No. 01-188

IN THE
Supreme Court of the United States

PHARMACEUTICAL RESEARCH
AND MANUFACTURERS OF AMERICA,
Petitioner,

v.

KEVIN CONCANNON, COMMISSIONER, MAINE
DEPARTMENT OF HUMAN SERVICES, *et al.*,
Respondents.

**On Writ of Certiorari to the
United States Court of Appeals
for the First Circuit**

BRIEF FOR THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AS AMICUS CURIAE IN SUPPORT OF PETITIONER

ROBIN S. CONRAD
NATIONAL CHAMBER
LITIGATION CENTER, INC.
1615 H Street, N.W.
Washington, D.C. 20062
(202) 463-5337

JOHN G. ROBERTS, JR.*
CATHERINE E. STETSON
HOGAN & HARTSON L.L.P.
555 Thirteenth Street, N.W.
Washington, D.C. 20004
(202) 637-5810

* Counsel of Record

Counsel for Amicus Curiae

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STATEMENT OF INTEREST

The Chamber of Commerce of the United States of America ("Chamber") is the world's largest business federation.[1]

[1] No counsel for any party authored this brief in whole or in part, and no person or entity, other than the amicus curiae and its members, made a monetary contribution to the preparation or submission of this brief. S. Ct. Rule 37.6. The brief is filed with the

It represents an underlying membership of more than three million businesses and organizations in every industrial sector and geographic region of the country. The Chamber has participated as amicus curiae in several hundred cases before this Court, including numerous cases addressing the Supremacy Clause, *see*, *e.g.*, *Crosby* v. *National Foreign Trade Council*, 530 U.S. 363 (2000); *Geier* v. *American Honda Motor Co.*, 529 U.S. 861 (2000); *United States* v. *Locke*, 529 U.S. 89 (2000), and the Commerce Clause, *see*, *e.g.*, *Crosby*, 530 U.S. 363; *General Motors Corp.* v. *Tracy*, 519 U.S. 278 (1997). The Chamber filed a brief supporting the petition for certiorari in this case.

SUMMARY OF ARGUMENT

The Maine Rx Act's prior-authorization regime is pre-empted by the federal Medicaid Act. The Medicaid Act directs States administering Medicaid programs—including Maine—to administer the Medicaid program in keeping with the best interests of Medicaid recipients. Maine's Rx Act, however, directs that manufacturers who do not agree to pay "rebates" to Maine to fund a prescription drug plan that benefits all state residents *except* Medicaid recipients will have their drugs placed on Medicaid prior-authorization status—meaning that Medicaid recipients and their physicians must seek approval before those drugs may be prescribed. There is no Medicaid-related reason for such drugs to be placed on prior-authorization status; a manufacturer's refusal to enter into the *non*-Medicaid "rebate" arrangement is the only predicate to the prior-authorization determination.

The burden of prior authorization, however, is borne by Medicaid recipients. For drugs designated by the State as requiring prior authorization, Medicaid recipients must seek prior approval from the State before they may be prescribed

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consent of the parties, and copies of the consent letters have been filed with the Clerk.

drugs they once received as a matter of course. Indeed, the State conceded below that some Medicaid recipients will not receive their first-choice drugs at all as a result of the prior authorization requirement. Maine's use of Medicaid prior authorization as a coercive tool to fund its non-Medicaid Rx Program is squarely at odds with the Medicaid Act's directive that the Act and its terms be administered in the best interests of *Medicaid* recipients.

The Rx Act also conflicts with the Commerce Clause. This Court has repeatedly held that a State may not enact legislation regulating transactions taking place wholly outside its borders. Yet that is exactly what the Rx Act does, by imposing "rebate" obligations on out-of-state manufacturers who contract out-of-state with predominantly out-of-state wholesalers. The Act not only improperly changes the terms of a transaction occurring outside Maine; its prior-authorization regime, coupled with its draconian "no-exit" anti-retaliation provisions, forces manufacturers to recoup their lost revenues by charging consumers in *other* States more for their prescription drugs. And if other States, spurred by increasing prescription drug costs in their own jurisdictions, follow Maine's lead, the impact on interstate commerce and the drug industry will be substantial and grave. The First Circuit's decision should be reversed.

