
Products Liability - Drug Manufacturers - An Absolute Duty to Warn Exists Notwithstanding Miniscule Statistical Probability of Harm

Ronald Neville

Follow this and additional works at: <https://via.library.depaul.edu/law-review>

Recommended Citation

Ronald Neville, *Products Liability - Drug Manufacturers - An Absolute Duty to Warn Exists Notwithstanding Miniscule Statistical Probability of Harm*, 18 DePaul L. Rev. 829 (1969)
Available at: <https://via.library.depaul.edu/law-review/vol18/iss2/33>

This Case Notes is brought to you for free and open access by the College of Law at Via Sapiientiae. It has been accepted for inclusion in DePaul Law Review by an authorized editor of Via Sapiientiae. For more information, please contact digitalservices@depaul.edu.

is intended to put teeth into the enforcement of a landlord's general covenant to keep the land in repair—a covenant wherein both parties contemplate that the landlord will continually, upon being given notice, strive to make the premises safe for those who would rightfully enter the dwelling or place of business. *Reitmeyer* goes further and seeks to enforce a covenant not necessarily contemplated by section 357—a covenant to make specific repairs. When stripped of its reliance upon the *Restatement*, the liability imposed upon the landlord is based upon nothing but negligent nonfeasance.³⁰ A criticism of the decision, therefore, is that it amounts to judicial legislation. As Chief Justice Bell observed in his dissenting opinion: "What is the use of talking about *Stare Decisis*, or increased litigation, or the terrible backlog of cases, if a majority of this Court bury *Stare Decisis* at their daily or weekly or monthly wish or whim?"³¹

Robert Karr

³⁰ See generally PROSSER, *supra* note 3, at § 54.

³¹ *Supra* note 19, at 399.

PRODUCTS LIABILITY—DRUG MANUFACTURERS—
AN ABSOLUTE DUTY TO WARN EXISTS NOTWITHSTANDING
MINISCULE STATISTICAL PROBABILITY OF HARM

In 1963, Glynn Richard Davis, age thirty-nine and in good health, received Sabin oral polio vaccine (type III) at a West Yellowstone, Montana, mass-immunization clinic. The vaccine administered was manufactured by Wyeth Laboratories, Inc., under standards devised by a subdivision of the United States Department of Health, Education and Welfare, the Division of Biologic Standards, which, prior to the drug's dispensation, had tested the drug and authorized its release. Prior to delivery to the clinic, however, several reports—including a Surgeon General's Special Report—had indicated that use of type III vaccine could potentially result in paralytic disease.¹ Such potentiality of paralysis was extremely minimal when the drug was administered to children, but as to the adult population the risks were greater, albeit still statistically slight. Wyeth placed pertinent portions of these findings on each bottle of the vaccine; however, these findings were neither read by Davis, nor was Davis told of the risk involved in use of the drug. Shortly after receiving the vaccine, he evidenced paralysis and other poliomyelitic symptoms which subsequently resulted in permanent paralysis from

¹ See 1962 SURGEON GEN. REP. (March and Dec.), and 1962 ASS'N ST. TERR. HEALTH (Sept.).

the waist down. Davis filed suit in the United States District Court seeking damages for breach of Wyeth's implied warranty as to the vaccine, resulting in Davis' contraction of polio. At trial, the court instructed the jury that "the implied warranty involved in this case does not mean . . . that this vaccine could be used with absolute safety, but means only that the vaccine must have been reasonably fit and reasonably safe for use by the public as a whole."² A jury verdict was rendered for defendant Wyeth and judgment was entered accordingly.³ On appeal, Davis challenged this instruction, alleging that the court should have construed the warranty as applying to himself, rather than to the public as a whole. Rejecting this contention as far-reaching and premature, the United States Court of Appeals nonetheless reversed the district court, but on different grounds. The court of appeals held that the district court had erred in failing to instruct the jury that strict liability attached to the sale of the drug to Davis; that consequently, there existed a duty to warn Davis of the risk involved; and that defendant was therefore liable if found to be in breach of that duty. *Davis v. Wyeth Laboratories Inc.*, 399 F.2d 121 (9th Cir. 1968).

