Learned Intermediaries and Sophisticated Users: Encouraging the Use of Intermediaries to Transmit Product Safety Information

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LEARNED INTERMEDIARIES AND SOPHISTICATED USERS: ENCOURAGING THE USE OF INTERMEDIARIES TO TRANSMIT PRODUCT SAFETY INFORMATION

Richard C. Ausness†

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INTRODUCTION

The general rule, under both negligence principles and strict products liability, is that a producer or supplier is required to warn users or consumers of its products. In most cases, this duty can be satisfied by placing a warning label on the product itself or by providing safety information in an owner’s manual or in other literature attached to or enclosed with the product. However, there are some situations where it is difficult or impracticable to provide a direct warning to the ultimate user or consumer. In such cases, producers and suppliers should be able

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to satisfy their duty to warn by providing safety information to intermediaries who may be expected to pass this information along to the ultimate users or consumers of the product.

The drafters of the Restatement (Second) of Torts ("Restatement") have acknowledged the legitimacy of warning through intermediaries in section 388. This, in turn, has given rise to a number of specialized doctrines, such as the learned intermediary rule and the sophisticated user doctrine, which permit product producers and suppliers to warn through intermediaries in certain situations. The learned intermediary doctrine, though often criticized by legal commentators, seems to work well in the relatively narrow domain of pharmaceutical products. The sophisticated user doctrine, and related concepts commonly applied to suppliers of component parts and bulk products, is less satisfactory. Some courts employ a duty-oriented approach, which allows producers and suppliers to rely on intermediaries to convey warnings to product end users. Other courts utilize a balancing approach, but this provides little guidance to producers and suppliers about when reliance on intermediaries is appropriate and when it is not.

This article proposes a "general rule" to cover most situations where warning through intermediaries is feasible. This proposed rule would allow producers and suppliers to rely on intermediaries in virtually all cases to transmit warnings to users and consumers of products. Part I provides a brief overview of the duty to warn under negligence and strict products liability. Part II examines the caselaw on warning through intermediaries, focusing on pharmaceutical products, products designed for industrial use, component parts and bulk products. Part III discusses the feasibility of a general rule on warning through intermediaries and evaluates the advantages and disadvantages of a duty-oriented approach and a balancing approach. Finally, part IV introduces a specific proposal based on a duty-oriented approach.

I. THE DUTY TO WARN

Manufacturers and others in the distributive chain have a duty

2. See Restatement (Second) of Torts § 388 cmt. n (1965).
3. See infra part II.A.
4. See infra part II.B.1.a.
5. See infra part II.B.1.a.
6. See infra part IV.
7. See Dix W. Noel, Products Defective Because of Inadequate Directions or Warnings, 23 Sw. L.J. 256, 281 (1969) ("The duty to warn runs to those the manufacturer
to provide adequate warnings about product-related risks to foreseeable users and consumers of their products. This duty exists under both negligence and strict liability principles. Section 388 of the Restatement sets forth the duty to warn under a negligence standard. This provision declares that the supplier of a product may be held liable to foreseeable users or consumers of the product if: (1) the supplier knows, or should know, that the product could be dangerous under normal or foreseeable use; (2) the supplier realizes that prospective users or consumers may not be aware of the product’s dangerous condition; and (3) the supplier fails to exercise reasonable care to inform users or consumers about product-related risks.

Product sellers may also be held liable for failure to warn under the doctrine of strict products liability. According to section 402A of the Restatement, commercial sellers will be held liable, regardless of fault, to consumers for any personal injuries caused by products that are

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.

8. See M. Stuart Madden, The Duty to Warn in Products Liability: Contours and Criticism, 89 W. VA. L. REV. 221, 279 (1987) (“Liability for failure to provide adequate warnings may be imposed upon all entities within the chain of distribution, including not only manufacturers, but suppliers, wholesalers, distributors and retailers as well.”).

9. Product sellers also may be held liable for failing to provide proper directions or instructions. See, e.g., Edwards v. California Chem. Co., 245 So. 2d 259, 260-65 (Fla. Dist. Ct. App. 1971) (instructions on insecticide found to be inadequate because they did not advise customers to wear respirator and protective clothing while using product); Tompkins v. Log Systems, Inc., 385 S.E.2d 545, 547 (N.C. Ct. App. 1989) (reasonable person could conclude that instructions included in pre-packaged kits for construction of log homes were inadequate because they failed to explain how to make sure that building walls were plumb).


10. See Douglas R. Richmond, Renewed Look at the Duty to Warn and Affirmative Defenses, 61 Def. Couns. J. 205, 205 (1994). Failure to warn may also subject a manufacturer to liability for breach of implied warranty. See Madden, supra note 8, at 250; Candada J. Moore, Comment, Duty to Warn Within the Implied Warranty of Merchantability, 41 Ohio St. L.J. 747, 754 (1980).

11. See Restatement (Second) of Torts § 388 (1965). Each of these conditions must be met in order for there to be liability. Douglas R. Richmond, When Plain English Isn’t: Manufacturers’ Duty to Warn in a Second Language, 29 Tort & Ins. L.J. 588, 589 (1994).

defective and unreasonably dangerous. A product that is otherwise properly made, will be regarded as defective and unreasonably dangerous if the manufacturer fails to provide adequate warning in appropriate circumstances.

Many courts and commentators have concluded that the duty to warn is essentially the same under either negligence or strict liability theories. However, this view is by no means universally accepted.

14. See id. § 402A, cmt j. See also Koonce v. Quaker Safety Prods. & Mfg. Co., 798 F.2d 700, 716 (5th Cir. 1986) ("The absence of adequate warnings or directions may render a product defective and unreasonably dangerous, even if the product has no manufacturing or design defects."); Pavlides v. Galveston Yacht Basin, Inc., 727 F.2d 330, 338 (5th Cir. 1984) ("The lack of adequate warnings renders a product defective and unreasonably dangerous even though there is no manufacturing or design defect in the product."); Jackson v. Coast Paint & Lacquer Co., 499 F.2d 809, 811 (9th Cir. 1974) ("A product may be perfectly manufactured and meet every requirement for its designed utility and still be rendered unreasonably dangerous through failure to warn of its dangerous characteristics."); Lee v. Butcher Boy, 215 Cal. Rptr. 195, 201 (Cl. App. 1985) ("Even if the product is faultlessly made, it may be found defective if unreasonably dangerous when placed in the hands of a user without adequate warning.").
15. See, e.g., DiPalma v. Westinghouse Elec. Corp., 938 F.2d 1463, 1466 (1st Cir. 1991) ("The duty to warn, the violation of which is actionable by means of the so-called strict liability cause of action, is measured... by the same standard as the duty to warn that is enforceable in a negligence cause of action."); Smith v. Walter C. Best, Inc., 927 F.2d 736, 741 (3d Cir. 1990) ("The standard imposed upon the defendant meeting a claim of strict liability based upon a failure to warn is the same as that imposed upon the defendant faced with a claim of negligent failure to warn."); Pottle v. Up-Right, Inc., 628 A.2d 672, 675 (Me. 1993) ("Regardless of whether a 'failure to warn is phrased in terms of negligence or strict liability, the analysis... is basically the same."); Germann v. F.L. Smithe Mach. Co., 381 N.W.2d 503, 508 (Minn. Ct. App. 1986) ("In failure to warn cases, there is essentially no distinction between negligence and strict liability.").
16. See M. STUART MADDEN, 1 PRODUCTS LIABILITY § 10.3 (2d ed. 1988) ("In the context of failure to warn jurisprudence, the functional characteristics of strict liability and negligence theories are almost indistinguishable."); Robert D. Cooter, Defective Warnings, Remote Causes, and Bankruptcy: Comment on Schwartz, 14 J. LEGAL STUD. 737, 740 (1985) ("The two verbal formulations are materially equivalent because the scope of responsibility and the extent of liability are the same."); Madden, supra note 8, at 225. ("In the context of defining the suppliers' duty to warn, however, the jurisprudence of negligence and strict liability have converged."); Richmond, supra note 11, at 591. ("In the warnings context negligence and strict liability have converged.").
17. See Mark M. Hager, Don't Say I Didn't Warn You (Even Though I Didn't): Why the Pro-Defendant Consensus on Warning Law Is Wrong, 61 TENN. L. REV. 1125, 1130-34 (1994) (criticizing the view that strict liability and negligence theories are the same in failure to warn cases); Patricia R. v. Sullivan, 631 P.2d 91, 102 (Alaska 1981) ("We are in accord with those authorities which hold that in strict liability cases the need for and the sufficiency of a warning should be expressed without reference to negligence principles."); Little v. PPG Indus., Inc., 594 P.2d 911, 914 (Wash. 1979) ("It is the adequacy of the warning which is given, or the necessity of such a warning, which must command the jury's... regards as defective and unreasonably dangerous.")
Some courts, for example, impute knowledge of product-related risks to manufacturers under strict liability, but not under negligence, particularly in asbestos cases. However, most courts reject this "hindsight" approach and merely require manufacturers to warn of risks that are "scientifically knowable" at the time the product is marketed.

In general, there is no duty to warn, under either negligence or strict products liability, about product-related hazards that are known to the general public. Manufacturers have invoked this "obvious hazard" principle to defeat claims arising from the use of such diverse products as lawn mowers, above-ground swimming pools, alcohol-
ic beverages, motor vehicles, children's toys, and other familiar, but potentially dangerous, products. It should be noted, however, that a growing number of courts have rejected the obvious danger rule as an absolute limitation on the duty to warn. According to these courts, obviousness of risk is treated as only one factor to be considered in determining whether or not a warning should be given.

23. See Pemberton v. American Distilled Spirits Co., 664 S.W.2d 690, 693 (Tenn. 1984) (no duty to warn teenager about the health risks of drinking large quantity of undiluted grain alcohol at one time); Joseph E. Seagram & Sons, Inc. v. McGuire, 814 S.W.2d 385, 388 (Tex. 1991) (manufacturer of alcoholic beverages had no duty to warn consumers about the consequences of prolonged and excessive drinking).

24. See Westchem Agric. Chems., Inc. v. Ford Motor Co., 990 F.2d 426, 431-32 (8th Cir. 1993) (manufacturer of pickup truck owes no duty to warn consumer that improperly splicing into vehicle's electrical wiring system could cause fire); Shaffer v. AMF, 842 F.2d 893, 897-98 (6th Cir. 1988) (because danger of riding motorcycle was open and obvious, manufacturer did not have to warn user of risk of serious injuries in the event of a collision with a larger vehicle).

25. See Borjorqaez v. House of Toys, Inc., 133 Cal. Rptr. 483, 484 (Dist. Ct. App. 1976) ("Ever since David slew Goliath young and old alike have known that slingshots can be dangerous and deadly."); Bookout v. Victor Compiometer Corp., 576 P.2d 197 (Colo. App. 1978) (potential for danger inherent in BB gun is readily apparent and no warning is required); Atkins v. Aslans Dep't Store of Norman, Inc., 522 P.2d 1020, 1022 (Okla. 1974) (manufacturer is not required to warn against danger of throwing pointed darts in the direction of another person).

26. See, e.g., Bilski v. Scientific Atlanta, 964 F.2d 697, 700 (7th Cir. 1992) (maker of satellite dish had no duty to warn user about danger of climbing up on dish to remove snow from it); Argutright v. Beech Aircraft Corp., 868 F.2d 764, 766-67 (5th Cir.), cert. denied, 493 U.S. 934 (1989) (danger of unlocked pilot seat during takeoff was sufficiently obvious that airplane manufacturer, who had included seat lock inspection in preflight checklist, was not required to provide a specific warning against this risk); McPhail v. Municipality of Culebra, 598 F.2d 603, 607 (1st Cir. 1979) (danger involved in sailing boat with an aluminum mast into power line was patent and obvious); Lorfano v. Dura Stone Steps, Inc., 569 A.2d 195, 197 (Me. 1990) (dangers posed by use of steps without a handrail held to be patently obvious and apparent to all); Morrison v. Grand Forks Hous. Auth., 436 N.W.2d 221, 228-29 (N.D. 1989) (manufacturer of battery-powered smoke detector not required to warn users that product would not operate if batteries were removed).

27. See Banks v. Iron Hustler Corp., 475 A.2d 1243, 1252 (Md. Ct. Spec. App. 1984) ("[I]t is clear that the 'obviousness' of the danger is but one element in the equation."); Olson v. A.W. Cheserson Co., 256 N.W.2d 530, 537 (N.D. 1977) ("There is no valid reason for automatic preclusion of liability based solely upon 'obviousness' of danger in an action [based on fault to warn].").

