

International Product Law Manual

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Chapter 3

An Overview of Product Liability Law in the United States

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Chapter 3

An Overview of Product Liability Law in the United States

Thomas E. Riley & Allison M. Alcasabas

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1. INTRODUCTION

At the most basic level, product liability involves a claim by a single plaintiff against a single manufacturer or seller for personal injuries, but the challenges that face manufacturers and suppliers in the United States (U.S.) can extend far beyond lawsuits by individual consumers. While many of the underlying legal doctrines are well-established, new theories continually emerge and present novel legal issues. Recent trends, for example, include the use of consumer fraud statutes to recover economic damages for alleged misrepresentations in advertising and promotional materials, and legal theories such as public nuisance that plaintiffs have sought to adapt to the product liability arena. Moreover, the defence of pre-emption, the potential for class actions, and availability of punitive damages are distinguishing features of the U.S. legal system. In many instances, regulatory proceedings at both the state and federal level arising out of product safety concerns may run in parallel with litigation. Thus, the multifaceted field of U.S. product liability often encompasses a host of concerns; virtually any manufacturer that makes or sells products for public consumption can be affected.

U.S. product liability law varies significantly across states, although there are general concepts and principles in the vast majority of jurisdictions, if not all. The fundamental premise of U.S. product liability law is that the manufacturer or seller has a duty to protect consumers from unreasonable hazards, in many cases even if the hazard stems from the consumer's own negligence.

U.S. courts reason that a manufacturer is best positioned to understand the benefits and risks of the product, and to make optimal choices in designing the product to minimize unnecessary risk. The manufacturer's duty encompasses research, design, testing and production; if, by its nature, the product poses risks even though it is properly designed and manufactured, the manufacturer may also be required to warn consumers of the risks.

Product liability claims can generally be asserted under three legal theories, with bases in both tort and contract: strict liability, negligence, and breach of warranty. Each theory provides a separate cause of action, but product liability plaintiffs often assert all three.

2. STRICT LIABILITY

Strict liability is a unique cause of action first recognized in a landmark ruling by the California Supreme Court in 1963¹ and is the primary cause of action in U.S. product liability litigation. Being tort-based, the theory eliminates requirements, such as privity and notice, that apply to contract-based claims and prevents the use of disclaimers to avoid liability. The theory differs from negligence by eliminating the plaintiff's need to show that the manufacturer failed to exercise due care. The focus of a strict liability claim is the product itself, whereas negligence focuses on the manufacturer's conduct and degree of care.

The rationale behind strict liability is that the manufacturer is best positioned to prevent the introduction of defective products into the market and that the manufacturer, rather than the consumer, should bear the cost of injuries caused by defective products, even if the manufacturer is not negligent.

While a plaintiff alleging strict liability may recover damages without showing that the manufacturer failed to exercise due care, the claim is not so expansive that a manufacturer bears liability for all injuries that may be caused by a product. The theory is reflected in § 402A of the Restatement (Second) of Torts,² which imposes liability for physical harm caused by 'any product *in a defective condition unreasonably dangerous to the user or consumer or to his property*'.³ Thus, the touchstone for determining strict liability is the existence of a defect. A product is not defective merely because it poses risks to the consumer; nor does strict liability require a manufacturer to produce the safest possible product.

1. *Greenman v. Yuba Power Prod.*, 377 P.2d 897 (Cal. 1963).

2. The Restatement is a treatise published by the American Law Institute describing the law in a given area and guiding its development. Though the Restatements are frequently cited, they are not officially binding on courts.

3. Restatement (Second) of Torts (Restatement (Second)) § 402A (1965).

U.S. courts have developed a variety of tests to determine whether a product is defective for purposes of strict liability. The majority use some form of ‘risk-utility’ balancing test, which recognizes that there are trade-offs between consumer safety and a manufacturer’s numerous product-design considerations. These include the utility of the product to the individual and to the public, the likelihood of injury, the possibility of designing a safer but functional and reasonably priced alternative, the consumer’s awareness of the dangers, and the consumer’s ability to avoid injury.⁴ Even though strict liability is not regarded as a fault-based concept, the risk-utility test is infused with negligence precepts because it involves an assessment of the reasonableness of the manufacturer’s design choices. Some courts apply a risk-utility test, but impute to the manufacturer knowledge of the product’s dangers, including dangers that may not have been known when the product was designed and manufactured. Under this standard, a product is considered defective if it should not have been marketed had the manufacturer known of its risks at the time it was made. Other courts have adopted the consumer-expectations test, which examines whether the product is more dangerous than the ordinary consumer would contemplate, with knowledge common to the community of its characteristics. Still other courts recognize a combination of both tests,⁵ yet may decide to apply only the risk-utility test if determination of the alleged design defect at issue involves primarily technical or scientific information.⁶

Although § 402A applies strict liability to all products, comment k recognizes an exception to the general rule. Under this provision, ‘unavoidably unsafe’ products, such as prescription drugs, are given special treatment. Comment k provides that when a product is ‘incapable of being made safe for its intended and ordinary use’, the manufacturer will not be strictly liable for a design defect, if the product is ‘properly prepared, and accompanied by proper directions and warning’. This exception is based on recognition of the public health benefits conferred by prescription medications, and the concern that the threat of strict liability could discourage the introduction of new medications. Comment k thus seeks to balance a manufacturer’s responsibility for product safety with the public interest in fostering new products.⁷ Thus, comment k allows the manufacturer of a prescription medication to avoid strict liability, if the risks of the medication were unavoidable and proper directions and warnings were given.

4. See, e.g., *Voss v. Black & Decker Mfg. Co.*, 450 N.E.2d 204 (N.Y. 1983).

5. See *Mikolajczyk v. Ford Motor Co.*, 901 N.E.2d 329 (Ill. 2008).

6. See *Kokins v. Teleflex, Inc.*, 621 F.3d 1290 (10th Cir. 2010) (finding no error in district court’s election to instruct the jury only on the risk-utility, and not the consumer expectations, test for defective design, despite Colorado’s recognition of both standards).

7. See *Brown v. Superior Court*, 751 P.2d 470, 475–77 (Cal. 1988).

Courts have taken different approaches to the application of comment k, with most applying it on a case-by-case basis. These courts apply comment k, for example, only to prescription medications for which there is an ‘exceptional social need’,⁸ or if there is no reasonable alternative design to the medication in question.⁹ Other courts, however, have applied comment k broadly, such that all prescription medications with adequate warnings and instructions are exempt from strict liability¹⁰ to foster the public interest in new medications.

The Restatement (Third) of Torts: Products Liability, adopted in 1997, sought to clarify these conflicting interpretations. Section 6(c) provides that a prescription medication or a medical device is defectively designed if the product’s foreseeable risks of harm are ‘sufficiently great in relation to its foreseeable therapeutic benefits that reasonable healthcare providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for any class of patients’.¹¹ Thus, a prescription drug maker is not subject to strict liability for defective design if a reasonable healthcare provider would prescribe it to any class of patients; a medication that is beneficial to a small group is not defective, even if it will cause serious injury to many others. The standard relies on the prescribing doctor’s expertise and rejects the case-by-case approach taken by most courts under the Restatement (Second). Moreover, unlike the Restatement (Second), § 6(c) would apply a different liability standard to prescription medications or medical devices than to all other products.

Some courts may be reluctant to embrace the approach taken in the Restatement (Third).¹² First, courts are wary of the ‘reasonable physician’ standard, because it presumes that a physician has at least as much knowledge about the risks and benefits of a prescription medication as the manufacturer. Second, § 6(c) treats all drugs equally, even if they do not have equal social utility. Fundamentally, § 6(c) presumes that prescription medications differ from other products; that is, as a category, they have greater social utility than other products. Many courts, however, have refused to adhere to such a bright-line distinction, reasoning that not all prescription drugs confer important societal benefits. Thus, they conclude that there is no justification for treating all prescription medications as a favoured category, and prefer a case-by-case approach.

8. *Hill v. Searle Labs.*, 884 F.2d 1064, 1069 (8th Cir. 1989).

9. See *Toner ex rel. Toner v. Lederle Labs.*, 732 P.2d 297 (Idaho 1987).

10. See 751 P.2d 470; *Grundberg v. Upjohn Co.*, 813 P.2d 89 (Utah 1991); *Young ex rel. Young v. Key Pharm., Inc.*, 922 P.2d 59 (Wash. 1996).

11. Restatement (Third) of Torts: Prod. Liab. (Restatement (Third)) § 6(c) (1998); see also *id.*, § 6(c) cmts. b, f.

12. See *Freeman v. Hoffman-La Roche, Inc.*, 618 N.W.2d 827 (Neb. 2000).

3. OTHER COMMON LAW THEORIES

3.1. NEGLIGENCE

Although strict liability has supplanted negligence as the leading theory of product liability in the U.S., negligence remains a distinct and alternative theory of recovery. Unlike strict liability, which focuses on the product's condition, a negligence claim requires a showing that the manufacturer's conduct deviated from the accepted standard of care.

A negligence claim is based on four intertwined elements: duty, breach, causation and damages. In the product liability context, a manufacturer has a duty to use reasonable care in the design, manufacture and sale of its product. A manufacturer also has a duty to test its product to discover latent defects, to stay abreast of scientific knowledge and technical advances in the field, and to know the hazards presented by the product. Where a product is dangerous when used as intended, the manufacturer may be required to warn the user if the user would be unaware of the danger.

A manufacturer's duty generally extends to product users, to whom there is a foreseeable risk of harm. Thus, the duty may extend not only to the purchaser but also to household members and others (e.g., automobile passengers, purchaser's employees). Some courts hold that the duty encompasses reasonably foreseeable risks, even if they arise from an unintended use of the product. Thus, a manufacturer may be required to warn against the consumer's own negligence in misusing the product.

To show a breach of the duty of care, a plaintiff must prove that the manufacturer failed to act as a 'reasonable person' would have acted in the same circumstances, such as by failing to provide a safety device, to test properly, or to warn of product hazards. What constitutes due care will depend on the likelihood and nature of the potential harm, balanced against the burden and cost of precautionary steps to prevent the injury. The degree of care that is required is proportionate to the risk posed by the product; the greater the danger, the greater the care that must be utilized.

The concepts of duty and proximate cause are related. Like duty, the issue of proximate cause depends on whether it is foreseeable that the manufacturer's conduct might create a risk of harm and whether the claimed injury was a foreseeable consequence of the manufacturer's conduct. Both concepts involve consideration of whether the manufacturer's responsibility should extend to the circumstances in question, as a matter of policy. Where the alleged injury is a remote consequence of the manufacturer's conduct, the claim is too attenuated and should be dismissed.

