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PRODUCT LIABILITY AND SAFETY

Product liability and safety in the United States: overview

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SOURCES OF LAW

1. What are the main areas of law and regulation relating to product liability?

Product liability law in the US is an amalgam of state and federal laws and the common law, which makes it difficult to clearly describe the law and legal requirements for importers, manufacturers and product sellers.

For product liability, most of the US law is common law that has developed in each state. It is court-made law and is based on prior case law from the trial courts and appellate courts. Some product liability law was first established in the common law and then adopted or modified by state legislatures in state laws. Some state legislatures first adopted product liability laws in their state despite the lack of case precedents on which to base their statutory law.

Through this process, the law has developed differently in the various states. Therefore, the key to determining an entity's potential responsibility for an injury or damage is first knowing which state law applies.

There is generally no federal product liability common law. It is viewed as a matter for each state to establish as it is local law that affects state residents and companies that sell into each state.

There are federal laws that affect product safety and three main government agencies that deal with it: the Consumer Product Safety Commission, the National Highway Traffic Safety Administration, and the Food and Drug Administration. The Congress passes laws that create pre-sale and post-sale product safety responsibilities for various entities and then the agencies pass regulations to implement these laws. Violation of these laws and regulations can result in fines and lawsuits by the agencies against manufacturers and product sellers. The fines and lawsuits can adversely affect pending or future product liability cases.

2. What is required to establish liability under the most common causes of action? When is a product defective? Does strict liability apply in certain circumstances?

The original theory of liability in product liability cases is negligence. In negligence cases the injured party must prove:

- There was a defect in the product that caused the plaintiff harm.
- The product was defective when it left the hands of the manufacturer or product seller.
- The defect was brought about through the defendant's negligence.

The original basis for proving a defect was the consumer expectations test. 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 criticised as being too vague and not providing much guidance to manufacturers or juries. The risk-utility test was therefore developed in the 1970s, which 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. Therefore, even if the product was more dangerous than the plaintiff realised, the manufacturer may prevail.

The 'risk utility' test, which originally applied to strict liability, is very close to negligence as it allows a manufacturer's conduct or fault to be considered. As a result, in the 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 that still use the consumer expectations test. In those states, they still talk about negligence and strict liability as separate theories of liability.

In most lawsuits, the plaintiff sues for both negligence and strict liability. As the case progresses through discovery, they may drop one of these theories as they can affect the type of evidence that may be admissible into court during a trial.

3. Who is potentially liable for a defective product? What obligations or duties do they owe and to whom?

Any entity in the supply chain can be liable for a defective product. This includes the raw material supplier, component part supplier, finished product manufacturer, distributor, retailer and maybe a company that does the installation or delivery of the product.

The obligations and duties are complex as they are dependent on where the entity is in the supply chain. The raw material supplier may have obligations and duties under a contract with the component part supplier. Therefore, they have no direct obligations and duties with the finished product manufacturer or the product seller or consumer.

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The finished product manufacturer has contracts with its immediate suppliers of components and its immediate purchasers. However, there can be multiple tiers of suppliers and sellers where each relationship has different contractual requirements. Therefore, identifying the exact obligations and duties in any given situation is very fact specific.

Product liability law in the US abolished the necessity of privity of contract and therefore the injured party can sue any entity in the supply chain directly. Despite that, various procedural rules and contractual rules will help to determine which entity in the supply chain is ultimately responsible. However, a jury can hold everyone who has been sued jointly liable and then the defendants can determine which entity pays what amount (*see Question 20*).

Defences

4. What are the defences to a product liability claim? Is there a time limit in which proceedings can be brought?

The primary defence to product liability claims (strict liability, negligence and breach of warranty) is lack of causation. These claims usually centre around design or manufacturing defect, failure to adequately warn or instruct, and breach of implied and express warranties related to product safety. The thrust of a lack of causation defence is that the product is not defective, but even if defective, the defect was not the proximate cause of the injury. Similarly, even if product warnings are defective in failing to sufficiently warn, causation does not exist where a plaintiff failed to read them.

The theory of liability dictates the available defences, often as a matter of state law. Negligence claims evaluate the conduct or fault of a defendant. As a defence, a defendant can raise a plaintiff's conduct, for example product misuse, as having caused or contributed to the injury by asserting contributory or comparative negligence. Intervening negligence of third parties can also be a defence. As strict liability typically does not evaluate the conduct of a defendant, but rather simply whether the product is defective, defences in some states are narrower than with negligence claims.