28. See Horen v. Coleco Indus., Inc., 426 N.W.2d 794, 796 (Mich. Ct. App. 1988) ("Although such a determination [that the danger is obvious] may be utilized as one factor among others to conclude that the manufacturer has no duty to warn because the product is not unreasonably dangerous, the new test is whether the risks are unreasonable in light of the foreseeable injuries."); Campos v. Firestone Tire & Rubber Co., 485 A.2d 305, 309-10 (N.J. 1984) ("[I]n our state the obviousness of a danger, as distinguished from a plaintiff's subjective knowledge of a danger, is merely one element to be factored into the analysis to determine whether a duty to warn exists.").
Once a court concludes that the manufacturer has a duty to warn, it must then determine whether the warning actually given was adequate.29 An adequate warning is one that is reasonable under the circumstances.30 This is usually regarded as a question of fact for the jury to decide31 and involves a consideration of a number of factors: First, the warning's factual content must be adequate. A warning must provide information about all significant risks associated with the product's use,32 and must reveal the actual likelihood and gravity of such risks when they are known by the manufacturer.33 Second, the physical format of the warning is also important, and a warning will be considered inadequate if its print size is too small to be noticed by the user,34 or if the warning is not placed in a prominent position on the

30. See Brochu v. Ortho Pharmaceutical Corp., 642 F.2d 652, 657 (1st Cir. 1981) ("An adequate warning is one reasonable under the circumstances."); Graham v. Wyeth Lab., 666 F. Supp. 1483, 1498 (D. Kan. 1987) ("An adequate warning is one that is reasonable under the circumstances."); Ortho Pharmaceutical Corp. v. Chapman, 388 N.E.2d 541, 553 (Ind. Ct. App. 1979) ("To be adequate, a warning must be reasonable under the circumstances.").
31. See Gracyalny v. Westinghouse Elec. Corp., 723 F.2d 1311, 1316 (7th Cir. 1983) ("We hold that the adequacy of a particular warning is an issue of fact to be determined by the jury."); Bryant v. Technical Research Co., 654 F.2d 1337, 1345 (9th Cir. 1981) ("The adequacy of a warning under products liability is a question of fact to be left to the jury."); Alm v. Aluminum Co. of Am., 717 S.W.2d 588, 592 (Tex. 1986) ("The adequacy of a warning is a question of fact to be determined by the jury."). But see Werckenthin v. Bucher Petrochemical Co., 618 N.E.2d 902, 909 (Ill. Ct. App. 1993) (holding as a matter of law that a warning was adequate).
32. See Little v. Liquid Air Corp., 939 F.2d 1293, 1300 (5th Cir. 1991) ("Because the principal purpose of the warning is to permit the user to make an informed decision whether to expose himself to the risks of the product, however, a manufacturer or distributor 'fulfills its duty to warn in this context only if it warns of all dangers associated with its products of which it has actual or constructive knowledge.'") (quoting Jackson v. Johns-Manville Sales Corp., 750 F.2d 1314, 1320 (5th Cir. 1985)); Lindsay v. Ortho Pharmaceutical Corp., 637 F.2d 87, 91 (2d Cir. 1980) ("The manufacturer's duty is to warn of all potential dangers which it knew, or in the exercise of reasonable care should have known, to exist."); Deines v. Vermeer Mfg. Co., 755 F. Supp. 350, 353 (D. Kan. 1990) ("The manufacturer's duty is to warn of all potential dangers which it knew, or in the exercise of reasonable care should have known, to exist.").
33. See Martinkovic v. Wyeth Lab., Inc., 669 F. Supp. 212, 216 (N.D. Ill. 1987) (warning provided to prescribing physician of DTP vaccine could be considered inadequate because it characterized risk of convulsions as "exceedingly rare," when some studies showed the risk to be as high as one in 1,750).
34. See Gardner v. Q.H.S., Inc., 448 F.2d 238, 243 (4th Cir. 1971) (warning about flammability of hair rollers held to be inadequate because it was in the same print size as other material on the product's label); Spruill v. Boyle-Midway, Inc., 308 F.2d 79, 86 (4th Cir. 1962) (warning on furniture polish found to be inadequate because print was too small to attract attention of users).
Third, a warning must be phrased with a degree of intensity that is commensurate with the danger and must not be ambiguous, equivocal, or contradictory. Fourth, an effective warning must be written in such a way that it can be easily understood by its intended audience. A warning that uses technical language not easily understood by members of the general public may not be adequate.

35. See D'Arienzo v. Clairol, Inc., 310 A.2d 106, 111 (N.J. Super. 1973) (jury issue presented as to adequacy of warning which placed information about risk of allergic reaction to hair dye at the end of instructions on how to apply patch test).


37. See Givens v. Lederle, 556 F.2d 1341, 1345 (5th Cir. 1977) (oral polio vaccine warning characterizing risk of paralysis as one in three million found to be potentially inadequate because it also expressed doubt about whether there was any causal link at all between vaccine and paralysis); Bean v. Ross Mfg. Co., 344 S.W.2d 18, 23-24 (Mo. 1961) (describing drain solvent as “effervescent” not sufficient to warn user that violent explosion might result when product came into contact with water in a confined space); Mahr, 390 N.E.2d at 1231 (oral contraceptive warning concluding that causal connection had been established between birth control pills and strokes diluted the effect of warning).

An otherwise satisfactory warning may be diluted by qualifying language or accompanying representations of safety that blunt the effects of the warning. See McFadden v. Haritatos, 448 N.Y.S.2d 79, 81 (N.Y. App. Div. 1984); Givens, 556 F.2d at 1345 (expression of doubt about causal connection between oral polio vaccine and paralysis diluted the effect of warning); Salmon, 520 F.2d at 1363 (expression of doubt about whether chloramphenicol caused aplastic anemia diluted the effect of disclosure about the need to take precautions against anemia); Maize v. Atlantic Ref. Co., 41 A.2d 850, 852 (Pa. 1945) (the words “Safety-Kleen” prominently displayed on the product’s label held to have diluted the effect of the warning).

A warning may also be diluted by subsequent advertising and promotional activities which downplay the product’s risks. See Stevens v. Parke, Davis & Co., 507 P.2d 653, 662 (Cal. 1973) (warning provided to physicians by drug company about the risk of aplastic anemia from administration of Chloromycetin antibiotic to patients was nullified by subsequent overpromotion); Incolligo v. Ewing, 282 A.2d 206, 220 (Pa. 1971) (warning provided to physicians by drug company about the risk of aplastic anemia from administration of Chloromycetin antibiotic to patients was nullified by subsequent overpromotion).

38. Schwartz & Driver, supra note 9, at 61. See Bryant v. Technical Research Co., 654 F.2d 1337, 1345-46 (9th Cir. 1981) (“An important factor in evaluating the adequacy of a warning is the clarity of the warning.”).

39. See MacDonald v. Ortho Pharmaceutical Corp., 475 N.E.2d 65, 71-72 (Mass. 1985) (warning that oral contraceptive might cause “cerebral thrombosis” did not adequately communicate the risk of a stroke to users). In addition, some courts have concluded that warnings printed solely in English may not be sufficient. Those that failed to use pictograms or Spanish when the expected users of the product were known to be incapable of understanding an English warning were inadequate. See Hubbard-Hall Chem. Co. v.
Finally, an otherwise acceptable warning may be found inadequate if it has not been communicated through the most effective channels.40

II. RELIANCE ON INTERMEDIARIES: A DOCTRINAL OVERVIEW

As mentioned above, section 388, comment n, of the Restatement describes in general terms the circumstances under which a product supplier may rely on intermediaries to transmit safety information to users or consumers. In addition to section 388, there are several doctrines that permit product suppliers to warn through intermediaries in certain situations. The first of these, the learned intermediary rule, is applicable to sales of pharmaceutical products. The second doctrine, the sophisticated user doctrine, applies primarily to commercial transactions. Each of these doctrines will be examined in some detail below.

Silverman, 340 F.2d 402, 405 (1st Cir. 1965) ("[T]he jury could reasonably have believed that defendant should have foreseen that its admittedly dangerous product would be used by, among others, persons like plaintiff's intestates, who were farm laborers, of limited education and reading ability, and that a warning . . . would not, because of its lack of a skull and bones or other comparable symbols or hieroglyphics, be 'adequate.'"); Stanley Indus., Inc. v. W.M. Barr & Co., 784 F. Supp. 1570, 1576 (S.D. Fla. 1992) ("In light of the defendants' joint advertising in Miami's Hispanic media and the nature of the product, this court likewise finds that it is for the jury to decide whether the defendant could have foreseen that boiled linseed oil would be used by persons such as Gallery's Nicaraguan Spanish-Speaking unskilled laborers."); Campos v. Firestone Tire & Rubber Co., 485 A.2d 305, 310 (N.J. 1984) ("In view of the unskilled or semi-skilled nature of the work and the existence of many in the work force who do not read English, warnings in the form of symbols might have been appropriate."); but see Ramirez v. Plough, Inc., 863 P.2d 167, 173 (Cal. 1993) ("To preserve . . . uniformity and clarity, to avoid adverse impacts upon the warning requirements mandated by the federal regulatory scheme, and in deference to the superior technical and procedural lawmaking resources of legislative and administrative bodies, we adopt the legislative/regulatory standard of care that mandates nonprescription drug package warnings in English only."); Thomas v. Clairol, Inc., 583 So. 2d 108, 110-11 (La. Ct. App. 1991) ("[P]laintiff . . . had the burden to show the use [of the defendant's hair dye product] was sufficient [among illiterate consumers] that defendant should have foreseen it and provided additional warnings or other safety precautions.").

40. See Yarrow v. Sterling Drug, Inc., 263 F. Supp. 159 (D.S.D. 1967), aff'd, 408 F.2d 978 (8th Cir. 1969) (failure to use detail men to warn physicians about risk of vision loss from the use of Aralen rendered warning ineffective); Richards, 625 P.2d at 1192 (holding that a jury might conclude that changing contraindication for neomycin in package inserts and PDR might not be sufficient to communicate newly discovered danger of using antibiotic to irrigate open wounds when this use had been recommended for more than 10 years).
A. The Learned Intermediary Rule

Ordinarily, the manufacturer of a prescription drug does not have to inform a patient about drug-related dangers as long as it provides an adequate warning to the patient's prescribing physician.\(^{41}\) Warnings to physicians may be conveyed by means of a package insert, by advertisement in the *Physician's Desk Reference*, an advertisement in medical journals, direct letters to physicians, or by personal visits to physicians' offices by company representatives known as "detail men."\(^{42}\) The legal sufficiency of a particular method of communication will depend on the circumstances.\(^{43}\)

This limitation on the manufacturer's duty to warn is known as the learned intermediary rule because the physician is expected to act as an intermediary between the manufacturer and the patient.\(^{44}\) Accordingly, once the manufacturer informs the physician about drug-related risks, the burden shifts to the physician to disclose this information to the

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\(^{41}\) See Thomas v. Hoffman-LaRoche, Inc., 949 F.2d 806, 811 (5th Cir.), *cert. denided*, 504 U.S. 956 (1992) (failure to warn patient of product's risk does not render product defective or unreasonably dangerous so long as manufacturer adequately warns learned intermediary); Anderson v. McNeilab, Inc., 831 F.2d 92, 93 (5th Cir. 1987) (prescription drug manufacturer discharges its duty to warn when it reasonably informs physicians of the dangers of harm from the drug); Beyette v. Ortho Pharmaceutical Corp., 823 F.2d 990, 992 (6th Cir. 1987) (manufacturer of pharmaceutical product has a duty to warn the medical profession, not the patient, of any risks inherent in the use of a product that the manufacturer knows or should know exists); Plummer v. Lederle Lab., Div. of Am. Cyanamid Co., 819 F.2d 349, 356 (2d Cir.), *cert. denided*, 484 U.S. 898 (1987) (in the case of prescription drugs dispensed by physicians, manufacturer's obligation is to warn the physician); Swayze v. McNeil Labs., 807 F.2d 464, 470 (5th Cir. 1987) (where prescription drugs are concerned, a manufacturer's duty extends only to the physician and not to patient); Tracy v. Merrell Dow Pharmaceuticals, Inc., 569 N.E.2d 875, 878 (Ohio 1991) (where a drug has been prescribed for a patient, manufacturer discharges its duty to warn if it adequately warns the prescribing physician); *but see* Proctor v. Davis, 656 N.E.2d 23, 31 (III. App. Ct. 1995) (holding that a drug manufacturer has no duty to warn if the risk is generally known within the medical community).


\(^{43}\) Compare Wyeth Labs., Inc. v. Fortenberry, 530 So. 2d 688, 692-93 (Miss. 1988) (warning about routine risks communicated by means of package insert held to be adequate as a matter of law) with Yarrow, 263 F. Supp. at 163 (holding that manufacturer should have used detail men to communicate warning to physicians).

patient. However, if the manufacturer fails to provide an effective warning to the prescribing physician, the patient will have a direct cause of action against the manufacturer for any injuries that occur as the result of this breach of duty. Although severely criticized by some legal commentators, the learned intermediary rule continues to be recognized by the vast majority of courts.

I. Prescription Drugs

The learned intermediary rule was formulated by a federal appeals court almost thirty years ago in Sterling Drug, Inc. v. Cornish. In that case, the court offered the following rationale for requiring the manufacturer to warn the prescribing physician rather than the patient:

Moreover, in this case we are dealing with a prescription drug rather than a normal consumer item. In such a case the purchaser's doctor is a learned intermediary between the purchaser and the manufacturer. If the doctor is properly warned of the possibility of a side effect in some patients, and is advised of the symptoms normally accompa-

45. See Brooks v. Medtronic, Inc., 750 F.2d 1227, 1232 (4th Cir. 1984) ("Once adequate warnings are given to the physician, the choice of treatment and the duty to disclose properly fall on the doctor."). This duty to warn patients about risks associated with the use of a prescription drug is based on the doctrine of informed consent. See Alan R. Styles, Note, Prescription Drugs and the Duty to Warn: An Argument for Patient Package Inserts, 39 CLEV. ST. L. REV. 111, 121 (1991).

46. See Wooderson v. Ortho Pharmaceutical Corp., 681 P.2d 1038, 1050 (Kan. 1984), cert. denied, 469 U.S. 965 (1984) ("Although the duty of the ethical drug manufacturer is to warn the doctor, rather than the patient, the manufacturer is directly liable to the patient for a breach of such duty.") (quoting McEwen v. Ortho Pharmaceutical Corp., 528 P.2d 522, 529 (Or. 1974).

47. See Margaret Gilhooley, Learned Intermediaries, Prescription, Drugs and Patient Information, 30 St. Louis U. L.J. 633, 657-58 (1986) ("The change in the informed consent doctrine makes appropriate a corresponding change in the role that the physician should perform as a 'learned intermediary.'"); Susan A. Casey, Comment, Laying an Old Doctrine to Rest: Challenging the Wisdom of the Learned Intermediary Doctrine, 19 WM. MITCHELL L. REV. 931, 958 (1993) ("[T]he learned intermediary doctrine is based on medical paternalism that is inconsistent with the concept of informed consent."); Thompson, supra note 42, at 146 ("By placing the warning into the hands of the physician, who is given sole discretion to determine what risk, if any, will be communicated to the patient, the current system of manufacturer warnings perpetuates paternalism and aggravates the problem of informed consent.").


49. 370 F.2d 82 (8th Cir. 1966).
nying the side effect, there is an excellent chance that injury can be avoided.  

