
Supreme Court
of the State of Washington

JOSETTE TAYLOR as Personal Representative of the Estate of
FRED E. TAYLOR, deceased; and on behalf of the Estate of FRED E. TAYLOR;
and JOSETTE TAYLOR,

Petitioners

vs.

INTUITIVE SURGICAL, INC.,
a foreign corporation doing business in Washington,

Respondent

BRIEF OF *AMICUS CURIAE* ON BEHALF OF
PRODUCT LIABILITY ADVISORY COUNCIL, INC.

Of Counsel:
Hugh F. Young, Jr.
Product Liability Advisory Council, Inc.,
1850 Centennial Park Drive
Suite 510
Reston, VA 20191
(703) 264-5300

CHRISTOPHER W. TOMPKINS
WSBA #11686
Betts, Patterson & Mines, P.S.
One Convention Place
701 Pike Street, Suite 1400
Seattle, WA 98101-3927
(206) 268-8682

JAMES M. BECK (PA #37137)
Reed Smith LLP
Three Logan Square
Suite 3100
1717 Arch Street
Philadelphia, PA 19103-7301
(215) 851-8168

Amicus Curiae on behalf of Product Liability Advisory Council, Inc.

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I. INTRODUCTION & INTEREST OF *AMICUS*

Plaintiffs allege, *inter alia*, that a complex prescription medical device – used for robotic prostate surgery – had “defective” warnings. The trial court gave a negligence instruction under established Washington law. Plaintiff claims that strict liability should have been charged. Both the trial court and the unanimous Court of Appeals rejected this argument.

The Product Liability Advisory Council, Inc. (“PLAC”) is a non-profit association with 98 corporate members (listed in the Appendix) from a broad cross-section of American and international product manufacturers. Several hundred leading product-liability defense attorneys are sustaining (non-voting) PLAC members.

PLAC seeks improvement and reform of law affecting product liability in the United States and elsewhere. PLAC’s point of view reflects its members’ experience in diverse manufacturing industries. Since 1983, PLAC has filed over 1,075 briefs as *amicus curiae* in state and federal courts, including this Court, presenting the broad perspective of product manufacturers seeking fairness and balance.

Many PLAC members have a strong interest in ensuring that unavoidably unsafe prescription medical products are not driven from the marketplace due to their inherent risks. Washington’s longstanding statutory regime incorporating Restatement (Second) of Torts §402A,

comment k (1965) (“comment k”), does this effectively, and its use of negligence principles in warning cases is squarely within the legal mainstream of product-liability jurisprudence nationwide.

This *amicus curiae* brief is respectfully submitted to the Court to address the public importance of these issues apart from and beyond the immediate interests of the parties to this case.

II. ISSUES TO BE ADDRESSED BY *AMICUS*

Plaintiff’s assertion of strict liability in a warning case involving a prescription medical product challenges decades of Washington precedent. Plaintiff makes two arguments: (1) that comment k does not mandate negligence analysis of warning claims, and (2) if it does, comment k should not be applied here. *Amicus* addresses these arguments first under Washington law, and then demonstrates that Washington’s jurisprudence is in the mainstream of product-liability law nationwide.

III. ARGUMENT

A. From Its Inception, Washington Law Has Uniformly Applied Comment K’s Negligence Standard To Warning Claims Involving Prescription Medical Products.

The drafters of Restatement (Second) of Torts §402A (1965) included comment k to prevent liability for the inherent risks of prescription drugs. Many of the drafters would have exempted prescription drugs from §402A altogether. Section 402A’s drafter, Dean William Prosser,

obtained agreement to address such products in a comment, rather than in §402A's black letter. *See* James A. Henderson, Jr. & Aaron D. Twerski, "Drug Design Liability: Farewell to Comment K," 67 *Baylor L. Rev.* 521, 523-24 (2015) (describing drafting process in detail.)¹

The result was comment k, addressing "unavoidably unsafe products," which – insofar as relevant to warnings – provides:

- Products "incapable of being made safe for their intended and ordinary use" are "especially common in the field of drugs."
- An unavoidably unsafe "product . . . accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous."
- This "is true of many other drugs, vaccines, and the like, . . . which for this very reason cannot legally be sold except . . . under the prescription of a physician."
- "[E]xperience . . . justifies the marketing and use of the drug notwithstanding a medically recognizable risk."
- "The seller of such products, [provided] they are properly prepared and marketed, and proper warning is given . . . is not to be held to strict liability."