Defences to breach of implied and express warranty claims include lack of notice to the defendant of the claim prior to filing the lawsuit, and some states permit the defence of lack of privity of contract between the injured plaintiff and the defendant. Additionally, statutes of limitation and statutes of repose impose restrictions on the time within which a claim must be brought. Statutes of limitations and repose vary by state, and vary by claim. For example, in some states a plaintiff must bring a strict liability case within four years of the injury but has six years within which to bring a negligence claim. Some states have enacted statutes of repose that impose absolute limits on the time frame for asserting any product liability claim.

Excluding/limiting liability

5. Can a supplier limit its liability for defective products and are there statutory restrictions on a supplier doing this? Do consumer protection laws apply? Are guarantees or warranties as to quality implied by law? Is there a mandatory or minimum warranty period for consumer products?

There are many ways a manufacturer can reduce or limit its liability for injury, damage and loss resulting from selling defective products. A finished product manufacturer buys components to incorporate into its products. Through the contract, it can achieve some protection against liability when the component supplier is negligent or sells a defective component or the wrong component for the finished product; the buyer or manufacturer wants to use warranties and indemnification clauses given by the component part supplier to protect itself.

The manufacturer is also a seller of a finished product. In this role, they also want to use the contract with their purchaser to protect themselves or limit their liability. They want to provide a reasonable warranty and then include warranty disclaimers and limitation of liability clauses to put some cap on their potential liability.

For the product itself, there are a multitude of techniques that are meant to reduce the chance that the product has a manufacturing defect, design defect or defect in warnings and instructions. Quality assurance programmes help with manufacturing defects. Risk assessment and other safety evaluations help reduce the risk of design defects and defects in warnings and instructions.

The goal is to anticipate risks from intended use and reasonably foreseeable misuse, and then design and manufacture a product that results in reasonable risks. Warnings and instructions can be given for residual risks that cannot be designed out.

PRODUCT LIABILITY LITIGATION

6. In which courts are product liability cases brought? Are product liability disputes generally decided by a judge or a panel of judges? Are juries used in certain circumstances?

Product liability lawsuits can be brought in either state or federal court depending on the (state) citizenship of the parties and the amount and nature of damages at issue. Product liability and its related negligence causes of action are constructs of state law. If the case is commenced in state court, a state court judge will preside over the case and will rule on evidentiary issues in accordance with state substantive and procedural law. The parties may request a trial by jury or by the presiding judge. A federal district court may have jurisdiction where the lawsuit involves a plaintiff and defendant that are citizens of different states. In that case, the federal court will follow the state substantive law and federal procedural law. As in state court, the parties may request a trial by jury or a bench trial by the presiding judge. Typically, federal district judges preside over the conduct of the trial and hearings involving evidentiary issues. An appointed magistrate judge will preside over hearings involving discovery and other pre-trial matters, and may preside over trials by consent of the parties.

7. How are proceedings started?

A case is typically commenced by filing a complaint in state or federal court (*see, for example, Federal Rules of Civil Procedure 3*). In some states, a case officially commences with the formal service of the complaint on a defendant or by publication. In those states, procedural rules ordinarily require the plaintiff to file the complaint with the court within a certain period of time, for example within one year after service on the defendant.

8. Who has the burden of proof and to what standard?

The plaintiff has the burden of proof, which means that he must produce evidence of the product's liability. When the plaintiff presents evidence, the burden of production shifts to the defendant to present evidence that contradicts or answers the plaintiff's evidence.

The plaintiff has the burden of persuasion to prove the defendant's guilt in a civil case by a preponderance of the evidence, meaning that for the jury or judge to find in favour of the plaintiff, they must conclude based on the evidence presented that it is more likely than not that the defendant's product is defective and caused the

plaintiff's injuries. In some states that allow punitive damages in product liability cases, the plaintiff has a heightened burden of persuasion and must demonstrate entitlement to punitive damages by clear and convincing evidence.

9. How is evidence given in proceedings and are witnesses cross-examined?

Evidence can be testimonial, opinion, real or demonstrative. Evidence can be presented through live testimony of witnesses or qualified expert witnesses, can be read into the record or can be judicially noticed by the court (*see Federal Rules of Evidence 201; 601*). A party's witnesses can be cross-examined by the opposing party. However, the scope of cross-examination is generally limited to the subject matter of the direct examination and to issues bearing on the credibility of the witness (*see Federal Rules of Evidence 611*).

