



Product Liability

in 33 jurisdictions worldwide

Contributing editors: Harvey L Kaplan,
Gregory L Fowler and Simon Castley

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United States

Gregory L Fowler and Marc E Shelley

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Civil litigation system

1 The court system

What is the structure of the civil court system?

The federal government and the individual 50 states maintain independent judiciaries. The federal judiciary is one of limited jurisdiction, while state courts are of general jurisdiction and may hear any matter.

Courts in the United States are based upon the English common law model. The sole exception is the Louisiana judiciary, which is based on the Civil Code. However, because there is no federal 'common law' except in cases such as admiralty law, federal courts primarily apply either federal statutes, or the common law or statutory law of the state where the federal court sits.

The federal court system

The federal courts consist of three levels: the district courts (trial courts); the circuit courts of appeal (first-level appellate courts); and the United States Supreme Court (the final federal appellate court). The district and circuit courts are organised geographically and every state has at least one district court or more, depending on the size of the state. There are also a number of specialty federal courts to hear cases under maritime, patent and bankruptcy law.

The federal district courts may exercise their limited jurisdiction over only two types of cases. Under 'federal question' jurisdiction, the district courts have original jurisdiction of all civil actions arising under the United States Constitution, laws or treaties of the US. Under 'diversity' jurisdiction, the district courts have original jurisdiction of all civil actions between states, where the parties are citizens of different states, one party is a citizen of a foreign state or one party is a foreign state.

The circuit courts of appeal will not retry cases, but instead apply a 'standard of review' based upon the district court record and briefs by the parties.

The US Supreme Court is the ultimate arbiter of federal law, including interpretation of the US Constitution. In practice, the Supreme Court only reviews a small percentage of the writs it receives. Only in rare exceptions will the Supreme Court maintain original jurisdiction (for example, actions involving ambassadors or controversies between the US and a state).

The state court system

Most state judiciaries are structured similarly to the federal judiciary, with three layers to each court system. First, there is a trial court, which may be of limited or general jurisdiction. There is usually a subcategory for municipal courts that generally hear smaller matters (for example, fewer than US\$10,000 in controversy).

Most states maintain an intermediate appellate court where an appeal is first heard. Parties almost always have the right to appeal the first final determination of their case. Like the federal circuit courts of appeal, the standard of review of the state appellate courts is limited.

Each state maintains its own 'supreme' court, which serves as the final arbiter of claims in that jurisdiction. These courts generally only review cases involving an issue as to which the courts of appeal have come to different conclusions or that present a novel issue of law.

The federal judiciary and the states' judiciaries all maintain their own rules of procedure, and often each judge within each district maintains his or her own particular practices. Due to the diversity of substantive and procedural law, the importance of the forum and venue cannot be underestimated.

2 Judges and juries

What is the role of the judge in civil proceedings and what is the role of the jury?

Federal judges are appointed by the president and confirmed by Congress. Some state judges are appointed by the state governments, while others are elected by popular vote. Unlike other court systems in which the judge may assume an investigational role, American judges oversee the adverse parties who shape the issues at trial. In a jury trial, the judge will conduct the proceedings, maintain order in the court, determine what legal standards to apply, determine the admissibility of evidence and instruct the jury on the law and how the law should be applied to the evidence at the close of trial. In a bench trial the judge also serves as the ultimate finder of fact.

The parties generally have a constitutional right to have their claims decided by a lay jury in civil cases. This right, which is waivable, applies only to legal claims, whereas equitable claims, such as those requesting injunctive relief, may be heard by a judge.

Jurors are picked to hear a particular case through a process called *voir dire* intended to eliminate those persons who are unable to be unbiased fact-finders and decision-makers. Most jurisdictions prescribe a jury of 12 individuals in criminal cases, and between six and 12 jurors in civil cases. The jurors are instructed by the judge on the law and are free to decide for either party on any of the issues presented. In civil cases, some jurisdictions require a unanimous jury verdict for certain issues, while others require only a simple majority, and still others fall somewhere in between. If the jury finds for the plaintiff, it may award damages that it finds appropriate, even if less than the amount the plaintiff demanded.

3 Pleadings and timing

What are the basic pleadings filed with the court to institute, prosecute and defend the product liability action and what is the sequence and timing for filing them?

