

Chapter 21

UNITED STATES

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Introduction

Product liability was born in the United States in the early 1900s primarily with food contamination cases. There was a view with some judges that product manufacturers should be 'strictly liable' to consumers who use their products and suffer injury. Subsequently, courts decided that this theory of strict liability should expand to all types of products. This expansion, which finally culminated in the 1960s with the adoption of strict liability as an accepted theory of liability, served as the basis for an explosion of litigation in the United States and the adoption of strict liability in many countries around the world. This chapter will discuss the main theories of liability, the development of product safety regulations in the United States, a broad outline of the litigation system which has become so prominent in the United States and elsewhere, and a discussion of international treaties and agreements.

Theories of liability

Law within the United States comes mainly from two sources: common law created by the courts and legislative law created by the federal and State legislatures and government agencies.

Contract and warranty

Claims and lawsuits based on breach of contract and breach of warranty obviously involve a contract between two parties for the purchase of a product. Usually these claims are between the direct parties to the contract,

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especially the product seller, but these claims can also involve third parties, such as the manufacturer or even a user of the product. The *Uniform Commercial Code* (UCC), which governs the sale of most products in the US, allows additional theories based on breach of warranty, either express or implied. Even if a manufacturer and product seller do not provide an express warranty, the UCC provides for an ‘implied warranty of merchantability’ that can be the basis of a product liability action unless it has been disclaimed.

Express warranty

Warranties are created by operation of law under the UCC. Express warranties are created by the following:

- (1) Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain.
- (2) Any description of the goods which is made part of the basis of the bargain.
- (3) Any sample or model which is made part of the basis of the bargain.

The above law creates an express warranty that the goods shall conform to the fact or promise, description or sample or model. It is not necessary that the seller use formal words such as ‘warrant’ or ‘guarantee’ or that it have a specific intention to make a warranty. However, it is necessary that these statements occur at the time of or before the purchase is consummated. In other words, the purchaser will say that they relied on these statements, sample or model in deciding to purchase the product.

Creating an express warranty

An express warranty can also be created by any written or oral statement or even by the appearance of the product. These statements are included in the sales and marketing literature, catalogues, website, and all statements by sales people.

While terms and conditions usually attempt to limit any express warranty to ‘defects in workmanship and material’ or state that they only ‘conform to the specifications in the catalog’, the purchaser will seize on any inconsistent or expansive language to argue that additional express warranties were provided and that they relied on them to buy the product.

Implied warranty

The UCC also creates an implied warranty of merchantability and fitness for a particular purpose. These warranties are implied in every sale of a product that is subject to the UCC unless they have been disclaimed. Most terms and conditions disclaim these warranties, however, it is possible that the terms and conditions may not apply to the sale and these warranties will not be disclaimed.

Since these are implied warranties, the scope of their applicability is governed by the UCC. However, the definition of ‘fitness for a particular purpose’ has some relevance. The UCC section says:

Where the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods, there is ... an implied warranty that the goods shall be fit for such purpose.

Many statements in written material assist the purchaser in determining the type of product to buy. Therefore, even if this implied warranty is disclaimed, it is possible that there will be an express warranty created that the goods are fit for the purpose expressed in a company's written material. Some type of contractual claim, usually involving a breach of warranty, is many times part of a product liability lawsuit unless the purchase was made too long ago or some procedural requirements in the UCC have not been met.

In many situations, the damages that can be awarded under these theories are much larger than typical damages that can occur where an injury is involved. This is because damages could involve thousands of products that have been sold and a class action has been filed (see below) or it could involve a single incident resulting in significant property damage and significant consequential damages such as lost earnings.

Negligence

Negligence, which has been in existence for hundreds of years, is judged on three variables:

- (1) the probability that injury would result from the manufacturer's conduct;
- (2) the gravity of the harm that could be expected to result should injury occur; and
- (3) the burden of taking adequate precautions to avoid or minimize the injury.

In other words, if the probability of harm and the gravity of the harm are greater than the burden of taking precautions to reduce the risk, then the manufacturer is negligent if they do not minimize the risk. Another way to state it is that the manufacturer failed to exercise reasonable care in manufacturing its product and this failure was the proximate cause of the injury.

In negligence cases, the injured party has to prove there was a defect in the product that caused plaintiff's harm, that the product was defective when it left the hands of the manufacturer or product seller, and that the defect was brought about through the defendant's negligence.

Product users generally could not sue manufacturers in the 1800s and early 1900s because the law only allowed consumers to sue the party from whom they purchased the product. This usually was the retailer or dealer and not the manufacturer. The law developed in this way to insulate the manufacturer from liability so that they could feel free to develop products without the risk of legal liability.

The result is that injured consumers brought very few lawsuits, and they rarely recovered any money for their injuries. Courts recognized in the

early 1900s that it was very difficult for the plaintiff to prove the last requirement – which person caused the defect by being negligent.

As the manufacturing process became more complex and the courts began to believe that the current system was unfair, they started to make it easier for injured parties to prove negligence. First, the courts dropped the requirement that the injured party could only sue the immediate party to the contract. Next, the courts started to drop the requirement that the injured party had to prove who was negligent.

Courts began to allow juries to ‘infer’ that a product was negligently made if there was no other cause for it and the product was in the control of the manufacturer or seller until sale. In addition, the courts began to apply ‘strict liability’ to cases involving food and beverage where it was virtually impossible to prove how the foreign matter got into that food or beverage.

Strict liability

Finally, in the 1960s, strict liability was adopted for any product, not just food and beverages. What strict liability did was eliminate the third requirement of proof of negligence. No longer did the plaintiff have to prove negligence and who was responsible for it. All they had to prove was that there was a defect in the product at the time it left the manufacturer’s or seller’s control, that the defect made the product unreasonably dangerous, and that the defect caused the injury.

The California Supreme Court created this new theory of liability with the specific intent of making it easier for consumers and product users to recover against manufacturers and product sellers. They said:

The purpose of such liability is to insure that the costs of injuries resulting from defective products are borne by the manufacturers that put such products on the market rather than by the injured persons who are powerless to protect themselves.

The rationale for the adoption of strict liability was that manufacturers would be more likely to make safer products if they could more easily be held liable for injuries. And, if their insurance costs went up from this expanded liability, they could pass along these costs to the consumers through an increase in the price of their products.

Under strict liability, the manufacturer was liable even if their quality control and manufacturing procedures were reasonable and not negligent. In other words, even if they were very careful in manufacturing the product, but the product turned out to be defective and injured a consumer, they were liable.

The adoption of strict liability started an explosion of claims and lawsuits because consumers began to understand that they could more easily recover against manufacturers and, more importantly, they could find lawyers who were willing to take their cases and sue the manufacturer.

The basis of proving a defect in the 1960s was a test called ‘consumer expectations’. This meant that a manufacturer is liable ‘where the product

is, at the time it leaves the seller's hands, in a condition not contemplated by the ultimate consumer, which will be unreasonably dangerous to him'. This requires proof that 'The article sold must be dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics'.

This test allowed a consumer to say that the product was more dangerous than they expected and that this caused their injury. The result was that many cases were brought against manufacturers, and attorneys believed that proving their case would be fairly easy.

However, this test was criticized as being too vague and not providing much guidance to manufacturers or juries. So a new test was developed in the 1970s, referred to as a risk-utility test, that was adopted by many courts and, in 1998, was incorporated into the new *Restatement of Torts 3d: Product Liability* (Restatement), a leading source for the description of product liability law as it existed in 1998 and for the development of product liability law in the future.

Under the risk-utility test, there are various relatively clear factors that the jury can use to decide if the product is defective or not. These factors allow the jury to weigh the risks in the product against the ability of the manufacturer to reduce the risks. This test is viewed as making it harder for plaintiffs to recover because the manufacturer can defend itself by saying that it made the product as safe as necessary or as possible. So, even if the product was more dangerous than the plaintiff realized, the manufacturer might prevail.

The risk-utility test, which originally applied to strict liability, is really negligence since it allows a manufacturer's conduct or fault to be considered. As a result, in those States that have adopted risk-utility, there has arguably been a merging of the concepts of strict liability and negligence.

Today, the majority of States use the risk-utility test. The *Restatement* adopted risk-utility and rejected consumer expectations. However, there are some States which still use the consumer expectations test. In those States, they still talk about negligence and strict liability as separate theories of liability.

Pre-sale defects

Under negligence or strict liability, the question initially asked is whether there was a defect in the product when it left the manufacturer's control. So now let's describe the kinds of defects that the plaintiff usually alleges.

Manufacturing defect

A manufacturing defect exists if the product 'departs from its intended design even though all possible care was exercised in the preparation and marketing of the product.' In other words, even if the manufacturer's

quality control is the best in the world, the fact that the product departs from its intended design means that it has a manufacturing defect.

Under strict liability, the plaintiff need not prove that the manufacturer was negligent, just that the product was defective. The focus is on the product, not on the conduct of the manufacturer.