3.2. BREACH OF EXPRESS AND IMPLIED WARRANTY

An action for breach of warranty sounds in contract. The claim focuses on the condition of the goods rather than on the fault, if any, of the manufacturer in supplying the goods. Further, a claim for breach of warranty may enable a plaintiff who only suffered economic damages (i.e., loss of the product) to maintain an action that would be precluded under tort law. A warranty can be express or implied in law, and Article 2 of the Uniform Commercial Code (UCC) governs both.¹³

When a seller makes an ‘affirmation of fact or promise’ to the buyer about the goods that becomes part of the ‘basis of the bargain’, the seller creates an express warranty that the goods shall conform to the affirmation or promise; an express warranty can also arise from a ‘description’, ‘sample’, or ‘model’. The ‘basis of the bargain’ requirement is analogous to the common law requirement of reliance. The affirmation must be such that its natural tendency is to induce the buyer to purchase the product. General statements about the product’s qualities, which amount to ‘puffing’, are held not to create an express warranty.

The UCC sets forth two types of implied warranties: an implied warranty of merchantability and an implied warranty of fitness for a particular purpose.¹⁴ Under the UCC, ‘a warranty that goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind’. Among other requirements, to be merchantable, the goods must be ‘fit for the ordinary purpose for which such goods are used’ and must ‘conform to the promises or affirmations of fact made on the container or label’.¹⁵ The implied warranty of merchantability is premised on the consumer’s expectation that the product should perform like goods of the same kind. There is no need for a plaintiff to prove a specific representation or reliance in order to support a claim for breach of implied warranty of merchantability.

An implied warranty of fitness for a particular purpose is created when, at the time of the sale, ‘the seller . . . has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller’s skill or judgment to select or furnish suitable goods’.¹⁶

Some courts have suggested that breach of implied warranty is subsumed by strict liability, or that the difference between the claims is one of terminology. This approach is consistent with the Restatement (Third), which suggests that in order to prevent jury confusion, factually identical claims should not be submitted to a jury on different legal theories.¹⁷

13. UCC §§ 2-313, 2-314, 2-315 (1977).

14. UCC §§ 2-314, 2-315.

15. UCC § 2-314(1) and (2).

16. UCC § 2-315.

17. Restatement (Third) § 2 cmt. n.

Other courts have preserved the distinction between strict liability and breach of implied warranty. New York state's highest court has ruled that the claims are not coextensive, despite significant overlap, and that a manufacturer may be liable for breach of warranty, even when a claim for strict liability cannot be established. The court reasoned that the key element of defect is 'subtly different' under the two theories. The risk-benefit analysis, the court said, differentiates a strict liability claim from one for breach of warranty because the latter focuses on the consumer's expectations regarding the product's performance. Thus, the court said, liability for breach of implied warranty may be based on a finding that the product 'was not minimally safe for its expected purpose', without regard to the feasibility of alternative designs or the reasonableness of the manufacturer's design choices. At bottom, the court said, the claims have different origins—breach of warranty is derived from contract, whereas strict liability is tort-based and concerns social policy and risk allocation.¹⁸

Previously, a claim for breach of warranty required a direct contractual relationship with the defendant. Today, the privity requirement is far less constrictive,¹⁹ but the concept is still a part of the breach of warranty analysis. Privity has two aspects: vertical (who can be sued) and horizontal (who can sue). The UCC does not explicitly address vertical privity; instead, courts have determined whether vertical privity is required for a breach of implied warranty claim.²⁰ In most jurisdictions, the vertical privity requirement has been abandoned; the manufacturer and all others in the distribution chain can be held liable for breach of implied warranty. The UCC sets forth three alternative provisions regarding horizontal privity; the alternative that has been adopted by most states allows the purchaser, household members, and guests to bring a claim for breach of warranty.²¹

4. CATEGORIES OF PRODUCT DEFECT

U.S. courts have generally recognized three categories of product defect: manufacturing, design, and failure to warn or instruct.²² Thus, a product may be defective because it deviates from its specified design, the design itself is flawed, or it is not accompanied by an adequate warning.

18. *Denny v. Ford Motor Co.*, 662 N.E.2d 730 (N.Y. 1995).

19. See, e.g., *Henningesen v. Bloomfield Motors, Inc.*, 161 A.2d 69 (N.J. 1960).

20. See UCC § 2-318 cmt. 3.

21. UCC § 2-318. Other versions permit suit by any natural person or, alternatively, by 'any person' (including an individual or an organization) 'who may reasonably be expected to use, consume or be affected by the goods'.

22. See Restatement (Third) § 2.

4.1. MANUFACTURING DEFECT

A defect in manufacturing occurs as a result of a malfunction in the manufacturing process; the product is flawed in comparison to other units in the same product line because it deviates from the manufacturer's own specifications. Proof of a manufacturing defect does not require a showing that an alternative design for the product was feasible, because the basis for the claim is that the product was misconstructured.

Section 3 of the Restatement (Third) makes unnecessary proof of a specific defect. The existence of a defect may be inferred when the incident that harmed the plaintiff: (1) was of a kind that ordinarily occurs as a result of a product defect; and (2) was not solely the result of causes other than a product defect existing at the time of sale or distribution. Thus, a plaintiff alleging manufacturing defect generally must seek to disprove that something other than a defect in the product caused the incident. Moreover, the plaintiff must prove that the defect was present in the product at the time it left the defendant's control.

4.2. DESIGN DEFECT

A design defect involves an inherent flaw in the standard product design that potentially makes all units unreasonably dangerous when used in a reasonably foreseeable manner. The defect results from improper planning, design, or testing of all units in the product line. The test for determining whether a product's design is defective may depend on the legal theory on which the claim is based—that is, negligence or strict liability—but the theories as applied may be indistinguishable in the court's analysis. Thus, when examining a design defect case, courts inevitably must assess the advantages and disadvantages of the manufacturer's chosen design. Most courts apply some form of risk-utility analysis, which is 'rooted in a recognition that there are both risks and benefits associated with many products and that there are instances in which a product's inherent dangers cannot be eliminated without simultaneously compromising or completely nullifying its benefits'. Thus, 'a weighing of the product's benefits against its risks is an appropriate and necessary component of the liability assessment'.²³

Many courts have held that in order to establish a design defect claim, a plaintiff must present evidence that the product, as designed, was not reasonably safe because it presented a substantial likelihood of harm and because it was feasible to design the product in a safer manner.²⁴ Likewise, § 2(b) of the

23. 662 N.E.2d at 735.

24. See, e.g., *Adamo v. Brown & Williamson Tobacco Corp.*, 900 N.E.2d 966 (N.Y. 2008).

Restatement (Third) provides that the plaintiff must show that the product's risk of harm could have been reduced or avoided by the use of a reasonable alternative design, and that the omission of the alternative design rendered the product not reasonably safe. Many factors may be considered in determining whether an alternative design is reasonable, including the magnitude and likelihood of the potential harm, the relative advantages and disadvantages of the alternative design, its associated costs, and the instructions and warnings that accompany the product.²⁵

4.3. FAILURE TO WARN

In some instances, even if the product is properly designed, it may be defective if the manufacturer fails to provide adequate warnings about dangers inherent in the product or fails to include proper instructions for use.²⁶ In general, the manufacturer has an obligation to warn consumers of latent dangers associated with the product, of which the manufacturer is or should be aware.²⁷ Considerations in determining whether the manufacturer is required to provide a warning include, for example, the nature of the potential harm, the usefulness of a warning, foreseeable misuses of the product, the user's knowledge of the danger, and the duty and role of others, such as the consumer's physician or employer.

In assessing a manufacturer's duty to warn, U.S. courts generally hold that manufacturers must stay abreast of medical and scientific developments regarding potential hazards. Most courts hold that the manufacturer's knowledge should be determined as of the time the product left its control; thus, there is no liability for failure to warn of a danger that was unknowable at that time. Other courts, however, have ruled that in a strict liability case, it is irrelevant whether the manufacturer knew the hazards associated with the product when the manufacturer placed the product into commerce because fault is not an element of the claim. Under the Restatement (Third), the latter view is rejected, and liability for failure to warn is imposed only when the risk was foreseeable by the manufacturer at the time of distribution. The Restatement (Third) reasons that 'for the liability system to be fair and efficient', liability must be assessed based on 'knowledge of risks and risk-avoidance techniques reasonably attainable at the time of distribution'.²⁸

25. Restatement (Third) § 2 cmt. f.

26. See, e.g., *Martinez v. Dixie Carriers, Inc.*, 529 F.2d 457 (5th Cir. 1976); see also *Moore v. Ford Motor Co.*, 332 S.W.3d 749 (Mo. 2011) (discussing cases distinguishing defective design from failure to warn claims).

27. *Rastelli v. Goodyear Tire & Rubber Co.*, 591 N.E.2d 222 (N.Y. 1992).

28. Restatement (Third) § 2 cmt. a.

In evaluating the adequacy of product warnings and instructions, courts must carefully weigh a variety of concerns. As the Restatement (Third) points out, educated or experienced users ‘may benefit from inclusion of more information about the full spectrum of product risks, whereas less-educated or unskilled users may benefit from more concise warnings and instructions stressing only the most crucial risks and safe-handling practices’. Thus, there are ‘no easy guidelines’ for assessing the adequacy of product warnings and instructions, but relevant factors include the warning’s content and comprehensibility, intensity of expression, and the characteristics of expected users.²⁹

In some jurisdictions, a postsale duty to warn may arise if the manufacturer later becomes aware of a hazard associated with the product.³⁰ Relevant factors include whether the seller knows that the product poses a substantial risk of harm, whether consumers can be identified and are unaware of the risk, whether the warning can be effectively communicated and acted upon, and whether the risk of harm is great enough to justify the burden of providing the warning.³¹

5. STATUTORY MODIFICATIONS OF COMMON LAW

In many states, aspects of product liability law have been codified by statute. Thus, statutory provisions in the jurisdiction in question must be consulted in any product liability action.

For example, the New Jersey Product Liability Act³² is the ‘sole basis of relief . . . available to consumers injured by a defective product’ under state law.³³ Pursuant to the Act, negligence is no longer viable as a separate claim for harm caused by a defective product, although statutory exceptions permit actions for breach of express warranty and environmental torts.

6. FRAUD AND MISREPRESENTATION

Plaintiffs in product liability actions sometimes assert claims for fraud, fraudulent concealment, and negligent misrepresentation. These claims are often based on representations in, or omissions from, advertising and marketing materials in which the manufacturer allegedly misrepresented the safety of

29. *Ibid.*, cmt. i.

