Changes in U.S. Law between 2012 and 2018 as it relates to Pre-sale Duty to Warn and Post-sale Duty to Warn

Editor's Note [Kenneth Ross]

I asked each of the chapter authors to describe significant changes in the law since 2012 in their jurisdiction. These descriptions are set forth below. However, I wanted to first include a short summary, so you can get a sense of what follows.

Pre-sale Duty to Warn in U.S.

There are a number of cases dealing with the duty of component part manufacturers to warn users of products in which their components are installed. Many of them deal with asbestos in finished products and one case enunciating a duty on a respirator manufacturer to warn about the hazards of asbestos that can arise when cleaning the respirator after use (State of Washington).

There are a number of cases discussing the duty to warn by generic and brand name drug manufacturers and one state that held a brand name drug manufacturer liable when generic drug manufacturers of the same drug failed to warn (Massachusetts). In addition, there are a number of new cases discussing federal pre-emption for drug manufacturers.

Lastly, there is a recent case holding that while manufacturers are required to provide adequate instructions, they have no duty to train users in the safe use of the product (Minnesota).

Post-sale Duty to Warn in the U.S.

Since 2012, three states (Alabama, Minnesota, and New Hampshire) have adopted section 10 of the Restatement (Third) of Torts: Products Liability which sets forth a post-sale duty to warn. However, New Hampshire also adopted the Restatement law that there is no duty on behalf of a manufacturer to inform users of post-sale safety improvements on an otherwise non-defective product.

Also, three states (Connecticut, Nebraska, and Tennessee) made it clear that there is no post-sale duty to warn for manufacturers who have safety issues in their states. Tennessee also ruled that internet sales distributors have no post-sale duty to warn. Of course, this only affects the common law and there are still rigorous regulatory requirements to report to various government agencies who may require manufacturers to recall their products or warn consumers.

International Pre-sale and Post-sale Duty to Warn

In jurisdictions outside the United States, as you would expect, there are many more legislative changes than changes in the caselaw. In particular, China, Korea, and Brazil have enacted a number of changes, many of them relating to post-sale duties and recalls. In addition, the European Union has issued a new guidance on risk assessment methodology which should be used by manufacturers to evaluate their duty to inform the government authorities of post-sale safety issues and whether there is a need to recall the product.

United States[1]

Alabama

In Alabama, the primary developments in product liability warnings law, and product liability law generally, over the last seven years have concerned legislative action and the courts' reaction to it. In 2011, the Alabama legislature enacted "innocent seller" provisions designed to protect distributors and sellers from liability when they are merely conduits of a product. Ala. Code §§6-5-501, 6-5-521 (1975). The Supreme Court of Alabama has yet to apply these enactments in a meaningful way to gauge the breadth of their protection.

Specific to drug and device cases, the Supreme Court of Alabama held in a landmark 2014 decision that drug companies may be held liable for fraud or misrepresentation "based on statements it made in connection with the manufacture of a brand-name prescription drug by a plaintiff claiming physical injury caused by a generic drug manufactured by a different company." *Wyeth, Inc. v. Weeks*, 159 So. 3d 649 (Ala. 2014). In the wake of *Weeks*, the Alabama legislature enacted a statute to abrogate its holding, requiring plaintiffs to prove "that the defendant designed, manufactured, sold, or leased the particular product the use of which is alleged to have caused the injury on which the claim is based, and not a similar or equivalent product" in "any civil action for personal injury, death, or property damage caused by a product." Ala. Code §6-5-530 (1975)(b).

Other notable decisions have addressed when a defendant can voluntarily assume a duty to warn; the applicability of the "bare metal" defense in asbestos litigation; the lack of continued viability of the "apparent manufacturer doctrine" (when a defendant that is not a manufacturer may be treated like one when it adds its own brand name to a product); a successful application of the product alteration defense; and when a plaintiff's claims may fail for lack of expert testimony.

Alaska

The only significant change in Alaska law since the last compendium was published is the Alaska Supreme Court's adoption of the Restatement (Third) of Torts: Products Liability §10 as the test to determine when a manufacturer has a post-sale duty to warn.

Arizona

The learned intermediary doctrine continues to apply in Arizona provided that the warning to the intermediary is adequate. The Court rejected a proposed exception for "direct to the consumer" advertising, *Watts v. Medicis Pharmaceutical*.

The *Watts* case also reinforces Arizona's reliance on Restatement (Third) when there is no contrary state law.

Federal pre-exemption is recognized and prevents any direct claims against the manufacturer. However, as it relates to post-sale duties, a plaintiff can claim that the manufacturer failed to report an adverse event on a drug case and can recover if it can prove that the FDA would have responded and taken action in time to prevent plaintiff's injury, *Conklin v. Medtronic*.

Arkansas

No significant developments since 2012.

[1] Summaries were submitted by chapter authors.

