No. 12-142

IN THE

Supreme Court of the United States

MUTUAL PHARMACEUTICAL COMPANY, INC.,
Petitioner,

v.

KAREN L. BARTLETT,
Respondent.

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

BRIEF OF JOHN AND TAMMY GILBERT, DEBORAH KINTER, DONALD BROWN, AND ALICE SZROMBA, ON BEHALF OF PERSONS INJURED BY PROPOXYPHENE, AS AMICI CURIAE IN SUPPORT OF RESPONDENT

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INTEREST OF THE AMICI CURIAE[1]

Amici John and Tammy Gilbert, Deborah Kinter, Donald Brown, and Alice Szromba submit this brief on behalf of persons injured by the prescription drug propoxyphene (sold both as a generic drug and under the brand names Darvon and Darvocet). Propoxyphene is a paradigm example of an unreasonably dangerous prescription drug that should never have been sold. Thousands of persons suffered serious cardiac injuries or death as a result of their use of propoxyphene before November 2010, when the federal Food and Drug Administration ("FDA") finally concluded that the drug's serious risks outweighed its questionable therapeutic benefits and asked all manufacturers of propoxyphene to withdraw the drug from the United States market. *Amici* Gilbert, Kinter, Brown, and Szromba are all plaintiffs in pending product liability lawsuits against manufacturers of propoxyphene in which plaintiffs have asserted, *inter alia*, causes of action for strict liability design defect and/or closely related causes of action under state law. Their claims may be directly affected by the Court's ruling in this case.

John and Tammy Gilbert's only child, Kira, a healthy 22-year old, died suddenly of a heart attack after ingesting generic propoxyphene, prescribed to

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[1] No counsel for a party authored this brief in whole or in part, and no party or its counsel made a monetary contribution intended to fund the preparation or submission of this brief. No person or entity other than *amici curiae* or their counsel made any monetary contribution to this brief's preparation or submission. The parties' letters of blanket consent to the filing of amicus briefs have been filed with the Clerk.

her for pain relief. Their lawsuit against the propoxyphene manufacturer, transferred to the Darvon, Darvocet, and Propoxyphene Multidistrict Litigation ("MDL") proceeding before the U.S. District Court for the Eastern District of Kentucky, was dismissed on grounds of preemption and is now on appeal to the United States Court of Appeals for the Sixth Circuit. Deborah Kinter's brother, Blaine, died at age 58 from cardiac dysrhythmia (an abnormal heartbeat) as a result of his use of generic propoxyphene. Her claims against the manufacturers were also dismissed by the MDL district court and are now pending before the Sixth Circuit. Donald Brown experienced chest pains, angina, fatigue, and heart arrhythmias as a result of his use of both brand-name and generic propoxyphene. He eventually developed supraventricular tachycardia ("SVT"), which necessitated an SVT ablation and the implantation of a heart pacemaker. Mr. Brown's claims against the manufacturers of generic propoxyphene were dismissed by the MDL court, but his claims against the manufacturers of Darvon remain pending. Alice Szromba, the mother of two young children, suffered atrial fibrillation and other heart injuries, necessitating ablation surgery, as a result of a single ingestion of a generic propoxyphene product. Her lawsuit against the propoxyphene manufacturer was filed in Imperial County Superior Court in California, subsequently removed to federal court, and at present awaits a ruling on a pending motion to remand.

Darvon was first approved by the FDA in 1957 for the treatment of mild to moderate pain. At the time, federal law did not require drug manufacturers to prove that a drug was safe and effective in order to obtain FDA approval; instead, the FDA was required

to approve an application to market a new prescription drug unless it could establish that the drug was unsafe. *Wyeth v. Levine*, 555 U.S. 555, 566 (2009). In 1972, the FDA approved Darvocet, a product combining propoxyphene with acetaminophen. Following the passage of the federal Drug Price Competition and Patent Term Restoration Act ("Hatch-Waxman Amendments") in 1984, Pub. L. No. 98-417, 98 Stat. 1585, numerous generic drug companies obtained approval to market generic versions of both Darvon and Darvocet.

