



ST.MARY'S
UNIVERSITY

St. Mary's Law Journal

Volume 9 | Number 1

Article 6

3-1-1977

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Recommended Citation

David E. Chamberlain, *The Diminishing Role of Negligence in Manufacturers' Liability for Unavoidably Unsafe Drugs and Cosmetics.*, 9 ST. MARY'S L.J. (1977).

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THE DIMINISHING ROLE OF NEGLIGENCE IN MANUFACTURERS' LIABILITY FOR UNAVOIDABLY UNSAFE DRUGS AND COSMETICS

DAVID E. CHAMBERLAIN

MER-29, a drug synthesized in 1956 by Richardson-Merrell, Inc., was designed to reduce the cholesterol level in heart patients. After development, it was sent to the company's laboratories for testing on rats, dogs, and monkeys. In 1958 and 1959 MER-29 was tested on two-thousand human patients. In June of 1960 the drug was placed on the market and made available through prescription. By October of 1960 all of the company's rats had developed cataracts and total blindness. In January, 1961, the company received reports from other laboratories that MER-29 had produced cataracts in the laboratories' rats and dogs. The first report of cataracts in a human was received by Richardson-Merrell in January of 1961. In the summer of 1961 another long term study of the drug's effects revealed that eye trouble had developed in seventy-five percent of the animals. The Mayo Clinic reported two incidents of cataracts in human patients in October of 1961. Two months after this report, Richardson-Merrell made its first warning about the potentially harmful side effects of MER-29. On May 22, 1962, Richardson-Merrell withdrew MER-29 from druggists' shelves. An estimated five thousand people suffered injuries, principally eye damage, from the use of the drug.¹ In *Cudmore v. Richardson-Merrell, Inc.*² a Texas appellate court affirmed a take-nothing judgment and stated that the defendant manufacturer was not liable because within the state of medical knowledge the incidence of plaintiff's injuries was not foreseeable in an appreciable class of persons.³

With the advent of section 402A of the *Restatement (Second) of Torts*⁴ and strict products liability, plaintiffs have generally been relieved of the burden of proving a seller's or manufacturer's negligence in suits for injuries caused by defective products.⁵ One exception to this rule involves unavoidably unsafe products such as drugs and cosmetics which, although pure and manufactured as intended, cannot be made safe for use by the

1. *Toole v. Richardson-Merrell, Inc.*, 60 Cal. Rptr. 398 (Dist. Ct. App. 1967); *Cudmore v. Richardson-Merrell, Inc.*, 398 S.W.2d 640 (Tex. Civ. App.—Dallas 1965, writ ref'd n.r.e.), cert. denied, 385 U.S. 1003 (1967); *Rheingold, The MER-29 Story—An Instance of Successful Mass Disaster Litigation*, 56 CALIF. L. REV. 116, 117-21 (1968).

2. 398 S.W.2d 640 (Tex. Civ. App.—Dallas 1965, writ ref'd n.r.e.), cert. denied, 385 U.S. 1003 (1967).

3. *Id.* at 644.

4. *RESTATEMENT (SECOND) OF TORTS* § 402A (1965).

5. W. PROSSER, *HANDBOOK OF THE LAW OF TORTS* § 98 (4th ed. 1971).

entire public.⁶ The courts have uniformly required that the injured consumers of these products prove not only that their harm was foreseeable but also that the manufacturer failed to act reasonably to prevent the harm.⁷ The preservation of this fault concept under section 402A in suits involving injuries caused by unavoidably unsafe drugs and cosmetics has precipitated unnecessary confusion in the law and caused inconsistent judicial treatment of consumers and manufacturers alike. In response to this, some of the more recent decisions indicate, without so holding, that a possible departure from the fault concept may be in the offing and that strict liability may also be imposed on drug and cosmetic manufacturers.⁸

TRADITIONAL THEORIES OF RECOVERY

The traditional negligence theory of products liability was developed in the early part of this century when many American courts began to depart from the *caveat emptor*⁹ rule in suits for injuries caused by defective products. The earliest cases allowed recovery for the negligent preparation and sale of articles inherently dangerous to human safety,¹⁰ and the doctrine was eventually expanded to include all products that became dangerous when negligently made.¹¹ It was reasoned that a seller assumed a noncontractual responsibility to the buyer not to place a product on the market that would be dangerous if negligently made.¹² Thus, under the traditional fault concept, it became incumbent upon the plaintiff to prove that the manufacturer or seller negligently exposed him to an unreasonable risk of harm and that the product was the proximate cause of his injuries.¹³

Warranty, another theory in products liability, is of contractual origin.

6. RESTatement (SECOND) OF TORTS § 402A, Comment k (1965).

7. See, e.g., *Basko v. Sterling Drug, Inc.*, 416 F.2d 417, 426 (2d Cir. 1969) (Aralen); *Merrill v. Beaute Vues Corp.*, 235 F.2d 893, 898 (10th Cir. 1956) (home permanent); *Krug v. Sterling Drug, Inc.*, 416 S.W.2d 143, 151 (Mo. 1967) (Aralen).

8. *Tinnerholm v. Parke, Davis & Co.*, 285 F. Supp. 432, 444 (S.D.N.Y. 1968), *aff'd*, 411 F.2d 48 (2d Cir. 1969); *Stromsdot v. Parke, Davis & Co.*, 257 F. Supp. 991, 994 (D.N.D. 1966), *aff'd*, 411 F.2d 1390 (8th Cir. 1969); *Crocker v. Winthrop Laboratories, Inc.*, 514 S.W.2d 429, 432 (Tex. 1974).

9. In *Winterbottom v. Wright*, 152 Eng. Rep. 402 (Ex. 1842) the court applied the *caveat emptor* rule and reasoned that the growth of industry would be hindered if the seller or maker of a product were liable for injuries caused by use of the product. *Id.* at 405; accord, *Lebourdais v. Vitrified Wheel Co.*, 80 N.E. 482, 483 (Mass. 1907); *Hasbrouck v. Armour & Co.*, 121 N.W. 157, 161 (Wis. 1909).

10. *Huset v. J.I. Case Threshing Mach. Co.*, 120 F. 865, 870 (8th Cir. 1903) (threshing machine); *Thomas v. Winchester*, 6 N.Y. 396, 409 (1852) (poison).

11. *MacPherson v. Buick Motor Co.*, 111 N.E. 1050, 1053 (N.Y. 1916) (dealer is not only one to be protected).

12. See generally W. PROSSER, HANDBOOK OF THE LAW OF TORTS § 96 (4th ed. 1971).

13. E.g., *Smith v. S.S. Kresge Co.*, 79 F.2d 361, 363 (8th Cir. 1935) (hair comb); *Simmons Co. v. Hardin*, 43 S.E.2d 553, 559-60 (Ga. Ct. App. 1947) (sofa bed); *Carter v. Yardley & Co.*, 64 N.E.2d 693, 696 (Mass. 1946) (perfume).

