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DIAGNOSIS OF A LEGAL HEADACHE: LIABILITY FOR UNFORESEEABLE DEFECTS IN DRUGS

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INTRODUCTION

Tort law has long distinguished drugs from most other products. For example, the privity requirement imposed by *Winterbottom v. Wright*¹ in 1842 remained the law for most products² until *MacPherson v. Buick Motor Co.*³ was decided in 1916.

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¹ 152 Eng. Rep. 402 (1842). The *Winterbottom* plaintiff was injured when the mail-coach he was operating broke down and he was hurled to the ground. *Id.* at 403. The defendant had been hired by the Postmaster-General to maintain the mail-coaches in a "fit, proper, safe and secure state and condition." The plaintiff alleged that his injuries were caused by the defendant's negligence in performing the maintenance contract. *Id.* at 402-03. Noting that the defendant could be held liable in negligence only if he owed the plaintiff a duty of care, the court determined that a duty in this case could only arise out of the contract between the defendant and the Postmaster-General. *Id.* at 405. Thus, the court held that only those parties in privity to the contract could bring an action for its negligent performance. *Id.* If such a limitation were not imposed, the court concluded, "the most absurd and outrageous consequences . . . would ensue." *Id.* See generally L. FRUMER & M. FRIEDMAN, PRODUCTS LIABILITY § 5.01 (1978).

² See, e.g., *S.H. Kress & Co. v. Lindsey*, 262 F. 331 (5th Cir. 1919); *Cadillac Motor Car Co. v. Johnson*, 221 F. 801 (2d Cir. 1915); *Huset v. J.I. Case Threshing Mach. Co.*, 120 F. 865 (8th Cir. 1903); *Altorfer Bros. Co. v. Green*, 236 Ala. 427, 183 So. 415 (1938); *Chrystal Coca-Cola Bottling Co. v. Cathey*, 83 Ariz. 163, 317 P.2d 1094 (1957) (dictum); *Pelletier v. Dupont*, 124 Me. 269, 128 A. 186 (Me. 1925); *Pittman v. Gas & Elec. Co.*, 241 Mass. 322, 135 N.E. 223 (1922); *Wood v. Sloan*, 20 N.M. 127, 148 P. 507 (1915); *McCaffrey v. Mossberg & Granville Mfg. Co.*, 23 R.I. 381, 50 A. 651 (1901); *Burkett v. Studebaker Bros. Mfg. Co.*, 126 Tenn. 467, 150 S.W. 421 (1912). For an interesting early discussion in which the author concluded that the *Winterbottom* privity requirement was the exception rather than the rule, see 32 HARV. L. REV. 89 (1918).

By the early twentieth century the *Winterbottom* privity rule had been adopted in a majority of jurisdictions. See FRUMER & FRIEDMAN, *supra* note 1, at § 5.01; W. PROSSER, LAW OF TORTS § 96, at 641-42 (4th ed. 1971). Two basic reasons were given for the rule. First, the manufacturer could not foresee or anticipate injury to those other than his immediate purchaser. The weakness of this reasoning is apparent, however, when one recalls that a manufacturer's immediate purchaser is usually a retailer, not a consumer. The second and more forceful reason was stated by the court in *Huset v. J.I. Case Threshing Mach. Co.*, 120 F. 865 (8th Cir. 1903):

[A] wise and conservative public policy has impressed the courts with the view that there must be a fixed and definite limitation to the liability of manufacturers and vendors in the construction and sale of complicated machines and structures which are to be operated or used by the intelligent and the ignorant, the skillful and the incompetent, the watchful and the careless, parties that cannot be known

Long before *MacPherson*, however, the New York Court of Appeals, in *Thomas v. Winchester*,⁴ held a drug manufacturer liable to a remote user not in privity with the defendant, recognizing that the drug in question was an "inherently dangerous" product which should be governed by different liability rules.

Today, tort law seems to be moving towards strict liability for most products.⁵ Yet, the landmark cases in this movement generally

to the manufacturer or vendors, and who use the articles all over the country hundreds of miles distant from the place of their manufacture or original sale. . . .

Id. at 867. See generally W. PROSSER, *supra*, § 96.