Each state has its own particular rules of pleading, but there are two basic types of methods. Notice pleading, followed by the federal courts, is based on the premise that the pleadings need only provide basic notice of the issues, and relies on pre-trial discovery to further delineate the particular facts at issue. However, in two recent decisions, *Bell Atlantic Corp v Twombly* and *Ashcroft v Iqbal*, the

Supreme Court clarified that the statements in the complaint must contain enough information for the court to conclude that the claim is plausible. Fact pleading requires that the facts be pleaded with greater particularity and is generally the practice followed in state courts.

The complaint

The plaintiff files an initial pleading, usually called a complaint or a petition, that initiates the action and is intended to frame the issues. The complaint must generally contain a short and plain statement of the court's jurisdiction, the claim showing that the pleader is entitled to relief and the plaintiff's demand for judgment for the relief.

The answer

A defendant may either answer or move to dismiss a complaint. The answer may admit, deny or deny for lack of knowledge the allegations of the complaint. The answer must also set forth, or forever waive, any affirmative defences such as statute of limitations, fraud, estoppel, res judicata and others. Some states allow a general denial of the complaint, while others (including federal court) require specific denials of specific parts of the complaint. Averments in the complaint that are not denied are deemed admitted.

Motion to dismiss

The most common form of motion to dismiss in federal practice is a '12(b)(6) motion', in which a party seeks to dismiss a claim as a matter of law on the basis that, even if all facts averred in the complaint are true, no legal claim exists for which relief can be granted (for example, lack of subject matter jurisdiction, lack of personal jurisdiction, improper venue, improper service of process or failure to join an indispensable party).

Counterclaim and crossclaim

A defendant may also assert claims against the plaintiff by filing a counterclaim. Plaintiffs and defendants may also assert claims against each other by filing cross claims. Compulsory counterclaims (those arising out of the same transaction or occurrence that is the subject of the other party's claim) must be asserted in the same action or are forever waived. Conversely, permissive counterclaims are not waived if not asserted in the same action.

Joinder of additional parties

A party may also move to join an additional party if complete relief cannot be afforded without such joinder, the person to be joined claims an interest in the subject matter of the action and either that party's ability to protect those interests may be impaired, or that party may be subject to a substantial risk of multiple or inconsistent obligations.

Motion for summary judgment

A motion for summary judgment may be made by any party, usually some time before trial following discovery and the development of a factual record. Summary judgment shall be granted if the pleadings, discovery, affidavits and depositions demonstrate that there is no genuine issue as to any material fact, and that the moving party is entitled to judgment as a matter of law on all or some of the claim.

4 Pre-filing requirements

Are there any pre-filing requirements that must be satisfied before a formal law suit may be commenced by the product liability claimant?

No. While other causes of action (for example, employment claims and claims against the government) occasionally require preliminary administrative steps prior to filing a lawsuit, there is no pre-filing requirement that a plaintiff must meet before commencing a product liability lawsuit against a private company involved in the manufacture of an allegedly defective product.

However, from a practical standpoint, under the fact-pleading standard in federal courts following the decisions in *Twombly* and *Iqbal*, one could view the necessity of collecting all the facts needed to support the cause of action as a form of pre-filing requirement.

5 Summary dispositions

Are mechanisms available to the parties to seek resolution of a case before a full hearing on the merits?

Yes. US civil procedure provides for two opportunities to dismiss a case before it reaches trial (see motions to dismiss and for summary judgment described in response to question 3).

6 Trials

What is the basic trial structure?

A typical civil trial begins with opening statements by the attorneys for each party. The plaintiff's attorney will then put on plaintiff's case-in-chief, primarily by calling witnesses to the witness stand and conducting a 'direct examination' or by admitting other forms of documentary or tangible evidence. The defence counsel then has the right to cross-examine that witness. Plaintiff's counsel may re-examine the witness, sometimes followed by a recross. Once the plaintiff rests its case, the defence presents its case in the same fashion. After the defence rests, the plaintiff may present a rebuttal case. The parties then make a closing argument, the judge instructs the jury on the law and the jury deliberates and renders a verdict.

Trials are conducted on consecutive days and are usually public, subject to the judge's discretion to set the schedule and to bar the public from certain sensitive proceedings.