In 1965, when Restatement §402A was adopted, prescription medical devices barely existed, and were not fully regulated by the FDA until 1976. "Almost all courts" – including this Court – "have extended the

¹ Professors Henderson and Twerski would replace comment k with the Restatement (Third) of Torts (1998), which imposes negligence standards in all warning cases, *see id.* at §2(c), and abolishes design liability for prescription medical products altogether, except in the narrow circumstance where such a product is so dangerous it could not be "reasonabl[ly]" prescribed "for any class of patients." *Id.* §(c).

unavoidably unsafe product doctrine to medical devices.” James M. Beck & Anthony Vale, “Drug & Medical Device Product Liability Deskbook,” at 2.02-12 to -14 & n.14 (2014) (collecting precedent from 20 jurisdictions).

This Court first adopted comment k in *Terhune v. A. H. Robins Co.*, 90 Wn.2d 9, 577 P.2d 975 (1978), “determin[ing] that the principles set forth in [comment k] appl[ied]” to a medical device – the Dalkon Shield IUD. *Id.* at 18, 577 P.2d at 980. This Court rejected any product-specific exception to comment k:

The principles stated in comment k do not rest upon a finding or an assumption that all drugs, vaccines or other products obtainable only through a physician have been tested by the Food and Drug Administration. Rather they have their basis in the character of the medical profession and the relationship which exists between the manufacturer, the physician and the patient. . . .

Id. at 16, 577 P.2d at 979. Since the device was “acceptable” to the “medical profession” when used, “[t]he superior court quite properly held as a matter of law that [it] was not unreasonably dangerous or defective, as defined in comment k.” *Id.* at 17, 577 P.2d at 979.

In 1981, the Legislature passed the Washington Products Liability Act, R.C.W. 7.72 (“WPLA”), and replaced the common law with a statutory “product liability claim” predicated on “negligence of the manufacturer in that the product was . . . not reasonably safe because

adequate warnings or instructions were not provided.” R.C.W. 7.72.030(1)(b). This Court held in *Ayers v. Johnson & Johnson Baby Products Co.*, 117 Wn. 2d 747, 763, 818 P.2d 1337, 1345 (1991), that WPLA warning claims applied a strict liability standard, but has declined to extend strict liability to prescription medical products under comment k.

This Court applied a negligence standard under comment k to post-WPLA cases in *Rogers v. Miles Laboratories, Inc.*, 116 Wn.2d 195, 802 P.2d 1346 (1991). The Court unanimously held that adequacy of prescription-medical-product warnings is judged by the negligence “knew or should have known” standard and rejected strict liability in comment k cases because it would impose liability for not warning of scientifically undiscovered risks. “[W]hether the risk [at issue] was knowable and whether defendants satisfied their duty to warn are *negligence* issues.” *Id.* at 197-98, 802 P.2d at 1347 (emphasis added). “[T]he Restatement of Torts would impose no strict liability for what are classified as ‘unavoidably unsafe products.’” *Id.* at 203, 802 P.2d at 1351.²

Comment k justifies an exception from strict liability by focusing on the product and its relative value to society. . . . Some products are necessary regardless of the risks involved to the user. The alternative would be that a product, essential to sustain the life of some individuals,

² Quoting Roger J. Traynor, “The Ways & Meanings of Defective Products & Strict Liability,” 32 Tenn. L. Rev. 363, 367-68 (1965).

would not be available-thus resulting in a greater harm to the individual than that risked through use of the product.

Id. at 204, 802 P.2d at 1351. Following *Terhune*, this Court placed blood products in “this category” with no product-specific analysis. *Id.*

Rogers expressly applied negligence in comment k warning cases. “If the manufacturer of an unavoidably unsafe product fails to provide an adequate warning, it has been negligent – but it is liable in negligence and not in strict liability.” *Id.* at 207, 802 P.2d at 1353. The Court “agreed” with California’s resolution of the same question:

[T]he principle [comment k] states is based on negligence. That is, comment k would impose liability on a drug manufacturer only if it failed to warn of a defect of which it either knew or should have known. This concept focuses . . . on the fault of the producer . . . an idea which rings of negligence.

Id. (quoting *Brown v. Superior Court*, 751 P.2d 470, 476-77 (Cal. 1988)).

Young v. Key Pharmaceuticals, Inc., 130 Wn.2d 160, 168, 922 P.2d 59 (1996), reaffirmed both comment k’s general applicability to prescription medical products and its reliance on negligence principles. The plaintiffs sought to impose strict liability for a risk only confirmed after plaintiffs’ injury. *Id.* at 165, 922 P.2d at 62. The Court rejected this attempt. “[W]hen a manufacturer of an unavoidably unsafe product fails to adequately warn of its inherent dangers, comment k imposes liability only for negligence, not strict liability.” *Id.* at 168, 922 P.2d at 63.

The test stated in comment k is to be distinguished from strict liability for failure to warn. Although both concepts identify failure to warn as the basis of liability, comment k imposes liability only if the manufacturer knew or should have known of the defect at the time the product was sold or distributed. Under strict liability . . . the manufacturer is liable even if it neither knew or could have known of the defect about which the warning was required.

