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 Second Circuit**

## BRIEF OF THE COUNCIL OF STATE GOVERNMENTS AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENT

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## TABLE OF CONTENTS

## TABLE OF AUTHORITIES

Page

**CASES:**

**STATUTES**



**OTHER MATERIALS**

## INTEREST OF *AMICI CURIAE*[1]

*Amicus curiae*, the Council of State Governments ("CSG"), is the Nation's only organization serving all three branches of state government. CSG is a region-based forum that fosters the exchange of insights and ideas to help state officials shape public policy. This offers unparalleled regional, national and international opportunities to network, develop leaders, collaborate, and create problem-solving partnerships.

All three branches of state government play roles in the development and evolution of traditional state tort law doctrines and liability rules. State legislatures and governors may enact legislation that alters or abrogates traditional common law tort liability rules, including products liability law. Further, state courts traditionally have played a leading role in the development and application of state tort law. For these reasons, all branches of state governments in general have an interest in retaining state sovereignty and control over the substance of state tort law, without expansion of implied federal pre-emption doctrines that may frustrate and defeat state law.

## SUMMARY OF ARGUMENT

The question for this Court is whether federal law impliedly pre-empts longstanding, traditional tort liability for selling unreasonably dangerous products in the context of prescription drugs produced by generic manufacturers. The answer is no.

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[1] Counsel for *amicus curiae* authored this brief in its entirety. None of the parties or their counsel, nor any other person or entity other than *amicus* or its counsel, made a monetary contribution intended to fund the preparation or submission of this brief. Consent letters from counsel for both petitioner and respondent for the filing of *amicus curiae* briefs are on file with the Clerk. Sup. Ct. R. 37.6.

The Court adopted the correct approach to prescription drug pre-emption in large part in *Wyeth v. Levine*, 555 U.S. 555 (2009), when it held that state law inadequate warning claims against brand name manufacturers of prescription drugs were not pre-empted because state law did not "conflict[] with the text of the relevant federal statute or with the federal regulations authorized by that text." 555 U.S. at 588 (Thomas, J., concurring). In other words, "the relevant federal law did not give Wyeth a right that the state-law judgment took away." *Id*. at 593. Based on clear provisions of the same federal statutes, *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), held that a state law failure to warn claim against generic prescription drug manufacturers is pre-empted.

Both cases, however, involved a narrow and specific state law claim premised on a manufacturer's duty to provide adequate warnings, a claim that is fundamentally different than the more general design defect claim at issue in this case. Furthermore, the argument that the FDA has taken over the regulation of the *content of warnings* for prescription drugs is far stronger than any argument that the FDA has monopolized the business of providing compensation for patients injured by unreasonably dangerous prescription drugs. *Cf. Cipollone v. Liggett Group*, 505 U.S. 504 (1992) (recognizing significant federal role regarding warnings in the context of tobacco regulation). The latter notion simply is not borne out by the relevant federal statutes and regulations.

The Court in the prescription drug pre-emption cases has focused on impossibility analysis, not the theory of so-called "obstacle" pre-emption, and with good reason – there is no evidence of congressional intent to pre-empt traditional state tort law in this

arena. Moreover, a majority of the Court continues to apply a presumption against pre-emption in implied "conflict" cases such as this one. Petitioner and its *amici* effectively invite the Court to disregard both of these fundamental propositions, in particular by asking the Court to engage in a free-wheeling "obstacle" inquiry and effectively to apply a "presumption *in favor of* pre-emption."

The Court, instead, should reject those invitations and apply "impossibility" pre-emption and the traditional presumption against pre-emption. Only "[w]here state and federal law 'directly conflict'" must state law "give way," *Mensing*, 131 S. Ct. at 2577 (quoting *Wyeth*, 555 U.S. at 583 (Thomas, J., concurring)), and there is no such direct conflict here, because federal law does not require Petitioner to sell Sulindac. The mere fact that the Hatch-Waxman Amendments in part promote the use of generic drugs does not equate to an intention to promote generics "at all costs." *Cf. Williamson v. Mazda Motor of America*, 131 S. Ct. 1131, 1139 (2011); DAN DOBBS, THE LAW OF TORTS at 1036 (2000). Moreover, the Court recognizes that Congress legislates against the backdrop of traditional common law norms such as the design defect doctrines at issue here.

Ultimately, the "general rule" of no pre-emption that the Court recognized in *Wyeth* counsels strongly against extending the limited pre-emption holding of *Mensing* to the distinct and more fundamental category of state law tort liability for design defects. The tort law standards to prove a design defect claim may be high, but that decision is for the States to make; the federal courts should not grant manufacturers a legal immunity in the guise of implied pre-emption

when Congress has not mandated – or even suggested – that result.

Finally, if New Hampshire has, as Petitioner and its *amici* suggest, truly crafted a body of tort law unique to the Granite State, and FDA may soon eliminate pre-emption of inadequate warning claims against generic manufacturers (as the United States now suggests, U.S. Br. 15 n. 2), then the Court should not expend its resources to decide a case that does not involve the question whether design defect claims in general are pre-empted by federal law in cases involving prescription drugs. Instead, it may be appropriate for the Court to consider dismissing the case as improvidently granted or to certify disputed issues of New Hampshire tort law to the New Hampshire Supreme Court.

## ARGUMENT

### I. IN THE PRESCRIPTION DRUG CONTEXT, THE COURT FOCUSES ON THE "IMPOSSIBILITY" PRE-EMPTION ANALYSIS — NOT "OBSTACLE" PRE-EMPTION.