10. Are parties able to rely on expert opinion evidence and are there special rules or procedures for it?

Expert opinion is often required in product liability cases where the subject matter is beyond the layperson's common knowledge and experience. In federal court, an expert must be qualified as an expert in the subject matter, the opinion must be helpful to the determination of the issues, and must be based on sufficient facts or data. The opinion must also be the product of reliable principles and methods, and it must be applicable to the facts of the case (*see Federal Rules of Evidence 702*). Additionally, the facts and data on which the expert opinion relies must be of the kind that would be reasonably relied on by experts in the subject matter (*see Federal Rules of Evidence 703*). The court acts as a gatekeeper to the admissibility and scope of expert opinion testimony. Consequently, before presenting the opinion to the trier of fact, the court will evaluate:

- Whether the theory or technique can be (and has been) tested.
- Whether the theory or technique has been subjected to peer review and publication.
- The known or potential rate of error.
- Whether there are applicable standards.
- Whether the theory has been generally accepted.
- Any other factor that can bear on the reliability of the expert opinion.

(See *Daubert v Merrell Dow Pharmaceuticals, Inc, 509 US 579 (1993); Kumho Tire Co v Carmichael, 119 SCt 1167 (1999); General Elec Co v Joiner, 522 US 136 (1997)*). Some states apply slightly different expert admissibility criteria, most notably as it relates to novel scientific evidence or non-scientific evidence, with a focus on general acceptance and foundational reliability.

Federal court rules generally require that an expert retained to provide expert opinions prepare a report that must be disclosed 90 days before trial or as set out in the court's pre-trial scheduling order (*see Federal Rules of Civil Procedure 26(a)(2)(D)*). The expert's report must contain a complete statement of opinions and bases for them, facts or data relied on, describe exhibits that will be used to summarise or support the opinions, a description of the witness' qualifications with a list of publications, a list of prior testimony and a billing summary (*Federal Rules of Civil Procedure 26(a)(2)(B)*). Witnesses that a party intends to provide expert testimony at trial but who are not specially retained, such as employees of a party (for example, engineers, accountants, and so on) or treating physicians, need not provide a report, however, the party must disclose the subject matter on which the witness will testify and a summary of facts or opinions (*Federal Rules of Civil Procedure 26(a)(2)(C)*). Generally, expert opinions must be disclosed in the expert's report, rebuttal report (if permitted) or during the expert's deposition. The expert will be prohibited from testifying as to any undisclosed opinion at trial. State court rules may differ insofar as some do not require preparation of any expert report, and some do not permit the expert to be deposed prior to trial absent special circumstances.

11. Is pre-trial disclosure/discovery required and which rules apply? If not, are there other ways to obtain evidence from a party or a third party?

Federal Rules require parties to exchange initial disclosures shortly after the commencement of a lawsuit (*see Federal Rules of Civil Procedure 26(a)*). Under this rule, each party must identify witnesses, disclose documents, electronically stored information (ESI) and tangible things the party will use to support its claims or defences, a description of damages, and whether there is any applicable insurance coverage. In usual cases, parties can subsequently serve requests for production or inspection (of documents, ESI and tangible things), written interrogatories, requests for admission and requests for mental or physical examination on other parties (*see Federal Rules of Civil Procedure 33 to 36*). Additionally, parties can perpetuate or obtain testimony through depositions (*see Federal Rules of Civil Procedure 30 to 31*). Parties must also make expert disclosures in accordance with applicable court orders and in any event under Federal Rules of Civil Procedure 26(a)(2). Parties must also disclose trial witnesses and evidence in accordance with applicable court orders and in any event under Federal Rules of Civil Procedure 26(a)(3). For evidence in the possession, custody or control of third parties, any party can obtain testimony and production by subpoena under Federal Rules of Civil Procedure 45. Most state courts operate under similar rules. The exception ordinarily is for expert witness disclosures, which are often not required before trial. Additionally, state courts have limited jurisdiction to issue subpoenas.

12. Is there liability for spoliation of evidence/a remedy for destruction of or failure to preserve evidence (in particular, the product)?