In the instant case, after issuance of the various reports, Wyeth Laboratories was left in the position of having manufactured a drug which had a one-in-a-million chance of causing poliomyelitis in a user although the drug was as safe as human manufacture could make it. How then can it be said that the drug was defective? It is the purpose of this note to explore the liability of a manufacturer whose drug causes injury to a consumer notwithstanding the fact that the drug was prepared under expert standards and was as free from harmful side-effects as was medically possible.

Products liability can be realized under a variety of theories: (1) negligence—requiring proof of the existence of a duty and breach of that duty proximately resulting in injury;⁴ (2) warranty—requiring proof of the existence of an express or implied warranty and its breach;⁵ (3) fraud and misrepresentation—requiring proof that false representations were made as to a given product, that the defendant had knowledge of the product's dangerous propensities, that the plaintiff relied on those representations, and that a

² *Davis v. Wyeth Laboratories, Inc.*, 399 F.2d 121, 126 n.5 (9th Cir. 1968).

³ *Davis v. Wyeth Laboratories, Inc.*, 399 F.2d 121 (9th Cir. 1968).

⁴ *Heichel v. Lima-Hamilton Corp.*, 98 F. Supp. 232 (D. Ohio 1951); *Thomason v. Ballard & Ballard Co.*, 208 N.C. 1, 179 S.E. 30 (1935); *Hampton v. Thomasville Coca-Cola Bottling Co.*, 208 N.C. 331, 180 S.E. 584 (1935); *Henderson v. National Drug Co.*, 343 Pa. 601, 23 A.2d 743 (1942).

⁵ *Tinnerholm v. Parke-Davis & Co.*, 285 F. Supp. 432 (S.D.N.Y. 1968); *Gottsdanker v. Cutter Laboratories*, 182 Cal. App. 2d 602, 6 Cal. Rptr. 320 (1960) (holding that an implied warranty could not be negated by express warranty or disclaimer). See PROSSER, TORTS § 97 (4th ed. 1966); UNIFORM COMMERCIAL CODE §§ 2-314 to 2-318.

reasonable use of the product as represented resulted in the injury;⁶ and (4) nuisance—on the theory that the manufacturer's or supplier's responsibility runs not only to the ultimate consumer, but also to anyone who could reasonably have been expected to be in the vicinity of the product's use.⁷ Recovery from a manufacturer or seller of a product alleged to have caused the injury is barred, however, unless the product is shown to be defective and capable of causing injury,⁸ the defendant is identified as the manufacturer or seller of the product,⁹ and the defect is causally related to the plaintiff's injury.¹⁰

In addition to the above requirements, when a products liability action is brought, the requirement of privity of contract must be considered.¹¹ The privity requirement had its origin in England in the case of *Winterbottom v. Wright*, wherein the court concluded that absent the privity requirement, a person not privity to a warranty could not recover for its breach, else a flood of litigation would ensue.¹² The American courts adopted the rationale of *Winterbottom*, and the general rule evolved that a manufacturer or seller of a product alleged to have caused injury cannot be held liable for negligence, to one with whom he is not in privity.¹³ Today, however, where a products liability action is based on negligence, the trend has been to allow recovery notwithstanding the privity requirement. The rationale behind such a change was expressed in *Henningsen v. Bloomfield Motors, Inc.*, wherein the court stated:

⁶ *Wennerhold v. Stanford Univ. School of Medicine*, 20 Cal. 2d 713, 128 P.2d 522, 141 A.L.R. 1358 (1942).

⁷ *Moran v. Pittsburly-Des Moines Steel Co.*, 166 F.2d 908 (3d Cir. 1948), *cert. denied*, 334 U.S. 846 (1948).

⁸ *Shaw v. Swift & Co.*, 351 Ill. App. 135, 114 N.E.2d 330 (1953); *Jacquot v. Wm. Filene's Sons Co.*, 337 Mass. 312, 149 N.E.2d 635 (1958); *Henderson v. National Drug Co.*, *supra* note 4; *Gottsdanker v. Cutter Laboratories*, *supra* note 5; *Tinnerholm v. Parke-Davis & Co.*, *supra* note 5.