The Court should only apply traditional "impossibility" pre-emption to resolve this case. Petitioner and its *amici*, however, invite this Court to do considerable violence to the Court's general pre-emption principles, including no less than asking the Court (1) to engage in a free-wheeling judicial inquiry under the guise of "obstacle" pre-emption, and (2) to adopt a presumption in favor of pre-emption in the context of prescription drugs. Ultimately, the question the Court must resolve here is whether it wants to be drawn into "policing" imaginary lines, lines that Congress did not draw—indeed lines that Congress has declined to draw—and which fail to accord any

respect to state tort law, all in furtherance of a tort reform agenda thinly disguised as a constitutional pre-emption analysis. With all due respect, the Court's answer should be an emphatic "no thanks."

From an analytical standpoint, this case is on a par with *Wyeth v. Levine*, 555 U.S. 555 (2009), and *PLIVA v. Mensing*, 131 S. Ct. 2567 (2011), in the sense that the Court's primary focus in all of the prescription drug cases has been on so-called "impossibility" pre-emption. The Court long has recognized that state and federal law are most obviously in conflict—and state law therefore necessarily pre-empted—when "compliance with both federal and state regulations is a physical impossibility." *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963). As *Wyeth* and *Mensing* reiterated, impossibility pre-emption doctrine remains the focus in prescription drug cases.

**A.** Petitioner and its *amici*, however, invoke so-called "obstacle" pre-emption, which may operate where state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941). Simply put, this doctrine has no role here.

To begin, there are strong constitutional arguments against the invocation of "obstacle" pre-emption in any case, because obstacle pre-emption allows federal courts "to vacate a judgment issued by another sovereign based on nothing more than assumptions and goals that were untethered from constitutionally enacted federal law." *Williamson v. Mazda Motor of America, Inc.*, 131 S. Ct. 1131, 1141-43 (2011) (Thomas, J., concurring); *Wyeth*, 555 U.S. at 604 (Thomas, J., concurring) (the doctrine "leads to decisions giving improperly broad pre-emptive ef-

fect to judicially manufactured policies"); *Pharm. Research & Mfrs of Am. v. Walsh*, 538 U.S. 644, 678 (2003) (Thomas, J., concurring in judgment); *Camps Newfound / Owatonna, Inc. v. Town of Harrison*, 520 U.S. 564, 617 (1997) (Thomas, J., dissenting).[2] For these reasons, one Justice has rejected the entire concept of "obstacle" pre-emption, *id*., while four others have expressly acknowledged that such an analysis threatens to result in a "free-wheeling judicial inquiry into whether a state [law] is in tension with federal objectives," *Chamber of Commerce v. Whiting*, 131 S. Ct. 1968, 1985 (2011), and to "undercut the principle that it is the Congress rather than the courts that pre-empts state law." *Id*. (quoting *Gade*

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[2] In addition, obstacle pre-emption "encourages an overly expansive reading of statutory text" and "inevitably leads [courts] to assume that Congress wanted to pursue those policies 'at all costs' – even when the text reflects a different balance." *Wyeth*, 555 U.S. at 601 (Thomas, J., concurring). Indeed, there is no factual basis for the Court to assume "that every policy seemingly consistent with federal statutory text has necessarily been authorized by Congress and warrants pre-emptive effect." *Id*. at 602. *Cf*. Caleb Nelson, *Preemption*, 86 VA. L. REV. 225, 280 (2000) (even if the Court were to "suppose that all members of Congress can agree on the 'full purposes and objectives' behind a particular federal statute[,] [t]here still is no reason to assume that they would want to displace whatever state law makes achieving those purposes more difficult."); *id*. at 281 (the "mere fact that Congress enacts a statute to serve certain purposes … does not automatically imply that Congress wants to displace all state law that gets in the way of those purposes.") *See, e.g., Pac. Gas & Elec. Co. v. State Energy Res. Conservation & Dev. Comm*., 461 U.S. 190, 222 (1983) (a federal law encouraging the use of nuclear power did not pre-empt the States' authority to decline to issue a license to build a nuclear plant because Congress' purpose of "the promotion of nuclear power is not to be accomplished 'at all costs'").

*v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 111 (1992) (Kennedy, J., concurring)).

Indeed, obstacle preemption finds its best—and likely only legitimate—home in federal common law cases. In that rare—and notably statute-free—zone, "obstacle" pre-emption may properly apply because the "conflict with federal policy need not be as sharp as that which must exist for ordinary pre-emption when Congress legislates." *Boyle v. United Technologies Corp.*, 487 U.S. 500, 507 (1988). This federal common law fit serves to highlight that the Court acts as a quasi-legislature when it applies "obstacle" preemption doctrine. *Cf. O'Melveny & Myers v. FDIC*, 512 U.S. 79, 89 (1994) (holding that the weighing of factors, beyond statutory text and structure, in the proposed creation of federal common law is more appropriately a legislative function). While that legislative role may be appropriate in limited circumstances such as the federal common law of foreign relations, see *Zschernig v. Miller*, 389 U.S. 429, 441 (1968) (applying obstacle pre-emption to further judicially presumed federal foreign policy goals because Congress had not spoken to the issue), exercising such power is inappropriate here where the Court sits in its traditional role of interpreting statutes. *See Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 388–91 (2000) (Scalia, J., joined by Thomas, J., concurring) (when presented with a statute, pre-emption analysis must focus solely on the text).

