

Legal 500

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United States

Product Liability

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This country-specific Q&A provides an overview of product liability laws and regulations applicable in United States.

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United States: Product Liability

1. What are the main causes of action upon which a product liability claim can be brought in your jurisdiction, for example, breach of a statutory regime, breach of contract and/or tort? Please explain whether, for each cause of action, liability for a defective product is fault-based or strict (i.e. if the product is defective, the producer (or another party in the supply chain) is liable even if they were not individually negligent).

Product liability actions typically are based on theories of strict liability, negligence, and/or breach of warranty. Depending on the applicable state's law, a claimant may also be able to assert other tort claims based on defective products, including fraud, negligent misrepresentation, and claims under state consumer-protection statutes. A few states have also adopted Restatement (Second) of Torts § 402B, under which defendants engaged in the business of selling any type of chattel that make material misrepresentations regarding the character or quality of that chattel are strictly liable for physical harm to consumers caused by justifiable reliance upon the misrepresentations. As a general rule, aside from strict liability and breach of warranty claims, most product liability causes of action are fault-based.

2. What is a 'product' for the purpose of the relevant laws where a cause of action exists? Is 'product' defined in legislation and, if so, does the definition include tangible products only? Is there a distinction between products sold to, or intended to be used by consumers, and those sold for use by businesses?

The Restatement (Third) of Torts: Products Liability defines "product" as follows: "(a) A product is tangible personal property distributed commercially for use or consumption. Other items, such as real property and electricity, are products when the context of their distribution and use is sufficiently analogous to the distribution and use of tangible personal property that it is appropriate to apply the rules stated in this Restatement. (b) Services, even when provided commercially, are not products." Restatement (Third) of Torts: Prod. Liab. § 19(a)-(b) (1998). However, many states have product liability statutes that may define

"product" differently, so it is important to review the law of the forum from which the case arises.

Generally, there is no distinction between causes of action based on products for consumers versus products for professionals/businesses, although there are some defences that may apply in the context of certain products for professionals/businesses (e.g., learned intermediary doctrine, sophisticated user defence) that are unlikely to apply to products sold directly to ordinary consumers.

3. Who or what entities can bring a claim and for what type(s) of damage? Can a claim be brought on behalf of a deceased person whose death was caused by an allegedly defective product?

Any individual or entity that has suffered an injury in fact caused by a defective product can bring a claim. Depending on the cause of action(s) asserted, the claimant can recover for physical injuries, mental or emotional injuries, harm to property, and/or economic losses. There are two types of actions that may be brought on behalf of a deceased person. In a survival action, the administrator of the decedent's estate asserts the decedent's own cause of action seeking damages for the decedent's losses, including the decedent's pain and suffering. In a wrongful death action, the spouse, parents, or children of the decedent sue for their own losses resulting from the decedent's death. Each state has its own wrongful death statute and some of these statutes limit who can assert such claims.

4. What remedies are available against a defendant found liable for a defective product? Are there any restrictions on the types of loss or damage that can be claimed?

The types of compensatory damages recoverable in a product liability action vary by state. Typically they include past and future economic damages (e.g., medical expenses, lost earnings, etc.) and noneconomic damages (e.g., pain and suffering, physical impairment, permanent disability). Some states have statutory caps on the amount of noneconomic damages that can be recovered. In many states, a claimant may not recover purely economic damages under a tort theory unless he or she

also suffered physical injury or injury to property. The spouse of the injured party may also have his or her own loss of consortium claim for the monetary value of the deprivation of the benefits of married life (e.g., society, companionship, etc.) caused by the defendant. Some states also allow loss of consortium claims by the parents or children of the injured party. In most states, punitive damages are recoverable for strict-liability product actions. Typically, the claimant must demonstrate an egregious level of misconduct by the defendant (e.g., fraud, malice, gross negligence, etc.) by a heightened evidentiary standard (i.e., clear and convincing evidence). In some states there are statutory caps on punitive damages. Moreover, any punitive damage award cannot be so grossly excessive that it violates due process.

5. When is a product defective? What must be shown in order to prove defect?

With a strict liability claim, the focus is on the condition of the product itself, rather than the reasonableness of the defendant's conduct. A product may be defective because of (i) a flaw in the manufacturing process, (ii) inadequate instructions or warnings, and/or (iii) a defect in the product's design. The claimant typically must demonstrate that (i) the product was defectively manufactured, designed, or marketed, (ii) the defect existed at the time it left the defendant's possession, and (iii) the defect caused the claimant's injuries. Additionally, in some states, to prevail on a product liability action based on defective design, the claimant must also prove that there existed a safer alternative design, which (i) was economically and technologically feasible for the manufacturer at the time the product was designed and produced, (ii) would not have materially affected the product's utility, and (iii) would have prevented or reduced the claimant's injuries.