Common examples of manufacturing defects are products that are physically flawed, damaged, incorrectly assembled, or do not comply with the manufacturer's design specifications. In other words, the product turned out differently from that intended by the manufacturer. If that difference caused injury, the manufacturer will be liable. There are very few defences. For example, if only 1 per cent of the products had a manufacturing defect, the manufacturer would still be liable.

Defective design

As previously discussed, strict liability was first developed in the early 1900s in cases involving food contamination cases. These cases all dealt with manufacturing defects. A common example is foreign material in a box of cereal. This was an objective test. Much later, strict liability was expanded to include the design of the product.

The *Restatement* states that a product's design is defective if a reasonably foreseeable risk of harm posed by the product 'could have been reduced or avoided by the adoption of a reasonable alternative design' and the failure to use this alternative design makes the product not reasonably safe. As was said above, if the manufacturer could have made the product safer but did not, it sounds like negligence.

This test is much more subjective than the test for manufacturing defects and this subjectivity is the cause of many of the problems in product liability today. In determining whether there is a reasonable alternative design, the jury is allowed to consider various factors such as the effect of the alternative design on product longevity, maintenance, repair, cost and aesthetics. Given the subjectivity of this test and reliance on the jury to make the decision, the manufacturer has very little guidance in determining whether their product contains a design defect.

Warnings and instructions

The third main kind of defect involves inadequacies in warnings and instructions. The definition is similar to that of design defect and says that there is a defect if reasonably foreseeable risks of harm posed by the product 'could have been reduced or avoided by ... reasonable instructions or warnings' and this omission makes the product not reasonably safe.

Again, this is an extremely subjective test that uses negligence principles as a basis for the jury to decide. This makes it difficult for a manufacturer to know when to warn and how to warn.

There is an interrelationship between adequate design and adequate warnings. Some courts have held that a manufacturer must first try to design out the hazard before warning of the risk. This is because warnings

can be ignored, and therefore, are not as effective. The result is the jury can rule that while the warning may have been adequate, the plaintiff was still injured and the manufacturer could have and should have designed a safer product. There was a 'reasonable alternative design' and the manufacturer was liable for not adopting it.

The courts are pretty clear in stating that a manufacturer has a duty to warn where:

- (1) the product is dangerous;
- (2) the danger is or should be known by the manufacturer;
- (3) the danger is present when the product is used in the usual and expected manner; and
- (4) the danger is not obvious or well known to the user.

Difficult issues to analyse here are what is a usual and expected use of the product and what is an unforeseeable misuse of the product. Also, what is an obvious hazard and is it obvious to the reasonably foreseeable user?

Once the decision has been made to warn, the manufacturer needs to determine whether the content of the warning is adequate. Generally, the adequacy of a warning in a particular situation is a question of fact to be decided by the jury. However, various courts and commentators have described a list of requirements and goals of an adequate warning.

One court stated as follows:

If warning of the danger is given and this warning is of a character reasonably calculated to bring home to the reasonably prudent person the nature and extent of the danger, it is sufficient to shift the risk of harm from the manufacturer to the user. To be of such character the warning must embody two characteristics: first, it must be in such form that it could reasonably be expected to catch the attention of the reasonably prudent man in the circumstances of its use; secondly, the content of the warning must be of such a nature as to be comprehensible to the average user and to convey a fair indication of the nature and extent of the danger to the mind of a reasonably prudent person.

Other courts have said that an adequate warning will:

- alert the consumer or user to the severity of the hazard (severity being defined as the magnitude of the hazard and the likelihood of it being encountered);
- clearly state the nature of the hazard;
- clearly state the consequences of the hazard;
- provide instructions on how to avoid the hazard.

Case law treats the duty to warn and instruct separately. So, including adequate warnings in the instructions may not be enough to meet the duty to instruct. And, adequate instructions in the manual may not fulfil the duty to warn.

There are very few cases talking about the adequacy of instruction manuals as instructions and not warnings. And the case law is not particularly illuminating. The cases only say that manuals should be 'adequate, accurate, and effective', and 'clear, complete, and adequately communicated.'

Marketing defects

Another area of potential liability in the pre-sale area involves misrepresentation. If a manufacturer or product seller makes a material misrepresentation about some aspect of the product that turns out not to be true and is relied on by consumers or users to their detriment, it could be the basis of a product liability case. This can be based on negligence or strict liability.

Advertising and promotional literature provide the most significant source of product representations. It has been said that much of product liability reflects the inability of engineering to match the claims made for products by advertisers.

One of the more famous cases involved the Jeep. An accident occurred when a Jeep pitched over and killed and severely injured the passengers. The roll bar did not protect the passengers from the accident. The theory was that American Motors advertised the vehicle in such a way as to create a greater risk of forward pitch overs and that the passengers thought the roll bar would protect them in such an accident.

The advertising consisted of a campaign that stressed the Jeep's ability to drive up and down steep hills and to drive up steep mountains in what were called J-turns (the turn looks like a J and is done at high speed). The instruction manual also contained instructions on how to safely drive down a steep grade. On the design of the roll bar, American Motors admitted that the roll bar was only for side-roll incidents and not for pitch over. However, there was no evidence that the purchaser or passengers were aware of this limitation. The courts upheld a verdict for the plaintiffs against American Motors partly on a theory of misrepresentation in their advertising campaign.

More recently, plaintiffs' attorneys have even used misrepresentation as a basis for suing on behalf of all purchasers of a particular product in a class action. Some purchasers have been injured, but in some cases, the claim alleges that some defect made the product less valuable or unusable. Therefore, product liability can even involve claims that the product's resale value has been harmed.

Post-sale duties

One other theory of liability that is very important in a product liability case is negligent conduct by the manufacturer after sale of the product. A manufacturer may have a duty, after sale, to warn customers about hazards in the product that the manufacturer learns about after sale. This duty can arise even if the product was not defective or hazardous when sold. This

duty is clearly based on negligence and involves any of the three kinds of defects described above.

Not all State courts have accepted this post-sale duty. Despite that, since manufacturers must consider their post-sale duties on a national and even international basis, this summary, which comes from the *Restatement*, provides the best description available today and gives a manufacturer some principles on which to base a decision as to whether a duty arises.

The *Restatement* says that a product manufacturer or seller can be liable for failing to provide a warning after sale or distribution of a product if a reasonable person in the seller's position would have provided such a warning. Then, the section provides four requirements for a post-sale warning to be required:

- A seller knows or reasonably should know that the product poses a substantial risk of harm to persons or property.
- Those to whom a warning might be provided can be identified and can reasonably be assumed to be unaware of the risk of harm.
- A warning can be effectively communicated to and acted on by those to whom a warning might be provided.
- The risk of harm is sufficiently great to justify the burden of providing the warning.

These requirements make it clear that the post-sale duty is independent of an allegation that the product was defective when sold. Therefore, selling a defective product can result in a claim that the product was defective at the time-of-sale and a claim that the manufacturer failed to issue a post-sale warning.

In addition, the law makes it clear that if the product was defective when sold, the manufacturer cannot avoid liability for selling a defective product merely by issuing a post-sale warning. Therefore, a manufacturer may comply with its post-sale duties but still be held liable for selling a defective product.

This theory of liability is especially important since most punitive damages awarded are for a manufacturer's failure to react responsibly when it learns of post-sale safety problems.

Legislative and regulatory product safety requirements

US federal legislation and regulations

There are four main federal government agencies that deal with product safety and post-sale duties involving product withdrawals and recalls. They are the Consumer Product Safety Commission (CPSC), the National Highway Traffic and Safety Administration (NHTSA), the Food and Drug Administration (FDA) and the Department of Agriculture's Food Safety

and Inspection Service (FSIS). Below is a short description of the jurisdiction for these agencies and some of the functions of each agency.

Consumer Product Safety Commission

The first question to be answered is whether a product would be considered a consumer product under the *Consumer Product Safety Act* (CPSA) and related regulations such as the *Federal Hazardous Substances Act*. The CPSA defines consumer product as follows:

The term 'consumer product' means any article, or component part thereof, produced or distributed (i) for sale to a consumer for use in or around a permanent or temporary household or residence, a school, in recreation, or otherwise, or (ii) for the personal use, consumption or enjoyment of a consumer in or around a permanent or temporary household or residence, a school, in recreation, or otherwise.

Next, before sale of a consumer product in the United States, a manufacturer must identify any mandatory safety standards that have been enacted by the CPSC. There are many standards for products such as lawnmowers, all terrain vehicles, toys, children's products, infant furniture, and certain household products that contain hazardous chemicals. The manufacturer must comply with these requirements or they will have to recall their product.

Most of the activity by the CPSC involves requirements after sale. The CPSC requires manufacturers, importers, distributors and retailers to notify the Commission immediately if they obtain information that reasonably supports the conclusion that a product distributed in commerce:

- (1) fails to meet a consumer product safety standard or banning regulation;
- (2) contains a defect which could create a substantial product hazard to consumers;
- (3) creates an unreasonable risk of serious injury or death; or
- (4) fails to comply with a voluntary standard upon which the Commission has relied under the CPSA.