Concerns about propoxyphene's risks arose many years ago. The first Citizen Petition asking for propoxyphene to be banned as an "imminent hazard" was submitted to the U.S. Department of Health, Education and Welfare in 1978. Public Citizen, *Petition to Ban All Propoxyphene (Darvon) Products* (Feb. 28, 2006), *available at* http://www.citizen.org/Page.aspx?pid=697.

In 2005, the British government began a phased withdrawal of propoxyphene products, on the grounds that the drug's efficacy in treating pain was poorly established and the risk of toxic reactions was unacceptable. *Id.* The British government statement concluded: "It has not been possible to identify any patient group in whom the risk-benefit [ratio] may be positive." *Id*. In 2009, the European Medicines Agency recommended that member countries begin a phased withdrawal of propoxyphene products. *See* Letter from Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research to Public Citizen (July 6, 2009), at 6 (on file with author). The same year, an FDA Advisory Committee recommended that propoxyphene be withdrawn from the market. *Id*.

Finally, in November 2010, when the FDA determined that even approved therapeutic doses of propoxyphene put patients at risk of potentially serious or even fatal heart rhythm abnormalities, the FDA asked all manufacturers of propoxyphene products to withdraw their products from the market. *See* FDA, *FDA Drug Safety Communication: FDA Recommends Against the Continued Use of Propoxyphene* (Nov. 19, 2010), *available at* http://www.fda.gov/Drugs/DrugSafety/ucm234338.htm. The FDA request was based on the FDA's conclusion that "the safety risks of propoxyphene outweigh its benefits for pain relief at recommended doses." *Id.*

In response to the FDA's request, manufacturers of propoxyphene voluntarily stopped selling their products. But this action came too late to prevent injury to the *amici* or their decedents.

INTRODUCTION AND SUMMARY OF ARGUMENT

FDA approval of a drug does not give its manufacturer "the unfettered right, for all time, to market its drug." *Wyeth v. Levine*, 555 U.S. 555, 592 (2009) (Thomas, J., concurring in the judgment). "It does not represent a finding that the drug . . . can never be deemed unsafe by later federal action, or as in this case, the application of state law." *Id.* Design-defect liability—and related common law bases for liability, such as negligent design, negligent marketing, and breach of the implied warranty of merchantability—provide important protection for persons injured by unreasonably dangerous products "that complements FDA regulation." *Id.* at 579 (majority opinion).

Design-defect claims are fundamentally different from failure-to-warn claims, such as the claims at issue in *Pliva, Inc. v. Mensing*, 131 S. Ct. 2567 (2011). A defectively-designed product is one that has been manufactured in accordance with its intended design, but that design poses unreasonable risks to users of the product. Such a product is "unreasonably dangerous" when the risks of the product exceed its benefits.

The absence of an adequate warning is not an element of a strict liability design-defect cause of action. Indeed, a defendant may be held strictly liable even where an adequate warning has been provided: warnings are not a substitute for supplying a reasonably safe product. The district court properly applied these principles in this case.

State-law design-defect claims are entirely consistent with and complementary to the FDA's regulatory system. Like the claims at issue in *Levine*, design-defect claims not only provide critically important compensation to persons injured by unreasonably dangerous drugs, they also provide incentives for manufacturers to respond promptly to emerging safety risks with their products and supplement the FDA's limited resources for monitoring the safety of drugs after they have been approved. Importantly, the test for imposing design-defect liability is the same as that employed by the FDA to determine whether a drug is unsafe for use: both ask whether a drug's risk of harm outweighs its therapeutic benefits.

Nor does state-law design-defect liability conflict with Congress's purposes in enacting the Hatch-Waxman Amendments. Although Congress

undoubtedly wanted to encourage the availability of less expensive generic versions of safe and effective prescription drugs, it certainly did not intend to ensure the sale of unreasonably dangerous drugs, whether branded or generic.