⁹ *Linddroth v. Walgreen Co.*, 407 Ill. 121, 94 N.E.2d 847 (1950); *Tiedje v. Haney*, 184 Minn. 569, 239 N.W. 611 (1931); *Wilson v. Faxon, Williams & Faxon*, 208 N.Y. 108, 101 N.E. 799 (1913).

¹⁰ *Ohio County Drug Co. v. Howard*, 201 Ky. 346, 256 S.W. 705, 31 A.L.R. 1355 (1923); *Haberer v. Moorman Mfg. Co.*, 341 Ill. App. 521, 94 N.E.2d 611 (1950); *Tuscany v. U.S. Standard Products Co.*, 243 S.W.2d 207 (Tex. Civ. App. 1951).

¹¹ *Zierer v. Daniels*, 40 N.J. Super. 130, 122 A.2d 377 (1956); *Greenberg v. Lorenz*, 9 N.Y.2d 195, 213 N.Y.S.2d 39 (1961).

¹² 10 Mees & W. 109, 152 Eng. Rep. 402 (1842).

¹³ *White v. Rose*, 241 F.2d 94 (10th Cir. 1957); *Thrash v. U-Drive-It Co.*, 158 Ohio St. 465, 110 N.E.2d 419 (1953); *Dunn v. Ralston Purina Co.*, 38 Tenn. App. 229, 272 S.W.2d 479 (1954); *Parkinson v. California Co.*, 233 F.2d 432 (10th Cir. 1956); *Bezner v. Howell*, 230 Wis. 1, 233 N.W. 758 (1930); *Smith v. Atco Co.*, 6 Wis. 2d 371, 94 N.W.2d 697, 74 A.L.R.2d 1095 (1959).

[T]he limitations of privity in contracts for the sale of goods developed their place in the law when marketing conditions were simple, when maker and buyer frequently met face to face on an equal bargaining plane and when many of the products were relatively uncomplicated and conducive to inspection by a buyer competent to evaluate their quality.¹⁴

In line with this reasoning, many states have restricted¹⁵ or abolished¹⁶ the privity requirement where the products liability action is based upon a negligence theory.

On the other hand, where the products liability action is based upon a breach of warranty theory, the privity requirement seemingly remains indispensable.¹⁷ However, there are some exceptions to the privity requirement which involve products intended for human consumption¹⁸ and products intended for intimate bodily use.¹⁹ Some states requiring privity also recognize exceptions where the product is "inherently"²⁰ or "imminently"²¹ dangerous.

¹⁴ 32 N.J. 358, 379, 161 A.2d 69, 80 (1960).

¹⁵ Greenman v. Yuba Power Prod. Inc., 59 Cal. App. 2d 57, 377, 27 Cal. Rptr. 697 P.2d 897 (1962); Suvada v. White Motor Co., 32 Ill. 2d 612, 210 N.E.2d 182, *aff'g* 51 Ill. App. 2d 318, 201 N.E.2d 313 (1964); Hill v. Harbor Steel & Supply Corp., 374 Mich. 194, 132 N.W.2d 54 (1965).

¹⁶ Green v. Equitable Powder Mfg. Co., 95 F. Supp. 127 (D. Ark. 1951); Walker v. General Motors Corp., 115 F. Supp. 267 (D. La. 1953); Todd Shipyards Corp. v. United States, 69 F. Supp. 609 (D. Me. 1947); Stull's Chemicals v. Davis, 263 S.W.2d 806 (Tex. Civ. App. 1953); Eades v. Spencer-Adams Paint Co., 82 Ga. App. 123, 60 S.E.2d 543 (1950).

¹⁷ Collins Baking Co. v. Savage, 227 Ala. 408, 150 S.E. 336 (1933); Crystal Coca-Cola Bottling Co. v. Cathey, 83 Ariz. 163, 317 P.2d 1094 (1957); Green v. Equitable Powder Mfg. Co., *supra* note 16; Albin v. Illinois Crop Improv. Assoc. Inc., 30 Ill. App. 2d 283, 174 N.E.2d 697 (1961); Prince v. Smith, 254 N.C. 768, 119 S.E.2d 923 (1961); Hochgertel v. Canada Dry Corp., 409 Pa. 610, 187 A.2d 575 (1963); Esborg v. Bailey Drug Co., 61 Wash. 2d 347, 378 P.2d 298 (1963).

