No. 12-142

IN THE
Supreme Court of the United States

MUTUAL PHARMACEUTICAL COMPANY, INC.,
Petitioner,

v.

KAREN L. BARTLETT,
Respondent.

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

BRIEF FOR RESPONDENT IN OPPOSITION

STEVEN M. GORDON
CHRISTINE M. CRAIG
SHAHEEN & GORDON
107 Storrs Street
Concord, NH 03302
(603) 749-5000

KEITH M. JENSEN
Counsel of Record
JENSEN & ASSOCIATES, PLLC
1024 N. Main Street
Fort Worth, Texas 76164
(817) 334-0762
(kj@kjensenlaw.com)

Counsel for Respondent

October 31, 2012

QUESTION PRESENTED

Whether this Court should grant certiorari to review the First Circuit's conclusion that federal law does not preempt respondent's strict products liability claim seeking compensation for severe injuries resulting from use of a generic pain medication manufactured by petitioner, where the First Circuit's decision does not conflict with any decision of this Court or of any other court of appeals.

TABLE OF CONTENTS

Page

QUESTION PRESENTED i

TABLE OF AUTHORITIES iv

STATEMENT 2

REASONS FOR DENYING THE PETITION 7

I. THE PETITION FAILS TO JUSTIFY THIS COURT'S INTERVENTION 7

A. There Is No Circuit Conflict 7

B. The Petition Provides No Basis For Granting Review In The Absence Of A Circuit Conflict 12

1. The petition does not present a question of recurring national importance 12

2. Sulindac is not an essential drug, and petitioner presented no contrary evidence 15

3. The district court cases cited by petitioner do not justify this Court's review 16

C. Petitioner Has Not Demonstrated The Suitability Of This Case As A Vehicle To Decide The Question Presented 19

II. THE COURT OF APPEALS' DECISION IS CORRECT AND DOES NOT CONFLICT WITH *PLIVA* 20

A. The Court Of Appeals Correctly Concluded That Compliance With Federal And State Law Is Not Impossible In This Case 21

1. New Hampshire law imposes strict, but not automatic, liability on sellers of unreasonably dangerous products 21

2. Nothing in federal law precluded petitioner from complying with New Hampshire law 23

B. The Court Of Appeals' Decision Does Not Conflict With This Court's Decision In *PLIVA* 24

1. There is no conflict between this case and *PLIVA* because *PLIVA* involved a different state-law duty 24

2. New Hampshire law did not require petitioner to perform any act that federal law prohibits 25

C. Petitioner's Other Criticisms Of The First Circuit's Decision Lack Merit 27

D. Petitioner's Position Depends On A Mischaracterization Of New Hampshire Law 29

1. New Hampshire law does not require petitioner to change the design of its drug 29

2. Design-defect and failure-to-warn claims are distinct under New Hampshire law 29

3. Petitioner's waiver of its comment k defense precluded the jury from finding liability based on an inadequate warning 31

CONCLUSION 32

TABLE OF AUTHORITIES

Page

CASES

Aucoin v. Amneal Pharm., LLC, Civil Action No. 11-1275, 2012 WL 2990697 (E.D. La. July 20, 2012) 16, 17, 18, 19

Bellotte v. Zayre Corp., 352 A.2d 723 (N.H. 1976).....22

Brockert v. Wyeth Pharm. Inc., 287 S.W.3d 760 (Tex. App. 2009)..... 18

Brown v. Superior Court, 751 P.2d 470 (Cal. 1988)..... 12

Cipollone v. Liggett Group, Inc., 505 U.S. 504 (1992) 28

Darvocet, Darvon & Propoxyphene Prods. Liab. Litig., In re, No. 2:11-md-2226-DCR, 2012 WL 718618 (E.D. Ky. Mar. 5, 2012)..... 16

Demahy v. Actavis, Inc.:

593 F.3d 428 (5th Cir. 2010), *rev'd sub nom. PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) 11

650 F.3d 1045 (5th Cir. 2011) 11

Demahy v. Wyeth Inc.:

586 F. Supp. 2d 642 (E.D. La. 2008), *aff'd sub nom. Demahy v. Actavis, Inc.*, 593 F.3d 428 (5th Cir. 2010), *rev'd sub nom. PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) 10-11

No. 08-CV-3616 (E.D. La. Nov. 14, 2008)..... 11

Eckhardt v. Qualitest Pharm. Inc., 858 F. Supp. 2d 792 (S.D. Tex. 2012)..... 13-14, 16, 18, 19

Edwards v. Basel Pharm., 933 P.2d 298 (Okla. 1997) 12

Ferebee v. Chevron Chem. Co., 736 F.2d 1529 (D.C. Cir. 1984) 28

Fernandez v. Chardon, 681 F.2d 42 (1st Cir. 1982), *aff'd sub nom. Chardon v. Fumero Soto*, 462 U.S. 650 (1983) 27

Fisher v. Pelstring, 817 F. Supp. 2d 791 (D.S.C. 2011) 14

Fosamax (Alendronate Sodium) Prods. Liab. Litg. (No. II), *In re*, Civil No. 08-008, 2011 WL 5903623 (D.N.J. Nov. 21, 2011) 16, 18

Fullington v. PLIVA, Inc., No. 4:10CV00236 JLH, 2011 WL 6153608 (E.D. Ark. Dec. 12, 2011) 17

Gaeta v. Perrigo Pharm. Co.:

562 F. Supp. 2d 1091 (N.D. Cal. 2008), *rev'd and remanded*, 630 F.3d 1225 (9th Cir.), *vacated and remanded sub nom. L. Perrigo Co. v. Gaeta*, 132 S. Ct. 497 (2011) 8, 9

No. C 05-04115 JW (N.D. Cal. July 25, 2008) 8

No. C 05-04115 JW (N.D. Cal. Dec. 15, 2008) 8

672 F. Supp. 2d 1017 (N.D. Cal. 2009) 8

630 F.3d 1225 (9th Cir.), *vacated and remanded sub nom. L. Perrigo Co. v. Gaeta*, 132 S. Ct. 497 (2011) 8

469 F. App'x 556 (9th Cir. 2012) 9

Geier v. American Honda Motor Co., 529 U.S. 861 (2000) 28, 29

Gross v. Pfizer, Inc., 825 F. Supp. 2d 654 (D. Md. 2011) 12, 16, 17

Hahn v. Richter, 673 A.2d 888 (Pa. 1996)..... 12

Hurley v. Lederle Lab. Div. of Am. Cyanamid Co., 863 F.2d 1173 (5th Cir. 1988)..... 7

Johnson v. Teva Pharm. USA Inc., No. 2:10 CV 404, 2012 WL 1866839 (W.D. La. May 21, 2012).....16, 18, 19

Kelleher v. Marvin Lumber & Cedar Co., 891 A.2d 477 (N.H. 2005) 3, 22, 29

Kurns v. Railroad Friction Prods. Corp., 132 S. Ct. 1261 (2012)..... 30

L. Perrigo Co. v. Gaeta, 132 S. Ct. 497 (2011) 9

LeBlanc v. American Honda Motor Co., 688 A.2d 556 (N.H. 1997) 30

Lyman v. Pfizer, Inc., No. 2:09-cv-262, 2012 WL 368675 (D. Vt. Feb. 3, 2012).....16, 17, 18

Martin v. Hacker, 628 N.E.2d 1308 (N.Y. 1993)..... 12

Mason v. SmithKline Beecham Corp., 596 F.3d 387 (7th Cir. 2010)..... 7

Mensing v. Wyeth, Inc.:

562 F. Supp. 2d 1056 (D. Minn. 2008), *aff'd in part, rev'd in part*, 588 F.3d 603 (8th Cir. 2009), *rev'd sub nom. PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) 10

588 F.3d 603 (8th Cir. 2009) 10, 26

658 F.3d 867 (8th Cir. 2011) 11

No. 08-3850 (8th Cir. Sept. 29, 2011) 11

Morris v. Wyeth, Inc.:

No. 1:07-CV-176-R (W.D. Ky. Oct. 24, 2008), *aff'd*, 657 F.3d 420 (6th Cir. 2011) 9