30. See, e.g., *Densberger v. United Techs. Corp.*, 297 F.3d 66 (2d Cir. 2002) (applying Connecticut law); *Adams v. Genie Indus., Inc.*, 929 N.E.2d 380 (N.Y. 2010).

31. Restatement (Third) § 10.

32. N.J. Stat. Ann. § 2A:58C-1 et seq. (West 2010).

33. *Port Auth. of N.Y. & N.J. v. Arcadian Corp.*, 189 F.3d 305, 313 (3d Cir. 1999).

the product or concealed alleged dangers. In these instances, the plaintiff must establish the traditional elements of a claim for fraud: that the defendant committed a material misrepresentation of fact (or concealed a material fact); that the defendant knew that the statement was false and intended to induce the plaintiff to rely on the misrepresentation; and that the plaintiff justifiably relied on the statement and suffered injury as a result.³⁴ However, concealment may amount to fraud only when the seller has a duty to speak; many courts hold that this requires a fiduciary or other confidential relationship with the buyer.

In order to support a claim for misrepresentation, a consumer's reliance on the manufacturer's misrepresentation must be justifiable. Thus, a consumer's supposed reliance on advertisements portraying beer as 'a positive activity, attractive and harmless' did not support a cause of action for misrepresentation, because the dangers of alcohol consumption are common knowledge and the consumer could not reasonably have relied on the advertisements to conclude that 'prolonged and excessive use of alcohol is safe and acceptable'.³⁵

Some jurisdictions have recognized a cause of action for innocent misrepresentation. The Restatement (Third) provides that a product seller or distributor who, in connection with the sale, makes a fraudulent, negligent 'or innocent' misrepresentation of material fact about the product may be liable for personal injury or property damage caused by the misrepresentation.³⁶

Under this theory, a defendant may be strictly liable for harm due to a misrepresentation (through advertisement or otherwise) regarding the character of a defective product, even though the misrepresentation was an innocent one.³⁷ Because the cause of action sounds in tort, privity is not required. At least one state high court has expressly refused to adopt this theory of liability.³⁸

Some states, by statute, impose liability if the product does not conform to the manufacturer's or supplier's representation even though the representation was not made fraudulently or negligently.³⁹

7. CONSUMER PROTECTION LAWS

Many states have passed consumer protection statutes that attempt to ease the burden on consumers in bringing fraud claims. These statutes vary in scope and accord different remedies but generally are broadly worded and prohibit

34. Restatement (Second) §§ 310, 311.

35. *Gawloski v. Miller Brewing Co.*, 644 N.E.2d 731 (Ohio Ct. App. 1994).

36. Restatement (Third) § 9; see also Restatement (Second) § 402B.

37. Restatement (Second) § 402B cmt. a.

38. See 618 N.W.2d at 845.

39. See Ohio Rev. Code Ann. § 2307.77 (West 2010).

‘unfair’ or ‘deceptive’ conduct. Statutory damages are usually limited to economic loss and are not available for personal injuries. The statutes may also allow equitable relief, treble or punitive damages, and recovery of attorneys’ fees.⁴⁰

Increasingly, plaintiffs have relied upon these statutes to support claims against product manufacturers and sellers based on alleged misrepresentations in advertising and promotional materials. Commonly, the claims are brought as purported class actions. One reason for this trend is that, in some states, the statute weakens or eliminates the reliance requirement necessary to establish a common law fraud claim. Because plaintiff-specific inquiries into reliance may not be necessary, consumer protection statutes may enable plaintiffs to repackage common law claims for fraud or misrepresentation into statutory-based class actions.⁴¹

8. DEFENCES

There are a number of defences to product liability claims.

8.1. DEFENCES BASED ON THE PLAINTIFF’S CONDUCT

Myriad defences focus on the plaintiff’s own conduct as a cause of the injuries alleged. These defences may reduce the amount of damages awarded or even completely bar the claims.

8.1.1. Contributory Negligence/Comparative Fault

Contributory negligence is a plaintiff’s failure to exercise reasonable care for his or her own safety; historically, it was a complete bar to recovery. However, nearly all U.S. jurisdictions have abandoned contributory negligence in favour of some form of comparative fault.

Under comparative fault, a plaintiff’s damages are diminished in proportion to the percentage of his or her own negligence. ‘Pure’ comparative fault jurisdictions permit the plaintiff to recover damages in an amount reduced by the plaintiff’s percentage of fault, even if such percentage exceeds that of the defendant. ‘Modified’ comparative fault jurisdictions limit a plaintiff’s recovery to a reduced amount of damages, but recovery is barred if the plaintiff’s negligence equals or exceeds the defendant’s.

40. See, e.g., N.J. Stat. Ann. § 56:8-19 (West 2010); N.Y. Gen. Bus. § 349(h) (2010); Conn. Gen. Stat. § 42-110g(a) (2009).

41. See, e.g., *Pella Corp. v. Saltzman*, 606 F.3d 391 (7th Cir. 2010).

Misuse of a product, product alteration or modification, and non-compliance with product instructions are all examples of conduct that may amount to a plaintiff's fault, depending on the case facts. When a consumer's misuse, alteration, or disregard of instructions is foreseeable, such conduct may be considered in assessing whether the manufacturer should have employed a different design, and for purposes of apportioning fault. The manufacturer may be relieved of liability where the consumer's conduct was reckless, illegal, or so unusual that the manufacturer had no duty to guard against it.

8.1.2. Assumption of Risk

A plaintiff's knowing assumption of risk may be a separate defence; often, however, the defence is subsumed under comparative fault. States that recognize assumption of risk as a separate defence tend to distinguish between primary and secondary assumption of risk (sometimes also referred to as express and implied assumption of risk, respectively).

Primary assumption of risk often arises in sporting contexts and absolves the defendant from liability where the injured participant made an informed decision about the risks involved in the activity and willingly participated in it.⁴² Primary assumption of risk is best understood as a principle of no duty—the defendant's duty is discharged by making the conditions as safe as they appear.⁴³ This is because certain activities are, or should be, known, by their nature, to involve inherent risk. A plaintiff's participation in the activity manifests his or her consent to assume the risk. However, consent does not extend to acts that are intentional or reckless.

Secondary, or implied, assumption of risk is an issue of comparative fault—the defendant's duty of care is not discharged as in primary assumption of risk, and the fact-finder must examine the relative responsibility of the parties in causing the alleged injuries.⁴⁴

8.1.3. Open and Obvious Danger

Many courts hold that a manufacturer has no duty to warn of dangers that are patent or commonly known—a warning is unnecessary where the risk of

42. *Morgan v. State*, 685 N.E.2d 202, 207 (N.Y. 1997); compare *Anand v. Kapoor*, 15 N.Y.3d 946, 948 (N.Y. 2010) (dismissing claims of golfer who was hit in the eye by a misdirected ball because the manner of injury 'reflects a commonly appreciated risk of golf'), with *Ashbourne v. City of New York*, 82 A.D.3d 461 (1st Dep't 2011) (reversing summary judgment dismissal of action because injured rollerblader did not consent to the negligent maintenance of a public sidewalk).

43. *Turcotte v. Fell*, 502 N.E.2d 964, 967 (N.Y. 1986).

44. See generally, *Trupia ex rel. Trupia v. Lake George Cent. Sch. Dist.*, 927 N.E.2d 547 (N.Y. 2010).

injury is open and obvious. For example, in *Robinson v. Brandtjen & Kluge, Inc.*, the plaintiff brought suit claiming failure to warn of the dangers involved in feeding paper into a printing press, after her hand was caught in the device. In affirming dismissal of the case, the court held that '[t]he danger of placing one's hand between two massive and converging metal surfaces is sufficiently obvious that no warning is necessary'.⁴⁵

The open and obvious doctrine may not, however, provide manufacturers complete protection from failure-to-warn claims. For example, in *Liriano v. Hobart Corp.*, a federal appeals court upheld a plaintiff's verdict for a meat cutter who injured his hand while operating a meat grinder that lacked a safety guard.⁴⁶ The court reasoned that even though meat grinders are widely known to be dangerous, the jury could properly find that the plaintiff should have been warned not to use the meat grinder without a safety guard because some meat cutters might be unaware that such safety devices exist.

8.2. LEARNED INTERMEDIARY AND SOPHISTICATED USER

The 'learned intermediary' and 'sophisticated user' defences arise out of the same policy considerations as the open and obvious danger rule, that is, there is an understanding that the ultimate user is, or will be made, aware of the product's risks.

The 'learned intermediary' defence is generally asserted by pharmaceutical and medical device manufacturers to argue that their duty is limited to providing adequate warnings and information about the product's risks to intermediary persons (such as healthcare professionals) who prescribe the product. The policy behind this defence is that the intermediary is better-positioned than the manufacturer to communicate to the ultimate user information about product usage and risks (e.g., a trusted doctor who is familiar with the patient's health history and is better-positioned to evaluate pertinent safety concerns).⁴⁷

Likewise, the 'sophisticated user' defence may exempt a manufacturer from the duty to warn end-users about risks associated with the product. This defence generally arises under two scenarios; in both, a warning would have little effect in deterring product use: (i) where the warning is conveyed to the user through a 'sophisticated' or knowledgeable purchaser of the product (e.g., a medical professional or the user's employer); and (ii) where the user is a 'professional' or has particular expertise relating to

45. 500 F.3d 691, 696–97 (8th Cir. 2007).

46. 170 F.3d 264 (2d Cir. 1999).

47. Mass inoculations (e.g., clinics giving flu shots) may present an exception to the 'learned intermediary' rule; in such circumstances, the manufacturer is under a duty to directly warn the patient of the risks of the vaccines because of the unsupervised nature of the vaccinations. See Restatement (Third) § 6 cmt. e.

the product. Where the manufacturer or supplier reasonably believes that the end-user does or will recognize the product's risks due to specialized circumstances, no warnings to the end-user are required.⁴⁸

8.3. INTERVENING AND SUPERSEDING CAUSES

A defendant may raise the defence of intervening or superseding cause where an independent act that was neither anticipated nor reasonably foreseeable—and which is itself adequate to bring about the resulting injury—breaks the causal nexus between the defendant's negligence and the resulting injury. Examples of intervening/superseding causes include forces of nature, the act of a third party, or even the acts of the plaintiff.⁴⁹ Likewise, where the intervening act is criminal, the burden is on the plaintiff to establish 'that the criminal act was so foreseeable that a duty arises to guard against it'.⁵⁰

8.4. COMPLIANCE WITH STATUTES, REGULATIONS, AND INDUSTRY STANDARDS

Statutes and safety regulations that set forth specific guidelines for manufacturers may establish a minimum standard of care. Compliance with applicable statutes and regulations usually is a factor considered in determining whether the manufacturer exercised due care. As the Restatement (Third) provides:

a product's compliance with an applicable product safety statute or administrative regulation is properly considered in determining whether the product is defective with respect to the risks sought to be reduced by the statute or regulation, but such compliance does not preclude as a matter of law a finding of product defect.⁵¹

Typically, compliance provides a rebuttable presumption in the defendant's favour.⁵²

Similarly, evidence that the manufacturer complied with (or deviated from) industry custom and practice may be offered to show that the manufacturer exercised (or failed to exercise) due care, but a manufacturer's compliance with industry custom and practice does not preclude a finding of liability.⁵³

48. See, e.g., *O'Neal v. Celanese Corp.*, 10 F.3d 249, 251 (4th Cir. 1993); *Insua v. JD/BBJ, LLC*, 913 So. 2d 1262, 1264 (Fla. Dist. Ct. App. 2005).