ARGUMENT

I. THE RX ACT IS PREEMPTED BY THE FEDERAL MEDICAID ACT.

1. The Medicaid Act, 42 U.S.C. § 1396 *et seq.*, is a cooperative venture between the federal government and the States, "designed to provide medical assistance to persons whose income and resources are insufficient to meet the costs of necessary care and services." *Atkins* v. *Rivera*, 477 U.S. 154, 157 (1986); 42 U.S.C. § 1396. The Act requires States, in exchange for federal funding, to provide Medicaid benefits

to the "categorically needy"—those eligible for financial assistance under either the Supplemental Security Income for the Aged, Blind, and Disabled (SSI) program or the Aid to Families with Dependent Children (AFDC) program. *Atkins*, 477 U.S. at 156; *see* 42 U.S.C. § 1396a(a)(10)(A)(i)(IV), (VI), (VII). "[O]ne is eligible for AFDC or SSI only if, in a given month, he or she earns less than what has been determined to be required for the basic necessities of life." *Atkins*, 477 U.S. at 156. The Medicaid program also permits States to extend benefits to the "medically needy"—"persons lacking the ability to pay for medical expenses, but with incomes too large to qualify for categorical assistance." *Schweiker* v. *Gray Panthers*, 453 U.S. 34, 37 (1981); *see* 42 U.S.C. § 1396a(a)(10)(C).

Every State operates its own Medicaid program, jointly funded by state and federal contributions. *See* 42 U.S.C. § 1396a; *see also* 22 Me. Rev. Stat. Ann. § 3174 (describing eligibility requirements for Maine Medicaid program, which provides assistance to state residents lacking "sufficient income or other resources to provide a reasonable subsistence compatible with decency and health"). States must submit their Medicaid program plans to the federal government for approval, and the plan must "provide such safeguards as may be necessary to assure that * * * care and services will be provided, in a manner consistent with simplicity of administration and the best interests of [Medicaid] recipients." 42 U.S.C. § 1396a(a)(19). *See Harris* v. *McRae*, 448 U.S. 297, 309 (1980).

2. Concluding that state residents were paying too much for prescription drugs, Maine's legislature passed a law titled "An Act to Establish Fairer Pricing for Prescription Drugs," 2000 Me. Legis. Ch. 786—the "Rx Act" for short. The Rx Act was enacted "to make prescription drugs more affordable for qualified Maine residents, thereby increasing the overall health of Maine residents, promoting healthy communities

and protecting the public health and welfare." 22 Me. Rev. Stat. Ann. § 2681(1).

The Rx Act requires every drug manufacturer whose products ultimately are sold in the State to "enter into a rebate agreement" with Maine's Department of Human Services, and to make rebate payments to the State each calendar quarter—an arrangement similar to the federal prescription drug rebate program set forth in the Medicaid statute. *Id.* § 2681(3).[2] The Commissioner of the Department of Human Services must "negotiate the amount of the rebate required" under the Rx Act and must use his "best efforts to obtain an initial rebate amount equal to or greater than the rebate calculated under the Medicaid program." *Id.* § 2681(4)(B). The rebates obtained under the Rx Act are used to compensate participating retail pharmacies for providing discounted drug prices to Maine residents. *Id.* § 2681(9). The Rx Act is not limited to those eligible for Medicaid but is instead "open to all State residents." Pet. App. 3.

Drug manufacturers who do not enter into rebate agreements under the Rx Act face severe penalties. The Act directs the State Department of Human Services to impose Medicaid prior-authorization requirements "for the dispensing of prescription drugs provided by those manufacturers" who do not meet the State's terms. 22 Me. Rev. Stat. Ann. § 2681(7). Subjecting a drug to prior authorization under the Medicaid statute means that prescribing physicians must seek approval from state Medicaid officials before the drug may be dispensed. *See* 42 U.S.C. § 1396r-8(d)(1)(A).

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[2] The Medicaid statute contains a mechanism for collecting "rebates" from manufacturers supplying drugs to Medicaid recipients. 42 U.S.C. § 1396r-8. Put simply, manufacturers pay rebates to each State based on the number of units of their drugs dispensed to Medicaid beneficiaries and paid for by the State under its Medicaid plan, pursuant to a formula set forth in the statute. *See id.*

The Rx Act further provides that *any* manufacturer—whether it pays the required rebates or not—who "[i]ntentionally prevents, limits, lessens or restricts the sale or distribution of prescription drugs in [Maine] in retaliation for the provisions of" the Rx Act is deemed to have "engage[d] in illegal profiteering." 22 Me. Rev. Stat. Ann. § 2697(2)(D). Manufacturers who violate this "profiteering" prohibition are subject to injunctive relief and civil penalties of $100,000 for each violation, an action by the State for treble damages, and additional claims for punitive damages for "willful or repeated violation[s]" of the law. *Id.* § 2697(3)-(4).

3. The Supremacy Clause "requires the invalidation of any state legislation that burdens or conflicts in any manner with any federal laws." *De Canas* v. *Bica*, 424 U.S. 351, 357 n.5 (1976); U.S. Const. art. VI, cl.2. A state law conflicts with federal law if it " 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress'—whether that 'obstacle' goes by the name of 'conflicting; contrary to; * * * repugnance; difference; irreconcilability; inconsistency; violation; curtailment; * * * interference,' or the like." *Geier* v. *American Honda Motor Co.*, 529 U.S. 861, 873 (2000) (quoting *Hines* v. *Davidowitz*, 312 U.S. 52, 67 (1941)); *see also Savage* v. *Jones*, 225 U.S. 501, 533 (1912).

