CHAPTER 8

PRODUCTS LIABILITY

SECTION A. INTRODUCTION

Products liability law has become so important that it is virtually a legal field unto itself. This field is conveniently defined in contrast to the abnormally dangerous activities examined in Chapter 7, which explored the liability of defendants who exercised direct control over dangerous instrumentalities at the time they caused injury. Products liability law, on the other hand, governs the activities of manufacturers, distributors, and sellers who have placed a product in the stream of commerce and are *no longer* in possession of it when it causes damage.

As befits its complexity, products liability law has a rich and dense history, which can be roughly divided into four periods. The first period ran from approximately the mid-nineteenth century to the early twentieth century, when the major debate was whether to allow an injured party to sue either product manufacturers or sellers. Courts often held that the "privity" limitation prevented the injured party—whether consumer, user, or bystander—from suing the "remote" supplier of the product in question, that is, one who has no direct contractual relationship with the injured party. Instead an injured consumer or user could sue only the immediate vendor of the product; an injured bystander could sue only the party in possession of the product just before the injury occurred.

The last half of the nineteenth century witnessed a gradual erosion of this privity limitation, as exceptions were created for products known to hold hidden dangers that manifested themselves when either the plaintiff or some third party put them to ordinary use. This second period began when MacPherson v. Buick Motor Co., 111 N.E. 1050 (N.Y. 1916), rejected the privity limitation outright by imposing liability for negligence on a remote seller.

The third stage of products liability law was inaugurated by the famous concurring opinion of Justice Traynor in Escola v. Coca Cola Bottling Co., 150 P.2d 436, 440 (Cal. 1944), which argued that strict liability, not negligence principles, should govern the manufacturer's liability. Traynor's view steadily gained adherents and became the dominant view by 1965, when the American Law Institute incorporated a general principle of strict liability into section 402A of the Second Restatement. For a discussion of the early development of strict liability through the Second Restatement, see Epstein, Modern Products Liability Law (1980); Prosser, The Assault Upon the Citadel (Strict Liability to the Consumer), 69 Yale L.J. 1099 (1960).

Soon after the Second Restatement was adopted, products liability law entered a period of rapid expansion. The three dominant themes in debates leading up to the Second Restatement focused on the role of manufacturers: their market power, their capacity to obtain insurance, and their ability to internalize the costs of accidents associated with their products. Taken together, these three issues pointed to placing nearly "absolute liability" on the manufacturer, and perhaps others in the chain of distribution. As Priest, The Invention of Enterprise Liability: A Critical History of the Intellectual Foundations of Modern Tort Law, 14 J. Legal Stud. 461, 527 (1985), laments "[t]he presuppositions themselves do not incorporate any conceptual limit to manufacturer's liability."

condition was known by the defendant. The court remanded the case for trial, noting that it was "perhaps improbable" that the defendant had knowledge of the imminently dangerous character of the machine at the time of delivery.

Some cases did succeed under this third exception. In Kuelling v. Roderick Lean Manufacturing Co., 75 N.E. 1098, 1101 (N.Y. 1905), the defendants sold a roller to a dealer who then resold it to the plaintiff. The roller was made out of weak wood and contained a knot that prevented a safe hook-up of the roller to the team of horses that pulled it. The defect was deliberately concealed by putty and paint. Bartlett, J., allowed the action:

> In the case at bar we have, not only fraudulent deceit and concealment, but what amounts to an affirmative representation that the tongue of the roller was sound, as the manufacturer by filling the defect with putty and painting the entire surface so that the eye could not detect any weakness by reason of the knot, knothole filled up, the kind of wood employed and the fact that it was cross-grained, must be held to have represented that the roller as offered for sale was in a perfectly marketable condition.

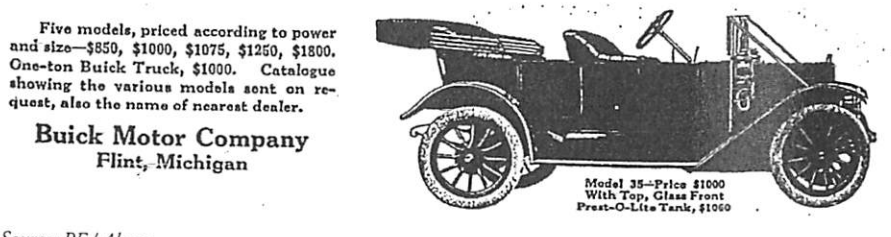
MacPherson v. Buick Motor Co.

111 N.E. 1050 (N.Y. 1916)

CARDOZO, J. The defendant is a manufacturer of automobiles. It sold an automobile to a retail dealer. The retail dealer resold to the plaintiff. While the plaintiff was in the car, it suddenly collapsed. He was thrown out and injured. One of the wheels was made of defective wood, and its spokes crumbled into fragments. The wheel was not made by the defendant; it was bought from another manufacturer. There is evidence, however, that its defects could have been discovered by reasonable inspection, and that inspection was omitted. There is no claim that the defendant knew of the defect and willfully concealed it. The case, in other words, is not brought within the rule of Kuelling v. Lean Mfg. Co. The charge is one, not of fraud, but of negligence. The question to be determined is whether the defendant owed a duty of care and vigilance to any one but the immediate purchaser.

Exhibit 8.1 1910 Buick Model 10

"The Buick Model 10 was introduced in 1908. The Gentlemen's Light Four-cylinder Roadster body-style soon became the company's best seller. Over 4,000 examples were created during its first year and that figure doubled the following year to 8,100. The last year was in 1910, with production approaching 11,000 units." 1910 Buick Model 10, Conceptcarz, http://www.conceptcarz.com/vehicle/z7409/Buick-Model-10.aspx.



Source: PF / Alamy

The foundations of this branch of the law, at least in this state, were laid in Thomas v. Winchester (6 N.Y. 397 (1852)). A poison was falsely labeled. The sale was made to a druggist, who in turn sold to a customer. The customer recovered damages from the seller who affixed the label. "The defendant's negligence," it was said, "put human life in imminent danger." A poison falsely labeled is likely to injure anyone who gets it. Because the danger is to be foreseen, there is a duty to avoid the injury. . . .

Thomas v. Winchester became quickly a landmark of the law. In the application of its principle there may at times have been uncertainty or even error. There has never in this state been doubt or disavowal of the principle itself. The chief cases are well known, yet to recall some of them will be helpful. Loop v. Litchfield (42 N.Y. 351 (1870)) is the earliest. It was the case of a defect in a small balance wheel used on a circular saw. The manufacturer pointed out the defect to the buyer, who wished a cheap article and was ready to assume the risk. The risk can hardly have been an imminent one, for the wheel lasted five years before it broke. In the meanwhile the buyer had made a lease of the machinery. It was held that the manufacturer was not answerable to the lessee. Loop v. Litchfield was followed in Losee v. Clute (51 N.Y. 494 (1873)), the case of the explosion of a steam boiler. That decision has been criticised but it must be confined to its special facts. It was put upon the ground that the risk of injury was too remote. The buyer in that case had not only accepted the boiler, but had tested it. The manufacturer knew that his own test was not the final one. The finality of the test has a bearing on the measure of diligence owing to persons other than the purchaser.

These early cases suggest a narrow construction of the rule. Later cases, however, evince a more liberal spirit. First in importance is Devlin v. Smith (89 N.Y. 470 (1882)). The defendant, a contractor, built a scaffold for a painter. The painter's servants were injured. The contractor was held liable. He knew that the scaffold, if improperly constructed, was a most dangerous trap. He knew that it was to be used by the workmen. He was building it for that very purpose. Building it for their use, he owed them a duty, irrespective of his contract with their master, to build it with care.

From Devlin v. Smith we pass over intermediate cases and turn to the latest case in this court in which Thomas v. Winchester was followed. That case is Statler v. Ray Mfg. Co. (195 N.Y. 478, 480 (1909)). The defendant manufactured a large coffee urn. It was installed in a restaurant. When heated, the urn exploded and injured the plaintiff. We held that the manufacturer was liable. We said that the urn "was of such a character inherently that, when applied to the purposes for which it was designed, it was liable to become a source of great danger to many people if not carefully and properly constructed."

It may be that Devlin v. Smith and Statler v. Ray Mfg. Co. have extended the rule of Thomas v. Winchester. If so, this court is committed to the extension. The defendant argues that things imminently dangerous to life are poisons, explosives, deadly weapons — things whose normal function it is to injure or destroy. But whatever the rule in Thomas v. Winchester may once have been, it has no longer that restricted meaning. A scaffold (Devlin v. Smith, *supra*) is not inherently a destructive instrument. It becomes destructive only if imperfectly constructed. A large coffee urn . . . may have within itself, if negligently made, the potency of danger, yet no one thinks of it as an implement whose normal function is destruction. What is true of the coffee urn is equally true of bottles of aerated water (Torgeson v. Schultz, 192 N.Y. 156 (1908)). We have mentioned only cases in this court. But the rule has received a like extension in our courts of intermediate appeal. . . .

[Cardozo, J., then reviews the parallel English decisions.]

We hold, then, that the principle of Thomas v. Winchester is not limited to poisons, explosives, and things of like nature, to things which in their normal operation are implements of destruction. If the nature of a thing is such that it is reasonably certain to place life and limb in peril when negligently made, it is then a thing of danger. Its nature gives

warning of the consequences to be expected. If to the element of danger there is added knowledge that the thing will be used by persons other than the purchaser, and used without new tests, then, irrespective of contract, the manufacturer of this thing of danger is under a duty to make it carefully. That is as far as we are required to go for the decision of this case. There must be knowledge of a danger, not merely possible, but probable. It is *possible* to use almost anything in a way that will make it dangerous if defective. That is not enough to charge the manufacturer with a duty independent of his contract. Whether a given thing is dangerous may be sometimes a question for the court and sometimes a question for the jury. There must also be knowledge that in the usual course of events the danger will be shared by others than the buyer. Such knowledge may often be inferred from the nature of the transaction. But it is possible that even knowledge of the danger and of the use will not always be enough. The proximity or remoteness of the relation is a factor to be considered. We are dealing now with the liability of the manufacturer of the finished product, who puts it on the market to be used without inspection by his customers. If he is negligent, where danger is to be foreseen, a liability will follow. We are not required at this time to say that it is legitimate to go back of the manufacturer of the finished product and hold the manufacturers of the component parts. To make their negligence a cause of imminent danger, an independent cause must often intervene; the manufacturer of the finished product must also fail in *his* duty of inspection. It may be that in those circumstances the negligence of the earlier members of the series is too remote to constitute, as to the ultimate user, an actionable wrong. . . . We leave that question open. We shall have to deal with it when it arises. The difficulty which it suggests is not present in this case. There is here no break in the chain of cause and effect. In such circumstances, the presence of a known danger, attendant upon a known use, makes vigilance a duty. We have put aside the notion that the duty to safeguard life and limb, when the consequences of negligence may be foreseen, grows out of contract and nothing else. We have put the source of the obligation where it ought to be. We have put its source in the law.

From this survey of the decisions, there thus emerges a definition of the duty of a manufacturer which enables us to measure this defendant's liability. Beyond all question, the nature of an automobile gives warning of probable danger if its construction is defective. This automobile was designed to go fifty miles an hour. Unless its wheels were sound and strong, injury was almost certain. It was as much a thing of danger as a defective engine for a railroad. The defendant knew the danger. It knew also that the car would be used by persons other than the buyer. This was apparent from its size; there were seats for three persons. It was apparent also from the fact that the buyer was a dealer in cars, who bought to resell. The maker of this car supplied it for the use of purchasers from the dealer just as plainly as the contractor in Devlin v. Smith supplied the scaffold for use by the servants of the owner. The dealer was indeed the one person of whom it might be said with some approach to certainty that by him the car would not be used. Yet the defendant would have us say that he was the one person whom it was under a legal duty to protect. The law does not lead us to so inconsequent a conclusion. Precedents drawn from the days of travel by stage coach do not fit the conditions of travel today. The principle that the danger must be imminent does not change, but the things subject to the principle do change. They are whatever the needs of life in a developing civilization require them to be.

In reaching this conclusion, we do not ignore the decisions to the contrary in other jurisdictions. . . . The earlier cases are summarized by Judge Sanborn in Huset v. J. I. Case Threshing Machine Co. (120 Fed. Rep. 865). . . . Judge Sanborn says . . . that the contractor who builds a bridge, or the manufacturer who builds a car, cannot ordinarily foresee injury to other persons than the owner as the probable result. We take a different view. We think that injury to others is to be foreseen not merely as a possible, but as an almost inevitable result. Indeed,

Judge Sanborn concedes that his view is not to be reconciled with our decision in Devlin v. Smith. The doctrine of that decision has now become the settled law of this state, and we have no desire to depart from it.

[Cardozo, J., then reviews the English cases from *Winterbottom* onward and continues:] From these cases a consistent principle is with difficulty extracted. The English courts, however, agree with ours in holding that one who invites another to make use of an appliance is bound to the exercise of reasonable care. That at bottom is the underlying principle of Devlin v. Smith. The contractor who builds the scaffold invites the owner's workmen to use it. The manufacturer who sells the automobile to the retail dealer invites the dealer's customers to use it. The invitation is addressed in the one case to determinate persons and in the other to an indeterminate class, but in each case it is equally plain, and in each its consequences must be the same. . . .

. . . Subtle distinctions are drawn by the defendant between things inherently dangerous and things imminently dangerous, but the case does not turn upon these verbal niceties. If danger was to be expected as reasonably certain, there was a duty of vigilance, and this whether you call the danger inherent or imminent. In varying forms that thought was put before the jury. We do not say that the court would not have been justified in ruling as a matter of law that the car was a dangerous thing. If there was any error, it was none of which the defendant can complain.

We think the defendant was not absolved from a duty of inspection because it bought the wheels from a reputable manufacturer. It was not merely a dealer in automobiles. It was a manufacturer of automobiles. It was responsible for the finished product. It was not at liberty to put the finished product on the market without subjecting the component parts to ordinary and simple tests. Under the charge of the trial judge nothing more was required of it. The obligation to inspect must vary with the nature of the thing to be inspected. The more probable the danger, the greater the need of caution. . . .

The judgment should be affirmed with costs.

Bartlett, C.J., dissenting. . . . [In Thomas v. Winchester,] Chief Judge Ruggles, who delivered the opinion of the court, distinguished between an act of negligence imminently dangerous to the lives of others and one that is not so, saying: "If A. build a wagon and sell it to B., who sells it to C. and C. hires it to D., who in consequence of the gross negligence of A. in building the wagon is overturned and injured, D. cannot recover damages against A., the builder. A.'s obligation to build the wagon faithfully, arises solely out of his contract with B. The public have nothing to do with it. . . . So, for the same reason, if a horse be defectively shod by a smith, and a person hiring the horse from the owner is thrown and injured in consequence of the smith's negligence in shoeing the smith is not liable for the injury." . . .

I do not see how we can uphold the judgment in the present case without overruling what has been so often said by this court and other courts of like authority in reference to the absence of any liability for negligence on the part of the original vendor of an ordinary carriage to any one except his immediate vendee. The absence of such liability was the very point actually decided in the English case of Winterbottom v. Wright, and the illustration quoted from the opinion of Chief Judge Ruggles in Thomas v. Winchester assumes that the law on the subject was so plain that the statement would be accepted almost as a matter of course. In the case at bar the defective wheel on an automobile moving only eight miles an hour was not any more dangerous to the occupants of the car than a similarly defective wheel would be to the occupants of a carriage drawn by a horse at the same speed; and yet unless the courts have been all wrong on this question up to the present time there would be no liability to strangers to the original sale in the case of the horse-drawn carriage.

Escola v. Coca Cola Bottling Co. of Fresno

150 P.2d 436 (Cal. 1944)

[The plaintiff was a waitress. As part of her job, she was placing into the restaurant's refrigerator bottles of Coca-Cola that had been delivered to the restaurant at least 36 hours earlier. As she put the fourth bottle into the refrigerator, it exploded in her hand, causing severe injuries. The plaintiff alleged that the defendant had been negligent in selling "bottles containing said beverage which on account of excessive pressure of gas or by reason of some defect in the bottle was dangerous . . . and likely to explode."

The jury entered a verdict for the plaintiff that was affirmed on appeal. Gibson, J., wrote as follows: "The bottle was admittedly charged with gas under pressure, and the charging of the bottle was within the exclusive control of the defendant. As it is a matter of common knowledge that an overcharge would not ordinarily result without negligence, it follows under the doctrine of res ipsa loquitur that if the bottle was in fact excessively charged an inference of defendant's negligence would arise."]

Traynor, J. I concur in the judgment, but I believe the manufacturer's negligence should no longer be singled out as the basis of a plaintiff's right to recover in cases like the present one. In my opinion it should now be recognized that a manufacturer incurs an absolute liability when an article that he has placed on the market, knowing that it is to be used without inspection, proves to have a defect that causes injury to human beings. MacPherson v. Buick Motor Co. established the principle, recognized by this court, that irrespective of privity of contract, the manufacturer is responsible for an injury caused by such an article to any person who comes in lawful contact with it. In these cases the source of the manufacturer's liability was his negligence in the manufacturing process or in the inspection of component parts supplied by others. Even if there is no negligence, however, public policy demands that responsibility be fixed wherever it will most effectively reduce the hazards to life and health inherent in defective products that reach the market. It is evident that the manufacturer can anticipate some hazards and guard against the recurrence of others, as the public cannot. Those who suffer injury from defective products are unprepared to meet its consequences. The cost of an injury and the loss of time or health may be an overwhelming misfortune to the person injured, and a needless one, for the risk of injury can be insured by the manufacturer and distributed among the public as a cost of doing business. It is to the public interest to discourage the marketing of products having defects that are a menace to the public. If such products nevertheless find their way into the market it is to the public interest to place the responsibility for whatever injury they may cause upon the manufacturer, who, even if he is not negligent in the manufacture of the product, is responsible for its reaching the market. However intermittently such injuries may occur and however haphazardly they may strike, the risk of their occurrence is a constant risk and a general one. Against such a risk there should be general and constant protection and the manufacturer is best situated to afford such protection.

The injury from a defective product does not become a matter of indifference because the defect arises from causes other than the negligence of the manufacturer, such as negligence of a submanufacturer of a component part whose defects could not be revealed by inspection, or unknown causes that even by the device of res ipsa loquitur cannot be classified as negligence of the manufacturer. The inference of negligence may be dispelled by an affirmative showing of proper care. If the evidence against the fact inferred is "clear, positive, uncontradicted, and of such a nature that it cannot rationally be disbelieved, the court must instruct the jury that the nonexistence of the fact has been established as a matter of law." An injured person, however, is not ordinarily in a position to refute such evidence or identify the cause of the defect, for he can hardly be familiar with the manufacturing process as the manufacturer himself is. In leaving it to the jury to decide whether the inference has been dispelled, regardless of the evidence

against it, the negligence rule approaches the rule of strict liability. It is needlessly circuitous to make negligence the basis of recovery and impose what is in reality liability without negligence. If public policy demands that a manufacturer of goods be responsible for their quality regardless of negligence there is no reason not to fix that responsibility openly.

Exhibit 8.3 Roger Traynor

Justice Roger Traynor (1900–1983), whose thirty-year tenure on the California Supreme Court encompassed twenty-four years as an associate justice (1940–1964) and six as chief justice (1964–1970), is the subject of a chapter in White, Tort Law in America: An Intellectual History ch. 6 (2003). According to White, the Traynor years were marked by "a strong interest in academic literature as source material; an effort to preserve, where possible, the lawmaking power of courts [in the face of "an increasingly detailed legislative apparatus"], and a search for a harmony of result and doctrine in his opinions." White, *supra*, at 182.

White further explains: "The basis for Traynor's faith in the judiciary as a lawmaking force . . . was his conviction that rationality could be achieved through enlightened judging." *Id.* at 188. Traynor, who "never departed from his belief that rationality was an achievable judicial goal . . . was not disturbed by the 'activist judge' label often attached to him." *Id.*

Source: Law School Archives, University of California, Berkeley

Indeed, and as shown by his concurrence in *Escola* and decision in *Greenman v. Yuba Power Products*, Inc., Traynor, "[i]n his activist conception of judging . . . was one of the pioneers of his time and one of the precursors of a 'policymaking' role for judges in tort cases. . . . Traynor was committed to using his powers as fully as possible to promote social policies in which he believed and to reorient the common law of California in directions he thought rational and desirable." *Id.* at 208.