As a theory of recovery, warranty was first applied in cases resulting from the marketing of defective foods¹⁴ and products intended for intimate bodily use.¹⁵ This theory was eventually expanded to allow recovery in cases involving a wide assortment of products.¹⁶ Presently, a manufacturer's or seller's warranty may be express if certain assurances are made about the product's safety,¹⁷ or implied if the product is unmerchantable¹⁸ or unfit for its particular purpose.¹⁹ The warranty theory requires no proof of the manufacturer's or seller's negligence,²⁰ but it does require that the product be the proximate cause of the plaintiff's injuries.²¹ In actions based on breach of warranty, the unwary plaintiff is often defeated by such traditional defenses as disclaimer, timely notice, and privity of contract.²²

The difficult problems in proof of negligence and the barriers to recovery in warranty actions have caused many courts to find the defendant liable on a strict liability theory.²³ In *Greenman v. Yuba Power Products, Inc.*²⁴

14. *Coca-Cola Bottling Works v. Lyons*, 111 So. 305, 307 (Miss. 1927) (soda water) (food manufacturer's warranty to consumer similar to covenant that runs with land); *Jacob E. Decker & Sons, Inc. v. Capps*, 139 Tex. 609, 614-15, 164 S.W.2d 828, 830-31 (1942) (meat); *LaHue v. Coca-Cola Bottling, Inc.*, 314 P.2d 421, 422 (Wash. 1957) (soda water).

15. *Worley v. Proctor & Gamble Mfg. Co.*, 253 S.W.2d 532, 535 (Mo. Ct. App. 1952) (dishwashing detergent); *Rogers v. Toni Home Permanent Co.*, 147 N.E.2d 612, 614 (Ohio 1958) (permanent wave solution).

16. *Deveny v. Rheem Mfg. Co.*, 319 F.2d 124, 129-30 (2d Cir. 1963) (water heater); *Simpson v. Powered Prods., Inc.*, 192 A.2d 555, 560 (Conn. C.P. 1963) (power golf cart); *Goldberg v. Kollsman Inst. Corp.*, 240 N.Y.S.2d 592, 594-95 (1963) (airplane).

17. *Baxter v. Ford Motor Co.*, 35 P.2d 1090, 1092 (Wash. 1934); see W. PROSSER, HANDBOOK OF THE LAW OF TORTS § 97 (4th ed. 1971).

18. *Stromsodt v. Parke, Davis & Co.*, 257 F. Supp. 991, 994-95 (D.N.D. 1966), aff'd, 411 F.2d 1390 (8th Cir. 1969).

19. *Tinnerholm v. Parke, Davis & Co.*, 285 F. Supp. 432, 440 (S.D.N.Y. 1968), aff'd, 411 F.2d 48 (2d Cir. 1969); *Pietrus v. Watkins Co.*, 38 N.W.2d 799, 802 (Minn. 1949).

20. In a warranty action the court in *Valases v. Montgomery Ward & Co.*, 377 F.2d 846 (3d Cir. 1967) rejected defendant's contention that it was not liable without proof of negligence and stated that "lack of skill or foresight on the part of the seller in discovering the product's flaw was never meant to bar liability." *Id.* at 850; see J. WHITE & R. SUMMERS, HANDBOOK OF THE LAW UNDER THE UNIFORM COMMERCIAL CODE § 9-1 (1972).

21. *McCrossin v. Hicks Chevrolet, Inc.*, 248 A.2d 917, 920 (D.C. Ct. App. 1969) (expert testified that faulty carburetor probably caused fire); *Jakubowski v. Minnesota Mining & Mfg.*, 199 A.2d 826, 829 (N.J. 1964) (plaintiff has burden of establishing probability not possibility); see J. WHITE & R. SUMMERS, HANDBOOK OF THE LAW UNDER THE UNIFORM COMMERCIAL CODE § 9-8 (1972).

22. U.C.C. § 2-316 (disclaimer); *id.* § 2-318 (privity); *id.* § 2-607(3) (timely notice). See generally W. PROSSER, HANDBOOK OF THE LAW OF TORTS § 97 (4th ed. 1971); J. WHITE & R. SUMMERS, HANDBOOK OF THE LAW UNDER THE UNIFORM COMMERCIAL CODE chs. 11, 12 (1972); Prosser, *The Assault Upon the Citadel (Strict Liability to the Consumer)*, 69 YALE L.J. 1099, 1124-34 (1960).

23. See, e.g., *Greenman v. Yuba Power Prods., Inc.*, 27 Cal. Rptr. 697, 701 (1962) (en banc); *Suvada v. White Motor Co.*, 210 N.E.2d 182, 185 (Ill. 1965); *Dealer's Transp. Co. v. Battery Distrib. Co.*, 402 S.W.2d 441, 446-47 (Ky. 1965); *Wights v. Staff Jennings, Inc.*, 405 P.2d 624, 629 (Ore. 1965); see Keeton, *Products Liability—The Nature and Extent of Strict*

the court rejected the traditional warranty defenses and stated, “[a] manufacturer is strictly liable in tort when an article he places on the market, knowing that it is to be used without inspection for defects, proves to have a defect that causes injury to a human being.”²⁵ Under section 402A, proof of negligence is not required and the traditional warranty defenses will not defeat recovery.²⁶

While adoption of section 402A seemingly revolutionized the law of products liability, it was not a blanket extension of strict tort liability to drug and cosmetic manufacturers for injuries caused by their products.²⁷ The draftsmen of the *Restatement (Second)* recognized that there were “some products” which were useful but nonetheless unsafe.²⁸ These “unavoidably unsafe products” are those which cannot be made absolutely safe “in the present state of human knowledge.”²⁹ Comment *k* to that section suggests that the marketing of an unsafe but generally useful product, such as a drug, is fully justified if it is accompanied by proper directions and warnings.³⁰ Moreover, comment *j* states that a warning of an unsafe characteristic in a product is required only if the characteristic is unsafe to a “substantial number” of people.³¹ As a result, it has been held that foreseeability of risk or harm is a proper element in a products liability case if the product is pure or produced as designed.³² These exceptions have led many courts and commentators to conclude that negligence, implied warranty, and strict liability are *not* distinguishable in most drug injury cases.³³

Liability, 1964 U. ILL. L.F. 693, 697; Wade, *Strict Tort Liability of Manufacturers*, 19 Sw. L.J. 5, 10 (1965).

24. 27 Cal. Rptr. 697 (1962).

25. *Id.* at 700.

