

United States Court of Appeals For the First Circuit

No. 00-2446

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,

Plaintiff, Appellee,

v.

KEVIN CONCANNON, COMMISSIONER, MAINE DEPARTMENT OF
HUMAN SERVICES, and MAINE ATTORNEY GENERAL,

Defendants, Appellants.

APPEAL FROM THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MAINE

[Hon. D. Brock Hornby, U.S. District Judge]

Before

Bownes, Senior Circuit Judge,
Keeton and Saris*, District Judges.

Andrew S. Hagler, Assistant Attorney General, with whom G. Steven Rowe, Attorney General, Paul Stern, Deputy Attorney General, John R. Brautigam, Assistant Attorney General, Cabanne Howard, and University of Maine Law School, were on brief, for appellant.

Thomas C. Bradley, Arn H. Pearson and Maine Citizen Leadership Fund on brief for Viola Quirion, Michelle Campbell, Maine Council of Senior Citizens and Richard Donahue, M.D., amici curiae.

Kathleen M. Sullivan, with whom Daniel M. Price, Allen S.

Rugg, Marinn F. Carlson, Powell, Goldstein, Frazer & Murphy, L.L.P., Bruce C. Gerrity and Preti, Flaherty, Beliveau, Pachios & Haley L.L.C., were on brief, for appellees.

Daniel J. Popeo, Richard A. Samp and Washington Legal Foundation, on brief for Washington Legal Foundation, Allied Educational Foundation, International Patient Advocacy Association, Kidney Cancer Association, The Seniors Coalition, and The 60 Plus Association, amici curiae.

Steven J. Rosenbaum, David H. Remes, Covington & Burling, Robin S. Conrad and National Chamber Litigation Center on brief, for the Chamber of Commerce of the United States, amicus curiae.

Edwin D. Schindler on brief pro se, amicus curiae.

May 16, 2001

*Of the District of Massachusetts, sitting by designation.

BOWNES, Senior Circuit Judge. In this case, we consider whether a Maine statute providing for affordable prescription drugs can survive facial constitutional challenges. On October 26, 2000, the district court issued a preliminary injunction preventing the implementation of the statute on the ground that it is preempted by the Supremacy Clause and violates the dormant Commerce Clause. We reverse.

I. BACKGROUND

On May 11, 2000, the Governor of Maine signed into law an Act to Establish Fairer Pricing for Prescription Drugs, 2000 Me. Legis. Ch. 786 (S.P. 1026) (L.D. 2599) (the "Act"), which establishes the "Maine Rx Program" (the "Program").¹

The statute was enacted because of the Maine Legislature's concern that many Maine citizens who were not Medicaid recipients could not afford necessary prescription

¹The full text of the relevant provisions of the Act is set forth in the Appendix, infra.

drugs. It is predicated on the economic reality that volume buying of prescription drugs by Medicaid administrators, insurance companies and health maintenance organizations ("HMOs") resulted in substantially lower prices for these entities than for individual purchasers. A minority staff report for the United States House Committee on Government Reform and Oversight found that the average retail price for individual elderly purchasers was 86 percent higher than the price charged to the federal government and other favored customers, such as HMOs.

The Program is open to all State residents, and allows enrollees to purchase prescription drugs from participating Maine pharmacies at a discounted price. The discount offered by the pharmacies is reimbursed by the State out of a dedicated fund created with the money raised from "rebate payments" collected from participating drug manufacturers. Me. Rev. Stat. Ann. tit. 22, § 2681. The obligation to pay the "rebate" is triggered by the retail sale of the manufacturer's drugs to a Program enrollee through a participating pharmacy.

The Act directs the Commissioner of Maine's Department of Health Services to negotiate rebate agreements with manufacturers. Id. § 2681(3). These rebate agreements are similar in form to the rebate agreements required of

manufacturers participating in the Maine Medicaid outpatient drug program. Id. § 2681(4). In negotiating the rebate, the Commissioner is directed to "consider" the rebate amount calculated under the Federal Medicaid Rebate Program, 42 U.S.C. § 1396r-8, and to use his or her "best efforts" to obtain an initial rebate in the same amount. Me. Rev. Stat. Ann. tit. 22, § 2681(4)(A)-(C). Rebate payments are made quarterly on the basis of retail sales records for that quarter. Id. § 2681(3).

In order to create an incentive for manufacturers to enter rebate agreements with the Commissioner, the Act provides that names of manufacturers who do not enter into agreements be released to health care providers and the public. Id. § 2681(7). More importantly, the drugs of all noncompliant manufacturers are required to be subject, "as permitted by law," to the "prior authorization requirements" in the State Medicaid program. Id. § 2681(7). When subjected to prior authorization, a drug may not be dispensed to a Medicaid beneficiary without the approval of the State Medicaid administrator.

The plaintiff-appellee, Pharmaceutical Research & Manufacturers of America ("PhRMA"), brought an action in the United States District Court in the District of Maine against defendant-appellants Commissioner of the Maine Department of Human Services and the Maine Attorney General, challenging the

constitutionality of the Act. PhRMA claimed that the Act violated the dormant Commerce Clause and was preempted by the federal Medicaid statute under the Supremacy Clause, and moved for a preliminary injunction to prevent the implementation of the Act.

The district court issued the preliminary injunction and found the Act unconstitutional on the two asserted grounds. First, the district court held that the Act had an impermissible extraterritorial reach by regulating the revenues out-of-state pharmaceutical manufacturers receive when selling to out-of-state pharmaceutical distributors, thereby violating the dormant Commerce Clause. As to those distributors located in the State of Maine, the district court held that the Act was preempted under the Supremacy Clause because it conflicted with the federal Medicaid program.²

II. DISCUSSION

A. Standard of Review

²The Act also contained a provision that made 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 for Prescription Drugs, § 2697(2), 2000 Me. Legis. Ch. 786 (S.P. 1026) (L.D. 2599) (to be codified at Me. Rev. Stat. Ann. tit. 22, § 2697(2)). The district court found this provision unconstitutional. The State of Maine has not appealed this ruling.

"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 public interest." Langlois v. Abington Hous. Auth., 207 F.3d 43, 47 (1st Cir. 2000) (citing Ross-Simons of Warwick, Inc. v. Baccarat, Inc., 102 F.3d 12, 15 (1st Cir. 1996)). When a district court's grant of a preliminary injunction is appealed, our standard of review depends on the issue under consideration: we review pure issues of law de novo, findings of fact for clear error, and "judgment calls" with considerable deference. Id. (noting that our standard of review is sometimes summarized as being for "abuse of discretion").

The district court concluded that PhRMA's likelihood of success on the merits of most of its constitutional challenges was "overwhelming." Accordingly, it dealt only cursorily with the remaining preliminary injunction factors. Our review also focuses on PhRMA's likelihood of success on the merits of its challenges under the Supremacy Clause and the Commerce Clause. See Weaver v. Henderson, 984 F.2d 11, 12 (1st Cir. 1993) (stating that the "sine qua non" of preliminary injunction analysis is whether plaintiff is likely to succeed on merits of claim).

B. Standing

The initial question we face is whether PhRMA has prudential standing to challenge the prior authorization provision of the Act. PhRMA contends that Maine's standing argument was not briefed to the district court, and therefore was waived. We assume, without deciding, that Maine may assert this standing challenge on appeal, and hold that PhRMA falls within the relevant "zone of interest."³

The Supreme Court recently reiterated the standard for determining prudential standing:

[I]n applying the "zone of interests" test, we do not ask whether, in enacting the statutory provision at issue, Congress specifically intended to benefit the plaintiff. Instead, we first discern the interests "arguably . . . to be protected" by the statutory provision at issue; we then inquire whether the plaintiff's interests affected by the agency action in question are among them.

³There is some dispute among the circuits as to whether prudential standing (as opposed to Article III standing) can be raised for the first time on appeal. Compare Animal Legal Def. Fund v. Espy, 23 F.3d 496, 499 (D.C. Cir. 1994) (prudential standing is non-waivable); Thompson v. County of Franklin, 15 F.3d 245, 248 (2d Cir. 1994) (same); Cnty. First Bank v. Nat'l Credit Union Admin., 41 F.3d 1050, 1053 (6th Cir. 1994) (same) with Pershing Park Villas Homeowners Ass'n v. United Pac. Ins. Co., 219 F.3d 895, 899 (9th Cir. 2000) (prudential standing is waivable); Lindley v. Sullivan, 889 F.2d 124, 129 (7th Cir. 1989) (same). Because we hold that Maine's challenge to PhRMA's standing would be unsuccessful in any event, as explained *infra*, it is not necessary for us to decide the waiver issue now.

Nat'l Credit Union Admin. v. First Nat'l Bank & Trust Co., 522 U.S. 479, 492 (1998).

Maine contends that PhRMA's interest is purely financial and is limited to ensuring that its members' drugs are prescribed instead of competitors' drugs. Nothing in the Medicaid statute, Maine argues, suggests that Congress intended to protect sales of any particular drugs. See Tap Pharms. v. U.S. Dep't of HHS, 163 F.3d 199, 208 (4th Cir. 1998) (holding that pharmaceutical manufacturer lacked standing to challenge Medicare rules reducing reimbursement amounts paid for their products because manufacturer's financial interests were not within zone of interests protected by Medicare).

