach that obscures "the practical effect" of the statute under review); *Best & Co. v. Maxwell*, 311 U.S. 454 (1940) ("The commerce clause forbids discrimination, whether forthright or ingenious. In each case it is our duty to determine whether the statute under attack … will in its practical operation work discrimination against interstate commerce").

Facially nondiscriminatory regulations with only "incidental" effects on interstate commerce may only be invalidated if "the burden imposed on such commerce is clearly excessive in relation to the putative local benefits." *Pike,* 397 U.S. at 142. A facially nondiscriminatory regulation supported by the state's legitimate interest in lower prices, as is the Maine Rx Program, must be upheld unless it fails this test. *See Brown-Forman Distillers Corp.*, 476 U.S. at 580 ("a State may seek lower prices for its consumers, [so long as it does] not insist that producers or consumers in other States surrender whatever competitive advantages they may possess"); *Grant's Dairy* at * 11 (upholding statute without engaging in balancing); *see also* Kathleen Sullivan, *Post-Liberal Judging: The Roles of Categorization and Balancing,* 63 U. Colo. L. Rev. 293 (1992) ("Under dormant commerce clause review, facially neutral laws . . . are not invalidated virtually per se as are facially discriminatory laws").

Courts have required *Pike* balancing even for statutes with as direct and immediate an effect on interstate commerce as an outright ban. *See, e.g., Cotto Waxo* 46 F.3d 790 (outright ban on the goods of an out-of-state manufacturer); *New York v. Brown*, 721 F.Supp. 629 (D.N.J. 1989) (prohibition on the sale of certain milk produced out-of-state). Moreover, it is clear that the Court of Appeals may conduct *Pike* balancing even where the district court found a *per se* violation of the dormant Commerce Clause. *See, e.g., Instructional Systems, Inc. v.*

Computer Curriculum Corporation, 35 F.3d 813 (3d Cir. 1994) cert. denied 513 U.S. 1183 (1995)..

The Maine Rx Program satisfies *Pike* because it places absolutely no burden on interstate commerce. Indeed, the district court enjoined the Program because of its alleged extraterritorial reach, not because of any actual effect on interstate commerce. Plaintiffs have not alleged – and there is nothing in the record to show – that the statute will have any actual market effect such as improving or worsening the terms of manufacturers' wholesale sales or increasing or decreasing the volume of their business. There is therefore no adverse effect to balance against the statute's unquestioned public health goal of ensuring that Maine residents receive the medications their doctors prescribe. Even if there were some allegation of a "practical effect" on interstate commerce, there is nothing in the record to substantiate the nature and extent of that effect such that *Pike* balancing could possibly weigh in favor of the manufactures.

5. The Maine Rx Program Would Also Easily Satisfy The *Complete Auto* Test Governing Dormant Commerce Clause Analysis Of State Legislation Imposing Financial Exactions On Interstate Commerce.

Admittedly, we have found no case in the *Pike* line (or the *Brown-Forman* line) analyzing a non-discriminatory state rebate requirement such as Maine's. This is because Maine's unique approach does not fit easily into any existing dormant Commerce Clause rubric. There is, however, a firmly established line of

dormant Commerce Clause cases recognizing the constitutional ability of states to require payments from out-of-state firms in connection with those firms' commercial activities within the state. These cases, most importantly *Complete Auto Transit, Inc. v. Brady*, 430 U.S. 274 (1977), provide an alternative, if not perfect, analytical framework.

In *Complete Auto*, the Supreme Court held that a state tax imposed on out-of-state business does not violate the dormant Commerce Clause if it is (1) applied to an interstate activity with a substantial nexus with the state; (2) is fairly apportioned, (3) does not discriminate against interstate commerce, and (4) is fairly related to services provided by the State. *Id.* at 277-78.