Finally, several Justices have sworn off quasi-legislative dalliances akin to those embedded in "obstacle" pre-emption doctrine in the closely related field of implied causes of action. *See Alexander v. Sandoval*, 532 U.S. 275, 287 (2001) ("Having sworn off the habit of venturing beyond Congress's intent,

we will not accept respondents' invitation to have one last drink."); *Correctional Services Corp. v. Malesko*, 534 U.S. 61, 75 (2001) (Scalia, J., joined by Thomas, J., concurring) (implied cause of action doctrine "is a relic of the heady days in which this Court assumed common-law powers to create causes of action."). Thus, the barkeep has already yelled "last call" on legislating from the bench in the guise of enforcing amorphous federal goals, and the Court should reject Petitioners' invitation for one more round.[3]

**B.** In any event, in *Wyeth*, the Court effectively rejected the claim that obstacle pre-emption operates in prescription drug cases, and the Court's most recent decision relied solely and exclusively on an impossibility pre-emption analysis. *Mensing*, 131 S. Ct. at 2577 n. 4 ("We do not address whether state and federal law 'directly conflict' in circumstances beyond 'impossibility'"). The Court should similarly limit its consideration in this case.

The intent of Congress "'is the ultimate touchstone in every pre-emption case.'" *Wyeth*, 555 U.S. at 565 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)). In *Wyeth*, the Court emphasized that Congress is well aware of the existence of state tort litigation involving FDA-approved drugs, and yet Congress has never purported to pre-empt any state law tort claims involving prescription drugs. That state of

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[3] Moreover, the Court of Appeals in this case did not address obstacle pre-emption, and Petitioner's Question Presented in its petition for a writ of certiorari identified the decision below as in conflict with *Mensing*, but *Mensing* is undeniably and solely based on impossibility pre-emption. 131 S. Ct. at 2577 n. 4. Thus, the Court could reject Petitioner's belated efforts to make this an obstacle pre-emption case on procedural as well as substantive grounds.

affairs contrasts sharply with Congress' enactment of an express pre-emption provision regarding medical devices. *See Wyeth*, 555 U.S. at 574 (Congress did not "enact[] such a provision for prescription drugs").

Nor does the fact that this case involves generic prescription drug manufacturers change the analysis or holding of *Wyeth* rejecting "obstacle" pre-emption, because "[t]he Hatch-Waxman amendments [addressing generic drugs] contain no provision expressly pre-empting state tort claims." *Mensing*, 131 S. Ct. at 2577 n. 5. Instead, the congressionally drawn distinction between prescription drugs (brand name or generic) on the one hand, and medical devices on the other, "is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." *Wyeth*, 555 U.S. at 575 (citing *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.") (internal quotation marks omitted)). *See also Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 256 (1984) (the Price-Anderson Act does not pre-empt state tort actions arising from accidents at nuclear facilities because "in enacting and amending the Price-Anderson Act, Congress assumed that state law remedies … were available to those injured by nuclear incidents" even though "there is tension between the conclusion that safety regulation is the exclusive concern of the federal law and the conclusion that a State may nevertheless award damages based on its own law of liability.")

## II. THE COURT APPLIES A "PRESUMPTION AGAINST PRE-EMPTION" IN IMPLIED PRE-EMPTION CASES.

**A.** Petitioner's arguments, and those of its *amici*, seem to start with a presumption *in favor of* pre-emption, which is of course exactly backwards. One of the cornerstones of pre-emption doctrine is that courts presume that Congress does not intend to displace state law, particularly in areas of traditional state concern and where the States traditionally have exercised their police powers: "Consideration under the Supremacy Clause starts with the basic assumption that Congress did not intend to displace state law." *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981); *see also Altria Group, Inc. v. Good*, 555 U.S. 70, 77 (2008) ("When addressing questions of express or implied pre-emption, we begin our analysis 'with the assumption that the historic police powers of the States [are] not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'") (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

The presumption *against* pre-emption arises from the Court's recognition of the fundamental nature of federalism and dual sovereignty under the Constitution. Indeed, the presumption acts to "further the spirit of *Garcia* [*v. San Antonio Metropolitan Transit Auth.*, 469 U.S. 528 (1985)] by requiring that decisions restricting state sovereignty be made in a deliberate manner by Congress, through the explicit exercise of its lawmaking power …." LAURENCE H. TRIBE, AMERICAN CONSTITUTIONAL LAW § 6-28, at 1175-76 (3d ed. 2000). *Cf. Gregory v. Ashcroft*, 501 U.S. 452, 464 (1991).

Although the argument for applying a presumption against pre-emption may be strongest in the context of claims of express pre-emption, the principle also has force in the implied pre-emption context, as the Court has recognized. Indeed, in *Wyeth*, the Court reaffirmed the applicability of the presumption in precisely this context:

> Wyeth argues that the presumption against pre-emption should not apply to this case because the Federal Government has regulated drug labeling for more than a century. That argument misunderstands the principle: We rely on the presumption because respect for the States as "independent sovereigns in our federal system" leads us to assume that "Congress does not cavalierly pre-empt state-law causes of action." The presumption thus accounts for the historic presence of state law but does not rely on the absence of federal regulation.
>
> For its part, the dissent argues that the presumption against pre-emption should not apply to claims of implied conflict pre-emption at all, but this Court has long held to the contrary.

*Wyeth*, 555 U.S. at 565 n. 3.