In the case of foodstuffs, the public policy of the state is formulated in a criminal statute. . . . Statutes of this kind result in a strict liability of the manufacturer in tort to the member of the public injured.

The statute may well be applicable to a bottle whose defects cause it to explode. In any event it is significant that the statute imposes criminal liability without fault, reflecting the public policy of protecting the public from dangerous products placed on the market, irrespective of negligence in their manufacture. While the Legislature imposes criminal liability only with regard to food products and their containers, there are many other sources of danger. It is to the public interest to prevent injury to the public from any defective goods by the imposition of civil liability generally.

The retailer, even though not equipped to test a product, is under an absolute liability to his customer, for the implied warranties of fitness for proposed use and merchantable quality include a warranty of safety of the product. This warranty is not necessarily a contractual one; see 1 Williston on Sales, 2d ed., §§197–201, for public policy requires that the buyer be insured at the seller's expense against injury. The courts recognize, however, that the retailer cannot bear the burden of this warranty, and allow him to recoup any losses by means of the warranty of safety attending the wholesaler's or manufacturer's sale to him. . . . Such a procedure, however, is needlessly circuitous and engenders wasteful litigation. Much would be gained if the injured person could base his action directly on the manufacturer's warranty.

The liability of the manufacturer to an immediate buyer injured by a defective product follows without proof of negligence from the implied warranty of safety attending the sale. Ordinarily, however, the immediate buyer is a dealer who does not intend to use the product himself, and if the warranty of safety is to serve the purpose of protecting health and safety it must give rights to others than the dealer. In the words of Judge Cardozo in the *MacPherson* case: "The dealer was indeed the one person of whom it might be said with some approach to certainty that by him the car would not be used. Yet, the defendant would have us say that he was the one person whom it was under a legal duty to protect. The law does not lead us to so inconsequent a solution." While the defendant's negligence in the *MacPherson* case made it unnecessary for the court to base liability on warranty, Judge Cardozo's reasoning recognized the injured person as the real party in interest and effectively disposed on the theory that the liability of the manufacturer incurred by his warranty should apply only to the immediate purchaser. It thus paves the way for a standard of liability that would make the manufacturer guarantee the safety of his product even when there is no negligence.

This court and many others have extended protection according to such a standard to consumers of food products, taking the view that the right of a consumer injured by unwholesome food does not depend "upon the intricacies of the law of sales" and that the warranty of the manufacturer to the consumer in absence of privity of contract rests on public policy. Dangers to life and health inhere in other consumers' goods that are defective and there is no reason to differentiate them from the dangers of defective food products.

In the food products cases the courts have resorted to various fictions to rationalize the extension of the manufacturer's warranty to the consumer: that a warranty runs with the chattel; that the cause of action of the dealer is assigned to the consumer; that the consumer is a third party beneficiary of the manufacturer's contract with the dealer. They have also held the manufacturer liable on a mere fiction of negligence: "Practically he must know [the product] is fit, or bear the consequences if it proves destructive." Such fictions are not necessary to fix the manufacturer's liability under a warranty if the warranty is severed from the contract of sale between the dealer and the consumer and based on the law of torts as a strict liability. Warranties are not necessarily rights arising under a contract. An action on a warranty "was, in its origin, a pure action of tort," and only late in the historical development of warranties was an action in assumpsit allowed. (Ames, The History of Assumpsit, 2 Harv. L. Rev. 1, 8; 4 Williston on Contracts (1936) §970.) . . .

As handicrafts have been replaced by mass production with its great markets and transportation facilities, the close relationship between the producer and consumer of a product has been altered. Manufacturing processes, frequently valuable secrets, are ordinarily either inaccessible to or beyond the ken of the general public. The consumer no longer has means or skill enough to investigate for himself the soundness of a product, even when it is not contained in a sealed package, and his erstwhile vigilance has been lulled by the steady efforts of manufacturers to build up confidence by advertising and marketing devices such as trademarks. (See Thomas v. Winchester, 6 N.Y. 697; Baxter v. Ford Motor Co.[, 12 P.2d 409 (Wash. 1932)].) Consumers no longer approach products warily but accept them on faith, relying on the reputation of the manufacturer or the trademark. Manufacturers have sought to justify that faith by increasingly high standards of inspection and a readiness to make good on defective products by way of replacements and refunds. (See Bogert and Fink, Business Practices Regarding Warranties in the Sale of Goods, 25 Ill. L. Rev. 400.) The manufacturer's obligation to the consumer must keep pace with the changing relationship between them; it cannot be escaped because the marketing of a product has become so complicated as to require one or more intermediaries. Certainly, there is greater reason to impose liability on the manufacturer than on the retailer who is but a conduit of a product that he is not himself able to test.

The manufacturer's liability should, of course, be defined in terms of the safety of the product in normal and proper use, and should not extend to injuries that cannot be traced to the product as it reached the market.

NOTES

1. ***Rationales.*** At a factual level, does the switch to a theory of strict liability resolve the question of whether the Coca-Cola bottles were excessively charged in the factory or were mishandled by subsequent parties? As a theoretical matter, how sound are the various rationales for strict liability that Traynor, J., offers?

a. ***Loss Minimization.*** One rationale offered is that the manufacturer, rather than the unwitting consumer, is most knowledgeable and is therefore in the best position to minimize the losses that arise out of the general use of its product. If correct, should we also require strict liability for defective premises owned by commercial enterprises, or for that matter, strict liability for automobile accidents, at least when business enterprises are defendants? Recall Hammontree v. Jenner, *supra* Chapter 2, at 105. On this rationale, what adjustments should be made if the plaintiff or some downstream third party is in a better position to take the desired precautions? What if the plaintiff shook the bottle in use, or stored it in a hot place? Is it consistent with the loss minimization rationale to allow the manufacturer to contract out of liability with the consumer? Does a negligence rule fail to create the necessary incentives for the manufacturer to take appropriate cost-justified precautions?

b. ***Loss Spreading.*** A second defense of the strict liability rule in *Escola* rests upon the ability of the defendant producer to spread the damages among many consumers, thus cushioning the "overwhelming misfortune" of the injured person or her family. This risk-spreading rationale for strict liability was challenged in Wights v. Staff Jennings, Inc., 405 P.2d 624, 628 (Or. 1965), where the court observed:

> The rationale of risk spreading and compensating the victim has no special relevancy to cases involving injuries resulting from the use of defective goods. The reasoning would seem to apply not only in cases involving personal injuries arising from the *sale* of defective goods, but equally to any case where an injury results from the risk creating conduct of the seller in any stage of the production and distribution of goods. Thus a manufacturer would be strictly liable even in the absence of fault for any injury to a person struck by one of the manufacturer's trucks being used in transporting his goods to market. It seems to us that the enterprise liability rationale employed in the *Escola* case proves too much and that if adopted would compel us to apply the principle of strict liability in all future cases where the loss could be distributed.

c. ***Elimination of Proof Complications.*** Traynor, J., also defends strict liability in *Escola* because it simplifies the law by eliminating the need to resort to res ipsa loquitur—the same reason used to defend strict liability in Rylands v. Fletcher. See Chapter 2, *supra* at 85. In all contexts, a strict liability rule switches the residual risk of unavoidable accidents from the plaintiff to the defendant. With exploding soda bottles, that risk is generally quite small given the stringent quality control and inspection devices incorporated into the manufacturing process. How does res ipsa loquitur apply when misconduct by the plaintiff or a third party is also at issue? Should it make any difference that the plaintiff in *Escola* could not produce the pieces of the broken bottle for inspection and examination?

d. ***The Foodstuffs Analogy.*** A fourth defense of strict liability rests on the analogy between adulterated foodstuffs and product defects. In this regard, the law after *MacPherson* and before *Escola* drew a distinction between foodstuffs that were sold in sealed

containers and those that were not. For goods sold in sealed containers, the law exempted the retailer from liability but allowed a direct suit against the manufacturer, albeit on a negligence theory. See, e.g., Richenbacher v. California Packing Corp., 145 N.E. 281 (Mass. 1924), sustaining the use of res ipsa loquitur when the plaintiff's mouth was cut by glass found in a container of spinach. In contrast, when goods were not packaged, the general rule imposed negligence liability, if at all, on the retailer, but not on the original food supplier. Is *Richenbacher* an easier case for res ipsa loquitur than *Escola*? Why?

e. ***Corrective Justice.*** Another argument for strict liability in products cases—one not pressed by Traynor—is that the loss should be placed upon the party who created the dangerous condition, not the party who suffered from it. This reasoning is similar to the argument for strict liability in ordinary trespass cases, or even under the rule in Rylands v. Fletcher: Once the plaintiff establishes the causal connection to the defendant's act (in *Escola*, the defective bottling under pressure that caused harm), then, prima facie, the defendant should be held liable. Note, however, one structural difference between the two types of cases. With abnormally dangerous activities, the defendant is virtually always in possession of the dangerous instrumentality just before it causes the accident, so the class of defenses based upon plaintiff's conduct remains quite small. See *supra* Chapter 2, Note 2, at 66, and Chapter 7, Note 4, at 487. With products liability, the defendant is never in possession of the dangerous product when it causes injury, so that the older privity limitation might be a sensible way for liability to track possession (and hence control), except in those few cases in which a party out of possession is in a better position to avoid the loss. See Epstein, The Historical Origins and Economic Structure of Workers' Compensation Law, 16 Ga. L. Rev. 775, 806–08 (1982), defending privity for workplace injuries on the ground that employer's liability is both cheaper and more efficient than manufacturer's liability.

2. *Criticisms.* For an early criticism of strict liability in products cases, see Plant, Strict Liability of Manufacturers for Injuries Caused by Defects in Products—An Opposing View, 24 Tenn. L. Rev. 938, 945 (1957), in which it is noted that "[t]he element which is most disturbing to manufacturers is not the potential judgment of legal liability but the injury which is done to the reputation of the product and its producers." Note that modern "event studies" establish that the decline in the value of the shares of a publicly traded company after a major product incident is greater than the anticipated amount of the liability. For evidence of the impact of these studies, see Prince & Rubin, The Effects of Product Liability Litigation on the Value of Firms, 45 Am. L. & Econ. Rev. 44 (2002):

> [F]irms facing lawsuits for their products suffer capital market losses approximately equal to a worst-case scenario associated with the litigation. Thus, it appears that individual firms may suffer reputation costs as a consequence of product liability lawsuits but that these reputation losses are smaller than losses from government actions such as recall.

See also Dranove, Delivering Bad News: Market Responses to Negligence, 55 J.L. & Econ. 1, 2 (2012), which notes some "anecdotal evidence" that points to some reputational effect:

> For example, sales of Johnson & Johnson's Tylenol plummeted in 1982 after the product was tainted by tampering, and ValuJet lost customers and even changed its name after the 1996 crash of flight 592. More recently, the spate of vehicle recalls faced by Toyota over allegedly defective acceleration put the automaker under intense public scrutiny and caused its U.S. market share to plummet. . . .

To what extent should the negative effect depend on the perceived fault of the defendant in bringing about the incident? The promptness of its corrective actions? The willingness to

remove product from the market? Is the perception of fault likely to be greater for airline crashes and brake failures than for contaminations known to be caused downstream by malicious third parties?

3. ***Implied Warranty: Elimination of Privity in Contract Law.*** The early privity limitation in Chysky v. Drake, *supra* at 555, was overruled thirty-eight years later in Greenberg v. Lorenz, 173 N.E.2d 773 (N.Y. 1961). There the plaintiff was injured when she ate canned salmon that contained sharp metal slivers, sold by the defendant retail food dealer to her father. The court below dismissed the plaintiff's complaint because the plaintiff had not purchased the salmon herself. The Court of Appeals reversed. Just about that time, the warranty provisions of the law of sales were reworked under a new Uniform Commercial Code, which offers three possible approaches to the scope of the warranty.

UNIFORM COMMERCIAL CODE

§2-318. Third Party Beneficiaries of Warranties Express or Implied

Alternative A

A seller's warranty whether express or implied extends to any natural person who is in the family or household of his buyer or who is a guest in his home if it is reasonable to expect that such person may use, consume or be affected by the goods and who is injured in person by breach of the warranty. A seller may not exclude or limit the operation of this section.

Alternative B

A seller's warranty whether express or implied extends to any natural person who may reasonably be expected to use, consume or be affected by the goods and who is injured in person by breach of the warranty. A seller may not exclude or limit the operation of this section.

Alternative C

A seller's warranty whether express or implied extends to any person who may reasonably be expected to use, consume or be affected by the goods and who is injured by breach of the warranty. A seller may not exclude or limit the operation of this section with respect to injury to the person of an individual to whom the warranty extends.

New York originally adopted alternative A. In 1975, however, it adopted alternative B (N.Y. U.C.C. Law §2-318 (2023)). If *X* steals a roll from *Y*, who had purchased it from *Z*, should *X* recover from *Z* under the variations of section 2-318 when injured by a piece of sharp metal baked into the roll? Why should the parties, unlike the dealer in *Baxter*, *supra* at 555, be unable to contract out of this provision?

4. ***Henningsen: Implied Warranty with a Vengeance.*** In Henningsen v. Bloomfield Motors, Inc., 161 A.2d 69 (N.J. 1960), Henningsen purchased a new Plymouth automobile, manufactured by the defendant Chrysler Corporation, from the defendant Bloomfield Motors, Inc. Henningsen gave the car to his wife, after indicating to the dealer his intention to make it a gift. The contract of sale between Mr. Henningsen and the two defendants expressly disclaimed all warranties by the dealer or manufacturer, except one that limited the liability of the defendants to the original purchaser and only then for replacement of defective parts within ninety days or 4,000 miles, whichever occurred first. Shortly after the car was purchased, the plaintiff, Mrs. Henningsen, was driving along a clear road when the steering mechanism suddenly went awry. The car went out of control and veered off the road and

into a wall, injuring her. She sued on theories of negligence and warranty. After the trial court dismissed the negligence claim, the jury found for the plaintiff against both defendants on the warranty claim and the defendants appealed. In a very lengthy opinion, Francis, J., examined how the courts had extended the implied warranty of merchantability to individuals who were not party to the original sales agreement, a development he found absolutely necessary as manufacturers increasingly distanced themselves from sales act liability to consumers by a complex web of contracts. He insisted that the limited protection to the plaintiff under this express warranty was a "sad commentary" on the marketing practices of automobile manufacturers.

Although he thought the ordinary warranty of merchantability might technically survive this disclaimer clause, Francis, J., did not rely on any interpretative techniques. Instead he voided the disclaimer clause on the ground that it "was not fairly obtained." It followed that the benefit of the implied warranty ran to the plaintiff, even in the absence of privity, so long as the defendant "puts a new automobile in the stream of trade and promotes its purchase by the public."

A breakthrough for its time, *Henningsen*'s importance appears to have waned somewhat, not because courts have rejected its outcome, but because, ironically, its implied warranty theory tied products liability actions too closely to the law of sales. Modern cases, however, still occasionally allow a jury to find liability under a warranty theory while denying recovery under a tort theory. In Denny v. Ford Motor Co., 662 N.E.2d 730, 736 (N.Y. 1995), the plaintiff was injured when her Ford Bronco, owing to its high center of gravity, rolled over after she slammed on the brakes. The jury found that the vehicle was not "defective" but awarded her $1,200,000 in damages ($2,423,535 in 2023 dollars) on an implied warranty theory. The court rejected Ford's contention that tort had "completely subsumed" warranty theory, noting that the "negligence-like risk/benefit component of the defect element differentiates strict products liability claims from U.C.C.-based breach of implied warranty claims in cases involving design defects."

Can a product without a defect flunk the merchantability test? In Castro v. QVC Network, 139 F.3d 114, 118 (2d Cir. 1998), the plaintiff was badly burned when a twenty-five-pound Thanksgiving turkey fell on her legs and ankles. It caused second- and third-degree burns after it slipped out of a roaster manufactured by defendant U.S.A. T-Fal Corp. and sold by defendant QVC over its home-shopping network. The trial judge refused to offer separate instructions on both strict liability and warranty counts, but after the jury found for the defendants, Calabresi, J., relied on *Denny* to grant a new trial: "The imposition of strict liability for an alleged design 'defect' is determined by a risk-utility standard. The notion of 'defect' in a U.C.C.-based breach of warranty claim focuses, instead, on consumer expectations." Here, according to Calabresi, J., the purpose for which the product was marketed (cooking a large turkey) was different from its designed-for use (cooking low-volume baked goods). Will all "dual-purpose" goods henceforth require separate jury instructions?

What if a product component is unfit for its ordinary purpose? In Nemes v. Dick's Sporting Goods, Inc., 521 F. Supp. 3d 328, 343–44 (S.D.N.Y. 2021), a case about a crossbow with an allegedly-defective finger guard, Roman, J., distinguished *Castro*:

> That holding does not reflect that a product's component parts, e.g., the handle of the pan, define the ordinary purpose of that product. . . . [T]he ordinary purpose of a good is not usually defined by the individual function of an ancillary component. . . . Instead, the implied warranty is breached where the product in question is not fit for the ordinary purpose for which it is to be used.

Is the court's holding sound given that consumers expect product components to serve the functions for which they are designed?

5. *Strict Liability in Torts: The Greenman Reformulation.* Shortly after *Henningsen*, the tort side of products liability also gravitated toward strict liability. In Greenman v. Yuba Power Products, Inc., 377 P.2d 897, 900–01 (Cal. 1963), the plaintiff's wife gave him a Shopsmith combination power tool, manufactured by the defendant, that could be used as a saw, a drill, and a wood lathe. The plaintiff read the manufacturer's brochure, which contained the following statements: "(1) WHEN SHOPSMITH IS IN HORIZONTAL POSITION—Rugged construction of frame provides rigid support from end to end. Heavy centerless-ground steel tubing insures perfect alignment of components. (2) SHOPSMITH maintains its accuracy because every component has positive locks that hold adjustments through rough or precision work." In the course of working the lathe, a piece of wood "suddenly flew out of the machine and struck him on the forehead, inflicting serious injury." There was substantial evidence that the plaintiff's injuries were caused by the defective construction of the Shopsmith, whose set screws were of insufficient strength to hold the wood in place while the lathe was being operated. The plaintiff recovered damages from the manufacturer for negligence and breach of both express and implied warranties.

One of the defendant's contentions on appeal was that the plaintiff's cause of action was barred because he failed to give notice of his injury within a "reasonable time" as required by section 1769 of the California Civil Code. Traynor, J., speaking for the entire court, sidestepped the "intricacies" of the warranty provisions by opting for strict liability in tort:

> A manufacturer is strictly liable in tort when an article he places on the market, knowing that it is to be used without inspection for defects, proves to have a defect that causes injury to a human being. Recognized first in the case of unwholesome food products, such liability has now been extended to a variety of other products that create as great or greater hazards if defective.
>
> Although in these cases strict liability has usually been based on the theory of an express or implied warranty running from the manufacturer to the plaintiff, the abandonment of the requirement of a contract between them, the recognition that the liability is not assumed by agreement but imposed by law, and the refusal to permit the manufacturer to define the scope of its own responsibility for defective products make clear that the liability is not one governed by the law of contract warranties but by the law of strict liability in tort. Accordingly, rules defining and governing warranties that were developed to meet the needs of commercial transactions cannot properly be invoked to govern the manufacturer's liability to those injured by their defective products unless those rules also serve the purposes for which such liability is imposed.
>
> We need not recanvass the reasons for imposing strict liability on the manufacturer. The purpose of such liability is to insure that the costs of injuries resulting from defective products are borne by the manufacturers that put such products on the market rather than by the injured persons who are powerless to protect themselves. Sales warranties serve this purpose fitfully at best. In the present case, for example, plaintiff was able to plead and prove an express warranty only because he read and relied on the representations of the Shopsmith's ruggedness contained in the manufacturer's brochure. Implicit in the machine's presence on the market, however, was a representation that it would safely do the jobs for which it was built. Under these circumstances, it should not be controlling whether plaintiff selected the machine because of the statements in the brochure, or because of the machine's own appearance of excellence that belied the defect lurking beneath the surface, or because he merely assumed that it would safely do the jobs it was built to do. It should not be controlling whether the details of the sales from manufacturer to retailer and from retailer to plaintiff's wife were such that one or more of the implied warranties of the sales act arose. (Civ. Code, §1735.) "The remedies of injured consumers ought not to be made to depend upon the intricacies of the law of sales." To establish the manufacturer's liability it was sufficient that plaintiff proved that he was injured while using the Shopsmith in a way it was intended to be used as a result of a defect in design and manufacture of which plaintiff was not aware that made the Shopsmith unsafe for its intended use.

