No. 12-142

IN THE

Supreme Court of the United States

MUTUAL PHARMACEUTICAL COMPANY, INC.,

Petitioner,

v.

KAREN L. BARTLETT,

Respondent.

ON WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

BRIEF OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AND PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

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

Counsel for Chamber of Commerce of the U.S.

BERT W. REIN
Counsel of Record
MICHAEL L. STURM
WILEY REIN LLP
1776 K Street, N.W.
Washington, DC 20006
(202) 719-7000
brein@wileyrein.com

Counsel for Amici Curiae

January 22, 2013

(Additional Counsel on Inside Cover)

245486

COUNSEL PRESS
(800) 274-3321 • (800) 359-6859

James M. (Mit) Spears
Melissa B. Kimmel
Pharmaceutical Research &
Manufacturers of America
950 F Street, NW
Washington, DC 20004
(202) 835-3400

Counsel for Pharmaceutical Research and Manufacturers of America

TABLE OF CONTENTS

Table of Contents

TABLE OF CITED AUTHORITIES

Page

FEDERAL CASES

Cited Authorities

FEDERAL STATUTES

Page

SESSION LAWS

CONSTITUTION

Page

REGULATIONS

LEGISLATIVE MATERIALS

OTHER AUTHORITIES

BRIEF OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AND PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

INTEREST OF THE *AMICI CURIAE*[1]

The Chamber of Commerce of the United States of America (the Chamber) is the world's largest business federation. The Chamber represents 300,000 direct members and indirectly represents the interests of more than three million companies and professional organizations of every size, in every industry, from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. To that end, the Chamber regularly files *amicus curiae* briefs in cases that raise issues of vital concern to the Nation's business community.

The Pharmaceutical Research and Manufacturers of America (PHRMA) is a voluntary, nonprofit association representing the nation's leading research-based pharmaceutical and biotechnology companies. PhRMA's member companies research, develop, and manufacture

[1]The parties' consent to the filing of *amicus* briefs has been filed with the Clerk. Under Rule 37.6 of the Rules of this Court, *amici curiae* state that no counsel for a party has authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person or entity, other than *amici curiae*, their members, or their counsel, has made a monetary contribution to this brief's preparation or submission.

medicines that allow patients to live longer, healthier, and more productive lives. In 2011 alone, PhRMA member companies invested an estimated $49.5 billion to discover and develop new medicines. PhRMA's mission is to advocate public policies that encourage the discovery of life-saving and life-enhancing medicines. PhRMA closely monitors legal issues that affect the pharmaceutical industry and frequently participates as an *amicus curiae* in cases before this Court.

The free flow of commerce within the United States is at the heart of the Founders' vision of our federal union. The movement of goods and services across state boundaries, unimpeded by parochial state interests, is essential to a strong national economy, job creation, and consumer welfare. The First Circuit's decision condoned individual state determinations that the shipment of nationally distributed and federally regulated prescription drugs into a state could be a wrongful act for which tort liability can be imposed on the drug manufacturer. That holding not only would isolate physicians and their patients within the affected state but also would have extraterritorial effects on the national drug distribution system. The First Circuit's decision is particularly egregious because it sustains a jury determination that a risk-benefit balance should have precluded Petitioner Mutual Pharmaceutical Company, Inc. (Mutual) from selling its sulindac drug in New Hampshire – even though the federal agency congressionally mandated to determine that *same* balance reached the *opposite* conclusion when authorizing Mutual to engage in interstate shipment of sulindac. Moreover, the First Circuit's "stop selling" theory, if adopted in other contexts, threatens to eviscerate the federal preemption defense that is essential to promoting the

free flow of federally regulated goods in numerous sectors of the economy. Because the decision below jeopardizes the public health, threatens to contribute to further balkanization of the national economy, and conflicts with the Supremacy Clause, the Commerce Clause, and the precedents of this Court, *amici* respectfully urge that it be reversed.