Id. at 168-69, 922 P.2d at 64 (quoting *Brown*, 751 P.2d at 476 & n.4). *Young* reiterated this Court’s rejection of “case-by-case analysis” of whether prescription medical products are “unavoidably unsafe.” *Id.* at 169, 922 P.2d at 64. “[U]nder Washington law, a separate determination of whether a product is unavoidably unsafe need not be made on a case-by-case basis if that product is a prescription drug.” *Id.* at 170, 922 P.2d at 64 (citing *Rogers* and *Terhune*) (footnote omitted).

The dissent in *Young* did not support case-by-case application of comment k – this Court unanimously rejected that argument. It criticized “both the majority and the Court of Appeals” for applying a negligence standard to warnings. *Id.* at 179, 922 P.2d at 69.³ The dissent contended, first, that California had changed its mind and now applied strict liability to warning claims, *id.* at 184-86, 922 P.2d at 71-72, and second that most courts found it “immaterial” “whether the risks [are] known or knowable”

³ Although described in dissent as a “majority,” on this question the Court was evenly divided. See *Ruiz-Guzman v. Amvac Chemical Corp.*, 141 Wn. 2d 493, 507 & n.9, 7 P.3d 795, 802 & n.9 (2000).

in strict liability. *Id.* at 186-87, 922 P.2d at 72-73. The next section of this brief will demonstrate that both of these contentions are incorrect.

Most recently, in *Ruiz-Guzman v. Amvac Chemical Corp.*, 141 Wn.2d 493, 7 P.3d 795 (2005), this Court held that – where comment k “unavoidably unsafe” status is sought for *non-prescription* products – product-specific evaluation is appropriate. *Id.* at 509-10, 7 P.3d at 803. However, *Ruiz-Guzman* flatly refused to retreat from its comment k precedent with respect to prescription medical products:

[I]t is not appropriate for us . . . to reject the view that all prescription drugs are exempted from strict liability analysis and exchange it for a product-by-product approach. . . .

By its own terms, comment k is especially applicable to medical products. The exceptions for medical products recognize the unique protection provided to the consumers of such products by the prescribing physician [who]. . . possesses the medical training to assess adverse health effects of a medical product and to tailor that assessment to a particular patient.

Id. at 508, 7 P.3d at 802-03 (quotation from *Terhune* omitted).⁴

The Court of Appeals and federal courts under Washington law have faithfully applied this Court’s precedent to prescription medical products. *See Payne v. Paugh*, 190 Wn. App. 383, 409, 360 P.3d 39, 53

⁴ *Ruiz-Guzman* also confirmed what had been implicit in *Rogers* and *Young* – that comment k applied to the statutory cause of action created by the WPLA. 141 Wn. 2d at 506, 7 P.3d at 801-02.

(2015) (applying comment k “negligence standard” to “an unavoidably unsafe product such as a medical device”); *La Montagne v. Bristol-Meyers Squibb*, 127 Wn. App. 335, 343-44, 111 P.3d 857, 861 (2005) (“Whether a prescription drug manufacturer provides adequate warnings . . . is governed by [comment k’s] negligence standard”); *Transue v. Aesthetech Corp.*, 341 F.3d 911, 915-17 (9th Cir. 2003) (“comment k provides an exemption for medical products generally”; applies to medical devices) (applying Washington law); *Adams v. Synthes Spine Co.*, 298 F.3d 1114, 1117 (9th Cir. 2002) (comment k applies “more broadly, to medical products where the physician acts as a ‘learned intermediary’”) (applying Washington law); *Luttrell v. Novartis Pharmaceuticals Corp.*, 894 F. Supp. 2d 1324, 1342 (E.D. Wash. 2012) (under comment k “whether defendant satisfied duty to warn is governed by negligence standard”), *aff’d*, 555 F. Appx. 710 (9th Cir. 2014); *Laisure-Radke v. Par Pharmaceutical, Inc.*, 426 F. Supp.2d 1163, 1171 (W.D. Wash. 2006) (comment k “is an exception to strict liability” and “distinguish[es] prescription drug products from . . . consumer products”). A pattern jury instruction likewise invokes negligence for prescription-medical-product cases. *See* WPI 110.02.01 (“whether a manufacturer exercised reasonable care is to be determined by what the manufacturer knew or reasonably should have known at the time of the plaintiff’s injury”).

Application of negligence standards to warning claims, without case-specific and product-specific inquiries into whether the defendant's product was "unavoidably unsafe" under comment k, should be affirmed here as squarely supported by decades of this Court's precedent.

