

KLUWER LAW INTERNATIONAL

International Product Law Manual

Edited by

Arundel McDougall

Prashant Popat Q.C.



Wolters Kluwer

Law & Business

AUSTIN

BOSTON

CHICAGO

NEW YORK

THE NETHERLANDS

Published by:

Kluwer Law International
PO Box 316
2400 AH Alphen aan den Rijn
The Netherlands
Website: www.kluwerlaw.com

Sold and distributed in North, Central and South America by:

Aspen Publishers, Inc.
7201 McKinney Circle
Frederick, MD 21704
United States of America
Email: customer.service@aspublishers.com

Sold and distributed in all other countries by:

Turpin Distribution Services Ltd.
Stratton Business Park
Pegasus Drive, Biggleswade
Bedfordshire SG18 8TQ
United Kingdom
Email: kluwerlaw@turpin-distribution.com

Printed on acid-free paper.

ISBN 978-90-411-2638-2

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Printed in Great Britain.

About the Editors

Arundel McDougall

Arundel McDougall is head of Ashurst's Product Liability practice and joined Ashurst as a Litigation Partner in 2000. Before joining Ashurst, he specialized in product liability as a partner at Rowe & Maw for 14 years. Over his career, he has been active on some of the best known group actions in the English courts, including the defence of the Norplant and Sabril Group Actions and the DMF litigation. Arundel is highly rated by clients and in the legal directories for his work within the life sciences sector. He is recommended in Chambers 2010 as 'a tried-and-tested winner in this area' and is recognized as having an 'excellent reputation for his product liability work' and 'always at the forefront of the most interesting cases'. Arundel is a member of the International Associate of Defence Counsel, DRI (Europe), European Justice Forum and the City of London Law Society Litigation Subcommittee. He has published widely on pharmaceutical product liability issues.

Prashant Papat Q.C.

Prashant Papat Q.C., was called to the Bar of England and Wales in 1992 and took 'silk' in 2008. He practices from Henderson Chambers in London and for more than a decade he has specialized in product liability and regulatory claims. He has been involved in most of the significant product liability actions, particularly group actions in respect of pharmaceutical products, in that period. He has experience in product liability litigation in all courts in England and in the European Court of Justice. He is recommended by all legal directories as a leader in this field. He read Jurisprudence at Oxford. He was a Judicial Assistant to the Master of the Rolls. He is a co-author of 'A Guide to Civil Advocacy' and a contributing editor of Halsbury's Laws of England – Civil Procedure.

Chapter 3

An Overview of Products Liability Law in the United States

Thomas E. Riley

Mr. *Thomas E. Riley* is head of the Firm's litigation department. He has more than 25 years of experience in the products liability area. Mr. Riley has extensive experience coordinating the defense of hundreds of products liability cases around the United States, including complex matters such as class actions and cases involving claims for medical monitoring. He has successfully defended manufacturers in trials around the country, and also provides advice to defendants in products liability cases in courts throughout the world. Mr. Riley earned his law degree in 1979 from New York University School of Law, where he was a staff member and editor of the *Journal of International Law and Politics*. Before joining Chadbourne & Parke LLP, he served as Law Clerk to U.S. District Court Judge John T. Elfvin in the U.S. District Court for the Western District of New York. Mr. Riley is a member of the International Association of Defense Counsel (Amicus Curiae and Products Liability Committees); New York State Bar Association (Commercial and Federal Litigation Section—Trial Evidence Committee); the American Bar Association; and the University Settlement Society of New York (Board of Directors, 1992–2004).

Allison M. Alcasabas

Ms. *Allison M. Alcasabas* has nearly two decades of experience in defending major manufacturers against complex products liability claims, including lawsuits brought by individual plaintiffs, consumer groups and governmental entities, as well as class actions. Ms. Alcasabas has assisted in the successful defense of products liability litigation both throughout the United States, and internationally in jurisdictions such as Central and Eastern Europe, the Middle East, Africa, Asia, Canada, and Ireland. She was head of the products liability

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department in the Firm's London office from 2005–2009, until she returned to the New York office. Ms. Alcasabas earned her law degree in 1992 from Cornell Law School, where she served as a staff member and an editor of the *Cornell Law Review*. She is admitted to practice in the courts of New York, New Jersey, Connecticut, and Washington State.