SUMMARY OF ARGUMENT

The judgment in this case should be reversed because the state law tort claim on which it is founded is preempted under federal law. The jury's determination that Mutual's sulindac formulation has a design defect under state law, based on the jury's own risk-benefit analysis, is irreconcilable with the expert determination by the United States Food and Drug Administration (FDA) that sulindac is safe and effective and should be available as a matter of federal law to prescribing physicians and their patients. The First Circuit's remarkable conclusion that Mutual could comply with its federal license to make and sell sulindac nationwide *and* its state law duty not to do so by "choos[ing] not to make the drug at all," *Bartlett v. Mut. Pharm. Co.*, 678 F.3d 30, 37 (1st Cir. 2012), is contrary to this Court's recent decision in *PLIVA, Inc. v. Mensing*, ___ U.S. ___, 131 S. Ct. 2567 (2011), and would effectively eviscerate much of this Court's preemption jurisprudence.

The judgment also should be reversed because it is antithetical to important Commerce Clause principles. Fostering the free flow of goods in a national market was a central goal of the Founders in adopting the Constitution; that goal consistently has been reflected in this Court's jurisprudence, even recognizing that

states have certain regulatory powers within their own borders. This Court repeatedly has rejected state attempts – legislative or judicial – to isolate a state from the national stream of commerce or to extend the effects of its regulation beyond its borders. As articulated by the First Circuit, the judgment at issue would do precisely that, by allowing a determination by a New Hampshire jury effectively to supersede FDA's expert determination that sulindac should be available on a nationwide basis. Such an approach to pharmaceutical manufacturing and distribution is contrary to federal health care policy, and the deleterious effects on the public health can hardly be overstated. Moreover, there can be no doubt that, if left to stand, enterprising plaintiffs' attorneys will advance the First Circuit's "stop selling" theory in lawsuits against every other federally regulated manufacturer, contributing to economic balkanization.

ARGUMENT

I. THE PLAIN CONFLICT BETWEEN MUTUAL'S FDCA-IMPOSED FEDERAL LAW DUTIES AND ITS JURY-IMPOSED STATE LAW DUTIES REQUIRES A FINDING OF PREEMPTION.

A. The Claim at Issue Is Preempted Because of the Conflict Between Mutual's Federal and State Law Duties.

The First Circuit erred in rejecting Mutual's preemption defense. Under Section 505(a) of the Federal Food, Drug, and Cosmetic Act (FDCA), formulations of the active ingredient sulindac could not be sold as a drug without preauthorization from the United States Food and Drug Administration (FDA). Pub. L. No. 75-717, § 505(a),

52 Stat. 1040, 1052 (1938) (codified as amended at 21 U.S.C. § 355(a)). With respect to any new drug application (NDA), FDA is required to weigh the safety risks associated with the new drug against the therapeutic benefits it offers, and strike a balance. *See* 21 U.S.C. § 355(d); *see also* 21 C.F.R. § 314.50(d)(5)(viii) (requiring NDAs to include a "summary of the benefits and risks of the drug, including a discussion of why the benefits exceed the risks under the conditions stated in the labeling"). In the case of sulindac, which was originally approved under the trade name Clinoril, one such risk, albeit remote, was the possibility of Stevens-Johnson Syndrome or toxic epidural necrosis (SJS/TEN). That risk has long been known to FDA and is reflected in the required FDA-approved labeling. As acknowledged by the district court, the FDA-approved labeling "expressly listed SJS/TEN as potential adverse reactions." *Bartlett v. Mut. Pharm. Co.*, 731 F. Supp. 2d 135, 142 (D.N.H. 2010).

Mutual obtained its approval by satisfying the requirements of Section 505(j) of the FDCA – the provision for expedited approval of generic drugs that are therapeutically equivalent to the innovator (reference drug) product. 21 U.S.C. § 355(j). To gain approval under Section 505(j), Mutual demonstrated that its sulindac: (i) had the same active ingredient as the approved reference listed drug, Clinoril; (ii) was bioequivalent to Clinoril; (iii) was formulated with the same strength, in the same dosage form, and for the same route of administration; and (iv) was labeled identically to Clinoril except for minor variations reflecting a different manufacturer. These "sameness" requirements are intended to ensure that FDA's risk-benefit determination undertaken in the full NDA process applies equally to the proposed generic drug. *See Bartlett v. Mut. Pharm. Co.,* 678 F.3d 30, 34-

35 (1st Cir. 2012) (acknowledging "statutory 'safe and effective' designation that the original manufacturer had secured and on which Mutual was entitled to piggyback"); 21 U.S.C. § 355(b)(1), (d); *id.* § 355(j)(2)(A); 21 C.F.R. §§ 314.92, 314.94.

