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Product Liability & Safety

USA: Law & Practice

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Law and Practice

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1. Product Safety

1.1 Product Safety Legal Framework

The main laws and regulations governing product safety in the United States are set out below.

General Regulation

The Consumer Product Safety Act of 1972, 15 U.S.C. § 2051 et seq, created the Consumer Protection Safety Commission (CPSC) and authorises CPSC to develop product safety standards, pursue product recalls, and ban products from the US market under certain circumstances. Subsequent amendments have expanded CPSC's authority. CPSC issues regulations (Code of Federal Regulations, Title 16) that define certain standards that particular classes of products must meet to ensure the safety of consumer products (eg, products used in homes, schools or otherwise).

The Consumer Product Safety Improvement Act of 2008, Pub. L. 110-314, 122 Stat. 3017 (2008), imposed safety standards for a broad category of children's products and gave CPSC additional enforcement authority.

Sector-Specific Regulation

Children's safety

Other statutes require safety measures for products intended for use by, or posing a danger to, children, including:

- the Children's Gasoline Burn Prevention Act, 15 U.S.C. § 2056;
- the Federal Hazardous Substances Act, 15 U.S.C. § 1261;
- the Child Safety Protection Act, 15 U.S.C. § 1261;
- the Poison Prevention Packaging Act, 15 U.S.C. § 1471; and
- the Child Nicotine Poisoning Prevention Act of 2015, 15 U.S.C. § 1471.

Specific products

Additional statutes require labelling and safety measures for specific products, including:

- the Flammable Fabrics Act, 15 U.S.C. § 1191;
- the Labeling of Hazardous Art Materials Act, 15 U.S.C. § 1277;
- the Refrigerator Safety Act, 15 U.S.C. § 1211;
- the Virginia Graeme Baker Pool and Spa Safety Act, 15 U.S.C. § 8001; and
- the Drywall Safety Act of 2012, 15 U.S.C. § 2051.

Food and drugs

The Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 et seq, authorises the Food and Drug Administration (FDA) to regulate food and drug safety and approve new drugs and medical devices. Among other things, the FDCA prohibits adulteration or misbranding of food, drugs, devices or cosmetics, 21 U.S.C. § 331. The FDA issues regulations (Code of Federal Regulations, Title 21) to ensure the safety of products, including food, drugs, medical devices, cosmetics and tobacco products.

The FDCA and subsequent amendments require new drugs and devices to be approved by the FDA through an established process, and authorise the FDA to evaluate these products' risks. The FDA has issued comprehensive regulations governing review and approval of these products (Code of Federal Regulations, Title 21).

The Food Safety Modernization Act, Pub. L. 11-353, 124 Stat. 3885 (2011), seeks to prevent, detect and respond to food safety issues. The FDA has issued rules to accomplish these goals.

Transport

The Highway Safety Act of 1970, 23 U.S.C. § 401, created the National Highway Traffic Safety Administration (NHTSA) to oversee traffic and vehicle safety standards and programmes. The NHTSA issues regulations (Code of Federal Regulations, Title 49) to prevent and reduce vehicle crashes.

The National Traffic and Motor Vehicle Safety Act, 15 U.S.C. § 1381, imposes vehicle safety standards, which motor vehicle manufacturers must follow.

The Transportation Recall Enhancement, Accountability and Documentation (TREAD) Act, 49 U.S.C. § 30101, requires the NHTSA to issue regulations concerning tires and child restraints, and requires vehicle or equipment manufacturers to report claims to the NHTSA so the agency can identify potential safety issues.

The Federal Aviation Act of 1958, 49 U.S.C. § 40101, created the Federal Aviation Administration (FAA) and gives the FAA authority to regulate the airline industry. The FAA issues regulations (Code of Federal Regulations, Title 14) imposing airworthiness standards for planes and parts.

The Clean Air Act, 42 U.S.C. § 7401; Federal Environmental Pesticide Control Act, 7 U.S.C. § 136; Clean Water Act, 33 U.S.C. § 1251; and other statutes impose environmental protections and are administered by the Environmental Protection Agency (EPA). The EPA regulates pesticides and other chemical products to protect the environment and public health (Code of Federal Regulations, Title 40).

Unfair competition

The Federal Trade Commission Act created the Federal Trade Commission (FTC), which protects consumers and promotes

competition. Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45(a)(1), declares "[u]nfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce" to be unlawful. Each state has statutes (often enforced by attorneys general) or common law, which also protect consumers from false, misleading or deceptive claims, including claims about the safety or performance of a product.

1.2 Regulatory Authorities for Product Safety

The main US agencies regulating product safety are the FDA, CPSC, the NHTSA, and the FTC. Agency authority to regulate products is defined by statute.

The FDA is responsible for safeguarding and advancing public health. It regulates food; drugs; medical devices; radiation-emitting products; vaccines, blood and biologics; animal and veterinary; cosmetics; and tobacco products. The FDA's authority is defined by the FDCA, which authorises the FDA to regulate drug safety, issue food safety standards, and inspect factories.

CPSC regulates over 15,000 consumer products to prevent unreasonable risk of injury or death. Its authority is outlined by the CPSA, which authorises CPSC to develop safety standards and initiate product recalls and bans.

The NHTSA enforces Federal Motor Vehicle Safety Standards for vehicles and component parts. The NHTSA regulates vehicle and highway safety to reduce deaths, injuries and motor vehicle accident costs. The NHTSA's scope of power is found in the National Traffic and Motor Vehicle Safety Act, which authorises the NHTSA to issue safety standards and recall vehicles and component parts.

The FTC protects consumers and promotes competition. Under the Federal Trade Commission Act, the FTC has authority to investigate violations of, and enforce, consumer protection and antitrust laws. The FTC's Bureau of Consumer Protection gathers consumer complaints, conducts investigations, and sues companies that break the law.

1.3 Obligations to Commence Corrective Action

The FDA, CPSC and the NHTSA can request or require corrective action, including removing a product from the market – known as a recall. The standards governing manufacturers' obligations to commence the recall process vary by agency.

FDA

The FDA recalls involve correction or removal. There are three types of FDA recalls, based on the potential danger posed by a defective or potentially harmful product: Class I for products that predictably could cause serious harm; Class II for products that might cause harm; and Class III for products unlikely to cause harm. Most recalls are voluntary, but the FDA can request recalls. If a company concludes a recall is necessary, it will notify the FDA that it intends to implement a recall and will propose a recall plan. The FDA supervises a company's recall strategy and effectiveness, and examines whether the company has made reasonable efforts to remove or fix the product (eg, by providing enhanced warnings or making repairs or adjustments). The FDA issues a weekly recall report and may publicise recalls to inform the public.

