No. 00-2446

UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,
Plaintiff-Appellee,
v.

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

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MAINE

BRIEF OF APPELLEES

Kathleen M. Sullivan
559 Nathan Abbott Way
Stanford, CA 94305
(650) 725-9875

Daniel M. Price
Powell, Goldstein, Frazer & Murphy LLP
1001 Pennsylvania Ave. NW
Washington, D.C. 20004
(202) 347-0066

***Of Counsel*:**
Allen S. Rugg
Marinn F. Carlson
Powell, Goldstein, Frazer & Murphy LLP

Bruce C. Gerrity
Preti, Flaherty, Beliveau, Pachios & Haley LLC

CORPORATE DISCLOSURE STATEMENT

Appellee Pharmaceutical Research and Manufacturers of America ("PhRMA") hereby certifies, pursuant to Fed. R. App. P. 26.1, that it has no parent corporations, and that no publicly held company owns 10% or more of its stock. PhRMA is a business membership association established as a non-profit corporation under the laws of Delaware; a list of its members is available at http://www.phrma.org.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

RULES

OTHER AUTHORITIES

QUESTIONS PRESENTED

1. Under the Commerce Clause, may a state regulate the terms of transactions that take place in other states?
2. Under the Supremacy Clause, may a state restrict patient access to drugs within the Medicaid program to punish a drug manufacturer for refusing to subsidize an unrelated state program?

STATEMENT OF FACTS

This is an appeal from a District Court decision preliminarily enjoining enforcement of a Maine law enacted last summer that requires drug manufacturers to subsidize retail price discounts to Maine residents under a new state program called the "Maine Rx Program." The statute punishes a manufacturer that does not provide the required subsidies for patients in the Maine Rx Program by, *inter alia*, restricting access to the manufacturer's drugs by patients in the federal Medicaid program.

The District Court found Plaintiff-Appellee PhRMA "overwhelmingly" likely to prevail on its claims that the Maine law (1) violates the Commerce Clause by regulating transactions between manufacturers and wholesalers that take place in other states, and (2) violates the Supremacy Clause by restricting the availability of a manufacturer's drugs to patients in the federal Medicaid

program to punish the manufacturer for not subsidizing discounts to patients in the unrelated Maine Rx Program. The District Court also found the other prerequisites for a preliminary injunction satisfied.

I. THE MAINE RX PROGRAM

Maine's Act to Establish Fairer Pricing for Prescription Drugs, 2000 Me. Legis. Ch. 786 (S.P. 1026) (L.D. 2599) (the "Act") entered into force on August 11, 2000. That law provided for, *inter alia*, the creation of a program, funded wholly by "rebates" from drug manufacturers, to subsidize retail prescription drug purchases for Maine citizens. 22 M.R.S.A. § 2681. The Act's rebate requirements are conjoined with provisions prohibiting drug manufacturers from engaging in "profiteering," defined to include, *inter alia*, charging "unconscionable" prices and reducing sales or distribution of drugs in Maine "in retaliation for" the Act. 22 M.R.S.A. § 2697(2). In addition, the Act contemplates imposing direct price controls on retailers in 2003 if the Maine Rx Program does not lower drug prices to the State's satisfaction. 22 M.R.S.A. §§ 2691, 2693(1).

The Act requires all drug manufacturers whose drugs are sold in Maine to enter into "rebate agreements" with the State's Department of Human Services ("Department"), under which the manufacturers will make payments to the

State based on the quantity of drugs dispensed to Maine Rx participants by retailers. 22 M.R.S.A. § 2681(3).[1] Using the Maine Rx Program, Maine residents will be able to purchase prescription drugs from retail pharmacies at discounts funded by those rebates. 22 M.R.S.A. § 2681(5).

The Maine Rx Program manufacturer "rebate" does not involve rebates in the conventional sense of a refund paid by a seller to a purchaser. Typically, drug manufacturers sell to wholesalers and distributors. The Maine Rx Program rebate involves remission by drug manufacturers to Maine residents, via the State, of part of the purchase price that the manufacturers receive from their customers (wholesalers). Although the rebate is channeled to residents through State coffers, the State does not purchase or subsidize the purchase of any drugs itself.

Likewise, the Maine Rx Program does not involve "agreements" freely entered into—the Act mandates that manufacturers "shall" subsidize Maine Rx drugs. 22 M.R.S.A. §§ 2681(3),(4). If a manufacturer does not provide the required rebates, its nonparticipation is punished by restricting patient access to

[1] Specifically, the rebate requirement applies to all manufacturers whose drugs are sold in Maine through "publicly supported pharmaceutical assistance programs" such as the nationwide federal Medicaid program. 22 M.R.S.A. § 2681(3). PhRMA members participate in Medicaid. (JA 12)

and sales of its drugs in the unrelated, federal Medicaid program.[2] 22 M.R.S.A. § 2681(7). In addition, the Act threatens nonparticipating manufacturers with prosecution under its "anti-profiteering" provisions, which make it illegal for manufacturers to, *inter alia*, obtain "unreasonable" profits. 22 M.R.S.A. § 2697(2). Those same provisions also put manufacturers at risk of prosecution if they make business decisions to rearrange their interstate distribution channels in response to the Act. 22 M.R.S.A. § 2697(2)(D).

The state Maine Rx Program is distinct from the federal Medicaid program. Maine Rx is a state program serving the population of Maine.[3] Medicaid is a nationwide, federal program that delivers health services to qualifying individuals, as defined by Congress. Maine Rx is not authorized, nor funded, nor even contemplated by the federal Medicaid program.

---

[2] Medicaid is a federally mandated, state administered program that operates under federal guidelines to provide medical care to certain statutorily-specified low-income populations. 42 U.S.C. § 1396. If states elect to offer prescription drug benefits, Medicaid covers Medicaid beneficiaries' costs for drugs, provided the drug's manufacturer has entered into a nationwide rebate agreement with the Secretary of Health and Human Services to pay statutorily-calculated rebates to the states. 42 U.S.C. § 1396r-8.

[3] Contrary to Maine's characterizations (*e.g.* Br. 5), neither the Act nor the proposed implementing regulations limits participation based on income, insurance, age, or any qualification other than Maine residency. 22 M.R.S.A. §§ 2681(2)(D), (5).

Nevertheless, the Act enforces the state Maine Rx Program using *Medicaid* regulatory powers to require "prior authorization" by state officials for prescriptions dispensed to Medicaid patients. Prior authorization creates a procedural obstacle to Medicaid patients' access to listed drugs, which in turn reduces Medicaid-funded purchases of those drugs. By the terms of the Act, Maine will require prior authorization for Medicaid prescriptions of drugs made by manufacturers who do not pay Maine Rx rebates. 22 M.R.S.A. § 2681(7).

