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PRODUCTS DEFECTIVE BECAUSE OF INADEQUATE DIRECTIONS OR WARNINGS

by

Dix W. Noel*

IN RECENT suits for injuries from defective products, plaintiffs have alleged a great variety of dangerous defects, and where negligence is involved, many different kinds of careless conduct. In many of these suits, however, the complaint has been that the product was not accompanied either by adequate directions for use, or by sufficient warning of dangers which might arise during some foreseeable handling of the product. The advent of strict liability in many jurisdictions has not checked this trend, for even where negligence is not required, it still is necessary to allege defectiveness, and what often makes a product defective and unreasonably dangerous is the lack of adequate warnings or directions for use.1 This Article will concern the increased requirements in recent years with reference to warnings and directions, both in negligence and strict liability cases. To place this development in the proper setting the present state of general products law will be briefly indicated.

I. RECENT GENERAL DEVELOPMENTS IN PRODUCTS LIABILITY

It would be difficult to find an area of law expanding as rapidly as that relating to consumer protection from defective products. One aspect of this expansion relates to "strict liability." After a period of doubt as to whether negligence could be dispensed with in products cases, an increasing number of jurisdictions have decided to accept the Restatement (Second) of Torts' view that proof of negligence should not be required in the situation described in section 402A.2 Under that section a manufacturer or other person in the business of selling who permits a product to leave his hands in a "defective condition unreasonably dangerous to the consumer or user" may be liable to remote users even though he has used "all possible care" in its preparation and sale.

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1 The latest comprehensive article on this matter was written in 1955, and deals only with negligence. Dillard & Flart, Products Liability: Directions for Use and the Duty To Warn, 41 Va. L. Rev. 145 (1955). This outstanding Article has been cited in hundreds of decisions.


It should not be hastily concluded, however, that negligence is no longer significant in a products case. Negligence concepts are firmly embedded in the minds of judges and lawyers, and while the Restatement dispenses with proof of negligence, it still requires that the product be "unreasonably dangerous" as well as defective. In the determination of what is unreasonably dangerous, the negligence rules doubtless will have considerable effect.4

Furthermore, most complaints in products cases still contain a specific negligence count, along with a strict liability claim. One reason for this is that both courts and juries are apt to regard substantial damages as more appropriate when evidence of actual carelessness can be produced. A second reason is that strict liability has been mainly restricted to users or consumers of the product.5 Although users are broadly defined in the Restatement to include such persons as a passenger in a car, or even an employee making repairs6 on the vehicle, the American Law Institute was unwilling to impose strict liability to a mere bystander, such as a pedestrian struck by a defective vehicle. A few decisions have gone beyond the Restatement and allowed non-users to recover under strict liability principles,7 but generally a non-user can not count on recovery unless he can establish negligence. Where negligence is established, liability extends not only to users and consumers of the product but to anyone the defendant "should expect to be endangered by its probable use."8 Thirdly, where the manufacturer of a component part is involved, negligence liability is clear,9 while strict liability of the component part manufacturer still is doubtful.10 Thus, the negligence count reaches more defendants, protects more plaintiffs, and is apt to lead to a more substantial recovery.

Where it is claimed simply that an individual item was carelessly constructed, the negligence most frequently alleged is inadequate inspection or testing.11 Sometimes, however, the plaintiff claims that the product when made as intended is defective and hazardous. It is in this area that the more recent negligence developments have occurred.

When the plaintiff undertakes to show that the defendant's product as a whole creates an unreasonable risk of injury, the negligence asserted ordinarily relates to the basic design of the product, or to inadequate warnings or directions for use.12 Such cases have been increasingly successful,

4 See Wade, Strict Tort Liability of Manufacturers, 19 Sw. L.J. 1, 11, 25 (1965).
5 See 2 Restatement (Second) of Torts § 402A (1965).
6 See id. § 402A, comment l, caveat (1).
8 2 Restatement (Second) of Torts § 395 (1965).
9 See id. § 395, comment m.
12 1 L. Frumer & W. Friedman, Products Liability §§ 7-8 (Supp. 1968) [hereinafter cited
but many courts still hesitate to allow juries to pass on designs prepared by experts, particularly when the purchaser can choose between different designs, and when an adverse verdict will affect a product already extensively manufactured. This reluctance is illustrated in Evans v. General Motors Corp., involving a Chevrolet station wagon designed with an "X" frame without protective side rails in case of a side impact collision. Other cars were advertised as having safer perimeter frames with side rails. It was alleged that because of the absence of a perimeter frame, the side of the station wagon collapsed inward when struck by another car, resulting in fatal injuries to the driver. A divided court held that the duty of the manufacturer was simply to make a product reasonably fit for its intended purpose, and that "the intended purpose of an automobile does not include participation in collisions with other objects."

Of course a collision is not an "intended use" of an automobile, but between a fourth and two-thirds of all automobiles are at some time involved in a collision producing injury or death; collisions are incident to an expectable use of automobiles. While the main function of the automobile is to provide efficient transportation, manufacturers stress safety and comfort as well. It has been shown in recent years that safety involves not only a design which will help prevent collisions, but one that will provide protection from the second collision, when passengers are thrown about after the original impact.

The decision in the Evans case was influenced by automobile safety legislation then pending, although, as the dissenting judge observed, "the possibility of future adequate legislative standards does not remove the necessity of deciding whether plaintiffs should or should not have an opportunity to prove the allegations made in the complaint." There remains, however, the consideration that legislative and administrative regulation may provide the better remedy. An administrative agency, after extensive and impartial research, can understand engineering complexities better than a jury, and can better balance against safety the other interests such as economy, style, and performance. Administrative regulation also has the considerable advantage of taking effect before the motor vehicle or other product is manufactured. It also provides a more uniform standard as to what is needed for reasonable safety than can be achieved through diverse judicial decisions. Doubtless these considerations influenced the court in the Evans case, and numerous other courts reluctant to let juries pass on the safety of a particular automobile design. One recent case, however,
clearly asserts that a car manufacturer has a common law duty to design his product safely, and in such a way as to minimize the effect of accidents.\textsuperscript{20}

Now that the National Traffic and Motor Vehicle Safety Act of 1966\textsuperscript{21} has been enacted, what effect will a failure to comply with the Act have on suits based on negligence of design? The Act requires the Secretary of Transportation to establish minimum safety standards for all new motor vehicles, and initial standards have been issued.\textsuperscript{22} The Act further provides civil penalties for violation of the standards, up to a thousand dollars for each offense, but does not indicate whether or not a violation gives rise to a private cause of action.

Generally, where a statute is designed to protect a certain class of persons from a particular hazard, violation of the Act constitutes negligence as a matter of law, or at least is evidence of negligence.\textsuperscript{23} It is an evident purpose of the new Act to protect the occupants of motor vehicles from both the original collision and from the so-called “second collision” (when the occupants are thrown about after the impact). Consequently, the courts will probably implement the Act by finding that violation of the Act or of the safety standards set by the Secretary of Transportation constitutes at least evidence of actionable negligence. Such a holding would not involve giving power to juries to pass on the safety of complicated designs, nor would it place any retroactive burden on manufacturers.

This does not mean, conversely, that where a design feature alleged to be essential for safety but not yet required by regulations issued under the Act is involved, the case should always be dismissed.\textsuperscript{24} As in related situations the plaintiff should be permitted to prove common law negligence,
for when due care requires a particular safety feature, courts and juries should be able to supplement the standards set up by legislation. To remove any doubt about this matter, it is expressly provided in the Act that compliance with any safety standard issued under the Act "does not exempt any person from liability under the common law."

While the courts are reluctant to let a jury declare unsafe a design prepared by experts, there are other situations in which a jury must pass on the work of specialists, such as where the conflicting claims of medical witnesses are weighed. The fact that a design is "hallowed by a brand name and a corporate shield" should not protect the defendant where the plaintiff secures substantial expert testimony that the design is unsafe.

Likewise even though a decision that a particular design is unsafe may lead to a multiplicity of suits, this is not adequate grounds for letting plaintiffs suffer their losses, for widespread injury should lead to widespread liability.

Furthermore, the basic concept of the new Act is that the manufacturer should assume responsibility for safety of design, not only to avoid collisions, but to protect passengers from further injury after the collision, and even to protect persons from injury while the vehicle is not in operation. Legislative adoption of this general concept should encourage courts to recognize a common law responsibility to use due care in these areas, as well as in the process of construction. Judges distrustful of design suits, however, still may be reluctant to give much weight to the express statement that the Act is not intended to exempt any person from liability under the common law, and may continue to hold that a design feature which has escaped regulation under the national Act is not unreasonably dangerous.

II. ADVANTAGES OF BASEING CASE ON INADEQUATE DIRECTIONS OR WARNINGS

Aware of the difficulties in establishing design negligence, plaintiffs have turned with increasing frequency to allegations of inadequate directions for use, or insufficient warning of dangers which may arise if directions are not closely followed or if the product is used differently from the way intended. A case along these lines can be established without the difficulty and expense of securing expert testimony, or of preserving the physical evidence needed to establish a design defect. Such evidence may be difficult to secure since the product often is so badly damaged that it cannot be reconstructed. Additionally, prescribed accident reports stress the human element in accident causation, and provide little help as to defects in the vehicle which may have played a part in the accident. In any event, it is easier for the jury to understand the need for better direc-

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30 See Kessler, Products Liability, 76 Yale L.J. 887, 930 (1967).
32 See Nader & Page, supra note 16, at 663.
35 Nader & Page, supra note 16, at 666.
tions and warnings than to understand the deficiencies of some complex design, particularly when the testimony is by experts who know more about technical matters than about explaining things to laymen.31

Sometimes the problem in establishing design negligence results from the fact that the manufacturer is a foreign one over whom it is difficult to secure jurisdiction. In this situation it may be possible, where the suit is based on inadequate directions or warnings, to secure jurisdiction over a local party, such as the dealer, on the ground that he should have discovered these inadequacies and supplemented the directions or warnings or corrected the defect.32

Where it is complained that directions or warnings are inadequate, such deficiencies ordinarily can be corrected by more careful labeling or advertising. Consequently, an adverse verdict is far less serious to the defendant than in a design case, and there is not the same judicial reluctance to let the case go to the jury.

Once the plaintiff establishes a breach of duty to warn or to give adequate directions, he has overcome the problem of showing that the product was defective at the time it left the manufacturer's hands. A plaintiff often is unable to get to the jury because the defect which caused the accident may be due to alteration or misuse of an originally sound product. Where, however, it is shown that the defendant failed to give adequate instructions or warnings, it ordinarily is clear that the accident cannot be attributed to intervening factors. Furthermore, where a duty to warn against the use to which plaintiff has put the product is established, the plaintiff has gone far toward defeating the defense of unusual or careless use of the product.

Attorneys for manufacturers and other suppliers, as well as those for plaintiffs, should give special attention to the matter of warnings and directions for use, for this is an area where clients can be advised how to avoid accidents and resulting suits. While lawyers do not know enough about product engineering to suggest the need for a safer basic design, they can determine that a particular set of directions or warnings on labels, leaflets, or advertising matter fails to measure up to the standards of clarity or intensity required under court decisions. People immersed in the manufacture or distribution of a product, and thoroughly familiar with its characteristics, may attribute more knowledge and awareness of risk to consumers than in fact exists. The use of time and imagination by attorneys in advising a manufacturer or retailer how to make directions and warnings more effective may forestall an injury, and the resulting litigation.

31 So where a plane crashed when the pilots were asphyxiated by carbon dioxide in the cockpit, it was easier to establish a duty to warn of a need for masks than to establish negligence of design. See DeVito v. United Airlines, Inc., 98 F. Supp. 88 (E.D.N.Y. 1951) (applying New York law), discussed at note 33 infra, and accompanying text.
32 McKinney v. Frodsham, 57 Wash. 2d 126, 356 P.2d 100 (1960), involving defectively designed door latch on a car. Likewise where a car made by an English company had a gas tank in the trunk, with no vents through which vapor could escape, the local distributor was liable for failure to discover and warn of this defect. Blitzstein v. Ford Motor Co., 288 F.2d 738 (5th Cir. 1961) (applying Alabama law).
There are cases, however, where the manufacturer probably would have been negligent even had a warning been given. In *DeVito v. United Airlines, Inc.*, a Douglas DC-6 aircraft crashed in good weather, with loss of forty-three lives. The manufacturer had previously discovered that during fire fighting or fire testing operations carbon dioxide gas was apt to filter into the habitable parts of the plane when the gas was discharged into the baggage compartments. It also was learned from a medical report that any considerable concentration of carbon dioxide tended to drive out needed oxygen and cause unconsciousness. Just before this plane crashed carbon dioxide had been discharged into the forward baggage compartment. The jury concluded that gas had entered the cockpit and rendered both pilots incapable of controlling the plane. The manufacturer was found liable because of failure to warn the airline of this danger, and of the need to use full oxygen masks after the release of carbon dioxide into any fuselage compartment. It is likely, however, that there was a duty not simply to warn of this danger but to correct the design which permitted such a hazardous concentration of gas in the cockpit.

