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 TORTS PROFESSORS AS *AMICI CURIAE* IN SUPPORT OF RESPONDENT

ANDY BIRCHFIELD
BEASLEY, ALLEN, CROW, METHVIN, PORTIS & MILES, P.C.
234 Commerce St.
Post Office Box 4160
Montgomery, AL 36103

CLAYTON CLARK
CLARK, LOVE & HUTSON
440 Louisiana St., Suite 1600
Houston, TX 77002

MICHAEL F. STURLEY
Counsel of Record
LYNN E. BLAIS
727 E. Dean Keeton St.
Austin, TX 78705
(512) 232-1350
msturley@law.utexas.edu

Counsel for Amici Curiae

February 20, 2013

COCKLE LAW BRIEF PRINTING CO. (800) 225-6964
OR CALL COLLECT (402) 342-2831

TABLE OF CONTENTS

TABLE OF CONTENTS – Continued

TABLE OF CONTENTS – Continued

TABLE OF CONTENTS – Continued

TABLE OF AUTHORITIES

Page

CASES

TABLE OF AUTHORITIES – Continued

Page

TABLE OF AUTHORITIES – Continued

TABLE OF AUTHORITIES – Continued

STATUTES

SCHOLARLY SOURCES

TABLE OF AUTHORITIES – Continued

TABLE OF AUTHORITIES – Continued

OTHER AUTHORITIES

STATEMENT OF INTEREST OF *AMICI CURIAE*[1]

Amici are professors who regularly teach and write about the law of torts. Each has taught for 20 years or more and each has written extensively in the field. *Amici* have no stake in the outcome of this case other than their academic interest in the logical and rational development of the law. Because this case implicates fundamental tort law issues, *amici* believe that their unique perspective may assist the Court in resolving this case. The Appendix includes further biographical information.

SUMMARY OF ARGUMENT

Petitioner misconstrues the role of strict product liability for design defects in the regulatory scheme. Such liability does not impose any affirmative duties on manufacturers with respect to the design and distribution of their products. Rather, strict liability allocates responsibility for accident costs to manufacturers to serve several important non-fault-based goals. Strict liability in this context ensures that victims are not denied compensation due to evidentiary and privity hurdles, allocates accident costs to

[1] The parties have consented to the filing of this brief. No counsel for a party authored this brief in whole or in part and no person other than *amici* and their counsel made a monetary contribution intended to fund its preparation or submission.

the party best able to bear and distribute them, and encourages manufacturers to consider whether and in what quantity to produce and distribute their products on the market.

With respect to the manufacture of prescription drugs, those important social goals often give way to the more compelling need in society for innovation and distribution of pharmaceuticals. When prescription drugs provide important social benefits yet remain unavoidably unsafe, comment k to Restatement (Second) of Torts § 402A (1965) exempts their manufacturer from strict liability. That exemption from the background assumption of strict products liability is available to defendants as an affirmative defense, by pleading and proving the basic elements of comment k itself, or by satisfying the state's risk-utility analysis. In either case, the burden is on the defendant to prove the elements of the affirmative defense, and petitioner – having waived its comment k defense before trial – cannot seek the benefit of it in this Court.

The Solicitor General has misconstrued the New Hampshire law of products liability for design defect. The New Hampshire strict liability doctrine applies without regard to fault or the breach of a legal duty to allocate to defendants the costs of injuries caused by the manufacture of unreasonably dangerous products. That doctrine differs from a no-fault liability regime in that it applies only in the narrow category of cases in which the product is found to be unreasonably

unsafe. Nonetheless, it is employed expressly for the purpose of spreading the risk of such injuries.

Nor does the New Hampshire strict liability regime include a "duty to warn" that implicates this Court's decision in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011). In New Hampshire, the presence or absence of a warning may be, but is not necessarily, a factor in determining if a product is unreasonably dangerous. In a case such as this, in which a warning would have been futile, the presence or absence of a warning would be irrelevant to the resolution of a design defect claim.

ARGUMENT

I. Strict Liability For Design Defects Does Not Impose Affirmative Duties On Manufacturers, But Rather Allocates Responsibility For Accident Costs To Manufacturers To Serve Important Non-Fault-Based Goals

States have adopted strict products liability for defective designs in order to advance social goals that are not premised on any fault-based behavior of the manufacturer. As a result, liability for design defects does not impose affirmative duties on manufacturers except to assume a "special responsibility toward any member of the consuming public who may be injured by" the product. Restatement (Second) of Torts § 402A, comment c (1965).

A. Unlike traditional tort liability, strict liability for design defects is a special rule that applies without regard to whether a manufacturer has breached any affirmative duty

Traditional tort liability is fault-based. Negligence liability, for example, is premised on a breach of the affirmative duty to use reasonable care. *See* Gregory C. Keating, *Nuisance as a Strict Liability Wrong*, 4 J. TORT LAW 1, 3 (2012) ("When liability is predicated on fault, the law targets the conduct responsible for the infliction of injury. A judgment of fault asserts that defendant's conduct was wrongful, that the defendant should have conducted itself differently and thereby avoided inflicting injury."); *see also* John C.P. Goldberg & Benjamin C. Zipursky, *Tort Law and Moral Luck*, 92 CORNELL L. REV. 1123, 1167 (2007) ("[T]ort law fashions a set of obligations that help maintain civil society as a non-atomistic, not purely contractual social world."). Similarly, failure-to-warn claims are negligence claims premised on a duty to provide an adequate warning. *See, e.g.*, MICHAEL I. KRAUSS, PRINCIPLES OF PRODUCTS LIABILITY 104-108 (2011); *see also* John L. Watts, *Fairness and Utility in Products Liability: Balancing Individual Rights and Social Welfare*, 38 FLA. ST. U. L. REV. 597, 632 (2011) (noting that the modern approach to duty-to-warn cases, "despite the strict liability misnomer used by some courts, is identical to a negligence approach"). Because the substance of a state-law failure-to-warn claim is the assertion that

the manufacturer has acted unreasonably in failing to provide an adequate warning, successful failure-to-warn claims reflect a state-imposed affirmative duty to provide a particular type of warning. *See PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2573 (2011) ("It is undisputed that Minnesota and Louisiana tort law require a drug manufacturer that is or should be aware of its product's danger to label that product in a way that renders it reasonably safe.").