Chadbourne & Parke LLP

Chadbourne & Parke LLP, an international law firm headquartered in New York City, provides a full range of legal services, including mergers and acquisitions, securities, project finance, private funds, corporate finance, venture capital and emerging companies, energy/renewable energy, communications and technology, commercial and products liability litigation, arbitration/IDR, securities litigation and regulatory enforcement, special investigations and litigation, intellectual property, antitrust, domestic and international tax, insurance and reinsurance, environmental, real estate, bankruptcy and financial restructuring, employment law and ERISA, trusts and estates and government contract matters. Major geographical areas of concentration include Russia, Central and Eastern Europe, the Middle East and Latin America. The Firm has offices in New York, Washington, DC, Los Angeles, Mexico City, London (an affiliated partnership), Moscow, St. Petersburg, Warsaw, Kyiv, Almaty, Dubai and Beijing.

Chadbourne & Parke LLP

30 Rockefeller Plaza

New York, NY 10112

United States of America

Tel.: +1-212-408-5100

Fax: +1-212-541-5369

E-mail: triley@chadbourne.com; aalcasabas@chadbourne.com

Web: www.chadbourne.com

Chapter 3

An Overview of Products Liability Law in the United States

Thomas E. Riley & Allison M. Alcasabas

Chadbourne & Parke LLP

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 products liability arena. Moreover, the defense 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. products liability often encompasses a host of concerns; virtually any manufacturer that makes or sells products for public consumption can be affected.

U.S. products 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. products 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.

Products 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 products 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. products 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*," even if the manufacturer has exercised due care and in the absence of privity.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.

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

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).

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

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.⁶ 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.

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,"⁷ or if there is no reasonable alternative design to the medication in question.⁸ Other courts, however, have applied comment k broadly, such that all prescription medications with adequate warnings and instructions are exempt from strict liability⁹ to foster the public interest in new medications.

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 *Brown v. Superior Court*, 751 P.2d 470, 475-477 (Cal. 1988).

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

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

9. 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).

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."¹⁰ 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).¹¹ 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 favored category, and prefer a case-by-case approach.

3. OTHER COMMON LAW THEORIES

3.1. NEGLIGENCE

Although strict liability has supplanted negligence as the leading theory of products 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.

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

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

A negligence claim is based on four intertwined elements: duty, breach, causation and damages. In the products 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.¹²

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

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.¹³ 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.”¹⁴ 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.”¹⁵

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.¹⁶

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

13. UCC §§ 2-314, 2-315.

14. UCC § 2-314(1) and (2).

15. UCC § 2-315.

16. Restatement (Third) § 2 cmt n.

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.¹⁷

Previously, a claim for breach of warranty required a direct contractual relationship with the defendant. Today, the privity requirement is far less constrictive,¹⁸ 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.¹⁹ 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.²⁰

4. CATEGORIES OF PRODUCT DEFECT

U.S. courts have generally recognized three categories of product defect: manufacturing, design, and failure to warn or instruct.²¹ 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.

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.

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

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

19. *See* UCC § 2-318 cmt 3.

20. 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.”

21. *See* Restatement (Third) § 2.

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.”²²

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.²³ Likewise, § 2(b) of the 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.²⁴

22. 662 N.E.2d at 735.

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

24. Restatement (Third) § 2 cmt f.

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.²⁵ 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.²⁶ 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."²⁷

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.²⁸

In some jurisdictions, a postsale duty to warn may arise if the manufacturer later becomes aware of a hazard associated with the product.²⁹ Relevant

25. See, e.g., *Martinez v. Dixie Carriers, Inc.*, 529 F.2d 457 (5th Cir. 1976).

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

27. Restatement (Third) § 2 cmt a.

28. *Id.* cmt i.