PhRMA has not asserted an action to enforce rights under the Medicaid statute, however, but rather a preemption-based challenge under the Supremacy Clause. In this type of action, it is the interests protected by the Supremacy Clause, not by the preempting statute, that are at issue. St. Thomas-St. John Hotel & Tourism Ass'n v. Virgin Islands, 218 F.3d 232, 241 (3d Cir. 2000). As the Third Circuit recently pointed out, an entity does not need prudential standing to invoke the protection of the Supremacy Clause:

We know of no governing authority to the effect that the federal statutory provision which allegedly preempts enforcement of local legislation by conflict must confer a

right on the party that argues in favor of preemption. On the contrary, a state or territorial law can be unenforceable as preempted by federal law even when the federal law secures no individual substantive rights for the party arguing preemption.

Id. Thus, regardless of whether the Medicaid statute's relevant provisions were designed to benefit PhRMA, PhRMA can invoke the statute's preemptive force. Cf. Burgio & Campofelice, Inc. v. N.Y. State Dep't of Labor, 107 F.3d 1000, 1006 (2d Cir. 1997) (concluding that the Supremacy Clause creates an implied right of action for injunctive relief against state officers who are threatening to violate federal law).

Given that PhRMA has prudential standing grounded in the Supremacy Clause, we think it may fairly assert the rights of Medicaid recipients for purposes of this action. Where a party has established a concrete injury in fact, and otherwise has standing to challenge the lawfulness of the statute, it is "entitled to assert those concomitant rights of third parties that would be 'diluted or adversely affected' should [its] constitutional challenge fail and the statute[] remain in force." Craig v. Boren, 429 U.S. 190, 195 (1976) (quoting Griswold v. Connecticut, 381 U.S. 479, 481 (1965)). Accordingly, "vendors and those in like positions have been uniformly permitted to resist efforts at restricting their

operations by acting as advocates of the rights of third parties who seek access to their market or function." Id.; see also 1 L. Tribe, American Constitutional Law, § 3-19, p. 438 (3d ed. 2000).

C. Preemption

Having decided that PhRMA has standing to challenge the Maine Act on preemption grounds, we now turn to the merits of that argument. The district court addressed preemption only with regard to the Act's regulation of sales to in-state distributors, after concluding that such regulation would not be barred by the Commerce Clause. It held that the prior authorization review requirement of the Act, Me. Rev. Stat. Ann. tit. 22, § 2681(7), conflicted with the purposes of the Medicaid program such that the requirement was invalid under the Supremacy Clause.⁴ If we affirm the district court's preemption holding, it would invalidate the Act as to all distributors, not just those who operate in Maine, and would obviate the need to

⁴Only the prior authorization review requirement of the Act is at issue for preemption purposes, not the public identification requirement. Therefore, for simplicity's sake, our use of the terms "the Act" or "Maine Rx Program" refer solely to the prior authorization review requirement.

address the Commerce Clause. Therefore, we analyze the issue of preemption first.⁵

Under the Supremacy Clause, a federal law may expressly or impliedly preempt state law. U.S. Const. art. VI, cl. 2 (stating that federal law "shall be the supreme law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding"). As the parties agree, only "implied conflict preemption" is at issue here.⁶ Our task, therefore, is to consider if "compliance with both state and federal regulations is impossible" or if "state law interposes an

⁵An amicus curiae brief offers another basis for federal preemption: Edwin D. Schindler, Major Stockholder and Patent Attorney, argues that the Maine Act is preempted by federal patent law. Because these issues were raised for the first time on appeal by an amicus, not by a party, we do not consider them. Am. Fed'n of Gov't Employees, Local 3936 v. Fed. Labor Relations Auth., 239 F.3d 66, 69 (1st Cir. 2001); United States v. Sturm, Ruger & Co., 84 F.3d 1, 6 (1st Cir. 1996) ("an amicus cannot introduce a new argument into a case").

⁶Express preemption of a state law occurs where "a federal statute explicitly confirms Congress's intention to preempt state law and defines the extent of that preclusion." Grant's Dairy-Me., LLC v. Comm'r of Me. Dep't of Agric., Food & Rural Res., 232 F.3d 8, 15 (1st Cir. 2000). There is no explicit language in the Medicaid statute that forbids the Maine Rx Program. Nor is the doctrine of "field" preemption relevant, as Medicaid is a cooperative federal and state program. This form of implied preemption applies only when a federal regulatory scheme is so pervasive as to create the inference that Congress did not intend for the states to pass supplemental law in that area. Gade v. Nat'l Solid Wastes Mgmt. Ass'n, 505 U.S. 88, 98 (1992). Therefore, we consider only implied conflict preemption as a basis for PhRMA's argument.

obstacle to the achievement of Congress's discernable objectives." Grant's Dairy-Me., LLC v. Comm'r of Me. Dep't of Agric., Food & Rural Res., 232 F.3d 8, 15 (1st Cir. 2000) (citing Gade v. Nat'l Solid Wastes Mgmt. Ass'n, 505 U.S. 88, 98 (1992)).

In doing so, we assume "that the historic police powers of the States [are] not to be superceded by . . . Federal Act unless that [is] the clear and manifest purpose of Congress." Id. at 14-15 (quoting Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947)). We also recognize that federal preemption of a state law is "strong medicine," and is "not casually to be dispensed." Id. at 18. This is especially true when the federal statute creates a program, such as Medicaid, that utilizes "cooperative federalism": "Where coordinated state and federal efforts exist within a complementary administrative framework, and in the pursuit of common purposes, the case for federal preemption becomes a less persuasive one." Wash., Dep't of Soc. & Health Servs. v. Bowen, 815 F.2d 549, 557 (9th Cir. 1987) (quoting N.Y. Dep't of Soc. Servs. v. Dublino, 413 U.S. 405, 421 (1973)).

To determine whether the state regulation is consistent with the federal statute, we examine the "structure and purpose of the [federal] statute as a whole." Gade, 505 U.S. at 98.

The primary purpose of Medicaid is to enable states to provide medical services to those whose "income and resources are insufficient to meet the costs of necessary medical services" 42 U.S.C. § 1396 (2000). Congress expressly intended that the provision of medical services be administered by the state "in a manner consistent with simplicity of administration and the best interests of the recipients." Id. § 1396a(a)(19).

We perceive no conflict between the Maine Act and Medicaid's structure and purpose. Neither the letter nor the intent of the Medicaid statute prevents states from imposing prior authorization requirements; indeed, they are explicitly permitted. 42 U.S.C. § 1396r-8(d)(1)(A) (states may "subject to prior authorization any covered outpatient drug"). The statute sets forth only two limitations on a state's use of prior authorization: the state must provide "response by telephone or other telecommunication device within 24 hours of a request for prior authorization;" and, with respect to most drugs, provide for "the dispensing of at least 72-hour [sic] supply of a covered outpatient prescription drug in an emergency situation (as defined by the Secretary)." Id. § 1396r-8(d)(5)(A) and (B).

The plain text of the Maine Act appears to incorporate these Medicaid requirements. It provides: "The department shall impose prior authorization requirements in the Medicaid

program under this Title, as permitted by law, for the dispensing of prescription drugs" Me. Rev. Stat. Ann. tit. 22, § 2681(7) (emphasis added). We read the language "as permitted by law" to limit the Act's application to only those situations in which prior authorization is permitted by Medicaid.⁷ As the Department is charged with administering the Maine Rx Program, we owe deference to its interpretation of the Act. Fireside Nissan, Inc. v. Fanning, 30 F.3d 206, 212 (1st Cir. 1994).

Moreover, as set forth in the affidavit of Kevin Concannon, Commissioner of the Maine Department of Human Services, Maine has proposed administrative rules governing prior authorization aimed at ensuring that Medicaid recipients will have access to needed medications. Specifically, the decision to place a drug on the prior authorization list may be made only by the State's Medicaid Drug Utilization Review [DUR] Committee, which exclusively comprises physicians and pharmacists licensed to prescribe or dispense medications in Maine. Concannon states:

In making its determination of whether or not a prior authorization requirement is

⁷Kevin Concannon, Commissioner of the Maine Department of Human Services, affirms in an affidavit that the Department will not impose prior authorization that would conflict with the Medicaid requirements.

clinically appropriate, the DUR Committee shall be guided by the law of Medicaid, and particularly the principle that Medicaid recipients shall be assured access to all medically necessary prescription drugs.

PhRMA contends that prior authorization, however implemented, necessarily interferes with the delivery of Medicaid services by placing an administrative burden on physicians and patients. This interference is acceptable, it says, when performed in the usual course of the Medicaid regulations concerning prior authorization, 42 U.S.C. § 1396r-8(d)(5), because there is a countervailing "legitimate" purpose of preventing abuse or overprescription of certain expensive medications. In the case of a prior authorization under the Maine Rx Program, however, PhRMA argues (and the district court agreed) that there is no "Medicaid purpose" or "benefit" to Medicaid that offsets the interference. Hence, it contends, only when a prior authorization is motivated by the refusal to enter into a Maine Rx Program rebate agreement is it preempted.

This argument is unpersuasive. First, we are not convinced that the Medicaid statute is concerned with the motivation behind imposing prior authorization, as long as the 24-hour response and the 72-hour drug-supply requirements, 42 U.S.C. § 1396r-8(d)(5), are satisfied. Thus, even if the district court's conclusion that "Maine can point to no Medicaid

purpose in this new prior authorization requirement" is true, it does not necessarily mean that the prior authorization scheme conflicts with the objectives of the Medicaid program. We see no basis for inflicting the "strong medicine" of preemption on a state statute that, in the absence of an actual conflict, merely fails to directly advance the purpose of the federal program.

