**No. 00-2446**

*In The*

*UNITED STATES COURT OF APPEALS*

*For The First Circuit*

**PHARMACEUTICAL RESEARCH and MANUFACTURERS OF AMERICA**
**Plaintiffs-Appellees**

**v.**

**KEVIN CONCANNON, COMMISSIONER, MAINE DEPARTMENT OF HUMAN SERVICES, and G. STEVEN ROWE, MAINE ATTORNEY GENERAL**
**Defendants-Appellants**

**ON APPEAL FROM THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF MAINE**
**THE HONORABLE D. BROCK HORNBY, PRESIDING**
**(DISTRICT OF MAINE CASE NO. 00-CV-157-B)**

# REPLY BRIEF OF APPELLANTS


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## INTRODUCTION

In its brief, Pharmaceutical Research and Manufacturers of America ("PhRMA") repeats the themes it sounded in the District Court: that the Maine Rx Program, though not expressly preempted by the federal Medicaid statute, nonetheless is implicitly preempted by those laws; and that the Maine Rx Program, though not discriminatory against interstate commerce, should nonetheless be invalidated because it purportedly regulates out-of-state transactions in violation of the dormant Commerce Clause. Both of these grounds – implied preemption and the use of the dormant Commerce Clause against nondiscriminatory statutes – are disfavored by the courts. The constitutionally appropriate remedy for PhRMA is to address its concerns to Congress, which can always expressly preempt state law or use its affirmative powers under the Commerce Clause to declare illegal any state barriers to interstate commerce which it determines are undesirable. For the reasons set forth in more detail below, the federal courts should not lightly interfere with Maine's effort to lower prescription drug prices for its 325,000 uninsured residents.

## I. PLAINTIFF LACKS PRUDENTIAL STANDING TO BRING ITS PREEMPTION CHALLENGE.[1]

Each of PhRMA's members surely has a financial interest in seeing that its drug, and not that of a competitor, is widely dispensed through Maine's Medicaid program. However, the purpose of Medicaid is to insure that patients receive the drugs they need. Thus, any argument that the Maine Rx Program will deprive Medicaid patients of medically necessary drugs is one appropriately made only by a Medicaid recipient – not an association of drug manufacturers.

The standing doctrine known as the zone of interests test is meant to ensure that the right parties appear in court. In a Supremacy Clause challenge, that test

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[1] Doubts regarding whether PhRMA has standing were expressed in a footnote in our brief in the district court, and as a defense in our answer to the complaint. *See* Appellants' Br. at 12 n. 4; App. (A-049). We submit that this issue was not waived and may not be waived. "The rules of standing, whether as aspects of the Art. III case-or-controversy requirement or as reflections of prudential considerations defining and limiting the role of the courts, are threshold determinants of the propriety of judicial intervention." *Bender v. Williamsport Area School District*, 475 U.S. 534, 546 n.8 (1986). While this Court has not previously decided whether prudential standing may be waived, it has not favored waiver. *See, e.g., Libertad v. Welch*, 53 F.3d 428, 435-36 (1st Cir. 1995) (requiring briefing on constitutional and prudential standing issue raised for the first time during oral argument on appeal). Three Circuits have recognized that prudential standing cannot be waived. *Animal Legal Defense Fund, Inc. v. Espy*, 23 F.3d 496, 499 (D.C. Cir. 1994); *Thompson v. County of Franklin*, 15 F.3d 245, 248 (2nd Cir. 1994); *Community First Bank v. National Credit Union Admin*., 41 F.3d 1050, 1053 (6th Cir. 1994); *but see Pershing Park Villas Homeowners Assoc. v. United Pacific Ins. Co*., 219 F.3d 895 (9th Cir. 2000), *Lindley v. Sullivan,* 889 F.2d 124 (7th Cir. 1989).

is satisfied only when the party seeking to vindicate the primacy of a supposedly "preempting" federal law has some interest falling within the zone of interests protected or regulated by the federal law.

PhRMA maintains that the interests of its members fall within the zone of interests protected or regulated, not by Medicaid, but by the Supremacy Clause. [2] Br. 34-35. PhRMA is correct to the extent that the zone of interests test is generally satisfied when a party can show that its interests are protected by a guarantee found in the Constitution. *See Association of Data Processing Service Organizations, Inc. v. Camp,* 397 U.S. 150, 153 (1970); *see also Boston Stock Exchange v. State Tax Commission*, 429 U.S. 318, n. 3 (1977). PhRMA is wrong,

[2] PhRMA asserts alternatively that even if it must have standing under the federal Medicaid statute to mount its preemption challenge, it satisfies the zone of interests test because its members *are regulated* by Medicaid. Br. 36, n. 21. The activities of drug manufacturers are in no way regulated by Medicaid. Medicaid exists pursuant to Congress's powers under the Spending Clause, and is not an example of Congressional regulation under the Commerce Clause. Under the program, federal dollars are available to assist the states in their purchase of drugs for state Medicaid recipients. A caveat imposed by Congress is that federal funds may only be spent for those drugs which manufacturers have *agreed* to sell to the States at a discount – a discount collected by the states via a rebate mechanism. 42 U.S.C. § 1396r-8. Nothing in the Medicaid law *requires* a manufacturer to enter into a Medicaid rebate agreement. They do so, and make rebate payments "consistent with the provisions" of Medicaid, only because they have voluntarily elected to take advantage of the sizable market for their products created by Medicaid. Offering a discount in order to gain entry into this market can hardly be viewed as a form of "regulation" of the drug industry.

however, to rely on interests supposedly "protected by the Supremacy Clause" to satisfy the test. Br. 34.