A comparable case involved a baby bathinette with supports made of magnesium alloy. If the supports caught fire, water used to extinguish the fire would release inflammable hydrogen, which in turn would produce an intense emission of bluish flames. In this case the flames shot far enough to burn the plaintiff in another room. The court sustained a directed verdict on the ground that the bathinette was not dangerous in its ordinary use. Judge Frank, dissenting, thought that a household fire was foreseeable and that the purchaser should have been warned that "the presence of the bathinette could easily transform an ordinary house or apartment into a fire trap." He then remarked, "To comprehend the nature of defendants' negligence, one has but to ask whether defendants could have sold their bathinettes, if there had been affixed an easily-readable notice saying, 'If fire happens in your home, this bathinette will probably increase the dangers greatly, because the magnesium may ignite, causing unusual spurts of flame which will be peculiarly difficult to extinguish.' The answer to this inquiry by Judge Frank is that the bathinette constituted an unreasonable hazard and should not have been sold, with or without adequate warning. The basic negligence lies in the use of an unduly inflammable material in a product designed for use in the home. A warning would not correct this defect.
It may be found that a product is defective and unreasonably dangerous under strict liability principles, as well as on negligence grounds, even when accompanied by a warning. Such a decision involved a jacket found to be highly inflammable. A child of five was severely burned when a spark from a schoolyard fire around which he and some other children were playing started an uncontrollable fire in the jacket. A jury finding that the garment was defective and unreasonably dangerous within the meaning of the Restatement was sustained. There was no warning in this case that the jacket was inflammable, and had not been treated with flame retardant, but the opinion is based chiefly on the consideration that highly inflammable materials should not be used in a garment prepared for a child, who foreseeably might play with or around a fire. The court emphasized that a flame retardant would have added only a few cents to the cost of the jacket, with no impairment of usefulness, and the decision probably would have been the same notwithstanding a warning statement that the fabric had not been treated with an adequate flame retardant.

IV. Distinction between Directions for Use and Warnings

A distinction should be made between the duty to give adequate directions for use and the duty to warn. Sometimes a manufacturer will point out after an accident that had the plaintiff followed the directions given for use of the product, no harm would have occurred. The difficulty with this defense is that the user of a product often regards the directions as intended simply to secure the efficient use of the product, and fails to realize that some minor departure from these directions may create a serious danger. Where that is the case, an additional duty to warn of the danger may arise. So in a case involving heat blocks designed to help revive injured persons, the court indicated that giving instructions to wrap the blocks in insulating material before use did not relieve the manufacturer of the duty to warn of the danger of serious burns if insulation was not used. The opinion states, “the instructions, not particularly stressed, do not amount to a warning of the risk at all, and . . . it was foreseeable that the small print instructions might never be read and might be disregarded even if read.”


1 Restatement (Second) of Torts § 402A (1964).


A different sort of case involved a crop-dusting chemical designed to kill plants with broad leaves appearing in rice fields. The dust drifted to cotton fields and damaged plaintiff’s broadleafed cotton. The manufacturer had circulated a warning of the risk of damaging cotton and other broadleafed crops. He nevertheless was held liable, without proof of negligence, for engaging in what was found to be an ultra-hazardous enterprise. Chapman Chem. Co. v. Taylor, 215 Ark. 630, 222 S.W.2d 820 (1949). It may well be that this dust, assuming it had a tendency, even on a calm day, to drift long distances and damage crops, would be regarded as defective and unreasonably dangerous under the strict liability view even though accompanied by a warning. Like an automobile without a bumper or seat belts, it probably should not be placed on the market.

1 Frumer & Friedman § 8.05 (1).


In some cases liability can be based simply on failure to give adequate directions for use, as where there are no directions to lubricate a safety ratchet to prevent its deterioration, or where the purchaser of a hay baler is directed to re-engage twine with moving rollers in a manner which is hazardous. This is in accord with the Restatement which indicates a duty not only to use due care to design a product safely, but to attach directions adequate to insure its safe use. Moreover, even though the purchaser has been made aware of danger, liability may result because of failure to give the user of the product adequate instructions on how to avoid the peril to which he has been alerted; and where the risk of injury from failure to follow directions is grave, the directions for use may be inadequate unless placed on the product itself, or upon the container.

V. When Duty To Warn Arises Under Negligence Principles

If there were an obligation to warn against all injuries that conceivably might result from the use or misuse of a product, manufacturers would find it practically impossible to market their goods. On the other hand, the complexity of modern chemical and mechanical products has increased the possibilities of harm to unsophisticated users. In the balancing of these considerations, however, it is becoming apparent that the duty to warn, like the duty to avoid a defective design, is being expanded.

The basic duty to warn under negligence principles was set forth in the Restatement of Torts and is reaffirmed with minor changes in the new revision. In negligence cases, three factors are of special importance in balancing the considerations described above.

N.Y.S.2d 407, 412 (1962). See also Farley v. Edward E. Tower & Co., 271 Mass. 210, 171 N.E. 619 (1930) (inflammable combs; liability for failure to warn, even though instructions not followed). In Panther Oil & Grease Mfg. Co. v. Segerstrom, 224 F.2d 216 (9th Cir. 1955) (applying Washington law) there were directions not to heat a “roof primer” because this would damage its waterproofing qualities. When the plaintiff applied heat, this caused an explosion. The court found that the instructions, directed toward utility, did not dispense with the need to warn of danger from heating the product.


2 Restatement (Second) of Torts § 397, comment b (1965).


See 1 R. Husk, Products Liability § 2.36 (Supp. 1968); 2 Restatement (Second) of Torts § 397, comment b (1965).

2 Restatement of Torts § 388 (1934).

2 Restatement (Second) of Torts § 388 (1965). The revised language is:

One who supplies directly or through a third person a chattel for another to use is subject to liability to those whom the supplier should expect to use the chattel with the consent of the other or to be endangered by its probable use, for physical harm caused by the use of the chattel in the manner for which and by a person for whose use it is supplied, if the supplier

(a) Knows or has reason to know that the chattel is or is likely to be dangerous for the use for which it is supplied, and

(b) has no reason to believe that those for whose use the chattel is supplied will realize its dangerous condition, and

(c) fails to exercise reasonable care to inform them of its dangerous condition or of the facts which make it likely to be dangerous.

Chattel Known to be Dangerous for Intended Use

2 Restatement of Torts § 388 (1934).
determining the existence of a duty to warn. First, how likely is an accident to occur when the product is put to a more or less expectable use; second, if an accident does occur, how serious an injury is likely to result; and third, how feasible is it to give an effective warning? 51

The balancing of these factors may be illustrated by the case where an oil company furnished science teachers a display consisting of a set of oil samples. 52 The company had placed water in the bottle marked kerosene, to make the display more mailable, avoid discoloration, and increase safety. Unfortunately, a teacher used fluid from the bottle labeled kerosene to illustrate how metallic sodium is preserved by kerosene. When the water came into contact with the sodium a serious explosion resulted. In permitting the jury to find a duty to warn, the court weighed the gravity of the possible harm against the practicality of a warning, observing that it "would have been so easy to have warned" of the inaccurate labeling. If the harm from a possible accident had been less serious, perhaps no duty to warn would have been found, since the chances of the water being used for this experiment were remote.

It sometimes is urged by the manufacturer that the product involved a hazard of which he was unaware. The duty to warn arises, however, not only when the manufacturer actually knows about the danger, but also when he "has reason to know" of it. 53 The plaintiff sometimes is aided by a presumption that the manufacturer knows the nature and ingredients of his product. 54 Furthermore the manufacturer may be under a duty to test the materials and parts from which his product is made, particularly where a defect may result in grave injury. 55

Where a new product is involved, it may be necessary to test the safety of its use in different parts of the country. So in one case a new insecticide was safely useable in the northern area where it was manufactured and tested, but proved hazardous to crops in a southern climate, where it had not been tested. Liability was imposed for failure to warn of the localized danger, which could have been discovered by more widespread testing. 56

A special problem arises as to drugs in their clinical stages. It often is necessary to test new drugs on human subjects as well as on animals before they can be approved as safe for general marketing. In that connection it may be desirable, from a scientific angle, to say very little either to the doctor who administers the drug or to the patient who takes it, in order

52 Pease v. Sinclair Ref. Co., 104 F.2d 183 (2d Cir. 1939) (applying New York law); see also Wagner v. Larsen, 237 Iowa 1202, 136 N.W.2d 312 (1965) (jury question as to whether manufacturer and dealer should have warned owner of danger in improperly starting a silo unloader after it became stuck).
54 Thornhill v. Carpenter-Morton Co., 220 Mass. 193, 108 N.E. 474 (1911); 1 Frumer & Friedman § 12.01 (1).
55 2 Restatement (Second) of Torts § 395, comment e (1965); 1 Frumer & Friedman § 8.01; L. Hursh, supra note 48, § 2.22.
to secure more objective evaluations. It would seem, however, that the manufacturer should have a duty to communicate to the doctor, and indirectly to the patient, a warning that the drug is untested, and that its use may involve unknown hazards. Where a specific serious danger is suspected, the doctor and the patient should be advised at least of the seriousness of the risk, if not of its precise nature. It has been said by a leading physician that "however desirous [the practitioner] may be of learning, of making progress, or of doing something for the common good, [he] must not yield to the temptation to 'sell' his proposal and thus acquire the necessary authorization."7 If the doctor has an ethical duty to warn the patient of hazards, it would seem equally clear that the manufacturer has a duty to transfer to the doctor whatever information is needed to give this warning.8

There still are cases where the defendant is excused from liability on negligence grounds because the danger is unknown. So it was found that the manufacturer of a weed killer was not bound to know of the danger from skin absorption, in the absence of previous injuries of this kind.9 It is evident, however, that manufacturers are being held to keep abreast of scientific advances.10 Thus, in a case11 involving a chemical used to kill weeds and brush, the manufacturer was found liable for an unusual sort of injury. The product had been used to kill willow trees along a drainage ditch which adjoined the plaintiff's pasture. When it was sprayed on the trees it left on the leaves a salty residue which made the leaves attractive to cattle. It further appeared that as the willows died, a considerable amount of nitrate had been drawn into their leaves from the soil. The plaintiff's registered Herefords ate large quantities of the leaves and died of nitrate poisoning.

It was urged that this risk was unknown to the defendant, and not reasonably foreseeable. The court held, however, that the jury could find a foreseeable risk. Consequently, there was a duty to warn of this danger, at least where the product itself had been labeled as "not hazardous to livestock"; as a result of failure to so warn, the cattle were not removed from the field. While this risk was not in fact foreseen, the court observed that "in manufacturing and distributing chemical weedkillers, DuPont is held to the skill of an expert, is charged with superior knowledge of the nature and qualities of its products, and is obligated reasonably to keep abreast of scientific information, discoveries, and advances with respect thereto." If in this case the danger were known only to a few scientists, the manufacturer probably could not be found negligent in failing to warn of a

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7 Ayd, Medical Tribune, Sept. 17, 1962, at 12, as quoted in Rheingold, Products Liability—The Ethical Drug Manufacturer's Liability, 18 Rutgers L. Rev. 947, 958 n.19 (1964).
8 See Rheingold, Products Liability—The Ethical Drug Manufacturer's Liability, 18 Rutgers L. Rev. 947, 958 (1964).
10 1 R. Hursh, supra note 48, § 2.29.
11 LaPlant v. E.I. DuPont de Nemours & Co., 146 S.W.2d 231 (Mo. App. 1941).
risk of which he was justifiably ignorant; judgment for the plaintiff
would then have to be based on strict liability principles.

VI. WHEN A DUTY TO WARN ARISES UNDER
STRICT LIABILITY PRINCIPLES

With many courts adopting the principles of strict liability, the issue
arises as to when a product is “defective and unreasonably dangerous”
under section 402A of the Restatement (Second) of Torts because not
accompanied by adequate warnings or directions. It is said in a comment
to the Restatement that “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.” This duty probably is similar to that arising
under negligence law, for while “foreseeability is a standard used to de-
terminate fault, . . . it is also an important factor in determining the appli-
cability of section 402A, when the defectiveness and unreasonable dan-
ger of the product for a particular use is being considered.

Since it is also provided in section 402A that a seller incurs liability even
though he has exercised “all possible care,” presumably the duty to warn
may arise even though there is no sufficient foreseeability of harm to give
rise to such a duty under negligence principles; that is, a lesser degree of
risk may be enough to establish a duty to give warnings or directions
under strict liability rules. For example, in a recent case involving Type
III oral Sabin polio vaccine, the fact that this drug caused polio in a
minute proportion of users, less than one in a million persons, did not
preclude the product from being defective and unreasonably dangerous
under strict liability principles, unless “accompanied by proper directions
and warnings.” After distinguishing this case from the allergy situation,
where only a susceptible class is involved, and observing that here the
danger was not to a special class of persons but applied in some degree to
all, the court concluded that neither a jury nor a court could exempt the
manufacturer from a duty to warn. The opinion states:

There will, of course, be cases where the personal risk, although existent
and known, is so trifling in comparison with the advantage to be gained as to
be de minimis. Appellee so characterizes this case. It would approach the prob-
lem from a purely statistical point of view: less than one out of a million is
just not unreasonable. This approach we reject. When, in a particular case,
the risk qualitatively (e.g., of death or major disability) as well as quanti-
tatively, on balance with the end sought to be achieved, is such as to call for
a true choice judgment, medical or personal, the warning must be given.

