No. 12-142

IN THE
Supreme Court of the United States

MUTUAL PHARMACEUTICAL COMPANY, INC.,
Petitioners,

v.

KAREN L. BARTLETT,
Respondent.

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

BRIEF OF PUBLIC LAW SCHOLARS AS *AMICI CURIAE* IN SUPPORT OF RESPONDENTS

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[1] Pursuant to Rule 37.6, *amici* affirm that no counsel for a party authored this brief in whole or in part, and that no person other than *amici* and their counsel made a monetary contribution to the preparation or submission of this brief.

Amici have each written extensively on questions involving the preemption of state law by federal statutes and regulations. We submit this brief as an opportunity to bring our scholarship to bear on questions of public importance facing the Court.

SUMMARY OF ARGUMENT

This case raises three significant questions. The first is a general one concerning this Court's preemption doctrine: What showing is necessary to establish conflict preemption under a federal statutory regime that expressly preserves a role for state law? This is a crucial question for the balance of our federalism. Under contemporary interpretations of Congress's Article One powers, national regulatory authority is largely concurrent with that of the states, so that the boundary between federal power and state regulatory autonomy is largely defined by the scope and limits of federal preemption. For that reason, this Court has organized its jurisprudence around the "presumption against preemption" recognized in *Rice v. Santa Fe Elevator Co.*, 331 U.S. 218, 230 (1947). In cases of implied conflict preemption, that presumption both limits the scope of relevant purposes that may create a conflict with federal law and requires that such conflicts be serious before preemption is warranted. In this case, *Rice* requires rejection of both Petitioner's broad theory of impossibility preemption and its equally broad and open-ended argument for "purposes and objectives" preemption.

The second question concerns the role of state tort law under the federal regulatory regime governing prescription drugs. That regime explicitly preserves a role for state law. And, unlike the otherwise

parallel regime for medical devices, it does not feature an express preemption provision displacing state law "requirements" that diverge from federal law. This Court has thus construed state law as serving a complementary function to federal regulation of prescription drugs. *See Wyeth v. Levine*, 555 U.S. 555 (2009). State law provides compensation for persons injured by dangerous drugs—a function that federal law makes no effort to duplicate. And while federal regulation focuses on the premarket approval of prescription drugs, state tort law provides a mechanism and incentives for *ex post* review of those drugs after they enter the marketplace—a function that this Court has recognized the federal Food and Drug Administration is ill-equipped to carry out. *See id.* at 579 & n.11. Both Petitioners' impossibility and "purposes and objectives" arguments—which are variations on the same theme—would eliminate state law's complementary role by holding that federal approval provides not only permission but a *right* to market a drug free of any state law constraint. This Court should not presume, absent clear evidence to the contrary, that Congress intended this result.

The third question requires a careful analysis of *state* law, in order to determine whether that law actually conflicts with the federal regulatory regime. New Hampshire imposes strict liability—that is, liability without fault—on manufacturers of unreasonably dangerous products. The New Hampshire Supreme Court has made clear that this liability does not impose any duty other than to compensate persons injured by such products; there is, to use the language of express preemption clauses

in other statutes, no state law "requirement" that manufacturers alter their product (much less stop selling it). Petitioners dispute this reading of state law, but they primarily rely on *this Court*'s holdings, under various express preemption statutes inapplicable here, that state tort duties *always* impose "requirements" that manufacturers alter their products. Not only are those statutes inapplicable to this case, but this Court is bound, as always, by the state courts' construction of the duties imposed under state law. And in any event, even if state law *did* require Petitioners to stop selling their product in New Hampshire, the First Circuit correctly concluded that that obligation would not create a conflict sufficient to warrant preemption.

ARGUMENT

I. THIS COURT SHOULD REQUIRE EVIDENCE OF A SIGNIFICANT CONFLICT WITH CONGRESS'S CLEAR INTENT BEFORE FINDING PREEMPTION.

In assessing the scope of federal preemption, this Court has generally appreciated "the practical importance of preserving local independence, at retail, i.e., by applying pre-emption analysis with care, statute by statute, line by line, in order to determine how best to reconcile a federal statute's language and purpose with federalism's need to preserve state autonomy." *Egelhoff v. Egelhoff*, 532 U.S. 141, 160 (2001) (Breyer, J., dissenting). This Court's enumerated powers jurisprudence has generally given wide scope to Congress's regulatory authority, *see, e.g.*, *United States v. Comstock*, 130 S. Ct. 1949 (2010); *Gonzales v. Raich*, 545 U.S. 1 (2005), with the result that that authority is now, with certain important but relatively narrow exceptions,

largely concurrent with that of the states. Under these circumstances, it is particularly critical that the preemptive effect of federal legislation stretch no further than Congress clearly intended. *See* Ernest A. Young, *"The Ordinary Diet of the Law": The Presumption Against Preemption in the Roberts Court,* 2011 Sup. Ct. Rev. 253, 265-69; Stephen A. Gardbaum, *The Nature of Preemption*, 79 Cornell L. Rev. 767, 805-07 (1994). Hence, this Court has applied a "presumption against preemption" in construing the meaning of federal statutes and assessing potential conflicts between state and federal law. *See Rice*, 331 U.S. at 230.