The Maine Rx Program rebate provision, though not a tax, easily satisfies the *Complete Auto* four-part test, should this Court find that test applicable. First, the rebate is triggered by activity having a substantial nexus with the state because it only applies upon the retail sale within Maine of the manufacturer's products. Second, the rebate payment, which is determined under the law by the volume of a manufacturer's products sold in the Maine Rx Program, is exactly proportionate to the manufacturer's activity within the state and is therefore "fairly apportioned." Third, as the district court found, the rebate provisions do not discriminate against interstate commerce. Order at 8-9 (Add. 8-9). And fourth, the rebate is fairly related to the benefits reaped by the manufacturers in Maine because it is the

ultimate sale of the manufacturer's product to retail consumers that makes possible the manufacturers' profits, and it is that very same sale that determines the quarterly rebate calculations. The "fair relation" test requires only that "'the incidence of the [payment] as well as its measure [must be] tied to the earnings which the state … has made possible …'" *Id.* at 626 (quoting *Wisconsin v. J.C. Penney Co.,* 311 U.S. 435, 466 (1940)).[17]

Complete Auto establishes that the Constitution permits a State to exact payment from a business engaged in interstate commerce, to the extent that such commerce winds up within the State. A State must therefore surely be able to take the lesser step of requiring manufacturers to negotiate a quarterly rebate on the precisely the same goods at the same point in the stream of commerce.

IV. THE DISTRICT COURT ERRED IN FINDING THAT PLAINTIFF WILL SUFFER IRREPARABLE HARM WITHOUT A PRELIMINARY INJUNCTION, AND IT DID NOT PROPERLY APPLY THE BALANCE OF HARMS AND PUBLIC INTEREST PRONGS OF THE TEST.

"The criteria for the grant of a preliminary injunction are the familiar four: likelihood of success, risk of irreparable harm, the balance of equities and the

[17] *Complete Auto's* fourth prong is satisfied by nothing more than Maine's maintenance of a viable in-state economy offering the opportunity to make money in the State. *See Commonwealth Edison Co. v. Montana,* 453 U.S. 609, (1981) (the test is satisfied by "opportunities which [the state] has given, to protection which it has afforded, to benefits which it has conferred by the fact of being an orderly civilized society").

public interest." *Langlois v. Abington Housing Authority*, 207 F.3d 43, 47 (1st Cir. 2000). We set forth above the basis for this Court's *de novo* review of the lower court's analysis of the likelihood of success on the merits. We now address why the district court's manipulation of the remaining prongs of the test should be reversed.

A. The Court Erred In Finding That Plaintiff Will Be Irreparably Harmed Without A Preliminary Injunction

The opinion below did not use the words "irreparable harm." Nonetheless, the district court was persuaded that without injunctive relief, manufacturers entering into rebate agreements will be unable to recoup any Maine Rx Program rebate payments that they make to the State in the event that the Act is ultimately struck down. Order at 15 (Add. 15). The court incorrectly found that an injunction is necessary because PhRMA members need not make rebate payments during the period in which this case is being litigated. The Rebate Agreement itself does not seek the first rebate payments until at least September 30, 2001. *Concannon Aff.,* ¶ 5 (App. A-144), *Maine Rx Rebate Agreement,* sec. II(a) (App. A-150). Until that time the only threat of financial harm would be the manufacturers' contractual obligation to make payments at that time.

The district court held that plaintiff's members would be "submitting themselves contractually to an obligation" to pay the rebates upon executing a rebate agreement, and that this obligation would be enforceable even if they

ultimately succeed in their lawsuit and final judgment is entered in their favor. Order at 15 (Add. 15). This conclusion is based upon principles of contracts law, and is therefore reviewed de novo. The conclusion is wrong for two reasons. First, the Agreement proposed by the Commissioner does not require payment if the statute is voided. Second, such payment would not be enforceable under principles of contract law.

A plain reading of the Maine Rx Program Rebate Agreement offered by the Department indicates that the State could not enforce a manufacturer's agreement to pay Maine Rx Program rebates in the event that the statute is ultimately struck down. Specifically, paragraph VII (d) of the Rebate Agreement provides that "[n]othing in this Agreement shall be construed as a waiver or relinquishment of any legal rights of the Manufacturer…under the Constitution, the Social Security Act, [sic] other Federal laws or State laws." *Maine Rx Rebate Agreement,* sec. VII(d) (App. A-154).