Petitioner can "independently do under federal law what state law requires of it." *Mensing*, 131 S. Ct. at 2579. Nothing in federal law prohibits Petitioner from compensating Ms. Bartlett for her injuries caused by Petitioner's drug. Indeed, federal law does not even require drug manufacturers to sell their products. Petitioner was free to voluntarily withdraw its generic sulindac from the market at any time. That option enabled Petitioner to avoid any risk of liability for selling an unreasonably dangerous drug.

ARGUMENT

I. DEFECTIVE-DESIGN CLAIMS ARE FUNDAMENTALLY DIFFERENT FROM FAILURE-TO-WARN CLAIMS.

Petitioner Mutual Pharmaceutical Company, Inc. (hereinafter "Mutual") bases much of its argument for extending this Court's preemption ruling in *Mensing* on a startling proposition: "that failure-to-warn claims are in fact design-defect claims." Pet'r's Br. 34 (citing *Kurns v. R.R. Friction Prods. Corp.*, 132 S. Ct. 1261, 1268 & n.4 (2012) for this proposition); *see also id.* ("At least in the prescription-drug context, *design-defect claims are failure-to-warn claims*.") (emphasis in original). *Kurns* does not support Mutual's argument. And, as even a cursory examination of product liability precedent, treatises, restatements, or academic

literature makes clear, the proposition is false. Design-defect and failure-to-warn claims are analytically distinct causes of action, two of the three legs of the product liability triad (along with manufacturing defect claims). Unlike the warning claims at issue in *Mensing*, the absence of an adequate warning is not an element of a cause of action for defective design. While the presence of an effective warning can ameliorate—and, in some cases, perhaps even overcome—the risks of an unreasonably dangerous design, the absence of such a warning does not give rise to design-defect liability. The District Court here carefully considered and applied the distinctions between warning and design claims in its management of the litigation in this case.

A. The Absence of an Adequate Warning Is Not a Necessary Element of Design-Defect Liability.

As the *Restatement (Third) of Torts: Products Liability* succinctly observes:

> Abundant authority recognizes the division of product defects into manufacturing defects, design defects, and defects based on inadequate instructions or warnings. . . . Support among the treatise writers for a functional definition of defect, differentiating among manufacturing, design, and failure to warn defects, is equally strong. . . . Law review commentary similarly recognizes the distinction as necessary to a coherent discussion of the bases of liability.

Restatement (Third) of Torts: Products Liability, § 1, Reporters' Note, cmt. A (collecting authorities). New Hampshire law is in accord with this consensus and distinguishes among defects in manufacturing, design, and warnings. *See, e.g.*, *LeBlanc v. Am. Honda Motor Co.*, 688 A.2d 556, 562 (N.H. 1997).

Contrary to Petitioner's contention, this Court's decision last Term in *Kurns* did not equate failure-to-warn and design-defect claims. It simply held that both types of claims fell within the exclusively federal field of "regulating locomotive equipment," and thus were preempted.[2] Indeed, the Court's preemption discussion was careful to distinguish between, and separately analyze, the plaintiff's failure-to-warn and design-defect claims. 132 S. Ct. at 1268 (quoting *Restatement (Third) of Torts: Products Liability*, § 2(e), cmt. l for the proposition that "[r]easonable designs and instructions or warnings both play important roles in the production and distribution of reasonably safe products").

New Hampshire law recognizes this distinction. As the New Hampshire Supreme Court stressed in *LeBlanc*: "The plaintiff's design defect and failure to warn claims are separate." 688 A.2d at 562. The absence of an adequate warning is not an element of the strict liability design-defect cause of

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[2] The Court had long ago held that Congress, in enacting the Locomotive Inspection Act, had "manifest[ed] the intention to occupy the entire field of regulating locomotive equipment." *Napier v. Atlantic Coast Line R.R. Co.*, 272 U.S. 605, 611 (1926). In light of that long-standing precedent, the central issue in *Kurns* was whether the plaintiff's state-law claims implicated locomotive equipment in any way and thus fell within that preempted field.

action in New Hampshire (or anywhere else, for that matter).