Recently, four members of the Court reiterated that the danger of a "free-wheeling judicial inquiry into whether a state [law] is in tension with federal objectives," is that it will "undercut the principle that it is the Congress rather than the courts that preempts state law." *Whiting*, 131 S. Ct. at 1985 (2011) (quoting *Gade*, 505 U.S. at 111 (Kennedy, J., concurring)). Thus, the same four Justices endorsed the proposition 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.'" *Id*. (emphasis added) (quoting, *Gade*, 505 U.S. at 110 (Kennedy, J., concurring)).

More to the point, five Justices rejected Petitioner's "no presumption against pre-emption" position in *Mensing*. To be sure, a plurality of the Court discussed the notion that the Supremacy Clause "suggests that courts should not strain to find ways to reconcile federal law with seemingly conflicting state law." *Mensing*, 131 S. Ct. at 2579–80 (plurality opinion). But just as assuredly, Justice Kennedy declined to join that section (III.B.2.) in *Mensing*, *id*. at 2572 n.*, and the four dissenting Justices embraced the traditional presumption against pre-emption. *Id*. at 2589 (Sotomayor, J., dissenting). Because nothing distinguishes this case from *Mensing* or *Whiting* vis-à-vis the presumption against pre-emption, a majority of the Court favors continued application of the venerable rule here.

**B.** In fact, applying the presumption in "impossibility" conflict cases makes perfect sense for several reasons. **First**, state law often provides the only remedy for injured persons, and courts should be particularly reluctant to extinguish the only avenue of relief for potentially catastrophic harm. *Sprietsma v. Mercury Marine*, 537 U.S. 51, 64 (2002); *Bates v. Dow Agrosciences, LLC*, 544 U.S. 431, 449-50 (2005). **Second**, federal statutes and regulations often reflect compromises between those advocating stricter federal standards and those seeking more lenient standards in exchange for not displacing additional state law standards. *Wyeth*, 555 U.S. at 601 (Thomas, J., concurring) ("Federal legislation is often the result of compromise between legislators" and thus "a statute's text might reflect a compromise between parties who wanted to pursue a particular goal to different

extents"). **Third**, Congress might well want additional enforcers on patrol, watching for dangerous drugs, especially given the limited resources and massive responsibilities of federal agencies such as FDA. *Wyeth*, 555 U.S. at 578 (noting FDA's "limited resources to monitor the 11,000 drugs on the market"). **Fourth**, state-law litigation or regulatory action often produce new information about product safety, information that may be of great value and assistance to federal regulators. *Id*., at 579.

These considerations—the multiple rationales for the presumption against pre-emption—apply with force no matter the nature of the claim of pre-emption. If Congress wants a federal regulatory regime to operate exclusive of state regulation, Congress has the power to achieve that goal. But Congress must make its intent clear in order to overcome the presumption; otherwise a court finding pre-emption will be undermining the political accountability of Congress, shielding Congress from potentially unpopular political reaction to overreaching federal schemes.

Thus, before a court concludes that is it impossible for an actor to comply with both federal and state law requirements, the court should give the benefit of the doubt to according state law a place, particularly when state law traditionally has had a significant role in the area at issue. If there is any ambiguity about whether compliance with the laws of both sovereigns is impossible, the presumption favors a conclusion that there is no pre-emption. If Congress disagrees with a court giving state law that benefit of the doubt, Congress can amend the relevant statute(s) to take away the presumption in particular areas. *See Circuit City Stores, Inc. v. Adams*, 532 U.S.

105, 120 (2001) ("It is for the Congress, not the courts, to consult political forces and then decide how best to resolve conflicts in the course of writing the objective embodiments of law we know as statutes.") (Kennedy, J.).

## III. THE HATCH-WAXMAN AMENDMENTS DO NOT PRE-EMPT THE TRUE DESIGN DEFECT CLAIMS AT ISSUE HERE.

Turning to this case, the bottom line is inescapable: The Hatch-Waxman Amendments do not pre-empt design defect claims against the manufacturers of generic prescription drugs.

Unlike the narrower inadequate warning claim which effectively assumes that the plaintiff would have no claim if additional or different warnings been given, a design defect claim in some states may starkly present the all-or-nothing choice for a defendant to, as Petitioner puts it, "stop selling" the offending and harmful product if it wants to avoid the prospect of liability. That notion is neither new nor unusual in the context of common law tort principles. Could the producers (brand name or generic) of the anti-miscarriage drug commonly known as DES, *see, e.g.*, *Sindell v. Abbott Laboratories*, 26 Cal.3d 588, 607 P.2d 924 (1980), have avoided all liability simply by including more detailed warnings on their product? The answer is no, because there is a well-established tort law distinction between a design defect claim and an inadequate warning claim.

"Impossibility pre-emption is a demanding defense." *Wyeth*, 555 U.S. at 573. "The question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it." *Mensing*, 131 S. Ct. at 2579; *see also*

*Wyeth*, 555 U.S. at 588 (Thomas, J., concurring) ("Pre-emption must turn on whether state law conflicts with the text of the relevant federal statute or with the federal regulations authorized by the text"); *Mensing*, at 2582 (Sotomayor, J., dissenting) ("We have traditionally held defendants claiming impossibility to a demanding standard"), 2587 ("a defendant seeking to set aside state law bears the burden to prove impossibility"). Nothing in the jury's finding on the record in this case that the risks of Petitioner's drug outweigh its benefits requires Petitioner to violate federal law. Nor does Petitioner need "the Federal Government's special permission and assistance," *id*. at 2581, in order to comply with state law.