Strict liability for design defects, by contrast, is a limited but important exception to this basic fault-based regime. Unlike negligence liability, strict liability is not premised on the blameworthiness of the tortfeasor. Kenneth S. Abraham, *Strict Liability in Negligence*, 61 DEPAUL L. REV. 271, 274 (2012) ("It would be difficult to exaggerate the extent to which the distinction between negligence and strict liability is embedded in tort law. . . . Negligence is the failure to exercise reasonable care; strict liability is the imposition of liability even when reasonable care has been exercised."). "Whereas negligence addresses responsibility for harm which should have been avoided, strict liability addresses responsibility for harm which should *not* have been avoided, and focuses on who should bear the costs of that harm." Keating, *supra*, 4 J. TORT LAW at 6; *see also Freeman v. Hoffman-La Roche, Inc.*, 618 N.W.2d 827, 833 (Neb. 2000) ("In a cause of action based on negligence, the question involves the manufacturer's conduct, that is, whether the manufacturer's conduct was reasonable in view of the foreseeable risk of injury; whereas in a

cause of action based on strict liability in tort, the question involves the quality of the product, that is, whether the product was unreasonably dangerous."); JOHN C.P. GOLDBERG & BENJAMIN C. ZIPURSKY, TORTS 90 (2010) (explaining the distinction, of "theoretical and practical significance," between "negligence law's ordinary care standard and the idea of strict liability, also known as no-fault liability"). Strict products liability for design defect is a classic example of no-fault strict liability. As section 402A of the Restatement (Second) of Torts makes clear, strict liability for design defects is a "special rule . . . making the seller subject to liability to the user or consumer even though he has exercised all possible care in the preparation and sale of the product." Restatement (Second) of Torts § 402A, comment a (1965).

The controversy surrounding Restatement (Third) of Torts: Products Liability § 2(b) (1997) – and its subsequent rejection by many states, including New Hampshire – further evidences the importance to the strict-liability inquiry under the Restatement (Second) of considerations beyond the tort concepts of fault and duty. Section 2(b) seeks to recharacterize design-defect liability as a fault-based standard applying traditional negligence balancing factors, including the requirement that the plaintiff present evidence of a safer alternative design. The Restatement (Third) has been the subject of substantial scholarly criticism. *See, e.g.,* John F. Vargo, *The Emperor's New Clothes: The American Law Institute Adorns a "New Cloth" for Section 402A Products*

Liability Design Defects – A Survey of the States Reveals a Different Weave, 26 U. MEMPHIS L. REV. 493 (1996); David A. Logan, *When the Restatement is not a Restatement: The Curious Case of the "Flagrant Trespasser,"* 37 WM. MITCHELL L. REV. 1448, 1462 (2011) ("Born in controversy and at odds with the original rationales for and concepts of strict liability, the core provisions of the products liability project were perceived as anti-consumer. And, as critics predicted, in the ensuing years, key new provisions have been rejected by some courts because the rules go 'beyond the law,' set the bar for recovery too high, and amount to a 'regression in the law.'") (footnotes and citations omitted). In addition, several states, including New Hampshire, have rejected § 2(b) precisely because it is insufficiently attentive to the non-fault-based goals served by strict liability for design defects. *See*, *e.g.*, *Vautour v. Body Masters Sports Industries, Inc.*, 784 A.2d 1178, 1182-84 (N.H. 2001) (explaining that § 2(b) undermines the goal of consumer compensation); *Halliday v. Sturm, Ruger & Co.*, 792 A.2d 1145, 1154 (Md. 2002) (noting that "[s]ubstitution of a risk-utility analysis . . . , especially as formulated in the RESTATEMENT (THIRD), has attracted considerable criticism and has been viewed by many as a retrogression, as returning to negligence concepts and placing a very difficult burden on plaintiffs").

B. Strict liability for design defects serves three important non-fault-based goals

Not being fault-based, the strict liability design-defect regime imposes no affirmative duties on manufacturers. Rather, a strict liability regime allocates accident costs to manufacturers, without regard to the breach of any duty, in order to serve several non-fault-based social goals. *See* William L. Prosser, *The Assault Upon the Citadel (Strict Liability to the Consumer)*, 69 YALE L.J. 1099, 1122-24 (1960) (explaining that strict liability has been adopted by courts to serve three non-fault-based goals); *see also* Mary J. Davis, *Design Defect Liability: In Search of a Standard of Responsibility*, 39 WAYNE L. REV. 1217, 1226-27 (1993) (discussing the goals of strict liability for design defects).

1. Strict liability for design defects ensures that consumers are compensated for their injuries

Strict liability eliminates privity requirements and evidentiary barriers, thereby ensuring that consumers injured by unreasonably dangerous products are compensated for their injuries. Prosser, 69 YALE L.J. at 1123-24 (Obtaining compensation for injuries caused by defective products in the absence of strict liability "is an expensive, time-consuming, and wasteful process, and it may be interrupted by insolvency, lack of jurisdiction, disclaimers, or the statute of limitations, anywhere along the line. What is needed is a blanket rule which makes any supplier in

the chain liable directly to the ultimate user, and so short-circuits the whole unwieldy process."); *see also Brooks v. Beech Aircraft Corp.*, 902 P.2d 54, 58 (N.M. 1995) ("[P]laintiffs injured by an *unreasonably* dangerous product should be compensated for their injuries. At the heart of this judgment lies the conclusion that although the manufacturer has provided a valuable service by supplying the public with a product that it wants or needs, it is more fair that the cost of an *unreasonable* risk of harm lie with the product and its possibly innocent manufacturer than it is to visit the entire loss upon the often unsuspecting consumer. . . .").