¹⁸ McGee v. Wyeth Laboratories, Inc., 214 Cal. App. 2d 340, 29 Cal. Rptr. 322 (1963); Albin v. Illinois Crop Improv. Assoc. Inc., *supra* note 17; Asher v. Coca-Cola Bottling Co., 172 Neb. 855, 112 N.W.2d 252 (1961); Hochgertel v. Canada Dry Corp., *supra* note 17; Tinnerholm v. Parke-Davis, *supra* note 5; Cudmore v. Richardson-Merrell, Inc., 398 S.W.2d 640 (Tex. Civ. App. 1966); Brewer v. Oriard Powder Co., 66 Wash. 2d 187, 401 P.2d 844 (1965); For a complete analysis of each state's views and decisions as to the requirement of privity, see 1 HURSH, AMERICAN LAW OF PRODUCTS LIABILITY §§ 6:68-6:117 (1961); Prosser, *Fall of the Citadel*, 50 MINN. L. REV. 791 (1965-66); Jaeger, *Privity of Warranty: Has the Tocsin Sounded?* 1 DUQUESNE L. REV. 1 (1963).

¹⁹ Brown v. Chapman, 304 F.2d 149 (9th Cir. 1962), *aff'g* 198 F. Supp. 78 (D. Hawaii); Lartique v. R.J. Reynolds Tobacco Co., 317 F.2d 19 (5th Cir. 1963).

²⁰ Levis v. Zapolitz, 72 N.J. Super. 168, 178 A.2d 44 (1962); Spruill v. Boyle-Midway, Inc., 308 F.2d 79 (4th Cir. 1962); Pellitier v. Dupont, 124 Me. 269, 128 A. 186 (1925).

²¹ Hunter v. Quality Homes Inc., 45 Del. 100, 68 A.2d 620 (1949); Biller v. Allis Chalmers Mfg. Co., 34 Ill. App. 2d 47, 180 N.E.2d 46 (1962); Moberly v. Sears Roebuck & Co., 4 Ohio App. 2d 126, 211 N.E.2d 839 (1965); Tinnerhold v. Parke-Davis, *supra* note 5; Bish v. Employers Liability Assur. Corp., 236 F.2d 62 (5th Cir. 1956). *See*

Drugs represent a singular problem within the scope of products liability because of the inability to know their full effect until they are ingested by human subjects.²² In 1963 it was reported that 1.3 million individuals suffered drug reactions either requiring medical attention or resulting in days lost from work.²³ Notwithstanding voluminous tests performed by drug manufacturers, they cannot know, with any degree of certitude, what side effects might possibly occur. The courts, taking notice of this situation, have not allowed recovery simply because the plaintiff was injured as a result of using the drug. More must be shown: "[T]here is no presumption of negligence from mere fact of injury."²⁴

Individuals injured by drugs also cannot recover where it is shown that they are allergic to or had an idiosyncratic reaction to the particular drug in question.²⁵ Allergic or idiosyncratic individuals are people more susceptible to harm after the ingesting of a given drug than the vast majority of people.²⁶ They are individuals whose body chemistries react adversely and in unforeseen ways to a given chemical.²⁷ The no-recovery rule for idiosyncratic and allergic injuries rests on the dual theories that the manufacturer cannot know what will happen to a hypersensitive person and that the benefit to the general public in the use of the drug outweighs the harm to the injured few.²⁸ Recovery is denied in these cases where the buyers' allergic or idiosyncratic reactions are found only in an insignificant percentage of the population.²⁹ The rationale of such decisions is that if the drug is not harmful to a significant number, then it is reasonably fit for the purpose for which it is sold. It, therefore, cannot then be said that the injury stemmed proximately from

Hungerholt v. Land O'Lakes Creameries Inc., 209 F. Supp. 177 (D. Minn. 1962), *aff'd* 319 F.2d 352 (8th Cir. 1963); Canifex v. Hercules, 237 Cal. App. 2d 44, 46 Cal. Rptr. 522, 1965); Prosser, *supra* note 18, at 811; RESTATEMENT (SECOND) OF TORTS §§ 402A, comments j & k, 497 (1966). *See also*, Note, *The Manufacturer's Duty to Warn of Dangers Involved in Use of Product*, 1967 WASH. U.L.Q. 206-11.

