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Product Liability

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Introduction

Law of Torts

Tort is a wide and amorphous area of common law which includes all instances of harmful behavior, from personal physical attack to interference with personal material possessions and usage and this also includes personal honor, reputation, and privacy. This concept encompasses only those civil wrongs independent of contracts, and recognized by law as grounds for a lawsuit. These wrongs result in an injury or harm which constitute the basis for a claim by the injured party. The primary aim of tort law is to provide relief for the damages incurred and deter others from committing the same. The injured person may sue for an injunction to prevent the continuation of the conduct causing the injury or for monetary damages.

Product Liability

Product liability is an important concept under tort law, which holds not just the manufacturer of a defective product liable for damages, but also any or all parties along the chain of manufacture of that product. This includes the manufacturer of component parts (at the top of the chain), an assembling manufacturer, the wholesaler, and the retailer (at the bottom of the chain). Pharmaceutical products including prescription drugs are "products" within the meaning of this concept. Hence, any damage caused to the patient by prescription drugs may attract the provisions of this concept.

Historical Overview of the Product Liability Law

To understand pharmaceutical product liability, it is important to appreciate how the product liability law evolved during the last two centuries. The first important case to attempt to determine product liability occurred in 1842 (*Winterbottom* v. *Wright*). In this case, one Mr. Winterbottom was seriously injured when he was driving a poorly constructed mail coach drawn by horses. The mail coach had been sold to the Postmaster General by its manufacturer, Mr. Wright. The Postmaster had a contract with a company to supply horses to pull the coach. It was that company (contracted by the Postmaster) which hired Mr. Winterbottom to drive the coach.

Mr. Winterbottom sued Mr. Wright for damages, but his case was dismissed – rather contemptuously – because there was no privity of contract between Mr. Winterbottom and Mr. Wright. In effect, this decision established that a product seller cannot be sued, even for proven negligence, by someone with whom he has not contracted, or, in the words of the law, someone with whom he is not in privity (Figure 1).

The Era of Absolute Consumer Liability

It is interesting to conjecture what would have happened at this time if a similar case had occurred then in relation to prescribed drugs. Fortunately parallels can be drawn. A drug manufacturer supplies a spurious or outdated drug to a retailer; the retailer passes it on to the prescribing doctor and the doctor finally prescribes the drug to the ultimate consumer, the patient. If the patient suffers some injury because of this defective drug, despite the fact the manufacturer was negligent, the patient could not sue him because he was not in privity of contract with the manufacturer. This was, in a way, an era of absolute consumer liability (Figure 2).

The Fall of the Privity of Contract

Just ten years after the Winterbottom case, in 1852, the New York Court of Appeals discarded the concept of privity of contract, but only in cases of inherently dangerous medicines (see Table 1). For other products absence of contract continued to be an important defense for the manufacturer.

The next important case in product liability law occurred in 1916 (*Macpherson* v. *Buick Motor Co.*). In this case, the defendant, Buick Motor Co., a manufacturer of automobiles, sold an automobile to a retail dealer (X). The retail dealer resold it to MacPherson, the plaintiff. While the plaintiff was in

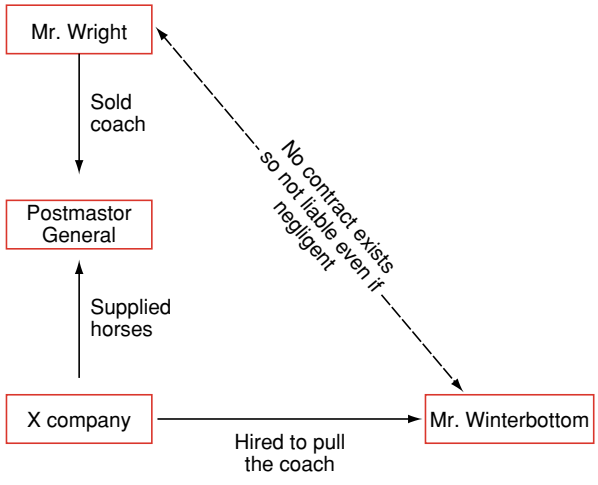

Figure 1 Product liability law as under Winterbottom (1842).

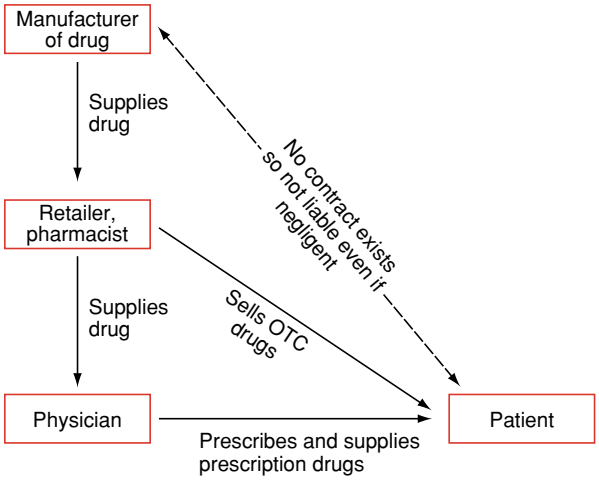

Figure 2 Equivalent pharmaceutical product liability law as under Winterbottom (1842).