California

Strict Liability in Tort

CACI 1205[2] has been modified to include medical knowledge. Further, in prescription product cases the duty to warn runs to the physician not the patient, because it is through the physician that a patient learns of the properties and proper use of the drug or implant.[3]

Negligence

- **Factors determining the adequacy of a warning**: Where a supplier fails to warn the ultimate user of such danger in the product, or its use, of which such manufacturer or supplier knows or should know the supplier or manufacturer must have sufficient reason for believing the intermediaries sophistication is likely to operate to protect the user or the user is likely to discover such hazard otherwise.[4]
- **Duty to warn for another manufacturer's product**: Distinguished from Tellez Cordova, where the defendant's product was intended to be used with another product for the very activity that created the hazardous situation; in Sherman, where the hazard arises entirely from another product and the defendant's product does not create or contribute to that hazard, liability is not appropriate.[5]
- **Sophisticated user doctrine**: A manufacturer is not liable for failure to warn to a user who should be aware of the characteristics of the product, if such user knew or should have known of that risk, harm or danger.[6] The focus of the Sophisticated user doctrine is whether the danger in question was so generally known within the trade or profession that a manufacturer should not have been expected to provide a warning specific to the group to which plaintiff belonged.[7]
- **Causation**: A plaintiff's self-serving testimony regarding what plaintiff would have done differently, had there been an adequate warning, was admissible. Prior to appellate review, defendant raised such contention in a motion in limine, which was denied. The trial court admitted the testimony, and the Court of Appeals found such "self-serving" testimony was admissible because it was "reasonable, credible and solid value and supports the finding of a reasonable jury."[8]

Colorado

No major developments have occurred in the context of failure-to-warn cases in Colorado. However, we have made changes to the post-sale duty section to reflect the predominant view of the *Downing* case.

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[2] CACI Jury Instruction No. 1205

[3] *Bigler-Engler v. Breg, Inc.* (2017) 7 Cal.App 5th 276, 319.

[4] *Webb v. Special Electric Co., Inc.* (2016) 63 Cal.4th 167, 189.

[5] *Sherman v. Hennessy Industries, Inc.* (2015) 188 Cal.App.4th 1133, 1142

[6] Restatement (2d) of Torts § 388; Chavez v. Glock, Inc. (2012) 207 Cal.App.4th 1283, 1304; *Johnson v. Honeywell Internat., Inc.* (2009) 179 Cal.App.4th 549.

[7] *Collin v. CalPortland* (2014) 228 Cal.App.4th 582, 601.

[8] *Colombo v. BRP US INC* (2014). 230 Cal.App.4th 1442

Connecticut

Since the last edition, the most significant development in Connecticut's products liability law occurred in 2016 where the Connecticut Supreme Court declined to adopt the Restatement (Third) of Torts: Products Liability and reaffirmed its allegiance to §402A of the Restatement (Second) of Torts. *Bifolck v. Philip Morris, Inc.,* 324 Conn. 402, 152 A.3d 1183 (2016). Although *Bifolck* addressed design defect claims brought pursuant to the Connecticut Products Liability Act, it also clarified the existing law on failure to warn claims.

Our Connecticut Supreme Court held that a consumer's awareness of a product's potential danger does not preclude recovery or establishing that the product is in a defective and unreasonably dangerous condition. See, *Izzarelli v. R.J. Reynolds Tobacco Co.*, 321 Conn. 172, 136 A.2d 1232 (2016); *Bifolck v. Philip Morris, Inc.,* 324 Conn. 402, 136 A.3d 1232 (2016)

This chapter has also been updated with recent cases analyzing failure to warn claims, but these cases do not change the principles of the Connecticut Products Liability Act.

Delaware

In Delaware there have not been any significant changes in the law since 2012, however changes noted in the Delaware chapter include: 5A Del. C. §2-318 recodified as 6 Del. C. §2-318; and updated case citations added under: General Scope of the Duty to Warn and Instruct; Duty to Warn—Component Part Supplier; Who Do You Have to Warn?—Sophisticated Users and Learned Intermediary; and What Defenses Are Available to Those Within The Chain of Distribution.

District of Columbia

No significant developments since 2012.

Florida

Restatement: The Florida Supreme Court has rejected the use of the Restatement (Third) of Torts and instead relies on the Restatement (Second) of Torts with respect to strict products liability. *Aubin v. Union Carbide Corp.*, 177 So. 3d 489 (Fla. 2015).

Pre-emption: The Medical Device Amendments to the Food Drug and Cosmetic Act (FDCA), 21 U.S.C.A. §360k(a), expressly preempts state requirements different from, or in addition to, any requirement applicable to the device under federal law. *McClelland v. Medtronic, Inc.*, 944 F. Supp. 2d 1193 (M.D. Fla. 2013).

Georgia

There have been no significant changes to Georgia law with regards to pre-sale and post-sale duties to warn. However, *CertainTeed Corp v. Fletcher*, a 2016 Georgia Supreme Court case, made the determination of who a manufacturer must warn more ambiguous. *CertainTeed Corp. v. Fletcher*, 300 Ga. 327, 331, 794 S.E.2d 641, 645 (2016). In that case, the court established that a manufacturer may not always be required to warn a third party who could be foreseeably harmed by a defect. *Id.* Instead, in imposing a duty to warn third parties, a court must be cognizant of how far the duty would extend. *Id.* The court held that duties must be limited to avoid creating an infinite class of plaintiffs. *Id.* It remains unclear where exactly the line should be drawn when considering who should and should not be warned.