As a matter of federal law, Mutual's sulindac could be shipped in interstate commerce only if Mutual continued to maintain the federally required sameness with Clinoril; Mutual could not continue to ship sulindac in commerce if it changed the formulation or labeling of its sulindac drug. As the First Circuit acknowledged, "Mutual cannot legally make sulindac in another composition (nor is it apparent how it could alter a one-molecule drug anyway)." *Bartlett*, 678 F.3d at 37. Despite the known risks of sulindac, including the risk of SJS/TEN, FDA determined that the benefit of having sulindac available as a treatment option for prescribers and patients outweighed these risks. Sulindac continues to be sold in interstate commerce, with full FDA approval. *See Bartlett v. Mut. Pharm. Co.,* 760 F. Supp. 2d 220, 228-29 (D.N.H. 2011) ("Sulindac remains on the market to this day, with FDA approval."); *Bartlett*, 678 F.3d at 34 (acknowledging that FDA has "never withdrawn" its "'safe and effective' designation.").

The First Circuit recognized this Court's determination "that the FDCA preempts failure-to-warn claims against generic drug manufacturers [who] . . . unlike brand-name manufacturers cannot unilaterally change their labels, 21 C.F.R. § 314.94(a)(8)(iv), and thus cannot comply with both federal labeling standards and state law requirements deviating from those standards." *Bartlett,* 678 F.3d at 37 (emphasis omitted) (citing *Mensing*, 131 S. Ct. at 2578). The court acknowledged that this Court's rejection of a brand name manufacturer's preemption defense in *Wyeth*

v. Levine, 555 U.S. 555 (2009), a failure-to-warn case on which the First Circuit relied, rested on the possibility "for brand name manufacturers to comply with both federal labeling requirements and state tort law effectively requiring a stronger label." *Bartlett,* 678 F.3d at 37, n.2. That possibility was not available to Mutual as a generic manufacturer.

Nevertheless, clearly distressed by the fact that Bartlett "lost her warning claim by the mere chance of her drug store's selection of a generic," *id.* at 38, the court resorted to sleight of hand to preserve her "design defect" claim. First, the court read *Levine* broadly to reject any "implied preemption" under the FDCA and to endorse state law as a "complementary form of drug regulation." *Id.* at 37. Next, it interpreted *Mensing* as only a limited "exception" *to Levine* and confined *Mensing* to failure-to-warn claims even though *Mensing* turned on the impossibility of PLIVA's complying with its obligations under both federal and state law rather than on any warning-specific principle. *Id.* Emphasizing the general anti-preemption rule it discerned in *Levine*, the First Circuit then distinguished design defect claims from failure-to-warn claims and speculated that "the FDCA might permit states to tell Mutual it ought not be [making the drug at all] if risk-benefit analysis weighs against the drug, despite what the Supreme Court made of similar arguments in the labeling context." *Id.* The court speculated that "the Supreme Court might be less ready to deprive Bartlett of her remaining [design defect] avenue of relief" when its *Mensing* decision had foreclosed her failure to warn claim. *Id.* at 38. Based on that speculation, and the concept that Mutual could comply with New Hampshire's determination that sulindac was unreasonably dangerous by choosing "not to make

the drug at all," even though it was FDA approved, the First Circuit rejected Mutual's impossibility preemption defense. *Id.*