B. Nationwide Precedent Applies Negligence Standards in Warning Cases Involving Prescription Medical Products.

Tracking the dissent in *Young*, Plaintiff contends, first, that California has receded from *Brown v. Superior Court*, *supra*, concerning comment k and negligence. Second, Plaintiff broadly challenges use of negligence principles in product-liability litigation involving prescription medical products. In both instances, Plaintiff is mistaken.

1. California Utilizes Negligence Concepts In All Warning Cases.

In California, strict liability *as a whole* has been modified in warning cases, a fundamental fact that explains that state's subsequent interpretation of *Brown*. By now, the California Supreme Court "ha[s] repeatedly held that strict products liability law . . . may incorporate negligence concepts without undermining the principles fundamental to a strict liability claim." *Johnson v. American Standard, Inc.*, 179 P.3d 905, 916 (Cal. 2008). The turning point was *Anderson v. Owens-Corning Fiberglas Corp.*, 810 P.2d 549 (Cal. 1991), a post-*Brown* asbestos case

that reintroduced “negligence” reasonableness and foreseeability concepts into “strict liability” warning claims.

Anderson held that admission of state-of-the-art evidence in strict liability was proper. “[T]he claim that a particular component ‘rings of’ or ‘sounds in’ negligence has not precluded its acceptance in the context of strict liability.” *Id.* at 557. Strict liability “has incorporated some well-settled rules from the law of negligence and has survived judicial challenges asserting that such incorporation violates fundamental principles of the defense.” *Id.* at 558. Warning claims, in particular, “cannot” be evaluated “without reference to the conduct of the manufacturer.” *Id.* *Anderson* recognized:

[T]he “warning defect” theory is “rooted in negligence” to a greater extent than are the manufacturing – or design-defect – theories. The “warning defect” relates to a failure extraneous to the product itself. Thus, while a manufacturing or design defect can be evaluated without reference to the conduct of the manufacturer, the giving of a warning cannot. The latter necessarily requires the communicating of something to someone.

Id. (citations omitted). Since *Anderson*, “[g]enerally, foreseeability is relevant in a strict liability analysis.” *O’Neil v. Crane Co.*, 266 P.3d 987, 1005 (Cal. 2012) (asbestos warning case).

Brown, however, preceded *Anderson*, and concern that prescription-medical-product manufacturers should not be liable for

scientifically unknowable risks (also present in this Court's *Rogers* and *Young* decisions) figured in its treatment of comment k. The decision Plaintiff relies upon, *Carlin v. Superior Court*, 920 P.2d 1347 (Cal. 1996), involved a post-*Anderson* landscape, where strict-liability warning claims *generally* were judged by foreseeability criteria such as available knowledge.

We recognized [in *Anderson*] that the knowledge or knowability requirement for failure to warn infuses some negligence concepts into strict liability cases. Indeed, in the failure-to-warn context, strict liability is to some extent a hybrid of traditional strict liability and negligence doctrine. . . . Thus . . . *Anderson*, following *Brown*, incorporated certain negligence concepts into the standard of strict liability for failure to warn, [but] did not thereby adopt a simple negligence test.

920 P.2d at 1350-51. *See also Finn v. G.D. Searle & Co.*, 677 P.2d 1147, 1152 (Cal. 1984) (warnings may “inform[] a consumer (or, in the case of prescription drugs, the physician) of potential risks or side effects which may follow foreseeable use of the product”).

Washington, unlike California, does not temper non-prescription-medical-product-warning cases with “negligence” concepts like foreseeability. Instead, “foreseeability of harm is not an element of a strict liability warning claim.” *Simonetta v. Viad Corp.*, 165 Wn. 2d 341, 330, 197 P.3d 127, 142 (2008) (asbestos); *accord Ayers*, 117 Wn. 2d at 761, 818 P.2d at 1344 (same proposition) (baby oil). Unless and until this Court follows

California's lead and allows consideration of reasonableness and foreseeability in all strict-liability warning cases, Plaintiffs' California analogy is inapt. Washington's current approach to comment k remains necessary to protect prescription medical products from excessive liability for all of the reasons stated in *Rogers, Young, and Brown*.

2. Negligence Standards Govern Prescription Medical Product Warning Claims in Many States.

In prescription-medical-product-warning cases, “[m]ost jurisdictions . . . rely on comment k as authority for applying what is effectively a negligence standard when they assess the adequacy of warnings.” *Shirkey v. Eli Lilly & Co.*, 852 F.2d 227, 232 (7th Cir. 1988) (applying Wisconsin law). “Comment k exempts from this strict-liability rule ‘unavoidably unsafe products.’” *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 234 (2011). While “some courts thought [comment k] required a case-specific showing that a product was ‘unavoidably unsafe;’ many others thought it categorically exempted certain types of products from strict liability.” *Id.* at 243 (footnote omitted).⁵