Hawaii

No significant changes since 2012.

Idaho

There have been no significant changes in Idaho law since 2012 in the area of product liability warnings. The Idaho Product Liability Reform Act has not been amended since 2005 and Idaho case law has not departed from its earlier decisions. Some developments of note stem from the federal District Court for the District of Idaho's continued interpretation of Idaho law. This includes discussion on a post-sale duty to warn that appears to be implicitly recognized by statute but not yet discussed by the Idaho courts and continued developments in the area of federal preemption for certain drug labels and medical devices.

Illinois

No significant developments since 2012.

Indiana

No significant developments since 2012.

Iowa

No significant developments since 2012.

Kansas

No significant developments since 2012.

Kentucky

No significant developments since 2012.

Louisiana

No significant developments since 2012.

Maine

No significant developments since 2012.

Maryland

Maryland law has mostly remained the same since 2012 with respect to the duty to warn. The most notable change arises from *May v. Air & Liquid Systems Corp.*, 446 Md. 1 (2015). Prior to the *May* decision, there was no Maryland case that addressed whether a manufacturer of a non-defective component part owes a duty to warn a user of dangers posed by the end product into which the non-defective component part is incorporated. In 2012, we surmised that the case of *Ford Motor Co. v. Wood*, 119 Md. App. 1 (1998), *abrogated on other grounds, John Crane, Inc. v. Scribner*, 369 Md. 390 (2002), likely indicated that such a duty would not exist.

However, the *May* case demonstrated that, under narrow circumstances, manufacturers have a duty to warn of asbestos-containing parts that they have not placed into the stream of commerce. In its decision, the court concluded that where a manufacturer's product contains asbestos components, and those components must be replaced periodically with new asbestos components, the risk of harm to the machinist is foreseeable. This foreseeability weighed heavily in favor of imposing a duty to warn on the manufacturers.

Massachusetts

In recent years, Massachusetts courts have continued to uphold long standing law with regards to duty to warn. *See Pantazis v. Mack Trucks, Inc.,* 92 Mass. App. Ct. 477 (2017) (supplier of component part containing no latent defect had no duty to warn assembler of danger that may occur after component parts are assembled); *Neidner v. Ortho-McNeil Pharmaceutical, Inc.,* 90 Mass. App. Ct. 306 (2016) (despite the learned intermediary doctrine, manufacturer of a contraceptive patch had a duty to provide adequate warnings directly to consumer); *Rose v. Highway Equipment Co*, 86 Mass. App. Ct. 204 (2014) (jury properly instructed on unreasonable use defense when plaintiff ignored warning label, did not read safety manual and had been drinking).

In 2018, however, the Massachusetts Supreme Judicial Court issued a significant decision that very few states have adopted when it addressed the duty a brand name drug manufacturer owes to a consumer of a generic drug in *Rafferty v. Merck & Co., Inc*., 479 Mass. 141 (2018). The Court held that brand name drug manufacturers owe a duty to consumers of the generic version of the drug to not act recklessly. *Id*. at 157.

The Court held that brand name drug manufacturers owed no duty to a plaintiff under a general negligence claim for failure to warn where it did not make the product. *Id*. at 157. The Court determined that while "brand-name manufacturers are in the best position, because of their Federal labeling, to prevent injury arising from the inaccurate or inadequate warning on a generic drug, they are not in the best position to bear its costs." *Id*. at 153.

The Court, however, left open a narrow window of liability in an effort to provide a remedy for injured generic drug consumers as generic drug manufacturers are immune from State law claims. The Court recognized that simply ruling that brand name drug manufacturers owed no duty to warn generic drug consumers, prevented those consumers from any sort of recourse in the event of an injury. *Id*. at 154. As brand name drug manufacturers essentially control the labeling on the generic version of the drug, a duty still remains to generic drug users to not act recklessly. *Id*. at 157. "A brand name drug manufacturer that intentionally fails to update the label on its drug to warn of an unreasonable risk of death or grave bodily injury, where the manufacturer knows of this risk or knows of facts that would disclose this risk to any reasonable person, will be held responsible for the resulting harm." *Id* at 158.

This recent ruling is significant in terms of the potential liability for brand name drug manufacturers. Unlike the majority of states that have chosen to not adopt this specific liability, this ruling makes Massachusetts a plaintiff friendly state for potential claims of injury resulting from the use of a generic drug. Not only is Massachusetts in the minority of states to impose potential liability on brand name manufacturers for generic drugs, but currently it is also the only state to limit such liability to reckless disregard of the risk of death or grave bodily injury.

As such, brand name drug manufacturers need to be aware of its duty to not act recklessly in terms of updating the labeling on its drugs.