26. *RESTATEMENT (SECOND) OF TORTS* § 402A (1965).

27. *Id.* Comment *k*.

28. *Id.* Comment *k*.

29. *Id.* Comment *k*.

30. *Id.* Comment *k*.

31. *Id.* Comment *j*.

32. C.A. Hoover & Son v. O.M. Franklin Serum Co., 444 S.W.2d 596, 598 (Tex. 1969).

33. Basko v. Sterling Drug, Inc., 416 F.2d 417, 426-27 (2d Cir. 1969) (comment *k* simply adopts ordinary negligence concept of duty to warn); Greeno v. Clark Equip. Co., 237 F. Supp. 427, 429 (N.D. Ind. 1965) (court noted that strict liability as imposed by § 402A is similar to implied warranty absent contract defenses such as privity, disclaimer, notice, and limitation by express warranty); Merrill, *Compensation for Prescription Drug Injuries*, 59 VA. L. REV. 1, 31 (1973) (functionally interchangeable). See also Keeton, *Manufacturer's Liability: The Meaning of "Defect" in the Manufacture and Design of Products*, 20 SYRACUSE L. REV. 559, 563 (1969) (proof required for strict liability will also sustain proof of negligence); W. PROSSER & J. WADE, *CASES AND MATERIALS ON TORTS* 727 n.2 (5th ed. 1971) (in drug liability cases strict liability is not distinguishable from negligence).

DUTIES OF DRUG AND COSMETIC MANUFACTURERS

The duties of a manufacturer of drugs and a manufacturer of cosmetics are very similar. The drug manufacturer has the duty to develop the product, test it for harmful side effects, and seek legal approval for its marketing.³⁴ Both manufacturers have the duty to be fully knowledgeable about their products' characteristics and to keep abreast of scientific knowledge that becomes available concerning their products.³⁵ Introduction of ingredients into the product that might cause harm to the average consumer must be prevented.³⁶ If a drug manufacturer becomes aware of adverse reactions to its drug, it must warn prescribing and treating physicians.³⁷ A cosmetic manufacturer, however, must warn the public directly of harmful effects that are incident to the normal use of the product.³⁸ While discharging these duties, both classes of manufacturers are held to the knowledge of an expert in their respective fields.³⁹

An adequate warning is essential to the marketing of a product that has known unsafe characteristics.⁴⁰ Once this duty has been discharged, the manufacturer must take care to ensure that this warning is not negated

34. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355 (Supp. V 1975).

35. Schenebeck v. Sterling Drug, Inc., 423 F.2d 919, 922 (8th Cir. 1970) (must notify physicians of discovered side effects); O'Hare v. Merck & Co., 381 F.2d 286, 291 (8th Cir. 1967) (exercise reasonable care to discover); see Pietrus v. Watkins Co., 38 N.W.2d 799, 802 (Minn. 1949); Krug v. Sterling Drug, Inc., 416 S.W.2d 143, 149 (Mo. 1967).

36. West v. Alberto Culver Co., 486 F.2d 459, 461 (10th Cir. 1973) (shampoo contained excess bacteria); Ireland v. Louis K. Liggett Co., 137 N.E. 371, 372 (Mass. 1922) (glass in cold cream); C.A. Hoover & Son v. O.M. Franklin Serum Co., 444 S.W.2d 596, 598 (Tex. 1969) (drug contained dangerous ingredient).

37. Schenebeck v. Sterling Drug, Inc., 423 F.2d 919, 922 (8th Cir. 1970); Krug v. Sterling Drug, Inc., 416 S.W.2d 143, 146 (Mo. 1967) (manufacturer required to warn treating or prescribing physician, not general public, of dangers in prescription drugs). *But see* Davis v. Wyeth Laboratories, Inc., 399 F.2d 121, 131 (9th Cir. 1968) (duty to warn patient directly in the case of mass immunization).

38. Whitehurst v. Revlon, 307 F. Supp. 918, 921 (E.D. Va. 1969); Moran v. Williams, 313 A.2d 527, 532 (Md. Ct. Spec. App. 1974).

39. Hruska v. Parke, Davis & Co., 6 F.2d 536, 538 (8th Cir. 1925); Pietrus v. Watkins Co., 38 N.W.2d 799, 802 (Minn. 1949); Incollingo v. Ewing, 282 A.2d 206, 219 (Pa. 1971); Henderson v. National Drug Co., 23 A.2d 743, 748 (Pa. 1942).

40. In Cunningham v. Phizer Prods., PROD. LIAB. REP. (CCH) ¶ 7318, at 13,394 (Okla. 1974) the court reasoned that the absence of an adequate warning of the product's unsafe characteristics rendered the product defective as marketed. *Accord*, Ethicon, Inc. v. Parten, 520 S.W.2d 527, 532 (Tex. Civ. App.—Houston [14th Dist.] 1975, no writ). In Davis v. Wyeth, 399 F.2d 121 (9th Cir. 1968) the court held that the absence of an adequate warning did not render the product defective but rather unreasonably dangerous. *Id.* at 129; *see* Wade, *Strict Tort Liability of Manufacturers*, 19 Sw. L.J. 5, 14-15 n.53 (1965). In Reyes v. Wyeth Laboratories, Inc., 498 F.2d 1264 (5th Cir. 1974) the court reasoned that "defective condition" and "unreasonably dangerous" were interchangeable and that there was no reason for distinction between the two terms. *Id.* at 1272; *see* Keeton, *Product Liability and the Meaning of Defect*, 5 ST. MARY'S L.J. 30, 32 (1973).

by overpromotion.⁴¹ One example of drug overpromotion that has resulted in the negation of an otherwise adequate warning is the aggressive sales behavior of a manufacturer's salesman.⁴² If constant assurances of the drug's usefulness and safety overcome or negate the previous warning, the manufacturer may be held strictly liable for the subsequent injury caused to the consumer by the drug's unsafe characteristics.⁴³ Further, under section 402B, *Restatement (Second) of Torts*,⁴⁴ a manufacturer who makes statements of the drug's absolute safety may be held strictly liable for all foreseeable or unforeseeable harm regardless of the fact that he had no actual knowledge of any dangers.⁴⁵ While there have been no cases that have held a cosmetic manufacturer strictly liable under section 402B for misrepresentations of the product's safety, the same result has been reached by holding a manufacturer liable under a theory of express warranty.⁴⁶

THE KNOWN RISK

It is a commercial reality that certain products cannot be made safe for all individuals to use or consume.⁴⁷ Equally clear is the idea that a manufacturer who attempts to satisfy public demand by furnishing an apparently useful and beneficial product should not be strictly liable simply because some portion of the population suffers harm following the use of the product.⁴⁸ Accordingly, the *Restatement (Second)* provides, and the

41. In *Love v. Wolf*, 38 Cal. Rptr. 183, 196 (Dist. Ct. App. 1964) the court stated that "if the overpromotion can reasonably be said to have induced the doctor to disregard the warnings previously given, the warning given is thereby withdrawn or cancelled . . ." *Accord*, *Stevens v. Parke, Davis & Co.*, 107 Cal. Rptr. 45, 53 (1973) (*en banc*) (manufacturer failed to adequately warn of dangerous propensities of drug by so "watering down" previous warnings that physician prescribed drug when not justified); *Incollingo v. Ewing*, 282 A.2d 206, 221-22 (Pa. 1971) (warning cancelled by sales effort of manufacturer).