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 Buick Motor Co., but had been bought in from some other manufacturer (Y). There was, however, evidence that its defects could have been discovered by a reasonable inspection by the Buick Motor Co., but that inspection was not done. The charge brought against the company was of negligence. The question to be determined was whether the defendant owed a duty of care and vigilance to any one but the immediate purchaser.

Had this case been judged by the older *Winterbottom* standard, Buick Motor Co. would not have had to pay any damages to MacPherson, simply because it never entered into a contract with him. It was the retail dealer (X) who had sold the car to MacPherson and thus he (MacPherson) had a contractual relationship only with the retail dealer (X). But in a remarkable conceptual leap, Judge Cardozo of the New York Court of Appeals held that if a company was negligent (as Buick Motor Co. had been in not inspecting the defective wheel), then it was liable, even if it had no privity of contract with the sufferer (Figure 3). For the first time, the concept of "privity of contract" was discarded in a case *not* involving dangerous medicines. For many legal commentators of the time, it was "the conquest of tort over contract."

Parallels can be drawn here too. A drug manufacturer gets a chemical component from a supplier (Y). Y supplies a defective chemical (it may be of a low potency, or completely deteriorated). The drug manufacturer – by a reasonable inspection – could have discovered that it was defective but fails to do the inspection and subsequently manufactures the drug, which is sold to the pharmacist (X). The consumer buys the drug from X and suffers injury. The consumer is fully entitled to get a compensation from the drug manufacturer (Figure 4).

The Rise of Strict Liability

It is important to note that in *MacPherson* although there was no privity of contract between MacPherson and the Buick Motor Co., the damages were awarded to MacPherson, because the company was negligent. It is interesting to conjecture what would have happened if the company had not been negligent, i.e., if it had taken all reasonable precautions (such as careful inspection of the wheels, etc.) to see that a defective part was not incorporated in their automobile and yet somehow it got incorporated in the automobile. If the very same MacPherson had sued the company for damages in this hypothetical case, it is almost sure he would not have won. It is important to appreciate that he had won on the concept of negligence, and in the absence of negligence on the part of Buick Motor Co., no damages could have been awarded to him. The next 50 years were to see a radical change in this concept.

Implied Warranty of Safety

The early 1960s saw the rise of two very interesting concepts in product liability law: those of implied warranty of safety and strict liability. The former of these came with *Henningsen* v. *Bloomfield Motors, Inc*. In this case Henningsen (H) bought a car from D's dealership. Just ten days after delivery, the steering malfunctioned and H's wife was involved in an accident. H sued the dealer and the car manufacturer. The dealer (D) argued that there was a clause in the warranty signed by H that freed D from any liability for personal injuries. The warranty was only for replacement of defective parts for the period of 90 days or 4000 miles (6400 km). But the court awarded damages to Henningsen. It argued that with the sale of every object there was an implied warranty of safety. Nor could the defendant argue that since it was Henningsen's wife (who had not bought the car from him) who suffered damages, he was not responsible. According to the court, the warranty extended "to every foreseeable user of the product." Even if, for example, Henningsen's friend had used the car and had suffered injury, he could have claimed for damages (Figure 5).

Figure 6 depicts the equivalent pharmaceutical product liability as under *Henningsen*.

Strict or Absolute Liability

The modern concept of strict liability (also sometimes referred to as absolute liability) arose with *Greenman* v. *Yuba Power Products, Inc*. Strict liability is liability