The most important basis for reporting to the Commission is number (2) above, which requires both a defect and the possibility of a substantial product hazard. The regulations accompanying the CPSA provide some guidance on how to analyse the need to report. The first question is whether there is a defect. Under this section, a product without a defect is not subject to the reporting requirements even if injuries occur. Many products are reasonably safe and not defective but people still get hurt.

To help a company decide whether its product has a defect, the Commission's regulations say:

At a minimum, defect includes the dictionary or commonly accepted meaning of the word. Thus, a defect is a fault, flaw, or irregularity that causes weakness, failure, or inadequacy in form or function. A defect, for example, may be the result of a manufacturing or production error; that is, the consumer

product as manufactured is not in the form intended by, or fails to perform in accordance with, its design. In addition, the design of and the materials used in a consumer product may also result in a defect.

A design defect may also be present if the risk of injury occurs as a result of the operation or use of the product or the failure of the product to operate as intended. A defect can also occur in a product's contents, construction, finish, packaging, warnings and/or instructions. With respect to instructions, a consumer product may contain a defect if the instructions for assembly or use could allow the product, otherwise safely designed and manufactured, to present a risk of injury.

The Commission distinguishes products that hurt people but are not defective by saying:

Not all products that present a risk of injury are defective. A kitchen knife is one such example. The blade has to be sharp to allow the consumer to cut or slice food. The knife's cutting ability is not a product defect, even though some consumers may cut themselves while using the knife.

The Commission encourages manufacturers to report even when in doubt about whether the product is defective. It says:

If the information available to a company does not reasonably support the conclusion that a defect exists, the firm need not report to the Commission under the defect reporting provision of Section 15(b)(2). However, since a product may be defective even when it is designed, manufactured, and marketed exactly as intended, a company in doubt as to whether a defect exists should still report.

The next question to be answered is whether this 'defect' could create a 'substantial product hazard.' The Commission starts this analysis by saying:

Generally, a product could create a substantial hazard when consumers are exposed to a significant number of units or if the possible injury is serious or is likely to occur. However, because a company ordinarily does not know the extent of public exposure or the likelihood or severity of potential injury when a product defect first comes to its attention, the company should report to the Commission even if it [sic] in doubt as to whether a substantial product hazard exists.

Then the regulations provide factors a manufacturer must consider in determining if there is a substantial product hazard: pattern of defect, number of defective products in commerce, severity of risk, and likelihood of injury. There is no exact rule on reporting. It is based on future risk of harm and the severity of that harm.

If a report is necessary, the CPSA requires companies to report immediately. The Commission defines this requirement as follows:

A company must report to the Commission within 24 hours of obtaining reportable information. The Commission encourages companies to report *potential* substantial product hazards even while their own investigations are continuing. However, if a company is uncertain whether information is

reportable, the firm may spend a reasonable time investigating the matter. That investigation should not exceed ten working days unless the firm can demonstrate that a longer time is reasonable in the circumstances.

In order to encourage manufacturers to report even when they are not sure if they are required to do so, the Commission has said:

Reporting a product to the Commission under section 15 does not automatically mean that the Commission will conclude that the product creates a substantial product hazard or that corrective action is necessary. The CPSC staff works with the reporting firm to determine if corrective action is appropriate. Many of the reports received require no corrective action because the staff concludes that the reported product defect does not create a substantial product hazard.

On 14 August 2008, a new law took effect modifying the CPSA. It is meant to strengthen the CPSC and give it new powers to force more recalls, make products safer, and allow it to penalize companies who don't comply. Below is a description of some of the important new provisions:

New limits on lead and phthalates – Congress lowered the acceptable limits on the amount and type of lead allowed in many products and banned certain kinds of phthalates in toys and child care articles. These limits and bans are still being interpreted and implemented. In 2010, manufacturers and importers will be required to have 3rd testing and certification to confirm compliance with these new requirements. Currently, while these requirements must still be complied with, the testing and certification requirements have been postponed until next year. Non-compliance with these requirements must be reported to the CPSC.

Civil and criminal penalties – civil penalties will rise to \$100,000 per violation with a cap of \$15 million. Congress provided a list of factors that the CPSC must consider in deciding whether to fine and how much to fine a company and required the CPSC to develop a regulation interpreting these factors. Criminal penalties also increased permitting imprisonment and forfeiture of assets. In addition, a corporation can be criminally liable even if the directors, officers and agents were not first informed by the CPSC that they were violating the law.

Searchable database – requires CPSC to establish a searchable database on the Internet that is accessible by consumers. Information will include reports on deaths and injuries caused by consumer products. It will include the name of the product and the manufacturer's name. The database has to be established by March 2011. There are protections built into the legislation that may protect materially incorrect information and trade secrets and manufacturers will be allowed to comment before the information is posted on the database. This is one of the most significant changes which could have an adverse effect on a company's reputation and on product liability litigation.

Given all of the above, manufacturers and others in the chain of production and distribution need to understand their legal obligations and make some critical decisions so they can deal with their statutory obligations and avoid being fined for violating these requirements.

And, since there is additional liability for injuries suffered as a result of an inadequate recall, this makes compliance with these requirements even more important.

Unfortunately, compliance with the CPSC's requirements is not a defence in a product liability case. So even if the response to your recall is very good and the CPSC agrees with the corrective actions, the plaintiff can still argue that the manufacturer could have done more to prevent plaintiff's injury.

National Highway Traffic Safety Administration

The National Highway Traffic Safety Administration (NHTSA) governs motor vehicles and motor vehicle equipment. Similar to the CPSC, it has mandatory safety standards that must be complied with before sale. However, much of the NHTSA's activities deal with post-sale reports and recalls.

The NHTSA must be contacted quickly after a manufacturer discovers a 'defect that affects motor vehicle safety.' Then, usually, the manufacturer recalls the product or undertakes some kind of field campaign.

Food and Drug Administration

The FDA has jurisdiction over most foods and all cosmetics, drugs, and medical devices. There are many safety standards and requirements for many products under the jurisdiction of the FDA. With some products, there is intensive scrutiny by the FDA prior to sale and with others, not as much. With some products, there is no scrutiny of the product's safety prior to sale.

As with the other agencies, much of the work of the FDA deals with post-sale issues. There are many different reporting responsibilities depending on whether the product is a drug, medical device, or some food or cosmetic. Here is how the FDA describes its recall policy:

The manufacturers or distributors of the product carry out most recalls of products regulated by FDA voluntarily. In some instances, a company discovers that one of its products is defective and recalls it entirely on its own. In others, FDA informs a company of findings that one of its products is defective and suggests or requests a recall. Usually, the company will comply.

Department of Agriculture, Food Safety Inspection Service

The United States Department of Agriculture's Food Safety and Inspection Service (FSIS) is responsible for meat and poultry that is in interstate commerce. Intrastate food safety is the responsibility of State and local food inspectors.

The FSIS's primary role is to closely monitor the effectiveness of the firm's recall procedures and to provide scientific and technical advice. FSIS has a standing Recall Committee that works with the company to coordinate the recall. It is chaired by the Recall Management Division and consists of scientists, technical experts, field inspection managers, enforcement personnel, and communications specialists.

Here is how FSIS describes a food recall:

A food recall is a voluntary action by a manufacturer or distributor to protect the public from products that may cause health problems or possible death. A recall is intended to remove food products from commerce when there is reason to believe the products may be adulterated or misbranded.

There have been many serious food safety problems over the last several years that have resulted in a number of deaths and injuries or illnesses. It is expected that the Congress will pass new legislation that will increase pre-sale food safety and post-sale food recall requirements.

State legislative reform

The federal government is primarily responsible for product safety for all products sold in the US. This is to prevent inconsistent safety standards from State to State which would have an adverse effect on the ability of manufacturers to sell their products in all 50 States. Therefore, generally, the federal government's safety requirements preempt any inconsistent State requirement.

Despite that, a number of individual States have adopted product safety laws that exceed the requirements of the federal government. In particular, many States have adopted restrictions on lead in children's products that exceed those of the CPSC. To deal with this legislation, the new CPSC legislation enacted in 2008 included a provision to preempt this inconsistent legislation because it would make it very difficult for a manufacturer to decide how to comply with different safety laws depending on where the product was sold.

Any manufacturer selling into the United States needs to identify any applicable federal and State law or regulation to be sure it complies.

Voluntary safety standards

Mandatory safety standards are enacted by the federal government. These come from the federal government or the government takes a voluntary standard and inserts the standard into their law, thereby making it mandatory.

However, the federal government lacks safety standards for many products. As a result, voluntary safety standards enacted by independent groups are important in producing a product that might be considered reasonably safe.

Groups like the American National Standards Institute (ANSI), American Society for Testing and Materials (ASTM), Canadian Standards Association (CSA), Underwriter's Laboratory (UL) and Society for Automotive Engineering (SAE) sponsor many standards. These standards are created by groups that have manufacturers and others as members.

Compliance with an applicable voluntary safety standard is necessary to show that the product met industry practices. However, as a legal

matter, compliance with a voluntary safety standard is not an absolute defence in a product liability case. The jury may consider the standard as a 'minimum' and conclude that the manufacturer should have exceeded the standard in order to produce a reasonably safe product.