Even if this reservation of rights clause were not part of the agreement, it is a tenet of contract law that an agreement "mandated by a statute which is itself later declared unconstitutional…is invalid." R. Lord, *Williston on Contracts,* 4th ed., § 19:44 at 406 (1990). The district court found that participation in the Maine Rx Program is not voluntary. Order at 13-15 (Add. 13-15) (noting that the Act "says that manufacturers 'shall enter' into rebate agreements and speaks of

negotiating the 'rebate *required* from a manufacturer.'") Thus, if the requirement to enter into a rebate agreement is made mandatory by the Act, and if the Act is ultimately stuck down, the agreement simply cannot be enforced. *See Union County Utilities v. Bergen County Utilities Authority*, 995 F.Supp. 506, 516-17 (D.N.J. 1998) (agreements entered pursuant to a statutory scheme later determined to be unconstitutional may be unenforceable pursuant to the contract doctrines of mutual mistake, prevention by governmental regulation or order, supervening impracticability, supervening frustration, and the principle that contracts against public policy are void).

To summarize, if the Act is to be struck down, it will likely be struck down before the first rebate payment is due, and the striking of the statute, on constitutional grounds, would itself relieve the plaintiff of any obligation to pay rebates for drugs already dispensed through the Maine Rx Program. Accordingly, the district court's determination that the plaintiff will suffer irreparable harm prior to trial was in error.

B. The State's Interest, And The Public Interest, Weighs Against The Imposition Of A Preliminary Injunction.

The district court's weighing of the parties' interests in the injunction is reviewed for an abuse of discretion. *Langlois, supra,* 207 F.3d at 47. The district court recognized that the "State has a strong interest in assisting its economically

and medically needy citizens" including those "uninsured citizens who must cope with astronomical prescription drug prices." Order at 3, 15 (Add. 3, 15). It was also correct in finding that the State's interest is congruent with the public interest. *Id*.

As set forth in the Statement of Facts above, the Act was intended to secure fair drug prices for the estimated 325,000 Maine citizens who do not have prescription drugs coverage. Maine's interest in promoting the health of those citizens is among the most weighty interests a State may have. This public interest, and the harm that will continue to be suffered by the individuals the Maine Rx Program was enacted to help, outweigh whatever financial harms might conceivably be suffered by plaintiff's members if the program is permitted to operate the way it was intended while the legal challenge to the Act is pending.

The district court, while clearly cognizant of the tremendous harm suffered by those who cannot afford to fill their drug prescriptions, abused its discretion in not considering this harm as part of the four-prong preliminary injunction test. Indeed, the district court ignored the "balance of harms" and "public interest" prongs altogether. The court simply reached the tautology that there can be no legitimate interest in achieving the important goals of the Act "through unconstitutional legislation." Order at 15(Add. 15).

We submit that the district court should have divorced its consideration of the "balance of equities" and "public interest" prongs of the preliminary injunction test from the question of whether plaintiff is likely to succeed on the merits of its legal challenge to the Act. By folding the "likelihood of success on the merits" prong into the balance of equities and public interest prongs of the test, the district court abused its discretion.

A proper weighing of the harm that will be felt by the State's uninsured residents should they be unable to secure the lower prescription drug prices promised by the Act against the harm which might be suffered by plaintiff's members under the Maine Rx Program tips decidedly against granting preliminary injunctive relief. The manufacturers have completely failed to supply any record evidence demonstrating overall financial loss if they are required to pay Maine Rx rebates. In fact, by lowering prescription drug prices for the uninsured, the Maine Rx Program is likely to increase sales volume. *See* Steven C. Tighe and Gregory B. Gilbert, *Pharmaceuticals -- A Medicare Drug Benefit: May not be so Bad,* Merrill Lynch Report, June 23, 1999, at 3 (suggesting that "when you either cut drug prices, provide a prescription benefit, or both, then volumes will go up with increased drug utilization"). Nothing in the record refutes the evidence that this will surely dampen, if not eliminate, any adverse effect on plaintiff's members' profit margins. For this reason, and because the interest of Maine's uninsured

citizens in obtaining affordable prescription drugs so overwhelms the countervailing interests of the plaintiff in enjoining the Act, the Order granting the preliminary injunction should be reversed.

CONCLUSION

For the foregoing reasons the preliminarily injunction barring enforcement of the prior authorization provision of the Act should be vacated.

Dated: January 8, 200

Respectfully submitted,

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