2. Strict liability for design defects imposes costs on the party that is best able to either bear or redistribute them

Imposing accident costs on manufacturers without regard to fault allocates risks and costs to the party best able to bear or redistribute them. Prosser, 69 YALE L.J. at 1122 (explaining that strict liability "justifies the imposition, upon all suppliers of such products, of full responsibility for the harm they cause, even though the supplier has not been negligent"); *see also Azzarello v. Black Brothers Co.*, 391 A.2d 1020, 1023 (Pa. 1978) ("The realities of our economic society as it exists today forces the conclusion that the risk of loss for injury resulting from defective products should be borne by the suppliers, principally because they are in a position to absorb

the loss by distributing it as a cost of doing business.").

3. Strict liability for design defects ensures that manufacturers bear the full costs their products impose on society, thereby encouraging them to reduce that risk by controlling their activity level

By imposing the costs of accidents on manufacturers without regard to fault, a strict liability regime ensures that manufacturers bear the full costs that their products impose on society. Only if all the costs are included in a manufacturer's production decisions can it accurately determine how much of the unreasonably dangerous product to sell, or even whether to sell it at all. As Professor Kenneth Abraham recently explained:

> Exercising reasonable care does not eliminate the risk of injury. Other things being equal, therefore, the more a party engages in an activity, even if she exercises reasonable care, the more often injury or damage will result. The threat of liability for negligence thus generates no incentive to determine whether it would be more sensible to engage in less of the activity because exercising reasonable care will insulate a party from any liability for injury or damage that results from engaging in the activity. . . .

> Threatening to impose strict liability for injury or damage resulting from engaging in an activity can therefore create an additional incentive. Because a party will be held liable even for harm that results when it exercises reasonable care, liability costs can be reduced by engaging in less of the activity or partially or fully substituting a different, cost-effective activity.

Abraham, *supra*, 61 DEPAUL L. REV. at 278-279; *see also Indiana Harbor Belt Railroad Co. v. American Cyanamid Co.*, 916 F.2d 1174, 1177 (7th Cir. 1990) (Posner, J.) ("The baseline common law regime of tort liability is negligence. When it is a workable regime, because the hazards of an activity can be avoided by being careful . . . there is no need to switch to strict liability. Sometimes, however, a particular type of accident cannot be prevented by taking care but can be avoided . . . by reducing the scale of the activity in order to minimize the number of accidents caused by it. . . . By making the actor strictly liable . . . we give him an incentive, missing in a negligence regime, to experiment with methods of preventing accidents that involve not greater exertions of care, assumed to be futile, but instead . . . reducing (perhaps to the vanishing point) the activity giving rise to the accident.") (citations omitted); Steven Shavell, *Strict Liability Versus Negligence*, 9 J. LEGAL STUD. 1, 2-3 (1980) (explaining that strict liability can affect activity levels whereas negligence liability tends to affect only safety levels).

This additional goal of strict liability – to encourage manufacturers to consider and, in certain cases, adjust their activity level with respect to unreasonably dangerous products if, despite taking all reasonable care in the manufacturing of the product, the product's risks still outweigh its utility – comports with the First Circuit's recognition that federal law does not require drug manufacturers to sell their products. Pet. App. 10a ("But although [petitioner] cannot legally make sulindac in another composition (nor is it apparent how it could alter a one-molecule drug anyway), it certainly can choose not to make the drug at all. . . .").

C. None of the important non-fault-based goals served by the application of strict liability for design defects imposes affirmative duties on manufacturers beyond the duty to assume the costs of injuries resulting from their products

None of these social goals is premised on fault-based duties, and none imposes any affirmative requirements on manufacturers. Under a strict liability design-defect regime, the manufacturer of an unreasonably dangerous product is faced with only one obligation as a result of marketing its product – the obligation to assume the costs of any injuries that might occur as a result of its actions. This obligation does not entail a judgment that the action was blameworthy, or, concomitantly, that the action

should be avoided. *See* Guido Calabresi & Jon T. Hirschoff, *Toward a Test for Strict Liability in Torts*, 81 YALE L.J. 1055, 1060-61 (1972) ("Instead of requiring a judgment as to whether an injurer *should* have avoided the accident costs because the costs of avoidance were less than the foreseeable accident costs as the [negligence] test does, the strict liability test would simply require a decision as to whether the injurer or the victim was in the better position both to judge whether avoidance costs would exceed foreseeable accident costs and to act on that judgment. The issue becomes not *whether* avoidance is worth it, but which of the parties is relatively more likely to find out whether avoidance is worth it.") (footnote omitted).

In asserting (at 41) that "all common law liability is premised on the existence of a legal duty" (citations and quotations omitted), petitioner ignores these important distinctions between negligence and strict liability.

Petitioner also conflates state tort liability in the context of federal regulatory schemes that expressly preempt additional state-law requirements or occupy the field with the effect of tort liability in areas in which Congress has evidenced no intent to preempt all state-law claims. In an area in which Congress has expressly preempted state requirements "different from, or *in addition to*," federal requirements, Congress has determined that federal law sets a ceiling on the regulatory requirements to which a manufacturer should be subject. *Riegel v. Medtronic,*

Inc., 552 U.S. 312, 321 (2008) (emphasis added; internal quotation marks omitted). Similarly, in regulatory schemes that occupy the field in which they operate, federal decisions not to regulate are as important as decisions to take affirmative action. *See*, *e.g.*, *San Diego Building Trades Council v. Garmon*, 359 U.S. 236, 248 (1959) ("Even the States' salutary effort to redress private wrongs or grant compensation for past harm cannot be exerted to regulate activities that are potentially subject to the exclusive federal regulatory scheme [embodied in the NLRA]."). Thus, the imposition of damages pursuant to a state-law action may alter behavior in a field that Congress has chosen to occupy, impermissibly interfering with federal decision-making in a pervasively regulated field. *See Kurns v. Railroad Friction Products Corp.*, 132 S. Ct. 1261, 1269-70 (2012); Caleb Nelson, *Preemption*, 86 VA. L. REV. 225, 261-262 (2000) (discussing the effect of state liability in the context of field preemption and noting that in cases of field preemption, "if a state purports to regulate the forbidden field, a court would have to choose between giving legal effect to the state regulation and giving legal effect to the federal rule depriving such regulations of authority").