The Maine Rx Act's prior authorization regime conflicts with the Medicaid Act and is therefore preempted. The state law directs the Commissioner of Maine's Department of Human Services to subject to Medicaid prior-authorization requirements the drugs of any manufacturer who refuses to enter into Rx Act "rebate" agreements. The necessary result of that directive is that drugs will be placed on prior authorization status not for any *Medicaid*-related reason, but solely because manufacturers decline to participate in *another* state-run program.

The burden of prior authorization, however, falls squarely on Medicaid beneficiaries. If Medicaid recipients' first-choice prescription drugs are subject to prior authorization, recipients and their doctors will be forced to seek affirmative permission from the State before those drugs may be dispensed—where before the Rx Act, those drugs were regularly dispensed without prior authorization. And Medicaid recipients forced to seek prior authorization may not get their first-choice drugs at all: Maine conceded in the Court of Appeals that it "will not authorize payment for the first-choice drug manufactured by a non-participant where there is another drug for the ailment manufactured by a participant." Pet. App. 15.

The Rx Act's use of the prior-authorization requirement in a manner that impedes or frustrates Medicaid recipients' access to their first-choice prescription drugs conflicts with the Medicaid Act's express directive to administer the state Medicaid program in keeping with "the best interests of [Medicaid] recipients." 42 U.S.C. § 1396a(a)(19); *Davis* v. *Elmira Savings Bank*, 161 U.S. 275, 283 (1896) (state law is preempted if it "either frustrates the purpose of the national legislation or impairs the efficiency of those agencies of the Federal government to discharge the duties, for the performance of which they were created"). It is plainly not in the best interests of Medicaid recipients to force their physicians to seek administrative permission from the State before recipients may be prescribed the drug of their choice—for wholly collateral reasons having nothing to do with the Medicaid program. Nor is it in the best interests of Medicaid recipients to force them to accept a second- or third-choice drug in place of their first choice, for no reason other than that the first-choice manufacturer will not participate in a separate state program. *See* U.S. Br. (petition stage) 11 (noting that "the State program on its face is designed to serve the State's *non-Medicaid* population by imposing a burden on the ability of *Medicaid* recipients to receive an otherwise covered outpatient drug") (emphases in original).

The First Circuit concluded otherwise, opining that so long as Maine administered the prior authorization requirements " '[a]s permitted by law' "—that is, provided for 24-hour notice of approval or declination, and allowed for dispensation of a 72-hour supply of a drug—the State would not run afoul of the Medicaid Act. Pet. App. 11 (quoting 22 Me. Rev. Stat. Ann. § 2681(7) and citing 42 U.S.C. § 1396r-8(d)(5)(A) and (B)); Pet. App. 11 n.7 (referencing affidavit from respondent Concannon purporting to affirm that prior authorization "would not conflict with the Medicaid requirements"). But that is not the proper question in this preemption inquiry. Whether the state law employs prior authorization in accordance with the Medicaid Act's *procedural* requirements is irrelevant. It is the Commissioner's use of prior authorization in the first place for a non-Medicaid purpose that burdens Medicaid recipients' access to their first-choice prescription drugs. The Act's procedural protections are cold comfort to a Medicaid recipient who is told (within 24 hours) that he must accept a different drug treatment than the one his doctor recommended and that he prefers, solely because the manufacturer of his first-choice drug will not contribute money to a wholly separate state program.

The First Circuit also concluded that the "purposes of the Medicaid statute, read broadly, are consonant with the purposes of the Rx Act." Pet. App. 13. According to the Court of Appeals, the state program "furthers Medicaid's aim of providing medical services to those whose 'income and resources are insufficient to meet the costs of necessary medical services,' * * * even if the individuals covered by the Maine Rx Act are not poor enough to qualify for Medicaid." *Id.* (citing 42 U.S.C. § 1396a). That does not add up. The Medicaid Act provides for medical and drug coverage for a specified population of eligible people; it is that population to which the Act refers when it identifies those whose "income and resources are insufficient to meet the costs of necessary medical services," and it is on behalf of that population that States administer their Medicaid programs. The

Rx Act, on the other hand, affords drug discounts for *every* citizen in Maine not already receiving them under Medicaid—from the borderline Medicaid-ineligible to the well-off. Pet. App. 3. To say that a state law furthers the Medicaid Act's aims when it applies to—indeed, is specifically directed at—everyone in Maine *but* Medicaid recipients stretches the Medicaid Act's purpose beyond all credence.

