Fordham Law Review

Volume 48 | Issue 5 Article 4

1980

The Liability of Pharmaceutical Manufacturers for Unforeseen Adverse Drug Reactions

Kathleen H. Wilson

NOTES

THE LIABILITY OF PHARMACEUTICAL MANUFACTURERS FOR UNFORESEEN ADVERSE DRUG REACTIONS

INTRODUCTION

Illness is the common companion of life; medicine aids the body in responding to illness, but "[a]dverse reactions to drugs are as old as Medicine."[1] Harm inflicted when healing was anticipated has always been an unwelcome surprise evoking a desire for redress. This feeling is reflected as far back as 2200 B.C. in the Code of Hammurabi, which declared that a physician who caused the death of a patient should suffer the loss of his hand.[2] Illness or death resulting from a drug taken for its curative value still affronts the sensibilities. Injured parties increasingly look to the legal system to fix the responsibility and determine who will bear the cost of an adverse drug reaction.

An adverse drug reaction is a "noxious and unintended" response "which occurs at doses used in man for prophylaxis, diagnosis or therapy."[3] The majority of these reactions are either mild physical effects that do not require treatment, or moderate reactions that necessitate discontinuation of the offending agent and may demand some countermeasures.[4] These drug reactions may be classified medically as an insult to the body, but it is doubtful that the insult is of a sufficient magnitude to require a legal remedy.[5] In contrast, the severe adverse drug reaction that brings a person close to death and results in

---

1. Davies, *History and Epidemiology*, in Textbook of Adverse Drug Reactions 1, 1 (D Davies ed. 1977) [hereinafter cited as Adverse Drug Reactions]

2. *Id.*

3. Bennett & Lipman, *Comparative Study of Prospective Surveillance and Voluntary Reporting in Determining the Incidence of Adverse Drug Reactions*, 34 Am J. Hosp. Pharm. 931, 931 (1977). This Note considers only adverse reactions to drugs taken at or near the recommended dosage, and not problems presented by overdose, either intentional or accidental, and drug abuse

4. *Id.* at 932-33.

5. *See* Cochran v. Brooke, 243 Or. 89, 95, 409 P.2d 904, 907 (1966) The *Cochran* court feared that imposing liability for an unforseeable injury would result in absolute liability, thereby rendering the pharmaceutical manufacturer liable for even mild gastric distress induced by aspirin. *Id. But see* Note, *Strict Liability in Tort: Its Applicability to Manufacturers of Prescription Drugs*, 7 U. Cal. D. L. Rev. 487 (1974). This Note suggests that a pharmaceutical manufacturer should be liable for "[a] substantial injury [that] might be defined as one requiring medical attention or causing the loss of a day's work." *Id.* at 505 Such a proposal is unsatisfactory, because broadly defining "substantial injury," would involve an enormous potential for liability. In 1973, 1.5 billion prescriptions were filled by drugstores in the United States Balter, *Coping With Illness: Choices, Alternatives, and Consequences*, in Drug Development and Marketing 27, 37 (R. Helms ed. 1975). An intensive in-hospital study of adverse drug reactions revealed that 3.6% of drug exposures were associated with a reaction serious enough to require discontinuation of medication. Jick, *The Boston Collaborative Drug Surveillance Programme*, in Adverse Drug Reactions 61, 64 (D. Richards & R. Rondel eds. 1972) [hereinafter cited as Drug Reactions]. Administration of a drug should not be stopped without medical consultation, and if the broad definition of substantial injury was applied, pharmaceutical manufacturers would be exposed to liability in 54 million cases per year by applying the aforementioned percentages.

extensive medical treatment or permanent injury, and the lethal drug reaction, may be conducive to tort litigation.[6]

---

6. *See* notes 27-29 *infra* and accompanying text. Most adverse drug reactions involve the drug's toxicity. *See* Dalke v. Upjohn Co., 555 F.2d 245 (9th Cir. 1977) (discoloration of forming bone by tetracycline resulting in permanent staining of child's teeth); Carlsen v. Javurek, 526 F.2d 202 (8th Cir. 1975) (liver dysfunction following anesthesia administration); Salmon v. Parke, Davis & Co., 520 F.2d 1359 (4th Cir. 1975) (chloramphenicol induced aplastic anemia); Hoffman v. Sterling Drug, Inc., 485 F.2d 132 (3d Cir. 1973) (permanent eye damage from chronic ingestion of chloroquine); O'Hare v. Merck & Co., 381 F.2d 286 (8th Cir. 1967) (potassium chloride induced intestinal lesion); Ortho Pharm. Corp. v. Chapman, 388 N.E.2d 541 (Ind. Ct. App. 1979) (abnormal blood clotting, thrombophlebitis associated with administration of oral contraceptives); Smith v. E.R. Squibb & Sons, Inc., 405 Mich. 79, 273 N.W.2d 476 (1979) (anaphylactic shock following injection of X-ray contrast media); Johnston v. Upjohn Co., 442 S.W.2d 93 (Mo. Ct. App. 1969) (antibiotic induced anaphylactic reaction); Hill v. Squibb & Sons, E.R., 592 P.2d 1383 (Mont. 1979) (cortisone administration resulting in the formation of cataracts and the development of osteoporosis); Torsiello v. Whitehall Lab., 165 N.J. Super. 311, 398 A.2d 132 (Super. Ct. App. Div. 1979) (aspirin related gastrointestinal hemorrhaging), Michael v. Warner/Chilcott, 91 N.M. 651, 579 P.2d 183 (Ct. App. 1978) (kidney failure following chronic ingestion of phenacetin); Baker v. St. Agnes Hosp., 70 A.D.2d 400, 421 N.Y.S.2d 81 (2d Dep't 1979) (intrauterine bleeding and fetal brain damage associated with maternal administration of an anticoagulant); Crocker v. Winthrop Lab., 514 S.W.2d 429 (Tex. 1974) (debilitating addiction to pain killing medication). There has been increasing concern over the possible carcinogenic, teratogenic, and mutagenic effects of drugs. A carcinogenic effect is related to the ability of a particular agent to cause cancer, as exemplified by diethylstilbestrol (DES), a drug routinely taken from 1945 to 1955 for prevention of miscarriage. Siegler, Wang & Friberg, *Fertility of the Diethylstilbestrol-Exposed Offspring,* 31 Fertility & Sterility 601, 601 (1979). It is estimated that DES exposure in utero (as a fetus in the womb) of female children has resulted in a risk of clear cell adenocarcinoma of between 1.4/1,000 and 1.4/10,000. *Id.* at 602. DES also has teratogenic activity, which, by definition, alters the normal development of the fetus. Stedman's Medical Dictionary 1412 (4th unabr. lawyers' ed. 1976). Ninety percent of female offspring of DES treated mothers have benign abnormalities of the genital tract. Siegler, Wang & Friberg, *supra,* at 602. Alleged DES related injuries have been the subject of recent litigation. Mink v. University of Chicago, 460 F. Supp. 713 (N.D. Ill. 1978); Gray v. United States, 445 F. Supp. 337 (S.D. Tex. 1978); McCreery v. Eli Lilly & Co., 87 Cal. App. 3d 77, 150 Cal. Rptr. 730 (1978); Bichler v. Willing, 58 A.D.2d 331, 397 N.Y.S.2d 57 (1st Dep't 1977). Special problems raised by DES litigation are discussed in Comment, *DES and a Proposed Theory of Enterprise Liability,* 46 Fordham L. Rev. 963 (1978). A drug with mutagenic effects causes mutations. In Jorgensen v. Meade Johnson Labs., Inc., 483 F.2d 237 (10th Cir. 1973), the Tenth Circuit recognized a cause of action for the husband of a woman whose ingestion of oral contraceptives allegedly resulted in the birth of twins who were afflicted with Down's Syndrome, a genetic defect. *Id.* at 240-41. The direct involvement of a drug in chromosome damage and the relationship between fetal abnormalities to such damage is a burgeoning field of scientific research and controversy. Balson & Roberts, *Chromosome Disorders,* in Adverse Drug Reactions, *supra* note 1, at 54-63.

The increasingly complex and artificial environment is replete with potentially toxic agents, which, like pharmaceuticals, carry the risk of harm as well as the promise of benefit. *See, e.g.,* Harless v. Boyle-Midway Div., 594 F.2d 1051 (5th Cir. 1979) (death from inhalation of aerosol kitchen product); Karjala v. Johns-Manville Prods. Corp., 523 F.2d 155 (8th Cir. 1975) (asbestos exposure); Borel v. Fibreboard Paper Prods. Corp., 493 F.2d 1076 (5th Cir. 1973), *cert. denied,* 419 U.S. 869 (1974) (same); Harig v. Johns-Manville Prods. Corp., 284 Md. 70, 394 A.2d 299 (1978) (same); Heck v. Beryllium Corp., 424 Pa. 140, 226 A.2d 87 (1966) (air pollution from beryllium). This Note is limited to an exploration of the problems encountered when harm is produced by a drug "intended for use in the diagnosis, cure, mitigation, treatment, or prevention

The scope of the problem of adverse drug reactions is not narrow, either in its cost to the affected individual or to society. The reported frequency in studies of these reactions ranges from less than one in one hundred to more than one in four drug administrations.[7] The Boston Surveillance Group conducted an intensive in-hospital study to obviate the problems encountered with previous studies that were poorly controlled and designed.[8] The survey lasted four years and involved eleven hospitals and 6,750 patients. Almost five percent of all drug exposures were associated with an adverse event. One of every 200 drug exposures was associated with a "life threatening" adverse reaction, and 0.4% of the monitored patients died of drug attributable causes.[9] In addition to the physical effects on the human body, estimates of the monetary cost of adverse drug reactions range from one billion dollars per year,[10] three billion dollars per year and one-seventh of all hospital days,[11] to four and one half billion dollars per year.[12]

The drugs that cause these adverse reactions are developed, produced, and marketed by pharmaceutical manufacturers. Drug-related injuries are increasingly the basis of causes of action brought in strict liability in tort.[13] These

---

of disease in man." Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321(g)(1)(B) (1976). A medical definition of "drug" is "a chemical substance or product available for an intended diagnostic, prophylactic or therapeutic purpose." Bennett & Lipman, *supra* note 3, at 931. The Food, Drug, and Cosmetic Act definition continues to embrace "articles (other than food) intended to affect the structure or any function of the body of man or other animals." 21 U.S.C. § 321(g)(1)(C) (1976). This more expansive definition includes materials such as the processed animal bone employed in orthopedic operations, the subject of suit in E.R. Squibb & Sons, Inc. v. Stickney, 274 So. 2d 898 (Fla. Dist. Ct. App. 1973), *cert. denied*, 416 U.S 961 (1974), and E.R. Squibb & Sons, Inc. v. Jordan, 254 So. 2d 17 (Fla. Dist. Ct. App 1971).

7. Davies, *supra* note 1, at 3. The enormous disparity in the reported frequency of adverse drug reactions is a major concern of the medical profession. Poorly designed studies yield data that has little significance in determining the true usefulness of a drug. Bennett & Lipman, *supra* note 3, at 935.

8. Jick, *supra* note 5, at 61.

9. *Id.* at 64. The subjects of the study were in-hospital patients suffering from a condition serious enough to require hospitalization prior to drug administration. The patients were also subject to multiple drug administrations. During a "short stay" averaging 14 days, the patients received a mean of 8.4 different drugs; a mean of 8.9 various medications were administered during a "long stay" averaging 26 days. *Id.* at 63

10. M. Silverman & P. Lee, Pills, Profits and Politics 264 (1974). The cost of adverse drug reactions is the subject of considerable debate. The authors derived this figure from a speech; the same person was quoted in a separate source as placing the cost of adverse drug reactions at $1 billion per day per year. Gagnon, *Public Health Issues in Medicine Use Control*, in Perspectives on Medicines in Society 36, 45 (A. Wertheimer & P. Bush eds. 1977) [hereinafter cited as Perspectives]. The latter figure would place the cost of adverse drug reactions at $365 billion per year. The total health expenditures in the United States in 1976 were $139.3 billion, and drug expenditures during the same period accounted for $11.2 billion. Campbell & Smith, *Profitability and the Pharmaceutical Industry*, in The Pharmaceutical Industry 105, 112 (C. Lindsay ed. 1978) [hereinafter cited as Pharmaceutical Industry].

11. Melmon, *Preventable Drug Reactions—Causes and Cures*, 284 New Eng. J. Med. 1361, 1361 (1971).

12. M. Silverman & P. Lee, *supra* note 10, at 265.

13. Developments in this field have rapidly changed. As late as 1955, products liability

cases "defin[e] the outer limits of strict liability [and present the] most difficult questions of policy."[14] This Note explores these outer limits and addresses these policy questions. It examines the problems encountered by imposing strict liability for unforeseen adverse drug reactions[15] on pharmaceutical manufacturers, and compares this approach to their liability under the recently proposed Model Uniform Product Liability Act (Model Act).[16]

I. STRICT LIABILITY IN TORT AND DRUG RELATED INJURIES

Originally, negligence was the primary vehicle for recovering damages from manufacturers for physical injuries caused by their products.[17] The success of the action turned on the plaintiff's ability to isolate the defendant's specific negligent act and prove by a preponderance of the evidence that the negligence was the proximate cause of the plaintiff's injury.[18] Courts, frequently faced with a severely injured plaintiff, strained to ease this burden,[19] and they

---

did "not yet rank as a term of art in the courts of law." Wilson, *Products Liability—Part I: The Protection of the Injured Person*, 43 Cal. L. Rev. 614, 614 (1955).