Spoliation is the intentional destruction, mutilation, alteration or concealment of evidence. The duty to preserve evidence begins when litigation is pending or reasonably foreseeable. Destroying or failing to preserve information that is relevant to the lawsuit is spoliation. Sanctions for spoliation vary depending on state law. In some states an adverse inference jury instruction is warranted in cases of intentional or even negligent spoliation of evidence. The instruction may be that they (jurors) are to presume that the lost or spoliated evidence, if produced, would have been detrimental or unfavourable to the party who destroyed or lost the evidence. In federal cases, spoliation is generally defined by state law, however, federal law will control what inference can be drawn from that spoliation. Sanctions can range from dismissal of a plaintiff's claims or striking of a defendant's defences, to an adverse inference or some lesser sanction depending on the gravity of the harm.

13. What types of interim relief are available before a full trial and in what circumstances?

Apart from procedures to perpetuate testimony and secure evidence, a product liability plaintiff must litigate through to the conclusion of the matter, whether by settlement or trial, to obtain relief or an enforceable judgment. Procedural mechanisms can

allow the defence to obtain relief (dismissal) through a motion to dismiss or motion for summary judgment.

14. Can the successful party recover its costs associated with the litigation, such as legal fees and experts costs and to what extent?

Generally, each side pays its own attorney's fees and costs in the absence of a statutory or contractual provision providing otherwise (*Key Tronic Corp v United States, 511 US 809 (1994)*). However, the prevailing party in a trial can recover certain costs, such as court filing fees, copies, transcripts, expert, witness and interpreter fees (*see Federal Rules of Civil Procedure 54(d); 28 USC § 1920*). The prevailing party is loosely defined as the party who prevails on the significant issues of the case. Costs must be reasonably necessary to the case or related to the trial proceeding, rather than simply investigative. Recoverable costs include those associated with witness travel and lodging for trial, provided they are at the most economical rate. In some states, attorney's fees and costs may be recoverable to the prevailing party in limited circumstances, such as in actions under certain consumer protection statutes, or in actions determined to be frivolous.

15. What types of appeal are available?

Appeal from a civil trial judgment and interlocutory appeals are available from state and federal court proceedings. Court decisions prior to judgment, for example on motions to dismiss or for summary judgment that do not dispose of the case entirely, or certain orders given during discovery, may be subject to an interlocutory appeal (*see 28 USC § 1292(b)*). A party can also seek a writ of mandamus for interlocutory rulings. A party may seek interlocutory appeal where the decision involves a controlling question of law that is critical to the outcome of the case, and that cannot be reasonably addressed on a standard appeal after judgment. Federal rules permit appeal of decisions granting or deny class certifications (*Federal Rules of Civil Procedure 23(f)*). An appeal is typically a claim that the lower court erred in an evidentiary or legal ruling. An appellate court reviews a trial court's evidentiary rulings on an abuse of discretion standard, while reviews of rulings regarding a point of law will be reviewed de novo. Appellate courts typically empanel three judges for an appeal. A party may petition the appellate court for an en banc hearing of the entire appellate court.

Class actions/representative proceedings

16. Are class actions, representative proceedings or co-ordinated proceedings available? If so, what are the basic requirements? Are they commonly used?

Class actions are available under either state or federal law in which one or more class representatives sue on behalf of a class of persons similarly situated. Federal Rules allow class actions only if the class is so numerous that joinder of all members is impracticable, where there are questions of law or fact common to the class, where the claims or defences of the representatives are typical of the class, and where the court finds the representative parties will fairly and adequately protect the interests of the class (*Federal Rules of Civil Procedure 23(a)*). The party seeking class certification must also demonstrate that "questions of law or fact common to the members of the class predominate over any questions affecting only individual members" and that the class action is "superior to other available methods for the fair and efficient adjudication of the controversy" (*Federal Rules of Civil Procedure 23(b)*). A party seeking class certification must affirmatively demonstrate compliance with each element in this rule (*Wal-Mart Stores, Inc v Dukes, 564 US 338 (2011)*). Individuals falling within the class must usually affirmatively opt out if they wish to preserve their individual cause of action. Settlements usually require court approval. Class action product liability litigation has become more common in recent years. However, because issues of causation and damages in personal injury claims are usually personal to the individual plaintiff, class certification is often denied. Class actions are a preferred method to recover economic damages.