Rice's presumption governs this case. In recent years, this Court has soundly rejected arguments for restricting *Rice*'s applicability, and it has recognized that *Rice* requires not only a clear statement of Congress's intent in express preemption cases but also a significant conflict in implied preemption cases. Critically, this Court insisted just two terms ago that "[o]ur precedents 'establish that a high threshold must be met if a state law is to be pre-empted for conflicting with the purposes of a federal Act." *Chamber of Commerce v. Whiting*, 131 S. Ct. 1968, 1985 (2011) (quoting *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 110 (1992) (Kennedy, J., concurring in part and in the judgment)). Petitioners' broad view of impossibility preemption would subvert this "high threshold" by finding such preemption whenever state law potentially forbids something that federal law permits. Worse still, Petitioners' open-ended arguments for "purposes and objectives" preemption would obviate the limits on impossibility preemption by permitting displacement of state law in an even

broader class of cases, limited only by courts' creativity in imputing purposes to Congress.

It is crucial to constrain preemption doctrine within narrower limits than those Petitioners propose. Contemporary federalism doctrine relies largely on two sets of institutional safeguards to preserve state autonomy: the representation of the States in Congress, and the procedural difficulty of enacting supreme federal law. *See* Bradford R. Clark, *Separation of Powers as a Safeguard of Federalism*, 79 Tex. L. Rev. 1321 (2001). In order to respect these safeguards, courts should find preemption based only on the text enacted by Congress and necessary implications from that text.

A. The presumption against preemption governs this case.

This Court has acknowledged "the historic primacy of state regulation of matters of health and safety," *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996), and accordingly applied a "presumption that state and local regulation of health and safety matters can constitutionally coexist with federal regulation," *Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 716 (1985). *Wyeth*, in particular, emphasized that "'[i]n all pre-emption cases, and particularly in those in which Congress has 'legislated . . . in a field which the States have traditionally occupied,' . . . we 'start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'" 555 U.S. at 565 (quoting *Medtronic*, 518 U.S. at 485, in turn quoting *Rice*). The defendants in *Wyeth* argued that *Rice* should not apply because of

the longstanding federal regulatory presence in the field of prescription drugs, but the Court specifically rejected this argument, noting that "[t]he presumption . . . accounts for the historic presence of state law but does not rely on the absence of federal regulation." *Id.* at 565 n.3

Wyeth likewise explicitly rejected an argument the *Rice* does not apply to claims of implied conflict preemption, stating that "this Court has long held to the contrary." *Id.* (citations omitted). It is worth re-emphasizing in this case, however, the implications of that holding. In express preemption cases, the *Rice* presumption operates as an aid for determining the meaning of ambiguous statutory text. It cannot play that same role when preemption rests not on the express language of the statute but rather on a conflict with federal requirements or purposes. Conflict preemption cases require an assessment not only of whether "federal law . . . is in tension with state law," but also "whether this tension is sufficiently severe to warrant the displacement of state law." Thomas W. Merrill, *Preemption and Institutional Choice*, 102 Nw. U. L. Rev. 727, 743 (2008) ; *see also* Young, 2011 Sup. Ct. Rev. at 274-76. As this Court noted in *Whiting*, the relevant precedents set a "high threshold" for conflict preemption. 131 S. Ct. at 1985.

In a conflict preemption scenario, the presumption against preemption operates in two distinct ways: It increases the *level* of conflict necessary to find preemption, and it narrows the range of federal purposes that may create a potential conflict with state law. The first of these dimensions governs Petitioners' impossibility argument, *see* Petitioner's Brief at 29-45, while both are relevant to

Petitioners' arguments for "purposes and objectives" preemption, *see id.* at 45-62.

B. Petitioners' theory of impossibility preemption is overbroad.

Impossibility preemption "is a demanding defense," *Wyeth*, 555 U.S. at 573, that requires defendants to demonstrate that "compliance with both federal and state [law] is a physical impossibility," *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963); *see also id.* at 143 (requiring proof of an "inevitable collision" between federal and state law). As we explain further in Part III, there is no serious argument in the present case that it is physically impossible to comply with state tort law. Federal law does not prohibit compensating persons injured by prescription drugs. Nor does it require manufacturers to continue or discontinue selling their drug upon a state law finding that the drug is defectively designed.

In this case, Petitioners appear to take the position that when a federal agency approves a drug for marketing, that approval operates as a license preempting any state-law duty that might discourage or prohibit such marketing. "Impossibility" occurs, on this view, when state law discourages action approved by federal regulators. That would be a radically broad reading of impossibility preemption, based on a fundamental misconception of the federal regime governing prescription drugs. That regime, as we elaborate in Part II, preserves state tort law as a complementary form of regulation to federal pre-market approval.