The Maine Rx discounts and rebates established by the Act are tied to prices charged around the country. Initially, the Act provides for manufacturer rebates at least as large as those paid into the nationwide federal Medicaid program. 22 M.R.S.A. § 2681(4). In later phases, the Maine Rx rebates are to be equal to or greater than those paid under any federal program. *Id.* Department of Human Services Commissioner Concannon implemented this statutory mandate by presenting manufacturers with a Maine Rx Rebate Agreement, for signature no later than November 1, 2000, that specified payment of "the Medicaid Rebate amount" to Maine for drugs dispensed under Maine Rx. (JA 64, 67)

II. THE DISTRICT COURT'S ORDER

On October 26, 2000, the District Court found PhRMA's likelihood of

success on its principal constitutional challenges to be "overwhelming," and issued a preliminary injunction against the rebate and certain anti-profiteering provisions of the Act. (JA 255) In his Order, Judge Hornby concluded that the Maine Rx Program, while directed at a worthy legislative goal of promoting public health, nevertheless offended the Commerce Clause and federal Medicaid law by its choice of means.

Judge Hornby held that Maine had exceeded the territorial limits of its regulatory authority under the Commerce Clause. He found that, by exacting rebates with respect to transactions occurring outside the State (such as the typical manufacturer's out-of-state sale of drugs to a wholesaler or distributor) the Maine Rx Program necessarily—and unconstitutionally—regulates the terms of those commercial transactions in other states. (JA 248-50) The District Court held that the Commerce Clause likewise bars any application of the Act's "profiteering" prohibitions to manufacturers' out-of-state transactions. (JA 243-44) The District Court rejected Maine's efforts to escape Commerce Clause scrutiny by claiming the status of a "market participant," explaining that "Maine is using its leverage [prior authorization authority] in the Medicaid market, where it is a participant, to exert a *regulatory* effect in the uninsured market for prescription drugs, in which it is not a participant." (JA 247, emphasis supplied)

Judge Hornby also ruled that the principal mechanism by which Maine compels rebate payments—using its Medicaid "prior authorization" power to penalize manufacturers who do not subsidize discounts under the State's Maine Rx Program—was invalid under the Supremacy Clause. Because requiring advance clearance before Medicaid-funded drugs may be dispensed to Medicaid beneficiaries is by definition an obstacle to the provision of federal Medicaid benefits, the Court found the "prior authorization" penalty to be preempted by federal law.

Recognizing that Maine has no colorable interest in assisting its citizens through unconstitutional legislation, and likewise that the public interest lies with upholding the Constitution, the District Court enjoined the State from enforcing the Maine Rx rebate requirement through Medicaid prior authorization, and from applying the Act's profiteering bans to out-of-state transactions.[4] (JA 255-56)

[4] Maine has elected to appeal from the preliminary injunction only as it applies to the Maine Rx Program. (Br. 2-3 & n.2) Accordingly, the "anti-profiteering" provisions of the Act are not before the Court.

SUMMARY OF ARGUMENT

The District Court correctly concluded that the Maine Rx rebate requirement violates the Commerce Clause by regulating transactions that take place in other states. Under the Commerce Clause, a state's regulatory powers are limited to transactions that take place within its borders. This is a territorial, jurisdictional, limit on state power. The Maine Rx Program, however, controls the terms of drug manufacturers' sales to their wholesalers and distributors, even when those sales take place outside Maine.

Because a state lacks power to project its authority beyond its borders, it is irrelevant whether the Maine law is also discriminatory or protectionist. Moreover, the "market participant" exception does not save the Act: that doctrine does not allow a state to project its power beyond its borders, and in any event, a state cannot use its participation in one market to leverage regulatory control into another market.

The District Court also correctly concluded that the Act violates the Supremacy Clause. As Judge Hornby recognized, the federal Medicaid statute does not allow Maine to restrict Medicaid patients' access to a manufacturer's drugs in order to promote non-Medicaid objectives. Such use of "prior authorization"—whether to force drug manufacturers to subsidize consumer discounts under non-Medicaid programs, or to finance public works or other

undertakings unrelated to Medicaid—conflicts with Medicaid's purposes and goals and is therefore preempted.

Maine's argument that PhRMA lacks "prudential standing" to challenge the Maine law on preemption grounds is similarly without merit. PhRMA's standing to challenge the Maine Act, which directly and adversely affects its members, simply does not depend on whether they are within the zone of interests protected or regulated by the federal Medicaid law. Maine has waived this argument, moreover, by failing to press it below.

Finally, the District Court's preliminary injunction was properly founded upon PhRMA's "overwhelming" likelihood of success on the merits of its constitutional claims, its impending irreparable harm, and the public's interest in enforcing the Constitution. However worthy the State's intentions, they cannot be furthered by unconstitutional legislation.

ARGUMENT

The Act's Maine Rx Program is unconstitutional in at least two respects. First, it demands payment on, and thereby regulates the terms of, prescription drug sales occurring wholly outside the State of Maine. That extraterritorial reach violates the dormant Commerce Clause. Second, it enforces its rebate requirement by using a regulatory power under the federal Medicaid program to penalize noncompliance with the State's unrelated Maine Rx Program. The Act's use of Medicaid "prior authorization" is preempted under the Supremacy Clause as an obstacle to the achievement of Congress's Medicaid objectives of delivering health benefits.

I. MAINE RX REBATES REGULATE COMMERCE EXTRATERRITORIALLY, IN VIOLATION OF THE DORMANT COMMERCE CLAUSE

Relying on "bedrock principles concerning the territorial limits of a state's power," (JA 248, citing *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511 (1935)), the District Court held that the Maine Rx Program violates the Commerce Clause. Judge Hornby observed that requiring a Maine Rx rebate from manufacturers necessarily changes the terms of those manufacturers' drug sales. To the extent that those sales take place outside Maine, the Maine Rx

rebate oversteps the Commerce Clause's territorial limits: "Maine has no power to regulate the prices paid earlier in transactions in other states." (JA 249)

A. The Act Regulates Transactions Occurring in Other States

The Maine Rx rebate's extraterritorial reach is straightforward. Drug manufacturers typically sell their drugs to wholesalers and distributors in transactions that take place outside Maine, and have no role in the further transactions that result in the drugs' retail sale in Maine. Nevertheless, Maine Rx will extract payments from these manufacturers if their drugs eventually reach consumers in Maine. That levy necessarily changes the economic terms of the only sales transactions in which manufacturers are engaged—namely, sales outside the State—by effectively reducing the prices the manufacturers receive for their products from their wholesale customers.

Because it applies indiscriminately to all manufacturers' drug sales, Maine's rebate requirement cannot help but regulate the terms of extraterritorial transactions. Most manufacturers' sales of prescription drugs occur outside of Maine, in direct, arms-length transactions with wholesalers and distributors. Often, both the manufacturers and their customers (independent wholesalers and distributors) are located outside Maine. More importantly, the drugs are typically delivered at the manufacturers' facilities outside Maine, and title and risk of loss passes outside Maine. And frequently the drugs are then shipped by

common carrier to warehouses and distribution centers outside Maine. (JA 54-55, 57-58, 75-76, 87-88, 100-01) The wholesalers and distributors then sell the drugs to their customers, including customers in Maine.