Injuries caused by an "imminently" or "inherently" dangerous product provided the only notable exception to the privity rule. See, e.g., *Huset v. J.I. Case Threshing Mach. Co.*, 120 F. 865, 870 (8th Cir. 1903) (dictum); *Blood Balm Co. v. Cooper*, 83 Ga. 457, 10 S.E. 118 (1889); *Roberts v. Anheuser-Busch Brewing Ass'n*, 211 Mass. 449, 98 N.E. 95 (1912); *Thomas v. Winchester*, 6 N.Y. 397 (1852). The "inherently dangerous" rule was often applied to defective food. See *Tomlinson v. Armour & Co.*, 75 N.J.L. 748, 70 A. 314 (1908); *Catani v. Swift & Co.*, 251 Pa. 52, 95 A. 931 (1915); *Mazetti v. Armour & Co.*, 75 Wash. 622, 135 P. 633 (1913); note 4 *infra*.

³ 217 N.Y. 382, 111 N.E. 1050 (1916). The plaintiff in *MacPherson* was injured when the wheel of his car "crumbled into fragments." *Id.* at 385, 111 N.E. at 1051. Although the wheel had not been manufactured by the defendant, its defective condition was deemed to have been discoverable by the defendant when the car was assembled. *Id.* at 385, 111 N.E. at 1051. Rejecting the privity requirement, the court reasoned that since there was "knowledge of a danger, not merely possible, but probable," which "in the usual course of events" could "be shared by others than the buyer," *id.* at 389-90, 111 N.E. at 1053, liability could properly be imposed for a third party's injuries. Observing that "[p]recedents drawn from the days of travel by stagecoach do not fit the conditions of travel to-day," *id.* at 391, 111 N.E. at 1053, the *MacPherson* court concluded that liability should be imposed upon an auto manufacturer regardless of a plaintiff's privity because a car is "reasonably certain to place life and limb in peril when negligently made." *Id.* at 389, 111 N.E. at 1053.

⁴ 6 N.Y. 397 (1852). Holding a drug manufacturer liable for a remote user's injuries notwithstanding lack of privity, *id.* at 409-10, the *Thomas* court reasoned that where "an act of negligence imminently dangerous to the lives of others" is committed, "the party guilty of the negligence is liable to the party injured, whether there be a contract between them or not" *Id.* at 410. Later cases clarified the *Thomas* rationale, holding that negligence could be inferred where it was shown that the product was inherently dangerous and that plaintiff was injured by contact with the substance. *Karr v. Inecto, Inc.*, 247 N.Y. 360, 160 N.E. 398 (1928); *Maier v. Clairol, Inc.*, 263 App. Div. 848, 31 N.Y.S.2d 751 (2d Dep't 1941); *Petzold v. Roux Labs.*, 256 App. Div. 1096, 11 N.Y.S.2d 565 (2d Dep't 1939); *Bundy v. Ey-Teb, Inc.*, 160 Misc. 325, 289 N.Y.S. 905 (N.Y.C. Civil Ct. Kings County 1935). *But see Sanders v. Clairol, Inc.*, 2 App. Div. 2d 857, 155 N.Y.S.2d 945 (2d Dep't 1956) (mem.). Either lack of adequate warning or mislabeling could provide a basis for relief under this theory. See *Commissioners of State Ins. Fund v. City Chemical Corp.*, 290 N.Y. 64, 48 N.E.2d 262 (1943); *Willson v. Faxon, Williams & Faxon*, 208 N.Y. 108, 101 N.E. 799 (1913); *Halloran v. Parke, Davis & Co.*, 245 App. Div. 727, 280 N.Y.S. 58 (2d Dep't 1935) (per curiam); *Marcus v. Specific Pharm., Inc.*, 82 N.Y.S.2d 194 (Sup. Ct. N.Y. County 1948); *Bundy v. Ey-Teb, Inc.*, 160 Misc. 325, 289 N.Y.S. 905 (N.Y.C. Civil Ct. Kings County 1935). *But see Parker v. State*, 201 Misc. 416, 105 N.Y.S.2d 735 (Ct. Cl. 1951) (dictum), *aff'd*, 280 App. Div. 157, 112 N.Y.S.2d 695 (3d Dep't 1952).