CSPC

When CPSC receives a report that a product is defective, poses harms or fails to comply with safety standards, as required by CPSA Section 15, it classifies the danger as follows: a Class A Hazard exists when death or grievous injury is likely or very likely, or serious injury is very likely; a Class B Hazard exists when death or grievous injury is possible, serious injury is likely, or moderate injury is very likely; and a Class C Hazard exists when serious or moderate injury is possible. Each class requires corrective action, such as a recall to recover, repair or replace the product. After CPSC and the company agree to a recall, they work together to develop an implementation plan for the recall and to monitor the company's efforts. As part of the recall process, companies must inform the public so consumers can act accordingly. Public notice may include press releases, information on the company's website or social media, or advertisements, among other methods. When the company believes the recall has been successfully implemented, it can request that the recall no longer be monitored. Other remedial actions ("corrective action plans") include returning the product for a refund, repairing the product, or notifying the public of the hazard. CPSC has a Fast Track Product Recall Program that permits expedited recalls if, among other criteria, the company can implement a recall or corrective action within 20 days of submitting its report to CPSC. The benefit of the programme is that CPSC will not make a finding that the product is defective.

NHTSA

If the NHTSA receives multiple complaints about a product, it may investigate whether a defect exists or a recall should be recommended. A recall is issued when a vehicle or product poses an unreasonable safety risk. If a recall is issued, the company must inform owners within 60 days. The company must provide a free remedy, such as repairing, replacing, refunding or repurchasing the vehicle or product. Most recalls are voluntary, but the NHTSA can require a recall.

1.4 Obligations to Notify Regulatory Authorities

The triggers for reporting product safety issues to regulating authorities vary by agency. Some reporting is risk-based; some is incident-based.

FDA

The FDA has different reporting requirements for different products. For example – for pharmaceutical products – drug, biologic and device manufacturers; device importers; and certain healthcare facilities must all report adverse events or product problems via Form FDA 3500A or in electronic form. Specifically, if a drug or biologic manufacturer learns of a serious adverse event associated with its product – such as death, disability or life-threatening injury – it must inform the FDA within 15 days of receiving the information, 21 C.F.R. §§ 310.305, 314.80, 600.80. Under the Medical Device Reporting regulations (Code of Federal Regulations, Title 21, Part 803), medical device manufacturers and importers and certain healthcare facilities must inform the FDA of adverse events and product problems, as follows:

- manufacturers and importers must report to the FDA within 30 days of learning their device could have contributed to or caused serious injury or death, 21 C.F.R. §§ 803.40, 803.50;
- manufacturers must inform the FDA within 30 days of discovering malfunctions that could contribute to or cause serious injury or death, 21 C.F.R. § 803.50;
- manufacturers must sometimes report events requiring corrective action within five days, 21 C.F.R. § 803.53;

- healthcare facilities must inform the FDA within 10 days if they suspect a medical device caused death, and must inform the device manufacturer or the FDA of serious injury, 21 C.F.R. § 803.30; and
- healthcare facilities must submit annual safety reports to the FDA, 21 C.F.R. § 803.33.

Finally, healthcare providers, caregivers, patients and consumers may, but are not required to, submit voluntary reports of adverse events and product problems. These reports help the FDA monitor product safety and may prompt corrective action.

CSPC

CPSC also has mandatory risk-based and incident-based reporting requirements. CPSA Section 15 requires companies to report products that are defective, pose harm or fail to comply with safety standards, and Child Safety Protection Act Section 102 requires companies to report choking incidents involving children. Companies must report these issues to CPSC's Office of Compliance and Field Operations within 24 hours of receiving reportable information. If a company is unsure whether the information is reportable, it can investigate for no more than ten working days, with some exceptions. Additionally, CPSA Section 37 requires manufacturers to report lawsuits and settlements concerning a product within 30 days after a judgment or settlement in the last of three lawsuits involving the product.

NHTSA

Similarly, the NHTSA requires companies to provide risk-based and incident-based reports. For instance, an equipment or vehicle manufacturer must submit a Defect and Noncompliance Information Report to the NHTSA within five working days of concluding the vehicle or equipment poses a danger or fails to comply with safety standards, 49 C.F.R. § 573.6. Manufacturers also must inform the NHTSA of recalls or corrective actions in foreign countries within five days of deciding to conduct the action or receiving notice from a foreign government that the action is required, 49 C.F.R. § 579.11. Under the TREAD Act and implementing regulations, manufacturers must submit early warning reports to the NHTSA. Large manufacturers of vehicles and all tire and child restraint system manufacturers must report information that could indicate potential danger, such as incidents of death or injury, warranty claims, and consumer complaints. All other manufacturers must report incidents of death. Finally, manufacturers must submit copies of their communications concerning defects and other matters to the NHTSA, 49 U.S.C. § 30166(f).

FTC

The FTC collects consumer complaints regarding a wide range of topics, including computers and online privacy, telemarketing scams, sweepstakes, health and weight loss products, and more.

1.5 Penalties for Breach of Product Safety Obligations

The FDA can impose various civil penalties, including fines, injunctions, warning letters requesting remedial action, recalls, and seizures. Those who violate the FDCA may also face criminal penalties, including imprisonment for no longer than one year, a fine of no more than USD1,000, or both, 21 U.S.C. § 333. Second offences and other violations can result in longer prison terms and higher fines, 21 U.S.C. § 333.

Similarly, CPSC can impose penalties. For example, it is unlawful to sell, manufacture, distribute or import consumer products subject to corrective action, 15 U.S.C. § 2068. Those engaging in this conduct (and other acts prohibited in 15 U.S.C. § 2068) are subject to civil and criminal penalties, 15 U.S.C. §§ 2069, 2070. Failure to submit mandatory reports to CPSC also can result in civil or criminal penalties. For example, in 2018, Polaris Industries, Inc agreed to pay a civil penalty of USD27.25 million after it failed to report defects in two off-road vehicle models. As part of the settlement, the company agreed to maintain a compliance programme.

The NHTSA can impose civil and criminal penalties for vehicle safety violations and for falsifying or failing to provide required information, 49 U.S.C. §§ 30165, 30170. Civil penalties can cost

up to USD21,000 per violation, with a maximum penalty of USD105 million for related violations, 49 U.S.C. § 30165. Those who violate reporting requirements with intent to mislead the NHTSA about safety issues are subject to fines, imprisonment of no longer than 15 years, or both, 49 U.S.C. § 30170. For example, TK Holdings Inc entered a settlement with the NHTSA after it failed to timely file defect information reports; its total penalty was USD200 million.