14. Kessler, *Products Liability*, 76 Yale L.J. 887, 930 (1967).

15. These reactions are medically classified as Type B Adverse Drug Reactions. They would be the "totally aberrant effects that are unrelated to a drug's normal pharmacology. . . . They are usually unpredictable and are not observed during conventional toxicological screening programmes. Although their incidence and morbidity are usually low, their mortality may be high." Rawlins & Thompson, *Pathenogenesis of Adverse Drug Reactions*, in Adverse Drug Reactions, *supra* note 1, at 10, 10. In contrast, Type A reactions are usually "the result of an exaggerated, but otherwise normal, pharmacological action of a drug." *Id.* For example, a Type A reaction would be the incidence of transient hypotension (low blood pressure) caused by an antihypertensive drug. Agranulocytosis, a severe and often fatal blood disorder incurred following the administration of chloramphenicol, the generic name of chloromycetin, would be an example of a Type B reaction. *Id.* A number of reported cases have involved Type B reactions to chloromycetin. Salmon v. Parke, Davis & Co., 520 F.2d 1359 (4th Cir. 1975); Stevens v. Parke, Davis & Co., 9 Cal. 3d 51, 507 P.2d 653, 107 Cal. Rptr. 45 (1973); Love v. Wolf, 226 Cal. App. 2d 378, 38 Cal. Rptr. 183 (1964); Parke, Davis & Co. v. Mayes, 124 Ga. App. 224, 183 S.E.2d 410 (1971); Mulder v. Parke Davis & Co., 288 Minn. 332, 181 N.W.2d 882 (1970); Whitley v. Cubberly, 24 N.C. App. 204, 210 S.E.2d 289 (1974); Incollingo v. Ewing, 444 Pa. 263, 282 A.2d 206 (1971).

16. 44 Fed. Reg. 62,714 (1979).

17. *See, e.g.*, Halloran v. Parke, Davis & Co., 245 A.D. 727, 280 N.Y.S. 58 (2d Dep't 1935); Henderson v. National Drug Co., 343 Pa. 601, 23 A.2d 743 (1942).

18. *See* Webb v. Sandoz Chem. Works, Inc., 85 Ga. App. 405, 69 S.E.2d 689 (1952); Merrill, *Compensation for Prescription Drug Injuries*, 59 Va. L. Rev. 1, 29 (1973). In *Webb*, a woman was partially blinded by the use of Cafergone, a patented medicine, and her husband sued the drug manufacturer for the expenses of her illness. 85 Ga. App. at 405-06, 69 S.E.2d at 690. The plaintiff was nonsuited for failing to supply specific evidence of the defendant's negligence, and the court refused to apply the doctrine of res ipsa loquitur. *Id.* at 410, 69 S.E.2d at 693.

19. *See, e.g.*, Gottsdanker v. Cutter Lab., 182 Cal. App. 2d 602, 6 Cal. Rptr. 320 (1960); MacPherson v. Buick Motor Co., 217 N.Y. 382, 111 N.E. 1050 (1916). In *Gottsdanker*, the defendants manufactured Salk polio vaccine. Shortly after administration of the vaccine, two children contracted crippling poliomyelitis. Although there was "substantial evidence to sustain a finding that the vaccine contained live virus of poliomyelitis [the virus contained in the Salk vaccine should not be viable,] and that the injected vaccine caused the disease in each child," the jury concluded " 'that the defendant . . . was not negligent either directly or by inference.' " 182 Cal. App. 2d at 605, 6 Cal. Rptr. at 322. The plaintiffs also alleged breaches of the implied warranties of merchantibility and of fitness for the intended use. *Id.* The jury found for the

recognized a cause of action for personal injury under a contract-like theory of breach of implied warranty.[20] The American Law Institute finalized the process by adopting a formulation for strict products liability.[21] Section 402A of the Restatement (Second) of Torts delineates strict products liability for physical harm to the user or consumer:

---

plaintiffs on the warranty counts, and the defendant's appeal asserted a lack of privity because there had been no direct sale from the defendant manufacturer to the plaintiffs. *Id* at 606, 6 Cal. Rptr. at 323. The district court of appeal noted that the privity requirement had been dispensed with in many jurisdictions when the product in question was "food for human consumption." *Id.*, 6 Cal. Rptr. at 322. The implied warranties of merchantability and of fitness ran with the food, allowing the consumer to recover from the food producer, despite the absence of privity, for injury resulting from the ingestion of a contaminated food product. *Id.* at 607, 6 Cal Rptr at 323. The court considered the administration of the vaccine simply another form of "ingestion" and therefore held that the warranties ran with the drugs. *Id.*

20. *See* Gottsdanker v. Cutter Labs., 182 Cal. App. 2d 602, 607, 6 Cal Rptr 320, 323 (1960); Henningsen v. Bloomfield Motors, Inc., 32 N.J. 358, 384, 161 A.2d 69, 83-84 (1960). Warranty has been termed "a freak hybrid born of the illicit intercourse of tort and contract." Prosser, *The Fall of the Citadel (Strict Liability to the Consumer)*, 50 Minn. L Rev 791, 800 (1966). Recognition of a warranty cause of action raised contract problems of privity and sales problems of notice in tort law. *See* Gottsdanker v. Cutter Labs., 182 Cal App. 2d at 606-07, 6 Cal. Rptr. at 322-23 (court was obliged to dispose of the privity problem before a cause of action in warranty could be recognized because there had been no direct sale from defendant to plaintiff); Redfield v. Mead, Johnson & Co., 266 Or. 273, 283-84, 512 P.2d 776, 781 (1973). *But cf.* Berry v. G.D. Searle & Co., 56 Ill. 2d 548, 556, 309 N.E.2d 550, 555 (1974) (court ignored the problem of notice in breach of warranty action under the U C C. for a stroke following administration of birth control pills because neither party raised the issue). A court may actually dispense with the timely notice requirement under U.C.C. § 2-607 in a drug-related personal injury suit. Fischer v. Mead Johnson Labs., 41 A.D.2d 737, 341 N Y S.2d 257 (2d Dep't 1973). Privity problems in warranty actions have generally been resolved *See* Oresman v. G.D Searle & Co., 321 F. Supp. 449, 453 (D.R.I. 1971) (rejecting privity requirement for drug related personal injury suit brought in warranty); U.C.C. § 2-318 (third parties may sue for breach of express or implied warranties). Dean Prosser pointed out that warranty was from its inception "only a rather transparent device to accomplish the desired result of strict liability " Prosser, *supra*, at 802.

21. Restatement (Second) of Torts § 402A (1965) Dean Prosser pointed out that the acceptance of strict liability through the Restatement was achieved without recourse to "warranty." Prosser, *supra* note 20, at 802. Strict liability has superseded implied warranty in several drug cases. *See* Christofferson v. Kaiser Foundation Hosps., 15 Cal App. 3d 75, 80, 92 Cal Rptr. 825, 828 (1971); Grinnell v. Charles Pfizer & Co., 274 Cal App 2d 424, 432, 79 Cal Rptr 369, 373 (1969). In Goodman v. Mead Johnson & Co., 388 F. Supp. 1070, 1072-73 (D N J 1974), *rev'd on other grounds*, 534 F.2d 566 (3d Cir. 1976), *cert. denied*, 429 U.S 1038 (1977), the court refused to apply the contract statute of limitations for a personal injury action brought in breach of warranty. Section 103 of the Model Uniform Product Liability Act [hereinafter cited as Model Act] preempts the U.C.C. for products liability actions, except in cases of economic loss. Model Act § 103, 44 Fed. Reg. 62,714, 62,720 (1979). Other courts, however, recognize both the tort and warranty theories of products liability in dealing with drug related injuries Reyes v Wyeth Labs., 498 F.2d 1264, 1271 (5th Cir.), *cert. denied*, 419 U.S. 1096 (1974), Raymond v Eli Lilly & Co., 412 F. Supp. 1392, 1403 (D.N H. 1976), *aff'd*, 556 F 2d 628 (1st Cir 1977). These courts apply a different statute of limitations when the action is brought in warranty, than if it is brought in tort. Allen v. Ortho Pharm. Corp., 387 F. Supp 364, 367 (S D Tex 1974), Berry v G.D. Searle & Co., 56 Ill. 2d 548, 553-54, 309 N.E.2d 550, 553-54, (1974); Redfield v Mead, Johnson & Co., 266 Or. 273, 275-79, 512 P.2d 776, 777-79 (1973)

(1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if

(a) the seller is engaged in the business of selling such a product, and

(b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.

(2) The rule stated in Subsection (1) applies although

(a) the seller has exercised all possible care in the preparation and sale of his product, and

(b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.[22]

The Model Act[23] varies from section 402A by distinguishing the product manufacturer from the product seller in determining duties and liabilities. The manufacturer is "subject to liability to a claimant who proves by a preponderance of the evidence that the claimant's harm was proximately caused because the product was defective."[24] Other "product seller[s]," such as retailers and wholesalers, are liable only when the claimant proves that the proximate cause of his injury was "such product seller's failure to use reasonable care with respect to the product."[25]

Physical harm is a basic element in establishing a prima facie case of strict products liability under section 402A.[26] The actual physical injury is usually apparent in drug products liability cases, ranging from blindness,[27] to ir-

22. Restatement (Second) of Torts § 402A (1965). Thirty-seven states and the District of Columbia have adopted this section, and the remaining states, with three exceptions, have recognized some form of strict products liability in tort. [1978-1979 Transfer Binder] Prod. Liab. Rep. (CCH) ¶ 4016.

23. 44 Fed. Reg 62,714 (1979).

24. Model Act § 104, 44 Fed. Reg. 62,714, 62,721 (1979).

25. *Id.* § 105, 44 Fed. Reg. at 62,726. The intermediary steps in the marketing chain from manufacturer to consumer do not appear to be subject to strict liability under the Model Act. This would accord with cases such as Bichler v. Willing, 58 A.D.2d 331, 397 N.Y.S.2d 57 (1st Dep't 1977), in which the court declined to apply the theory of strict products liability to a drug retailer who had sold DES to the plaintiff's mother.

26. Restatement (Second) of Torts § 402A(1) (1965).

27. MER/29, known as triparanol, a drug developed to lower blood cholesterol, produced irreversible eye damage from chronic administration. Roginsky v. Richardson-Merrell, Inc., 378 F.2d 832 (2d Cir. 1967); Hornung v. Richardson-Merrill, Inc., 317 F. Supp. 183 (D. Mont. 1970); Toole v. Richardson-Merrell Inc., 251 Cal. App. 2d 689, 60 Cal. Rptr. 398 (1967); Cudmore v. Richardson-Merrell, Inc., 398 S.W.2d 640 (Tex. Civ. App. 1965), *cert. denied,* 385 U.S. 1003 (1967). Aralen, known generically as chloroquine, a drug originally marketed for acute administration in the treatment of malaria, was found effective in controlling both lupus erythematosus, a severe collagen disorder, and rheumatoid arthritis. Treatment of these two conditions required chronic administration of the drug and resulted in irreversible eye damage. Hoffman v. Sterling Drug, Inc., 485 F.2d 132 (3d Cir. 1973); Singer v. Sterling Drug, Inc., 461 F.2d 288 (7th Cir.), *cert. denied,* 409 U.S. 878 (1972); Schenebeck v. Sterling Drug, Inc., 423 F.2d 919 (8th Cir. 1970); Basko v. Sterling Drug, Inc., 416 F.2d 417 (2d Cir. 1969); Sterling Drug, Inc. v. Yarrow, 408 F.2d 978 (8th Cir. 1969); Sterling Drug, Inc. v. Cornish, 370 F.2d 82 (8th Cir. 1966); Christofferson v. Kaiser Foundation Hosps., 15 Cal. App 3d 75, 92 Cal. Rptr. 825 (1971); Bine v. Sterling Drug, Inc., 422 S.W.2d 623 (Mo. 1968); Krug v. Sterling Drug, Inc., 416 S.W.2d 143 (Mo. 1967); Oppenheimer v. Sterling Drug, Inc., 7 Ohio App. 2d 103, 219 N.E.2d 54 (1964); Cochran v. Brooke, 243 Or. 89, 409 P.2d 904 (1966).

reversible brain damage,[28] to death.[29] The Model Act does not limit the cause of action to physical harm. It includes "mental anguish or emotional harm caused by the claimant's being placed in direct personal physical danger."[30] The action, however, lies only with the injured person and not with third parties.[31]

To recover under Section 402A, a plaintiff must prove that the proximate cause of his injury was a defect in the product that rendered it "unreasonably dangerous."[32] Under the Model Act, a defect is proved by showing that the product was "unreasonably unsafe" in construction, in design, or because adequate warnings or instructions were not provided.[33]

---

28. A change in preservative in Quadrigen, a children's vaccine, resulted in a severe central nervous system reaction and brain damage. Ezagui v. Dow Chem. Corp., 598 F.2d 727 (2d Cir 1979); Parke-Davis & Co. v. Stromsodt, 411 F.2d 1390 (8th Cir 1969); Tinnerholm v Parke Davis & Co., 285 F. Supp. 432 (S.D.N.Y. 1968), *aff'd*, 411 F.2d 48 (2d Cir. 1969), Vincent v Thompson, 79 Misc. 2d 1029, 361 N.Y.S.2d 282 (Sup. Ct. 1974), *rev'd*, 50 A D.2d 211, 377 N.Y.S.2d 118 (2d Dep't 1975).