⁵ Many other states, like Washington, apply comment k to all prescription medical products. *Hurley v. Heart Physicians, P.C.*, 898 A.2d 777, 783 (Conn. 2006) (“[p]rescription drugs generally fall within the classification of unavoidably unsafe products”); *Hahn v. Richter*, 673 A.2d 888, 891 (Pa. 1996) (applying comment k to all prescription products); *Grundberg v. Upjohn Co.*, 813 P.2d 89, 94-95 (Utah 1991) (“we are troubled by the lack of uniformity and certainty inherent in the

In Pennsylvania “where the adequacy of warnings associated with prescription drugs is at issue, . . . negligence, is the only recognized basis of liability.” *Hahn v. Richter*, 673 A.2d 888, 891 (Pa. 1996).

[A] manufacturer of drugs is not strictly liable for unfortunate consequences attending the use of otherwise useful and desirable products which are attended with a known but apparently reasonable risk. Rather, such a manufacturer is liable only if he fails to exercise reasonable care to inform those for whose use the article is supplied of the facts which make it likely to be dangerous.

Baldino v. Castagna, 478 A.2d 807, 810 (Pa. 1984).

case-by-case approach” to comment k); *Brown*, 751 P.2d at 477 (rejecting case-by-case approach to comment k); *Stone v. Smith, Kline & French Laboratories*, 447 So. 2d 1301, 1304 (Ala. 1984) (comment k is “exception” to strict liability for all prescription products); *McKee v. Moore*, 648 P.2d 21, 23 (Okla. 1982) (prescription products are “unavoidably unsafe products”); *Kinney v. Hutchinson*, 468 So. 2d 714, 718 (La. App. 1985) (applying comment k without drug-specific analysis); *Perfetti v. McGhan Medical*, 662 P.2d 646, 650 (N.M. App. 1983) (following *Terhune*); *Ortho Pharmaceutical Corp. v. Chapman*, 388 N.E.2d 541, 546-47 (Ind. App. 1979) (“no difficulty” in holding all oral contraceptives “unavoidably unsafe”; comment k “carved out an exception” for prescription medical products); *Bravman v. Baxter Healthcare Corp.*, 984 F.2d 71, 76 (2d Cir. 1993) (all “medical devices that must be prescribed and inserted by a physician are unavoidably unsafe products”) (applying New York law); *Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1230-31 (4th Cir. 1984) (applying comment k without device-specific analysis) (applying South Carolina law); *Lindsay v. Ortho Pharmaceutical Corp.*, 637 F.2d 87, 90 (2d Cir. 1980) (prescription drugs categorically are “unavoidably unsafe products”) (applying New York law); *Hackett v. G.D. Searle & Co.*, 246 F. Supp.2d 591, 595 (W.D. Tex. 2002) (“all FDA-approved prescription drugs are unavoidably unsafe as a matter of law”). *Accord* N.C. Gen. Stat. §99B-6(d).

In Illinois, *Woodill v. Parke Davis & Co.*, 402 N.E.2d 194, 196 (Ill. 1980), recognized negligence principles as governing warning claims involving prescription drugs. “[I]mposition of a knowledge requirement is a proper limitation to place on a manufacturer’s strict liability in tort predicated upon a failure to warn of a danger inherent in a product.” *Id.* at 198. This does not “infuse negligence principles into strict liability,” but rather inheres in §402A’s “unreasonably dangerous” requirement:

[A] product is unreasonably dangerous at the time of sale if the ordinary man, knowing the risks and dangers actually involved in its use, would not have marketed the product without supplying more information about the risks and dangers involved in its use and ways to avoid harm therefrom.

Id. (citation and quotation marks omitted).

In Utah, as here, the highest court found the California Supreme Court’s rationale in *Brown* persuasive and applied comment k broadly in light of “the significant public policy considerations noted in *Brown*.” *Grundberg v. Upjohn Co.*, 813 P.2d 89, 95 (Utah 1991). As to warnings specifically, *Grundberg* applied a “negligent[] fail[ure] to warn” standard that “if a manufacturer knows or should know of a risk associated with its product, it is directly liable to the patient if it fails to adequately warn the medical profession of that danger.” *Id.* at 97.

In *Vassallo v. Baxter Healthcare Corp.*, 696 N.E.2d 909 (Mass. 1998), Massachusetts' highest court overruled prior precedent and allowed foreseeability to be asserted in strict-liability warning cases, holding:

The majority of States, either by case law or by statute, follow the principle expressed in [§402A] that the seller is required to give warning against [a danger], if he has knowledge, or by the application of reasonable, developed human skill and foresight should have knowledge, of the danger.”

Id. at 922 (citations and quotation marks omitted).