For these reasons the court reversed a judgment for the defendant, finding
the vaccine defective and unreasonably dangerous as a matter of law

63 2 Restatement (Second) of Torts §§ 402A (1965).
64 2 Restatement (Second) of Torts § 402A, comment j (1965). See also Traynor, The
67 Davis v. Wyeth Laboratories, Inc., 399 F.2d 121 (9th Cir. 1968) (applying Idaho law).
68 Id. at 129.
in the absence of a warning." The case was remanded for determination of the causation issue, but illustrates how the duty to warn under strict liability principles may be more demanding than under negligence principles, particularly where the court decides for itself that the product is defective and unreasonably dangerous. In a negligence suit the "duty to warn" issue might well have been left to the jury in this border line situation where the risk, while one of grave harm, was extremely remote.70

In the polio vaccine case the manufacturer was quite aware of the remote risk involved. Suppose there is no such awareness; may a duty to warn still arise? It is indicated in the Restatement that at least as to claims based on allergic reactions the duty to warn does not arise even under strict liability principles unless the seller "has knowledge, or by the application of reasonable developed human skill and foresight should have knowledge, of the presence of the ingredient and of the danger."71

There is considerable authority supporting this limitation on the duty to warn even in a strict liability situation, at least in the area of allergic injuries.72 It is submitted, however, that the limitation should not be applied to products harmful to the population generally, since it involves foreseeability of a kind usually associated with negligence. This is one of the problems involved as to cigarettes, where harmful effects are not ordinarily regarded as allergic reactions. Two courts have said that even where the action is based on breach of warranty or some other theory of strict liability, there is no responsibility where, at the time of the smoking, the state of medical knowledge was not such as to enable the manufacturer to foresee that cancer would result from cigarette smoking.72

There is a possibility, however, that a product may be regarded as defective and unreasonably dangerous irrespective of the state of human knowledge. In Green v. American Tobacco Co.73 it was found by a Florida court, in an advisory opinion to the federal court, that there could be a breach of the implied warranties of merchantability and fitness on account of harm arising from the sale of cigarettes during a period when the manufacturer "could not by the reasonable application of human skill and foresight have known of the danger" that users of cigarettes might contract lung cancer. It was added in this opinion that the "contention that the wholesomeness of a product should be determined on any standard other than its actual safety for human consumption when supplied for that

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70 The court cited in support of its conclusion that a drug may be "defective" under 2 Restatement (Second) of Torts § 402A (1961) because of inadequate warning, Toole v. Richardson-Merrill, 60 Cal. Rptr. 398 (Dist. Ct. App. 1967), holding that MER/29 was within the strict liability principle if marketed without adequate warning of known dangers. Accord, Crane v. Sears Roebuck & Co., 218 Cal. App. 2d 853, 32 Cal. Rptr. 714 (1963).
71 See Prosser, The Fall of the Citadel (Strict Liability to the Consumer), 50 Minn. L.J. 791, 808 n.91 (1966).
72 Ross v. Phillip Morris & Co., 328 F.2d 3 (8th Cir. 1964) (applying Missouri law) (no liability for harm "without regard to 'developed human skill and foresight'"),' Lartigue v. R.J. Reynolds Tobacco Co., 317 F.2d 19 (5th Cir.), cert. denied, 371 U.S. 861 (1963) (applying Louisiana law) (no liability for harmful effects which no developed skill or foresight could avoid).
73 See also Gottsdanker v. Cutter Laboratories, 182 Cal. App. 2d 602, 6 Cal. Rptr. 320 (1960) (no warning of polio risk; strict liability imposed as to new drug).
purpose, . . . has no foundation in the decided cases." Under this ruling, a jury could find defectiveness even though the danger in the product was completely unknown and unsuspected. Actually, the jury found that the cigarettes were "reasonably" fit and wholesome for human consumption and that no warranties had been breached.

There was an appeal, however, from this finding, and the plaintiff finally prevailed. It was held that a verdict should be directed in his favor on the liability issue, on the ground that Florida decisions since the advisory opinion in the Green case, as to products intended for human use generally, had not "anywhere modified or limited the requirement of fitness or wholesomeness to 'reasonable' fitness or 'reasonable' wholesomeness." Consequently, since a jury had found in the earlier trial that one of the proximate causes of Green's cancer was the smoking of the defendant's cigarettes, "his personal representative and widow are entitled to hold the manufacturer absolutely liable for the injuries already found by a prior jury to have been sustained by him." Accordingly the case was sent back for a new trial on the issue of damages alone.

There was a dissenting opinion, urging that except in the case of clearly "defective" products, such as a can of food contaminated with a piece of tin or harmful bacteria, the Florida law still requires a finding by the jury that the product is not "reasonably" fit for human consumption, and that there is no breach of warranty unless the harmful effects of a product are felt by "a substantial segment of the public."

A petition to rehear the case has been granted. The prevailing opinion seems questionable unless the jury finding at the original trial amounted to an incidental finding that a substantial number of heavy smokers are apt to contract lung cancer as a result of their smoking. The jury at the second trial apparently were not impressed by the testimony of the plaintiff's experts "that cigarette smoking causes approximately ten per cent of heavy cigarette smokers to die of lung cancer after about twenty years of smoking," since they found the cigarettes to be "reasonably" fit for human consumption, although instructed by the trial judge that cigarettes were "unwholesome if they affect any responsible segment of the general public . . . as to . . . lung cancer." It may well be, as urged by the dissenting judge, that this finding should have put an end to the litigation.

Where the danger is in fact unknowable and unsuspected, it is difficult to see what kind of a warning the manufacturer could give to protect himself from the unusually strict liability imposed by this appeal of the Green case. In defense of the ruling, however, it should be observed that there are other situations in which a supplier incurs liability completely without fault under warranty principles, as where a retailer sells in a

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75 154 So. 2d at 173.
76 Id. at 170.
78 Id. at 106.
79 Id.
80 Id. at 111.
81 See 394 F.2d 156, 157 n.2 (5th Cir. 1968).
82 391 F.2d at 103.
83 See id. at 101 (applying Florida law).
sealed container a product containing some harmful object. Furthermore it is difficult to class any risks as clearly "unknowable." It may be that at the time of the cigarette smoking involved in the Green case, scientific knowledge had in fact developed enough to give rise to a strong but unconfirmed suspicion in the industry that cigarettes may cause cancer. If so, it does not seem unfair to require the manufacturer to give the consumer a warning of these suspicions, as suggested in Pritchard v. Liggett & Meyer Tobacco Co.

Assuming an adequate warning is given, there is much to be said for the prevailing view that cigarettes are not defective and unreasonably dangerous, in view of the amount of satisfaction they produce, and the economic importance of the industry. So in the Restatement, it is asserted that "good tobacco is not unreasonably dangerous merely because the effects of smoking may be harmful," since cigarettes are not "dangerous" to an extent beyond that which would be contemplated by the ordinary consumer. This does not mean that a more effective warning than the one presently employed ("Caution: cigarettes may be hazardous to your health") should not be required. As scientific evidence accumulates which shows that cigarette smoking causes a substantial amount of lung cancer or heart disease, manufacturers should be required to strengthen the present mild warning to avoid having their product classed as defective and unreasonably dangerous, or as unmerchantable under warranty concepts.

Turning to the situation where the supplier actually knows, or has reason to know, of the dangers involved in the use of his product, it is clear that a failure to warn may be used as the basis for a strict liability case as well as one based on negligence. So it has been found that a drug is defective and unreasonably dangerous because not accompanied by adequate warnings as to harmful side effects.

Where adequate warning is given and the side effect is one which cannot be eliminated, the tendency has been to find as a matter of law that the product is not defective. A more difficult problem arises where some batches of a useful product are likely to be contaminated, but it is not possible to discover and eliminate the contamination, as where blood plasma happens to contain hepatitis virus. So far the courts have refused to impose strict liability for illness caused by such plasma where there is adequate warning of this risk. The most recent case, however, shifts to

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84 See 2 Frumer & Friedman § 19.03(4) (c).
85 295 F.2d 292 (3d Cir. 1961) (applying Pennsylvania law).
86 See 2 Restatement (Second) of Torts § 402A, comment i (1965).
87 See Traynor, supra note 64, at 371.
88 Davis v. Wyeth Laboratories, Inc., 399 F.2d 121 (9th Cir. 1968) (applying Idaho law); Sterling Drug, Inc. v. Cornish, 370 F.2d 82 (8th Cir. 1966); Yarrow v. Sterling Drug, Inc., 263 F. Supp. 159 (S.D.S.D. 1967) (applying South Dakota law). Likewise it was found that shoes likely to slip on wet asphalt tile could be found defective and unreasonably dangerous if not accompanied by a warning of this danger, but this was later reversed because all shoes have some tendency to become slippery when wet, and the failure to warn against this well known danger did not make the shoes "unreasonably dangerous." Fanning v. LeMay, 78 Ill. App. 2d 166, 222 N.E.2d 815, rev'd, 38 Ill. 2d 209, 230 N.E.2d 182 (1967).
89 Carmen v. Eli Lilly & Co., 109 Ind. App. 84, 32 N.E.2d 729, 731 (1941); 2 Restatement (Second) of Torts § 402A, comment k (1965).
the defendant the burden of showing that the virus is incapable of discovery and removal, although the court as a whole declined to pass upon, as premature, the question of whether liability should be imposed if under the present state of knowledge hepatitis virus could not be discovered or removed. In a concurring opinion Judge Roberts did face this problem, and said no distinction should be made between a practical impossibility of obtaining knowledge of a dangerous condition, as where a defendant fails to discover a foreign object in a sealed can, and a scientific impossibility, as where a virus cannot be discovered because of current lack of human knowledge and skill. Judge Roberts did distinguish the undetectable virus case from a case involving a "pure" drug with unknown and currently unknowable side effects, where the Florida court denied a retailer's liability. This distinction was based on the ground that the blood plasma is in fact defective, since it contains hepatitis virus which would harm anyone. Judge Roberts thought that any other holding would be inconsistent with the Green cigarette case, which emphasizes that "a manufacturer's or seller's actual knowledge or opportunity for knowledge of a defective or unwholesome condition is wholly irrelevant to his liability on the theory of implied warranty . . . ." The cigarettes in the Green case, however, were made of merchantable tobacco, and it is not known whether the cancer resulted from some generally harmful ingredient in merchantable tobacco, or as a side effect from excessive smoking. It may be that even if tobacco contains a generally harmful ingredient, blood plasma still is distinguishable from cigarettes in that the plasma is a vitally needed drug, and the exact nature of the calculated risk from undetectable hepatitis virus is more plainly indicated than is the risk from cigarette smoking.

It has been suggested that the risk of hepatitis could best be assumed by the supplier, even though this risk is undiscoverable and adequate warning is given. One factor in support of this view is that plasma containing this virus perhaps can more easily be regarded as defective than can a pure drug with potential side effects. Furthermore, even though no fault is involved, the risk may be one that the supplier can insure against more effectively than can the occasional hepatitis victim. The chief reason for rejecting this approach is that if the plasma is as pure as it can be made, and accompanied by adequate warnings, the courts hesitate to class it as defective and unreasonably dangerous, or as unmerchantable or unfit, even where contaminated with a virus. In this connection the manufacturer of

N.W.2d 805 (1965) (no warranty though blood purchased from charitable blood bank; no strict liability in tort); Perlmutter v. Beth David Hosp., 308 N.Y. 100, 123 N.E.2d 792 (1954) (no sale to give rise to a warranty); cf. Sloneker v. St. Joseph's Hosp., 213 F. Supp. 105 (D. Colo. 1964) (expressing serious doubt as to duty of hospital, as distinguished from supplier, to give warning).

1 Community Blood Bank, Inc. v. Russell, 196 So. 2d 115 (Fla. 1967). There are indications that current research will reveal a practical method of eliminating the hepatitis risk. See Newsweek, Nov. 18, 1968, at 84.


4.2 FRUMER & FRIEDMAN § 19.02(2), at 102.5; James, supra note 24, at 1558; Traynor, supra note 64, at 368.
a product to which a substantial group of users or consumers are allergic escapes liability if he gives an adequate warning; perhaps a warning should be equally effective to protect the producer of blood plasma which occasionally will harm a user.

VII. Effect of Obviousness of Danger on Duty To Warn

There is no need to warn of dangers that are obvious (e.g., that a sharp knife will cut) or of dangers actually known to the user of the product. Sometimes it is not easy to determine what will be regarded as obvious. In the leading case on this point an exerciser known as a "Lithe-Line," a rubber rope with loops at the ends, slipped off the plaintiff's foot and struck her in the eye, detaching a retina. The court divided as to whether the risk of such an accident was obvious. The majority stressed that everyone knows rubber contracts violently when released; the dissenting judges thought the user might not realize a loop might slip, and that if it did her eye would be in the direct path of the recoil.

It has been urged that the duty to warn arises only when the alleged defect, such as the absence of a safety device, is "latent." Many older cases support this view, but the courts are beginning to recognize that recovery should not always be denied simply because the absence of some safety device is apparent. In *Schipper v. Levitt & Sons* it was evident to the owner of a mass-produced house that the plumbing lacked a mixing valve designed to prevent delivery to the faucets of excessively hot water. It was not clear, however, whether the owner realized the risk that his small son might be gravely burned from failure to turn on the cold water before the hot, as recommended in a booklet delivered to the original purchaser. In holding that a jury could find negligence, the court rejected the requirement that there must always be a latent defect or concealed danger, and emphasized instead the unreasonable danger test, thus following writers rather than earlier decisions on this point. In another case, Judge Clark, in a dissenting opinion, criticized as a "sterile definitional quibble" the inquiry as to whether an injury was caused by a "latent" or "patent" defect, and directed attention to reasonable foreseeability of danger.