The First Circuit also surmised that the Maine Rx Act could actually "reduce Medicaid expenditures" by making prescription drugs less expensive for Maine residents not on federal assistance. Pet. App. 13. The court suggested that if people not eligible for Medicaid nonetheless were "unable to purchase necessary medication, their conditions may worsen, driving them further into poverty and into the Medicaid program." *Id.* But Medicaid's express charge to the States is to make coverage decisions under the Act that further the best interests of those *currently* receiving Medicaid assistance, *see* 42 U.S.C. § 1396a(a)(19)—not the interests of potential Maine Medicaid recipients, and certainly not the interests of those in Maine's middle and upper classes, who are equally eligible to participate in the Maine Rx Act.

Finally, the First Circuit concluded that petitioner PhRMA had not shown that the Maine Rx Act "on its face, controverts the Medicaid goal of 'best interests.' " Pet. App. 15. The court was wrong; PhRMA made out a compelling facial challenge to the state law. *See* U.S. Br. (petition stage) 11 (observing that the Rx Act "on its face is designed to serve the State's *non-Medicaid* population by imposing a burden on the ability of *Medicaid* recipients to receive an otherwise covered outpatient drug") (emphases in original). The proof is, among other places, in the Rx Act itself. The reason the prior authorization provision was considered by the Maine legislature to be an effective coercive tool was that prior authorization decreases a drug manufacturer's market share. The State did not contest PhRMA's affidavits to that effect in the District Court. *See* Pet. App. 71 (noting uncontested

"affidavits that a prior authorization listing often results in substantially reduced market share for a manufacturer"). Reduced market share means fewer drugs are being sold, because Medicaid recipients are not getting the first-choice drugs they previously were prescribed and received without encumbrance or delay.

This Court in similar circumstances has not hesitated to find a state law preempted, even without concrete evidence that the conflict apparent on the face of the statute would actually come to pass. The Illinois licensing law at issue in *Gade* v. *National Solid Wastes Management Ass'n*, 505 U.S. 88, 94 (1992), for example, was challenged before it went into effect. No one required the respondent there to gather concrete evidence that the onerous state requirement in fact precluded some of its members from being state-licensed; that was plain from the state law's terms. So too here. The Rx Act on its face hampers—and as the State concedes, in some cases forecloses—Medicaid recipients' access to the drugs of their choice. If the law did not have that effect—if it did not result in a direct impact on a manufacturer's sales—it would wholly fail to achieve the purposes of its sponsors.

The First Circuit panel stressed that it was particularly reluctant to find preemption where a state statute implicated a coordinated federal-state aid program: " '[w]here coordinate[d] state and federal efforts exist within a complementary administrative framework, and in the pursuit of common purposes, the case for federal pre-emption becomes a less persuasive one.' " Pet. App. 10 (quoting *New York State Dep't of Social Servs.* v. *Dublino*, 413 U.S. 405, 421 (1973)). But that formulation assumes what the Rx Act lacks: that the state law is "in pursuit of common purposes" with the federal statute. The Rx Act's prior authorization provision does not even purport to pursue a purpose in common with the Medicaid program. *See* Pet. App. 71 ("The State makes no argument that the * * * condition of prior approval serves any

purpose of the Medicaid program.").[3] The prior-authorization provision was put in place to force manufacturers to contribute to the Rx fund, at the expense of Medicaid recipients' unencumbered access to the prescription drugs of their choice.

To be sure, a State may impose a prior authorization requirement on certain drugs before the drugs may be prescribed for Medicaid patients, *see* 42 U.S.C. § 1396r-8(d)(1)(A), but any prior authorization requirement must further the best interests of Medicaid recipients. For example, drugs with serious cumulative side effects over time, those that are overprescribed, or those with serious addictive potential might legitimately be subject to prior authorization, if Medicaid administrators concluded that doing so was in the best interests of Medicaid patients. *See* Pet. App. 71 n.14 (noting affidavit from the Medical Director for the Maine Bureau of Medicaid Services stating that "the primary purpose of a prior authorization requirement is to ensure that a drug is not being used inappropriately"). What the State may *not* do is impose Medicaid prior authorization requirements that lack any pretense of a legitimate Medicaid rationale, and then employ those requirements in a manner that impairs the interests of Medicaid recipients in order to benefit an entirely separate, non-Medicaid-eligible, population. The Rx Act's prior authorization provision is preempted.

II. THE RX ACT VIOLATES THE COMMERCE CLAUSE.

The Commerce Clause grants Congress the power to "regulate Commerce * * * among the several States." U.S. Const. art. I, § 8, cl. 3. The Clause has long been held to carry an "implied limitation" on States' power to interfere with inter-

[3] In *Dublino*, moreover, this Court remanded to the court of appeals to consider "the issue of specific conflict between the state and federal programs" at issue there, after holding that federal law did not *entirely* preempt the State's program. 413 U.S. at 422.

state commerce. *Western & Southern Life Ins. Co.* v. *State Bd. of Equalization of Cal.*, 451 U.S. 648, 652 (1981). This implicit prohibition is directed at state regulation "that discriminates against or unduly burdens interstate commerce and thereby 'imped[es] free private trade in the national marketplace.' " *General Motors Corp.* v. *Tracy*, 519 U.S. at 287 (quoting *Reeves, Inc.* v. *Stake*, 447 U.S. 429, 437 (1980)); *see also H.P. Hood & Sons* v. *Du Mond*, 336 U.S. 525, 534-535 (1949); *Welton* v. *Missouri*, 91 U.S. 275 (1876).