49. See W. Page Keeton et al., *Prosser and Keeton on the Law of Torts* 301 (5th edn 1984).

50. *Clark v. Flach*, 604 F. Supp. 2d 1, 5 n.7 (D.D.C. 2009) (emphasis in original).

51. Restatement (Third) § 4(b).

52. See, e.g., Fla. Stat. Ann. § 768.1256 (West 2010); Colo. Rev. Stat. Ann. § 13-21-403(2) (West 2005).

53. See Restatement (Third) § 4.

Some states expand the defence to provide a rebuttable presumption if the product was manufactured or designed in compliance with industry standards *or other nongovernmental regulations or standards*.⁵⁴ Other states limit the defence only to the defendant's compliance with industry standards.⁵⁵

8.5. CONTRACTUAL DEFENCES/DISCLAIMERS

Contractual defences such as disclaimers are generally inapplicable in product liability cases other than those alleging breach of warranty. Some courts have held that allowing suppliers and manufacturers to disclaim liability for injuries caused by defective products violates public policy.

Contract-based defences generally are inapplicable in strict liability actions.⁵⁶ However, some courts have given effect to disclaimers or exculpatory clauses in strict liability actions involving commercial parties, reasoning that public policy is not violated where, for example, the parties are commercial entities of equal bargaining power; the exculpatory clause is clear and unambiguous; there is no evidence of fraud or duress, or contrary legislative directive; and the damage at issue involves property, not physical harm.⁵⁷

8.6. STATE-OF-THE-ART

The 'state-of-the-art' defence may protect manufacturers from liability if the product was designed, manufactured and tested in accordance with the best known standards existing at the time. This defence is available by statute or by case law in most, but not all, states. In states where the defence is available, the degree of protection varies. Some states' state-of-the-art defence provides manufacturers with a complete shield against liability;⁵⁸ others provide a rebuttable presumption of non-defectiveness.⁵⁹

8.7. FEDERAL PRE-EMPTION

Unique to U.S. jurisprudence is the defence of federal pre-emption, which implements the mandate of the U.S. Constitution that federal laws trump state

54. N.D. Cent. Code Ann. § 28-01.3-09 (West 2009).

55. Ark. Code Ann. § 16-116-104(2) (West 2009).

56. Restatement (Second) § 402A cmt. m.

57. *Chicago Steel Rule & Die Fabricators Co. v. ADT Sec. Sys., Inc.*, 763 N.E.2d 839 (Ill. App. Ct. 2002).

58. See, e.g., N.J. Stat. Ann. 2A:58C-3.

59. See, e.g., Ky. Rev. Stat. 411.310(2) (West 2009); Colo. Rev. Stat. § 13-21-403(1) (West 2010).

laws that ‘interfere with, or are contrary to’ them.⁶⁰ Common law tort (e.g., failure to warn and design defect) and statutory (e.g., consumer protection) claims are generally considered to be state legal requirements subject to potential pre-emption by federal law.

Traditionally, courts recognize a presumption *against* pre-emption in light of the tradition of allowing states wide autonomy to regulate conduct affecting their interests, with limited federal interference. Thus, under certain circumstances, courts have concluded that Congress intended federal requirements to complement, rather than supplant, state requirements.⁶¹ The U.S. Supreme Court has observed that, particularly in fields which the states have traditionally occupied, courts ‘start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress’.⁶²

The U.S. product liability bar has a strong interest in the development of federal pre-emption doctrine. From defendants’ perspective, favourable pre-emption rulings can result in the pretrial dismissal of state-law claims (sometimes before costly document and other discovery has commenced), and may deter the filing of similar claims. From plaintiffs’ perspective, avoiding pre-emption may allow them to present tort claims to juries who tend to focus more on a product’s safety risks than on the balance between such risks and the product’s efficacy intentionally struck by those with greater technical or scientific expertise (such as a federal agency).⁶³

Congressional intent or purpose is the cornerstone of every pre-emption analysis. A pre-emptive intent may be express (i.e., based upon the express language of the applicable law) or implied. Federal law, federal regulations, and even, in some instances, formal administrative agency action, may have pre-emptive effect.⁶⁴

Implied pre-emption may arise from the pervasive depth and breadth of a congressional scheme that occupies the legislative field (‘field pre-emption’), or because state-law conflicts with a congressional enactment that either renders it ‘impossible for a private party to comply with both state and federal requirements’, or where state law ‘stands as an obstacle to the accomplishment

60. *Gibbons v. Ogden*, 22 U.S. (9 Wheat.) 1, 211 (1824) (Marshall, C.J.).

61. See, e.g., *Wyeth v. Levine*, 555 U.S. 555 (2009).

62. *Ibid.*, at 560.

63. See *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 325 (2008); see also *Bruesewitz v. Wyeth LLC*, 131 S.Ct. 1068, 1080 (2011) (statute as drafted ‘reflects a sensible choice to leave complex epidemiological judgments about vaccine design to the [Federal Drug Administration] and the National Vaccine Program rather than juries’).

64. Compare, e.g., *Geier v. Am. Honda Motor Co.*, 529 U.S. 861 (2000) (finding federal automobile regulation pre-empted state tort suit), with *Williamson v. Mazda Motor of Am., Inc.*, 131 S.Ct. 1131 (2011) (finding a different section of an amended version of the same federal regulation did not have pre-emptive effect).

and execution of the full purposes and objectives of Congress'⁶⁵ ('conflict' or 'obstacle' pre-emption).

A few general principles have guided pre-emption analysis. Courts often carefully examine the text, context and legislative history of the relevant federal law to determine whether Congress expressly or by implication intended to preempt state law. In addition, particularly in conflict pre-emption disputes, courts also review the role of federal agencies vested with authority to regulate the design and/or promotion of various products, such as the Food and Drug Administration (FDA), the Federal Trade Commission, and the Consumer Product Safety Commission.⁶⁶ Assessing the depth, breadth and consistency of these agencies' regulations is often an essential component of divining whether Congress intended for federal requirements to pre-empt state laws.

After determining the scope of relevant federal legal requirements, courts then examine state requirements (e.g., the specific state-law tort duty that plaintiff alleges was breached) to evaluate whether such requirements impose conflicting duties with federal law.

The U.S. Supreme Court has issued several recent decisions involving a variety of products, reflecting – with one notable exception – the Court's unwillingness to displace state law absent a clear articulation of Congressional intent to do so.

Riegel v. Medtronic, Inc., a medical device case, demonstrates a clear-cut application of express pre-emption based on Congress' stated intent to preempt state law reflected in a federal statute. The Court held that a manufacturer of a catheter subjected to a 'rigorous' pre-approval process was shielded from claims that sought to impose requirements other than those imposed by the FDA.⁶⁷ The Court determined that the plaintiffs' state-law tort claims alleging that Medtronic had negligently designed and labelled its catheter were expressly pre-empted by a Congressional statute that prohibits states from establishing any requirement which is different from, or in addition to, any requirement applicable under [federal law] to the device. . . .'⁶⁸

Riegel notwithstanding, even where a federal statute contains an express pre-emption clause, state-law claims may not necessarily be pre-empted. In *Altria Group Inc. v. Good*, a 5-4 majority concluded that the Federal Cigarette Labeling and Advertising Act (Labeling Act) did not expressly preempt claims

65. *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995); see, e.g., *Geier v. Am. Honda Motor Co.*, 529 U.S. 861 (2000).

66. See 21 U.S.C. §§ 301 et seq. (2006) (Federal Food, Drug, and Cosmetic Act); 15 U.S.C. §§ 41–58 (2006) (Federal Trade Commission Act); 15 U.S.C. §§ 2051–2089 (2006) (Consumer Product Safety Act).

67. 552 U.S. at 317, 328; but see *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996) (finding no pre-emption of state tort claims involving a medical device that was not subject to premarket approval, but had been approved under a less rigorous process).

68. 552 U.S. at 316; see also 131 S.Ct. 1068 (finding that state-law design-defect claims were preempted because the language of the childhood vaccine statute at issue clearly deemed adverse side effects, including those resulting from the vaccine's design, to be 'unavoidable' provided proper manufacture and warning).

brought pursuant to a Maine consumer protection statute alleging that a cigarette manufacturer had defrauded plaintiffs by using advertising descriptors such as 'lights' and 'low tar' to imply that such cigarettes were less harmful than regular cigarettes. The Court held that Congress did not intend for the Labeling Act's express pre-emption clause to preclude fraudulent misrepresentation claims regarding low tar descriptors, because these claims were based on a general state law 'duty not to deceive', rather than a more narrowly defined duty to provide specific health information about cigarettes.⁶⁹

In *Wyeth v. Levine*, a case involving an anti-nausea medication, the Supreme Court determined that the FDA's decades-long regulation and continued approval of the warning labelling for Phenergan did not pre-empt a claim for failure to warn. Plaintiff alleged that the manufacturer should have provided a stronger warning regarding the risks of gangrene if Phenergan was administered intravenously via the 'IV-push' method. The majority concluded that the manufacturer 'failed to demonstrate that it was impossible for it to comply with both federal and state requirements', because the mere fact that the FDA approved the manufacturer's label did not establish that a stronger warning could not have been used. The Court reasoned that 'it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times', and that state tort suits complement rather than frustrate federal regulatory goals by 'uncover[ing] unknown drug hazards and provid[ing] incentives for drug manufacturers to disclose safety risks promptly'.⁷⁰

Yet, in a decision that some may view as a direct contradiction of *Wyeth*, a majority of the Court held in *Pliva, Inc. v. Mensing*,⁷¹ that state-law failure to warn claims against manufacturers of a generic drug used to treat digestive tract problems were conflict pre-empted due to the impossibility of the manufacturers' compliance with both state and federal law. Specifically, the majority found that the generic manufacturers could not simultaneously comply with, first, the federal requirement that generic drug labels at all times match those of the corresponding brand-name drug, as well as second, their state-law duty (as alleged) to provide a safer, stronger warning regarding the long-term neurological effects of the drug's use. The Court distinguished its decision in *Wyeth* by focusing on the differing federal laws that apply to brand-name versus generic drugs. Because a federal regulation permitted a brand-name drug manufacturer like *Wyeth* to take the unilateral step to provide a stronger warning without prior FDA approval, and *Wyeth* had offered no clear evidence that the FDA would have rescinded such a change in the warning, the Court found that *Wyeth* had failed to demonstrate the impossibility of complying with both federal and state laws.⁷²

69. 555 U.S. 70 (2008).