In *Mensing*, by contrast, if the warnings were inadequate, the defendant there could not change or add to the warnings without violating federal law. In the context of a claim based on the sale of a product that is unreasonably dangerous because its risks outweigh its benefits, the drug company may not be able to change the design or composition of the drug, but the feasibility of an "alternative design" is not the only measure of liability under traditional state law on design defects. Rather, as the Restatement recognizes, even drugs that cannot be designed in any different, safer way, may still result in liability for the manufacture if the drug remains unreasonably dangerous or defective in light of the relevant circumstances, as explained in Part IV below. Only "[w]here state and federal law 'directly conflict'" must state law "give way." *Mensing*, 131 S. Ct. at 2577 (quoting *Wyeth*, 555 U.S. at 583 (Thomas, J., concurring)).

Furthermore, the touchstone of pre-emption is the intent of Congress, but there is no evidence of congressional intent to pre-empt design defect claims:

"The Hatch-Waxman Amendments contain no provision expressly pre-empting state tort claims." *Mensing*, 131 S. Ct. at 2577 n. 5. Further, as the Court recognized in *Williamson*, 131 S. Ct. at 1139, it is wrong to "treat all [] federal standards as if they were maximum standards, eliminating the possibility that the federal agency seeks only to set forth a minimum standard potentially supplemented through state tort law." *Id*. In fact, "[f]ood and drugs are regulated heavily, but with no obvious preemptive intent." DAN DOBBS, THE LAW OF TORTS at 1036 (2000).

Here, Respondent is not asking the Court to "distort federal law to accommodate conflicting state law," *Mensing*, 131 S. Ct. at 2580, because there is no conflicting state law. "Indeed, in protecting our constitutional government, 'the preservation of the States, and the maintenance of their governments, are as much within the design and care of the Constitution as the preservation of the Union and the maintenance of the National government." *Wyeth,* 555 U.S. at 585 (Thomas, J., concurring) (quoting *Texas v. White*, 74 U.S. (7 Wall.) 700, 725 (1869)).

Despite Petitioner's protestations against a "stop-selling" rule, as respondent explains, New Hampshire's law of strict products liability requires only that petitioner compensate respondent for her injuries. *See* Resp. Br. 18-23. Moreover, the notion that state law might impose liability on one who sells an unreasonably dangerous product is far from radical. Traditional state tort law takes the position that, in some instances, the proper option for a product manufacturer that does not want to incur liability for selling an unreasonably dangerous product is to stop selling the product, not just to include or expand a

warning label, or to try redesigning the product. According to the Third Restatement, "[s]ome courts, for example, while recognizing that in most cases involving defective design the plaintiff must prove the availability of a reasonable alternative design, also observe that such proof is not necessary in every case involving design defects." RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2, comment b (1997).

Thus, some states, including New Hampshire, hold that manufacturers of unreasonably dangerous products may have to choose between paying damages for the harm caused or removing the product from the market, *i.e.*, not to sell it at all, because there may not be any alternative design that makes the product reasonably safe. *See, e.g.*, *Vautour v. Body Masters Sports Indus., Inc.*, 784 A.2d 1178, 1183 (N.H. 2001) ("while proof of an alternative design is relevant in a design defect case, it should be neither a controlling factor nor an essential element that must be proved in every case"), *id.* at 1184 ("the rigid prerequisite of a reasonable alternative design places too much emphasis on one of many possible factors that could potentially affect the risk-utility analysis"); *O'Brien v. Muskin Corp.*, 463 A.2d 298, 306 (N.J. 1983) ("even if there are no alternative methods of making bottoms for above-ground pools, the jury might have found that the risk posed by the pool outweighed the utility."); *Potter v. Chicago Pneumatic Tool Co.*, 694 A.2d 1319, 1327-1336 (Conn. 1997) (alternative design is only one factor to be considered, not a requirement for liability); *McCarthy v. Olin Corp.*, 119 F.3d 148, 155 (2d Cir. 1997) (applying New York law and concluding that "the risk of injury to be balanced with the utility is a risk not intended as the primary function of the product. There is no reason to search for

an alternative safer design where the product's sole utility is to kill and maim").

Traditional state tort law, then, may find that some products, given their inherent qualities, are so dangerous that the risks of harm to users substantially outweigh any benefits to the public. That notion is not novel in state tort law. Nor has Congress even remotely expressed intent to pre-empt state laws that give effect to that tradition. *Cf. Bruesewitz v. Wyeth*, 131 S. Ct. 1068, 1080 (2011) (noting the Court's previously expressed "doubt that Congress would quietly pre-empt product-liability claims without providing a federal substitute"); *United States v. Locke*, 529 U.S. 89, 108 (2000) (courts should be particularly reluctant to find implied pre-emption with regard to "medical negligence," a state liability area much like products liability, because it is "a subject historically regulated by the States"). This Court should not use the theory of impossibility pre-emption to do what Congress has declined to do.

Ultimately, nothing in federal law requires Petitioner to sell any particular generic drug, so it is not impossible for Petitioner to comply with both federal and state law here, even assuming that state law indicates that selling the drug at all is unwarranted under tort principles. To stop sales of the drug will not violate federal law, but to keep selling it may well violate state law, and certainly may result in serious harm to some users of the drug. In other words, in a design defect case, state law does not impose any affirmative duty on a drug manufacturer that federal law prohibits the manufacturer from fulfilling. That simple fact distinguishes this case from *Mensing*, and supports application of the general rule of *Wyeth* that state law tort claims are not pre-empted here.