6. Which party bears the burden of proof? Can it be reversed?

The claimant bears the burden of proof on the elements of its claim, while the defendant bears the burden of proof on the elements of any affirmative defences. In some states there may be circumstances where the burden of proof on a particular element of the claim shifts to the opposing party, but this is rare.

7. What factors might the court consider when assessing whether a product is defective? To

what extent might the court account for a breach of regulatory duty, such as a breach of a product safety regulation?

Among other things, the court may consider whether (i) the alleged defect existed at the time the product left the defendant's control, (ii) the product reached the user without a substantial change in the condition in which the product was sold, (iii) the defective condition was unreasonably dangerous, (iv) the product was unsafe for its intended use, (v) there is a feasible, safer alternative design, (vi) the defect was open and obvious, and/or (vii) the product was misused, and if so, whether that misuse was foreseeable. The extent to which a product's compliance or noncompliance with applicable regulations is taken into account varies by state. In some states, there is a rebuttable presumption that a product was not defective if it complied with applicable regulations. In other states, the fact that the product complied or did not comply with applicable regulations is simply evidence for the trier of fact to consider.

8. Who can be held liable for damage caused by a defective product? If there is more than one entity liable, how is liability apportioned?

Manufacturers are subject to liability based on the products they manufacture. In many states, nonmanufacturing sellers, retailers, suppliers, and/or others within the chain of distribution may also be held liable under product liability theories. Although a few states automatically impose joint-and-several liability in product liability cases where multiple defendants are found liable, most states apportion a defendant's liability based on the percentage of its responsibility. Joint-and-several liability may still be available, however, if the claimant can demonstrate that the defendants acted in concert with each other.

9. What defences are available?

The availability of particular defences depends on the applicable state law and the product liability theories asserted. Some of the more common defences include: Assumption of Risk: This defence may apply when the claimant used the product despite being aware of the defect and associated danger. In some states, the claimant is completely barred from recovery under these circumstances, while in other states the claimant's damages will be reduced in proportion to the degree of his or her own fault. Product Misuse: This defence may apply when the claimant used the product in a manner

not reasonably intended or foreseen by the manufacturer or seller. Substantial Alteration: This defence may apply when the product was substantially altered or modified after it left the manufacturer's possession and such alteration or modification caused the claimant's injury. State of the Art: This defence may apply if the product conformed to the level of scientific and technical knowledge considered to be "state of the art" at the time of its design, manufacture, or sale. Depending on the applicable state, a state-of-the-art product may (i) provide a complete bar to liability, (ii) create a rebuttable presumption that the product is not defective, or (iii) merely be one of many factors to be considered by the jury. Government-Approved Products/Compliance with Government Standards or Regulations: In some states, the fact that a product complies with applicable government standards and regulations, or was approved by a governmental agency such as the FDA, may provide a complete defence against recovery or a rebuttable presumption that the product is not defective. Learned Intermediary Doctrine: Under this doctrine, manufacturers of prescription drugs or medical devices satisfy their duty to warn if they provide adequate warnings to the prescribing physician. Sophisticated Intermediary Defence: Similar to the learned intermediary doctrine, this defence allows a supplier to discharge its duty to warn if it (i) adequately warns the product's immediate purchaser (the intermediary), or sells to a sophisticated purchaser that the supplier knows is or should be aware of the specific risks, and (ii) reasonably relies on that intermediary to convey the appropriate warnings to downstream users. Sophisticated User Defence: Under this defence, a manufacturer is not liable for failing to warn a sophisticated user of its product if that user knew or should have known of the risk or danger associated with the product.

10. What is the relevant limitation period(s) for bringing a claim? Does a different limitation period apply to claims brought on behalf of deceased persons?

The limitation periods vary by state. Typically, strict liability claims are subject to a 2- or 3- year statute of limitations, but in some states it can be as little as 1 year or as many as 6 years. A strict liability claim generally accrues when the claimant discovers, or by the exercise of reasonable diligence should have discovered, the causal connection between the product (or the defendant's conduct) and the injuries suffered. In some states, the statute of limitations may be tolled for an inherently unknowable injury or when there has been fraudulent concealment of the claim. The statute of

limitations for a wrongful death claim will vary depending on the particular state's wrongful death statute. For survival actions, the statute of limitations is typically the same as it would have been had the decedent not died.