Finally, the FTC and/or state attorneys general can seek to enjoin companies from making false, misleading or deceptive claims relating to the safety or performance of a product through fines, injunctive relief or consent decrees. For example, in April 2020, in response to an FTC complaint and administrative action, Whole Leaf Organics agreed to stop claiming that one of its supplements reduces the risk of COVID-19 and to stop claiming that three of its CBD-based products are effective cancer treatments.

2. Product Liability

2.1 Product Liability Causes of Action and Sources of Law

Product liability is a creature of state rather than federal law, and the law can vary, sometimes significantly, by state.

The main common law causes of action are strict liability, negligence, breach of warranties, consumer protection, fraud, and negligent misrepresentation. Claims generally can be brought against a product's manufacturer, seller, distributor or retailer. "Sellers" include everyone within the chain of commerce, including wholesalers, even if they were unaware of the defect.

Strict Liability

Strict liability requires showing that:

- the product was sold in an unreasonably dangerous condition when it left the manufacturer, seller, distributor or retailer;
- the defect was unchanged when it reached the plaintiff; and
- the defect injured the plaintiff.

Regardless of a defendant's intent or level of care, it can be held liable for injury. Generally, prescription drug manufacturers should not be held liable under strict liability. Restatement (Second) of Torts § 402A, cmt. k.

Negligence

Negligence claims require a plaintiff to show:

- the defendant owed a duty of care to the plaintiff;
- the defendant breached that duty;
- the breach caused the plaintiff's injury; and
- the plaintiff was injured or damaged.

Negligence claims focus on the reasonableness of the defendant's conduct and whether the manufacturer breached it duty of care. The principles discussed in **2.10 Courts in which Product Liability Claims Are Brought** and **2.12 Defences to Product Liability Claims**, concerning causation and damages, apply to negligence claims. A defendant owes a duty of reasonable care to consumers in designing, manufacturing and providing adequate warnings.

Breach of Warranty

Warranty claims are based on express writing, promises of performance, or implied warranties of fitness for particular purpose or merchantability. The source of law is common law contract principles, except in the case of personal injuries.

A breach of express warranty occurs when the seller explicitly promises the product will meet a certain standard and the product fails to meet that standard. These promises are typically written into sales contracts, but can exist when there is no written contract if assurances are made verbally.

A breach of implied warranty of fitness for a particular purpose occurs when the product fails to be usable for the consumer's purpose for purchasing that product. To prove a claim, plaintiffs must show that they told the defendant of a specific need for the product, the defendant assured that the product would meet those needs, and the product failed to meet those needs.

A breach of implied warranty of merchantability occurs when the product is not fit for the purpose for which it is typically used. To prove this claim, plaintiffs must show that the defect in the product renders it unfit for its ordinary, intended use.

Consumer Protection

Federal and state consumer protection laws are generally broad and protect against unfair business practices including false or misleading advertising or labelling, misrepresentations about the quality of goods, safety violations and anti-competitive practices. The standard of proof varies by statute, but typically private plaintiffs must show intent and reliance on the misleading information to prevail.

Fraud

To establish a fraud claim, plaintiffs must show that:

- the defendants knowingly made false representations about the product to induce the plaintiff to purchase the product;

- the plaintiff relied on those representations when purchasing the product; and
- the plaintiff was damaged by those false representations.

Fraud allegations provide a way for plaintiffs to seek punitive damages.

Negligent Misrepresentation
Negligent misrepresentation requires plaintiffs to show that:

- there were false or misleading representations about the product;
- the defendant should have known that the information was false or misleading;
- the plaintiff relied on that representation; and
- the plaintiff was damaged by that representation.

The key distinction between fraud and negligent misrepresentation is the defendant's intent. Fraud requires intentional conduct while negligent misrepresentation only requires that the defendant made the misrepresentation carelessly or lacked reasonable grounds for believing the statement's truth.

Statutory Liability
In some states, the common law causes of action have been replaced by a product liability statute or act. Generally, the statute will combine the common law principles and provide a single cause of action that focuses on product defect. Product liability statutes often contain specific defences for non-manufacturer distributors or sellers and limits on damages. In Indiana, for example, punitive damages cannot exceed three times compensatory damages or USD50,000, whichever is greater, I.C. § 34-51-3-4. In Connecticut, punitive damages cannot exceed twice the amount of damages, Conn. Gen. Stat. § 52-240b.

Nature of Defect
Defects in manufacturing, design or packaging and inadequate warnings can all give rise to liability. A manufacturing defect is where the product is different from its intended design and was defective when it left the defendant's control. A design defect is where the overarching design of the product is defective, so that all products produced under that design are defective, and where the foreseeable risks of harm could have been reduced or avoided with a reasonable alternative design. A warning defect is where the foreseeable risks of the product are not adequately disclosed, the warnings are inadequate to properly warn of the product's danger, or the failure to warn makes the product not reasonably safe. Failure to warn claims can be brought as strict liability or negligence claims.

To determine whether a product is defective, states typically use the consumer expectations test, the risk utility test, or a combination of both. Under the consumer expectations test, the product is defective if it is unreasonably dangerous and that level of danger exceeds what the ordinary consumer would expect. Restatement (Second) of Torts: Product Liability § 402(a). Under the risk utility test, the product is defective if the product's risks outweigh its utility. Restatement (Third) of Torts: Product Liability § 2(b).

Duty to Warn
There may also be instances when a manufacturer has a post-sale duty to warn. There are several approaches to determine whether this duty is triggered, and several states do not impose this duty at all. For example, under the Restatement (Third) § 10, this duty is triggered when:

- the manufacturer knows or reasonably should know that the product poses a substantial risk of harm;
- those who would be warned can be identified and are likely unaware of the risk;
- the warning can be communicated and acted upon; and
- the risk of harm is substantially great to justify the burden of providing the warning.

Another approach is the reasonable person standard, which weighs how reasonable it would be to provide the warning. This approach considers factors such as the product type, nature of harm that would occur without the warning, economic burden on the manufacturer, and likelihood of harm.

Causation
Liability also requires a finding that the defect was the "cause" or "proximate cause" of an injury. Causation is expressed in terms of whether "but for" the defect the injury would not have occurred. Proximate cause focuses on whether the chain of events leading to the injury are "too remote" from the defect. If the injury is too remote or indirectly related to the defect, the defendant cannot be held liable. The precise formulation for causation varies by state.