To make out a design-defect claim in New Hampshire, a plaintiff must prove that

> (1) the design of the product created a defective condition unreasonably dangerous to the user;
>
> (2) the condition existed when the product was sold by a seller in the business of selling such products;
>
> (3) the use of the product was reasonably foreseeable by the manufacturer; and
>
> (4) the condition caused injury to the user or the user's property.

Vautour v. Body Masters Sports Indus., Inc., 784 A.2d 1178, 1181 (N.H. 2001) (citing *Chellman v. Saab-Scania AB*, 637 A.2d 148, 150 (1993)). "[W]hether a product is unreasonably dangerous . . . is determined by the jury using a risk-utility balancing test. Under [that test], a product is defective as designed 'if the magnitude of the danger outweighs the utility of the product.'" *Id.* at 1182 (quoting William Lloyd Prosser, *et al.*, *Prosser and Keeton on the Law of Torts* § 99, at 699 (5th ed. 1984)). The district judge's instructions to the jury in this case required them to find each of these elements. J.A. 538.

That the product at issue in this case was a prescription drug does not alter this analysis. Contrary to Petitioner's assertion, Pet'r's Br. 34-35, comment k to the *Restatement (Second) of Torts* § 402A, does not convert design-defect claims involving unreasonably dangerous drugs into failure-to-warn claims.[3]

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[3] Comment k provides, in full:

> k. Unavoidably unsafe products. There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it,

Any discussion of the implications of comment k is irrelevant in this case, given that Mutual expressly waived its comment k defense before trial. Pet. App. 7a. In any event, Petitioner misunderstands comment k.

Comment k applies only to "unavoidably unsafe" products and exempts them from strict liability, so long as they are "properly prepared, and accompanied by proper directions and warning." *Restatement (Second) of Torts* § 402A, cmt. k. An "unavoidably unsafe" product is "an apparently useful and desirable product, attended with a known but apparently reasonable risk," *id.*, that is, a product with utility that outweighs its risks. Thus, by definition, an "unreasonably dangerous" product—one with risks that exceed its utility—cannot be an "unavoidably unsafe" one.

In the vast majority of states, including New Hampshire, the comment k defense must be applied on a case-by-case basis; it does not afford blanket design-defect immunity to all prescription drugs. *See Brochu v. Ortho Pharm. Corp.*, 642 F.2d 652, 655 (1st Cir. 1981) ("We are unwilling to say that under New Hampshire's balancing test no drug can ever be classified as unreasonably dangerous.").[4] In *Toner v.*

> is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

Restatement (Second) of Torts § 402A, cmt. k (1965).

[4] Only three states appear to apply comment k to all prescription drugs: California, Utah, and Washington. *See*

Lederle Laboratories, 732 P.2d 297 (Idaho 1987), the Idaho Supreme Court explained the reasons for case-by-case application of comment k:

> The comment refers to *'some'* products which are unavoidably unsafe; . . . the comment cites certain examples from that field deserving of its protection and notes that '[t]he same is true of *many* new or experimental drugs . . .' Obviously, the comment does not apply to *all* drugs. Rather, the comment applies 'when the situation calls for it,' which is when the product is unavoidably unsafe, but is 'an apparently useful and desirable product, attended with a known but apparently reasonable risk' . . . . It is equally obvious that not all drugs are so perfectly designed that they cannot be made more pure or more safe, or that there are not safer, suitable alternatives; nor do the benefits of all drugs necessarily outweigh their risks.

Id. at 308. Thus, where a jury finds that a drug is unreasonably dangerous, comment k does not apply and, therefore, design-defect liability may be imposed even if the drug was "properly prepared, and accompanied by proper directions and warnings."

Brown v. Superior Court, 751 P.2d 470 (Cal. 1988); *Grundberg v. Upjohn Co.*, 813 P.2d 89 (Utah 1991); *Young v. Key Pharms.*, 922 P.2d 59 (Wash. 1996) (en banc).