C. "Purposes and objectives" preemption should be construed narrowly.

To the extent that federal law may displace state law even when it is not impossible to comply with both, the *Rice* presumption speaks both to the severity of the conflict and the scope of relevant federal purposes. This Court has said that "the inquiry is whether there exists an irreconcilable conflict between the federal and state regulatory schemes. The existence of a hypothetical or potential conflict is insufficient to warrant the pre-emption of the state statute." *Rice v. Norman Williams Co.*, 458 U.S. 654, 659 (1982); *see also English v. Gen. Elec. Co.*, 496 U.S. 72, 90 (1990) ("The "teaching of this Court's decisions . . . enjoins seeking out conflicts between state and federal regulation where none clearly exists.'" (quoting *Huron Cement Co. v. Detroit*, 362 U.S. 440, 446 (1960))). As Justice Kennedy has pointed out, "[a] freewheeling judicial inquiry into whether a state statute is in tension with federal objectives would undercut the principle that it is Congress rather than the courts that pre-empts state law." *Gade*, 505 U.S. at 111 (Kennedy, J., concurring in part and in the judgment).

Virtually any federal statute may be construed to embody a range of potential purposes. The primary purpose of federal drug regulation is to protect public safety, but the FDCA regime also promotes competition in the drug market and seeks to reduce the compliance costs of drug manufacturers. It is not wholly implausible to see many FDA approvals as involving a balancing of these values, and from that perspective, *any* form of state regulation that might, say, increase costs to augment safety would be a movement away from the balance struck by federal

law. To take this view, however, would be to categorically exclude any form of supplemental state regulation; it would be, in other words, to make every federal floor a ceiling as well. *See generally* William W. Buzbee, *Asymmetrical Regulation: Risk, Preemption, and the Floor/Ceiling Distinction*, 82 N.Y.U. L. Rev. 1547 (2007). That conclusion is directly at odds with *Wyeth* and in tension with a long line of cases rejecting similar conclusions in other federal regulatory fields. *See, e.g.*, *Bates v. Dow AgroSciences LLC*, 544 U.S. 431, 450-51 (2005) (holding that state law suits can supplement federal requirements and rejecting complaints that such suits increase costs for manufacturers).

In order to avoid this categorical approach to implied conflict preemption, *Rice* requires a narrower focus on a statute's primary objective. As Justice Kennedy has observed, "this type of pre-emption should be limited to state laws which impose prohibitions or obligations which are in direct contradiction to Congress's primary objectives, as conveyed with clarity in the federal legislation." *Gade*, 505 U.S. at 110 (Kennedy, J., concurring in part and in the judgment). This approach, moreover, constrains judges from engaging in a "freewheeling" inquiry that risks imputing purposes that Congress did not contemplate. *See Bates*, 544 U.S. at 459 (Thomas, J., concurring in judgment in part and dissenting in part). In this case, for instance, a key question is whether Congress's purpose in creating a pre-marketing approval scheme administered by the FDA was simply to provide initial safety review before drugs go into public use, or instead to eliminate pre-existing state rights of action for

injured patients. *Rice* suggests the Court should adopt the narrower view of Congress's purpose.

Most legal regimes involve a tradeoff between conflicting purposes, and *Rice* can also speak to the degree to which state law may pursue a policy in tension with federal purposes. Here, for instance, one purpose of the Hatch-Waxman Act is to increase the availability of generic drugs, and Petitioners have argued that any state rule that tends to discourage the marketing of a generic drug or affects generic manufacturers' costs of doing business is therefore preempted. The question, however, is whether state law can pursue its purpose of ensuring compensation for injured consumers and providing back-end safety review even when that may impose some additional costs on generic drug manufacturers. *Rice* suggests that this sort of tension is tolerable; it also suggests, as we discuss further in Part II, that Congress's purpose should not be construed as promoting generic drugs *uber alles*, but rather as encouraging generic use so long as that is consistent with the states' traditional role of compensating injured patients and supplementing federal safety review.

D. Doctrines limiting federal preemption of state law play a critical role in maintaining the federal balance.

Given the broad scope of potential federal regulatory authority under current law, preemption is the most critical piece of the Court's federalism doctrine in terms of preserving meaningful state autonomy. By ending state regulatory authority so far as preemption extends, an unduly expansive preemption doctrine undermines the core values of

federalism—that is, the states' ability to respond to geographically divergent conditions and voter preferences, to experiment with innovative policy solutions, and to compete with other jurisdictions to offer the most attractive mix of policies to businesses and individuals. *See generally Gregory v. Ashcroft*, 501 U.S. 452, 458 (1991); *Wyeth*, 555 U.S. at 583-84 (Thomas, J., concurring in the judgment). Broad preemption of state law in the field of medical regulation, for example, would end state experimentation as to the best ways to generate new information concerning drug safety and to compensate victims of unsafe products. *Cf. United States v. Lopez*, 514 U.S. 549, 581 (1995) (Kennedy, J., concurring) (stressing the value of state experimentation). Preemption thus poses a greater threat to state autonomy than, for example, attempts to subject the states to damages liability, *see, e.g.*, *Seminole Tribe v. Florida*, 517 U.S. 44 (1996), or the extreme (but largely symbolic) instances of commerce clause legislation that the Court has struck down as exceeding Congress's constitutional power, *see, e.g.*, *Lopez*, 514 U.S. at 567-68.