70. 555 U.S. 555, 562-65, 568-69.

71. 131 S.Ct. 2567 (2011).

72. *Ibid.*, at 2577-78, 2581.

In line with the *Wyeth* decision, recent rulings involving food and beverage manufacturers display a willingness by some courts to permit state-law claims to coexist alongside an extensive federal regulatory scheme.⁷³

9. DEVELOPMENTS IN U.S. PRODUCT LIABILITY LITIGATION

9.1. PUBLIC NUISANCE

With increasing frequency, the doctrine of public nuisance has been imported into the product liability arena in cases involving a variety of products, including lead paint, asbestos, tobacco, fire arms and fossil fuels.

For example, various state and local governments have sued to recover from manufacturers the costs of detecting and removing lead paint from homes and buildings, and of providing medical care to residents affected by lead poisoning. The lawsuits effectively sought to aggregate state-wide claims without meeting class action requirements and without proving the essential elements of product liability claims.

In *State v. Lead Indus. Ass'n Inc.*, the Rhode Island Supreme Court reversed a judgment for public nuisance against manufacturers for health problems allegedly caused by lead paint in private homes, which had awarded statewide abatement costs estimated in the billions of dollars. The court rejected the state's effort to impose liability merely for manufacturing and marketing lead paint:

[E]ven if a lawsuit is characterized as a public nuisance cause of action, the suit nonetheless sounds in products liability if it is against a manufacturer based on harm caused by its products. Regardless of the label placed on the cause of action, the elements of products liability still must be met to properly maintain such a product-based proceeding. It is essential that these two causes of action remain just that—two separate and distinct causes of action.⁷⁴

The court recognized that allowing public nuisance claims to be applied in this context would 'open the courthouse doors to a flood of limitless, similar

73. *Holk v. Snapple Beverage Corp.*, 575 F.3d 329 (3d Cir. 2009) (reversing lower court's dismissal on implied pre-emption grounds of class action against beverage manufacturer arising out of the use of the term 'All Natural' in its advertising); *Wright v. Gen. Mills, Inc.*, No. 08cv1532, 2009 WL 3247148 (S.D. Cal. 30 Sep. 2009) (finding no pre-emption of claims for misleading advertising and packaging against granola bar manufacturer); *Lockwood v. Conagra Foods, Inc.*, 597 F. Supp. 2d 1028 (N.D. Cal. 2009) (denying manufacturer's motion to dismiss action for misleading advertising of pasta sauce).

74. 951 A.2d 428, 457 (R.I. 2008). A California court applied similar reasoning in affirming the dismissal of a municipality's public nuisance action against asbestos manufacturers. See *City of San Diego v. U.S. Gypsum*, 35 Cal. Rptr. 2d 876 (Cal. Ct. App. 1994); see also *Tioga Pub. Sch. Dist. No. 15 v. U.S. Gypsum Co.*, 984 F.2d 915 (8th Cir. 1993) (dismissing nuisance claims seeking recovery of the cost of removing asbestos-containing products).

theories of public nuisance . . . against a wide and varied array of other commercial and manufacturing enterprises and activities'.⁷⁵ Other state courts have likewise rejected governments' public nuisance claims against lead paint manufacturers.⁷⁶

A California appellate court, however, refused to dismiss a class action brought by various governmental entities against paint manufacturers. The court ruled that the nuisance claim could proceed because it was premised on the defendants' alleged promotion of lead paint despite knowledge of the potential hazard this would create, even though the plaintiffs also alleged traditional product liability claims.⁷⁷

In lawsuits against firearm manufacturers, various state and local governments alleged that the defendants' marketing practices created an unreasonable threat to public safety because they knowingly permitted illegal sales. Several courts dismissed these actions on various grounds: the lawful sale of products does not meet the requirement that the alleged nuisance interfere 'with a right common to the general public'; the manufacturers lacked control over the nuisance-causing instrumentality; and any alleged injuries are too remote from the conduct complained of to permit recovery.⁷⁸ In other cases, however, public nuisance claims were allowed to proceed against gun manufacturers on the ground that a public nuisance action 'can be maintained for injuries caused by a product if the facts establish that the design, manufacturing, marketing, or sale of the product unreasonably interferes with a right common to the general public.'⁷⁹

Several recent court decisions have dismissed public nuisance claims in the context of litigation involving greenhouse gas emissions, air pollution, and climate change. In one, the U.S. Supreme Court reversed the Second Circuit appellate court's decision permitting federal public nuisance claims by several states, a municipality and others against defendant power plants for greenhouse gas emissions that allegedly contributed to global warming. Specifically, the Court determined that the 'federal common law of nuisance' (upon which the Second Circuit had relied) was 'displaced' by federal legislation authorizing the Environmental Protection Agency (EPA) to regulate power plant emissions. Because the EPA is expected to issue its standards for such emissions within the forthcoming year, the Court found 'no room for a parallel track' through court intervention at this juncture.⁸⁰ In another action,

75. 951 A.2d at 457.

76. *City of St. Louis v. Benjamin Moore & Co.*, 226 S.W.3d 110 (Mo. 2007); *In re Lead Paint Litig.*, 924 A.2d 484 (N.J. 2007).

77. *County of Santa Clara v. Atl. Richfield Co.*, 40 Cal. Rptr. 3d 313 (Cal. Ct. App. 2006).

78. See, e.g., *Camden County Bd. of Chosen Freeholders v. Beretta, U.S.A. Corp.*, 273 F.3d 536 (3d Cir. 2001); *City of Chicago v. Beretta U.S.A. Corp.*, 821 N.E.2d 1099 (Ill. 2004); *Ganim v. Smith & Wesson Corp.*, 780 A.2d 98 (Conn. 2001).

79. *City of Cincinnati v. Beretta U.S.A. Corp.*, 768 N.E.2d 1136, 1142 (Ohio 2002).

80. *Am. Elec. Power Co. v. Connecticut*, 131 S.Ct. 2527, 2538 (2011).

a federal appellate court dismissed a state's public nuisance claim arising out of interstate air emissions from the defendant's coal-fired plants.⁸¹

9.2. MARKET SHARE LIABILITY

The theory of market share liability eases a plaintiff's usual burden of proof in product liability cases. It allows a consumer to recover damages without proof that a particular manufacturer's product caused the injuries, where the product is fungible with others on the market and the identity of the particular manufacturer cannot be proven. Under this theory, a plaintiff may seek damages from each manufacturer in proportion to the manufacturer's share of the total market for the product; the burden of proof shifts to the manufacturer to show that it could not have made the specific product that injured the plaintiff.⁸²

Market share liability originated in cases involving diethylstilbesterol (DES), a synthetic estrogen once prescribed to prevent miscarriage but which caused various health problems among women exposed *in utero*. Plaintiffs were often unable to identify which particular manufacturer had supplied the drug to their mothers, because a large number of manufacturers used an identical drug formula, and because of the long passage of time between exposure and resulting injury, and lack of adequate records. California's Supreme Court ruled 4-3 that there were 'forceful arguments' for allowing the plaintiff to proceed with her claims against 11 drug companies, even though she could not prove any of them actually made the drug consumed by her mother. The court explained that 'as between an innocent plaintiff and negligent defendants, the latter should bear the cost of the injury', as imposition of liability 'will provide an incentive to product safety'. The court held that the claims could proceed if the plaintiff joined as defendants enough manufacturers to constitute a 'substantial share' of the market.⁸³ The burden would shift to each defendant to show that it did not make the particular product in question; damages, if any, would be apportioned among the remaining defendants according to the market share held by each.

The doctrine was adopted or modified by some states⁸⁴ in DES cases but rejected by others.⁸⁵ The latter reasoned that the doctrine would 'abrogate a fundamental precept of tort law', broaden manufacturers' potential liability,

81. *N.C. ex rel. Cooper v. Tenn. Valley Auth.*, 615 F.3d 291 (4th Cir. 2010); see also *Native Vill. of Kivalina v. ExxonMobil Corp.*, 663 F. Supp. 2d 863 (N.D. Cal. 2009), *appeal pending*, No. 09-17490 (9th Cir.) (dismissing village's lawsuit against energy and utility companies alleging that global climate change caused by defendants threatened the habitability of the village).

82. See generally *Sindell v. Abbott Labs.*, 607 P.2d 924 (Cal. 1980).

83. *Ibid.*, at 936-37.

84. *Conley v. Boyle Drug Co.*, 570 So. 2d 275 (Fla. 1990); *Hymowitz v. Eli Lilly & Co.*, 539 N.E.2d 1069 (N.Y. 1989); *Martin v. Abbott Labs.*, 689 P.2d 368 (Wash. 1984).

85. *Smith v. Eli Lilly & Co.*, 560 N.E.2d 324 (Ill. 1990); *Mulcahy v. Eli Lilly & Co.*, 386 N.W.2d 67 (Iowa 1986); *Zafft v. Eli Lilly & Co.*, 676 S.W.2d 241 (Mo. 1984).

diminish product research and development (without necessarily improving product safety), and turn individual manufacturers into insurers for the entire industry.⁸⁶

Outside the DES context, plaintiffs in a lawsuit involving injury allegedly caused by DPT vaccine have been permitted by a California federal court to invoke market share liability,⁸⁷ but New Jersey's Supreme Court rejected application of the doctrine to vaccine manufacturers on the ground that public policy considerations weigh against expanding liability.⁸⁸ The doctrine has also been applied in litigation involving plasma,⁸⁹ but courts have largely refused to impose market share liability in cases involving asbestos⁹⁰ and lead paint.⁹¹

9.3. MEDICAL MONITORING CLAIMS

Medical monitoring is a non-traditional tort claim that has developed in some states to allow plaintiffs who have been exposed to harmful substances to recover medical expenses incurred to test for the development of a latent disease, where the plaintiff has not suffered a manifest physical injury. In these cases (typically brought as class actions), the plaintiffs assert that the manufacturer is liable for the cost of periodic medical testing to detect and facilitate treatment for injuries that may arise in the future. Under traditional tort rules, the plaintiffs' claims would be precluded by the lack of a current injury.