The First Circuit's reasoning rests on a distinction without a difference. The command of federal law to Mutual with respect to the formulation or "design" of its sulindac was identical to the command with respect to the labeling of its sulindac. Mutual could no more change its formulation than it could its labeling while remaining within the bounds of its FDA approval to distribute sulindac in commerce. *See* 21 U.S.C. § 355(j)(2)(A)(ii) (sameness requirement for active ingredient), *id.* § 355(j)(2)(A)(iii) (sameness requirement for route of administration, dosage forms, and strength), *id.* § 355(j)(2)(A)(v) (sameness requirement for labeling). If state law determined Mutual's sulindac to be inadequately labeled or improperly designed, Mutual's only compliant choices under New Hampshire law were to make changes in violation of federal law or withdraw its sulindac from the market. As this Court recognized in *Mensing,* the Supremacy Clause forecloses New Hampshire from imposing that Hobson's choice on Mutual. *See Bartlett*, 678 F.3d at 38 (First Circuit acknowledges that its decision is in "tension" with *Mensing*); *Mensing,* 131 S. Ct. at 2579 ("We do not read the Supremacy Clause to permit an approach to pre-emption that renders conflict pre-emption all but meaningless."); *see also McDermott v. Wisconsin*, 228 U.S. 115, 131-32 (1913) (noting that "the State may not, under the guise of exercising its police powers or otherwise, impose burdens upon or discriminate against interstate commerce, nor may it enact legislation in conflict with the statutes of Congress passed for the regulation of the subject, and if it does, to the extent that the state law interferes with or frustrates the operation of the acts of

Congress, its provisions must yield to the superior Federal power given to Congress by the Constitution.") (finding that state labeling law imposed requirements contrary to federal law and was therefore preempted).

B. Under the Supremacy Clause, FDA's Expert Federal Law Risk-Benefit Analysis Cannot Be Overridden by a Lay Jury Acting Under State Law.

The judgment at issue is premised on a jury finding that sulindac is unreasonably dangerous and "defective" under New Hampshire law; that finding is directly contrary to the expert conclusion of FDA based on its risk-benefit analysis. The injuries suffered by Respondent Bartlett arose from the inherent risk that administration of sulindac could result in SJS/TEN in a small number of patients. *See Bartlett*, 760 F. Supp. 2d at 240. This risk was disclosed in sulindac's labeling and necessarily evaluated by FDA in determining whether the branded reference listed drug, Clinoril, to which Mutual's sulindac was identical, should be approved for national distribution. *See Bartlett*, 731 F. Supp. 2d at 142-43 (discussing labeling of sulindac for SJS/TEN); *Bartlett*, 760 F. Supp. 2d at 229 (rejecting claim that FDA would have revoked approval had it known of risks as "contrary to what actually happened.").

Since the FDCA was amended in 1962, FDA has been required to assess both the risks and benefits of drugs for which approval is sought. S. Rep. No. 87-1744, at 15 (1962); s*ee also* FDCA § 505(d) (codified as amended at 21 U.S.C. § 355(d)); 21 C.F.R. § 314.50(d)(5)(viii) (requiring new drug applicants to provide a "summary of the benefits and risks of the drug, including a discussion of why the

benefits exceed the risks under the condition stated in the labeling."). FDA necessarily concluded that the Clinoril formulation to which Mutual's sulindac was identical had a positive risk-benefit balance taking into account the known SJS/TEN risk disclosed in its labeling.

As part of its responsibility under the FDCA, FDA collects information about adverse reactions to approved drugs and has the authority to revoke the approval of a drug if its risk-benefit balance becomes unfavorable. 21 U.S.C. § 355(e). FDA has not revoked its approval of Clinoril and thus continues to authorize the interstate distribution of Clinoril and its generic equivalents, including Mutual's sulindac. *See Bartlett,* 760 F. Supp. 2d at 228-29 ("sulindac remains on the market to this day, with FDA approval."); *Bartlett*, 678 F.3d at 34 (FDA has "never withdrawn" its "'safe and effective' designation.").

The New Hampshire jury assessed sulindac's risk-benefit balance using the same factors as FDA but weighed them differently to reach the opposite conclusion. There is no indication in any decision below that the information available to the jury was materially different from the information on which FDA had acted. To the contrary, the plaintiff's evidence at trial was mostly "drawn directly from the medical literature or published FDA analyses." *Bartlett,* 760 F. Supp. 2d at 233-36.[2]

[2]The Court suggested in *Wyeth v. Levine* that state tort lawsuits may "uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly." 555 U.S. 555, 579 (2009). But there was nothing new uncovered here; as the lower court opinions reflect, the claim was expressly premised on second-guessing FDA's risk-benefit determination as to a known, labeled risk. *See Bartlett*, 678 F.3d at 38.