SECTION C. THE RESTATEMENTS

1. A Tale of Two Texts

RESTATEMENT (SECOND) OF TORTS

§402A. Special Liability of Seller of Product for Physical Harm to User or Consumer

(1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if

(a) the seller is engaged in the business of selling such a product, and

(b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.

(2) The rule stated in Subsection (1) applies although

(a) the seller has exercised all possible care in the preparation and sale of his product, and

(b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

Caveat: The Institute expresses no opinion as to whether the rules stated in this Section may not apply

(1) to harm to persons other than users or consumers

(2) to the seller of a product expected to be processed or otherwise substantially changed before it reaches the user or consumer or

(3) to the seller of a component part of a product to be assembled.

Comment f. Business of Selling: The rule stated in this Section applies to any person engaged in the business of selling products for use or consumption. It therefore applies to any manufacturer of such a product, to any wholesale or retail dealer or distributor, and to the operator of a restaurant. . . .

The rule does not, however, apply to the occasional seller of food or other such products who is not engaged in that activity as a part of his business. Thus it does not apply to the housewife who, on one occasion, sells to her neighbor a jar of jam or a pound of sugar. Nor does it apply to the owner of an automobile who, on one occasion, sells it to his neighbor, or even sells it to a dealer in used cars, and this even though he is fully aware that the dealer plans to resell it. The basis for the rule is the ancient one of the special responsibility for the safety of the public undertaken by one who enters into the business of supplying human beings with products which may endanger the safety of their persons and property, and the forced reliance upon that undertaking on the part of those who purchase such goods. This basis is lacking in the case of the ordinary individual who makes the isolated sale, and he is not liable to a third person, or even to his buyer, in the absence of his negligence. . . .

Comment g. Defective Condition: The rule stated in this Section applies only where the product is, at the time it leaves the seller's hands, in a condition not contemplated by the ultimate consumer, which will be unreasonably dangerous to him. The seller is not liable when he delivers the product in a safe condition, and subsequent mishandling or other causes make it harmful by the time it is consumed. The burden of proof that the product was in a defective condition at the time that it left the hands of the particular seller is

upon the injured plaintiff; and unless evidence can be produced which will support the conclusion that it was then defective, the burden is not sustained.

Safe condition at the time of delivery by the seller will, however, include proper packaging, necessary sterilization, and other precautions required to permit the product to remain safe for a normal length of time when handled in a normal manner.

Comment h: A product is not in defective condition when it is safe for normal handling and consumption. If the injury results from abnormal handling, as where a bottled beverage is knocked against a radiator to remove the cap, or from abnormal preparation for use, as where too much salt is added to food, or from abnormal consumption, as where a child eats too much candy and is made ill, the seller is not liable. . . .

The defective condition may arise not only from harmful ingredients, not characteristic of the product itself either as to presence or quantity, but also from foreign objects contained in the product, from decay or deterioration before sale, or from the way in which the product is prepared or packed. No reason is apparent for distinguishing between the product itself and the container in which it is supplied; and the two are purchased by the user or consumer as an integrated whole. Where the container is itself dangerous, the product is sold in a defective condition. Thus a carbonated beverage in a bottle which is so weak, or cracked, or jagged at the edges, or bottled under such excessive pressure that it may explode or otherwise cause harm to the person who handles it, is in a defective and dangerous condition. . . .

Comment i. Unreasonably Dangerous: The rule stated in this Section applies only where the defective condition of the product makes it unreasonably dangerous to the user or consumer. Many products cannot possibly be made entirely safe for all consumption, and any food or drug necessarily involves some risk of harm, if only from over-consumption. Ordinary sugar is a deadly poison to diabetics, and castor oil found use under Mussolini as an instrument of torture. That is not what is meant by "unreasonably dangerous" in this Section. The article sold must be dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics. Good whiskey is not unreasonably dangerous merely because it will make some people drunk, and is especially dangerous to alcoholics; but bad whiskey, containing a dangerous amount of fusel oil, is unreasonably dangerous. Good tobacco is not unreasonably dangerous merely because the effects of smoking may be harmful; but tobacco containing something like marijuana may be unreasonably dangerous. Good butter is not unreasonably dangerous merely because, if such be the case, it deposits cholesterol in the arteries and leads to heart attacks; but bad butter, contaminated with poisonous fish oil, is unreasonably dangerous.

Comment j. Directions or Warning: In order to prevent the product from being unreasonably dangerous, the seller may be required to give directions or warning, on the container, as to its use. The seller may reasonably assume that those with common allergies, as for example to eggs or strawberries, will be aware of them, and he is not required to warn against them. Where, however, the product contains an ingredient to which a substantial number of the population are allergic, and the ingredient is one whose danger is not generally known, or if known is one which the consumer would reasonably not expect to find in the product, the seller is required to give warning against it, if he has knowledge, or by the application of reasonable, developed human skill and foresight should have knowledge, of the presence of the ingredient and the danger. Likewise in the case of poisonous drugs, or those unduly dangerous for other reasons, warning as to use may be required.

But a seller is not required to warn with respect to products, or ingredients in them, which are only dangerous or potentially so, when consumed in excessive quantity, or over a long period of time, when the danger, or potentiality of danger, is generally known and recognized. Again the dangers of alcoholic beverages are an example, as are also those of foods containing such substances as saturated fats, which may over a period of time have a deleterious effect upon the human heart.

Where warning is given, the seller may reasonably assume that it will be read and heeded; and a product bearing such a warning, which is safe for use if it is followed, is not in defective condition, nor is it unreasonably dangerous.

Comment k. Unavoidably Unsafe Products: There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

Comment m. "Warranty": The rule stated in this Section does not require any reliance on the part of the consumer upon the reputation, skill, or judgment of the seller who is to be held liable, nor any representation or undertaking on the part of that seller. The seller is strictly liable although, as is frequently the case, the consumer does not even know who he is at the time of consumption. The rule stated in this Section is not governed by the provisions of the Uniform Sales Act, or those of the Uniform Commercial Code, as to warranties; and it is not affected by limitations on the scope and content of warranties, or by limitation to "buyer" and "seller" in those statutes. Nor is the consumer required to give notice to the seller of his injury within a reasonable time after it occurs, as is provided by the Uniform Act. . . .

Comment n. Contributory Negligence: Since the liability with which this Section deals is not based upon negligence of the seller, but is strict liability, the rule applied to strict liability cases (see §524) applies. Contributory negligence of the plaintiff is not a defense when such negligence consists merely in a failure to discover the defect in the product, or to guard against the possibility of its existence. On the other hand the form of contributory negligence which consists in voluntarily and unreasonably proceeding to encounter a known danger, and commonly passes under the name of assumption of risk, is a defense under this Section as in other cases of strict liability. If the user or consumer discovers the defect and is aware of the danger, and nevertheless proceeds unreasonably to make use of the product and is injured by it, he is barred from recovery.

NOTES

1. *Second Restatement §402A.* Until the adoption of the Restatement (Third) of Torts: Products Liability, section 402A and its comments formed the basic text of modern products liability law. At its inception, section 402A was noted for its adoption of a broad strict liability rule for product defects. Its early drafts were originally confined to foodstuffs and products intended for intimate bodily use, but by 1965 the strict liability rule was extended to all products. This broad application made it more difficult to devise a single rule to cover an endless diversity of products, for example, the unique issues raised by pharmaceuticals. Accordingly, Prosser and other drafters of the Second Restatement addressed many difficult questions in the comments to the basic text, which, over time, have become as important as the basic provision itself. Even today, the Third Restatement has not displaced the Second across the board, so it is critical to gain mastery over both. On the adoption of section 402A, see Epstein, Modern Products Liability Law ch. 6 (1980); Priest, The Invention of Enterprise Liability: A Critical History of the Intellectual Foundations of Modern Tort Law, 14 J. Legal Stud. 461, 505–19 (1985).

The Second Restatement also contains section 402B, "Misrepresentation by Seller of Chattels to Consumer," which adopts a strict liability standard for a product seller, proclaiming that one "who, by advertising, labels, or otherwise, makes to the public a misrepresentation of a material fact concerning the character or quality of a chattel sold by him is subject to liability for physical harm to a consumer of the chattel caused by justifiable reliance upon the misrepresentation." Section 402B has been swallowed up in litigation by section 402A. Does it provide a superior basis for liability in *Henningsen*? *Greenman*?

2. *Bystander's Recovery.* Current case law has gone beyond the Second Restatement by allowing injured bystanders to sue the original manufacturer. The initial hesitation regarding bystander cases rested in part on the uncertainty of whether any implied warranty or misrepresentation theory could hold the defendant accountable to anyone outside the chain of contracts. The bystander is not lured into using the product by the defendant's representations. Neither is she an immediate or ultimate beneficiary of any seller or manufacturer warranty. The bystander's case for strict liability in tort is far stronger: As with abnormally dangerous activities, the bystander has been hurt by a process that was in no sense her making because she never used the product at all. Though in practice bystander injuries are relatively infrequent compared to the numerous injuries to product consumers or users, today the liability of the manufacturer or seller to the bystander is universally allowed. See, e.g., Elmore v. Am. Motors Corp., 451 P.2d 84 (Cal. 1969); Codling v. Paglia, 298 N.E.2d 622 (N.Y. 1973); Noel, Defective Products: Extension of Strict Liability to Bystanders, 38 Tenn. L. Rev. 1 (1970).

RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY

§1. Liability of Commercial Seller or Distributor for Harm Caused by Defective Products

One engaged in the business of selling or otherwise distributing products who sells or distributes a defective product is subject to liability for harm to persons or property caused by the defect.

§2. Categories of Product Defects

[For purposes of determining liability under section 1:]

A product is defective when, at the time of sale or distribution, it contains a manufacturing defect, is defective in design, or is defective because of inadequate instructions or warnings. A product:

(a) contains a manufacturing defect when the product departs from its intended design even though all possible care was exercised in the preparation and marketing of the product;

(b) is defective in design when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the alternative design renders the product not reasonably safe;

(c) is defective because of inadequate instructions or warnings when the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the instructions or warnings renders the product not reasonably safe.

NOTES

1. ***Into the Next Generation.*** The Third Restatement reflects the transformation of products liability law after 1965. Most significantly, it adopts the now dominant tripartite classification of manufacturing, design, and warning defects, and establishes a distinct liability rule for each class. It keeps the original strict liability rule for products with manufacturing defects but imposes only the more limited obligation to make product designs, warnings, and instructions "reasonably safe." Although the Third Restatement rejects RST §402A's caveat on bystander liability, many of the old rules still carry over, such as the exclusion of "casual sellers." See RTT: PL §1, comment *c*. Subsequent provisions of the Third Restatement examine each class of defects, and contain additional provisions to deal with prescription drugs, issues of causation, and affirmative defenses. For an early discussion of the revisions of the Second Restatement, by the joint reporters for the Third Restatement, see Henderson & Twerski, A Proposed Revision of Section 402A of the Restatement (Second) of Torts, 77 Cornell L. Rev. 1512 (1992). For an acceptance of the Third Restatement over the Second, see Evans v. Lorillard Tobacco Co., 990 N.E.2d 997, 1013–14 (Mass. 2013); for a continued preference for the Second Restatement over the Third, see Tincher v. Omega Flex, Inc., 104 A.3d 328, 335 (Pa. 2014), *infra* at 596.

2. ***Who Chooses to Adopt the Third Restatement?*** The Pennsylvania Supreme Court in *Tincher* wrestled with whether the courts, rather than the legislature, should play an active role in deciding whether to adopt the Third Restatement. While the court in *Tincher* believed this decision should be left to the democratically elected General Assembly, is it ever justified to leave this decision to the courts?

2. The Theory of Products Liability: Tort or Contract

The early history of products liability law reveals a consistent tension between the contract-based theory of implied warranty and the tort theory sounding either in negligence or strict liability. The adoption of the Second Restatement in 1965 largely endorsed the tort theory for personal injuries, while the treatment of damage to property remained less clear, as the Second Restatement intimated that matters of "economic loss" were best left to voluntary agreement between the parties. But how are those losses defined? Everyone agrees that disappointed expectations about product performance are outside section 402A, as when a truck constantly stalls out on the highway, causing its owner to make late deliveries. But do these losses also cover economic losses that flow from physical damage to the product sold? The following materials explore the difficulties that arise in policing the line between products liability and contract law respectively.

3. Proper Defendants Under Section 402A

Second Restatement §402A only applies to sellers who are "engaged in the business of selling . . . a product."

Loomis v. Amazon.com LLC

277 Cal. Rptr. 3d 769 (Ct. App. 2021)

OHTA, J. Kisha Loomis brought suit against Amazon.com LLC (Amazon) for injuries she suffered from an allegedly defective hoverboard. The hoverboard was sold by a third party seller named TurnUpUp through the Amazon website. The trial court granted summary judgment in favor of Amazon. The primary issue on appeal is whether Amazon may be held strictly liable for Loomis's injuries from the defective product. . . . We reverse and remand with directions.

FACTS

Loomis ordered a hoverboard on Amazon's website on November 28, 2015. The listing identified the seller to be TurnUpUp, a name used by SMILETO to sell its products on Amazon's marketplace. SMILETO is allegedly a company based in China. . . . Loomis gifted the hoverboard to her son. On New Year's Eve, he plugged it into an outlet in Loomis's bedroom to charge. Loomis's boyfriend later discovered a fire burning in her bedroom. Her bed and the hoverboard were on fire. Loomis suffered burns to her hand and foot as a result of fighting the fire. . . .

Amazon.com is an online marketplace where Amazon and third party sellers list their products for sale. Amazon describes its marketplace as "an online mall" which provides an "online storefront" to third party sellers. Where Amazon is the seller of a product, it is identified as the seller on the product detail page, and it sources the product, sets the price, and holds title to it. This case does not involve an Amazon-listed product. Where a third party is the seller, it is identified as such on the product detail page and again on the order confirmation page before the user places the order. The third party sources the product, sets the price, and holds title to it.

All third party sellers operate under the Amazon services business solutions agreement (BSA). . . .

ANALYSIS

Vertical Chain of Distribution

As technology advances, innovation is paving the way to new business practices. Amazon is on the leading edge of e-commerce. Based on our review of Amazon's third party business model under the BSA, we are persuaded that Amazon's own business practices make it a direct link in the vertical chain of distribution under California's strict liability doctrine.

Contrary to Amazon's assertion that it merely provided an online storefront for TurnUpUp and others to sell their wares, it is undisputed Amazon placed itself squarely between TurnUpUp, the seller, and Loomis, the buyer, in the transaction at issue. When Loomis wanted to buy a hoverboard for her son, she perused product listings on Amazon's website. Amazon took Loomis's order and processed her payment. It then transmitted the order to TurnUpUp, who packaged and shipped the product to Loomis. . . . TurnUpUp was not allowed to communicate with Loomis directly. If Loomis had wanted to return the hoverboard, the return would have been routed through Amazon.

Amazon remitted Loomis's payment to TurnUpUp after deducting its fees, including a 15 percent referral fee based on the total sale price. These facts undermine Amazon's

characterization of its marketplace as an online mall providing online storefronts for sellers. Owners of malls typically do not serve as conduits for payment and communication in each transaction between a buyer and a seller. Moreover, they do not typically charge a per-item fee rather than a fixed amount to rent their storefronts. Instead, these actions—(1) interacting with the customer, (2) taking the order, (3) processing the order to the third party seller, (4) collecting the money, and (5) being paid a percentage of the sale—are consistent with a retailer or a distributor of consumer goods.

Stream of Commerce Approach

Although we conclude Amazon is a link in the vertical chain of distribution, we nevertheless recognize e-commerce may not neatly fit into a traditional sales structure. The stream of commerce approach or market enterprise theory offers an alternative basis for strict liability. . . . [A] defendant may be strictly liable under the stream of commerce approach if:

(1) the defendant received a direct financial benefit from its activities and from the sale of the product;
(2) the defendant's role was integral to the business enterprise such that the defendant's conduct was a necessary factor in bringing the product to the initial consumer market; and
(3) the defendant had control over, or a substantial ability to influence, the manufacturing or distribution process.

[The court then holds that the 15 percent referral fee satisfied the first condition; it holds that the second issue was triable because "it has presented no evidence of its role in bringing TurnUpUp's hoverboards to market." It then holds that the third factor was satisfied because Amazon could exert influence over the process thanks to its "ability to require safety certification, indemnification, and insurance before it agrees to list any product."]

Policy Considerations Underlying the Doctrine Are Furthered by Imposing Strict Products Liability in This Case

In analyzing whether strict liability is appropriate in new circumstances, courts assess whether relevant public policy goals are furthered by its application. . . . [T]he relevant public policy considerations are:

(1) Whether Amazon may play a substantial part in insuring that the product is safe or may be in a position to exert pressure on the manufacturer to that end;
(2) Whether Amazon may be the only member in the distribution chain reasonably available to the injured plaintiff; and
(3) Whether Amazon is in a position to adjust the costs of compensating the injured plaintiff amongst various members in the distribution chain.

We address each in turn.

[Ohta, J., holds that the limited steps that Amazon could take satisfied the first test, and predicts that a strict liability rule will encourage Amazon to "expand its safety compliance requirement, and to use its "gatekeeper" rule to pressure upstream suppliers to take additional precautions.]

As to consumer compensation, Amazon may be the only member of the distribution chain reasonably available for an injured consumer to recover damages. Amazon contends there is no evidence to show how frequently an injured plaintiff is truly left without recourse. The record shows, however, that Forrinx, the only other defendant in this matter, failed to appear and a default was taken against it. . . .

As to loss spreading, Amazon can adjust the costs of consumer protection between it and third party sellers through its fees, indemnity requirements, and insurance. . . .

Accordingly, we hold the application of strict liability to Amazon's third party seller business model is supported by the relevant public policy considerations[.]

WILEY, J., concurring. [W]e have an easy case that beautifully illustrates the deep structure of modern tort law: a judicial quest to minimize the social costs of accidents — that is, the sum of the cost of accidents and the cost of avoiding accidents. Judges have been applying this social cost-benefit analysis as a felt instinct for a long time. . . . That deep structure makes this case simple to decide. When efforts to minimize accident costs are relatively inexpensive and apt to be effective, courts impose tort duties. Amazon has cost-effective options for minimizing accident costs. Amazon therefore has a duty in strict liability to the buyers from its site, including Kisha Loomis. . . .

Amazon's options are practical and cost-effective; indeed, Amazon says it is *already* taking these actions. Amazon thus must face strict liability for Loomis's fiery encounter with the hoverboard she bought from Amazon's site. Imposing this duty on Amazon creates financial incentives that back up Amazon's good words about its concern for customer safety.

Some suggest considerations of moral justice can compete with tort law's calculus of social benefit. . . . If they ever do, moral justice and cost-benefit analyses do not conflict in this case.

NOTES

1. ***Online Platforms: The Fifth Stage of Products Liability?*** Sharkey, Products Liability in the Digital Age: Online Platforms as "Cheapest Cost Avoiders," 73 Hastings L.J. 1327 (2022), heralds the arrival of a new stage of products liability in the digital age. Moreover, *Loomis* fits the pattern that, at each new juncture,

> judges have relied explicitly on deterrence, or prevention of harm, rationales to address new forms of risks and prevent them from materializing into harms. This is no less true as we enter a new stage of digital e-commerce risks faced by society in the 21st century.

Sharkey, The Irresistible Simplicity of Preventing Harm, 16 J. Tort L. 143, 151 (2023). Twerski & Janger, The Heavy Hand of Amazon: A Seller Not a Neutral Platform, 14 Brook. J. Corp. Fin. & Com. L. 259, 267 (2020), likewise prods courts to recognize how "Amazon itself controls access to the site, the manner in which the items are displayed, and receives compensation at every stage. In fact, except for the formality of title, the level of integration in Amazon's supply chain is comparable to that of a standard brick-and-mortar seller."