Personal injury plaintiffs can opt for a mass tort action where pre-trial matters are consolidated and a few of the individual cases are selected to be bellwether trials, that is, cases usually selected by agreement of the lead counsel for both parties or the court as being exemplary of the parties' respective claims and defences. The intention is that the outcome of these bellwether trials will inform the parties on likely outcomes of future trials on these claims and issues and facilitate resolution of the other cases short of trials. Mass tort actions brought in state court can be removed to federal court and consolidated under the Class Action Fairness Act (*see 28 USC § 1332(d)(11)*). Federal statutes also provide a mechanism to co-ordinate or consolidate several cases pending in different federal districts in one judicial district where all pre-trial matters are conducted (multi-district litigation) (*28 USC § 1407*).

Litigation funding

17. Is litigation funding by third parties allowed? Is it common? Are contingency fee or no win no fee arrangements allowed?

Rules applicable to third-party financing of lawsuits have relaxed in recent years and it is now generally permissible in the US. However, litigation financing presents risks to the protections afforded by the attorney-client relationship and under the rules of professional conduct. The more common and preferred method of financing product liability lawsuits is through contingency fee agreements, where counsel will receive a percentage of the recovery as fees, in addition to costs. Contingency fee arrangements are generally governed by each state's rules of professional conduct.

Remedies

18. What remedies are available to a successful party in a product liability claim?

Remedies available in product liability lawsuits vary by state and are generally compensatory in nature, which typically include pecuniary loss (economic damages, including medical expenses, lost wages and earning capacity) and non-pecuniary (pain and suffering, loss of consortium, counsel, aid and comfort). Many states impose statutory caps on recovery of certain damages, like loss of consortium or pain and suffering. Plaintiffs can also recover punitive or exemplary damages, although the standard for showing entitlement to these damages is much greater than for product defect or negligence. In some states a plaintiff is prevented from asserting a claim for punitive damages in the initial complaint, but must file a motion showing prima facie evidence of the defendant's malice or deliberate disregard for safety. If the court approves the motion, a plaintiff can usually include a punitive damages instruction to the jury. In most cases, punitive damages can be obtained only where the plaintiff proves the defendant's malicious or deliberate disregard by clear and convincing evidence.

19. How are damages calculated and are there limitations on them? Are punitive or exemplary damages available and in what circumstances?

See *Question 18*.

20. Is liability joint and several/how is liability apportioned, including where a partially responsible entity is not a party to the proceedings?

Each state has its own product liability statutes, including statutes that govern joint and several liability, comparative fault or contributory negligence, and apportionment of liability. In pure comparative fault jurisdictions, a plaintiff's damages will be reduced by the percentage of fault that is apportioned to the plaintiff. In other jurisdictions, a plaintiff cannot recover anything if his percentage of responsibility for the injury is greater than the percentage of fault attributed to the alleged product defect.

Many states have abolished or limited joint and several liability as part of larger tort reform efforts. The doctrine allows a solvent defendant only minimally at fault to bear the full burden of judgment where the tortfeasor to whom the major portion of fault was attributable is either insolvent or unavailable. Even in jurisdictions retaining joint and several liability, its liability can only extend to economic damages. In other jurisdictions, a defendant is jointly and severally liable only where a jury has found its fault greater than 50% of the total, or, if its fault is less than 50%, where its fault is aggregated with a co-defendant's fault with a finding of common enterprise for a total combined fault of greater than 50%. In many jurisdictions, particularly those that have abolished joint and several liability, a jury can only allocate liability to an empty chair (for example, settled defendant, employer immune from suit under workers' compensation laws, or unavailable third party) non-party that a jury determines caused or contributed to the alleged injury or damages.

PRODUCT SAFETY

21. What are the main laws and regulations for product safety?

Product safety is governed by the common law of product liability unless there is a government agency or state law that provides additional requirements.

Industrial products (mostly products used in a workplace by employees or workers) have no government agency that dictates safety requirements directly imposed on manufacturers. The Occupational Health and Safety Administration (OSHA), however, has requirements for employers for the machinery used in a workplace.

For workplace machinery, most of the product safety requirements for manufacturers come from safety standards issued by industry groups made up of the manufacturers of such products. US manufacturers also pay attention to the requirements of Directive 2006/42/EC on machinery, and amending Directive 95/16/EC (recast). The machinery directive was subsequently amended by Directive 2009/127/EC with regard to machinery for pesticide application.