Table 1 Twenty major events in the evolution of the concept of product liability

Event number	*Year*	*Event*
1	1700–1800	English doctrine of *caveat emptor* (let the buyer beware) adopted by the American colonies. This principle in the law of commercial transactions meant that the buyer purchases at his own risk in the absence of an express warranty in the contract. The concept of product liability does not exist at all
2	1842	*Winterbottom* v. *Wright* establishes that there *has* to be a contractual relationship between the injured party and the party supplying defective products, before the injured party can sue and be awarded damages. In other words, privity of contract is a must in order to get compensation
3	1852	The New York Court of Appeals takes the first step towards abolishing the privity of contract, but only in respect of extremely dangerous medicines. In *Thomas* v. *Winchester*, Mrs. Thomas sustained injuries from the effects of a quantity of extract of belladonna, administered to her by mistake as extract of dandelion (because of careless labeling). Court awards damages to Mrs. Thomas despite the fact there is no privity of contract between Thomas and Winchester. The court observes: ''The liability of the dealer in such case arises, not out of any contract or direct privity between him and the person injured, but out of the duty which the law imposes upon him to avoid acts in their nature dangerous to the lives of others. He is liable therefore, though the poisonous drug with such label may have passed through many intermediate sales before it reaches the hands of the person injured''
4	Early1900s	States begin to pass workmen's compensation statutes
5	1916	Justice Cardozo of the New York Court of Appeals in *MacPherson* v. *Buick Motor Co.* makes a sharp shift from *Winterbottom* and lays foundation to the origin of modern product liability law. Among other things, the case establishes the following concepts: 1. It is the manufacturer's duty to conduct necessary tests to ensure safety of product 2. The negligent manufacturer could now be held liable to the ultimate purchaser, despite lack of a contractual relationship. Privity of contract defense in negligence (established 75 years earlier by *Winterbottom*) eviscerated 3. It is the seller's responsibility for design and manufacturing integrity
6	1923	The American Law Institute (ALI) embarks upon an effort to collect and organize the divergent decisional law which define the common law rules of torts throughout the USA. The efforts were to culminate in the first ever *Restatement of Torts*. University of Pennsylvania Professor Francis H. Bohlen appointed by the ALI as the original Reporter
7	1934–1939	Restatement of Torts adopted by the ALI
8	1954	Berkeley's then Dean William L. Prosser appointed as the Reporter to revise the *Restatement of Torts*. The task of compiling the *Restatement of Torts (Second)* begins
9	1960	The New Jersey Supreme Court in *Henningsen* v. *Bloomfield Motors, Inc.*, disallows the defense of privity of contract in the case where negligence was absent. The implied warranty of safety, extends to all products and to every foreseeable user of the product
10	1963	Chief Justice Roger Traynor of the California Supreme Court in *Greenman* v. *Yuba Power Products, Inc.* introduces strict tort liability as a viable concept. Within a few years, the majority of states would adopt strict tort liability. Under strict tort liability, it is no longer necessary to prove negligence
11	1965	ALI promulgates *Restatement (Second) of Torts* §420A, which ushers in the concept of strict liability. It is no more necessary for the plaintiff to show negligence. Only two things need be shown: (1) that the product was unduly dangerous and (2) that injury occurred as a result of that product. No matter how careful the manufacturer was, he would still be liable under the concept of strict liability
12	1979	Uniform Product Liability Act (UPLA) proposed by US Commerce Department as model law for adoption by states to standardize product liability statutes and insurance premiums
13	1981	Product Liability Risk Retention Act allowed for self-insurance and collective bargaining for lower commercial liability premiums
14	1984	First of many US Congressional bills to limit product liability fails
15	1996	President Clinton vetoes the Product Liability Legal Reform Bill. Among other things it proposed: (1) a US $250 000 cap on punitive damages for small business, (2) a drug and alcohol defense, which would bar a claim if a plaintiff was under the influence when an accident occurred and intoxication was the principal cause of the accident, (3) severe restrictions of the claims of persons who grossly misuse a product and then sue the defendant (with an eye to monetary gain). Studies had earlier shown that when states pass tort reform, productivity and employment increase
16	1997	Senator Ashcroft introduces the Product Liability Reform Bill of 1997. The bill is an exact replica of the failed legislation of 1996. Defeated again
17	1998	The ALI recognizes that the subject of torts had become too broad and too intricate to be encompassed in a single project and undertakes to compile the *Restatement (Third)* in segments. Adopts *Restatement (Third) of Torts: Products Liability*. §6 and §10 of this *Restatement* relate specifically to pharmaceutical product liability. §6 defines the liability of seller or other distributor for harm caused by defective prescription drugs and medical devices. §10 deals with the liability of commercial product seller or distribution for harm caused by post-sale failure to warn

Continued

Table 1 Continued

Event number	*Year*	*Event*
18	1999	In *Perez* v. *Wyeth Laboratories, Inc.*, the New Jersey Supreme Court jettisons the well-established and well-entrenched ''learned intermediary doctrine.'' It effectively means that the manufacturers of prescribed drugs owe a kind of strict liability towards consumers
19	2001	In *Yugler* v. *Pharmacia & Upjohn Co.* the court asserts that the manufacturers cannot take the defense of learned intermediary doctrine even if physician recommended the over-the-counter drug. This means that the manufacturer continues to owe a duty to warn to the patient regarding an OTC drug, even if it were prescribed by a physician
20	2004	Manufacturers continue to seek – unsuccessfully – federal tort reform

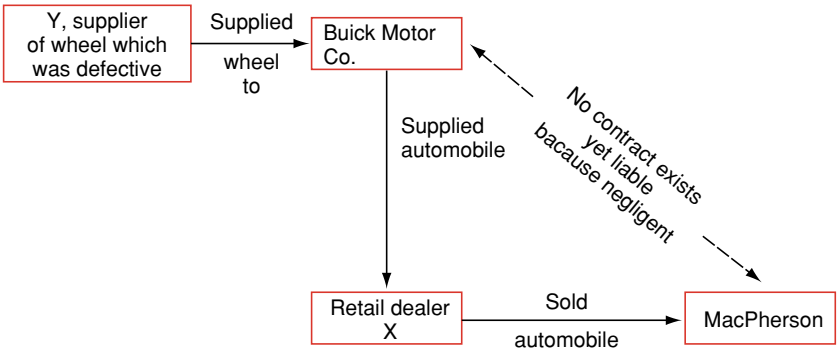

Figure 3 Product liability as it emerged under *MacPherson* (1916).