No. 1:07-CV-176-R (W.D. Ky. Feb. 20, 2009) 9

No. 1:07-CV-176-R (W.D. Ky. Feb. 23, 2009) 9

No. 1:07-CV-176-R (W.D. Ky. Mar. 20, 2009) 10

Napier v. Atlantic Coast Line R.R. Co., 272 U.S. 605 (1926) 30

Pamidronate Prods. Liab. Litig., *In re*, 842 F. Supp. 2d 479 (E.D.N.Y. 2012) 16, 17, 18

PLIVA, Inc. v. Mensing:

131 S. Ct. 2567 (2011) 1, 6, 7, 8, 9, 10, 11, 16, 17, 20, 21, 24, 25, 26, 27, 28, 31, 32

132 S. Ct. 55 (2011) 27

Price v. BIC Corp., 702 A.2d 330 (N.H. 1997)..... 22

Propper v. Clark, 337 U.S. 472 (1949) 32

Riegel v. Medtronic, Inc., 552 U.S. 312 (2008)..... 7, 28

Schaerrer v. Stewart's Plaza Pharmacy, Inc., 79 P.3d 922 (Utah 2003)..... 12

Smith v. Wyeth, Inc.:

No. 5:07-CV-18-R, 2008 WL 4697002 (W.D. Ky. Oct. 24, 2008), *aff'd*, 657 F.3d 420 (6th Cir. 2011), *cert. denied*, 132 S. Ct. 2103 (2012) 9

No. 5:07-CV-18-R, 2009 WL 425032 (W.D. Ky. Feb. 20, 2009)..... 9

657 F.3d 420 (6th Cir. 2011), *cert. denied*, 132 S. Ct. 2103 (2012) 10

Sprietsma v. Mercury Marine, 537 U.S. 51 (2002) 20-21

Stevens v. PLIVA, Inc., Civil No. 6:10-0886, 2011 WL 6224569 (W.D. La. Nov. 15, 2011), *report and recommendation adopted*, 2011 WL 6224556 (W.D. La. Dec. 2, 2011) 16, 18

Tatum v. Schering Corp., 795 F.2d 925 (11th Cir. 1986) 12

Thibault v. Sears, Roebuck & Co., 395 A.2d 843 (N.H. 1978)..... 21

Tobin v. Astra Pharm. Prods., Inc., 993 F.2d 528 (6th Cir. 1993)..... 7

United States v. Mendoza, 464 U.S. 154 (1984)..... 12

Vautour v. Body Masters Sports Indus., Inc., 784 A.2d 1178 (N.H. 2001) 22, 23, 30

Wilson v. PLIVA, Inc.:

No. 3:07-CV-378-R (W.D. Ky. Feb. 20, 2009) 9

No. 3:07-CV-378-R (W.D. Ky. Mar. 20, 2009)..... 9

Wilson v. Wyeth, Inc.:

No. 3:07-CV-378-R (W.D. Ky. Oct. 24, 2008), *aff'd*, 657 F.3d 420 (6th Cir. 2011), *cert. denied*, 132 S. Ct. 2103 (2012) 9

No. 3:07-CV-378-R (W.D. Ky. Feb. 20, 2009) 9

Wimbush v. Wyeth, 619 F.3d 632 (6th Cir. 2010)..... 12

Wyeth v. Levine, 555 U.S. 555 (2009) 6, 7, 8, 21, 28, 32

STATUTES AND REGULATIONS

Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* 20

Hatch-Waxman Amendments, Pub. L. No. 98-417, 98 Stat. 1585..... 20

Locomotive Inspection Act, 49 U.S.C. § 20701 *et seq.* 30

La. Rev. Stat. Ann. § 9:2800.56..... 13

21 C.F.R. § 314.81(b)(3)(iii)(1) 23

21 C.F.R. § 314.150(c) 23

OTHER MATERIALS

Br. for Resps. Gladys Mensing and Julie Demahy, *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) (Nos. 09-993 et al.) (filed Feb. 23, 2011)..... 26

Br. of Appellee Julie Demahy, *Demahy v. Actavis, Inc.*, 593 F.3d 428 (5th Cir. 2010) (No. 08-31204) (filed Mar. 30, 2009) 11

5 Louis R. Frumer & Melvin I. Friedman, *Products Liability* (2012).....13, 14

W. Page Keeton et al., *Prosser and Keeton on the Law of Torts* (5th ed. 1984) 22

Restatement (Second) of Torts (1965).....3, 4, 12, 13, 14, 19, 21, 22, 29

Restatement (Third) of Torts: Products Liability (1998) 12, 13, 14

The petition erroneously attempts to depict the court of appeals' decision as having blatantly departed from this Court's holding in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011). In *PLIVA*, this Court held that federal law preempted state tort suits premised on the alleged failure of manufacturers of a generic drug to warn patients about one of that drug's side effects. The Court concluded that federal law prohibited the manufacturers from providing warnings different from those approved for the corresponding brand-name medication. Because it therefore would have been *impossible* for the manufacturers to comply with a state-law duty to provide an additional warning, the state-law claims were preempted.

In this case, respondent Karen Bartlett suffered grievous injuries after taking sulindac, a generic pain medication manufactured by petitioner. The district court dismissed Ms. Bartlett's failure-to-warn claim before trial, and her suit against petitioner was tried to a jury on one theory: that sulindac was unreasonably dangerous because its risks outweighed its benefits. The jury found liability, and the First Circuit affirmed. In response to petitioner's argument that Ms. Bartlett's state-law claim is preempted under *PLIVA*, the court of appeals explained that, unlike in *PLIVA*, compliance with both federal and state law is not *impossible* here because New Hampshire law does not require petitioner to take any action that federal law prohibits.

Petitioner fails to show that the First Circuit's decision created a circuit conflict, and its arguments that the court of appeals erred or departed from *PLIVA* lack merit. Petitioner's disagreement with the First Circuit principally concerns the proper interpretation of New Hampshire law – a dispute that in all events does not warrant this Court's review.

STATEMENT

1. This case "arises out of severe and permanent injuries sustained by plaintiff Karen Bartlett after taking sulindac, a generic non-steroidal anti-inflammatory drug ('NSAID') manufactured by" petitioner. App. 3a. Sulindac "is known to cause" a condition called "Stevens-Johnson Syndrome and its more generic cousin toxic epidermal necrolysis ('SJS/TEN')." *Id.* SJS/TEN is a severe allergic reaction characterized by extensive loss of skin. Sulindac "is a recognized cause of SJS/TEN – potentially a leader among NSAIDs in that respect – and the drug carries other risks as well." App. 23a.

In December 2004, Ms. Bartlett visited her doctor complaining of shoulder pain. Ms. Bartlett's physician prescribed sulindac "under the brand-name Clinoril made by the original provider, and her pharmacist dispensed generic sulindac" manufactured by petitioner. App. 3a; *see* App. 32a.

"The consequences were," in the First Circuit's words, "disastrous." App. 3a. In early 2005, Ms. Bartlett developed SJS/TEN. *Id.* "TEN is diagnosed when 30 percent or more of the outer skin layer on a patient's total body surface area has deteriorated, been burned off or turned into an open wound." *Id.* In Ms. Bartlett's case, "the percentage rose to 60-65 percent of her body." *Id.*

The First Circuit characterized Ms. Bartlett's injuries as "truly horrific," and her burn surgeon "described the experience as 'hell on earth.'" App. 22a-23a. Ms. Bartlett "spent months in a medically-induced coma," "spent a year being tube fed," and "endured two major septic shock episodes." *Id.* "She suffered through 12 eye surgeries and has many more ahead of her." App. 23a. As the district court

stated, "[n]o one who witnessed the trial in this case could deny the horror of Bartlett's injuries." App. 101a.