As between the competing federal and state risk-benefit balances, the balance struck by FDA under its congressional mandate must prevail, at least absent the kind of evidence arising after FDA's decision that was presented in *Levine*. Article VI of the Constitution unequivocally makes the "Laws of the United States . . . the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the contrary notwithstanding." U.S. Const. art. VI cl. 2. FDA determined that sulindac was legally safe and effective based on essentially the same risk evidence presented to the New Hampshire jury. Any judgment premised on a contrary determination under state law should not stand.

II. THE FIRST CIRCUIT'S "STOP SELLING" THEORY IS ANTITHETICAL TO THE COMMERCE CLAUSE.

A. The Commerce Clause Was Designed To Foster the Free Flow of Commerce in a Single, National Market.

Even apart from well-settled federal impossibility preemption principles, the First Circuit's decision urgently requires reversal because of the threat it poses to the free flow of interstate commerce and the supremacy of federal risk-benefit decisions. The First Circuit's decision endorsed the authority of a state to sanction as wrongful the sale within its borders of a product moving in interstate commerce consistent with its federally mandated composition and labeling. The exercise of that authority by a state contravenes the Commerce Clause and should be rejected by this Court.

The Commerce Clause entrusts Congress with the "Power . . . [t]o regulate Commerce with foreign Nations and among the several States . . .." U.S. Const. art. I, § 8, cl. 3. Promoting the free flow of commerce via a single, national market was a central goal of the 1787 Constitutional Convention and, as anticipated by the Framers, has been a continuing boon to our economy. As James Madison explained, "[t]he defect of power in the existing [Articles of Confederation] to regulate the commerce between its several members [has] been clearly pointed out by experience." THE FEDERALIST, No. 42 (James Madison). Absent federal power to displace conflicting state laws, the Framers feared that "[e]ach State, or separate confederacy, would pursue a system of commercial polity peculiar to itself. This would occasion distinctions, preferences, and exclusions, which would beget discontent." THE FEDERALIST, No. 7 (Alexander Hamilton. As Hamilton elsewhere remarked, "[t]he importance of the Union, in a commercial light, is one of those points about which there is least room to entertain a difference of opinion, and which has in fact commanded the most general assent of men who have any acquaintance with the subject." THE FEDERALIST, No. 11 (Alexander Hamilton). This Court likewise has explained the fundamental importance of the commerce power to the adoption of the Constitution:

> The sole purpose for which Virginia initiated the movement which ultimately produced the Constitution was "to take into consideration the trade of the United States; to examine the relative situations and trade of the said States, and to consider how far a uniform system in their commercial regulations may be necessary

> to their common interest and their permanent harmony."

H.P Hood & Sons, Inc. v. Du Mond, 336 U.S. 525, 533 (1949) (quoting *Formation of the Union*, H.R. Doc. No. 398, 12 H. Docs., 69th Cong., 1st Sess., p. 38).

The union contemplated by the Framers required both that the national government have authority to pass uniform laws governing interstate commerce, and that those laws supersede contrary laws enacted under the authority of the states. As Hamilton stated, "[t]he government of the Union must be empowered to pass all laws, and to make all regulations . . . in respect to commerce." The Federalist, No. 23 (Alexander Hamilton). That was a principal reason the Framers determined that "[t]he character of such a governme[nt] ought . . . to be paramount to the state constitutions." James Madison, *Notes of the Constitutional Convention* (May 29, 1787), in 1 The Records of The Federal Convention of 1787, 17-23 (Max Farrand ed., 1911). Thus, the Constitution's combination of the Commerce Clause and the Supremacy Clause created the framework for a national market.