In *Sterling Drug*, the manufacturer was held liable because it failed to warn either the physician or the patient. However, as *Swayze v. McNeil Laboratories, Inc.* illustrates, the manufacturer's duty to warn extends only to the physician and not the patient. In *Swayze*, the victim suffered severe brain damage after receiving an overdose of fentanyl, an anesthetic drug, during an operation to remove a bullet from his leg. Although the manufacturer had warned the medical profession about the dangers of administering fentanyl without adequate supervision, the plaintiff contended that it should have provided warnings directly to patients. The court, however, firmly rejected this suggestion, declaring that the relationship between physician and patient was such that the physician, not the manufacturer, should be held responsible for advising the patient about the risks of anesthesia.

Notwithstanding the fact that the learned intermediary rule is generally applicable to prescription drugs, there are a few situations where the courts have required manufacturers to provide direct warnings to the ultimate consumers of their products. The first is where a patient receives a vaccine administered as part of a mass immunization program. Since there is rarely any personal contact between physicians and patients in such programs, it is felt that direct warnings are

50. *Id.* at 85.
51. *Id.*
52. 807 F.2d 464 (5th Cir. 1987).
53. *See also* Anderson v. McNeilab, Inc., 831 F.2d 92, 93 (5th Cir. 1987) (prescription drug manufacturer discharges its duty to warn when it reasonably informs prescribing physicians of the dangers of harm from the drug); Beyette v. Ortho Pharmaceutical Corp., 823 F.2d 990, 992 (5th Cir. 1987) (manufacturer of pharmaceutical product has a duty to warn the medical profession, not the patient, of any risks inherent in the use of a product); Plummer v. Lederle Labs., 819 F.2d 349, 356 (2d Cir.), cert. denied 484 U.S. 898 (1987) (in the case of prescription drugs dispensed by physicians, manufacturer's obligation is to warn the physician).
55. *Id.* at 469.
56. *Id.* at 470-71.
57. *See* Petty v. United States, 740 F.2d 1428, 1440 (8th Cir. 1984) (swine flu vaccine administered in mass immunization program); Reyes v. Wyeth, 498 F.2d 1264, 1270 (5th Cir.), cert. denied, 419 U.S. 1096 (1974) (polio vaccine administered through mass immunization program); Davis v. Wyeth Lab., 399 F.2d 121, 122 (9th Cir. 1968) (polio vaccine administered through mass immunization program); Cunningham v. Charles Pfizer & Co., 532 P.2d 1277, 1379 (Okla. 1975) (polio vaccine administered through mass immunization program).
necessary to allow patients to make informed choices about the risks and benefits of immunization.58

A few cases have exempted oral contraceptives from the reach of the learned intermediary rule.59 For example, in MacDonald v. Ortho Pharmaceutical Corp., the plaintiff alleged that oral contraceptive pills manufactured by the defendant caused a stroke.60 Although the manufacturer warned about the danger of "abnormal blood clotting" in a package insert which accompanied the pills, the plaintiff argued that the warning was not sufficient to inform her about the risk of a stroke.61 On appeal from a jury verdict in the plaintiff's favor, the Massachusetts Supreme Court affirmed that the manufacturer owed a duty to warn the patient directly of the dangers inherent in the use of birth control pills.62

However, the reasoning of the oral contraceptive cases has generally not been extended to intrauterine devices ("IUDs").63 Odom v. G.D. Searle & Co. is illustrative of the prevailing view.64 The plaintiff in Odom became sterile as the result of two ectopic pregnancies allegedly caused by an IUD manufactured by the defendant.65 The trial court granted the defendant's motion for summary judgment.66 Affirming the lower court's decision, a federal appeals court declared that the learned intermediary rule was applicable to IUD cases.67 The court concluded that the plaintiff should not be allowed to challenge to

58. Casey, supra note 47, at 949.
60. MacDonald, 475 N.E.2d at 66.
61. Id. at 66-67.
62. Id. at 68.
64. 975 F.2d 1001 (4th Cir. 1992).
65. Id. at 1001-02.
66. Id. at 1003.
67. Id. ("It is plain that Mrs. Odom's claim is governed by the 'learned intermediary' doctrine.").
the sufficiency of the warning since the manufacturer had fully informed
the physician about the risk.68

2. Medical Devices and Implants

Recently, a number of courts have extended the learned interme-
diary rule to medical devices and prosthetics.69 For example, in Brooks
v. Medtronic, Inc., the plaintiff sued the manufacturer of a cardiac
pacemaker which failed shortly after being implanted in his body.70
The failure occurred because the lead of the pacemaker became
dislodged from the plaintiff’s heart tissue causing the pulse generator to
send electrical impulses at the wrong times.71 The plaintiff claimed,
inter alia, that the manufacturer was negligent because it had failed to
warn him about the risk of lead dislodgement.72

On appeal from a judgment for the defendant, the federal circuit
court concluded that the manufacturer did not have to warn the plaintiff
directly.73 The court observed that the pacemaker was chosen as the
result of an individualized decision by the plaintiff’s physician in much
the same manner that chemical drugs are prescribed.74 Distinguishing
this decisionmaking process from the dispensing of vaccines in mass
immunization programs, the court declared that “each pacemaker
candidate presents different problems requiring individualized profes-
sional judgments about lead models and generator units.”75 In
addition, the court in Brooks emphasized the physician’s role as a filter
of information so that cardiac patients could be protected against the

68. Id. at 1063-04.
69. See Willett v. Baxter Int’l, 929 F.2d 1094, 1098 (5th Cir. 1991) (artificial heart
valve); Phelps v. Sherwood Med. Indus., 836 F.2d 296, 303 (7th Cir. 1987) (heart catheter);
Attempts by manufacturers of nonpharmaceutical products to invoke the learned
intermediary rule have been largely unsuccessful. See Hall v. Ashland Oil Co., 625 F.
Supp. 1515, 1519 (D. Conn. 1986) (“The validity of applying the learned intermediary
document in the area of employer/employee relationships is far from self-evident.”);
document of responsible intermediary should not be applied to the facts of this case for the
reason that there appears to be several significant distinctions between the case of the
physician, as in Wofleruber, and PRIDE, as in this case, which warrant such limitation.”).
70. 750 F.2d 1227, 1228-29 (4th Cir. 1984).
71. Id. at 1229.
72. Id.
73. Id. at 1222.
74. Id.
75. Brooks, 750 F.2d at 1232.
undue stress.\textsuperscript{76} For these reasons, the court affirmed the lower court's judgment for the manufacturer.\textsuperscript{77}

A number of courts have also limited the manufacturer's duty to warn in cases where medical implants or protheses are involved.\textsuperscript{78} Most of these decisions have involved silicone gel breast implants. \textit{Lee v. Baxter Healthcare Corp.} is illustrative.\textsuperscript{79} The litigation arose as the result of injuries suffered by the plaintiff when a breast implant ruptured.\textsuperscript{80} The plaintiff claimed that the manufacturer failed to warn her of this risk.\textsuperscript{81} The court, however, ruled that no warning to the patient was required as long as one was communicated to the prescribing physician.\textsuperscript{82} The court declared that physicians were in a better position to evaluate warnings and interpret them for their patients in the case of implants, just as they were in the case of drugs and medical devices.\textsuperscript{83} Since the manufacturer warned the plaintiff's doctor about the risk of implant rupture, the court rejected the plaintiff's failure-to-warn claim\textsuperscript{84} and granted the manufacturer's motion for summary judgment.\textsuperscript{85}

B. The Sophisticated User Doctrine and Related Concepts

The "sophisticated" or "knowledgeable" user doctrine relieves a manufacturer of its duty to warn the ultimate user if the immediate purchaser is knowledgeable about product-related hazards.\textsuperscript{86} Courts apply this doctrine in two different situations. The first situation involves \textit{professional users} of a product. Virtually all courts agree that the manufacturer has no duty to inform professional users about

\begin{itemize}
\item \textsuperscript{76} Id.
\item \textsuperscript{77} Id.
\item \textsuperscript{79} 721 F. Supp. 89 (D. Md. 1989).
\item \textsuperscript{80} Id. at 91-92.
\item \textsuperscript{81} Id. at 94.
\item \textsuperscript{82} Id. at 95.
\item \textsuperscript{83} Id.
\item \textsuperscript{84} \textit{Lee}, 721 F. Supp. at 95 ("Consequently, Baxter had no duty to warn Ms. Lee, and her claims for failure to warn must fail as a matter of law.").
\item \textsuperscript{85} Id. at 96.
\end{itemize}
product-related risks that they should already know about.\(^{87}\) The second situation involves knowledgeable *purchasers* of products acquired for industrial or commercial use. Courts invoke the doctrine in this context to relieve producers and suppliers of the duty to warn employees of the purchaser\(^{88}\) and others about product-related risks.\(^{89}\) The discussion below will focus on this latter situation.

It should be noted at the outset that some courts treat the manufacturer's duty to warn as nondelegable and, therefore, refuse to apply the sophisticated user doctrine in any situation.\(^{90}\) For example, in *Sheehan v. Cincinnati Shaper Co.*, an injured worker brought suit against the manufacturer of metal shearing machine that had been

\(^{87}\) See Beck v. Somerset Technologies, Inc., 882 F.2d 993, 997 (5th Cir. 1989) (reasonable jury could find that experienced operator was aware of inherent danger posed by unguarded rotating steel cylinders on rewinding machine at paper mill); Todd Shipyards Corp. v. Hercules, Inc., 859 F.2d 1224, 1226 (5th Cir. 1988) (no duty to inform ship repairer that thermal barrier cloth could burn); Spankle v. Bower Ammonia & Chem. Co., 824 F.2d 409, 412-13 (5th Cir. 1987) (no duty to warn knowledgeable worker about danger of exposure to anhydrous ammonia); Loughan v. Firestone Tire & Rubber Co., 749 F.2d 1519, 1525 (11th Cir. 1988) (tire manufacturer not required to inform experienced mechanic about the danger of mismatching multipiece rim-wheel assemblies); Wansor v. George Hantscho Co., 595 F.2d 218, 221 (5th Cir. 1979) (no duty to inform print shop employee about danger of injury from printing press); Baughman v. General Motors Corp., 627 F. Supp. 871, 877 (D.S.C. 1985), aff'd, 780 F.2d 1131 (4th Cir. 1986) (no duty to warn tire mechanic of the danger of explosive separation of multipiece wheel rim assembly); Bakunas v. Life Pack, Inc., 531 F. Supp. 89, 92 (E.D. La. 1982), aff'd, 701 F.2d 946 (5th Cir. 1983) (professional stunt man was aware of the risk of using an air cushion to absorb impact from 323-foot fall); Lockett v. General Elec. Co., 376 F. Supp. 1201, 1209 (E.D. Pa. 1974), aff'd, 511 F.2d 1394 (3d Cir. 1975) (supplier of driveshaft gear not required to warn shipbuilder's employees about dangers known to assemblers' profession); McCaleb v. Mackey Paint Mfg. Co., 343 So. 2d 511, 514 ( Ala. 1977) (manufacturer of flammable liquid not required to warn machinery operators about low flash point of product); Henderson Bros. Stores, Inc. v. Smilee, 120 Cal. App. 3d 903, 917 (1981) (roofers were generally aware of the risk of fire from "tar kettles" containing heated asphalt).


90. See Brown v. Caterpillar Tractor Co., 741 F.2d 656, 660 (3d Cir. 1984) ("A holding that the manufacturer's responsibility runs to the ultimate consumer is in accordance with Pennsylvania's justification for the imposition of strict liability, namely, risk-spreading."); Minert v. Harsco Corp., 614 P.2d 686, 691 (Wash. Ct. App. 1980) ("We agree that the manufacturer has a duty to warn the ultimate user of any dangers in its product (other than those that are open and obvious). This duty is non-delegable.").
manufactured by the defendant without a safety guard over the blade. The defendant claimed that it had warned the plaintiff's employer about the danger and had offered to install a safety guard on the machine. The court, however, refused to exculpate the defendant on this basis and declared that the defendant had a duty to warn the plaintiff, the ultimate user of the product, and thus, its alleged warning to the plaintiff's employer was not sufficient to impute knowledge of the risk to the plaintiff. Consequently, the court in Sheehan affirmed a jury verdict for the plaintiff.

Another group of courts recognize the sophisticated user defense in negligence actions, but reject the doctrine when it is raised in strict products liability cases. The apparent basis for this distinction is that under a theory of strict liability, knowledge that an employer will fail to warn its employees is imputed to a manufacturer by means of a hindsight test, whereas under negligence principles, a manufacturer should not be held responsible for an employer's failure to warn as long as the manufacturer's reliance is reasonable. As a New Jersey intermediate appellate court explained in Olencki v. Mead Chemical Co.:

Knowledge of the risk that employers may not adequately warn their employees is imputed to the defendants in a strict liability action. Thus, in a strict liability action against a manufacturer, the manufacturer cannot be absolved of the duty to warn. However, under negligence law, knowledge of the risk that an employer will not warn its employees is not imputed to a manufacturer.

Thus, in states which distinguish between negligence and strict liability, plaintiffs can avoid the sophisticated user doctrine by predicating their

92. Id. at 1354-55.
93. Id. at 1355.
94. Id. at 1356.
95. See Whitehead v. St. Joe Lead Co., 729 F.2d 238, 253 (3d Cir. 1984) ("Because knowledge of the risk that the vendee may not warn is imputed under section 402A, such cases have no applicability to strict liability for failure to warn."); Russo v. Abex Corp., 670 F. Supp. 206, 207 (E.D. Mich. 1987) (citing Menna v. Johns-Manville Corp., 585 F. Supp. 1178, 1184-85 (D.N.J. 1984), aff'd, 772 F.2d 895 (3d Cir. 1985)) ("[T]he sophisticated user defense does not exist under strict liability in tort principles because, in that context, a seller is duty-bound to warn all foreseeable users and the risk of an employer's failure to warn employees is one of the risks imputed to the seller as a matter of law.").
96. See Menna, 585 F. Supp. at 1185 ("As knowledge of the risk that Owens-Corning may not warn its employees is imputed to [the] defendants [under strict liability], they cannot absolve themselves of this duty [to warn] by relying on Owens-Corning's sophistication.").
failure-to-warn claims on strict liability instead of relying on negligence as a liability theory.