29. Carlsen v. Javurek, 526 F.2d 202 (8th Cir. 1975) (anesthesia related death), Daly v McNeil Labs., Inc., 509 F.2d 617 (6th Cir. 1975) (same); Gelley v. Astra Pharm. Prods., Inc., 466 F. Supp. 182 (D. Minn. 1979) (same); Brick v. Barnes-Hines Pharm. Co., 428 F Supp. 496 (D.D.C. 1977) (death from liver damage from chronic administration of drug for treatment of tuberculosis); Stevens v. Parke, Davis & Co., 9 Cal. 3d 51, 507 P.2d 653, 107 Cal Rptr 45 (1973) (fatal cases of aplastic anemia associated with administration of chloromycetin); Magee v Wyeth Labs., Inc., 214 Cal. App. 2d 340, 29 Cal. Rptr. 322 (1963) (death from a blood disorder, agranulocytosis, a known side effect of a promazine tranquilizer), Lawson v G. D. Searle & Co., 64 Ill. 2d 543, 356 N.E.2d 779 (1976) (death from multiple pulmonary emboli following administration of oral contraceptives); Smith v. E.R. Squibb & Sons, Inc., 405 Mich 79, 273 N.W.2d 476 (1979) (patient died from anaphylactic shock following injection of x-ray contrast media); Whitley v. Cubberly, 24 N.C. App. 204, 210 S.E.2d 289 (1974) (aplastic anemia); Incollingo v. Ewing, 444 Pa. 263, 282 A.2d 206 (1971) (same); Crocker v. Winthrop Labs., 514 S.W.2d 429 (Tex. 1974) (death related to addiction to a pain killer). Courts have refused, however, to recognize a cause of action for mental distress for parents whose children were adversely affected by drugs. Mink v. University of Chicago, 460 F. Supp. 713, 716 (N.D. Ill. 1978); Woodill v. Parke Davis & Co., 58 Ill. App. 3d 349, 355, 374 N.E.2d 683, 687-88 (1978), *aff'd*, No. 50745 (Ill. Feb. 22, 1980); *cf.* Becker v. Schwartz, 46 N.Y.2d 401, 415, 386 N.E.2d 807, 814, 413 N.Y.S.2d 895, 902 (1978) (disallowing parental recovery for negligent infliction of mental distress for "wrongfully born" child); Tobin v. Grossman, 24 N.Y 2d 609, 617-19, 249 N.E.2d 419, 423-24, 301 N.Y.S.2d 554, 560-62 (1969) (bystander has no cause of action for negligent infliction of mental distress). *Contra*, Shepard v. Superior Court, 76 Cal. App. 3d 16, 19-20, 142 Cal. Rptr. 612, 614 (1977); *cf.* Dillon v. Legg, 68 Cal. 2d 728, 740-43, 441 P.2d 912, 920-22, 69 Cal. Rptr. 72, 80-82 (1968) (sanctioning third party cause of action for negligent infliction of mental distress).

30. Model Act § 102(F), 44 Fed. Reg. 62,714, 62,717 (1979).

31. *See id.*

32. Restatement (Second) of Torts § 402A(1) (1965). Controversy exists concerning the independent meanings of "unreasonably dangerous" and "defective." The use of the term unreasonably dangerous was specifically rejected in Cronin v. J.B.E. Olson Corp , 8 Cal. 3d 121, 501 P.2d 1153, 104 Cal. Rptr. 433 (1972). This attempt to purge "unreasonably dangerous" from strict liability terminology, however, has met with opposition. *See generally* Keeton, *Product Liability and the Meaning of Defect*, 5 St. Mary's L.J. 30 (1973); Wade, *On the Nature of Strict Tort Liability for Products*, 44 Miss. L.J. 825 (1973); 42 Fordham L. Rev 943 (1974)

33. Model Act § 104, 44 Fed. Reg. 62,714, 62,721 (1979). A product will be considered defective if "it did not conform to the product seller's express warranty " *Id*

The construction or manufacturing defect generally occurs on the production line.[34] In these cases, the product fails to meet the standards set by the manufacturer and differs significantly from other units. Such cases are rare with pharmaceuticals[35] because of intensive and effective quality control.[36] Injury from a manufacturing defect, however, renders the producer strictly liable under both section 402A and the Model Act, despite the most elaborate and detailed control system.[37]

Although drugs may be properly manufactured, it is not presently possible to design an effective but completely safe drug.[38] Almost all drugs have the potential to inflict serious harm.[39] A problem arises in determining when this potential renders these drugs defective within the meaning of the law.[40]

Comment k to section 402A specifically identifies certain drugs as *"unavoidably unsafe products."* It states that

> [s]uch a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. . . . The seller of such products . . . is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.[41]

---

34. *E.g.*, Abbott Labs. v. Lapp, 78 F.2d 170 (7th Cir. 1935); Croft v. York, 244 So. 2d 161 (Fla. Dist. Ct. App. 1971); Sandel v. State, 115 S.C. 168, 104 S.E. 567 (1920).

35. Evidence existed of the presence of a live virus in the Salk polio vaccine manufactured by the defendant in Gottsdanker v. Cutter Labs., 182 Cal. App. 2d 602, 6 Cal. Rptr. 320 (1960). Drugs contaminated with foreign bacteria have caused serious injury and have sometimes been fatal. Abbott Labs. v. Lapp, 78 F.2d 170 (7th Cir. 1935); Croft v. York, 244 So. 2d 161 (Fla. Dist. Ct. App. 1971).

36. Dunne, *Assessment of Quality and Safety of Drugs*, in Adverse Drug Reactions, *supra* note 1, at 32, 32.

37. Restatement (Second) of Torts § 402A (1965); Model Act § 104(A), 44 Fed. Reg. 62,714, 62,721 (1979); *see* Winthrop Labs. v. Crocker, 502 S.W.2d 850, 858-59 (Civ. App. 1973), *rev'd on other grounds*, 514 S.W.2d 429 (Tex. 1974).

38. W. Prosser, Handbook of the Law of Torts § 99, at 661 (4th ed. 1971). A degree of toxicity is an essential element of an effective pharmaceutical. *See* note 148 *infra* and accompanying text.

39. *See generally* Berman & Francke, *Medicines and Drug Use Tomorrow—Some Biological and Social Considerations*, in Perspectives, *supra* note 10, at 533, 536-37.

40. Compliance with the provisions of the Food, Drug, and Cosmetic Act is required prior to the movement of a new drug in interstate commerce. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(a) (1976). Compliance is merely evidence that the drug was not defective as designed. McDaniel v. McNeil Labs., Inc., 196 Neb. 190, 200-01, 241 N.W.2d 822, 828 (1976). The evidentiary value of this compliance varies from very pertinent, Brick v. Barnes-Hines Pharm. Co., 428 F. Supp. 496, 498 (D.D.C. 1977), to merely an indication that the pharmaceutical manufacturer has met a minimum standard. Stevens v. Parke, Davis & Co., 9 Cal. 3d 51, 65, 507 P.2d 653, 661, 107 Cal. Rptr. 45, 53 (1973); Michael v. Warner/Chilcott, 91 N.M. 651, 654, 579 P.2d 183, 186 (Ct. App. 1978). On the other hand, noncompliance gives rise to a presumption of negligence. Toole v Richardson-Merrell Inc., 251 Cal. App. 2d 689, 703, 60 Cal. Rptr. 398, 409 (1967). The jury may consider that the defendant manufacturer had violated the regulations, Hoffman v. Sterling Drug, Inc., 485 F.2d 132, 139 (3d Cir. 1973), even though such a violation does not necessarily give rise to a private cause of action

41. Restatement (Second) of Torts § 402A, Comment k (1965).

Comment k does not limit drug liability under all conditions. It employs a "risk benefit" analysis by comparing the reasonableness of the risk with the benefit to be derived from the product.[42] A product will be considered unreasonably dangerous only if its utility does not outweigh the magnitude of the danger.[43] A problem arises in determining when to balance the risk and the benefit. Dean Keeton suggested that the benefit of the product should be weighed by the "magnitude of the scientifically perceivable danger *as it is proved to be at the time of trial.*"[44] Courts have held, however, that the balance is to be struck with the knowledge available at the time of injury.[45] This accords with the language in Comment k referring to a "known but apparently reasonable risk."[46] Similarly, section 106 of the Model Act holds a seller liable only if he knew of the drug's dangerous aspect and acted unreasonably by marketing it.[47] The protection afforded by Comment k and the Model Act may be lost, however, if a drug that offered no substantial benefit caused an injury, even if it was not foreseeable.[48] Such a drug could be considered "unreasonably dangerous" as marketed.[49]

The majority of drugs from which litigation has arisen over the past twenty years are still marketed.[50] The risk benefit ratio of these drugs still favors marketing. The defect, if any, lies neither in the manufacturing process nor in the formulation, but in the adequacy of the warning accompanying such

---

42. *Id.*

43. Borel v. Fibreboard Paper Prods. Corp., 493 F.2d 1076, 1087 (5th Cir. 1973), *cert. denied*, 419 U.S. 869 (1974). Professor Wade has suggested factors to consider in this balancing process. "(1) The usefulness and desirability of the product—its utility to the user and to the public as a whole. (2) The safety aspects of the product—the likelihood that it will cause injury, and the probable seriousness of the injury. (3) The availability of a substitute product which would meet the same need and not be as unsafe. (4) The manufacturer's ability to eliminate the unsafe character of the product without impairing its usefulness or making it too expensive to maintain its utility. (5) The user's ability to avoid danger by the exercise of care in the use of the product. (6) The user's anticipated awareness of the dangers inherent in the product and their avoidability, because of general public knowledge of the obvious condition of the product, or of the existence of suitable warnings or instructions. (7) The feasibility, on the part of the manufacturer, of spreading the loss by setting the price of the product or carrying liability insurance." Wade, *supra* note 32, at 837-38 (footnote omitted). Professor Willig contends that the value and threat to the community must be considered, and not simply the individual benefits versus the individual danger. Willig, *The Comment k Character: A Conceptual Barrier to Strict Liability*, 29 Mercer L. Rev. 545, 556 (1978).

44. Keeton, *supra* note 32, at 38 (emphasis in the original).

45. Borel v. Fibreboard Paper Prods. Corp., 493 F.2d 1076, 1088-89 (5th Cir. 1973) (the decision to market entails a balancing of known danger and utility), *cert. denied*, 419 U.S. 869 (1974); Ortho Pharm. Corp. v. Chapman, 388 N.E.2d 541, 545-46 (Ind. Ct. App. 1979) (same, citing *Borel*).

46. Restatement (Second) of Torts § 402A, Comment k (1965).

47. Model Act § 106(B)(1), 44 Fed. Reg. 62,714, 62,727 (1979).

48. For a discussion of this possibility in relation to the Quadrigen cases see Comment, *The Diminishing Role of Negligence in Manufacturers' Liability for Unavoidably Unsafe Drugs and Cosmetics*, 9 St. Mary's L.J. 102, 112-14 (1977). Quadrigen was a children's vaccine altered for convenience with disastrous consequences. *See* note 28 *supra*.

49. *See* note 88 *infra* and accompanying text.

50. *See generally* Physician's Desk Reference (33d ed. 1979).

pharmaceuticals.[51] Comment h to section 402A provides that "[w]here . . . [the seller] has reason to anticipate that danger may result from a particular use . . . he may be required to give adequate warning of the danger . . . and a product sold without such warning is in a defective condition."[52] The Model Act is in accord, and generally defines a defective product as one that was "unreasonably unsafe because adequate warnings or instructions were not provided."[53] If the product, for example, a drug, is one with "unavoidably dangerous aspects," the Model Act holds the product seller liable if he failed to warn of the known danger.[54] Courts have uniformly expressed a willingness to impose strict liability for drug related injuries when the duty to warn existed and was breached.[55] Furthermore, failure to warn when a warning is required has been held sufficient to establish a defect.[56] The plaintiff need not establish that the product reached him without substantial change[57] because the defect is predicated on the warning, which is under the direct control of the manufacturer.[58] Although the failure to warn must be established as the proximate cause of the harm,[59] there is a presumption that an adequate warning will be heeded.[60]

The threshold question involves delineating the parameters of the duty to warn. The proper role of foreseeability in the duty to warn is an integral aspect when discussing strict liability for unforeseen adverse drug reactions. Additionally, it must be determined when the duty arises, to whom it is owed, and what constitutes an adequate warning.

---

51. *See* Restatement (Second) of Torts § 402A, Comment h (1965).

52. *Id.*

53. Model Act § 104(C), 44 Fed. Reg. 62,714, 62,721 (1979).

54. *Id.* § 106, 44 Fed. Reg. at 62,727.

55. *E.g.*, Sterling Drug, Inc. v. Yarrow, 408 F.2d 978, 991 (8th Cir. 1969) (a properly manufactured drug is unreasonably dangerous if unaccompanied by a reasonable warning); Davis v. Wyeth Labs., Inc.. 399 F.2d 121, 128-29 (9th Cir. 1968) (when duty to warn is not fulfilled, seller may be held strictly liable in tort); Toole v. Richardson-Merrell Inc., 251 Cal. App. 2d 689, 710-11, 60 Cal. Rptr. 398, 413-14 (1967) (exemption from strict liability depends on all surrounding facts, including the warning given of known side effects); Ortho Pharm. Corp. v. Chapman, 388 N.E.2d 541, 545-46 (Ind. Ct. App. 1979) (strict liability is avoided only when proper warnings accompany a product).