Thus many manufacturers' only sales of prescription drugs take place outside Maine. Although some of those drugs eventually reach Maine for retail sale, the manufacturers are not involved in sales transactions there. Nevertheless, the Act requires rebates from these manufacturers based on the fact that the drugs they sell outside Maine wind up in Maine.

As the District Court cogently explained, "[i]t is undisputable that the practical effect of [the Maine Rx rebate] is to limit the revenue an out-of-state manufacturer can obtain when it sells drugs to out-of-state distributors that ultimately send or bring the drugs to Maine." In other words, "whatever price the manufacturer originally received for that out-of-state transaction is automatically reduced [by the Maine Rx rebate] when the drug comes to Maine." (JA 249-50)

B. The Extraterritorial Reach of the Act Violates the Commerce Clause

The Commerce Clause prohibits state laws and regulations that have the effect of controlling commerce beyond the state's borders. The "bedrock principles" underlying the District Court's holding are succinctly stated in *Seelig*, in which the Supreme Court explained that a state "has no power to

project its legislation into [another state] by regulating the price to be paid in that state for [goods] acquired there." 294 U.S. at 521 (internal punctuation omitted). As the Court has repeatedly confirmed since, a state may not dictate the terms on which buyers and sellers do business outside the state. *See, e.g., Brown-Forman Distillers Corp. v. New York State Liquor Auth.*, 476 U.S. 573, 583-84 (1986); *Healy v. The Beer Institute*, 491 U.S. 324, 338 (1989).[5]

Courts look to three factors articulated in *Healy* to evaluate whether a state statute has an unconstitutional extraterritorial reach or effect (which, if found, renders the statute invalid on a nearly *per se* basis): (i) whether the regulation is applied to commerce "wholly outside of the State's borders," (ii) whether "the practical effect" of the regulation is to control such commerce, and (iii) what effect the regulation has on other states' regulations, as well as what

---

[5] The State misunderstands PhRMA's argument when it cites to cases permitting in-state regulation with incidental out-of-state effects (JA 46-47, citing *Exxon Corp. v. Maryland*, 437 U.S. 117 (1978) and *Cotto Waxo Co. v. Williams*, 46 F.3d 790 (8th Cir. 1995)). PhRMA does not contend that the Act is invalid because it disproportionately affects out-of-state entities (*Exxon*) or because it has upstream or downstream economic ripple effects outside Maine (*Cotto Waxo*). The Act is not an in-state regulation with some out-of-state effects (like, for example, a price control on in-state pharmacies that might affect the market-clearing price in upstream out-of-state manufacturer-wholesaler transactions). Instead, it reaches outside the state to extract payments directly from entities and transactions in other states—an approach that brings it squarely within the scope of *Seelig*, *Healy*, and *Dean Foods*.

effect would result "if not one, but many or every, State adopted similar legislation." 491 U.S. at 336.

Consistent with these teachings, courts will not permit states to regulate the price or terms at which goods are sold outside the state simply because the goods are later re-sold within the state. Rather, the courts have limited the reach of a state's powers to transactions that actually take place there. *See Seelig*, 294 U.S. at 528; *Schwegmann Bros. Giant Super Mkts. v. Louisiana Milk Comm'n*, 365 F. Supp. 1144, 1156 (M.D. La. 1973), *aff'd* 416 U.S. 922 (1974); *Louisiana Dairy Stabilization Bd. v. Dairy Fresh Corp.*, 631 F.2d 67 (5th Cir. 1980).

The Seventh Circuit, for example, recently demonstrated a straightforward application of the Commerce Clause's prohibition on extraterritoriality in *Dean Foods Co. v. Brancel*, 187 F.3d 609, 614-15 (7th Cir. 1999). There the Court of Appeals weighed factors much like those that describe the drug industry (*supra*) to conclude that a Wisconsin statute regulating pricing terms in the sale of milk could not constitutionally be applied to certain transactions that were found to occur in Illinois. Centrally, the Court reiterated that "the fact that a particular transaction may affect or impact a state does not license that state to regulate commerce which occurs outside of its

jurisdiction." *Id.* at 619-20; *see also Schwegmann*, 365 F. Supp. at 1156; *Louisiana Dairy*, 631 F.2d at 69.

Like the milk sold in *Dean Foods*, the drugs targeted for Maine Rx rebates are typically sold by manufacturers in out-of-state transactions with wholesalers and distributors. When the State demands drug price rebates from manufacturers who sold those same drugs outside Maine, it necessarily changes the terms of those out-of-state sales, just as clearly as if it had, like Wisconsin, dictated constraints on the price charged.[6] Under the Commerce Clause, Maine lacks the power to regulate those sales. It may regulate the prices charged in Maine pharmacies; it may even regulate prices charged in (or extract rebates from) any manufacturer sales that do take place in Maine, consistent with the

[6] The State's claims that it is "utterly indifferent to manufacturers' decisions to increase or decrease prices charged to their customers" and that "[m]anufacturers in the [Maine Rx] program may charge whatever they wish, to whatever customers they wish, without any consequences whatsoever," border on disingenuous. (Br. 36) Though the anti-profiteering provisions of the Act are not a subject of this appeal, Maine cannot pretend that their explicit prohibition of "unconscionable" manufacturer prices and "unjust or unreasonable" manufacturer profits does not exist. 22 M.R.S.A. § 2697(2). Furthermore, it is clear that the Act's focus on manufacturers (and its decision to require rebates from them, rather than, for example, imposing price controls on in-state pharmacies) stems from the Legislature's express finding that "[p]harmaceutical companies are charging the citizens of Maine excessive prices for prescription drugs." Act § A-5 (JA 34).

Commerce Clause. It may not, however, regulate the terms of sales that do not take place in the State.

Maine seeks to avoid the force of these principles by arguing that the Commerce Clause's territorial limits apply only if the state law in question also embodies a discriminatory or protectionist intent to favor in-state commerce over interstate commerce. In Maine's view, such cases as *Seelig* and *Healy* condemn extraterritorial laws only because the laws also have a protectionist or discriminatory element. Because the Act would exact rebates on the same terms from both in-state and out-of-state manufacturers, and does not seek to beggar its neighboring states, the State treats *Seelig* and *Healy* (which do discuss the perils of protectionism) as irrelevant. What Maine fails to recognize, however, is that these cases condemned state laws on the basis of the fundamental tenet that a State cannot project its legislation onto commerce occurring entirely in other states. *See BMW of North Am. v. Gore*, 517 U.S. 559, 571 (1996) ("No State can legislate except with reference to its own jurisdiction.") (citation omitted).[7] Protectionism is not a necessary prerequisite to invalidating such extraterritorial overreaching.