1. The Duty Approach and the Balancing of Factors Approach

Courts that recognize the sophisticated user doctrine generally apply one of two approaches. Under the "duty" approach, the duty to warn shifts to each succeeding purchaser of the product. Thus, a manufacturer who provides adequate safety information to its immediate vendee thereby satisfies its duty to warn and is not responsible if that information fails to reach end users of the product. The second approach relies on the balancing test employed by section 388, comment n, of the Restatement. Under this approach, a manufacturer who provides safety information to its immediate vendee is relieved of liability only if its conduct is deemed to be reasonable in light of the factors enumerated in comment n.

98. One student commentator identified a third position which he describes as a "mixed duty/Restatement approach." See Willner, supra note 89, at 605-06. Under this approach, a court balances a variety of factors to determine whether the producer's or supplier's reliance on the intermediary was reasonable. Willner, supra note 89, at 605-06. If this reliance is determined to be reasonable, the court would then conclude that the producer or supplier had no duty to provide direct warnings to end users of the product. Willner, supra note 89, at 605-06.


100. See id. at 1446 ("[W]henever a third party has a duty to warn of a dangerous condition in the workplace, that duty is discharged by informing the employer of the dangerous condition—warning to each of the employer's individual employees who may be threatened by the dangerous condition then becomes the responsibility of the employer."); Younger v. Dow Corning Corp., 451 P.2d 177, 184 (Kan. 1969) ("[T]he manufacturer of a product which is potentially hazardous to health and who gives adequate warning of such potential hazard, by label or otherwise, to its immediate vendee, an industrial user, has no additional duty to warn the vendee's employee of such hazards, and is not liable in a negligence action to such employee for failure to do so.") (emphasis in original); Jodway v. Kennametal, Inc., 525 N.W.2d 883, 889 (Mich. Ct. App. 1994) ("[T]he suppliers could reasonably rely on the purchaser/employer to warn its employees without the suppliers having actual knowledge that such warnings were indeed being given.").


a. The Duty Approach

A number of states employ a duty analysis in connection with the sophisticated user doctrine. In these states, the manufacturer’s duty ordinarily runs only to its immediate vendee; the vendee, in turn, is required to warn the next party in the chain of distribution. Furthermore, even if the manufacturer does not provide adequate product safety to its vendee, it is still relieved of liability if its vendee is already aware of the risk and fails to warn end users of the product.

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103. See Willner, supra note 89, at 590.
104. See Willner, supra note 89, at 591-92.
105. See Scallan v. Duriron Co., 11 F.3d 1249, 1252 (5th Cir. 1994) (pump manufacturer not required to warn about danger of inhaling chlorine); Washington v. Department of Transp., 8 F.3d 396, 300-01 (5th Cir. 1993) (manufacturer of wet-dry vacuum cleaner owed no duty to warn employee of sophisticated user, such as plaintiff’s employer, about explosion from sparks emitted by the vacuum cleaner); Rusin v. Glendale Optical Co., 805 F.2d 650, 654 (6th Cir. 1986) (maker of protective eyeglasses is not obligated to inform employee about the superior impact resistance of plastic glasses when employer was “independently skilled in the intricacies of protective spectacles”); Marshall v. H.K. Ferguson Co., 623 F.2d 882, 887 (4th Cir. 1980) (suit against manufacturer of breeding equipment dismissed because employer was knowledgeable about operation of the equipment); McWaters v. Steel Serv. Co., 597 F.2d 79, 80 (6th Cir. 1979) (supplier of steel rods not liable for failing to warn construction company employee that improperly “guyed” rods might collapse); Jacobson v. Colorado Fuel & Iron Corp., 409 F.2d 1263, 1271-72 (9th Cir. 1969) (manufacturer of steel strand was not required to warn that the strand might snap during pre-stressing operation when victim’s employer was already aware of the risk); Marker v. Universal Oil Prods., 250 F.2d 603, 606 (10th Cir. 1957) (supplier of catalyst used in construction of petroleum refining vessel not required to warn victim’s employer about danger of asphyxiation from carbon monoxide gas generated by the catalyst); Cruz v. Texaco, Inc., 589 F. Supp. 777, 780 (S.D. Ill. 1984) (seller of truck designed to transport heavy equipment had no duty to warn employee of truck company when employer was already aware of danger of driving truck too fast); Littlehale v. E.I. DuPont de Nemours Co., 268 F. Supp. 791, 799 (S.D. N.Y. 1966) (supplier of blasting caps not required to warn end users when employer was already aware of dangers associated with product); In re Asbestos Litig. (Mergenthaler), 542 A.2d 1205, 1211-12 (Del. Super. Ct. 1986) (asbestos suppliers could rely on employer, who was a sophisticated purchaser, to protect its employees against harm); Stiltjes v. Ridco Exterminating Co., 343 S.E.2d 715, 719 (Ga. Ct. App.), aff’d on other grounds, 347 S.E.2d 568 (Ga. 1986) (supplier of pesticides to professional pest control operator had no duty to warn vendee’s employees against danger of exposure to pyrethrins); Mays v. Ciba-Geigy Corp., 661 P.2d 348, 365 (Kan. 1983) (suppliers of pipe for gas pipeline have no duty to warn pipeline employees about the risk of gas explosions); Slate v. Bethlehem Steel Corp., 510 N.E.2d 249, 252 (Mass. 1987) (repairer of press was entitled to rely on employer to protect employees against injury from machine).
Learned Intermediaries

Davis v. Avondale Industries provides a good illustration of the duty approach. In Davis, a welder, who contracted lung disease as the result of inhaling fumes from the use of cadmium-based brazing rods, brought suit against the rods’ manufacturer. The plaintiff contended that the manufacturer should have warned her about the dangers of fumes emitted by the brazing rods. It appears that the defendant did not warn either the plaintiff or her employer but assumed that the employer would act to protect its employees. The trial court refused the defendant’s proposed instruction on the sophisticated user doctrine and the jury held in the plaintiff’s favor. However, this decision was reversed on appeal.

The federal appeals court agreed with the defendant that the plaintiff’s employer was a sophisticated purchaser and user of cadmium-based brazing rods and, as such, should have been familiar with the product’s inherent risks. In addition, the court found that since its vendee owed an independent duty to maintain a safe workplace environment, the defendant could reasonably assume that the employer would take adequate precautions to assure the safety of its employees. Under these circumstances, the court ruled, the manufacturer was not required to take any action on its own to protect the vendee’s employees.

b. The Restatement’s Balancing of Factors Approach

The balancing of factors approach, which is based on the Restatement section 388, comment n, focuses on the overall reasonableness of the manufacturer’s conduct. According to comment n, one factor

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106. 975 F.2d 169 (5th Cir. 1992).
107. Id. at 171.
108. Id.
109. Id. at 174.
110. Id. at 171.
111. Davis, 975 F.2d at 175.
112. Id. at 174.
113. Id.
114. Id.
is the reliability of the intermediary. Although the supplier may not rely upon an intermediary who is known to be irresponsible, comment n declares that the supplier may ordinarily assume that the intermediary will act responsibly and rely on him or her to convey a warning to the actual user. The magnitude of the risk is another factor. Comment n provides that the supplier must exercise even greater care in the selection of an intermediary if the chattel is likely to be extremely hazardous to the user without a proper warning. Furthermore, according to comment n, there are situations where the risk is so great that the supplier may not rely on an intermediary at all, but must provide a direct warning to the user of the chattel. The third, and final, factor is the burden or expense to the supplier of direct disclosure of safety information to the ultimate user of the chattel. Comment n observes that it may be necessary in some cases for the supplier to convey warnings directly to the users of chattels by means of appropriate labels or packaging. The assumption is that these forms of direct communication are more reliable than intermediaries and,...
therefore, should be used when they are not unduly burdensome to the supplier.

_Eagle-Picher Industries, Inc. v. Balbos_, decided by the Maryland Court of Appeals in 1992, provides a good example of this balancing of factors approach. In _Eagle-Picher_, the personal representatives of two shipyard workers who died of mesothelioma brought suit against various suppliers of asbestos insulation products. The plaintiffs argued that the defendants failed to provide adequate warnings to the workers about the dangers of exposure to asbestos fibers. The defendants could not show that they provided any warnings between 1942 and 1944, the period during which the decedents were exposed to asbestos. The court found that the defendants should have known at that time about the health risks of exposure to asbestos. At trial, the defendants sought to present a sophisticated user defense, arguing that the decedents’ employer, Bethlehem Steel Corporation, was aware of the health risks of asbestos and was in a better position to warn its workers. However, the trial court ruled that the sophisticated user doctrine was not applicable to the facts of the case, and the jury returned a verdict for the plaintiffs.

On appeal, the Maryland court emphasized that the Restatement approach focused on the defendant’s conduct, not on the intermediary’s conduct. Consequently, the fact that the intermediary was aware of the danger did not automatically relieve the supplier of its duty to warn the ultimate user of the product. Instead, the court considered a variety of factors to determine whether it was reasonable for the supplier to rely on intermediaries to warn the end users of the product. According to the court, those factors included:

(1) The dangerous condition of the product; (2) the purpose for which the product is used; (3) the form of any warnings given; (4)

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122. _Id._ at 449.
123. _Id._
124. _Id._ at 465.
125. _Id._ at 453.
126. _Eagle-Picher_, 604 A.2d at 463-64.
127. _Id._ at 464.
129. _Eagle-Picher_, 604 A.2d at 464.
130. _Id._
131. _Id._
the reliability of the third party as a conduit of necessary information about the product; (5) the magnitude of the risk involved; and (6) the burdens imposed on the supplier by requiring that he directly warn all users.\textsuperscript{132}

A review of these factors supported the trial court’s conclusion that the facts of the case did not justify submission of the sophisticated user doctrine to the jury.\textsuperscript{133} First, the defendants knew at the time that asbestos products were inherently dangerous.\textsuperscript{134} In addition, the defendants knew that the products would be sawed, broken, ripped, crushed and stirred by shipyard employees as a part of normal construction activities, thereby making exposure to asbestos dust a virtual certainty.\textsuperscript{135} Moreover, the defendants made no attempt to warn either Bethlehem or its employees during the period in question.\textsuperscript{136} Furthermore, the defendants had no reason to believe that Bethlehem was aware of the dangers of exposure to asbestos insulation products.\textsuperscript{137} The defendant knew that the magnitude of the risk of exposure to asbestos was extremely high involving as it did the likelihood of serious lung disease or even death.\textsuperscript{138} Finally, the burden of providing direct warnings to Bethlehem’s employees was not unreasonably great because the products arrived at the workplace in forms such as blocks, tubing, blankets, cloth and powder, to which labels could be easily affixed.\textsuperscript{139} Accordingly, the court in \textit{Eagle-Picher} upheld the compensatory damage awards for the plaintiffs.\textsuperscript{140}

2. \textit{Particular Applications of the Sophisticated User Doctrine and Related Principles}

The sophisticated user doctrine has been invoked in a variety of situations. The majority of cases involve industrial machinery and other products designed for workplace use.\textsuperscript{141} However, courts have applied

\textsuperscript{133. Id. at 465.}
\textsuperscript{134. Eagle-Picher, 604 A.2d at 458, 464.}
\textsuperscript{135. Id. at 457-58.}
\textsuperscript{136. Id. at 465.}
\textsuperscript{137. Id.}
\textsuperscript{138. Id. at 453.}
\textsuperscript{139. Eagle-Picher, 604 A.2d at 458, 464}
\textsuperscript{140. Id. at 473.}
\textsuperscript{141. See, e.g., Washington v. Department of Transp., 8 F.3d 296 (5th Cir. 1993); Rusin v. Glendale Optical Co., 805 F.2d 650 (6th Cir. 1986); Jones v. Meat Packers Equip. Co., 723 F.2d 370 (4th Cir. 1983); Hopkins v. Chip-in-Saw, Inc., 630 F.2d 616 (8th Cir.}
a similar concept to the sale of component parts. In addition, those who supply products in bulk form to manufacturers for further processing have also relied on a variant of the sophisticated user doctrine to limit their duty to warn end users of their products.

a. Products Designed for Industrial Use

The sophisticated user doctrine is expressly invoked most often in cases which involve industrial machinery or other products used in a workplace environment. Cases which follow the duty approach tend to exculpate product manufacturers, whether they warn their immediate vendees or not, on the theory that the vendee, usually an employer, is or should be aware of the risk involved and should be primarily responsible for protecting its employees against the risk.

For example, in Washington v. Department of Transportation, a worker brought an action against Shop-Vac, the manufacturer of a wet-dry vacuum cleaner alleging that it failed to provide adequate warnings. The plaintiff was injured when sparks from the machine ignited acetone vapors present at the job site. Applying the duty test, the court concluded that Shop-Vac owed no duty to warn the plaintiff since his employer, OTECH, was already aware of the danger.


144. 8 F.3d 296, 298 (5th Cir. 1993).

145. Id.
of operating power equipment such as the vacuum in the presence of acetone vapors. The court also observed that OTECH was already under a statutory duty to warn its employees about this sort of risk.

The court in Singleton v. Manitowoc, Inc. employed similar reasoning. In that case, a worker was injured when a crane rotated on its base, trapping the plaintiff’s hand between the crane’s superstructure and a toolbox affixed to the crane. The plaintiff brought suit against the manufacturer of the crane, alleging, inter alia, that it failed to warn about the existence of blind spots on the crane. The court granted the defendant’s motion for summary judgment, concluding that the manufacturer should not be required to warn end users of the product when it provided adequate safety information to the user’s employer, particularly when it was reasonable to assume that the employer would pass this information on to its employees.