Role of judge and lawyer

There is no barrister or solicitor distinction in the United States. Attorneys play the predominant role at trial by examining witnesses, presenting evidence and arguing to the jury.

As stated in question 2, the proceedings are adversarial (rather than inquisitorial) and the role of the judge is to decide only questions of law in a jury trial, while in a bench trial the judge will also serve as the finder of fact.

7 Group actions

Are there class, group or other collective action mechanisms available to product liability claimants? Can such actions be brought by representative bodies?

Both federal and state laws provide for the prosecution of collective or 'class' actions in which one or more class representatives assert legal claims on behalf of a defined 'class' of individuals. While the requirements for certification vary, most are based on the federal model.

Rule 23(a) of the Federal Rules of Civil Procedure requires the party seeking class certification to prove the threshold requirements that: the class is so numerous that joinder of all members is impracticable; there are questions of law or fact common to the class; the claims or defences of the class representatives are typical of the other class members; and the class representatives will fairly and adequately protect the interests of the class. The party must also prove that the proposed class satisfies one or more bases for the different subsets of rule 23(b), such as an 'injunctive relief' class, a 'limited fund' class or other grounds. A class action brought pursuant to rule 23 typically requires class members to expressly opt out of the class in order to avoid being bound by the judgment. Finally, the court must be satisfied that any proposed class action settlements are fair, adequate and reasonable.

8 Timing

How long does it typically take a product liability action to get to the trial stage and what is the duration of a trial?

The length of time between filing a case and trial depends on several factors, including the complexity of the case and the need for discovery and pre-trial motion practice, the shape of the court's docket, the time needed to try the case and the nature of the case itself. It is not uncommon for two or three years (or more) to pass before a complex case reaches trial.

Filing to judgment

Once the case reaches trial, the length of trial is likewise a function of the complexity of the case, the pace of the presentation of the evidence and the court's schedule. Simple cases may take less than a week to try; complex cases may take several months. Jury deliberation will last as long as required to reach a verdict, or until it is hopelessly deadlocked, in which case a mistrial will be declared. After a verdict is reached and the court enters final judgment, the parties typically have 30 days to appeal.

Evidentiary issues and damages**9 Pre-trial discovery and disclosure**

What is the nature and extent of pre-trial preservation and disclosure of documents and other evidence? Are there any avenues for pre-trial discovery?

Federal and most state courts provide for liberal pre-trial discovery, not only through interrogatories and depositions, but through requests for the production of documents as well. The federal courts and many state courts require the parties to file or exchange 'initial disclosures' before trial to identify all individuals, documents and tangible things that may be relevant to the issues in the case.

The federal and state rules also generally provide for broad document discovery procedures through which a party may discover any non-privileged information reasonably calculated to lead to the discovery of relevant evidence. The responding party may either simply produce the information sought, object and produce the discovery, or object and refuse to produce the discovery. It may additionally seek a protective order from the court. Discovery disputes are generally resolved initially among the parties themselves, or later by a motion to compel. The court is generally empowered to punish discovery misconduct through sanctions up to and including entry of judgment against the offending party.

10 Evidence

How is evidence presented in the courtroom and how is the evidence cross-examined by the opposing party?

Both federal and state courts allow the admission of a wide variety of evidence, but each court has its own rules of evidence before evidence may be admitted. Generally, the proponent of the evidence must lay a foundation for the evidence to demonstrate that it is authentic and admissible.

Live witness testimony and depositions are the most common type of evidence. Witnesses may be either lay or fact witnesses or expert witnesses. Lay witnesses may testify only to personal knowledge. Expert witnesses may offer opinions in a case when helpful to the determination of fact and when the opinions are based on scientifically reliable principles.

Expert and lay witnesses are expected to testify in person rather than submit expert reports or depositions. Such out-of-court declarative statements are generally barred as inadmissible hearsay if offered to prove the truth of the matters asserted in the reports or depositions. A party's sworn responses to written discovery, however, may generally be admitted as evidence against that party. Depositions may also be used to impeach a witness, even if not admissible as substantive evidence.

The parties may also admit real or tangible evidence, such as the actual malfunctioning product, where it is first established that the evidence is authentic, or what the proponent claims it to be.

11 Expert evidence

May the court appoint experts? May the parties influence the appointment and may they present the evidence of experts they selected?