PhRMA's thesis that the Supremacy Clause itself supplies the sort of constitutional guarantee which can satisfy the zone of interests test is flawed for the simple reason that the Supremacy Clause "is not a source of any federal rights." *Dennis v. Higgins*, 498 U.S. 449, 450 (1991) (punctuation and citations omitted). Rather, it merely "secure[s] federal rights by according them priority whenever they come in conflict with state law." *Id.* This is in contrast with the Commerce Clause, which does create rights and interests sufficient to satisfy prudential standing.

In *Boston Stock Exchange v. State Tax Commission*, 429 U.S. 318, n. 3 (1977), the Court held that a party engaged in interstate commerce has interests which necessarily fall within the "zone of interests" protected by the Commerce Clause sufficient to satisfy the prudential standing requirement. Then, in *Dennis v. Higgins*, 498 U.S. 439, 449 (1991), the Court relied upon its "zone of interests" analysis in *Boston Stock Exchange* to hold that those same interests may be vindicated as federal rights in a § 1983 action. But, in *Golden State Transit v. City of Los Angeles,* 493 U.S. 103, 107 (1989), the Court held that a party may not bring an action under 42 U.S.C. § 1983 for violation of the Supremacy Clause for the fundamental reason that the Supremacy Clause does not itself confer federal

rights. *See also Chapman v. Houston Welfare Rights Organization*, 441 U.S. 600 (1979) (Supremacy Clause does not supply "rights" sufficient to invoke federal court jurisdiction under 28 U.S.C. § 1343(3)). Reading *Dennis*, *Boston Stock Exchange*, and *Golden State Transit* together, the Supremacy Clause cannot be said to supply a "federal interest" sufficient to support prudential standing under the zone of interests test. PhRMA is therefore incorrect to insist that it "it is really a party's interests protected by the Supremacy Clause (not the preempting statute) that are vindicated when it advances a colorable preemption claim." Br. 34-35. Under PhRMA's hypothesis, the zone of interests test would be eviscerated in the context of preemption challenges because anyone, no matter how far removed from the interests protected or regulated by a federal statute, would have prudential standing.

This Court has apparently never decided whether a party bringing a Supremacy Clause challenge must have an interest falling within the zone of interests protected or regulated by the federal statute. Br. 35, n.2. PhRMA suggests that absence of this issue in the First Circuit preemption cases somehow reveals either that the question has been resolved, *sub silento*, in this Circuit, or that it is not an important issue. *Id.* While such an argument is suspect on its face, the cases PhRMA cites do not advance its theory. In each the cases PhRMA cites, the zone of interests test was not discussed because it was so plainly satisfied.

For instance, the plaintiff in *Grant's Dairy Maine, LLC v. Commission of Maine Department of Agriculture, Food & Rural Resources*, 232 F.3d 8, 14 (1st Cir. 2000) was a "fully federally regulated" milk dealer under a federal statute. By claiming that Maine's regulations removed a benefit plaintiff had received under the federal statute, Grant's Dairy was clearly seeking to vindicate interests protected and regulated by the federal statute. It is thus hardly surprising that the issue raised in this case – whether a party has prudential standing to assert preemption when its interests do not fall within the zone of the relevant federal law – was not raised or discussed in *Grant's Dairy*. Likewise, in *Massachusetts Association of Health Maintenance Organizations v. Ruthardt*, 194 F.3d 176 (1st Cir. 1999), the plaintiffs were creatures of the federal Medicare + Choice program, which extensively regulates, among other things, the services they must provide. Their interest in not being required to provide a prescription drug benefit, as the challenged Massachusetts statute mandated, was within the zone of interests protected and regulated by the federal statute. Finally, in *National Foreign Trade Council v. Natsios,* 181 F.3d 38, *aff'd*, *Crosby v. National Foreign Trade Council,* 530 U.S. 363 (2000), this Court was asked to consider whether a federal law involving restrictions on trade with Burma preempted Massachusetts' attempt to legislate in the same area. The plaintiff, an association of companies engaged in foreign trade, including trade with Burma, clearly had an interest directly protected

and regulated by the Federal Burma Law. Thus, none of these cases presented the issue whether a plaintiff without interests protected or regulated by an allegedly "preempting" federal statute has prudential standing to challenge a state law on Supremacy Clause grounds. PhRMA reads too much into the fact that the issue was neither raised by the parties nor discussed by the court.