U.S. courts have adopted divergent views toward medical monitoring claims. Some courts permit recovery even in the absence of a current physical illness,⁹² reasoning that the claim is consistent with the goal of the tort system to deter manufacturers from irresponsible conduct, and encourages plaintiffs to detect and treat injuries as soon as possible.⁹³

Other courts refuse to recognize medical monitoring claims. In *Badillo v. Am. Brands, Inc.*, the Supreme Court of Nevada refused to allow a medical monitoring claim for exposure to second-hand tobacco smoke because creating new causes of action is 'a legislative, not a judicial, function'. The court also cited the 'many complex issues of legal causality and proof' that would arise, including uncertainty about the length and intensity of exposure

86. See, e.g., 560 N.E.2d at 341–44.

87. See *Morris v. Parke, Davis & Co.*, 667 F. Supp. 1332 (C.D. Cal. 1987).

88. *Shackil v. Lederle Labs., a Div. of Am. Cyanamid Co.*, 561 A.2d 511 (N.J. 1989).

89. *Smith v. Cutter Biological, Inc., a Div. of Miles, Inc.*, 823 P.2d 717 (Haw. 1991).

90. See, e.g., *Perrin v. AC&S*, 68 F.3d 1122 (8th Cir. 1995); *Robertson v. Allied Signal, Inc.*, 914 F.2d 360 (3d Cir. 1990); but see *Wheeler v. Raybestos-Manhattan*, 11 Cal. Rptr. 2d 109 (Cal. Ct. App. 1992) (plaintiff could bring action under market share theory against manufacturers of asbestos-containing brake pads).

91. See *Santiago v. Sherwin Williams Co.*, 3 F.3d 546 (1st Cir. 1993).

92. See, e.g., *In re Tobacco Litig.*, 600 S.E.2d 188 (W. Va. 2004); *Redland Soccer Club, Inc. v. Dep't of the Army*, 696 A.2d 137 (Pa. 1997).

93. See, e.g., *In re Paoli R.R. Yard PCB Litig.*, 916 F.2d 829 (3d Cir. 1990).

necessary to increase significantly the risk of disease and the potential impact of contributing risk factors unrelated to the defendants' products.⁹⁴

Similarly, in a case arising under federal common law and the Federal Employers' Liability Act, the U.S. Supreme Court held that, absent symptoms of present physical harm, a plaintiff is not entitled to recover costs for future medical examinations to detect latent diseases such as cancer. The Court cautioned against medical monitoring claims, noting, for example, uncertainty among medical professionals concerning which additional tests would be most useful, and the corresponding difficulties in determining what 'extra' monitoring beyond usual medical care would be needed. Additionally, the Court expressed concern over the 'unlimited and unpredictable liability' that would result if actual injury were not required to support recovery of medical expenses, given the vast number of people exposed to potentially harmful substances, and that a 'flood' of medical monitoring claims against a particular manufacturer would impair recovery by the more severely injured.⁹⁵ Consistent with this reasoning, several state high courts have held that recovery for medical monitoring is permissible only where the plaintiff can demonstrate a present physical injury.⁹⁶

Medical monitoring claims are also the subject of specific legislation in some states.⁹⁷

9.4. THIRD-PARTY PAYORS' COST REIMBURSEMENT CLAIMS

The U.S. has witnessed a rising number of lawsuits brought not by injured consumers, but by third parties whose claims are indirect. Claimants such as state and local governments, healthcare providers, insurance companies, and health and benefit trust funds have sought reimbursement for medical and other expenses allegedly incurred on behalf of injured consumers. Manufacturers and distributors have advanced various defences to reimbursement claims, including lack of standing, lack of proximate cause due to the indirect nature of the claim, and the speculative nature of claims for future expenditures.

Because the plaintiffs in these actions do not assert any direct injury caused by a defective product, a number of courts have rejected reimbursement

94. 16 P.3d 435, 440–41 (Nev. 2001); see also *Sheridan v. NGK Metals Corp.*, 609 F.3d 239 (3d Cir. 2010) (affirming summary judgment dismissal of medical monitoring class action claim due to plaintiffs' failure to prove Pennsylvania law's requirement that toxic exposure proximately caused a significantly increased risk of contracting a serious latent disease).

95. *Metro-North Commuter R.R. Co. v. Buckley*, 521 U.S. 424, 441–42 (1997).

96. See, e.g., *Sinclair v. Merck & Co., Inc.*, 948 A.2d 587 (N.J. 2008); *Lowe v. Philip Morris USA, Inc.*, 183 P.3d 181 (Or. 2008). Medical monitoring claims have also been brought on the theory that subclinical or subcellular changes in the body, absent symptomatic manifestations of disease, constitute a present physical injury so as to permit recovery for medical monitoring costs. Such a claim was allowed in *Donovan v. Philip Morris USA, Inc.*, 914 N.E.2d 891 (Mass. 2009), but rejected in *June v. Union Carbide*, 577 F.3d 1234 (10th Cir. 2009).

97. See, e.g., La. Civ. Code Ann. Art. 2315 (1999); Fla. Stat. Ann. § 774.204 (West 2010).

claims based on ‘remoteness’, that is, the disconnect between a third-party’s injury (e.g., increased healthcare costs for injured consumers) and the alleged tort committed by the defendant.⁹⁸ For example, in *Blue Cross and Blue Shield of N.J., Inc. v. Philip Morris USA Inc.*, the NY Court of Appeals held that a third-party payor of medical expenditures may not recover for injuries suffered by its insured, and lacked standing to sue under a state consumer protection statute. The court observed that ‘what is required is that the party actually injured be the one to bring suit’. Because the plaintiff-insurer ‘was not directly injured in this sense’, the court concluded that its claims were too remote and that it lacked a cognizable injury.⁹⁹

Similarly, in *Ashley County v. Pfizer, Inc.*, the plaintiff counties sued makers of non-prescription cold medications on the theory that the defendants sold their products in a manner that permitted the illicit manufacture of methamphetamine. The plaintiffs sought recoupment of the costs of law enforcement, healthcare, and other government services. The court affirmed judgment for the defendants, concluding that cold medicine sales were not the proximate cause of a methamphetamine epidemic and increased government costs.¹⁰⁰

In contrast, the court in *Desiano v. Warner-Lambert Co.* concluded that health insurers had suffered direct economic injuries in connection with the purchase price of a diabetes medication, which the insurers claimed they would not have funded but for misrepresentations concerning the drug’s side effects. Finding that the plaintiffs’ economic injuries were ‘unaffected by whether any given patient who ingested Rezulin became ill’, the court held that the plaintiffs had stated a cognizable claim against the drug’s manufacturer.¹⁰¹

9.5. SUITS UNDER THE ALIEN TORT CLAIMS ACT

The Alien Tort Claims Act (ATCA) is an antipiracy statute dating back to 1789, but developing case law has encouraged foreign claimants in a variety of contexts, including product liability, to rely on the statute in seeking relief in U.S. courts for injuries suffered overseas. The statute grants to federal district courts jurisdiction over ‘any civil action by an alien for a tort only, committed in violation of the law of nations or a treaty of the United States’.¹⁰²

The U.S. Supreme Court has recognized that the ATCA grants jurisdiction to federal courts to hear a ‘very limited category’ of claims by private parties. The

98. See, e.g., *City of Philadelphia v. Beretta U.S.A. Corp.*, 277 F.3d 415, 423 (3d Cir. 2002); *UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121 (2d Cir. 2010); but see *City of Cincinnati v. Beretta U.S.A. Corp.*, 768 N.E.2d 1136 (Ohio 2002).

99. 818 N.E.2d 1140, 1145 (N.Y. 2004).

100. 552 F.3d 659 (8th Cir. 2009).

101. 326 F.3d 339, 349 (2d Cir. 2003).

102. 28 U.S.C. § 1350 (2006).

Court stressed that such claims must be based upon international norms that reflect ‘definite content and acceptance among civilized nations’, and that courts should exercise ‘great caution in adapting the law of nations to private rights’.¹⁰³

Notwithstanding these strictures, some courts have accepted an expanded view of international law, and have upheld federal court jurisdiction over claims against product manufacturers under the ATCA. In *Abdullahi v. Pfizer, Inc.*, for example, citizens of Nigeria claimed that a U.S. drug manufacturer, in concert with Nigerian officials, conducted clinical trials of a newly-developed antibiotic without obtaining informed consent. They claimed that the manufacturer knew that the antibiotic had life-threatening side effects, and sought damages for a variety of injuries. The court held that the plaintiffs had alleged facts sufficient to state a claim that the manufacturer violated ‘the norm of customary international law prohibiting medical experimentation on human subjects without their consent’.¹⁰⁴

In contrast, in *Vietnam Ass’n for Victims of Agent Orange v. Dow Chemical Co.*, the court affirmed the dismissal of claims against manufacturers of Agent Orange and other herbicides deployed by the U.S. military during the Vietnam War, finding that the record showed that Agent Orange was used as a defoliant and not as a poison targeted at human populations; therefore, the plaintiffs did not allege a violation of any well-defined and universally-accepted rule of international law.¹⁰⁵

The continuing viability of ATCA claims against corporate product manufacturers recently has fallen into question, at least in the Second Circuit, following that court’s announcement of a bright-line rule rejecting subject matter jurisdiction under ATCA over corporations.¹⁰⁶ Other federal appellate courts, however, have decided the issue differently, and continue to hold that ATCA claims may be brought against corporate entities.¹⁰⁷

10. CLASS ACTIONS

Class actions have been a feature of the U.S. legal system for over forty years. In these types of lawsuits, an individual or a small group of individuals brings a claim on behalf of others who are similarly situated. Class actions may be filed in federal or state court. The court is required to ‘certify’ the proposed

103. *Sosa v. Alvarez-Machain*, 542 U.S. 692, 712, 728, 732 (2004).

104. 562 F.3d 163, 187 (2d Cir. 2009), *abrogated on other grounds by Kiobel v. Royal Dutch Petroleum Co.*, 621 F.3d 111 (2d Cir. 2010).

105. 517 F.3d 104 (2d Cir. 2008).

106. *Kiobel v. Royal Dutch Petroleum Co.*, 621 F.3d 111 (2d Cir. 2010), *cert. granted*, 2011 WL 4905479 (U.S. 17 Oct. 2011).