42. See *Crocker v. Winthrop Laboratories, Inc.*, 514 S.W.2d 429, 430-33 (Tex. 1974).

43. See cases cited note 41 *supra*.

44. *RESTATEMENT (SECOND) OF TORTS* § 402B (1965).

45. *Id.* Comment a. In *Crocker v. Winthrop Laboratories, Inc.*, 514 S.W.2d 429 (Tex. 1974) the Texas Supreme Court, after rejecting the manufacturer's contention that the consumer's death was unforeseeable, stated:

Whatever the danger and state of medical knowledge, and however rare the susceptibility of the user, when the drug company positively and specifically represents its product to be free and safe from all dangers . . . and the treating physician relies upon that representation, the drug company is liable when the representation proves to be false and害 results.

Id. at 433.

46. *Spiegel v. Saks*, 34th St., 252 N.Y.S.2d 852, 856-58 (App. Div. 1964) ("safe"); *Rogers v. Toni Home Permanent Co.*, 147 N.E.2d 612, 616 (Ohio 1958); *cf. Wright v. Carter Prods., Inc.*, 244 F.2d 53, 61 (2d Cir. 1957) (court indicated that manufacturer could be held liable on basis of negligent advertising of product's "harmless" nature).

47. See *Restatement (Second) of Torts* § 402A, Comment k (1965).

48. See *id.* Comment j.

courts have uniformly held, that an "unavoidably unsafe product" that is properly manufactured and is accompanied by adequate warnings is not defective or unreasonably dangerous.⁴⁹ A problem lies, however, in determining the circumstances under which the risk of injury is sufficiently apparent to require a manufacturer to warn.

Appreciable Class Test

The conservative view, as supported by the *Restatement (Second)*, dictates that a risk of injury is not apparent until it can be foreseen that the adverse side effects of a drug or cosmetic would affect a "substantial number" of the population.⁵⁰ A Colorado Supreme Court decision, *Howard v. Avon Products, Inc.*,⁵¹ is indicative of this view. Howard brought suit for injuries suffered allegedly from a common preservative injected in Avon's cosmetics. The court affirmed the trial court judgment for Avon and stated that the manufacturer would not be held liable for an injury due to some idiosyncracy peculiar to the plaintiff which made her hypersensitive to a product unless the reaction was common to an "identifiable class" of persons.⁵² It was noted further that to hold otherwise would have been to impose upon the manufacturer the liability of an insurer.⁵³

The "appreciable class" rule was tempered somewhat in *Reyes v. Wyeth Laboratories, Inc.*⁵⁴ There the appellant's child contracted polio after ingesting appellee's trivalent oral polio vaccine.⁵⁵ Wyeth contended that it had no duty to warn of the possibility of contracting polio from the use of its vaccine since there was not a "substantial number" of consumers known to react similarly.⁵⁶ The Court of Appeals for the Fifth Circuit, purporting

49. *Id.* Comments j, k; e.g., *O'Hare v. Merck & Co.*, 381 F.2d 286, 291 (8th Cir. 1967); *Howard v. Avon Prods., Inc.*, 395 P.2d 1007, 1010, 1011 (Colo. 1964) (declining to hold manufacturer an insurer); see *Magee v. Wyeth Laboratories, Inc.*, 29 Cal. Rptr. 322, 329 (Dist. Ct. App. 1963); *Robbins v. Alberto Culver Co.*, 499 P.2d 1080, 1083 (Kan. 1972).

50. RESTatement (SECOND) OF TORTS § 402A, Comment j (1965); see, e.g., *Merrill v. Beaute Vues Corp.*, 235 F.2d 893, 897 (10th Cir. 1956) (rare); *Bonowski v. Revlon, Inc.*, 100 N.W.2d 5, 8 (Iowa 1959) (one in five million); *Esborg v. Bailey Drug Co.*, 378 P.2d 298 (Wash. 1963).

51. *Howard v. Avon Prods., Inc.*, 395 P.2d 1007 (Colo. 1964) (en banc).

52. *Id.* at 1010. A *hypersensitive* individual is one who is unusually susceptible to a certain drug injury. This is commonly the result of sensitization from earlier consumption of the same drug. An *allergy* refers to a peculiar antigen-antibody reaction. An *idiosyncratic* reaction is a rare event that occurs in a small portion of the population. M. DIXON, DRUG PRODUCT LIABILITY § 4.04[7]-[9] (1975).

53. *Howard v. Avon Prods., Inc.*, 395 P.2d 1007, 1010-11 (Colo. 1964) (en banc).

54. *Reyes v. Wyeth Laboratories*, 498 F.2d 1264 (5th Cir.), cert. denied, 419 U.S. 1096 (1974). See also *Noel, Defective Products: Abnormal Use, Contributory Negligence, and Assumption of Risk*, 25 VAND. L. REV. 93, 104 (1972) (where it is noted that the size of class needed before duty to warn arises is shrinking but still no recovery for isolated injury).

55. *Reyes v. Wyeth Laboratories*, 498 F.2d 1264, 1269 (5th Cir.), cert. denied, 419 U.S. 1096 (1974).

56. *Id.* at 1278-79.

to apply Texas law, rejected appellee's contention and held that the appellant should properly recover.⁵⁷ The court stated that although appellant's child was not a member of a significant class, she was nonetheless a member of a *susceptible class*, and as such the manufacturer should have warned of reasonably calculable reactions although the number of persons so affected might have been small.⁵⁸

Alternatives to the Appreciable Class Test

In terms of public policy, the appreciable class test for the manufacturer's duty to warn seems ill suited to protect either the public from unnecessary injury or the manufacturer from unnecessary liability. The manufacturer's desire to increase sales may cause it to determine that the known and dangerous side effects of its product are rare and that there is no need to warn.⁵⁹ While the first of the injured consumers will be denied recovery because the class is not appreciable, those who are injured later may recover if the adverse side effect does not prove to be rare.⁶⁰ It seems manifestly unfair and judicially inconsistent to allow recovery strictly on the basis of the time at which the injury occurs. It is quite possible that many injuries and the manufacturer's concurrent liability could be avoided if an adequate warning is given as soon as the risk becomes known.