Typically, experts are called by one of the parties to testify, not the court. Courts may appoint expert witnesses in cases, although this is rarely done in practice. Experts may offer opinions when it will be helpful to the determination of a fact in issue and the witness's testimony is based on scientifically reliable principles. Generally, an expert witness must be qualified as an expert in a particular field in order to offer an expert opinion.

12 Compensatory damages

What types of compensatory damages are available to product liability claimants and what limitations apply?

In most jurisdictions, compensatory damages may include both pecuniary (economic loss such as out-of-pocket expenses, medical expenses, property damage) and non-pecuniary (intangible loss such as pain and suffering) damages, which are often capped due to the danger of unlimited verdicts.

13 Non-compensatory damages

Are punitive, exemplary, moral or other non-compensatory damages available to product liability claimants?

In most states, punitive or exemplary damages are recoverable when the defendant's injurious act is accompanied by aggravating conduct such as malice or gross negligence. The purpose of punitive damages is generally to punish and to deter. While the defendant's finances may often be considered to determine the quantum of punitive damages, many states have begun scrutinising, limiting and even banning these awards altogether due to the proliferation of high verdicts.

Litigation funding, fees and costs**14 Legal aid**

Is public funding such as legal aid available? If so, may potential defendants make submissions or otherwise contest the grant of such aid?

Every jurisdiction makes some provision for providing legal aid to indigent individuals. Contingency fees and punitive damages, however, have made legal aid unnecessary in most personal injury and product liability suits.

15 Third-party litigation funding

Is third-party litigation funding permissible?

While technically prohibited in most jurisdictions by common law, statute or public policy, the prohibition is usually enforced under usury laws governing the loan arrangement. Moreover, some states permit offensive uses of the prohibition to invalidate such agreements. A few states have begun permitting third-party funding for appeals, or only for non-personal injury claims, such as intellectual property.

16 Contingency fees

Are contingency or conditional fee arrangements permissible?

Contingency fees are allowed and typically governed only by the rules of professional conduct. Most contingency fees range between 25 per cent and 40 per cent of the judgment.

17 'Loser pays' rule

Can the successful party recover its legal fees and expenses from the unsuccessful party?

Under the American rule, each party pays their own legal fees regardless of who prevails. There are limited exceptions to this rule such as when a statute, most often a consumer protection statute, authorises the payment of attorneys' fees by the losing party, or when attorney conduct or equity demand it. Notwithstanding, the state of Texas, for example, adopted a tort reform measure in 2011 that grants judges the discretion to award costs and reasonable attorney's fees to the prevailing party in conjunction with a ruling on a motion to dismiss. The state of Tennessee adopted a similar measure in 2012 that awards up to US\$10,000 to a party if the court finds that the claim does not have a basis in fact or law.

Sources of law**18 Product liability statutes**

Is there a statute that governs product liability litigation?

There is no uniform product liability statute or common law in the United States. Each of the 50 states defines product liability law under its own standards, but typically product liability claims are brought under strict product liability theory, tort (negligence or fraud) theory or warranty theory.

19 Traditional theories of liability

What other theories of liability are available to product liability claimants?

Strict liability

Most states recognise some form of strict liability, which focuses solely on the product in issue and the key question of whether that product was defective, irrespective of whether the defendant's conduct was negligent or whether a contract was breached.

Generally, under the strict product liability theory, a manufacturer or seller is liable for any product in a defective condition that is unreasonably dangerous to the user or consumer, that causes personal injury, property damage and damage to the product itself if the seller (which includes the manufacturer) is engaged in the business of selling the product, and the product reaches the user or consumer without substantial change in the condition in which it is sold. There are essentially three types of defects: manufacturing defects, design defects and warning defects.

Negligence

Negligence, the most common tort theory, focuses upon the conduct of the manufacturer rather than the nature of the product itself. Negligence is described as the failure to use ordinary care, which is usually described as the care that a reasonable person would use under the same or similar circumstances. In a product liability claim, the duty will generally be expressed in terms of a duty to manufacture and market a reasonably safe product, and the alleged breach will be expressed in terms of a manufacturing, design or warning defect.

Fraud

Fraud is an 'intentional tort' that requires specific intent to deceive. The two primary varieties of fraud recognised are fraudulent misrepresentation and fraudulent concealment. In a product liability context, courts have generally held that a manufacturer has a duty to disclose non-obvious dangers of its products.