11. To what extent can liability be excluded, if at all?

In many states, a defendant will not be held liable for failing to warn of an open and obvious danger associated with its product. Some states have adopted comment k to Restatement (Second) of Torts § 402A, which immunizes manufacturers and sellers of certain unavoidably unsafe products, such as prescription drugs, from strict liability if the products were properly prepared and accompanied by sufficient directions and warnings. Additionally, various federal statutes preempt certain product liability claims. For example, the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., preempts state law claims against generic drug manufacturers based on inadequate drug warnings. Similarly, the Medical Device Amendments of 1976, 21 U.S.C. § 360c, preempts state common-law claims based on the design, labeling, and manufacture of Class III medical devices that have undergone the rigorous premarket approval process mandated by the statute.

12. Are there any limitations on the territorial scope of claims brought under a strict liability statutory regime?

A product liability action must be brought in a court (i) in which there is proper venue, and (ii) in a state in which the defendant is subject to personal jurisdiction. Personal jurisdiction can be general or specific. General jurisdiction exists when the defendant is "at home" in the forum state, such as the state(s) in which a corporate defendant is incorporated or has its principal place of business. Under those circumstances, the defendant can be sued in that state regardless of where the events forming the basis of the action occurred. Specific jurisdiction exists when (i) a non-resident defendant has purposefully availed itself of the privilege of conducting activities in the forum state, or has purposefully directed its conduct into the forum state, and (ii) the plaintiff's claim arises out of, or relates to, the defendant's conduct in the forum state. The court in which the action is brought must also be located in a proper venue. There are often multiple venues in which the plaintiff can bring an action. For example, plaintiffs can typically sue in any judicial district in which (i) the defendant does business, (ii) the plaintiff resides, or (iii) the events giving rise to the action occurred. Even when an action is brought in a

proper venue, if that venue is inconvenient to the parties or witnesses, the court may transfer it to another proper venue that is more convenient.

13. What does a claimant need to prove to successfully bring a claim in negligence?

When asserting a product liability claim under a negligence theory, the claimant typically must prove that he or she was injured as a result of the defendant's failure to act reasonably in designing, manufacturing, marketing, or selling the product. In some states, a product manufacturer may owe post-sale duties to warn or to remedy defects if it learns of defects or dangers associated with the product after it has been sold.

14. In what circumstances might a claimant bring a claim in negligence?

As with strict liability claims, claimants can bring negligence claims based on manufacturing defect, design defect, and/or failure to warn. In some states, claimants may also be able to assert claims based on negligent misrepresentation.

15. What remedies are available? Are punitive damages available?

The types of compensatory damages recoverable in a negligence-based product liability action vary by state, but are typically the same as the types of compensatory damages recoverable in a strict-liability product action (discussed above). In most states, punitive damages are recoverable for negligence-based product liability actions, so long as the claimant can demonstrate a more egregious level of misconduct by the defendant than mere negligence (e.g., fraud, malice, gross negligence, etc.), typically by a heightened evidentiary standard (i.e., clear and convincing evidence). In some states there are statutory caps on punitive damages. Moreover, any punitive damage award cannot be so grossly excessive that it violates due process.

16. If there are multiple tortfeasors, how is liability apportioned? Can a claimant bring contribution proceedings?

Although a few states automatically impose joint-and-several liability in product liability cases where multiple defendants are found liable, most states apportion a defendant's liability based on the percentage of its

responsibility. Joint-and-several liability may still be available, however, if the claimant can demonstrate that the defendants acted in concert with each other. The ability for a defendant to seek contribution from other tortfeasors varies by state.

17. Are there any defences available?

Many of the same defences available for strict liability claims (discussed above) are available for negligence claims. It varies by state and occasionally a defence may apply to a negligence claim but not to a strict liability claim (or vice versa). Additionally, most states have adopted the principles of comparative negligence. Some of these states apply pure comparative negligence, under which a claimant's damages will be reduced in proportion to his or her own degree of fault. In those states, even if the claimant is 99% responsible, he or she can still recover 1% of the damages. Other states apply a modified version of comparative negligence, under which a claimant will be barred from recovery if his or her own percentage of fault exceeds a specified threshold (e.g., 50%). A few states, however, still apply contributory negligence principles, under which the claimant is barred from recovery if he or she is determined to be even minimally responsible for his or her own injuries.