²² Rheingold, *Products Liability—The Ethical Drug Manufacturer's Liability*, 18 RUTGER L. REV. 947 (1963-64).

²³ DRUG NEWS WEEKLY, Jan. 30, 1963, at 8, col. 2. These reactions included blood transfusions and vaccinations.

²⁴ *Mobberly v. Sears Roebuck & Co.*, *supra* note 21.

²⁵ *Merrill v. Beaute Vues Corp.*, 235 F.2d 893 (10th Cir. 1956); *Stanton v. Sears Roebuck & Co.*, 312 Ill. App. 496, 38 N.E.2d 801 (1942); *Bonowski v. Revlon, Inc.*, 251 Iowa 141, 100 N.W.2d 5 (1959).

²⁶ *Lewis v. Casenburg*, 157 Tenn. 187, 7 S.W.2d 808, 60 A.L.R. 254 (1928).

²⁷ *Vogt v. Ford Motor Co.*, 138 S.W.2d 684, 688 (Mo. App. 1940).

²⁸ "The utility of the product outweighs the risk assuming that it is not known, and should not be known to be unduly great." Prosser, *supra* note 18, at 809.

²⁹ *McGee v. Wyeth Laboratories*, *supra* note 18; *Casagrande v. F. W. Woolworth Co.*, 340 Mass. 552, 165 N.E.2d 109 (1960); *Marra v. Jones Store Co.*, 170 S.W.2d 441 (Mo. App. 1943).

a defect in the product, but rather that the injury resulted because of the existence of the idiosyncrasy or allergy in the injured party.³⁰

Where a significant number of consumers are susceptible, however, courts have held the manufacturer liable on the theory that the jury could reasonably have found that the manufacturer should have known and recognized the danger of his product and warned the consuming public of this defect.³¹ This class of persons need not actually be known or discovered prior to the injury; there need only be such a class of which the manufacturer could reasonably have known.³²

A drug is considered "legally defective"³³ when the manufacturer had knowledge or ought to have had knowledge of the harm the drug could cause, and the manufacturer failed to warn the consuming public of risks attendant to use of the drug in that condition.³⁴ Knowledge that the drug is dangerous can be either actual or constructive; the manufacturer must have known or should reasonably have known of the drug's dangerous propensities.³⁵ The manufacturer is held to be an expert with respect to the drug he manufactures, and has a corresponding duty to adequately test his product and keep abreast of any advances in connection with it.³⁶ Where the product was not reasonably known to be defective when placed on the market but subsequently such fact became known or reasonably susceptible of knowledge, the manufacturer may be required to warn the public as of the time these dangers became apparent.³⁷ The reason that an absolute duty to warn does not exist upon discovery of the harmful nature of the drug stems from the rule that the manufacturer is not liable for possible injury, but only for probable injury, and thus the knowledge gained may not be sufficient to warrant a warning.³⁸

³⁰ *Mogensen v. Hicks*, 253 Iowa 139, 110 N.W.2d 563 (1961). See generally Comment, 63 COLUM. L. REV. 515 (1963).

³¹ *Carter v. Yardley*, 319 Mass. 92, 64 N.E.2d 693, 164 A.L.R. 559 (1946); *Gould v. Slater*, 147 Mass. 315, 17 N.E. 531 (1888); *Tinnerholm v. Parke-Davis*, *supra* note 5.

³² Comment, *supra* note 30, at 527 n.72, citing *Branchi v. Denholm & McKay Co.*, 302 Mass. 469, 19 N.E.2d 697 (1939).

³³ See *Dickerson, Products Liability: How Good Does A Product Have To Be?*, 42 IND. L.J. 301, 331 (1967).

³⁴ *Wright v. Carter Prods. Inc.*, 244 F.2d 53 (2d Cir. 1957); *Crotty v. Shartenberg's New Haven, Inc.*, 147 Conn. 460, 162 A.2d 513 (1960); *Gerkin v. Grown & Schler Co.*, 177 Mich. 45, 143 N.W. 48 (1913).