“Where liability is predicated on a failure to warn, New York views negligence and strict liability claims as equivalent.” *Martin v. Hacker*, 628 N.E.2d 1308, 1311 n.1 (N.Y. 1993) (prescription-drug case). “[A] prescription drug is by its nature an inherently unsafe product,” and for it “a defense is provided” by the terms of comment k. *Id.* Thus, in New York, “[t]he manufacturer’s duty is to warn of all potential dangers in its prescription drugs that it knew, or, in the exercise of reasonable care, should have known to exist. *Id.*

In New Jersey, “[w]hen the strict liability defect consists of an improper . . . warning, reasonableness of the defendant’s conduct is a factor in determining liability.” *Feldman v. Lederle Laboratories*, 479 A.2d 374, 385 (N.J. 1984) (citations omitted).

The question in [a] strict liability . . . warning case[] is whether, assuming that the manufacturer knew of the defect

in the product, he acted in a reasonably prudent manner . . .
in providing the warnings given. . . .

Id. “[A]n adequate warning . . . reveals the risks attendant on all foreseeable uses.” *Kendall v. Hoffman-La Roche, Inc.*, 36 A.3d 541, 554 (N.J. 2012) (citation and quotation marks omitted).

Likewise, in the District of Columbia, “a strict liability action for failure to warn is really nothing more than a ground of negligence liability described as the sale of a product in a defective condition.” *McNeil Pharmaceutical v. Hawkins*, 686 A.2d 567, 578 (D.C. 1996) (citation and quotation marks omitted). “[N]egligence concepts and those of strict liability have morphed together . . . in failure to warn cases.” *Gourdine v. Crews*, 955 A.2d 769, 782 (Md. 2008) (citations and quotation marks omitted) (prescription-drug case). “[W]hen the factual issue . . . is whether the manufacturer has provided adequate warnings, the existence of a product defect and a breach of duty is determined by the same standard reasonable care under the circumstances.” *Smith v. E. R. Squibb & Sons, Inc.*, 273 N.W.2d 476, 480 (Mich. 1979).

In Florida, *Buckner v. Allergan Pharmaceuticals, Inc.*, 400 So.2d 820, 823 (Fla. App. 1981), expressly followed this Court’s explanation of comment k in *Terhune*. Thus, the relevant jury instruction provides:

A product is defective when the foreseeable risks of harm from the product could have been reduced or avoided by

providing reasonable instructions or warnings, and the failure to provide those instructions or warnings makes the product unreasonably dangerous.

In re Standard Jury Instructions in Civil Cases (Products Liability), 160 So.3d 869, 875 (Fla. 2015) (approving jury instruction).⁶

Other states utilizing negligence concepts in §402A warning cases involving prescription medical products are: **Alaska**: *Shanks v. Upjohn Co.*, 835 P.2d 1189, 1200 (Alaska 1992) (warning must “reasonably communicate the extent or seriousness of harm . . . in such a manner as to alert the reasonably prudent person”); **Connecticut**: *Tomer v. American Home Products Corp.*, 368 A.2d 35, 38 (Conn. 1976) (warning claims in both negligence and strict liability are “dependent upon the state of knowledge concerning [the product] at the time”); **Indiana**: *Ortho Pharmaceutical Corp. v. Chapman*, 388 N.E.2d 541, 548 (Ind. App. 1979) (comment k is a “refus[al] to hold the maker liable for the unforeseeable harm”) (citation and quotation marks omitted); **Kansas**: *Johnson v. American Cyanamid Co.*, 718 P.2d 1318, 1324 (Kan. 1986) (“[i]n determining warning issues,

⁶ Three additional states follow Third Restatement’s version of the learned intermediary rule, which provides that “[a] prescription drug or medical device” requires “reasonable instructions or warnings regarding foreseeable risks of harm.” *Restatement (Third) of Torts, Products Liability* §6(d) (1998). See *Watts v. Medicis Pharmaceutical Corp.*, 365 P.3d 944, 949 (Ariz. 2016); *Larkin v. Pfizer, Inc.*, 153 S.W.3d 758, 761 (Ky. 2004); *Freeman v. Hoffman-La Roche, Inc.*, 618 N.W.2d 827, 842 (Neb. 2000).