The "Commerce Clause * * * precludes the application of a state statute to commerce that takes place wholly outside of the State's borders, whether or not the commerce has effects within the State." *Edgar* v. *MITE Corp.*, 457 U.S. 624, 642-643 (1982) (plurality opinion); *see Dean Foods Co.* v. *Brancel*, 187 F.3d 609, 615 (7th Cir. 1999) ("There is a long line of cases holding that states violate the Commerce Clause by regulating or controlling commerce occurring wholly outside their borders."). If the "practical effect" of a state statute is to control commerce occurring outside the State, the statute "exceeds the inherent limits of the enacting State's authority and is invalid." *Healy* v. *Beer Inst.*, 491 U.S. 324, 336 (1989); *see also Maine* v. *Taylor*, 477 U.S. 131, 138 (1986).

The Rx Act fails that test. The law imposes conditions on transactions occurring wholly outside Maine, and it forces consumers in other States to subsidize the Maine legislature's policy choice. And if more States follow Maine's lead—an issue this Court traditionally examines in Commerce Clause challenges—the impact on interstate commerce, and on the drug manufacturing industry generally, will be severe.

1. Every drug manufacturer PhRMA represents is located outside Maine. Pet. App. 60. "[B]y far the greater bulk of their customers—wholesalers and distributors—are likewise

outside Maine." *Id.*[4] Manufacturers sell to wholesalers or distributors "at [a] place of business outside Maine" (with one exception, *see* n.4), and those wholesalers or distributors in turn contract with retailers in the State to sell the drugs. *Id.* Maine's Rx Act requires those out-of-state manufacturers—who contract out-of-state with predominantly out-of-state entities—to pay "rebates" to the State for the benefit of state residents participating in the Rx Program, based on the number of units of their drugs ultimately sold by others in the State. The Act thus is directed at entities that do not themselves transact business in Maine, and it effectively changes the terms of transactions between manufacturers and wholesalers that do not occur in Maine. The Rx Act's regime bears the same stamp as the state laws this Court struck down in *Baldwin* v. *G.A.F. Seelig, Inc.*, 294 U.S. 511, 519 (1935), *Brown-Forman Distillers Corp.* v. *New York State Liquor Auth.*, 476 U.S. 573, 575 (1986), and *Healy* v. *Beer Institute*, 491 U.S. at 327, and it, too, should fall.

In *Baldwin*, 294 U.S. at 519, this Court examined a New York law prohibiting the sale in the State of milk bought outside the State unless the price paid to out-of-state milk producers "was one that would be lawful upon a like transaction within the state." Finding that New York had improperly "project[ed] its legislation" beyond its boundaries, the Court struck down the law. *Id.* at 521. As the Court explained, a State may not bolster its citizens' economic interests at another State's expense; "commerce between the states is burdened unduly when one state regulates by indirection the prices to be paid to producers in another." *Id.* at 524.

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[4] The District Court noted three "limited exceptions" where distributors or wholesalers operated facilities in Maine, but observed that two of those three entities contracted outside the State to import drugs to Maine. Just one distributor operates facilities in Maine and contracts with a drug manufacturer in the State. Pet. App. 60.

Similarly, in *Brown-Forman*, 476 U.S. at 575, the Court examined a New York statute requiring every liquor distiller or producer that sold liquor to wholesalers in the State to sell at a price that was "no higher than the lowest price the distiller charges wholesalers anywhere else in the United States." The state law violated the dormant Commerce Clause, the Court concluded, because it effectively "regulat[ed] out-of-state transactions" by prohibiting producers from changing their prices in other States. *Id.* at 582. The fact that the law applied evenhandedly to all producers and distillers was irrelevant: "Economic protectionism is not limited to attempts to convey advantages on local merchants; it may include attempts to give local consumers an advantage over consumers in other States." *Id.* at 580 (citing *New England Power Co.* v. *New Hampshire*, 455 U.S. 331, 338 (1982)).

Finally, in *Healy*, 491 U.S. at 327, the Connecticut legislature, seeking to reduce prices of beer sold in the State, enacted a statute requiring out-of-state brewers and shippers to affirm that their prices in Connecticut "were and would remain no higher than the lowest prices they would charge for each beer product in the border States." The Court struck the statute down, finding that it "has the undeniable effect of controlling commercial activity occurring wholly outside the boundary of the State." *Id.* at 337. By linking in-state beer prices to the price of transactions in neighboring States, the state law had the "extraterritorial effect, condemned in *Brown-Forman*," of preventing brewers from altering their pricing in other States to accommodate changing market conditions. *Id.* at 338. Because the law improperly benefited Connecticut consumers at the expense of those in other States, it could not stand. *Id.* at 339.