29. See, e.g., *Densberger v. United Techs. Corp.*, 297 F.3d 66 (2d Cir. 2002) (applying Connecticut law).

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.³⁰

5. STATUTORY MODIFICATIONS OF COMMON LAW

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

For example, the New Jersey Product Liability Act³¹ is the “sole basis of relief . . . available to consumers injured by a defective product” under state law.³² 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 products 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 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.³³ 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

30. Restatement (Third) § 10.

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

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

33. Restatement (Second) §§ 310, 311.

the consumer could not reasonably have relied on the advertisements to conclude that “prolonged and excessive use of alcohol is safe and acceptable.”³⁴

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.³⁵

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.³⁶ 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.³⁷

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.³⁸

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 “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 attorneys’ fees.³⁹

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.⁴⁰

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

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

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

37. *See* 618 N.W.2d at 845.

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

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

40. *See, e.g., Pella Corp. v. Saltzman*, 606 F.3d 391 (7th Cir. May 20, 2010).

8. DEFENSES

There are a number of defenses to products liability claims.

8.1. DEFENSES BASED ON THE PLAINTIFF'S CONDUCT

Myriad defenses focus on the plaintiff's own conduct as a cause of the injuries alleged. These defenses 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 favor 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.

Misuse of a product, product alteration or modification, and noncompliance 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 defense; often, however, the defense is subsumed under comparative fault. States that recognize assumption of risk as a separate defense 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.⁴¹ 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.⁴² 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.⁴³

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 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.”⁴⁴

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.⁴⁵ 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” defenses arise out of the same policy considerations as the open and obvious danger rule, that is,

41. *Morgan v. State*, 685 N.E.2d 202, 207 (N.Y. 1997).

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

43. *See generally, Trupia ex rel. Trupia v. Lake George Cent. Sch. Dist.*, 14 N.Y.3d 392 (N.Y. Apr. 6, 2010).

44. 500 F.3d 691, 696–697 (8th Cir. 2007).

45. 170 F.3d 264 (2d Cir. 1999).

there is an understanding that the ultimate user is, or will be made, aware of the product's risks.

The “learned intermediary” defense 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 defense 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).⁴⁶

Likewise, the “sophisticated user” defense may exempt a manufacturer from the duty to warn end-users about risks associated with the product. This defense 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 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.⁴⁷

8.3. INTERVENING AND SUPERSEDING CAUSES

A defendant may raise the defense 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 plaintiff.⁴⁸ 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.”⁴⁹

46. 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.

47. *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).

48. *See* W. Page Keeton et al., *Prosser and Keeton on the Law of Torts*, 5th edn (St. Paul: West, 1984), 301.

49. *Clark v. Flach*, 604 F. Supp. 2d 1, 5-6 n.7 (D.D.C. 2009) (emphasis in original).

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.⁵⁰

Typically, compliance provides a rebuttable presumption in the defendant's favor.⁵¹

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.⁵² Some states expand the defense to provide a rebuttable presumption if the product was manufactured or designed in compliance with industry standards *or other nongovernmental regulations or standards*.⁵³ Other states limit the defense only to the defendant's compliance with industry standards.⁵⁴

8.5. CONTRACTUAL DEFENSES/DISCLAIMERS

Contractual defenses such as disclaimers are generally inapplicable in products 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 defenses generally are inapplicable in strict liability actions.⁵⁵ 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

50. Restatement (Third) § 4(b).

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

52. *See* Restatement (Third) § 4.