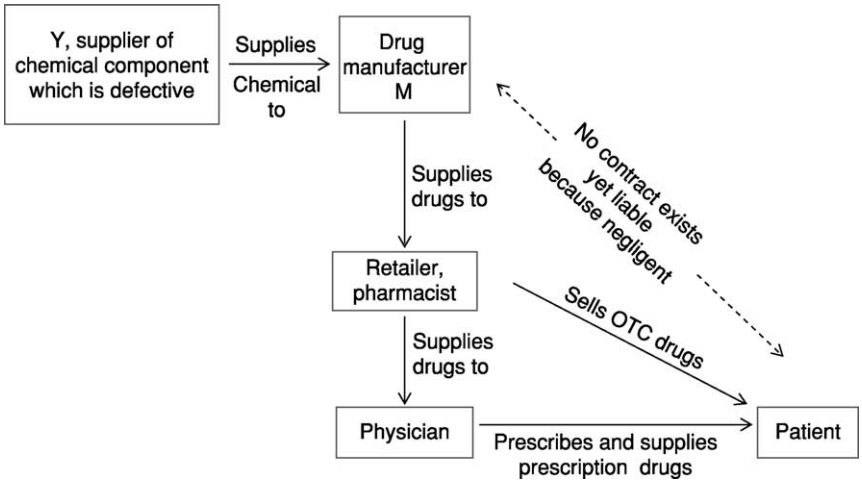

Figure 4 Equivalent pharmaceutical product liability law as under *MacPherson* (1916).

without privity of contract and even without negligence. If MacPhersons case had been judged by standards of strict liability, he would have won even in the latter hypothetical case, where the Buick Motor Co. had not been negligent. In *Greenman* v. *Yuba*, Greenman (the plaintiff) had bought a gadget called "Shopsmith," which was a combination power tool that could be used as a saw, drill, and wood lathe. The plaintiff watched a Shopsmith being demonstrated by the retailer and studied a brochure prepared by the manufacturer. He decided to buy a Shopsmith for his home workshop. However, his wife bought and gave him one for Christmas in 1955. In 1957 he bought the necessary attachments to use the Shopsmith as a lathe for turning a large piece of wood he wished to make into a chalice. After he had worked on the piece of wood several times without difficulty, it suddenly flew out of the machine and struck him on the forehead, inflicting serious injuries. He sued both the retailer and the manufacturer. During the trial he

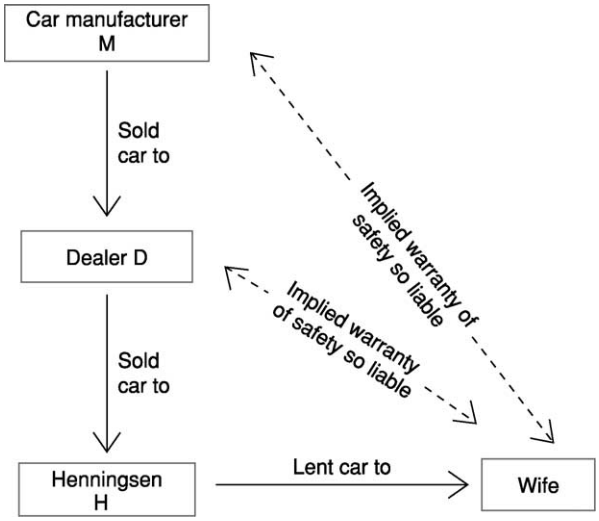

Figure 5 Product liability law as under *Henningsen* (1960).

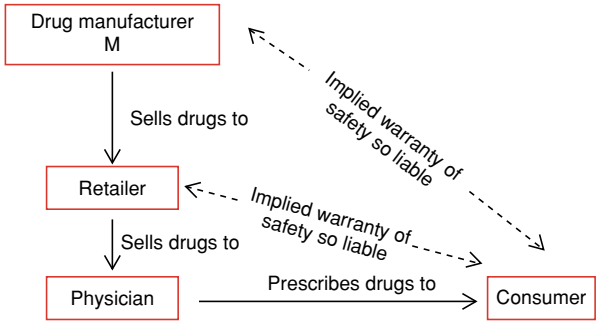

Figure 6 Equivalent pharmaceutical product liability law as under *Henningsen* (1960).

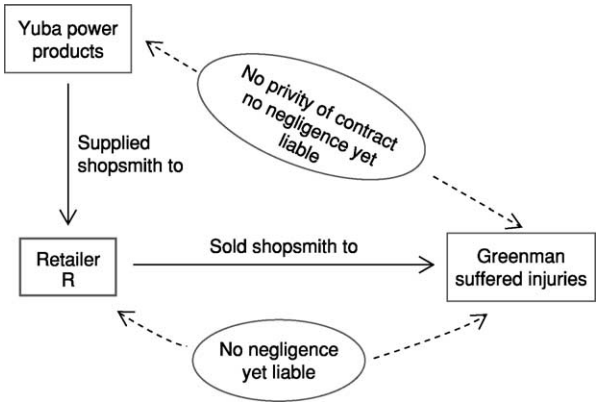

Figure 7 Product liability law under *Greenman* (1963).

introduced substantial evidence that his injuries were caused by defective design and construction of the Shopsmith. No evidence was found that the retailer and manufacturer were negligent or had breached any express warranty, yet the court ruled in favor of Greenman. According to the court, the only thing that needed to be shown now was that a product was defective and that it was being used in a way it was intended to be used and yet injury had occurred (Figure 7). The plaintiff need not demonstrate any negligence on the part of manufacturer or retailer.