The liberal view, as evidenced by the trend of the recent cases, is to reject the appreciable class requirement.⁶¹ In *Krug v. Sterling Drug, Inc.*⁶² the defendant, Sterling Drug, raised the idiosyncratic reaction defense and asserted that it had no duty to warn an "unidentifiably small class" of users of an unusual reaction to its drug.⁶³ The court rejected this contention and held that there was a duty to warn all consumers once it became

57. *Id.* at 1278-79.

58. *Id.* at 1279.

59. See generally *Toole v. Richardson-Merrell, Inc.*, 60 Cal. Rptr. 398 (Dist. Ct. App. 1967); *Cudmore v. Richardson-Merrell, Inc.*, 398 S.W.2d 640 (Tex. Civ. App.—Dallas 1965, writ ref'd n.r.e.), cert. denied, 385 U.S. 1003 (1967); *Rheingold, The MER-29 Story—An Instance of Successful Mass Litigation*, 56 CALIF. L. REV. 116, 117-21 (1968).

60. In *Cudmore v. Richardson-Merrell, Inc.*, 398 S.W.2d 640, 644 (Tex. Civ. App.—Dallas 1965, writ ref'd n.r.e.), cert. denied, 385 U.S. 1003 (1967) the court affirmed the trial court's judgment for Richardson on the basis that the manufacturer was under no duty to warn unless harm to an appreciable number of people was foreseeable. Two years later, a California appellate court, in *Toole v. Richardson-Merrell, Inc.*, 60 Cal. Rptr. 398, 413 (Dist. Ct. App. 1967), held Richardson liable for injuries from the same drug on the basis of strict liability for marketing a drug without adequate warning.

61. *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82, 85 (8th Cir. 1966); *Bine v. Sterling Drug, Inc.*, 422 S.W.2d 623, 629-30 (Mo. 1968) (manufacturer required to warn of danger even if only a few persons are seriously injured by the product); *Crocker v. Winthrop Laboratories, Inc.*, 514 S.W.2d 429, 432 (Tex. 1974) (dictum) (manufacturer may be held strictly liable for failure to warn of danger to small percentage of users).

62. 416 S.W.2d 143 (Mo. 1967).

63. *Id.* at 151.

known that there were any dangers in an apparently harmless product.⁶⁴ Thus, if the state of scientific knowledge puts the manufacturer on actual or constructive notice that its product has unsafe characteristics, he must warn of those potential dangers to even an allergic or idiosyncratic group.⁶⁵

There is not a reported decision that has held a manufacturer of a drug or cosmetic liable simply because harm has followed the use of the product. It has been suggested, however, that liability should be imposed on the drug manufacturer although he has adequately warned of any and all known and foreseeable harm.⁶⁶ This approach impliedly negates the manufacturer's defense of consumer's assumption of the risk. The basic rationale underlying the imposition of absolute liability is twofold. First, the manufacturer is in a better position than the prescribing physician or the consumer to prevent the harm from occurring.⁶⁷ Secondly, if injury does result from the use of the drug, the manufacturer is the logical party to compensate the injury and spread the expense to all consumers as a matter of enterprise liability.⁶⁸

The desirability of imposing absolute liability upon the manufacturer of drugs or cosmetics is at best questionable. Absolute liability would tend to discourage the development and marketing of new products that are generally beneficial to society but contain some degree of risk.⁶⁹ Too strict a standard could limit the manufacturer to marketing only those products that are virtually risk free, and such products, particularly in the pharmaceutical fields, are undoubtedly few in number. Alternatively, if the manufacturer were so bold as to market an unavoidably unsafe product, the threat of absolute liability would make the price prohibitively expensive.

The imposition of the duty to warn of *any* known or knowable harmful side effects would encourage the manufacturer to keep abreast of available scientific research regarding its product and continue to carefully observe its effects. Furthermore, a proper warning is infinitely more consistent with the reasonable expectations of physicians and consumers upon prescrip-

64. *Id.* at 151.

65. Note, *Strict Liability for Product Marketing: Misrepresentation and Duty to Warn*, 12 Hous. L. Rev. 469, 474 (1975).

66. Merrill, *Compensation for Prescription Drug Injuries*, 59 VA. L. REV. 1, 107-08 (1973); Comment, *Strict Liability in Tort: Its Applicability to Manufacturers of Prescription Drugs*, 7 U. CAL. D.L. REV. 487, 506 (1974).

67. Merrill, *Compensation for Prescription Drug Injuries*, 59 VA. L. REV. 1, 109 (1973); Comment, *Strict Liability in Tort: Its Applicability to Manufacturers of Prescription Drugs*, 7 U. CAL. D.L. REV. 487, 506 (1974).

68. Merrill, *Compensation for Prescription Drug Injuries*, 59 VA. L. REV. 1, 108 (1973) (manufacturer best equipped, next to government, to spread the expense of injuries); Comment, *Strict Liability in Tort: Its Applicability to Manufacturers of Prescription Drugs*, 7 U. CAL. D.L. REV. 487, 506 (1974) (deep-pocket rationale).

69. See generally Connolly, *The Liability of a Manufacturer for Unknowable Hazards Inherent in His Product*, 32 INS. COUNSEL J. 303, 306 (1965).

tion or purchase of the product. If properly informed, a prescribing physician or consumer may intelligently assume or reject the potential risk of harm.⁷⁰ Even upon assuming the risk, a properly warned physician or consumer may prevent serious injury by the early detection of adverse side effects from the use of the product.⁷¹ A timely and adequate warning that is reasonably calculated to reach the prescribing physician or consumer should absolve the manufacturer of all liability for injuries due to the disclosed risk. It seems reasonable, therefore, that the imposition of an immediate duty to warn of *any* harmful effects should result in fewer injuries, fewer lawsuits, and consequently, fewer judgments against the responsible manufacturer.

UNKNOWN RISK

Pure Negligence Approach

New and experimental drugs and cosmetics present peculiar problems for the injured consumer seeking recovery. The courts have uniformly held that a manufacturer of a new drug or cosmetic is not liable for any injuries resulting from the unknown dangers attendant with the product.⁷² A Missouri case, *Johnston v. Upjohn Co.*,⁷³ is illustrative of this point. The plaintiff suffered an allergic reaction to Lincocin within the first year after the antibiotic had been marketed.⁷⁴ She contended that the package insert "constituted an affirmative assurance of safety" from any adverse reaction to the new drug.⁷⁵ The appellate court affirmed the trial court's order granting a new trial for the defendant and stated that since a similar reaction had never occurred before, the manufacturer could not have known about the danger.⁷⁶ The court further noted that there was no duty to warn absent constructive or actual knowledge that the product had dangerous propensities.⁷⁷ Therefore, under the pure negligence approach

70. RESTATEMENT (SECOND) OF TORTS § 402A, Comment n (1965) (assumption of the risk is a defense under this section).

71. *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82, 85 (8th Cir. 1966); *Krug v. Sterling Drug, Inc.*, 416 S.W.2d 143, 151-52 (Mo. 1967).