In an area governed by conflict preemption, however, only those state-law obligations that affirmatively conflict with a federal requirement are preempted. The imposition of strict liability for design defects does not assign fault and does not demand any affirmative action, except to assume the cost of

injuries caused by unreasonably dangerous drugs. Unlike the duty to provide an adequate warning, which in the case of generic drugs is impossible to discharge under current FDA regulations, *see PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), the duty to compensate consumers injured by unreasonably dangerous drugs has no FDA counterpart with which it could conflict. Thus, compliance with both federal regulations and state law is not a "physical impossibility." *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-143 (1963).

Nor does the incentive created by strict design-defect liability for manufacturers to consider how much of the drug (if any) to market in a particular state conflict with any affirmative duty imposed by the FDCA. Approval by the FDA is a prerequisite for introducing drugs into the market. 21 U.S.C. § 355(a). The FDCA does not, however, "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." U.S. Br. 21. In the context of state law design-defect claims, there is neither a federal affirmative duty to market a drug, nor a state affirmative duty to cease marketing the drug, and thus no conflict exists. The FDA's role in prescription drug regulation leaves important room in the regulatory scheme for states to create incentives for manufacturers to remove drugs from the market if the incremental risk of offering the drug to consumers outweighs its incremental benefits, even if that drug is approved for marketing by the FDA.

Contrary to the Solicitor General's assertion (at 18-20), the *Mensing* Court did not reject the complementary nature of the incentive to decrease or cease marketing operations of an unreasonably dangerous but FDA-approved drug. As the Solicitor General concedes, respondents in *Mensing* did not raise that argument and therefore this Court did not address it. *See* U.S. Br. at 19 n.4; *see also Mensing*, 131 S. Ct. at 2587 n.8 (Sotomayor, J., dissenting) (noting that the decision below had "suggested" that the manufacturers could not show impossibility because federal law merely permitted them to market generic drugs but did not require them to do so, and stating that "Respondents have not advanced this argument, and I find it unnecessary to consider.").[2]

[2] The *Mensing* plaintiffs belatedly advanced the argument in a rehearing petition, which this Court summarily denied. *See PLIVA, Inc. v. Mensing*, 132 S. Ct. 55 (2011). That summary denial lacks precedential force and does not control here. *See Connecticut v. Doehr*, 501 U.S. 1, 12 n.4 (1991) ("A summary disposition does not enjoy the full precedential value of a case argued on the merits and disposed of by a written opinion."); *Fernandez v. Chardon*, 681 F.2d 42, 51 n.7 (1st Cir. 1982) ("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").

II. Most States Follow The Restatement In Providing An Exemption From Strict Liability For Design Defects In Prescription Drugs If The Manufacturer Proves That The Drug Is Unavoidably Unsafe, But Petitioner Has Waived This Affirmative Defense

As discussed above, strict products liability for design defects is a limited exception to the general fault-based negligence regime. Within this small window of strict liability, the Restatement (Second) recognizes that some products are incapable of being made safe for their intended use but are nonetheless so socially important that the compensation, risk-spreading, and activity-level incentives of strict liability are inappropriate. Restatement (Second) § 402A, comment k. Comment k labels such products "unavoidably unsafe" and exempts the manufacturer of those products from strict liability for design defects. Some states apply the exemption on a case-by-case basis, even to prescription drugs, while others have held that all prescription drugs are exempted from strict liability for design defects. Whether applied as blanket immunity or in individual cases, the exemption from strict liability for prescription drugs under comment k has been generously available to manufacturers of prescription drugs. In all events, however, the exemption offered by comment k is an affirmative defense to strict liability, and that defense must be pleaded and proved by the manufacturer.

A. Consistent with the importance of the goals underlying strict liability for design defects, comment k is best read not to confer blanket immunity from strict liability on all prescription drugs

Comment k exempts from strict liability those products "which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use." Restatement (Second) of Torts § 402, comment k. While pharmaceuticals may fall into this category, there is no reason to believe that *all* drugs will satisfy the comment k criteria. Indeed, the comment itself makes clear that there will be drugs that do not satisfy the criteria by noting that such unavoidably unsafe products "are *especially common* in the field of drugs." *Id*. (emphasis added). The comment further identifies the Pasteur treatment for rabies as an example of a product deserving immunity, and then notes that "the same is true of many other drugs, vaccines, and the like." If comment k were intended to indicate that blanket immunity for all prescription drugs was appropriate, it would make no sense to offer examples of drugs that may qualify for such immunity. Thus, while it may be especially common for pharmaceuticals to qualify as unavoidably unsafe products, comment k should not be read to provide a blanket exception from strict liability for *all* drugs.

Given the importance of the policies underlying strict scrutiny for defective products, many states

apply comment k to prescription drugs only if the manufacturer can demonstrate that the drug is unavoidably unsafe. *See Freeman*, 618 N.W.2d at 836 (noting that "[t]he majority of jurisdictions that have adopted comment k. apply it on a case-by-case basis, believing that societal interests in ensuring the marketing and development of prescription drugs will be adequately served without the need to resort to a rule of blanket immunity") (overruling prior decision to the contrary); *see also Feldman v. Lederle Laboratories*, 479 A.2d 374, 383 (N.J. 1984) ("Whether a drug is unavoidably unsafe should be decided on a case-by-case basis; we perceive no justification for giving all prescription drug manufacturers a blanket immunity from strict liability . . . design defect claims under comment k."); *Hill v. Searle Laboratories*, 884 F.2d 1064, 1069 (8th Cir. 1989) ("The better reasoned opinions support the view that the unavoidably unsafe exception should only apply [to prescription drugs] upon a showing of exceptional social need."); *cf. Tansy v. Dacomed Corp.*, 890 P.2d 881, 886 (Okla. 1994) (holding that comment k *can*, not *must,* apply to medical devices).