An analogy can perhaps make the concept simpler to understand. Suppose a person (X) decides to keep a dangerous snake as a pet in his house. He takes utmost precautions to contain the snake in a cage and yet the snake escapes somehow and injures a neighbor (Y). It is no defense for X to assert that he had taken utmost precautions to contain the snake and that he was not negligent at all. The only facts that Y needs to prove (to be awarded damages) are (1) X had an exceedingly and inherently dangerous animal as his pet and (2) he suffered an injury due to that pet.

The concept of strict liability is mostly used in connection with objects which are exceedingly and inherently dangerous (sometimes termed as "unavoidably unsafe") such as dangerous animals, radioactive material, explosives, guns (and prescription drugs as some jurisdictions would assert), but various jurisdictions have applied this concept to other objects also. Used in connection with prescription drugs, it implies that if a defective drug causes injury to a patient, he is entitled for recovery of damages. It is not a defense for the manufacturer to show that he was not negligent. Only three things need be demonstrated by the patient to get damages: (1) that the drug was deficient; (2) that he used it as it was intended to be used (i.e., he did not, for example, ingest a syrup meant to be instilled in his eye); and (3) injury occurred as a result (Figure 8).

Restatement (Third) of Torts: Products Liability

As stated at the beginning of this article, the law of torts is a vast and amorphous body of law which lies scattered in various judicial rulings. To crystallize and codify these concepts, the American Law Institute (ALI) started an effort in 1923 and produced the first *Restatement of Torts*. The *Restatement* was exactly what the name implied – a "re-statement" of the common law. As case law kept growing, the restatement needed to be revised. ALI brought out the *Restatement (Second) of Torts* in 1965. § 402A of this dealt with the complex area of products liability. *Comment k* under this section dealt mainly with pharmaceutical product liability.

It gradually became apparent that such a complex subject as product liability law needed a separate codification. In 1998, the ALI brought out *Restatement (Third) of Torts: Products Liability*, a separate body of law dealing just with products liability. It has 21 sections (distributed in four chapters) and as of

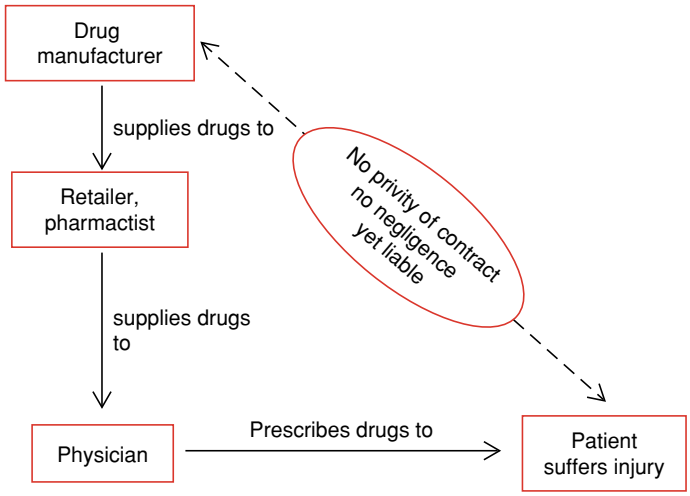

Figure 8 Equivalent pharmaceutical product liability law as developed under *Greenman* (1963).

now this body of law is the guiding principle in all cases of products liability. This *Restatement*, which supersedes the earlier *Restatement (Second) of Torts*, represents a thorough reformulation and expansion of § 402A and related sections of the *Restatement (Second)*. Especially notable are the careful separation of product defect into distinct categories and the development of separate rules for special products and their markets. Also covered in detail is liability of product sellers not based upon defects at the time of sale, including liability for post-sale failure to warn, and successor liability.

Many states have enacted their own comprehensive product liability statutes. These state-specific statutory provisions can be very diverse. Because of this, the US Department of Commerce produced the "Model Uniform Products Liability Act" (MUPLA), which serves as a voluntary guide for use by the states. At present there is no federal products liability law. In several other countries such as India and the UK, pharmaceutical product liability is addressed mainly under various Consumer Protection Acts, although various inherent provisions of the law of torts also apply.

Legal Theories behind Product Liability Claims

Product liability claims can be based on three legal theories – negligence, breach of warranty of fitness, and strict liability.