107. See, e.g., *Flomo v. Firestone Nat. Rubber Co.*, 643 F.3d 1013, 1017 (7th Cir. 2011), *Doe v. Exxon Mobil Corp.*, Nos. 09-7125, 09-7127, 09-7134, 09-7135, 2011 WL 2652384 (D.C. Cir. 8 July 2011), *Sinaltrainal v. Coca-Cola Co.*, 578 F.3d 1252 (11th Cir. 2009).

class of litigants as having satisfied specific requirements before the action may proceed on the merits.

Federal court actions are governed by Rule 23 of the Federal Rules of Civil Procedure. At the state court level, a majority of the fifty states has adopted some form of Rule 23 in their local procedural rules.

Class actions allow for a single proceeding to determine the merits of many plaintiffs' claims, which in turn may prevent costly repeat litigation, duplicative discovery, and potentially inconsistent adjudications. Yet, class actions may contribute to the increasing number of lawsuits filed in already-congested court systems, and risk error if complex issues with significant consequences are decided by one fact-finder rather than by a consensus of multiple, separate trials. Nevertheless, for some plaintiffs, a class action may provide a remedy when it is not economically feasible or prudent to obtain relief through a traditional individual lawsuit because the claim may involve a minor amount that would be far surpassed by the inevitable litigation expenses.

10.1. CLASS ACTION REQUIREMENTS

Rule 23 imposes a two-pronged test for certification: the proposed class must meet four requirements under subsection (a) of the Rule, and at least one category identified in subsection (b). For product liability actions in which plaintiffs seek the recovery of monetary damages, the relevant subsection of Rule 23(b) is subpart (3).¹⁰⁸

A threshold inquiry, however, is the existence of a 'definable class', that is, a court must be able to ascertain whether a particular individual is a class member based on objective criteria.¹⁰⁹ A proper class definition is of critical importance because it identifies the persons bound by the judgment, and thus entitled to notice so that they may exercise the right to opt-out of the class and bring individual actions.¹¹⁰

10.1.1. Rule 23(a) Requirements

The four Rule 23(a) criteria that a proposed class must satisfy are: (1) numerosity; (2) commonality; (3) typicality; and (4) adequacy of representation. The burden of proof with respect to each requirement is on the party seeking certification. The first two requirements aim to ensure that class action treatment is an efficient manner of proceeding; the objective of the second two

108. Subparts (1) and (2) of Rule 23(b) focus on class actions seeking equitable recovery rather than monetary damages.

109. See *In re Fosamax Prods. Liab. Litig.*, 248 F.R.D. 389, 395 (S.D.N.Y. 2008).

110. *Ibid.*, at 396.

requirements is to confirm capability, proper incentive, and the absence of conflict between class representatives and absent class members.

Under Rule 23(a)(1), a class action may be brought if ‘the class is so numerous that joinder of all members is impracticable’. Joinder must be difficult or inconvenient, but need not be impossible. While there is no specified minimum threshold that satisfies this requirement, some courts have deemed the requirement fulfilled when the number of class members exceeds forty.¹¹¹

The second prong in determining the propriety of class certification is whether there are ‘questions of law or fact common to the class’. The court must assess whether the proposed class members share one or more issues relevant to the dispute that can be adjudicated on a collective basis. Courts are split regarding whether this requirement can be met within the product liability context.¹¹² Some courts have held that the commonality threshold is not high,¹¹³ and that the inquiry is ‘qualitative rather than quantitative’.¹¹⁴ For example, a New York federal court ultimately denied certification, but did find that the proposed class of patients who took a bone disorder drug met the commonality threshold because they shared one common question capable of generalized proof: that medical monitoring made early detection of the subject disease possible.¹¹⁵

Rule 23(a)(3) requires that the claims or defences of the representative parties are typical of the class. A class representative’s claims may be deemed typical if they arise out of the same event, or if the claims are based upon the same legal theories.

The final inquiry under Rule 23(a) is whether class representatives and counsel fairly and adequately protect class interests. The larger the class, and the more varied the plaintiffs’ claims, the more challenging for plaintiffs to demonstrate that putative class members actually have a common interest and are adequately represented by the same counsel.¹¹⁶

10.1.2. Rule 23(b)(3) Requirements

In order for a class action for damages to be certified, two additional requirements must be met: questions of law or fact common to members of the

111. See, e.g., *Stewart v. Abraham*, 275 F.3d 220, 226–227 (3d Cir. 2001); *Consol. Rail Corp. v. Town of Hyde Park*, 47 F.3d 473, 483 (2d Cir. 1995).

112. *Compare Iron Workers Local Union No. 17 Ins. Fund v. Philip Morris Inc.*, 182 F.R.D. 523 (N.D. Ohio 1998) (where health funds sought damages for costs of medical treatment for tobacco-related illnesses, plaintiffs satisfied commonality requirement), with *Chamberlain v. Am. Tobacco Co.*, 70 F. Supp. 2d 788 (N.D. Ohio 1999) (in action alleging that tobacco manufacturers conspired to conceal information about the health risks of smoking, commonality was lacking because plaintiffs smoked different brands of cigarettes produced by different manufacturers and at different times).

113. See *Mullen v. Treasure Chest Casino*, 186 F.3d 620, 625 (5th Cir. 1999).

114. 182 F.R.D. at 532.

115. 248 F.R.D. at 398.

116. See *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 626 (1997) (holding that plaintiffs did not adequately represent the class because the interests of the currently injured in obtaining

proposed class must predominate over individual issues and the class action must be the superior method of adjudicating the controversy.

The predominance test is met when significant factual and/or legal issues are common to each class member's claim or to the defence of such claims. Thus, the predominance test has both quantitative elements (how many questions are common to the class) and qualitative components (whether the common questions are key to the controversy).

In addition to predominance, courts must determine whether a class action is the 'superior method of adjudication' with regard to manageability, efficiency, and fairness. Where each plaintiff's claim depends upon individualized proof on issues such as liability, affirmative defences and damages, a class action cannot satisfy the superiority requirement because class proceedings would result in a multitude of mini-trials to adjudicate individual issues.

In general, courts may be somewhat less reluctant to certify classes that seek purely economic recovery under contract-based theories¹¹⁷ than those that seek tort-based recovery for personal injury, because the elements of a personal injury claim are so highly individualized.¹¹⁸

The U.S. Supreme Court recognized the inappropriateness of the class action device in a case involving hundreds of thousands of individuals exposed to asbestos. The Court decertified the class because differences in the plaintiffs' claims failed to satisfy the predominance requirement:

In contrast to mass torts involving a single accident, class members in this case were exposed to different asbestos-containing products, in different ways, over different periods, and for different amounts of time; some suffered no physical injury, others suffered disabling or deadly diseases.¹¹⁹

Other courts have similarly discussed the unsuitability of class actions in product liability actions:

[i]n product liability actions ... individual issues may outnumber common issues. No single happening or accident occurs to cause similar

immediate payments were not aligned with the interests of the exposed, but not yet injured, plaintiffs in ensuring an inflation-protected fund for the future).

117. See, e.g., *Daffin v. Ford Motor Co.*, 458 F.3d 549, 552–53 (6th Cir. 2006) (affirming certification of class of automobile owners who claimed manufacturer breached express warranty by providing vehicles with defectively designed parts, so that plaintiffs received vehicles worth less than if vehicles conformed to the warranty agreement); but see *McLaughlin v. Am. Tobacco Co.*, 522 F.3d 215 (2d Cir. 2008) (reversing certification of a class of smokers who sought recovery for alleged overpayments made when purchasing 'Light' cigarettes based on predominance of individualized issues, including reliance, causation and damages).
118. Specific causation and damages invoke inquiries into individualized issues such as cause-in-fact, proximate causation, comparative negligence, product usage, extent of exposure, other disease risk factors, reliance, knowledge of product risks, and damage.
119. 521 U.S. at 609; see also *Georgine v. Amchem Prods., Inc.*, 83 F.3d 610 (3d Cir. 1996) (vacating court-approved settlement and ordering decertification of nation-wide personal injury class action of persons exposed to asbestos).

types of physical harm or property damage. No one set of operative facts establishes liability. No single proximate cause applies equally to each potential class member and each defendant. Furthermore, the alleged tortfeasor's affirmative defenses (such as failure to follow directions, assumption of the risk, contributory negligence, and the statute of limitations) may depend on facts peculiar to each plaintiff's case.¹²⁰

In contrast to various decisions denying certification in cases seeking damages for personal injury, some courts have allowed class actions in other contexts. By way of example, the Supreme Court of Appeals of West Virginia in *In re Rezulin Litigation* reversed the lower court's denial of certification of a class who had used a diabetes medication. Plaintiffs sought the costs of medical monitoring to determine whether they already had sustained injury, or would in the future, due to the use of the medication, as well as damages under the state's consumer protection statute. The court found that common issues predominated based on the state's medical monitoring claim requirements. Furthermore, specific damages proof was not necessary under the consumer protection statute, only proof that the consumer 'purchased an item that is different from or inferior to that for which he bargained'.¹²¹

Yet, in a proposed nation-wide class action also arising out of the use of Rezulin, a federal court in New York held the opposite. Given the absence of a medical consensus on the need for medical monitoring for Rezulin patients, together with the fact that the various states' laws on medical monitoring vary, the court held that plaintiffs had not met the class certification requirements.¹²²

10.2. CONSUMER CLASS ACTIONS

All fifty states have passed statutes authorizing the state or private parties to prosecute consumer fraud or deceptive trade practices. Actions brought under these statutes may permit recovery, and even class certification, where such remedies would not be available under traditional tort theories.

In such consumer fraud lawsuits, claims are not based upon personal injuries, but rather on economic injuries. Plaintiffs bringing consumer fraud actions assert that a class has suffered economic damage as a result of unfair, deceptive, or misleading acts by the defendant. Actual economic injury is necessary for proposed class representatives to have standing to bring an action of this type—they cannot simply allege that they purchased a product that caused harm to

120. *In re N. Dist. of Cal., Dalkon Shield IUD Prod. Liab. Litig.*, 693 F.2d 847, 853 (9th Cir. 1982); see also *Cimino v. Raymark Indus.*, 151 F.3d 297, 319 (5th Cir. 1998) ('causation must be determined as to 'individuals, not groups').

121. *In re West Virginia Rezulin Litig.*, 585 S.E.2d 52, 75 (W. Va. 2003).

122. *In re Rezulin Prod. Liab. Litig.*, 210 F.R.D. 61 (S.D.N.Y. 2002).

non-parties, and that they want their money back.¹²³ Typically, plaintiffs seeking redress for purely economic loss will allege that based on a defendant's false representation, they over-paid for a product that turned out to be different from or inferior to the product they expected to receive.