Whereas *Loomis* relied on the common law evolution of products liability in California, other jurisdictions have declined to find liability under their respective product liability statutes. E.g., Amazon.com, Inc. v. McMillan, 625 S.W.3d 101 (Tex. 2021); Stiner v. Amazon.com, Inc., 164 N.E.3d 394 (Ohio 2020). Given the volume and diversity of merchant offerings, is Amazon in the best position to eliminate the unsafe character of products in the first instance? Would adding a vetting process for merchants hinder the business prospects of new or small merchants? What about requiring foreign sellers to designate domestic parties who could then bear liability?

2. ***Liability of Retailers and Distributors.*** Products liability law has long applied uniformly to all ordinary product retailers and distributors in the initial chain of distribution. Traynor, J., made this case in Vandermark v. Ford Motor Co., 391 P.2d 168, 171–72 (Cal. 1964), holding an automobile dealer strictly liable for product defects:

> Retailers like manufacturers are engaged in the business of distributing goods to the public. They are an integral part of the overall producing and marketing enterprise that should bear the cost of injuries resulting from defective products. In some cases the retailer may be the only member of that enterprise reasonably available to the injured plaintiff. In other cases the retailer himself may play a substantial part in insuring that the product is safe or may be in a position

> to exert pressure on the manufacturer to that end; the retailer's strict liability thus serves as an added incentive to safety. Strict liability on the manufacturer and retailer alike affords maximum protection to the injured plaintiff and works no injustice to the defendants, for they can adjust the costs of such protection between them in the course of their continuing business relationship.

Does *Vandermark* require liability in *Loomis*?

The Third Restatement follows the Second, as product sellers include "nonmanufacturing sellers and distributors such as wholesalers and retailers," RTT: PL §1, comment *e*, even when they act as mere conduits that do nothing to make the products dangerous. In addition, section 20, comment *f*, treats commercial lessors and bailors as product sellers, such that a dealer will be held to the same rules when he allows a test drive as when he sells a car. Section 2, comment *o*, acknowledges that nonmanufacturing sellers "often are not in a good position feasibly to adopt safer product designs or better instructions or warnings." But it reiterates that nonmanufacturing sellers are nonetheless subject to the same standards applicable to manufacturers: "As long as the plaintiff establishes that the product was defective when it left the hands of a given seller in the distributive chain, liability will attach to that seller." §2, comment *c*. Should a retailer be liable if it has no control over the manufacture, design, or warnings associated with a given product? What might the safety implications be?

In Defries v. Yamaha Motor Corp., 300 Cal. Rptr. 3d 670, 678 (Ct. App. 2022), Raphael, J., over a strong dissent, extended *Vandermark* and section 2, comment *c*, to hold that an upstream distributor "had a nondelegable duty to deliver a dirt bike to [the plaintiff] free from dangerous defects, regardless of whether those defects were caused by . . . one of [its] dealers in the final assembly." How is a distributor of partially unassembled products to monitor the quality of a downstream dealer's assembly? Is there an indemnity over?

Some cases have imposed liability on parties involved in only a fraction of the production cycle. In Sprung v. MTR Ravensburg, Inc., 788 N.E.2d 620, 623 (N.Y. 2003), Kaye, J., applied a strict liability regime to a custom fabricator for General Motors, arguing:

> Like other manufacturers, custom fabricators engaged in the regular course of their business hold themselves out as having expertise in manufacturing their custom products, have the opportunity and incentive to ensure safety in the process of making those products, and are better able to shoulder the costs of injuries caused by defective products than injured consumers or users.

Feinman, J., followed suit in Matter of Eighth Jud. Dist. Asbestos Litig., 129 N.E.3d 891 (N.Y. 2019), holding that the manufacture of a coke oven that was custom-fabricated for a steel plant had a duty to warn. Who was in the better position to warn end users about asbestos dangers? Does it matter that tort claims against employers are often precluded by workers' compensation schemes?

3. *Sales Versus Services.* Inevitably questions arise about whether a particular seller is providing a product or a service. One concern is that the broad definition of a seller in products liability cases could allow its strict liability rules to spill over into areas that have traditionally been governed under negligence law. In Cafazzo v. Central Medical Health Services, Inc., 668 A.2d 521, 525, 526, 527 (Pa. 1995), that concern led Montemuro, J., to reject an attempt to hold a hospital and physician strictly liable for the defects in a mandibular prosthesis used during an operation. Montemuro, J., held that supplying the product was "ancillary" to the provision of medical services, even if there happened to be a surcharge on the medical product:

> [I]t must be noted that the "seller" need not be engaged solely in the business of selling products such as the defective one to be held strictly liable. An example supporting this proposition appears in comment *f* of the Restatement (Second) of Torts, §402A and concerns the owner of a

> motion picture theater who offers edibles such as popcorn and candy for sale to movie patrons. The analogue to the instant case is valid in one respect only: both the candy and the . . . implant are ancillary to the primary activity, viewing a film or undergoing surgery respectively. However, beyond that any comparison is specious. A movie audience is free to purchase or not any food items on offer, and regardless of which option is exercised the primary activity is unaffected. On the other hand, while the implant was incidental to the surgical procedure here, it was a necessary adjunct to the treatment administered, as were the scalpel used to make the incision, and any other material objects involved in performing the operation, all of which fulfill a particular role in provision of medical service, the primary activity.

Montemuro, J., reasoned that strict liability would not provide an incentive for hospitals and doctors to choose different services, as they rely on the FDA's stamp of approval. He warned against allowing the "selection of the wrong product [to] become[] a matter of professional negligence for which recovery is available." Nor did he think strict liability was needed to compensate the injured party, finding that the "net effect of this cost spreading would further endanger the already beleaguered health care system."

The Third Restatement follows the Second by holding that "[s]ervices, even when provided commercially, are not products," RTT: PL §19(b), including those services to inspect, repair, and maintain machinery of the original product seller. A replacement part therefore is subject to products liability, but its installation is not.

4. *Information as a Product.* Does products liability law apply to information? The Third Restatement defines products as "tangible personal property distributed commercially for use or consumption." RTT: PL §19. The Restatement generally excludes intangible property like information contained in books or media due to free speech concerns: "Most courts, expressing concern that imposing strict liability for the dissemination of false and defective information would significantly impinge on free speech have, appropriately, refused to impose strict products liability in these cases." This reluctance to extend liability to intangible products presents new complications in our increasingly digital world. Consumers engage with intangible products like computer software and smartphone apps constantly, raising questions as to whether the owners of these platforms can be held liable for the information disseminated through them.

Section 230(c)(1) of the Communications Decency Act of 1996 (CDA) has been broadly construed to immunize online companies from liability arising from third-party information content. Its text reads: "No provider or user of an interactive computer service shall be treated as the publisher or speaker of any information provided by another information content provider." 47 U.S.C. §230(c)(1). If these providers can't be held liable for the content on their platforms, can they be held liable under a products liability theory for the algorithms that bring content to consumers' attention?

In Twitter v. Taamneh, 143 S. Ct. 1206 (2023), plaintiffs sued Twitter for damages under the Antiterrorism Act, 18 U.S.C. §2333, alleging, inter alia, that its recommendation algorithms helped ISIS recruit members, which contributed to a terrorist attack that harmed plaintiffs. A unanimous Supreme Court held that plaintiffs failed to state a claim for aiding and abetting as required under the statute. In Gonzalez v. Google, 143 S. Ct. 1191 (2023), a parallel case, the Court heard arguments challenging the Ninth Circuit's determination that CDA §230 barred similar claims against Google, regardless of whether liability could be found under the Antiterrorism Act. The Court punted on this question, remanding the case in light of *Taamneh* given that, without liability under the Antiterrorism Act, plaintiff stated no independent claim for relief. *Gonzalez* thus left for a further day resolution of the scope of CDA §230 immunity in the context of algorithms. What result if plaintiffs cast their claim as a product liability theory?

In Maynard v. Snapchat, Inc., 870 S.E.2d 739, 743 (Ga. 2022), the plaintiff sued Snapchat after being rear-ended by a car going 107 miles per hour, driven by a Snapchat user who

told her passengers prior to the accident that she was " 'just trying to get the car to 100 m.p.h. to post it on Snapchat' using Snapchat's Speed Filter." Colvin, J., held:

> [T]he Maynards asserted a conventional design-defect claim based on the ordinary design duty recognized under our decisional law. . . . [They] alleged that . . . Snap knew that other drivers were using the Speed Filter while speeding at 100 miles per hour or more as part of "a game," purposefully designed its products to encourage such behavior, [and] knew of at least one other instance in which a driver who was using Snapchat while speeding caused a car crash. . . .

What result in *Maynard* if the Speed Filter had been designed by another user?

The court in a recent multidistrict litigation crafted a test to determine when platforms are subject to products liability. In re Soc. Media Adolescent Addiction, No. 4:22-MD-3047, 2023 WL 7524912 (N.D. Cal. Mar. 10, 2023). Evaluating whether specific "functionalities" of platforms are analogous to physical products, Rogers, J., allowed design defect claims for platforms' omissions of parental and screen-time controls, among others, to survive a motion to dismiss.

5. ***Used and Reconditioned Products.*** How does products liability law apply to the sale of used or reconditioned products? In Tillman v. Vance Equipment Co., 596 P.2d 1299, 1303–04 (Or. 1979), the court refused to apply the strict liability rule of section 402A to a defendant who sold a good on an "as is" basis, noting that "it would work a significant change in the very nature of used goods markets"; parties who want warranties typically bargain for them.

Roughly speaking, the Third Restatement (see RTT: PL §8) follows cases like *Tillman* by limiting liability of the seller of used products to those defects that it created, or those created by predecessors in the same commercial chain of distribution. The Third Restatement also requires the reseller of used products to comply with all applicable regulations in force at the time of resale. *Id.* §8(d). In some states, legislation addresses the issue. See, e.g., Kan. Stat. Ann. §60-3306(b)(3) (2023), which explicitly offers sellers of used products protection against liability in a products liability claim when "the product was sold in substantially the same condition as it was when it was acquired for resale" and judgment against the manufacturer is "reasonably certain of being satisfied."

6. ***Successor Liability.*** Can a corporation that acquires either the assets or shares of an original product seller be sued for its predecessor's torts after the original corporation liquidates? The leading case in support of successor liability is Ray v. Alad Corp., 560 P.2d 3, 9 (Cal. 1977), where the new defendant corporation simply took over the business of the prior corporation and exploited its goodwill without any change in operation or control. The court rested its case for successor liability on three separate grounds:

> (1) the virtual destruction of the plaintiff's remedies against the original manufacturer caused by the successor's acquisition of the business, (2) the successor's ability to assume the original manufacturer's risk-spreading role, and (3) the fairness of requiring the successor to assume a responsibility for defective products that was a burden necessarily attached to the original manufacturer's good will being enjoyed by the successor in the continued operation of the business.

A majority of courts, however, decline to recognize the product line exception. In Semenetz v. Sherling & Walden, Inc., 851 N.E.2d 1170, 1174 (N.Y. 2006), the New York Court of Appeals expressed a common concern that small businesses with limited assets face "economic annihilation" if burdened with the liabilities of their predecessors in ways that could deter the resale of existing assets, even though the liquidation of that corporation also cuts off tort liability for the user of its products. Accordingly, RTT: PL §12 allows successor liability only when the acquisition

> (a) is accompanied by an agreement for the successor to assume such liability; or (b) results from a fraudulent conveyance to escape liability for the debts or liabilities of the predecessor; or (c) constitutes a consolidation or merger with the predecessor; or (d) results in the successor becoming a continuation of the predecessor.

For a proposal that all corporations wishing to go out of business by either sale or liquidation be required to get asset insurance, see Green, Successor Liability: The Superiority of Statutory Reform to Protect Products Liability Claimants, 72 Cornell L. Rev. 17 (1986). For a defense of using successor liability to induce corporate purchasers to exact greater diligence in their asset acquisitions, see Cupp, Redesigning Successor Liability, 1999 Ill. L. Rev. 845.

SECTION D. PRODUCT DEFECTS

1. Manufacturing Defects

RESTATEMENT OF THE LAW (THIRD) OF TORTS: PRODUCTS LIABILITY

§3. Circumstantial Evidence Supporting Inference of Product Defect

It may be inferred that the harm sustained by the plaintiff was caused by a product defect existing at the time of sale or distribution, without proof of a specific defect, when the incident that harmed the plaintiff:

(a) was of a kind that ordinarily occurs as a result of product defect; and

(b) was not, in the particular case, solely the result of causes other than product defect existing at the time of sale or distribution.

Speller v. Sears, Roebuck and Co.

790 N.E.2d 252 (N.Y. 2003)

GRAFFEO, J. In this products liability case, defendants — a product manufacturer and retailer — were granted summary judgment dismissing plaintiffs' complaint. Because we conclude that plaintiffs raised a triable issue of fact concerning whether a defective refrigerator caused the fire that resulted in plaintiffs' injuries, we reverse and reinstate the complaint against these defendants.

Plaintiffs' decedent Sandra Speller died in a house fire that also injured her seven-year-old son. It is undisputed that the fire originated in the kitchen. Plaintiffs commenced this action against Sears, Roebuck & Co., Whirlpool Corporation and the property owner alleging negligence, strict products liability and breach of warranty. Relevant to this appeal, plaintiffs asserted that the fire was caused by defective wiring in the refrigerator, a product manufactured by Whirlpool and sold by Sears.

A party injured as a result of a defective product may seek relief against the product manufacturer or others in the distribution chain if the defect was a substantial factor in causing the injury. . . .

In this case, plaintiffs' theory was that the wiring in the upper right quadrant of the refrigerator was faulty, causing an electrical fire which then spread to other areas of the kitchen and residence. Because that part of the refrigerator had been consumed in the fire, plaintiffs noted that it was impossible to examine or test the wiring to determine the precise nature of the defect. Thus, plaintiffs sought to prove their claim circumstantially by establishing that the refrigerator caused the house fire and therefore did not perform as intended. [The defendant's experts claimed that the fire started on the stove, but they conceded "that a fire would not occur in a refrigerator unless the product was defective."]

Of course, if a plaintiff's proof is insufficient with respect to either prong of this circumstantial inquiry, a jury may not infer that the harm was caused by a defective product unless plaintiff offers competent evidence identifying a specific flaw.

Here, in their motion for summary judgment, defendants focused on the second prong of the circumstantial inquiry, offering evidence that the injuries were not caused by their product but by an entirely different instrumentality—a grease fire that began on top of the stove. This was the conclusion of the Fire Marshall who stated during deposition testimony that his opinion was based on his interpretation of the burn patterns in the kitchen, his observation that one of the burner knobs on the stove was in the "on" position, and his conversation with a resident of the home who apparently advised him that the oven was on when the resident placed some food on the stovetop a few hours before the fire.

In order to withstand summary judgment, plaintiffs were required to come forward with competent evidence excluding the stove as the origin of the fire. To meet that burden, plaintiffs offered three expert opinions: the depositions of an electrical engineer and a fire investigator, and the affidavit of a former Deputy Chief of the New York City Fire Department. Each concluded that the fire originated in the refrigerator and not on the stove.

In his extensive deposition testimony, the electrical engineer opined that the fire started in the top-right-rear corner of the refrigerator, an area that housed the air balancing unit, thermostat, moisture control and light control. He stated that the wiring in this part of the appliance had been destroyed in the fire, making it impossible to identify the precise mechanical failure and, thus, he could only speculate as to the specific nature of the defect. He testified that the "most logical probability" was that a bad connection or bad splice to one of the components in that portion of the unit caused the wire to become "red hot" and to ignite the adjacent plastic. He tested the combustibility of the plastic and confirmed that the "plastic lights up very easily, with a single match" and continues to burn like candle wax. The engineer observed that the doors of the refrigerator were "slightly bellied out," indicating they were blown out from the expanding hot gases inside the refrigerator. The wall behind the refrigerator was significantly damaged and the upper right quadrant was burned to such a degree that it was not likely to have been caused by an external fire. Interpreting the burn patterns differently from the Fire Marshall, the electrical engineer found that the cabinets above the stove, although damaged, were not destroyed to the extent he expected to find if there had been a stovetop grease fire.

Plaintiffs' fire investigator similarly opined that the fire originated in the refrigerator's upper right corner, in part basing his conclusion on his observations of the scene three days after the fire and his examination of the appliances. He also interviewed a witness to the fire. He testified that he eliminated the stove as the source of the fire after his examination of that appliance and the cabinets above it. Contrary to the testimony of the Fire Marshall, he observed that all of the burner knobs on the stove were in the same position, either all "off" or all "on." He further examined the burn patterns, noting that if the blaze had been caused by a grease fire on the stove, the cabinets directly above would have been consumed in the fire. Instead, they were merely damaged. He acknowledged that he did not know exactly how the fire started inside the refrigerator but indicated he suspected there had been a poor connection in the wiring that caused the wire to smolder until it ignited the highly combustible foam insulation inside the unit.

The former Deputy Chief of the New York City Fire Department asserted in his affidavit that the "fire damage to the area around the refrigerator when compared to that of the stove clearly shows the longer and heavier burn at the refrigerator," indicating the fire originated there. He also stated that he had ruled out all other possible origins of the fire.

Upon review of these expert depositions and affidavit, we conclude that plaintiffs raised a triable question of fact by offering competent evidence which, if credited by the jury, was sufficient to rebut defendants' alternative cause evidence. In other words, based on plaintiffs' proof, a reasonable jury could conclude that plaintiffs excluded all other causes of the fire.

We therefore disagree with the Appellate Division's characterization of plaintiffs' submissions as equivocal. Plaintiffs' experts consistently asserted that the fire originated in the upper right quadrant of the refrigerator and each contended the stove was not the source of the blaze. Both parties supported their positions with detailed, non-conclusory expert depositions and other submissions which explained the bases for the opinions.

Defendants contend that after they came forward with evidence suggesting an alternative cause of the fire, plaintiffs were foreclosed from establishing a product defect circumstantially but were then required to produce evidence of a specific defect to survive summary judgment. We reject this approach for two reasons. First, such an analysis would allow a defendant who offered minimally sufficient alternative cause evidence in a products liability case to foreclose a plaintiff from proceeding circumstantially without a jury having determined whether defendant's evidence should be credited. Second, it misinterprets the court's role in adjudicating a motion for summary judgment, which is issue identification, not issue resolution. . . . [P]laintiffs directly rebutted defendants' submissions with competent proof specifically ruling out the stove as the source of the blaze. Because a reasonable jury could credit this proof and find that plaintiff excluded all other causes of the fire not attributable to defendants, this case presents material issues of fact requiring a trial.

[Reversed.]

NOTES

1. ***Proof of Manufacturing Defect.*** What role, if any, did the decedent or her son play in bringing about the fire? Even if the fire started in the refrigerator, did the plaintiffs introduce any evidence of an original defect in the equipment? If so, was it a manufacturing (construction) defect or a design defect? As should be evident, the switch from negligence to strict liability in manufacturing defect cases does not eliminate difficult causal questions that arise when the plaintiff's conduct occupies an uncertain place in the chain of causation, a problem exemplified by long-lived products subject to intensive and protracted use. Indeed many states have adopted statutes of repose that limit the availability of products liability suits to a certain number of years after purchase.

In Jagmin v. Simonds Abrasive Co., 211 N.W.2d 810 (Wis. 1973), the plaintiff was struck in the face by a grinding wheel that broke into pieces while he was operating it. The plaintiff established that the wheel was manufactured by the defendant. He further testified that he had used the wheel in the proper manner, that he had not placed undue stress on it, that he had no evidence suggesting that any other person had used the wheel while he was away from his job, and that the wheel had several hours of useful life left at the time the accident took place. The wheel itself was destroyed after it broke. The trial court refused to allow the case to go to the jury, ruling that there was insufficient evidence on the question of "defect." The Wisconsin Supreme Court reversed, allowing an "exceedingly close" case to reach the jury on a modified version of res ipsa loquitur. The plaintiff's evidence tended to exclude the possibility of any responsible cause of the injury apart from an original product defect even if that defect could not be identified. Does the plaintiff's evidence negate the possibility that the wheel was damaged in shipment or in installation? Does the plaintiff's evidence explain why the wheel worked as long as it did? Does

Henderson's account of the *MacPherson* facts, *supra* at 554, argue in favor of requiring a specific identification of a product defect in manufacturing cases? Does the information-forcing rationale for res ipsa loquitur put forth in *Ybarra*, *supra* Chapter 3, at 211, apply here? Do modern discovery rules mitigate any information disparities between the consumer and the product manufacturer?