Negligence

Negligence is a relatively simple concept. In short, negligence is the failure to exercise ordinary care to avoid injuring someone to whom one owes the duty of care. Ordinary care is the care that a reasonable person would take based on the circumstances known to him at the time. Thus it is the manufacturer's duty to inform the patient that a particular drug is meant only for oral consumption, or that it must only be taken under instructions from the prescribing physician. To establish a charge under negligence, the traditional four Ds must be proved: duty, dereliction, damage, and direct causation. Stated plainly and simply, the sufferer must show that the manufacturer owed a duty to him; he was derelict in his duty; a damage occurred as a result of that dereliction; and finally damage was a direct result of that dereliction.

Ignorance is not a defense to the manufacturer in such cases. There raises the question of what a reasonable person would have been aware of under the circumstances. This is known as "constructive knowledge" in contrast to "actual knowledge." If a person actually knows that he is driving at, say, 120 $\mathrm{km\,h^{-1}}$ in a busy street (actual knowledge), he should know that someone may get hurt (constructive knowledge). If a manufacturer is selling drugs without proper instructions and warnings (actual knowledge), the manufacturer must know that someone may suffer injuries because of this lack of instructions (constructive knowledge).

A claim of negligence focuses on the actions of the drug manufacturer in designing and producing a product. In other words, did the company fail to exercise reasonable care in the manufacture of the product, and/or did it ignore its own (or industry standard) production, inspection, and safety guidelines?

It is important to realize that each and every person in the drug distribution chain may be held liable for negligence. It is, however, the manufacturer who is most likely to have been negligent. He may be found negligent because of a number of reasons:

1. Careless design of the product. (Thalidomide has been said to be an example of a design defect. Some even assert that the capacity of aspirin to cause gastric bleeding or of carbimazole to cause agranulocytosis are also examples of design defects).
2. Careless manufacture.
3. Careless performance of (or failure to perform) reasonable inspections and tests of finished products (drugs).
4. Failure to package and ship in a reasonably safe way.
5. Failure to take reasonable care to obtain quality components from a reliable source.
6. Failure to provide sufficient instructions and warnings.

It may be extremely difficult for an injured customer to bring a product liability claim under negligence, simply because he has to prove too many things (the four Ds). It would be much better if he brought the claim under the theory of strict liability. Why then in the first place would anyone sue a manufacturer under negligence? One simple answer is because it is possible. Although the sufferer needs just one theory (negligence, breach of warranty, or strict liability), pleading all three claims usually serves a strategic purpose. By asserting more than one theory, a plaintiff is allowed to obtain more kinds of information about the defendant (drug manufacturer) during the discovery phase of the litigation, information that the defendant may not want the plaintiff to discover about its operation. For example, by alleging negligence, a plaintiff may be able to discover detailed information about how the product was manufactured, information that would not be relevant if the only issue was whether the product was defective (as in a strict liability claim). Similarly, by alleging the breach of an express warranty a plaintiff may be entitled to obtain information about how the product is marketed – information to which the plaintiff might not otherwise be entitled if he had alleged only a strict liability claim. Most courts would, however, restrict a plaintiff to one or two theories at trial to avoid confusing the jury.

Breach of Warranty

Warranty claims are governed by contract law. In simple terms, a warranty is a promise, claim, or representation made about the quality or performance of a product. After *Henningsen* v. *Bloomfield Motors* (see above), the law assumes that a seller always provides some kind of warranty concerning the product sold and is required to meet the obligation created by the warranty. Under the Uniform Commercial Code (UCC) – adopted in every state of the USA – there are two kinds of warranties: express and implied.

Express warranty An express warranty can be created in several ways. It can be made in the following ways:

- through an affirmation of fact made by the seller to the buyer
- written into a sales contract
- by spoken words during negotiations
- by silence in situations where not saying something has the effect of creating a mistaken impression about the quality of the goods sold
- by samples shown to the buyer
- by design specifications
- by an earlier purchase of the same kind of product (where the buyer reasonably assumed that a second shipment would be of the same quality as the first)
- by advertising or marketing claims.

Implied warranty While an express warranty is created by an affirmative act, an implied warranty is presumed to exist unless the buyer clearly and unambiguously disclaims it in writing as a part of the sales agreement (that is why so many disclaimers are found on drug labels).

There are two kinds of implied warranties in the UCC. The "implied warranty of merchantability" is a kind of minimum requirements warranty. It means that the goods supplied "will pass without objection in the trade" and that "they are fit for the ordinary purposes for which such goods are used." Typically, the implied warranty also includes a warranty of reasonable safety (see *Henningsen* v. *Bloomfield Motors, Inc.* above).

The "implied warranty of fitness for a particular purpose" imposes a similar requirement in cases where the seller knows or has reason to know of a particular purpose for which the goods are required. In such a case, where the buyer relies on the seller to select or furnish goods that are suitable for a particular purpose, and the seller in fact has such expertise, an implied warranty of fitness for a particular purpose is created by law. If a school teacher requests a doctor to supply cough lozenges, for example, to 10–12-year-old children in her school, there is an implied warranty that the lozenges would be fit for that particular purpose, i.e., to soothe cough in 10–12-year-old children. If the lozenges contained a component suitable only for adults (say codeine), and the children suffered damages as a result, the teacher would be entitled to recover damages.