The Court should reach the same result here as it did in *Healy*, *Brown-Forman*, and *Baldwin*. As the Court explained in *Healy*, "[t]he critical inquiry is whether the practical effect of the regulation is to control conduct beyond the boundaries

of the State." 491 U.S. at 336. And as the District Court correctly recognized, "the practical effect of what Maine has done here is to limit the revenue an out-of-state manufacturer can obtain when it sells drugs to out-of-state distributors that ultimately send or bring the drugs to Maine." Pet. App. 66. That arrangement is exactly the sort of regime condemned in *Healy* and its predecessor cases.

The First Circuit glibly distinguished those cases by concluding that they "involve[d] price control, price affirmation or price tying," while the Rx Act implicated manufacturers' revenues. Pet. App. 21; *see id.* at 23. But the Commerce Clause prohibits States from creating impediments to interstate commerce, not just from fixing interstate prices.[5] *See*, *e.g.*, *New England Power Co.* v. *New Hampshire*, 455 U.S. at 335; *Hunt* v. *Washington State Apple Adver. Comm'n*, 432 U.S. 333, 351 (1977); *Pike* v. *Bruce Church, Inc.*, 397 U.S. 137, 142 (1970); *see also Louisiana Dairy Stabilization Bd.* v. *Dairy Fresh Corp.*, 631 F.2d 67, 69 (5th Cir. Unit A 1980) (finding "ineffectual" respondents' proposed distinction between "attempts at fixing the price of out-of-state products" and other extraterritorial regulation), *aff'd*, 454 U.S. 884 (1981).

This Court has also rejected the notion that a state law with an improper extraterritorial effect is legitimate if it only impacts manufacturers' revenues. In *West Lynn Creamery, Inc.*, v. *Healy*, 512 U.S. 186, 195 & n.11 (1994), petitioner challenged a state pricing order requiring every milk dealer operating in Massachusetts to make "premium payments" into a state fund based on their sales to state retailers, to be

[5] As PhRMA explained below, moreover, the Rx Act *does* impermissibly tie prices. The rebates manufacturers pay to the State are linked to Medicaid rebates set at the national level, and thus are affected by price changes in other States; if a manufacturer lowers its price in Virginia and that price becomes the new "best price" for Medicaid rebates, the manufacturer will pay a higher Rx Act rebate in Maine.

distributed to Massachusetts dairy farmers. *Id.* at 190. This Court found the order to violate the Commerce Clause, because it effectively imposed a tax on out-of-state milk. *Id.* at 194.[6] The Court observed that in certain circumstances, out-of-state milk producers might still remain competitive in the Massachusetts market by cutting their prices—and thus sacrificing their profits—but the Court recognized that that possibility "would not immunize a discriminatory measure." *Id.* at 195.

The Court reached a similar conclusion in *New Energy Co. of Indiana* v. *Limbach*, 486 U.S. 269, 275 (1988), rejecting the contention that a state law that "only" placed out-of-state products at a "commercial disadvantage" comported with the Commerce Clause. The *New Energy* Court observed that the appellant in *Baldwin* v. *G.A.F. Seelig, Inc.*, "in order to sell [milk] in New York, only had to cut its profits by increasing its purchase price above the market price sufficiently to meet the New York-prescribed premium." 486 U.S. at 269. Similarly, the petitioner in *New Energy*, "in order to sell its product in Ohio, only ha[d] to cut its profits by reducing its sales price below the market price sufficiently to compensate the Ohio purchaser-retailer for the forgone tax credit." *Id.* But the state regime in *Baldwin* was held to be " 'an economic barrier against competition' that was 'equivalent to a rampart of customs duties,' " *id.* (quoting *Baldwin*, 294 U.S. at 527), and the law at issue in *New Energy* met a similar fate. 486 U.S. at 279. So too here. The fact that Maine's extraterritorial forced rebate arrangement "only" operates to reduce manufacturers' revenues does not insulate it from a Commerce Clause challenge.

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[6] The pricing order applied to all milk sales in the State, but its "effect on Massachusetts producers [wa]s entirely (indeed more than) offset by the subsidy provided exclusively to Massachusetts dairy farmers." *Id.* at 194.