18. What is the relevant limitation period(s) for bringing a claim?

The limitation periods vary by state and by type of claim. Typically, negligence claims are subject to a 2- or 3-year statute of limitations, but in some states it can be as little as 1 year or as many as 6 years. Negligence claims generally accrue when the claimant discovers, or by the exercise of reasonable diligence should have discovered, the causal connection between the product (or the defendant's conduct) and the injuries suffered. The limitations period for misrepresentation claims also vary by state, but are typically between 2-6 years. Misrepresentation claims typically accrue when the deception is, or should have been, discovered. In some states, the statute of limitations for negligence or misrepresentation claims may be tolled for an inherently unknowable injury or when there has been fraudulent concealment of the claim.

19. To what extent can liability be excluded, if at all?

Many of the same exclusions that apply to strict liability claims (discussed above) also apply to negligence-based

product liability claims. Liability for misrepresentation claims typically can also be excluded if the claimant cannot demonstrate justifiable reliance, or, with negligent misrepresentation claims, if the defendant did not owe a duty to disclose.

20. Do the laws governing contractual liability provide for any implied terms that could impose liability where the product that is the subject of the contract is defective or does not comply with the terms of sale?

Contract-based product liability claims can be asserted for breach of express or implied warranty. Warranties are typically governed by the Uniform Commercial Code (or derivations thereof as adopted by a particular state). When a seller makes an affirmation of fact or promise to induce a buyer to purchase a product, which then becomes part of the basis of the bargain and on which the buyer relies, an express warranty is created that the goods conform to the affirmation or promise. Such a seller can be held liable for a breach of that express warranty causing injury to the claimant. There are also two types of implied warranties associated with the sale of goods: an implied warranty of merchantability and an implied warranty of fitness for a particular purpose. Under the implied warranty of merchantability, a defendant can be held liable if it sells a product that is not fit for the ordinary purposes for which such goods are used. The implied warranty of fitness for particular purpose, on the other hand, concerns the specific use for which the buyer requires the product, rather than the ordinary purpose for which it is used. A seller can be held liable under this theory if it has reason to know the particular purpose for which the product is required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods.

21. What remedies are available, and from whom?

Warranty claims are typically brought against manufacturers, wholesalers, or sellers for compensatory damages, although certain claims may be contractually limited to the repair or replacement of the nonconforming goods or parts.

22. What damages are available to consumers and businesses in the event of a contractual breach? Are punitive damages available?

Damages for breach of warranty may include the loss resulting from the seller's breach and/or the difference between the value of the accepted goods and the value they would have had if they had been as warranted. In some circumstances, incidental and consequential damages may be recoverable, including for injuries to person or property proximately resulting from the breach. Punitive damages are not typically available.

23. To what extent can liability be excluded, if at all?

Liability may be excluded to the extent certain defences (discussed below) apply. Additionally, a defendant cannot be held liable for breach of the implied warranty of merchantability if it is not a "merchant" (i.e., someone that regularly deals in goods of the kind involved or otherwise has a professional status with regard to the goods involved, such that it could be expected to have specialized knowledge or skill peculiar to those goods).

24. Are there any defences available?

Depending on the state and claim asserted, defences may include where the warranty has been disclaimed, failure to provide timely notice of breach, and/or lack of horizontal or vertical privity.

25. Please summarise the rules governing the disclosure of documents in product liability claims and outline the types of documents that are typically disclosed.

Document disclosure is governed by the Federal Rules of Civil Procedure in federal court, or by state procedural rules in state court. Parties generally may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defence. The court may limit certain discovery requests to the extent they are unduly burdensome or unreasonably cumulative/duplicative. The types of documents that may be obtained include writings, drawings, graphs, charts, photographs, sound or video recordings, images, and other data or data compilations.

26. How are product liability claims usually funded? Is third party litigation funding permitted in your jurisdiction and, if so, is it regulated?

Most defence attorneys charge an hourly rate. Some plaintiffs' attorneys also charge an hourly rate, but more

often they will work under a contingency fee arrangement. Under this type of arrangement, the attorney is paid a percentage of any financial recovery at the end of the case. If the claimant loses the case, the attorney receives no legal fees. There are also expenses that are incurred in any litigation. Many attorneys will advance the funds to pay these expenses with the understanding that these costs will be reimbursed out of any financial recovery received by the client. Third-party funding is permitted in some states and forbidden (or severely restricted) in others. A number of states have passed legislation regulating third-party funding.