As a result, a manufacturer must identify any applicable voluntary safety standard and determine whether meeting the standard is sufficient or whether they need to exceed the standard. At a minimum, they need to be aware of what all other manufacturers of this product are doing.

If many or all other manufacturers are exceeding the voluntary standard, then the manufacturer had better also do so. Not doing so can lead to liability, not for violating the standard, but for falling below the 'state of the art.'

Litigation system

In general

The United States is a constitution-based federal union of 50 States, one federal district, and five major and several smaller territories. There are both federal and State court systems. Each system has trial level courts and appellate courts. Federal judges are appointed to their judgeships for life by the President. These appointments must be ratified by the US Senate. State court judges are selected in a variety of ways. In many States, they are initially appointed to the bench for a period of years by the state's governor but must then stand for election in order to retain their positions. These are often contested partisan elections in which other candidates for the position are on the ballot. In some States, however, voters simply vote for or against retaining the judge in that position. In these systems, a judge who the voters decide not to retain is replaced by a newly-appointed judge.

Jurisdiction

Products liability cases may arise and be resolved in either the federal or a State court system. However, federal courts have limited jurisdiction. They may hear and decide only those cases that raise a question of federal law ('federal question jurisdiction'), or involve a dispute among plaintiffs and defendants who are citizens of different States and that involves a minimum amount in dispute of more than \$75,000 ('diversity jurisdiction'). In order for a case to come within a federal court's diversity jurisdiction, the diversity of citizenship must be complete. In multi-party lawsuits, this means that no plaintiff may be a citizen of the same State as any defendant or *vice versa*.

Most product liability lawsuits are begun in a State court. However, defendants sued in State court commonly remove the case to federal court and may do so as long as the federal court has jurisdiction to hear the case and the notice of removal is given within the time allowed by law.

Procedures in general

While there are differences in many of the procedures used in the federal and State courts, the general process employed in a typical products liability action is as follows:

Initiation and trial of a lawsuit

A lawsuit is typically initiated by the filing of a document most commonly called a 'complaint'. The complaint sets forth the basis of the plaintiff's claim against the defendant and normally includes a brief recitation of the facts alleged, one or more theories of liability, and a very general description of the relief requested. This document is formally filed with the court and a copy is delivered to or 'served on' the defendant. The defendant, within the time allowed by the court's rules, must then file some kind of response, typically called an 'answer'. An answer usually disputes the plaintiff's factual claims and, at least implicitly, the legal conclusions to be drawn from the facts. For example, the plaintiff's complaint may state that there is a feasible alternative safer way to design a product and that the defendant's failure to adopt that alternative design makes the product defective. The defendant might answer by denying that the plaintiff's proposed alternative design is not feasible and that, as a consequence, the defendant's product employs a sufficiently safe design. Because the parties dispute the feasibility of the alternative design proposed by the plaintiff, they will gather evidence on that issue for presentation at trial. The jury will ultimately resolve the factual controversy and decide whether there is, in fact, a safer feasible alternative design for the product.

Before the case comes up for trial, both parties undertake an extensive process of discovery (discussed in greater detail below) in order to gather information relevant to the issues in the case that is in the other party's knowledge or possession. Requests to the court, typically in the form of 'motions', are made to clarify the issues that are to be tried, the evidence that will be admissible at trial, and other matters.

When the case comes up for trial, prospective jurors are questioned by the judge, or in many courts, by the lawyers, to determine whether they are biased about the issues in the case or about one of the parties. Lawyers may 'strike' or eliminate any prospective jurors who have demonstrated a lack of impartiality ('challenge for cause'). A lawyer may also strike a very limited number of prospective jurors without giving any reason ('peremptory challenge'). Those who are selected make up the jury that will ultimately resolve the case. The size of juries varies depending upon the court but is usually between six and twelve.

Once the jury is selected, the judge will ask the plaintiff's lawyer to make an opening statement that is not an argument but describes in a summary fashion the evidence that the plaintiff will submit for consideration by the jury. The plaintiff begins because he or she has the burden of proving the claims set forth in the complaint. The defendant's lawyer then makes a similar opening statement.

The plaintiff's lawyer presents his case by calling his witnesses. By asking questions of the witnesses, the lawyer elicits answers that establish what the witness knows about the facts relevant to the case. During the questioning, the lawyer may also offer documents or other evidence to help the jury understand the story the lawyer is trying to tell. After each witness is questioned by the plaintiff's lawyer, she is then cross-examined by the defendant's lawyer. The defence lawyer's questions may put the information initially provided by the witness in a different light, elicit additional or inconsistent information, or may show that the witness was mistaken, lying or biased. The lawyer's examination of each witness, which lie at the heart of this adversarial process, should give the jury a basis for judging how much the witness really knows and how credible the witness might be.

When all of the plaintiff's witnesses have testified, the defendant's witnesses give testimony on her behalf. These witnesses, in response to the defence lawyer's questions, often give a different picture of the facts from that given by the plaintiff's witnesses. After each of the defence witnesses is examined by the defendant's lawyer, the plaintiff's lawyer cross-examines the witness.

After all of the witnesses have testified and the documents or other non-testimonial evidence have been submitted for the jury's consideration, the plaintiff's lawyer and then the defendant's lawyer make closing arguments to the jury. The plaintiff typically also may rebut the defendant's closing argument. These arguments are designed to emphasize the evidence that favours each lawyer's client and to persuade the jury to resolve the case in his favour.

After the jury has heard all of the evidence and arguments, the court instructs the jury regarding the relevant law. In some courts, the judge's instructions are given to the jury before closing arguments. The judge decides what instructions to give, but the lawyers for each side first suggest instructions that favour their positions and theories. The judge tells the jury to decide what the facts are and then to apply the legal rules given in the court's instructions. Thus instructed, the jury deliberates the case in secret and then delivers its verdict, concluding the trial phase of the case.

Once the jury has resolved the case in favour of one party or the other, a disappointed party may file certain post-trial motions. Two common post-trial motions are, first, a 'motion for judgment as a matter of law' (in federal court) or 'motion notwithstanding the verdict' (as it is called in many State courts). This motion asserts that the evidence does not legally justify the jury's verdict. The other common post-trial motion is a motion for a new trial. If a significant error occurred at trial – for example, the admission of evidence that should not have been admitted or incorrect instructions to the jury – there is a strong possibility that the error may have influenced the jury's decision. In such a case, the trial judge, recognizing the error, may grant a new trial. Once any post-trial motions are decided, the judge enters a judgment for the prevailing party.

Appeals

Finally, after the resolution of any post-trial motions and entry of judgment by the trial court, a dissatisfied party may appeal. The federal, and most state, court systems have both intermediate courts of appeal and a supreme court. An appeal is first made to the intermediate court of appeals that typically must hear and decide the appeal. A party who remains dissatisfied with the outcome of the case after the first appeal may then ask the Supreme Court to consider a second appeal. However, both federal and State supreme courts typically have considerable discretion in deciding which appeals to hear.

Consolidation and class actions

Where a defective product injures hundreds or thousands of individuals, the courts have recognized the judicial economy and the fairness to the parties of aggregating similar cases for the purpose of pretrial management, trial or settlement. In both State and federal courts, large numbers of product liability cases may be aggregated by assigning them to a single judge. In the federal courts, cases filed in different courts may be transferred for consolidated pre-trial treatment by one court under the Federal *Multidistrict Litigation Statute* (MDL). And both State and federal courts may certify cases as 'class actions' in which large numbers of people may have their claims litigated by representative parties.

Consolidation

Under the applicable procedural rules, both federal and State trial courts are vested with considerable managerial authority and discretion to consolidate actions involving common questions of law or fact. Consolidation of two or more cases may avoid unnecessary trials, prevent delay, reduce expense to the courts and parties, and eliminate the injustice which may follow from inconsistent results in separate actions. But the trial court must balance convenience and efficiency against the possibility of prejudice to one or more of the parties.

Multidistrict litigation

Related product liability actions pending in different federal trial courts may be consolidated for pretrial purposes under the Federal *Multidistrict Litigation Statute* (MDL). This statute gives the Judicial Panel on Multidistrict Litigation broad authority to transfer civil actions pending in one or more federal district courts and involving one or more common issues of fact to any federal court for consolidated treatment when the Panel finds that the transfer 'will be for the convenience of the parties and witnesses and will promote the just and efficient conduct of such actions'. This MDL process has the benefit of placing all related federal court actions before a single judge who can structure pretrial proceedings to consider all the parties' discovery needs while ensuring that discovery demands and

other pretrial matters do not duplicate activity that has already occurred or is occurring in other actions. The MDL court can also rule on other pretrial issues such as class certification, summary judgment and the admissibility of expert testimony.

Consolidation under the MDL statute is for pretrial purposes only. Once the pretrial proceedings are completed, the Panel sends each case back or 'remands' it to its original venue for further proceedings and trial. Although the MDL court has no jurisdiction to conduct a trial, the court may effectively resolve the litigation, either by ruling on motions that dispose of the case without trial or by entering a consent decree pursuant to the parties' settlement. As a practical matter, most MDL cases are settled rather than remanded for trial.