Prior to the New Deal, this Court's doctrine of "dual federalism" severely constrained preemption by simply foreclosing federal regulation in many areas. But with the Court's abandonment of dual federalism in cases like *Wickard v. Filburn*, 317 U.S. 111 (1942), the enumerated powers doctrine became a considerably less important constraint on the scope of federal law. *See generally* Young, 2011 Sup. Ct. Rev. at 257-61. Unless this Court is prepared radically to narrow the scope of Congress's authority under the Commerce and Necessary and Proper Clauses, the scope of federal regulation and the

corresponding zone of state autonomy will be largely defined by *Congress*'s choices. *See, e.g.*, *AT&T v. Iowa Utils. Bd.*, 525 U.S. 366 (1999) (interpreting the 1996 Telecommunications Act to transfer a vast swath of regulatory authority over the local telephone market from state regulators to the Federal Communications Commission). Two aspects of that situation are vital: First, Congress—to at least some extent—represents the states. And second, Congress can make law only through a relatively arduous process. Both these aspects of the constitutional scheme suggest that courts should find preemption only in light of clear congressional intent or a serious conflict with a clear congressional policy.

This Court has long suggested that the primary institutional safeguard for state autonomy in our system derives from the states' representation in the national political process. *See San Antonio Metro. Transit Auth. v. Garcia*, 469 U.S. 528 (1985). The importance of that representation undergirds this Court's oft-stated rule that "the purpose of Congress is the ultimate touchstone in every pre-emption case." *Medtronic*, 518 U.S. at 485. It also supports *Rice*'s presumption, because "a presumption against preemption promotes legislative deliberation" about the impact of proposed federal statute on state law. Robert R. M. Verchick & Nina Mendelson, *Preemption and Theories of Federalism*, in Preemption Choice: The Theory, Law, and Reality of Federalism's Core Question 13, 23 (William W. Buzbee ed. 2009). As Justice O'Connor wrote for the Court, "'to give the state-displacing weight of federal law to mere congressional *ambiguity* would evade the very procedure for lawmaking on which *Garcia* relied to protect states' interests.'" *Gregory*, 501 U.S. at

464 (quoting Laurence H. Tribe, *American Constitutional Law* § 6-25 (2d ed. 1988)).

Our constitutional structure augments these "political safeguards" of federalism with *procedural* safeguards as well. As Bradford Clark has explained, "[t]he lawmaking procedures prescribed by the Constitution safeguard federalism in an important respect simply by requiring the participation and assent of multiple actors. . . . In short, the imposition of cumbersome federal lawmaking procedures suggests that the Constitution 'reserves substantive lawmaking power to the states and the people both by limiting the powers assigned to the federal government and by rendering that government frequently incapable of exercising them.'" Clark, 79 Tex. L. Rev. at 1339-40 (citations omitted). Justice Thomas has thus rightly read the Supremacy Clause to require "that pre-emptive effect be given only to those federal standards and policies that are set forth in, or necessarily follow from, the statutory text that was produced through the constitutionally required bicameral and presentment procedures." *Wyeth*, 555 U.S. at 586 (Thomas, J., concurring in the judgment). This "structural limitation" precludes implied preemption "based on [the Court's] interpretation of broad federal policy objectives, legislative history, or generalized notions of congressional purposes that are not contained within the text of federal law." *Id.* at 586, 587.

These general propositions do not, of course, decide particular cases. But they do underscore the importance of the arguments set out earlier in this part: that *Rice*'s presumption against preemption should be scrupulously enforced; that impossibility

preemption should be narrowly construed; and that preemption should not be found based on an open-ended construction of Congress's "purposes and objectives." The importance of preemption to federalism doctrine generally also reinforces the arguments that follow, which argue for reading state law to complement, rather than contradict, the federal regulatory scheme at issue in this case.

II. STATE TORT LAW COMPLEMENTS THE FEDERAL REGULATORY SCHEME FOR PRESCRIPTION DRUGS.

When it enacted the FDCA, "Congress took care to preserve state law." *Wyeth*, 555 U.S. at 567. The 1962 amendments to the FDCA included a savings clause, "indicating that a provision of state law would only be invalidated upon a 'direct and positive conflict' with the FDCA." *Id.* (quoting FDCA, Pub. L. No. 87-781, § 202, 76 Stat. 780, 793 (1962)). And while Congress has added an express preemption provision for medical devices, it has conspicuously failed to do so for prescription drugs. *Compare Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008) (finding preemption under the medical devices provision). As the Court observed in *Wyeth*, "[i]f Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA's 70-year history. But despite its 1976 enactment of an express pre-emption provision for medical devices . . . Congress has not enacted such a provision for prescription drugs." 555 U.S. at 574.[2]

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[2] *See also id.* at 575 ("[Congress's] silence on the issue, coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend

Wyeth thus rejected the broad arguments advanced both by Petitioners and the Government in this case that the FDA approval process, combined with post-marketing review of drugs by the agency, is the exclusive protection for consumers. In recognizing the complementary role of state tort law, moreover, *Wyeth* necessarily rejected broad claims that juries are incapable of making judgments about medical safety. Rather, this Court's cases have recognized that state tort law serves valuable functions not fully accounted for by federal law: state law compensates persons injured by unsafe products, provides incentives and a forum for the development of new information about drug safety, and compensates for the limited resources of the FDA. These functions are no less essential with respect to generic drugs than with respect to brand name products. They are also equally applicable to claims of defective design as to claims of failure to warn. In each of these areas, there is no reason to depart from *Wyeth*'s conclusion that Congress intended to preserve the complementary role of state law.