---

[7] *See, e.g., Bigelow v. Virginia*, 421 U.S. 809, 822-23 (1975) ("The Virginia Legislature [cannot] regulate[] [nor] proscribe[] activity" in another state.); *New York Life Ins. Co. v. Head*, 234 U.S. 149, 161 (1914) ("[I]t would be impossible to permit the statutes of Missouri to operate beyond the jurisdiction of that State

(footnote continued)

Maine's defense of the Act is also belied by the Seventh Circuit's decision in *Dean Foods*, 187 F.3d at 614-15. The Court of Appeals' holding that the Wisconsin statute could not, consistent with the Commerce Clause, be applied to transactions occurring outside Wisconsin did not rest on any assessment of the statute's discriminatory animus or effects. Likewise, the Maine Rx rebate requirement cannot be constitutionally applied to transactions occurring outside Maine: in the words of the District Court, "[b]ecause Maine has no power thus to extend its power extraterritorially and to impose this burden on interstate commerce, it is irrelevant whether its program actually discriminates against out-of-staters." (JA 250)

Maine also suggests that the Act can be measured against an alternative line of Commerce Clause precedents: *Complete Auto Transit, Inc. v. Brady*, 430 U.S. 274 (1977) and its companion tax cases. (Br. 52-53) Yet the District

---

. . . without throwing down the constitutional barriers by which all the States are restricted within the orbits of their lawful authority and upon the preservation of which the Government under the Constitution depends. This is so obviously the necessary result of the Constitution that it has rarely been called in question and hence authorities directly dealing with it do not abound."); *Huntington v. Attrill*, 146 U.S. 657, 669 (1892) ("Laws have no force of themselves beyond the jurisdiction of the State which enacts them, and can have extra-territorial effect only by the comity of other States."). Many of these cases struck down extraterritorial regulations even though they were neither protectionist nor discriminatory. *See Gore* (automobile disclosures); *Bigelow* (abortion services); *New York Life Ins.* (terms of a contract).

Court's decision enforcing the territorial limits of state power is substantially strengthened, not undermined, by those very cases.

The *Complete Auto* line of decisions explicitly establishes that the mere fact that a product "winds up within the state," Br. at 53, is an insufficient basis upon which to impose a tax on out-of-state entities. *Id.* at 277-79. The Maine Rx rebate thus fails the Supreme Court's tests in this area as well, because the Commerce Clause "requires 'some definite link . . . between a state and the person, property or transaction it seeks to tax.'" *National Bellas Hess v. Department of Revenue of Ill.*, 386 U.S. 753, 756 (1967) (quoting *Miller Bros. Co. v. Maryland*, 347 U.S. 340, 344-45 (1954)) (overruled in part on other grounds); *see also Complete Auto*, 430 U.S. at 277-79 (requiring a tax to be "applied to an activity with a substantial nexus with the taxing State" to satisfy the Commerce Clause).

As a result, the Supreme Court has, "more than once . . . struck down taxes directly imposed on or resulting from out-of-state sales which were held to be insufficiently related to activities within the taxing State, despite the fact that the vendor knew that the goods were destined for use in that State." *American Oil Co. v. P.G. Neil*, 380 U.S. 451, 457 (1965) (citations omitted). As with regulatory power generally in *Seelig* and *Healy*, the Commerce Clause places a territorial limit upon the state's taxation power. *See National Bellas*

Hess, 386 U.S. at 759 (vendor whose only contacts with taxing state are by mail or common carrier lacks substantial nexus required by Commerce Clause).

States may, as Maine contends, "require payments from out-of-state firms in connection with those firms' commercial activities *within the state.*" (Br. 52-53, emphasis supplied) However, they cannot tax out-of-state firms in connection with activities that are wholly outside of the state. The Maine Rx law extracts payments from manufacturers indiscriminately, even when they play no role in delivering their products to, and make no sales within, the State, and indeed, even when their transactions involve no physical presence of the manufacturer in Maine (*see supra* p. 11). The State thus attempts to "tax" manufacturers' interstate activities even where the "taxed" drugs have no nexus at all, much less a substantial one, with the State of Maine. When Maine exacts Maine Rx rebates on manufacturers' out-of-state transactions, merely because the drugs sold "wind[] up within the state," the Act's rebate requirement necessarily fails the *Complete Auto* Commerce Clause test for taxes. *See Complete Auto*, 430 U.S. at 277-79; *see also Quill Corp. v. North Dakota*, 504 U.S. 298, 311, 315 n.8 (1992); *National Bellas Hess*, 386 U.S. at 759; *P.G. Neil*, 380 U.S. at 457-58.

C. The Act's Price Tying also Violates the Commerce Clause

In its motion below, PhRMA also challenged the Act's unconstitutional use of out-of-state price benchmarks, an issue not reached in the District Court's decision because it was unnecessary to the grant of the preliminary injunction on other grounds. This additional instance of extraterritorial regulation in the Act provides yet another ground for affirming the District Court's Commerce Clause holding.[8]

Like the state statutes at issue in *Seelig, Healy*, and *Brown-Forman*, the Act does something that Maine itself acknowledges, Br. at 39, as constitutionally fatal: it "expressly tie[s] in-state prices to out-of-state prices." *Id.* Such price tying is not only extraterritorial; it also embodies the very protectionism that Maine believes (incorrectly) to be essential to a finding of unconstitutionality.

The Act specifies that the "rebate required from a manufacturer," to be obtained by the Commissioner's best efforts, shall be at least equal to, if not greater than, rebates charged around the country under Medicaid and other federal programs. 22 M.R.S.A. § 2681(3), (4). This use of an out-of-state price benchmark for Maine's in-state mandatory rebate offends the Commerce Clause

---

[8] *See Dandridge v. Williams*, 397 U.S. 471, 475 n.6 (1970) (Court of Appeals may consider grounds for affirmance not reached below).

in just the protectionist ways noted in *Brown-Forman* and *Healy*: the regulated business can no longer determine its out-of-state (or national) price based solely on the out-of-state (or national) market conditions. Instead, when setting prices[9] in out-of-state (or national) transactions, the business now must also factor the in-state price ramifications into its pricing calculations. Such price-tying by one state thus interferes with market-based competition in other states (or national markets)—an effect explicitly condemned *per se* by the Supreme Court. *See, e.g., Healy*, 491 U.S. at 332.

D. The Pike *Balancing Test Does Not Apply*

No doubt part of Maine's reason for wishing to avoid the application of *Seelig*, *Healy*, and *Dean Foods* is to avoid also their rule that extraterritorial state legislation is invalidated on "virtually a *per se*" basis. Laurence Tribe, 1 *American Constitutional Law* § 6-8, at 1074 (3d ed. 2000) ("The Court has

---

[9] The federal Medicaid rebate amount for each brand-name drug is not a fixed figure. In any given quarter, it is the greater of (1) 15.1% off the manufacturer's average price to retail customers, or (2) the discount embodied in the manufacturer's "best price" to any commercial customer in the country (further adjusted if the manufacturer's retail price has increased faster than inflation). 42 U.S.C. § 1396r-8(c)(1). Accordingly, it may change in response to market decisions. Similarly, a manufacturer's discounted Federal Supply Schedule price is subject to periodic renegotiation in a process that uses the manufacturer's commercial prices throughout the country as benchmarks. Thus these "national prices" identified in the Act are variable and vulnerable to the same pricing dynamics and extraterritorial effects as the individual states' prices described in *Healy* and *Brown-Forman*.

articulated virtually a *per se* rule of invalidity for extraterritorial state regulations—*i.e.* laws which directly regulate out-of-state commerce, or laws whose operation is triggered by out-of-state events."). Maine instead urges this Court to weigh the Act under the balancing test described in *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970).