Strict Liability

Strict liability is the most straightforward head under which damages can be claimed. For a plaintiff to claim damages under this head, he need not show that he entered into any contract with the manufacturer; indeed he does not even have to show the manufacturer was negligent. The only two things he need to prove are (1) that the product (drug) was defective and (2) that injury occurred as a result.

A manufacturer would generally be liable under this heading when his product is deemed to be both defective and unsafe. It is a finer point of law however, because by and large, an unsafe product is presumed to be defective. A product can be rendered defective and unsafe when there was (1) a design defect, (2) a manufacturing defect, or (3) a failure to warn.

Strict product liability applies not only to the product's manufacturer, but also to its retailer, and indeed any other person in the chain of distribution (e.g., a wholesaler) who is in the business of selling such products.

Strict liability versus negligence A difference between strict liability and negligence is enunciated here. While the important guiding factor in claims of strict liability is the quality of product, the guiding factor in claims of negligence is the manufacturer's behavior or conduct in producing the product. The demonstration of utmost carefulness by the drug manufacturer during manufacture is a reasonably good defense in claims of negligence, but of no consequence under claims of strict liability.

Successor Liability

A drug manufacturer who discovers that spurious medicines manufactured by him have reached the ultimate consumer and have started causing injuries, may try to evade the law by selling his company to an unsuspecting buyer, merging it with some other company, altering its name, or some such other device. Attempts such as this are thwarted by the concept of successor liability enshrined under § 12 of the *Restatement (Third)*. The following is the verbatim statement of § 12

> *§ 12 – **Liability of Successor for Human Caused by Defective Products Sold Commercially by Predecessor.** A successor corporation or the business entity that acquires assets of a predecessor corporation or other business entity is subject to liability for harm to persons or property caused by a defective product sold or otherwise distributed commercially by the predecessor if 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 processor;*
> *(c) constitutes a consolidation or merger with the predecessor; or*
> *(d) results in the successor becoming a continuation of the predecessor.*

Joint and Several Liability

The common law rule of joint and several liability makes each and every defendant in a tort lawsuit liable for the entire amount of plaintiff's damages, regardless of that defendant's proportion of fault for the damage done. In other words, it allows a person to recover damages from one or more defendants. Even if a defendant is found to be 1% liable, he may be required to pay the entire amount of the judgment.

Defenses against Pharmaceutical Product Liability Suits

The manufacturer of drugs has the following valid defense against pharmaceutical product liability suits.

Statute of Limitations

A sufferer cannot wait to sue the manufacturer according to his whims and fancies. He must file a suit within a stipulated period of time, which varies from country to country. The time limit defined by the "Trade Practices Act of 1992" is three years from the time he or she becomes aware (or ought reasonably to have become aware) of the loss, the defect, and the identity of the manufacturer.

Statutes of Repose

Statutes of repose are similar to statutes of limitations but, instead of running from a date of injury, the time limitation usually runs from the date on which the product was made or sold. This time varies from place to place, but is generally ten years.

Contributory Negligence

When the injury occurred as a result of both the manufacturer and the user being negligent, it becomes a case of contributory negligence. There are at least five types of contributory negligence as listed below.

Comparative fault If the jury determines that the user was, for example, 20% responsible for his injuries, then he would get only 80% of the damages that he would have got if he had not been negligent at all. In other words, the damages are apportioned between the manufacturer and the sufferer depending on their

quantum of negligence. In several jurisdictions, if the patient was more than 50% negligent, he would not get any claim at all.

Assumption of risk This doctrine is also known by its Latin equivalent *Violenti non fit injuria*. It effectively means that when a patient voluntarily exposes himself to some medication (after proper warning), he assumes the risk contingent upon taking that medicine.

Misuse In this case an injury occurs as a result of misuse of the drug by the patient, as for example instilling a medicine in the eye, which was meant for oral ingestion.

Alteration This arises when the patient alters the medication in some way and then takes it (as when he boils it "to sterilize" it).

Failure to mitigate If a patient discovers that he is, for example, developing some adverse reactions to a drug, he should immediately stop taking that drug and report the matter to the physician. Instead, if he keeps taking the drug and aggravates his injury, the damages he would receive would be reduced by the amount by which he aggravated his own injury.

Federal Preemption

When there is a federal law on a particular subject, it shall override any state law on the same subject.

Intervening or Superseding Negligence

This defense, also known by its Latin equivalent "*Novus actus interveniens*," effectively implies that the negligence on which the suit is based springs from the negligence of a third party, and that the negligence was unforeseeable. The success of this kind of defense is highly dependent on individual facts of a particular case. For example, if a doctor writes a (supposedly) illegible prescription, which the pharmacist reads incorrectly and does not confirm from the doctor and then dispenses the wrong medicine to the patient, who suffers an injury. The doctor could perhaps take this defense in this case.