³⁵ *Gahimer v. Virginia Cal. Chemical Corp.*, 241 F.2d 836 (7th Cir. 1957); *Witt Ice & Gas Co. v. Bedway*, 72 Ariz. 152, 231 P.2d 952 (1951); *Pedroli v. Russell*, 157 Cal. App. 2d 281, 320 P.2d 873 (1958).

³⁶ *Dothan-Chero Coca-Cola Bottling Co. v. Weeks*, 16 Ala. App. 639, 80 So. 734 (1918); *Wright v. Carter Products Inc.*, *supra* note 34.

³⁷ *Comstock v. General Motors Corp.*, 358 Mich. 163, 99 N.W.2d 627 (1959); *Mobberly v. Sears Roebuck & Co.*, *supra* note 21.

³⁸ *Mobberly v. Sears Roebuck & Co.*, *supra* note 21.

The duty to warn extends to that class of people for which the drug was intended. Where the drug is a prescription drug, courts have held that warning the doctor who is to redispense the drug to the patient is sufficient.³⁹ This rule rests on the theory that the doctor is better prepared to ascertain whether or not the particular drug defect will affect his patient adversely. Where the drug is not prescribed by a doctor, however, the warning must then reach the public—the ultimate consumer.⁴⁰ Where the product is obviously dangerous, and no latent danger exists, the manufacturer has no duty to warn.⁴¹ Also, no duty to warn exists where the consumer knows or should know of the drug's obvious danger.⁴²

Once warning is given by the manufacturer, the question of the adequacy of that warning arises and is ordinarily considered to be a question of fact in each case.⁴³ It has been held that an inadequate warning has the same result as no warning at all.⁴⁴ The warning must specify the extent of the danger; therefore, a warning simply stating that the product is dangerous is insufficient.⁴⁵ And where the manufacturer warns but his warning is lost in "a volume of verbiage,"⁴⁶ or where the dangers were minimized within advertisements designed to sell the drug,⁴⁷ the duty to warn has also not been satisfied. The warning must be accurate,⁴⁸ strong and clear,⁴⁹ and placed in such a position that it will be readily noticed.⁵⁰ The force of the warning must be equal to the danger involved; that is, it must be sufficient to raise an appropriate caution in the user.⁵¹ Where the product was not used as

³⁹ *McGee v. Wyeth Laboratories*, *supra* note 18; *Tinnerholm v. Parke-Davis Co.*, *supra* note 5.

⁴⁰ *Sterling Drug Inc. v. Cornish*, 370 F.2d 82 (8th Cir. 1967); *Love v. Wolf*, 226 Cal. App. 2d 378, 38 Cal. Rptr. 183 (1964); *Marcus v. Specific Pharmaceutical*, 82 N.Y.S.2d 94 (Sup. Ct. 1948).

⁴¹ *Winkler v. Macon Gas Co.*, 361 Mo. 1017, 238 S.W.2d 386 (1951).

⁴² "No one needs notice of what he already knows," and "knowledge of the danger is equivalent to prior notice." *Jamieson v. Woodward & Lathrop*, 247 F.2d 23, 26 (D.C. Cir. 1957).

⁴³ *Carmen v. Eli Lilly & Co.*, 109 Ind. App. 76, 32 N.E.2d 729 (1941); *Halloran v. Parke-Davis & Co.*, 245 App. Div. 727 (1935); *Marcus v. Specific Pharmaceuticals Inc.*, *supra* note 40.

⁴⁴ *Crane v. Sears Roebuck & Co.*, 218 Cal. App. 855, 32 Cal. Rptr. 754 (1963).

⁴⁵ *Gonzalez v. Virginia-Carolina Chem. Co.*, 239 F. Supp. 567 (E.D.S.C. 1965).

⁴⁶ *Crane v. Sears Roebuck & Co.*, *supra* note 44.

⁴⁷ *Love v. Wolf*, *supra* note 40; *Tinnerholm v. Parke-Davis & Co.*, *supra* note 5.

⁴⁸ *Lovejoy v. Minneapolis-Moline Power Implement Co.*, 248 Minn. 319, 79 N.W.2d 688 (1956).