Although New Hampshire courts have not spoken definitively to the issue, there is no reason to believe that they would interpret comment k as an across-the-board exemption from strict liability for all prescription drugs. *See Brochu v. Ortho Pharmaceutical 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."). The New Hampshire Supreme Court's refusal to adopt the stricter § 2(b) of the Restatement (Third) over its more relaxed Restatement (Second) counterpart, *see Vautour*, 784 A.2d at 157, because it would "impose an undue burden on plaintiffs" further suggests that it would reject a blanket immunity for prescription drug manufacturers under comment k. *Cf. Freeman*, 618 N.W.2d at 840 (rejecting Restatement (Third) § 6(c), which provides more extensive immunity for prescription drug manufacturers, because it "has no basis in the case law" and is "too strict of a rule, under which recovery would be nearly impossible."). States adopting the case-by-case approach have, in essence, concluded that "[i]t does not serve society that an unavoidably unsafe product, which has occasional or fractious benefit, should enjoy insulation from strict liability in tort when the product's predominant effects are detrimental to individual and public safety." Sidney H. Willig, *The Comment* k *Character: A Conceptual Barrier to Strict Liability*, 29 MERCER L. REV. 545, 545 (1978).

In states adopting the case-by-case application of comment k, determining whether a product – even a pharmaceutical product – is unavoidably unsafe requires a weighing of relevant risk-utility factors. *See Freeman*, 618 N.W.2d at 837 ("Although a variety of tests are employed among jurisdictions that apply comment k. on a case-by-case basis, the majority apply the comment as an affirmative defense, with the trend toward the use of a risk-utility test to determine whether the defense applies."); *see also*

Tansy, 890 P.2d at 886 (embracing the holdings of other courts that "a risk-utility analysis must be employed before Comment k will bar recovery under products liability"). Relevant factors include: "(1) whether, when distributed, the product was intended to confer an exceptionally important benefit that made its availability highly desirable; (2) whether the then-existing risk posed by the product was both 'substantial' and 'unavoidable'; and (3) whether the interest in availability (again measured as of the time of distribution) outweighs the interest in promoting enhanced accountability through strict liability design defect review." *Savina v. Sterling Drug, Inc.*, 795 P.2d 915, 925 (Kan. 1990) (quoting and expressly adopting the reasoning of *Kearl v. Lederle Laboratories*, 172 Cal. App. 3d 812 (1985), *overruled by Brown v. Superior Court (Abbot Labs)*, 751 P.2d 470 (1988)); *see also Toner v. Lederle Laboratories,* 732 P.2d 297, 306 (Idaho 1987). This risk-utility analysis complements, rather than conflicts with, the FDA's drug approval process. *See Feldman*, 479 A.2d at 383 ("Indeed, the FDA's determination, even if it consisted of a risk-utility analysis, would not supplant the risk-utility balancing required in the judicial process.").

To be sure, some states have taken a more expansive view of the exemption offered in comment k. Those states generally hold that a prescription drug that is properly manufactured and accompanied by an adequate warning of the risks known to the manufacturer at the time of the sale is not defectively designed as a matter of law. *See*, *e.g.*, *Young v. Key*

Pharmaceuticals, Inc., 922 P.2d 59, 64 (Wash. 1996) (en banc); *Grundberg v. Upjohn Co.*, 813 P.2d 89, 90 (Utah 1991); *Brown*, 751 P.2d at 478-480. Those states have concluded that the non-fault-based goals of strict liability in design defect are superseded by the recognition of the unique nature and value of prescription drugs, *Grundberg*, 813 P.2d at 95, and concerns that the added expense of providing compensation for injuries caused by prescription drugs will discourage or delay innovation in the pharmaceutical industry. *See*, *e.g.*, *Brown*, 751 P.2d at 479-480.

B. Exemption from liability under comment k is an affirmative defense, and the burden is on the manufacturer to raise and prove the elements of this defense

Regardless whether it is applied on a case-by-case basis or across the board, whether comment k insulates a drug manufacturer from strict liability for design defects is an affirmative defense. *See Tansy*, 890 P.2d at 886 ("The Comment does not provide blanket protection for all medical devices. Rather, it applies only as an affirmative defense. . . ."). An affirmative defense is "[a] defendant's assertion of facts and arguments that, if true, will defeat the plaintiff's . . . claim, even if all the allegations in the complaint are true." BLACK'S LAW DICTIONARY 451 (8th ed. 2004).

Because it is an affirmative defense, the defendant bears the burden of proving all of the elements of the defense. *See Tansy*, 890 P.2d at 886; *Coursen v. A.H. Robbins Co.*, 764 F.2d 1329, 1338 (9th Cir. 1985); *see also* Pet. App. 127a ("courts generally place the initial burden of proving the various [comment k] factors on the defendant"; holding plaintiff's design defect claim survived summary judgment) (internal quotation marks omitted). Thus, once the plaintiff's prima facie case for design defect is established, a manufacturer will be relieved of strict liability only when it demonstrates that its product satisfies the relevant state law criteria for establishing that its product is unavoidably unsafe. *See Freeman*, 618 N.W.2d at 840.

Petitioner (at 34-35) and the Solicitor General (at 17) claim that a defective-drug-design claim often overlaps with a failure-to-warn claim via the comment k affirmative defense. They argue that defective-drug-design claims are therefore preempted under this Court's reasoning in *Mensing*. That argument is both speculative and irrelevant. First, the New Hampshire Supreme Court has not yet embraced comment k and thus has not specified the elements of that defense if applicable in New Hampshire. Second, as noted above (at 19-20), relevant precedent suggests that New Hampshire would adopt a case-by-case risk-utility version of the comment k defense, which does not necessarily include an inquiry into the adequacy of the manufacturer's warning. Finally, and most importantly, petitioner lost any

opportunity it might have had to implicate the adequacy of its warning in Respondent's design defect claim when it waived its comment k defense "on the eve of trial." *See* Pet. App. 36a, 60a-61a.

III. Under New Hampshire Law, Strict Liability In Tort Is Consistent With The General Non-Fault-Based Goals Of Ensuring Compensation, Allocating Costs To The Party Best Able Either To Bear Or To Redistribute Them, And Ensuring That Manufacturers Internalize External Costs

The general principles discussed above are applicable in New Hampshire. The New Hampshire Supreme Court has expressly recognized and adopted the goals of strict liability that have been followed elsewhere.