Ms. Bartlett's "permanent damage is severe." App. 23a. She "cannot eat normally due to esophageal burns, cannot have sexual relations due to vaginal injuries, and cannot engage in aerobic activities due to lung injuries." *Id.* Ms. Bartlett "is almost blind now and faces some likelihood of complete and permanent blindness." *Id.* She "cannot read or drive to work," and she "is seriously disfigured in face and body." *Id.* That is only "a brief summary of the suffering detailed for the jury." *Id.*

2.a. Ms. Bartlett filed suit against petitioner in New Hampshire state court, asserting products-liability claims under New Hampshire law. *See* App. 3a, 32a. After petitioner removed the action to federal court, the district court granted summary judgment for petitioner on Ms. Bartlett's claim that petitioner failed adequately to warn of sulindac's risks. *See* App. 3a-4a, 32a-34a. The court concluded that, in light of the testimony of Ms. Bartlett's doctor that he had not read the drug's labeling, Ms. Bartlett could not prove causation for a failure-to-warn claim. *See id.*

Ms. Bartlett's remaining claim was "that sulindac's risk[s] outweighed its benefits, making it a defective product unreasonably dangerous to consumers." App. 35a; *see* App. 4a. New Hampshire has adopted the theory of strict products liability set forth in Section 402A of the Restatement (Second) of Torts (1965).[1] Section 402A holds the seller of "any prod-

---

[1] *See Kelleher v. Marvin Lumber & Cedar Co.*, 891 A.2d 477, 492 (N.H. 2005).

uct in a defective condition unreasonably dangerous to the user or consumer" strictly liable for any injuries caused by the product, irrespective of whether "the seller has exercised all possible care in the preparation and sale of his product." Restatement § 402A(1)-(2); *see id.* cmt. a. Strict liability is justified because "the seller, by marketing his product for use and consumption, has undertaken and assumed a special responsibility toward any member of the consuming public who may be injured by it," and "the burden of accidental injuries caused by products intended for consumption [should] be placed upon those who market them, and be treated as a cost of production against which liability insurance can be obtained." *Id.* cmt. c.

Comment k to § 402A creates an exemption from strict liability for "[u]navoidably unsafe products," which are defined as those that, "in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use." *Id.* cmt. k. Such products are not considered "defective" or "*unreasonably* dangerous," and therefore are exempt from strict liability, "notwithstanding the unavoidable high degree of risk which they involve." *Id.* To qualify for comment k's exemption from strict liability, the product in question must be not only "unavoidably unsafe" but also "properly prepared, and accompanied by proper directions and warning." *Id.*

During pre-trial proceedings, petitioner asserted a "comment k" defense. But, "on the eve of trial, without explanation," petitioner abandoned that defense. App. 36a; *see* App. 7a, 30a. With petitioner's "'comment k' defense out of the case, the adequacy of sulindac's warning . . . was no longer an issue for trial." App. 36a.

b. In August and September 2009, the district court held a 14-day trial. Ms. Bartlett presented, among other evidence, expert testimony from a pharmacologist/toxicologist showing "that sulindac had a worse record of causing SJS/TEN than other available drugs, and a safety profile similar to other drugs deemed dangerous enough to have been withdrawn from the market." App. 4a-5a; *see also* App. 39a-58a (discussing evidence on risks and benefits).

Petitioner had designated its own expert on that topic, as well as other witnesses. *See* App. 5a. But petitioner "chose not to call any of its own witnesses at trial, foregoing the opportunity to rebut Bartlett's evidence and put sulindac in a better light." App. 30a-31a; *see also* App. 49a (petitioner evidently "chose not to present its own experts because it feared that they would actually strengthen, not weaken, Bartlett's case").

The jury rendered a verdict for Ms. Bartlett and awarded $21.06 million in compensatory damages. *See* App. 5a, 39a. The district court denied petitioner's post-trial motions for judgment as a matter of law and for a new trial. *See* App. 29a-103a.

3. The First Circuit affirmed. Relevant here, the court of appeals rejected petitioner's contention that federal law preempts Ms. Bartlett's claim. The court recognized that New Hampshire's common law "imposes liability for selling any product in a defective condition unreasonably dangerous to the user or consumer when the product causes injury to the user or consumer." App. 6a (internal quotations omitted). To prevail on that theory, an injured consumer need not show that there existed a safer alternative design that the manufacturer could have adopted. *See* App. 6a-7a. In addition, as the First Circuit understood

the record, sulindac cannot, in any event, be "made in a different and safer form" because it "is a one-molecule drug; and the variations in sulindac as sold consist of inactive ingredients that ordinarily do not have significant pharmacological effects." App. 6a.

In light of New Hampshire law and the facts of this case, the First Circuit concluded that nothing in federal law renders compliance with state law impossible. The court observed that, consistent with federal law, petitioner "certainly can choose not to make the drug at all." App. 10a.

The First Circuit explained that this Court's decision in *PLIVA* did not require a different conclusion. There, this Court held that federal law "preempts failure-to-warn claims against generic drug manufacturers" because "[g]eneric drug manufacturers, unlike brand-name manufacturers, cannot unilaterally change their labels" under federal law, and thus cannot comply with a state-law duty to provide a stronger warning. App. 9a-10a. Here, however, the manufacturer can comply with state law without running afoul of federal law: although "the generic maker has no choice as to label," "the decision to make the drug and market it in New Hampshire is wholly its own." App. 10a-11a.

The First Circuit also rejected the notion that New Hampshire law as applied in this case constitutes an unacceptable obstacle to the accomplishment of Congress's purposes and objectives. It noted that, in *Wyeth v. Levine*, 555 U.S. 555 (2009), this Court rejected purposes-and-objectives preemption in the drug context, "saying that 'Congress did not intend [Food and Drug Administration ("FDA")] oversight to be the exclusive means of ensuring drug safety and effectiveness' and that state law serves as a 'comple-

mentary form of drug regulation.'" App. 9a (quoting *Levine*, 555 U.S. at 575, 578) (citations omitted). Against that backdrop, the First Circuit perceived nothing in federal law that would preclude "states [from] tell[ing]" petitioner that "it ought not be" selling sulindac "if risk-benefit analysis [weighs] against the drug." App. 10a.

REASONS FOR DENYING THE PETITION

I. THE PETITION FAILS TO JUSTIFY THIS COURT'S INTERVENTION

A. There Is No Circuit Conflict

There is no circuit conflict that might warrant this Court's review. Aside from failure-to-warn claims against generic drug manufacturers, which this Court addressed in *PLIVA*, the courts of appeals have generally concluded, consistent with the decision below, that federal drug regulation does *not* preempt state products-liability actions.[2] The court of appeals' decision in this case is the first – and only – post-*PLIVA* circuit court decision to address whether federal law preempts tort claims against generic drug manufacturers involving theories other than failure to warn. Further review of the issue is unwarranted at this time.

---

[2] *See, e.g.*, *Tobin v. Astra Pharm. Prods., Inc.*, 993 F.2d 528, 537-38 (6th Cir. 1993) ("We reject the argument that FDA approval preempts state product liability claims based on design defect.") (citing *Hurley v. Lederle Lab. Div. of Am. Cyanamid Co.*, 863 F.2d 1173, 1176-77 (5th Cir. 1988)); *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 343 n.16 (2008) (Ginsburg, J., dissenting) (collecting cases); *see also Mason v. SmithKline Beecham Corp.*, 596 F.3d 387, 390-91 (7th Cir. 2010) ("Until the early 2000s, prescription drug companies infrequently invoked the preemption defense, and when they did, it rarely succeeded.").

Petitioner incorrectly asserts that, after *PLIVA*, other courts of appeals have "considered . . . state law *design-defect* claims" – which this Court did not consider in *PLIVA* – and "found them to be preempted." Pet. 19 (emphasis added). In fact, the court of appeals decisions that petitioner cites (*see id.*) addressed only *failure-to-warn* claims (the same type of claim addressed by this Court in *PLIVA*).

In *Gaeta v. Perrigo Pharmaceuticals Co.*, the district court held that the "Plaintiffs' causes of action are preempted to the extent that they allow for liability *based on a lack of adequate warning* on the company's [over-the-counter] generic drug labeling." 562 F. Supp. 2d 1091, 1098 (N.D. Cal. 2008) (emphasis added).[3] After the plaintiffs stipulated that the district court's order disposed of all of their claims, the district court entered a final judgment, and the plaintiffs appealed.[4] The Ninth Circuit reversed, addressing only failure to warn and holding that "federal law does not preempt state law failure-to-warn claims against generic manufacturers, provided there is no 'clear evidence' that the FDA would not have approved the proposed stronger warning." 630 F.3d 1225, 1227 (9th Cir. 2011); *see also id.* at 1230 (describing the "focal issue in th[e] appeal" as whether *Levine* applies to claims against generic manufacturers), 1239 (summarizing holding).

This Court subsequently granted the manufacturers' certiorari petition, vacated the Ninth Circuit's

---

[3] *See also* 672 F. Supp. 2d 1017 (N.D. Cal. 2009) (denying post-judgment motion for reconsideration in light of *Wyeth v. Levine*).