Michigan

No significant developments since 2012.

Minnesota

The Minnesota Supreme Court further clarified the scope of the duty to warn. For example, the Court reaffirmed that there is no duty to warn of every conceivable risk of harm, no matter how remote or tenuous the risk. *See Mack v. Stryker Corp.*, 893 F.Supp.2d 976 (D. Minn. 2012) (finding the seller of a medical device had no duty to warn of potential injuries when existing scientific literature did not objectively forewarn of injury).

The Court also declined to expand the scope of a manufacturer's duty to warn to include a duty to train users in the safe use of a product. *Glorvigen v. Cirrus Design Corp.*, 816 N.W.2d 572 (Minn. 2012). In *Glorvigen*, the Court held that a manufacturer adequately discharged its duty to warn when it provided *written instructions* that (1) attracted the attention of those the product could harm; (2) explained the mechanism and mode of injury; and (3) provided instructions on ways to safety use the product to avoid injury. *Id*.

The Minnesota Supreme Court also formally adopted the Restatement (Third) of Torts: Products Liability §10 with respect to the post-sale duty to warn. *Great Northern Insurance Co. v. Honeywell International, Inc.*, 911 N.W.2d 510 (Minn. 2018). The Court in Great Northern praised the Restatement for identifying conjunctive factors that would reduce the confusion that arose from the fact-intensive and case-by-case application of *Hodder*.

Mississippi

The MPLA was amended in 2014 by the Mississippi legislature. *See* MS LEGIS 383 (2014), 2014 Miss. Laws Ch. 383 (H.B. 680) (effective July 1, 2014). We revised the 2018 chapter of the DRI Compendium on Warnings to reflect this change. The only other additions were citations to more recent cases, but those new cases did not involve changes in the law.

Missouri

Missouri products liability law has not seen fundamental changes over the past five years. Citations have been updated to include more recent case law, where available. Instead, Missouri case law trends appear to be focused on broader issues which will greatly impact products liability cases, including expert witness standards, collateral source, and personal jurisdiction.

Montana

No significant changes since 2012.

Nebraska

There have been no substantive changes in Nebraska statutory or common law concerning the duty to warn since 2012.

In 2014, a United States District Court reiterated a prior holding of the 8th Circuit Court of Appeals that Nebraska product liability law suggests that the Nebraska Supreme Court would not impose a post-sale duty to warn on product manufacturers.[9]

Nevada

No significant changes since 2012.

New Hampshire

The revised chapter adds in sections related to "factors to consider" with respect to whether the warning or instruction was adequate, as well as a section on "obvious hazards." The revised chapter also addresses whether there is a post-sale or continuing duty to warn in products liability cases. The New Hampshire Supreme Court ruled that there is a post-sale duty to warn as set forth in section 10 of the Restatement (Third) of Torts: Products Liability. A New Hampshire Superior Court, however, ruled that there is no post-sale duty to inform customers of post-sale safety advancements.

New Jersey

Since 2012, there have been no changes to the text of the New Jersey Product Liability Act, which governs all product liability claims. Moreover, while there have been several unpublished and therefore nonbinding decisions issued by the New Jersey Appellate Division on issues related to the duty to warn, there has been only one published decision, *Hughes v. A.W. Chesterton Co.*, 435 N.J. Super. 326 (App. Div. 2014).

In the *Hughes* matter, the Appellate Division again broadened the scope of the duty to warn when it held that a manufacturer's duty to warn may extend to products it has not placed in the stream of commerce. Specifically, when a manufacturer *requires* the use of a component part, the danger posed by the replacement part for that component is reasonably anticipated. As such, a manufacturer has a duty to warn that component parts, which had to be replaced regularly as part of routine maintenance of a manufacturer's product contained asbestos. Ultimately, however, the Appellate Division upheld the trial court's grant of summary judgment as the plaintiff could not prove causation. *Hughes,*, *supra*. at 340–41. We have not seen any similar holding in the non-asbestos context.

New Mexico

There have not been any significant changes in New Mexico law. The only changes to the 2012 compendium have been a citation to the jury instructions regarding the duty to warn when there is an obvious danger and a citation to one case rejecting adoption of one portion of the Restatement (Third) of Torts, Product Liability.

New York

In New York, long standing principles regarding the duty to warn and liability surrounding warnings have remained essentially untouched since the publication of the 2012 version of this chapter. New developments in the case law citing these principles, however, have continued to broaden the circumstances under which the issue of a manufacturer's duty to warn will be decided by the jury.

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[9] *Vallejo v. Amgen, Inc.*, No. 8:14CV50, 2014 WL4922901 (citing *Anderson v. Nissan Motor Co.*, 139 F.3d 599, 602 (8th Cir. 1998).

Two of the most prominent examples of this expansion were seen in the area of toxic exposure cases. In a case involving alleged asbestos exposure, the Court of Appeals, New York's highest court, held that, under some circumstances, a manufacturer may have a duty to warn against certain combined uses of its product with product made by a third party, I*n re New York City Asbestos Litigation* 27 N.Y.3d 765, 59 N.E.3d 458, 37 N.Y.S.3d 723 (N.Y. 2016).