the test is reasonableness”); **Louisiana:** *Kinney v. Hutchinson*, 468 So.2d 714, 718 (La. App. 1985) (“at the point of warning of drug side effects . . . negligence and strict liability become one”) (citation and quotation marks omitted); **New Mexico:** *Serna v. Roche Laboratories*, 684 P.2d 1187, 1189 (N.M. App. 1984) (“the warning must reasonably communicate the extent or seriousness of the harm” and “must be adequate to alert a reasonably prudent person to the danger”); **Ohio:** *Daniel v. Fisons Corp.*, 740 N.E.2d 681, 684 (Ohio App. 2000) (“adequate” warning “discloses to the medical professional all known or reasonably discoverable risks inherent in the use of the drug”) (footnote omitted); **Rhode Island:** *Castrignano v. E.R. Squibb & Sons, Inc.*, 546 A.2d 775, 782 (R.I. 1988) (“a seller need only warn of those dangers that are reasonably foreseeable and knowable at the time of marketing”) (footnote omitted); **Tennessee:** *Pittman v. Upjohn Co.*, 890 S.W.2d 425, 429 (Tenn. 1994) (quoting and following *Serna, supra*); **West Virginia:** *Wilkinson v. Duff*, 575 S.E.2d 335, 340 (W. Va. 2002) (“In ascertaining whether a duty to warn exists, the fundamental inquiry is whether it was reasonably foreseeable that the product would be unreasonably dangerous if distributed without a particular warning.”); **Wyoming:** *Rohde v. Smiths Medical*, 165 P.3d 433, 441 (Wyo. 2007) (“Unlike traditional strict liability claims, a claim for failure to provide adequate warnings incorporates some negligence components in

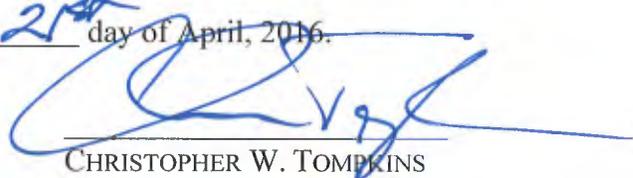
determining whether a warning is necessary and/or whether the warnings provided were adequate.”) (citation omitted).

Thus, the weight of nationwide precedent, in addition to this Court’s precedents, supports affirmance. For practical and policy reasons, negligence, not strict liability, should continue to apply in warning claims involving prescription medical products, as contemplated in comment k

IV. CONCLUSION

For all of the above reasons, the decisions of the courts below, that it was proper to apply a negligence standard under Restatement (Second) of Torts §402A, comment k (1965) to this warning case involving a prescription medical device, should be affirmed.

Respectfully submitted this 25th day of April, 2016.



Of Counsel:
HUGH F. YOUNG, JR.
Product Liability Advisory Council,
Inc.
1850 Centennial Park Drive
Suite 510
Reston, VA 20191
(703) 264-5300

CHRISTOPHER W. TOMPKINS
WSBA #11686
Betts, Patterson & Mines, P.S.
One Convention Place
701 Pike Street, Suite 1400
Seattle, WA 98101-3927
(206) 268-8682

JAMES M. BECK (PA #37137)
Reed Smith LLP
Three Logan Square, Suite 3100
1717 Arch Street
Philadelphia, PA 19103-7301
(215) 851-8168

Amicus Curiae on behalf of Product Liability Advisory Council, Inc.

APPENDIX

Corporate Members of the Product Liability Advisory Council

As of 4/11/16

Total: 98

3M	Exxon Mobil Corporation
Altec, Inc.	FCA US LLC
Altria Client Services LLC	Ford Motor Company
Astec Industries	Fresenius Kabi USA, LLC
Bayer Corporation	General Motors LLC
BIC Corporation	Georgia-Pacific LLC
Biro Manufacturing Company, Inc.	GlaxoSmithKline
BMW of North America, LLC	The Goodyear Tire & Rubber Company
The Boeing Company	Great Dane Limited Partnership
Bombardier Recreational Products, Inc.	Harley-Davidson Motor Company
Boston Scientific Corporation	The Home Depot
Bridgestone Americas, Inc.	Honda North America, Inc.
Bristol-Myers Squibb Company	Hyundai Motor America
C. R. Bard, Inc.	Illinois Tool Works Inc.
Caterpillar Inc.	Intuitive Surgical, Inc.
CC Industries, Inc.	Isuzu North America Corporation
Celgene Corporation	Jaguar Land Rover North America, LLC
Chevron Corporation	Jarden Corporation
Cirrus Design Corporation	Johnson & Johnson
Continental Tire the Americas LLC	Kawasaki Motors Corp., U.S.A.
Cooper Tire & Rubber Company	KBR, Inc.
Crane Co.	Kia Motors America, Inc.
Crown Cork & Seal Company, Inc.	Kolcraft Enterprises, Inc.
Crown Equipment Corporation	Lincoln Electric Company
Daimler Trucks North America LLC	Magna International Inc.
Deere & Company	Mazak Corporation
Delphi Automotive Systems	Mazda Motor of America, Inc.
Discount Tire	Medtronic, Inc.
The Dow Chemical Company	Merck & Co., Inc.
E.I. duPont de Nemours and Company	Meritor WABCO
Emerson Electric Co.	Michelin North America, Inc.