Class actions in general

The rules of procedure for both federal and State courts provide for certain claims to be treated as class actions. Almost all such actions arise in federal court. They are intended to conserve the resources of the court and the parties by permitting an issue that may affect many individuals to be litigated in a fair, speedy and relatively inexpensive fashion. A class action is especially appropriate when the complex nature of the litigation or the relatively small value of individual claims would otherwise deter litigation. In certain circumstances, a class action may be brought with respect to particular issues only or a class may be divided into subclasses and each subclass treated as a separate class to address choice of law issues, different types or degrees of injury or varying requests for relief.

Under the *Federal Rules of Civil Procedure*, a party moving for class certification must prove that:

- (1) the members of the class are so numerous that consolidation of all individual plaintiffs' cases is impracticable;
- (2) there are questions of law or fact common to the class;
- (3) the claims or defences of the representative parties are typical of the claims or defences of the class; and
- (4) the representative parties will fairly and adequately protect the interests of the class.

The rules also require that plaintiffs seeking to pursue a class action show either that:

- (1) the resolution of individual lawsuits would create a risk of inconsistent or varying results with respect to individual members of the class which would establish incompatible standards of conduct for the party opposing the class, or which would as a practical matter be dispositive of the interests of others who are not parties to the action or substantially impair their ability to protect their interests;

- (2) the party opposing the class has acted or refused to act on grounds generally applicable to the class thereby making appropriate injunctive or declaratory relief with respect to the class as a whole; or
- (3) that the questions of law or fact common to the members of the class predominate over any questions affecting only individual members and a class action is superior to other available methods for the fair and efficient adjudication of the controversy.

The requirement that the class representative's claims are 'typical' of all class members' claims presents the greatest difficulty for plaintiffs in mass product liability actions. Even if the claims arise from the same product and the same course of conduct, individual issues related to injury, causation and comparative fault are almost invariably present. The 'common questions of law or fact' requirement for class certification is also often difficult to satisfy due to the applicability of the varying law in the many different States in which the alleged injuries occurred and the often unique factual context of each injury.

If, for example, a car manufacturer produced large numbers of cars with a defect in the braking system that caused an unusual amount of noise when the brakes were applied, representative buyers of those cars seeking damages for the cost of repairs to eliminate the noise may be able to have their claim certified as a class action because their claims would be typical of all members of the class. If, however, the brake defect caused the car not to stop when the brakes were applied so that large numbers of accidents and injuries resulted, it is unlikely that all injury victims could be represented in a class action. The individual issues related to the nature and extent of their injuries and the drivers' own conduct that may have contributed to the accident would mean that many important issues of law and fact would differ from one plaintiff to another so that no claim is 'typical' and truly representative of all of the personal injury claims.

Therefore, for these and other reasons, and despite the benefits of class treatment, federal courts have remained reluctant to certify product liability class actions. Furthermore, in most class actions, individual class members are free to opt out of the class and bring their own individual lawsuits.

Class Action Fairness Act

In 2005, the US Congress enacted the *Class Action Fairness Act* (CAFA) to remedy perceived abuses of the class action process, including large awards of attorneys' fees at the expense of class members' recovery, coupon settlements of little or no value to class members, confusing notices preventing class members from understanding and exercising their rights, and State court judges ruling on issues of national importance. These abuses, Congress found, had harmed legitimate class members and responsible defendants, adversely affected interstate commerce and undermined public respect for the judicial system.

To address these concerns, CAFA expands federal courts' original jurisdiction over class actions, relaxes jurisdictional limitations on defendants' ability to remove large actions from State to federal court, constrains federal courts' authority to remand actions to State court, and more closely regulates class action settlements by, among other things, requiring notice to State and federal authorities and placing restrictions on so-called 'coupon' settlements. CAFA also defines a new category of cases called 'mass actions' (defined as any lawsuit in which the claims for monetary relief of one hundred or more plaintiffs are proposed to be tried jointly and each such claim satisfies the more than \$75,000 minimum amount in controversy requirement for federal court diversity jurisdiction) that are deemed to be class actions subject to CAFA's liberal standards that allow removal of such cases to federal court.

Discovery

Discovery in product liability cases, as in all civil actions, is tailored to the issues in the specific case and the facts relevant to proving or defending against the underlying claims and alleged damages. In the discovery phase of litigation, the plaintiff is generally interested primarily in discovering information relevant to the condition of the product and the conduct of the defendant. The defendant is generally interested in the plaintiff's conduct, the cause of the injury and plaintiff's claimed damages. Discovery typically proceeds in two distinct phases beginning with written discovery, during which the parties answer interrogatories and exchange documents, and followed by depositions of parties, witnesses and experts.

The discovery process is intended to be self-effectuating, without the parties needing to resort to the court, and its scope is quite broad. So long as the information sought is relevant to the claims or defences of any party involved in the pending action, it is discoverable unless it is protected by a legal privilege. Some privileges include communications between the client and her lawyers and the lawyer's work and opinions in preparing the case. The information sought need not be admissible as evidence at the trial if it appears reasonably calculated to lead to the discovery of admissible evidence. Any disputes among the parties as to the discoverability of certain information is resolved by the court which may also issue protective orders to prevent the disclosure of trade secrets or other confidential business information that is subject to discovery.

Plaintiffs in product liability actions typically seek to discover information not only about the product involved in the case, but also may attempt to discover information about related or similar product models or component parts. Such discovery is generally allowed if it involves predecessor or sufficiently similar products but attempts to discover information about product models that do not share sufficient similarities with the product at issue will be precluded.

Plaintiffs also typically seek to discover information related to other accidents, occurrences, complaints or lawsuits involving the product at

issue in order to use such evidence to prove that the product is defective, how the defect caused the injury, or the defendant's knowledge of a product-related risk. Such information is generally discoverable even if other incidents may not be substantially similar enough to be admissible at trial so long as it is reasonably likely to lead to the discovery of admissible evidence.

Information subject to the attorney-client privilege is not subject to discovery. An attorney has a professional ethical obligation to not reveal, without the client's consent, any communication made by the client to the attorney or the attorney's advice given thereon in the course of providing legal representation. When the purposes of the discovery rules and the attorney-client privilege conflict, the privilege almost always prevails. Its purpose is not to thwart the disclosure of otherwise discoverable facts, but to encourage clients to communicate openly and fully with their attorneys, without fear that such confidences will be divulged to others, thereby enabling their attorneys to act more effectively on their behalf. However, the privilege may not be used to shield communications regarding future or ongoing crime or fraud. If, for example, a client communicated to her lawyer her intent to provide false and misleading information about a product's safety to a regulatory agency, that communication would not be privileged.

The discovery of materials prepared for litigation by or at the direction of a lawyer is limited by the 'work product doctrine' which is codified in both the federal and many States' rules of procedure. The doctrine is designed to prevent unwarranted inquiries into the files and mental impressions of an attorney, recognizing that it is essential that a lawyer work with a certain degree of privacy, free from unnecessary intrusion by opposing parties and their counsel. Material may be exempted from discovery as work product if the party seeking protection from discovery makes three showings:

- (1) the material must be a document or tangible thing;
- (2) it must have been prepared in anticipation of litigation; and
- (3) it must have been prepared by or for the party or its representative.

There is no work product immunity for documents prepared in the regular course of business rather than for purposes of litigation.

Interrogatories

Interrogatories are written questions posed by one party to the other. They are useful in product liability actions to discover facts, learn the identity of witnesses and to require a party to explain its legal theories. Both the federal and State rules allow for interrogatories although the rules may vary. In federal courts, the number of interrogatories is limited to 25. State court rules also limit the number of interrogatories though that number may be greater than allowed under the federal court rules. A party may seek the court's permission to increase this number, a request often

honoured in complex product liability actions, especially when both parties so stipulate.

Requests for documents and other things

Both federal and State discovery rules allow a party, upon demand to another party, to inspect and copy any designated documents or to inspect, test or sample any tangible things which are in the possession or control of the other party. In a products liability case, such things may include the specific product that allegedly caused the plaintiff's injury, a sample of like products, as well as test data, design drawings, and records of product safety testing.

Electronic discovery

In the past, information was stored in conventional paper-based records and correspondence. Now, much important information relevant to product liability litigation is stored in electronic form, and it has become a routine part of the discovery process for parties to request this information (notably including e-mail) from one another. Electronic discovery (typically called e-discovery) simply refers to the process by which electronic data is sought, located, and searched with the intent of using it as evidence in litigation. The *Federal Rules of Civil Procedure* and several States' discovery rules now include provisions that relate specifically to e-discovery. These rules provide guidelines for limiting discovery of electronically-stored information that is not reasonably accessible because of undue burden or cost; address issues related to the format of the information that is produced; establish procedures for the return to the producing party of inadvertently-produced privileged documents; and protect a party from sanctions for failing to provide electronically stored information lost as a result of the routine, good-faith operation of an electronic information system. However, when litigation is reasonably anticipated, a party has a duty to preserve information stored in any form that may be relevant to the anticipated litigation. In the case of electronically-stored information, this means that a party must preserve such information by suspending any routine deletion or destruction of such information.