The Commerce Clause both affirmatively empowers Congressional regulatory action and, as this Court has held, bars states from impairing the free flow of interstate commerce. The Court recognized that principle as early as its decision in *Gibbons v. Ogden*, 22 U.S. 1 (1824). There, the Court protected the right of federally licensed steamships to enter the ports and navigate the waters of the State of New York against New York's effort to protect sailing ships by foreclosing steamship activity in its waters and ports. Per Chief Justice Marshall, in words directly

applicable to New Hampshire's determination that Mutual was wrongly selling sulindac under its FDA approval:

> The word "license," means permission, or authority; and a license to do any particular thing, is a permission or authority to do that thing; and if granted by a person having power to grant it, transfers to the grantee the right to do whatever it purports to authorize. It certainly transfers to him all the right which the grantor can transfer, to do what is within the terms of the license.
>
> * * *
>
> … all inquiry into this subject seems to the Court to be put completely at rest, by the act already mentioned, entitled, "An act for the enrolling and licensing of steam boats."
>
> * * *
>
> This act demonstrates the opinion of Congress, that steam boats may be enrolled and licensed, in common with vessels using sails. They are, of course, entitled to the same privileges, and can no more be restrained from navigating waters, and entering ports which are free to such vessels, than if they were wafted on their voyage by the winds, instead of being propelled by the agency of fire. *The one element may be as legitimately used as the other, for every commercial purpose authorized by the laws of the Union; and the act of a State inhibiting*

> *the use of either to any vessel having a license under the act of Congress, comes, we think, in direct collision with that act.*

Id. at 213-14, 220-21 (emphasis added). *Gibbons* thus establishes the primacy of a federal license over any conflicting state restrictions. The importance of the constitutional protection against state impedance of interstate commerce was further articulated by Justice Johnson in his concurring opinion in *Gibbons*: "if there was any one object riding over every other in the adoption of the constitution, it was to keep the commercial intercourse among the States free from all invidious and partial restraints." *Id.* at 231.

This Court has never deviated from the teaching of *Gibbons v. Ogden*. As explained by Justice Cardozo in *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511, 522-23 (1935), the Court has protected interstate commerce from undue state interference by recognizing that the Constitution was "framed upon the theory that the peoples of the several States must sink or swim together, and that in the long run prosperity and salvation are in union and not division." *See also Kassel v. Consolidated Freightways Corp.*, 450 U.S. 662, 670-71 (1981) (invalidating state restriction on truck length and holding that "the incantation of a purpose to promote the public health or safety does not insulate a state law from Commerce clause attack."). Thus, while states may to some extent apply their police powers to activities in interstate commerce if not preempted by Congress from doing so, they may not exercise those powers to foreclose interstate commerce or effectively exclude their territory from the national market. *See, e.g., Brown-Forman Distillers Corp. v. N.Y. State Liquor*

Auth., 476 U.S. 573, 582-83 (1986) (no State can "project its legislation into [other States]") (citation omitted); *Bibb v. Navajo Freight Lines, Inc.*, 359 U.S. 520, 525-28 (1959) (invalidating Illinois law that required trucks entering the State to install unique mudflaps).

B. Allowing a State Tort Claim Based on "Second Guessing" a Federal Determination That a Product Could Be Lawfully Manufactured and Sold Would Undermine the National Market Promoted by the Commerce Clause.

The First Circuit interpreted New Hampshire law to permit a jury "second guessing the FDA" to find that Mutual's distribution of sulindac in New Hampshire was wrongful because sulindac failed the jury's risk-benefit balancing. *Bartlett*, 678 F.3d at 37-38. Mutual was then sanctioned by a $21 million award to Bartlett premised on its wrongful conduct. New Hampshire's exercise of the power to enter that award is not meaningfully distinct from the imposition of a ban on sulindac entering New Hampshire enforceable by a civil penalty. This Court has consistently rejected the contention that an award of civil damages is any less an exercise of state regulatory power than a civil penalty payable to the state. *See, e.g., Cipollone v. Liggett Group, Inc.* 505 U.S. 504, 521-22 (1992) (plurality opinion) ("[S]tate regulation can be as effective exerted through an award of damages as through some form of preventive relief." (citation and emphasis omitted)); *see also id.* at 548-49 (Scalia and Thomas, JJ., concurring in relevant part); *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 324 (2008) ("[C]ommon-law liability is premised on the existence of a legal duty, and a tort judgment therefore establishes that the defendant has violated a

state obligation. And while the common-law remedy is limited to damages, a liability award can be, indeed is designed to be, a potent method of governing conduct and controlling policy." (quotation marks and citations omitted)); *Mensing*, 131 S. Ct. 2567 (common law failure-to-warn claim preempted).