56. Reyes v. Wyeth Labs., 498 F.2d 1264, 1275 (5th Cir.), *cert. denied*, 419 U.S. 1096 (1974); Woodill v. Parke Davis & Co., 58 Ill. App. 3d 349, 351, 374 N.E.2d 683, 685 (1978), *aff'd*, No. 50745 (Ill. Feb. 22, 1980); Smith v. E.R. Squibb & Sons, Inc., 405 Mich. 79, 89, 273 N.W.2d 476, 479 (1979); Incollingo v. Ewing, 444 Pa. 263, 287, 282 A.2d 206, 219 (1971). In New York, "the failure to provide adequate warnings here establishes a prima facie case of product defect." Ezagui v. Dow Chem Corp., 598 F.2d 727, 733 (2d Cir. 1979) (construing New York law). A similar rule applies generally to drugs sold over-the-counter. Torsiello v. Whitehall Labs., 165 N.J. Super. 311, 320, 398 A.2d 132, 136-37 (Super. Ct. App. Div. 1979).

57. *See* Reyes v. Wyeth Labs., 498 F.2d 1264, 1273 (5th Cir.), *cert. denied*, 419 U.S. 1096 (1974).

58. *Id.*

59. *Id.*; Ortho Pharm. Corp. v. Chapman, 388 N.E.2d 541, 555 (Ind. Ct. App. 1979), Vaughn v. G.D. Searle & Co., 272 Or. 367, 369, 536 P.2d 1247, 1248, (1975), *cert. denied*, 423 U.S. 1054 (1976); Gravis v. Parke-Davis & Co., 502 S.W.2d 863, 869-70 (Tex. Civ. App. 1973).

60. Restatement (Second) of Torts § 402A, Comment j (1965).

II. DRUGS AND THE DUTY TO WARN

A. *Foreseeability and the Duty to Warn*

1. The Requirement of Foreseeability For Adverse Drug Reactions

Between seventy and eighty percent of adverse drug reactions result from the known side effects of established drugs.[61] The pharmaceutical manufacturer has a duty to warn of these side effects.[62] A drug marketed without a warning of known dangers is clearly defective, and the manufacturer will be held strictly liable for any resultant injury.[63] Problems may arise, however, when a consumer is injured by an unforeseen, totally aberrant side effect of the drug.[64] These cases negate the manufacturer's ability to insulate itself from strict liability through an adequate warning because the formulation of an effective warning of unknown dangers presents insuperable semantic difficulties.[65] Moreover, the alternative to liability for aberrant effects—withholding the drug from the market and continuing testing until all possible effects are revealed—is equally impractical because of the inherent limitations of such testing.[66] Therefore, to promote the availability of beneficial new drugs, the law provides protection from strict liability for the pharmaceutical manufacturer when it cannot protect itself.[67] Because imposition of the duty to warn is justified by the actual and constructive knowledge of the manufacturer,[68] strict liability is not imposed for the failure to warn of unknowable adverse effects.[69] The drug is considered defective only if the manufacturer does not warn of a known hazard.[70]

---

61. It has been suggested that the majority of adverse drug reactions are not only known effects, but predictable and perhaps preventable. M. Silverman & P. Lee, *supra* note 10, at 266. The proportion of adverse reactions actually attributable to new drugs may be overestimated, since physicians are more likely to report new drug toxicity at the urging of monitoring systems. W. Wardell & L. Lasagna, Regulation and Drug Development 100-01 (1975).

62. *See* notes 51-56 *supra* and accompanying text.

63. *See* notes 52-56 *supra* and accompanying text.

64. *See* note 15 *supra*.

65. *See* Christofferson v. Kaiser Foundation Hosps., 15 Cal. App. 3d 75, 79-80, 92 Cal. Rptr. 825, 827 (1971).

66. A potentially serious side effect may have a very low incidence of occurrence. The drug might have to be tested on thousands of patients before the hazard is revealed. Furthermore, there may be a "long latency" period, and the side effect may not appear until many years after administration. Dunne, *supra* note 36, at 38.

67. *See* Leibowitz v. Ortho Pharm. Corp., 224 Pa. Super Ct. 418, 433, 307 A 2d 449, 458 (1973).

68. Sterling Drug, Inc. v. Yarrow, 408 F.2d 978, 990 (8th Cir. 1969); Ortho Pharm. Corp. v. Chapman, 388 N.E.2d 541, 552-53 (Ind. Ct. App. 1979); McDaniel v. McNeil Lab., Inc., 196 Neb. 190, 202, 241 N.W.2d 822, 829 (1976). This requirement would also apply to drugs being researched. Gaston v. Hunter, 121 Ariz. 33, 47, 588 P.2d 326,.340 (Ct. App. 1978).

69. Restatement (Second) of Torts § 402A, Comment j (1965), provides that the product seller must warn "if he has knowledge, or by the application of reasonable, developed human skill and foresight should have knowledge, of . . . the danger." A similar position is taken by the Model Act: "[P]roduct seller shall not be subject to liability for harm caused by an unavoidably dangerous aspect of a product unless [he] knew or had reason to know of the aspect and failed to meet a duty to instruct or warn under Subsection 104(C) . . . ." Model Act § 106(B), 44 Fed. Reg. 62,714, 62,727 (1979).

70. *See* Givens v. Lederle, 556 F.2d 1341, 1345 (5th Cir. 1977). In contrast, foreseeability is

Basing the imposition of a duty to warn on the manufacturer's knowledge of the danger introduces the element of foreseeability into strict liability.[71] Strict liability normally represents a shift in focus from the reasonableness of the actions of the manufacturer based on its apprehension of a perceived risk, to the essential character of the product.[72] This incorporation of the negligence concept of foreseeability into the duty to warn has been criticized as a step backward "denying strict liability an independent viability."[73]

2. The Appropriate Foreseeability Standard

Several courts have acknowledged this incorporation of negligence elements into strict drug products liability,[74] particularly when liability is based on breach of the duty to warn.[75] Other courts have noted the similarities, but differentiated negligent breach of the duty to warn from strict liability based on the duty to warn.[76] In *Phillips v. Kimwood Machine Co.*,[77] the Oregon Supreme Court made a further departure from negligence by purging the foreseeability concept from strict liability. The court's proposed test "to determine the dangerousness of the article, as distinguished from the seller's culpability, is to assume the seller knew of the product's propensity to injure as it did, and then to ask whether, with such knowledge, he would have been negligent in selling it without a warning."[78] This standard has been approved

---

not required when the defect results from manufacturing error, *see* note 37 *supra* and accompanying text, or when the manufacturer has made positive representations of safety. *See* notes 84-87 *infra* and accompanying text.

71. *See generally* McClellan, *Strict Liability for Drug Induced Injuries: An Excursion Through the Maze of Products Liability, Negligence and Absolute Liability*, 25 Wayne L. Rev. 1 (1978); Polelle, *The Foreseeability Concept and Strict Products Liability: The Odd Couple of Tort Law*, 8 Rut.-Cam. L.J. 101 (1976).

72. *See* Phipps v. General Motors Corp., 278 Md. 337, 344, 363 A.2d 955, 958 (1976); McClellan, *supra* note 71, at 28.

73. McClellan, *supra* note 71, at 31.

74. *E.g.*, Gaston v. Hunter, 121 Ariz. 33, 45, 588 P.2d 326, 338 (Ct. App. 1978); Carmichael v. Reitz, 17 Cal. App. 3d 958, 988, 95 Cal. Rptr. 381, 400 (1971). The Texas Supreme Court held that res judicata barred the plaintiff from proceeding in strict liability in a drug related injury case when a judgment based on the same facts had been returned for the defendant manufacturer in negligence. Abbott Labs. v. Gravis, 470 S.W.2d 639 (Tex. 1971).

75. Chambers v. G.D. Searle & Co., 441 F. Supp. 377, 380 (D. Md. 1975), *aff'd*, 567 F.2d 269 (4th Cir. 1977). Separate jury instructions on negligence and strict liability have been denied in this situation. *See* Basko v. Sterling Drug, Inc., 416 F.2d 417, 427 (2d Cir. 1969). Although the jury need not reach additional findings of fact, an additional finding of law is required for strict liability, that because "the manufacturer [was] negligent in endeavoring to warn of a risk, the product is in a 'defective condition unreasonably dangerous.' " Ortho Pharm. Corp. v. Chapman, 388 N.E. 2d 541, 551-52 (Ind. Ct. App. 1979).

76. *E.g.*, Dunkin v. Syntex Labs., Inc., 443 F. Supp. 121, 124-26 (W.D. Tenn. 1977); Ortho Pharm. Corp. v. Chapman, 388 N.E.2d 541, 551 (Ind. Ct. App. 1979).

77. 269 Or. 485, 525 P.2d 1033 (1974).

78. *Id.* at 498, 525 P.2d at 1039. *Phillips* did not involve a drug related injury. The plaintiff was hurt by a piece of wood that was accidently ejected from a tool. *Id.* at 488, 525 P.2d at 1034. This imputation of knowledge to the manufacturer is still the minority view in products liability, even outside the ethical drug industry. Johnson v. Clark Equip. Co., 274 Or. 403, 547 P.2d 132 (1976) (plaintiff's arms severed by a forklift); Little v. PPG Indus., Inc., 19 Wash. App. 812, 579

by only one reported drug related injury case. In *Hamilton v. Hardy*,[79] the plaintiff suffered a stroke after taking the defendant manufacturer's oral contraceptives for eleven months.[80] The Colorado Court of Appeals held that the appropriate test to determine if the evidence is sufficient for the plaintiff to recover in strict liability would " 'assume the seller knew of the product's propensity to injure as it did.' "[81]

Recently, the Indiana Court of Appeals expressly rejected the *Phillips* test in discussing drug related injuries.[82] Even the *Phillips* court has acknowledged that the duty to warn is partially based on constructive knowledge.[83] Foreseeability of harm is disregarded, however, in certain aspects of drug products liability. In *Crocker v. Winthrop Laboratories*,[84] the manufacturer's representatives promoted Talwin, a pain killer, as being positively nonaddictive. There was no evidence at the time of marketing that the drug was addictive. Mr. Crocker took Talwin, became addicted, and subsequently died from his debilitating addiction.[85] The manufacturer was held liable because it went beyond merely stating that there was no evidence of harmful effects by actually promoting the drug as being without such effects.[86] The positive representation negated the absence of foreseeability. This type of "express warranty" of a "material fact" also renders a manufacturer liable under the Model Act.[87] In this situation, the manufacturer is claiming knowledge it does not have. It provides a false assurance of safety and induces unjustified reliance by the drug user, thereby losing the defense of unforeseeability.

The *Crocker* court recognized that because some products are so dangerous, the manufacturer should be liable without reference to his actual or constructive knowledge.[88] "[I]n the case of a generally beneficial or good product," when the manufacturer's liability is predicated on the adequacy of the

---

P.2d 940 (1978) (death from drowning subsequent to inhalation of a chemical), *modified*, 92 Wash. 2d 118, 594 P.2d 911 (1979).

79. 37 Colo. App. 375, 549 P.2d 1099 (1976).

80. *Id.* at 377, 549 P.2d at 1102.

81. *Id.* at 385, 549 P.2d at 1108 (citing Phillips v. Kimwood Mach. Co., 269 Or. 485, 498, 525 P.2d 1033, 1039 (1974)). The trial court had refused to give the jury the plaintiff's tendered instruction on strict liability for failure to warn, in addition to the negligence instructions. The Colorado Court of Appeals held this refusal to be reversible error *Id* at 382-83, 549 P 2d at 1106.

82. Ortho Pharm. Corp. v. Chapman, 388 N.E.2d 541, 547-48 (Ind Ct App 1979)

83. McEwen v. Ortho Pharm. Corp., 270 Or 375, 389, 528 P 2d 522, 530 (1974)

84. 514 S.W.2d 429 (Tex. 1974).

85. *Id.* at 429-30.

86. *Id.* at 433.

87. "In order to determine that the product was unreasonably unsafe because it did not conform to an express warranty, the trier of fact must find that the claimant, or one acting on the claimant's behalf, relied on an express warranty made by the manufacturer or its agent about a material fact or facts concerning the product and this express warranty proved to be untrue

"A 'material fact' is any specific characteristic or quality of the product. It does not include a general opinion about, or praise of, the product.

"The product seller may be subject to liability under Subsection (D) although it did not engage in negligent or fraudulent conduct in making the express warranty." Model Act § 104(D), 44 Fed. Reg. 62,714, 62,721 (1979).

88. Crocker v. Winthrop Labs., 514 S.W.2d 429, 432 (Tex. 1974).

warning, however, even the *Crocker* court was not prepared to compare the warning given with the facts known at the time of trial.[89] A problem in strict liability is setting limits,[90] and like the *Crocker* court, other courts have stopped short of imposing strict liability for failure to warn when the hazard was unknown.[91] The duty to warn can arise only when there is knowledge of the hazard.[92] This knowledge is not imputed to the manufacturer from the facts available at the time of trial, but is determined by what was known at the time of injury.[93] The Model Act also adopts this approach by requiring actual or constructive knowledge when liability is based on a breach of the duty to warn.[94]

This adherence to a foreseeability standard may wed strict tort liability to negligence when the action is based on the breach of a duty to warn. Dean Prosser's 1960 statement that "there is not one case in a hundred in which strict liability would result in recovery where negligence does not"[95] continues to be valid in these cases.[96] Commentators have noted the concern that this adherence to the negligence standard will work a hardship on the plaintiff through the imposition of a heavy burden of proof.[97]

When the severely injured victim of an adverse drug reaction is before the court, however, there is a reluctance to let the injury go unremedied.[98] An examination of the elements of the duty to warn illustrates the exercise of judicial flexibility, even within the bounds of foreseeability, in providing redress.

3. When Is There A Duty To Warn?

When the defect in a drug is the failure to warn, this failure "is by definition the manufacturer's dereliction."[99] Therefore, the plaintiff need not prove either that "the defect existed at the time the [drug] left the hands of the

89. *Id.* at 433.