Physical and mental examinations, medical records

When a plaintiff in a product liability action claims a physical or mental injury, the defendant may ask the court to obtain the plaintiff's medical records, at least those records with information directly relating to the plaintiff's claimed injuries, and to order the plaintiff to undergo examination by a physician or mental health expert selected by the defendant. Good cause must be shown in order for the court to order such an examination but courts tend to construe this rule liberally. The examining physician or psychologist may review the plaintiff's medical records

obtained by the defendant and typically does so prior to examining the plaintiff himself.

A plaintiff may request from a defendant documents or information containing health or medical information that the defendant (for example, a drug or medical device manufacturer) has received from consumers. Courts may prevent such information from being discovered, especially if the information sought would invade the privacy of those consumers by including their names or other information that could lead to their identification.

Product inspection and testing

Product liability actions often give rise to a request to produce for inspection the product alleged to have caused the plaintiff's harm so that the plaintiff's lawyer and experts may examine, photograph and test the product. The plaintiff may also ask to inspect an accident scene or a defendant's manufacturing facilities. Such requests may be successfully resisted by the defendant if the proposed inspection or testing would destroy relevant evidence or cause annoyance, embarrassment, oppression or undue burden or expense.

Depositions

Depositions are live cross-examinations, under oath, of witnesses with some knowledge of the relevant issues in a case. Generally speaking, a party may depose any person so long as the information sought from that person is relevant to the litigation. Product liability actions tend to be deposition intensive. Depositions are routinely taken to establish facts relating to defect, causation and damages. Deponents will include the plaintiffs, the defendant manufacturer's key past and present employees and, depending on the type of case, may include product distributors and their employees, repair and service personnel, accident eye-witnesses, injury and damages witnesses (typically plaintiff's friends and family or care providers), other users and past owners of the product, landlords and property owners, the plaintiff's employer and co-workers, investigators and emergency response personnel, prescribing and treating physicians and other health care workers.

Evidentiary issues

As in any civil litigation, the plaintiff in a products liability case has the 'burden of proof'. He must prove each element of his case (negligence or defect, causation, damages) by a 'preponderance of the evidence' in order to succeed. Under this preponderance of the evidence standard, the jury must conclude that it is more probable than not that each of the plaintiff's allegations are true. If the jury thinks only that the plaintiff's claims might be true, the plaintiff will not prevail.

Product liability lawsuits often raise important evidentiary issues related to the plaintiff's burden of proving that the product that caused his

injury was defective, that it was manufactured or supplied by the defendant, and that the defect caused his harm. Some of these issues can arise before trial at the summary judgment stage where a plaintiff's failure to produce the evidence necessary to sustain a *prima facie* case may result in dismissal. Other key evidentiary issues, such as the admissibility of evidence relating to state of the art, subsequent remedial measures and other accidents and occurrences, arise at trial as the subject of requests submitted to the judge to limit or exclude certain evidence ('motions in limine'). The resolution of these evidentiary issues falls within the broad discretion of the trial judge and may have a dramatic impact on the outcome of the case.

The admission of expert testimony (discussed in more detail below) is another fundamental and ubiquitous evidentiary issue that arises in product liability actions.

Product identification

Identifying the manufacturer or seller of a product is a threshold requirement in any products liability action. The plaintiff must prove that the defendant, not someone else, manufactured or supplied the injury-causing product. Thus, if the plaintiff can show only that the defendant was one of two or more equally possible manufacturers, the plaintiff has failed to carry the burden of proving that it is more likely than not that it was the defendant that made the product. In some cases, however, the product is no longer available to be identified or, due to the nature of the product, the manufacturer cannot be readily determined. Sometimes a plaintiff may not know who manufactured the product, but only who sold it. If the seller cannot establish the identity of the manufacturer, the seller remains potentially liable in strict liability actions. A manufacturer's or supplier's liability often hinges, therefore, on the nature and sufficiency of the proffered evidence on product identification.

In a few States, where the plaintiff knows that the injury was caused by a certain product but cannot identify the specific manufacturer because the product is generic and there are no identifying labels, shapes, colours or other differences to distinguish one manufacturer's product (such as the prescription drug DES) from that of another, the plaintiff may attempt to recover from all defendants, in proportion to their relative sales in the market, under a 'market share' theory of liability. In other States, where the plaintiff can identify all of the product manufacturers but cannot prove which caused the harm, a court may shift the burden to the defendants under an 'alternative liability' theory to prove that they did not manufacture the product. In most States, however, attempts to apply these theories to product liability cases have not been successful, and the burden of product identification remains entirely on the plaintiff.

Evidence of subsequent remedial measures

A common issue in products liability cases is whether changes made by a product manufacturer to a product's design or to the warnings or

instructions accompanying the product are admissible to establish that the product design is defective or that the warnings or instructions are inadequate. The fact that a manufacturer has eliminated the very danger responsible for a plaintiff's injury is powerful evidence that the particular change was both practicable and reasonable at the time the change in the product was made. Such evidence would generally be relevant to liability and, therefore, presumptively admissible in a products liability case.

As a matter of policy, however, both federal and State rules of evidence generally bar the introduction of evidence of remedial measures taken after the event giving rise to the plaintiff's injury. The rule excluding such evidence is intended to encourage manufacturers to make products safer by acting promptly to correct perceived flaws without fear that the corrections will subsequently be used against them by plaintiffs. If manufacturers know that making safer products will expose them to liability for products already sold, they might hesitate to improve their products.

Evidence of other accidents and lawsuits

Evidence of other accidents or lawsuits may demonstrate that the product's defect is known to the defendant or may help show causation and is, therefore, generally admissible. Courts recognize, however, that admitting similar-incident evidence may confuse the jury, or result in more prejudicial effect than probative value. For example, a defendant may not only have to defend against the plaintiff's claims but also implicitly have to prove that the prior accident was not its fault. In order to ensure that the focus of the trial stays on the specific accident forming the basis of the plaintiff's case, the party seeking to introduce evidence of other accidents must, therefore, show that they occurred under 'substantially similar' circumstances and involved substantially similar products or components. Likewise, evidence of other accidents or incidents must be relevant to a genuine issue in the case, or its probative value may be outweighed by its prejudicial effect or tendency to mislead a jury.

Spoliation of evidence

'Spoliation' refers to the destruction of evidence or the failure to preserve evidence for another's use in pending or future litigation. Spoliation is a significant issue that can determine the outcome in product liability cases. The preservation of an allegedly defective product is very important in both proving and defending against product liability actions. When the allegedly defective product is lost, destroyed or fundamentally altered, a defendant may be deprived of the opportunity to confirm product identification, to disprove the existence of a manufacturing defect or, in a design defect case, to challenge causation based upon misuse or alteration of the product. To protect the defendant from prejudice, the court may exclude evidence relating to the missing product. And in some circumstances, that may result in dismissal of the plaintiff's cause of action.

To avoid a spoliation claim, a party must provide notice before altering or destroying any evidence that may be potentially relevant in litigation. Such notice is intended to provide the manufacturer an opportunity to prepare for negotiation and litigation and provide a safeguard against claims being asserted after it is too late for the manufacturer to investigate them.

Expert witnesses in general

Expert testimony is almost always a feature of products liability litigation. The rules of evidence provide that if scientific, technical, or other specialized knowledge will assist the jury to understand the evidence or to determine a fact in issue, a witness qualified as an 'expert' by knowledge, skill, experience, training, or education, may provide testimony in the form of an opinion or otherwise.

Products liability cases typically involve evaluation by and testimony from experts regarding every element of the plaintiff's case, including duty, defect, causation and damages. In many cases, expert testimony is essential to meet the burden of proof for a claim or defence. If a witness cannot be qualified as an expert to testify to these matters at trial, the plaintiff's case may be summarily dismissed. Even when expert testimony is not required for purposes of proof, it may be invaluable for purposes of persuasion because juries sometimes give more weight to an expert's testimony. As a practical matter, therefore, when one party intends to present expert opinion testimony on an issue, the opposing party will enlist an expert to testify to the contrary. Expert witnesses not only add persuasive strength to the case, but also can provide great assistance to attorneys during the litigation process.

Qualification and admissibility of expert testimony

Both federal and State courts have rules governing the admissibility of expert testimony. The standards for admissibility of such evidence, particularly scientific or technical evidence, may vary depending upon whether the case is brought in federal court or State court. These rules establish standards designed to ensure that only relevant, trustworthy, dependable and scientifically reliable expert testimony is admitted as evidence in the case. The function of the expert is to assist the fact-finder in reaching a correct conclusion from the facts in evidence. Such testimony is admissible, therefore, only if it is necessary to aid the members of the jury, having the knowledge and general experience common to every member of the community, in their consideration of the issues in the case.