A. The New Hampshire Supreme Court adopted the principles of Restatement § 402A to ensure that the risks of unreasonably dangerous products would "be borne by the companies that profited from their sale, rather than by the unfortunate individual consumers"

Prior to 1969, New Hampshire followed the traditional common-law rule under which a plaintiff generally could not recover for injuries caused by a defective product unless he or she could prove a breach of warranty or negligence on the part of the defendant. *See*, *e.g.*, *Smith v. Salem Coca-Cola*

Bottling Co., 25 A.2d 125 (N.H. 1942); *Howson v. Foster Beef Co.*, 177 A. 656 (N.H. 1935). Thus "a products liability claim was actionable under warranty and negligence theories," but not under "the strict liability concept." *Waid v. Ford Motor Co.*, 484 A.2d 1152, 1155 (N.H. 1984); *see also*, *e.g.*, *Bagley v. Controlled Environment Corp.*, 503 A.2d 823, 825 (N.H. 1986) (Souter, J.) ("strict liability for damages has traditionally met with disfavor in this jurisdiction").

In *Buttrick v. Arthur Lessard & Sons*, 260 A.2d 111 (N.H. 1969), the New Hampshire Supreme Court first held that an injured plaintiff may proceed against the non-negligent seller of a defective product under "the theory of strict liability in tort as defined in Restatement (Second), Torts, [§ 402A]." 260 A.2d at 112. After quoting the full text of § 402A, the court explained:

> The basis for the present rule of strict liability is the "ancient one of the special responsibility for the safety of the public undertaken by one who enters into the business of supplying human being[s] with products which may endanger the safety of their persons and property, and the forced reliance upon that undertaking on the part of those who purchase such goods."

260 A.2d at 113 (quoting Restatement § 402A, comment f).

Subsequent cases have explained in greater detail that the purpose of the strict liability remedy is

to require those who sell unreasonably dangerous products to internalize the cost of the harm caused by those products. In *Heath v. Sears, Roebuck & Co.*, 464 A.2d 288, 293 (N.H. 1983), for example, the court noted that there were "many" "reasons for the evolution of the law in the area of products liability," but it relied primarily on the belief "that if today's products are capable of causing illness or physical injury, the risk of liability is best borne by the companies that profited from their sale, rather than by the unfortunate individual consumers."

B. The New Hampshire strict liability doctrine applies to cases in which a defendant has breached no legal duty

The New Hampshire Supreme Court has frequently noted that its strict liability doctrine applies when a defendant has breached no legal duty. When Justice Souter served on that court, he carefully defined "strict liability" in those terms:

> Legal liability is said to be strict when it is imposed even though the defendant has committed no legal fault consisting of the violation of a common law or statutory duty.

Bagley, 503 A.2d at 825 (Souter, J.). In *Bolduc v. Herbert Schneider Corp.*, 374 A.2d 1187, 1189 (N.H. 1977), the court distinguished strict liability from a common carrier's liability with the observation that "under strict tort liability . . . one may be held liable even though he exercised the highest degree of care

and thus was not negligent." *See also*, *e.g.*, *Kelton v. Hollis Ranch, LLC*, 927 A.2d 1243, 1246 (N.H. 2007) (quoting *Bagley*).

C. The New Hampshire strict liability doctrine differs from a general "no-fault" liability regime because it applies in only a narrow category of cases

The New Hampshire Supreme Court has made it abundantly clear that the strict liability remedy adopted in *Buttrick* is very different from the no-fault liability for personal injuries that exists in other contexts, such as workers' compensation or no-fault automobile insurance.

Even before *Buttrick*, the New Hampshire Supreme Court emphasized one limit on the strict liability remedy. In *Elliott v. Lachance*, 256 A.2d 153 (N.H. 1969) – a case that was pending at the same time as *Buttrick* but announced five months earlier – the court "presaged" the impending adoption of the Restatement § 402A approach. *Buttrick*, 260 A.2d at 113. Noting three difficulties with bringing a personal injury action under a warranty theory, the *Elliott* court explained that "there has arisen another remedy. . . . It imposes strict liability in tort for the sale of a defective product unreasonably dangerous to an intended user or consumer." 256 A.2d at 155 (citing out-of-state cases, Restatement § 402A, and academic commentary). But the *Elliott* court immediately stressed the limits of the strict liability remedy:

> "Strict liability does not make the manufacturer or seller an insurer nor does it impose absolute liability." . . . In other words, unlike absolute liability, the mere injury from a product does not create liability. . . .
>
> [When] proceeding . . . on a strict tort liability based on a defective product which is unreasonably dangerous, the plaintiff has the burden of proving that her injury resulted . . . from a defect [of the product].

256 A.2d at 156 (quoting *Dippel v. Sciano*, 155 N.W.2d 55, 63 (Wis. 1967)). Because the *Elliott* plaintiff was unable to establish causation, her action failed and it was unnecessary for the court formally to adopt the strict liability approach.

After *Buttrick*, the New Hampshire Supreme Court has limited the scope of the strict liability doctrine in various ways. Perhaps most obviously, the court has repeatedly declined to extend the doctrine outside of the context of defective products. *See*, *e.g.*, *Bagley v. Controlled Environment Corp.*, 503 A.2d 823 (N.H. 1986) (declining to impose strict liability for environmental damages caused by the discharge of hazardous waste); *Moulton v. Groveton Papers Co.*, 289 A.2d 68, 72 (N.H. 1972) (declining to impose strict liability for flooding damages when a dam failed); *Dumas v. State Farm Mutual Automobile Insurance Co.*, 274 A.2d 781, 784 (N.H. 1971) (declining to impose strict liability for damages caused by an insurer's failure to settle a case within policy limits). As Justice Souter explained in *Bagley*, "this court has

recognized only one cause of action for damages based on strict liability, that being for the benefit of the user or consumer of an unreasonably dangerous and defective product." 503 A.2d at 825 (citing *Buttrick*; Restatement § 402A).