Moreover, even assuming that this inquiry into the underlying objectives of the Act is appropriate, we disagree that the Act serves no purpose related to Medicaid. The purposes of the Medicaid statute, read broadly, are consonant with the purposes of the Maine Rx Program. First, the Maine Rx Program furthers Medicaid's aim of providing medical services to those whose "income and resources are insufficient to meet the costs of necessary medical services," 42 U.S.C. § 1396, even if the individuals covered by the Maine Rx Program are not poor enough to qualify for Medicaid. Second, there is some evidence in the record that by making prescription drugs more accessible to the uninsured, Maine may reduce Medicaid expenditures. When people whose incomes fall outside Medicaid eligibility are unable to purchase necessary medication, their conditions may worsen, driving them further into poverty and into the Medicaid program, requiring more expensive treatment that could have been

avoided had earlier intervention been possible. See Stephen B. Soumerai, Sc.D., Dennis Ross-Degnan, Sc.D., Inadequate Prescription-Drug Coverage for Medicare Enrollees - A Call to Action, New England Journal of Medicine, Vol. 340, No. 9, March 4, 1999 (contained in district court record); 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, October 9, 1998 (same).⁸

Thus, we disagree with the district court's statement that "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." Neither highway construction nor school funding relate in any way to the purposes of providing medical services to the needy, see 42 U.S.C. § 1396, or of cost-effective administration of the Medicaid program, see id. §

⁸Moreover, the Amicus Curiae Brief of Viola Quirion, Michelle Campbell, Maine Council of Senior Citizens and Richard Donahue, M.D. attaches an affidavit from Maine resident Viola Quirion indicating that because many older persons cannot afford the high costs of prescription drugs, there may be increased enrollment in nursing homes and an increased burden on Medicaid.

1396a(a)30(A) (state plans must assure that payments are consistent with, inter alia, efficiency and economy).

PhRMA further contends that the Maine Rx Program will necessarily harm Medicaid recipients by impeding access to their doctors' first-choice medications. The district court agreed with this argument, concluding that the Maine Act conflicted with the Medicaid provision setting forth a general requirement that a state Medicaid plan contain safeguards 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). PhRMA vigorously presses the argument that the prior authorization provision is more than a de minimus obstacle to achieving these best interests of the Medicaid recipient because it will effectively require a doctor to shift to her second choice drug where the first choice drug is manufactured by a company that does not participate in the rebate program. The state concedes that it will not authorize payment for the first-choice drug manufactured by a non-participant where there is another drug for the ailment manufactured by a participant, but insists that the Medicaid recipient will always receive medically necessary drugs. At this point in the proceedings, we find insufficient basis for concluding that the Maine Act, on its face, controverts the Medicaid goal of "best interests."

Because this is a facial challenge to a statute, PhRMA has a difficult burden of showing that Medicaid recipients will be harmed by the Maine Rx Program. "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). "The existence of a hypothetical or potential conflict is insufficient to warrant the preemption of the state statute." Rice v. Norman Williams Co., 458 U.S. 654, 659 (1982).

Here, the parties submitted competing affidavits discussing whether the Maine Rx Program will necessarily inflict harm on Medicaid patients. Dr. Scott Howell, Vice President of National Accounts, Managed Care, SmithKline Beecham Corporation, states that "when used wrongly," prior authorizations hurt medical professionals and patients by adding administrative burdens, delays, anxiety and confusion. He opines that the Maine Rx Program "will create a high likelihood" of harm by leading to inappropriate prescribing of medications, needlessly burdening doctors, and causing unnecessary inconvenience for Medicaid recipients. "[P]rior authorization of drugs, without regard to safety or efficacy, will lead to drugs being prescribed that are less safe and efficacious."

Dr. Timothy S. Clifford, the Medical Director for the Maine Bureau of Medical Services, which administers the Medicaid program, disagrees with Dr. Howell's affidavit on several points. He contends that the Department will address safety and efficacy concerns in administering the Maine Rx Program's prior authorization requirement; that it will consider the availability of alternative drugs in deciding whether to subject a particular drug to the requirement; and that Medicaid recipients will continue to have access to medically necessary drugs. Dr. Clifford states: "The Department certainly will not subject any single-source drug that fulfills a unique therapeutic function to the prior authorization process, regardless of whether the manufacturer participates in the Maine Rx Program"

Dr. H. Burt Richardson, Jr., a Maine pediatrician and Maine Medicaid provider, states that he supports the Maine Rx Program "so long as the decision to put a prior authorization on particular drugs is clinically appropriate, feasible for a medical office, and accompanied by the assurance that all Maine Medicaid recipients have access to medically necessary drugs."

These affidavits, along with other materials in the record, fall short of establishing that the Act will inflict

inevitable or even probable harm on Medicaid patients or their providers. In reviewing a preemption-based facial challenge, "we do not rest our decision on consequences that, while possible, are by no means predictable." Dep't of Taxation and Fin. of N.Y. v. Milhelm Attea & Bros., Inc., 512 U.S. 61, 69 (1994). There is no evidence that the prior authorization procedure is likely to foreclose a patient from receiving a necessary drug. Although prior authorization review is triggered by a manufacturer's refusal to participate in the Maine Rx Program, the record indicates that the final decision to require prior authorization for a particular drug is based primarily on clinical criteria applied by health care professionals.

Since both sides agree that the prior authorization requirement is the "hammer" or "force" that coerces manufacturers to enter into the Program, the possibility that first-choice drugs will not be readily approved where second-choice inferior alternatives exist concerns us. The possibility that the administrative implications of the prior authorization requirement will affect the quality of medical care for Medicaid recipients in more subtle ways, i.e. through inconveniencing prescribing physicians, also concerns us. Dr. Howell's affidavit, however, is controverted by the affidavits of other

qualified individuals. We simply cannot say on this record that the Act conflicts with Medicaid's requirement that state Medicaid plans assure that care will be provided in a manner consistent with the recipients' best interests. 42 U.S.C. § 1396a(a)(19).

This decision is without prejudice to PhRMA's right to renew its preemption challenge after implementation of the Act, should there be evidence that Medicaid recipients are harmed by the prior authorization requirement "as applied." See United States v. Hilton, 167 F.3d 61, 71 (1st Cir.), cert. denied, 528 U.S. 844 (1999) ("It makes little sense to strike down an entire statute in response to a facial attack when potential difficulties can be remedied in future cases through fact-specific as-applied challenges."); see also Corgain v. Miller, 708 F.2d 1241, 1251 (7th Cir. 1983) (upholding facial adequacy of plan for prisoner's access to law library, but not foreclosing future challenge to plan as implemented).

D. Dormant Commerce Clause

Holding that the Maine Act is not preempted by the Medicaid statute, we next consider whether it violates the dormant Commerce Clause. The Constitution provides that Congress shall have 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 constitutional provision affirmatively granting Congress the authority to legislate in the area of interstate commerce “has long been understood, as well, to provide ‘protection from state legislation inimical to the national commerce [even] where Congress has not acted. . . .’” Nat’l Foreign Trade Council v. Natsios, 181 F.3d 38, 61 (1st Cir. 1999) (alterations in original) (quoting Barclays Bank PLC v. Franchise Tax Bd. of Cal., 512 U.S. 298, 310 (1994)), aff’d sub nom. Crosby v. Nat’l Foreign Trade Council, 530 U.S. 363 (2000). This negative command, known as the dormant Commerce Clause, prohibits states from acting in a manner that burdens the flow of interstate commerce. Okla. Tax Comm’n v. Jefferson Lines, Inc., 514 U.S. 175, 179-80 (1995); Healy v. Beer Inst., 491 U.S. 324, 326 n.1 (1989).

The restriction imposed on states by the dormant Commerce Clause is not absolute, and “the States retain authority under their general police powers to regulate matters of legitimate local concern, even though interstate commerce may be affected.” Maine v. Taylor, 477 U.S. 131, 138 (1986) (internal quotation marks omitted). The prohibitions imposed upon state regulation by the dormant Commerce Clause have fallen into several identifiable categories. To determine whether a

statute violates the dormant Commerce Clause, we apply one of several levels of analysis, depending on the effect and reach of the legislation.

First, a state statute is a per se violation of the Commerce Clause when it has an "extraterritorial reach." Healy, 491 U.S. at 336. "[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." Id. When a state statute regulates commerce wholly outside the state's borders or when the statute has a practical effect of controlling conduct outside of the state, the statute will be invalid under the dormant Commerce Clause. Cotto Waxo Co. v. Williams, 46 F.3d 790, 793 (8th Cir. 1995) (citing Healy). A statute will have an extraterritorial reach if it "necessarily requires out-of-state commerce to be conducted according to in-state terms." Id. at 794.

Second, if a state statute discriminates against interstate commerce, we apply strict scrutiny. It will be scrutinized under a "virtually per se invalid rule," which means that the statute will be invalid unless the state can "show that it advances a legitimate local purpose that cannot be adequately

served by reasonable nondiscriminatory alternatives." Or. Waste Sys., Inc. v. Dep't of Env'tl. Quality of Or., 511 U.S. 93, 100-01 (1994) (alteration and internal quotation marks omitted). This level of scrutiny will be applied if the state statute discriminates against interstate commerce on its face or in practical effect. Taylor, 477 U.S. at 138; see also Bacchus Imports, Ltd. v. Dias, 468 U.S. 263, 270 (1984) (indicating that a finding of discriminatory purpose or discriminatory effect can constitute economic protectionism subjecting the state statute to a "stricter level of invalidity"). When a state statute "discriminates against interstate commerce, or when its effect is to favor in-state economic interests over out-of-state interests, we have generally struck down the statute without further inquiry." Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth., 476 U.S. 573, 579 (1986).

Third, a lower standard of scrutiny is applied when the state statute regulates evenhandedly and has only incidental effects on interstate commerce. In this situation, a balancing test is applied. Pike v. Bruce Church, Inc., 397 U.S. 137, 142 (1970). "Where the statute regulates evenhandedly to effectuate a legitimate local public interest, and its effects on interstate commerce are only incidental, it will be upheld

unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits." Id.