## IV. PETITIONER CONFLATES DESIGN DEFECT AND INADEQUATE WARNING CLAIMS, CONTRARY TO FUNDAMENTAL TORT LAW PRINCIPLES.

Petitioner and its *amici* seem to recognize that *Mensing* does not apply to a true design defect claim, so they float the ruse that design defect and inadequate warning doctrines are really the same. In so doing, they rely heavily on *Kurns v. Railroad Friction Prod. Corp.*, 132 S. Ct. 1261 (2012), for the erroneous proposition that such claims are interchangeable in determining whether FDA regulation pre-empts state law tort claims. Their argument is fundamentally wrong, both as a matter of substantive tort law and because *Kurns* involved field pre-emption, not impossibility pre-emption.

### A. Tort Law Distinguishes Between Manufacturing, Design and Warning Defect Claims.

Traditional tort law originally based liability for harm caused by products on theories of negligence and implied warranty. DOBBS, at §§ 352-353; DAN DOBBS, ET AL., PROSSER AND KEETON ON TORTS §§ 95A-96 (5th ed. 1984). But since at least the 1960s, the common law and the Second Restatement of Torts have recognized three distinct theories for products liability in addition to traditional negligence claims: (1) manufacturing defects, (2) design defects, and (3) inadequate warnings. DOBBS, at 975 and n. 12; PROSSER, at § 97. In this case, it is important to recognize the distinction between design defect and inadequate warning claims.

Unlike both *Wyeth* and *Mensing*, both of which involved much narrower inadequate warning claims,

this case involves the issue whether federal law pre-empts the more general *design defect* claims. As the Court of Appeals here posited, the distinction between these claims is clear and of legal significance in a case involving a claim of implied *impossibility* pre-emption, not *field* pre-emption.

Field pre-emption – the claim at issue in *Kurns* – necessarily is concerned with *any* tort claim that touches upon the general area of law in which Congress has allegedly pre-empted state regulation. Impossibility pre-emption, in stark contrast, depends critically on the precise nature of the underlying state tort duty; only by comparing the state-law duty under each basis for potential liability and the options available to comply with both federal and state law can a court determine whether simultaneous compliance is "impossible."

Petitioner and its *amici* appear to proceed from the premise that all tort law claims for liability caused by prescription drugs are the same, or at least interchangeable, for pre-emption purposes. Such an assertion fundamentally misstates general tort law products liability principles, and if accepted likely would lead a court to engage in a blunderbuss field pre-emption analysis rather than the carefully nuanced impossibility analysis this Court in fact has applied to such claims. A broad legal immunity from state tort liability may well be the goal of Petitioner and its *amici*, but that goal would be more appropriately sought in Congress if at all, not in this Court in the guise of implied pre-emption analysis.

1. *The Restatement (Second) of Torts Section 402A Recognized Three Distinct Theories.*

Originally, products liability claims were evaluated as negligence or implied warranty claims, with im-

portant limiting doctrines (like "privity" between the seller and the person harmed) that restricted liability. DOBBS, at §§ 352-53. But around 1960, some state courts began applying a broader notion of liability for harm caused by products, what some termed "strict" liability. *Id.* at § 353. That shift in conceptualization gained considerable momentum when "Dean Prosser, drafting the Restatement Second of Torts, picked up [that] idea and incorporated it in a new section, § 402A." *Id.* at 974.

"Section 402A provided that if a product was defective and the defect caused harm, liability would be imposed upon the manufacturer and distributors, *whether or not they were at fault* and whether or not they were in privity with the plaintiff." DOBBS, at 974-75 (emphasis added). Section 402A proved to be very influential in the state courts, which "widely adopted § 402A and regarded it as their guide, philosopher, and friend." *Id.* at 975. Importantly for the pre-emption issue in this case, "[a]fter the promulgation of § 402A, courts and writers began to think that three types of product defect should be distinguished from one another. These were (1) manufacturing defects or production flaws, (2) design defects, and (3) information or warning defects, also called 'marketing defects.'" *Id.* "These categories are now generally recognized." *Id.* at n. 12. *Cf.*, PROSSER at 695 (identifying the same three categories).

When evaluating a design defect claim under the Second Restatement, courts "generally adopted a risk-utility test to determine whether a harmful design is also a defective design." DOBBS, at 980-81. The more recent Products Liability Restatement (discussed in the next subsection) "adopts the risk-utility test of defectiveness." *Id.* at 981, 985.

It is true that the Restatement Second's Comment k provided an exception to the rule of strict liability "for unavoidably dangerous products if a proper warning was given." DOBBS, at 989. But the Second Restatement did not thereby convert all design defect claims into inadequate warning claims as Petitioner and its *amici* effectively claim. Rather, the two claims remained largely distinct and separate, with inadequate warning claims well-recognized as a much narrower category than design defects. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 1, Comment a, n.1.

2. *The Products Liability Restatement Expressly Recognizes The Same Three Distinct Theories for Liability for Prescription Drugs.*

As a general matter, the Third Restatement, explains that "'strict products liability' is a term of art that reflects the judgment that products liability is a discrete area of tort law which borrows from both negligence and warranty. It is not fully congruent with classical tort or contract law." § 1, comment a. The Restatement goes on to identify and define the three now familiar rationales for liability: a product is "defective" if it has "a manufacturing defect, is defective in design, or is defective because of inadequate instructions." RESTATEMENT (THIRD) OF TORTS § 2. Necessarily, allegations of design defect and warning defect require "[s]ome sort of independent assessment of advantages and disadvantages, to which some attach the label 'risk-utility balancing' …." *Id.*, cmt. a.