The First Circuit more fundamentally disagreed that the Rx Act was directed at out-of-state transactions, opining that the Act "[u]ltimately * * * simply regulates activity that occurs in state: (1) the purchase of the prescription drugs that triggers the rebate; (2) the negotiation of a rebate amount; and (3) the State's action subjecting a manufacturers' drug to prior authorization and releasing the manufacturer's name to health care providers and the public [all] occur[] in state." Pet. App. 24. This Court confronted a similar line of argument in *Brown-Forman* and rejected it: "The mere fact that the effects of New York's ABC Law are triggered only by sales of liquor within the State of New York * * * does not validate the law if it regulates the out-of-state transactions of distillers who sell in-state." 476 U.S. at 580. Exactly so here. The transaction that the Rx Act purports to regulate is that between out-of-state drug manufacturers—the only entities responsible for Rx Act "rebates"—and the predominantly out-of-state distributors with whom those manufacturers contract. The Act is invalid under *Healy*, *Brown-Forman*, and *Baldwin*. *See also Dean Foods*, 187 F.3d at 617 ("extraterritoriality principles ban a state from regulating 'sales that take place wholly outside it' ") (quoting *In re Brand Name Prescription Drugs Antitrust Litig.*, 123 F.3d 599, 613 (7th Cir. 1997), *cert. denied*, 522 U.S. 1153 (1998)).

The First Circuit also suggested that because the Rx Program is "voluntary," the provisions of the Rx Act did not violate the Commerce Clause. Pet. App. 23. But a Hobson's choice is no choice at all. The Act directs that manufacturers "*shall* enter into a rebate agreement" with the State, and that they are "*require[d]*" to pay the rebate to the State each calendar quarter. 22 Me. Rev. Stat. Ann. § 2681(3) (emphasis added). The Commissioner is similarly directed to use his "best efforts" during one-sided "negotiat[ions]" with the manufacturers over the amount of the "rebate *required*," to obtain a rebate amount at least equal to the Medicaid rebate. *Id.* § 2681(4)(A)-(B) (emphasis added). Manufacturers have absolutely no leverage in their "negotiations" with the Com-

missioner: if they decline to pay the "required" rebates, or offer anything less than an amount equal to or greater than the Medicaid rebate, the State may terminate negotiations and direct that the manufacturer's drugs be placed on the Medicaid prior-authorization list, whereupon the manufacturer's market share plummets. *See* Pet. App. 71. If a manufacturer attempts to avoid or minimize the effect of the prior authorization regime by directing less of its product to the State, it will be sued for treble damages. And even if a manufacturer bends to the State's coercive terms and agrees to pay rebates, the manufacturer may not adjust its transactions in the State to minimize the impact of those rebates on its revenues; that, too, would trigger an action for treble damages. The Rx Act, in other words, is a coercive statute from all angles; there is nothing remotely "voluntary" about its operation.

2. The Maine Rx Act also has a discriminatory effect on out-of-state commerce—and on out-of-state consumers in particular—because of two especially pernicious aspects of its construction. In a freely operating interstate market, a manufacturer confronted with an onerous state tax or regulatory regime can do one of two things: it can increase prices to consumers within the State, or it can take steps to limit the flow of its products into the State. *See*, *e.g.*, *National Elec. Mfrs. Ass'n* v. *Sorrell*, 272 F.3d 104, 110-111 (2d Cir. 2001), *cert. denied*, 122 S. Ct. 2358 (2002).[7]

The Rx Act takes those options off the table. Drug manufacturers who have agreed to pay rebates cannot increase drug prices in Maine to recoup lost revenues; their rebate obligations will simply increase accordingly. Nor, as we

[7] It of course would not be a defense to a Commerce Clause challenge to extraterritorial or unconstitutionally protectionist state legislation that a manufacturer is free to stop selling its product in the State. The Clause guarantees a national market—not a choice between participating or not in a Balkanized one.

have just explained, can any manufacturer—whether an Rx Act participant or an Rx Act dissenter who has lost substantial market share because of prior authorization—restructure its transactions with wholesalers to avoid any ultimate sale of its drugs in Maine. Manufacturers face severe civil penalties and punitive damages if they seek to avoid sales in the State because of the operation of the Rx Act. *See* 22 Me. Rev. Stat. Ann. §§ 2697(2)(D), (3)-(4). Because Maine has foreclosed the two options normally available to manufacturers confronted with an increased cost of doing business in a particular State, manufacturers can recoup their lost revenues only *outside* Maine—by charging consumers in other States more for their prescription drugs. The dormant Commerce Clause forbids that result. *See Brown-Forman*, 476 U.S. at 580 ("While a State may seek lower prices for its consumers, it may not insist that producers or consumers in other States surrender whatever competitive advantages they may possess"); *South Carolina State Highway Dep't* v. *Barnwell Bros.*, 303 U.S. 177, 184 n.2 (1938) ("State regulations affecting interstate commerce, whose purpose or effect is to gain for those within the state an advantage at the expense of those without" violate Commerce Clause); *National Elec. Mfrs. Ass'n*, 272 F.3d at 110 (regulatory regime in *Healy* and similar cases unconstitutional because "the state necessarily prevented firms from recouping any of the costs imposed by state statute from the residents of the state itself"); *cf. New Hampshire Auto Dealers Ass'n* v. *General Motors Corp.*, 801 F.2d 528, 531 (1st Cir. 1986) (Breyer, J.) (recognizing dormant Commerce Clause implications if state consumer-protection law forced manufacturers to increase prices in other States, "thereby hurting the consumers who live there").