The Learned Intermediary Doctrine

"Learned intermediary rule" is yet another defense for the drug manufacturer and retailer. According to this rule, the manufacturer of a prescription drug is only required to warn a patient's prescribing physician, and once an adequate warning is given, the drug manufacturer is relieved of any duty to warn the patient directly. The doctor or the healthcare provider is the "learned intermediary" (between the manufacturer and the patient) who must give adequate warning to the patients. At least four rationales have traditionally been forwarded to support this rule. First and foremost, a special and unique relationship exists between the physicians and patients. Physicians "know" their patients better and are in a better position to weigh the benefits and risks of prescription drugs for each patient. Second, they also have a direct communication with their patients (unlike the manufacturer) and are thus in a better position to convey warnings of prescription drugs. Indeed, they have a duty to do so under the doctrine of informed consent. Third, direct-to-consumer warnings (by the manufacturer) simply are not practicable. Not only do pharmaceutical manufacturers lack the means to effectively communicate warnings to consumers, but it is virtually impossible for manufacturers to reach every patient. Finally, the complexity of the warnings and risks inherent in prescription drugs makes it extremely difficult for pharmaceutical manufacturers to warn lay patients in a manner that is not unduly complicated and confusing.

By and large, the learned intermediary doctrine is inapplicable to cases involving over-the-counter (OTC) drugs. With respect to OTC drugs, there is no "learned intermediary" to warn. Therefore, a manufacturer has a duty to warn the consumer directly of the foreseeable risks of harm associated with an OTC drug.

One of the most recent cases illustrating this defense is *Vitanza* v. *The Upjohn Co*. In this case, the plaintiff brought a product liability action against The Upjohn Company, after her husband died as a result of ingesting an anti-inflammatory drug manufactured by Upjohn. Upjohn manufactured the drugs and distributed them to the plaintiff's physician who in turn gave them to the plaintiff as a sample. The plaintiff's husband took the drugs even though they were not prescribed to him, and died from an allergic reaction. Plaintiff's suit was based on the assertion that Upjohn should have provided adequate warnings on the drug package. The defendant Upjohn could successfully invoke this doctrine as a defense.

This doctrine however has fallen in rough weather recently. In 1999, in *Perez* v. *Wyeth Laboratories, Inc*., the New Jersey Supreme Court abandoned this doctrine. The reasoning given by the court was that there had been a phenomenal rise in direct manufacturer-to-consumer advertising through newspapers, magazines, radio, television, and even the internet, known as "direct-to-consumer" (DTC) advertising. It influenced the patients so much that they requested their doctor for a particular drug (for

example, a birth control pill). If the manufacturer had the capacity to influence the patient's decision to take a particular drug manufactured by him, he also owed a responsibility – that of providing adequate warnings. This reasoning, in effect, makes the prescribing physician merely a conduit between the manufacturer and the patient. The patient – who is so influenced by advertisements that he has already decided to take a particular drug – needs a doctor only because a valid prescription to buy this drug is needed. Many legal commentators – quite rightly – consider that the *Perez* decision has perhaps gone too far in applying the concept of strict liability to the manufacturers.

Summary

A manufacturer of defective medical equipment or a spurious medicine is liable for damages under the concept of product liability. In the beginning of the evolution of this concept, in order to defend himself the manufacturer only needed to show that he was not in privity of contract with the consumer. But this concept was discarded as legal theories concerning product liability evolved. The concept of product liability is now based mainly on the concept of strict liability, where in order to get compensation the patient needs only to show that he used the drug in the way it was intended to be used, and yet it caused injury. The manufacturer can no longer take the defense that he was not in privity of contract with the patient. However, the manufacturer can take certain defenses such as the statute of limitations, contributory negligence by the patient, federal preemption, and intervening or superceding negligence. One of the most convincing of these defenses has been that of the learned intermediary doctrine, whereby it is assumed that it is the doctor – the learned intermediary – who is in a better position to warn the patient about the ill-effects of the drug. The manufacturer is therefore absolved of any liability to warn the patients. In a recent case – *Perez* v. *Wyeth Laboratories* – this defense has however been set aside. Many legal commentators think that this decision has been rather harsh on the manufacturers. As legal theories regarding product liability continue to evolve, we may see further twists and turns in this fascinating area of medical law.

See Also

Complaints Against Doctors, Healthcare Workers and Institutions; **Drug-Induced Injury, Accidental and Iatrogenic**; **Medical Malpractice – Medico-legal Perspectives:** Negligence, Standard of Care

Further Reading

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Testamentary Capacity

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Introduction

In the UK, the number of older people has grown rapidly. In 1961, there were 2.1 million people over the age of 75 years in the UK. By 2001, there were 4.5 million over the age of 75 years, and 336 000 of those were aged 90 or more.

Despite concerns about the elderly having to use capital to fund nursing care in their old age, the over-50s in the UK hold 80% of all wealth and 60% of all savings. In comparison to the working population they are asset-rich and income-poor. Such assets can become the subject of bitter internal family disputes after the death of a relative.

A will stipulates how assets are to be dispersed after the maker's death. Doctors may be asked