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

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

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

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.⁵⁶

8.6. STATE-OF-THE-ART

The “state-of-the-art” defense 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 defense is available by statute or by case law in most, but not all, states. In states where the defense is available, the degree of protection varies. Some states’ state-of-the-art defense provides manufacturers with a complete shield against liability;⁵⁷ others provide a rebuttable presumption of nondefectiveness.⁵⁸

8.7. FEDERAL PRE-EMPTION

Unique to U.S. jurisprudence is the defense of federal pre-emption, which implements the mandate of the U.S. Constitution that federal laws trump state laws that “interfere with, or are contrary to” them.⁵⁹ 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 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.⁶⁰ 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.”⁶¹

The U.S. products 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

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

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

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

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

60. *See, e.g.*, *Wyeth v. Levine*, 129 S. Ct. 1187, 1202 (2009).

61. *Id.* at 1194–1195.

(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).⁶²

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.

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 and execution of the full purposes and objectives of Congress'"⁶³ ("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 pre-empt 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.⁶⁴ 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 the Court's unwillingness to displace state law absent a clear articulation of Congressional intent to do so.

62. See *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 325 (2008).

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

64. 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).

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.⁶⁵ The Court determined that the plaintiffs' state-law tort claims alleging that Medtronic had negligently designed and labeled 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. . . ."⁶⁶

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 pre-empt claims 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.⁶⁷

In *Wyeth v. Levine*, a case involving an antinausea medication, the Supreme Court determined that the FDA's decades-long regulation and continued approval of the warning labeling 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."⁶⁸

65. 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).

66. 552 U.S. at 316.

67. 129 S. Ct. 538, 547 (2008).

68. 129 S. Ct. at 1197-1199, 1202.

Recent rulings involving food and beverage manufacturers likewise display a willingness by some courts to permit state-law claims to coexist alongside an extensive federal regulatory scheme.⁶⁹

9. DEVELOPMENTS IN U.S. PRODUCTS LIABILITY LITIGATION

9.1. PUBLIC NUISANCE

With increasing frequency, the doctrine of public nuisance has been imported into the products 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 products 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 state-wide 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.⁷⁰

69. *Holk v. Snapple Beverage Corp.*, 575 F.3d 329, 339 (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. Sep. 30, 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).

70. 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).

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 theories of public nuisance . . . against a wide and varied array of other commercial and manufacturing enterprises and activities.”⁷¹ Other state courts have likewise rejected governments’ public nuisance claims against lead paint manufacturers.⁷²

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 products liability claims.⁷³

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.⁷⁴ 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.”⁷⁵

Two recent federal appellate decisions may indicate that the public nuisance doctrine retains significant vitality, at least in the context of litigation involving greenhouse gas emissions and climate change. In one, the court held that several states and a municipality could bring public nuisance claims against owners of electric power plants, alleging that greenhouse gas emissions contribute to global warming.⁷⁶ In the second, the court held that a proposed class of property owners along the Mississippi Gulf coast could proceed with a lawsuit against oil, chemical and electric generation companies; the plaintiffs claimed that the defendants unreasonably produced

71. 951 A.2d at 457.

72. *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).

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

74. *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).

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

76. *Connecticut v. Am. Elec. Power Co. Inc.*, 582 F.3d 309 (2d Cir. 2009).

massive amounts of greenhouse gases, contributing to global warming, which in turn caused sea levels to rise and increased the strength of Hurricane Katrina.⁷⁷

9.2. MARKET SHARE LIABILITY

The theory of market share liability eases a plaintiff's usual burden of proof in products 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.⁷⁸

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.⁷⁹ 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.

77. *Comer v. Murphy Oil USA*, 585 F.3d 855 (5th Cir. 2009), *reh'g en banc granted*, 598 F.3d 208 (5th Cir. 2010); *but see Native Vill. of Kivalina v. Exxon Mobil Corp.*, 663 F. Supp. 2d 863 (N.D. Cal. 2009) (dismissing lawsuit against energy and utility companies alleging that global climate change caused by defendants had led to the loss of Arctic sea ice).

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

79. *Id.* at 936-937.