90. Phillips v. Kimwood Mach. Co., 269 Or. 485, 491, 525 P.2d 1033, 1036 (1974).

91. *E.g.*, Basko v. Sterling Drug, Inc., 416 F.2d 417, 426 (2d Cir. 1969); Ortho Pharm. Corp. v. Chapman, 388 N.E.2d 541, 548 (Ind. Ct. App. 1979)

92. Dalke v. Upjohn Co., 555 F.2d 245, 248 (9th Cir. 1977); Basko v. Sterling Drug, Inc., 416 F.2d 417, 426 (2d Cir. 1969); Woodill v. Parke Davis & Co., 58 Ill. App. 3d 349, 353, 374 N.E.2d 683, 686-87 (1978), *aff'd*, No. 50745 (Ill. Feb. 22, 1980); Ortho Pharm. Corp. v. Chapman, 388 N.E.2d 541, 548 (Ind. Ct. App. 1979); Smith v. E.R. Squibb & Sons, Inc., 69 Mich. App. 375, 382, 245 N.W.2d 52, 55-56 (1976), *aff'd*, 405 Mich. 79, 273 N.W.2d 476 (1979); McEwen v. Ortho Pharm. Corp., 270 Or. 375, 386, 528 P.2d 522, 528 (1974).

93. Daly v. McNeil Labs., Inc., 509 F.2d 617, 618 (6th Cir. 1975); Chambers v. G.D. Searle & Co., 441 F. Supp. 377, 381 (D. Md. 1975), *aff'd per curiam*, 567 F.2d 269 (4th Cir. 1977); Tomer v. American Home Prods. Corp., 170 Conn. 681, 687, 368 A.2d 35, 38 (1976); Donigi v. American Cyanamid Co., 57 A.D.2d 760, 760, 394 N.Y.S.2d 422, 422-23 (1st Dep't 1977), *aff'd mem.*, 43 N.Y.2d 935, 374 N.E.2d 1245, 403 N.Y.S.2d 894 (1978).

94. Model Act §§ 104(C), 106(B)(3), 44 Fed. Reg. 62,714, 62,721, 62,727 (1979).

95. Prosser, *The Assault Upon the Citadel (Strict Liability to the Consumer)*, 69 Yale L.J. 1099, 1114 (1960).

96. Merrill, *supra* note 18, at 31.

97. *See* McClellan, *supra* note 71, at 2; Merrill, *supra* note 18, at 50.

98. *See* pts. II(B)-(D) *infra*.

99. Reyes v. Wyeth Labs., 498 F.2d 1264, 1272 (5th Cir.), *cert. denied*, 419 U.S. 1096 (1974) (emphasis deleted).

defendant,"[100] or that the defendant actually knew of the hazard that caused the injury. It is enough that knowledge of the hazard existed.[101] The pharmaceutical manufacturer is accountable as an expert in the field and is attributed both actual and constructive knowledge of its product.[102]

Actual knowledge is first acquired through extensive premarket testing.[103] A manufacturer that does not test its product may be precluded from raising the defense that no available test could have revealed the adverse effect that caused the injury.[104] Once the drug is marketed, the manufacturer is responsible for knowledge received from reports of adverse reactions.[105] A single letter reporting one adverse event may be offered as evidence of the manufacturer's actual knowledge.[106] The manufacturer may be charged with the duty to warn even if the exact nature of the adverse reaction is unknown.[107]

The duty to warn continues after marketing is commenced. New information concerning the drug's composition and effects must be incorporated into the warning.[108] Information contained in medical journals and other scientific literature will be imputed to the manufacturer because of the duty to keep abreast of these sources.[109] If the adverse drug effect is reported in any of these sources prior to a particular plaintiff's injury, the determination whether the defendant "was or should have been sufficiently certain" of this

---

100. *Id.* (citing Gravis v. Parke-Davis & Co., 502 S.W.2d 863, 868 (Tex. Civ App 1973)).

101. A time continuum is emphasized in duty to warn cases. Courts attempt to determine at what point sufficient knowledge was present, thereby creating the duty. Basko v. Sterling Drug, Inc., 416 F.2d 417, 426 (2d Cir. 1969); Sterling Drug, Inc. v. Yarrow, 408 F.2d 978, 985 (8th Cir. 1969); Davis v. Wyeth Labs., Inc., 399 F.2d 121, 129 (9th Cir. 1968)

102. Dalke v. Upjohn Co., 555 F.2d 245, 248 (9th Cir. 1977), O'Hare v. Merck & Co., 381 F.2d 286, 291 (8th Cir. 1967); Krug v. Sterling Drug, Inc., 416 S.W 2d 143, 152 (Mo. 1967), McDaniel v. McNeil Labs., Inc., 196 Neb. 190, 203-04, 241 N.W.2d 822, 829-30 (1976); Baker v St. Agnes Hosp., 70 A.D.2d 400, 405-06, 421 N.Y.S.2d 81, 85-86 (2d Dep't 1979); Bichler v. Willing, 58 A.D.2d 331, 335, 397 N.Y.S.2d 57, 59 (1st Dep't 1977); McEwen v. Ortho Pharm. Corp., 270 Or. 375, 386, 528 P.2d 522, 528 (1974).

103. *See* notes 156-63 *infra* and accompanying text. The duty to warn would be breached by a failure to include information on adverse drug reactions observed only in animal tests. E.R. Squibb & Sons, Inc. v. Heflin, [1978-1979 Transfer Binder] Prod. Liab. Rep (CCH) ¶ 8499, at 18,428 (Tex. Civ. App. 1979).

104. Justice Jackson's dissent in Dalehite v. United States, 346 U.S. 15 (1953), noted that "[t]he claim that a hazard was not foreseen is not available to one who did not use foresight appropriate to his enterprise." *Id.* at 52 (Jackson, J., dissenting); *see* Hoffman v. Sterling Drug, Inc., 485 F.2d 132, 141 (3d Cir. 1973) (citing Justice Jackson). In contrast, one court rejected a plaintiff's contention that animal tests available at the time would have demonstrated the teratogenic effects of DES. McCreery v. Eli Lilly & Co., 87 Cal. App. 3d, 77, 86, 150 Cal. Rptr. 730, 736 (1978); *see* note 6 *supra*.

105. Baker v. St. Agnes Hosp., 70 A.D.2d 400, 406, 421 N.Y.S.2d 81, 85 (2d Dep't 1979).

106. Krug v. Sterling Drug, Inc., 416 S.W.2d 143, 150 (Mo. 1967)

107. Bine v. Sterling Drug, Inc., 422 S.W.2d 623, 629 (Mo. 1968).

108. Schenebeck v. Sterling Drug, Inc., 423 F.2d 919, 922 (8th Cir 1970); Model Act § 104(C)(6), 44 Fed. Reg. 62,714, 62,721 (1979).

109. Schenebeck v. Sterling Drug, Inc., 423 F.2d 919, 922 (8th Cir. 1970), Krug v. Sterling Drug, Inc., 416 S.W.2d 143, 149 (Mo. 1967); McEwen v. Ortho Pharm. Corp., 270 Or 375, 386, 528 P.2d 522, 531 (1974).

effect to be under a duty to warn may be left to the jury.[110] Once the duty to warn arises, the manufacturer must effectively transmit the warning to the consumer.

B. *To Whom Must The Warning Be Given?*

Initially, the pharmaceutical manufacturer was under no duty to warn persons who were allergic to the product or who experienced an idiosyncratic reaction.[111] A warning was required only when an appreciable number of persons experienced a particular side effect.[112] These limitations have been specifically rejected. Allergies and physical idiosyncracies are merely factors to consider in determining the parameters of the duty to warn.[113] Although it may be harder to anticipate allergic reactions.[114] these reactions are considered foreseeable and a duty to warn is imposed,[115] regardless of the nonexistence of appreciable numbers.[116] A duty to warn exists even if the people affected represent a "small number of idiosyncratic or hypersensitive users."[117] In reality, the actual chance of occurrence may be very small. For example, the manufacturer of Sabin polio vaccine was charged with the duty to warn even though the risk of vaccine-induced polio was, at maximum, one in three million administrations.[118]

The duty to warn of dangers in prescription drugs is generally discharged when an adequate warning is transmitted to the consumer's physician.[119]

---

110. Sterling Drug. Inc. v. Cornish, 370 F.2d 82, 84 (8th Cir. 1966). The Eighth Circuit has suggested that when foreseeability is an issue, the defendant should be required to offer evidence that no one could have foreseen the danger. Ross v. Philip Morris & Co., 328 F.2d 3, 12-13 (8th Cir. 1964).

111. Oakes v. Geigy Agric. Chems., 272 Cal. App. 2d 645, 651, 77 Cal. Rptr. 709, 713 (1969); Webb v. Sandoz Chem. Works Inc., 85 Ga. App. 405, 409, 69 S.E.2d 689, 692 (1952)

112. Cudmore v. Richardson-Merrell, Inc., 398 S.W.2d 640, 644 (Tex. Civ. App. 1965), *cert denied*, 385 U.S. 1003 (1967).

113. Carmichael v. Reitz, 17 Cal. App. 3d 958, 993-94, 95 Cal. Rptr. 381, 404 (1971)

114. McEwen v. Ortho Pharm. Corp., 270 Or. 375, 389, 528 P.2d 522, 530 (1974). The court may consider this difficulty when hearing the case. *Id.*

115. Davis v. Wyeth Labs., Inc., 399 F.2d 121, 129 (9th Cir. 1968); Sterling Drug, Inc. v. Cornish, 370 F.2d 82, 85 (8th Cir. 1966).

116. The Texas Supreme Court has noted that "[t]he failure to warn of a danger cannot always be excused by the mere fact that the potentially endangered users are few in number " Crocker v. Winthrop Labs., 514 S.W.2d 429, 432 (Tex. 1974).

117. Basko v. Sterling Drug, Inc., 416 F.2d 417, 430 (2d Cir. 1969).

118. Givens v. Lederle, 556 F.2d 1341, 1343 (5th Cir. 1977).

119. McCue v. Norwich Pharm. Co., 453 F.2d 1033, 1035 (1st Cir. 1972); Dunkin v. Syntex Labs., Inc., 443 F. Supp. 121, 123 (W.D. Tenn. 1977); Pierluisi v. E.R. Squibb & Sons, Inc., 440 F. Supp. 691, 695 (D.P.R. 1977); Dyer v. Best Pharm. Corp., 118 Ariz. 465, 468, 577 P.2d 1084, 1087 (Ct. App. 1978); Love v. Wolf, 226 Cal. App. 2d 378, 395, 38 Cal. Rptr. 183, 193 (1964); Hawkins v. Richardson-Merrell, Inc., 147 Ga. App. 481, 483, 249 S.E.2d 286, 288 (1978); Parke, Davis & Co., v. Mayes, 124 Ga. App. 224, 224, 183 S.E.2d 410, 410 (1971); Gravis v. Parke-Davis & Co., 502 S.W.2d 863, 870 (Tex. Civ. App. 1973). If the prescription drug is one meant for animals, the duty to warn is discharged by a warning transmitted to the veterinarian. Haste v. American Home Prods. Corp., 577 F.2d 1122, 1124-25 (10th Cir. 1978), *cert. denied*, 439 U.S. 955 (1979).

Although the consumer need not be directly apprised of any danger, both the prescribing and the treating physician must be warned.[120] Because drug effects are so complex, only a medical expert is expected to be able to appreciate and balance the potential benefits of the drug with the hazards of administration.[121] Therefore, the physician stands as the " 'learned intermediary' between manufacturer [or seller] and consumer."[122] The Model Act adopts this reasoning and provides that "[f]or products that may be legally used only by or under the supervision of a class of experts, warnings or instructions may be provided to the using or supervisory expert."[123] The transmission of the warning to the consumer is dependent on the medical judgment of the physician.[124]

Nevertheless, when a prescription drug is distributed in such a way that the role of the "learned intermediary" is eliminated, as with the mass polio immunization program,[125] no one stands between manufacturer and consumer. In such cases, the warning must run directly to the consumer.[126] Even the administration of a vaccine by a doctor in his private office may be sufficiently clinic-like so that the duty to warn is not discharged by transmitting a warning only to the physician.[127] In all cases, the duty to warn will be discharged only by the effective transmission of an adequate warning.

C. *What Is An Adequate Warning?*

It is presumed that an adequate warning will be heeded,[128] but the essence of an adequate warning is not easily adduced. Federal law requires that drugs be labeled with appropriate instructions for use,[129] as well as information on

---

120. Hoffman v. Sterling Drug, Inc., 485 F.2d 132, 142 (3d Cir. 1973); McEwen v. Ortho Pharm. Corp., 270 Or. 375, 387, 528 P.2d 522, 529 (1974). Oral contraceptives are an exception to this general rule. The manufacturer is required to transmit information on the effectiveness and possible effects of the contraceptive directly to the consumer through a patient package insert. 21 C.F.R. § 310.501 (1978).

121. Reyes v. Wyeth Labs., 498 F.2d 1264, 1276 (5th Cir.), *cert. denied*, 419 U.S. 1096 (1974).

122. *Id.* Similarly, the duty to warn for intrauterine contraceptive devices is satisfied by notifying the physician. Terhune v. A.H. Robins Co., 90 Wash. 2d 9, 14, 577 P.2d 975, 978 (1978).