Where, however, the danger as well as the defect is evident to most users

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1 See notes 207-08 infra, and accompanying text. But see James, *supra* note 24, at 1518, where allergy cases imposing liability are used as grounds for urging strict liability for defective plasma. 2 Villanueva v. Kent Nowlin, 77 N.M. 174, 420 P.2d 764 (1966); 2 RESTATEMENT (SECOND) OF TORTS § 388, comment k (1965). See also Vroman v. Sears, Roebuck & Co., 387 F.2d 732 (6th Cir. 1967) (applying Michigan law), finding no duty to warn that foreign objects could be expelled from lawnmower's discharge chute, and other mower cases, discussed in Noel, *Recent Trends in Manufacturers' Negligence as to Design, Instructions or Warnings*, 19 SW. L.J. 43, 46 (1965).


of a product, the courts are reluctant to find a duty to warn an occasional inexperienced user. This is illustrated by the cases involving burns resulting from ready-mixed concrete containing lime. This product is used for the most part by contractors or others who realize the risk, but even plaintiffs who have never used the product before have failed to recover on the ground that the risk is obvious.\textsuperscript{102} It would seem that the manufacturer should be under a duty to warn do-it-yourself users, even though the experts fully realize the danger.\textsuperscript{103} As to those who have actual knowledge and realization of the danger, however, there is no duty to warn even though the danger may be somewhat latent.\textsuperscript{104}

A recent case, \textit{Thibodaux v. McWane Cast Iron Pipe Co.},\textsuperscript{105} raises the issue of whether there is a duty to warn where the purchaser is an expert who should realize the danger but apparently does not realize it. The defendant manufacturer had supplied cast iron pipe for underground use for a natural gas system in a city in southern Louisiana. The soil in this area was of such a nature as to cause cast iron to corrode at an unusually rapid rate. As a result of corrosion an explosion occurred which injured the plaintiff, living in a house situated above the pipe, and killed his wife and daughter.

The court assumed that pipe manufactured for the sole purpose of distributing natural gas was “highly dangerous and was likely to cause injury to persons” in this city, and that the manufacturer was chargeable with this knowledge. In affirming dismissal of this action the court stated that since the manufacturer was chargeable with knowledge of the danger, there ordinarily would be a duty to warn. It found no duty in this case because the city or its consulting engineers were “likewise chargeable with the same knowledge,” adding that there is no duty to warn “where the other party is already aware of the danger.”\textsuperscript{106}

This decision seems questionable. There was no evidence of actual awareness of the danger by the purchaser or by its consulting engineers. While a duty to know of the danger, as an expert, might well bar an action by the purchaser, it is difficult to see why the purchaser’s duty to know should bar a suit by a resident of the city. Intervening negligence might place the result outside the risk, if this were unforeseeable, but here it was quite evident that the pipe was being ordered for use in what the court de-


\textsuperscript{103} 1 \textsc{Frumer & Friedman} \S 8.04; Noel, \textit{supra} note 12, at 859. Furthermore, even though experts realize the danger, as where physicians generally realize the risk from the drug Lactigen when it becomes coagulated, a duty to warn may be found; in this situation the court said “Sometimes it is well to have our attention called to the things we know best . . . .” \textit{Abbott Laboratories v. Lapp}, 78 F.2d 170 (7th Cir. 1935) (applying Illinois law).

\textsuperscript{104} \textit{Morrocco v. Northwest Eng’r Co.}, 310 F.2d 809 (6th Cir. 1962) (applying Michigan law). \textit{See also} \textit{Ball v. Mallinkrodt Chem. Works}, 53 Tenn. App. 218, 381 S.W.2d 563 (1964) (cert. denied, Tenn. Sup. Ct.), finding no duty to warn surgeon in specialized area that a contrast agent could cause paralysis. Likewise in \textit{Brown v. General Motors Corp.}, 355 F.2d 814 (4th Cir. 1966), \textit{cert. denied}, 386 U.S. 1036 (1967), there was no duty to warn against starting bulldozer in gear when plaintiff knew from protective shield designed to guard against starting except in neutral that bulldozer could, but should not, be started in gear.

\textsuperscript{105} 381 F.2d 491 (5th Cir. 1967) (applying Louisiana law).

\textsuperscript{106} \textit{Id.} at 495.
scribes as "a highly dangerous manner." If through a mistake, negligent or otherwise, a product is ordered for a use which will endanger the lives of third persons, should not the manufacturer have his usual duty to warn of the danger? This might result in loss of the sale; but even if the purchaser still wants to go ahead, the manufacturer should refuse to do so, since it has become evident that the product will be used in such a way as to endanger life, and thus falls into the category of things that are unsafe even with a warning. Perhaps an unexpressed reason for the decision was that the pipes had been in the ground for twenty years; the court may have doubted whether negligence so far back should be regarded as a significant cause of the accident, particularly since the plaintiff already had made a substantial settlement with the city.

The rule that there is no duty to warn of obvious dangers applies as well to strict liability cases. In the comment to the Restatement it is said there is no duty to warn of dangers from excessive use of a product where "the danger, or the potentiality of danger is generally known and recognized." It is further stated that the user who "discovers a defect and is aware of the danger, and nevertheless proceeds unreasonably to use the product" cannot recover. It is immaterial if a third party who is not aware of the risk is injured, since strict liability normally is restricted to users or consumers of the product. Furthermore apparent dangers of this sort do not violate the normal expectations of the typical user of the product, and as a result the product is not defective, even in absence of a warning, since it is not "dangerous 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."

Likewise, where strict liability is based on warranty, recovery is apt to be denied where the defect is obvious, on the ground that discoverable defects are not covered by the warranty. So it is said in the Uniform Commercial Code that when the buyer has full opportunity to examine the goods there is no implied warranty with regard to defects which an examination ought to have revealed. The official comment adds, "if the buyer discovers the defect and uses the goods anyway, resulting injuries may be found to result from his own action rather than proximately from a breach of warranty."

VIII. WARNINGS AS TO UNFORESEEABLE USES OF PRODUCT

A manufacturer does not have to warn against dangers arising only if the product is used in an unforeseeable way. The manufacturer is entitled to anticipate that his product will be put to a more or less normal and

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107 See notes 33-40 supra. In this connection, however, the risk from inhalation of fumes was not regarded as known to an experienced painter in absence of evidence that he actually realized the danger from toxic silicone waterproofing. Rice v. Gulf States Paint Co., 406 S.W.2d 273 (Tex. Civ. App. 1966).

108 See 2 Restatement (Second) of Torts § 402A, comment j (1965).

109 Id., comment n.

110 Id., comment I.

111 Id., comment j.

112 See Uniform Commercial Code § 2-316(3)(b), and comment 8.
appropriate use, whether the plaintiff's case is based on negligence or on strict liability. So if a man buys an automobile tire that is safe for normal driving, but installs it on a racing car, he cannot complain that he was not warned of the risk of a blowout at racing speed. The tire is not defective because it fails to withstand the special strains to which a racing tire is subject.

Formerly the courts were reluctant to find liability unless the product was being used precisely as intended. Twenty years ago a housewife who splashed cleaning fluid into her eye was unable to recover for permanent injury because "the cleaning preparation was not intended for use in the eye." More recently, however, where a painter let a dripping brush come in contact with the eye of his helper, and the paint contained a chemical strong enough to cause almost immediate blindness, the jury was permitted to find liability in the absence of any adequate warning of this foreseeable risk.

A later case extends responsibility for unusual uses even further, holding that a manufacturer could incur liability on both negligence and warranty grounds where a child of six sprayed her hair and dress with inflammable hair spray, as if it were perfume, and the dress later caught fire. Other decisions permit a jury to find it foreseeable that a chair may be used to stand on as well as for sitting, that a supplier of toys for nontoxic use should anticipate that children may put most anything in their mouths, and that a boy of five might play with and around an open fire while wearing an inflammable jacket.

A recent case illustrates the difficulty of determining what uses of a product may be foreseeable. In Simpson Timber Co. v. Parks the manufacturer packaged doors for overseas shipment, placing them in bundles about forty-two inches high. Each door had a large opening in which a pane of glass was to be installed at destination, and these openings were lined up so that they formed a well. A thin cardboard cover was wrapped around the bundle. This left the solid wooden edges of the doors exposed, but concealed the interior cavity, so that the completed bundle looked as if it were made up of solid doors. The label on the bundle read "fine doors," with no warning that the cardboard covered a well. The bundles were delivered to the docks at Portland, Oregon. When they were stowed for shipment, the longshoremen used bundles already laid down as a floor in stor-

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113 Sawyer v. Pine Oil Sales Co., 157 F.2d 855 (5th Cir. 1946) (applying Louisiana law).
114 Haberly v. Reardon Co., 319 S.W.2d 859 (Mo. 1958).
116 Victory Sparkler & Specialty Co. v. Latimer, 23 F.2d 3 (8th Cir. 1931) (3-year-old child ate a "spit devil" firework containing toxic ingredients; defense of unintended use unsuccessful in negligence action).
118 369 F.2d 324 (9th Cir. 1966) (applying Oregon law).
ing the next layer. When the top layer was reached, there were open spaces left and a number of hundred pound flour sacks were placed between the bundles to stabilize the layer. While carrying one of these sacks the plaintiff stevedore stepped on the cardboard over a well and fell into the cavity, suffering permanent injuries. The cardboard covering was so weak that it would not have supported even an unburdened man.

There was testimony as to a general and long continued practice on the part of stevedores to walk on each layer of cargo as they loaded the next layer. A packaging expert testified that he had been consulted by twenty-five to thirty door manufacturers, all of whom knew of the custom of walking on doors, and that he had packaged their products so that the bundles would be safe to walk on during loading, either by cutting holes in the packaging to expose the cavity, or by placing warning notices on bundles which appeared to be solid but were not. The plant manager of the defendant, however, testified he did not know the cargo was walked upon, and representatives of two other door manufacturers likewise said they lacked such knowledge.

The jury were told they could find negligence if (1) the manufacturer "knew, or in the exercise of reasonable care should have known" workmen might walk on the packaged doors, and (2) the bundles created a dangerous situation which a person of ordinary prudence would have guarded against by a warning or otherwise. Judgment for plaintiff was affirmed on a first appeal with one of the three judges dissenting. This first opinion emphasized that the manufacturer, a shipper of around 17,000 doors a year, was under a duty to possess the knowledge of an expert, and that "there was ample evidence in the record in this case to establish both a common practice to walk on cargo during loading and general knowledge of this usage among those who held themselves out as qualified to carry on the business of packing cargo for export."121

After a petition for rehearing, the case was heard en banc by nine judges, who divided five to four in favor of the defendant.128 It was held the case should go back for a new trial, with instructions to find liability only if the defendant actually knew of the practice of walking on the cargo. It was conceded that "the bundle of doors was a trap," if used as a floor, but the court found no duty to learn of loading practices when "the product is such an ordinarily harmless item as a package of doors, a product which cannot explode, ignite, strike, poison or cause skin diseases and which, without doubt, was not intended to be used, ultimately or at any time, as a floorway."129

The plaintiff sought review in the Supreme Court, which on certiorari reversed.13d The final opinion is a single sentence, citing an earlier decision135 holding that actual knowledge of a peril is not essential where a dangerous

121 Id. at 327.
128 Simpson Timber Co. v. Parks, 369 F.2d 324 (9th Cir. 1966) (applying Oregon law).
129 Id. at 329.
situation is foreseeable. This final decision in *Parks* is in accord with general negligence principles. As pointed out in the *Restatement*,[128] the basic issue is whether an unreasonable danger has been created. This is determined by balancing the likelihood of harm and its gravity against the burden of making precautions which would avoid the risk.[127] It is no longer necessary that the product be "inherently" or "intrinsically" dangerous.[128]

*Parks* may conflict with an earlier decision[129] which held that the manufacturer of steel casements was under no duty to foresee that crossbars apparently firmly affixed would be used by workmen as a ladder, in spite of a common practice of this effect; but it seems more sound to require the manufacturer to guard not only against risks he actually realizes, but ones a reasonable manufacturer would anticipate. Ordinarily a manufacturer is held to the knowledge and skill of an expert in his trade, whether he possesses it or not.[130] If most shippers knew that cargo was used as a floor, and the custom was a general one, a jury could find that this large shipper should have learned of the custom and taken account of it. The defendant's plant manager admitted he had seen the holds of ships, and often "wondered" how cargo was moved to portions of the hold away from the hatches. Perhaps he should have stopped wondering and found out. As the dissenters in the en banc opinion observed, the slightest effort on Simpson's part could have disclosed both the risk and the simple precautions necessary to avoid harm.[131] To hold that a manufacturer may rely on lack of knowledge of risks which a reasonably prudent person engaged in the business would have discovered places a premium on ignorance and certainly does not promote safety.

One commentator in approving the original *Parks* opinion for the plaintiff may go too far in imposing a duty on the manufacturer to discover what he calls "unforeseeable but common uses of the product."[132] All the original decision holds is that a jury could find this use was in fact foreseeable by a manufacturer engaged in extensive export shipping. It seems odd to say, as does this comment, that a product use which is both common and generally known by others in the business can, at the same time, be regarded as unforeseeable. Unless the use is foreseeable, there would seem to be no basis for liability in a negligence action, and it would be difficult to prove the defectiveness and unreasonable danger essential for strict liability. On the other hand, where the unusual use is foreseeable, it does not seem harsh to impose a duty, particularly when the danger can be avoided by a simple warning.

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128. *2 Restatement (Second) of Torts* § 395 (1965).
127. See *2 Harper & James* § 28.4, at 1542.
126. See *2 Restatement (Second) of Torts* § 395, comment d (1965); *Smith v. Aeco Co.*, 6 Wis. 2d 371, 381, 94 N.W.2d 697, 704 (1959).
125. *McCready v. United Iron & Steel Co.*, 272 F.2d 700 (10th Cir. 1959). See also *Mannsz v. MacWhyte Co.*, 155 F.2d 445 (3d Cir. 1946) (denying, questionably, a duty to foresee that wire rope made for elevator use would be used for scaffold).
While it is evident that the manufacturer is being required to foresee more and more in the way of unusual uses, there are limits to what is expected of him. This may be illustrated by a case where a boy’s arm was severed when he opened the cover of a school laundry machine while the spinner was revolving. A safety device which prevented the cover from being raised while the extractor was spinning had been provided, but this device had broken and had not been replaced. The jury found negligence in the failure to place a warning on the machine. On appeal the court found no duty to warn against a danger which would arise only if a safety feature provided by the manufacturer should be broken or improperly maintained by the user of the product. There is no obligation to foresee that the user of the product “will alter its condition so as to make it dangerous, or that he will continue to use it after it becomes dangerous due to alteration of safety devices intended to protect the user from harm.”