[4] *See* Order re: Pls.' Objection, No. C 05-04115 JW (N.D. Cal. July 25, 2008) (ECF No. 251); Am. Judgment, No. C 05-04115 JW (N.D. Cal. Dec. 15, 2008) (ECF No. 330).

judgment, and remanded for further consideration in light of *PLIVA*. *See L. Perrigo Co. v. Gaeta*, 132 S. Ct. 497 (2011). On remand, the Ninth Circuit affirmed "the district court's grant of summary judgment in favor of [the defendants]," 469 F. App'x 556, 557 (9th Cir. 2012) – a decision that, as noted, was limited to preemption of claims based on a failure to warn, *see* 562 F. Supp. 2d at 1098.

Similarly, in *Smith v. Wyeth, Inc.*, "the assertion that Defendants failed to adequately warn [the plaintiff] of the long-term negative effects of" the drug in question was "[c]entral to all of" the plaintiff's claims. No. 5:07-CV-18-R, 2008 WL 4697002, at *1 (W.D. Ky. Oct. 24, 2008).[5] In affirming the dismissal

---

[5] *See also* 2008 WL 4697002, at *2-*6. The district court issued essentially identical opinions in the other two cases that were consolidated before the Sixth Circuit in *Smith*. *See* Mem. Op., *Wilson v. Wyeth, Inc.*, No. 3:07-CV-378-R (W.D. Ky. Oct. 24, 2008) (ECF No. 83); Mem. Op., *Morris v. Wyeth, Inc.*, No. 1:07-CV-176-R (W.D. Ky. Oct. 24, 2008) (ECF No. 93).

In a subsequent order in *Smith*, the district court specified that the plaintiff in that case "did not allege a design defect claim." No. 5:07-CV-18-R, 2009 WL 425032, at *1 n.2 (W.D. Ky. Feb. 20, 2009). Although the court suggested that the plaintiffs in *Wilson* and *Morris* had pleaded such claims, it "decline[d] to consider th[e] issue . . . until it is properly briefed by both parties in a separate motion before the Court." Mem. Op. at 2 n.2, *Wilson v. PLIVA, Inc.*, No. 3:07-CV-378-R (W.D. Ky. Feb. 20, 2009) (ECF No. 98); Mem. Op. at 3 n.2, *Morris v. Wyeth, Inc.*, No. 1:07-CV-176-R (W.D. Ky. Feb. 20, 2009) (ECF No. 110). Neither plaintiff elected to pursue a non-warning claim. *See* Order, *Wilson v. Wyeth, Inc.*, No. 3:07-CV-378-R (W.D. Ky. Feb. 20, 2009) (ECF No. 100) (noting parties' agreement that the court's disposition of the case was final and suitable for appeal); Order, *Morris v. Wyeth, Inc.*, No. 1:07-CV-176-R (W.D. Ky. Feb. 23, 2009) (ECF No. 112) (same); Order, *Wilson v. PLIVA, Inc.*, No. 3:07-CV-378-R (W.D. Ky. Mar. 20, 2009) (ECF No. 102)

of those claims as preempted, the Sixth Circuit focused exclusively on failure-to-warn liability, following *PLIVA* in affirming the district court's conclusion that the "state-law failure-to-warn claims against the generic defendants" were preempted. 657 F.3d 420, 423 (6th Cir. 2011).

Petitioner's reliance on the Fifth and Eighth Circuits' decisions on remand from this Court's decision in *PLIVA* is equally misplaced. As those cases came to this Court, neither involved non-warning claims. The district court in *PLIVA* noted that "at the core of all of Plaintiff's claims is the basic assertion that [the generic manufacturers] failed to adequately warn about" a particular risk. *Mensing v. Wyeth, Inc.*, 562 F. Supp. 2d 1056, 1058 (D. Minn. 2008).[6] On appeal, the plaintiff did "not challenge[] the district court's characterization that 'at the core' [her claims] all assert[ed] failure to warn." *Mensing v. Wyeth, Inc.*, 588 F.3d 603, 605 (8th Cir. 2009) (quoting 562 F. Supp. 2d at 1058).[7] Accordingly, the Eighth Circuit addressed only "the generic defendants' argument that federal law preempts state failure to warn claims against them." *Id.*

Likewise, in the Fifth Circuit case that this Court consolidated with *PLIVA*, the district court had denied the generic manufacturer's motion to dismiss the plaintiff's failure-to-warn claim, *see Demahy v. Wyeth Inc.*, 586 F. Supp. 2d 642, 643-62 (E.D. La.

(final judgment); Order, *Morris v. Wyeth, Inc.*, No. 1:07-CV-176-R (W.D. Ky. Mar. 20, 2009) (ECF No. 117) (same).

[6] *See* 562 F. Supp. 2d at 1061 n.6 ("[A]ll of Plaintiff's claims are essentially 'failure to warn' claims and are encompassed by the Court's preemption analysis.").

[7] *See also* 588 F.3d at 604 (describing suit as a "failure to warn and misrepresentation case").

2008), and had certified that ruling for interlocutory appeal as a "controlling question of law," Order, *Demahy v. Wyeth Inc.*, No. 08-CV-3616 (E.D. La. Nov. 14, 2008) (ECF No. 40). The Fifth Circuit thus explained that the case "present[ed] one issue on appeal: whether the federal regulatory regime governing pharmaceuticals preempts state-law failure-to-warn claims against manufacturers of generic drugs." *Demahy v. Actavis, Inc.*, 593 F.3d 428, 430 (5th Cir. 2010); *see also* Br. of Appellee Julie Demahy at 2, No. 08-31204 (5th Cir. filed Mar. 30, 2009) (identifying only failure-to-warn theory in discussing claims).

After this Court reversed the Fifth and Eighth Circuits' judgments in *PLIVA*, the Eighth Circuit on remand vacated the portions of its prior opinion that addressed preemption and entered a judgment affirming the district court's decision, which (as noted) was limited to preemption of claims based on a failure to warn. *See Mensing v. Wyeth, Inc.*, 658 F.3d 867 (8th Cir. 2011); Judgment, *Mensing v. Wyeth, Inc.*, No. 08-3850 (8th Cir. Sept. 29, 2011). The Fifth Circuit similarly vacated the district court's order denying the defendant's motion to dismiss and remanded for entry of judgment in favor of the defendant. *See Demahy v. Actavis, Inc.*, 650 F.3d 1045 (5th Cir. 2011) (per curiam).

In short, petitioner has identified no other circuit court decision addressing whether federal law preempts design-defect or other non-warning claims involving generic drugs. Its assertion (at i, 6, 18, 34) of a "circuit split" is therefore erroneous.

B. The Petition Provides No Basis For Granting Review In The Absence Of A Circuit Conflict

Petitioner fails to show that this case justifies an exception from this Court's general practice of "permitting several courts of appeals to explore" an issue and "waiting for a conflict to develop" before granting review. *United States v. Mendoza*, 464 U.S. 154, 160 (1984).

1. The petition does not present a question of recurring national importance

Strict-liability claims asserting that the design of a prescription drug is defective – that is, cases premised on a defect in the design of the drug itself, as opposed to a failure to warn about a hazard posed by the drug as designed – are rare and exceedingly difficult to prove.[8]

Courts in several states have declined altogether to recognize strict-liability claims based on the design of a prescription drug.[9] Those states' courts have taken the view that prescription drugs are, by definition, "unavoidably unsafe" within the meaning of the Restatement's comment k. *See supra* pp. 3-4 (discussing

---

[8] *See generally* App. 5a ("courts 'traditionally have refused to review the reasonableness of the designs of prescription drugs'") (quoting Restatement (Third) of Torts: Products Liability § 6 cmt. f (1998) (Reporter's Note)).