2.2 Standing to Bring Product Liability Claims

An individual alleging injury has standing to bring a product liability claim. The original purchaser is not necessarily the only one with standing; in certain instances, individuals who have used the product in a way that was foreseeable can sue if injured. For breach of warranty claims, courts typically require privity of contract for standing, meaning that only an individual who was a party to the agreement can bring the suit, unless there are personal injuries. In most states, breach of express or implied warranty claims can be brought by third-party beneficiaries – ie, intended recipients of a contract's benefits who are not parties to the agreement, UCC § 2-318; Greenman v Yuba Power Products, Inc, 377 P.2d 897 (Ca. 1963).

A spouse, and in some jurisdictions, children, have standing to bring a loss of consortium (loss of care and comfort) claim. There are also wrongful death and survivor statutes that define when heirs can bring actions in a deceased's name. There are also limited circumstances when individuals in the "zone of danger" of an injury may bring emotional distress claims. Under the zone of danger rule, plaintiffs who were not injured can recover for emotional distress if they witnessed another person being injured and they were within the zone of physical danger.

2.3 Time Limits for Product Liability Claims

Depending on the cause of action and the jurisdiction, the statute of limitations for bringing an action can range from one to six years. Some jurisdictions do not have a specific statute of limitations for product liability actions, so the time limits for torts or civil actions apply.

Generally, the statute of limitations begins to run when the injured party becomes aware of the injury. In some states, the clock begins to run at the time of injury. However, most states have adopted the discovery rule. This means the statute of limitations will not begin to run until the plaintiff discovers, or should have discovered, the injury, cause and/or wrongful conduct of the defendant. If, through reasonable diligence, a plaintiff should have discovered the injury on a certain date, that is the date on which the clock will begin to run. If a plaintiff is unreasonably delayed in discovering the injury, he or she cannot toll the statute of limitations to the date of discovery.

Different states have different requirements for the discovery rule. Most states fit into one of three categories. A large number of states require plaintiffs to discover the injury and cause for the statute to run. In a small number of states, it will begin to run when plaintiffs discover the injury only. Other states require plaintiffs to discover the cause of action, which usually means discovering all essential facts to prove each element of the cause of action.

For example, in Alaska, the discovery rule tolls the statute of limitations "until the claimant discovers, or reasonably should have discovered, the existence of all elements essential to the cause of action." Jarvill v Porky's Equip, Inc, 189 P.3d 335, 339-340 (Alaska 2008). In Mississippi, however, the cause of action begins to accrue when plaintiffs knew or should have known of the injury. PPG Architectural Finishes, Inc v Lowery, 909 So.2d 47, 50 (Miss. 2005) (citing Miss. Code § 15-1-49).

2.4 Jurisdictional Requirements for Product Liability Claims

State Jurisdiction

For a plaintiff to maintain a suit over the defendant, the court in which the suit is brought must have personal jurisdiction over the defendant. A court has general jurisdiction to hear all claims over a party where it is incorporated or has its principal place of business. Specific jurisdiction only allows a court to hear a particular case against a party.

Bristol-Myers Squibb Co v Superior Court of California, 137 S. Ct. 1773 (2017), clarified the scope of specific jurisdiction. There, a group of plaintiffs (some from California and some from other states) sued a defendant corporation incorporated in Delaware and headquartered in New York. The Court found the defendant's relationship with a third party (a California company distributing the defendant's product nationwide) was insufficient to establish specific jurisdiction over the non-resident plaintiffs' claims, noting specific jurisdiction requires more than a general connection with the forum; rather, it requires "an affiliation between the forum and the underlying controversy, principally, [an] activity or an occurrence that takes place in the forum State." Id. at 1781 (citation and quotations omitted). Given this clarified standard, multi-plaintiff product actions face jurisdictional hurdles. Indeed, in BMS, the Court observed that resident and non-resident plaintiffs can only join in a consolidated action in a state with general jurisdiction over a defendant. In the absence of that general jurisdiction finding, individual plaintiffs would likely be required to bring claims in their own states of residency. This prevents plaintiffs' lawyers from filing multi-plaintiff claims in plaintiff-friendly states, even if those plaintiffs have no connection to the state.

Federal Jurisdiction

Federal courts have jurisdiction over "federal question" cases involving civil actions under the US Constitution, federal laws or treaties, 28 U.S.C. § 1331. Federal courts also have "diversity jurisdiction" when the parties are diverse citizens (every plaintiff is from a different state or foreign country than every defendant) and the amount in controversy exceeds USD75,000, 28 U.S.C. § 1332(d).

Federal courts are available for certain class or mass actions that involve more than 100 plaintiffs or over USD5 million in damages under the Class Action Fairness Act (CAFA), 28 U.S.C. § 1332(d). Under CAFA, there must be minimal diversity, meaning that at least one member of the class is diverse from one defendant. There are two exceptions to CAFA that require the case to be heard in state court: the home state exception and the local controversy exception. The home state exception is where at least two thirds of class members and the primary defendants are citizens of the state where the action was filed originally. The local controversy exception applies if:

- at least two thirds of class members and at least one defendant are citizens of the state where the action was originally filed;

- the alleged harm occurred in that state;
- significant relief is sought from a local defendant whose conduct forms a significant basis for the claims; and
- no other class action was filed in the past three years by the same parties.

If the federal jurisdiction prerequisites are not met, claims must be brought in the state court that has jurisdiction.

2.5 Pre-action Procedures and Requirements for Product Liability Claims

There generally are not requirements for pre-action procedures. If plaintiffs bring product liability claims with professional negligence claims (such as medical malpractice), some states will require the plaintiff to secure an expert certification of merit or proceed through an administrative process before bringing the professional negligence claim. Failure to complete pre-action steps can lead to dismissal of the complaint until the steps are taken.

Additionally, some jurisdictions require parties bringing breach of warranty claims to provide notice of a breach to the opposing party within a reasonable time of discovering that breach, UCC § 2-607. See, for example, Hepper v Triple U Enterprises, Inc, 388 N.W.2d 525, 529 (S.D. 1986). This is intended to allow the other party to cure the breach. In other jurisdictions, filing the lawsuit itself satisfies this notice requirement. See, for example, Connick v Suzuki Motor Co, 675 N.E.2d 584, 590 (Ill. 1996).

2.6 Rules for Preservation of Evidence in Product Liability Claims

Once parties "reasonably anticipate" becoming party to a litigation or the target of a governmental investigation, they have a common law duty to preserve all potentially relevant documents, electronically stored information (ESI), and tangible items that may be discoverable in that litigation or investigation. See *Sedona Conference Commentary on Legal Holds, Second Edition: The Trigger & The Process* (2019).