The doctrine was adopted or modified by some states⁸⁰ in DES cases but rejected by others.⁸¹ The latter reasoned that the doctrine would “abrogate a fundamental precept of tort law,” broaden manufacturers’ potential liability, diminish product research and development (without necessarily improving product safety), and turn individual manufacturers into insurers for the entire industry.⁸²

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,⁸³ 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.⁸⁴ The doctrine has also been applied in litigation involving plasma,⁸⁵ but courts have largely refused to impose market share liability in cases involving asbestos⁸⁶ and lead paint.⁸⁷

9.3. MEDICAL MONITORING CLAIMS

Medical monitoring is a nontraditional 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,⁸⁸ reasoning that the claim is consistent with the goal of the tort system

80. *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).

81. *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).

82. *See, e.g.*, 560 N.E.2d at 341–344.

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

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

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

86. *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).

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

88. *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).

to deter manufacturers from irresponsible conduct, and encourages plaintiffs to detect and treat injuries as soon as possible.⁸⁹

Other courts refuse to recognize medical monitoring claims. In *Badillo*, the Supreme Court of Nevada refused to allow a medical monitoring claim for exposure to secondhand 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 necessary to increase significantly the risk of disease and the potential impact of contributing risk factors unrelated to the defendants’ products.⁹⁰

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.⁹¹ 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.⁹²

Medical monitoring claims are also the subject of specific legislation in some states.⁹³

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

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

90. *Badillo v. Am. Brands, Inc.*, 16 P.3d 435, 440–441 (Nev. 2001).

91. *Metro-North Commuter R.R. Co. v. Buckley*, 521 U.S. 424, 441–442 (1997).

92. 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).

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

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 defenses 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 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.⁹⁴ 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 cognizable injury.⁹⁵

Similarly, in *Ashley County v. Pfizer, Inc.*, the plaintiff counties sued makers of nonprescription 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.⁹⁶

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.⁹⁷

94. See, e.g., *City of Philadelphia v. Beretta U.S.A. Corp.*, 277 F.3d 415, 423 (3d Cir. 2002); but see *City of Cincinnati v. Beretta U.S.A. Corp.*, 768 N.E.2d 1136 (Ohio 2002).

95. 818 N.E.2d 1140, 1145 (N.Y. 2004).

96. 552 F.3d 659, 670–671 (8th Cir. 2009).

97. 326 F.3d 339, 349 (2d Cir. 2003).

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 products 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.”⁹⁸

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 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.”⁹⁹

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.”¹⁰⁰

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.¹⁰¹

98. 28 U.S.C. § 1350 (2006).

99. *Sosa v. Alvarez-Machain*, 542 U.S. 692, 712, 728, 732 (2004); see also *In re S. African Apartheid Litig.*, 617 F. Supp. 2d 228 (S.D.N.Y. 2009) (upholding claims that by selling specialized military vehicles and computer software to South African military forces, the defendant manufacturers aided and abetted violations of international law, but dismissing claims against the defendants for the sale of cars and trucks without military customization, and for the sale of computer systems that were not “sufficiently tied” to violations of customary international law).

100. 562 F.3d 163, 187 (2d Cir. 2009).

101. 517 F.3d 104 (2d Cir. 2008).

10. CLASS ACTIONS

Class actions have been a feature of the U.S. legal system for over 40 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 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 50 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).¹⁰²

A threshold inquiry, however, is the existence of a “definable class,” i.e., a court must be able to ascertain whether a particular individual is a class member based on objective criteria.¹⁰³ 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.¹⁰⁴

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

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

104. *Id.*, at 396.

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 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 40.¹⁰⁵

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 products liability context.¹⁰⁶ Some courts have held that the commonality threshold is not high,¹⁰⁷ and that the inquiry is “qualitative rather than quantitative.”¹⁰⁸ 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.¹⁰⁹

Rule 23(a)(3) requires that the claims or defenses 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.

105. 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).

106. 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).

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

108. 182 F.R.D. at 532.

109. 248 F.R.D. at 398.

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.¹¹⁰

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 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 defense 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 defenses 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 theories¹¹¹ than those that seek tort-based recovery for personal injury, because the elements of a personal injury claim are so highly individualized.¹¹²

The U.S. Supreme Court recognized the inappropriateness of the class action device in a case involving hundreds of thousands of individuals

110. 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 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).