[9] *See*, *e.g.*, *Schaerrer v. Stewart's Plaza Pharmacy, Inc.*, 79 P.3d 922, 928 (Utah 2003); *Hahn v. Richter*, 673 A.2d 888, 889-91 (Pa. 1996); *Martin v. Hacker*, 628 N.E.2d 1308, 1311 (N.Y. 1993); *Brown v. Superior Court*, 751 P.2d 470, 482-83 (Cal. 1988); *Edwards v. Basel Pharm.*, 933 P.2d 298, 300 (Okla. 1997); *Wimbush v. Wyeth*, 619 F.3d 632, 637 (6th Cir. 2010) (Ohio law); *Tatum v. Schering Corp.*, 795 F.2d 925, 926 (11th Cir. 1986) (Alabama law); *Gross v. Pfizer, Inc.*, 825 F. Supp. 2d 654, 658 (D. Md. 2011) (Maryland law), *cited in* Pet. 19.

Restatement and comment k). Thus, in those jurisdictions, alleged defects in a drug's design do not support a claim for strict products liability. Rather, to establish liability, an injured patient must prove either that the manufacturer failed to warn of a foreseeable risk or that the drug was not properly manufactured.

Other states apply comment k on a case-by-case basis.[10] In those jurisdictions, if a manufacturer makes a case-specific showing that the drug in question is "unavoidably unsafe," it will qualify for comment k's exemption from strict products liability. Although design-defect claims are possible in those jurisdictions, a plaintiff seeking to overcome a manufacturer's reliance on comment k still must show that the hazard that caused her injury was "avoidable" – a very high hurdle.[11]

Many states also require patients to prove as an element of their case the existence of a safer alternative design for the drug that the manufacturer could have adopted. *See* La. Rev. Stat. Ann. § 9:2800.56; *Eckhardt v. Qualitest Pharm. Inc.*, 858 F. Supp. 2d

---

[10] *See generally* 5 Louis R. Frumer & Melvin I. Friedman, *Products Liability* § 50.03A[3], at 50-59 to 50-61 (2012) (collecting cases and discussing "the wide adoption of comment k").

[11] Under the approach of the most recent Restatement, a prescription drug is unreasonably dangerous only "if the foreseeable risks of harm posed by the drug . . . 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 . . . *for any class of patients*." Restatement (Third) of Torts: Products Liability § 6(c) (emphasis added). According to the accompanying commentary, "[g]iven this very demanding objective standard, liability is likely to be imposed only under *unusual circumstances*." *Id.* § 6 cmt. f (emphasis added).

792, 801 (S.D. Tex. 2012) (Texas law); *Fisher v. Pelstring*, 817 F. Supp. 2d 791, 817-18 (D.S.C. 2011); *see also Products Liability* § 50.03A[3], at 50-58.1 ("Many – but not all – states require the plaintiff to prove the existence of a safer alternative design at the time of manufacture to prevail in defective design cases [involving prescription drugs].") (footnote omitted).

Considering the stringent standards applicable to design-defect claims involving prescription drugs, it is not surprising that "[f]ailure to instruct or warn is the major basis of liability for manufacturers of prescription drugs." Restatement (Third) of Torts: Products Liability § 6 cmt. d. Cases such as this one, in which an injured patient obtains a damages judgment against a drug manufacturer based on a products liability theory other than failure to warn, are exceedingly rare.[12] They certainly do not recur with sufficient frequency to warrant this Court's review of the question whether federal law preempts the underlying theory of liability.

Moreover, petitioner could have avoided liability altogether by showing that sulindac was "unavoidably unsafe" under comment k, but, after relying on comment k for more than a year, it inexplicably withdrew that defense on the eve of trial. The question presented here thus both lacks national import and arises in an apparently unprecedented setting, where the manufacturer essentially threw in the towel before trial on its main defense – a defense that is frequently successful for pharmaceutical manufacturers in cases nationwide.

---

[12] Indeed, we are aware of no instance in which an FDA-approved drug was withdrawn from the market as a result of a state tort verdict (let alone a verdict on a design-defect claim).

2. Sulindac is not an essential drug, and petitioner presented no contrary evidence

As the district court stated, "[t]he FDA has recommended that five NSAIDs be removed from the market due, in part, to their risk of SJS/TEN as demonstrated by adverse event reports (sometimes fewer than 15)." App. 46a. "From 1980 to 1997, the FDA's adverse event reporting database – which collects spontaneous reports of drug side effects from doctors, manufacturers, patients, etc. – received *89 reports* of SJS/TEN attributed to sulindac, more than the number of reports for any other NSAID on the market and all but four drugs of any kind." App. 44a (emphasis added). A report prepared by petitioner's own dermatology expert showed that "sulindac may have had the highest SJS/TEN reporting rate among NSAIDs from 1980 to 1997." App. 17a-18a. In addition, there is no evidence that sulindac "is more or less risky than other NSAIDs with regard to various other [non-skin-related] known side effects." App. 45a. Ms. Bartlett's experts thus "opine[d] that sulindac's overall risk/benefit profile was unfavorable for marketing." App. 12a. Petitioner did not call a single witness to counter that evidence. *See* App. 5a.

Petitioner asserted that Ms. Bartlett was required to present evidence of a safer alternative *product*, despite the absence of any "authority for such a requirement." App. 64a. Although "not required to do so," Ms. Bartlett "presented considerable evidence for the jury to consider with regard to safer alternative products": "her experts testified that sulindac is part of two NSAID groups . . . believed to have a greater risk of SJS/TEN than other NSAIDs, with no greater benefits." App. 65a. Other NSAIDs "have no risk of SJS/TEN" and "are equally effective in treat-

ing conditions like shoulder pain (for which Bartlett took sulindac)." *Id.* The district court explained that, under New Hampshire Supreme Court authority, "it was up to the jury . . . to determine how much weight (if any) to give Bartlett's evidence regarding safer alternative products." App. 66a.

3. The district court cases cited by petitioner do not justify this Court's review

Petitioner cites (at 19) a list of nine district court decisions that it claims decided the question presented differently from the First Circuit. That claim is incorrect, and those cases provide no reason to grant review.

At the outset, each of those cases was filed before *PLIVA*, and the plaintiffs' principal theory of liability generally involved an alleged failure to warn.[13] In one case, the plaintiff failed even to oppose the defendants' motion to dismiss in light of *PLIVA*.[14] In the others, the courts rejected the plaintiffs'

---

[13] *See Eckhardt*, 858 F. Supp. 2d at 798 ("[T]his is primarily a failure to warn case."); *In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.*, No. 2:11-md-2226-DCR, 2012 WL 718618, at *3 n.7 (E.D. Ky. Mar. 5, 2012) ("the plaintiffs have merely repackaged their failure-to-warn claims"); *Aucoin v. Amneal Pharm., LLC*, Civil Action No. 11-1275, 2012 WL 2990697, at *1-*2 (E.D. La. July 20, 2012); *Johnson v. Teva Pharm. USA Inc.*, No. 2:10 CV 404, 2012 WL 1866839, at *1-*2 (W.D. La. May 21, 2012); *Lyman v. Pfizer, Inc.*, No. 2:09-cv-262, 2012 WL 368675, at *1 (D. Vt. Feb. 3, 2012); *In re Pamidronate Prods. Liab. Litig.*, 842 F. Supp. 2d 479, 484-85 & n.7 (E.D.N.Y. 2012); *Gross*, 825 F. Supp. 2d at 658; *Stevens v. PLIVA, Inc.*, Civil No. 6:10-0886, 2011 WL 6224569, at *2 (W.D. La. Nov. 15, 2011), *report and recommendation adopted*, 2011 WL 6224556 (W.D. La. Dec. 2, 2011); *see also In re Fosamax (Alendronate Sodium) Prods. Liab. Litg. (No. II)*, Civil No. 08-008, 2011 WL 5903623, at *9 (D.N.J. Nov. 21, 2011).

[14] *See Pamidronate*, 842 F. Supp. 2d at 481.

efforts to avoid *PLIVA*'s preemption holding by re-characterizing their warning claims as non-warning claims. Several of the courts concluded that the plaintiffs had failed to plead facts that would give rise to a plausible claim for defective design.[15] In another case, the district court held that the applicable state law did not even recognize a design-defect claim.[16] As those pre-*PLIVA* cases work their way through the judicial process, the likelihood of these issues recurring will become even more remote.