This duty extends to all relevant materials created, modified, sent or received that are within the party's possession, custody or control, regardless of their geographic location. Courts have made clear, however, that perfection is not required; the standard is one of reasonableness, tempered by considerations of proportionality and accessibility. When assessing "reasonable anticipation," companies should consider:

- the source and specificity of threats;
- the extent to which similar conduct has previously triggered litigation or an investigation;
- pending litigation or investigations involving industry peers;
- commencement of a pre-emptive internal investigation; and
- whether the attorney work-product doctrine has already been invoked.

If a credible argument can be made that litigation or an investigation is likely, it is best practice to promptly implement a legal hold. When litigation holds are not implemented or adhered to properly and relevant electronically stored information (ESI) is lost, Fed. R. Civ. P 37(e) governs the consequences parties may face.

In the product liability context, parties must also consider preservation of tangible things, and consideration should be given to what physical items may be relevant. This often includes the product alleged to be defective. For example, the Fourth Circuit upheld dismissal of a product liability case because the plaintiff breached his duty not to destroy evidence by failing to preserve the vehicle at issue in the litigation, Silvestri v GMC, 271 F.3d 583 (4th Cir. 2001).

2.7 Rules for Disclosure of Documents in Product Liability Cases

Rules 26, 34, and 45 of the Federal Rules of Civil Procedure govern the discovery process in federal court. State court discovery rules tend to be similar in structure, but more expansive in application. Rule 26(b)(1) defines the scope of discovery as "any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case." Proportionality requires consideration of "the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden of expense of the proposed discovery outweigh its likely benefit." Rule 26 also governs discovery timing, including initial disclosures to opposing parties.

Rule 34 governs production of documents and things, whether physical or electronic, including emails and other communications. Parties may serve Rule 45 subpoenas on non-parties to obtain relevant information; for example, records from a plaintiff's healthcare provider.

A party may object to a request on several grounds, including proportionality, but must be specific in describing the factual basis for the objection. To safeguard the confidentiality of produced documents, parties often request that courts enter protective orders. When parties cannot reach agreement on the scope of discovery, they can bring motions to compel the production of certain documents. Courts can punish parties who do not comply with discovery or engage in misconduct.

2.8 Rules for Expert Evidence in Product Liability Cases

Federal Courts

Rules 702 and 703 of the Federal Rules of Evidence govern expert witness testimony. For expert testimony to be admissible, Rule 702 requires:

- the expert's scientific, technical or specialised knowledge to help the trier of fact understand the evidence or determine a fact at issue;
- the testimony be based on sufficient facts or evidence;
- the testimony be the product of reliable methods and principles; and
- the expert to reliably apply those methods and principles to the facts of the case.

Under Rule 703, experts may base their opinions on facts of which they have either been made aware or which they have personally observed. If experts in that specific field would rely on certain types of data, that data need not be admissible for the opinion to be admitted.

Daubert Standard

Federal courts and around half of state courts use the Daubert standard. See, for example, In re Amendments to the Florida Evidence Code, 278 So. 3d 551 (Fla. May 23, 2019); State v Coon, 974 P.2d 386 (Alaska 1999). Under Daubert, the trial judge acts as a gatekeeper and should admit expert testimony only if the Rule 702 requirements are met, Daubert v Merrell Dow Pharm, Inc, 509 U.S. 579 (1993). Daubert also sets forth a non-exhaustive list of factors for courts to assess the reliability of an expert's methodology:

- whether the theory is testable;
- whether the theory is subject to peer review and publication;
- whether there is a known or potential error rate; and
- whether the theory is generally accepted in the field.

Courts typically also apply additional factors identified by the Ninth Circuit in Daubert on remand: "whether the experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying because the former provides important, objective proof that the research comports with the dictates of good science." Daubert v Merrell Dow Pharm, 43 F.3d 1311, 1313 (9th Cir. 1995). In addition to challenging methodology under Daubert, courts can review the experts' conclusions in determining admissibility, Joiner v G.E., 522 U.S. 136 (1997).

State Courts

Around half of state courts use the Frye standard. Under Frye, an expert's testimony is admissible if the expert's methodology is generally accepted by experts in that particular field, Frye v United States, 293 F. 1013 (D.C. Cir. 1923). Methods that are at an experimental stage or not well-recognised will generally not be admissible. While general acceptance is required under Frye, it is only a factor to consider for reliability under Daubert.

2.9 Burden of Proof in Product Liability Cases

Plaintiffs bear the burden of proof in product liability cases. A plaintiff must prove each element by preponderance of evidence, which means the plaintiff's evidence must show that each element is more likely than not. The defendant bears the burden on its defences, such as the statute of limitations or product misuse.

In some states, specifically for design defect cases, plaintiffs also have the burden of presenting a feasible, alternative design that is safer than the defendant's design.

In some states, the burden can shift. For example, in California, the plaintiff has the initial burden of producing evidence that he or she was injured while the product was being used in an intended or reasonably foreseeable manner. If this burden is met, the burden of proof shifts to the defendant to prove that the plaintiff's injury resulted from misuse of the product. See Perez v VAS S.p.A. 188 Cal.App.4th 658, 678 (2010).

2.10 Courts in which Product Liability Claims Are Brought

For the most part, juries decide product liability cases. If parties do not demand a jury trial, the entirety of the case will be decided by a judge. Even if a trial has a jury, a judge still has the power to rule on motions, including motions to exclude testimony, exclude evidence, dismiss the case, or grant summary judgment before trial if there are no genuine issues of material fact. If motions to dismiss and for summary judgment fail, the case will proceed to trial for either a judge or jury to decide its outcome.

Damages must have some basis and cannot be entirely speculative. There are ways for defendants to challenge exorbitant jury awards. Principles of due process limit awards that "shock the conscience." Rochin v California, 342 U.S. 165 (1952). If a verdict does shock the conscience, such as if a judge sees the award as manifestly and grossly unjust, the judge can either force the plaintiff to take a lower-value verdict or retry the case. Some jurisdictions place caps on damages and, in particular, punitive damages. Principles of due process also limit punitive damages awards to, generally, a multiple of ten times compensatory dam-

ages, State Farm Mut Auto Insurance Co v Campbell, 538 U.S. 408 (2003).