B. An Adequate Warning Does Not Automatically Shield an Unreasonably Dangerous Product From Design-Defect Liability.

Indeed, even where a defendant provides an ideal warning, it may still be held strictly liable when the product's risks outweigh its benefits. Warnings are not an adequate substitute for supplying a reasonably safe product.

To begin with, "instructions and warnings may be ineffective because users of the product may not be adequately reached, may be likely to be inattentive, or may be insufficiently motivated to follow the instructions or heed the warnings." *Restatement (Third) of Torts: Products Liability* § 2, cmt. l. Moreover, some products will remain unreasonably dangerous even when warnings are followed. In the drug context, for example, certain side effects will occur in some number of cases even when all instructions for safe use and warnings are heeded. If the risks posed by those side effects are found to outweigh the drug's benefits to the public as a whole, then the manufacturer will be obligated to compensate the injured patient, regardless of the presence of warnings regarding those risks.

This is not to say that the warnings provided by a manufacturer are always irrelevant to a claim of strict liability design defect. In some cases, an effective warning, by potentially alerting consumers (or, in the case of prescription drugs, prescribing physicians) about a product's dangers, can reduce those risks; on occasion, a warning or instruction for safe use might even shift the overall risk-utility balance from unreasonably dangerous to reasonably

so. For this reason, New Hampshire law identifies "the presence and efficacy of a warning to avoid an unreasonable risk of harm" as one of the factors that a jury may evaluate to determine whether a product is unreasonably dangerous. *Price v. BIC Corp.*, 702 A.2d 330, 333 (N.H. 1997).

As the district court recognized, however, a warning can only ameliorate the risks inherent in a product's design; it cannot increase them. If a product's design is not unreasonably dangerous without any warning, it cannot become unreasonably dangerous when a warning (however inadequate) is added. Evidence of warning can therefore only aid a defendant in a design-defect claim. Thus, the district court's repeated admonition that Ms. Bartlett "needed to prove that sulindac's risks outweighed its benefits '*despite* its warning, not *because* of it." Pet. App. 37a (emphasis in original) (quoting *Bartlett v. Mutual Pharm. Co.*, No. 08-cv-00358-JL, 2010 WL 3303864, at *1 (Aug. 15, 2010)). And, when it came time to instruct the jury, the district court was careful to emphasize this distinction:

> The warning. If you determine that sulindac was unreasonably dangerous, you may consider the presence and efficacy (or effectiveness) of a warning *to avoid an unreasonable risk of danger* from foreseeable uses of the product. The plaintiff must prove that the product was unreasonably dangerous *even with its warning*.

J.A. 539 (emphasis added).

Assuming, as we must, that the jury followed the court's instructions, *see Marshall v. Lonberger*, 459 U.S. 422, 438 n.6 (1983) ("the crucial assumption underlying the system of trial by jury is that juries will follow the instructions given them by the trial judge") (internal quotations and citations omitted), it could not have found Mutual liable due to inadequacies in the warnings it provided. The jury held Mutual liable for defective design, not for failing to provide an adequate warning.

II. STATE – LAW DESIGN - DEFECT LIABILITY FOR PRESCRIPTION DRUGS COMPLEMENTS AND SUPPORTS THE FDA REGULATORY SYSTEM.

A. Just as in *Wyeth v. Levine,* State Design-Defect Liability Is Consistent With the Purposes of the FDCA.

Just like the failure-to-warn claim in *Levine*, the strict liability design-defect cause of action at issue in this case is entirely consistent with—and complementary to—the federal regulatory scheme. In *Levine*, this Court articulated the ways in which state law complements federal law:

> The FDA has limited resources to monitor the 11,000 drugs on the market, and manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge. State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to

> disclose safety risks promptly. They also serve a distinct compensatory function that may motivate injured persons to come forward with information. . . . Thus, the FDA long maintained that state law offers an additional, and important, layer of consumer protection that complements FDA regulation.

555 U.S. at 578-79; *see also id.* at 574 ("state-law remedies further consumer protection by motivating manufacturers to produce safe and effective drugs").