The *Pike* test, however, is inapplicable where, as here, a state attempts to regulate beyond its borders. *See, e.g., Edgar v. MITE Corp.*, 457 U.S. 624, 644 (1981) ("Insofar as the Illinois law burdens out-of-state transactions, there is nothing to be weighed in the balance to sustain the law."). Accordingly, the District Court made no findings measuring the benefits and burdens of the Act. Maine lacks the constitutional power to regulate transactions wholly beyond its borders. Where the Act's regulation of those transactions is illegitimate in the first instance, the State's interests (however weighty) in that regulation do not enter into the calculation.

E. Maine Cannot Escape Commerce Clause Scrutiny by Claiming To Be a "Market Participant"

Maine seeks to avoid Commerce Clause scrutiny altogether by arguing that the Maine Rx Program constitutes "market participation" rather than state regulation. The District Court rejected this argument, noting that Maine does not participate in the prescription drug market for uninsured or underinsured populations. At best, Maine is leveraging power from a different market—

Medicaid purchases—in order to regulate and secure the commercial behavior (rebates) it prefers in the Maine Rx market. Such leveraging, however, takes Maine out of the "market participant" exception's protection. (JA 246-47)

The "market participant" exception should not even be available as against extraterritorial, rather than protectionist, state activities. As it is typically formulated, "a State acting in its proprietary capacity as a purchaser or seller may favor its own citizens over others." *Camps Newfound/Owatonna, Inc. v. Town of Harrison*, 520 U.S. 564, 592-93 (1997). States may exercise this favoritism, for example, by purchasing local-made products, or preferring local residents in its hiring; like a private party, the State is free to choose with whom it will transact business. However, PhRMA's principal Commerce Clause objection to the Maine Rx Program is not that it exhibits in-state favoritism, but that it reaches outside the State—and beyond in-state transactions—altogether. The Maine Rx Program is thus outside the intended ambit of the market participant exception.

Even if the market participant exception were available, Maine cannot benefit from it, for the reasons stated by the District Court. First, Maine does not buy, sell, insure, or subsidize prescription drugs purchased in the Maine Rx

Program.[10] The State plays no commercial role in Maine Rx; it merely administers a regulatory mechanism to pass through monies that it obtains from manufacturers to individual patients.[11] While market participation need not be strictly confined to buying and selling, Maine's program has no analogue to private sector *commercial* activities.

In the proceedings below, Maine never claimed to be a market participant in the uninsured (Maine Rx) drug market. Instead, it acknowledged that it was

---

[10] Maine Rx is crafted to be entirely budget-neutral for the State. Although the Act provides an initial loan of State funds to get the Maine Rx Program started and cover the "float" between the pharmacies' provision of discounts and the receipt of manufacturer payments, those funds are to be repaid in full in fiscal year 2002-2003. Going forward, the Maine Rx Program is to be funded exclusively by the manufacturers' payments, which are deposited in a Maine Rx-dedicated fund. 22 M.R.S.A. § 2681(9).

[11] *Amici curiae* Quirion *et al.* suggest that the Maine Rx Program does involve market activity by the State – namely, the provision of services akin to those supplied by private sector Pharmacy Benefits Managers ("PBMs"). But while the Maine Rx Program may carry out certain administrative functions similar to PBMs, it lacks the essential economic or "market" component of those private services: the use of market power (in the form of promised volumes of sales) to negotiate discounts. Here, Maine is not making purchases, and cannot even promise sales volume indirectly, in order to give manufacturers commercial incentives to participate in the Maine Rx program—in effect, it exercises no economic leverage in the Maine Rx Program. Lacking the economic leverage that a true market actor (such as a PBM) brings to the bargaining table, Maine has resorted instead to regulatory compulsion—by mandating participation by statute, and enforcing it through the Medicaid program (*see* JA 253-55). If administrative functions alone were enough to make a state a market participant, the exception would swallow the rule.

leveraging its purchasing power in the Medicaid market (through prior authorization) in order to obtain manufacturer rebates under Maine Rx. (Opposition Br. on Motion for Preliminary Injunction at 24-25, Docket #13) However, that concession is fatal to its case, for "the market participant doctrine is not carte blanche to impose any conditions that the State has the economic power to dictate, and does not validate any requirement merely because the State imposes it upon someone with whom it is in contractual privity." *National Foreign Trade Council v. Natsios*, 181 F.3d 38, 63 (1st Cir. 1999) (quoting *South Cent. Timber Dev., Inc. v. Wunnicke*, 467 U.S. 82 (1984) (plurality op.)). When a state tries to "leverage" its commercial power in one market (Medicaid) to control behavior in other markets where it has no commercial role (Maine Rx), it crosses the line from market participation to market regulation. *See Wunnicke*, 467 U.S. at 97-98. [12] The District Court

[12] Nor is the Supreme Court's *Wunnicke* rule against leveraging limited to a prohibition on efforts to influence "downstream" or "post-sale" markets, as Maine suggests. (Br. 34-35) In *Natsios*, Massachusetts conditioned government purchases of goods and services on the suppliers' lack of economic ties to Burma. This Court rejected Massachusetts' market participant defense, and refused to permit the State to leverage its in-state purchasing power into distinct and distant markets—regardless of whether those markets were "upstream" or "downstream" from the state's own purchases or sales. 181 F.3d at 63-65.

applied that straightforward principle to reject Maine's market participant defense. (JA 246-48)

On appeal, Maine has reshaped its market participant argument, contending now that it is the State's activities as a whole (in both Medicaid and Maine Rx) that should be considered "market participation."[13] Maine cites *White v. Massachusetts Council of Construction Employers, Inc.*, 460 U.S. 204 (1983), as support for the proposition that it is a market participant even where it is imposing restrictions reaching well beyond the immediate (Medicaid) transaction in which it is a purchaser. (Br. 33)

White's teaching, however, leads to just the opposite result. In that case, Boston was permitted to impose hiring preference requirements on its contractors because, in effect, both the contractors and their employees were ultimately "working for the city." 460 U.S. at 211 n.7; *Wunnicke*, 467 U.S. at 95 (characterizing *White*). To properly analogize to *White*, however, Maine

---

[13] Maine also attempts to draw comfort from the notion that Medicaid and Maine Rx "benefit the same group of needy citizens"—suggesting, presumably, that Medicaid and Maine Rx transactions are in the same market. Maine's factual premise, however, is inaccurate. Medicaid benefits are available to specific populations of needy and disabled persons who meet the qualifications set by federal statute and regulation, and they are administered in a carefully delineated regulatory framework. Maine Rx benefits, in contrast, are available to every resident of the State of Maine, and Maine Rx drug purchases are effectively unfettered. To suggest that these programs are identical or overlapping fundamentally mischaracterizes the prescription drug markets.

would have to be suggesting that *both* Medicaid drugs and Maine Rx drugs are ultimately "bought by the State." This is not the case—Maine Rx drugs are bought by Maine Rx participants in a transaction in which the State plays no economic role at all.