⁵ See Donnelly, *After the Fall of the Citadel: Exploitation of the Victory or Consideration of All Interests?*, 19 SYRACUSE L. REV. 1 (1967); Gilliam, *Products Liability In a Nutshell*, 37 OR. L. REV. 119 (1958); Jenkins, *The Product Liability of Manufacturers: An Understanding And Exploration*, 4 AKRON L. REV. 135 (1971); Keeton, *Products Liability—Current*

have involved machines, such as cars⁶ and manufacturing equipment,⁷ rather than drugs. The purpose of this Article is to consider whether the strict liability rules developed in the machinery cases should be applied to drugs, particularly to the increasing numbers of drugs whose defects are "unforeseeable."⁸ The past controversy over thalidomide and the recent controversy over "DES", a synthetic hormone given to pregnant women to prevent miscarriages but which increases the risk of cervical and vaginal cancer in their daughters, provide two examples of unforeseeable drug defects. Cases such as these may be among the rising number of drug liability cases in the lower state and federal courts, at least some of which may soon be ripe for authoritative decision by higher courts.

It may be well to begin by considering some of the significant ways in which drugs differ from machines. First, the vast majority of machine defects result from failures in the manufacturing process and may properly be termed "construction defects."⁹ In contrast, when drugs reach the consumer they are, generally speaking, in the condition their manufacturer intended. Injuries resulting from their reasonable use usually are attributable to a defect in "design,"¹⁰

Developments, 40 TEX. L. REV. 193 (1961); Prosser, *The Fall of the Citadel (Strict Liability to the Consumer)*, 50 MINN. L. REV. 791 (1961); Prosser, *The Assault Upon the Citadel (Strict Liability to the Consumer)*, 69 YALE L.J. 1099 (1960); Rheingold, *The Expanding Liability of the Product Supplier: A Primer*, 2 HOFSTRA L. REV. 521 (1974).

⁶ *E.g.*, Cronin v. J.B.E. Olson Corp., 8 Cal. 3d 121, 501 P.2d 1153, 104 Cal. Rptr. 433 (1972) (en banc); Elmore v. American Motors Corp., 70 Cal. 2d 578, 451 P.2d 84, 75 Cal. Rptr. 652 (1969) (en banc); Henningsen v. Bloomfield Motors, Inc., 32 N.J. 358, 161 A.2d 69 (1960); Codling v. Paglia, 32 N.Y.2d 330, 298 N.E.2d 622, 345 N.Y.S.2d 461 (1973); Bolm v. Triumph Corp., 33 N.Y.2d 151, 305 N.E.2d 769, 350 N.Y.S.2d 644 (1973).

⁷ *E.g.*, Messina v. Clark Equip. Co., 263 F.2d 291 (2d Cir.), cert. denied, 359 U.S. 1013 (1959); Fleming v. John Deere Plow Co., 158 F. Supp. 399 (W.D. Pa. 1958); Greenman v. Yuba Prods., Inc., 59 Cal. 2d 57, 377 P.2d 897, 27 Cal. Rptr. 697 (1962) (en banc); Winnet v. Winnet, 57 Ill. 2d 7, 310 N.E.2d 1 (1974); Krahn v. J.L. Owens Co., 125 Minn. 33, 145 N.W. 626 (1914); Micallef v. Miehle Co., 39 N.Y.2d 376, 348 N.E.2d 571, 384 N.Y.S.2d 115 (1976).

⁸ For purposes of this Article, "unforeseeable" defects are those which cannot be discovered by use of "due care." All defects may be discoverable given infinite time, money and talent to conduct research, but the limited resources actually available to even the largest manufacturers make many defects, in practice, "unforeseeable" when they are marketed.

⁹ "Construction defect" implies that the product which entered the market place was a departure from the intended design. As Professor Wade has noted, in the context of products liability, it is the construction defect, the flaw in the metal, the cracked soft drink bottle, which is most often associated with strict liability in tort. Wade, *On the Nature of Strict Tort Liability for Products*, 44 MISS. L.J. 825, 829-30, 833 (1973). The strict-liability doctrine assumes that product-construction defects usually result from fault which exists but may be difficult to prove. Keeton, *Products Liability and the Meaning of Defect*, 5 ST. MARY'S L.J. 30, 34 (1973); Wade, *supra*, 825-26.