PhRMA contends that the Maine Act is an impermissible exercise in extraterritorial regulation and, therefore, is per se violative of the dormant Commerce Clause. It argues that the Act necessarily regulates the transaction that occurs between the manufacturer and the distributor outside the borders of Maine.

Maine first argues that we need not reach the issue of whether the Act violates the dormant Commerce Clause because it is acting as a "market participant" and is therefore exempt from Commerce Clause restrictions.⁹ See South-Central Timber Dev., Inc. v. Wunnicke, 467 U.S. 82, 93 (1984) ("if a State is acting as a market participant, rather than as a market regulator, the dormant Commerce Clause places no limitation on its activities"). We hold that Maine does not fall under the market participant exception to the dormant Commerce Clause. Maine is not a market buyer of prescription drugs, except as required by the Medicaid statute. Its citizens will continue to directly purchase prescription drugs as needed. Nothing in the Act makes Maine a market participant.

⁹See Judge Lynch's opinion in Nat'l Foreign Trade Council, 181 F.3d at 62-65, for a thorough scholarly discussion of a state as a market participant.

Maine alternatively argues that the Act evenhandedly regulates in-state conduct that only has an incidental effect on interstate commerce. Maine contends that we should apply the lower level of scrutiny, use the Pike balancing test, and find that the local benefits of the Maine Rx Program outweigh the incidental burden on interstate commerce.

The Maine Act represents a novel legislative approach to one of the serious problems of our time, one that resists easy analysis. We address each of the potentially applicable dormant Commerce Clause prohibitions to determine the appropriate analysis and level of scrutiny.

1. Per Se Invalidity: Extraterritorial Reach

A state may not pass laws that have the "'practical effect' of regulating commerce occurring wholly outside that State's borders" Healy, 491 U.S. at 332. When evaluating the practical effect of the statute, the court should consider the statute itself, and "how the challenged statute may interact with the legitimate regulatory regimes of other States and what effect would arise if not one, but many or every, State adopted similar legislation." Id. at 336.

PhRMA relies on three cases to support its argument that the Maine Act is per se invalid because it regulates conduct beyond the borders of Maine. The cases cited, however,

are inapposite to the facial construction of the Maine Act. PhRMA construes these cases as standing for the proposition that, "a state may not dictate the terms on which buyers and sellers do business outside of the state." See, e.g., Healy, 491 U.S. at 338; Brown-Forman, 476 U.S. at 583-84. This is partially correct but does not reflect the entire picture. The cases on which PhRMA relies, however, involve price control, price affirmation or price tying schemes. See Healy, 491 U.S. at 326; Brown-Forman, 476 U.S. at 575-76; Baldwin v. G.A.F. Seelig, 294 U.S. 511, 519 (1935) ("Seelig"). The statutes in these cases involved regulating the prices charged in the home state and those charged in other states in order to benefit the buyers and sellers in the home state, resulting in a direct burden on the buyers and sellers in the other states.

In Healy, the Court struck down a Connecticut Liquor Control Act that required out-of-state shippers of beer to affirm that the prices at which the products were sold to Connecticut wholesalers were no higher than prices at which those same products were sold in bordering states. 491 U.S. at 326. The Court held the statute to be unconstitutional because it controlled prices in neighboring states and interfered with the regulatory schemes in those states. Id. at 338-39.

In Brown-Forman, the Court struck down a provision of the New York Alcoholic Beverage Control Law that required liquor distillers to affirm that their prices were no higher than the lowest price at which the same product would be sold in any other state during the month. 476 U.S. at 575-76. The Court determined that this was an extraterritorial reach violative of the Constitution. It held that "[o]nce a distiller has posted prices in New York, it is not free to change its prices elsewhere in the United States during the relevant month. Forcing a merchant to seek regulatory approval in one State before undertaking a transaction in another directly regulates interstate commerce." Id. at 582 (footnote omitted).

In Seelig, the Court struck down the New York Milk Control Act, which set minimum prices for milk purchased from in-state and out-of-state producers and banned the resale of milk in New York when that milk had been purchased out-of-state for a lower price. 294 U.S. at 519. By requiring New York wholesalers to buy out-of-state milk at certain prices, the effect of the statute was to essentially set out-of-state milk prices. The Court recognized that the Commerce Clause does not permit a state to create a "scale of prices for use in other states, and to bar the sale of products . . . unless the scale has been observed." Id. at 528.

The Maine Act is different from these statutes. Unlike these price affirmation and price control statutes, the Maine Act does not regulate the price of any out-of-state transaction, either by its express terms or by its inevitable effect. Maine does not insist that manufacturers sell their drugs to a wholesaler for a certain price.¹⁰ Similarly, Maine is not tying the price of its in-state products to out-of-state prices. There is nothing within the Act that requires the rebate to be a certain amount dependent on the price of prescription drugs in other states. The Act merely says that the Commissioner of the Maine Department of Human Services shall use "best efforts to obtain an initial rebate amount equal to or greater than the rebate calculated under the Medicaid program" Me. Rev. Stat. Ann. tit. 22, § 2681(4)(B). Furthermore, unlike Brown-Forman and Seelig, the Maine Act does not impose direct controls on a transaction that occurs wholly out-of-state.

PhRMA argues strenuously that the effect of the Act will be to regulate the transaction that occurs between the manufacturer and the wholesaler -- a transaction that occurs entirely out of state. It argues that as a result of the rebate provision, manufacturers will lose a portion of their profits

¹⁰As noted above, supra fn.2, the anti-profiteering provision of the Act was held unconstitutional and is not part of this appeal.

otherwise obtained from distributors. Admittedly, it is possible that the rebate provisions of the statute may decrease the profits of manufacturers. Simply because the manufacturers' profits might be negatively affected by the Maine Act, however, does not necessarily mean that the Maine Act is regulating those profits.

The Act does not regulate the transaction between manufacturers and wholesalers. It provides for a negotiated rebate agreement between "[a] drug manufacturer or labeler that sells prescription drugs in [Maine] through the elderly low-cost drug program . . . or any other publicly supported pharmaceutical assistance program" Me. Rev. Stat. Ann. tit. 22, § 2681(3). The rebate program is voluntary and either the manufacturer or the State may withdraw at any time with sixty days' notice. The Act directs the commissioner to "use the commissioner's best efforts" to negotiate the amount of the rebate required from the manufacturer. Id. § 2681(4)(B). We note that the commissioner's "best efforts" may become coercive or otherwise inappropriate, but we cannot say so on this facial challenge. This may be an issue that needs to be revisited once the Act takes effect. On a facial challenge, however, the use of the commissioner's "best efforts" indicates that the Act is not "regulating" prices, but merely "negotiating" rebates.

The Act clearly does not interfere with regulatory schemes in other states. Ultimately, the Maine Act simply regulates activity that occurs in state: (1) the purchase of the prescription drugs that triggers the rebate; (2) the negotiation of a rebate amount; and (3) the State's action subjecting a manufacturer's drug to prior authorization and releasing the manufacturer's name to health care providers and the public occurs in state. Because the regulation only applies to in-state activities, there is no extraterritorial reach and the Act is not per se invalid under the Commerce Clause.

One final consideration is the consequence of other states passing similar statutes. See Healy, 491 U.S. at 336 (considering "what effect would arise if not one, but many or every, State adopted similar legislation"). The most apparent effect of similar statutes being passed in other states would be a loss in profits for manufacturers. It does not appear, and PhRMA does not argue, that statutes similar to the Maine Act, if enacted, would result in manufacturers having inconsistent obligations to states, or in creating a "price gridlock" linking prices in some states to the prices in other states. See Healy, 491 U.S. at 340. Therefore, at this time, when we are dealing with a facial challenge to the Act, there is no evidence that adverse effects on interstate commerce will occur if such

legislation were passed in other states. The Act is not per se violative of the Commerce Clause.

2. Strict Level of Scrutiny: Discriminatory Statute

A statute enacted for a discriminatory purpose is subject to strict scrutiny. See Bacchus Imports, Ltd., 468 U.S. at 270. Under this strict scrutiny analysis, a statute violates the Commerce Clause unless the state can show that the statute serves a legitimate local purpose that is unrelated to economic protectionism and that the same purpose could not be achieved by nondiscriminatory means. Hughes v. Oklahoma, 441 U.S. 322, 336 (1979). PhRMA does not contend, nor did the district court find, that the Maine Act discriminates on its face or in its effects. Therefore, we need not discuss it further.

3. Low Level of Scrutiny: Pike Balancing Test

When a state statute regulates evenhandedly and has only incidental effects on interstate commerce, that statute will be upheld unless the burden on interstate commerce is "clearly excessive in relation to the putative local benefits." Pike, 397 U.S. at 142.

Where the statute regulates evenhandedly to effectuate a legitimate local public interest, and its effects on interstate commerce are only incidental, it will be upheld unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits. If a legitimate local purpose is found, then the

question becomes one of degree. And the extent of the burden that will be tolerated will of course depend on the nature of the local interest involved, and on whether it could be promoted as well with a lesser impact on interstate activities. Occasionally the Court has candidly undertaken a balancing approach in resolving these issues, but more frequently it has spoken in terms of "direct" and "indirect" effects and burdens.

Id. (internal citations omitted). The Maine Act is neither an impermissible extraterritorial reach nor is it discriminatory; rather, it regulates evenhandedly and only has incidental effects on interstate commerce. Therefore, we apply this lower level of scrutiny, known as the Pike balancing test.