123. Model Act § 104(C)(5), 44 Fed. Reg. 62,714, 62,721 (1979).

124. Dunkin v. Syntex Labs., Inc., 443 F. Supp. 121, 123 (W.D. Tenn. 1977); Calabrese v. Trenton State College, 162 N.J. Super. 145, 156-57, 392 A.2d 600, 606 (Super. Ct. App. Div. 1978); Gravis v. Parke-Davis & Co., 502 S.W.2d 863, 870 (Tex. Civ. App. 1973).

125. *See* Davis v. Wyeth Labs., Inc., 399 F.2d 121 (9th Cir. 1968).

126. Reyes v. Wyeth Labs., 498 F.2d 1264, 1274-76 (5th Cir.), *cert. denied*, 419 U.S. 1096 (1974); Davis v. Wyeth Labs., Inc., 399 F.2d 121, 131 (9th Cir. 1968); Cunningham v. Charles Pfizer & Co., 532 P.2d 1377, 1381 (Okla. 1974).

127. Givens v. Lederle, 556 F.2d 1341, 1345 (5th Cir. 1977). In *Givens*, a mother developed polio following administration of Salk polio vaccine to her child. *Id.* at 1343. The impact of this and other Sabin polio vaccine cases on the duty to warn is discussed in Note, *Duty to Warn Extended to Bystander in Close Contact with Polio Vaccine*, 29 Mercer L. Rev. 643 (1978).

128. Carmichael v. Reitz, 17 Cal. App. 3d 958, 991, 95 Cal. Rptr. 381, 402 (1971); Restatement (Second) of Torts § 402A, Comment j (1965).

129. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 352(f) (1976).

contraindications, side effects, and effectiveness.[130] Although compliance with these regulations does not make the warning adequate as a matter of law for purposes of civil liability,[131] it may establish a minimum standard.[132] Conversely, noncompliance may constitute negligence per se.[133] Under the Model Act, compliance is evidence that the product is not defective, while noncompliance is accorded similar evidentiary weight in showing a defect.[134]

"[A] proper warning must adequately state the risk."[135] In determining when the risk is adequately stated, a balance must be achieved. A warning may be adequate when experts say that a stronger warning would be incorrect.[136] The warning must be strong enough, however, for if it remains unchanged when the manufacturer knows it is being widely disregarded, it will be considered inadequate.[137] Finally, even the clearest, most complete, and most comprehensive warning will be inadequate if it can be shown that the manufacturer dissipated or eroded the effectiveness of the warning through overpromotion of the drug.[138]

Specific guidelines for an adequate warning do not exist. The warning must be "reasonable under the circumstances."[139] Circumstances vary, however, and jurisdictions define "reasonable" differently.[140] Although these differences may lead to inconsistent results, the consistency provided by absolute strict liability that removes foreseeability from the duty to warn would lead to even greater injustice.

III. THE EFFECT OF IMPOSING STRICT LIABILITY FOR UNFORESEEABLE ADVERSE DRUG EFFECTS

Foreseeability of harm could be eliminated as a necessary element in establishing liability for a breach of the duty to warn. The pharmaceutical manufacturer would simply be liable for any adverse drug reaction unless an

130. *Id.* § 352(n). The Food and Drug Administration (FDA) requirements for the content and format of the drug label are set out in 21 C.F.R. § 201.56 (1979).

131. Bristol-Myers Co. v. Gonzales, 548 S.W.2d 416, 423 (Civ. App. 1976), *rev'd on other grounds,* 561 S.W.2d 801 (Tex. 1978).

132. Stevens v. Parke, Davis & Co., 9 Cal. 3d 51, 65, 507 P.2d 653, 661, 107 Cal. Rptr. 45, 53 (1973); Michael v. Warner/Chilcott, 91 N.M. 651, 654, 579 P.2d 183, 186 (Ct. App. 1978)

133. Ezagui v. Dow Chem. Corp., 598 F.2d 727, 733 (2d Cir. 1979).

134. Model Act § 108, 44 Fed. Reg. 62,714, 62,730 (1979).

135. Willig, *supra* note 43, at 568.

136. Carlsen v. Javurek, 526 F.2d 202, 206 (8th Cir. 1975).

137. Incollingo v. Ewing, 444 Pa. 263, 292, 282 A.2d 206, 222 (1971).

138. Salmon v. Parke, Davis & Co., 520 F.2d 1359, 1362-63 (4th Cir. 1975); Stevens v. Parke, Davis & Co., 9 Cal. 3d 51, 65, 507 P.2d 653, 661, 107 Cal. Rptr. 45, 53 (1973); Whitley v. Cubberly, 24 N.C. App. 204, 207-08, 210 S.E.2d 289, 292 (1974); Incollingo v. Ewing, 444 Pa. 263, 291, 282 A.2d 206, 221 (1971). A drug is overpromoted when an aggressive sales program may cause a doctor to disregard a warning. Stevens v. Parke, Davis & Co., 9 Cal. 3d at 65, 507 P.2d at 661, 107 Cal. Rptr. at 53; Whitley v. Cubberly, 24 N.C. App. at 207-08, 210 S.E.2d at 292. The theory that overpromotion dissipates the adequacy of a given warning parallels the rationale underlying the imposition of liability in the presence of positive representations of safety. *See* notes 84-87 *supra* and accompanying text. In both situations, the pharmaceutical manufacturer's own actions negate the protection from strict liability.

139. Michael v. Warner/Chilcott, 91 N.M. 651, 655, 579 P.2d 183, 187 (Ct. App. 1978).

140. Merrill, *supra* note 18, at 49-50.

adequate warning was previously transmitted. The complexity of drug products litigation might be reduced, and it would no longer be necessary to prove what information was known, when it was known, and if it was sufficiently known. This simplistic approach, however, is not one chosen by the courts[141] or proposed in the Model Uniform Product Liability Act.[142] Foreseeability is retained because its removal would clash with the two policies that justify the imposition of strict liability—providing incentives to more careful conduct, and risk allocation to the one in the best position to insure against failures.[143]

The incentive theory is premised on the belief that strict products liability results in safer products.[144] Of all products, however, this justification seems especially inappropriate as applied to ethical drugs.[145] Drugs are properly characterized as "unavoidably unsafe products,"[146] or products with "[u]navoidably dangerous aspects."[147] They are by nature toxic, although administration of the drug seeks to maximize the toxic effect in those parts of the body afflicted with the disease and to minimize it in other parts of the body.[148] For these reasons, it is irrational to suppose that a legal obligation imposed on a pharmaceutical manufacturer can alter the essential nature of a drug. Moreover, it is unlikely that the threat of strict liability would spur the manufacturer toward more intensive and extensive premarketing tests to reveal latent dangers.[149]

The pharmaceutical industry is heavily regulated by statute[150] and by the

141. *See* Reyes v. Wyeth Labs., 498 F.2d 1264 (5th Cir.), *cert denied*, 419 U.S. 1096 (1974); Basko v. Sterling Drug, Inc., 416 F.2d 417 (2d Cir. 1969); Chambers v. G.D. Searle & Co., 441 F. Supp. 377 (D. Md. 1975), *aff'd*, 567 F.2d 269 (4th Cir. 1977); Christofferson v. Kaiser Foundation Hosps. 15 Cal. App. 3d 75, 92 Cal. Rptr. 825 (1971); Ortho Pharm Corp. v. Chapman, 388 N.E.2d 541 (Ind. Ct. App. 1979); Leibowitz v. Ortho Pharm Corp., 224 Pa. Super. Ct. 418, 307 A.2d 449 (1973); pt. II *supra*.

142. Model Act. § 104, 44 Fed. Reg. 62,714, 62,721-22 (1979). The role of foreseeability in strict liability is discussed in Willig, *supra* note 43, and criticized in McClellan, *supra* note 71, and Polelle, *supra* note 71.

143. *See* Hall v. E.I. Du Pont de Nemours & Co., 345 F. Supp. 353 (E.D.N.Y. 1972). *See also* Polelle, *supra* note 71, at 104.

144. Phillips v. Kimwood Mach. Co., 269 Or. 485, 503, 525 P.2d 1033, 1041-42 (1974) (en banc).

145. Rheingold, *Products Liability—The Ethical Drug Manufacturer's Liability*, 18 Rutgers L. Rev. 947, 1015 (1964).

146. Restatement (Second) of Torts § 402A, Comment k (1965).

147. Model Act § 106, 44 Fed. Reg. 62,714, 62,727 (1979).

148. Altschule, *Bad Law, Bad Medicine*, 3 Am. J. L. & Med. 295, 298 (1977).

149. Even the supporters of strict liability recognize the problems involved with the incentive approach. McClellan, *supra* note 71, at 25-28 (the deterrence view must be abandoned as a primary goal of strict liability if one wishes to dispense with reasonableness and foreseeability); Polelle, *supra* note 71, at 113 (the incentive approach leads back to problems of foreseeability); Rheingold, *supra* note 145, at 1015 (strict liability seems unlikely to produce a greater degree of care by a drug manufacturer).

150. *E.g.*, Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-392 (1976); Act of Mar. 4, 1913, ch. 145, 37 Stat. 832 (codified at 21 U.S.C. §§ 151-158 (1976)). Federal regulation of the pharmaceutical industry has often been undertaken in response to drug related disasters. The death of 10 children from a diphtheria vaccine tainted with tetanus prompted the passage of the Virus, Serum, and Toxin Act of 1902. Act of July 1, 1902, Pub. L. No. 57-244, 32 Stat. 728-29 (current version at 42 U.S.C. § 262 (1976)); *see* Taylor, *Introduction*, in Drug Induced Clinical

Food and Drug Administration (FDA).[151] The Federal Food, Drug, and Cosmetic Act[152] prohibits the marketing of a new drug until the FDA approves a New Drug Application submitted by the manufacturer that demonstrates the drug's "safety" for its intended use.[153] The thalidomide disaster, which caused the birth of severely deformed children, facilitated the adoption of the 1962 Harris-Kefauver Amendments.[154] They require "safety and efficacy" for new drug approval, and provide for the withdrawal of approval of older drugs if new evidence reveals a serious challenge to their "safety or efficacy."[155] The FDA requires exhaustive premarket testing before it will approve a new drug.[156] If the premarket testing plan is approved,[157] the clinical investigation proceeds in three phases. Phase I examines the pharmacologic effects of the drug on human beings—what the drug does to humans and in what doses.[158] In Phase II, the drug is administered to persons as therapy for a specific medical condition. The physiologic changes produced by the drug are intensively monitored. Such changes may be beneficial, in the form of treatment, or harmful, in the form of side effects.[159] Phase III clinical studies involve larger numbers of patients. The studies continue to be carefully monitored and are used to define the most appropriate drug dosage and treatment techniques.[160] The FDA must be informed of results and

---

Toxicity xv, xvi (McMahon ed. 1974) [hereinafter cited as Clinical Toxicity]. The Pure Food and Drug Act was passed in 1906. Food & Drugs Act of June 30, 1906, Pub. L. No. 59-384, 34 Stat. 768 (current version at 21 U.S.C. § 301 (1976)). By 1927, the FDA was an independent regulatory agency. L. Cluff, G. Caranasos, & R. Stewart, Clinical Problems With Drugs 7 (1975). The early legislation primarily focused on baseless claims of curative power. The "elixir sulfanilamide disaster" of 1937, in which more than one hundred people died when a sulfa drug was dissolved in diethylene glycol and distributed without testing, facilitated the passage of the Food, Drug, and Cosmetic Act in 1938. Federal Food, Drug, and Cosmetic Act of 1938, Pub. L. No. 75-717, 52 Stat. 1040 (codified at 21 U.S.C. §§ 301-392 (1976)); *see* W. Wardell & L. Lasagna, *supra* note 61, at 7-8.

151. 21 C.F.R. §§ 1-1300 (1978 & 1979).

152. 21 U.S.C. §§ 301-392 (1976).

153. 21 U.S.C. § 355(a) (1976); Gagnon, *supra* note 10, at 38.

154. Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (codified in scattered sections of 21 U.S.C.).

155. L. Cluff, G. Caranasos & R. Stewart, *supra* note 150, at 8. Currently, drug reform legislation submitted to Congress in May of 1979 is still pending. *See Drug Law Reform: The Record is Still Open*, 19 Am. Pharm. 10 (1979).

156. *See* 21 U.S.C. § 355(a) (1976). The testing required to gain FDA approval may last from five to eleven years and may cost from five to fifteen million dollars. *Editorial*, 18 Am. Fam. Physician 67, 67 (1978). FDA approval of the premarket testing plan is also necessary prior to interstate shipment of the drug for clinical investigation. M. Dixon, Drug Product Liability § 5.03, at 5-12 (1979). Furthermore, before human clinical studies are initiated, the sponsor of a new drug must submit a Notice of Claimed Investigational Exemption for a New Drug (IND) to the FDA. 21 C.F.R. § 314.1(d) (1978). The IND reports the results of animal toxicity studies and includes a detailed outline (a protocol) of the proposed investigation. M. Dixon, *supra*, § 5.03, at 5-13 n.1.

157. 21 C.F.R. § 314.105 (1978).

158. M. Dixon, *supra* note 156, § 5.03, at 5-13.

159. *Id.*

160. *Id.*

progress throughout the entire testing process.[161] Many drugs may pass the first three phases but receive only limited FDA approval that requires postmarketing surveillance and initially, controlled distribution.[162] This has been termed Phase IV, and eventually may represent an additional step for all drugs prior to full approval.[163]

Strict liability is justified on the purely economic ground that the manufacturer is in the best position to absorb and distribute the cost of minimizing the risks associated with the product.[164] Nevertheless, the incentive theory, with its resultant extensive testing, is an inadequate justification for imposing strict liability on pharmaceutical manufacturers because of the costs involved. Under present regulations, the cost of developing a new pharmaceutical is estimated at twelve million dollars.[165] The pharmaceutical industry is the major source for the development of new drugs, and, because it is a profit motivated industry,[166] the cost of more extensive testing for safer drugs would be reflected in higher drug prices. This result, however, may be equitable, because drug consumers directly benefit from increased safety and would directly bear the cost of minimizing the risk. Nevertheless, despite this one equitable argument, other costs of more extensive testing cannot be so fairly distributed and mitigate against imposing strict liability.