PhRMA also misconstrues a passage of *St. Thomas-St. John Hotel & Tourism Association, Inc. v. United States Virgin Islands*, 218 F.3d 232 (3d Cir. 2000) ("*St. Thomas*"), in which the Third Circuit states that when a party seeks to strike a state statute on preemption grounds, the allegedly preempting federal statute need not confer a right on that party. Br. 34, citing *St. Thomas*, 218 F.3d at 241. We do not disagree with this statement because being regulated pursuant to an allegedly preempting federal statute also satisfies the zone of interests test, as PhRMA acknowledges. Br. 36, n. 21, citing *Association of Data Processing Svc. Orgs., Inc. v. Camp*, 397 U.S. 150, 153 (1970). In *St. Thomas*, the interests of the plaintiff employers association were plainly within the zone of interests "regulated by" the National Labor Relations Act, "a comprehensive code passed by Congress

to *regulate* labor relations in activities affecting interstate and foreign commerce." *St. Thomas*, 218 F.3 at 238 (emphasis added, citation omitted). [3]

In contrast, PhRMA is not regulated by the allegedly "preempting" statute here. *See* footnote 2, *supra.* *Medicaid* is a program administered by the federal and state governments with its genesis in Congress's spending power. The federal government's Medicaid requirements – extensive though they may be – are not regulations of the pharmaceutical industry but rather conditions on federal spending. [4]

If the prior authorization provision of the Maine Rx Program offends any requirements of Medicaid, then the federal government is the proper party to

[3] In fact, the *St. Thomas* court went further by noting that the NLRA is a "federal statute which grants employers as well as employees substantive federal rights" which include the right "to be free of governmental regulation within the zone of Machinists preemption." 218 F.3d at 241.

[4] The other cases cited by plaintiff, *ANR Pipeline Co. v. Corporation Comm'n of Oklahoma*, 860 F.2d 1571 (10th Cir. 1988), and the district court opinion in *Blue Sky Entertainment v. Town of Gardiner*, 711 F.Supp. 678 (N.D.N.Y. 1989) are inapposite for the same reason. In *ANR Pipeline*, the plaintiff's pipeline business was extensively regulated by the "comprehensive rules and regulations of the Federal Energy Regulatory Commission acting under the [federal] Natural Gas Act and the [federal] Natural Gas Policy Act." Id. at 1579. Similarly, in *Blue Sky*, the plaintiffs' parachute jumping and airport operations were subjected to the extensive, field-preempting regulatory scheme of the Federal Aviation Act.

complain.[5] *See Brogdon v. National Healthcare Corp.,* 103 F.Supp.2d 1322, 1339 (N.D. Ga. 2000) (suggesting that the federal interests under federal spending programs have primacy because Congress provides the spending power, not because of the Supremacy Clause). PhRMA's financial interests in avoiding prior authorization in the Medicaid program are not within the zone of interests protected or regulated by Medicaid. It therefore lacks prudential standing to mount a preemption challenge to the Maine Rx Program.

## II. THE PRIOR AUTHORIZATION PROVISION OF THE MAINE RX PROGRAM DOES NOT CONFLICT WITH THE FEDERAL MEDICAID STATUTE.

PhRMA apparently concedes that nowhere in the vast and detailed Medicaid statute can there be found statutory language limiting a state's discretion to impose prior authorization requirements. PhRMA also does not dispute that there is a strong presumption against preemption or that a court should not lightly find that a state statute frustrates the fundamental purposes of a federal statute. To satisfy this high standard, the court must first determine what are the "primary objectives" of

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[5] 42 U.S.C. § 1396c provides such a remedy by permitting the Secretary of DHHS to withhold federal funds if Maine is found to have violated Medicaid's requirements. A Medicaid recipient might also have standing to complain, provided a court were to hold that Medicaid confers upon recipients an enforceable right to access to drugs free from prior authorization requirements we doubt whether such a right exists. *Suter v. Artist M.*, 503 U.S. 347 (1992); *Massachusetts Medical Society v. Dukakis*, 815 F.2d 790 (1st Cir.), *cert. denied* 484 U.S. 896 (1987); *Evelyn V. v. Kings County Hospital Center*, 819 F.Supp. 183, 196 (E.D.N.Y. 1993).

the federal statute, as "conveyed with clarity in the federal legislation." *Gade v. National Solid Waste Management Association*, 505 U.S. 88, 110 (1992) (Kennedy, J., concurring), and then ask whether the alleged conflict between the state statute and the clearly expressed purpose of the federal statute is "irreconcilable" as opposed to "hypothetical" or "potential." *Id.*

The "primary objective" of the Medicaid drug benefit is to provide medically necessary drug therapy to needy persons. 42 U.S.C. §1396a(a)(54). This objective is fully accomplished whenever a Medicaid patient receives the drug he or she needs. So long as this primary objective is accomplished, it does not matter which of the competing pharmaceutical products is ultimately dispensed, or whether a state makes available on an equal footing all possible drugs which could be prescribed to treat a given medical condition. Indeed, Congress expressly authorized states to favor some drugs over others through imposition of prior authorization requirements. 42 U.S.C. §1396r-8. Most importantly – and this PhRMA also concedes – the Medicaid statute is completely silent as to what factors a state may consider in imposing prior authorization requirements.