FDA oversight to be the exclusive means of ensuring drug safety and effectiveness."); *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 166-67 (1989) ("The case for federal pre-emption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to stand by both concepts and to tolerate whatever tension there [is] between them."). In the context of the prescription drug regime, Congress's failure to enact an express preemption clause simply underscores the savings clause enacted as part of the 1962 amendments.

A. This Court's cases recognize the ways in which state tort law complements federal regulation of prescription drugs.

The *Wyeth* Court noted that "Congress did not provide a federal remedy for consumers harmed by unsafe or ineffective drugs. . . . Evidently, it determined that widely available state rights of action provided appropriate relief for injured consumers." 555 U.S. at 574. Moreover, Congress "may also have recognized that state-law remedies further consumer protection by motivating manufacturers to produce safe and effective drugs and to give adequate warnings." *Id.* Later in the opinion, the Court explained that

> The FDA has limited resources to monitor the 11,000 drugs on the market, and manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge. State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly. They also serve a distinct compensatory function that may motivate injured persons to come forward with information.

555 U.S. at 578-79 (citing recent studies indicating that the FDA's post-marketing review process is inadequate, standing alone, to ensure public safety).

This Court has rejected efforts to construe the federal scheme as leaving no room for state tort law. In *Wyeth*, the FDA had promulgated a "preamble" in which it "declared that the FDCA establishes 'both a

floor and a ceiling,' so that 'FDA approval of labeling . . . preempts conflicting or contrary State law.'" 555 U.S. at 575 (citations omitted).[3] Nonetheless, this Court rejected the argument for preemption, observing that "Congress has repeatedly declined to pre-empt state law, and the FDA's recently adopted position that state tort suits interfere with its statutory mandate is entitled to no weight. Although we recognize that some state-law claims might well frustrate the achievement of congressional objectives, this is not such a case." 555 U.S. at 581.

Wyeth's conclusion that state tort liability does not obstruct the purposes and objects of the FDCA scheme forecloses Petitioners' argument for implied preemption here. It also forecloses, *a fortiori*, any argument that it is "impossible" to comply with both the FDA's approval of sulindac and a state tort judgment finding sulindac to be defectively designed. Both the purposes and objects argument in *Wyeth* and Petitioners' impossibility argument here are predicated on the notion that FDA regulation provides both a ceiling and a floor—that is, that no drug can be marketed without FDA approval, but that approval confers a *right* to market that drug without interference from state law. Given that impossibility is an even more demanding standard for preemption than purposes and objects, *Wyeth*'s rejection of the latter necessarily disposes of the former.

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[3] The preamble "further stated that certain state-law actions, such as those involving failure-to-warn claims, 'threaten FDA's statutorily prescribed role as the expert Federal agency responsible for evaluating and regulating drugs.'" 555 U.S. at 575-76.

B. State law's complementary functions are no less important when they involve generic drugs or defective design claims.

Nothing in *Wyeth*'s vision of state and federal law as complementary safeguards for public health is limited to either failure-to-warn claims or branded drugs. As the facts of this case illustrate, the victims of defectively designed drugs need compensation just as do those injured by a failure to warn. And the incentives provided by state law for manufacturers to continue to identify and respond to safety risks, even after FDA approval of a drug, are no less important if danger stems from a drug's design rather than its warning.

It is true that, in *Wyeth*, federal law specifically permitted manufacturers of branded drugs to change their labels (pending FDA approval) in order to comply with state tort law duties to warn. Here, by contrast, the state-law finding of defective design goes to the underlying product itself, not simply the label. But unless the FDCA preempts defective design claims altogether, it will always be possible that a particular product might be so inherently defective that it cannot be made safe—that is, that the manufacturer may be forced either to compensate those injured by the product in the future or to withdraw the product from the market. To say that putting the manufacturer to that choice is irreconcilable with federal pre-market approval of the drug is to hold *all* design defect claims categorically preempted. If Congress had intended such a radical impact on state tort law, it surely would have said something about it in the statute. *Cf. Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457,

468 (2001) ("Congress, we have held, does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes.").