In a modern twist on *Speller*, the plaintiff in Red Hed Oil, Inc. v. H.T. Hackney Co., 292 F. Supp. 3d 764, 775, 778 (E.D. Ky. 2017), sued the distributor and manufacturers of e-cigarettes that allegedly caught fire and caused extensive damage to the plaintiff's convenience store. The plaintiff's manufacturing and design defect claims failed on similar causation issues as those originally raised in *Speller*. According to Hood, J.:

> Plaintiffs fail to provide factual allegations that these e-cigarettes did, in fact, cause this fire. Plaintiffs blame it on a defect, but they do not specify what defect, which product was defective, or how the defect sparked the fire. . . .
>
> The plaintiffs do not allege an alternative design, how the products deviated from the intended design, how the e-cigarettes were assembled wrong, or how the e-cigarettes fail the risk-utility test. Plaintiffs cannot rely on general assertions that the e-cigarettes were dangerous; they must make at least some factual allegations as to *how*.

2. *Manufacturing Defects in Food Cases.* In *Escola*, food cases were one of the original battlegrounds for a theory of strict liability. In particular, the early common law held manufacturers strictly liable for any "foreign object" that was found within the food, be it a sliver of tin or some waste impurities from animals. By the same token, the earlier cases refused to hold manufacturers liable under any theory for substances "natural" to the product served. Thus the leading case of Mix v. Ingersoll Candy Co., 59 P.2d 144, 148 (Cal. 1936), held that "[b]ones which are natural to the type of meat served cannot legitimately be called a foreign substance, and a consumer who eats meat dishes ought to anticipate and be on his guard against the presence of such bones."

Modern cases have uniformly rejected this approach in favor of a reasonable expectations test. In Schafer v. JLC Food Systems, 695 N.W.2d 570, 575 (Minn. 2005), the plaintiff took a bite from a pumpkin muffin served at the defendant's restaurant only to experience a sharp pain in her throat, which later turned into a serious infection. Page, J., wrote:

> Under the [Third] Restatement approach, consumer expectations are based on culturally defined, widely shared standards allowing a seller's liability to be resolved by judges and triers of fact based on their assessment of what consumers have a right to expect from preparation of the food in question. §7 cmt. b. . . .
>
> Instead of drawing arbitrary distinctions between foreign and natural substances that caused harm, relying on consumers' reasonable expectations is likely to yield a more equitable result. After all, an unexpected natural object or substance contained in a food product, such as a chicken bone in chicken soup, can cause as much harm as a foreign object or substance, such as a piece of glass in the same soup.

Page, J., next allowed the plaintiff to get to the jury even though she could not "present evidence identifying the object that cause the alleged harm," relying again on the strict liability analog to res ipsa loquitur, whereby, as in *Jagmin*, the plaintiff's task is to exclude all other causes of harm. Should this test be adopted in cases of food poisoning that manifest themselves a day after eating in the restaurant?

Berkheimer v. REKM, LLC, 206 N.E.3d 90, 94 (Ohio Ct. App. 2023), denied recovery to a plaintiff who could have reasonably expected to find a bone in a "boneless chicken wing." Hendrickson, J., reasoned that "reasonable expectations" depend on whether a part is a natural to the food at issue. Is this a return to the foreign-natural test by another name?

available, but these were both uncomfortable to wear and somewhat less maneuverable. After citing RST §402A, comment *i*, Bowman, J., held that "[a]n otherwise completely effective protective vest cannot be regarded as dangerous, much less unreasonably so, simply because it leaves some parts of the body obviously exposed." The Third Restatement endorses *Linegar*. See RTT: PL §2, illus. 10.

b. Consumer Expectations versus Risk-Utility Tests

Barker v. Lull Engineering Co.

573 P.2d 443 (Cal. 1978)

Tobriner, C.J. In August 1970, plaintiff Ray Barker was injured at a construction site at the University of California at Santa Cruz while operating a high-lift loader manufactured by defendant Lull Engineering Co. and leased to plaintiff's employer by defendant George M. Philpott Co., Inc. Claiming that his injuries were proximately caused, inter alia, by the alleged defective design of the loader, Barker instituted the present tort action seeking to recover damages for his injuries. The jury returned a verdict in favor of defendants, and plaintiff appeals from the judgment entered upon that verdict, contending primarily that in view of this court's decision in Cronin v. J. B. E. Olson Corp. 501 P.2d 1153 (Cal. 1972), the trial court erred in instructing the jury "that strict liability for a defect in design of a product is based on a finding that the product was unreasonably dangerous for its intended use. . . ."

As we explain, we agree with plaintiff's objection to the challenged instruction and conclude that the judgment must be reversed. . . .

[W]e have concluded from this review that a product is defective in design either (1) if the product has failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner, or (2) if, in light of the relevant factors discussed below, the benefits of the challenged design do not outweigh the risk of danger inherent in such design. In addition, we explain how the burden of proof with respect to the latter "risk-benefit" standard should be allocated.

This dual standard for design defect assures an injured plaintiff protection from products that either fall below ordinary consumer expectations as to safety, or that, on balance, are not as safely designed as they should be. At the same time, the standard permits a manufacturer who has marketed a product which satisfies ordinary consumer expectations to demonstrate the relative complexity of design decisions and the tradeoffs that are frequently required in the adoption of alternative designs. Finally, this test reflects our continued adherence to the principle that, in a product liability action, the trier of fact must focus on the *product*, not on the *manufacturer's conduct*, and that the plaintiff need not prove that the manufacturer acted unreasonably or negligently in order to prevail in such an action. . . .

1. The facts of the present case

[Barker, a substitute driver, was injured while using a Lull High-Lift Loader, which was designed to be kept level on a sloping terrain. He had received only limited instruction in the use of the loader. While attempting to lift a load of lumber eighteen-or-so feet on uneven ground, he tried to maneuver the forks on the base of the load to compensate for sloping ground. As he lost control of the loader, he attempted to jump away from it, and was struck and seriously injured by some falling timber.

Barker claimed that the loader was defective in several respects: first, that it was not equipped with seat belts or a roll-bar; second, that it was not equipped with "outriggers" that might have given it greater lateral stability; third, that it was not equipped with an automatic

locking device on its leveling mechanism; and, fourth, that it was not equipped with a separate park gear. In response to this assignment of defects, the defendant argued as follows: first, that seat belts or roll-bars were in fact dangerous because they prevented any quick escape from the loader; second, that the outriggers were not needed if the loader was operated on level terrain as was intended, that none of the defendant's competitors had such outriggers, and that a regular crane should have been called in if work on uneven terrain was required; third, that the leveling device used was the most convenient and safe for the operator; and, fourth, that none of the transmissions manufactured for loaders incorporated a park position. The defendant also argued that the plaintiff's inexperience and panic were the sole source of his injury.

The jury returned a verdict for the defendant by a vote of ten to two.] . . .

3. A trial court may properly formulate instructions to elucidate the "defect" concept in varying circumstances. In particular, in design defect cases, a court may properly instruct a jury that a product is defective in design if (1) the plaintiff proves that the product failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner, or (2) the plaintiff proves that the product's design proximately caused injury and the defendant fails to prove, in light of the relevant factors, that on balance the benefits of the challenged design outweigh the risk of danger inherent in such design. . . .

As this court has recognized on numerous occasions, the term defect as utilized in the strict liability context is neither self-defining nor susceptible to a single definition applicable in all contexts.[8] . . . [T]he concept of defect raises considerably more difficulties in the design defect context than it does in the manufacturing or production defect context.

In general, a manufacturing or production defect is readily identifiable because a defective product is one that differs from the manufacturer's intended result or from other ostensibly identical units of the same product line. For example, when a product comes off the assembly line in a substandard condition it has incurred a manufacturing defect. . . . A design defect, by contrast, cannot be identified simply by comparing the injury-producing product with the manufacturer's plans or with other units of the same product line, since by definition the plans and all such units will reflect the same design. Rather than applying any sort of deviation-from-the-norm test in determining whether a product is defective in design for strict liability purposes, our cases have employed two alternative criteria in ascertaining, in Justice Traynor's words, whether there is something "wrong, if not in the manufacturer's manner of production, at least in his product." (Traynor, The Ways and Meanings of Defective Products and Strict Liability, 32 Tenn. L. Rev. 363, 366 [1965].)

First, our cases establish that a product may be found defective in design if the plaintiff demonstrates that the product failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner. This initial standard, somewhat analogous to the Uniform Commercial Code's warranty of fitness and merchantability (Cal. U. Com. Code, §2314), reflects the warranty heritage upon which California product liability doctrine in part rests. As we noted in *Greenman*, "implicit in [a product's] presence on the market . . . [is] a representation that it [will] safely do the jobs for which it was built." When a product fails to satisfy such ordinary consumer expectations as to safety in its intended or reasonably foreseeable operation, a manufacturer is strictly liable for resulting injuries. . . .

8. One commentator has observed that, in addition to the deficiencies in the "unreasonably dangerous" terminology noted in *Cronin*, the Restatement's language is potentially misleading because "[i]t may suggest an idea like ultrahazardous, or abnormally dangerous, and thus give rise to the impression that the plaintiff must prove that the product was unusually or extremely dangerous." (Wade, On the Nature of Strict Tort Liability for Products, 44 Miss. L.J. 825, 832 (1973).) We agree with this criticism and believe it constitutes a further reason for refraining from utilizing the "unreasonably dangerous" terminology in defining a defective product.

As Professor Wade has pointed out, however, the expectations of the ordinary consumer cannot be viewed as the exclusive yardstick for evaluating design defectiveness because "[i]n many situations . . . the consumer would not know what to expect, because he would have no idea how safe the product could be made." . . . Numerous California decisions have implicitly recognized this fact and have made clear, through varying linguistic formulations, that a product may be found defective in design, even if it satisfies ordinary consumer expectations, if through hindsight the jury determines that the product's design embodies "excessive preventable danger," or, in other words, if the jury finds that the risk of danger inherent in the challenged design outweighs the benefits of such design. . . .

A review of past cases indicates that in evaluating the adequacy of a product's design pursuant to this latter standard, a jury may consider, among other relevant factors, the gravity of the danger posed by the challenged design, the likelihood that such danger would occur, the mechanical feasibility of a safer alternative design, the financial cost of an improved design, and the adverse consequences to the product and to the consumer that would result from an alternative design. . . .

Although our cases have thus recognized a variety of considerations that may be relevant to the determination of the adequacy of a product's design, past authorities have generally not devoted much attention to the appropriate allocation of the burden of proof with respect to these matters. . . . The allocation of such burden is particularly significant in this context in as much as this court's product liability decisions, from *Greenman* to *Cronin*, have repeatedly emphasized that one of the principal purposes behind the strict product liability doctrine is to relieve an injured plaintiff of many of the onerous evidentiary burdens inherent in a negligence cause of action. Because most of the evidentiary matters which may be relevant to the determination of the adequacy of a product's design under the "risk-benefit" standard—e.g., the feasibility and cost of alternative designs—are similar to issues typically presented in a negligent design case and involve technical matters peculiarly within the knowledge of the manufacturer, we conclude that once the plaintiff makes a prima facie showing that the injury was proximately caused by the product's design, the burden should appropriately shift to the defendant to prove, in light of the relevant factors, that the product is not defective. Moreover, inasmuch as this conclusion flows from our determination that the fundamental public policies embraced in *Greenman* dictate that a manufacturer who seeks to escape liability for an injury proximately caused by its product's design on a risk-benefit theory should bear the burden of persuading the trier of fact that its product should not be judged defective, the defendant's burden is one affecting the burden of proof, rather than simply the burden of producing evidence. . . .

Because the jury may have interpreted the erroneous instruction given in the instant case as requiring plaintiff to prove that the high-lift loader was ultrahazardous or more dangerous than the average consumer contemplated, and because the instruction additionally misinformed the jury that the defectiveness of the product must be evaluated in light of the product's "intended use" rather than its "reasonably foreseeable use" . . . , we cannot find that the error was harmless on the facts of this case. In light of this conclusion, we need not address plaintiff's additional claims of error, for such issues may not arise on retrial.

The judgment in favor of defendants is reversed.

NOTES

1. ***What Is a Design Defect?*** Some jurisdictions today follow *Barker* and allow either the consumer expectations test or the risk-utility test to prove a design defect. Other jurisdictions adopt just one of the two tests. In Aubin v. Union Carbide Corp., 177 So. 3d 489, 510 (Fla. 2015), the plaintiff alleged he developed mesothelioma from exposure to asbestos contained

in defendant's construction products. The jury found in favor of the plaintiff, but the intermediate appellate court reversed on the ground that the trial court failed to instruct the jury using the Third Restatement's reasonable alternative design test for design defect claims. Pariente, J., in turn reversed the intermediate court. In so doing he rejected the Third Restatement's view on alternative design while extolling the virtues of the consumer expectations test:

> The important aspect of strict products liability that led to our adoption [of the consumer expectations test] remains true today: the burden of compensating victims of unreasonably dangerous products is placed on the manufacturers, who are most able to protect against the risk of harm, and not on the consumer injured by the product. Increasing the burden for injured consumers to prove their strict liability claims for unreasonably dangerous products that were placed into the stream of commerce is contrary to the policy reasons behind the adoption of strict liability. . . .

Other design defect tests were propounded during the late 1970s but have receded in recent years as most courts have adopted the *Barker* test. For example, Azzarello v. Black Bros. Co., Inc., 391 A.2d 1020, 1027 (Pa. 1978), held that even though the supplier was not "an insurer of all injuries caused by the product," it nonetheless was cast "in the role of a guarantor of his product's safety," under which the words "unreasonably dangerous" had no part. Instead "the jury may find a defect where the product left the supplier's control lacking any element necessary to make it safe for its intended use or possessing any feature that renders it unsafe for the intended use." Pennsylvania retreated from the *Azzarello* test in Tincher v. Omega Flex, Inc., 104 A.3d 328, 335 (Pa. 2014), but refused to adopt the Third Restatement reasonable alternative design test. In *Tincher*, the plaintiff sought to show that corrugated stainless-steel tubing used to transport natural gas to the Tinchers' first floor fireplace was defective because it was punctured by a lightning strike. Castille, C.J., reversed a jury verdict and announced this test for product defect:

> [W]e conclude that a plaintiff pursuing a cause upon a theory of strict liability in tort must prove that the product is in a "defective condition." The plaintiff may prove defective condition by showing either that (1) the danger is unknowable and unacceptable to the average or ordinary consumer, or that (2) a reasonable person would conclude that the probability and seriousness of harm caused by the product outweigh the burden or costs of taking precautions. The burden of production and persuasion is by a preponderance of the evidence.

An approach to design defects more restrictive than *Barker*'s was taken in Wilson v. Piper Aircraft Corp., 577 P.2d 1322, 1327–28 (Or. 1978), a wrongful death action brought by the representatives of two passengers who died in the crash of a Piper Cherokee airplane manufactured by the defendants. The plaintiffs claimed that the defective design was the engine's susceptibility to icing, in part because the aircraft was not equipped with a state-of-the-art injection-type fuel system. Holman, J., parted with *Barker* by imposing stringent requirements that the plaintiff present evidence "from which the jury could find the suggested alternatives are not only technically feasible but also practicable in terms of cost and the over-all design and operation of the product." Further the Federal Aviation Administration (FAA) had awarded the defendant a certificate of airworthiness, which in its own terms set only minimum design standards. The court concluded that

> in a field as closely regulated as aircraft design and manufacture, it is proper to take into consideration, in determining whether plaintiffs have produced sufficient evidence of defect to go to the jury, the fact that the regulatory agency has approved the very design of which they complain after considering the dangers involved.

2. *State of the Art: Time of Sale or Time of Trial?* In setting the appropriate design standard for product safety, many judicial decisions look in part to the state of the art in the product supplier's trade or business. The state of the art refers to something more

stringent than the "common practice" in the industry and embraces the scientific, technological, and safety standards that are reasonably feasible at the time of product design. Thus in Kim v. Toyota Motor Corp., 424 P.3d 290, 296 (Cal. 2018), Kruger, J., distinguished industry custom—"the use of the challenged design within the relevant industry," i.e., "what is done"—from state of the art evidence—"what can be done under present technological capacity." See also RTT: PL §2, comment *d*.

Most courts today do not allow compliance with the state of the art to resolve the design defect question in the defendant's favor but nonetheless treat it as a factor to consider, which "is both necessary and probative on the issue of 'unreasonably dangerous.' " Reed v. Tiffin Motor Homes, Inc., 697 F.2d 1192, 1197 (4th Cir. 1982). In Bruce v. Martin-Marietta Corp., 544 F.2d 442, 447 (10th Cir. 1976), the court measured the state of the art at the time the defendant's airplane seats entered the stream of commerce in 1952, not at the time of the crash in 1970. The record showed that the seats met all FAA standards as well as the applicable state of the art for 1952. In the court's view, the crucial test was the "expectation of the ordinary consumer," who "would not expect a Model T to have safety features which are incorporated in automobiles today." See *The T.J. Hooper, supra* Chapter 3, at 150. Contrast with City of Pomona v. SQM North America Corp., 801 Fed. App'x. 488, 489–90, 492 (9th Cir. 2020), which involved "Pomona's strict product liability claim that fertilizer manufactured by SQM contaminated the city's water supply with a toxic chemical called perchlorate." Under *Barker* "the jury must determine 'through hindsight' whether 'the risk of danger inherent in the challenged design outweighs the benefits of such design.' " Accordingly, in an action for current harm, the court allowed "jurors to consider risks that were not, and could not have been, known to the manufacturer at the time of manufacture." This prompted a vigorous dissent from Lee, J.:

> Notably, the City conceded at oral argument that it has not located a single California state court ruling—in the forty years since *Barker*'s issuance—that applied *Barker* to hold a party liable based on scientific knowledge that was unknowable at the time of the incident but known at the time of trial.

3. *Subsequent Improvements.* The substantive disputes in state of the art cases frequently raise evidentiary inquiries: Can evidence of subsequent design changes be introduced to show the defectiveness of the defendant's basic design? In Ault v. International Harvester Co., 528 P.2d 1148, 1152 (Cal. 1974), the California Supreme Court allowed such evidence, saying:

> The contemporary corporate mass producer of goods, the normal products liability defendant, manufactures tens of thousands of units of goods; it is manifestly unrealistic to suggest that such a producer will forego making improvements in its product, and risk innumerable additional lawsuits and the attendant adverse effect upon its public image, simply because evidence of adoption of such improvement may be admitted in an action founded on strict liability for recovery on an injury that preceded the improvement.

Nonetheless, a strong majority of courts have refused to admit the evidence in both negligence and strict liability cases. See Cann v. Ford Motor Co., 658 F.2d 54, 60 (2d Cir. 1981). Federal Rule of Evidence 407 provides:

> When measures are taken that would have made an earlier injury or harm less likely to occur, evidence of the subsequent measures is not admissible to prove:
>
> - negligence;
> - culpable conduct;
> - a defect in a product or its design; or
> - a need for a warning or instruction.

Or, as Baron Bramwell put it, the rule rejects the notion that "because the world gets wiser as it gets older, therefore it was foolish before." Hart v. Lancashire & Yorkshire Ry. Co. (1869) 21 LT 261, 263 (quoted in Note of Advisory Committee on Proposed Rule 407).

4. *Product Modification.* Much litigation has focused on the question whether a product alteration made after a manufacturer has shipped goods constitutes a superseding cause sufficient to relieve the original manufacturer of liability for design defects. Young v. Aeroil Products Co., 248 F.2d 185 (9th Cir. 1957), represents the traditional view of protecting manufacturers from liability based on subsequent alterations. There the decedent had been crushed to death when the portable elevator he had been operating toppled. The decedent's employer had previously added additional equipment to the elevator, causing its imbalance. Even though the defendant had sold the elevator with the express warranty that it was balanced, the court held that the warranty was unavailing because "[t]he thing being used was not the thing sold."