Because Mutual's ability to distribute sulindac in New Hampshire was federally conditioned on using the formulation and labeling that New Hampshire found to fail its common law risk-balancing test, the effect of New Hampshire's decision was to foreclose any non-tortious distribution of Mutual's sulindac in New Hampshire. As the First Circuit acknowledged, Mutual's only lawful course of action to satisfy both federal and state requirements was to "choose not to make the drug at all," *Bartlett,* 678 F.3d at 37, a result in conflict with the Commerce Clause and requiring reversal by this Court. Like the federal license upheld in *Gibbons v. Ogden*, FDA's nationwide authorization to sell, granted only after an extensive approval process, would have far less value if it could be superseded by contrary jury determinations in any or all states. This is not the national market contemplated by the Framers.

The First Circuit's decision advises Mutual that it may comply with both federal and state law by not making and selling sulindac for use in New Hampshire. *Bartlett,* 678 F.3d at 37. The consequences of the New Hampshire judgment, however, cannot be easily confined to New Hampshire. When a product like sulindac is distributed nationally through multiple distribution entities and layers – *e.g.*, wholesalers' warehouses, pharmacy chains, etc. – restricting its availability in a single state is a complex

problem. As a practical matter, keeping sulindac out of New Hampshire could require ceasing to distribute it at all or at least restricting its distribution in adjacent states that New Hampshire residents can readily access. Moreover, sulindac cannot be labeled to exclude use in New Hampshire, even assuming that such labeling would be effective, because Mutual is not permitted to change its FDA-approved label. 21 U.S.C. § 355(j)(2)(A)(v); *Bartlett,* 678 F.3d at 37 ("generic makers cannot alter the labeling."). Nor is it apparent how a manufacturer could be expected to know that in New Hampshire, but only in New Hampshire, its FDA-approved drug could be deemed "defective." *Cf. Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341, 350 (2001) ("As a practical matter, complying with FDA's detailed regulatory regime in the shadow of 50 States' tort regimes will dramatically increase the burdens facing potential applicants – burdens not contemplated by Congress in enacting the FDCA and the MDA.").

The spillover of New Hampshire's law into other states raises the type of Commerce Clause problems this Court has addressed by foreclosing enforcement of state laws with troublesome extraterritorial effects. In our federal union, states must limit their regulatory initiatives to their own territory; this Court has not hesitated to strike down state laws that effectively constrain activities otherwise permissible in sister states. *Healy v. Beer Institute*, 491 U.S. 324, 335-36 (1989) (observing that the Constitution has a "special concern both with the maintenance of a national economic union unfettered by state-imposed limitations on interstate commerce and with the autonomy of the individual States within their respective spheres" (footnote omitted)) (invalidating

state price-posting statute based on extraterritorial effects). As this Court most recently stated in *BMW v. Gore*, 517 U.S. 559, 570-72 (1996): "one State's power to impose burdens on the interstate market . . . is not only subordinate to the federal power over interstate commerce, but is also constrained by the need to respect the interest of other States." Manufacturers distributing in interstate commerce and consumers in states other than New Hampshire that seek to benefit from sulindac (as well as New Hampshire consumers) should not be foreclosed from accessing sulindac by a New Hampshire jury's idiosyncratic disagreement with FDA's balancing of sulindac's risks and benefits.

III. THE FIRST CIRCUIT'S "MARKET WITHDRAWAL" THEORY EVISCERATES THE PREEMPTION DEFENSE AND THREATENS ECONOMIC BALKANIZATION.