Maine is a regulator, not a market participant, in the Maine Rx market. The Act's Maine Rx Program is thus fully exposed to Commerce Clause scrutiny—and invalidation.

II. THE MAINE RX PROGRAM'S USE OF MEDICAID PRIOR AUTHORIZATION AUTHORITY CONFLICTS WITH, AND IS PREEMPTED BY, THE MEDICAID STATUTE

A. Maine Rx Prior Authorization Is an Obstacle to the Delivery of Medicaid Benefits

If manufacturers do not pay rebates to Maine to fund the Maine Rx Program, the Act directs the Commissioner to penalize them (1) by publicizing their noncompliance, and (2) by restricting access to (and hence sales of) their drugs in the federal Medicaid program. 22 M.R.S.A. § 2681(7).

Access is restricted by imposing a "prior authorization" requirement for Maine Medicaid beneficiaries. If a drug is placed on prior authorization, advance clearance from a state Medicaid official is required before the drug may be dispensed to a Medicaid beneficiary and paid for by the Medicaid program. Typically, this means that the prescribing physician must contact the

state Medicaid authority and provide written documentation to justify prescribing the drug to his or her Medicaid patient. *See* Maine Medical Assistance Manual, Ch. II § 80.07-3, -4 (JA 177-79). Even if requests are commonly approved, the procedural burden of obtaining prior authorization can deter physicians from prescribing the drugs in the first instance. Medicaid beneficiaries' access to their doctors' first-choice drug is necessarily impeded. (JA 122-25)

Prior authorization does have legitimate uses in the Medicaid program. It can, for example, be used to prevent abuse or overprescription of popular but expensive medications, thereby ensuring the Medicaid drug benefit's efficient and cost-effective operation. It is still the case that prior authorization burdens the provision of Medicaid benefits to Medicaid patients, but that burden can be outweighed by the benefits to the Medicaid program. Congress thus empowered the states, who administer and partially fund the federal Medicaid program, to impose prior authorization requirements for prescriptions paid for by Medicaid.[14] 42 U.S.C. § 1396r-8(d)(1).

---

[14] In the wake of the District Court's injunction, Maine refrained from finalizing its implementing regulations for the Maine Rx Program (including certain revisions to the Maine Medicaid regulations). (Br. 24 n.7) It did, however, put into effect on January 15, 2001 other revisions to the Medicaid regulations, and substantially expanded the Maine Medicaid program's use of prior

(footnote continued)

Here, however, the sole and explicit purpose served by the Act's imposition of Medicaid prior authorization is to coerce funding of the State's own, unrelated Maine Rx Program. Maine is imposing a burden on the Medicaid patients that Congress intended to assist, without serving any offsetting beneficial Medicaid purpose. In addition, Maine Rx-triggered prior authorization consumes Medicaid resources, such as the time and resources of the Medicaid Drug Utilization Review Committee. (JA 145, 171)

Put plainly, Maine cannot make Medicaid patients pay the price to punish drug manufacturers for not participating in a non-Medicaid program. The District Court clearly understood this basic problem with the Act's approach, and held that when prior authorization is used to limit the dispensing of *Medicaid* drugs for the benefit of the unrelated *Maine Rx* program, it is preempted by federal law. As Judge Hornby explained,

> Maine has not just passed a law that might conflict with the objectives of a federal law. It has actually taken the federal Medicaid program and altered it to serve Maine's local purposes. (JA 252)

---

authorization. *See* Maine Medical Assistance Manual (10-144 Code of Maine Rules 101), Ch. II § 80 (as amended effective Jan. 15, 2001).

Because prior authorization—however implemented[15]—necessarily interferes with the delivery of Medicaid services, and because that interference is not offset by any benefit to the Medicaid program, the District Court correctly held that its imposition burdens and conflicts with the Medicaid program. (JA 252-53) State laws that impose "obstacles to the accomplishment and execution of the Congressional objectives" of the federal Medicaid program cannot stand. *Pacific Gas & Elec. Co. v. State Energy Resources Conservation & Dev. Comm'n*, 461 U.S. 190, 203-04 (1983).

Maine objects to the District Court's holding on the grounds that the Medicaid statute does not expressly bar its appropriation of Medicaid prior authorization authority for non-Medicaid purposes. Accordingly, the State argues, it may employ this federal statutory leverage to any purpose and for any reason at all (so long as minimum procedural requirements are met). (Br. 26-

[15] As will be discussed in greater detail below, Maine contends that this obstacle is small, because its proposed implementing regulations for the Maine Rx program may not impose prior authorization on every non-Maine Rx drug, and because they will insure that when prior authorization is required, truly "medically necessary" prescriptions will ultimately be approved. (Br. 22-25, *citing* Maine Medical Assistance Manual, Ch. II § 80.05-3 (proposed) (JA 171)) Nevertheless, it cannot deny that prior authorization by definition imposes a procedural burden on Medicaid doctors, pharmacies, and patients, who must secure the State's advance permission in order to obtain the listed drugs, and on the Medicaid authorities themselves, who must review drugs and respond to prescription authorization requests.

28) But even if Congress created the means, it cannot have intended to see them used against its intended beneficiaries, to serve not Congress's but the Maine Legislature's ends.

Maine rejects any suggestion that Medicaid prior authorization must serve the Medicaid program. The District Court comprehended—and correctly rejected—the expansiveness of Maine's approach: "If Maine can use its authority over Medicaid authorization to leverage [rebates for Maine Rx], then it can just as easily put the rebates into a state program for highway and bridge construction or school funding." (JA 252) Yet Congress surely did not intend to permit States to restrict Medicaid beneficiaries' access to prescription drugs in order to fund other budget items or promote its non-Medicaid social goals.[16] As Judge Hornby explained, "[i]t may never have occurred to Congress that the Medicaid program could by hijacked to provide leverage for other purposes." (JA 253 n.12)

---

[16] It is no answer to argue, as Maine does, that because Congress did not explicitly prohibit non-Medicaid uses of Medicaid prior authorization, or direct that it be used solely to benefit the Medicaid program, Congress intended that Maine should be free to use this regulatory tool to any end. To the contrary, the limited legislative history and the federal Health Care Financing Agency's ("HCFA") proposed implementing regulations contemplate the use of prior authorization in relatively narrow circumstances, all of which further *Medicaid* objectives. (JA 253 n.12)

Maine also suggests that the District court erred by failing to acknowledge a statutory construction and implementing regulations that narrow the Act's prior authorization penalty. Maine asserts that § 2681(7) is saved from preemption because the Act directs the State to use the prior authorization penalty only "as permitted by law," which it takes to mean that prior authorization cannot be imposed in a manner that ultimately prevents Medicaid recipients from receiving "necessary" drugs. Accordingly, the State has proposed implementing regulations[17] under which some Maine Rx-affected drugs might not be prior authorized after all (if, for example, it were deemed "clinically inappropriate" to restrict access to them). (Br. 23-24, JA 171) This provision, Maine argues, renders the Maine Rx prior authorization requirement fully compatible with Medicaid.