The district court found the Maine Act to be per se invalid, and therefore never determined whether it survives the Pike balancing test. Though the district court did not undertake such an analysis, we may conduct the Pike balancing test for the first time on appeal. See Instructional Sys., Inc. v. Computer Curriculum Corp., 35 F.3d 813, 826 (3d Cir. 1994). In Instructional Systems, the Third Circuit considered a facial challenge to the New Jersey Franchise Practices Act after the district court had declared the statute per se invalid under the dormant Commerce Clause. Id. at 826. The court found that the statute, from a facial standpoint, survived the Pike test, and reversed the district court judgment which had declared the

statute unconstitutional. Id. at 827. The Third Circuit recognized, however, that the issue of whether the statute, when applied, burdens interstate commerce could not be resolved as a matter of law. Id.

Applying the Pike balancing test to the Maine Act, we consider: (1) the nature of the putative local benefits advanced by the statute; (2) the burden the statute places on interstate commerce; and (3) whether the burden is "clearly excessive" as compared to the putative local benefits. See Pike, 397 U.S. at 142.

Arguably, the only burden imposed on interstate commerce by the Maine Act is its possible effects on the profits of the individual manufacturers. As the Third Circuit stated, however, "the fact that a law may have 'devastating economic consequences' on a particular interstate firm is not sufficient to rise to a Commerce Clause burden." Instructional Sys., 35 F.3d at 827 (quoting Ford Motor Co. v. Ins. Comm'r, 874 F.2d 926, 943 (3d Cir. 1989)); see also Exxon Corp. v. Governor of Md., 437 U.S. 117, 127-28 (1978) (stating that "the [Commerce] Clause protects the interstate market, not particular interstate firms, from prohibitive or burdensome regulations.").

We next consider the local benefits of the Act, which we find to be substantial. The Maine Rx Program will

potentially provide prescription drugs to Maine citizens who could not otherwise afford them. The Maine Legislature has decided that without the Maine Rx Program, needy Maine citizens will continue to be deprived of necessary medical care because of rising prescription drug costs. When measuring manufacturers' possible loss of profits against the increased access to prescription drugs for Maine citizens, the local benefits appear to outweigh the burden on interstate commerce. At the very least, the burden on interstate commerce is not "clearly excessive" as compared to the local benefits.

It is necessary to recognize the difficulty in foreseeing what events actually will occur from the enforcement of this Act, which admittedly makes the Pike balancing test more challenging to apply. We are forced to balance the possible effects, instead of the actual effects of the statute in action. For now, it is enough to say that the Act survives the facial challenge under the dormant Commerce Clause.¹¹

¹¹On appeal, Maine argues in the alternative that the Act does not violate the dormant Commerce Clause because if the rebate provision of the Act is construed as a tax, it satisfies the requirements set forth in the Complete Auto line of cases dealing with taxation on interstate commerce. See Complete Auto Transit, Inc. v. Brady, 430 U.S. 274, 279 (1977) (holding that a state's tax on interstate commerce will be upheld only if it "is applied to an activity with a substantial nexus with the taxing State, is fairly apportioned, does not discriminate against interstate commerce, and is fairly related to the services provided by the State."). PhRMA replies, arguing that

E. Remaining Preliminary Injunction Factors

Having concluded that PhRMA is not likely to succeed on the merits of its constitutional challenges, we need not delve into the three remaining preliminary injunction factors (risk of irreparable harm, the balance of equities and the public interest). This court has recognized that the "sine qua non" of the preliminary injunction analysis is whether the plaintiff is likely to succeed on the merits of the claim. Weaver v. Henderson, 984 F.2d 11, 12, 14 n.5 (1st Cir. 1993) (concluding that, after determining that there was no likelihood of success on the merits, it was not necessary to examine the other factors). We must conclude that PhRMA has not satisfied its burden to obtain a preliminary injunction preventing the implementation of the Act.

III. CONCLUSION

In this facial challenge, we perceive no conflict between the Maine Act and the Medicaid statute that would result

the Complete Auto test is not satisfied. We need not address this argument on the merits, however, because this legal theory was not raised before the district court. "'If any principle is settled in this circuit, it is that, absent the most extraordinary circumstances, legal theories not raised squarely in the lower court cannot be broached for the first time on appeal.'" Boateng v. Interamerican Univ., Inc., 210 F.3d 56, 62 (1st Cir. 2000) (quoting Teamsters Union, Local No. 59 v. Superline Transp. Co., 953 F.2d 17, 21 (1st Cir. 1992)). This is not one of those extraordinary circumstances.

in federal preemption. The Act sets forth prior authorization procedures that are consistent with those explicitly permitted by Medicaid. PhRMA has not established at this point that the administrative burden imposed by prior authorization will likely harm Medicaid recipients. In the absence of such evidence, we cannot conclude that the Act violates the Supremacy Clause.

Nor does the Act offend the dormant Commerce Clause. It is not an extraterritorial regulation on interstate commerce because it does not regulate conduct occurring outside the state, but only regulates in-state activities. Moreover, from a facial standpoint, the local benefits of the Act appear to outweigh any incidental burden on interstate commerce. For the reasons stated, the Maine Act survives the facial dormant Commerce Clause challenge.

This is a close case but we do not think that, under the applicable law, the State of Maine should be prohibited from putting the Act into play. We heed the dissent of Justice Louis Brandeis in New State Ice Co. v. Liebmann, 285 U.S. 262, 310 (1932):

To stave experimentation in things social and economic is a grave responsibility. Denial of the right to experiment may be fraught with serious consequences to the nation. It is one of the happy incidents of the federal system that a single courageous state may, if its citizens choose, serve as a laboratory; and try novel social and

economic experiments without risk to the rest of the country. This Court has the power to prevent an experiment. We may strike down the statute which embodies it on the ground that, in our opinion, the measure is arbitrary, capricious, or unreasonable. We have power to do this, because the due process clause has been held by the Court applicable to matters of substantive law as well as to matters of procedure. But, in the exercise of this high power, we must be ever on our guard, lest we erect our prejudices into legal principles. If we would guide by the light of reason, we must let our minds be bold.

(footnote omitted).

The decision of the district court is REVERSED and the temporary injunction is VACATED.

- Concurring Opinion Follows -

APPENDIX

The relevant provisions of the Act are as follows:

The Maine Rx Program, referred to in this subchapter as the "program," is established to reduce prescription drug prices for residents of the State. The program is designed for the State to utilize manufacturer rebates and pharmacy discounts to reduce prescription drug prices. In implementing the program, the State shall serve as a pharmacy benefit manager in establishing rebates and discounts on behalf of qualified residents.

1. Program goals. The Legislature finds that affordability is critical in providing access to prescription drugs for Maine residents. This subchapter is enacted by the Legislature to enable the State to act as a pharmacy benefit manager in order to make prescription drugs more affordable for qualified Maine residents, thereby increasing the overall health of Maine residents, promoting healthy communities and protecting the public health and welfare. It is not the intention of the State to discourage employers from offering or paying for prescription drug benefits for their employees or to replace employer-sponsored prescription drug benefit plans that provide benefits comparable to those made available to qualified Maine residents under this subchapter.

* * * *

3. Rebate agreement. A drug manufacturer or labeler that sells prescription drugs in this State through the elderly low-cost drug program under section 254 or any other publicly supported pharmaceutical assistance program shall enter into a rebate agreement with the department for this program. The rebate agreement must require the

manufacturer or labeler to make rebate payments to the State each calendar quarter or according to a schedule established by the department.

4. Rebate amount. The commissioner shall negotiate the amount of the rebate required from a manufacturer or labeler in accordance with this subsection.

A. The commissioner shall take into consideration the rebate calculated under the Medicaid Rebate Program pursuant to 42 United States Code, Section 1396r-8, the average wholesale price of prescription drugs and any other information on prescription drug prices and price discounts.

B. The commissioner shall use the commissioner's best efforts to obtain an initial rebate amount equal to or greater than the rebate calculated under the Medicaid program pursuant to 42 United States Code, Section 1396r-8.

KEETON, District Judge (concurring).

I. Introduction

I concur in the judgment reversing the decision of the district court and vacating the preliminary injunction. Because the appropriate grounds of the decision involve issues that are fundamental to harmonizing interests in liberty and order under the Constitution of the United States, I conclude that it is appropriate, if not obligatory, that I state in a concurring opinion the grounds as I see them for reaching this judgment.

For reasons associated with undisputed facts about Pharmaceutical Benefit Managers (PBMs) and relationships between interests they represent and interests of citizens of Maine represented by the Commissioner, Maine Department of Human Services, Maine's Legislature, and Maine's Attorney General, I turn first to a more extended recitation of background facts regarding standing and jurisdiction than appears in the opinion of the Court of Appeals, delivered by Judge Bownes.

**II. Background Facts on Standing and Jurisdiction
to Consider Group or Association Contentions**

Did the district court have authority, and does the Court of Appeals have authority, to consider positions stated in briefs on behalf of groups or associations seeking to represent the interests of their members that they claim are materially

affected by orders made, or that might be made, in the district court and on appeal?

The case before us is styled Pharmaceutical Research and Manufacturers of America, Plaintiff, Appellee, v. Kevin Concannon, Commissioner, Maine Department of Human Services, and Maine Attorney General, Defendants, Appellants.

Plaintiff/Appellee's CORPORATE DISCLOSURE STATEMENT says that "plaintiff/appellee, Pharmaceutical Research and Manufacturers of America, by and through its undersigned counsel, and, pursuant to Fed.R.Civ.P. 26.1, states that it has no parent company and that no publicly held company owns any of its stock."

In its brief, which uses the short title PhRMA to designate itself, Plaintiff/Appellee refers to additional characteristics and rights of PhRMA.