72. *O'Hare v. Merck & Co.*, 381 F.2d 286, 291 (8th Cir. 1967) (no liability if "developed human skill" afforded no notice of potentially dangerous effects); *Howard v. Avon Prods., Inc.*, 395 P.2d 1007, 1012 (Colo. 1964) (manufacturer not liable for injury absent actual knowledge of product's dangerous propensities); *Leibowitz v. Ortho Pharmaceutical Corp.*, 307 A.2d 449, 458 (Pa. 1973) (manufacturer cannot be held liable on basis of discoveries made after particular cause of action accrued); cf. *Oakes v. Geigy Agricultural Chemicals*, 77 Cal. Rptr. 709, 713 (Dist. Ct. App. 1969) (while not involving new product, court refused to require manufacturer to warn of unknown risks or to make it an absolute insurer of product's safety).

73. 442 S.W.2d 93 (Mo. Ct. App. 1969).

74. *Id.* at 94-95.

75. *Id.* at 95.

76. *Id.* at 97.

77. *Id.* at 97.

the manufacturer of an unadulterated drug or cosmetic will not be liable for subsequent injury to the consumer unless it knew of the attendant danger and was negligent in failing to act reasonably in marketing the product without adequate warnings,⁷⁸ or it was negligent in failing to discover the scientifically perceivable injurious side effects of its product.⁷⁹

It has been forcefully argued that the need for beneficial products, particularly life-saving medicine, demands that the industry producing such products be given the best possible production environment.⁸⁰ Conversely, the imposition of strict liability would considerably dampen the experimentation with and production of these products that society demands.⁸¹ One noted authority has suggested that the imposition of strict liability might well have deterred drug companies from producing and selling "two of the greatest medical boons," cortisone and penicillin.⁸² Furthermore, it has been suggested that the imposition of strict liability for the unknown risk would be impracticable because that expense which is unknown could not effectively be passed on to the consumer.⁸³

Strict Liability Approach

A few courts have intimated, without so holding, that a manufacturer *may* be liable for unknown risks that cause injuries to the consumer or user.⁸⁴ In *Crocker v. Winthrop Laboratories, Inc.*⁸⁵ plaintiff's decedent died from the unexpected addiction to the defendant's drug, Talwin.⁸⁶ The Texas Supreme Court stated that Talwin was generally safe and beneficial

78. See cases cited note 61 *supra*.

79. *Tinnerholm v. Parke, Davis & Co.*, 285 F. Supp. 432, 446 (S.D.N.Y. 1968), *aff'd*, 411 F.2d 48 (2d Cir. 1969). An analogous situation under the doctrine of strict liability is the law of dog bites. An owner of a domesticated dog that bites a human is not subject to strict liability unless the owner knew or had reason to know of his dog's vicious propensities. See *Barger v. Jimerson*, 276 P.2d 744, 745 (Colo. 1954); *Perrotta v. Picciano*, 175 N.Y.S. 16, 17 (App. Div. 1919); W. PROSSER, *HANDBOOK OF THE LAW OF TORTS* § 76 (4th ed. 1971).

80. W. PROSSER, *HANDBOOK OF THE LAW OF TORTS* § 99 (4th ed. 1971); Connolly, *The Liability of a Manufacturer for Unknowable Hazards Inherent in His Product*, 32 INS. COUNSEL J. 303, 306 (1965).

81. *Leibowitz v. Ortho Pharmaceutical Corp.*, 307 A.2d 449, 458 (Pa. 1973); Connolly, *The Liability of a Manufacturer for Unknowable Hazards Inherent in His Product*, 32 INS. COUNSEL J. 303, 306 (1965) ("it does seem that if any new products would be kept off the market, it would be those most worth the risk").

82. W. PROSSER, *HANDBOOK OF THE LAW OF TORTS* § 99 (4th ed. 1971).

83. Connolly, *The Liability of a Manufacturer for Unknowable Hazards Inherent in His Product*, 32 INS. COUNSEL J. 303, 307 (1965) (the only rationalization is the deeper pocket).

84. *Tinnerholm v. Parke, Davis & Co.*, 285 F. Supp. 432, 444 (S.D.N.Y. 1968), *aff'd*, 411 F.2d 48 (2d Cir. 1969); *Stromsdot v. Parke, Davis & Co.*, 257 F. Supp. 991, 994 (D.N.D. 1966), *aff'd*, 411 F.2d 1390 (8th Cir. 1969); *Crocker v. Winthrop Laboratories, Inc.*, 514 S.W.2d 429, 432 (Tex. 1974).

85. 514 S.W.2d 429 (Tex. 1974).

86. *Id.* at 430.

but "some products, though manufactured as designed and intended, are so dangerous in fact that the manufacturer should be liable for resulting harm though he did not and could not have known of the danger at the time of marketing."⁸⁷ It seems, therefore, that a manufacturer of a dangerous and a generally unbeneficial drug or cosmetic could be held strictly liable and that liability could be predicated upon the inadequacy of the warning measured by those facts known at the time of trial.

A problem lies, however, in determining whether a manufacturer has produced a drug or cosmetic that is so unsafe and unbeneficial that strict liability is warranted. Comment *i* of section 402A suggests that in order for an article to be *unreasonably dangerous* it "must be dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics."⁸⁸ This test has been criticized, however, because the ordinary consumer has no understanding of the complex composition of drugs and cosmetics.⁸⁹

Another test, which heretofore has not been applied in drug and cosmetic cases where the risk is unknown, is the *utility test*. Under this view, a product is unreasonably dangerous if it is apparent at the time of trial that the dangers attendant with the use of the product outweigh the benefits provided by its use.⁹⁰ Dean Page Keeton has suggested that strict liability is appropriate if the court finds that the risk of injury is not justified by the benefits to society that a product provides.⁹¹

Quadrigen is an excellant example of a drug whose risks outweighed its benefits. It was developed by Parke, Davis & Co. to immunize children

87. *Id.* at 432.