Due to the fact-specific nature of the Restatement’s balancing of factors test, courts which adhere to this approach are more likely to send failure-to-warn cases to the jury than courts which employ the duty approach. Jones v. Meat Packers Equipment Co. is illustrative. The plaintiff in Jones was injured while cleaning a meat mixing machine at her place of employment. The injury occurred because the machine activated itself even though the stop button had been pushed. The manufacturer was aware of the danger and had

146. Id. at 299-300.  
147. Id. at 300.  
149. Id. at 219.  
150. Id. at 222.  
151. Id. at 227-28.  
152. Id. at 226 (“When, as here, a manufacturer provides its product to a knowledgeable, industrial user and it is reasonable to expect the user to pass on warnings to his employees who operate or work with the product, then the manufacturer is relieved of the duty to warn employees of risks and dangers of which the user could reasonably be expected to be aware.”).  
154. 723 F.2d 370 (4th Cir. 1983).  
155. Id. at 371.  
156. Id.
warned the plaintiff's employer about it several years prior to the accident. The employer, however, failed to pass this information on to its employees. The plaintiff contended that warning her employer by letter was not enough and that the manufacturer should have affixed some sort of warning label to the machine itself.

The trial court told the jury that an adequate warning to the plaintiff's employer was sufficient and that the defendant had no duty to warn users of the machine directly. The jury found in favor of the defendant manufacturer. On appeal, the court observed the duty to warn was governed by section 388 of the Restatement and the factors set forth in comment n. The court concluded that under the Restatement's approach "a factual issue arises about the adequacy of a warning to an intermediary rather than to the person directly exposed to the danger." According to the court, the jury, not the trial court, should have determined whether the defendant acted reasonably in relying on the plaintiff's employer to warn its employees about the danger. Therefore, the court reversed the lower court's judgment and remanded the case for a new trial.

A federal district recently reached a similar result in Reibold v. Simon Aerials, Inc. In that case, a mechanic whose hand was cut by an unshielded cooling fan blade in the engine of an aerial lift machine brought suit against the machine's manufacturer. The plaintiff alleged that the manufacturer was negligent because it failed to inform him of the risk posed by the cooling fan. The defendant moved for summary judgment on the plaintiff's failure to warn claim on the theory that the plaintiff's employer, Hertz, was a sophisticated user of the product. While acknowledging that Hertz was a sophisticated user, the court declared that the defendant manufacturer still had "a duty to balance the factors in comment n, including the burden of

157. Id. at 372.
158. Id.
159. Jones, 722 F.2d at 373.
160. Id.
161. Id. at 371.
162. Id. at 373 (citing RESTATEMENT (SECOND) OF TORTS § 388 cmt. n (1965)).
163. Id. at 374.
164. Jones, 723 F.2d at 374.
165. Id.
167. Id. at 194.
168. Id. at 196.
169. Id. at 200.
placing a warning sign [on the product].” The court concluded that
the record was not sufficiently complete at this stage of the proceeding
to determine whether the defendant met the requirement of comment
n. Accordingly, it denied the defendant’s motion for summary
judgment on the ground of sophisticated user.

It should be noted that courts will sometimes rule as a matter of
law that a defendant has satisfied its duty to warn under the
Restatement’s balancing of factors approach. O’Neal v. Celanese
Corp., provides an interesting example of this. O’Neal involved a
suit by a welder who suffered lead poisoning when he inhaled fumes
from lead-based paint. The plaintiff’s employer purchased the
contents of a factory owned by the defendant, Celanese Corpora-
tion. These contents included a number of spinning machines used
to weave acetate yarn. A primer and sealant compound known as
“red lead” had been used on the machine, although this was not visible
until they were partially dismantled. The plaintiff was exposed to
lead fumes when he used a cutting torch to dismantle one of the
spinning machines.

The plaintiff claimed that Celanese breached its duty to warn him
about the presence of red lead in the interior of the machines. At
trial, the jury returned a verdict for the plaintiff on the liability issue,
but the court rendered a judgment notwithstanding the verdict in favor
of the defendant. On appeal, the federal circuit court considered six
factors. In its evaluation of the first two factors, the court conclud-
ed that the product was not inherently dangerous, but would become so
only if a worker used a torch to cut up the machine without wearing

170. Id. at 201.
172. Id. (summary judgment granted on breach of warranty ground).
1990); Morsberger v. Uniking Conveyor Corp., 647 F. Supp. 1297, 1299 (W.D. Va. 1986);
174. 10 F.3d 249 (4th Cir. 1993).
175. Id. at 249.
176. Id.
177. Id. at 250.
178. Id.
179. O’Neal, 10 F.3d at 250.
180. Id. at 249.
181. Id. at 249-50.
182. Id. at 252.
Moreover, the plaintiff’s employer had extensive experience concerning salvage operations of this type and could be expected to recognize the existence of lead paint, and the dangers associated with it, when the welding operation first revealed the distinctive red-orange color of red lead paint. Furthermore, the court found that Celanese had warned the plaintiff’s employer about those hazards that were unique to the factory and its equipment. Finally, the court concluded that since the sale included thousands of different pieces of equipment in the plant, it would have been impractical for Celanese to have provided warnings about the hazards associated with each individual item. Consequently, the appeals court held as a matter of law that the defendant was not required to warn the plaintiff about the existence or dangers of red lead paint on the machines that it sold to the plaintiff’s employer.

b. Component Parts

Most courts impose liability on the suppliers of defective component parts which are incorporated into larger pieces of machinery. At the same time, suppliers of nondefective component or replacement parts are generally immune from design defect liability for injuries that result in a defect in the final product. This same reasoning is

183. Id. at 252.
184. O’Neal, 10 F.3d at 252-53.
185. Id. at 253-54.
186. Id. at 254
187. Id.
188. See Kuziw v. Lake Eng’g Co., 586 F.2d 33, 36-37 (7th Cir. 1978) (judgment n.o.v. reversed for manufacturer of hydraulic control valve incorporated into paper baling machine because plaintiff introduced testimony at trial that valve might be defectively designed); Travelers Ins. Co. v. Chrysler Corp., 845 F. Supp. 1122, 1126 (M.D.N.C. 1994) (rejecting defendant’s motion for summary judgment in light of allegation by plaintiff’s expert that defendant supplied defective rubber hoses to manufacturer of mobile food service vehicle); Scott v. Allen Bradley Co., 362 N.W.2d 734, 739 (Mich. Ct. App. 1984) (lower court judgment for plaintiff against supplier of defectively designed punch press safety switch affirmed on appeal).
applicable to suppliers of replacement component parts which are installed after the finished product has left the manufacturer’s control.\textsuperscript{190}

The issue is less clear, however, whether the supplier of an otherwise nondefective part can be held liable under a failure to warn theory when it relies on the manufacturer of the finished product to provide safety information about the product to the ultimate user. It should be noted at the outset that courts rarely mention the sophisticated user doctrine by name in component part cases. Instead, courts usually focus on the component part supplier’s knowledge of the risk and its control over the finished product and seldom emphasize the sophistication or reliability of the intermediary.\textsuperscript{191} Nevertheless, the situation of component part suppliers is similar to that of suppliers of industrial machinery and bulk products in the sense that another party in the distributive chain is often in a better position to warn end users. For this reason, it seems appropriate to include component part suppliers in this discussion of the sophisticated user doctrine.

Courts in component supplier cases take one of two approaches. Most courts hold that it is the responsibility of the manufacturer of the finished product, not the supplier of a nondefective component part, to warn the ultimate user about risks associated with the finished product.\textsuperscript{192} These courts emphasize the fact that suppliers of compo-


\textsuperscript{191.} But see Orion, 502 F. Supp. at 178 (granting summary judgment for component part supplier when the assembler had expertise); Sliman v. Aluminum Co. of Am., 731 F.2d 1267, 1272 (Idaho 1986) (holding in a component supplier case, that “reasonable assurance” that the intermediary would convey a warning was a jury question).

\textsuperscript{192.} See Lockett v. General Elec. Co., 376 F. Supp. 1201, 1209 (E.D. Pa. 1974), aff’d, 511 F.2d 1394 (3d Cir. 1975) (“Since a supplier of a component part is under no duty to warn the subsequent assembler of dangers which are generally known in the assembler’s profession, the supplier has no duty to warn the assembler’s employees.”); Lee v. Butcher Boy, 215 Cal. Rptr. 195-202 (Cal. Ct. App. 1985) (“[T]he manufacturer of the finished product is in the best position to protect against and warn of the danger that arises after the nondefective component part is installed in the finished product.”); Jacobini v. V. & O. Press Co., 588 A.2d 476, 480 (Pa. 1991) (“Thus, we perceive no basis for requiring the component part manufacturer . . . to investigate the use of its part . . . which by itself was inert and safe.”).
inent parts seldom have any control over the design of the finished product. Other courts, however, are more willing to require suppliers of component parts to warn end users of finished products, particularly when they are aware of the risk their product will pose when it is incorporated into a larger product by another manufacturer. These courts are more likely to send such cases to the jury rather than granting requests by defendants for summary judgments.

_Searls v. Doe_ is illustrative of the former approach. In that case, an employee of a brewery brought suit against the suppliers of component parts for conveyor system. The plaintiff was injured when he stepped on a can that had fallen onto the floor from an accumulator table after being ejected from the conveyor line by an electronic inspection device. Affirming a lower court's summary judgment for the defendants, the court declared that the component part manufacturers had no duty to warn about potential design defects in the conveyor system when they had not participated in the system's design. The court reached this conclusion in spite of the fact that the plaintiff presented evidence that indicated that both defendants should have known that cans might overflow from the accumulator table and fall onto the floor, thus becoming a hazard to employees.

193. See Sperry v. Bauermeister, Inc., 804 F. Supp. 1134, 1140 (E.D. Mo. 1992) ("Defendant had no connection with the design or installation of the electrical system which would have included an interlock safeguard and/or a warning light; consequently it had no duty to warn plaintiff of any dangerous condition of the electrical system or the overall design of the mill."); Vines v. Beloit Corp., 631 So. 2d 1003, 1006 (Ala. 1994) ("It is clear that Scott Paper retained control over its plant and equipment and that Beloit did not have the power to force Scott Paper to paint its floors orange, install warning signs in the mill, or adopt particular safety practices.").
194. See Koonce v. Quaker Safety Prod. & Mfg., 798 F.2d 700, 715 (5th Cir. 1986) (holding that supplier of safety suit could be held liable failing to warn user even if suit was considered to be a component of an interrelated safety system); Roy v. Star Chopper Co., 584 F.2d 1124, 1128 (1st Cir. 1978), cert. denied, 440 U.S. 916 (1979) (supplier of pinch rollers for electroplating machine subject to liability for failure to warn); Beauchamp v. Russell, 547 F. Supp. 1191, 1198 (N.D. Ga. 1982) (supplier of component part for casestacker machine subject to liability under failure to warn theory).
195. See Beauchamp, 547 F. Supp. at 1198-99 (motion for summary judgment rejected where supplier of air pressure valve installed in casestacker machine failed to provide instructions on how to bleed air pressure out of valve); Sliman, 731 P.2d at 1272 (affirming jury verdict for plaintiff against supplier of soft drink bottle cap).
197. Id. at 288.
198. Id.
199. Id. at 290.
200. Id. at 289-90.
Maake v. Ross Operating Valve Co. exemplifies the latter approach. In that case, the plaintiff, who was injured while operating a 30-ton power press, sued the supplier of a "Handsaver valve" and two palm buttons which had been installed on the machine. Although the plaintiff had not depressed the palm buttons, the ram mechanism went through another power stroke and smashed his hands. The plaintiff claimed that the defendant should have warned about the need to install additional safety equipment on the power press to prevent unexpected recycling by the machine. The court observed that the defendant was aware that its products were commonly used on power presses and that it could foresee the type of injury that in fact occurred. In the court’s view this knowledge was sufficient to present a jury issue as to whether the valve and palm buttons were unreasonably dangerous without a warning.

c. Raw Materials and Bulk Products

Many courts hold that a bulk seller, whose products are not sold in packages or containers that can be readily labeled, fulfills its duty to warn when it conveys information about product-related risks to its immediate vendee. A number of courts have expressly referred to the sophisticated or knowledgeable user doctrine in such cases.

202. Id. at 924.
203. Id.
204. Id. at 925.
205. Id. at 926.
206. Maake, 717 P.2d at 926.
207. See Forest v. E.I. DuPont de Nemours & Co., 791 F. Supp. 1460, 1465 ("A bulk supplier who supplies a dangerous product to a sophisticated purchaser cannot be held liable for not warning the ultimate users of the product of its dangers."); Cohen v. Steve’s Ice Cream, 737 F. Supp. 8, 9 (D. Mass. 1990) ("A bulk seller has no duty . . . to issue warnings to the ultimate consumer, when sufficient warning has been given to the immediate purchaser."); Higgins v. E.I. DuPont de Nemours & Co., 671 F. Supp. 1055, 1061 (D. Md. 1987), aff’d, 863 F.2d 1162 (4th Cir. 1988) ("There is no duty on product suppliers to warn ultimate users (whether employees or customers) of product-related hazards in products supplied in bulk to a knowledgeable user.").
while other courts have relied on an explicit bulk supplier doctrine rationale. This so-called "bulk supplier doctrine," however, appears to be nothing more than a specialized version of the sophisticated user doctrine. In any event, most bulk product cases are decided on the basis of either a duty analysis or a balancing of factors approach. 

Most bulk product cases involve: (1) raw materials which are to be used in the production of finished products; (2) raw materials which have already been processed into finished products; or (3) products that are sold in bulk to employers for use in the workplace.

i. Raw Materials to Be Used in the Production of Finished Products

A number of cases have been brought by employees against suppliers of raw materials that their employers have purchased for processing into finished products. Although a few courts have...
invoked a duty-oriented rule to relieve bulk suppliers of their duty to warn, the majority have employed the Restatement’s balancing of factors approach. However, even courts that purport to balance factors have not been reluctant to grant summary judgments for bulk product suppliers in some cases. Smith v. Walter Best, Inc. exemplifies this approach. In Smith, a foundry worker brought suit against various bulk suppliers of sand, claiming that they failed to warn him about the danger of contracting silicosis from inhaling silica dust contained in the sand. After weighing the factors set forth in comment n, the trial court granted the defendants’ motion for summary judgment. On appeal, the circuit court concluded that the defendants rightly relied on the plaintiff’s employer to protect its workers against the dangers of silicosis.