Despite these limits, product liability verdicts at the trial court level can range in the millions or tens of millions of dollars for a single plaintiff. These verdicts are reviewed and can be revised by the appellate courts. Currently, there are a number of cases on appeal where there are damages in the tens of millions. For example, a jury recently awarded USD55 million in compensatory damages and USD2 billion in punitive damages to a couple who allegedly developed cancer from Roundup weed killer. This amount was reduced by the court to USD17 million in compensatory damages and USD69 million in punitive damages, Pilliod v Monsanto Co, No. RG17862702 (Cal. Super. Ct. 2017). In a similar case, a jury awarded the plaintiff USD289 million, which the judge reduced to USD78 million, Johnson v Monsanto Co, No. 3:2016cv01244 (N.D. Cal. 2016). A third Roundup case resulted in an USD80 million jury verdict, Hardeman v Monsanto Co, No. 3:16-cv-00525 (N.D. Cal. 2016). Each case is on appeal.

2.11 Appeal Mechanisms for Product Liability Claims

In the federal court system, district courts serve as trial courts. Generally, a party may appeal a decision if it is final. A decision becomes final when the court formally enters a judgment, Fed. R. Civ. P. 58. There are some instances when a party may appeal the district court's ruling before the trial has concluded. This is an interlocutory appeal, 28 U.S.C. § 1292.

If a party wishes to appeal a final decision, the party will appeal to the circuit court in which that district court sits. Instead of trying the case again, the appellate court will review the record. To challenge a circuit court's ruling (or a state supreme court's ruling if there is a federal question), a party can file a writ of certiorari to the US Supreme Court to review the case, which grants a only a small number of these petitions. Generally, in a civil case, a party has 30 days to file a notice of appeal from the entry of judgment to a circuit court or 90 days to file a writ of certiorari to the US Supreme Court Fed. R. App. P. 4(a)(1)(A); Supreme Ct. R. 13.

In the state court system, states typically have trial, intermediate and supreme courts. After a trial court makes a decision, a party can appeal to the intermediate and then to supreme courts. The timeframes and procedures for appeals vary by state.

2.12 Defences to Product Liability Claims

There are many affirmative defences in product liability actions. When a defence is affirmative, the burden of proof is on the defendants.

Negligence

The most common defences are comparative and contributory negligence. Most states follow comparative negligence principles, which means that damages will be apportioned based on the parties' fault. For example, if one defendant is 25% at fault, that defendant will be responsible for 25% of the damages. If the plaintiff is partially at fault, the plaintiff's award will be reduced based on his or her percentage of fault. Some states employ a modified comparative negligence rule where plaintiffs are barred from recovery if they are more than 50% at fault. A small number of states follow the contributory negligence rule, which means that even if the plaintiff is only 1% at fault, the plaintiff cannot recover at all. States may also have additional, special rules in this area. For example, in Michigan, a comparative negligence state, if the plaintiff's percentage of fault is greater than the defendant(s), the economic award is reduced by that percentage of fault and the plaintiff cannot recover for noneconomic damages. MCL § 600.2959; David Yates, *Defenses to Product Liability Claims* (4 April 2019). Some states preclude the comparative negligence defence in strict liability actions unless the defendant shows that the plaintiff voluntarily and unreasonably proceeded against a known danger. Restatement (Second) of Torts § 402A. For example, Pennsylvania precludes negligence as a defence to strict liability or a way to reduce damages but allows evidence of the plaintiff's negligence (such as misuse of the product) in the causation analysis. Dodson v Beijing Capital Tire Co, No. 3:14-CV-01358, 2017 U.S. Dist. LEXIS 158484, at *11 (M.D. Pa. Sept. 27, 2017); Madonna v Harley Davidson, Inc, 708 A.2d 507, 508 (Pa. Super. Ct. 1998).

Other Defences

Assumption of risk

This is an affirmative defence where the defendant must show the plaintiff was, or should have been, aware of the risk of harm and voluntarily used the product anyway.

Alteration

This is a defence where the defendant must show the plaintiff made alterations to the product and it was these alterations that caused the injury.

Intended user doctrine

This states that manufacturers and sellers are only liable to the product's intended user, not an unintended user even if using the product in a foreseeable way.

Unforeseeable use

This applies where the plaintiff misused the product in a way that was unforeseeable to the manufacturer and the ordinary person.

State of the art
This is an affirmative defence where the defendant-manufacturer argues that there was no way for it to know the dangers of the product at the time of manufacture or sale; this typically applies when all safety standards and scientific or technical knowledge available at the time were considered to ensure the product's safety.

Product misuse
This is an affirmative defence where the defendant must show the plaintiff was injured because he or she was misusing the product.

Federal pre-emption
This applies when a plaintiff brings a state law claim that is barred by a federal statute governing that particular product. Federal law pre-empts state law when (i) Congress explicitly says so, (ii) the state law conflicts with federal law, or (iii) Congress has indicated that a certain area is not subject to state law. For example, certain drug labelling requirements are governed by federal law and not state law. Automobiles and pesticides are other products where pre-emption is commonly used as a defence. The determination of pre-emption for a failure-to-warn claim is a legal question for the judge, not a jury, Merck Sharp & Dohme Corp v Albrecht, 139 S. Ct. 1668 (2019).

The statute of repose
This, unlike the statute of limitations, begins to run on the date of the defendant's wrongful conduct, even if the plaintiff has not been injured yet or the plaintiff has not discovered the injury yet.

The sophisticated user defence
This applies when the manufacturer's duty to warn is discharged because the user is sophisticated enough to recognise the product's risks. This is usually an objective standard and considers the user's background and experience. Restatement (Second) of Torts § 388. In drug and medical device cases, the defence is referred to as the learned intermediary doctrine. Under this doctrine, a prescription drug or medical device manufacturer has no duty to warn the end user of the product's risks if the manufacturer provides an adequate warning to the prescribing physician, who acts as the learned intermediary and warns the patient of the product's risks. Restatement (Third) of Torts, Products Liability § 6(d). The majority of states have adopted this doctrine.

The economic loss doctrine
This prohibits a plaintiff from recovering damages in negligence or strict liability actions if a product defect only results in economic loss and damage to the product, but does not cause personal injury or property damage.

2.13 The Impact of Regulatory Compliance on Product Liability Claims

Generally, compliance with regulatory regulation does not prevent a finding of negligence when reasonable measures would suggest additional precautions. Restatement (Second) Of Torts § 288. Conversely, failure to comply with regulations can be evidence of breach of duty or negligence per se.

Regulatory compliance can be relevant to rebut a claim of exemplary or punitive damages. While meeting the regulations is not always a defence, compliance is a factor in determining whether the product is defective.