3. This Court in *Healy* directed that the "practical effect" of a state statute challenged under the Commerce Clause "must be evaluated not only by considering the consequences of the statute itself, but also by considering how the challenged statute may interact with the legitimate regulatory

regimes of other States and what effect would arise if not one, but many or every, State adopted similar legislation." 491 U.S. at 336-337. The First Circuit concluded that the "most apparent effect of similar statutes being passed in other states would be a loss in profits for manufacturers," but concluded that on PhRMA's "facial challenge" to the Rx Act, the petitioner had shown "no evidence that adverse effects on interstate commerce will occur if such legislation were passed in other states." Pet. App. 24. That was wrong. If more States follow Maine's lead—strong-arming manufacturers into "rebate" schemes and imposing harsh "no-exit" penalties if manufacturers leave state markets to avoid the effect of those coercive schemes—interstate commerce, and drug manufacturing and innovation, will suffer gravely.

From the Constitution's creation through the present day, federal laws have protected manufacturers' revenue streams to encourage them to further innovate and refine their inventions. *See* U.S. Const. art. I, § 8; 35 U.S.C. § 154(a)(2). And in the drug industry in particular, Congress has repeatedly ensured that manufacturers who spend large sums of money to develop, test, gain federal approval of, and market a drug have a protected revenue stream for a period after the drug is approved for sale.[8] *See*, *e.g.*, 21 U.S.C. § 355(j)(C)(3)(D) (granting to "pioneer" drug manufacturers periods of market exclusivity ranging from two to ten years, depending on the drug's active ingredients); *id.* § 355a(a), (c) (granting terms of market exclusivity to drug manufacturers who perform pediatric studies); *id.* § 360cc (granting seven years market

[8] Manufacturers fund their research and development efforts with their revenues. *See* Jerry Stanton, Comment, *Lesson For The United States From Foreign Price Controls On Pharmaceuticals*, 16 Conn. J. Int'l L. 149, 153 (2000) ("The costs for traditional R&D efforts come from profits derived from the sale of products already in the marketplace, so current drug sales fund future research.") (citing Henry Grabowski, *Health Reform & Pharmaceutical Innovation* 19 (1994)).

exclusivity to manufacturers of "orphan drugs"—those aimed at treating a population of fewer than 200,000 people in the United States).

Congress has done so because developing new drugs is a long, risky, and astronomically expensive business. It takes ten to fifteen years to develop a new drug; the cost of developing a drug currently tops $800 million; and just three drug products out of every ten produce returns higher than their research and development costs. *See* PhRMA Industry Profile 2002, Ch. 2, "Research and Development: The Key To Innovation," at 12, 18-20, *available at* http://www.phrma.org/publications/publications/profile02/chapter2.pdf (last visited Sept. 19, 2002).[9]

If more States follow Maine's lead, two negative results will occur, one after the other. First, residents of States slow or reluctant to enact Maine's brand of policy fix would increasingly bear the brunt of the policy choice of the States following the Maine regime. And as more and more States protect their interests and enact Maine-style statutes, drug manufacturers' revenues will be siphoned off at an exponential rate. That in turn will have a direct effect on the resources manufacturers have at hand to devote to research and development efforts.

To be sure, States' nondiscriminatory regulatory efforts may impact manufacturers' revenues without running afoul of the Commerce Clause. Some such regulations further state residents' interests while impacting interstate commerce only glancingly. Others legitimately tax goods and services sold in the State. Maine's law has neither of those redeeming qualities. It extracts money from out-of-state manufacturers to benefit state residents, changing the terms of out-of-state

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[9] *See also* S. Rep. No. 105-43, at 6-7 (1997) (study "suggested an average development time of fifteen years and average costs in the range of 500 million dollars per new drug").

transactions and forcing out-of-state consumers to pick up the tab for Maine's policy choice. The law should be struck down.

CONCLUSION

For the foregoing reasons, the judgment below should be reversed.

Respectfully submitted,

ROBIN S. CONRAD
NATIONAL CHAMBER
LITIGATION CENTER, INC.
1615 H Street, N.W.
Washington, D.C. 20062
(202) 463-5337

JOHN G. ROBERTS, JR.*
CATHERINE E. STETSON
HOGAN & HARTSON L.L.P.
555 Thirteenth Street, N.W.
Washington, D.C. 20004
(202) 637-5810

* Counsel of Record

Counsel for Amicus Curiae