Generic drug manufacturers are in the same boat as branded manufacturers with respect to defective design claims. After all, a branded manufacturer forced to redesign its drug would have to secure FDA approval for the new version, just as a generic manufacturer who redesigned a generic drug would, in effect, be seeking approval for a new version of the drug altogether. Hence, although generic and branded manufacturers have different obligations with respect to failure to warn claims, their obligations are identical with respect to claims predicated on the drug's design or composition. In the face of a successful defective design claim, both branded and generic manufacturers have the same three options: seek FDA approval for a new, redesigned drug; stop selling the old drug; or simply choose to compensate any person injured by the drug. The special obligations and policies of the Hatch-Waxman Act can thus add nothing to Petitioners' impossibility argument, and in any event, that Act evinces no congressional intent categorically to preempt design defect claims.

Moreover, as Justice Sotomayor noted in her *PLIVA* dissent, generic drugs "dominate the market. . . . Ninety percent of drugs for which a generic version is available are now filled with generics. In many cases, once generic versions of a drug enter the market, the brand-name manufacturer stops selling the brand-name drug altogether." *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2584 (2011) (citations omitted). Given the market

dominance of generics, state law can hardly serve as a complementary back-end safety regime if it is limited to claims against branded drug manufacturers.

III. THE NEW HAMPSHIRE TORT RULE AT ISSUE HERE DOES NOT CONFLICT WITH THE FEDERAL REGULATORY SCHEME.

Resolution of conflict preemption claims requires careful interpretation not only of the federal statutory scheme at issue but also of the content of the relevant state law. The parties in this case do not agree as to the proper characterization of the state law duties here. *Amici* agree with Respondent that New Hampshire's rule of strict liability for unreasonably dangerous products is best read not as an obligation to withdraw defective products from the market, but rather simply as a duty to compensate the (possibly very small) class of individuals who are injured by those products. Read in this way, the state law is not inconsistent with the FDA's pre-market judgment that the drug may be marketed because, overall, its benefits outweigh its risks. Rather, drug manufacturers may comply with both state and federal law by marketing their product while effectively insuring the small class of persons harmed by that product for their injuries.

On the other hand, Petitioners read New Hampshire law as a duty *not* to market an unreasonably dangerous product. Even if that reading were correct, there should be no preemption in this case. Design defect claims may require a manufacturer to stop selling a particular product, and there is no clear evidence in this case that Congress intended categorically to preempt design

defect claims. Nor can the preemption rationale of *PLIVA*, which relied upon the special constraints that federal law imposes on generic manufacturers, be extended to cover cases in which the underlying product itself has been found to be unreasonably dangerous.

A. New Hampshire law does not require Petitioners to stop selling their drug, and the obligation to compensate injured persons does not conflict with federal law or policy.

State law does not require a drug manufacturer in Petitioner's shoes either to violate federal law or to stop selling its product. It can, after all, simply choose to continue marketing its product while paying damages to persons injured by the drug. The New Hampshire Supreme Court has made clear that, under state law, liability is not premised on the breach of a legal duty: "Legal liability is said to be strict when it is imposed even though the defendant has committed no legal fault consisting of the violation of a common law or statutory duty." *Bagley v. Controlled Env't Corp.*, 503 A.2d 823, 825 (N.H. 1986) (Souter, J.); *see also id.* at 559 (identifying New Hampshire's "cause of action for damages . . . for the benefit of the user or consumer of an unreasonably dangerous and defective product" as "based on strict liability"). Similarly, New Hampshire products liability law does not premise liability on a duty to improve the product's design. *See Kelleher v. Marvin Lumber & Cedar Co.*, 891 A.2d 477, 492 (N.H. 2005) (noting that "the plaintiff is not required to present evidence of a safer alternative design"). And damages, under New Hampshire law, are imposed solely to compensate the victim rather than to

impose incentives for manufacturers to change their products. *See, e.g.*, *Stewart v. Bader*, 907 A.2d 931, 943 (N.H. 2006) ("Punitive damages are not allowed in New Hampshire" and "'[n]o damages are to be awarded as a punishment to the defendant or as a warning and example to deter him and others from committing like offenses in the future.'" (quoting *Aubert v. Aubert*, 529 A.2d 909, 914 (N.H. 1987))).

If the incidence of SJS/TEN is actually very low, and the drug is beneficial and therefore valuable to many other persons, then the most rational course for a manufacturer may well be simply to continue selling its product and compensate the small number of people who develop harmful side effects. The primary function of tort law in this setting is simply to shift the financial loss to the party best able to bear it. *See, e.g., Heath v. Sears, Roebuck & Co.*, 464 A.2d 288, 293 (N.H. 1983) (observing that "the risk of liability is best borne by the companies that profited from their sale, rather than by the unfortunate individual consumers").[4] A manufacturer's decision to continue to market a product known to cause bad reactions in a small but unidentifiable subset of consumers would, in effect, amount to a decision to insure those unfortunate patients by compensating

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[4] Even in contract law, it has long been recognized that some agreements are best interpreted not as imposing an obligation to perform but simply an obligation to pay damages in the event that one does not or cannot perform. Justice Holmes famously observed that "in the case of a binding promise that it shall rain to-morrow, the immediate legal effect of what the promisor does is, that he takes the risk of the event, within certain defined limits, as between himself and the promisee." Oliver Wendell Holmes, Jr., *The Common Law* (1881), in 3 The Collected Works of Justice Holmes 268 (S. Novick ed. 1995).

them for their loss. This is all that New Hampshire law requires in strict liability cases that are not based on a failure to warn.