Similarly, in a case involving alleged silica dust inhalation, the Fourth Department, one of New York's mid-level appellate courts, in a split decision with an extensive dissenting opinion, refused to extend the "sophisticated intermediary doctrine" to bar a failure to warn claim against the silica manufacturers who sold the silica to plaintiff's employer, *Rickicki v. Borden Chemical, Division of Borden, Inc.* 159 A.D.3d 1457, 72 N.Y.S.3d 302 (4th Dep't. 2018).

North Carolina

No significant changes since 2012.

North Dakota

In clarifying the relationship between the duty to warn and the manufacturer's duty of safe design, the North Dakota Supreme Court recently held that "even though the manufacturer may be found not to be negligent in the design of the product, the manufacturer may be found negligent for failure to warn if the product is dangerous." *Messer v. B & B Hot Oil Serv.*, 2015 ND 202, ¶10, 868 N.W.2d 373, 377. The distinction is contingent on the finder of fact determining the Defendant's status as a manufacturer. *Id.* ¶11.

Ohio

No significant developments since 2012.

Oklahoma

No significant developments since 2012.

Oregon

No significant developments since 2012.

Pennsylvania

The changes to the Pennsylvania Compendium come primarily as a result of the Pennsylvania Supreme Court decision in *Tincher v. Omega Flex, Inc.,* 628 Pa. 296, 104 A.3d 328 (2014). The *Tincher* Court overruled its prior decision in *Azzarello v. Black Bros. Co., Inc.,* 480 Pa. 547, 391 A.2d 1020 (1978), which held that a product must be provided with "every element" necessary to make it safe for use. While the Court in *Tincher* declined to adopt the Restatement (Third) of Torts, it did incorporate to some degree negligence concepts in strict liability design defect cases. The Court instituted a composite standard for determining when a product is unreasonably dangerous, which includes both a consumer expectations test and risk-utility test. Additionally, in another deviation from *Azzarello*, the *Tincher* Court held that the question of whether a product is defective on a design defect theory is initially a question of fact to be determined by the jury, only being removed from the jury's consideration where it is clear that reasonable minds could not differ on the issue. While *Tincher* is a design defect case, its impact on failure to warn cases in Pennsylvania is evolving.

Rhode Island

The only material change is that in determining whether a particular danger is open and obvious, the court should consider a plaintiff's age. If the plaintiff is a child or young adult, it is more difficult to establish that the plaintiff assumed the risk when the risk is intricate or less obvious.

South Carolina

In *Hickerson v. Yamaha Motor Corp.*, 882 F.3d 476 (4th Cir. 2018), the Fourth Circuit held that South Carolina law does not require a manufacturer to redesign a product to make it safe without the need of a warning, and acknowledged that South Carolina only requires expert testimony if the issue is outside of a jury's general knowledge and recognizes that jurors will likely have had exposure to various warnings.

The Supreme Court of South Carolina, in *Lawing v. Univar, USA, Inc.*, 415 S.C. 209, 781 S.E.2d 548 (2015), held that learned intermediary/sophisticated user defenses will not bar a failure to warn claim in the face of a wholly inadequate label. The Court reasoned that the fact that a more sophisticated user receives the product will not permit the supplier to decide whether or not to adequately label it a dangerous product.

The Supreme Court of South Carolina addressed federal preemption of state law for failure to warn in *Weston v. Kim's Dollar Store*, 399 S.C. 303, 731 S.E.2d 864 (2012) in the medical device context. The Court focused on a federal agency's authority to ensure safety and effectiveness of consumer products and affirmed that medical device warnings are subject to statutory preemption. However, *State ex rel. Wilson v. Ortho-McNeil-Janssen Pharm., Inc.*, 414 S.C. 33, 777 S.E.2d 176 (2015) determined that federal prescription drug labeling requirements do not preempt state law tort claims based on faulty labeling.

South Dakota

No significant developments since 2012.

Tennessee

The Tennessee Court of Appeals clarified that "suppliers are manufacturers" in relation to who has a duty to warn. As a result, suppliers are not afforded the protections of Tenn. Code Ann. §29-28-106 (*see Bissinger v. New Country Buffet*, No. M2011–02183–COA–R9–CV, 2014 WL 2568413, at *9 (Tenn. Ct. App. June 6, 2014)). Also, in *Bissinger*, the Court of Appeals discussed the scope of sellers' liability in light of the Tennessee Products Liability Act and stated that §29-28-106 protects sellers who are not in the position to discover the dangerous condition themselves.