88. RESTATEMENT (SECOND) OF TORTS § 402A, Comment *i* (1965).

89. Keeton, *Product Liability and the Meaning of Defect*, 5 ST. MARY'S L.J. 30, 37 (1973).

90. In *General Motors Corp. v. Hopkins*, 20 Tex. Sup. Ct. J. 191 (Feb. 26, 1977) the court noted that strict liability for design rests on knowledge of product's unsafe design at time of trial and not at the time it was produced or marketed. *Id.* at 195; accord, *Garcia v. Sky Climber, Inc.*, 470 S.W.2d 261, 268 (Tex. Civ. App.—Houston [1st Dist.] 1971, writ ref'd n.r.e.), quoting, Keeton, *Products Liability—Inadequacy of Information*, 48 TEXAS L. REV. 398, 403-04 (1970); see *Ross v. Up-Right, Inc.*, 402 F.2d 943, 946 (5th Cir. 1968); *Metal Window Prods. Co. v. Magnusen*, 485 S.W.2d 355, 358 (Tex. Civ. App.—Houston [14th Dist.] 1972, writ ref'd n.r.e.); Keeton, *Product Liability and the Meaning of Defect*, 5 ST. MARY'S L.J. 30, 38 (1973). For suggestions as to the proper inquiries to be made in balancing risk against utility in products liability cases, see *Henderson v. Ford Motor Co.*, 519 S.W.2d 87, 102 (Tex. 1974) (dissenting opinion). See also Donaher, Phiehler, Twerski, & Weinstein, *The Technological Expert in Products Liability Litigation*, 52 TEXAS L. REV. 1303, 1307-08 (1974). But see Connally, *The Liability of a Manufacturer for Unknowable Hazards Inherent in His Product*, 32 INS. COUNSEL J. 303, 306 (1965) (utility test not desirable because: (1) court poorly equipped to balance utility against risk; and (2) manufacturer will be discouraged from marketing new products if it is held strictly liable for unknown risks).

91. Keeton, *Product Liability and the Meaning of Defect*, 5 ST. MARY'S L.J. 30, 35-37 (1973).

against poliomyelitis, whooping cough, tetanus, and diphtheria.⁹² Following an injection of QuadriGen, a patient faced a much higher risk of an encephalopathic reaction⁹³ than he did if separate doses of Triogen⁹⁴ and polio vaccine were used.⁹⁵ In *Tinnerholm v. Parke, Davis & Co.*⁹⁶ the plaintiff brought suit against the manufacturer for injuries to his minor son resulting from an injection of QuadriGen. The court held the defendant liable under negligence⁹⁷ and implied warranty theories,⁹⁸ but the court was apparently prepared to hold the manufacturer strictly liable in any event because there was no justification for an early marketing of QuadriGen, especially when equally effective products were available.⁹⁹

While it may be that a trial court is not well equipped to weigh the risks and benefits of a product,¹⁰⁰ the strict liability approach intimated by the *Crocker* and *Tinnerholm* decisions seems the fairest method to compensate drug injuries caused by unknown risks inherent in a manufacturer's product. The manufacturer of a highly desirable product will not be liable simply because he attempted to satisfy a public need.¹⁰¹ On the other hand, the manufacturer of a product that proves to have little utility will be strictly liable for an injury his product causes. A product, such as a cosmetic, that has negligible utility will be subject to more scrutiny at the time of trial than a generally beneficial product, such as a life-saving medicine. This approach will not considerably dampen the incentives to produce much needed products, but will cause the manufacturer of a convenience item to produce and market it with extreme care.¹⁰²

92. *Tinnerholm v. Parke, Davis & Co.*, 285 F. Supp. 432, 436 (S.D.N.Y. 1968), *aff'd*, 411 F.2d 48 (2d Cir. 1969); *Stromsodt v. Parke, Davis & Co.*, 257 F. Supp. 991, 992 (D.N.D. 1966), *aff'd*, 411 F.2d 1390 (8th Cir. 1969).

93. Encephalopathy is "any degenerative disease of the brain." *Stromsodt v. Parke, Davis & Co.*, 257 F. Supp. 991, 997 n.2 (D.N.D. 1966), *aff'd*, 411 F.2d 1390 (8th Cir. 1969).

94. Triogen was produced to immunize against pertussis, tetanus, and diphtheria. *Tinnerholm v. Parke, Davis & Co.*, 285 F. Supp. 432, 439 (S.D.N.Y. 1968), *aff'd*, 411 F.2d 48 (2d Cir. 1969).

95. *Id.* at 439; *Stromsodt v. Parke, Davis & Co.*, 257 F. Supp. 991, 996-97 (D.N.D. 1966), *aff'd*, 411 F.2d 1390 (8th Cir. 1969).

96. 285 F. Supp. 432 (S.D.N.Y. 1968), *aff'd*, 411 F.2d 48 (2d Cir. 1969).

97. *Id.* at 448.

98. *Id.* at 444-46.

99. *Id.* at 445-46.

100. Connolly, *The Liability of a Manufacturer for Unknowable Hazards Inherent in His Product*, 32 INS. COUNSEL J. 303, 306 (1965).

101. See RESTATEMENT (SECOND) OF TORTS § 402A, Comment k (1965).

102. But see Rheingold, *Products Liability, The Ethical Drug Manufacturer's Liability*, 18 RUT. L. REV. 947, 1015 (1964). Imposing strict liability may not reduce risks of injury because: (1) existing medical standards; (2) internal production controls; (3) concern for reputation; (4) existing FDA requirements; and (5) negligence liability already impose a high standard of care. *Id.* at 1015.

Strict Liability for Defective Design

It is helpful to compare the liability of a manufacturer of a defectively designed drug or cosmetic with that of a manufacturer of other defectively designed products. As a general rule, foreseeability is properly an element in any products liability case when it appears that the product has been misused or the injured party has suffered an unusual reaction to it.¹⁰³ The plaintiff must prove the product's design was defective in the sense that it was the cause in fact of his injuries and his harm was a foreseeable result of the intended use of the product.¹⁰⁴ Although not involving drugs or cosmetics, several recent Texas decisions have departed from the proximate cause requirement and have predicated the manufacturer's liability for defective design on producing cause, thus eliminating the problem of proving foreseeability of harm.¹⁰⁵

In *Garcia v. Sky Climber, Inc.*,¹⁰⁶ the plaintiffs contended that the defendant manufacturer's scaffold equipment was defectively designed although there was no evidence that a similar accident had previously occurred. The Houston Court of Appeals for the First District reversed the trial court's judgment for the defendant and stated that if it is found that a product exposed the consumer to an unreasonable danger then "it is not relevant that he [the manufacturer] neither knew nor could have known nor ought to have known in the exercise of ordinary care that the unreasonable risk actually existed."¹⁰⁷ The court held that the evidence was sufficient to hold the manufacturer liable under this standard.¹⁰⁸

There is no reported decision extending strict liability to the manufacturer of a drug or cosmetic for defective design. The marketing of the drug Quadrigen presented a situation where the application of strict liability would have been well advised, as the interaction of two of the drug's ingredients precipitated the release of a toxin that caused the very disease the drug was designed to prevent.¹⁰⁹ Since a stated purpose for the imposi-

103. *Crocker v. Winthrop Laboratories, Inc.*, 514 S.W.2d 429, 432 (Tex. 1974); C.A. Hoover & Son v. O.M. Franklin Serum Co., 444 S.W.2d 596, 598 (Tex. 1969).