In Hoover v. New Holland North America, Inc., 11 N.E.3d 693 (N.Y. 2014), the plaintiff, a 16-year-old girl, was badly injured when "she was caught and dragged into the rotating driveline of a tractor-driven post hole digger distributed by defendant-appellant CNH America LLC (CNH) and sold by defendant-appellant Niagara Frontier Equipment Sales, Inc. (Niagara) (collectively, defendants)." The manufacturer of the device, Alamo/SMC Corporation (SMC), was not joined as a defendant in the suit. "The jury returned a verdict in favor of plaintiff in the amount of $8,811,587.29 and apportioned liability as follows: 35 percent to CNH, 30 percent to SMC, 30 percent to Smith [the owner of the digger], 3 percent to Gary Hoover [the plaintiff's stepfather], and 2 percent to Niagara."

The defendant's product had been distributed with extensive warnings, including: "DANGER! SHIELD MISSING DO NOT OPERATE!" and "KEEP ALL SHIELDS IN PLACE AND IN GOOD CONDITION." Smith was aware of these warnings but nonetheless decided not to replace the key shields on the device after they incurred damage over several years from installing between 1,000 and 2,000 posts per year. Smith testified that he removed the guard and continued to use the machine without replacing the guard, "because it was only going to break again."

Abdus-Salaam, J., rejected the defendant's motion for summary judgment on the ground that

> Smith did not modify the digger in order to "circumvent[]" the utility of the shield or to "adapt" the digger to suit his own needs. Rather, Smith removed the shield because its "functional utility" had already been destroyed, and his testimony raised a question of fact whether removal of the broken shield was to blame for plaintiff's injuries. Plaintiff also proffered Berry's expert affidavit, in which the engineer averred that the shield was "not reasonably safe" because it was not "designed to last the life" of the digger, and that defendants' failure to incorporate a safer yet feasible alternative design, such as an integral guard or metal shield, was "a substantial factor" in causing plaintiff's injuries.

Smith, J., dissented, arguing that the full liability should rest on Smith because "[h]e chose not to get a replacement shield—which would have cost $40 and taken no more than half an hour to install—because 'it's only going to get bent up and broke again.' " How does the case come out under the open and obvious defense?

In Singh v. Gemini Auto Lifts, Inc., 27 N.Y.S.3d 637, 638–39 (App. Div. 2016), the court extended *Hoover* to reach a situation where the plaintiff caught his hand in a hole on an automotive lift, from which the plastic cover had been removed. The court held that the plaintiff had raised triable issues of fact "as to whether the lift was intended to be used without the cover in place." Does it make sense for courts to resolve liability in the face of post-sale modifications in terms of design defect? What about liability for failure to warn? See *infra* at 616, Note 1.

The Third Restatement recognizes that product alteration and modification may defeat or diminish defendant's responsibility, but develops no specialized rules to deal with them, treating them (along with product misuse) as parts of the broader questions of product defect, causation, and plaintiff's conduct. RTT: PL §2, comment *p*.

c. The Third Restatement Reasonable Alternative Design Test

The Third Restatement rejected the consumer expectations test as part of its attempt to rein in what was perceived to be excessive liability arising out of the *Barker* dual-pronged standard.

RESTATEMENT OF THE LAW (THIRD) OF TORTS: PRODUCTS LIABILITY

§2. Categories of Product Defect

A product: . . .

(b) is defective in design when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the alternative design renders the product not reasonably safe. . . .

Comment a. Rationale: . . . The emphasis is on creating incentives for manufacturers to achieve optimal levels of safety in designing and marketing products. Society does not benefit from products that are excessively safe—for example, automobiles designed with maximum speeds of 20 miles per hour—any more than it benefits from products that are too risky. Society benefits most when the right, or optimal, amount of product safety is achieved.

Illustration 5: ABC Co. manufactures novelty items. One item, an exploding cigar, is made to explode with a loud bang and the emission of smoke. Robert purchased the exploding cigar and presented it to his boss, Jack, at a birthday party arranged for him at the office. Jack lit the cigar. When it exploded, the heat from the explosion lit Jack's beard on fire causing serious burns to his face. . . . [T]he finder of fact might find ABC liable for the defective design of the exploding cigar even if no reasonable alternative design was available that would provide similar prank characteristics. The utility of the exploding cigar is so low and the risk of injury is so high as to warrant a conclusion that the cigar is defective and should not have been marketed at all.

Does an alternative design test ensure optimal product-design safety?

NOTES

1. ***Alternative Designs.*** The reasonable alternative design test in the Third Restatement was developed largely in response to the New Jersey case of O'Brien v. Muskin Corp., 463 A.2d 298, 302–03, 305–06 (N.J. 1983). Muskin sold a pool to Arthur Henry, which, when assembled, had an embossed vinyl bottom and a depth of about three feet. The plaintiff, twenty-three years old, dove into the pool from either a nearby platform or from the eight-foot-high roof of the Henrys' garage. "As his outstretched hands hit the vinyl-lined pool bottom, they slid apart, and O'Brien struck his head on the bottom of the pool, thereby sustaining injuries." The plaintiff's expert claimed that the pool design was dangerous because wet vinyl was more than twice as slippery as the rubber latex used to line in-ground pools.

was promoted by one of the defendant's representatives whose expenses were reimbursed by the local medical organization. The court held that the defendant did not meet its duty to warn when it failed to inform the plaintiff of the one-in-a-million chance that the vaccine could cause polio, even when properly prepared and administered.

> Ordinarily in the case of prescription drugs warning to the prescribing physician is sufficient. . . .
>
> Here, however, although the drug was denominated a prescription drug it was not dispensed as such. It was dispensed to all comers at mass clinics without an individualized balancing by a physician of the risks involved. In such cases (as in the case of over-the-counter sales of nonprescription drugs) warning by the manufacturer to its immediate purchaser will not suffice. . . . In such cases, then, it is the responsibility of the manufacturer to see that warnings reach the consumer, either by giving warning itself or by obligating the purchaser to give warning. . . .
>
> This duty does not impose an unreasonable burden on the manufacturer. When drugs are sold over the counter to all comers warnings normally can be given by proper labeling. Such method of giving warning was not available here, since the vaccine came in bottles never seen by the consumer. But other means of communication such as advertisements, posters, releases to be read and signed by recipients of the vaccine, or oral warnings were clearly available and could easily have been undertaken or prescribed by appellee.

In *Reyes*, the court then let the jury decide whether the vaccine was the physical cause of the injury and whether an adequate warning would have led the plaintiff to change his behavior. Is this a higher or lower standard than in *MacDonald*? Note that the standard used is akin to the informed consent test. Is that an appropriate duty for the manufacturer? Does that duty change if a learned intermediary is involved?

The *Reyes* court continued: "In the absence of evidence rebutting the presumption, a jury finding that the defendant's product was the producing cause of the plaintiff's injury would be sufficient to hold him liable." Does this presumption make sense if the background rate of infection from the "wild strain" is known on average to be ten or one hundred times as great as that from vaccines?

Reyes and *Davis* were first-generation cases in which no warnings had been provided. Subsequent litigation focused on the adequacy of the warnings. In Givens v. Lederle, 556 F.2d 1341, 1343 (5th Cir. 1977), another Sabin vaccine case, the defendant Lederle's warning to physicians stated in full:

> Paralytic disease following the ingestion of live polio virus vaccines has been reported in individuals receiving the vaccine, and in some instances, in persons who were in close contact with subjects who had been given live oral polio virus vaccine. Fortunately, such occurrences are rare, and it could not be definitely established that any such case was due to the vaccine strain and was not coincidental with infection due to naturally occurring poliomyelitis, or other enteroviruses.

The package insert also noted that the risk, if any, was one in three million. The physician who had inoculated the plaintiff's daughter gave the plaintiff no warning of the risk because he thought that the insert was too "nebulous" to require it. On appeal, the court held that his testimony, together with evidence showing that such infections had occurred, supported the jury's verdict that the warning was inadequate, especially because the warning denied any definite connection between the vaccine and the disease. Dr. Sabin had testified for the defendant that his vaccine could not possibly cause polio.

The number of large damage awards in the late 1970s and 1980s substantially increased the costs of vaccines. See Manning, Changing Rules of Tort Law and the Market for Childhood Vaccines, 37 J.L. & Econ. 247, 248 (1994), whose econometric analysis shows that the price of the DPT vaccine between 1975 and 1990 increased by over 2,000 percent, and of that increase over 96 percent went to litigation costs.

In response to the crisis, Congress passed the National Childhood Vaccine Injury Act of 1986 (NCVIA), which provides for a complex system of no-fault compensation of up to

$250,000 for persons who suffer particular side effects from certain vaccine programs within specified time limits. 42 U.S.C. §300aa (2023). The statute raises many of the hard issues of proof of causation found in other products liability settings.

4. ***Federal Liability for Bad Vaccines Under the Federal Tort Claims Act (FTCA).*** The FDA has extensive regulatory authority of the general approval of new vaccines and the power to approve or withhold the release of particular vaccines to the marketplace. At the same time, like other federal agencies, it receives the protection of the discretionary function exception to the FTCA, which insulates the government from liability if the action challenged in the case involves the permissible exercise of policy judgment. In Berkovitz v. United States, 486 U.S. 531, 542, 546 (1988), the infant plaintiff suffered a severe case of polio after ingesting a dose of Orimune manufactured by Lederle Laboratories, which settled with the plaintiff. The case involved a two-step process. First the Division of Biologic Standards (DBS) gave general licensing approval for production of the vaccine, after which the Bureau of Biologics (BoB) had responsibility for releasing particular lots of the vaccine. Marshall, J., first rejected the government's position that the discretionary function exception precludes liability for any and all acts arising out of the regulatory programs of federal agencies. He then concluded that the DBS was not protected by that exception when "the DBS issued a product license without first receiving data that the manufacturer must submit showing how the product, at the various stages of the manufacturing process, matched up against regulatory safety standards" because the DBS has "no discretion to issue a license without first receiving the required test data." But with respect to the release of a particular lot, Marshall, J., held that "the discretionary function exception bars any claims that challenge the Bureau's formulation of policy as to the appropriate way in which to regulate the release of vaccine lots." Does that make sense if there are standard protocols that the BoB should use to decide whether or not to release vaccines? Or should the FDA receive a broader protection to encourage it to reduce erroneous releases by remaining in the inspection business, given the strict liability of the drug manufacturers?

5. ***Standardized Warnings.*** The decisions in both *MacDonald* and *Givens* that allow juries to treat FDA warnings as statutory minimums have prompted some legislative reform. Consider the Michigan Revised Judicature Act of 1961, Mich. Comp. Laws §600.2946(5) (2023), which allows for FDA warnings to be an absolute defense in duty to warn cases for drugs lawfully on the market unless the drug manufacturer during the drug approval process "intentionally withholds from or misrepresents" to the FDA information about the drug that results in it obtaining an approval that would have been denied if accurate information had been supplied. When the Michigan statute applies, a defendant can typically obtain summary judgment in a duty to warn case. Defenders of the statute point to the excessive risk aversion that the FDA has on the question of new drug approval. Opponents of the statute point to the serious gaps in the FDA approval process. For a review of the huge literature on this topic, see Struve, The FDA and the Tort System: Postmarketing Surveillance, Compensation, and the Role of Litigation, 5 Yale J. Health Pol'y L. & Ethics 587 (2005) (critical of the statute); Noah, Rewarding Regulatory Compliance: The Pursuit of Symmetry in Products Liability, 88 Geo. L.J. 2147 (2000) (supportive of the statute).

Vassallo v. Baxter Healthcare Corp.

696 N.E.2d 909 (Mass. 1998)

Greaney, J. In this products liability case, the plaintiff Florence Vassallo claimed that the defendants, Baxter Healthcare Corporation and Baxter International, Inc., were liable to her for damages because silicone breast implants, manufactured by a predecessor company to the defendants (Heyer-Schulte Corporation), that had been implanted in her were negligently

designed, accompanied by negligent product warnings, and breached the implied warranty of merchantability, with the consequence that she was injured. [The plaintiff underwent breast implant surgery in 1977, and her implants ruptured in 1992, and were replaced with saline implants in 1993. In 1976, the defendant's Dear Doctor letter did not address all possible adverse consequences that leakage could have on an implant user, including "risks of chronic inflammation, permanent tissue scarring, or possible effects on the immune system." The court reviews the plaintiff's expert evidence on the harm caused by the slow release of silicone gel. It also examines extensive testimony that Heyer-Schulte knew of the risk of rupture and of its adverse consequences. The plaintiff alleged that had she known of the true state of affairs, she would never have consented to the implants.] Plaintiff Vincent Vassallo claimed a loss of consortium. The plaintiffs also asserted a claim for violation of G.L. c. 93A, §§2(a) and 9. [The court affirms the judgment for the plaintiffs below on the negligence and statutory claims.]

We conclude, however, that we should change our products liability law to conform to the clear majority rule regarding what has to be shown to recover in a breach of warranty claim for failure to warn of risks associated with a product. . . .

We take this opportunity . . . to consider the defendants' argument that we should change our products liability law concerning the implied warranty of merchantability from what is stated in Hayes v. Ariens Co., 462 N.E.2d 273 (Mass. 1984), and that the law should be reformulated to adopt a "state of the art" standard that conditions a manufacturer's liability on actual or constructive knowledge of the risks.

Our current law, regarding the duty to warn under the implied warranty of merchantability, presumes that a manufacturer was fully informed of all risks associated with the product at issue, regardless of the state of the art at the time of the sale, and amounts to strict liability for failure to warn of these risks. This rule has been justified by the public policy that a defective product, "unreasonably dangerous due to lack of adequate warning[s], [is] not fit for the ordinary purposes for which [it is] used regardless of the absence of fault on [a defendant's] part."

At trial, [the judge followed *Hayes* by refusing to issue a "jury instruction that a manufacturer need only warn of risks 'known or reasonably knowable in light of the generally accepted scientific knowledge available at the time of the manufacture and distribution of the device.' "] While the judge's instruction was a correct statement of our law, we recognize that we are among a distinct minority of States that applies a hindsight analysis to the duty to warn.[17] . . .

The thin judicial support for a hindsight approach to the duty to warn is easily explained. The goal of the law is to induce conduct that is capable of being performed. This goal is not advanced by imposing liability for failure to warn of risks that were not capable of being known.

The Restatement (Third) of Torts: Products Liability §2(c) (1998), approved by the American Law Institute, reaffirms the principle expressed in Restatement (Second) of Torts, *supra* at §402A comment *j*, by stating that a product "is defective because of inadequate instructions or warnings when the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings . . . and the omission of the instructions or warnings renders the product not reasonably safe." The rationale behind the principle is explained by stating that "[u]nforeseeable risks arising from foreseeable product use . . . by definition cannot specifically be warned against." Restatement (Third) of Torts:

17. The Reporters' Note to the Restatement (Third) of Torts: Products Liability §2(c) comment *m*, at 106 (1998), lists four States taking the position that a manufacturer is charged with a duty to warn of risks without regard to whether the manufacturer knew or reasonably should have known of the risks, including Massachusetts; Hawaii; Pennsylvania; Washington.

Products Liability, *supra* at §2 comment *m*, at 34. However, comment *m* also clarifies the manufacturer's duty "to perform reasonable testing prior to marketing a product and to discover risks and risk-avoidance measures that such testing would reveal. A seller is charged with knowledge of what reasonable testing would reveal." *Id.* . . .

In recognition of the clear judicial trend regarding the duty to warn in products liability cases, and the principles stated in Restatement (Third) of Torts: Products Liability, *supra* at §2 and comment *m*, we hereby revise our law to state that a defendant will not be held liable under an implied warranty of merchantability for failure to warn or provide instructions about risks that were not reasonably foreseeable at the time of sale or could not have been discovered by way of reasonable testing prior to marketing the product. A manufacturer will be held to the standard of knowledge of an expert in the appropriate field, and will remain subject to a continuing duty to warn (at least purchasers) of risks discovered following the sale of the product at issue. In accordance with the usual rule governing retroactivity in this type of action, the standard just expressed will apply to all claims on which a final judgment has not been entered, or as to which an appeal is pending or the appeal period has not expired, and to all claims on which an action is commenced after the release of this opinion. [The court notes that the defendant could not take advantage of this change in law because of the adverse jury verdict on the negligence count, and the jury's apparent conclusion that defendant did have actual or constructive notice of the risks associated with their silicone implants.]

[Affirmed.]

NOTES

1. ***Post-Sale Duty to Warn.*** *Vassallo* recognizes a continuing duty to warn, even as it rejects a hindsight duty to warn. Assuming a company learns of a latent risk that had gone undiscovered despite reasonable pre-market testing, should it now have a duty to notify past buyers of the product of the newly discovered risk? See RTT: PL §10.

RESTATEMENT OF THE LAW (THIRD) OF TORTS: PRODUCTS LIABILITY

§10. Liability of Commercial Product Seller or Distributor for Harm Caused by Post-Sale Failure to Warn

(a) One engaged in the business of selling or otherwise distributing products is subject to liability for harm to persons or property caused by the seller's failure to provide a warning after the time of sale or distribution of a product if a reasonable person in the seller's position would provide such a warning.

(b) A reasonable person in the seller's position would provide a warning after the time of sale if:

(1) the seller knows or reasonably should know that the product poses a substantial risk of harm to persons or property; and

(2) those to whom a warning might be provided can be identified and can reasonably be assumed to be unaware of the risk of harm; and

(3) a warning can be effectively communicated to and acted on by those to whom a warning might be provided; and

(4) the risk of harm is sufficiently great to justify the burden of providing a warning.

Comment j. Distinguishing post-sale failures to warn from defects existing at the time of sale: When a product is defective at the time of sale, liability can be established without reference to a post-sale duty to warn. A seller who discovers after sale that its product was defective at the time of sale within the meaning of this Restatement cannot generally absolve itself of liability by issuing a post-sale warning.

RTT: PL §11 details the circumstances under which a manufacturer can be liable for a failure to recall. The Reporters delimited these sections as additional duties—not as a way for manufacturers to immunize themselves against liability for time-of-sale defects by issuing post-sale warnings. RTT: PL §10, comment *j*.

2. *Unavoidably Dangerous Products.* Closely related to RST §402A, comment *j*, is comment *k*, which deals with products known to be unavoidably dangerous, typically drugs. See *supra* at 567. In these cases, it is impractical to remove the product from the market or to alter its design or composition because mitigating the adverse side effects would undermine the effectiveness of the product. Consequently, a warning that allows informed consumer choice is the only workable alternative. Thus, in Nolen v. C.R. Bard Inc., 533 F. Supp. 3d 584, 592 (M.D. Tenn. 2021), Trauger, J., opined that, while defendant "may ultimately be entitled to the protection of Comment k," the "availability of that protection" depends on whether defendant "adequately warned physicians regarding the heightened risks" of the product.

Similarly, in the case of blood transfusions, jurisdictions have rejected the strict liability position for contaminated blood so long as adequate warning is provided. In Brody v. Overlook Hospital, 317 A.2d 392, 395 (N.J. Super. Ct. App. Div. 1974), the court reasoned that donor blood is a medical necessity, and without the capacity to cheaply test it for diseases, it is unavoidably unsafe. More than forty states have enacted legislation adopting the negligence standard in blood transfusion cases, including Illinois. 745 Ill. Comp. Stat. 40/3 (2023).

Hood v. Ryobi America Corp.

181 F.3d 608 (4th Cir. 1999)

WILKINSON, C.J. Wilson M. Hood lost part of his thumb and lacerated his leg when he removed the blade guards from his new Ryobi miter saw and then used the unguarded saw for home carpentry. Hood sued Ryobi, alleging that the company failed adequately to warn of the saw's dangers and that the saw was defective. Applying Maryland products liability law, the district court granted summary judgment to Ryobi on all claims.

The saw and owner's manual bore at least seven clear, simple warnings not to operate the tool with the blade guards removed. The warnings were not required to spell out all the consequences of improper use. Nor was the saw defective—Hood altered and used the tool in violation of Ryobi's clear warnings. Thus we affirm the judgment.