Microsoft Corporation
Mine Safety Appliances Company
Mitsubishi Motors North America, Inc.
Mueller Water Products
Novartis Pharmaceuticals Corporation
Novo Nordisk, Inc.
Pella Corporation
Pfizer Inc.
Pirelli Tire, LLC
Polaris Industries, Inc.
Porsche Cars North America, Inc.
RJ Reynolds Tobacco Company
Robert Bosch LLC
SABMiller Plc
The Sherwin-Williams Company
St. Jude Medical, Inc.
Stryker Corporation
Subaru of America, Inc.
Takeda Pharmaceuticals U.S.A., Inc.
TAMKO Building Products, Inc.
TASER International, Inc.
Teleflex Incorporated
TK Holdings Inc.
Toyota Motor Sales, USA, Inc.
U-Haul International
Vermeer Manufacturing Company
The Viking Corporation
Volkswagen Group of America, Inc.
Volvo Cars of North America, Inc.
Wal-Mart Stores, Inc.
Western Digital Corporation
Whirlpool Corporation
Yamaha Motor Corporation, U.S.A.
Yokohama Tire Corporation
ZF TRW
Zimmer Biomet

CERTIFICATE OF SERVICE

I, Michelle Temple, declare as follows:

1) I am a citizen of the United States and a resident of the State of Washington. I am over the age of 18 years and not a party to the within entitled cause. I am employed by the law firm of Betts Patterson & Mines, One Convention Place, Suite 1400, 701 Pike Street, Seattle, Washington 98101-3927.

2) By the end of the business day on the date indicated below, I caused to be served upon counsel of record at the addresses and in the manner described below, the following documents:

- **Brief of Amicus Curiae on Behalf of Product Liability Advisory Council, Inc., and**
- **this Certificate of Service.**

Kenneth W. Masters
Shelby R. Frost Lemmel
Masters Law Group, P.L.L.C
241 Madison Avenue North
Bainbridge Island, WA 98110

Via Email and U.S. Mail:
Ken@appeal-law.com
Shelby@appeal-law.com
Jaimie@appeal-law.com

Carol Nofziger Johnston
Jane Morrow
Otorowski Johnston Morrow & Golden
PLLC
298 Winslow Way W
Bainbridge Island, WA 98110

Via Email and U.S. Mail:
cnj@medilaw.com
jm@medilaw.com

Richard Friedman
William Siemon Cummings Friedman
Rubin
1126 Highland Ave
Bremerton, WA 98337-1828

Via Email and U.S. Mail:
rfriedman@friedmanrubin.com

Peter J. Mullenix
Friedman Rubin
51 University St Ste 201
Seattle, WA 98101-3614

Via Email and U.S. Mail:
wcummings@friedmanrubin.com
pmullenix@friedmanrubin.com

Philip Talmadge
Talmadge/Fitzpatrick
2775 Harbor Ave SW
Seattle, WA 98126

Via Email and U.S. Mail:
phil@tal-fitzlaw.com
Sidney@tal-fitzlaw.com
matt@tal-fitzlaw.com

Jeffrey Royal Johnson
Scheer & Zehnder
701 Pike Street, Suite 2200
Seattle, WA 98101

Via Email and U.S. Mail:
jjohnson@scheerlaw.com
tbaldwin@scheerlaw.com
JRowell@scheerlaw.com

Allen J. Ruby
Skadden, Arps, Slate, Meagher & Flom
525 University Ave.
Palo Alto, CA 94301

Via Email and U.S. Mail:
Allen.ruby@skadden.com

Catherine B. Stevens
Quinn Emanuel
51 Madison Avenue
New York, N.Y. 10010

Via Email and U.S. Mail:
CATHERINESTEVENS@QUINNEMANUEL.com

Karen M. Firstenberg
Morris Polich & Purdy LLP
1055 W. 7th Street, Suite 2400
Los Angeles, CA 90017

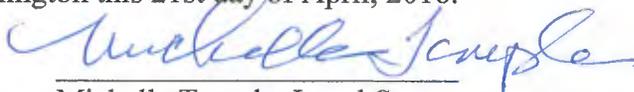
Via Email and U.S. Mail:
kfirstenberg@mpplaw.com

Brett S Durbin
Barbara Allan Shickich
Riddell Williams P.S.
1001 4th Ave Ste 4500
Seattle, WA 98154-1065

Via Email and U.S. Mail:
Email: bdurbin@riddellwilliams.com
bshickich@Riddellwilliams.com

I declare under penalty of perjury under the laws of the State of Washington that the foregoing is true and correct.

Executed at Seattle, Washington this 21st day of April, 2016.



Michelle Temple, Legal Secretary
Betts, Patterson & Mines, P.S.
701 Pike Street, Suite 1400
Seattle, WA 98101-3927
Ph: (206) 292-9988
Email: mtemple@bpmlaw.com