¹⁰ Generally, "design defect" refers to a finished product that conforms to a plan which for some reason proves to be flawed. In contrast to construction defects, design defects are not easily defined. The California courts' interpretation of the term, for example, varied before a dual theory of strict products liability was formulated in *Barker v. Lull Engineering*

rather than in "construction." This distinction in the nature of defects is critical in the area of strict products liability.

Second, the principles by which machines work are fairly well understood; close inspection of the design and relatively brief testing will reveal a machine's latent defects. The principles by which drugs work are less well understood, since drugs affect the complex mechanisms of the body in myriad ways, and the same drug may produce different effects in different individuals. Scrutiny of a drug's design and careful, expensive, time-consuming testing cannot insure discovery of all its latent hazards.¹¹ Injuries from drug hazards may, in practice, be unforeseeable, the result of scientific limitations rather than negligence in design or construction. Although machines often can be redesigned to eliminate defects without impairing their operation, redesign of a drug may be impossible. Side effects are frequently inseparable from the product itself and the current level of scientific knowledge about drug effects may not permit tailoring a drug to specific needs or conditions, much less to

Co., 20 Cal. 3d 413, 573 P.2d 443, 143 Cal. Rptr. 225 (1978). See, e.g., *Buccery v. General Motors Corp.*, 60 Cal. App. 3d 533, 132 Cal. Rptr. 605 (1976) (product with design which causes injury when used or misused in a foreseeable manner is defective if available technology could avoid the danger at a reasonable cost); *Baker v. Chrysler Corp.*, 55 Cal. App. 3d 710, 127 Cal. Rptr. 745 (1976) (determination of a defective design must include a consideration of the economic and technological feasibility of alternatives); *Hyman v. Gordon*, 35 Cal. App. 3d 769, 111 Cal. Rptr. 262 (1973) (overall design may be defective if a necessary article functions without injury in one area yet is the proximate cause of harm in another). For a discussion of the *Barker* test, see text accompanying notes 43-46 *infra*.

¹¹ Under the Food and Drug Act, 21 U.S.C. § 355(a) (1976):

No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) of this section is effective with respect to such drug.

Before an application can be filed, however, extensive laboratory research and testing must be performed. Animals are the most common subjects in this step of the testing process, but since the drugs are intended for human use, this testing is not optimal. See Hubbard, *Preclinical Problems of New Drug Development*, in *REGULATING NEW DRUGS* 35, 41-42 (R.L. Landau ed. 1973).

A new drug application made to the Federal Food and Drug Administration (FDA), is approved only after the FDA is convinced that the laboratory experiments support clinical trials. In the first clinical test, the drug is administered to a small group of patients who are observed to determine the rate and degree of absorption, metabolization and elimination of the drug as well as the tolerated dosage and obvious toxicity. The next step tests the drug's ability to prevent or counteract symptoms. In step three the drug is distributed to a larger patient population, often through out-patient services. Its purpose is to tailor development of the proper dosage. For a complete discussion of the premarketing testing procedure at the clinical level, see Gold & Azarnoff, *New Drug Investigations in Man: Continuing Unresolved Problems*, in *REGULATING NEW DRUGS* 62, 62-67 (R.L. Landau ed. 1973). As a result of the testing procedures, "[t]he maximum number of patients (3,000) likely to get a drug in Phase III testing, the last step before FDA approval, will give investigators a 95 percent chance of finding an adverse reaction that might occur once in 1,000 patients." W. Ross, *THE LIFE/DEATH RATIO* 207-08 (1977).

specific individuals. One who seeks a particular therapeutic effect often faces a difficult choice: either accept the drug's defects or forego its benefits.¹²

Finally, while the hazards of machine defects seldom depend upon the particular operator or user, a drug's hazards may vary with the consumer's age, genetic makeup, body chemistry, eating habits and state of health. Proper dosage also may vary between consumers, and foods eaten or other drugs consumed may affect a drug's therapeutic action as well as its side effects. In short, there is an infinite variety of drug reactions, and a proportionately large number of potential liability claims.