I

Hood purchased a Ryobi TS-254 miter saw in Westminster, Maryland on February 25, 1995, for the purpose of performing home repairs. The saw was fully assembled at the time of purchase. It had a ten-inch diameter blade mounted on a rotating spindle controlled by a finger trigger on a handle near the top of the blade. To operate the saw, the consumer would use that handle to lower the blade through the material being cut.

Co., 248 A.2d 151, 153 (Md. 1968). A clear and specific warning will normally be sufficient—"the manufacturer need not warn of every mishap or source of injury that the mind can imagine flowing from the product." Liesener v. Weslo, Inc., 775 F. Supp. 857, 861 (D. Md. 1991); see *Levin*, 248 A.2d at 154 (declining to require warning of the danger that a cracked syphon bottle might explode and holding "never use cracked bottle" to be adequate as a matter of law). In deciding whether a warning is adequate, Maryland law asks whether the benefits of a more detailed warning outweigh the costs of requiring the change.

Hood assumes that the cost of a more detailed warning label is minimal in this case, and he claims that such a warning would have prevented his injury. But the price of more detailed warnings is greater than their additional printing fees alone. Some commentators have observed that the proliferation of label detail threatens to undermine the effectiveness of warnings altogether. As manufacturers append line after line onto product labels in the quest for the best possible warning, it is easy to lose sight of the label's communicative value as a whole. Well-meaning attempts to warn of every possible accident lead over time to voluminous yet impenetrable labels—too prolix to read and too technical to understand.

By contrast, Ryobi's warnings are clear and unequivocal. Three labels on the saw itself and at least four warnings in the owner's manual direct the user not to operate the saw with the blade guards removed. Two declare that "serious injury" could result from doing so. This is not a case where the manufacturer has failed to include any warnings at all with its product. Ryobi provided warnings sufficient to apprise the ordinary consumer that it is unsafe to operate a guardless saw—warnings which, if followed, would have prevented the injury in this case.

It is apparent, moreover, that the vast majority of consumers do not detach this critical safety feature before using this type of saw. Indeed, although Ryobi claims to have sold thousands of these saws, Hood has identified only one fifteen-year-old incident similar to his. Hood has thus not shown that these clear, unmistakable, and prominent warnings are insufficient to accomplish their purpose. Nor can he prove that increased label clutter would bring any net societal benefit. We hold that the warnings Ryobi provided are adequate as a matter of law.

B

Hood's defective design claim is likewise unpersuasive [on the ground that the product alterations defeat liability].

Affirmed.

NOTES

1. ***Warnings, Design Modification, and the Heeding Presumption.*** In Liriano v. Hobart Corp., 700 N.E.2d 303, 308 (N.Y. 1998), the seventeen-year-old plaintiff caught his right hand and lower arm in a commercial meat grinding machine from which the employer had removed the safety guard. Unlike *Hood*, no warnings stated that it was dangerous to remove the guard. On an advisory opinion of a certified question from the Second Circuit, Ciparick, J., held that a duty to warn cause of action could survive even in cases where a product modification blocked liability under a design defect theory. The court noted that if the injured person is

> fully aware of the hazard through general knowledge, observation or common sense, or participated in the removal of the safety device whose purpose is obvious, lack of a warning about that danger may well obviate the failure to warn as a legal cause of an injury resulting from that

> danger. . . . Similarly, a limited class of hazards need not be warned of as a matter of law because they are patently dangerous or pose open and obvious risks.

Nonetheless the court then returned the failure to warn cause of action for a "fact-specific" inquiry in the Second Circuit.

Next, in Liriano v. Hobart Corp., 170 F.3d 264 (2d Cir. 1999), Calabresi, J., upheld a jury verdict for the plaintiff (subject to a one-third reduction for comparative negligence) because the youthful plaintiff had only recently immigrated to the United States; had worked for his employer—Super grocery store—for only a week, and had never been given instructions on how to operate the grinder, which he had used only two or three times. In light of the variation in product users, some users might not discover dangers that others find obvious. Accordingly, Calabresi, J., held that the

> jury could reasonably find that there exist people who are employed as meat grinders and who do not know (a) that it is feasible to reduce the risk with safety guards, (b) that such guards are made available with grinders, and (c) that the grinders should be used only with the guards.

Calabresi, J., further held that, on the question of causation, the burden of proof shifted to the defendant:

> When a defendant's negligent act is deemed wrongful precisely because it has a strong propensity to cause the type of injury that ensued, that very causal tendency is evidence enough to establish a *prima facie* case of cause-in-fact. The burden then shifts to the *defendant* to come forward with evidence that its negligence was *not* such a but-for cause.

The heeding presumption received an extensive analysis in Foster v. Ethicon, Inc., 529 F. Supp. 3d 992, 1002 (D.S.D. 2021), where the plaintiff brought claims for complications resulting from the installation of Ethicon's pelvic mesh, a medical device that aims to repair defective tissue in the pelvis. In this case, the plaintiffs argued that the warnings given to the physicians were insufficient to convey the seriousness of the risk. Lange, C.J., regarded that as beside the point, for, as the defendant argued, "Ms. Foster cannot show causation because Dr. Ferrell [the treating physician] did not rely on the TVT's [implanted device] warnings and would have prescribed the TVT for Ms. Foster even if he had received an adequate warning." Lange, C.J., continued, "Ms. Foster is entitled to a rebuttable presumption that Dr. Ferrell would have read and heeded an adequate warning. As explained below, however, Ethicon has rebutted the presumption and Ms. Foster has failed to show a material question of fact on causation."

2. *When Must a Warning Be Given? Latent Defects.* In Ayers v. Johnson & Johnson Co., 818 P.2d 1337, 1341 (Wash. 1991) (en banc), David Ayers, then aged fifteen months, had taken an unmarked bottle of Johnson's baby oil out of the purse of his thirteen-year-old sister. Just as he began to drink the oil, his mother yelled at him, causing him to gasp and inhale the oil in his lungs. Once there, the baby oil coated his air sacs and quickly led to oxygen deprivation that resulted in serious injuries: His leg motions became spastic; he had limited control over his head movements; and he suffered brain impairment, seizures, and lost any ability to speak.

Both sides agreed that once David inhaled the baby oil, no medical attention could have prevented these injuries. The plaintiff contended that a warning on the bottle was needed to alert users of this risk in order to keep baby oil out of the reach of infants in the first place. The plaintiff's mother testified that she read warnings, and kept dangerous products away from her young children, and instructed her teenage daughters to do the same. Both mother and daughters testified that they thought baby oil could cause diarrhea or stomach upset, but not more serious injuries. Johnson & Johnson argued that it was rank speculation to claim

that the additional knowledge would have led to different conduct since all members of the Ayers family knew that the baby oil was only for external use and was dangerous if taken internally. The jury found for the plaintiff, and its verdict was sustained on appeal:

> On the basis of this evidence, the jury was entitled to infer that if the Ayerses had known of the dangers of aspiration, they would have treated the baby oil with greater care; that they would have treated it with the caution they used in relation to items they recognized as highly dangerous, like cleaning products; and that had they done so, the accident would have never occurred. We conclude that the evidence of causation presented to the jury was sufficient to sustain the jury's verdict.

Should Johnson & Johnson change the warnings on its bottles? On its package inserts? If a warning should be included, what should it say?

3. *Duty to Warn: Patent Defects.* The risks in *Ayers* were both latent and remote. What ought to be done with respect to generic properties of common substances known to cause harm, such as alcohol? In Garrison v. Heublein, Inc., 673 F.2d 189, 189 (7th Cir. 1982), the court rejected the plaintiff's claim for "physical and mental injuries as a result of consuming the defendant's product [Smirnoff vodka] over a twenty-year period," holding that the defendant had no duty to warn of risks that were common knowledge.

"Screens out harmful ultraviolet rays, conditions skin, repels insects, won't wash off while swimming, will not stain most fabrics. Warning: Contact with eyes, ears, nose, or mouth may be fatal."

Source: Edward Frascino / The New Yorker Collection / The Cartoon Bank

Common knowledge, however, did not allow the defendant to obtain a summary judgment in Hon v. Stroh Brewery Co., 835 F.2d 510, 511 (3d Cir. 1987). The plaintiff's husband had died of pancreatitis that the plaintiff alleged had resulted mainly from his consumption of about eight to twelve cans of the defendant's beer each week over a period of several years. The court accepted the plaintiff's claim that a warning was required because it was not common knowledge that "*either* excessive *or* prolonged, even though moderate, use of alcohol may result in diseases of many kinds, including pancreatic disease." The court rejected the defendant's comment *j* defense in part because the jury could find that Stroh's advertising campaign linked the consumption of large quantities of beer to the "good life." It found that "comment *j* does not say that whenever alcohol is consumed over a long period of time the dangers are necessarily generally known. Rather it says that *when* the danger is generally known, no warning is required." Note that federal regulations, 27 C.F.R. §16.21 (2023), now require the following warning label to be attached conspicuously to containers of alcoholic beverages sold:

> GOVERNMENT WARNING: (1) According to the Surgeon General, women should not drink alcoholic beverages during pregnancy because of the risk of birth defects. (2) Consumption of alcoholic beverages impairs your ability to drive a car or operate machinery, and may cause health problems.

The bench and bar have abided by this elementary rule. They have learned to avoid injecting negligence—whether of the defendant or the plaintiff—into a products liability case. And they have understood the reason behind the distinction between negligence of any party and products liability. It was expressed over three decades ago by Justice Traynor in his concurring opinion in Escola v. Coca Cola Bottling Co.[, *supra* at 557]. . . .

Transferring the liability, or part of the liability, from the party responsible for putting the article in the stream of commerce to the consumer is precisely what the majority propose to do. They do this by employing a euphemism: the victim's recovery is to be "proportionately reduced." The result, however delicately described, is to dilute the defect of the article by elevating the conduct of the wounded consumer to an issue of equal significance. We can be as certain as tomorrow's daylight that every defendant charged with marketing a defective product will hereafter assert that the injured plaintiff did something, anything, that conceivably could be deemed contributorily negligent: he drove the vehicle with a defective steering mechanism 56 miles an hour instead of 54; or he should have discovered a latent defect hidden in the machinery; or perhaps he should not have succumbed to the salesman's persuasion and purchased the defective object in the first instance. I need no crystal ball to foresee that the pleading of affirmative defenses alleging contributory negligence—or the currently approved substitute terminology—will now become boilerplate. . . .

The defective product is comparable to a time bomb ready to explode; it maims its victims indiscriminately, the righteous and the evil, the careful and the careless. Thus when a faulty design or otherwise defective product is involved, the litigation should not be diverted to consideration of the negligence of the plaintiff. The liability issues are simple: was the product or its design faulty, did the defendant inject the defective product into the stream of commerce, and did the defect cause the injury? The conduct of the ultimate consumer-victim who used the product in the contemplated or foreseeable manner is wholly irrelevant to those issues. . . .

The majority note one "felicitous result" of adopting comparative negligence to products liability: the merger of assumption of risk—which they term a "bizarre anomaly"—into their innovative defense. I find that result neither felicitous nor tenable. In Barker v. Lull Engineering Co., we defined a defective product as one which failed to perform safely when used in an intended or foreseeable manner. If a consumer elects to use a product patently defective when other alternatives are available, or to use a product in a manner clearly not intended or foreseeable, he assumes the risks inherent in his improper utilization and should not be heard to complain about the condition of the object. One who employs a power saw to trim his fingernails—and thereafter finds the number of his fingers reduced—should not prevail to any extent whatever against the manufacturer even if the saw had a defective blade. I would retain assumption of risk as a total defense to products liability, as it always has been.

I would affirm the judgment.

NOTES

1. ***Foreseeable Misuse.*** In most crashworthiness cases, the plaintiff's misconduct goes far beyond the "normal and proper use" contemplated in *Escola*. In LeBouef v. Goodyear Tire & Rubber Co., 623 F.2d 985, 989 (5th Cir. 1980), the decedent purchased "a new, 1976 Mercury Cougar equipped with a 460 cubic-inch, a 425-horsepower engine, and with Goodyear HER78-15 Custom Polysteel Radial Tires." The car was capable of going 100 miles per hour, but Goodyear had tested the tires for safety only for speeds of eighty-five miles per hour. Ford's only warning was "a statement in the Cougar owner's manual that '[c]ontinuous driving over 90 mph requires using high-speed-capability tires'; the manual did not state whether the tires in question were or were not of high-speed-caliber." The decedent was driving while

intoxicated at speeds of 100 to 105 miles per hour and was killed when the car veered off the road. The trial court, sitting without a jury, found that the tire, although properly manufactured, was defective because of its insufficient warnings about the risk of tread separation at high speeds. It also found that "while [the decedent's] excessive speed was a contributory cause of the accident, his intoxication was not." It also rejected the contributory negligence and assumption of risk defenses. On appeal, the decision was affirmed, and the court had this to say about the misuse defense:

> Certainly the operation of the Cougar in excess of 100 miles per hour was not "normal" in the sense of being a routine or intended use. "Normal use," however, is a term of art in the parlance of Louisiana products liability law, delineating the scope of a manufacturer's duty and consequent liability; it encompasses all *reasonably foreseeable* uses of a product. . . . The sports car involved here was marketed with an intended and recognized appeal to youthful drivers. The 425 horsepower engine with which Ford had equipped it provided a capability of speeds over 100 miles per hour, and the car's allure, no doubt exploited in its marketing, lay in no small measure in this power and potential speed. It was not simply foreseeable, but was to be readily expected, that the Cougar would, on occasion, be driven in excess of the 85 miles per hour proven maximum safe operating speed of its Goodyear tires. Consequently, Ford cannot, on the basis of abnormal use, escape its duty either to provide an adequate warning of the specific danger of tread separation at such high speeds or to ameliorate the danger in some other way.

The foreseeable misuse standard has been criticized as creating a "moral hazard" problem by sanctioning reckless behavior and increasing the probability of accidents. In addition, foreseeable misuse creates an implicit transfer of wealth from careful to careless drivers because the manufacturer cannot differentiate in price charged between a retiree and a traveling salesman, or between the careful driver who has never had a ticket and the teenage hot-rodder. Epstein, Products Liability as an Insurance Market, 14 J. Legal Stud. 645 (1985), notes that first-party insurers routinely make these risk classifications in selling automobile insurance.

2. *The Restatement Position.* The Third Restatement follows *Daly* in what has become the majority position. See RTT: PL §17. In essence, the Third Restatement declines to treat product misuse, alteration, or assumption of risk as independent defenses. Rather, to the extent that these are traced to the plaintiff's conduct, they are governed by the comparative fault system in effect within the jurisdiction, usually pure comparative negligence or the 50 percent cut-off rule. Prior to the Third Restatement many states followed a rule that provided that the plaintiff was under no duty to discover latent defects contained in the defendant's product. Under the influence of comparative negligence, this defense may be allowed, at least in some cases: "[W]hen the defendant claims that the plaintiff failed to discover a defect, there must be evidence that the plaintiff's conduct in failing to discover a defect did, in fact, fail to meet a standard of reasonable care." RTT: PL §17, comment *d*.

RESTATEMENT OF THE LAW (THIRD) OF TORTS: PRODUCTS LIABILITY

§17. Apportionment of Responsibility Between or Among Plaintiff, Sellers and Distributors of Defective Products, and Others

(a) A plaintiff's recovery of damages for harm caused by a product defect may be reduced if the conduct of the plaintiff combines with the product defect to cause the harm and the plaintiff's conduct fails to conform to generally applicable rules establishing appropriate standards of care.

(b) The manner and extent of the reduction under Subsection (a) and the apportionment of plaintiff's recovery among multiple defendants are governed by generally applicable rules apportioning responsibility.

3. ***Contractual Defenses to Products Liability Actions.*** The Waiver Society Project, https://www.waiversociety.org/, is an ongoing project that tracks "the ubiquity of waivers in our world." Such express assumption of risk by contract is a complete defense to a tort action in some settings. One vital question is whether product sellers should be able, directly or through intermediaries, to contract out of their liability with potential product users and consumers. The contractual regime could redefine product defect, cap damages, or eliminate liability altogether. Since *Henningsen*, courts have uniformly rejected that approach, which also receives a chilly reception in the Third Restatement. See RTT: PL §18. The rule does not apply to cases of purely economic loss usually covered under the U.C.C., nor does it necessarily apply whenever product users and consumers are "represented by informed and economically powerful consumer groups or intermediaries." See RTT: PL §18, comment *d.* Does a reduction in price or increase in product or service access count as the necessary quid pro quo? How would the law of products liability have to be rewritten if the contractual waivers were freely accepted in all cases of physical injury or property damage?

RESTATEMENT OF THE LAW (THIRD) OF TORTS: PRODUCTS LIABILITY

§18. Disclaimers, Limitations, Waivers, and Other Contractual Exculpations as Defenses to Products Liability Claims for Harm to Persons

Disclaimers and limitations of remedies by product sellers or other distributors, waivers by product purchasers, and other similar contractual exculpations, oral or written, do not bar or reduce otherwise valid products-liability claims against sellers or other distributors of new products for harm to persons.

Comment a. Effects of contract defenses on products liability tort claims for harm to persons: . . . It is presumed that the ordinary product user or consumer lacks sufficient information and bargaining power to execute a fair contractual limitation of rights to recover. . . .

Comment d. Waiver of rights in contractual settings in which product purchasers possess both adequate knowledge and sufficient economic power: . . . This Section does not address whether consumers, especially when represented by informed and economically powerful consumer groups or intermediaries, with full information and sufficient bargaining power, may contract with product sellers to accept curtailment of liability in exchange for concomitant benefits, or whether such consumers might be allowed to agree to substitute alternative dispute resolution mechanisms in place of traditional adjudication. When such contracts are accompanied by alternative nontort remedies that serve as an adequate quid pro quo for reducing or eliminating rights to recover in tort, arguments may support giving effect to such agreements. Such contractual arrangements raise policy questions different from those raised by this Section and require careful consideration by the courts.

§21. Comment f. Harm to other property: disclaimers and limitations of remedies: . . . When a defective product causes harm to property owned by third persons, the contractual arrangements between the contracting parties should not shield the seller from liability to the third party. However, contractual limitations on tort liability for harm to property, when fairly bargained for, may provide an effective way for the contracting parties efficiently to allocate risks of such harm between themselves.

> date, no court has adopted the Third Restatement's strict liability test for prescription drugs, and one court [*Freeman*] has explicitly refused to adopt the test. . . .
> Moreover, we agree with the majority of courts that Comment *k* serves as an affirmative defense and that the defense has no application to claims of manufacturing defect or failure to warn.

Does section 6(c) functionally grant absolute immunity to all FDA-approved drugs?

For further criticism of the "complete overhaul" of the design defect provisions in the Third Restatement, see Conk, Is There a Design Defect in the Restatement (Third) of Torts: Products Liability?, 109 Yale L.J. 1087 (2000). But Professors Henderson and Twerski insist:

> A claim that seeks to find a given drug design defective because the manufacturer should have developed a safer alternative drug is inappropriate because courts are incapable of sensibly deciding whether the alternative proposed by the plaintiff would have met with FDA approval. Since any drug marketed in the United States must be approved by the FDA, a court must be able to determine that the FDA would have approved the drug. Given the many-year duration of the FDA approval process, which involves testing of thousands of patients, no court could rationally determine that an alternative drug would have been approved.

Twerski & Henderson Jr., Drug Design Liability: Farewell to Comment k, 67 Baylor L. Rev. 521, 577 (2015). Does this argument preclude the claim in *Bryant*? A malpractice action against the treating physician? Require federal preemption of state law? Sharkey, Field Preemption: Opening the "Gates of Escape" from Tort Law, 50 J. Legal Stud. S27, S47–50 (2021), argues that federal preemption, *infra* at 629, stunted the development of 6(c).

3. The Duty to Warn

Implicit in many design defect decisions is the view that it is better to design out certain dangerous conditions than it is to warn consumers and users of their dangers. Although that rule works well for many forms of equipment, it poses significant challenges for pharmaceutical and chemical products for which small changes in molecular composition can negate the effectiveness of the product for its intended purpose, or require a new round of approvals from, for example, the Food and Drug Administration or the Environmental Protection Agency. In these cases, the use of product warnings instead of design alterations may offer a sensible compromise, especially when the potential harms are not apparent to a product user from the appearance of the product or from common knowledge about its lurking dangers. What legal standards should apply in these warning cases?