To be sure, in several of the cases that petitioner cites, the district courts stated that federal law preempts design-defect claims. But those claims were premised on an alleged failure to *change* the drug's design, and therefore were fundamentally different from Ms. Bartlett's claim here. Under New Hampshire law, Ms. Bartlett did not need to assert, and did not assert, that the design of sulindac needed to be changed. In contrast, four of the cases that petitioner cites arose in states that require the plaintiff to plead and prove the existence of a reasonable alternative design that the defendant manufacturer

---

[15] *See Fullington v. PLIVA, Inc.*, No. 4:10CV00236 JLH, 2011 WL 6153608, at *5 (E.D. Ark. Dec. 12, 2011) ("While products liability law in Arkansas encompasses claims for relief other than failure to warn, Fullington has not adequately pled any such claims."), *cited in* Pet. 21; *Aucoin*, 2012 WL 2990697, at *10 ("[I]nstead of alleging either of the elements for a design defect claim, Plaintiff has merely recited the elements of the cause of action."); *Lyman*, 2012 WL 368675, at *4 n.4 (plaintiffs "have not adequately pled claims for . . . design defects"); *Pamidronate*, 842 F. Supp. 2d at 484 n.7 ("Plaintiffs' allegations of design defect also fail because they are not supported by factual allegations in the Complaint").

[16] *See Gross*, 825 F. Supp. 2d at 658.

could have adopted.[17] In other cases, the courts understood the plaintiffs' claims to be premised on alleged failures to improve a drug's design.[18]

Having concluded that the gravamen of the plaintiffs' claims in those cases was the failure to change the drug's design, the courts determined that compliance with federal and state law was impossible. Thus, for example, the district court in *Johnson* concluded that, because (in the court's view) federal law "prevented the Generic Defendants from altering unilaterally the design of the drug itself," the plaintiff could not "show that the Generic Defendants could have used an alternative design," as required by Louisiana law. 2012 WL 1866839, at *4, *5 n.13.

---

[17] *See Eckhardt*, 858 F. Supp. 2d at 801 ("For a plaintiff to prevail on a design defect claim under Texas law, he 'must prove that there is a safer alternative design.' 'In the absence of a safer alternative, a product is not unreasonably dangerous as a matter of law.'") (quoting *Brockert v. Wyeth Pharm. Inc.*, 287 S.W.3d 760, 769 (Tex. App. 2009)) (footnote omitted); *Johnson*, 2012 WL 1866839, at*4-*5 & n.13 (applying Louisiana statute requiring proof of an alternative design); *Aucoin*, 2012 WL 2990697, at *10 (same); *Stevens*, 2011 WL 6224569, at *2 (same).

[18] *See Lyman*, 2012 WL 368675, at *4 ("[plaintiffs'] claims that the Generic Defendants' metoclopramide should have been designed . . . differently are preempted as well") (citations omitted); *Fosamax*, 2011 WL 5903623, at *6 ("Here, plaintiffs allege that Generic Defendants' alendronate sodium should have been designed differently to comply with state tort law."); *Pamidronate*, 842 F. Supp. 2d at 484 ("federal law preempts state laws imposing a duty to change a drug's design on generic drug manufacturers"), 485 ("[b]ecause [the implied-warranty] cause of action is founded on the argument that pamidronate should have been designed differently, it fails").

The court therefore held that the plaintiff's "design defect claims" were "preempted." *Id.* at *4.[19]

In short, those district court decisions addressed a fundamentally different preemption issue from the one addressed by the First Circuit: they concerned whether an asserted state-law duty to change the design of a generic drug conflicted with federal law. This case does not present that question because it does not involve such a state-law duty.

C. Petitioner Has Not Demonstrated The Suitability Of This Case As A Vehicle To Decide The Question Presented

In all events, petitioner's withdrawal of its comment k defense makes this case an especially poor vehicle in which to address the question presented or for this Court's decision to apply beyond the unusual facts of this case. Petitioner voluntarily withdrew its comment k defense. The jury therefore could not premise liability on whether petitioner provided an adequate warning of sulindac's risks, making this case unlike the district court cases in which the primary theory of liability was failure to warn. In addition, if petitioner had not abandoned its comment k defense, it could have argued that Ms. Bartlett was required to show the existence of an alternative design for sulindac – to show that the drug is not "unavoidably unsafe." But, because it withdrew its primary defense (which was the premise for that argument), and because New Hampshire law does not otherwise require proof of a feasible alternative

---

[19] *Accord Aucoin*, 2012 WL 2990697, at *9 n.101 (citing *Johnson*); *Eckhardt*, 858 F. Supp. 2d at 801-02 (defendants "were not free to unilaterally pursue a safer alternative design in order to comply with state law," and "[t]he design defect claim is thus preempted").

design, the jury's verdict of liability did not depend in any way on any alleged failure by petitioner to change the design of its product.

Impossibility preemption requires a careful "compar[ison of] federal and state law." *PLIVA*, 131 S. Ct. at 2573. Accordingly, even if this Court were to consider the question whether federal law preempts design-defect claims involving generic manufacturers, it should do so in a case in which the applicable state law follows the majority approach and in which the drug manufacturer has presented a defense typical of litigation in this area (as opposed to no defense case at all). Petitioner has offered no reason why the question it seeks to present would not recur in a future case that would present a more suitable vehicle for this Court's review.

II. THE COURT OF APPEALS' DECISION IS CORRECT AND DOES NOT CONFLICT WITH *PLIVA*

The First Circuit correctly concluded that federal law does not preempt New Hampshire law in this case. Neither the Federal Food, Drug, and Cosmetic Act nor the Hatch-Waxman Amendments contains an express preemption provision for prescription drugs, and petitioner does not argue that federal law preempts the relevant field. Rather, petitioner's claim is that New Hampshire law is preempted because it "directly conflict[s]" with federal law. *PLIVA*, 131 S. Ct. at 2577 (internal quotations omitted). Such a conflict can arise when "it is impossible for a private party to comply with both state and federal requirements" or when "state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Sprietsma*

v. Mercury Marine, 537 U.S. 51, 64 (2002) (internal quotations omitted).

In this Court, petitioner does not assert – and therefore has forfeited – any claim that "recognition of [Ms. Bartlett's] state tort action creates an unacceptable obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Levine*, 555 U.S. at 563-64 (internal quotations omitted); *cf. PLIVA*, 131 S. Ct. at 2581 n.7 (noting that purposes-and-objectives preemption was not argued there). Instead, petitioner's claim is that a direct conflict exists in this case because "it is *impossible* for [petitioner] to comply with both state and federal requirements." *PLIVA*, 131 S. Ct. at 2577 (emphasis added; internal quotations omitted); *see* Pet. 23, 25. The court of appeals properly rejected that argument.

A. The Court Of Appeals Correctly Concluded That Compliance With Federal And State Law Is Not Impossible In This Case

Analysis of impossibility preemption requires the court "to compare federal and state law." *PLIVA*, 131 S. Ct. at 2573. The first step in that analysis is to "identify[] the state tort duties and federal . . . requirements applicable to the [m]anufacturer[]." *Id.*

1. New Hampshire law imposes strict, but not automatic, liability on sellers of unreasonably dangerous products

New Hampshire law imposes strict liability on manufacturers of products that are "unreasonably dangerous to the user." *Thibault v. Sears, Roebuck & Co.*, 395 A.2d 843, 846 (N.H. 1978) (internal quotations omitted). New Hampshire has "adopted the doctrine of strict liability of manufacturers for product defects in section 402A (1) of the *Restatement*

(Second) of Torts." *Kelleher*, 891 A.2d at 492. Under the Restatement, "'[o]ne who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer.'" *Id.* (quoting Restatement (Second) of Torts § 402A(1)) (emphasis omitted).

To determine whether a product is "unreasonably dangerous" – and therefore "defective" – New Hampshire courts ask whether the product is "'dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics.'" *Bellotte v. Zayre Corp.*, 352 A.2d 723, 725 (N.H. 1976) (quoting Restatement (Second) of Torts § 402A cmt. i). "Whether a product is dangerous to an extent beyond that which would be contemplated by the ordinary consumer is," in turn, "determined by the jury using a risk-utility balancing test." *Price v. BIC Corp.*, 702 A.2d 330, 332 (N.H. 1997).