+ It has the ability to challenge adverse treatment under the Maine Act, including a challenge on preemption grounds. Plaintiff/Appellee's Brief at 34.

+ It has members who are "regulated by and make payments consistent with the provisions of the Medicaid prescription drug program." Id. at 36 n.21.

Also, on the basis of the limited information available in the record, I infer that some of PhRMA's members are Pharmacy Benefit Managers (PBMs). No party or amicus, or attorney for a party or amicus, has called attention to any case explicitly declaring that PBMs have standing and a United States district court has jurisdiction to consider either a facial challenge or an as-applied challenge by a PBM to a state statute like Maine's Act to Establish Fairer Pricing for Prescription Drugs, and I am aware of none. Treating the issue as one of first impression, I would recognize both standing and jurisdiction, in the United States District Court for the District of Maine, and on appeal. In the world outside the court system, as a pragmatic matter no other person or entity is as active and effective in protecting benefits and beneficiaries of availability of pharmacy products at reasonable cost as PBMs. It is entirely appropriate in these circumstances that the standing of PBMs be recognized in United States district courts and on appeal from adjudications interpreting and applying state legislation affecting the benefits and interests of beneficiaries of marketing of pharmacy products. As the Court of Appeals for the First Circuit has previously stated, "Article III standing is largely . . . albeit not entirely . . . a practical jurisprudence." New Hampshire Hemp Council v. Marshall, 203 F.3d 1, 4 (1st Cir. 2000) (citing

13 Charles Alan Wright, Arthur R. Miller & Edward H. Cooper, Federal Practice and Procedure § 3531.1, at 352, 362-63 (2d ed.1984)).

The basis for the foregoing conclusions is a principled proposition that applies broadly. I state explicitly, for the sake of clarity, that in my view it applies to each of the following contentions, in addition to the standing of PhRMA and the standing of PBMs to make the contention stated above:

(A) claims of violation of the Supremacy Clause;

(B) claims of violation of Dormant Commerce Clause jurisprudence (as to which, with respect to PhRMA's standing, see also Part II.D of opinion of the Court of Appeals, delivered by Judge Bownes).

For the reasons explained in the remainder of this opinion concurring in the judgment, I would allow standing and jurisdiction but reject on the merits other specific challenges to the Maine Rx Program.

III. Madisonian Influences on Allocation of Legislative Power in the American Legal System

The roles of state legislatures and the Congress of the United States in the American legal system owe much to James Madison's seminal thinking expressed publicly and privately during debates over the structure of the new form of federalism to be established under a constitution drafted in May, 1787 to

cure deficiencies in the Articles of Confederation of 1777. See generally John P. Kaminski, Ph.D., Director, and Richard Leffler, Ph.D., Co-Director, The Center for Study of the American Constitution, The University of Wisconsin-Madison (Wisconsin Study), The Origins of the Three Branches of Government, Federal Judicial Center Traveling Seminar 3-9 (2001).

Madison, a Virginian, writing to Edmund Randolph of New York on 8 April 1787, mused:

I hold it for a fundamental point that an individual independence of the States, is utterly irreconcilable with the idea of an aggregate sovereignty. I think at the same time that a consolidation of the States into one simple republic is not less unattainable than it would be inexpedient. Let it be tried then whether any middle ground can be taken which will at once support a due supremacy of the national authority, and leave in force the local authorities so far as they can be subordinately useful.

. . . .

Let the national Government be armed with a positive & compleat authority in all cases where uniform measures are necessary. As in trade &c. &c. Let it also retain the powers which it now possesses.

Let it have a negative in all cases whatsoever on the Legislative Acts of the States as the K. of G.B. heretofore had. This I conceive to be essential and the least possible abridgement of the State Soveriegnities. Without such a defensive

power, every positive power that can be given on paper will be unavailing. . . .

Let this national supremacy be extended also to the Judiciary department. If the judges in the last resort depend on the States & are bound by their oaths to them and not to the Union, the intention of the law and the interests of the nation may be defeated by the obsequiousness of the Tribunals to the policy or prejudices of the States. It seems at least essential that an appeal should lie to some national tribunals on all cases which concern foreigners, or inhabitants of other States. . . .

The supremacy of the whole in the Executive department seems liable to some difficulty. Perhaps an extension of it to the case of the Militia may be necessary and sufficient.

A Government formed of such extensive powers ought to be well organized. . . .

. . . .

To give the new system its proper energy it will be desirable to have it ratified by the authority of the people, and not merely by that of the Legislatures.

The Origins of the Three Branches of Government, *id.*, at 4-5.

Madison concluded these thoughts with a statement that, fearing "you will think this project, if not extravagant, absolutely unattainable and unworthy of being attempted," he conceived it "to go no further than is essential." *Id.* at 6.

In his Notes of Convention Debates, Madison records Resolutions proposed by Mr. Randolph in Convention on May 29,

1787, including a set of proposals for a form of federalism remarkably similar to Madison's suggestions six weeks earlier.

Those Madisonian suggestions are reminders of two salient points relevant to our consideration of the issues presented in the present appeal.

First. The genius of the Constitution of the United States of America is that it establishes a unique form of federalism, unlike any ever fashioned before, that harmonizes and accommodates in new and distinctive ways national and state centers of governmental power.

Second. The authority for this new form of federalism is declared by "the people, and not merely by the Legislatures." See id. at 5.

The eighteenth-century debates in which Madison and Randolph were among the key participants occurred more than two centuries ago. Twenty-first century readers are even more removed than the lapse of time suggests from being in tune with the spirit and culture surrounding the debates over what became the Constitution of the United States and the Bill of Rights embodied in the Amendments adopted forthwith. Those debates were strikingly lively and thorough examinations of the history of peoples' ideas and efforts to form governments powerful enough to preserve the order essential to protection of

individual liberty and at the same time subject to inherent controls against abuse of power likely to lead to despotism.

Ideas about liberty and order are no less relevant now than they were when the Founders developed the Constitution of the United States of America. "The aim of the American legal system is liberty and justice for all. How close we come to that aim depends on good judging." Robert E. Keeton, Judging in the American Legal System 1 (Lexis Law Publishing 1999).

The quality of judging in a legal system depends on commitment. It depends, first, on commitment to the aim of justice. Second, it depends on commitment to professionalism. The declared beliefs of all professionals in the system - including advocates, counselors, and academic critics as well as judges - affect the quality of judging in the system. Third, the quality of judging depends on commitment to method. Judicial choice, at its best, is reasoned choice, candidly explained.

Id. at 5. Reasoned judicial choice in the matter currently pending before us requires, in my view, that we reject plaintiff's facial challenge to the constitutionality of the Maine statute, but does not require that we consider the constitutionality of every possible interpretation or application of the Maine statute. This view is reenforced by taking into account James Madison's contributions to federalist thought and actions. This historical background is especially relevant, in my view, to disputes over supremacy of national

legislation and associated issues of interpretation of the Maine statute that was before the district court and is before us in this appeal.

**IV. In the American Legal System,
a State is a Sovereign**

Under fundamental premises of the American legal system, the State of Maine, like all other States of the United States of America, is a sovereign. Each State has authority to govern persons and institutions and their transactions within its territorial boundaries.

I do not understand that any of the briefs before us challenges the sovereignty of states within the Union, and I do not understand the opinion of the Court of Appeals as challenging this proposition. Thus, I say no more here on the existence of sovereignty of states within the Union. Some important implications of this sovereignty, however, are noted in other sections of this opinion, infra.

V. A State May Act in Multiple Roles

A sovereign State of the United States, in addition to governing, may be an active participant in a market for any kind of goods or services that it seeks to buy for its own use, including a purchase for (1) a use such as obtaining furniture for a State office and (2) a use such as obtaining pharmacy

products for State-sponsored programs such as Medicaid and Medicare.

Thus, the State of Maine may act

- (1) as a sovereign,
- (2) as a market participant itself because it buys pharmacy products for Medicaid patients, and
- (3) in "the role of each State as a guardian and trustee for its people" who need pharmacy products at affordable prices. White v. Massachusetts Council of Constr. Employers, 460 U.S. 204, 207 n.3 (1983).

The third of these roles has special relevance to issues in this case because Maine has undertaken to represent "its people" who need pharmacy products at affordable prices.

It would be a curious irony indeed if dozens of privately organized groups of Pharmacy Benefit Managers (PBMs) could participate freely in the market for purchasing products from pharmacy product manufacturers but States as guardians and trustees for their people could not because the States are also sovereign. In my view, we should make the commonsense ruling that the State of Maine as well as PBMs may participate in the market for purchasing pharmacy products.

Any conflict of interest problems that might theoretically be raised are answered in the distinctive circumstances of this case by the fact that the State of Maine faces no conflicting interests because it believes that in all its roles it is trying to serve the best interests of its people and each of the groups of its people who have an interest in and need for pharmacy products.

VI. Interpreting "Best Efforts" Provisions of the Maine Statute

A. The Statutory Maine Rx Program

By a legislative enactment in the first quarter of the year 2000, the State of Maine established The Maine Rx Program ("the program"). Maine's Act to Establish Fairer Pricing for Prescription Drugs, 2000 Me. Legis. Ch. 786 (S.P. 1026) (L.D. 2599) ("The Act"). The Act established the program "to reduce prescription drug prices for residents of the State." Id., Me. Rev. Stat. Ann. tit. 22, § 2681 (unnumbered introductory paragraph).

The program is designed for the State to utilize manufacturer rebates and pharmacy discounts to reduce prescription drug prices. In implementing the program, the State shall serve as a pharmacy benefit manager in establishing rebates and discounts on behalf of qualified residents.

Id. (emphasis added).

The legislation was explicit in declaring program goals.