A significant change since 2012 is that the courts relaxed the requirement of expert testimony in all failure to warn claims. When the survey was last updated, the case law was dispositive that an expert was always required to establish a failure to warn claim. *Pride v. BIC Corp.*, 218 F.3d 566, 580–81 (6th Cir. 2000) (stating that "under Tennessee law, expert testimony is required to establish liability in cases alleging manufacturing and design defects") (citing *Fulton v. Pfizer Hosp. Prod. Grp., Inc.*, 872 S.W.2d 908, 912 (Tenn. Ct. App. 1993)). However, the Sixth Circuit recently limited *Pride*'s expert testimony requirement to dicta and held that expert testimony is required only when applying the prudent-manufacturer test rather than the ordinary-consumer test. *Bradley v. Ameristep, Inc.*, 800 F.3d 205, 210 (6th Cir. 2015). An explanation of each test, its requirements, and the case history has been added to the chapter.

Additionally, the preemption of the duty to warn with respect to specific products has been modified. The law has not changed in regard to cigarettes or pesticides; however, three Class III medical devices have

been specifically preempted under federal law since 2012. These products include coronary stents, bone graft devices, and surgically implanted penile prostheses. *See Hughes v. Cook*, 452 F. Supp. 2d 832 (W.D. Tenn. 2006); *Hafer v. Medtronic, Inc.*, 99 F. Supp. 3d 844, 858 (W.D. Tenn. 2006); *Spier v. Coloplast Corp.*, 121 F. Supp. 3d 809, 817 (E.D. Tenn. 2015).

Finally, Tennessee's position that there is no post-sale duty to warn has not changed. Since the last update, the Court of Appeals and the District Court for the Middle District of Tennessee have agreed that there is no post-sale duty to warn cause of action. *See Rodriguez v. Bridgestone/Firestone N. Am. Tire, LLC.*, 2017 WL 4513569 (Tenn. Ct. App. May 24, 2017); *Fox v. Amazon.com, Inc.*, No. 3:16–cv–03013, 2018 WL 2431628, at *10 (M.D. Tenn. May 30, 2018).

The District Court case in *Amazon* is particularly noteworthy because the court rejected the argument that the relationship between an Internet sales distributor, like Amazon, and a purchaser creates a post-sale duty to warn.

Texas

The general products liability law of Texas has largely remained consistent since the last update in 2012. Texas courts have referenced additional sections of the Restatement (Third) of Torts: Products Liability in analyzing products liability cases.

Most significantly, the United States Court of Appeals for the Fifth Circuit ruled in 2012 that Section 82.007(b)(1) of the Texas Civil Practice and Remedies Code relating to liability of a manufacturer or distributor of pharmaceuticals with respect to warnings is preempted by the Food, Drug, and Cosmetic Act provision dealing with fraud on the Food and Drug Administration ("FDA"). While Section 82.007(b)(1) provides that in a case involving a failure to provide adequate warnings or information with regard to a pharmaceutical product, the claimant may rebut the presumption that the defendant is not liable by establishing that "the defendant, before or after pre-market approval or licensing of the product, withheld from or misrepresented to the United States Food and Drug Administration required information that was material and relevant to the performance of the product and was causally related to the claimant's injury." The Fifth Circuit ruled that Section 82.007(b)(1) is preempted unless the FDA found actual fraud with respect to the warning.

The State Bar of Texas has also revised the Pattern Jury Charge for Defect in Warnings or Instructions (Marketing Defect).

Utah

No significant developments since 2012.

However, the issue of who a bulk supplier owes a duty to warn about a dangerous product was raised in *Riggs v. Asbestos Corp.*, 304 P.3d 61, ¶18 (UT Ct. App. 2013). The court did not fully reach the issue because of a failure to develop the issue in the trial court below. Yet, the court upheld the finding that the bulk supplier had not shown it fulfilled its duty to warn, even if it was only potentially owed to the manufacturer and not owed to the final end consumer. *Id.* at ¶24.

Vermont

No significant developments since 2012.

Virginia

No significant developments since 2012.

Washington

In *Macias v. Saberhagen Holdings, Inc*., 175 Wash. 2d 402, 282 P.3d 1069 (2012), the Washington Supreme Court held that a manufacturer of respirators had a duty to warn product users of the need to take precautions when cleaning the units in order to avoid exposure to asbestos which had been captured in the filtering. This opinion was significant because, prior to *Macias*, it was unclear whether a manufacturer that was outside of the chain of distribution of a dangerous product (*e.g.,* asbestos) and did not manufacture, sell, or select the dangerous product could be liable for failure to warn when its product (*e.g.,* respirator) was used as expected with the dangerous product.

The Washington Supreme Court also opined on the contours of the learned intermediary doctrine and a manufacturer's liability for unavoidably unsafe products. In *Taylor v. Intuitive Surgical, Inc*., 187 Wash 2d 743, 389 P.3d 517 (2017), the Court vacated a jury verdict rendered for Intuitive Surgical Inc. and ordered a new trial on whether the surgical robot maker provided proper warnings. In its *en banc* ruling, the *Taylor* Court reiterated its adoption of comment k of the Restatement (Second) of Torts Section 402A but noted that even if a product at issue qualifies as an unavoidably unsafe product, the manufacturer is still required to provide adequate warnings of its inherent danger. Manufacturers of unavoidably unsafe products are not shielded from strict liability if they fail to adequately warn, and the comment k exception applies only after the trier of fact determines that proper warnings accompanied the product. If the manufacturer fails to provide an adequate warning, the usual negligence strict liability standard applies. The *Taylor* Court also declined to expand the learned intermediary doctrine. Under the WPLA, a manufacturer, for example, owes a duty to provide adequate product warnings to a hospital that purchases a medical device. This duty is not excused when a manufacturer warns doctors who use the devices.