An expert witness must be qualified by knowledge, skill, experience, training or education. She must possess some practical knowledge or experience in the area of her testimony. Mere theoretical expertise is insufficient to qualify one as an expert. This knowledge requirement may be satisfied by either formal education or sufficient occupational experience.

The expert's opinion must also be reliable, meaning that it is based on facts in evidence that are sufficient to form an adequate foundation for an opinion.

Damages

Products liability law seeks to compensate those injured by defective products and to encourage manufacturers and sellers to make and market safe products. To that end, a products liability plaintiff may recover the full amount of compensatory damages required to make him whole to the extent that he would have been had no injury occurred. Compensatory damages arising from personal injury caused by a defective product are governed by the same damages principles applicable to all tort actions. The plaintiff is entitled to recover damages for past and future bodily and mental harm, such as pain, suffering, disability and emotional distress, as well as damages for pecuniary loss, such as medical and rehabilitation expenses and lost wages. The plaintiff's spouse may also seek an award of damages for loss of consortium. A spouse's consortium interest includes not only tangible services the other spouse provides, such as household chores and childcare duties, but also intangible elements inherent in the marital relationship, such as comfort, companionship and sexual relationship. Damages are typically allocated into past and future components for each category of damages claimed so that statutory provisions governing prejudgment interest and reductions for payments from others ('collateral sources') may be applied.

If the plaintiff claims that the defective product aggravated or exacerbated a pre-existing injury or medical condition, then he may recover only the additional injury caused by the aggravation over and above the consequences which the pre-existing disease or injury, running its normal course, would itself have caused if there had been no aggravation. The plaintiff has the burden of proving the extent of aggravation and resulting damages. If he is unable to separate damages caused by the pre-existing disability or medical condition from those caused by the accident, then he cannot recover these damages.

In addition to the jury's determination of compensatory damages, the plaintiff may be entitled to recover prejudgment interest on some kinds of past damages. Although both parties to litigation typically pay their own fees and costs, under certain limited circumstances (for example, where litigation was initiated frivolously or in bad faith) a party also may recover her own costs and attorney's fees from the other party. However, if the defendant has proved that the plaintiff bore some fault for his own injury, then total recoverable damages may be reduced by the plaintiff's comparative fault. In some States, collateral sources of compensation, such as insurance or workers' compensation payments, also may be deducted from the plaintiff's award pursuant to a statute.

While these general tort damages concepts apply to personal injury and property loss, damages due to the loss or diminished value of the

defective product itself, called 'economic loss', may not be recovered as part of a tort-based damages award. Instead, under the economic loss rule, such damages may only be pursued in most States through breach of warranty or contract theories.

Damages for emotional or mental harm

In cases where the plaintiff is physically injured by a defective product, the plaintiff may be entitled to recover for past and future emotional distress suffered as a result of that injury. Because the plaintiff's emotional damage is so closely related to a physical injury, its existence is relatively certain and the requirement of proximate cause is usually easily satisfied.

But in the absence of direct physical injury to the plaintiff, courts historically have expressed concern about the reliability of 'pure' emotional distress claims. For that reason, a plaintiff who is not physically injured may recover damages for negligently inflicted emotional distress only if she satisfies certain criteria.

Some States use a 'zone of danger' test, requiring that the plaintiff was within the zone of danger of physical injury created by the defect in the defendant's product, reasonably feared for her own safety, and suffered severe emotional upset with attendant physical manifestations, in order to recover damages for the emotional harm. The 'zone of danger' and 'physical manifestation' requirements provide objective evidence that the emotional distress claim is valid. For the same reason, a bystander who is within the zone of danger may be able to recover damages for distress caused not only by fearing for her own safety, but also for witnessing serious bodily injury to someone with whom she has a close, typically an immediate family, relationship. Many States use a more liberal rule, requiring only that the bystander-plaintiff be a contemporaneous witness to another's injury, closely related, and suffer severe distress, in order to recover.

Damages for fear of future harm, increased risk, and medical monitoring

Though such claims are relatively rare, some States recognize claims, and will award damages, for:

- (1) a plaintiff's emotional distress and anxiety caused by the uncertainty and fear of possibly developing a disease, often cancer, at some time in the future;
- (2) for the increased risk of certain health consequences not yet manifested; or
- (3) for the expense of ongoing medical monitoring related to those potential consequences.

Plaintiffs exposed to a toxic substance or some other disease-causing agent often assert 'fear of future harm' claims. In some States, the viability of this

claim depends on whether the plaintiff can demonstrate a present injury (even a very insignificant injury) that may worsen with time or evolve into some kind of disease. At least one State does not require that the plaintiff has suffered a present injury but allows for recovery for the fear of future harm if the plaintiff can prove that the future injury is more likely than not to occur. Some States that have considered such claims have refused to recognize fear of future harm as a harm for which damages can be awarded. And many States have statutory limits on the amount of damages that may be awarded for emotional distress or pain and suffering that would govern 'fear of' claims.

Unlike injuries in traditional products liability cases, the harmful health consequences of exposure to certain toxic chemicals or drugs may develop over long periods of time, often through repeated exposure. Sometimes a long latency period precedes the determination that harm has actually occurred. Other times the plaintiff is asymptomatic or the injury is in an early stage, and its future course, while potentially serious, is only speculative. To address these uncertainties, some courts have recognized claims for 'increased risk' of certain health consequences. The general rule in the States that recognize such claims is that the plaintiff may recover for increased risk only if she can prove that the future injury is more likely than not to occur. And in some of those States, a plaintiff must also prove that she suffers a present physical injury that causes an increased risk of physical harm in the future, even if no serious adverse health consequences have yet emerged, in order to recover increased-risk damages.

Claims for 'medical monitoring' typically seek to recover damages for the costs of future medical testing and surveillance to determine whether a plaintiff has developed a medical condition or side effect for which the manufacturer's allegedly defective product has put the plaintiff at risk. Approximately ten courts have considered the matter thus far and all recognize a claim for medical monitoring costs under certain conditions. Generally, the plaintiff must prove that:

- (1) the defendant's negligent conduct has increased the risk of a serious future injury or disease;
- (2) for which a medical test for early detection exists and for which early detection is beneficial, meaning that a treatment exists which can alter the course of illness; and
- (3) a qualified physician would prescribe such testing and monitoring for a person in the same circumstances as the plaintiff.

Medical monitoring claims are distinct from claims for fear of future harm and increased risk claims and considerably less speculative. The injury in a medical monitoring claim is the cost of the medical care that will, it is presumed, detect that injury and lead to earlier and more effective treatment. The other two claims are inherently speculative because courts and juries are forced to predict the probability of a future injury. The claim for medical monitoring costs is much less speculative because the issue for the

jury is the less conjectural question of whether the plaintiff needs medical surveillance and how much that service will cost.

Because medical monitoring claims are typically smaller value claims, they are potentially amenable to class treatment or other consolidation. In that context, medical monitoring claims often seek equitable relief, such as a court-administered fund that may cover not only the costs of medical evaluations for plaintiffs, but also the expense of compiling and analysing data to advance the understanding and treatment of the particular disease or condition. Medical monitoring trust funds also serve to ensure that medical surveillance damages will be paid only to compensate for medical examinations and tests actually administered, and will encourage plaintiffs to safeguard their health by not allowing them the option of spending the money for other purposes.

Punitive damages

Punitive damages also may be recoverable in product liability actions. Punitive or 'exemplary' damages may be awarded in some cases in addition to compensatory damages for personal injury or property damage or loss. Punitive damages are said to serve a state's legitimate interest in punishing unlawful conduct and deterring its repetition. Of course, compensatory damages also serve a deterrent function by making the defendant who has engaged in tortious conduct bear the cost of the plaintiff's harm. However, the primary focus of compensatory damages is compensation to the plaintiff. Where it is appropriate to make an example of and to punish a defendant and to provide an extraordinary measure of deterrence, punitive damages serve those purposes.

Because they perform some of the same functions as criminal sanctions, punitive damages claims are subject to more stringent standards of proof, often in a separate proceeding, and are typically subject to more careful review upon appeal. The United States Supreme Court has recently developed significant limitations on punitive damages and the process by which they are imposed, concluding that punitive awards that are 'grossly excessive' violate the due process clause of the Fourteenth Amendment to the US Constitution.

The requirements for recovery of punitive damages vary somewhat among the States. Often, the plaintiff must demonstrate that the defendant acted recklessly or deliberately and may have to prove this by 'clear and convincing evidence' or some similar requirement that imposes on the plaintiff a greater burden of proof than does the usual preponderance of the evidence standard. Punitive damages awards are subject to statutory maximum limits in several States. And because punitive damages are intended to punish a defendant and not to compensate the plaintiff who has already been compensated, a few States award only a portion of any punitive damages to the plaintiff with the remainder going into some kind of public fund.