Each of these arguments is equally applicable to strict liability design claims. The FDA's resources remain limited, and it must of necessity rely on manufacturers—both brand-name and generic—to alert the agency when new information indicates that a drug's risks are greater, or that it is less effective, than previously understood.[5] State product-liability claims help expose such risks and provide powerful incentives for drug manufacturers to address these dangers, by bringing the matter to the FDA's attention, pursuing strengthened labeling, or by withdrawing unreasonably dangerous products from the market. In so doing, state tort law directly supports and complements the federal regulatory system. And, of course, design-defect liability also provides critically important compensation to

[5] Although Congress expanded the FDA's powers to order post-approval studies, clinical trials, and/or labeling changes in 2007, 21 U.S.C. § 355(o) (Supp. V 2011), the agency still needs to be made aware of an emerging risk before it can address it. In any event, Ms. Bartlett's injury predated this statutory change.

persons injured by unreasonably dangerous drugs such as Karen Bartlett.

B. As the United States Acknowledges, Such State-Law Actions Largely Parallel the FDCA's Prohibition on the Sale of Misbranded Drugs.

Significantly, the standards for design-defect liability under state law largely parallel federal requirements governing prescription drugs. The United States acknowledges in its amicus brief that the FDA itself employs a risk-utility balancing test in deciding whether to approve a drug:

> Because "[n]o drug is absolutely safe" and "all drugs have side effects," FDA "generally considers a drug safe when the expected therapeutic gain justifies the risk entailed by its use," *United States* v. *Rutherford*, 442 U.S. 544, 555 (1979), *i.e.*, the drug's "probable therapeutic benefits must outweigh its risk of harm," *FDA* v. *Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 140 (2000).

U.S. Amicus Br. 3 (first internal citation omitted). That inquiry parallels the risk-benefit analysis used to determine whether a product is unreasonably dangerous and, therefore, whether the manufacturer is strictly liable under state law for injuries caused by that product.

FDA approval of a drug is based on the risk and benefit information available to the agency at the time. It does not give the manufacturer "the unfettered right, for all time, to market its drug."

Levine, 555 U.S. at 592 (Thomas, J., concurring in the judgment). New information that emerges after the drug enters the market may indicate that the drug is actually ineffective or unsafe.[6] If such information switches the risk-utility balance, *i.e.*, leads to the conclusion that the drug is unreasonably "dangerous to health when used" in accordance with its approved labeling, the drug becomes "misbranded" under federal law, 21 U.S.C. § 352(j). And federal law prohibits the sale of any misbranded drug. 21 U.S.C. §§ 331(a)-(c), (g), and (k).[7]

The United States concedes that a state design-defect cause of action that imposed liability on such misbranded drugs would not conflict with federal law. U.S. Amicus Br. 23. That is precisely the cause of action at issue here. The United States

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[6] As this Court explained in *Levine*, in discussing the 2008 amendment to the FDA's "changes being effected" regulation, such new information is not limited to new data, but also encompasses "new analyses of previously submitted data." The rule accounts for the fact that risk information accumulates over time and that the same data may take on a different meaning in light of subsequent developments: "[I]f the sponsor submits adverse event information to FDA, and then later conducts a new analysis of data showing risks of a different type or of greater severity or frequency than did reports previously submitted to FDA, the sponsor meets the requirement for 'newly acquired information.'" 555 U.S. at 569 (quoting 73 Fed. Reg. 49603, 49604, 49607 (Aug. 22, 2008)).

[7] This is exactly what happened with propoxyphene. New evidence of propoxyphene's risks emerged after the drug was marketed. This new evidence eventually led the FDA to reevaluate propoxyphene's risk-utility balance and ultimately to conclude that "the safety risks of propoxyphene outweigh its benefits." *See FDA Drug Safety Communication*, *supra*. It therefore called upon all manufacturers of propoxyphene to stop selling the drug. *Id.*

identifies no difference between the federal misbranding standard set forth in the statute and the "unreasonably-dangerous" analysis followed in New Hampshire and prescribed in the jury instructions in this case.