Contrary to PhRMA's assertions, the prior authorization provision of the Maine Rx Program, 22 M.R.S.A. § 2681(7) will not deny a single Medicaid

recipient access to medically necessary drugs. This is so because the Maine Act does not allow it, [6] the proposed administrative rules drafted by the Department of Human Services insure against it, [7] and both the Commissioner and Maine's Medicaid administrator have affirmed that all Medicaid recipients will receive the drugs they need. [8] The primary objectives of the federal statute will therefore be completely satisfied. Preemption therefore simply is not called for. *Grant's Dairy*

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[6] This limitation appears on the face of the Act: "[t]he Department shall impose prior authorization requirements in the Medicaid program…*as permitted by law,* for the dispensing of drugs provided by those manufacturers" which do not enter into Maine Rx Program rebate agreements. 22 M.R.S.A. §2681(7) (emphasis added).

[7] The administrative rules provide that drugs of nonparticipating manufacturers shall be "reviewed by the Department as to the clinic appropriateness of prior authorization…under Medicaid," that this review shall be conducted by the "Medicaid Drug Utilization Committee, for a final determination of whether those drugs should be prior authorized, in accordance with federal and state law," and that "[i]n all instances, Medicaid recipients shall be assured access to all medically necessary outpatient drugs." *Chapter II, section 80.05-3, Medical Assistance Manual.* (App. A-171).

[8] Commission Concannon affirmed that "[p]rior authorization requirements will not be implemented so as to prevent Medicaid recipients from obtaining medically necessary prescription drugs," and that "[i]n making its determination of whether or not a prior authorization requirement is 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."" *Conncannon Aff.*, ¶¶ 9,11 (App. A-145,46). Timothy Clifford, M.D., Director of the Maine Bureau of Medical Services, affirmed that "[i]n implementing the prior authorization provision of the Maine Rx Program, the Department will ensure that physicians will always be able to prescribe the safest and most efficacious drugs for their Medicaid patients." *Clifford Aff.*, ¶¶ 8-10 (App. A-140).

*Maine, LLC v. Commissioner of Maine Department of Agriculture, Food & Rural Resources*, 232 F.3d 8 (1st Cir. 2000).

As shown above, the Department's reading of the "as permitted by law" language of the Maine Act, and the administrative rules it has proposed to implement it, provides a construction that is plainly valid. In this facial challenge, that is enough. *United States v. Salerno*, 481 U.S. 739, 745 (1987) (to succeed in a facial challenge to a statute, "the challenger must establish that no set of circumstances exist under which the Act would be valid."). If Congress, now or in the future, thinks otherwise, it may act. Alternatively, the Secretary of the Department of Human Services may withhold federal Medicaid funds from the State. 42 U.S.C. §1396c. Either is preferable to the administration of the "strong medicine" of preemption, in the absence of any evidence that Congress intended otherwise.

While PhRMA cannot show that § 2681(7) will deprive Medicaid patients of necessary drug therapy, it focuses instead on a procedural burden that prior authorization supposedly creates. That burden is minimal -- simply the requirement that a patient's physician seek approval of the Medicaid administrator before dispensing the particular drug. Br. 28. Moreover, whatever slight inconvenience there may be is inherent in the Congressionally created prior authorization option. Second, PhRMA claims that prior authorization will reduce

patients' choice between different drugs used to treat the same medical condition, impermissibly forcing Medicaid patients to "pay the price to punish" nonparticipating manufacturers. Br. 27-29.

The flaw in this argument is that neither access to drugs free from prior authorization requirements, nor the promotion of robust choice in selecting drug therapy, are "primary objectives" of Medicaid "conveyed with clarity in the federal legislation." *Gade*, supra, 505 U.S. at 110; *Grant's Dairy Maine, LLC v. Commissioner of Maine Department of Agriculture, Food & Rural Resources*, 232 F.3d 8 (1st Cir. 2000) (preemption is reserved for instances in which state law clearly conflicts with the "overarching purposes" of the federal regulatory scheme, not merely where there is tension between them). Indeed, they are not Medicaid objectives at all. Certainly, PhRMA points to nothing in Medicaid to support such a proposition. In fact, the statute places no limit on the States' prior authorization authority. 42 U.S.C. §1396r-8(d)(1)(A) ("A State may subject to prior authorization *any* covered outpatient drug.") In any event, the "strong medicine" of preemption is unwarranted, even if the Maine statute may be in tension with some subsidiary goals Congress might have had in mind.

There is no doubt that the Maine Rx Program employs a novel mechanism to make prescription drugs affordable for Maine's uninsured citizens. Indeed, we agree that Congress may not have considered that the broad prior authorization

discretion it vested with the states would be used in the manner Maine has attempted. But this Court should not impute to Congress Pharma's view about what Maine has here attempted.