It should be noted that some courts have required suppliers of inherently dangerous raw materials like asbestos to provide direct warnings to workers. Adkins v. GAF Corp. is illustrative of this approach. Adkins involved a suit against asbestos suppliers by an employee of a building products manufacturer who contracted asbestosis manufacture of automobile windshields); Goodbar v. Whitehead Bros., 591 F. Supp. 552 (W.D. Va. 1984), aff’d sub nom. Bearle v. Hardy, 769 F.2d 213 (4th Cir. 1985) (sand used in steel foundry); Menna, 585 F. Supp. at 1178, (asbestos fibers used in the production of insulation products); Neal v. Carey Canadian Mines, Ltd., 548 F. Supp. 357 (E.D. Pa. 1982), aff’d sub nom. Van Buskirk v. Carey Canadian Mines, 760 F.2d 481 (3d Cir. 1985) (asbestos fibers used in the production of insulation products); Hammond, 454 N.E.2d at 210 (asbestos fibers used in the production of insulation products); A.P. Green Refractories Co., 630 A.2d at 874 (sand used in production of metal products).


215. 927 F.2d 736 (3d Cir. 1990).

216. Id. at 737-38.

217. Id. at 738.

218. Id. at 741.


220. 923 F.2d 1225 (6th Cir. 1991).
as the result of exposure to processed raw asbestos fibers during the course of his employment.\textsuperscript{221} The defendant had packaged the asbestos in burlap or paper bags which carried no warning about the dangerous nature of the product.\textsuperscript{222} The lower court held in favor of the employee.\textsuperscript{223} On appeal, the federal circuit court rejected the supplier's argument that the sophisticated user doctrine excused it from a duty to warn the employee.\textsuperscript{224} According to the court, since the supplier was aware of health problems at the employee's plant, it could not reasonably rely on the employer to warn employees of the dangers of asbestosis.\textsuperscript{225}

ii. Raw Materials that Have Been Processed into Finished Goods

A number of bulk product cases involve raw materials that have been converted by the purchaser into finished products. Frequently, the injured parties are workers who have used or been exposed to the finished products during the course of their employment.\textsuperscript{226} Most courts have concluded that bulk suppliers owe no duty to warn users of finished products.\textsuperscript{227} For example, in \textit{House v. Armour of America}, the widow of a slain police officer brought suit against the supplier of KELVAR fibers which had been used in bullet-resistant vests.\textsuperscript{228} The plaintiff claimed that the defendant should have warned users that the vest would not protect them against rifle fire.\textsuperscript{229} However, the court

\begin{itemize}
  \item \textsuperscript{221} \textit{Id.} at 1227-28.
  \item \textsuperscript{222} \textit{Id.} at 1229.
  \item \textsuperscript{223} \textit{See} Adkins v. GAF Corp., 706 F. Supp. 559 (S.D. Ohio 1988).
  \item \textsuperscript{224} \textit{Adkins}, 923 F.2d at 1229-30.
  \item \textsuperscript{225} \textit{Id.} at 1231.
  \item \textsuperscript{228} 886 P.2d 542, 545-47 (Utah Ct. App. 1994).
  \item \textsuperscript{229} \textit{Id.} at 550.
\end{itemize}
concluded that since the defendant, as a bulk supplier, had no realistic opportunity to provide a warning to the end users of its product, it had no duty to do so.\footnote{230}

A few courts have eschewed the duty approach and have elected to employ a balancing of factors approach.\footnote{231} However, with the exception of \textit{Cimino v. Raymark Industries, Inc.},\footnote{232} these courts have also found in favor of the suppliers.\footnote{233} In \textit{Cimino}, workers who were exposed to asbestos material in the production of insulation products sought damages from a supplier of raw asbestos.\footnote{234} The supplier attempted to avoid liability by claiming that it had warned the plaintiffs’ employer of the risk.\footnote{235} The court, however, concluded that under Texas law, a bulk supplier could not discharge its duty to warn merely by informing its immediate purchaser of the product’s dangers.\footnote{236} Rather, the bulk supplier was required to determine whether the intermediary was capable of passing the warning on to the ultimate consumers.\footnote{237} In this case, the court allowed the jury to consider whether the defendant’s reliance on its immediate purchasers was reasonable and the jury found that it was not.\footnote{238}

While most bulk product cases have involved employment-related injuries, the sophisticated user doctrine may also be invoked to defeat failure-to-warn claims brought by retail consumers of the finished product.\footnote{239} Recently, a number of lawsuits have been brought by recipients of medical implants made out of Teflon material supplied to

\footnote{230. \textit{Id.} at 554 ("Thus, DuPont had no duty nor opportunity to warn the ultimate vest user about the protection afforded by vests woven from KELVAR.").
235. \textit{Id.} at 331.
236. \textit{Id.} ("However, the mere presence of an intermediary does not excuse the manufacturer from warning those whom it should reasonably expect to be endangered by the use of its products.") (quoting \textit{Alm v. Aluminum Co. of Am.}, 717 S.W.2d 588, 591 (Tex. 1986)).
237. \textit{Id.}
238. \textit{Id.}
various manufacturers by DuPont.\textsuperscript{240} The plaintiffs in these cases have alleged that DuPont failed to warn them that Teflon was not suitable for use in implants. However, almost without exception, the courts have ruled that DuPont had no duty to warn the ultimate users of its product.\textsuperscript{241}

\textit{Forest v. E.I. DuPont de Nemours \& Co.} is one of the rare exceptions to this trend.\textsuperscript{242} In \textit{Forest}, a “Proplast TMJ Implant” was implanted in the plaintiff’s jaw to correct defects in her temporomandibular joint.\textsuperscript{243} The implant material was made from polytetrafluoroethylene (“PTFE”) resins and fibers, along with other ingredients.\textsuperscript{244} Although the implant was approved for sale by the Food and Drug Administration, it caused severe injuries to the plaintiff and many other implant recipients.\textsuperscript{245} The plaintiff brought suit against DuPont, which supplied raw PTFE to the implant manufacturer.\textsuperscript{246} In a motion for summary judgment, DuPont argued that since it warned the manufacturer that PTFE might not be suitable for use in TMJ implants, it had discharged its duty to warn and was not required to communicate directly with implant recipients such as the plaintiff.\textsuperscript{247}


\textsuperscript{241} See \textit{La Montagne}, 41 F.3d at 856-58; \textit{Apperson}, 41 F.3d at 1108; \textit{Rynders}, 21 F.2d at 842; \textit{Klem}, 19 F.3d at 1002-03; \textit{In re TMJ Implants}, 872 F. Supp. at 1028-33; \textit{Kealoha}, 844 F. Supp. at 594-95; \textit{Nowak}, 827 F. Supp. at 1334; \textit{Hegna}, 825 F. Supp. at 884; \textit{Miller}, 811 F. Supp. at 1292; \textit{Anguiano}, 808 F. Supp. at 719; \textit{Veil}, 803 F. Supp. at 234-35; \textit{Bond}, 868 P.2d at 1118; \textit{Longo}, 632 So. 2d at 1197.


\textsuperscript{243} \textit{Id.} at 1461.

\textsuperscript{244} \textit{Id.}

\textsuperscript{245} \textit{Id.}

\textsuperscript{246} \textit{Id.} at 1461-62.

\textsuperscript{247} \textit{Forest}, 791 F. Supp at 1462.
The court acknowledged that some form of protection for bulk suppliers was necessary to avoid unnecessary duplication when manufacturers and retail marketers were already required to provide warnings about product-related risks to their customers. However, the court declared that a bulk supplier should be required to verify that its immediate purchaser was aware of the raw material’s inherent risks and that it planned to warn the ultimate user of such risks. According to the court:

Thus, the relevant question in bulk supplier cases is whether the bulk supplier was objectively reasonable in relying on a knowledgeable intermediary to provide a warning to the ultimate user. This involves proof of two elements: 1) that the bulk supplier was reasonable in believing that the intermediary knew of the dangers associated with the bulk product, and 2) that the bulk supplier was reasonable in relying on the intermediary to warn the ultimate user of such danger.

Since the knowledge and reliability of the implant manufacturer were essentially factual issues, the court concluded that it was inappropriate to grant the defendant’s motion for a summary judgment.

iii. Products Purchased for Use or Consumption in the Workplace

Another group of cases involve products sold in bulk to an employer for use in connection with cleaning or maintenance operations in the plant. A number of courts have concluded that suppliers of

248. Id. at 1465.
249. Id.
250. Id. at 1466.
251. Id. at 1469 ("The issues associated with the bulk supplier doctrine make summary judgment on any record highly questionable.").
bulk products have little or no duty to warn employees of their vendees.\textsuperscript{253} Cohen v. Steve’s Ice Cream is illustrative of this reasoning.\textsuperscript{254} The plaintiff in Cohen was injured when flammable liquid leaked from its container and caught fire.\textsuperscript{255} The defendant supplied the liquid to the plaintiff’s employer in fifty-five gallon drums; however, the employer transferred the liquid into smaller containers for use in the workplace.\textsuperscript{256} Although the defendant placed warnings on the original containers, apparently these warnings were not passed on to the plaintiff by his employer.\textsuperscript{257} The plaintiff argued that the supplier owed a duty to warn him directly.\textsuperscript{258} However, the court concluded that the bulk product supplier satisfied its duty to warn by providing safety information to its immediate vendee, the plaintiff’s employer.\textsuperscript{259}

However, a few courts have employed a balancing of factors analysis.\textsuperscript{260} While this approach has allowed more cases to reach the jury, the results have not always been favorable to plaintiffs.\textsuperscript{261} In Dougherty v. Hooker Chemical Co., however, the balancing of factors analysis greatly aided the plaintiff’s case.\textsuperscript{262} In Dougherty, the widow of an aircraft manufacturer employee brought suit against the supplier of trichloroethylene (“TRI”), a chemical solvent.\textsuperscript{263} The plaintiff alleged that her husband died as a result of exposure to TRI, which had been used to clean helicopter transmissions.\textsuperscript{264} The defendant supplied TRI to the decedent’s employer in fifty-five gallon drums.\textsuperscript{265}

\textsuperscript{253} See Mason, 862 F.2d at 250; Cohen, 737 F. Supp. at 9; Werckenthein, 618 N.E.2d at 909; Mascarenas 492 N.W.2d at 516.
\textsuperscript{255} Id. at 8.
\textsuperscript{256} Id.
\textsuperscript{257} Id. at 8-9.
\textsuperscript{258} Id. at 9.
\textsuperscript{259} Cohen, 737 F. Supp. at 9.
\textsuperscript{262} 540 F.2d 174, 179 (3d Cir. 1976).
\textsuperscript{263} Id. at 175-76.
\textsuperscript{264} Id. at 176.
\textsuperscript{265} Id.
Warning labels affixed to these containers cautioned against exposure to TRI vapors, but did not mention that such exposure could cause death. The trial court directed a verdict for the defendant. However, on appeal, a federal circuit court concluded that the jury, after balancing the factors enumerated in comment n, had the right to decide whether the defendant could have reasonably relied upon the victim's employer to warn its employees that exposure to TRI could be fatal.

III. FORMULATING A GENERAL RULE ON WARNING THROUGH INTERMEDIARIES

There are two basic doctrines that permit product suppliers to rely upon intermediaries to transmit safety information to end users. One doctrine is the learned intermediary rule, which has traditionally been limited to pharmaceutical products. The other doctrine is the sophisticated user doctrine. In addition, some courts purport to apply separate doctrines to suppliers of component parts and bulk products. However, regardless of which doctrine is applied, courts tend to resolve duty to warn cases by using either a duty-oriented analysis or a balancing test. The learned intermediary rule and the duty version of the sophisticated user doctrine are illustrative of the first approach. These are essentially bright line rules which protect parties against liability as long as they behave in a certain way. The balancing of factors branch of the sophisticated user doctrine and its counterparts in component part and bulk products cases, is more open-textured, leaving it up to the jury to decide whether a defendant's reliance on an intermediary is legally sufficient or not.

Each of these approaches has its strengths and weaknesses. The duty-oriented analysis is relatively predictable—a desirable characteristic because it provides some assurance to producers and suppliers that their communication structures will pass muster in the courts. However, like most per se rules, the duty approach sometimes sacrifices fairness for administrative efficiency. The balancing approach, on the other hand, is more equitable in nature, but is less certain in its application, than the duty-oriented approach. This uncertainty makes it difficult for parties

266. Id. at 180.
267. Dougherty, 540 F.2d at 178.
268. Id. at 182 (“[I]t is the jury's function to determine, after balancing the § 388 considerations to which we have referred, whether Boeing's knowledge, if any, could have relieved Hooker from any requirement to warn Boeing's employees and thus, from any liability.”).
Learned Intermediaries
to predict when they may safely rely upon intermediaries to convey safety information to users or consumers.

In this part of the article, two issues will be considered. First, is it possible to formulate a general rule that is broad enough to cover all of the situations discussed in part II? Second, should this rule be duty-oriented or should it require the decisionmaker to balance various factors in order to determine liability?

A. Common Issues

At first blush, the relationships between the producers, intermediaries, and product users that we examined so far seem to be quite different. For example, where pharmaceuticals are involved, the producer is a product manufacturer, the intermediary is a physician, and the end user is the intermediary's patient. In the case of industrial machinery, the producer is a product manufacturer, the intermediary is an employer, and the end user is an employee of the intermediary. Where component parts are concerned, the producer is a component part supplier, the intermediary is a manufacturer of a finished product, and the end user is usually an employee of the purchaser of the finished product. Various relationships are also involved with bulk products. For example, in the case of raw materials prior to processing, the producer is a supplier of raw materials, the intermediary is an employer, and the end user is an employee of the intermediary. However, where raw materials have been incorporated into a finished product, the producer is a bulk product supplier, the intermediary is the manufacturer of a finished product, and the end user is usually an employee of the finished product's purchaser. Finally, where bulk products are purchased for use or consumption in the workplace, the producer is a bulk product supplier, the intermediary is an employer, and the end user is an employee of the intermediary.