Under that risk-utility balancing test, the trier of fact weighs the product's risks and benefits to determine whether "'the magnitude of the danger outweighs the utility of the product.'" *Vautour v. Body Masters Sports Indus., Inc.*, 784 A.2d 1178, 1182 (N.H. 2001) (quoting W. Page Keeton et al., *Prosser and Keeton on the Law of Torts* 699 (5th ed. 1984)); *see also id.* (discussing factors relevant to that inquiry). If a product's risks outweigh its benefits, then the product "is defective as designed." *Id.*

To establish liability under New Hampshire law, a plaintiff need not prove the existence of a reasonable alternative design that the manufacturer could have adopted. *See Kelleher*, 891 A.2d at 492 ("[T]he plain-

tiff is not required to present evidence of a safer alternative design."); *Vautour*, 784 A.2d at 1182-84; App. 58a-61a. The term "design defect" is thus a misnomer as applied to New Hampshire law. The question in New Hampshire is simply whether the product's risks outweigh its benefits; if so, the product is unreasonably dangerous, and the seller is subject to liability for injuries resulting from use of the product. That is so regardless of whether the design is otherwise "defective" or could be improved.

Applying those principles of New Hampshire law, the properly instructed jury in this case found that sulindac's risks outweighed its benefits, making it a defective product unreasonably dangerous to consumers. *See* App. 30a.

2. Nothing in federal law precluded petitioner from complying with New Hampshire law

Assuming federal law does not permit manufacturers of generic drugs to alter the design of their products, it does not require them to manufacture and sell those products. *See* App. 10a-11a.[20] Petitioner's "decision to make [sulindac] and market it in New Hampshire is wholly its own." App. 11a. Because petitioner "could independently do under federal law [anything] state law require[d] of it," the court of ap-

---

[20] FDA regulations provide that "FDA will withdraw approval of an application or abbreviated application if the applicant requests its withdrawal because the drug subject to the application or abbreviated application is no longer being marketed." 21 C.F.R. § 314.150(c). If a manufacturer is "the sole manufacturer" of a drug that is "life supporting, life sustaining, or intended for use in the prevention of a serious disease or condition" – a category that does not include sulindac – it must notify FDA at least six months before discontinuing manufacture of the drug. *Id.* § 314.81(b)(3)(iii)(1).

peals properly rejected petitioner's defense of impossibility preemption. *PLIVA*, 131 S. Ct. at 2579.

B. The Court Of Appeals' Decision Does Not Conflict With This Court's Decision In *PLIVA*

1. There is no conflict between this case and *PLIVA* because *PLIVA* involved a different state-law duty

The injured patients in *PLIVA* brought tort claims against manufacturers of the generic drug metoclopramide. *See* 131 S. Ct. at 2572. They asserted that the manufacturers "were liable under state tort law (specifically, that of Minnesota and Louisiana) for failing to provide adequate warning labels" – specifically, labels that adequately warned of the risk of developing tardive dyskinesia. *Id.* at 2573.

This Court began its preemption analysis by "identifying the state tort duties and federal labeling requirements applicable to the Manufacturers." *Id.* The parties did "not dispute that," under the facts alleged by the plaintiffs, "state law required the Manufacturers to use a different, safer label." *Id.* at 2574; *see id.* at 2577 (state law "required the Manufacturers to use a different, stronger label than the label they actually used"), 2578 ("[S]tate law imposed on the Manufacturers a duty to attach a safer label to their generic metoclopramide."). The parties did, however, dispute whether federal law permitted the generic manufacturers to strengthen the warnings on their drug labels. *See id.* at 2574-77. Resolving that dispute, this Court held that federal law "prevented the Manufacturers from independently changing their generic drugs' safety labels." *Id.* at 2577; *see id.* at 2578 ("Federal law . . . demanded that generic drug labels be the same at all times as the corresponding brand-name drug labels.").

The Court then "compare[d]" those requirements of "federal and state law" and concluded that it was "impossible for [the manufacturers] to comply with both [the] state and federal requirements." *Id.* at 2573, 2577 (internal quotations omitted). "The question for 'impossibility,'" the Court explained, "is whether the private party could independently do under federal law what state law requires of it." *Id.* at 2579. "If the Manufacturers had independently changed their labels to satisfy their state-law duty, they would have violated federal law." *Id.* at 2578. Consequently, "it was impossible for the Manufacturers to comply with both their state-law duty to change the label and their federal law duty to keep the label the same," *id.*, and the plaintiffs' claims were therefore preempted by federal law, *see id.* at 2581.

This case is fundamentally different from *PLIVA*. In *PLIVA*, state law required the generic manufacturers to do something that federal law prohibited – namely, change the labels of their drugs. Here, by contrast, nothing in New Hampshire law requires petitioner to change sulindac's design, and nothing in federal law prohibits petitioner from declining to sell the drug. A straightforward application of this Court's analysis in *PLIVA* thus compels the conclusion reached by the lower courts in this case – petitioner's defense of impossibility preemption lacks merit.

2. New Hampshire law did not require petitioner to perform any act that federal law prohibits

Petitioner argues that the court of appeals' decision is inconsistent with *PLIVA* because, in that case, the manufacturers could presumably have avoided liabil-

ity for failure to warn by declining to sell metoclopramide in Minnesota and Louisiana. According to petitioner, "[w]ere the holding below correct," *PLIVA* "would have come out the other way." Pet. 3.

Not so. In *PLIVA*, state law *required* the defendant to do something that federal law prohibited it from doing. State law required the manufacturers "to attach a safer label to their generic metoclopramide." 131 S. Ct. at 2578. Suspending sales of the drug might have been an indirect means of avoiding future tort liability for failing to comply with the duty to warn, but it was not the act required by the state-law duty. When, as in *PLIVA*, a holding under state law would obligate a party to take an action (such as changing the label for its product) that federal law prohibits, that claim is preempted, even if the party could avoid liability by removing its product from the market. Here, by contrast, the holding under New Hampshire law did not require petitioner to perform any act that federal law prohibits it from doing independently.

Moreover, as petitioner concedes, this Court in *PLIVA* did not in fact address the effect on preemption analysis of a manufacturer's ability to remove its product from the market. *See* Pet. 20; *PLIVA*, 131 S. Ct. at 2573-82. Although, as petitioner notes (at 3-4, 10-11, 20), the Eighth Circuit had relied on that ability as an additional reason supporting its conclusion that compliance with both federal and state law was possible, *see* 588 F.3d at 608-11, the plaintiffs did not raise the issue in their merits brief in this Court, *see* Br. for Resps. Gladys Mensing and Julie Demahy, *PLIVA*, *supra* (Nos. 09-993 et al.) (U.S. filed Feb. 23, 2011). As petitioner also observes (at 4, 13, 20), the plaintiffs in *PLIVA* argued in a rehearing petition,

which this Court summarily denied, *see PLIVA, Inc. v. Mensing*, 132 S. Ct. 55 (2011), that the manufacturers could have avoided liability under state law by suspending sales of their drugs. But that summary denial of rehearing lacks precedential force.[21] In addition, petitioner here did not raise in the court of appeals the alleged import of the denial of rehearing in *PLIVA*, making its criticism of the First Circuit for supposedly overlooking the point all the more unwarranted.

C. Petitioner's Other Criticisms Of The First Circuit's Decision Lack Merit

Petitioner claims that the First Circuit's decision "would render conflict pre-emption largely meaningless." Pet. 28, 31 (internal quotations omitted). But, as noted above, a regulated party's ability to stop selling its product does not negate preemption where it provides only an indirect means to avoid liability for failing to comply with an affirmative state-law duty. Under the law and facts of this apparently unprecedented case, however, no affirmative duty was imposed on petitioner that federal law prohibited it from fulfilling.