Moreover, in evaluating a product's risks, state law gives weight to the FDA's role in reviewing drug safety. States generally adhere to the basic tort principle, in negligence cases, that compliance with applicable regulatory requirements is relevant evidence that a defendant's conduct was not negligent; however, such evidence is not conclusive of non-liability where circumstances exist that would have led a reasonable manufacturer to take additional precautions. *See Restatement (Second) of Torts* § 288C (1965) ("Compliance with a legislative enactment or an administrative regulation does not prevent a finding of negligence where a reasonable man would take additional precautions."); *id.*, cmt. *a.* ("Where there are no such special circumstances, the minimum standard prescribed by the legislation or regulation may be accepted by the triers of fact, or by the court as a matter of law, as sufficient for the occasion; but if for any reason a reasonable man would take additional precautions, the provision does not preclude a finding that the actor should do so.").

Similarly, in the strict liability context, compliance with regulatory requirements can be relevant evidence that a product is not defective. *See Raymond v. Riegel Textile Corp.*, 484 F.2d 1025 (1st Cir. 1973) (applying New Hampshire law). The district judge so instructed the jury in this case. J.A. 541.

The jury was well aware that the FDA had approved sulindac (and its label). But Plaintiff presented the jury with significant evidence of sulindac's risks that became available only after sulindac had been approved and that had not been given to the FDA. Resp't's Br. 52. That evidence provided a more than sufficient basis for the jury to conclude that, despite the earlier FDA approval, sulindac was unreasonably dangerous at the time Karen Bartlett used the drug.

The United States now implies that all of that new information was considered by the FDA in its 2005 review of all NSAID products. U.S. Amicus Br. 7. Even if that were true,[8] Petitioner never argued that that 2005 FDA review should have been given preemptive effect. *See* Pet. App. 69a-76a (identifying

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[8] There is reason to doubt the FDA's description of its 2005 review as a "'comprehensive review of the risks and benefits, including the risk of SJS and TEN, of all NSAID products.'" U.S. Amicus Br. 7 (quoting FDA, *Decision Letter*, FDA Docket No. 2005P-0072/CP1, at 2 (June 22, 2006), *available at* http://www.fda.gov/ohrms/dockets/dockets/05p0072/05p-0072-pav0001-vol1.pdf). The 2005 review concerned the cardiovascular risk of non-steroidal anti-inflammatory drugs ("NSAIDs"), not their risk of skin reactions such as SJS/TEN. *See* Memorandum from John K. Jenkins, M.D., Director, Office of New Drugs to Steven Galson, M.D., Acting Director, Center for Drug Evaluation and Research re: Analysis and Recommendations for Agency Action Regarding Non-steroidal Anti-inflammatory Drugs and Cardiovascular Risk (Apr. 6, 2005), *available at* http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm106201.pdf. While the 2005 review did consider the reporting rate of SJS/TEN associated with Bextra (valdecoxib), as compared to the rate for other Cox-2 selective agents, there is no indication that the study considered the risk of SJS/TEN associated with non-selective NSAIDs such as sulindac. *See* Resp't's Br. 52-54.

preemption arguments raised by Mutual). Since preemption is an affirmative defense, the burden was on Mutual to raise a defense based on the 2005 NSAID review; its failure to do so means that any such argument has been waived.

C. Mutual's Argument that Design-Defect Liability "Thwarts Hatch-Waxman's Central Objective of Ensuring that Generic Drugs Are Available for Sale" Completely Misses the Point.

Mutual itself raises a different obstacle preemption argument. It argues that imposing state tort liability upon it for the sale of an unreasonably dangerous drug frustrates Congress's "central objective" in enacting Hatch-Waxman of "ensur[ing] that generic copies of previously approved drugs are available for sale." Pet'r's Br. 46; *see generally id.* at 45-53.