Conspiracy

Conspiracy is also an intentional tort requiring specific intent. It is a derivative tort that generally must be based on an agreement among two or more persons to commit another independent tort.

Contract

There are typically three varieties of contract breach in the product liability context that may be asserted simultaneously:

- breach of express warranty, where the product fails to conform to a promise made by the seller that served as part of the basis of the bargain;
- breach of implied warranty of fitness for a particular purpose, where a seller at the time of contracting knew of a particular purpose for which the goods are required; and
- breach of implied warranty of merchantability, where the product is not fit for the ordinary purpose for which the product is used.

20 Consumer legislation

Is there a consumer protection statute that provides remedies, imposes duties or otherwise affects product liability litigants?

Most states have some form of deceptive trade practices act or consumer protection statute. These statutes proscribe certain types of sales and marketing practices as unconscionable or deceptive. Some such statutes provide for enhanced penalties and presumptions in favour of the consumer.

21 Criminal law

Can criminal sanctions be imposed for the sale or distribution of defective products?

Despite unsuccessful efforts by Congress to adopt criminal penalties with regard to product safety, there is no general criminal liability unique to defective products. To be criminally liable under state law, a product manufacturer must have the required level of criminal intent for any other like crime. Otherwise, only the deliberate misrepresentations to federal regulatory bodies with regard to a product that results in death or serious injury may subject officers or agents to criminal sanctions.

22 Novel theories

Are any novel theories available or emerging for product liability claimants?

While many courts recognise the theory of medical monitoring, there is a split of opinion as to whether this theory is an independent cause of action or just a form of damages. Conceptually, medical monitoring is different from increased risk or fear of disease in which the compensation is for the incremental risk and the fear itself respectively. Instead, plaintiffs seek to recover the actual cost for the medical test, which has been previously recognised, but what makes medical monitoring controversial is the award in the absence of physical injury and its use in class actions.

23 Product defect

What breaches of duties or other theories can be used to establish product defect?

Within the United States, the various states determine product defect under one or a combination of two separate defect tests, known generally as the consumer expectations test, and the risk utility test. The consumer expectations test provides that a product is unreasonably dangerous if it is dangerous to an extent beyond that which would be contemplated by an ordinary consumer with knowledge of the product common to the community. The risk utility test attempts to balance the utility of the product against the risks of its particular design.

24 Defect standard and burden of proof

By what standards may a product be deemed defective and who bears the burden of proof? May that burden be shifted to the opposing party? What is the standard of proof?

Manufacturing defect

A manufacturing defect occurs when the product left the defendant's control, it deviated in some material way from the design specifications, formula or performance standards of the defendant, or from otherwise identical products manufactured under the same design specifications.

Design defect

A design defect occurs when something is wrong with the product even though it conforms to the design specifications of the product, or is in the condition intended by the manufacturer.

Warning defect

A warning defect involves a failure to warn or to adequately warn of a reasonably foreseeable danger of the product. Typically a warning defect arises where:

- inadequate warnings or instructions are given;
- the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable warnings or instruction by the manufacturer (or others); and
- the failure to provide such warnings or instructions rendered the product not reasonably safe.

25 Possible respondents

Who may be found liable for injuries and damages caused by defective products?

In theory, any entity in the stream of commerce (for example, the final manufacturer, the manufacturer of individual components in the product, sellers, distributors, importers) may be liable under a strict product liability claim for injury caused by a defective product. Under a negligence theory, only those respondents with a duty to the plaintiff will be potentially liable. This will usually include the manufacturer, but may additionally include the manufacturer of individual components. However, many states have sealed container or innocent seller statutes that insulate non-culpable retailers or middlemen importers from liability.

26 Causation

What is the standard by which causation between defect and injury or damages must be established? Who bears the burden and may it be shifted to the opposing party?

The plaintiff bears the burden of proving that the breach of duty in a tort claim, the breach of contract in a warranty claim or the product defect in a strict liability claim proximately caused the plaintiff's injury. This analysis typically involves two distinct concepts – cause in fact and policy concerns. The former is usually analysed under either the 'but for' causation standard or the substantial factor standard. The latter examines whether, even if the defendant's conduct factually caused the injury, it is too remote or indirect to warrant liability as a matter of public policy.