Defences

A product manufacturer's primary defences to products liability claims are claims that the plaintiff's own negligence either contributed to, or entirely caused, the harm ('contributory negligence') or that the plaintiff's behaviour demonstrates an intent on the part of the plaintiff to assume the risk of the injury that has resulted ('assumption of the risk'). These are called 'affirmative defences' which must be raised, and proved by a preponderance of the evidence, by the defendant. Statutes of limitation, limiting the time during which a plaintiff may bring a lawsuit may also provide a manufacturer with an effective defence. And any state-law-based claims that conflict with an important federal interest may be pre-empted by federal law.

Comparative fault

Virtually all States now have some kind of comparative negligence (most commonly called 'comparative fault') rules, allowing a defendant-manufacturer to compare her fault to the fault, if any, of the plaintiff. Under these rules, typically found in a statute, the damages award is reduced, at a minimum, by an amount reflecting the plaintiff's percentage share of total fault for the injury. There are two basic variations of comparative fault rules. In States using 'modified' comparative fault rules, the plaintiff's damage award will be reduced according to his share of fault, but if the plaintiff's fault is greater than (or in some States equal to) the defendant's fault, then the plaintiff recovers nothing. In 'pure' comparative fault States, the plaintiff's damages are reduced according to his share of the total fault so that a plaintiff may recover even if he is, for example, 95 per cent at fault for his own injury. In such a case, he would still recover five per cent of his total damages.

In many States, assumption of the risk may be a complete defence to a product manufacturer's liability. If the defendant can show that the plaintiff knew both the nature and extent of a product-related risk and acted in a manner demonstrating voluntary agreement to take that risk, then the plaintiff cannot recover for his injury.

Statutes of limitations

All States have statutes that limit the time during which a plaintiff may bring a claim for injury. The time periods established by these statutes vary widely depending upon the theory of liability and also vary from State to state. Warranty and other contract-based claims, for example, must typically be brought within four years of the alleged breach. Negligence and strict liability claims are subject to limitation periods that vary from one to as many as six years. Under a given state's law, the limitation period for negligence claims may be different than the period applicable to strict liability claims.

In most States, personal injury, and sometimes other, claims are subject to a 'discovery rule'. Under this rule, the limitation period does not begin until the plaintiff knows or has discovered both a physical manifestation of an injury and evidence of a causal connection between the injury and the defendant's product.

Pre-emption

Product manufacturers quite naturally tend to expect that compliance with federal safety laws and regulations will serve as an effective defence to product liability claims. Typically, however, compliance with federal law does not necessarily immunize a manufacturer from liability but only serves as evidence of the manufacturer's exercise of due care. However, for products that are subject to extensive and detailed federal health and safety regulation – including prescription drugs and medical devices, tobacco products, motor vehicles, pesticides and other hazardous substances – compliance with federal regulations governing the design, manufacture, labelling and marketing of these products may effectively preclude certain product liability claims. Under the pre-emption doctrine, a manufacturer's compliance with federal laws and regulations may offer a complete defence to at least some claims based on State statutes or common law. In recent years, the United States Supreme Court has created a complex body of law concerning pre-emption.

The federal pre-emption doctrine is founded upon the Supremacy Clause of the United States Constitution, which provides that the laws of the United States 'shall be the Supreme Law of the Land; ... anything in the Constitution or laws of any State to the contrary notwithstanding'. Thus, State law that conflicts with federal law is without effect. For pre-emption purposes, 'state law' includes not only statutes and regulations, but also common law. State regulation of product safety can be as effectively exerted through an award of damages as through some form of preventive relief. The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy.

State law causes of action must give way when such claims encroach on an objective that Congress has addressed either directly or indirectly through federal statutes or administrative regulations. Federal law may preempt State law either expressly or impliedly. Thus, where pre-emption is an issue, the central inquiry is Congress's intent. Because States are independent sovereigns in the federal system, courts begin a pre-emption analysis with the presumption that Congress did not intend to displace State law. The courts are careful to avoid an unintended encroachment on the authority of the States and tend to be particularly reluctant to find pre-emption when the subject is one traditionally governed by State law – subjects such as public health and safety. Therefore, unless Congress has either expressly or impliedly made its intent to preempt State law clear, the courts should assume that a federal statute does not supplant State law.

International treaties and agreements

Consumer protection

The United States has a multitude of agreements with foreign countries that affect foreign product manufacturers who import their products into the US. Most of these agreements involve the US Consumer Product Safety Commission (CPSC) and its foreign counterparts. More than a third of all consumer products that are subject to the jurisdiction of the CPSC are imported. Therefore, the CPSC attempts to coordinate its efforts and those of foreign consumer safety agencies with respect to consumer product safety standards development, harmonization efforts, inspection and enforcement coordination, consumer education, and information dissemination.

Service of process outside the United States

A US lawyer wishing to sue in a US court a person or entity located in a foreign country must initially determine which methods of service of process the other country will permit or what procedures are most likely to encourage its cooperation in obtaining personal jurisdiction over the foreign person or entity. Whatever process is employed must also be reasonably calculated to give actual notice to the person to be served so as to satisfy the due process requirements of the US Constitution.

If a prospective defendant has committed some act within the United States that makes it subject to process under either the federal or a state's statute providing for extraterritorial service ('long-arm statute') or if the foreign defendant has entered into a contract consenting to jurisdiction in the United States or has property within the United States, it is quite likely that a US court will have personal jurisdiction over the foreign defendant or its property. If the foreign entity has insufficient contacts in the United States to trigger a US court's ordinary extraterritorial jurisdiction provisions, the United States may have a treaty with the country in which service is to be made that deals with international judicial cooperation. These treaties typically prescribe the method for the service of judicial documents in each of the signatory nations.

For example, the United States is a signatory to the *Hague Convention on the Service Abroad of Judicial and Extrajudicial Documents*. The Convention provides that each signatory nation designate a central authority to oversee compliance with the Convention. That designee is charged with a number of responsibilities, including utilizing the method prescribed by the internal laws of the foreign state for service of process, obtaining a translation of the documents into the official language of the state if translation is required by that state's laws, and providing verification that the person to be served received actual notice of the action or was served by a method prescribed by the laws of the foreign state in which service was made before a default judgment may be entered.

Discovery

Most non-US legal systems do not provide for the sort of pretrial discovery by which litigants in US courts can obtain documents and information about their case and by which they can require their opponent's witnesses to answer detailed questions about the case prior to trial. Thus, a problem arises when a party is involved in a lawsuit in the United States but wants to obtain documents or take depositions in a foreign country. Similar problems arise when one is involved in litigation in a foreign country. In such situations, discovery can be limited or, at a minimum, cumbersome and time-consuming.

If a foreign party or witness domiciled abroad has significant contacts with a State in the United States, that person or entity may be subject to the jurisdiction of the courts of that State so that subpoenas and other procedural devices can be used to effectuate discovery requests. If the foreign company is a parent, subsidiary, or affiliate of a US company, it also may be possible to obtain discovery against the foreign entity if the information requested is deemed under the control of the US company. If the foreign entity is not subject to jurisdiction in a United States court, obtaining discovery will generally depend upon compliance with local laws.

The United Nations *Convention on the Taking of Evidence Abroad in Civil or Commercial Matters* (1972 Hague Convention) may be used when parties reside in signatory countries, but several signatory nations have laws that essentially bar the use of US-style discovery. Unless a country is bound by treaty to submit its citizens to discovery requests from US courts, it may be possible to conduct discovery against foreign citizens or businesses in those countries only if the entities voluntarily submit to the discovery.

In the absence of voluntary submission to discovery, a litigant may request a US court to issue a 'letter rogatory', a request submitted to a court of the foreign nation with jurisdiction over the person from whom discovery is sought. However, many foreign countries are reluctant to permit any discovery not permitted under their own law, especially if the discovery is sought from a non-party.

Enforcing judgments

A judgment against a foreign company obtained in a US court may be difficult to collect abroad. Outside the European Union, there are almost no international agreements requiring that judgments obtained in one country be recognized and enforced in another. The US is as concerned as any nation, and perhaps more concerned than many, that its citizens not be subject to foreign laws. Courts asked to enforce a judgment obtained in another country typically look at both the procedures employed in obtaining the judgment and at whether the foreign judgment resulted from a type of legal claim that is recognized under the law of the defendant's country. A foreign court will be understandably reluctant to recognize a judgment obtained against one of its citizens if the claim is based on a US legal theory that is not recognized in the other country's legal system.

In the US, the recognition and enforcement of foreign judgments is a question of State law. The general rule is that recognition of a judgment is prerequisite to its enforcement. Thus, a party who has obtained a foreign judgment typically commences a new lawsuit for recognition of that judgment in a US State court. A majority of US States have enacted some version of the *Uniform Foreign-Country Money Judgments Recognition Act*, drafted by the National Conference of Commissioners on Uniform State Laws. Under these laws, US courts generally recognize foreign money judgments but are required to deny recognition if the foreign court in which the judgment was obtained did not have personal or subject matter jurisdiction. On rare occasions, US courts have declined to recognize a foreign judgment for the reason that it was obtained under unfair procedures.

The US also is signatory to international conventions regulating the enforcement of arbitration awards, the Convention on the Recognition and Enforcement of Foreign Arbitral Awards and the Inter-American Convention on International Commercial Arbitration.