Finally, PhRMA makes a rhetorical argument that, if the Medicaid prior authorization power could be used to lower drug prices for those least able to afford them, then it could just as easily leverage money for highways, bridges, or schools. Br. 31; Order at 12 (App. A-252). This Court need not decide such an extreme case because Maine is only advancing the primary goals of promoting health which animate the entire federal Medicaid statute. Building bridges would not reduce Medicaid hospitalization costs, for example, while the Maine Rx Program very well might. Moreover, the federal agency charged with overseeing Maine's Medicaid program agrees that lowering prescription drug prices for the uninsured advances the primary purposes of Medicaid. In late January, 2001, HCFA granted Maine permission to institute a program similar to the Vermont program referenced in our initial brief. *See* Appellants' Br. at 29-30.[9] HCFA approved these programs because they expand prescription drug coverage and

[9] The district court for the District of Columbia denied PhRMA's motion for a preliminary injunction barring implementation of the Vermont Program, and that decision is on appeal in the D.C. Circuit. *Pharmaceutical Research and Manufacturers of America v. Tommy G. Thompson,* Docket # 01-5029.

therefore advance the primary goals of Medicaid by preserving limited Medicaid funds for those who are most needy. In any event, if these objectives, which are not the building of bridges, highways, or schools, conflict with what Congress intended to accomplish with the prior authorization discretion it created, Congress may easily say so. But where Congress has not spoken with clarity in its own statute, the federal courts should be reluctant to speak for it.

## III. THE MAINE RX REBATE PROGRAM DOES NOT INFRINGE THE DORMANT COMMERCE CLAUSE.

PhRMA cites no case in which any court has prohibited a State from asking manufacturers to pay rebates on retail sales within the State. This is a case of first impression, and we submit that PhRMA has asked this court to expand dormant Commerce Clause doctrine far beyond its anti-protectionist origins.

### A. For Purposes Of The Market Participation Exception The Market Is Defined To Be Patients Who Lack Private Insurance Benefits For Prescription Drugs.

Manufacturers who do not participate in the Maine Rx Program face only one consequence – the state may reduce its purchases of their products. The Maine Rx Program is a pure exercise of the state's economic power, with Maine tailoring its spending in the state's Medicaid program to achieve its objectives. The Maine Rx Program does not rely on the state's regulatory authority, and the market participant exception to the dormant Commerce Clause doctrine therefore applies.

PhRMA concedes that the Maine Rx Program only relies on Maine's Medicaid market power, and not the State's regulatory authority to compel lower retail prices. Nonetheless, PhRMA argues that the ends to which Maine seeks to use its market power are suspect because recipients of prescription drugs through the Maine Medicaid program are not in the same market as recipients of prescription drugs through the Maine Rx program. Br. at 22-24. In so doing, however, PhRMA relies on the distinctions created by the state and federal programs, not the economic reality.

The uninsured population of Maine is, for economic purposes, one undifferentiated group. The population served by Medicaid and the Maine Rx Program is Maine residents who lack private insurance coverage for prescription drugs. **(**Anyone who has insurance would not be eligible for Medicaid. Likewise, such a person would have no incentive to participate in Maine Rx Program because the discounted price in the program is still substantially higher than the co-pay typically required by private insurance plans.) In the absence of any government program there would be only one "market," and the presence of those programs does not change this basic economic reality.

Nothing in the precedents cited by PhRMA justifies parsing the market any more finely than that. PhRMA's artificial distinction between the uninsured Maine residents who get their drugs through Maine Rx, and the uninsured Maine residents

who get their drugs through Medicaid, hardly falls within this Court's analysis in *National Foreign Trade Council v. Natsios*, 181 F.3d 38 (1st Cir. 1999), relied upon by PhRMA, where the ends (improved human rights conditions in Burma) were as remote from the means (Massachusetts' contracting) as one could conceive.

Moreover, PhRMA attempts to support its cramped interpretation of the market by claiming that in *White v. Massachusetts Council of Construction Employers, Inc.,* 460 U.S. 204 (1983), the workers Boston sought to benefit were "working for the city." Br. at 26. But in fact, the workers in *White* were not actually city employees. The Court was willing to disregard that fact, allowing a measure of flexibility in determining the permissible ends to which the state's market power may be employed. *White* must be read as rejecting the type of market parsing PhRMA advocates here.[10]

### B. The Maine Rx Program Does Not Regulate The Terms Of Transactions In Other States.

PhRMA's entire Commerce Clause argument is based on its contention, set forth at pages 11-12 of its brief, that through the Maine Rx Program, Maine is "regulating transactions occurring in other states." PhRMA repeatedly characterizes the Maine Rx Program as an effort to regulate out-of-state wholesale

[10] Nor would such an outcome "swallow up the rule" against state regulation of interstate commerce. Amicus Curiae Brief of the Washington Legal Foundation at 13 (hereafter "WLF Br."). The exception is inherently limited by the fact that the states have finite economic power, even in large state programs such as Medicaid.

drug prices. *See* Br. at 1 (Maine Rx Program "regulate[s] the terms of transactions that take place in other states"); *id.* at 10 ("changes the terms"); *id.* at 11 ("reduc[es] the prices"); *id* at 13 ("dictate[s] the terms"); *id.* at 14 (" regulates the price or terms"); *id.* at 15 ("necessarily changes the terms"); *id*. at 16 ("regulates the terms of sales").[11]