Nation-wide class actions alleging statute-based consumer fraud pose complicated legal issues that may defeat certification due to variations in the statutes at issue. For example, some consumer protection statutes, such as Pennsylvania's, require proof of justifiable reliance on defendant's allegedly deceptive acts,¹²⁴ but others do not.¹²⁵

Class actions under consumer protection statutes may suffer other weaknesses with regard to the predominance requirement because plaintiffs generally differ with respect to product usage, product exposure, advertisements or other representations that they may have seen, knowledge of product risks, and nature and severity of damages.¹²⁶ However, some courts have carved out from such cases the 'common' issues (e.g., existence of a defect) and certified classes on those narrower bases, leaving issues such as causation and damages to individual trials.¹²⁷

10.3. THE CLASS ACTION FAIRNESS ACT¹²⁸

The Class Action Fairness Act (CAFA) was enacted in 2005 in response to what Congress recognized as 'abuses of the class action device', and to 'assure fairer outcomes for class members and defendants'.¹²⁹ In the decade prior to CAFA's enactment, plaintiffs' lawyers appeared to engage in forum shopping, filing class actions in state courts that were known for having biases against out-of-state corporate defendants, and laws more favourable to plaintiffs (including more liberal certification standards) than those applied by federal courts. The concern, according to CAFA supporters, was that a small number of plaintiff-biased states were setting the liability standards for the country.

123. See *Rivera v. Wyeth-Ayerst Labs.*, 283 F.3d 315 (5th Cir. 2002).

124. See, e.g., *Hunt v. U.S. Tobacco Co.*, 538 F.3d 217 (3d Cir. 2008).

125. See, e.g., *Yokoyama v. Midland Nat'l Life Ins. Co.*, 594 F.3d 1087 (9th Cir. 2010).

126. See, e.g., *UFCW Local 1776*, 620 F.3d 121 (reversing class certification order because causation elements of third-party payors' claims against drug manufacturer were not susceptible to generalized proof); *In re St. Jude Med., Inc.*, 522 F.3d 836 (8th Cir. 2008) (reversing certification of 'consumer protection class' of patients seeking damages for recalled prosthetic heart valve, finding individualized issues with respect to representations made, reliance, and causation); but see *Chamberlan v. Ford Motor Co.*, 402 F.3d 952 (9th Cir. 2005) (affirming certification of class of consumers who purchased vehicles with defective engine part).

127. See, e.g., *Pella*, 606 F.3d 391 (affirming limited certification of state-wide liability classes alleging window manufacturer violated state consumer fraud laws by failing to disclose defect).

128. 28 U.S.C. § 1332(d) (2005).

129. Class Action Fairness Act, Pub. L. No. 109-2, 119 Stat. 4 (2005).

As a result of these ‘abuses’, Congress crafted a law that broadened federal court jurisdiction over class actions and made it less difficult for defendants to remove such cases to federal court.

In the several years following CAFA’s enactment, the monthly average number of class actions filed in the federal courts based on diversity of citizenship jurisdiction approximately tripled, primarily comprising actions based on state-law contract claims, state consumer protection laws, and tortious property damage. In contrast, diversity class action removals initially increased following CAFA, then decreased again to match the downward trend and levels of pre-CAFA removals.¹³⁰

10.4. CLASS ARBITRATION

Form contracts for the provision of consumer services (such as banking, credit card, television and telephone services) commonly require that any dispute arising out of the contract is to be resolved by arbitration rather than litigation. Recently, the U.S. Supreme Court decided two cases addressing class arbitration that may portend a marked decrease in consumer class arbitration for the companies that provide such services.

In *AT&T Mobility LLC v. Concepcion*, a 5-4 majority of the Court held that the Federal Arbitration Act (FAA) pre-empted California’s common law that rejected as unconscionable class arbitration waivers, thus enforcing the waiver clause in the wireless telephone service agreement at issue. Specifically, the Court viewed the FAA’s overarching goal as ‘to ensure the enforcement of arbitration agreements according to their terms so as to facilitate streamlined proceedings. Requiring the availability of classwide arbitration interferes with fundamental attributes of arbitration and thus creates a scheme inconsistent with the FAA’.¹³¹

In so holding, the Court recognized that class arbitration undermines the primary advantage of informality that arbitrations offer, while simultaneously slowing down the resolution process, increasing costs, and imposing procedural rigor. The Court also noted that defendants face more significant exposure in class versus individual arbitration (and thus increased pressure to settle even questionable claims) due to the potential for greater losses that are not subject to the same appellate relief processes as class action lawsuits. The Court found ‘instructive’¹³² its year-old decision in *Stolt-Nielsen*

130. Emery G. Lee III & Thomas E. Willging, *The Impact of the Class Action Fairness Act of 2005 on the Federal Courts: Fourth Interim Report to the Judicial Conference Advisory Committee on Civil Rules* (2008), <[www.fjc.gov/public/pdf.nsf/lookup/cafa0408.pdf/\\$file/cafa0408.pdf](http://www.fjc.gov/public/pdf.nsf/lookup/cafa0408.pdf/$file/cafa0408.pdf)>.

131. 131 S.Ct. 1740, 1748 (2011).

132. *Ibid.*, at 1750.

S.A. v. AnimalFeeds Int'l Corp.,¹³³ and ultimately opined that '[a]rbitration is poorly suited to the higher stakes of class litigation'.¹³⁴

In essence, the Court's decision renders class action waivers enforceable (even if the consumer had no meaningful ability to negotiate the contract terms), thereby increasing the likelihood that consumer contract disputes will be resolved by individual arbitrations.

11. PUNITIVE DAMAGES

In U.S. courts, punitive damages may be awarded to further a state's 'legitimate interests in punishing unlawful conduct and deterring its repetition'.¹³⁵ The potential for punitive damages awards distinguishes the U.S. product liability system from that of other countries: 'punitive damages overall are higher and more frequent in the United States than they are anywhere else'.¹³⁶

While the applicable standard varies among states, punitive damages require a showing, in addition to the essential elements of the plaintiff's claim, that the defendant's conduct was sufficiently egregious to justify further sanctions.¹³⁷ Individual states have 'considerable flexibility' in setting the level of punitive damages awarded; in most states, this discretion is the jury's, subject to judicial review to insure that the award is reasonable.¹³⁸ Many states, however, have taken steps to limit punitive damage awards: some completely bar them, while others award them only when authorized by statute. Still other states limit the award to legal expenses, cap the amount, or set a maximum ratio of punitive to compensatory damages.

According to the U.S. Supreme Court, the jury's discretion to award punitive damages has neither 'mass-produced runaway awards' nor caused a 'marked increase' in the percentage of cases in which an award is made. Nevertheless, the Court has expressed concern regarding the wide range of punitive damages that may be awarded by juries—in 'outlier cases', defendants may be subject to punitive damages that 'dwarf' the award of compensatory damages: '[t]he real problem . . . is the stark unpredictability of punitive awards', deriving from 'the inherent uncertainty of the trial process'. Punitive damage awards that are 'eccentrically high' carry an 'implication of unfairness'.¹³⁹

133. 130 S.Ct. 1758, 1173-76 (2010) (holding that the arbitration panel had exceeded its powers by ordering class arbitration where the bilateral arbitration contract was silent as to the availability of class arbitration, and the parties had not expressly agreed to it).

134. 131 S.Ct. at 1752.

135. *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 568 (1996).

136. *Exxon Shipping Co. v. Baker*, 554 U.S. 471, 496 (2008).

137. See, e.g., N.Y. Pattern Jury Instructions – Civil, 2:278 (2011) (punitive damages 'may be awarded for conduct that represents a high degree of immorality and shows such wanton dishonesty as to imply criminal indifference to civil obligations').

138. 517 U.S. at 568; *Pac. Mut. Life Ins. Co. v. Haslip*, 499 U.S. 1, 15 (1991).

139. 554 U.S. at 497-504.

To guard against ‘grossly excessive or arbitrary’ punitive damage awards, the Court has recognized ‘procedural and substantive constitutional limitations on these awards’.¹⁴⁰ Thus, due process not only limits the amount of punitive damages awards, but also requires that courts adopt procedural safeguards to protect the defendant’s rights and to ‘cabin’ the jury’s discretion, including the provision of proper jury instructions.¹⁴¹

The Court has established three ‘guideposts’ to determine whether a particular award is grossly excessive: the degree of reprehensibility of the defendant’s conduct, the ratio between the potential harm suffered by the plaintiff and the amount of the punitive damages award, and the difference between the punitive damages award and the civil penalties imposed in similar cases.¹⁴² Considerations pertinent to assessing the reprehensibility of the defendant’s conduct include whether: the harm caused was physical or economic; the defendant’s conduct reflected reckless disregard of others’ health or safety; the target of the conduct was financially vulnerable; the conduct was isolated or recurring; and the injury resulted from an intentional act.¹⁴³

In examining the amount of a punitive damages award, the Court has said that ‘exemplary damages must bear a ‘reasonable relationship’ to compensatory damages’.¹⁴⁴ The Court has refused to adopt a ‘bright-line’ approach to this analysis, but has said that ‘few awards exceeding a single-digit ratio between punitive and compensatory damages, to a significant degree, will satisfy due process’.¹⁴⁵ The acceptable ratio may be higher where a particularly grievous act causes only a small amount of economic damage or where the injury is hard to detect; a lower ratio may be called for where the amount of compensatory damages is substantial.¹⁴⁶

Evidence of the defendant’s financial net worth is often introduced in support of a punitive damages claim, on the theory that a larger award is necessary to deter a defendant with substantial means. This evidence may serve to ‘anchor’ the jury’s consideration of the amount of a punitive damages award. However, the use of this evidence is controversial, as the Court has said that ‘[t]he wealth of a defendant cannot justify an otherwise unconstitutional punitive damages award’.¹⁴⁷

140. *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 416 (2003).

141. *Philip Morris USA v. Williams*, 549 U.S. 346, 352 (2007).

142. 517 U.S. at 574–575.

143. 538 U.S. at 419.

144. 517 U.S. at 580.

145. 538 U.S. at 425; see also 554 U.S. at 506 (advocating ‘pegging punitive to compensatory damages using a ratio or maximum multiple’ as a means of eliminating the unpredictable nature of punitive damage awards); 499 U.S. at 23–24 (ratio of ‘more than 4 times the amount of compensatory damages’ may be ‘close to the [permissible] line’).

146. 538 U.S. at 425.

147. *Ibid.*, at 427; see also *Honda Motor Co., Ltd. v. Oberg*, 512 U.S. 415, 432 (1994) (evidence of wealth creates risk that juries will ‘express biases against big businesses’ in verdict).