Maine's argument misses a simple point: if § 2681(7) is to have any meaning or effect, then it must be true that failure to pay Maine Rx rebates will trigger prior authorization of at least *some* drugs. And any prior authorization necessarily impedes Medicaid beneficiaries' access to those drugs that are

[17] Although the proposed Maine Rx regulations are inapposite for the reasons explained *infra*, it is worth noting that because they are not final, the regulations are neither binding nor owed any *Chevron*-style deference. *See Visiting Nurses Ass'n of North Shore, Inc. v. Bullen*, 93 F.3d 997, 1006-09 (1st Cir. 1996); *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1375 n.15 (11th Cir. 1999).

listed—drugs which, "but for" Maine Rx, would be accessible without delay and paid for by Medicaid without reservation. That burden of impaired access, even if applied only to a subset of the non-Maine Rx drugs, conflicts with Medicaid's objective of providing a drug benefit to Congress's designated beneficiaries. *See* 42 U.S.C. § 1396. Unless Maine is prepared to argue that § 2681(7) will never result in prior authorization, it is necessarily inconsistent with the federal statute—notwithstanding any narrowing language of the Act or features of Maine's implementing regulations.

B. PhRMA Has Standing to Challenge the Act on Preemption Grounds

Maine argues for the first time on appeal that PhRMA lacks "prudential" standing to raise its preemption challenge to the Act's prior authorization provision.[18] Maine's principal contention is that, because PhRMA is "not a Medicaid recipient, and [is] thus outside the zone of interests protected by Medicaid," it may not advance a preemption challenge based on the Medicaid

[18] Maine does not contest PhRMA's Article III standing to challenge the Maine Rx Law, which, because PhRMA members are the object of the Act and its rebate requirements, is virtually unassailable. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561-62 (1992) (noting that when "the plaintiff is himself an object of the action (or forgone action) at issue . . . there is ordinarily little question" that he has standing); *see also* Cass R. Sunstein, *Standing Injuries*, 1993 Sup. Ct. Rev. 37, 55 (noting that "no one denies that the objects of regulation are entitled to standing").

statute. (Br. 13) However that premise, and all the discussion of Medicaid that follows in Maine's brief, is off point.

Maine confuses PhRMA's ability to enforce rights under Medicaid (which this suit does not involve) with its ability to challenge adverse treatment under the Maine Act, including on preemption grounds. Yet PhRMA is not required to have prudential standing under a "preempting" federal law in order to invoke the protection of the Supremacy Clause. As the Third Circuit explained in *St. Thomas-St. John Hotel & Tourism Association, Inc. v. United States Virgin Islands*, there is

> 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.

218 F.3d 232, 241 (3d Cir. 2000).[19] That same rule applies here: PhRMA can invoke the preemptive force of the Medicaid statute, regardless of whether Medicaid's prior authorization provision was designed to benefit its members.[20]

---

[19] The context of the Third Circuit's holding in *St. Thomas-St. John* is remarkably analogous to this one: the government objected to an employers association's prudential standing to claim preemption by the NLRA of a wrongful discharge statute, on the grounds that employers (unlike employees) were not within the zone of interests of the preempting federal statutory provision. 218 F.3d at 242.

Put another way, the *St. Thomas-St. John* Court's statement implicitly recognizes that 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. This is true whether or not the specific statutory provision at issue was designed to benefit or regulate the plaintiff. *See St. Thomas-St. John,* 218 F.3d at 242; *ANR Pipeline Co. v. Corporation Comm'n of Oklahoma,* 860 F.2d 1571, 1579-81 (10th Cir. 1988) (pipeline companies asserting preemption stated claim "within the zone of interest protected by the Supremacy Clause"); *Blue Sky Entertainment v. Town of Gardiner*, 711 F. Supp. 678, 686-87 n.12 (N.D.N.Y. 1989) (same).

In sum, in assessing whether PhRMA has standing to challenge the Maine Rx law on preemption grounds, it is irrelevant whether Congress intended "to confer a right on . . . companies to object to prior authorization

---

[20] This concept is so noncontroversial that courts rarely pause to address it. *See, e.g., Grant's Dairy Maine, LLC v. Commissioner of Me. Dep't of Agric., Food & Rural Resources*, 232 F.3d 8 (1st Cir. 2000) (finding preemption, without examining plaintiff's prudential standing under, or zone of interests of, preempting federal law); *Massachusetts Assoc. of HMOs v. Ruthardt*, 194 F.3d 176 (1st Cir. 1999) (same); *National Foreign Trade Council v. Natsios*, 181 F.3d 38 (1st Cir. 1999) (same).

policies which might reduce the volume of their drugs dispensed through Medicaid."[21] (Br. 15)

The Court need not even pause to dismiss Maine's prudential standing challenge, because it was waived by the State's failure to brief it below. *See Pershing Park Villas Homeowners Assoc. v. United Pacific Ins. Co.*, 219 F.3d 895, 899 (9th Cir. 2000) (stating that "a party waives objections to nonconstitutional standing not properly raised before the district court"); *Lindley v. Sullivan*, 889 F.2d 124, 129 (7th Cir. 1989) (same).[22] *See generally Morais v. Central Beverage Corp.*, 167 F.3d 709, 712 (1st Cir. 1999) (stating "black letter law" of waiver).

---

[21] Even if PhRMA were, contrary to precedent, also required to demonstrate standing under the preempting federal law, it could do so here. Prudential standing extends to those in the "zone of interests to be protected *or regulated* by" the statute. *Association of Data Processing Svc. Orgs., Inc. v. Camp*, 397 U.S. 150, 153 (1970) (emphasis supplied). PhRMA's members are clearly regulated by, and make payments consistent with the provisions of, the Medicaid prescription drug program.

[22] *But see UPS Worldwide Forwarding, Inc. v. USPS*, 66 F.3d 621, 626 n.6 (3d Cir. 1995) (stating "it is uncertain whether prudential standing may be waived"); *Community First Bank v. National Credit Union Admin.*, 41 F.3d 1050, 1053 (6th Cir. 1995) (rejecting waiver of prudential standing objections).

III. THE DISTRICT COURT CORRECTLY FOUND THAT PHRMA WAS ENTITLED TO A PRELIMINARY INJUNCTION

The District Court's issuance of the preliminary injunction against the enforcement of the Act was fully consistent with this Court's standards. Judge Hornby properly considered "(1) the likelihood of success on the merits; (2) the potential for irreparable harm if the injunction is denied; (3) the balance of relevant impositions . . . and (4) the effect (if any) of the court's ruling on the public interest." *Ross-Simons of Warwick, Inc. v. Baccarat, Inc.*, 102 F.3d 12, 15 (1st Cir. 1996). The judge concluded that PhRMA's likelihood of success on its constitutional claims was "overwhelming."