Frequently repeating the price regulation mantra, however, does not make it true. A considerable leap of logic separates the practical economic operation of a rebate triggered by retail sales from a wholesale price control. The Maine Rx Program simply *does not regulate the price (or any other term) of out-of-state wholesale transactions.* It is PhRMA – not the statute – that creates the link between the rebate program and wholesale commerce. The Maine law manifestly does not impinge on the free market forces that dormant Commerce Clause doctrine evolved to protect.[12]

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[11] *Amicus Curiae* the Washington Legal Foundation takes this fiction to new levels. *See* WLF Br. at 22 (Maine Rx Program "operates directly on out-of-state prices" and "directly regulates out-of-state wholesale prices"); *but see id.* at 18 ("Maine is correct, of course, that it does not dictate to manufacturers the precise wholesale price at which they must sell their drugs").

[12] PhRMA has tacitly conceded – as it must – that the provisions at issue in this appeal are not discriminatory, protectionist or capable of producing interstate gridlock, which we submit are the usual grounds for invalidating state legislation under the dormant Commerce Clause.

PhRMA's only response to this simple fact is to invoke other provisions of Maine law not at issue in this appeal. Specifically, it asserts that because the separate anti-profiteering provisions enacted simultaneously with the Maine Rx Program *do* regulate wholesale prices, it is "disingenuous" of Maine to deny that the Maine Rx Program itself also regulates the price of wholesale transactions. *See* Br. at 15 n.6. But PhRMA's attempt to conflate the anti-profiteering provision (which, if read broadly, arguably does impose limits on wholesale prices), and the Maine Rx Program (which plainly does not) only emphasizes the fallacy of PhRMA's characterization of the rebate program as a regulation of out-of-state wholesale prices.[13]

Moreover, PhRMA's insistence on the term "regulate" in this context defies the ordinary understanding of the word, the paradigmatic expression of which is found in *Gibbons v. Ogden*, 22 U.S. (9 Wheat.) 1 (1824) (to regulate commerce is "to prescribe the rule by which commerce is to be governed"). Clearly, the payment of a rebate on retail sales will not govern or even affect the actual price paid by prescription drug wholesalers or the price received by PhRMA member

[13] Maine has declined to press an appeal of that portion of the District Court's order enjoining the anti-profiteering provisions.

companies.[14] As Justice Cardozo noted two years after *Seelig*, a state's exaction of a payment from an entity engaged in commerce does not amount to a "clog" on commerce. *Henneford v. Silas Mason Co.*, 300 U.S. 577, 587 (1937).

### C. The Dormant Commerce Clause Does Not Require A Categorical Prohibition On Non-Discriminatory State Statutes With Some Extraterritorial Reach.

PhRMA next argues that a "fundamental tenet" of the dormant Commerce Clause prohibits extraterritorial application of any state statute. Br. at 12-19. The genesis for this supposed prohibition on extraterritoriality is not the Commerce Clause itself, but the Supreme Court's statement in *Baldwin v. G.A.F. Seelig*, 294 U.S. 511 (1935), that the State has "no power to project its legislation into [another state] by regulating the price to be paid in that state." PhRMA's analysis goes astray, however, when it ignores the second clause of that sentence specifying the kind of "projecting" that concerned the Court. Maine has not "projected" its legislation to control prices elsewhere, as fully explained above. And, contrary to PhRMA's contention, *Seelig* simply did not hold that *any* extraterritorial reach of a state statute – as opposed to extraterritorial price controls – offends the dormant

[14] Moreover, the Maine Rx program's rebate mechanism is essentially identical to that in Medicaid. *Compare* 22 M.R.S.A. §2681 *with* 42 U.S.C. § 1396r-8. Yet no one would argue that the Medicaid program "regulates" the actual wholesale price of prescription drugs. To the contrary, the entire Medicaid pricing structure *assumes* the wholesale price as it is actually determined by market forces. *See* Br. at n. 9 (explaining that manufacturers' wholesale prices are the starting point for determining Medicaid rebates).

Commerce Clause. *See K-S Pharmacies, Inc. v. American Home Products Corp.,* 962 F.2d 728 (7th Cir. 1992) (Easterbrook, J.) (sustaining state pharmaceutical price fixing statute against claim that it impermissibly affected out-of-state transactions); *see also Instructional Systems, Inc. v. Computer Curriculum Corp.,* 35 F.3d 813, 825 (3rd Cir. 1994) (dormant Commerce Clause does not require that "each state's law [must stop] at the border.").