If accepted by this Court, the consequences of the First Circuit's market withdrawal approach could hardly be overstated. The impacts will, of course, be most immediately and obviously felt in the nation's health care system. Instead of one national, expert agency reviewing and approving drugs, there could be fifty state regulatory agencies plus unlimited individual jury outcomes making inconsistent determinations as to the proper design and availability of drugs. Even if the national drug distribution system could somehow be redesigned to take into account state-by-state variations in the lawfulness (and, thus, availability) of certain drugs, the impact on the distribution of drugs and the practice of medicine would be immense. The treatment of patients would vary more from state to state, as some FDA-approved drugs would

be unavailable to physicians in some states (*e.g.,* per the First Circuit's suggestion, sulindac in New Hampshire). The teaching and practice of medicine would become increasingly balkanized, to the detriment of physicians, patients, and the federal government itself, which by statute is deeply integrated into the health care system. *See, e.g.,* Social Security Amendments of 1965, Pub. L. No. 89-97, 79 Stat. 286 (1965) (establishing Medicare and Medicaid); Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 111 (2010). Not only would the quality of care decrease, the cost of drugs inevitably would increase as distribution became less efficient.

In addition to the problems inherent in having multiple decision-makers concerning the availability of individual drugs, FDA's risk-benefit analyses should be favored because they are objectively better in promoting public health than equivalent determinations by votes of lay jurors. In determining whether to approve an NDA, FDA relies on its experienced staff and panels of trained medical and pharmacological experts; there is no suggestion that the lay jury in New Hampshire had the benefit of such expertise. *See, e.g., Weinberger v. Bentex Pharms., Inc.,* 412 U.S. 645, 653-54 (1973) ("[t]he determination whether a drug is generally recognized as safe and effective . . . necessarily implicates complex chemical and pharmacological considerations."). FDA review of an NDA typically includes a year or more of close analysis; a jury trial may take a few days or weeks. FDA must balance the benefits of the proposed drug to the entire treatable population against the potential incidence of its known risks. In contrast, however instructed, a jury's attention cannot help but be focused on a single, grievously injured individual, particularly with skilled

plaintiffs' counsel maintaining that focus. *See, e.g., Riegel v. Medtronic, Inc.,* 552 U.S. at 325 ("A jury . . . sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped those benefits are not represented in court."). This focus magnifies the drug's risks and effectively nullifies its benefits. As Congress has established, and for the benefit of the health care system as a whole, the safety and efficacy of drugs is properly determined by FDA, based on controlled studies and judgments made by trained physicians and other scientists, not lay jurors in a courtroom determining whether a sympathetic plaintiff should be compensated for her injuries by a large drug company.

There is also ample reason to expect that the First Circuit's "stop selling" approach would spread beyond the pharmaceutical industry. If allowed to stand, the First Circuit's rationale will undoubtedly be relied upon in lawsuits involving the many federally regulated products that, like drugs, inherently carry some degree of risk, no matter how well they are designed. The availability of those products confers a benefit on society and to the economy as a whole. Where expert federal agencies make risk-benefit determinations that allow the marketing of such products, those assessments should not be overridden by state tort systems, especially in the absence of evidence of risks not considered by the agency.

A system such as that contemplated by the First Circuit, in which individual juries would retroactively second guess expert federal risk-benefit determinations based on application of malleable state tort standards, would allow sympathy for the few unpredictably but inevitably injured by these inherent risks to override the

interests of the many who would benefit from continued distribution. As the First Circuit itself hinted, *see* 678 F.3d at 44, confusing tort concepts of wrongful conduct and welfare interests of aiding the injured is bad public policy. If left intact, the First Circuit's decision will no doubt be used as a "stop selling" loophole to the federal preemption defense to products liability lawsuits – a defense that that enhances overall public welfare by serving as a bulwark against economic balkanization, helping to ensure that products whose risks outweigh their benefits remain in lawful distribution.

CONCLUSION

For the foregoing reasons, the judgment under review should be reversed.

January 22, 2013

Respectfully submitted,

Robin S. Conrad
Sheldon Gilbert
National Chamber
Litigation Center, Inc.
1615 H Street, N.W.
Washington, DC 20062
(202) 463-5337

Counsel for Chamber of Commerce of the U.S.

Bert W. Rein
Counsel of Record
Michael L. Sturm
Wiley Rein LLP
1776 K Street, N.W.
Washington, DC 20006
(202) 719-7000
brein@wileyrein.com

Counsel for Amici Curiae

James M. (Mit) Spears
Melissa B. Kimmel
Pharmaceutical Research &
Manufacturers of America
950 F Street, NW
Washington, DC 20004
(202) 835-3400

Counsel for Pharmaceutical Research and Manufacturers of America