In other settings, of course, tort law may perform other functions—including the function of shaping defendants' and potential defendants' behavior. But that hardly means that New Hampshire should not be permitted to erect a strict liability scheme of its own design, focused on compensating victims rather than imposing duties on manufacturers. *Wyeth*, after all, identified compensation of victims as one of the critical functions that the FDCA leaves to state law. State tort duties should thus not always be seen as competing "requirements" of the sort generally preempted by certain federal regulatory regimes. The "requirements" imposed by federal law, after all, are like property rules: they can be enforced by injunctions or even criminal prosecution. State tort law, on the other hand, generally imposes a liability rule, which allows the defendant an option to simply pay damages while continuing in his activity. *Cf.* Guido Calabresi & A. Douglas Melamed, *Property Rules, Liability Rules and Inalienability: One View of the Cathedral*, 85 Harv. L. Rev. 1089 (1972). To say that it is "impossible" to comply with federal and state law under these circumstances is to elide this important distinction.

B. This Court's recognition that state common law liability may impose a "requirement" under certain federal statutes is not a reason to disregard the New Hampshire Supreme Court's interpretation of state law.

Preemption depends not only on the intent of Congress but also on how that intent bears on the particular laws of each state. In this case, Petitioners propose to establish a uniform rule of preemption by treating "state tort law" as a generic category, without taking seriously the ways that state law may vary. This approach might be intellectually tidy, but it subverts basic purposes of our federalism. As Justice Kennedy has observed, "the theory and utility of our federalism are revealed" when "the States . . . perform their role as laboratories for experimentation to devise various solutions where the best solution is far from clear." *Lopez*, 514 U.S. at 581 (Kennedy, J., concurring). Whether state law conflicts with Congress's purposes may turn importantly on features of a particular state's common law regime—whether it allows punitive damages, for example, or imposes a duty not simply to pay compensation but also to withdraw a product from the market.

Here, both the Petitioner's and the Government's amicus briefs reject Respondents' reading of state law, suggesting that this Court has already determined that state tort liability *always* imposes "requirements" on manufacturers. *See* Petitioner's Brief at 41-42; Brief of the United States as *Amicus*

Curiae in Support of Petitioner, at 15-16. In *Riegel*, this Court said:

> Congress is entitled to know what meaning this Court will assign to terms regularly used in its enactments. Absent other indication, reference to a State's "requirements" includes its common-law duties. As the plurality opinion said in *Cipollone*, common-law liability is "premised on the existence of a legal duty," and a tort judgment therefore establishes that the defendant has violated a state-law obligation. [*Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 522 (1992).] 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.'" *Id.* at 521.

552 U.S. at 324. In *Riegel*, *Cipollone*, and a number of similar cases, the Court had to construe express preemption clause in various federal statutes foreclosing state imposition of "requirements" different from or in addition to those imposed by federal law. In those cases, the question was how *Congress* understood state tort law and what it intended to preempt.[5]

This Court's opinion in *Riegel* repeatedly stressed the importance of the express preemption clause for

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[5] We would not rule out the possibility that a state tort regime might feature a rule that fell outside Congress's view of "requirements," but whether Congress's language covered such a rule would remain a question of federal law. In the absence of such statutory language, however, this Court must look to what state law actually does, as understood by the state courts.

state law "requirements." *See, e.g.*, 552 U.S. at 326, 327. Moreover, there is good reason not to extend *Riegel*'s interpretation of "requirements" in the Medical Devices Amendments beyond its original context. The statutory text does not expressly address state tort law, and the *Medtronic* plurality concluded that "when Congress enacted [the MDA's preemption provision] it was primarily concerned with the problem of specific, conflicting state statutes and regulations rather than the general duties enforced by common-law actions." 518 U.S. at 489 (plurality opinion). *Riegel*, moreover, did not consider whether a state law regime that expressly imposed no duty on medical device manufacturers would be a preempted "requirement."

This Court's opinion in *Bates* strongly suggests that New Hampshire's strict liability rule would not be preempted even under an express preemption clause foreclosing state "requirements." Petitioner's argument is that holding it liable would induce it to either alter the design of its drug (in violation of federal law) or to stop selling that drug. Similarly, in *Bates*, the court of appeals found preemption on the ground that "a finding of liability on these claims would 'induce Dow to alter [its] label.'" 544 U.S. at 445 (citation omitted). This Court rejected, however, "[t]his effects-based test" on the ground that it "finds no support in the text of [the express preemption provision], which speaks only of 'requirements.'" *Id.* In language strikingly relevant to this case, the Court explained that

> A requirement is a rule of law that must be obeyed; an event, such as a jury verdict, that merely motivates an optional decision is not a requirement. The proper inquiry calls for an

> examination of the elements of the common-law duty at issue . . . it does not call for speculation as to whether a jury verdict will prompt the manufacturer to take any particular action (a question, in any event, that will depend on a variety of cost/benefit calculations best left to the manufacturer's accountants).