Notwithstanding the fact that different relationships may exist among the various parties, there is a certain amount of commonality among these various fact patterns. For example, in each case, there is no direct contact between the original producer and the end user of the product. Moreover, some characteristic of the product, the way it is used, or the way it is packaged, makes its difficult for the original producer to communicate effectively with end users. Finally, the intermediary usually has an independent legal duty to warn end users of the product. These common threads suggest that it may be possible to
formulate a general rule that is broad enough to cover most duty to warn situations.

B. Duty-Oriented Rules Versus Balancing Approaches

A general rule can incorporate a duty-oriented analysis or a balancing test. The discussion below will attempt to evaluate these approaches in terms of such policy goals as accident cost avoidance, minimization of administrative costs, and compensation of accident victims.

1. Accident Cost Avoidance

One of the most important goals of products liability law is to "deter" product-related accidents. This does not mean that accidents must be prevented at all costs; rather, the objective is to minimize the sum of accident costs and accident-prevention costs. Accident costs, in this context, include personal injuries, property damage, and direct pecuniary losses. Accident cost avoidance costs include expenditures for better product quality, safer product design, as well as the generation and transmission of product safety information to users and consumers.

a. Disclosure of Safety Information as an Accident Cost Avoidance Strategy

The disclosure of safety information, such as instructions or warnings, can be an effective accident cost avoidance strategy.269

269. See Jennifer H. Arlen, Compensation Systems and Efficient Deterrence, 52 MD. L. REV. 1093, 1096 (1993) ("Under economic theory, the optimal level of risk for any particular activity is the level at which the total social cost of accidents is minimized—that is, the level that minimizes the cost of reducing (or eliminating) the risk in question, plus the expected cost to the members of society of the resulting injuries."); Jon D. Hanson & Kyle D. Logue, The First-Party Insurance Externality: An Economic Justification for Enterprise Liability, 76 CORNELL L. REV. 129, 160 (1990) ("The deterrence goal of products liability law is to minimize the costs of product accidents, including the costs of preventing accidents.").

270. Warnings and instructions are by no means foolproof. Product users may fail to notice or read otherwise adequate warnings for the following reasons: (1) functional illiteracy; (2) inclusion within predictively inattentive or incompetent user groups; (3) misplaced or unavailable safety information; (4) failure of intermediaries to pass on warnings to end users; (5) reliance by consumers on general knowledge or experience; (6) information overload; and (7) competing demands on time and attention. See generally Howard Latin, "Good" Warnings, Bad Products, and Cognitive Limitations, 41 UCLA L. REV. 1193, 1207-20 (1994). Even those who do read and understand warnings may fail to heed them because of: (1) imperfect memory; (2) overconfidence; (3) reflexive actions
Potential users who are informed about a product’s inherent risks can choose less risky substitutes for the product or take appropriate precautions if they do use the product.

In order to be efficient, however, the benefits of accident cost avoidance measures must exceed their costs. When accident costs or accident avoidance costs are not known, it has been suggested that liability be imposed on the party who “is in the best position to make the cost-benefit analysis between accident costs and accident avoidance costs and to act on that decision once it is made.” Ordinarily, product manufacturers are considered to be the cheapest cost avoiders where manufacturing flaws or design defects are concerned because they have control over the ultimate manufacture and design of their products. However, this principle does not necessarily apply to safety information, particularly if we distinguish between the generation of safety information and its communication to product users. Sometimes one party may be in a better position to detect product-related risks in the first instance, while another party may be able to communicate more cheaply with product end users. In such cases, the first party would be the cheapest cost avoider with respect to the generation of safety information, but the second party would be the

during emergencies; (4) disregard of low probability risks; and (5) skepticism about manufacturer credibility. Id. at 1242-48. This suggests that, in some cases at least, improved product design may be a more effective accident-cost-reduction strategy than reliance on warnings. See A.D. Twerski et al., The Use and Abuse of Warnings in Products Liability—Design Defect Litigation Comes of Age, 61 CORNELL L. REV. 495, 509 (1976).


273. In the case of warnings, one such cost would be the expense of obtaining information about the nature and magnitude of product-related risks. This sort of data is usually generated through pre-market testing and research. However, in some cases, additional information may be acquired by post-market assessments of product performance. Once product safety information has been obtained, additional costs must be incurred in order to communicate this information to users or consumers of the product.


275. See David G. Owen, Rethinking the Policies of Strict Products Liability, 33 VAND. L. REV. 681, 711 (1980) (“Manufacturers today, especially those of products that are technologically complex, often are in a far better position than consumers to discover, evaluate, and act upon, dangers that inhere in the products that they make and sell.”).
cheapest cost avoider insofar as communication costs were concerned.276

i. The Generation of Product Safety Information

Ordinarily, manufacturers or producers are in the best position to generate safety information about their products.277 Not only are manufacturers familiar with the general characteristics of their products, but they have the ability to identify new safety risks by pre-market product testing or by post-market analysis of product performance data.278 In contrast, wholesalers, retailers, and others in the distributive chain seldom have the resources or the expertise to acquire new product safety information on their own. Users and consumers have even less ability to obtain such information.279

ii. The Communication of Product Safety Information

When it comes to the communication of product safety information, the product manufacturer will often be the cheapest cost avoider as well.280 For example, if the product in question reaches the ultimate user or consumer in its original packaging, the manufacturer can easily convey warnings and instructions by means of labels or package inserts. On the other hand, the original manufacturer may not be able to convey information effectively to end users when the product undergoes further

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280. See Michael D. Green, When Toxic Worlds Collide: Regulatory and Common Law Prescriptions for Risk Communication, 13 HARV. ENVTL. L. REV. 209, 223 (1989) (“Because the cost of providing a warning or other information is generally quite low . . . the tendency is to require more rather than less in the way of information communication.”); Bressler, supra note 278, at 396 (“In the warning cases, the cost of the warning is usually so minimal that the balance almost always weighs in favor of an obligation to warn.”).
processing or assembly or when it is used in an industrial setting. In such cases, someone else in the distributive chain may be the cheapest cost avoider.\textsuperscript{281}

b. Searching for the “Cheapest Cost Avoiders”

The foregoing discussion suggests that it is useful, when searching for the cheapest cost avoider, to distinguish between the generation of safety information and the communication of such information to end users. The party who can generate safety information most cheaply may not necessarily be the one who can most efficiently convey it to end users. This can be seen more clearly by an examination of various product distribution scenarios.

i. Pharmaceutical Products

Both drug manufacturers and prescribing physicians are potential accident cost avoiders when it comes to obtaining and communicating information about the risks of pharmaceutical products. As far as the \textit{generation} of basic research on product safety is concerned, pharmaceutical manufacturers are clearly the cheapest cost avoiders. Not only do drug manufacturers have superior resources to devote to research, but they are already required to conduct a thorough investigation of product-related risks in order to secure pre-marketing approval from the Food and Drug Administration.\textsuperscript{282} In contrast, physicians have neither the resources nor the expertise to conduct basic research on the biochemical properties of the pharmaceutical products that they prescribe. Furthermore, such research would be a waste of time and money because it would duplicate the efforts of drug companies.

On the other hand, when it comes to the \textit{communication} of product safety information, both product manufacturers and prescribing physicians are good accident cost avoiders. Both manufacturers and physicians have the ability to transmit safety information to patients: manufacturers can communicate with patients by means of package inserts, while physicians can do so through face-to-face contact with their patients.


ii. *Products Designed for Industrial Use*

The buyer of industrial machinery typically purchases it in order to produce goods or services for retail consumption. This machinery seldom poses any direct threat to retail consumers. However, employees of the purchaser may be endangered by industrial machinery and, as such, are entitled to receive safety information. The cheapest cost avoider may be the manufacturer of the industrial machinery or it may be the purchaser/employer.

Manufacturers of the industrial machinery appear to be in the best position to *generate* information about the safety of their products. Unlike suppliers of component parts or bulk products, manufacturers of industrial machinery usually have complete control over finished products and can easily determine how they will perform in the workplace. Any risks which are not detected by manufacturers prior to marketing will quickly be brought to their attention by purchasers. Accordingly, it is appropriate to impose a duty to generate safety information on the manufacturers of such products.

On the other hand, the purchaser/employers seem to have the advantage when it comes to *communicating* product safety information to their employees. To be sure, manufacturers can attach warning labels to the machinery they sell and may be able in some cases to provide other safety instructions as well. However, safety literature that is furnished to the purchaser may never reach the workers who are actually endangered by the product. In contrast, employers can see that safety literature provided by manufacturers actually reaches their employees. In addition, employers can improve the safety of the work environment by providing supervision and training for their employees. Thus, where industrial machinery is concerned, employers appear to be more efficient cost avoiders than manufacturers.

283. Manufacturers who provide multipurpose machines that undergo further modifications to meet the specific needs of the purchaser do not have this sort of control. However, these producers are usually treated as component part suppliers rather than vendors of finished products.
iii. Component Parts

Where mechanical component parts are incorporated into another product by the purchaser, the cheapest cost avoider is likely to be either the component part supplier or the manufacturer of the finished product. As far as the generation of safety information is concerned, the supplier of the component part may be in the best position to discover the risk if it is an inherent one which exists at the time that the component part leaves the supplier's control.\(^8\)

However, when it comes to the communication of a known risk, the manufacturer of the finished product is likely to be the cheapest cost avoider. The only way that a component part supplier can warn end users is to attach a label to the component part. This method of warning may be effective if the warning label remains visible after the component part is incorporated into a finished product. However, warning labels will not be visible, and therefore will not be effective, if the component part is incorporated internally into a finished product in such a way that it is not visible. Nor will the component parts supplier be able to communicate with end users of the finished product in some other way because it will not always know who they are.\(^9\)

On the other hand, the manufacturer can place warning labels on the finished product and thus disclose safety information to end users. Even if it is not feasible to place warning labels on the finished product, the manufacturer will still be in a better position to convey safety information to end users because it will be closer to them in the distributive chain.\(^{287}\)

iv. Raw Materials and Bulk Products

Where products delivered in bulk form to the manufacturer of a finished product, potential cheapest cost avoiders include the bulk product supplier and the manufacturer of the finished product. If the risk involved is an inherent one, the bulk product supplier is likely to be the cheapest cost avoider insofar as the generation of safety information is concerned.\(^{289}\)

\(^{287}\) However, when the risk arises because of something the manufacturer does to the finished product, the manufacturer may be in a better position to discover the risk.\(^{288}\)

\(^{288}\) See Schwartz & Driver, supra note 9, at 42.

\(^{289}\) On the other hand, the manufacturer of the finished product will probably be the cheapest cost avoider if the risk arises from the product's design.
On the other hand, manufacturers of finished products are often better able to communicate safety information about bulk products.\textsuperscript{290} When products are delivered to the manufacturer in containers, such as fifty-five gallon drums, the supplier can place a warning on the container. However, employees who use such products often do not see or understand these warning labels. Furthermore, warnings labels cannot be used at all when bulk products are delivered in tank cars, dump trucks, or other large containers.\textsuperscript{291} In contrast, manufacturers of finished products do have some ability to warn users and consumers. For example, when the bulk products are purchased as raw material for incorporation into finished products, manufacturers of the finished products can affix warning labels to their products or enclose safety information with them. Likewise, when bulk products are purchased for use in the workplace, purchasers can directly warn their employees about product hazards and can instruct them on safe use of these products.

c. Concerns about Reliability

If the party who can potentially communicate most cheaply with end users is not likely to do so, it may be necessary to shift the duty to warn to a more reliable party. Three factors negatively affect reliability: first, a party may fail to convey safety information because it lacks an adequate economic incentive to do so; second, even when a party is sufficiently motivated, safety information may fail to reach the intended recipients because the party cannot physically communicate with end users of the product; third, even when safety information is actually conveyed to end users, they may not be able to understand or act upon the information provided.

In the case of pharmaceutical products, tort liability provides a sufficient incentive for both manufacturer and physicians to convey product information to product consumers. Manufacturers who fail to disclose product-related risks are subject to liability under principles of strict products liability,\textsuperscript{292} while physicians who do not communicate safety information to their patients may be held liable under the doctrine


\textsuperscript{291} See Cheney, supra note 88, at 596.

of informed consent.\textsuperscript{293} However, the methods of communication available to physicians appear to be more reliable than those available to manufacturers: physicians can communicate directly with their patients, while manufacturers must rely on package inserts.\textsuperscript{294} Finally, patients are more likely to understand safety information that is conveyed by means of face to face conversations with their physicians than warnings that are transmitted by manufacturers in package inserts.\textsuperscript{295}

Where industrial machinery and related products are concerned, tort liability provides an incentive for manufacturers to transmit safety information to end users of their products.\textsuperscript{296} However, often there is no completely reliable way for the manufacturer to transmit such information.\textsuperscript{297} Warning labels may not remain attached to industrial machines throughout their useful life and safety literature may be lost or destroyed. Moreover, written warnings are not nearly as effective as formal instruction and training in product safety.\textsuperscript{298}

This suggests that employers are usually superior accident cost avoiders when it comes to workplace safety.\textsuperscript{299} Relying on information from the manufacturer, as well as on their own experience with workplace safety, employers can anticipate safety problems and take affirmative steps to prevent accidents from occurring. However, employers are not necessarily reliable accident cost avoiders, primarily because workers compensation laws do not always provide sufficient incentive to protect employee against accidents.\textsuperscript{300} Unlike others in the distributive chain, an employer’s liability is limited to the amount specified in the state workers compensation statute. Economic incentives are further diminished by the fact that workers compensation

\begin{itemize}
\item 293. See Styles, supra note 45, at 128.
\item 294. See Cheney, supra note 88, at 583 (“Because the manufacturer does not sell the packages directly to the consumer, the manufacturer cannot realistically ensure that warnings are on the package in the unit-of-use containers that the consumer ultimately receives.”).
\item 295. See Flannagan, supra note 48, at 413.
\item 296. See Cheney, supra note 88, at 566 (discussing manufacturers’ duty to warn under tort law).
\item 297. See Schwartz & Driver, supra note 9, at 68 (“The manner in which industrial products are marketed and distributed severely limits the manufacturer’s ability to communicate effective instructional warnings to the product user.”).
\item 298. Schwartz & Driver, supra note 9, at 79.
\item 299. Schwartz & Driver, supra note 9, at 79.
\item 300. Green, supra note 280, at 213; but see W. Kip Viscusi, Reforming Products Liability 11 (1991) (arguing that workers compensation programs do have some deterrent effect on employers).
\end{itemize}
awards are usually paid by insurance carriers rather than by employers themselves.\textsuperscript{301}

In the case of component parts, the choice is between the component part supplier and the manufacturer of the finished product. The threat of tort liability provides an incentive for both parties to comply with their duty to warn. However, there may be no reliable way for the component part manufacturer to reach end users if the component part is not visible to users of the finished product. For this reason, manufacturers of finished products seem to be more reliable than component part suppliers.