Some states provide inferences in favour of a plaintiff, such as a rebuttable presumption of defect where a product malfunctions. In some cases, when there is more than one defendant, and the plaintiff does not know which one is liable, the burden of proof may shift to the defendants to prove they are not the liable party or to show their relative percentage of liability.

27 Post-sale duties

What post-sale duties may be imposed on potentially responsible parties and how might liability be imposed upon their breach?

Generally a manufacturer has no per se common law duty to recall products. However, so-called voluntary recalls may be required as part of the manufacturer's post-sale duty to warn once a manufacturer discovers a serious or life-threatening hazard or a defect in a product. As the awareness of the frequency and gravity of the potential or actual harm increases, so too does the post-sale duty to warn, including the manufacturer's duty to recall the product.

Limitations and defences**28 Limitation periods**

What are the applicable limitation periods?

Many states' product liability statutes create specific periods of limitation. Under these statutes, the limit is usually set at two to three years after the date the cause of action accrues. Otherwise, the limitations period depends upon the cause of action at issue. For example, the period for personal injury actions is often two or three years from the date of accrual, while for contract actions it may be four years. Accrual has been defined generally as the date at which a plaintiff has the basic information it needs in order to sue. Under some state laws, the cause of action for personal injuries will accrue at the time of the injury, but most states apply a discovery rule to latent diseases or continuing torts. Under the discovery rule, the cause of action will not accrue until the plaintiff discovers or should have discovered the injury and the connection between the injury and the defendant.

Most states also impose either a general or product liability-specific statute of repose. Such statutes cut off claims after a certain number of years, generally running at between five and 10 years, from a specified event (usually the sale or delivery of the product). Certain statutes of repose will apply only to certain types of products, such as improvements to machinery. Statutes of repose typically trump statutes of limitation, and cut off a cause of action even if it accrues within the limitation period, regardless of when the cause of action is discovered.

29 State-of-the-art and development risk defence

Is it a defence to a product liability action that the product defect was not discoverable within the limitations of science and technology at the time of distribution? If so, who bears the burden and what is the standard of proof?

Evidence of a product's conformity with the state-of-the-art at the time of manufacture is typically not a bar to recovery under strict liability, but rather is evidence for the jury to decide whether a product was defective when it left the manufacturer. Likewise, under the negligence theory, the state-of-the-art is admissible to assess whether the manufacturer has met its duty of due care to make a reasonably safe product.

30 Compliance with standards or requirements

Is it a defence that the product complied with mandatory (or voluntary) standards or requirements with respect to the alleged defect?

In most jurisdictions, proof that a product complied with an applicable safety statute, administrative regulation or industry standard is at least admissible as some evidence of due care and in some states may create a rebuttable presumption of non-defectiveness. Only a minority of jurisdictions provide that such compliance is conclusive proof of the lack of defect or, conversely, preclude such evidence. Evidence of non-compliance with such standards is admissible in most states to prove defectiveness, although such evidence is not dispositive. Other states address this issue in the context of the state-of-the-art defence.

31 Other defences

What other defences may be available to a product liability defendant?

Comparative fault and comparative negligence

Some form of comparative fault or comparative negligence is a defence in most jurisdictions. This doctrine reduces the plaintiff's recovery based on the plaintiff's adjudged percentage of fault for its injury. Strict comparative fault reduces the plaintiff's amount of recovery by the percentage of the plaintiff's fault, and allows the plaintiff to recover some level of damages regardless of whether the plaintiff's level of fault exceeds that of the defendants. Modified comparative fault allows the plaintiff to recover damages where the plaintiff's percentage of fault is equal to or less than the defendants' percentage of fault (50 per cent or less). An alternative type of modified comparative fault only allows the plaintiff to recover damages if the plaintiff is less at fault than the defendants (less than 50 per cent).

Contributory negligence

A minority of states retain the defence of contributory negligence, which bars any recovery by the plaintiff where the plaintiff is at fault in any percentage for its injury. This defence has been largely abandoned, due to the fact that a plaintiff may be denied any recovery if even one per cent at fault.