Id. (citing *Cipollone*, 505 U.S. at 524 (plurality opinion)). Even in the presence of an express preemption clause, then, *Bates* makes two crucial points: first, even federal law does not categorically classify state tort rules as "requirements" governing defendants' behavior, but rather requires "an examination of the common-law duty at issue"; and second, federal preemption doctrine differentiates between state law rules that actually *require* a change in the manufacturer's behavior and those that simply impose costs that might induce a similar effect.

There is, in any event, no such express preemption clause here. The question is simply whether state law imposes a duty that makes it impossible to comply with both state and federal law, or that interferes with the purposes of Congress's regulatory scheme. The question is thus not what Congress meant by a statutory term, but rather what state law in fact requires. That is a question of state law, and this Court's precedents cannot be read as definitive constructions of that law—even in the unlikely event that this Court intended them as such. The meaning of state law must be evaluated state-by-state, and the final authority on that question is each state's supreme court. *See, e.g.*, *Mullaney v. Wilbur*, 421 U.S. 84, 692 (1975) ("This

Court . . . repeatedly has held that state courts are the ultimate expositors of state law . . . and that we are bound by their constructions except in extreme circumstances not present here." (citing, *inter alia*, *Murdock v. City of Memphis*, 87 U.S. (20 Wall.) 590 (1875))).

The rule that this Court is bound by the New Hampshire Supreme Court's interpretation of its own law should hardly require explication. It is grounded not only in the federal courts' general lack of authority to supply legal rules of decision in the absence of federal statutes or constitutional provisions, *see Erie Railroad Co. v. Tompkins*, 304 U.S. 64 (1938), and this Court's lack of jurisdiction over state law questions in appeals from the state supreme courts, *see Murdock*, 87 U.S. (20 Wall.) at 635, but also the superior expertise of the state courts concerning state law and the need for comity among courts in a federal system. The across-the-board characterization of state tort law as imposing regulatory requirements in cases like *Riegel* is thus not binding here, and that characterization must give way if the state courts have in fact construed state law otherwise.

C. Even if state law *did* require Petitioners to stop selling their product, that would not conflict with the federal regulatory scheme.

The tort claims in this case are not preempted even if New Hampshire law is best read as imposing a duty not to market the unreasonably dangerous product. *PLIVA* found impossibility preemption based on the notion that a successful failure-to-warn claim would impose a legal duty on generic

manufacturers to do something that federal law did not permit them to do: change their drug's label. *See* 131 S. Ct. at 2577 ("It was not lawful under federal law for the Manufacturers to do what state law required of them."). Any such change, after all, would violate the federal requirement that generic drugs' labeling be exactly the same as that of the brand name drug. The present case appears, at first blush, to pose a similar dilemma: Just as generic drug manufacturers cannot change their label, they also cannot change the chemical composition of their drug in response to a state-law finding that the drug is unreasonably dangerous. And while a generic manufacturer remains able to respond to that finding by ceasing to market the drug at all, that option—as Judge Boudin recognized, *see Bartlett v. Mutual Pharm. Co.*, 678 F.3d 30, 38 (1st Cir. 2012)—was available to the defendants in *PLIVA*, too.

The crucial difference, however, is that *PLIVA* came to this Court without any claim that the drug's risks outweighed its benefits—only a claim of failure-to-warn. The plaintiffs effectively conceded, in other words, that the drug in that case was appropriate to market. In that circumstance, it is unreasonable to force the manufacturer nonetheless to stop selling the drug simply because federal law forbids it to change the inadequate label. But in the present case, where the plaintiff's strict liability claim is precisely that the drug is unreasonably dangerous, obligating the manufacturer to take the drug off the market would be more reasonable. After all, it is likely that many products subject to successful design defect claims cannot be reengineered to an adequate level of safety, so that the only alternative to tort liability is to take them off the market. If

Congress intended to allow defective design claims *at all*, for branded drugs or generics, then that decision necessarily includes scenarios where a manufacturer may have to cease marketing its unsafe product to avoid the risk of future liability.

Congress could, of course, preempt such claims if it so wished. But that simply highlights the crucial difference between this case and *Wyeth*, on the one hand,[6] and *Riegel* on the other. A state law duty to stop selling a product might well qualify as a "requirement" under the express preemption language at issue in *Riegel* (and *Bates*). But Congress enacted no such statute here. As our discussion in Part I makes clear, preemption is about *Congress*'s action and *Congress*'s clear intent. That body's deliberate decision not to extend express preemption to the entire regime of FDA premarket approval should make a difference here.

CONCLUSION

The judgment of the United States Court of Appeals for the First Circuit should be affirmed.

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[6] As we have already explained, branded and generic manufacturers stand in precisely the same shoes with respect to design defect claims that do not involve a failure to warn. *See supra* Part II.B. That is particularly true of the one-molecule drug at issue in this case.

Respectfully submitted,

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