27. Can a successful party recover its costs from a losing party? Can lawyers charge a percentage uplift on their costs?

The general rule is that each litigant must bear its own litigation expenses, and a successful litigant may only recover the actual, reasonable costs of the action from the opposing party if (i) a statute permits awards of costs, (ii) a valid contract or stipulation provides for costs, or (iii) rules concerning damages permit recovery of costs. Uplift fees are not typically used in the United States, since contingency fee agreements are so prevalent. Whether an uplift fee is permissible will likely depend on the particular state's law.

28. Can product liability claims be brought by way of a group or class action procedure? If so, please outline the mechanisms available and whether they provide for an 'opt-in' or 'opt-out' procedure. Which mechanism(s) is most commonly used for product liability claims?

The most common type of product-liability-related group action is multi-district litigation (MDL). In an MDL, multiple lawsuits filed by different parties in different courts involving one or more common issues of fact are consolidated for pre-trial proceedings, including discovery, before a single judge. MDL proceedings are commonly used when a defective product or line of products causes injury to a large number of consumers. Once pre-trial proceedings are finished, if there has been no global resolution of claims, the MDL court will remand the cases to the courts in which they were originally filed for trial. Cases that fall within the purview of the MDL, including those filed in other courts after the MDL is created, are typically transferred to the MDL court and will remain there until the case is either resolved or remanded. Class actions are another type of product-liability-related group action. In a class action, a single

lawsuit is filed by a large number of claimants who have suffered similar harm by the same defendant(s). There are a number of requirements that must be satisfied in order for a lawsuit to be certified as a class action, including, but not limited to, that the class is so numerous that joinder of all members is impracticable and there are questions of law or fact common to the class. Because class certification requires that the class members have suffered a common injury, most product-liability class actions involve claims in which the defect decreased the value of the product itself or when the claimants paid an inflated price for the product based on misrepresentations. Any claimant can opt-out of a class action. Finally, under the rules of civil procedure, a court may consolidate multiple product liability actions that present common issues of law or fact for pre-trial proceedings and/or trial. As consolidation occurs pursuant to court order, the parties may object but cannot unilaterally opt out.

29. Please provide details of any new significant product liability cases in your jurisdiction in the last 12 months.

In December 2024, the Ohio Supreme Court, in answering a certified question from the Sixth Circuit Court of Appeals, held that all Ohio common-law public nuisance claims arising from the sale of a product are abrogated by the Ohio Product Liability Act (OPLA). *In re Natl. Prescription Opiate Litig.*, No. 2023-1155, 2024 WL 5049302 (Ohio Dec. 10, 2024). In the underlying case, a jury found three chain pharmacies liable for creating a public nuisance in two Ohio counties through their unlawful dispensing of prescription opioids. After a bench trial on remedies, the district court awarded injunctive relief and equitable abatement. On appeal, the plaintiffs' judgment was reversed after the Ohio Supreme Court determined that their common-law public nuisance claims constituted "product liability claims" abrogated by OPLA regardless of the fact that the plaintiffs had neither alleged that prescription opioids were defective nor sought compensatory damages.

30. Are there any policy proposals and/or regulatory and legal developments that could impact the current product liability framework, particularly given the advancements in new technologies and increasing focus on the circular economy?

Last year, the United States Supreme Court eliminated a long-standing doctrine (the *Chevron* doctrine) which

required courts to defer to federal agencies' interpretations of ambiguous statutes that were within their regulatory authority. In its decision, the Court held that judges must instead use their own independent judgment in interpreting ambiguous statutes and considering administrative actions. This ruling will lead to more uncertainty in product-liability litigation, as product-related regulations and agency actions are more likely to be challenged and potentially interpreted inconsistently by different judges across the country.

31. What trends are likely to impact upon product

liability litigation in the future?

As artificial intelligence (AI) is incorporated into more products, complex issues will continue to arise with respect to product liability claims involving those products. Because AI systems evolve and adapt as they incorporate more data, it may be difficult to prove that a defect arose from the manufacturer's design or manufacturing process as opposed to a defect created by the AI's self-evolution. Similarly, it may be difficult to prove the manufacturer's knowledge of an AI-created defect that arose after the product left the manufacturer's control.

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