Assumption of risk

Where recognised, assumption of the risk is a complete affirmative defence, which a defendant must plead and bear the burden of proof. Unlike contributory negligence, assumption of the risk involves a subjective standard that requires that the plaintiff actually knew the particular risks of the product and voluntarily assumed them. Many states have subsumed the concept of assumption of the risk within their comparative fault analysis, and no longer recognise it as a separate defence.

Open and obvious or commonly known risks

In the context of negligence claims, most states impose a duty to warn only for dangers that are not open and obvious. Where a danger is open and obvious, it is also difficult to prove that a defendant's failure to warn, whether in a strict liability context or a negligence context, was the cause of a plaintiff's injury. Where the particular danger is specifically known, the defence may rise to the level of assumption of the risk.

Product misuse

Unforeseeable misuse or abnormal use of a product by the consumer generally serves as a complete defence if the misuse was not reasonably foreseeable to the manufacturer at the time of sale or manufacture. Most states recognise misuse as an affirmative defence for which the defendant bears the burden of proof. However, a minority of states treat misuse as an element of comparative fault, rather than as a complete defence.

Learned intermediary

This defence applies to certain defined types of products such as prescription drugs or medical devices for which a 'learned intermediary' can be expected to provide warnings to the ultimate consumer. Therefore, the manufacturer or seller has a duty to warn only the learned intermediary, such as a physician.

Alteration

Most states provide that substantial alteration of a product is a complete defence to liability. A minority of states treat product alteration as a partial defence to be analysed in terms of comparative fault, and will reduce a plaintiff's recovery only to the extent to which the alteration resulted in a plaintiff's injuries.

Contract and warranty defences

Many states apply tort and strict liability-based defences to breach of warranty claims brought for personal injuries, viewing these claims as essentially strict liability claims. Several contract-based defences may apply against a breach of warranty claim. Where only economic damages are alleged, most states recognise a lack of privity as a defence.

32 Appeals

What appeals are available to the unsuccessful party in the trial court?

As stated in question 1, in both the federal and state systems, an unsuccessful party almost always has the right to appeal the first final determination of its case. The period for filing a claim after judgment is typically 30 days. The appeal is not a retrial, but a briefing of the claims of legal error, followed by oral argument before the appellate court. The appellate court assesses the arguments based on the applicable 'standard of review'. Depending on the court and issue, a further appeal may be granted by the state supreme court or the US Supreme Court. However, this review is often discretionary and permitted only if, over time, a split of opinion has developed among the appellate courts on the question of law.

A party need not always wait until the final judgment to seek review. In some instances, a party may seek appellate review through an interlocutory appeal or writ of mandate if a contested issue would conclusively determine the outcome of the case or if it would effectively be unreviewable if immediate appeal were not allowed. The best example in the product liability context is the interlocutory review of a decision certifying a class action.

Jurisdiction analysis**33 Status of product liability law and development**

Can you characterise the maturity of product liability law in terms of its legal development and utilisation to redress perceived wrongs?

Product liability law in the United States, which is largely a function of state law, is well-developed in most states, but is fluid and continues to adapt and respond to developing trends and theories. For example, abuses of the product liability laws in particular areas such as asbestos claims and pharmaceutical litigation have led to reform of procedural rules, like class actions, and other tort reforms in various states, like caps on damage awards. These measures have reduced the number of these types of product claims. However, countervailing measures continue to emerge to make new types of product claims available to consumers. In California, in addition to the imposition of public penalties, Proposition 65 has made it possible for private citizens to enforce a product manufacturer's failure to provide adequate warnings for products containing chemicals 'known to the state' to cause cancer or reproductive harm. These claims are often brought in conjunction with California's consumer protection statute, which also awards attorney's fees and injunctive relief, making their filing easier for consumers.

34 Product liability litigation milestones and trends

Have there been any recent noteworthy events or cases that have particularly shaped product liability law? Has there been any change in the frequency or nature of product liability cases launched in the past 12 months?