⁴⁹ *Crouse v. Wilbur-Ellis Co.*, 77 Ariz. 359, 272 P.2d 352 (1954).

⁵⁰ *Marigny v. Dejoie*, 172 So. 808 (La. App. 1937).

⁵¹ *Tampa Drug Co. v. Wait*, 103 So. 2d 603, 75 A.L.R.2d 765 (Fla. 1965). *See Hursh*, *supra* note 27, at §§ 2:28-2:57.

intended or the instructions given were not followed, the manufacturer is absolved from liability.⁵²

If the manufacturer has warned by the use of literature or the like, the individual or the class to be warned is presumed to have read the warning. In the case of a pamphlet, the doctor or consumer "is bound to consider the pamphlet as a whole and not single out and rely upon a single word or line or paragraph to the exclusion of the rest."⁵³ It has been held that there is a difference between "warnings" and "instructions" since they:

are not necessarily the same, the former call attention to danger, the latter prescribe procedures for efficient use of a product and for avoiding danger; a manufacturer might provide one and still be liable in failing to provide the other, as where instructions fail to alert the user to the danger they seek to avert, or where a warning alerts the user to a peril but does not enable him to avoid it.⁵⁴

In the instant case, by virtue of the Surgeon General's reports and confirmations thereof by certain local medical authorities,⁵⁵ Wyeth Laboratories could be feasibly found to be on notice of the possible harm resultant from the use of the Sabin Type III vaccine by adults. But is knowledge of a mere possibility sufficient for the imposition of an absolute duty to warn? Concededly, the Surgeon General's report considered the aggregate risk to adults and children to be less than one case per million doses.⁵⁶ Then is the *Wyeth* decision a liberalization of the standards of liability imposed upon drug manufacturers?

Courts have traditionally held that the manufacturer must protect against probabilities, and not against mere possibilities.⁵⁷ A "probability" has been defined as the "quality or state of being probable; the appearance of reality or truth, a reasonable ground or presumption; a likelihood."⁵⁸ Another court has said: "[P]robability arises in the law of negligence when viewed from the standpoint of judgment of a reasonably prudent man, as a reasonable thing to be expected."⁵⁹

⁵² *Vincent v. Nicholas E. Tsiknas Co.*, 337 Mass. 726, 151 N.E.2d 263 (1958); *Prosser*, *supra* note 18, 824.

⁵³ *Carmen v. Eli Lilly & Co.*, *supra* note 43.

⁵⁴ *Boyl v. California Chemical Co.*, 221 F. Supp. 669, 670 (D. Oregon 1963). See Noel, *Recent Trends in Manufacturer's Negligence as to Design, Instructions, or Warnings*, 19 S.W.L.J. 43, 44-46 (1965).

⁵⁵ The Idaho Public Health Service, Idaho Falls Medical Society, and the Association of State and Territorial Health Officers. See *supra* note 3, at 123-24.

⁵⁶ *Supra* note 3, at 124: "The level of risk can be approximated, but clearly is within range of less than 1 case per million doses. . . ."

⁵⁷ *Webb v. State*, 19 Okla. Crim. 450, 200 P. 719 (1921); *O'Brien v. Industrial Commission*, 90 Utah 266, 61 P.2d 418 (1936).

⁵⁸ *Coppinger v. Broderick*, 39 Ariz. 473, 295 P. 780, 781 (1931).

⁵⁹ *Shuptrine v. Herron*, 182 Miss. 315, 319, 180 So. 620, 622 (1938).

In *Merrill v. Beaute Vues Corp.*,⁶⁰ the court held that the plaintiff had no cause of action in view of the manufacturer's proof that the consumer's injury was due to an idiosyncrasy based on the fact that over 500,000,000 similar products had been sold to and used by persons and had caused only very rare ill effects. The court further found that the manufacturer did not know and could not have known that the drug was injurious to normal persons, to any class or persons, or to plaintiff. Thus, reasoned the court, it was a possibility rather than a probability that plaintiff would be injured. In *Bish v. Employers Liability Assurance Corp.*,⁶¹ where plaintiff suffered extreme injury from defendant's product, the court said that her injury was due to an unusual susceptibility and that no liability lies where only a remote possibility of danger exists. In *McGee v. Wyeth Laboratories, Inc.* where decedent died from an injection of Sparine, a drug which could only be prescribed by a doctor, it was shown that the decedent was sensitive to the drug. The court reiterated that the manufacturer is only required to guard against probabilities. These cases can be distinguished from the principal case in that they turned on the question of whether the manufacturer had actual or constructive knowledge of the product's danger, and it was shown that the manufacturers did not actually possess such knowledge, nor could such knowledge be attributed to them.