These distinctive aspects of drugs suggest at the outset that modern liability rules, which have developed primarily in the context of defective machinery cases, may be inadequate tools for apportioning losses which result from drug injuries, particularly those that were unforeseeable at the time of manufacture and sale. Although the early drug cases which sounded in negligence at first glance appear to be applicable, they focussed on adequacy of warning¹³ and, therefore, bear little on the problem of unforeseeable drug

¹² In making his decision, the user's own knowledge and observations leave him uniquely defenseless against a drug's latent defects. Adequate warning of risks and possible side effects is essential to permit safe use of a drug. See note 13 *infra*; Gardner, *Increasing Patient Awareness in Drug Therapy: Ramifications of a Patient Package Insert Requirement*, 66 GEO. L.J. 837 (1978).

¹³ Drug manufacturers' liability traditionally has been linked to adequacy of warning. What constitutes "adequate" in a particular circumstance is, of course, subject to dispute. Generally, a warning must be designed with respect to medium and urgency so that its message will be conveyed to the user. *Jackson v. Coast Paint & Lacquer Co.*, 499 F.2d 809, 814 (9th Cir. 1974); *Canifax v. Hercules Powder Co.*, 237 Cal. App. 2d 44, 46 Cal. Rptr. 552 (1965). A prescription drug's warning, however, need not be calculated to reach the ultimate user. Rather, its warning is adequate if the manufacturer has made reasonable efforts to warn the patient's physician, who will act as a "learned intermediary" in communicating the information. See *Sterling Drug, Inc. v. Yarow*, 408 F.2d 978, 993 (8th Cir. 1969); *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82, 85 (8th Cir. 1966); *Stottlemire v. Cawood*, 213 F. Supp. 897, 899 (D.D.C. 1963); *Love v. Wolf*, 226 Cal. App. 2d 378, 38 Cal. Rptr. 183 (1964).

Adequacy of warning is determined by negligence standards; *i.e.*, the manufacturer must employ reasonable efforts to inform the user of potential dangers. See generally *Parke-Davis & Co. v. Stromsodt*, 411 F.2d 1390 (8th Cir. 1969); *Carmen v. Eli Lilly & Co.*, 109 Ind. App. 76, 32 N.E.2d 729 (1941) (en banc); *Rumsey v. Freeway Manor Minimax*, 423 S.W.2d 387 (Tex. Ct. of Civ. App. 1968). Although actual warning is not required, the manufacturer must, in order to avoid liability, provide the warning in a manner which is reasonably designed to attract the user's attention. *Hubbard-Hall Chem. Co. v. Silverman*, 340 F.2d 402, 405 (1st Cir. 1965). Liability will not be imposed, however, if the user had actual notice of the danger, even if the warning as provided was inadequate. *Nelson v. Brunswick Corp.*, 503 F.2d 376, 379 (9th Cir. 1974).

Content, of course, is the most critical part of the warning. Since, however, the traditional duty to warn extends only to those hazards of which the manufacturer could or should

hazards that cannot be warned against.

This Article begins with a close look at the development of New York's common law of strict products liability. The succeeding sections leave the New York cases to consider solutions proposed by other jurisdictions and authorities. The Article concludes with a short discussion of more radical alternatives to drug liability problems which may resist the traditional solutions.

MANUFACTURER'S LIABILITY IN NEW YORK

Any discussion of the law of strict product liability in New York must begin with the court of appeals' landmark decision in *Codling v. Paglia*.¹⁴ The case arose out of an accident caused by a defect in the power steering system of a car manufactured by Chrysler Corp.¹⁵ The injured driver and passenger of the second car involved in the accident brought suit against the manufacturer of the first car, claiming negligence and breach of warranty.¹⁶ Focussing on the warranty claim, the court of appeals addressed the question whether New York would continue to recognize privity as an essential element of a warranty cause of action.¹⁷ Noting the many exceptions to the privity requirement that had been created to avoid injustices and the strong policy considerations weighing against continued adherence to the doctrine,¹⁸ the court concluded that the time had

have been aware at the time of manufacture, *Bichler v. Willing*, 58 App. Div. 2d 331, 335, 397 N.Y.S.2d 57, 59 (1st Dep't 1977); *Donigi v. American Cyanamid Co.*, 57 App. Div. 2d 760, 394 N.Y.S.2d 422, 423 (1st Dep't 1977), *aff'd*, 43 N.Y.2d 935, 374 N.E.2d 1245, 403 N.Y.S.2d 894 (1978) (mem.); *cf.* *Parker v. State*, 201 Misc. 416, 105 N.Y.S.2d 735, 741 (Ct. Cl. 1951), *aff'd*, 280 App. Div. 157, 112 N.Y.S.2d 695 (3d Dep't 1952) (manufacturer has no duty to provide warning of risks generally known), it seems clear that drug manufacturers' liability for unforeseeable hazards can in no way be predicated upon a breach of this duty.