Maine apparently objects to the fact that—in the particular context of a constitutional challenge—a court's strong conclusion regarding the merits of the plaintiff's constitutional attacks can partially truncate the analysis under the last three prongs of that injunction standard. However, the District Court's analysis has ample legal support, while Maine cites none. (Br. 57-60)

Maine and its officials have no legitimate interest in the enforcement of an unconstitutional law. *See Hyde Park Partners v. Connolly*, 839 F.2d 837, 854 (1st Cir. 1988); *Condon v. Andino*, 961 F. Supp. 323, 331 (D. Me. 1997) ("It is hard to conceive of a situation where the public interest would be served by enforcement of an unconstitutional law or regulation."); *Diva's, Inc. v. City*

of Bangor, 21 F. Supp. 2d 60, 66 (D. Me. 1998). In turn, the hardship of an injunction for the defendants is indistinguishable from the effect on the public interest, since the State officials' sole interest is "the safeguarding of . . . the public interest." *Hyde Park Partners*, 839 F.2d at 842. Maine's attack on this approach as a "tautology" (Br. 58) is without a logical or legal foundation.

The question of irreparable injury raises similar issues. Where a party is forced to choose between suffering injury as a result of complying with an unconstitutional law, and incurring penalties as a result of disobeying the law, the Supreme Court has found irreparable injury sufficient to support preliminary injunctive relief. *See Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 381 (1992).

Maine does not contest that PhRMA members would suffer irreparable injury if they disobeyed the Act's command to pay Maine Rx rebates. And PhRMA members would also suffer irreparable injury if they were to comply with the Act during the litigation. As a matter of law, PhRMA's constitutional injury alone is deemed "irreparable" and sufficient to support preliminary injunctive relief.[23] In the context of a constitutional challenge to a State statute,

---

[23] The District Court also identified irreparable injury in the form of Maine Rx payments made to the State that would be unrecoverable under the Eleventh Amendment. Maine objects on timing grounds, arguing that no such payments would actually be made for several months. Regardless, the injury to PhRMA

(footnote continued)

a party is presumed to suffer irreparable injury if enforcement of the legislation deprives the party of a constitutionally protected right that is then "irretrievably lost." *Springfield Terminal Co. v. United Transp. Union,* 688 F. Supp. 68, 69 (D. Me. 1988); *see also* 11A C. Wright & A. Miller, *Federal Practice and Procedure* § 2948.1 at 161 (1985) (in face of alleged constitutional violation, "no further showing of irreparable injury" required). That principle, frequently applied in the First Amendment context, is "plainly applicable to other prospective denials of constitutional rights," *Springfield Terminal,* 688 F. Supp. at 69, including violations of the Commerce Clause.[24] The prospective violation of PhRMA's members constitutional rights under the Commerce

---

members' constitutional rights if they were to comply with Maine Rx is itself irreparable.

[24] *See Kendall-Jackson Winery, Ltd. v. Branson*, 82 F. Supp. 2d. 844, 878 (N.D. Ill. 2000) ("A violation of these constitutional rights [under both the Commerce Clause and the Contracts Clause] constitutes irreparable injury. There is no adequate remedy at law for such a violation.") (citations omitted); *American Libraries Ass'n v. Pataki*, 969 F. Supp. 160, 168 (S.D.N.Y. 1997) ("by demonstrating that the Act threatens their rights under the Commerce Clause . . . the plaintiffs have shown both irreparable injury and a likelihood of success on the merits"); *Connecticut Carting Co. v. Town of East Lyme*, 946 F. Supp. 152, 157 (D. Conn. 1995) ("Deprivation of a constitutional right under the Commerce Clause constitutes irreparable injury."); *C & A Carbone, Inc. v. Town of Clarkstown*, 770 F. Supp. 848, 854 (S.D.N.Y. 1991) (finding that enforcement of local ordinance that "deprives plaintiffs of their constitutional rights, privileges, or immunities under the Commerce Clause...unquestionably constitutes irreparable injury"); *see also Allen v. Minnesota*, 867 F. Supp. 853, 859 (D. Minn. 1994); *Government Suppliers Consolidating Servs., Inc. v. Bayh*,
(footnote continued)

Clause constitutes irreparable injury that fully supports the grant of preliminary injunctive relief.

CONCLUSION

For the foregoing reasons, the District Court's Order granting a preliminary injunction should be affirmed.

---

734 F. Supp. 853, 864 (S.D. Ind. 1990).

Dated: Washington, D.C.
February 7, 2001

Respectfully submitted,

Kathleen M. Sullivan
559 Nathan Abbott Way
Stanford, CA 94305
(650) 723-4455

Daniel M. Price
Powell, Goldstein, Frazer & Murphy, L.L.P.
1001 Pennsylvania Ave. NW
Washington, D.C. 20004
(202) 347-0066

Of counsel:

Allen S. Rugg
Marinn F. Carlson
Powell, Goldstein, Frazer & Murphy, L.L.P.
1001 Pennsylvania Ave. NW
Washington, D.C. 20004
(202) 347-0066

Bruce C. Gerrity
Preti, Flaherty, Beliveau, Pachios & Haley L.L.C.
45 Memorial Circle
Augusta, ME 04332-1058
(207) 623-5300

CERTIFICATE OF FORMAT COMPLIANCE

I, Daniel M. Price, counsel for Appellee PhRMA, hereby certify that the foregoing Brief of Appellee (exclusive of portions exempted pursuant to Fed. R. App. P. 32(a)(7)(B)(iii)) contains 10,483 words in proportionally spaced 14 point Times New Roman font, and accordingly complies with the type-volume limitations of Fed. R. App. P. 32(a)(7).

Daniel M. Price

Daniel M. Price

February 7, 2001

CERTIFICATE OF SERVICE

I, Daniel M. Price, counsel for Appellee PhRMA, hereby certify that on this 7th day of February, 2001, I caused ten correct copies of the foregoing Brief of Appellee (nine paper copies and one copy in electronic format on diskette) to be delivered to a third-party commercial carrier, postage prepaid, for next-day delivery and filing with the Clerk of the Court. In addition and on the same day, I caused two correct copies of the foregoing Brief of Appellee (one paper copy and one copy in electronic format on diskette) to be delivered to a third-party commercial carrier, postage prepaid, for next-day delivery and service on upon the following counsel of record:

Appellants:
Andrew S. Hagler
Assistant Attorney General
Department of Attorney General
6 State House Station
Augusta, ME 04333-0006
(207) 626-8800

Amici Curiae Quirion et al:
Arn H. Pearson
Maine Citizen Leadership Fund
One Pleasant Street
Portland, ME 04101
(207) 780-8657

Daniel M. Price

::ODMA\PCDOCS\WSH\207597\1