111. See, e.g., *Daffin v. Ford Motor Co.*, 458 F.3d 549, 552–553 (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).

112. 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.

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.¹¹³

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

[i]n product liability actions . . . individual issues may outnumber common issues. No single happening or accident occurs to cause similar 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.¹¹⁴

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 the *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."¹¹⁵

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

113. 521 U.S. at 609; see also *Georgine v. Amchem Prods., Inc.*, 83 F.3d 610, 627 (3d Cir. 1996) (vacating court-approved settlement and ordering decertification of nation-wide personal injury class action of persons exposed to asbestos).

114. *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'").

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

monitoring vary, the court held that plaintiffs had not met the class certification requirements.¹¹⁶

10.2. CONSUMER CLASS ACTIONS

All 50 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 nonparties, and that they want their money back.¹¹⁷ 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 those in California and Pennsylvania, require proof of justifiable reliance on defendant's allegedly deceptive acts,¹¹⁸ but others do not.¹¹⁹

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.¹²⁰ However, some courts have carved out from such cases the “common” issues (e.g., existence of a defect) and

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

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

118. *See, e.g., Occidental Land, Inc. v. Superior Court of Orange County*, 556 P.2d 750 (Cal. 1976); *Weinberg v. Sun Co.*, 777 A.2d 442 (Pa. 2001).

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

120. *See, e.g., 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).

certified classes on those narrower bases, leaving issues such as causation and damages to individual trials.¹²¹

10.3. THE CLASS ACTION FAIRNESS ACT¹²²

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.”¹²³ 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.

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.

Preliminary data demonstrate that the monthly average number of class actions filed in or removed to the federal courts based on diversity of citizenship jurisdiction approximately doubled in the year after CAFA was enacted, primarily comprising actions based on state-law contract claims or state consumer protection laws.¹²⁴

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.”¹²⁵ The potential for punitive damage awards distinguishes the U.S. products liability system from that of other countries: “punitive damages overall are higher and more frequent in the United States than they are anywhere else.”¹²⁶

121. *See, e.g.*, 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).

122. 28 U.S.C. § 1332(d) (2005).

123. Class Action Fairness Act, Pub. L. 109-2, 119 Stat. 4 (Feb. 18, 2005).

124. Emery G. Lee III & Thomas E. Willging, *The Impact of the Class Action Fairness Act on the Federal Courts: An Empirical Analysis of Filings and Removals*, *University of Pennsylvania Law Review* 156 (2008): 1723, 1750, 1755.

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

126. *Exxon Shipping Co. v. Baker*, 128 S. Ct. 2605, 2623 (2008).

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.¹²⁷ 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.¹²⁸ 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 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."¹²⁹

To guard against "grossly excessive or arbitrary" punitive damage awards, the Court has recognized "procedural and substantive constitutional limitations on these awards."¹³⁰ 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.¹³¹

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.¹³² 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.¹³³

127. See, e.g., N.Y. Pattern Jury Instructions—Civil, PJI 2:278 (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").

128. 517 U.S. at 568; *Pac. Mut. Life Ins. Co. v. Haslip*, 499 U.S. 1, 15 (1991).

129. 128 S. Ct. at 2624–2627.

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

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

132. 517 U.S. at 574–575.

133. 538 U.S. at 419.

In examining the amount of a punitive damages award, the Court has said that “exemplary damages must bear a ‘reasonable relationship’ to compensatory damages.”¹³⁴ 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.”¹³⁵ 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.¹³⁶

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 Supreme Court has said that “[t]he wealth of a defendant cannot justify an otherwise unconstitutional punitive damages award.”¹³⁷

134. 517 U.S. at 580.

135. 538 U.S. at 425. *See also* 128 S. Ct. at 2629 (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”).

136. 538 U.S. at 425.

137. *Id.*, 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).