West Virginia

No significant developments since 2012.

Wisconsin

In early 2011, Wisconsin enacted the Omnibus Tort Reform Act 9 ("the Act"), extensive tort reform that will greatly impact product liability matters filed in Wisconsin. 2011 Wisconsin Act 2, *available at* **https://docs.legis.wisconsin.gov/2011/related/acts/2.pdf**. The new law took effect February 1, 2011 and applies to all new cases filed after that date, regardless of whether the injury or alleged wrongful conduct occurred prior to the bill's enactment and publication. Although it was enacted over 7 years ago, the case law interpreting it remains minimal. Accordingly, information regarding both the new and old standards are included.

Wyoming

No significant developments since 2012.

International

Australia

No significant changes since 2012.

Brazil

Since 2012, there have been no relevant developments in Brazilian legislation regarding recalls. The most important bills of law on the subject (mostly related to the vehicle industry) are still under evaluation at the Brazilian Federal Congress. One bill (Bill of Law n. 6624/2009, which aims to amend the Consumer Defense Code to establish a specific procedure for recall of vehicles)[10] was approved by the House of Representatives and is currently awaiting the Senate's analysis[11] and another (Bill of Law n. 4637/2012, which has a similar purpose[12]) is yet to have its final draft defined by the House of Representatives. On a related note, the National Recall Alerting System (NRAS)—found at **http://portal.mj.gov.br/recall/**—was created to identify defective products that are being removed from the market, bringing greater transparency and security to Brazilian consumer relations.

Canada (pre-sale)

The general scope of a manufacturer's pre-sale duty to warn in Canada has largely been settled. That is, manufacturers and others in the distribution chain have an ongoing duty to warn consumers and users of their products of the risks and dangers that are known or ought to be known to be inherent in the use of the product, as well as foreseeable misuses of the product.

In this update, we have incorporated new decisions that have refined and clarified issues that often arise in product liability claims. For example, a recent decision of the Ontario Court of Appeal suggests that a manufacturer's duty of care does not extend to protect the reputation of someone within the supply chain [*1688782 Ontario Inc v. Maple Leaf Foods* (2018 ONCA 407)]. Also, courts have considered a heightened duty to warn in matters involving critical safety elements of a product [*Canadian Natural Resources Ltd v. Wood Group Mustang (Canada) Inc*. (2017 ABQB 106); *Hans v. Volvo Trucks North America* (2016 BCSC 1155) and *Player Estate v. Janssen-Ortho Inc.* (2014 BCSC 1122)]. Additionally, reliance on obvious dangers as a defense has been considered [*Coady v. Burton Canada Co* (2013 NSCA 95)]. Finally, cases from Ontario have delved into the issue of causation, drawing a distinction between "legal" and "scientific" causation, and further delineating the distinction between "causation" and "association."

New Commentary has been included to address the potential impact of social media on a manufacturers' duty to warn. The emerging popularity of social media and online forums facilitate product promotion and brand awareness, but they may also affect liability of manufacturers who interact with consumers through these mediums, and may affect the standard of care analysis. Time will tell.

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[10] The bill of law aims to make it mandatory (i) for vehicles' suppliers to inform the National Department of Transportation (DENATRAN) of recalled vehicle's chassis number and (ii) for owners of recalled vehicles to demonstrate that the flaws have been fixed in order to obtain the vehicle license.

[11] Number of such Bill of Law at the Senate: Bill of Law n. 58/2017.

[12] This Bill of Law aims at establishing the procedure, deadline and other rules that must be followed by consumers and suppliers in the event of vehicles recalls in order to avoid accidents.

Canada (post-sale)

In the update, there are very few changes. The case law cited in the original text is still good law and has not been distinguished. The only substantive changes are in relation to the regulatory section. Specifically, we have removed reference to "property damage" under the definition of "incident." Please note, however, that if a product results in property damage but the event has the potential to harm individuals, it would be considered an "incident" (*i.e.* explosion or fire). In addition, there is no longer a dual reporting obligation to both Health Canada and the ESA. There is now only a reporting obligation to Health Canada. Finally, Health Canada's March 2011 guidelines have been replaced with an updated May 2018 version entitled "Reporting Adverse Reactions to Marketed Health Products—Guidance Document for Industry."

China

Under Chinese law, detailed product quality requirements are primarily provided in patchy and product-specific regulations. The past six years have witnessed intensive efforts from the legislative, judiciary, and administrative bodies in China not only to promulgate new regulations and amendments to existing ones, but also to proactively make drafts of bills available for public comment to improve efficiency and transparency in the legislative process. That being said, there still are ambiguities in the laws and regulations, such as what constitutes a producer for product quality and recall purposes.