104. C.A. Hoover & Son v. O.M. Franklin Serum Co., 444 S.W.2d 596, 598 (Tex. 1969); Sales, *An Overview of Strict Tort Liability in Texas*, 11 Hous. L. Rev. 1043, 1057 (1974).

105. *Helicoid Gage Div. of Am. Chain & Cable Co. v. Howell*, 511 S.W.2d 573, 575 (Tex. Civ. App.—Houston [14th Dist.] 1974, writ ref'd n.r.e.); *Williams v. General Motors Corp.*, 501 S.W.2d 930, 938 (Tex. Civ. App.—Houston [1st Dist.] 1973, writ ref'd n.r.e.); *Hartzell Propeller Co. v. Alexander*, 485 S.W.2d 943, 946 (Tex. Civ. App.—Waco 1972, writ ref'd n.r.e.); *Garcia v. Sky Climber, Inc.*, 470 S.W.2d 261, 268 (Tex. Civ. App.—Houston [1st Dist.] 1971, writ ref'd n.r.e.).

106. 470 S.W.2d 261 (Tex. Civ. App.—Houston [1st Dist.] 1971, writ ref'd n.r.e.).

107. *Id.* at 268; see Keeton, *Products Liability—Inadequacy of Information*, 48 TEXAS L. Rev. 398, 399 (1970).

108. *Garcia v. Sky Climber, Inc.*, 470 S.W.2d 261, 268 (Tex. Civ. App.—Houston [1st Dist.] 1971, writ ref'd n.r.e.).

109. *Tinnerholm v. Parke, Davis & Co.*, 285 F. Supp. 432, 439-40 (S.D.N.Y. 1968), aff'd,

tion of strict liability is to force manufacturers to stand behind products upon which the public relies,¹¹⁰ it is difficult to justify the special treatment of a manufacturer of drugs or cosmetics. Extension of the *Garcia* doctrine to the manufacturer of drugs or cosmetics would relieve the injured consumer of the onerous burden of proving foreseeability of harm.¹¹¹ If it is apparent at the time of trial that the manufacturer exposed the consumer to a risk that is unreasonable in the sense that it is not justified by the utility of the product, then the injured consumer should be allowed recovery regardless of the state of scientific knowledge about the drug or cosmetic at the time of sale.¹¹² Public policy undoubtedly demands that products intended for intimate bodily use, such as drugs or cosmetics, be as carefully designed as scaffold equipment. The imposition of strict liability in cases of defective design would encourage maximum care in safety and design and spread the expense of injury among all consumers of the product.¹¹³

CONCLUSION

The judicial objective in drug and cosmetic liability cases should be twofold. First, the applicable law should be greatly simplified, and second, both the manufacturer and the consumer should be treated fairly and consistently in each case. This can be achieved by balancing the existing reasonable expectations of both parties.

It is evident that the consumer does not expect to be seriously injured from an unknown danger in the use of an apparently beneficial product. It is equally clear that the manufacturer does not reasonably expect to be liable simply because he has attempted to provide a highly desirable product. Therefore, in determining whether strict liability is proper when a consumer has been injured by an unknown risk in the product, the court should carefully weigh the benefits to society that the product provides against the risks that are attendant with its use. Necessarily, the court should also consider the seriousness of the injury threatened and the availability and cost of similar and safer products. If the product should be found to contain an unreasonable risk at the time of trial, strict liability should be imposed on the manufacturer regardless of the state of scientific knowledge at the time of marketing. Since strict liability is not proper in the case of a highly desirable product, incentives for production would not be dampened in the case of a life-saving medicine. Such liability may be

¹¹⁰ 411 F.2d 48 (2d Cir. 1969); *Stromsdot v. Parke, Davis & Co.*, 257 F. Supp. 991, 995 (D.N.D. 1966), *aff'd*, 411 F.2d 1390 (8th Cir. 1969).

¹¹¹ *RESTATEMENT (SECOND) OF TORTS* § 402A, Comment c (1965).

¹¹² See generally cases cited note 105 *supra*.

¹¹³ See generally note 90 *supra* and accompanying text.

¹¹³ See generally G. CALABRESI, THE COSTS OF ACCIDENTS 73 (1970).

warranted, however, in the case of a product with negligible utility such as a cosmetic.

The extension of strict liability, with its resultant expense, to manufacturers of products that have an unknown and unreasonable risk attached could effectively prevent many injuries and spread the unexpected consumer loss among all of the manufacturer's customers. The threatened expense of such liability may deter the manufacturer from entering into the production of products that are potentially harmful and not justified in their utility and encourage the manufacturer to discover the dangers in its product before injury actually occurs.¹¹⁴ Alternatively, the expense of injuries from unknown risks in a new product could be considered nothing more than a foreseeable expense of being in the particular business.¹¹⁵

While the consumer may reasonably expect to be informed of any risk in the product as soon as it becomes known, the manufacturer does not expect to be held strictly liable for injuries after it has fully warned of a potential risk in the product. Therefore, a manufacturer should be held strictly liable if he fails to take all necessary steps to warn the consumer or prescribing physician of *any* known attendant danger in the product. Once proper warning is made, however, the consumer or prescribing physician may intelligently assume or reject the risk, and the manufacturer should not be held strictly liable for injuries resulting from that disclosed risk.

The practical effect of this proposed solution is evident. The consumer that suffers an injury from an unknown or undisclosed risk attendant with a drug or cosmetic will be compensated for his unexpected loss on the basis of strict liability. The manufacturer, under threat of strict liability, will use all conceivable diligence to discover any risks attendant with the use of its product and make them known as quickly as possible. Once the danger is known and disclosed, the risk of injury may be effectively shifted to the consumer or prescribing physician, thus preventing unexpected liability on the part of the manufacturer. Finally, the manufacturer of highly desirable products will be exempted from strict liability until the risk is known, so that the production of beneficial products will not be discouraged.

114. See generally *id.*

115. Cf. James, *The Untoward Effects of Cigarettes and Drugs: Some Reflections on Enterprise Liability*, 54 CALIF. L. REV. 1550, 1556 (1966) (those risks foreseeably created by the enterprise, whether known or unknown).