1. Program goals. The Legislature finds that affordability is critical in providing access to prescription drugs for Maine residents. This subchapter is enacted by the Legislature to enable the State to act as a pharmacy benefit manager in order to make prescription drugs more affordable for qualified Maine residents, thereby increasing the overall health of Maine residents, promoting healthy communities and protecting the public health and welfare.

It is not the intention of the State to discourage employers from offering or paying for prescription drug benefits for their employees or to replace employer-sponsored prescription drug benefit plans that provide benefits comparable to those made available to qualified Maine residents under this subchapter.

Me. Rev. Stat. Ann. tit. 22, § 2681 (emphasis added).

Some of the statutory definitions of terms are relevant to interpretive issues before us in this appeal.

2. Definitions. As used in this subchapter, unless the context otherwise indicates, the following terms have the following meanings.

. . . .

B. "Initial discounted price" means a price that is less than or equal to the average wholesale price, minus 6%, plus the dispensing fee provided under the Medicaid program under this Title.

. . . .

E. "Pharmacy benefit manager" means an entity that procures prescription drugs at a negotiated rate under a contract.

. . . .

G. "Secondary discounted price" means a price that is equal to or less than the initial discounted price minus the amount of any rebate paid by the State to the participating retail pharmacy.

Id.

Also relevant to the matters before us are the statutory provisions on rebate amount.

4. Rebate amount. The commissioner shall negotiate the amount of the rebate required from a manufacturer or labeler in accordance with this subsection.

. . . .

B. The commissioner shall use the commissioner's best efforts to obtain an initial rebate amount equal to or greater than the rebate calculated under the Medicaid program pursuant to 42 United States Code, Section 1396r-8.

C. With respect to the rebate taking effect no later than October 1, 2001, the commissioner shall use the commissioner's best efforts to obtain an amount equal to or greater than the amount of any discount, rebate or price reduction for prescription drugs provided to the Federal Government.

Id. (emphasis added).

Finally, statutory provisions on discounted prices for qualified residents, in subsection 5, are relevant to the matters before us.

B. Beginning January 1, 2001, a participating retail pharmacy shall offer the initial discounted price.

C. No later than October 1, 2001, a participating retail pharmacy shall offer the secondary discounted price.

Id.

B. Statutory Interpretation

We should be guided primarily by the plain language of all the provisions of the statute that are relevant to the issues before us, and the plain and ordinary meaning of the words used in all the relevant provisions. The relevant provisions include the definitions in the statute, the declaration of program goals, and the operational directives to Defendant/Appellant Kevin Concannon, Commissioner, Maine Department of Human Services. With these guideposts in mind, I conclude that a reasonable interpretation of the Maine statute includes the following elements:

- + The Maine statute authorizes "best efforts" of Maine administrators rather than requiring prohibitive administrative decisions and actions.
- + The courts should respect the legislative drafters' thoughtful use of the idea of "best efforts."
- + It would be a mistake to accept the suggestions of challenges to the Maine statute that propose to interpret it in a way that, in effect, reads "best efforts" out of the statute.

The provision that opponents describe as requiring authorization for participating pharmacies to offer discounted prices to some defined group of Maine residents and obtain rebates from a state fund, created by an assessment against manufacturers, is not a statutory mandate. Instead, the statute requires only "best efforts" of Administrators to achieve the legislative aim of protecting interests of the people of Maine by ongoing creative mediation and negotiation that appeals to the executives of pharmacy products manufacturers to cooperate with Maine's administration of legislatively authorized programs. The statutory provisions providing for "best efforts" and for "negotiation" make clear that the drafters intended the rebate process to entail negotiation and compromise between the state and the manufacturers to reach a mutually beneficial outcome. Although conceivably these "best efforts" could fail, and manufacturers could be subject to the prior authorization provisions of the statute, this outcome is not mandated by the language of the statute, and it is not necessary, in a facial challenge to the statute, to reach questions that may be presented in the future if "best efforts" fail.

As a practical matter, it is obvious that many, probably most, citizens of Maine who have a need for pharmacy products but have less than the economic resources of, say, the

top ten percent of citizens of the state, do not have adequate resources and practical means to get the pharmacy products they need unless

- (i) by travel to Canada, or
- (ii) by mail, or
- (iii) in some other way that
involves aid or
assistance comparable to
that PBMs provide.

If these citizens have a need for prescription medication, and choose to forgo that medication rather than resort to these resources, it may well be in the interests of PhRMA members to negotiate with the State of Maine. In light of allegations made in their submissions, I infer that PhRMA members believe that a rebate in the amount of the Medicaid rebate would not be in their best interest, but the plain language of the statute allows for negotiation in a way that will serve the best interests of both PhRMA members and previously unrepresented citizens of the State of Maine.

VII. The Timing of Adjudications on Constitutionality

The Maine statute, interpreted in the way explained in Part VI, is consistent with all State and Federal constitutional doctrines and is permissible legislation. The district court's

ruling to the contrary must be vacated. No federal law (constitutional, statutory, or decisional) preempts and thus forbids reasonable implementation of Me. Rev. Stat. Ann. tit. 22, § 2681.

Properly interpreted, that law is compatible with rather than conflicting with federal Medicaid legislation and administrative supervision of Medicaid.

It is error to say -- as is said in Defendants/Appellants' Brief at page 18 -- that the extent to which the Act advances the purposes of Medicaid is irrelevant. Also, it is error to say that the "proper question" in this appeal "is whether the Act conflicts with the purposes of Medicaid," as Defendants/Appellants' Brief asserts at page 18. The core question is multifarious, not singular. An evaluative legal test applies, not a bright-line elements legal test.

Plaintiff/Appellee proposes in its waiver and preclusion arguments that we should hold that the fact that Defendants/Appellants make these fallacious arguments bars relief to Defendants/Appellants in this appeal. I would reject this argument. It does not state a valid reason for depriving the citizens of Maine of a fair adjudication of their interests at stake in this appeal, based on a proper interpretation of the Maine statute. Our federal system permits a State's advocacy in

court in support of its interests and those of its people. Penalizing a state and its people whenever the state makes an argument rejected by the court is not appropriate.

Other arguments presented by Defendants/Appellants both here and in the district court are consistent with the interpretation of the Maine statute explained in Part VI of this opinion and support reversal of the judgment of the district court.

An unstated but implicit premise of Plaintiff/Appellee's position in this case is that all Plaintiff/Appellee need do to succeed in a facial challenge to the Maine Act is to show that the administration of the Act is putting pressure on Plaintiff/ Appellee, thus making its choice about how it responds to the circumstances developing under ongoing administration of the Act not entirely voluntary.

The fallacy of that position stems from the fact that few choices of individuals and entities in a geographical territory that has a government are entirely voluntary. True, some transactions are beyond governmental authority to intrude. They are "transactions beyond law" in the sense that individuals and private (non-governmental) entities they create and maintain have a large range of freedom under law to do as they please without governmental intrusion on that freedom. But a demand by

any individual or entity for entire freedom is fundamentally in conflict with having a government that maintains the order essential to protection of individual freedom.

It is possible, as explained in Part VIII, infra, to fashion remedies for any threats that may arise from overstepping the bounds of statutorily authorized "best efforts" of Maine's Commissioner of Human Services during the ongoing administration of the Maine Rx Program. It is appropriate to wait and see what happens, and fashion appropriate remedies for any overstepping, rather than declaring Maine's Act unconstitutional because of an outside chance that something beyond constitutional bounds will be attempted unless an advance declaration of facial invalidity of the statute by the district court is allowed to stand.

**VIII. Remedies for Threats
to Overstep Statutory Authorization**

A United States district court, confronted with a facial challenge to validity of a state statute on grounds like those asserted in this case, should dismiss the facial challenge for failure to meet the requirements of applicable precedents.

The court might also find it appropriate to declare explicitly that the dismissal on this ground would not be a bar to an otherwise properly supported claim for relief against a threatened administrative overstepping of the bounds of the

statutory authorization for administrative "best efforts" to negotiate and implement a suitable accommodation of legitimate interests by methods acceptable to Maine's Commissioner of Human Services, acting both for the State and as a PBM for its people, and to manufacturers of pharmacy products who wish to market their products in Maine consistently with the Maine Rx Program.

The decision would be one to wait and see, and act then if needed, instead of prohibiting legislatively sponsored administrative aid to the people of Maine because of a possibility that at some time in the future some administrator will overstep the bounds of the legislative authorization.

For example, acting under this wait-and-see principle, the Court of Appeals would vacate the District Court's preliminary injunction, but at the same time declare that its ruling would not stand as a bar to renewed proceedings in the District Court if at some future time the Legislative or Executive Branch of the sovereign State of Maine, or an Administrative Agency authorized to act to serve the declared legislative aim of the statute in issue, takes action that is an imminent threat to legally protected interests of a person or entity (including any out-of-state as well as any in-state person or entity) claiming a right to market pharmacy products in Maine. An as-applied challenge to state legislation is a

more flexible instrument of adjudication, more capable of reaching an outcome tailored to the circumstances and needs of a case at hand than the all-or-nothing nature of a facial challenge to validity.

A federal district or appellate court's acting in advance of overstepping, because of the possibility overstepping might occur in the future, is fundamentally inconsistent with the body of precedents establishing the elements of a successful facial challenge in a federal court to the consistency of a state statute with potentially preemptive federal law. See, e.g., California Coastal Comm'n v. Granite Rock Co., 480 U.S. 572, 579-80 (1987) (holding that state permit requirements were not preempted by federal law, and stating that the party arguing in favor of preemption would have to demonstrate "that there is no possible set of conditions that the [state] could place on its permit that would not conflict with federal law - that any state permit requirement is per se preempted") (underscoring added). These precedents would require PhRMA to demonstrate "that there is no possible" application of the statute that would not conflict with the structure and purpose of Medicaid. PhRMA cannot meet this burden. It could not do so even if we softened the legal standard a bit by substituting "reasonably

likely" for "possible." PhRMA's facial challenge must be denied.