The obverse was true in the case at hand. Wyeth had been told that adults over the age of 30 faced a risk of contracting polio from this particular type of vaccine. It could reasonably have been expected that some, although very few, could be harmed from the drug. In *Carter v. Yardley* it was said that a manufacturer's liability depended on whether or not the injury "must have been anticipated."⁶² Additional cases have shown that where the manufacturer has knowledge that his drug can harm the consumer, even though only a small percentage might be harmed, the manufacturer must warn the consuming public of such possible harm.⁶³

Wyeth knew that the vaccine was to be used in a mass immunization, and therefore knew that a mass of people would attend. This knowledge, in conjunction with the knowledge of the increased risk to adults over the age of thirty, a significant class of people, thus conferred on Wyeth the duty to warn those consumers. The instant decision cannot be considered an extension of existing cases since it has been held that evidence indicating that but a minuscule percentage of potential consumers would be in danger does not relieve the manufacturer of his duty to warn.⁶⁴

⁶⁰ *Supra* note 25.

⁶¹ 236 F.2d 62 (5th Cir. 1956).

⁶² *Carter v. Yardley*, 319 Mass. 92, 96, 64 N.E.2d 693, 696, 164 A.L.R. 559 (1946).

⁶³ *Supra* note 29.

⁶⁴ *Gover v. Revon Inc.*, 317 F.2d 47 (4th Cir. 1963); *Reynolds v. Natural Gas Equip.*,

Does not this duty to warn under circumstances similar to *Davis v. Wyeth Laboratories, Inc.* impose an undue hardship on drug companies? The hardship, if one insists on calling it such, is slight. At mass-immunization clinics, all that is required is that posters or a similar media containing appropriate warnings be brought to the attention of any participants.⁶⁵ Where the drug is a prescription drug, the drug companies need only notify the doctors;⁶⁶ in the case of non-prescription drugs, a simple statement of the danger could be placed on each bottle or package.⁶⁷

Finally, with particular regard to trial standards, a pure statistic will not alone determine liability. In *Wright v. Carter Products Inc.* the court stated that "duties to warn are not, in all cases, measured solely by quantitative standards."⁶⁸ Where the risk of injury might result in death or serious injury, it will not be a quantitative standard, but rather a qualitative standard that will be employed to determine fault—the standard that was imposed in *Davis v. Wyeth Laboratories, Inc.*

Drug companies are still protected from liability if they have no actual knowledge of any defects, but when the drug companies do possess such knowledge, all the courts require is that the choice of whether or not the drug is to be taken be placed with the consumer. If there is a chance of injury, the consumer and not the drug company should have the opportunity of weighing the risk involved in consumption of the drug. The consumer should be allowed to decide if he will accept the risk of contracting blindness, paralysis, or the like. Public policy demands that certain drugs be used notwithstanding the risk involved since the benefits of their use far outweigh their disadvantages. But public policy does not demand that the individual user be ignorant of certain risks involved in a particular drug's use. When the consumer is told of the dangers and given the choice, no one can be heard to complain if injury results.

Ronald Neville

184 Cal. App. 2d 724, 7 Cal. Rptr. 879 (1960); *Wright v. Carter Products Inc.*, *supra* note 34; *Tingey v. E. F. Houghton*, 30 Cal. 2d 97, 179 P.2d 807 (1947).

⁶⁵ *Tinnerholm v. Parke-Davis & Co.*, *supra* note 5.

⁶⁶ *McGee v. Wyeth Laboratories Inc.*, *supra* note 18.

⁶⁷ *Spruill v. Boyle-Midway, Inc.*, 308 F.2d 79 (4th Cir. 1962).

⁶⁸ *Supra* note 34, at 56.