In addition to recognizing that design defect law in some states may impose liability regardless of the availability of an alternative design, the Third Restatement, in section 6, recognizes that possibility in

a section that addresses liability for "Prescription Drugs and Medical Devices" in particular. Section 6, like Section 2, identifies the three familiar categories of "defect" in prescription drugs. See § 6. Subsection 6(c) specifically addresses design defect claims:

> (c) A prescription drug or medical device is not reasonably safe due to defective design if the foreseeable risks of harm posed by the drug or medical device are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for any class of patients.

§ 6(c). *See also id.* at § 6(d) (providing a detailed definition of inadequate warnings). Notably, §6(c) nowhere suggests that a plaintiff is required to prove that a defendant manufacturer had available a reasonable alternative design.

The comments to § 6 are very instructive with respect to pre-emption as well. For instance, the Restatement acknowledges that prescription drugs are subject to federal regulation, but strongly cautions that "unqualified deference to these regulatory mechanisms is considered by a growing number of courts to be unjustified. An approved prescription drug or medical device can present significant risks without corresponding advantages." *Id.* at § 6, cmt. b.

The Restatement unmistakably adopts the position that, although the standard for establishing design defect liability for a prescription drug may be rigorous, the liability standard is analytically distinct from the questions whether government regulation immunizes a manufacturer from such liability or whether federal law pre-empts such state law tort

claims altogether. Put another way, § 6(c) sets a general liability standard for prescription drugs, while § 4 (discussed in Part IV.A.3. below) creates a possible "affirmative defense" available to manufacturers. But the question of federal pre-emption of state tort law is yet a separate question from either of these substantive tort law questions.

In sum, the Second and Third Restatements both expressly recognize the familiar distinction between design defect and inadequate warning claims multiple times. Indeed, the Restatements plainly explain that design defect and failure-to-warn claims rely on *different* facts and *distinct legal concepts*. Moreover, the Restatements make clear that warnings are not a legal substitute for providing a reasonably safe product, because an inadequate warning claim takes the product's underlying design as a given, and asks if the product could have been used safely with proper warnings. A design defect claim, by contrast, asks whether the product is unreasonably dangerous, applying a risk-utility analysis. DOBBS, at §§ 357-361; see *supra*, at 17-18.

Thus, it would be wrong as a matter of substantive tort law to assert that in general a design defect claim "reflects a duty to alter FDA-approved labeling deemed inadequate." U.S. Br. at 12. As the United States recognizes, traditional design defect claims do not hinge on the "adequacy of labeling," *id*., and even the United States admits that "whether the FDCA would preempt" true design defect claims is a more "difficult and close" question than possible pre-emption of inadequate warning claims. *Id.*

*3. Compliance with Government Regulations is at Most an Affirmative Defense, Not a Basis for Pre-Emption-Based Immunity.*

Longstanding tort law could not be plainer in adopting the position that a defendant's compliance with statutory or regulatory safety regulations does not create legal immunity from harm caused by dangerous products. The Third Restatement § 4 makes clear that "a product's noncompliance with" such safety standards "renders the productive defective with respect to the risks sought to be reduced by the" standard. § 4(a). *Cf.* DOBBS, at 1033-34 ("Under the common law, the defendant's compliance with a statute is not in itself a defense to a negligence action." * * * The common law rule in products cases is the same—evidence of compliance with statute or regulation is relevant to judgments about the product's alleged [] defects and hence admissible but not by any means conclusive.").

Not surprisingly then, the Third Restatement, § 4(b), summarizes the traditional rule, uniformly embraced in the States, that "a product's compliance with an applicable product safety statute or administrative regulation is properly considered in determining whether the product is defective with respect to the risks sought to be reduced by the statute or regulation, *but such compliance does not preclude as a matter of law a finding of product defect*." (emphasis added). That foundational tort law principle is readily explained by the common law's view that safety regulations at most create a *floor* for the conduct and care expected of defendants, not a *ceiling*. DOBBS, at 1034. "In addition, even if legislatures and regulatory agencies are not 'captured' by the industries they regulate, statutes and regulations may reflect the heavy influence of the regulated industry as much as judicious concerns with safety." *Id.*

In a related and important principle applicable in this case, the Restatement cautions that the "doctrine of preemption based on supremacy of federal law should be distinguished from the proposition that compliance with statutory and regulatory standards satisfies the state's requirement for product safety." RESTATEMENT (THIRD) OF TORTS, at § 6, cmt. b. In other words, traditional tort law expressly rejects the proposition that compliance with federal regulation, such as FDA regulation of prescription drugs, as a matter of law equates with either (1) federal pre-emption of longstanding state tort law or (2) a tacit legal immunity from potential state tort liability. *Cf. Williamson*, 131 S. Ct. at 1139 (it is wrong to "treat all [] federal standards as if they were maximum standards, eliminating the possibility that the federal agency seeks only to set forth a minimum standard potentially supplemented through state tort law.").

Petitioner and its *amici*, however, effectively argue in favor of just such a proposition, a notion that the States' traditional tort law and this Court's pre-emption cases reject. Importantly, "[f]ederal lawmaking culture is oriented to regulation, not to private tort rights. Only a few federal statutes create private tort claims for personal injury. In many instances when state tort rights are displaced, no new comparable federal tort right is substituted." DOBBS, at 1035. Instead, "the manufacturer is subjected to regulation without being subjected to liability," *id.*, a truly unjustified windfall.