Petitioner's argument completely misses the point. A determination that a particular drug product is unreasonably dangerous applies equally to both branded and generic versions of that drug. *Cf.* U.S. Amicus Br. 30 ("brand-name and generic drugs should be treated the same for purposes of design-defect claims"). When Congress enacted Hatch-Waxman, it undoubtedly wanted to encourage the availability of less expensive generic versions of safe and effective drug products. But there is no reason to believe that Congress had any desire to encourage—let alone ensure—the sale of unreasonably dangerous prescription drugs, whether in branded or generic form. Indeed, the misbranding provisions of the federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§

331, 352(j), demonstrate that the opposite is true. So imposing state law liability for injuries caused by an unreasonably dangerous generic drug is not in conflict with congressional purposes.

III. IT WAS NOT IMPOSSIBLE FOR PETITIONER TO COMPLY WITH BOTH STATE AND FEDERAL LAW.

Finally, as the Court of Appeals recognized, it was quite possible for Mutual to comply with both state and federal law by not selling sulindac. Pet. App. 10a-11a. Therefore, there is no impossibility preemption here.

This Court has always held that conflict preemption based on impossibility is very narrowly circumscribed. The party arguing for preemption must establish that "compliance with both federal and state [law] is a physical impossibility." *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963). Physical impossibility only occurs where federal law prohibits conduct that state law requires, or vice versa. *See Barnett Bank of Marion Cnty., N.A., v. Nelson,* 517 U.S. 25, 31 (1996) (two statutes would "impose directly conflicting duties on national banks . . . if the federal law said, 'you must sell insurance,' while the state law said, 'you may not.'"). There is no physical impossibility if either law is permissive. *Michigan Canners and Freezers Ass'n, Inc. v. Agricultural Marketing and Bargaining Board*, 467 U.S. 461, 478 n.21 (1984) ("Because the [state statute] is cast in permissive rather than mandatory terms . . . this is not a case in which it is impossible for an individual to comply with both state and federal law.").

In *Mensing*, this Court added a qualification to this test: finding impossibility where federal law prohibits the defendant from "independently" complying with state law without intervening government action. 131 S. Ct. at 2579 ("The question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it.").[9]

In this case, federal law did not prohibit Mutual from complying with state law. Nothing in federal law prohibits Mutual from complying with the district court's judgment and compensating Ms. Bartlett for her injuries caused by Mutual's drug. Even if state law were understood to impose a duty not to sell unreasonably dangerous products—as opposed to a duty to pay compensation for injuries caused by unreasonably dangerous products—compliance with federal and state law would not be impossible. Federal law did not require Mutual to sell its generic sulindac, in New Hampshire or anywhere else. *See* U.S. Amicus Br. 21 (FDCA "does not expressly require that an approved drug be made available in any particular State or that the manufacturer be guaranteed the ability to make it so."). Drug manufacturers are generally free to decide to stop selling an approved drug at any time, whether due to safety concerns or for other reasons. *See, e.g.*, 21 C.F.R. § 314.161 (governing FDA actions

[9] This Court found impossibility in *Mensing* because federal law prohibited generic drug companies from adding new warnings to their labels without prior FDA action, and it was "not dispute[d] that . . . state law required the Manufacturers to use a different, safer label." *Id.* at 2574. "Thus, 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.* at 2578.

following a manufacturer's voluntary withdrawal of a listed drug).[10] As the Court of Appeals recognized, Mutual could have independently complied with both state and federal law by not selling sulindac. Pet. App. 10a-11a (Mutual "certainly can choose not to make the drug at all;" "the decision to make the drug and to market it in New Hampshire is wholly its own"). Because compliance with both laws was not impossible, Karen Bartlett's design-defect claim should not be preempted.

CONCLUSION

For the foregoing reasons, *amici curiae* John and Tammy Gilbert, Deborah Kinter, Donald Brown, and Alice Szromba urge this Court to affirm the judgment of the Court of Appeals.

February 20, 2013 Respectfully submitted,

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[10] Federal law only restricts a drug company's ability to withdraw from the market where it "is the sole manufacturer of a drug that is life-supporting; life sustaining; or intended for use in the prevention of a debilitating disease or condition." 21 U.S.C. § 356c. That provision does not apply here.

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