A recent case shows there is no duty to warn that a product may in some circumstances be combined with another so as to cause harm. This issue arose where sodium azide manufactured by the defendant was sold to a research laboratory engaged in secret research on solid fuel propellants for rocket engines. The plaintiff, a laboratory technician, acting under the direction of a chemist, added the sodium azide to a compound called fumaryl diazide, and started to filter out this compound. An explosion occurred which caused the loss of plaintiff’s hand. In directing a verdict for defendant, the court rejected the plaintiff’s claim of a duty to warn that sodium azide, if mixed with various other chemicals, would be likely to produce an explosion. The decision was partly on the ground that the product was furnished to expert chemists who would know the properties of sodium azide and the dangers of mixing it with various other chemicals.

A questionable decision involving a mixture concerned a drain solvent. When the solvent was used to unclog a pipe, a spray containing sodium hydroxide burst from the pipe with such force that it covered the walls and ceiling of the room where the plaintiff was working, and permanently blinded the plaintiff. There was expert testimony that the explosion was caused by a combination of the lye in the solvent with zinc fragments in the pipe, a combination which would produce hydrogen. The label on the solvent described the product as safe. There was no warning of the risk that explosive gases might be generated, or that it might be necessary to wear protective goggles.

A divided court held that a complaint against the manufacturer and the distributor should be dismissed. It was emphasized that the plaintiff, an experienced plumber, had used this solvent for years without experiencing any difficulty, and apparently there was no available evidence of other explosions. This does not establish that none ever occurred, nor does

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“a long history of good fortune” exclude a conclusion by the trier of fact that ordinary prudence requires a warning. Galvanized pipe frequently is coated with zinc. Hydrogen is particularly apt to form under high temperatures, and the user was directed to dissolve the solvent in “boiling water.” It seems clear that a jury could find this accident foreseeable by a manufacturer with a duty to possess expert knowledge, and that a warning of the danger of explosion was needed.

Failure To Follow Instructions as an Unusual Use. In some recent cosmetic cases recovery has been denied because the plaintiffs had failed to follow explicit instructions regarding the use of the product. One of these cases, Procter & Gamble Manufacturing Co. v. Langley, involved a home permanent wave solution. It was stated on the carton that the preparation was “[F]or any type of hair,” but an accompanying pamphlet added, “[I]f your hair is bleached, tinted, or color treated in any way . . . make test curls to see if your hair can take a wave.” As to the timing for the test curl, it was stated in the pamphlet, “[L]eave hair in curlers ten minutes,” and that if strands tested “feel sticky or gummy, use the liquid neutralizer at once and do not wave any more of your hair.” Further instructions stated, “if your test curls, when dry, are frizzy, discolored, break easily or show any other signs of hair damage, this also means that you should not wave the rest of your hair.”

The plaintiff, whose hair had been tinted, tested it by leaving the lotion on a test curl for four minutes instead of ten. She found the test curl was sticky but omitted to use the neutralizer, continuing to apply the lotion. Later her hair started breaking off near the scalp to the extent that she had to secure a wig.

The jury found the product unmerchantable and unfit for the purpose intended and judgment was entered for the plaintiff. The appellate court reversed, partly for lack of any substantial evidence that the product was defective. On a petition to rehear, however, the court seemed to assume that defectiveness and causation might have been established by circumstantial evidence, but emphasized as the basis for its decision that strict liability does not mean “a consumer may knowingly violate the plain unambiguous instructions and ignore the warnings, then hold the makers, distributors and sellers of a product liable in the face of the obvious misuse of the product.” As the court points out, it is provided in the Restatement that “[W]here a 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." There seems to be no evidence in the case, circumstantial or otherwise, that the product was defective or unreasonably dangerous when the directions and warnings were followed, although it may be that the warnings were not emphatic enough, or clearly enough separated from instructions for use.

Since it further appeared from the plaintiff's own testimony that she had read the directions in the pamphlet, understanding them to mean "just what they say," the court could properly find as a matter of law that the plaintiff deliberately assumed the risk. Some support for this conclusion may be derived from the Texas decision in Shamrock Fuel & Oil Sales Co. v. Tunks which clearly holds that ordinary contributory negligence is not a bar in a strict liability case, but makes it equally clear that deliberate assumption of a known risk by the plaintiff is a defense.

It seems doubtful, however, that Langley should be based on the grounds of improper use of the product, as distinguished from defectiveness. The lotion was being used for the very purpose for which it was intended. If the plaintiff had not read the instructions, she would be guilty of contributory negligence, but would be saved by the doctrine laid down in the Tunks case that ordinary contributory negligence is not a bar to a strict liability claim. It seems inconsistent to hold that failure to carefully read and follow instructions is something other than contributory negligence. It would seem that the defense of unusual use should be restricted to cases where the product is being used for some distinctly unintended and unforeseeable purpose, as if someone had used the lotion as a shampoo and had suffered harm as a result.

There is, however, another application of the abnormal use doctrine where instructions were not followed in Helene Curtis Industries, Inc. v. Pruitt, involving two separate bleaching products, Helene Curtis New Blue Bleach manufactured by Helene Curtis, and L'Oreal Creme Developer manufactured by Cosmair. Both products were intended for use only by professional beauticians, and on the Curtis bleach container was the statement, "For Professional use only—not for public sale." In this instance both products were purchased from a beauty parlor by a friend of the plaintiff, a Mrs. Hendren, who had no professional training. The two products were mixed together and Mrs. Hendren applied the mixture to the plaintiff's hair. As a result the plaintiff suffered third degree chemical burns on her scalp and ear.

The directions which accompanied the Helene Curtis bleach stated, "Do not mix Helene Curtis New Blue Bleach with anything except Helene Curtis Creme Developer (or a good-grade of fresh twenty volume hydrogen peroxide)." The label on the Cosmair bleach listed various products with which it might be mixed, not including Helene Curtis bleach.

After the mixture had been on the plaintiff's head for fifteen or twenty minutes she complained of a burning sensation. Mrs. Hendren then washed

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141 2 RESTATEMENT (SECOND) OF TORTS § 402A, comment j (1965).
142 416 S.W.2d 779 (Tex. 1967). See also 2 RESTATEMENT (SECOND) OF TORTS § 402A, comment w (1965).
143 385 F.2d 841 (5th Cir. 1967).
off the solution and called a physician, who testified that the chemical burns were produced "by the application of the bleaching substance she told me she used on her scalp."

The jury found both products contained "corrosive substances" which were a proximate cause of the plaintiff's injury, that the plaintiff had followed the directions which accompanied the product, and was not negligent in mixing or applying the products. On appeal from a judgment for $64,500 it was found the jury could not rationally have inferred that the products involved were defective. As an added basis for its decision the court added, "[m]oreover a mixture of these products amounted to an abnormal handling or substantial alteration which, because it was unintended and unforeseen, excuses the makers from responsibility for any harm." 4

It is significant that the plaintiff failed to introduce any evidence that it was customary for users of hair bleach to mix different brands. This factor as well as the failure to observe instructions not to mix the products supports the conclusion that the mixing amounted to an abnormal use. Likewise the failure to introduce evidence of any practice on the part of beauty shops to resell these products supports the conclusion that any use of this product by an amateur was an abnormal one. As pointed out, however, in connection with the Langley case there is risk that if any departure from instructions is regarded as an abnormal use, the court may in substance be permitting the defense of ordinary contributory negligence in a strict liability situation. 5

IX. Persons To Be Warned

The duty to warn runs to those the manufacturer should expect to use the chattel, or be endangered by its probable use, and the warning must be reasonably calculated to reach such persons, directly or indirectly. 6 This does not mean that every potential user must be warned by the manufacturer himself, as illustrated by Foster v. Ford Motor Co. 7 involving a tractor used by an employee of the purchaser. The tractor became stuck in the mud, and in attempting to unmire it, the employee engaged the clutch suddenly, with the result that the tractor upended and fell on the operator.

The purchaser had been warned of this danger, both by the salesman and in the owners' manual. The court found the warning to the actual purchaser sufficient to make the tractor safe, and that there was no duty to warn the individual operator of the danger which would arise only when unusual power was suddenly applied. If the danger of overturning had been greater, or if the product had been one likely to be used by someone without seeking instruction, the manufacturer probably would have been obliged to attach some warning to the machine itself. So where a gas re-

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4 Id. at 856.
6 See 1 Frumer & Friedman § 8.03 (3); 2 Harper & James § 28.7, at 1548; 2 Restatement (Second) of Torts § 388 (1965).
fridge was apt to emit dangerous carbon monoxide gas unless the burner was regularly cleaned, it was held that a secondhand purchaser could recover. Since there was doubt that a warning to the original purchaser would have been adequate to correct this danger, the jury was permitted to find a negligent design in the absence of a warning attached to the refrigerator itself.\footnote{148 Beadless v. Servel, 344 Ill. App. 133, 100 N.E.2d 405 (1951).}

Other decisions, however, hold as in the Foster case that there is no duty to warn employees of the purchaser.\footnote{149 Bertone v. Turco Prods., Inc., 252 F.2d 726 (3d Cir. 1958) (applying New Jersey law) (adequate warning of dangers from chemical on drum delivered to employer); West v. Hydro-Test, Inc., 196 So. 2d 158 (La. App. 1967) (no need to attach instructions to each item, exposed to all sorts of weather); McDaniel v. Williams, 23 App. Div. 2d 729, 217 N.Y.S.2d 702 (1965) (professional gallon jar of product sold to beauty parlor had warning on label); Thomas v. Arvon Prods. Co., 424 Pa. 365, 227 A.2d 897 (1967) (warning to employer of need for ventilation when using product; directions for use to employer sufficient).}

In one such case a workman developed a serious skin disorder, chlor-acne, as a result of contact with wax containing chlorinated napthalenes. The trial judge instructed that the defendant had a duty to directly warn every user of the wax, with warning labels on every container. On appeal it was found that this would place an impossible burden on the manufacturer, and that his duty was simply to assure himself that the "immediate vendee and distributor was so informed as to be able and likely to transmit to those who would purchase and use this wax knowledge of its dangers and of the needed precautions."\footnote{150 Weeks v. Michigan Chrome & Chem. Co., 352 F.2d 601 (6th Cir. 1965) (applying Michigan law).}

Consequently, if the warning to the distributor on the original containers was adequate, it could be found reasonable, under all the circumstances, to rely on the distributor for the re-labeling of smaller lots. This is in accord with the Restatement comment, that "life would be intolerable unless one were permitted to rely to a certain extent on others doing what they normally do, particularly if it is their duty to do so."\footnote{151 2 Restatement (Second) of Torts § 388, comment n (1965). So where drugs are sold only to physicians, it is enough to give adequate warnings and directions to them. Love v. Wolf, 226 Cal. App. 2d 378, 38 Cal. Rptr. 183 (1964); 3 Frumer & Friedman § 33.01(3) n.2.1.}

Where the product, however, is extremely dangerous, such reliance on others to transmit a needed warning may not be justified, for where improper use of the product involves risk of serious bodily harm or death, the supplier "is required to make the chattel carry its own directions by placing them upon the container."\footnote{152 2 Restatement (Second) of Torts § 397, comment b (1965). This duty to warn the user directly as to extremely dangerous products was upheld where a retailer was supplied with a mixture of gasoline and kerosene; supplier liable when death resulted from use of mixture to light stove, although retailer advised of the mistake. Kentucky Independent Oil Co. v. Schnitzler, 208 Ky. 507, 271 S.W. 570 (1925).} Perhaps in the chlor-acne case, where the product caused a severe skin condition all over the plaintiff's body, the trial judge thought the wax presented an extreme danger.

Even in the case of a dangerous product, such as high pressure shells designed for testing guns, there is no duty to warn a person against using the shells as ordinary ammunition where the manufacturer has no reason to foresee use of the overcharged shells by anyone other than manufacturers and dealers who would understand the meaning of the markings on this
ammunition. Likewise, a manufacturer of a fuse for dynamite caps may take into account that his product is intended for use only by skilled persons, and is not liable when he fails to warn an unsophisticated user of the short burning time of the fuse.

There is a decision of doubtful soundness involving a tear gas gun made to look like a fountain pen, with the clasp as a trigger. A customer picked up this harmless looking article and accidentally discharged the tear gas into his face. It was held by a divided court that since the purchaser was fully informed of the nature of the article, the manufacturer could not be found negligent. Since, however, the customer was advised to keep the gun in readiness on his desk, it would seem that there should have been some warning on the article itself of the danger involved in pressing the ordinary looking clasp which was in fact a trigger.

X. Adequacy of Warning

The adequacy of a particular warning ordinarily is decided by the jury. Often the warning is found inadequate because of lack of clarity, which may arise from contradictory statements, or from use of technical terms. So a statement that paint contained calcium oxide could be found inadequate as a warning, since the average person does not know this means lime, and that lime may cause blindness. One case raises the question of what must be done where the product, chemicals used for dusting and spraying crops, may be used by foreign or illiterate workers who cannot read English. Two Puerto Rican workmen died after using these chemicals for a day, apparently without the protective clothing and mask stated to be necessary on the manufacturer's label. The court allowed the jury to find the label inadequate on the ground that a skull and cross bones, or comparable symbols, should have been included, since it was foreseeable that the product would be used by persons of limited reading ability.