Courts may be more likely to consider compliance as a defence when the particular statute or regulation is recent, the standard specifically addresses the same issue as the case, and the court is "confident that the deliberative process by which the safety standard was established was full, fair, and thorough and reflected substantial expertise." Restatement (Third) of Torts: Product Liability § 4 cmt. e; see also Robert L. Rabin, *Symposium: Regulatory Compliance As A Defense To Products Liability: Keynote Paper Reassessing Regulatory Compliance*, 88 Geo. L.J. 2049, 2051 (July 2000).

2.14 Rules for Payment of Costs in Product Liability Claims

Under the American Rule of litigation, each party bears its own legal costs. There are circumstances when costs of litigation (including experts) can be recoverable. For example, there are provisions of "offers of judgment" under the federal rules. Under Fed. R. Civ. P. 68, a party defending the claim can make an offer to the other party at least 14 days before trial. If the other party rejects the offer and the final judgment is less favourable than the offer, the other party must pay the costs incurred after the offer.

State courts have similar rules. In California, any party may make an offer to the other party no less than 10 days before trial. If the offer is rejected, and the party rejecting the offer gets a less favourable award, that party is responsible for costs, California C.C.P. § 998.

If a party is successful at summary judgment or trial, certain costs (but not attorney fees) can be recovered, Fed. R. Civ. P. 54. A successful party may also make a motion to claim attorney fees and non-taxable expenses, unless the substantive law in that area requires that those fees be proved at trial as part of damages.

2.15 Available Funding in Product Liability Claims

Third-party litigation financing – arrangements through which non-parties provide financing in exchange for a portion of the ultimate proceeds – is a growing, multibillion-dollar industry in the USA. However, some states prohibit third-party financing arrangements under common law or statutory bans against champerty (an uninterested non-party's funding of a lawsuit to share in the proceeds).

Contingency fee arrangements are common and virtually the exclusive means for compensation in personal injury cases. In these arrangements, plaintiffs' counsel generally receives no fee if there is no recovery.

2.16 Existence of Class Actions, Representative Proceedings or Co-ordinated Proceedings in Product Liability Claims

Class actions are available if certain prerequisites are met:

- the class is so numerous that joinder is impracticable;
- the class presents common questions of law and fact;
- the class representative's claims or defences are typical of the class's claims and defences; and
- the representative will fairly and adequately protect the class's interests, Fed. R. Civ. P. 23(a).

Additionally, there are three types of classes that have unique requirements:

- limited fund actions, where prosecuting individual actions would create a risk of inconsistent adjudications or would impair the abilities of others to protect their interests;
- classes seeking injunctive relief; or
- classes seeking monetary damages, Fed. R. Civ. P. 23(b).

As one example, in a class seeking a monetary remedy, common questions of law or fact must predominate over questions affecting individual members, Fed. R. Civ. P. 23(b). States generally have similar requirements.

Although class actions are available, product liability and personal injury litigation is not generally susceptible to class action treatment because individualised assessments of causation and injury make it difficult to satisfy the federal and state prerequisites and requirements. See, for example, Amchem Prods, Inc v Windsor, 521 U.S. 591 (1997) (finding predominance and adequacy of representation not met for a class of hundreds of thousands of individuals who were, or may become, affected by asbestos exposure due to products manufactured by one or more of 20 different companies).

Multidistrict litigation (MDL) allows for co-ordinated discovery and pretrial proceedings in complex civil cases brought in federal courts. To qualify for MDL, the cases must involve at least one common factual question, 28 U.S.C. § 1407. As discussed in **3.1 Trends in Product Liability and Product Safety Policy**, MDL actions are common for product liability actions in the USA. Additionally, individual state courts may permit consolidated proceedings involving one particular product with similar claims of defects. See, for example, California's Judicial Counsel, which oversees co-ordination of civil actions involving common factual or legal questions.

2.17 Summary of Significant Recent Product Liability Claims

Pre-emption

There have been notable developments in product liability law arising from pre-emption. In Pliva v Mensing, 564 U.S. 604 (2011), the US Supreme Court held that federal regulations governing generic manufacturers pre-empt state failure-to-warn claims. In the wake of Pliva, some states have adopted an innovator liability theory, which allows plaintiffs to hold brand-name manufacturers liable for injuries caused by a generic drug. See, for example, T.H. v Novartis Pharm Corp, 407 P.3d 18 (Cal. 2017); Rafferty v Merck & Co, 92 N.E.3d 1205 (Mass. 2018). However, the majority of courts to consider the theory have rejected it. See, for example, Fullington v PLIVA, Inc, 720 F.3d 739, 744 (8th Cir. 2013); PLIVA, Inc v Dement, 780 S.E.2d 735 (Ga. App. 2015). More recently, in Merck Sharpe & Dohme Corp v Albrecht, 139 S. Ct. 1668 (2019), the US Supreme Court found that whether a failure-to-warn claim is pre-empted is a question of law to be decided by a judge.

Bankruptcy

The GM ignition switch litigation addresses the relationship between bankruptcy and product liability law. In Elliott v General Motors LLC, 829 F.3d 135 (2d Cir. 2016), General Motors Corporation (Old GM) petitioned for bankruptcy, and General Motors LLC (New GM) was formed after purchasing Old GM's assets "free and clear" (ie, free of all claims and other interests, including successor liability, other than expressly assumed liabilities). Thereafter, New GM recalled cars containing an ignition switch defect, which were manufactured by Old GM before the bankruptcy proceedings and sale – and about which Old GM did not provide notice to consumers. A class action was filed against New GM for injuries caused by the defect, and the plaintiffs argued New GM was liable under a successor liability theory. The Second Circuit Court of Appeals found that some claims could proceed against New GM because the plaintiffs received inadequate notice of the proposed sale and precluding their claims would violate due process. New GM tried to appeal, but its petition for writ of certiorari was denied by the US Supreme Court, Gen Motors v Elliott, 137 S. Ct. 1813 (2017).

Punitive Damages
Large punitive damages awards have been drawing attention. In State Farm Mutual Automobile Insurance Co v Campbell, 538 U.S. 408, 414-15 (2003), the jury awarded USD2.6 million in compensatory damages and USD145 million in punitive damages. The US Supreme Court found the punitive damages award violated the Due Process Clause of the Fourteenth Amendment, which prohibits excessive or arbitrary punishments. State Farm has since been applied by appellate courts to reduce or reverse significant punitive damages awards.