Apart from the cases already distinguished in Appellants' initial brief,[15] PhRMA bases its "extraterritoriality" argument on four Supreme Court decisions, none of which is apposite here. Two of those, *Huntington v. Attrill*, 146 U.S. 657 (1892) and *New York Life Ins. Co. v. Head*, 234 U.S. 149 (1914), (Br. at 17 n.7) address the Full Faith and Credit Clause and do not even mention the dormant Commerce Clause, let alone illuminate the limits of its current application.[16] PhRMA cites one modern case, *Bigelow v. Virginia,* 421 U.S. 809 (1975),

[15] *Seelig*, *Brown-Forman* and *Healy* all involved protectionist statutes that discriminated against interstate commerce originating and terminating wholly within other states. Their holdings therefore do not answer the question whether an admittedly non-discriminatory statute applied to products coming to rest within the State offends the dormant Commerce Clause.

[16] *New York Life Inc. Co.* held that the Missouri courts must give full faith and credit to a contract amendment entered into in New York. *Huntington* held that the Maryland courts must give full faith and credit to a civil judgment reached in New York.

(Br. at 16 n.7), for the uncontroversial proposition that the legislature in one state may not prohibit health care providers in another state from performing abortions – a far cry from a statute seeking rebate payments in connection with sales within the state's borders. PhRMA's final Supreme Court "extraterritoriality" citation (*BMW of North Am. v. Gore*, 517 U.S. 559 (1996)) is unpersuasive for two separate reasons. First, *Gore* examined whether a jury award was excessive under the Due Process clause, and the defendant's "extraterritorial" conduct was not considered relevant to that analysis by either the lower court or the Supreme Court. *See id*. at 573-74 ("Alabama Supreme Court therefore properly eschewed reliance on BMW's out-of-state conduct . . . and based its remitted award solely on conduct that occurred within Alabama."); *id.* at 608 ("the excessiveness of the [jury] award is the sole issue genuinely presented. The Court ultimately so recognizes.") (Ginsburg, J. dissenting); *id.* at 604 (extraterritoriality discussion of the majority opinion is "the purest dicta") (Scalia, J., dissenting). More fundamental here, the dictum upon which PhRMA relies – "No State can legislate except with reference to its own jurisdiction," Br. at 16 (quoting *Gore*, 517 U.S. at 571) – merely begs the question as to what those jurisdictional limits may be. In short, it appears that PhRMA's "bedrock" principle has rarely been mentioned and never applied.

PhRMA's contention that the dormant Commerce Clause categorically prohibits states from reaching beyond their borders is related to the discredited

claim that states may not "directly" regulate interstate commerce. *See Grant's Dairy,* 232 F.3d at 19 (declining to apply direct/indirect framework); *see generally* Donald Regan, *Siamese Essays,* 85 Mich. L. Rev. 1865 (1987). We submit that neither approach is valid because neither advances the value at the core of the dormant Commerce Clause – free trade among the States.

Conspicuously absent from PhRMA's analysis of the Supreme Court's extraterritoriality decisions is any mention of *CTS Corp. v. Dynamics Corp. of America*, 481 U.S. 69 (1987), which upheld an Indiana statute regulating both in-state and out-of-state stock transactions. In *CTS Corp.*, the Supreme Court acknowledged that the statute regulated transactions in other states, but said that the state's interest justified that burden. *Id.* at 94. After *CTS,* it cannot be said that the Supreme Court follows a *per se* rule to invalidate non-protectionist legislation that directly regulates extraterritorial transactions.

*Dean Foods Co. v. Brancel*, 187 F.3d 609 (7th Cir. 1999), relied upon by PhRMA, does not counsel a different outcome here. The Wisconsin statute at issue in *Dean Foods* specifically controlled the price term in wholesale milk transactions. The only issue for the court was whether those transactions constituted commerce "wholly outside the state." *Id.* at 616. The Court found that the statute could not be applied to a farmer who takes his milk to Illinois and sells it there for consumption in Illinois, because he was engaged in commerce "wholly

outside the state" and that "no commerce occurred in Wisconsin." *Id.* at 619, 620. It does not follow from *Dean Foods,* however, that an in-state rebate, collected only on goods that are actually purchased in retail transactions within the state, becomes a regulation of commerce "wholly outside the state" whenever the manufacturer happens to be located elsewhere. *Dean Foods* would apply if Maine were seeking rebates on retail sales *in another state*. Of course, the rebate provision is triggered only by sales within Maine.

In sum, 225 years of jurisprudence has not produced a single Supreme Court dormant Commerce Clause case that actually applied a categorical ban on extraterritorial reach in a non-discriminatory case. This is because the only truly "fundamental" rule of the dormant Commerce Clause is that one state may not enact economically protectionist legislation to the disadvantage of other states. The Maine statute easily satisfies that rule.[17]

[17] We concur with PhRMA's quotation from Lawrence Tribe's treatise on Constitutional Law (Br. at 21-22) defining "extraterritorial state regulations" as "laws which directly regulate out-of-state commerce, or laws whose operation is triggered by out-of-state events." Maine's law plainly is not an "extraterritorial regulation" under Tribe's definition because it does not "directly" regulate out-of-state commerce and its operation is only triggered by in-state sales.

### D. The Maine Rx Program's Reference To Medicaid Rebate Amounts Is Not Unconstitutional Price Tying Of The Sort Condemned In *Brown-Forman* And *Healy*.