Occasionally the warning is too narrow in scope. So where there was warning that a caustic drain cleaner was poisonous, but there was no in-

154 Canifax v. Hercules Powder Co., 237 Cal. App. 2d 44, 46 Cal. Rptr. 552 (1965); Littlehale v. E.I. du Pont de Nemours & Co., 268 F. Supp. 791 (S.D.N.Y. 1966), aff'd, 380 F.2d 274 (2d Cir. 1967) (no warning to expected purchaser of blasting caps needed, hence no duty to warn an unforeseeable repurchaser). See also cases discussed note 102 supra, involving harm from lime in cement. Statutes or regulations often require that highly dangerous articles such as poisons, explosives and inflammables shall bear on their face some prescribed notice of their dangerous character. 1 FRUMER & FRIEDMAN § 8.07(1). Compliance with these standards is some evidence of due care. Arata v. Tonegato, 152 Cal. App. 2d 837, 314 P.2d 130 (1957). It does not conclusively establish freedom from negligence, since the statutes and regulations establish simply certain minimum requirements. See notes 173-77 infra, and accompanying text.
158 Haberly v. Reardon Co., 319 S.W.2d 859 (Mo. 1958).
159 Hubbard-Hall Chem. Co. v. Silverman, 340 F.2d 402 (1st Cir. 1965) (applying Massachusetts law).
ication that if too much of the cleaner was poured into a drain this might cause not simply "effervescence" but a blinding explosion, the warning was inadequate. In a chemical weed killer case there was warning of danger from direct physical contact, but no sufficient warning of the danger from contact with earth on which the product had been spilled. Similarly, a warning that paint is irritating to skin is not a warning against the risk of injury to sight if the paint comes in contact with the eye.

Sometimes the difficulty is that the intensity of the warning has been watered down, or is diminished by a representation of safety. So where a manufacturer placed in large letters, on all four sides of a can of cleaning fluid containing carbon tetrachloride, the words "Safety-Kleen," with a warning in much smaller letters to use the product only in well ventilated places, the warning was found by the jury to be inadequate. The assurance of safety may be significant even though the actual user of the product does not see and rely on it, as where a child wearing inflammable material near a toy pistol which emitted "cold" sparks was burned. The pistol was represented as "absolutely harmless," and it was found immaterial that the child never saw the representation, for without the assurance of safety the child's parents would have been less likely to provide the child with this toy without adequate supervision or warnings.

Sometimes the warning is not sufficiently prominent. One case holds, questionably, that a warning in letters large enough to comply with "the standard of the industry" is sufficient as a matter of law. Granted that compliance with industry custom is evidence of ordinary care, still an industry should not be able to set its own uncontrolled standards, for occasionally a whole calling may lag in the adoption of adequate precautions. Thus, in Canifax v. Hercules Powder Co., the fact that suppliers

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105 Maize v. Atlantic Ref. Co., 352 Pa. 51, 41 A.2d 830 (1944). See also Love v. Wolf, 226 Cal. App. 2d 378, 38 Cal. Rptr. 18 (1964), second appeal, 249 Cal. App. 2d 822, 58 Cal. Rptr. 42 (1967). "Overpromotion" of chloromycetin, by advertising and representations of detail men regarded as bearing on adequacy of warning given; cf. Tampa Drug Co. v. Wait, 103 So. 2d 503 (Fla. 1958) (death from carbon tetrachloride; warning inadequate even though no assurance of safety). See also Krug v. Sterling Drug, Inc., 416 S.W.2d 143 (Mo. 1967) (risk of loss of sight from aralen; jury could find negligent failure to give to physicians adequate warning of this serious risk by reference to danger of "visual disturbances"); La Plante v. E. I. DuPont de Nemours & Co., 346 S.W.2d 231 (Mo. Ct. App. 1961) (mislabeling of weed killer so as to mislead into believing it was not harmful to humans found to be actionable negligence).
110 The T. J. Hooper v. Northern Barge Corp., 60 F.2d 737 (2d Cir. 1932). See also the statement by Holmes, "What usually is done may be evidence of what ought to be done, but what ought to be done is fixed by a standard of reasonable prudence, whether it usually is complied with or not." Texas & Pac. Ry. v. Behymer, 189 U.S. 468, 470 (1903).
of blasting fuses did not customarily give warning of the burning time of the fuse was not conclusive on the question of whether there was a duty to warn. On the other hand where a certain type of warning, such as the odorization of natural gas, is customary a failure to give this warning may constitute negligence as a matter of law.\(^\text{169}\)

Perhaps the most significant recent case dealing with the adequacy of a warning is *Yarrow v. Sterling Drug Co.*,\(^\text{170}\) involving failure to warn sufficiently of the risk of loss of vision from use of the drug aralen (chloroquine) for an arthritic condition. The company had advised physicians of the increasing risk of ocular complications by means of a series of product cards, by a letter, and in the Physicians Desk Reference Book. Even so the warnings were inadequate because of the company’s failure to utilize its detail men, employed to promote and explain its drugs, to keep physicians advised as to dangerous side effects. The court stated:

Where the doctor is inundated with the literature and product cards of the various drug manufacturers, as shown here by the facts, a change in the literature or an additional letter intended to present new information on drugs to the doctor is insufficient. The most effective method employed by the drug company in the promotion of new drugs is shown to be the use of detail men; thus, the Court feels that this would also present the most effective method of warning the doctor about recent developments in drugs already employed by the doctor, at no great additional expense. The detail men visit the doctors at frequent intervals and could make an effective oral warning, accompanied by literature on the development, that would affirmatively notify the doctor of side effects such as shown in the facts in this case.\(^\text{171}\)

This emphasis on using detail men to give warnings, even though other warnings are given, represents new development. Assuming physicians are increasingly relying on detail men, who often have considerable background in the drug field, it may well be that other courts also will insist on use of detail men for the communication of warnings.

Sometimes a subsequent warning may be utilized to show the inadequacy of an earlier one. So a plaintiff with aplastic anemia caused by chloromycetin contended that a warning label used in 1952, when the drug was prescribed by the plaintiff’s physician, was inadequate. The plaintiff’s doctor testified that had he seen a later warning label, used in 1961, he would not have prescribed chloromycetin. Defendant’s officials testified that both warnings were entirely adequate and essentially the same, but it was held that the 1961 label was admissible in evidence for the limited purpose of impeaching this testimony, and showing “the feasibility of eliminating the unclear warning of the earlier date.”\(^\text{172}\)

**Effect of Statutes and Regulations.** A manufacturer is not fully protected

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\(^{171}\) Id. at 163.

\(^{172}\) Love v. Wolf, 249 Cal. App. 2d 822, 831, 58 Cal. Rptr. 42, 48 (1967). A trial court’s admission of the warning for all purposes was not regarded as prejudicial, partly because the defendant’s attorney made no request for a limiting instruction, and partly because the inadequacy of the earlier warning was based mainly on evidence of overpromotion of the drug. See note 151 supra, and accompanying text.
by the fact that he has complied with applicable statutory or administra-
tive regulations. Thus in a carbon tetrachloride case the court observed
that while the Surgeon General had approved the labels used, this official
lacked authority to prescribe the standards of due care in Pennsylvania.
Likewise where workers were poisoned by the defendant’s spray, the fact
that the label was in the precise form submitted to the Department of Ag-

culture under the Federal Insecticide Act was merely evidence that due
care had been used. In a chloromycetin case, compliance with the warn-
ing regulation approved by the Food and Drug Administration was not
necessarily adequate, particularly when the defendant’s advertising played
down the warning. In two more recent drug cases where warnings of
side effects were found to be inadequate, government regulations were re-
garded as “minimal,” and compliance with these regulations was not suf-
ficient to establish an adequate warning.

In a recent Texas case involving roach poison (thallium) consumed
by a three-year-old boy, the poison had been placed by the mother in some
bottle caps on a high shelf, as directed, but the child consumed some of
the poison when it was removed by an older playmate. The product had
been registered under the Federal Insecticide, Fungicide and Rodenticide
Act, and the label, which included the word “poison” and a red skull
and crossbones, had been approved by the Secretary of Agriculture, as
well as by the State Department of Health, in compliance with the Texas
Hazardous Substance Act. As an antidote the label simply stated: “Give
a tablespoon of salt in a glass of warm water and repeat until vomit fluid
is clear. Have victim lie down and keep warm. Call a physician immedi-
ately!” Both federal and state statutes required that the label indicate either
an antidote or first aid treatment. The child was taken within a few min-
utes after the accident was discovered to a doctor, who searched in books
and inquired in vain for an antidote for thallium. Finally, a second doctor
took the child to a hospital where his stomach was pumped, but a fatal
amount of the poison had been absorbed.

A verdict was directed for the defendant, since all federal and state sta-
tutes and regulations had been complied with, but this action was reversed,
with the statement:

Neither the State nor the Federal Act purports to change the common law
duty to warn. It merely authorizes the marketing of specified economic poisons
if the statutes and regulations promulgated are complied with. Neither Act
purports to deal with property rights. It makes it a crime to market such a
product without complying with the Act. Failure to comply with the Act

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175 Hubbard-Hall Chem. Co. v. Silverman, 340 F.2d 402 (1st Cir. 1965) (applying Massa-
chusetts law).
176 Love v. Wolf, 226 Cal. App. 2d 378, 38 Cal. Rptr. 183 (1964), discussed at notes 151,
177 supra.
178 Sterling Drug Co. v. Cornish, 370 F.2d 82 (8th Cir. 1966) (applying Missouri law);
would be negligence per se. However, a mere compliance does not as a matter of law, in all cases, mean that the party is free from negligence.181

Consequently, a jury could find common law negligence from the failure to warn that there was no specific antidote, and that once the poison had been absorbed there was no way to counteract its fatal effects. The court found "a common law duty to warn of the full extent of the danger and certainly a poison for which there is no specific antidote has more potential for harm than does a poison for which there is a specific antidote."182 If a warning about the lack of an antidote had been given, the mother might immediately have used the emetic instead of taking the child to a physician, or the physician might have promptly emptied the child’s stomach instead of searching in vain for an antidote.

It is of course necessary to comply with the warning and labeling provisions prescribed in various statutes, such as the Federal Food, Drug and Cosmetics Act,183 the Hazardous Substances Act,184 and False Advertising Statutes.185 In that connection it should be noted that the Hazardous Substances Act recently has been amended by the Child Protection Act of 1966,186 to broaden its coverage. It is now necessary, for example, to warn consumers against possible injury from drugs, cosmetics and food in pressurized containers, and to avoid completely the sale of toys and other children’s articles containing hazardous substances, regardless of how they are packaged or labeled.187

In the area of motor vehicle defects, the National Traffic and Motor Vehicle Safety Act of 1966188 has a considerable impact on the duty to warn. The Act creates a new statutory duty on the part of every manufacturer of motor vehicles, whenever he discovers a defect, which he determines, in good faith, relates to motor vehicle safety, to notify the purchaser within a reasonable time after discovery of the defect. The notification must be sent by certified mail to the first purchaser of the vehicle for use, as well as to the dealer, and to any subsequent purchaser to whom the warranty has been transferred. The notice must not only describe the defect, but evaluate the risk it creates, and state the measures needed to repair the defect.189 A copy of all notices or bulletins sent to dealers about defects, as well as copies of the statutory notices, must be sent to the Secretary of Transportation, who may disclose to the public any information in the notices along with other information obtained under his own investigating powers, if he thinks such disclosure will further the purposes of the Act. Furthermore, if the Secretary determines after investigation and hearing that any motor vehicle does not meet an applicable safety

182 Id. at 393.
189 Id. §§ 1402(a), (b), (c) (Supp. 1968).
standard, or has a defect which relates to safety, he may direct the manufacturer to give the statutory notification to purchasers and dealers.  

It seems clear that failure to give any warning notice of a defect which is required under the statute will constitute evidence of negligence, or negligence per se. Where the warning has been given, persons injured as a result of the defect will have the benefit of a clear record that the defect exists, and the date of the notice may furnish evidence as to whether it was discovered with sufficient promptness. The wording of the notice may provide significant evidence as to whether the nature of the defect and the extent of the danger were made sufficiently clear, and whether adequate measures for the correction of the defect were indicated. On the defense side, the notice will help establish contributory fault on the part of a purchaser who continues to use the vehicle without taking the specified corrective measures.

XI. CONTINUING DUTY TO WARN

A recent development deals with the duty of a manufacturer to give warning of defects he discovers after his product has been sold and delivered. In the case of motor vehicles, as has been shown, a warning of this kind is specifically required by the new National Traffic and Motor Vehicle Safety Act of 1966. This duty arises not only with respect to defects arising as a result of the manufacturer's negligence, but as to any defects which relate to motor vehicle safety.

There is some basis for a common law duty to advise previous purchasers of newly discovered dangerous defects. In Comstock v. General Motors Corp., the manufacturer of one of the first cars with power brakes discovered, after thousands of cars had been sold, a defect which might cause a sudden loss of brake fluid with a resulting no-brake condition. Dealers were notified and supplied with kits for replacement of the defective unit.

A jury was permitted to find negligence from a failure to warn individual owners, even though no carelessness as to the original design was established, since the manufacturer "did not warn those into whose hands they had placed this dangerous instrument and whose lives (along with the lives of others) depended upon defective brakes which might fail without notice."