¹⁴ 32 N.Y.2d 330, 298 N.E.2d 622, 345 N.Y.S.2d 461 (1973).

¹⁵ *Id.* at 337, 298 N.E.2d at 625, 345 N.Y.S.2d at 465. The *Codling* plaintiff was injured when the Paglia's automobile suddenly swerved to the left, crossed the middle of the road, and collided with the car in which the plaintiff was a passenger. *Id.* at 335, 298 N.E.2d at 624, 345 N.Y.S.2d at 463. The plaintiff sued Paglia for negligence and Chrysler for negligence and breach of warranty. Paglia cross-claimed against Chrysler to recover any damages awarded *Codling* against him. *Id.* at 335, 298 N.E.2d at 624, 345 N.Y.S.2d at 463-64. The jury found Chrysler liable for breach of warranty, and both the defendants and the plaintiff recovered judgments against Chrysler. *Id.* at 336-37, 298 N.E.2d at 625, 345 N.Y.S.2d at 464.

¹⁶ *Id.* at 335, 298 N.E.2d at 624, 345 N.Y.S.2d at 463.

¹⁷ *See id.* at 338, 298 N.E.2d at 625-26, 345 N.Y.S.2d at 465-66.

¹⁸ As a justification for expanding manufacturers' liability for injuries caused by defective products, the court stated:

Today as never before the product in the hands of the consumer is often a most sophisticated and even mysterious article. Not only does it usually emerge as a sealed unit with an alluring exterior rather than as a visible assembly of component parts, but its functional validity and usefulness often depend on the application of

come to "lay down a broad principle, eschewing the temptation to devise more proliferating exceptions."¹⁹ Accordingly, the court articulated a theory of strict products liability, under which the absence of privity would not bar recovery:

[T]he manufacturer of a defective product is liable to any person injured or damaged if the defect was a substantial factor in bringing about his injuries or damages; provided: (1) that at the time of the occurrence the product is being used (whether by the person injured or damaged or by a third person) for the purpose and in the manner normally intended, (2) that if the person injured or damaged is himself the user of the product he would not by the exercise of reasonable care have both discovered the defect and perceived its danger, and (3) that by the exercise of reasonable care the person injured or damaged would not otherwise have averted his injury or damages.²⁰

Although the *Codling* court did not specify under what circumstances this newly adopted theory would apply, it seemed equally applicable to design and construction defects.²¹ This issue apparently was resolved some six months later in *Bolm v. Triumph Corp.*,²² where the court of appeals was again presented with the issue of manufacturer's liability for injuries attributable to a product defect. In contrast to the defective automobile steering mechanism in *Codling*, apparently the result of faulty *construction*, the subject of the *Bolm* action was a motorcycle parcel grid, located and *designed* in such a manner that it aggravated the plaintiff's injuries during a collision with another vehicle.²³ Predicating its decision on "general negligence principles,"²⁴ the *Bolm* court concluded:

electronic, chemical or hydraulic principles far beyond the ken of the average consumer. . . . In today's world it is often only the manufacturer who can fairly be said to know and to understand when an article is . . . safely made for its intended purpose.

Id. at 340, 298 N.E.2d at 627, 345 N.Y.S.2d at 468.

¹⁹ *Id.* at 339, 298 N.E.2d at 626, 345 N.Y.S.2d at 467.

²⁰ *Id.* at 342, 298 N.E.2d at 628-29, 345 N.Y.S.2d at 469-70.

²¹ The court's opinion was most notable as an expansion of strict products liability to include innocent bystanders. The question whether the test developed in *Codling* would be applied to design defects, however, was not before the court.

²² 33 N.Y.2d 151, 305 N.E.2d 769, 350 N.Y.S.2d 644 (1973).