The New Hampshire Supreme Court has also limited the scope of the strict liability doctrine by its narrow reading of the requirements of Restatement § 402A.[3] In particular, the court has construed § 402A(1) – which by its terms covers "any product in a defective condition unreasonably dangerous to the user or consumer" – so that the doctrine applies only when the risks created by the product outweigh the benefits of the product. *See*, *e.g.*, *Kelleher v. Marvin Lumber & Cedar Co.*, 891 A.2d 477, 492 (N.H. 2005); *Vautour*, 784 A.2d at 1182. "A product's design should meet risk-utility balancing standards as seen from the point of view of the public as a whole." *Price v. BIC Corp.*, 702 A.2d 330, 332 (N.H. 1997); *see also*, *e.g.*, *Vautour*, 784 A.2d at 1182.

The court has similarly limited the reach of strict liability by its narrow reading of other § 402A requirements. Thus in *Royer v. Catholic Medical Center*, 741 A.2d 74, 76 (N.H. 1999), for example, the

[3] The court acted quite deliberately in this regard. In *Price v. BIC Corp.*, 702 A.2d 330, 333 (N.H. 1997), for example, it forthrightly "caution[ed] that the term 'unreasonably dangerous' should not be interpreted so broadly as to impose absolute liability on manufacturers or make them insurers of their products."

court "recognized limits to the doctrine" with its restrictive reading of the "seller of goods" requirement.

D. The New Hampshire Supreme Court has recognized that the strict liability doctrine is "a system of spreading the risk"

On a few occasions, the New Hampshire Supreme Court has disclaimed the suggestion "that strict liability is in reality a tool of social engineering, and that manufacturers should be required to bear the entire risk and costs of injuries caused by products." *Thibault v. Sears, Roebuck & Co.*, 395 A.2d 843, 845 (N.H. 1978). *See also*, *e.g.*, *Heath*, 464 A.2d at 299 (quoting *Thibault*). Those disclaimers, however, simply make the same fundamental point as *Elliott v. Lachance*: strict liability does not guarantee damages for every victim of a personal injury in the same way that a workers' compensation statute provides compensation to those injured on the job or no-fault automobile insurance covers those injured in traffic accidents.

In *Elliott*, strict liability was more limited than under a general no-fault compensation system because the plaintiff could not prove causation. *See* 256 A.2d at 156. *Thibault* similarly stressed that "[t]he plaintiff in a defective design case must . . . prove causation. . . ." 395 A.2d at 847; *see also id*. at 850 ("the jury could have found . . . that the [allegedly

defective] design was not the cause of the accident"). Other aspects of the strict liability doctrine limiting its scope, *see supra* at 27-30, likewise distinguish it from a no-fault compensation system. *Thibault* noted some of those limitations, too. *See*, *e.g.*, 395 A.2d at 846 ("In a strict liability case alleging defective design, the plaintiff must first prove the existence of a 'defective condition unreasonably dangerous to the user.' ") (quoting *Buttrick*, 260 A.2d at 113).

In sum, the New Hampshire Supreme Court has not rejected risk-spreading as a justification for the strict liability doctrine. On the contrary, the *Thibault* court itself explicitly noted that "the doctrine of strict liability" could be "[v]iewed as a system of spreading the risk." 395 A.2d at 846. Of course, that internalizing of accident costs "had economic consequences," *id*., and thus the court would not allow risk-spreading to "undermine[ ] or abolish[ ]" the basic "common-law principle that fault and responsibility are elements of our legal system," *id*. The *Thibault* court accordingly "reaffirm[ed] *Buttrick*" but also "recognize[d] some limits to the doctrine of strict liability." *Id*. In particular, the court confirmed that strict liability is a narrow doctrine subject to specific requirements. *See id*. at 846-850. In the rare cases when the doctrine applies, however, it spreads the risk of loss without regard to the defendant's negligence or other breach of a legal duty by requiring those who sell unreasonably dangerous products to internalize the cost of the harm caused by those products.

IV. New Hampshire's Strict Liability Doctrine In Design-Defect Cases Does Not Include A "Duty To Warn" Element That Implicates *PLIVA, Inc. v. Mensing*.

In *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), this Court held that federal law preempts state tort claims based on a generic drug manufacturer's failure to provide adequate warning that long-term use of its product can cause severe medical problems. The Solicitor General (at 17) argues that *Mensing* controls here because "the state-law duty to design a non-defective product *includes* a duty to provide an adequate warning." The Solicitor General has misunderstood New Hampshire law.

To be sure, "the presence or absence of a warning" is a "factor to be considered" in appropriate cases. *Thibault*, 395 A.2d at 846. *See also*, *e.g.*, *Vautour*, 784 A.2d at 1182; *Price v. BIC Corp.*, 702 A.2d 330, 333 (N.H. 1997); *Chellman v. Saab-Scania AB*, 637 A.2d 148, 150 (N.H. 1993). But "the presence or absence of a warning" is simply one of many factors to be considered when appropriate. In *Thibault* itself, the court noted that a warning is not necessarily required even when a product is undoubtedly "dangerous." *See* 395 A.2d at 846. Conversely, "when an unreasonable danger could have been eliminated without excessive cost or loss of product efficiency, liability may attach even though . . . there was adequate warning." 395 A.2d at 847.

Here "the presence or absence of a warning" was neither controlling nor dispositive. And the warning's legal "adequacy" was irrelevant. Pet. App. 36a. Examination of the New Hampshire duty-to-warn cases illustrates that a warning is most relevant if the risk of injury is reduced when a consumer uses a potentially dangerous product in a less dangerous manner. In *Chellman*, 637 A.2d at 151, for example, an automobile was unreasonably dangerous in part because the defendants failed to warn of certain handling characteristics. Similarly, in *LeBlanc v. American Honda Motor Co.*, 688 A.2d 556 (N.H. 1997), the defendant had failed to warn of an automobile's braking and steering properties when driven on ice. Significantly, the *LeBlanc* court explicitly declared that "[t]he plaintiff's design defect and failure to warn claims are separate." *Id*. at 562.

In this case, there was no way for a consumer to use sulindac more safely. Respondent did not face a choice between a safe and a dangerous way to administer the drug, as in *Wyeth v. Levine*, 555 U.S. 555, 559 (2009). Respondent would not have escaped her horrific injuries if petitioner had warned her to avoid the long-term use of sulindac; after first taking the drug in December 2004, she "developed SJS/TEN early in 2005." Pet. App. 3a; *cf*. *Mensing*, 131 S. Ct. at 2572 ("long-term metoclopramide use can cause tardive dyskinesia"). In short, this is a very different case than *Chellman*, *LeBlanc*, *Wyeth*, or *Mensing*. While "the presence or absence of a warning" is a

"factor to be considered" in some cases, it was not dispositive here.