The same sort of continuing duty was imposed on the manufacturer of an airplane propeller system, who knew that at times the propeller could not be feathered when an engine had to be turned off, with consequent risk of decoupling and fire. This occurred, with the result that a large plane

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190 Id. § 1402(d).
191 See discussion at note 23 supra. See also Comment, Federal Motor Vehicle Safety Legislation, 29 OHIO ST. L.J. 177, 214 (1968).
192 See Nader & Page, supra note 16, at 671.
194 See note 189 supra. The notification must describe the defect, indicate any risk related to it, and repair measures.
196 99 N.W.2d at 634.
fell into the ocean. A device to prevent overspeeds in the propeller finally had been developed, about six months after this plane was delivered, and about five months before the accident. The manufacturer was found negligent not only in failing to make the new safety device available to the owners of this plane, but in failing to warn of numerous malfunctions of the propeller system prior to the accident. This decision and the Comstock case indicate that warnings comparable to those provided for in the National Traffic and Motor Vehicle Safety Act of 1966 may be required with reference to products generally, when the manufacturer discovers some dangerous defect in his product, even though there was no original negligence in connection with the defect. Of course, with the growing trend toward strict liability, it is to the manufacturer's interest to have all defects corrected, since he may incur responsibility for any defective and unreasonably dangerous condition which existed when the product left his hands, regardless of how it arose.

XII. THE DUTY TO WARN ALLERGIC USERS

Medical descriptions of how allergic reactions occur are complicated and still developing. From a legal standpoint, the established and significant factor is that an allergic reaction is one suffered by only a minority of the persons exposed to a particular substance. In this connection, a "sensitizer" is to be distinguished from a "primary irritant," which is something that produces irritation on the skin of the majority of normal persons.

The sensitizing capacity of various substances differs enormously. Sometimes many exposures are necessary to develop allergic reactions, and these reactions may be confined to a very few people. Where a "strong sensitizer" is involved, the allergic reaction develops within a very limited time of exposure in much larger numbers of people.

In the early allergy cases the plaintiff received little consideration. The action ordinarily was dismissed on the ground that the plaintiff's own

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197 Noel v. United Aircraft Corp., 142 F.2d 232 (1st Cir. 1964).
199 See also Cornish v. Sterling Drug Co., CCH PRODS. LIAB. RPRY. § 5415 (1965), aff'd, 370 F.2d 82 (8th Cir. 1966) (applying Missouri law); see FRUMER & FRIEDMAN § 8.02, citing additional cases.
200 See Nelson, Medical-Legal Aspects of Allergies, 24 TENN. L. REV. 840 (1957) defining allergy as "the condition or state of an individual who reacts specifically and with unusual symptoms to the administration of, or to contact with, a substance which when given in similar amounts to the majority of all other individuals proves harmless or innocuous." Ordinarily an allergic skin rash or other reaction does not occur with the first exposure to what is called the "sensitizer" in the product, but only at the time of a subsequent or "eliciting" exposure occurring five days or more after the original exposure. FRUMER & FRIEDMAN §§ 28.01(2), (7).
201 FRUMER & FRIEDMAN § 28.01(7). An up-to-date definition of a "strong sensitizer" is contained in the Federal Hazardous Substance Act, Pub. L. No. 86-613, 74 Stat. 372 (1960), as amended by the Child Protection Act of 1966, 15 U.S.C.A. §§ 1261-1273 (Supp. 1968), providing "The term 'strong sensitizer' means a substance which will cause on normal living tissue through an allergic or photodynamic process a hypersensitivity which becomes evident on re-application of the same substance and which is designated as such by the Secretary. Before designating any substance as a strong sensitizer, the Secretary, upon consideration of the frequency of occurrence and severity of the reaction, shall find that the substance has a significant potential for causing hypersensitivity." There is a more complete definition of a "strong allergic sensitizer" in 21 C.F.R. § 191.11(i) (1968).
sensitivity rather than the product was the sole proximate cause of the harm. This over-simplified approach was taken whether the case was based on negligence or breach of warranty. Occasionally this view is expressed by a contemporary writer.

The difficulty with this approach is that defendant's product as well as plaintiff's sensitivity is in fact one of the immediate causes of the injury, assuming harm results from contact with the product. Proof of causation is not established simply by showing that the plaintiff's illness followed the use of defendant's product, where the plaintiff is unable either to point to any deleterious substance in the product, or to exclude other possible causes, such as other cosmetics or detergents used by the plaintiff. So it was stated as to proof of causation in a hair dye case, "[t]he occurrence of skin damage is not such proof unless other possible causes are excluded by competent professional testimony."

Now that additional knowledge is developing with reference to serious allergic reactions from various chemicals about which the man on the street knows nothing, the courts are much less apt to deny flatly liability. They focus rather on whether the injury threatened is sufficiently widespread, serious, and predictable so that the producer should take some steps to protect the consumer. It still is generally accepted, however, that the supplier need not alter a formula of a product that is safe for a normal user in order to make it safe for the allergic user or consumer. The duty imposed, in an increasing number of the modern cases, is simply a duty to warn. This may arise on negligence grounds, or on strict liability principles, including breach of express or implied warranty and strict liability in tort. It will be useful to consider first the supplier's duty to warn under negligence law, then the extent to which this duty is increased where the case is based on strict liability. Finally, it can be considered what kind of warning may be required.

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204 See Friedman, Allergy and Products Liability Today, 24 Ohio St. L.J. 479, 511 (1963).
206 McGuiness v. Roux Distrib. Co., 19 Misc. 2d 916, 196 N.Y.S.2d 164, 165 (Sup. Ct. 1959). See also Zampino v. Colgate-Palmolive Co., 8 App. Div. 2d 304, 187 N.Y.S.2d 25 (1959), aff'd mem., 8 N.Y.2d 1069, 170 N.E.2d 415, 207 N.Y.S.2d 284 (1960), where a judgment for plaintiff in a deodorant case was reversed partly because of insufficient evidence of causation. In another hair dye case, Fein v. Bonetti, 307 N.Y. 682, 120 N.E.2d 854 (1954), the plaintiff's doctor testified that the allergic reaction was caused by the defendant's product, but conceded that other products used by the plaintiff might have caused similar symptoms, and causation was not established. In an insecticide case, where there was no testimony as to poisonous ingredients, the court said, "We think that the liability of a defendant in circumstances such as we have in this case, must be based upon something more than an assumption that because the plaintiff became ill following use of the defendant's product, the defendant was negligent in selling a dangerous substance or product without adequate warning of its lethal character." Scientific Supply Co. v. Zelinger, 139 Colo. 568, 341 P.2d 897, 898 (1959). In view of these decisions, it is vital for the defendant to secure a physical examination of the plaintiff to see if the injuries are of a kind likely to have been caused by defendant's product, as well as to determine the extent of the injuries.
207 Wright v. Carter Prods., Inc., 244 F.2d 53 (2d Cir. 1957) (applying Massachusetts law).
Negligence. No duty to warn allergic users on negligence principles arises unless defendant knows or should know of the danger. Some decisions state that the defendant must have actual knowledge of the presence of allergic reactions, but the more recent cases hold the defendant to a duty to warn of a danger he should know about as an expert, regardless of his actual knowledge.

Even where defendant actually knows of the danger there is no duty to warn unless the product creates risk of harm to a substantial class of users. Attention will be given to what constitutes a substantial class, but it is clear that unless plaintiff can establish allergic reactions in a number of persons besides himself he cannot recover. So in a case involving sun tan lotion, where the testimony was that only one person in five million was allergic to the lotion, the court stated that there could be no liability for negligence where only an “isolated buyer” would be harmed.

There is indeed one decision, Braun v. Roux Distributing Co., involving hair dye, which departs from this principle, where the plaintiff suffered an unusually grave allergic reaction. It was conceded by plaintiff that “unless the present case is an instance, that there has never been either a reported or an established case of periarteritis nodosa caused by paraphenylenediamine hair dye.” It appeared that ninety per cent of all hair dyes contain paraphenylenediamine, that there were approximately sixty-five million applications of hair dye a year, and still no case involving a systemic allergy of the type suffered by the plaintiff had been reported. The court nevertheless allowed the jury to find a duty to warn against this extremely remote risk. It is difficult to see how this case can be supported on negligence principles, when the possibility of harm is balanced against the utility of the product, even though hair dye may appear to appellate court judges to have little utility. In fact, even under strict liability principles a product involving so remote a likelihood of injury, and containing no primary irritant, would not seem to be defective and unreasonably dangerous.

How large must the class be, with reference to a particular product and risk, before the duty to warn arises? A leading case, Wright v. Carter Products, Inc., indicates that the number necessary to create a “substantial” class varies with the gravity of the injury involved, as foreseen by one with the expert knowledge which the defendant should have as the...

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210 Sterling Drug, Inc. v. Cornish, 170 F.2d 82 (8th Cir. 1966) (applying Missouri law); Wright v. Carter Prods., Inc., 244 F.2d 53 (2d Cir. 1957) (applying Massachusetts law); Howard v. Avon Prods., Inc., 155 Colo. 144, 395 P.2d 1007 (1964); Braun v. Roux Distrib. Co., 312 S.W.2d 738 (Mo. 1958). See also Kemple v. Lehn & Fink Prod. Corp., 21 App. Div. 2d 197, 249 N.Y.S.2d 846, 846 (1964) indicating that liability would have been imposed if the defendant “knew, or with reasonable diligence should have known” of the presence of a definite class of allergic users.
212 312 S.W.2d 718 (Mo. 1958).
213 Id. at 761.
214 W. Prosser, TORTS § 96, at 669 (3d ed. 1964); see Noel, supra note 208, at 343. Except for Braun v. Roux Distrib. Co., 312 S.W.2d 718 (Mo. 1958), the decisions clearly require that plaintiff establish a class of allergic users.
215 244 F.2d 53 (2d Cir. 1957) (applying Massachusetts law). See also note 195 supra.
maker of the product, and the feasibility of giving a warning which will effectively alert the user to the risk. Where the allergy is a common one, such as the one toward eggs or citrus fruits, there is no duty to warn even though the class affected is large, since the injury is not serious, and the person affected ordinarily is aware of his susceptibility.216 Even where the reaction is serious, and one of which the plaintiff has no suspicion, there ordinarily is no liability for a rare plaintiff's reaction. So where a sensitizer in a hair waving preparation caused permanent damage to an optic nerve, a modern decision found no duty to warn where 500 million sales caused reported ill effects to only three persons.217 Earlier decisions find the injury to be isolated even though a considerable proportion of users is affected, as where a plaintiff denied recovery was disparagingly referred to as "but one allergic woman out of 1000."218

Under contemporary standards a substance which severely affects one out of a thousand might well be regarded as a strong sensitizer, with a resulting duty to warn. Thus a Federal Trade Commission advisory panel of dermatologists defined a strong sensitizer as one which causes sensitization in one or more persons in 10,000 population or a lesser proportion if the sensitization is severe.219 A much smaller percentage of allergic reactions was involved in *Wright v. Carter Products, Inc.*,220 where during the four-year period prior to plaintiff's injuries the defendant sold eighty-two million jars of its deodorant and received only 373 complaints. Still the court set aside a finding that there was no duty to warn, stating that reliance had been placed too exclusively on solely quantitative standards and statistical analysis, with insufficient attention to the gravity of the injuries, the foreseeability of these injuries by the plaintiff, and "the difficulty, if any, of embodying an effective precaution in the labels or literature attached to the product."221 While the opinion does not definitely find a duty to warn, its general tone is sufficiently favorable to the plaintiff to assist a favorable settlement. A subsequent deodorant case found no duty to warn where only four complaints occurred in a year in which there were six hundred thousand sales of the defendant's product.222 Here the percentage of complaints was larger than in *Wright v. Carter Products, Inc.*, but still less than one out of a hundred thousand.

While uncertainty remains as to how large a class must be before a duty to warn arises under negligence law, the size of the needed class, assuming an injury of given seriousness, is declining, although there still are many

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217 Merrill v. Beaute Vues Corp., 231 F.2d 893 (10th Cir. 1956). See also Walstrom Optical Co. v. Miller, 59 S.W.2d 891 (Tex. Civ. App. 1933), denying any duty to warn where the allergic reaction was "most unusual," with no indication of other complaints.
219 See Freedman, *Allergy and Products Liability Today*, 24 Ohio St. L.J. 479, 507 n.102 (1963), referring to Food Chemical News, August 7, 1961, as the source for this information, and commenting on the difficulty of determining whether or not a particular sensitizer comes within this definition.
220 244 F.2d 53 (2d Cir. 1957) (applying Massachusetts law).
221 Id. at 59.
negligence cases where a duty to warn has not been established. In establishing a class, plaintiff will of course attempt to secure disclosure of other complaints after use of defendant's product. The defendant will attempt to restrict any disclosure order to cases involving the product while it had the exact same formula, and was used under similar conditions. Evidence of the number of prior injuries may be limited to showing notice of the danger, and defendant may then insist that discovery be limited to complaints prior to the date of the plaintiff's purchase. While disclosure may be allowed without difficulty under federal discovery rules, some state courts are reluctant to order the defendant to furnish the names of all persons who have complained of earlier injuries.

**Strict Liability.** Strict liability for allergic injury may be based on breach of warranty or on the principles in the Restatement. A further liability, in substance a strict one, since ordinarily no proof of actual negligence is required, may be established by showing violation of the labeling requirements of the Federal Food, Drug, and Cosmetic Act or of the Federal Hazardous Substances Act, or comparable state statutes. In recent years plaintiffs have turned to one or more of these remedies to avoid the burden of proving negligence. Except in the case of an express warranty, however, the plaintiff's burden may not be much eased, for he still must show that a substantial or appreciable class of allergic users or consumers is affected by the product.

Sometimes the defendant is confident enough of his product to expressly state it contains only "non injurious" materials. In this situation it has been held, with reference to a dress, that there was a breach of an express warranty even though the dress might not be harmful to any other users. The court observed "[t]he question is not whether the garment contained substances harmful to the skin of any wearer of it. The warranty is express. Cases in which the action is based on implied warranty of fitness or suitability with resulting injury to an allergic or idiosyncratical person are not in point. Thus the defendant may incur an unusually strict

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225 2 Restatement (Second) of Torts § 402A (1965).