Moreover, the First Circuit's reasoning on this point applies only to impossibility preemption – the only form of conflict preemption addressed in *PLIVA*. *See* 131 S. Ct. at 2581 n.7. Federal law continues to preempt state tort suits that frustrate the accomplishment of Congress's purposes and objectives, regardless of whether the defendant could comply

---

[21] *Cf. Fernandez v. Chardon*, 681 F.2d 42, 51 n.7 (1st Cir. 1982) ("surely the denial of a petition for rehearing can have no greater precedential effect than the denial of a petition for certiorari, which is to say none"), *aff'd sub nom. Chardon v. Fumero Soto*, 462 U.S. 650 (1983).

with state law by suspending sales of its product. *See*, *e.g.*, *Geier v. American Honda Motor Co.*, 529 U.S. 861, 881-82 (2000).[22]

Petitioner also mischaracterizes (at 4, 28) the First Circuit's decision as adopting a "so-called 'choice of reaction' thesis," under which state tort duties are not preempted because the defendant can pay any damages judgments and continue to comply with federal law. But that "thesis" assumes that the defendant will continue *to violate state law*, thus the need to continue to "'pay damages to successful tort plaintiffs.'" Pet. 4 (quoting *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529, 1542 (D.C. Cir. 1984)). The First Circuit's decision, by contrast, is premised on the conclusion that petitioner can simultaneously *comply* with state and federal law: it can avoid future liability for selling an unreasonably dangerous product without violating federal law, which does not require petitioner to sell sulindac.[23]

---

[22] Petitioner does not raise purposes-and-objectives preemption in this Court and therefore has waived it. This case accordingly provides no opportunity to consider whether the mere approval by the FDA of an application to market a generic drug preempts strict-liability claims arising from injuries caused by that product. In all events, the First Circuit correctly concluded that, under *Levine* and *PLIVA*, state tort suits against drug manufacturers do not present an unacceptable obstacle to Congress's purposes, when (as here) compliance with federal law and the holding under state law is possible. *See supra* pp. 6-7.

[23] In all events, petitioner's assertion (at 30) that this Court has "decisively rejected *Ferebee*'s claim that state-law damage awards do not constitute state regulatory 'requirements' that conflict with federal law" is incorrect. The cases that petitioner cites – *Riegel*, 552 U.S. at 324, and *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 521 (1992) (plurality opinion) – involved the interpretation of express-preemption provisions, not the application of implied conflict preemption. In the conflict-preemption

D. Petitioner's Position Depends On A Mischaracterization Of New Hampshire Law

1. New Hampshire law does not require petitioner to change the design of its drug

Petitioner asserts that New Hampshire law imposes on it a duty to change the design of its generic sulindac to make the drug safer. *See* Pet. 23, 25. That misstates New Hampshire law, which imposes liability for "'*sell[ing]*'" an unreasonably dangerous product. *Kelleher*, 891 A.2d at 492 (quoting Restatement (Second) of Torts § 402A(1)) (emphasis added). New Hampshire does not require proof of a safer alternative design, *see id.*, meaning that a seller of an unreasonably dangerous product is liable for resulting injuries regardless of whether it could have redesigned the product to avoid the harm. As the district court explained, petitioner "was not held liable for failing to change sulindac's design; it was held liable for selling an unreasonably dangerous product." App. 72a.[24]

2. Design-defect and failure-to-warn claims are distinct under New Hampshire law

Petitioner also erroneously asserts that "failure-to-warn and design-defect claims are one and the same" because, "under *comment k*, design-defect liability is

---

context, this Court has recognized, but not resolved, the question whether the incidental regulatory effects of state tort judgments create preemptive "obstacle[s]" to the accomplishment of federal purposes. *See Geier*, 529 U.S. at, 882. Regardless of the resolution of that question, petitioner cannot dispute that it is *possible* to pay the judgment to Ms. Bartlett without violating federal law.

[24] *See also* App. 165a ("[a]ssuming . . . that [federal law] would prevent the defendants from changing Sulindac's design, that would not conflict with the state law underlying the Bartletts' non-failure-to-warn claims" because "[t]hose claims allege that the defendants violated state law by distributing a product that was defectively designed" and "not fit for its intended use").

predicated on the absence of an adequate warning." Pet. 23-24 (footnote omitted). That, too, misstates New Hampshire law. In New Hampshire, failure to warn is a basis for liability separate and distinct from liability for selling an unreasonably dangerous product.[25] The existence of an adequate warning can in some cases be a factor that a jury applying New Hampshire's risk-utility balancing test can consider in determining whether a product is unreasonably dangerous. *See Vautour*, 784 A.2d at 1182; App. 36a-37a. But the basis for liability remains the sale of an unreasonably dangerous product. *See LeBlanc*, 688 A.2d at 562. As the district court explained, "[t]he warning was not sulindac's defective condition; the unreasonable danger was." App. 67a.[26]

---

[25] *See LeBlanc v. American Honda Motor Co.*, 688 A.2d 556, 562 (N.H. 1997) ("The plaintiff's design defect and failure to warn claims are separate. Under the design defect claim, the issue is whether the [automobile] was defective *in that* it had a fixed rear axle and whether that defect made the product unreasonably dangerous. The issue in the failure to warn claim, in contrast, is whether the danger inherent in the [automobile] was or could have been made reasonable by the issuance of adequate warnings.").

[26] In *Kurns v. Railroad Friction Products Corp.*, 132 S. Ct. 1261 (2012), the Court concluded that a claim that a manufacturer of asbestos-containing locomotive parts failed to warn of the risks of asbestos was "directed at the equipment of locomotives" and therefore fell within the broad preempted field of the Locomotive Inspection Act, as interpreted in *Napier v. Atlantic Coast Line Railroad Co.*, 272 U.S. 605 (1926). *Kurns*, 132 S. Ct. at 1268. But even if a failure-to-warn claim necessarily "alleges that the product itself is unlawfully dangerous," *id.*, that does not mean that a design-defect claim necessarily alleges that the product lacks "an adequate warning," Pet. 24. In fact, as explained in the text, design-defect liability does *not* necessarily turn on the adequacy of warnings. Moreover, petitioner's withdrawal of its comment k defense took the adequacy of sulindac's

3. Petitioner's waiver of its comment k defense precluded the jury from finding liability based on an inadequate warning

More fundamentally, petitioner's effort to equate the claim that was tried in this case with the failure-to-warn claim at issue in *PLIVA* disregards the law of the case. In the district court, petitioner "voluntarily withdrew" before trial its comment k defense. *See* App. 36a, 60a-61a. With petitioner's "'comment k' defense out of the case, the adequacy of sulindac's warning . . . was no longer an issue for trial." App. 36a. The court accordingly "instructed the jury *(at [petitioner]'s request)* that Mutual's 'conduct in . . . responding' to sulindac's safety risks, which included any failure to change its warning, was 'not relevant to this case, and you should put [it] out of your mind.'" App. 74a (emphasis added; alterations in original).

The district court also "ruled that warning-related evidence could be admitted at trial [only] for a limited purpose: if the jury found that sulindac's risks outweighed its benefits, then it could consider whether the warning – regardless of its adequacy – reduced those risks or increased those benefits to such an extent that it eliminated the unreasonable danger. In other words, the warning could operate only to [petitioner]'s benefit." App. 37a. Furthermore, Ms. Bartlett did not argue to the jury that a lack of an adequate warning rendered sulindac

---

warning out of this case entirely as a basis for liability. As the district court explained, the warning was not in the case "in the sense that Mutual could have been held liable for failing to change it"; rather, Ms. Bartlett had to "prove that sulindac was unreasonably dangerous *despite* its warning, not *because* of it." App. 74a (internal quotations omitted).

unreasonably dangerous; rather, her "sole" theory at trial centered on sulindac's propensity to cause SJS/TEN. App. 68a. In short, the trial record – and, in particular, petitioner's withdrawal of its comment k defense – forecloses petitioner from arguing now that liability in this case was "predicated on the absence of an adequate warning." Pet. 24.

In all events, any dispute about the content of state law would not warrant this Court's review. *See Propper v. Clark*, 337 U.S. 472, 486-87 (1949). In *PLIVA*, the meaning of state law was "undisputed," 131 S. Ct. at 2573, and this Court's analysis focused on the requirements imposed by federal law and their implications for preemption, *see id.* at 2574-82. Likewise, in *Levine*, the Court took it as a given that state law required Wyeth to provide a stronger warning for its drug Phenergan, and the Court's opinion centered on the content of federal law. *See* 555 U.S. at 568-81. The Court should not grant review here simply to review the First Circuit's understanding of New Hampshire law, particularly when that state's products-liability law differs from the law of many other states and petitioner's own litigation decision uniquely removed from the jury's consideration the one defense typically invoked by defendants.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

STEVEN M. GORDON
CHRISTINE M. CRAIG
SHAHEEN & GORDON
107 Storrs Street
Concord, NH 03302
(603) 749-5000

KEITH M. JENSEN
Counsel of Record
JENSEN & ASSOCIATES, PLLC
1024 N. Main Street
Fort Worth, Texas 76164
(817) 334-0762
(kj@kjensenlaw.com)

Counsel for Respondent

October 31, 2012