PhRMA claims that the Maine Rx Program ties Maine prices to extraterritorial prices just as the statutes in *Brown-Forman* and *Healy* did. Br. at 20-21.[18] The claim is based on the statute's directive that the Commissioner "shall negotiate the amount of the rebate" with manufacturers and when doing so "shall take into consideration the rebate calculated under the Medicaid Rebate Program." 22 M.R.S.A. §2681(4).

As an initial matter, we submit that PhRMA's "tying" argument is the only portion of its brief that correctly depicts the dormant Commerce Clause principles at work in this case. Tying prices in one state to prices in another state in a lockstep fashion would offend the dormant Commerce Clause because it would seek to obtain an economic advantage for the enacting state as against other states.

The fatal flaw in PhRMA's "tying" argument, however, is that it misconstrues the statute in several ways. First, §2681(4) does not dictate the *amount* of the rebate, but is only a directive to negotiate. While the Commissioner is required to "take into consideration" the Medicaid rebate amount, in his negotiations he must also consider other factors that may weigh either for or against using the Medicaid figures. *Id.* The statute, therefore, does not *mandate*

[18] The District Court did not address PhRMA's "tying" argument.

that manufacturers agree to the Medicaid rebate amount or any other price index. Furthermore, the Maine Rx rebate amount is determined by negotiation, not by other markets, leaving manufacturers free to adjust their prices elsewhere without considering the Maine rebate.

Second, §2681(4) does not dictate the *form* of the rebate. For example, it would not prohibit manufacturers from negotiating a fixed rebate amount rather than rebates that are calculated as a percentage of some other price scale. Plainly, such fixed rebate amounts would raise no question of "tying" because they do not hinge on any other price.

Third, the Medicaid "reference point" in the Maine statute cannot be compared to those in *Brown-Forman* and *Healy*. In those cases the statute linked prices to transactions in any one other state. Here, the purported "linkage" is to the entire national market, which, even if it were a lockstep link (it is not), does not seek to advantage Maine against another state and therefore does not constitute a protectionist act by Maine – the prevention of which is the core purpose of the dormant Commerce Clause.[19]

In short, the statute does not mandate lock-step price tying such as that in *Brown-Forman* and *Healy*. In this facial challenge, the statute cannot be

[19] In any event, PhRMA cites no authority for the proposition that a state price tied to a national market, as opposed to the market of another state, would offend the dormant Commerce Clause.

invalidated on the basis of PhRMA's speculation that it might be applied in a lock-step fashion because a sensible and constitutionally benign alternative is available.

### E. The Record Contradicts Phrma's Contention That Manufacturers Have No Role In Retail Sales Within Maine.

PhRMA contends – without citation to the record – that pharmaceutical manufacturers have no involvement with retail sales in Maine. Maine addresses this assertion briefly because it seems to play a significant role in various aspects of PhRMA's argument, including the discussion of *Complete Auto Transit, Inc. v. Brady,* 430 U.S. 274 (1977). *See, e.g.,* Br. at 11 (manufacturers "have no role" in retail transactions in Maine); Br. at 12 ("manufacturers are not involved in sales transactions [in Maine]"); Br. at 19 (law fails *Complete Auto* test because "[manufacturers] make no sales within the State [and have] no physical presence ... in Maine").

In truth, pharmaceutical manufacturers have extensive presence in every state, including Maine, for the express purpose of directly influencing retail purchases of their products. Even the limited record created in this preliminary injunction proceeding belies PhRMA's contention that its member companies have no in-state presence. For example, the nation's leading pharmaceutical manufacturers have long been engaged in marketing their products directly to prescribing physicians. In recent years, however, the record reflects that

manufacturers have embarked on an enormous new effort to reach out directly to individual consumers, spending over *$1.3 billion* on "direct-to-consumer" advertising in 1998.[20] More importantly, their local presence is not limited to advertising but includes an untold number of sales representatives or "detailers" whose job it is to personally visit doctors in Maine and elsewhere to encourage them to write more prescriptions for their products.[21] While the record thus far does not identify the precise extent of these practices within Maine, there is nothing to support PhRMA's implicit contention that these extraordinary marketing efforts by PhRMA member companies somehow bypass the State. PhRMA's assertion that its members "have no physical presence in Maine" simply cannot be credited.

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[20] *See* Testimony of the Blue Cross and Blue Shield Association on Prescription Drug Benefits and the Medicare Program for the Committee on Finance, U.S. Senate, presented by Dr. Morris B. Mellion, June 23, 1999, p.8, cited in *Factors Affecting the Growth of Prescription Drug Expenditures* (Washington DC: Nat'l Inst. for Health Care Management Research and Educational Foundation*, July 9, 1999,* at 12) (appended to Docket # 13).

[21] *See Factors Affecting The Growth Of Prescription Drug Expenditures, supra* note 10, at 14. The report does not indicate how much is spent on "detailing" nationally, but it found that total promotional spending by the industry aimed at professionals approached $7 billion in 1998. *Id.*

## CONCLUSION

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

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Respectfully submitted,

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