Most other products have a government agency that has some safety requirements that must be complied with before sale. Consumer products are governed by the Consumer Product Safety Commission (CPSC). Food is governed by the Food and Drug Administration (FDA) and the Department of Agriculture (USDA). Drugs and medical devices are governed by the FDA and motor vehicles of all types driven on public roads and accessories such as trailers are governed by the National Highway Traffic Safety Administration (NHTSA). Boats and other products used on the water are governed generally by the Coast Guard (USCG) and airplanes are governed by the Federal Aviation Administration (FAA).

The FDA has many safety requirements and, with some complex products, undertakes pre-sale analysis and testing of the medical devices before the manufacturer is authorised to start selling the product. The FDA also pays very close attention before sale to the quality and efficacy of drugs and the safety of food.

The NHTSA has a number of safety standards that must be complied with by vehicle manufacturers. However, these standards are not comprehensive and there are many more industry standards that provide safety requirements.

The CPSC has a number of safety regulations that must be complied with. However, unlike the FDA, the CPSC does not generally inspect or test or evaluate the safety of consumer products before they are sold. Their focus is much more on requiring consumer product manufacturers to report safety problems to them after sale and undertaking a corrective action programme to fix the problem.

The CPSC's laws and regulations do not define the term consumer; it is basically anyone who is not working at a business location. Therefore, a product can be deemed a consumer product if it subjects consumers to some risk, even though that person did not buy or is not using the product. A bystander who is subjected to a risk of harm by a consumer product is protected by the laws and regulations of the CPSC.

22. Are there general regulators of product safety issues? Are there specific regulators for particular goods or services? Briefly outline their role and powers.

See *Question 21* for a list of US regulators.

There are also state regulators in those states that have product safety related laws and regulations. Most of these agencies can force the manufacturer to stop selling its product and recall it. All of these agencies can issue safety regulations for products under their jurisdiction. The regulations and ability to enforce them differ from agency to agency. It is generally up to the people administering the agency as to how stringent they are on issuing and enforcing regulations. As people change in the agencies depending on which political party is in charge of Congress and the Presidency, the level of activity can change from year to year.

Product recall

23. Do rules or regulations specify when a product recall is required or how companies should make decisions regarding product recalls and other corrective actions? Are any criteria specified?

Each of the three main agencies have regulations concerning when a manufacturer or product seller has a duty to report a safety issue to them (*see Questions 21 and 22*). These regulations are significantly different between agencies. The Consumer Product Safety Commission mainly focuses on whether the product has a defect that can create a substantial product hazard. The National Highway Traffic Safety Administration focuses on whether the vehicle has a safety related defect. The Food and Drug Administration requirements differ significantly between drugs and medical devices and food.

The reporting requirements and the determination of an appropriate corrective action are based on an assessment of current and future risk, that is, whether there is a risk of a serious

injury or death to someone using the product or being near the product. The definition of defect varies from agency to agency and the acceptable or unacceptable probabilities of harm are also different with different products in the same agency.

Each safety issue is complex and very fact specific. Therefore, whether to report and whether to recall the product or perform some other corrective action is very dependent on many factors and it is up to the manufacturer and the agency to negotiate a plan that makes sense given the risks.

24. Are there mandatory advertising requirements for product recalls? Are there other rules governing how a product recall should be conducted?

There are rules on what kinds of public notices are necessary, which depend on future risk to consumers and the ability of the company to identify who bought the recalled product.

For example, with consumer products, the usual method of announcing a recall is through a press release issued by the Consumer Product Safety Commission (CPSC) and then putting up posters in stores. In most situations, the consumer is not known. In some circumstances, where serious accidents have occurred and continue to occur, the CPSC may want the company to take out paid advertising and issue a second press release. In addition, the CPSC may issue a video news release and possibly have a news conference. Where the product was sold through a membership warehouse store, that store knows what products were purchased by their members and they can send them an individual letter informing them of the recall.

With medical devices, there are usually direct letters to doctors informing them of the safety recall. If consumers are using the device at home, there could be a press release or a letter to the consumer if they can be identified. With motor vehicles, the car manufacturers can obtain the list of registered owners of the cars to be recalled and can directly send them a letter.

There have been many serious food recalls and the injuries can be significant. If there is a food recall, the distribution patterns will be analysed by the Food and Drug Administration (FDA), and the food distributor and retailer will have to quickly implement an appropriate recall strategy that is acceptable to the FDA.