The pre-sale duty to provide warnings and instructions, set forth in the PRC Product Quality Law as well as relevant State regulations, has remained largely unchanged.

The post-sale duty to recall, on the other hand, has seen a number of significant changes since 2013. In this article, we discuss changes to the recall regime set forth in the PRC Tort Liability Law (effective on July 1, 2010), the Law on the Protection of Consumer Rights and Interests (amended on October 25, 2013), the Consumer Products Recall Measures (effective on January 1, 2016) and its draft-for-comment regulations published in February 2018, as well as the large scale government re-organization that saw the primary product quality regulator merged into the larger State Administration for Market Regulation. One notable observation in these new laws and regulations is a clear intent of the government to introduce more severe penalties and remedies that may be imposed on non-compliant businesses, and to set up clearer procedural rules with respect to product defect notifications and recall actions.

European Union

There have been no major relevant changes to the overall EU product regulation regime in respect of duties to warn and post-sale duties since the 2012 edition of the DRI Warnings Compendium. Consumer products, the duties to warn or take action in respect of them, remain covered by either sector-specific, vertical measures, or horizontal measures—notably, the General Product Safety Directive.

However, Europe continues to innovate and legislate in the product sphere. Since the last edition, there has been a considerable volume of new, or updated, legislation, including in relation to low voltage electrical equipment, cosmetics, personal protective equipment, electromagnetic compatibility, radio equipment, waste electrical and electronic equipment and the restriction of hazardous substances.

In addition to these new provisions, the latest version of the European Union chapter has been updated to take account of new Goods Package proposals and updated European Commission guidance on risk assessment methodology.

France

An important decision has been rendered on 7 July 2017 by the French Supreme Court regarding the application of the strict liability regime for defective products. The French Supreme Court has ruled that, because a claimant attributed his damage to the insufficiency of the information on the labelling and packaging of a product, the Court of Appeal was obliged to examine whether the strict liability regime could apply. This means that French Courts must examine whether such regime is applicable to the case, even if the claimant did not bring his/her claim on these grounds. EU provisions on product liability therefore fall under public policy (French Supreme Court, 7 July 2017, No. 15-25651).

Finally, it should be noted that the obligations of a seller in terms of warnings during the pre-sale phase have strengthened. Today, a seller is expected to be proactively diligent to ensure that its product is suitable and adequately used. The duty to inform at the pre-sale stage was originally established by case-law. Since the 10 February 2016 Order, the general duty to inform has made its entry into the French Civil Code, under Article 1112-1.

Germany

There haven't been any major changes with regard to the manufacturer's obligation to warn against product risks since 2012. There was one judgment by the German Federal Court of Justice (Bundesgerichtshof „BGH") which is important to know as it gives some more clarity on the meaning of warnings and instructions (BGH, judgment of 5. February 2013 – VI ZR 1/12) and to what extent the instructions have an impact on the average product user to be addressed with warnings. The judgment is explained in more detail in the revised chapter.

Japan

New chapter.

Korea

Since 2012, there have been various changes to the Korean legal regime on product warnings and recall, but the most significant is the amendment to the Product Liability Act (PLA) in 2017.

Under the amended PLA, which was promulgated on March 30, 2017 and became effective on April 19, 2018, a court may presume existence of a product defect and causation between the defect and alleged harm if the plaintiff shows (i) he/she suffered the harm while using the product normally as intended, (ii) the harm arose within a part of the product within the manufacturer's exclusive control, and (iii) he/she would not have sustained the harm but for the defect.

The amended PLA also introduced treble damages for defective products. Under the amended PLA, a manufacturer who is aware of a product defect but intentionally fails to take appropriate measures, resulting in serious harm to life or body, will be liable for up to three times the actual damages.

Mexico

New chapter.

South Africa

The initial compendium submitted in respect of South Africa in 2012 was finalized and published shortly after the Consumer Protection Act no 68 of 2008 was enacted. As such, the initial submission was speculative as to how this new piece of legislation would affect the consumer landscape. As such, a major change to the South African compendium has been to remove the speculation and substitute it with commentary on the various sections of the Act where relevant.

In addition to the above, the South African submission now includes: the guidelines on product recalls which gives practical effect to section 60 of the Consumer Protection Act; the enforcement guidelines which establishes, inter alia, the functions of the National Consumer Commission; and commentary on the consumer goods and services ombudsman which plays a primary role in receiving consumer complaints.

Spain

No significant changes since 2012.

United Kingdom

As in 2012, the importance of warnings and instructions should not be underestimated. Recent cases have re-emphasised the court's willingness to take into account the way a product is marketed, as well as instructions and warnings, when determining the safety standards a person is generally entitled to expect.

Further, major changes are potentially on the horizon as a result of the UK's departure from the EU, but the exact nature and scope of these changes is not yet clear. Whether there will be changes to this area of law as a result of Brexit (for example if products laws will be amended to be more relaxed or stringent) is, therefore, yet to be seen.