A federal court's acting in advance of overstepping by state officials, and responding to a facial challenge, is also inconsistent with relevant precedents for a facial challenge on constitutional grounds. In United States v. Salerno, 481 U.S. 739 (1987), the Supreme Court stated that "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." Id. at 745.

It is true that the Salerno decision has been criticized in later opinions of some Justices of the Supreme Court. See, e.g., Washington v. Glucksberg, 521 U.S. 702, 740 (1997) (Stevens, J., concurring in the judgments) (declaring that the Court has never in fact applied "such a strict standard."); Janklow v. Planned Parenthood, 517 U.S. 1174, 1175-76 (1996) (Stevens, J., respecting the denial of the petition for certiorari) (calling the Salerno decision "draconian" and declaring that it "does not accurately characterize the standard for deciding facial challenges.").

Salerno, nevertheless, continues to be cited by both the Supreme Court and the Courts of Appeals. See, e.g.,

Anderson v. Edwards, 514 U.S. 143, 155 n.6 (1995); Reno v. Flores, 507 U.S. 292, 301 (1993); Rust v. Sullivan, 500 U.S. 173, 183 (1991). We need not reach the issue of the applicability of the Salerno test, however, because the statute in this case, as explained in Part VI of this opinion, is capable of an interpretation and an application that is respectful of limits imposed by the Constitution.

The application of facial-challenge jurisprudence in the circumstance of this case before the District Court and in this appeal is, in practical effect, a considerable stretch beyond any thus-far-successful facial challenge. If such an extension of the jurisprudence of facial challenges expressed in decisions of the Supreme Court of the United States is to occur, it is more appropriate that it occur in an opinion of that Court than in an opinion of a Court of Appeals.

My own reading of the array of Supreme Court opinions on this subject, even in light of the ongoing differences both within the Court and among scholars on the applicability of the Salerno test, is that precedent points away from rather than toward softening in any way the rigorous requirements for presenting a successful facial challenge to validity of a state statute.

This conclusion is supported not only by the opinions explicitly reasoned as part of the facial-challenge jurisprudence but also by other ongoing developments of federal law.

One ongoing development supportive of the conclusion I propose is the resurgence in recent years of emphasis on the respect that inferior federal courts are directed to show for the freedom of the people of a locality and local governmental institutions to make their own decisions. For illustrative citations, see Part IX of this opinion, infra. See also the Madisonian principles identified in Part III, supra. This emphasis is in part a feature of the distinctive version of federalism underlying what is commonly called the American legal system. It is associated with the Supreme Court's invoking the Commerce Clause not for the ordinary purpose of sustaining federal legislation but to strike down state legislation. This emphasis on federalism weighs in favor of sustaining rather than striking down the Maine Rx Program, as explained in Part IX, infra.

IX. The Commerce Clause and Concerns of Federalism

The Brief of Washington Legal Foundation and five other associations as Amici Curiae in support of affirming the preliminary injunction ordered by the District Court for the

District of Maine argues that the District Court was correct in "find[ing] that the [Maine Rx] Program violated the Commerce Clause because it attempted to regulate transactions taking place solely outside the State," and in adding, "Maine may have power over what pharmacies later do here in Maine, or over the few distributors who transact business in Maine, but it has no power to regulate the price paid in earlier transactions in other states." Brief of Washington Legal Foundation et al. at 6.

A similar position is developed in the Brief Amicus Curiae of the Chamber of Commerce of the United States in Support of Appellee Recommending Affirmance.

The Commerce Clause [of the United States Constitution] provides that "[t]he Congress shall have Power . . . [t]o regulate Commerce . . . among the several States. . . ." Art. I, §8, cl. 3. It is long established that, while a literal reading evinces a grant of power to Congress, the Commerce Clause also directly limits the powers of the States. . . . [Wyoming v. Oklahoma, 502 U.S. 437, 454 (1992) (citing authorities).]

Brief Amicus Curiae of the Chamber of Commerce of the United States in Support of Appellee Recommending Affirmance at 7. The citations relied upon include the following:

Healy v. The Beer Institute, 491 U.S. 324, 336 (1989) ("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."); see generally Laurence H. Tribe, American Constitutional Law, §6-12 at 1098 (3d ed. 2000) (referencing "the per se principle against extraterritorial state regulation").

Id. at 9.

These arguments are classic illustrations of the controversial efforts that have occurred from time to time to treat the Commerce Clause not only as authorizing legislation by the Congress of the United States but also as constraining state legislation.

Consider, for example, a case emphasized in the Brief of the Chamber of Commerce, Wyoming v. Oklahoma, 502 U.S. 437 (1992). Unlike the case before us, this was a direct clash between two States of the Union. Wyoming, a major coal-producing State, though not a seller of coal, imposed a severance tax on those who extracted coal. The direct impact of that severance tax on the price of Wyoming coal purchased by four Oklahoma electric utilities was obvious. The Oklahoma legislature passed an act requiring coal-fired electric utilities in Oklahoma to burn a mixture containing at least 10% Oklahoma-mined coal. The utilities reduced their purchases of

Wyoming coal. Wyoming's severance tax revenues declined. Wyoming sought relief under the original jurisdiction of the Supreme Court of the United States. The Court accepted Wyoming's complaint and held the Oklahoma act invalid under the "negative" aspect of the Commerce Clause on the reasoning that it "prohibits economic protectionism - that is, regulatory measures designed to benefit in-state economic interests by burdening out-of-state competitors." Id. at 454. Even so, the Court added that a clearly discriminatory statute will be struck down "unless the discrimination is demonstrably justified by a valid factor unrelated to economic protectionism," citing Maine v. Taylor, 477 U.S. 131 (1986).

I need not and do not consider whether the case before us would qualify for the exception. Instead, I conclude that the case before us is not one subject to the "negative" rule itself, quite apart from the exception.

Wyoming v. Oklahoma and other opinions of the Supreme Court that have gone farthest in the direction of a "negative" application of the Commerce Clause do not support the proposition that a federal court acts properly when it disregards all the indicia of the State's purpose in establishing the Maine Rx Program to regulate transactions within the territorial boundaries of Maine and to protect the

health of the people of Maine. In these circumstances a federal court does not act properly when it makes a judicial "finding" that the State's declaration of purpose is a facade and the real purpose was "to regulate the price paid in earlier transactions in other states."

First. The legislative aim of the Act was fully stated in the Act itself, as explained in Part VI.A of this opinion, supra. This is not a case of hidden or obscure aims.

Second. Any suggestion to the contrary in briefs before this court is in disregard of our obligation, and that of the District Court, in reading the statute, to be guided, as stated in Part VI.B of this opinion, by the plain language of the statute, the definitions in the statute, and the plain and ordinary meaning of the words used in the declaration of program goals, in the statutory definitions, and in the operational directives to Maine's Commissioner of Human Services. See Whiting v. Town of Westerly, 942 F.2d 18, 21 n.3 (1st Cir. 1991) ("In evaluating a facial challenge to a state law, a federal court must consider any limiting construction that a state court or enforcement agency has proffered.").

Third. As stated in Part VI.B, the provision of the Maine Act that opponents describe as requiring authorization for participating pharmacies to offer discounted prices to some

defined group of Maine residents and obtain rebates from a state fund, created by an assessment against manufacturers, is not a statutory mandate. Instead, it is a statement of aim. The statute requires only "best efforts" of Administrators to achieve the legislative aim of protecting interests of the people of Maine by ongoing creative mediation and negotiation.

Fourth. As stated in Part VI.B, many and probably most citizens of Maine who have a need for pharmacy products would not have adequate resources and practical means to get the pharmacy products they need absent the Maine Rx Program. In the course of the creative mediation and negotiation required by the statute, the pharmaceutical companies themselves may find it is in their best interests to enter into agreements to allow them to reach this previously untapped market for their products.

Fifth. In view of the foregoing four points, it cannot be proper for a federal court to make judicial "findings" contrary to Maine's legislative declarations and on that basis declare that Maine's Act is invalid because "it attempted to regulate transactions taking place solely outside the State" and attempted "to regulate the price paid in earlier transactions in other states." In so doing, the District Court acted beyond its authority.

The ideals of federalism explained above weigh in favor of respect for a state's experimentation and respect for a state's sovereignty. The precedents that govern our examination and that of the District Court of a facial challenge to state legislation are consistent with these ideals of federalism, and indeed are consistent with the delicate balance of power explained by Madison in his early writings.

The District Court's preliminary injunction must be vacated.

X. Conclusion and Order

The decision I would make, for the reasons explained in this concurring opinion, would not bar further proceedings, either in the civil action in which the preliminary injunction was issued or in a civil action newly filed at some future time, if at that time a showing could be made by the complaining party that the Legislative or Executive Branch of the sovereign State of Maine, or an Administrative Agency authorized to act to serve the declared legislative aim of the statute in issue, had taken action that is a threat to legally protected interests of a person or entity (including any out-of-state as well as any in-state person or entity) making the complaint. That person or entity might appropriately seek a form of limited injunctive relief needed to protect identified interests without deeper

intrusions on the State of Maine's legitimate interests than would be necessary and appropriate for that purpose.

For the reasons stated in this opinion, the District Court's preliminary injunction should be vacated, and I concur in the judgment of the Court of Appeals, delivered by Judge Bownes, so ordering.