### B. Unlike this Case, *Kurns* Involved Field Pre-emption.

Petitioner's reliance upon *Kurns* not only errs as a matter of tort law but also hits a sour note in terms

of pre-emption doctrine. The substantive differences between design defect and inadequate warning claims was not determinative in *Kurns* because that case involved *only* a claim of field pre-emption. *See* 132 S. Ct. at 1266 ("We deal here only with the latter [type of pre-emption], so-called field pre-emption."). Thus, in *Kurns* it did not matter whether the claim was for design defects or inadequate warnings because, in either event, such claims were "directed at the equipment of locomotives," and within the "field" that Congress preempted. 132 S. Ct. at 1268.

In the context of prescription drugs, however, there is no claim to *field* pre-emption. Instead, under impossibility pre-emption analysis, the difference between the rationales for state tort liability may make all the difference. Furthermore, the Court in *Kurns* analyzed the products at issue — locomotive brakeshoes and boilers that contained asbestos insulation — under the Third Restatement's general products liability provision, §2(c), not under the specific provision for prescription drugs, §6, the latter of which emphasizes in the very context of this case the distinction between design defects and inadequate warning claims.

At the end of the day, there is no denying that design defect and inadequate warning claims are fundamentally different claims. As three Justices correctly observed in *Kurns*, "failure-to-warn claims proceed on a fundamentally different theory of tort liability [than design defect claims] that does not implicate a product's physical composition at all." 132 S. Ct. at 1272. Indeed, as was true in *Kurns*, in most if not all States, design defect and failure to warn are "'distinct cause[s] of action under the theory of strict

products liability.'" *Id.* (quoting *Riley v. American Honda Motor Co.*, 856 P.2d 196, 198 (Mont. 1993)).

Most importantly, in *Wyeth* the Court expressly recognized the difference, observing "that a failure-to-warn claim is 'narrower' than a claim that alleges a defect in the underlying product." *Kurns*, at 1273 (quoting *Wyeth*, 555 U.S. at 565). Indeed, in conducting its impossibility pre-emption analysis in *Wyeth*, the Court expressly distinguished between design defect and failure to warn claims. 555 U.S. at 565. The fact that *Kurns* found both design defect and failure-to-warn claims subject to field pre-emption in the context of that case in no way demonstrates that such claims are substantively identical. To the contrary, it could not be clearer that design defect and inadequate warning claims are distinct, as the Court expressly and correctly recognized in *Wyeth*.

## V. DISMISSAL AS IMPROVIDENTLY GRANTED OR CERTIFICATION TO THE NEW HAMPSHIRE SUPREME COURT MAY BE WARRANTED HERE.

There is considerable argument in the parties' and the *amici curiae* briefs about exactly what New Hampshire law requires in order to establish tort liability for a prescription drug that causes harm. Moreover, the Solicitor General takes the position that New Hampshire law is in fact idiosyncratic so that this case does not actually present a "design defect" claim. U.S. Br. at 13. If the Court sees New Hampshire law as the Petitioner and its *amici* suggest, then the better course for the Court may be not to decide this case at all. *Cf. United States v. Shannon*, 342 U.S. 288, 294-95 (1952) (Frankfurter, J.) (the Court should dismiss because it became mani-

fest after argument that the cases "were legal sports. Neither is likely to recur; both are individualized instances…."); *New York v. Uplinger*, 467 U.S. 246, 249 n. 2 (1984) (*per curiam*) (dismissing in part because of uncertainty and confusion about underlying New York law); *Rescue Army v. Municipal Court*, 331 U.S. 549, 575 (1947) (dismissing where federal issue was presented "in highly abstract form" without the benefit of refinement of the relevant state law).[4]

At a minimum, the Court might consider seeking a definitive statement of New Hampshire law before deciding the pre-emption question. New Hampshire, like most states, permits certification. N.H. Sup. Ct. R. 34 ("This court may answer questions of law certified to it by the Supreme Court of the United States"). If the Court were to decide that the precise contours of New Hampshire tort law are determinative, or even very important, in deciding this case, then certification of those state law questions to the court with the authority to definitively answer them may be proper.

Certification can save "time, energy, and resources and helps build a cooperative judicial federalism." *Lehman Bros. v. Schein*, 416 U.S. 386, 391 (1974); *see also Arizonans for Official English v. Arizona*, 520 U.S. 43, 76 (1997) (certification "allows a federal court faced with a novel state-law question to put the question directly to the state's highest court, reducing the delay, cutting the cost, and increasing the assurance of gaining an authoritative response"); *cf.*

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[4] Further undermining the potential desirability of deciding this case is the recent representation of the United States that the "FDA is considering a regulatory change that *** [if] adopted, [] could eliminate preemption of failure-to-warn claims against generic-drug manufacturers." U.S. Br. at 15 n. 2.

*Employment Div. v. Smith*, 485 U.S. 660 (1988) (remanding to state court to answer question whether peyote use violated state law). The Court should be wary of trusting Petitioner's assertions about the bottom line of New Hampshire tort law; instead, the most reliable interpretation of New Hampshire tort law can only be given by that state's supreme court. Thus, this may be one of those infrequent cases in which certification by this Court of a crucial state law question is appropriate.

## CONCLUSION

The judgment of the court of appeals should be affirmed.

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