226 See note 183 supra.

227 See note 184 supra.


229 The court observed "[t]he question is not whether the garment contained substances harmful to the skin of any wearer of it. The warranty is express. Cases in which the action is based on implied warranty of fitness or suitability with resulting injury to an allergic or idiosyncratical person are not in point." Thus the defendant may incur an unusually strict
liability to an allergic plaintiff where an express warranty is involved, and apparently need not establish that a substantial class of allergic users would be affected.\textsuperscript{232}

Where breach of the implied warranty of merchantability or of fitness for use is asserted, it is necessary, as in a negligence case, to establish a substantial or appreciable class of allergic users.\textsuperscript{233} If the product can be used by a normal person without injury, ordinarily there is no breach of the warranty. Where, however, the plaintiff can show that a substantial class is affected, he can establish breach of an implied warranty. It has been suggested that for a breach of implied warranty the class must amount to at least five or ten per cent of the population.\textsuperscript{234} Actually while many plaintiffs have been unsuccessful in warranty cases in establishing that a substantial class is affected,\textsuperscript{235} there are a number of recent implied warranty decisions where recovery has been allowed without the plaintiff having established that the affected class amounted to a specific percentage. In Bianchi \textit{v. Denholm \& McKay Co.},\textsuperscript{236} involving aniline dyes in face powder, the plaintiff was allowed to recover after showing that "some" users were affected although the class of such users was not defined as to numbers or percentage. The court stated, "[w]e do not think that a seller of face powder containing a known irritant to 'some' persons' skins can be heard to say that he is not liable for breach of implied warranty of fitness where injury results from the use of the powder by one such as is described by the evidence in the case at bar."\textsuperscript{237} Likewise, in \textit{Reynolds v. Sunray Drug Co.},\textsuperscript{238} involving allergic injuries from the defendant's lipstick, the court upheld liability although "only a small proportion of those who use a certain article are injuriously affected thereby."\textsuperscript{239} In \textit{Zirpola v. Adam Hat Stores, Inc.},\textsuperscript{240} involving injury from an aniline derivative in a hat band, the court said, "the mere fact that only a small proportion of those who use a certain article would suffer injuries by reason of such use does not absolve

\textsuperscript{232}See 3 Frumer \& Friedman § 29.03 (2).
\textsuperscript{233}Zager \textit{v. F.W. Woolworth}, 30 Cal. App. 2d 324, 86 P.2d 389 (1939); Stanton \textit{v. Sears, Roebuck \& Co.}, 312 Ill. App. 496, 38 N.E.2d 801 (1942); Noel, supra note 208, at 344.
\textsuperscript{234}See Horowitz, \textit{Allergy of the Plaintiff as a Defense in Actions Based upon Breach of Implied Warranty of Quality}, 24 S. Cal. L. Rev. 221, 226-27 (1951).
\textsuperscript{236}See Horowitz, supra note 208, at 344.
\textsuperscript{237}See 3 Frumer \& Friedman § 29.03 (2).
\textsuperscript{238}Zager \textit{v. F.W. Woolworth}, 30 Cal. App. 2d 324, 86 P.2d 389 (1939); Stanton \textit{v. Sears, Roebuck \& Co.}, 312 Ill. App. 496, 38 N.E.2d 801 (1942); Noel, supra note 208, at 344.
\textsuperscript{239}See 3 Frumer \& Friedman § 29.03 (2).
\textsuperscript{240}Horowitz, \textit{Allergy of the Plaintiff as a Defense in Actions Based upon Breach of Implied Warranty of Quality}, 24 S. Cal. L. Rev. 221, 226-27 (1951).
the vendor from liability under the implied warranty.\textsuperscript{241} The court in Cassagrande v. F. W. Woolworth Co.\textsuperscript{242} declined to pass on whether one allergic user in 2,000, if that percentage had been firmly established, would constitute the "significant number" there required. In Esborg v. Bailey Drug Co.,\textsuperscript{243} involving hair tint, the court said that what constitutes an "appreciable class . . . of users is incapable of precise or quantitative definition,"\textsuperscript{244} and left this to the trier of fact with instructions to bear in mind "the usual and ordinary accepted meaning of the words employed."\textsuperscript{245} Doubtless the meaning of the words, "appreciable class" would and should vary considerably with the gravity of the injury involved.

In the implied warranty cases thus far considered there were no warnings and no instructions for the taking of a patch test. In Crotty v. Shartenberg's New Haven, Inc.\textsuperscript{246} the defendant, besides warning of the possibility of allergic injury, gave instructions for a patch test, but the test was ineffective. The court held that plaintiff could recover by showing that "the product contains a substance or ingredient which has a tendency to affect injuriously an appreciable number of people, though fewer in number than the number of normal buyers."\textsuperscript{247} Apparently this means that plaintiff must show that an appreciable number of those who receive a negative result on the recommended patch test are affected.\textsuperscript{248}

Since it is necessary to show in an implied warranty case, as in one based on negligence, a substantial or appreciable class, the process of determining whether the class is large enough to create a duty to warn probably should be similar in each type of case. In Howard v. Avon Products, Inc.\textsuperscript{249} where recovery was sought on both negligence and warranty counts, the court in finding that a substantial class was not affected did not seem to differentiate between the two counts. In a negligence case, as has been shown, there must be consideration not only of percentages but of the gravity of the injury, and of the ease with which an effective warning can be given.\textsuperscript{250} Assuming these factors also apply in a warranty case, the only difference as to proof in a warranty case is that the plaintiff need not establish negligence, and, in that connection, it would seem that the plaintiff need not show that the defendant knew or should have known of the existence of the substantial class. It should be enough that such a class in fact exists, for knowledge of the seller is not ordinarily essential for warranty liability.\textsuperscript{251} The state of the seller's knowledge is not relevant for the

\textsuperscript{241} A.2d at 75.
\textsuperscript{242} 140 Mass. 552, 165 N.E.2d 109 (1960).
\textsuperscript{243} 61 Wash. 2d 347, 378 P.2d 298 (1963).
\textsuperscript{244} 378 P.2d at 304-05.
\textsuperscript{245} Id. at 305.
\textsuperscript{246} 147 Conn. 460, 162 A.2d 513 (1960).
\textsuperscript{247} 162 A.2d at 516.
\textsuperscript{248} This interpretation is borne out by a later decision that there is no breach of warranty when "due and ample warning of any harmful and deleterious ingredient" is given. Hamon v. Diglioni, 148 Conn. 710, 174 A.2d 294 (1961).
\textsuperscript{249} 135 Colo. 444, 395 P.2d 1007 (1964).
\textsuperscript{250} See note 215 supra.
inquiry into scienter is here an inquiry into negligence, and liability for a breach of warranty is strict.\textsuperscript{2}

There is a Texas case, however, \textit{Cudmore v. Richardson-Merrill, Inc.},\textsuperscript{3} where a user of the drug MER/29 was denied recovery on grounds of implied warranty, for an injury, found by the jury to be an allergic reaction, when it also was found that at the time the plaintiff suffered injury, it was scientifically unknowable that the drug would cause cataracts in an appreciable class of persons. The opinion, assuming the truth of this finding, takes the position that at least in the case of a drug there is no liability for breach of an implied warranty unless the harmful results "ought reasonably to have been foreseen by a person of ordinary care in an appreciable number of persons."\textsuperscript{4} Likewise, in a Washington case it was stated that before recovery there must be a finding that a specific ingredient in the hair tint involved was harmful to a "reasonably foreseeable and appreciable class or number of potential users of the product."\textsuperscript{5} It has been said in this connection that, "while knowledge of danger is not ordinarily a prerequisite to liability for breach of warranty, the cases in this area [allergy] seem to stress the lack of such knowledge on the part of the supplier.\textsuperscript{6}

One writer suggests it is only in the case of cosmetics that the allergic plaintiff can recover, in many jurisdictions, simply by showing that an appreciable class is affected, and that foreseeability should be required in drug cases, where an allergic reaction or side effect is involved, as in the \textit{Cudmore} case.\textsuperscript{7} In support of this, it is urged that production of new drugs will be discouraged if, as an Oregon court puts it, the price of drugs must "include an amount sufficient to create a fund to compensate those who suffer unanticipated harm from the use of a beneficial drug."\textsuperscript{8} On the other hand it must be considered whether imposition of liability will reduce injuries by inducing manufacturers to expand their research as to possible allergic injuries or side effects. The inability of the person injured by an unpredictable allergic reaction, or side effect, to administer the risk himself should also be taken into account.

Where strict liability is asserted under the \textit{Restatement},\textsuperscript{9} it still is necessary, as in an implied warranty case, to show the presence of a substantial or appreciable class of allergic users or consumers. So it is said that where 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

\textsuperscript{2}ER 2 HARPER & JAMES § 28.20, at 1581; see, however, Howard v. Avon Prods., Inc., 155 Colo. 444, 395 P.2d 1007 (1964), where the court discusses the defendant's lack of knowledge or ability to know in finding "no reasonably foreseeable class" of allergic users in connection with the warranty count.

\textsuperscript{3}398 S.W.2d 640 (Tex. Civ. App. 1965), error ref. n.r.e., cert. denied, 385 U.S. 1003 (1967).

\textsuperscript{4}Id. at 643.


\textsuperscript{6}See 3 FRUMER & FRIEDMAN § 29.03(1).


\textsuperscript{9}2 RESTATEMENT (SECOND) OF TORTS § 402A (1965).
not expect to find in the product, the seller is required to give warning against it.\textsuperscript{500}

It would seem that since this section of the \textit{Restatement} imposes liability without proof of negligence, it should not be necessary to show more than that the product is "in a defective condition unreasonably dangerous"\textsuperscript{501} by reason of a risk to a substantial class of allergic users. A comment goes on to say, however, that in the allergy situation the duty to warn arises only where the seller "has knowledge or by the application of reasonably developed human skill and foresight should have knowledge, of the presence of the ingredient and the danger."\textsuperscript{502} Under this view the liability imposed by the \textit{Restatement} in the allergy situation is not in fact very strict, and resembles negligence liability more than it does strict liability based on breach of warranty. It may be, however, that the courts will decide not to follow this particular comment, which seems to conflict with the basic provision of the \textit{Restatement} imposing liability for defective and unreasonably dangerous products even though "the seller has exercised all possible care in the preparation and sale of his product."\textsuperscript{503}

As indicated earlier, consumer protection statutes such as the Federal Food, Drug and Cosmetic Act and the Federal Hazardous Substances Act\textsuperscript{504} now protect against sensitizers which produce allergic reactions. Where plaintiff can establish that he has been harmed by what the court finds to be a "strong sensitizer" within the meaning of the statute, and as specified in regulations thereunder, or that the labeling and warning provisions of the statute involved have not been observed, he has established a violation of the Act. This ordinarily is negligence per se, or at least is evidence of negligence.\textsuperscript{505}

\textbf{Nature of Warning.} Courts requiring a warning to allergic users of a product give little indication of what kind of warning should be given. Where a preliminary patch test is an effective means of determining whether a person is allergic to the product, it is clear that directions should be given for taking the needed test.\textsuperscript{506}

Where, as in the case of a deodorant, there may be no practical way of testing to determine whether a person is allergic to the product, it is clear that directions should be given for taking the needed test.\textsuperscript{506}

As indicated earlier, consumer protection statutes such as the Federal Food, Drug and Cosmetic Act and the Federal Hazardous Substances Act\textsuperscript{504} now protect against sensitizers which produce allergic reactions. Where plaintiff can establish that he has been harmed by what the court finds to be a "strong sensitizer" within the meaning of the statute, and as specified in regulations thereunder, or that the labeling and warning provisions of the statute involved have not been observed, he has established a violation of the Act. This ordinarily is negligence per se, or at least is evidence of negligence.\textsuperscript{505}

\textsuperscript{500} Id. § 402A, comment j.
\textsuperscript{501} Id. § 402A.
\textsuperscript{502} Id. § 402A, and comment j.
\textsuperscript{503} See id. § 402A (2) (A).
\textsuperscript{504} See notes 183, 184 supra, and accompanying text.
\textsuperscript{505} See W. Prosser, \textit{Torts} § 35, at 202 (3d ed. 1964); Comment, Products Liability Based on Violation of Statutory Standards, 64 Mich. L. Rev. 1388 (1966).
\textsuperscript{507} 244 F.2d 53 (2d Cir. 1957) (applying Massachusetts law), discussed at note 215 supra.
who, unknown to themselves, might have an allergy to the named sensitizer. Such a warning would, however, be useful to those who know they are allergic to the named sensitizer, and even where such knowledge is lacking, the warning of a possible allergic reaction would help those who apprehend such reactions and avoid known sensitizers. Even though a person has no apprehension of allergic reactions, and goes ahead and uses the product to his detriment, a warning of the risk of allergic reactions may lead him immediately to discontinue use of the product after a rash appears, and promptly seek medical aid to lessen the severity or duration of the reaction.

Where the sensitizer comes within the scope of the Federal Pure Food and Drug Act, the Federal Hazardous Substances Act, or other legislation to protect consumers, the labeling and warning precautions, including those for preliminary tests, must of course conform to any requirements laid down in the statute or regulations. The giving of such warnings and instructions will not always protect the defendant, however, since more adequate instructions or warnings may be required in a particular jurisdiction under common law principles.

It is evident that the duty to give warnings and directions for use is expanding and may arise not only under negligence principles, but in strict liability cases. The duty may extend to unusual but foreseeable uses of the product, and to unrepresentative users, such as those allergic to the product. With the growing concern for consumer protection, and the increasing number of suits based on injury from defective products, doubtless the courts will continue to enlarge the areas where a duty to warn or instruct arises, and indicate with increased precision what constitutes an adequate warning or direction for use in particular situations.

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869 See notes 23, 173-77 supra.