The same is true of products that are sold in bulk. Where bulk products are incorporated into finished goods, the prospect of tort liability for failure to warn is sufficient to induce both bulk product suppliers and manufacturers of finished products to provide safety information to the ultimate users or consumers of the finished products. However, manufacturers of finished products have control of the finished product’s packaging whereas component part suppliers do not. Furthermore, manufacturers of finished products are closer than component part suppliers to end users in the distributive chain.

Bulk products also expose workers to the risk of injury. This may occur when hazardous raw materials are used in the manufacture of finished products as well as when bulk products, such as solvents, are used for cleaning and maintenance operations in the workplace. In theory, the employer/purchaser is the cheapest cost avoider because of its control over the work environment. However, as mentioned earlier, workers compensation laws may discourage employers from investing in workplace safety.

d. Accident Cost Avoidance and the General Rule

The above discussion indicates that while original producers are best able to generate safety information, intermediaries, such as physicians, employers, or manufacturers of finished products, can usually communicate this information to end users more effectively and more cheaply. If this is correct, the general rule should permit original producers to rely upon intermediaries to transmit safety information.\textsuperscript{302} Requiring original producers as well as intermediaries to warn end users

\textsuperscript{301} Since liability insurers base the size of premiums on the claims experience of classes of employers, rather than on the experience of individual employers, insurance premiums provide little incentive to employers either. See Cheney, supra note 88, at 579.

\textsuperscript{302} See Willner, supra note 89, at 594.
increases accident avoidance costs without achieving any significant gain in accident cost reduction. This suggests that a duty-oriented rule would be the better approach as far as accident cost avoidance is concerned.

2. Minimization of Administrative Costs

Administrative costs refer to the costs of operating a particular system of accident cost avoidance or compensation. These costs include the expense various parties must incur in order to determine the extent of their legal responsibilities. They also include the legal expenses incurred by plaintiffs, defendants and liability insurers to adjudicate damage claims. A duty-oriented rule would entail far fewer administrative costs than a balancing test.

a. Information Costs

Legal rules that are specific are less costly than rules that are vague or open-ended. In the former case, parties can easily determine ex ante what they must do to avoid liability. On the other hand, when legal rules are uncertain, parties must spend more time and resources to ascertain what is required for compliance. A duty-oriented rule has a clear advantage here. Under such an approach, an original producer will know in advance that it satisfy its duty to warn by conveying product safety information to the appropriate intermediary. In contrast, a balancing test will impose significant information costs on many of the parties in the distributive chain. For example, under the Restatement’s balancing of factors approach, the original producer would have to determine whether the intermediary was likely to pass safety information on to end users of the product. In theory, the original producer might have to investigate the character and fitness of more than one intermediary if there were several parties in the distributive chain between the producer and the ultimate users or consumers of the product.

Even if the original producer concludes that an intermediary is reliable, it can never be entirely certain that it has satisfied its duty to

305. See Wilner, supra note 89, at 604.
warn under a balancing test. Section 388, comment n declares that direct warnings may still be required if the product is sufficiently hazardous or if the expense of providing is not too burdensome. Of course, there is no way for an original producer to know for sure how a jury will decide these issues.

b. Litigation Costs

Whether one views the tort system as a regulatory regime or as a compensation scheme, its administrative costs are enormous. In products liability cases, as in other tort actions, manufacturers or their insurers must spend large amounts of money to investigate, defend, and settle claims. Plaintiffs also incur heavy costs if their claims are contested. According to one study, more money is spent on products liability litigation than is paid out to accident victims.

Obviously, a legal rule that reduces litigation has an advantage over one that encourages it. In this respect, a duty-oriented approach seems preferable to a rule that requires a good deal of fact-finding. As suggested earlier, if a duty-oriented rule is adopted, the liability standard will be relatively clear ex ante. Thus, when injuries do occur, potential claimants (and their lawyers) will be able to determine whether or not potential defendants have satisfied their duty to warn. This will discourage plaintiffs from litigating frivolous claims and it will also give the parties an incentive to settle meritorious ones.

Balancing tests, on the other hand, invite litigation. As mentioned earlier, it is difficult under such tests for producers to know what they must do in order to satisfy their legal responsibilities. This uncertainty also presents problems after accidents occur. Because of the fact-specific nature of balancing tests, duty to warn issues will rarely be

306. See Willner, supra note 89, at 604.


308. See John G. Fleming, Is There a Future for Tort?, 44 LA. L. REV. 1193, 1207 (1984) ("Compensation under the tort system is dependent on issues of causation and fault, which require investigation and are frequently contested.").

resolved by the trial judge pursuant to a motion for summary judgment. Instead, liability can only be determined after a jury trial.\textsuperscript{310} Prior to trial, the parties can only guess at what a jury might conclude. Although this sort of uncertainty might encourage settlement before trial, it might also cause litigants, particularly plaintiffs, to gamble on the possibility of a favorable jury verdict.

Another disadvantage of balancing approaches is that they encourage multiparty litigation. For example, if A relies on B to warn C and B fails to do so, A might be liable to C, along with B, if a court concludes that A acted unreasonably in failing to warn C directly. In such a case, C would have a claim against both A and B. This means that either C will sue both A and B or, if C sues only one party, the other will be brought into the lawsuit as a third-party defendant. Since multiparty litigation is usually more expensive than traditional two-party litigation, balancing approaches seem to be inconsistent with the goal of reducing litigation costs.

3. Compensatory of Accident Victims

Compensation of accident victims is one of the traditional goals of tort law. Arguably, a general rule which relies on a balancing of factors does a better job of compensating accident victims than a duty-oriented approach. One reason is that balancing tests increase the chances that a plaintiff will be able to recover from more than one party. Under a duty-oriented analysis, once a producer warns the next party in the distributive chain it will not be held liable for someone else’s failure to warn. This means that injured parties can normally look to only one source for compensation in failure to warn cases. In contrast, the balancing approach extends liability to parties farther down the distributive chain without necessarily relieving parties who are farther up the chain.

Ordinarily, when a case goes to trial, joint and several liability will not have any effect on the size of the judgment since the jury will apportion the award between the defendants. However, joint and several liability favors plaintiffs, and thereby increase overall compensation to accident victims, in two situations. The first is where one of the defendants is insolvent or cannot be reached for suit. Assume that A warns B, who fails to warn C. Under a duty-oriented rule, C can only sue B and if B is insolvent, C will recover nothing. In other words, the

\textsuperscript{310} See Willner, supra note 89, at 599.
Joint and several liability also increases compensation for accident victims in cases where one of the responsible parties is the plaintiff's employer. Under a balancing approach, an injured employee who has received a worker's compensation award may still be able to seek additional compensation from other defendants if his or her employer fails to communicate a warning. On the other hand, under a duty-oriented rule, an injured employee is limited to a workers' compensation award if a product seller warns the employer and the employer does not warn the employee. Under the law of worker's compensation, the "exclusive remedy" doctrine provides that the schedule of benefits set forth in the worker's compensation statute is the sole and exclusive remedy of an employee against an employer. To the extent that worker's compensation awards are inadequate, an approach which allows victims to supplement their workers compensation awards by suing nonemployers increases their overall level of compensation.

A balancing approach favors accident victims in another way. As the discussion in part II demonstrates, when courts employ duty-oriented rules, they tend to decide cases by summary judgment, a practice which usually favors defendants. In contrast, when a balancing test is employed, cases are more likely to be decided by juries. Given the fact

312. See Cheney, supra note 88, at 577.
313. An employee would still be able to recover against a product supplier if the supplier failed to provide an adequate warning and knowledge of the product's dangerous characteristics was not imputed to the victim's employer.
that juries tend to favor plaintiffs in personal injury cases, balancing tests appear to benefit plaintiffs.\textsuperscript{316}

To summarize, a balancing test may be preferable to a duty-oriented rule as far as compensation is concerned. This is because plaintiffs may be able to sue more than one defendant under the former approach and thus can recover even if one of the parties is insolvent. The ability to sue multiple parties also allows workers to recover more from product sellers than they could from their employers under workers compensation. Finally, cases are more likely to be decided by juries under a balancing approach, a result that usually benefits plaintiffs.

4. A Final Evaluation

A duty-oriented rule allows parties to rely upon warning chains to transmit product safety information to end users. This approach achieves a high level of accident cost avoidance at relatively little cost. Although a balancing test would be a bit more reliable, it would force parties to duplicate their efforts to warn end users. Arguably, this increased cost will outweigh any marginal gain in reliability that occur from such duplication. A duty-oriented approach is also cheaper to administer because it provides more certainty to the parties than an open-ended balancing test. The only advantage of a balancing test is that it potentially provides more compensation for accident victims. All in all, a duty-oriented rule seems to be the better approach.

IV. A PROPOSED RULE

I would propose the following duty-oriented rule to govern the communication of safety information between producers and suppliers of products and end users of these products. The proposal does not designate who has the duty to generate safety information. This question is best decided under general duty to warn principles. Although it is expressed in statutory form, many states might prefer to implement the rule through common-law decisionmaking. In addition, some states may prefer to retain the traditional learned intermediary rule and limit the proposed rule to industrial products, component parts and bulk products. The proposed general rule would provide as follows:

A product supplier who sells to another either: (1) pharmaceutical products such as drugs, biologics and medical devices sold by

\textsuperscript{316} See Willner, supra note 89, at 599-600.
prescription, (2) products intended for use or consumption in a workplace or industrial setting, (3) nondefective component parts intended for assembly or incorporation into more complex systems or machines, or (4) materials in bulk form intended for further processing into finished goods, shall not be held liable, either in negligence or strict liability, for injuries to the ultimate users of these products arising from the supplier’s failure to warn such users, provided that the supplier has furnished adequate safety information about the product to its immediate vendee, or in the case of pharmaceutical products to the prescribing physician. In addition, a product supplier shall not be held liable for failing to warn the ultimate user or consumer of the product if the ultimate user’s prescribing physician, the supplier’s immediate vendee, or any other party in the distributive chain is already aware of the dangerous characteristics associated with the product or should be aware of such risks.

The intent of this proposal is to provide producers and suppliers with a clear statement of what they must do to avoid liability for failure to warn end users of their products. For example, unlike some versions of the sophisticated user doctrine, this proposal provides that a producer or supplier is fully protected if it warns the appropriate intermediary even though the intermediary fails to pass the information to others in the distributive chain. In other words, the producer or supplier does not have to worry about the reliability of an intermediary. There are two reasons for excluding reliability as an issue: first, reliability is a factual issue and this proposal is designed to eliminate as many factual issues as possible in order to achieve more certainty for the parties and thus reduce administrative costs. Consequently, the only issue of fact under this proposed rule is the adequacy of the safety information actually provided to the vendee.

The second reason for regarding liability is that it dilutes responsibility for warning about product risks. Thus, if A conveys safety information to B in order for B to transmit it to C, B should be fully liable for any failure to communicate a warning to C. Holding A liable in this situation reduces the incentive on B, the cheapest cost avoider, to act responsibly. Warning chains are likely to work most effectively if the duty to warn (and liability for failing to warn) is shifted entirely from one party in the chain to the next until the warning reaches the actual user or consumer of the product.

The proposal also relies on the concept of imputed knowledge to limit liability. Even if it fails to warn its immediate vendee, a producer or supplier can still defeat a failure to warn claim by proving that
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someone lower in the distributive chain is, or should be, knowledgeable about the product’s characteristics. This simply reflects the principle that a warning would serve no purpose when given to someone who already knows about the risk in question. However, it should be noted that knowledge of the product is not imputed to ordinary retail consumers or to workers who use or consume the product during the course of their employment.

At first blush, the proposed rule may seem to favor producers and suppliers over accident victims. However, it is fully consistent with the policy considerations discussed earlier in part III. From the perspective of accident cost avoidance, the rule encourages parties in the distributive chain to rely on warning chains in order to achieve accident cost avoidance at the lowest possible cost. The proposed rule also concentrates liability on the cheapest cost avoider instead of diffusing it among multiple parties. The proposed rule will also save administrative costs. By giving producers and suppliers a clear idea of what they must do to satisfy their duty to warn, the proposed rule will reduce information costs. The certainty provided by the proposed rule will also discourage litigation since all parties will know what the legal standard is. Furthermore, the proposed rule will also save administrative costs by discouraging multiparty litigation in failure to warn cases. The main disadvantage of the proposed rule is that it may cut off some avenues of recovery for injured parties. However, accident victims will not be left without any remedy at all if there is a breach of duty; they will simply be limited to a recovery against the party who actually failed to provide the necessary safety information.

CONCLUSION

Producers and suppliers should be required to disclose safety information about their products. Furthermore, this information must reach product end users if it going to do any good. This information may be conveyed directly to users or consumers or it may be transmitted through warning chains. The latter approach is often both cheaper and more effective than direct warnings and, therefore, should be encouraged. The general rule proposed above is intended to achieve this objective.