25. Is there a mandatory obligation to report dangerous products or safety issues to the regulatory authorities?

See *Questions 21* to *24*.

The triggers are different, and the time frames are different (*see Question 24*). There are no obligations on manufacturers of industrial or commercial products used in a workplace to report safety issues to a government agency. Other than those products, virtually every other product has a government agency that has jurisdiction over safety issues.

There are many examples of fines issued by these agencies against manufacturers and product sellers for failing to report or for reporting and providing incomplete or inaccurate information to the government agency.

The Consumer Product Safety Commission (CPSC) has a relatively low limit for fines, although the limit has recently been raised. In 2016, the CPSC levied a fine of more than US$15 million that concerned multiple violations. The Food and Drug Administration levied a fine in excess of US$10 million that also concerned multiple violations. The National Highway Traffic Safety Administration levied a fine of US$200 million against Takata, the airbag manufacturer, in 2015.

26. Is there a specific requirement to provide progress reports and/or keep the authorities updated about the progress of corrective actions? In practice, do authorities expect periodic update reports?

The Consumer Product Safety Commission (CPSC) requires monthly reports for an unspecified time. They can be submitted for around nine to 18 months depending on the number of returned products each month. If the returns are minimal, the CPSC will close the file and not require monthly reports with the understanding that the manufacturer must report any new serious incidents or injuries indicating an increase in the risk.

The National Highway Traffic Safety Administration requires quarterly reports for six quarters. The Food and Drug Administration requires monthly reports specific to the risk and recall results.

RECENT TRENDS AND REFORM

27. Are there any recent trends in product liability and safety law? Have there been any recent significant changes or important cases? Are there any legal or procedural issues that are attracting particular interest in your jurisdiction?

Product liability lawyers and scholars have considered new technology developments and made suggestions as to application of the law. The new technology includes autonomous vehicles, internet of things, 3-D printers and drones. There have been very few, if any, cases involving these products; however, it is still mostly an open question as to how safe these products must be and what duties a manufacturer of such products has.

The regulatory agencies have been adjusting to the change in political administrations. The likelihood is that the adoption of new safety regulations will significantly slow down and that enforcement of the existing regulations will somewhat lessen. Therefore, the threat of fines and other civil actions should be less in the foreseeable future.

On the litigation front, most of the significant litigation has involved a series of cases involving the same product and how the courts will efficiently resolve them. Cigarettes, asbestos, drugs, food and medical devices are the prominent series of cases that the courts are struggling with. The courts are also trying to deal with class actions that do not involve any injury. Questions abound on the certification of the class action and how to determine damages when no injury has occurred, and how to resolve the cases.

Many individual cases continue being litigated in state and some federal courts around the US, and there have been few significant opinions that would change the way in which some cases will proceed and be resolved. Unlike past years, the scope of product liability law and litigation is not really expanding.

28. Are there any proposals for reform and when are they likely to come into force?

See *Question 27*.

There have been some proposed laws and enacted laws in individual states that affect the product safety of products sold in these individual states. Most of them pertain to the types of chemicals allowed in certain products, especially toys, and what limits for those chemicals may be imposed on the manufacturers. As the federal government lightens the burden on manufacturers, or at a minimum does not impose significant new burdens, it can be expected that some states in the US will enact their own product safety regulations. Whether these are legal is still an open

question as manufacturers cannot sell different products in each state and therefore these state-wide regulations impose a burden on manufacturers who sell products nationally.

ONLINE RESOURCES

Consumer Product Safety Commission (CPSC)

W *www.cpsc.gov*

Description. This is the website of the CPSC, which has extensive information on reporting requirements and corrective action programmes.

Food and Drug Administration (FDA)

W *www.fda.gov*

Description. This is the website of the FDA, which has extensive information on reporting requirements and corrective action programmes.

National Highway Traffic Safety Administration (NHTSA)

W *www.nhtsa.gov*

Description. This is the website of the NHTSA, which has extensive information on reporting requirements and corrective action programmes.

Product Liability Prevention

W *www.productliabilityprevention.com*

Description. This website contains over 90 articles written by Kenneth Ross on most of the issues involved in product liability, product safety, regulatory compliance and product liability prevention. There is also a page on this website devoted to online resources in this area.

Practical Law Contributor profiles

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Publications. *The Rise of Commercial Drones, Emerging sUAS Manufacturer Concerns*, For the Defense Research Institute, Inc (December 2016) (most recent article).