MacDonald v. Ortho Pharmaceutical Corp.

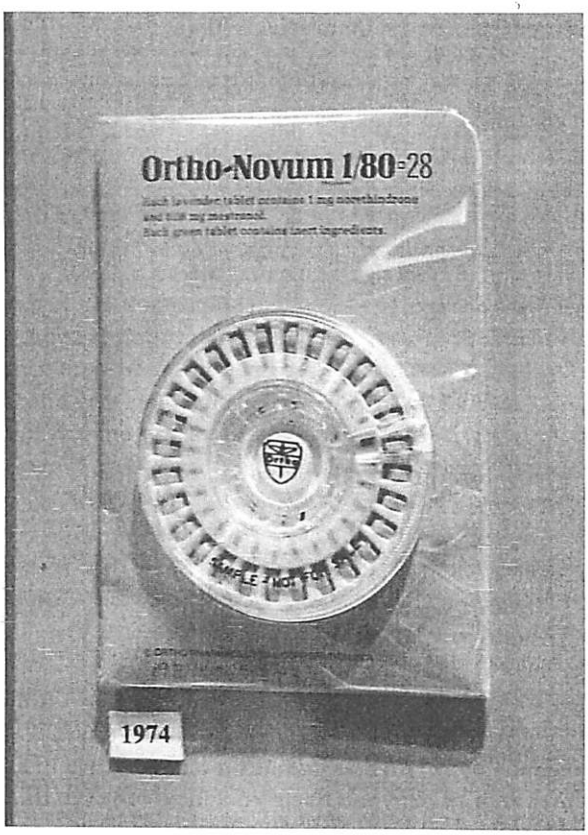
475 N.E.2d 65 (Mass. 1985)

Abrams, J. This products liability action raises the question of the extent of a drug manufacturer's duty to warn consumers of dangers inherent in the use of oral contraceptives. The plaintiffs brought suit against the defendant, Ortho Pharmaceutical Corporation (Ortho), for injuries allegedly caused by Ortho's birth control pills, and obtained a jury verdict in their favor. The defendant moved for a judgment notwithstanding the verdict. The judge concluded that the defendant did not owe a duty to warn the plaintiffs, and entered judgment for Ortho. The plaintiffs appealed. We transferred the case to this court on our own motion and reinstate the jury verdict.

We summarize the facts. In September, 1973, the plaintiff Carole D. MacDonald (MacDonald), who was twenty-six years old at the time, obtained from her gynecologist a prescription for Ortho-Novum contraceptive pills, manufactured by Ortho. As required by the

then effective regulations promulgated by the United States Food and Drug Administration (FDA), the pill dispenser she received was labeled with a warning that "oral contraceptives are powerful and effective drugs which can cause side effects in some users and should not be used at all by some women," and that "[t]he most serious known side effect is abnormal blood clotting which can be fatal." The warning also referred MacDonald to a booklet which she obtained from her gynecologist, and which was distributed by Ortho pursuant to FDA requirements. The booklet contained detailed information about the contraceptive pill, including the increased risk to pill users that vital organs such as the brain may be damaged by abnormal blood clotting. [The warning supplied listed the death and injury rates to women of various ages from taking the pill and noted "that women who have had blood clots in the legs, lungs, or brain [should] not use oral contraceptives."] The word "stroke" did not appear on the dispenser warning or in the booklet.

MacDonald's prescription for Ortho-Novum pills was renewed at subsequent annual visits to her gynecologist. The prescription was filled annually. On July 24, 1976, after approximately three years of using the pills, MacDonald suffered an occlusion of a cerebral artery by a blood clot, an injury commonly referred to as a stroke [or a "cerebral vascular accident"]. The injury caused the death of approximately twenty per cent of MacDonald's brain tissue, and left her permanently disabled. She and her husband initiated an action in the Superior Court against Ortho, seeking recovery for her personal injuries and his consequential damages and loss of consortium.



Ortho-Novum Dialpak dispenser
Source: B Christopher / Alamy

MacDonald testified that, during the time she used the pills, she was unaware that the risk of abnormal blood clotting encompassed the risk of stroke, and that she would not have used the pills had she been warned that stroke is an associated risk. [The court notes that the amended FDA regulations listed " 'the serious side effects of oral contraceptives, such as thrombophlebitis, pulmonary embolism, myocardial infarction, retinal artery thrombosis, *stroke*, benign hepatic adenomas, induction of fetal abnormalities, and gallbladder disease' (emphasis added). See 21 C.F.R. §310.501(a)(2)(iv) (1984)."] The case was submitted to a jury on the plaintiffs' theories that Ortho was negligent in failing to warn adequately of the dangers associated with the pills and that Ortho breached its warranty of merchantability. These two theories were treated, in effect, as a single claim of failure to warn. The jury returned a special verdict, finding no negligence or breach of warranty in the manufacture of the pills. The jury also found that Ortho

adequately advised the gynecologist of the risks inherent in the pills;[7] the jury found, however, that Ortho was negligent and in breach of warranty because it failed to give MacDonald sufficient warning of such dangers. The jury further found that MacDonald's injury was caused by Ortho's pills, that the inadequacy of the warnings to MacDonald was the proximate cause of her injury, and that Ortho was liable to MacDonald and her husband.

After the jury verdict, the judge granted Ortho's motion for judgment notwithstanding the verdict, concluding that, because oral contraceptives are prescription drugs, a manufacturer's duty to warn the consumer is satisfied if the manufacturer gives adequate warnings to the prescribing physician, and that the manufacturer has no duty to warn the consumer directly.

The narrow issue, on appeal, is whether, as the plaintiffs contend, a manufacturer of birth control pills owes a direct duty to the consumer to warn her of the dangers inherent in the use of the pill. We conclude that such a duty exists under the law of this Commonwealth.

1. Extent of Duty to Warn . . .

[The court first notes that the general rule was that the defendant must warn all "persons who it is foreseeable will come in contact with, and consequently be endangered by, that product." It then recognizes a "narrow" exception, as set out in Restatement (Second) of Torts §388, comment *n*, when warnings have been given to a responsible intermediary "so that the manufacturer has no duty directly to warn the consumer." It continues:]

The rule in jurisdictions that have addressed the question of the extent of a manufacturer's duty to warn in cases involving prescription drugs is that the prescribing physician acts as a "learned intermediary" between the manufacturer and the patient, and "the duty of the ethical drug manufacturer is to warn the doctor, rather than the patient, [although] the manufacturer is directly liable to the patient for a breach of such duty." McEwen v. Ortho Pharmaceutical Corp., 528 P.2d 522 (Or. 1974). Oral contraceptives, however, bear peculiar characteristics which warrant the imposition of a common law duty on the manufacturer to warn users directly of associated risks. Whereas a patient's involvement in decision-making concerning use of a prescription drug necessary to treat a malady is typically minimal or nonexistent, the healthy, young consumer of oral contraceptives is usually actively involved in the decision to use "the pill," as opposed to other available birth control products, and the prescribing physician is relegated to a relatively passive role.

Furthermore, the physician prescribing "the pill," as a matter of course, examines the patient once before prescribing an oral contraceptive and only annually thereafter. At her annual checkup, the patient receives a renewal prescription for a full year's supply of the pill. Thus, the patient may only seldom have the opportunity to explore her questions and concerns about the medication with the prescribing physician. Even if the physician, on those occasions, were scrupulously to remind the patient of the risks attendant on continuation of the oral contraceptive, "the patient cannot be expected to remember all of the details for a protracted period of time." 35 Fed. Reg. 9002 (1970).

Last, the birth control pill is specifically subject to extensive Federal regulation [which, inter alia, requires that "users of these drugs should, without exception, be furnished with written information telling them of the drug's benefits and risks."]

7. MacDonald stated at trial that her gynecologist had informed her only that oral contraceptives might cause bloating, and had not advised her of the increased risk of stroke associated with consumption of birth control pills. The physician was not joined as a defendant in this action, and no questions relating to any potential liability on his part are before us. MacDonald further testified at trial that she had read both the warning on the Dialpak tablet dispenser as well as the booklet which she received from her gynecologist.

The oral contraceptive thus stands apart from other prescription drugs in light of the heightened participation of patients in decisions relating to use of "the pill"; the substantial risks affiliated with the product's use; the feasibility of direct warnings by the manufacturer to the user; the limited participation of the physician (annual prescriptions); and the possibility that oral communications between physicians and consumers may be insufficient or too scanty standing alone fully to apprise consumers of the product's dangers at the time the initial selection of a contraceptive method is made as well as at subsequent points when alternative methods may be considered. We conclude that the manufacturer of oral contraceptives is not justified in relying on warnings to the medical profession to satisfy its common law duty to warn, and that the manufacturer's obligation encompasses a duty to warn the ultimate user. Thus, the manufacturer's duty is to provide to the consumer written warnings conveying reasonable notice of the nature, gravity, and likelihood of known or knowable side effects, and advising the consumer to seek fuller explanation from the prescribing physician or other doctor of any such information of concern to the consumer.[13]

2. Adequacy of the Warning

Because we reject the judge's conclusion that Ortho had no duty to warn MacDonald, we turn to Ortho's separate argument, not reached by the judge, that the evidence was insufficient to warrant the jury's finding that Ortho's warnings to MacDonald were inadequate. Ortho contends initially that its warnings complied with FDA labeling requirements, and that those requirements preempt or define the bounds of the common law duty to warn. We disagree. The regulatory history of the FDA requirements belies any objective to cloak them with preemptive effect. In response to concerns raised by drug manufacturers that warnings required and drafted by the FDA might be deemed inadequate by juries, the FDA commissioner specifically noted that the boundaries of civil tort liability for failure to warn are controlled by applicable State law. 43 Fed. Reg. 4214 (1978). Although the common law duty we today recognize is to a large degree coextensive with the regulatory duties imposed by the FDA, we are persuaded that, in instances where a trier of fact could reasonably conclude that a manufacturer's compliance with FDA labeling requirements or guidelines did not adequately apprise oral contraceptive users of inherent risks, the manufacturer should not be shielded from liability by such compliance. Thus, compliance with FDA requirements, though admissible to demonstrate lack of negligence, is not conclusive on this issue, just as violation of FDA requirements is evidence, but not conclusive evidence, of negligence. We therefore concur with the plaintiffs' argument that even if the conclusion that Ortho complied with FDA requirements were inescapable, an issue we need not decide, the jury nonetheless could have found that the lack of a reference to "stroke" breached Ortho's common law duty to warn.

The common law duty to warn, like the analogous FDA "lay language" requirement, necessitates a warning "comprehensible to the average user and . . . convey[ing] a fair indication of the nature and extent of the danger to the mind of a reasonably prudent person."

Whether a particular warning measures up to this standard is almost always an issue to be resolved by a jury; few questions are "more appropriately left to a common sense lay judgment than that of whether a written warning gets its message across to an average person." Ferebee v. Chevron Chem. Co., 552 F. Supp. 1293, 1304 (D.D.C. 1982). A court may, as a matter of law, determine "whether the defendant has conformed to that standard, in any case in which

13. This opinion does not diminish the prescribing physician's duty to "disclose in a reasonable manner all significant medical information that the physician possesses or reasonably should possess that is material to an intelligent decision by the patient whether to" take "the pill." Harnish v. Children's Hosp. Medical Center, 439 N.E.2d 240 (Mass. 1982).

the jury may not reasonably come to a different conclusion," Restatement (Second) of Torts §328B(d) and Comment *g* (1965), but judicial intrusion into jury decision-making in negligence cases is exceedingly rare. Further, we must view the evidence in the light most favorable to the plaintiffs. The test is whether "anywhere in the evidence, from whatever source derived, any combination of circumstances could be found from which a reasonable inference could be drawn in favor of the plaintiff."

Ortho argues that reasonable minds could not differ as to whether MacDonald was adequately informed of the risk of the injury she sustained by Ortho's warning that the oral contraceptives could cause "abnormal blood clotting which can be fatal" and further warning of the incremental likelihood of hospitalization or death due to blood clotting in "vital organs, such as the brain." We disagree. . . . We cannot say that this jury's decision that the warning was inadequate is so unreasonable as to require the opposite conclusion as a matter of law. The jury may well have concluded, in light of their common experience and MacDonald's testimony, that the absence of a reference to "stroke" in the warning unduly minimized the warning's impact or failed to make the nature of the risk reasonably comprehensible to the average consumer. Similarly, the jury may have concluded that there are fates worse than death, such as the permanent disablement suffered by MacDonald, and that the mention of the risk of death did not, therefore, suffice to apprise an average consumer of the material risks of oral contraceptive use.

We reverse the judgment, which the judge ordered notwithstanding the verdict, and remand the case to the Superior Court for the entry of judgment for the plaintiffs.

So ordered.

O'Connor, J., dissenting. . . . I would hold that, as a matter of law, by adequately informing physicians of the risks associated with its product and by complying with applicable FDA regulations, a contraceptive pill manufacturer fulfils the duty to warn that it owes consumers. . . .

I believe that the "prescription drug" rule, combined with the *Harnish* rule most fairly and efficiently allocates among drug manufacturers, physicians, and drug users, the risks and responsibilities involved with the use of prescription drugs. Furthermore, I believe that those rules best ensure that a prescription drug user will receive in the most effective manner the information that she needs to make an informed decision as to whether to use the drug. The rules place on drug manufacturers the duty to gather, compile, and provide to doctors data regarding the use of their drugs, tasks for which the manufacturers are best suited, and the rules place on doctors the burden of conveying those data to their patients in a useful and understandable manner, a task for which doctors are best suited. Doctors, unlike printed warnings, can tailor to the needs and abilities of an individual patient the information that that patient needs in order to make an informed decision whether to use a particular drug. Manufacturers are not in position to give adequate advice directly to those consumers whose medical histories and physical conditions, perhaps unknown to the consumers, make them peculiarly susceptible to risk. Prescription drugs—including oral contraceptives—differ from other products because their dangers vary widely depending on characteristics of individual consumers. Exposing a prescription drug manufacturer to liability based on a jury's determination that, despite adequately informing physicians of the drug's risks and complying with FDA regulations, the manufacturer failed reasonably to warn a particular plaintiff-consumer of individualized risks is not essential to reasonable consumer protection and places an unfair burden on prescription drug manufacturers.

NOTES

1. ***Physicians as Learned Intermediaries.*** Why did the plaintiffs not join the treating physician? To what extent is the decision in *MacDonald* strengthened or weakened by the

wide availability of all forms of product warnings on the Internet? The learned intermediary rule held firm in Harrison v. American Home Products Corp. (AHP), 165 F.3d 374, 379 (5th Cir. 1999), when the plaintiffs complained of adverse side effects from the contraceptive Norplant, a long-term birth control method. Jolly, J., stressed the "significant role" that physicians played "in prescribing Norplant and in educating their patients about the benefits and disadvantages to using it." He also rejected the view that AHP's aggressive direct-to-consumer marketing campaign undercut the physicians' duty to warn in the absence of any evidence that the plaintiffs "actually saw, let alone relied, on" any AHP marketing materials. What result if they had so relied?

Consider Perez v. Wyeth Laboratories, 734 A.2d 1245 (N.J. 1999), where the court imposed a direct duty to warn the plaintiff patient on Wyeth, the drug manufacturer, because of its "massive advertising campaign for Norplant in 1991, which it directed at women rather than at their doctors" through such women's magazines as *Glamour, Mademoiselle*, and *Cosmopolitan*. The *Perez* rule, however, has not caught on. In 2022, Owens, J., surveyed the landscape and noted that "only New Jersey has adopted a direct-to-consumer exception, but that decision has not been subsequently relied on." Dearinger v. Eli Lilly & Co., 510 P.3d 326, 331 (Wash. 2022) (en banc). Recently, Hunte v. Abbott Laboratories, Inc., 569 F. Supp. 3d 115 (D. Conn. 2021), certified to the Connecticut Supreme Court the question whether a direct-to-consumer marketing exception applies to infant formula for premature babies.

RESTATEMENT OF THE LAW (THIRD) OF TORTS: PRODUCTS LIABILITY

§6. Liability of Commercial Seller or Distributor for Harm Caused by Defective Prescription Drugs and Medical Devices

(d) A prescription drug or medical device is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to:

(1) prescribing and other health-care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings; or

(2) the patient when the manufacturer knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings.

On the status of the learned intermediary defense in birth control and mass vaccination cases, the Third Restatement takes a studious pass: "The Institute leaves to developing case law whether exceptions to the learned intermediary rule in these or other situations should be recognized." RTT: PL §6, comment *e*.

How does *MacDonald* come out under the Third Restatement test? In 2021, the United States Court of Appeals for the Eighth Circuit determined Nebraska "would follow what has become an 'overwhelming majority' rule" in adopting the Third Restatement's version of the learned intermediary doctrine, finding that Massachusetts in *MacDonald* "stands alone in unequivocally adopting" a prescription-contraceptives exception. Ideus v. Teva Pharms. United States, Inc., 986 F.3d 1098, 1102 (8th Cir. 2021).

Should drug manufacturers' direct promotional activities for other drugs be factored into the mix under section 6(d)(2)? For a sharp criticism of drug marketing practices, see Vukadin, Failure-to-Warn: Facing Up to the Real Impact of Pharmaceutical Marketing on the Physician's Decision to Prescribe, 50 Tulsa L. Rev. 75, 75, 104 (2014), insisting that "[f]ailure-to-warn jurisprudence should stop relying on empty paper compliance and recognize present-day

pharmaceutical marketing as a compelling and driving force in the decision to prescribe." Nonetheless, successful overpromotion cases are difficult to win, given the requirement that "such overpromotion caused the physician to initiate or maintain the prescription at issue. General claims of overpromotion are not sufficient." In re Zyprexa Prods. Liab. Litig., 649 F. Supp. 2d 18, 33 (E.D.N.Y. 2009). See also DiBartolo v. Abbott Labs., 914 F. Supp. 2d 601 (S.D.N.Y. 2012).

2. *Pharmacists' Duty to Warn.* A pharmacist's education and training justify the imposition of a set of standard duties: (1) a duty to fill a prescription correctly, (2) a duty to remedy inadequacies on the face of the prescription, (3) and a duty to take reasonable care in preparing or dispensing the medicine.

The vast majority of states retain the general common law rule that pharmacists do not have a duty to warn patients of the risks of medication. Under the learned intermediary doctrine, a court "could not place a greater burden on pharmacists" than on drug manufacturers because it is within the discretion of the physician, as the party who prescribes the drug, to warn the patient. Fakhouri v. Taylor, 618 N.E.2d 518, 519 (Ill. App. Ct. 1993). The Third Restatement §6(e) also restricts the liability of retail sellers of drugs and medical devices to cases of manufacturing defects (why?) or for failing "to exercise reasonable care and such failure causes harm to persons." Nonetheless some courts have required pharmacists to (1) inform a doctor of a contraindication or of an abnormally high dosage, (2) provide a detailed warning where, through advertising, the pharmacy claims to have an enhanced warning or safety system in place, and (3) provide a warning where the pharmacist knows or has reason to know a customer's allergies. Thus in Happel v. Wal-Mart Stores, Inc., 766 N.E.2d 1118, 1124 (Ill. 2002), the defendant maintained a registry that warned of possible adverse drug interactions or allergic reactions for all of its customers. A duty to warn was imposed because "[t]he burden on defendant of imposing this duty is minimal. All that is required is that the pharmacist telephone the physician and inform him or her of the contraindication. Alternatively, the pharmacist could provide the same information to the patient."

Dr. Albert Sabin

Source: Bettmann / Corbis

3. *Mass Vaccination Cases.* The dissemination and adequacy of warnings has proved critically important to mass immunization programs. Davis v. Wyeth Laboratories, Inc., 399 F.2d 121, 129–31 (9th Cir. 1968), and Reyes v. Wyeth Laboratories, Inc., 498 F.2d 1264 (5th Cir. 1974), are the watershed cases involving liability for the Sabin live-virus polio vaccine. In *Davis*, the plaintiff contracted polio after being vaccinated as part of a mass immunization program administered by the local pharmacist, when no physician was available to do the job. The program for immunization