Data supplied by laboratory tests on animal models are, by nature, of limited application to human beings because of species difference.[167] Ultimately, the effects of a drug on a human can only be determined by testing it on human subjects. The costs of this type of more extensive safety testing would be less equally apportioned among consumers. Phase I clinical trials, the first administration of the drug to a human being, require healthy volunteers, who are usually male and often inmates in penal institutions.[168] When a test drug is administered to any healthy subject, the attendant risk is

161. The present requirements for approval of a new drug are set out by the FDA in the U.S. Dep't. of Health, Education, and Welfare, Public Health Service, Food & Drug Administration, Publication No. 74-3015, *Clinical Testing For Safe and Effective Drugs* (undated). A thorough and detailed description of the process is available in M. Dixon, *supra* note 156, §§ 5.03-.04

162. W. Wardell & L. Lasagna, *supra* note 61, at 147-48

163. *See* Johnstone, *Phase IV Testing—Overview and Summary of Pending Legislative Proposals*, 33 Food Drug Cosm. L.J. 173, 175-76 (1978). The imposition of Phase IV appears imminent. Wall St. J., Jan. 23, 1980, at 14, col. 2.

164. W. Prosser, *supra* note 38, § 75, at 494 n.27, 494-95. Similarly, one aim of the Model Act is to place an incentive for preventing loss on the party best able to achieve that goal. Model Act, *Criteria for the Act*, 44 Fed. Reg. 62,714, 62,715 (1979).

165. Schnee & Caglarcan, *The Changing Pharmaceutical Research and Development Environment*, in Pharmaceutical Industry, *supra* note 10, at 91, 103

166. "[O]f the 70 most valuable compounds introduced to medicine [in] this century since the discovery of aspirin in 1899, only ten have come from Universities and Research Institutes. All the rest have been discovered and developed by scientists in the laboratories of an industry operating under the profit system." Dunlop, *The Assessment of the Safety of Drugs and the Role of Government in Their Control*, 7 J. Clin. Pharm. 184, 185-86 (1967); *see* Rheingold, *supra* note 145, at 954.

167. *See generally* Dunne, *supra* note 36, at 34, Taylor, *Animal-Human Correlations*, in Clinical Toxicity, *supra* note 150, at 1.

168. Frey, Wild & Teller, *Normal Ranges of Laboratory Parameters in Captive and Noncaptive Populations*, in Clinical Toxicity, *supra* note 150, at 45, 46.

very real, and the presence of a counterbalancing benefit to this individual is questionable.[169] The participants in Phase II and III clinical trials are seldom private patients. They have some chance to benefit from the drug because it was developed specifically to relieve their ailment. The preferred clinical trial, however, is a double-blind procedure in which the effects of a new drug are tested against either a placebo or an established therapeutic agent.[170] Neither the administering physician nor the volunteer patient know the identity of the drug administered.[171] The subject of such a trial assumes the risk of receiving no curative therapy if a placebo or a less effective treatment is assigned. Testing must actually be continued until one drug is proved significantly more effective to establish valid trial results.[172] If drug safety could be achieved through more extensive testing, the price could not be judged by monetary cost alone. There is a human cost that falls primarily on the incarcerated, the indigent, and the ill.

Furthermore, society pays for the imposition of strict liability by being denied the benefit of new therapeutic agents.

> [T]here are two risks involved in the development of new drugs: (1) the risk that unforeseen, perhaps catastrophic, injuries will result because a new drug is used in man too soon; and (2) the risk that needless human suffering and death will occur because a beneficial drug is withheld from mankind too long. Absolute liability for the adverse effects of new drugs would enlarge the latter risk to unacceptable proportions, while giving a remedy only to those injured by the former risk.[173]

Prolonged premarket testing by pharmaceutical manufacturers to limit liability would result in an increase in "drug lag"—the phenomenon of "new drugs being approved for use consistently later in the United States than in other medically advanced countries."[174] Drug lag results in drugs being withheld from the public, as the manufacturer attempts, through testing, to uncover potentially serious side effects.[175] A drug manufacturer will never be sued by

---

169. Prisoners are often the "most willing and the most vulnerable of all subjects of medical experimentation." Although they receive a small remuneration, they frequently participate under the misguided belief that such participation will be viewed favorably by the parole board. In most states, it will not. Address by Dean Robert McKay, American Bar Association Annual Meeting, Section of Science and Technology Educational Program (Aug. 5, 1977), *reprinted in* 19 Jurimetrics 336, 336-37 (1979).

170. *Who Shall Live? The Tribulations of Clinical Trials*, 19 Am. Pharm. 234, 234 (1979).

171. *Id.*

172. In these situations, the question arises "whether a physician could ethically allow a patient to agonize or die for the sake of the trial." *Id.* at 235.

173. Gaston v. Hunter, 121 Ariz. 33, 48-49, 588 P.2d 326, 341-42 (Ct. App. 1978). An almost identical theory has been proposed in an eminent medical journal. "The problem of drug-induced illness can be defined by the magnitudes of two risks—the added risk of illness experienced by users of a drug, and the baseline risk in the absence of the drug." Jick, *The Discovery of Drug-Induced Illness*, 269 New Eng. J. Med. 481, 481 (1977).

174. Wardell, *A Close Inspection of the 'Calm Look'*, 239 J.A.M.A. 2004, 2005 (1978). The significance of the "drug lag" resulting from present regulations and liability is a subject of continuing controversy. Dr. Wardell's article is a response to an earlier article by former FDA Commissioner Dr. Donald Kennedy. *See* Kennedy, *A Calm Look at 'Drug Lag'*, 239 J.A.M.A. 423 (1978).

175. *See generally* W. Wardell & L. Lasagna, *supra* note 61, at 93-107.

the multitudes who suffer because a drug was not released.[176] Moreover, the deterrent effect of strict liability can be awesome. For example, if a drug with the potential therapeutic impact of penicillin is not released because of overly stringent testing procedures, more people will be harmed by the deprivation of that single agent than "by all the toxicity that has occurred in the history of modern drug development."[177]

More extensive premarket testing can therefore increase the cost of a drug and delay or even prevent its release, yet still fail to reveal some aberrent effect.[178] The market is the ultimate laboratory, and the consumer is the ultimate test subject.[179] The desire for "effective drugs developed without attendant risk or toxicity" has been termed a desire for "something for nothing,"[180] a wish for " 'progress without price.' "[181] No theory of strict liability can fulfill that desire or grant that wish.

Although the imposition of strict liability for failure to warn of unforeseen hazards cannot prevent injury by producing significantly safer pharmaceuticals, it can provide that the manufacturer will bear the cost of any injury that ensues.[182] If drugs cannot be made completely safe, any loss suffered by the producer in compensating for consumer injury is a cost of engaging in such a business.[183] The risk allocation theory envisions that this loss can be "treated as a cost of production against which liability insurance can be obtained."[184] If the hazard is unforeseeable, however, the resulting damages are equally unforeseeable and impossible to reflect accurately in the "product price schedule."[185] The ability of the manufacturer to anticipate and absorb the cost of product related injuries is significantly impaired by an unknowable danger.[186] Furthermore, it is impossible to insure accurately against unforeseeable adverse drug reactions.[187] The sufficiency and cost of any insurance may be severely disproportionate to the actual risk or loss.[188] High

---

176. "Clearly, a decision has been made that some individuals will suffer from disease in order that others may be protected from drug-induced diseases. Such a decision appears to be based upon the value that a society should avoid the appearance of taking a life or otherwise directly causing suffering (in this case through drug-induced disease), though this may mean that some individuals, who contact [*sic*] a disease for which society has no direct responsibility, will suffer." Anthony, *The Patient As A Consumer*, in Perspectives, *supra* note 10, at 358, 363 (footnote omitted).

177. W. Wardell & L. Lasagna, *supra* note 61, at 138.

178. *See* Inman, *Detection and Investigation of Adverse Drug Reactions*, in Adverse Drug Reactions, *supra* note 1, at 41, 41; note 61 *supra* and accompanying text.

179. *See* W. Wardell & L. Lasagna, *supra* note 61, at 146.

180. Azarnoff, *Academic Drug Evaluation*, in Controversies in Clinical Pharmacology and Drug Development 19, 20 (R. Palmer ed. 1972).

181. McMahon, *Introduction*, in Future Trends in Therapeutics ix (F. McMahon ed. 1978).

182. *See* Greenman v. Yuba Power Prods., Inc., 59 Cal. 2d 57, 63, 377 P.2d 897, 901, 27 Cal. Rptr. 697, 701 (1963).

183. Rheingold, *supra* note 145, at 1017.

184. Restatement (Second) of Torts § 402A, Comment c (1965)

185. *See* Willig, *supra* note 43, at 547.

186. *See* Whittington v. Eli Lilly & Co., 333 F. Supp. 98, 101 (S.D. W. Va. 1971)

187. Rheingold, *supra* note 145, at 1015-16.

188. Model Act § 101(C), 44 Fed. Reg. 62,714, 62,716 (1979).

premiums may force manufacturers to go uninsured,[189] and manufacturers of high risk products, such as drugs, may become reluctant to develop new products.[190]

It is not suggested that pharmaceutical manufacturers will completely terminate research and development of new drugs if held strictly liable for all adverse reactions. The pharmaceutical industry is highly competitive;[191] new drugs must be produced to insure a company's continued existence,[192] and the potential benefits of a successful new drug are enormous.[193] Nevertheless, the introduction of new drugs would be delayed, and certain agents might never be marketed, because the marketing of a new drug involves multiple risk-benefit analyses. The risk of adverse drug reactions must be balanced against the drug's therapeutic effect. Furthermore, the risk of liability from adverse drug reactions must be weighed against the potential market for the drug. A drug with enormous therapeutic potential may have a limited market and be associated with a high degree of liability.[194] This type of drug would be most adversely affected by the imposition of strict liability because the pharmaceutical manufacturers would probably shelve such a drug to limit the potential losses.[195] For example, premature delivery is the major cause of infant death during the period immediately following birth, as well as a major cause of mental retardation.[196] The search for a drug to control premature labor is a primary clinical objective,[197] but the possible liability associated with marketing such a drug is substantial. The drug would be given during pregnancy, a high risk period for adverse effects. It would affect a high risk group, infants, particularly premature infants.[198] Furthermore, the statute of limitations would be extended by the infancy of the potential plaintiff.[199] Finally, the

---

189. Ross, *Current Trends And Reforms: Legislation--Judicial—Industry*, in Prevention and Defense of Manufacturers' Products Liability, Course Handbook Series No. 121, 855, at 858 (1978).

190. *Id.* Moreover, the cost of such insurance would probably be reflected in an increase in product price schedules. *See* Codling v. Paglia, 32 N.Y.2d 330, 341, 298 N.E.2d 622, 627-28, 345 N.Y.S.2d 461, 468-69 (1973). Such price increases might place the cost of essential drugs beyond the reach of some consumers. Rosenn, *Litigation Involving Manufacturer's Liability for Defective Medical Products: Judicial Perspectives*, 2 Am. J. L. & Med. 245, 251 (1976).

191. Schnee & Caglarcan, *Economic Structure and Performance of the Ethical Pharmaceutical Industry*, in Pharmaceutical Industry, *supra* note 10, at 23, 27. The proportionate share of the market shifts rapidly among the top firms. *Id.*

192. Rheingold, *supra* note 145, at 1017.

193. For example, SmithKline Corporation experienced a 95% increase in net earnings in one year due to the successful introduction of Tagamet, an ulcer remedy. N.Y. Times, Sept. 16, 1979, § C, at 1, col. 4.

194. *See* Lauersen, Merkatz, Tejani, Wilson, Roberson, Mann & Fuchs, *Inhibition of Premature Labor: A Multicenter Comparison of Ritodrine and Ethanol*, 127 Am. J. Obstet. & Gynecol. 837 (1977).

195. *See* Rosenn, *supra* note 190, at 251 (imposition of liability could force the drug manufacturer to remove a medically useful product from the market).

196. Lauersen, Merkatz, Tejani, Wilson, Roberson, Mann & Fuchs, *supra* note 194, at 838

197. *Id.* at 837-38.

198. Davies, *supra* note 1, at 6.

199. *See, e.g.*, Piasturo v. McCloud, 26 A.D.2d 610, 271 N.Y.S.2d 94 (4th Dep't 1966),

drug would have a limited market because it would be administered in acute, rather than chronic situations.[200]

In these cases, the manufacturer only apparently bears the loss; the true cost is borne by society. Strict liability cannot effectively help prevent the injury; neither the incentive nor the risk allocation theories justify its imposition on pharmaceutical manufacturers. Other methods of injury prevention and compensation for unforeseeable adverse drug reactions should be considered.

IV. SUGGESTIONS IN LIEU OF STRICT LIABILITY

Presently, the law has determined that the cost to society of strict liability for failure to warn of unforeseeable adverse drug effects is too high and, therefore, it exempts the manufacturer from liability in this limited situation.[201] The injured consumer left without remedy, however, may not appreciate the justification for this decision. Courts have endeavored, within the limits of foreseeability, to provide a remedy, and these efforts are frequently successful.[202] Further protection for the consumer, however, should be provided by the legislature.