The evolution of United States product liability law is marked by several seminal events, and is the product of thousands of court decisions, statutes and scholarly articles. Product liability case law perhaps originates in a 1916 case, *MacPherson v Buick Motor Co*, in which negligence 'duty' concepts were first applied in a product manufacturing and design defect context. Then in 1963, California

Update and trends

Last year, in the case of *PLIVA Inc. v. Mensing* 131 S. Ct. 2567 (2011), the US Supreme Court effectively closed the door on failure-to-warn claims filed against generic drug manufacturers. Justice Clarence Thomas wrote the five to four opinion in which the court held that 'federal drug regulations applicable to generic drug manufacturers directly conflict with, and thus pre-empt [...] state-law claims' for failure to provide adequate warnings. Ms Mensing and Ms Demahy each brought claims against Pliva and Actavis, the manufacturers of the generic equivalents of the brand-name drug Reglan. They alleged that the manufacturers knew or should have known about the high risk of a severe neurologic disorder associated with the drug. The parties did not dispute that, if those allegations were true, state law required the manufacturers to use a different, safer label. However, the controversy before the court was whether that requirement conflicted with the generic drug manufacturers' duties under federal labelling requirements. The court concluded that it did and barred the plaintiffs' failure-to-warn claims.

As a result of the ruling, dozens of other cases have been similarly denied and attorneys general (AGs) from 36 states, Washington DC, American Samoa, Guam, the Northern Mariana Islands, and Puerto Rico have written to Senators Patrick Leahy (D-Vt) and Al Franken (D-Minn) in support of legislation that would overturn the Mensing ruling. Their bill (S. 2295), known as the Patient Safety and Generic Labeling Improvement Act, would allow manufacturers to correct their labels in the same manner as brand-name manufacturers. According to the AGs' 11 May 2012 letter, 'The preemption holding produces arbitrary and unfair results [...] Consumers whose prescriptions happen to be filled with the brand-name version of a drug are protected by state law from inadequate warnings, but consumers whose pharmacists fill their prescriptions with the generic version are now denied this protection.' At the time of writing, the bill had been referred to committee for further review.

adopted the first strict liability theory of recovery in *Greenman v. Yuba Power Prods Inc.* In 1965, the American Law Institute codified strict liability in section 402A of its Restatement (Second) of Torts, which has been adopted by the vast majority of states. The Restatement (Third) of Torts, released in 1998, reframes strict liability law in several respects, but has not been adopted yet by most states.

According to the Administrative Office of the US Courts, which releases an annual statistical report on the federal judiciary, the number of product liability claims commenced in US district courts in the year 2000 was 15,349. This number doubled by the year 2005, and doubled again by 2010 when the number of cases commenced reportedly reached 64,367. In 2011, the number decreased slightly to 60,798.

Importantly, this number reflects only the cases in federal courts, and excludes state courts.

It is possible that at least some of this increase observed in federal courts since 2005 is due to the 2005 Class Action Fairness Act by the US Congress. The Act's goal was to expand federal jurisdiction over many large class action lawsuits and mass actions that previously were heard by state courts, which over time were viewed as less capable of rendering fair decisions, often marked by large and arguably unjustified awards, particularly in product liability cases.

In recent years, US courts have more closely considered the concept of federal pre-emption, which is a fundamental part of the US Constitution, in the context of state law consumer protection actions. This case law, which has primarily involved pharmaceutical and medical device products (see 'Update and trends'), may play a key role in the defence of consumer product claims since, in August 2008,

the US Congress approved the Consumer Product Safety Improvement Act (CPSIA). Although the CPSIA requires the Consumer Product Safety Commission to impose stricter requirements on consumer goods, it explicitly pre-empts certain product claims. It is still too early to tell how this measure and the jurisprudence on pre-emption will expand or restrict product liability claims.

Finally, an important tool for defending product liability claims, in the form of a preliminary motion to dismiss, has been sharpened recently by the US Supreme Court decisions of *Twombly* and *Iqbal*, which impose a higher pleading requirement than previously existed in federal courts.

35 Climate for litigation

Please describe the level of 'consumerism' in your country and consumers' knowledge of, and propensity to use, product liability litigation to redress perceived wrongs?

The diversity of US product liability law, the availability of punitive damages, the potential for class actions and the prevalence of contingency fees make the United States fertile ground for product liability litigation. It is fair to say that the United States has become the epicentre of product liability litigation in nearly every category of products. The US plaintiffs' bar is well-financed, well-organised and experienced. The dominant plaintiff firms have adopted an entrepreneurial attitude towards litigation, particularly product liability litigation. While tort reform has been achieved in many jurisdictions to discourage what some consider to be predatory, duplicative and meritless lawsuits, it is not yet apparent that litigation by consumers has slowed.



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