3. Recent Policy Changes and Outlook

3.1 Trends in Product Liability and Product Safety Policy

Opioid Litigation
The opioid litigation has seen state and local governments bringing new types of claims, seeking reimbursement for the health costs arising from use of a product. This follows a model first built in the context of tobacco-promotion litigation. Specifically, these governmental plaintiffs allege that opioid manufacturers misrepresented the risks of long-term opioid use and aggressively marketed their products, and that distributors failed to monitor suspicious orders of prescription opioids, thus contributing to the opioid epidemic. They bring claims ranging from negligence to public nuisance to violations of federal and state racketeering statutes. In August 2019, an Oklahoma judge found pharmaceutical companies' false and misleading marketing constituted a public nuisance under Oklahoma law, and awarded damages (in the form of abatement) in the amount of USD465 million dollars. Other actions brought by over 2,000 states, cities, municipalities, hospitals, payors and others are pending trial (and in some cases have settled). Many government plaintiffs have co-ordinated efforts to seek certification of a novel "negotiating class" as a way to facilitate resolution.

MDL
Multidistrict litigation (MDL) continues to grow, accounting for approximately 50% of all cases in federal courts, and with over 30% of pending MDLs in 2019 involving product liability. This trend toward co-ordination of cases has resulted in questions about whether the processes provided in MDLs are sufficient to address the mass of litigation. How to provide fairness in the MDL process has attracted legislative and rulemaking attention. See, for example, In re Opioid MDL (6th Cir. 2020) (granting writ of mandamus, reversing trial judge order allowing amendment of pleading contrary to federal rules).

Proportionality of Discovery
Due to the high volume of documents in discovery, the 2015 amendments to the Federal Rules of Civil Procedure attempted to streamline the discovery process and alleviate the costs of unreasonably burdensome production requests. The amendments focus on "proportionality" by requiring discovery to be proportional to the needs of the case. Courts must further limit discovery if it is too burdensome, cumulative or duplicative. Fed. R. Civ. P. 26(b)(1), (b)(2)(C). Additionally, because of the expense and time involved in producing electronically stored information (ESI), the amended rules restrict ESI discovery that is "not reasonably accessible" because of burden or cost. Fed. R. Civ. P. 26(b)(2)(B). Individual states are also starting to address issues concerning the need for discovery limits and have implemented rules that minimise this burden. For example, Illinois shares the emphasis on proportionality. Ill. R. Civ. P. 201(c)(3).

Specific Jurisdiction
Finally, another notable procedural development comes from Bristol-Myers Squibb Co v Superior Court of California, 137 S. Ct. 1773 (2017), which clarified the scope of specific jurisdiction and prevented plaintiffs' lawyers from aggregating plaintiffs with no connection to a state into one multi-plaintiff filing in plaintiff-friendly jurisdictions.

3.2 Future Policy in Product Liability and Product Safety

Machine law, artificial intelligence, the internet of things and automated vehicles will be a major focus of future policy, legislation and regulation. Two illustrative examples are regulatory guidance on digital health and automated vehicle safety.

The FDA has developed a Digital Health Program and has been examining digital health topics such as wireless medical devices, mobile medical apps, software as a medical device and cybersecurity. The FDA has also issued a Digital Health Innovation Plan, available at https://www.fda.gov/media/106331/download, to encourage digital advances and ensure public safety. The Plan observes that the FDA's traditional approach to medical devices may not be appropriate for software-based technologies and describes the FDA's plan to redesign its policies and processes.

Likewise, the US Department of Transportation (DOT), of which the NHTSA is a part, has issued guidance concerning technological developments in transportation – specifically, automated vehicles. Among other documents, DOT issued an October 2018 report, "Preparing for the Future of Transportation: Automated Vehicle 3.0," available at https://www.transportation.gov/sites/dot.gov/files/docs/policy-initiatives/automated-vehicles/320711/preparing-future-transportation-automated-vehicle-30.pdf. The report notes DOT's goals of ensuring safety and encouraging innovation and sets forth strategies for implementing and understanding automation.

An important question that will need to be addressed in future product liability cases is how to treat software for 3D printing. Historically, software has been considered a service, as opposed to a product. Thus, under traditional product liability principles, safety issues associated with software would not give rise to strict liability. Whether those traditional principles will continue to govern remains to be seen, but will have to be sorted out in future litigation, as software becomes more prevalent in consumers' lives.

3.3 Impact of COVID-19

Each federal district and state court system has issued its own policies for handling matters.

- The US Supreme Court, for example, has never allowed live audio or video feeds for arguments. However, it recently agreed to hear ten arguments over a two-week period via teleconference calls, which were live broadcast.
- Other courts have limited judges' responsibilities to COVID-19-related matters (such as criminal matters requiring resolution), which will cause backlogs of product liability and other civil cases.

In the geographic areas most profoundly impacted by COVID-19, it is likely there will not be a jury trial in calendar year 2020, and there will be growing experimentation with video platforms, like Zoom, for hearings and depositions.

Many industries have turned to fight the COVID-19 pandemic and have been provided with certain immunity from product liability actions. The Department of Health and Human Services issued a COVID-19 declaration under the Public Readiness and Emergency Preparedness (PREP) Act, announcing that manufacturers, distributors, programme planners, and other qualified persons are protected from liability for COVID-19 countermeasures. The declaration covers antivirals, drugs, biologics, diagnostics, devices and vaccines used to treat, diagnose, cure, prevent or mitigate COVID-19. It also covers products and technologies that increase efficacy or minimise adverse events associated with covered products. There are some exceptions to immunity, however, including claims involving wilful misconduct, claims unrelated to the countermeasure, claims based on activities that fall outside the scope of the declaration, and foreign claims where the USA has no jurisdiction.

Attorneys general have formed task forces with the FTC to look for COVID-19-related fraud, such as making unsubstantiated claims about the level of protection of PPE or potential cures, as early examples.

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Troutman Pepper is a national law firm known for its higher commitment to client care. With more than 1,100 attorneys in 23 U.S. cities, the firm partners with clients across every industry sector to help them achieve their business goals. The firm's health sciences department comprises 110 attorneys who collaborate across disciplines to solve complex legal challenges confronting clients throughout the health sciences spectrum. The department represents pharmaceutical and medical device manufacturers facing civil and criminal investigations by the DOJ and other agencies; actions by state attorneys general under consumer protection and Medicaid fraud statutes; tens of thousands of individual personal injury claims, whether presented individually, in MDLs, or in co-ordinated state court proceedings; and class actions by consumers and third-party payors. A hallmark of Troutman Pepper's practice is its track record as national counsel, assisting clients through simultaneous lawsuits, grand jury investigations and regulatory actions.

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