The most effective drug attacks the etiology of a disease rather than the symptoms. The etiology is often obscure or unknown, and, therefore, therapy can only be palliative. Often, ignorance is the cause of problems stemming from unforeseeable adverse drug reactions, and knowledge can alleviate these problems. In the risk benefit calculus, it is essential to determine whether the marketing of the product, even with warnings, was justified either legally[203]

Francies v. County of Westchester, 3 A.D.2d 850, 161 N.Y.S.2d 501 (2d Dep't 1957), N.Y. Civ. Prac. Law § 208 (McKinney 1972 & Supp. 1979).

200. *See* Lauersen, Merkatz, Tejani, Wilson, Roberson, Mann & Fuchs, *supra* note 194, at 839-40.

201. *See* notes 89-94 *supra* and accompanying text. Foreseeability will not be considered and the manufacturer will be held strictly liable when the injury resulted from a manufacturing defect, or if there was a positive representation of safety from the particular injurious defect. *See* notes 37, 84-87 *supra* and accompanying text. It is possible that the protection provided by unforeseeability could be lost if it is proved that the drug offers no substantial benefits. *See* notes 48, 88 *supra* and accompanying text.

202. *See, e.g.*, Givens v. Lederle, 556 F.2d 1341 (5th Cir. 1977) (warning must be transmitted even if the risk of injury was one in three million and the risk was not to the drug user but to the one in contact with the drug user); Sterling Drug, Inc. v. Yarrow, 408 F.2d 978 (8th Cir. 1969) (if a drug was promoted on a one-to-one basis via detail men, it would be reasonable under the circumstances to have the warning transmitted similarly); Davis v. Wyeth Labs., Inc., 399 F.2d 121 (9th Cir. 1968) (the warning of risk must be directly transmitted to the consumer under certain circumstances); Stevens v. Parke, Davis & Co., 9 Cal. 3d 51, 507 P.2d 653, 107 Cal. Rptr. 45 (1973) (overpromotion would make negligent prescription foreseeable), Bine v. Sterling Drug, Inc., 422 S.W.2d 623 (Mo. 1968) (drug manufacturer is under the duty to warn of side effects even if the exact nature of the side effect is not known); Incollingo v. Ewing, 444 Pa. 263, 282 A.2d 206 (1971) (an adequate warning can be nullified by the manufacturer's promotional efforts), Whitley v. Cubberly, 24 N.C. App. 204, 210 S.E.2d 289 (1974) (same), Crocker v. Winthrop Labs., Inc., 514 S.W.2d 429 (Tex. 1974) (a positive representation of safety will negate the foreseeability defense); *see* notes 99-138 *supra* and accompanying text.

203. *See* notes 41-49 *supra* and accompanying text.

or medically.[204] The key to such actual or constructive knowledge is a national reporting system for adverse drug effects.[205]

Currently, the FDA's Division of Drug Experience[206] "[c]ollect[s] and evaluate[s] information on drug usage, adverse reactions and other drug experience data."[207] Presently available surveillance sources have helped substantiate the causal relationship of certain drugs with rare adverse reactions,[208] such as DES and adenocarcinoma,[209] and potassium chloride and gastrointestinal ulcerations.[210] The recognized need to expand these information gathering sources has resulted in a joint project by the National Bureau of Standards,[211] the FDA, and the Joint Commission on Prescription Drug Use[212] to investigate practical techniques of postmarketing surveillance.[213] The results of this project will soon be available.[214] It already appears that the Phase IV period of monitored release prior to full FDA approval of new drugs will officially be required.[215] The United Kingdom has adopted a similar system, under which the physician is informed of the limited nature of the drug approval and commits himself "to supply specific information on the response of each patient" to the manufacturer.[216] Such a system performs a dual function. Information concerning the risks associated with the new drug is transmitted from the manufacturer to provide the basis for an informed choice.[217] Second, information concerning the consumer's reaction to the drug is transmitted back to the manufacturer to provide the basis for knowledgeable drug warnings and rational marketing policies.[218]

A surveillance system that efficiently furnishes information on the effectiveness and the effects of new drugs restricts the defense of unforeseeability by

---

204. The degree of risk inherent in a drug cannot be determined unless the incidence of adverse effects can be accurately established. Similarly, the benefit of a therapy cannot be judged without information concerning results in widespread use. *See* W. Wardell & L. Lasagna, *supra* note 61, at 131; Inman, *supra* note 178, at 42; Gross, *The Thorny Path of Clinical Pharmacology*, 24 Clin. Pharmacol. Ther. 383, 392 (1978).

205. W. Wardell & L. Lasagna, *supra* note 61, at 131; Inman, *supra* note 178, at 43; *see* Gross, *supra* note 204, at 391-92.

206. The Division of Drug Experience was established in 1970 pursuant to the reorganization of the Bureau of Drugs. Lee & Turner, *Food and Drug Administration's Adverse Drug Reaction Monitoring Program*, 35 Am. J. Hosp. Pharm. 929, 929 (1978).

207. *Id.*

208. *Id.* at 931.

209. Bichler v. Willing, 58 A.D.2d 331, 397 N.Y.S.2d 57 (1st Dep't 1977).

210. *See* O'Hare v. Merck & Co., 381 F.2d 286, 289-90 (8th Cir. 1967).

211. The National Bureau of Standards was created to establish consistent national standards of measurement. 15 U.S.C. § 272 (1976).

212. This free standing commission, largely supported by the Pharmaceutical Manufacturers Association, was established to investigate the effectiveness of adverse drug reaction monitoring systems. Telephone Interview with Dr. John Adams, Pharmaceutical Manufacturers Association (Mar. 12, 1980).

213. Lee & Turner, *supra* note 206, at 930.

214. *Id.*

215. *See* note 163 *supra* and accompanying text.

216. Dunne, *supra* note 36, at 39.

217. *See* Johnstone, *supra* note 163, at 174-75.

218. *See id.* at 174.

making the unknown known. Someone must be injured before the danger is known, however, and the unforeseeability defense should remain against this initial injury.[219] Any costs of unavoidable harms that would be shifted from the individual should be borne by society at large.[220] An insurance program "that will . . . compensate the occasional victims of serious unwanted effects" would not only serve as a remedy by spreading the cost to society, but would also facilitate the operation of a surveillance system.[221]

A federally sponsored program might provide the means for the establishment and operation of a viable system. The federal government already plays an integral regulatory role in the passage of a new drug into the market place.[222] No new drug can move in interstate commerce without government approval.[223] Furthermore, the government sets the standards of "efficacy and safety" required for approval prior to marketing[224] and is in the best position to distribute the costs of unforeseen adverse drug effects that result from marketing.[225] The National Swine Flu Immunization Program,

---

219. "If such reaction had never occurred before, defendant could not know about it or in the exercise of the required degree of care, could not have found out about it, and absent knowledge of such reaction, there could be no duty to warn." Johnston v. Upjohn Co., 442 S.W.2d 93, 97 (Mo. Ct. App. 1969).

220. Model Act, *Analysis*, § 106, 44 Fed. Reg. 62,714, 62,727-28 (1979).

221. Inman, *supra* note 178, at 43.

222. *See* notes 150-63 *supra* and accompanying text.

223. 21 U.S.C. § 355(a) (1976). Despite this requirement, the government disclaims any tort liability flowing from this approval. Federal courts have dismissed actions against the United States government based on injuries resulting from FDA approval of drugs, because drug approval is a discretionary function exempted under the Federal Tort Claims Act, 28 U.S.C. § 2680(a) (1976). Gelley v. Astra Pharm. Prods., Inc., 466 F. Supp. 182, 186 (D. Minn. 1979), Gray v. United States, 445 F. Supp. 337, 341-42 (S.D. Tex. 1978). *Contra*, Griffin v. United States, 500 F.2d 1059, 1063-64 (3d Cir. 1974) (decision to release a production lot of oral polio vaccine by the biologic standards division of the Department of Health, Education, and Welfare not considered exempt discretionary activity).

224. *See* notes 150-56 *supra* and accompanying text.

225. The need for and the appropriateness of government action in the area of products liability compensation was recognized by the establishment of the Federal Interagency Task Force on Product Liability in 1976 to investigate the "apparent crisis . . . in the field of product liability." Schwartz, *The Federal Government and the Product Liability Problem: From Task-Force Investigation to Decisions by the Administration*, 47 U. Cin. L. Rev. 573, 574 (1978). The Task Force noted, among other major findings, that products liability insurance premiums appeared to have significantly increased for pharmaceutical manufacturers, and that product liability problems in this field "have reinforced trends against new product development." *Id.* at 577. President Carter requested that the Department of Commerce prepare an "options paper," with recommendations based on the Task Force Report. *Id.* at 575. This paper was published for public comment on April 6, 1978. *The Department of Commerce Options Paper on Products Liability and Accident Compensation Issues*, 43 Fed. Reg. 14,612 (1978). The paper focused on methods of assisting manufacturers in obtaining insurance at reasonable rates for products liability injuries. Federal insurance was seen as a complicated and problematic area in which further government intervention should be reserved "in case the product liability problem reaches emergency proportions." *Id.* at 14,623. Both the Task Force and the Department of Commerce recognized the problems of providing a no-fault compensation system in the consumer product area. Schwartz, *supra*, at 586.

established pursuant to the Swine Flu Act of 1976,[226] is a direct precedent for this type of government action. This legislation provided an exclusive remedy against the United States for injuries resulting from the administration of the swine flu vaccine.[227] The government retained the right to sue the vaccine manufacturer for negligence or breach of contract in connection with the program.[228] The constitutionality of the Swine Flu Act has been upheld.[229] A similar program may provide an equitable way to compensate the victims of unforeseeable adverse drug reactions. Admittedly, the conception and implementation of such a program would not be without problems.[230] A program directly patterned on the Swine Flu Act, incorporating the limitation of an exclusive remedy against the government,[231] would not be desirable. The legislative goal should be to offer a government remedy when the plaintiff establishes the causal relation of injury and unforeseeable drug side effect, yet fails to demonstrate a breach of the duty to warn. Such legislation would compensate the injured plaintiff without inhibiting the development of beneficial new drugs. It would not result in lowering pharmaceutical industry safety standards because the manufacturer would still be directly liable for any breach of duty of care now imposed by the courts.[232] The legislation

226. Pub. L. No. 94-380, 90 Stat. 1113 (amending 42 U.S.C. § 247(b) (1976)).

227. *Id.* § 2(k)(1)(A)(ii), 90 Stat. at 1114, (codified at 42 U.S.C.A. § 247b(k)(1)(A)(ii) (Supp. 1978)).

228. *Id.* § 2(k)(5)(C)(7), 90 Stat. at 1117 (codified at 42 U.S.C.A. § 247b(k)(7) (Supp. 1978)).

229. *See* Ducharme v. Merrill-Nat'l Labs., 574 F.2d 1307, 1309-10 (5th Cir.) (denial of civil cause of action against drug manufacturer does not violate fifth amendment), *cert. denied,* 439 U.S. 1002 (1978). Wolfe v. Merrill Nat'l Labs., 433 F. Supp. 231, 236-37 (M.D. Tenn. 1977) (upholding denial of right to jury trial under the Swine Flu Act); Sparks v. Wyeth Labs., Inc., 431 F. Supp. 411, 418 (W.D. Okla. 1977) (same).

230. The Swine Flu Immunization Program has been the subject of recent criticism. *See* Morgenstern, *The Role of the Federal Government in Protecting Citizens From Communicable Diseases,* 47 U. Cin. L. Rev. 537, 564-67 (1978) (the method of injury compensation was inappropriate); Wecht. *The Swine Flu Immunization Program: Scientific Venture or Political Folly?* 3 Am. J. L. & Med. 425 (1977-78) (validity of the entire program was questionable). The Swine Flu Act was an emergency response to a potentially urgent situation. Time constraints made a "careful and indepth [*sic*] review" of the entire bill impossible, and it was sent back to the Senate from the Appropriations Committee "without prejudice or any specific recommendation." S. Rep. No. 1147, 94th Cong., 2d Sess. 1, *reprinted in* [1976] U.S. Code Cong. & Ad. News 1987, 1987. Compensation for victims of drug related injuries is a pressing problem, but it does not approach the status of national emergency created by a possible epidemic of killing flu. The legislature would not be under the same pressures and time constraints in dealing with this products liability problem, and the problems encountered with the Swine Flu Act could be minimized or negated.

231. 42 U.S.C.A. § 247b(k)(3) (Supp. 1978).

232. *See, e.g.,* Salmon v. Parke, Davis & Co., 520 F.2d 1359 (4th Cir. 1975) (manufacturer breached the duty of care by overpromotion of the drug); Reyes v. Wyeth Labs., 498 F.2d 1264 (5th Cir.) (manufacturer must effectively transmit the warning of potential injury, and when no physician intervenes as "learned intermediary," that warning must go directly to the consumer), *cert. denied,* 419 U.S. 1096 (1974); Gottsdanker v. Cutter Labs., 182 Cal. App. 2d 602, 6 Cal. Rptr. 320 (1960) (in the presence of a manufacturing defect, manufacturer may be held liable even though negligence could not be established); Crocker v. Winthrop Labs., 514 S.W.2d 429 (Tex. 1974) (positive representations of safety when knowledge was lacking would render the manufacturer liable). The private right of action should be maintained because one of the benefits of

required to deal with this sensitive area would necessarily be complex, but the problems raised by drug products liability are intricate. Complex questions are not well served by simplistic answers.

Kathleen H. Wilson

---

products liability litigation has been to focus the manufacturers' attention on product safety. Schwartz, *supra* note 225, at 589.