The Solicitor General's argument here is essentially the same as the defendant's argument that the New Hampshire Supreme Court rejected in *Vautour*. The *Vautour* plaintiffs argued that a "leg press machine" was unreasonably dangerous but they offered no evidence of a reasonable alternative design. Prior decisions had held that the availability of a reasonable alternative design – like the presence or absence of a warning – was a "factor to be considered" in appropriate cases. *See*, *e.g.*, *Price*, 702 A.2d at 333; *Thibault*, 395 A.2d at 846. On that basis,[4] the *Vautour* defendant argued that the availability of a reasonable alternative design was part of a defective-design case and that the plaintiffs must offer evidence addressing the issue. Rejecting the defendant's argument, the court explained:

> [W]hile proof of an alternative design is relevant in a design defect case, it should be neither a controlling factor nor an essential element that must be proved in every case. As articulated in *Thibault*, the risk-utility test requires a jury to consider a number of factors when deciding whether a product is unreasonably dangerous. *See Thibault*, [395 A.2d at 846]. This list is not meant to be

[4] The *Vautour* defendant also relied on Restatement (Third) of Torts § 2(b) (1998), which the New Hampshire Supreme Court "decline[d] to adopt." 784 A.2d at 1184. *See supra* at 20.

> exclusive, but merely illustrative. "Depending on the circumstances of each case, flexibility is necessary to decide which factors" may be relevant. *Armentrout v. FMC Corp.*, 842 P.2d 175, 184 (Colo. 1992) (explaining in dictum that relevant factors cannot be confined to a single list which must always be applied regardless of circumstances). Thus, the rigid prerequisite of a reasonable alternative design places too much emphasis on one of many possible factors that could potentially affect the risk-utility analysis.

784 A.2d at 1183-84. The Solicitor General's argument is no more persuasive here. The presence or absence of a warning is simply "one of many possible factors." It is "neither a controlling factor nor an essential element" of a design-defect case. The Solicitor General "places too much emphasis on one of many possible factors that could potentially affect the risk-utility analysis." Whether any particular factor is relevant "[d]epends on the circumstances of each case." Because no warning could have made respondent's use of sulindac any safer, the factor is simply irrelevant here.

The Solicitor General's argument is also inconsistent with more general tort principles. Many states distinguish design-defect claims from failure-to-warn claims. Restatement (Third) § 1, comment a, reporters' note 1, recognizes "[a]bundant authority" in numerous jurisdictions for differentiating between claims alleging "design defects" and those alleging "defects based on inadequate instructions or warnings." Scholarly

commentary, too, has long "recognize[d] the distinction as necessary to a coherent discussion of the bases of liability" for defective products. *Id*.

This Court itself has recognized as "perfectly clear" the distinction between common-law "claims for defective design" and a requirement "that manufacturers label . . . their products in any particular way." *Bates v. Dow AgroSciences LLC*, 544 U.S. 431, 444 (2005). The *Bates* Court accordingly held that, although federal law in that context might preempt a failure-to-warn claim, it does not preempt design-defect claims.

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted,

ANDY BIRCHFIELD
BEASLEY, ALLEN, CROW, METHVIN, PORTIS & MILES, P.C.
234 Commerce St.
Post Office Box 4160
Montgomery, AL 36103

MICHAEL F. STURLEY
Counsel of Record
LYNN E. BLAIS
727 E. Dean Keeton St.
Austin, TX 78705
(512) 232-1350
msturley@law.utexas.edu

CLAYTON CLARK
CLARK, LOVE & HUTSON
440 Louisiana St., Suite 1600
Houston, TX 77002

Counsel for Amici Curiae

February 20, 2013

APPENDIX

More detailed biographical information about each of the *amici* is as follows:

Mary J. Davis is the Stites & Harbison Professor of Law at the University of Kentucky College of Law. She is co-author of a leading Products Liability casebook and is currently co-authoring a treatise in the field. She has written extensively on the topic of federal preemption of common law damages actions, particularly regarding products liability. She has taught Torts and Products Liability for twenty years.

Heidi Li Feldman is a faculty member at Georgetown University Law Center. Since beginning her career as a law professor in 1991, she has taught torts; product liability; and tort law and federalism. Her scholarship includes articles on *Daubert* and the silicone breast implant litigation; issues of causation in mass torts; and the marketing practices of the pharmaceutical industry.

Thomas C. Galligan, Jr., is President and a professor at Colby-Sawyer College. From 1986 to 1998, he was a professor at LSU's Paul M. Hebert Law Center. From 1998 to 2006, he was the dean of the University of Tennessee College of Law. He is the author or co-author of many books and articles on torts and his scholarship has been extensively cited by courts and scholars. He has testified before Congress and the Louisiana legislature on issues related to torts and product liability.

Mark P. Gergen currently teaches at Boalt Hall School of Law, University of California at Berkeley. He has taught and written on the entire spectrum of the law of obligations: contracts, torts, and restitution. He was the reporter for *Restatement (Third) of Torts: Economic Torts and Related Wrongs*.

Thomas O. McGarity holds the Joe R. and Teresa Lozano Long Endowed Chair in Administrative Law at the University of Texas Law School, where he has taught torts for 35 years. One of his particular scholarly interests is the federal preemption of state tort law. One of his books, THE PREEMPTION WAR: WHEN FEDERAL BUREAUCRACIES TRUMP LOCAL JURIES (Yale University Press 2008), explored that subject in depth.

David W. Robertson holds the W. Page Keeton Chair in Tort Law and is a University Distinguished Teaching Professor at the University of Texas Law School. He has taught and written about torts for 45 years, and is the co-author of a leading torts casebook.

Wendy E. Wagner is the Joe A. Worsham Centennial Professor at the University of Texas Law School. She has taught and written about torts for over 20 years.