²³ *Id.* at 153-54, 305 N.E.2d at 770, 350 N.Y.S.2d at 645-46. David Bolm incurred aggravated pelvic and genital injuries in the course of a collision between his motorcycle and an automobile when he came into contact with a metal luggage rack, or parcel grid, which extended approximately three inches above the saddle and was located on top of the motorcycle's gas tank. *Id.* at 153-54, 305 N.E.2d at 770, 350 N.Y.S.2d at 646.

²⁴ *Id.* at 158, 305 N.E.2d at 772-73, 350 N.Y.S.2d at 649.

We perceive of no sound reason, either in logic or experience . . . why the manufacturer should not be held to a reasonable duty of care in the design of its vehicle consonant with the state of the art to minimize the effects of accidents. The manufacturers are not insurers but should be held to a *standard of reasonable care in design* to provide a reasonably safe vehicle in which to travel.²⁵

The *Bolm* plaintiff had alleged causes of action both in negligence and strict products liability. Although it is not clear from the opinion which claim the court was referring to,²⁶ subsequent author-

²⁵ *Id.* at 158, 305 N.E.2d at 773, 350 N.Y.S.2d at 650 (quoting *Larsen v. General Motors Corp.*, 391 F.2d 495, 502-03 (8th Cir. 1968)) (emphasis added). *Bolm* is more often cited for its discussion of two other significant issues in the area of products liability. First, it reaffirmed the latent-patent distinction adopted 25 years earlier in *Campo v. Scofield*, 301 N.Y. 468, 471, 95 N.E.2d 802, 804 (1950). In *Campo*, the New York Court of Appeals had established the rule that if the plaintiff's injuries were the result of a patent defect recovery should be denied:

If a manufacturer does everything necessary to make the machine function properly for the purpose for which it is designed, if the machine is without any latent defect, and if its functioning creates no danger or peril that is not known to the user, then the manufacturer has satisfied the law's demands . . . [T]he manufacturer is under no duty to render a machine or other article 'more' safe—as long as the danger to be avoided is obvious and patent to all.

Id. at 472, 95 N.E.2d at 804.

The latent-patent distinction, which had been the subject of much criticism, see *Merced v. Auto Pak Co.*, 533 F.2d 69, 76 n.8 (2d Cir. 1976); *Pike v. Hough Co.*, 2 Cal. 3d 465, 474, 467 P.2d 229, 235, 85 Cal. Rptr. 629, 635 (1970); *Bynnes v. Economic Mach. Co.*, 41 Mich. App. 192, 202, 200 N.W.2d 104 (1972); *Palmer v. Massey-Ferguson, Inc.*, 3 Wash. App. 508, 512, 476 P.2d 713, 718 (1970); 2 F. HARPER & F. JAMES, *THE LAW OF TORTS* § 28.5 (1956); Donaher, *The Technological Expert in Products Liability Litigation*, 52 TEX. L. REV. 1303, 1304 (1974); Marschall, *An Obvious Wrong Does Not Make a Right: Manufacturers' Liability for Patently Dangerous Products*, 48 N.Y.U.L. REV. 1065, 1081 (1973); Rheingold, *The Expanding Liability of the Product Supplier: A Primer*, 2 HOFSTRA L. REV. 521, 541 (1974); Twerski, *From Codling, to Bolm, to Velez: "Triptych of Confusion"*, 2 HOFSTRA L. REV. 489, 498-99 (1974), was finally discarded by the court of appeals in 1976. *Micallef v. Miehle Co.*, 39 N.Y.2d 376, 387, 348 N.E.2d 571, 578, 384 N.Y.S.2d 115, 122 (1976).

Bolm is also noted for its rejection of the so-called "second-collision" rule, under which manufacturers were absolved of liability when the defect merely contributed to the plaintiff's injuries but did not cause the accident. 33 N.Y.2d at 157, 305 N.E.2d at 772, 350 N.Y.S.2d at 649; see *Edgar v. Nachman*, 37 App. Div. 2d 86, 323 N.Y.S.2d 53 (3d Dep't 1971); Brown, *Products Liability: The Genesis of "Second Collision"*, N.Y.S.B.J. 21 (1979).

²⁶ Another design case, *Micallef v. Miehle Co.*, 39 N.Y.2d 376, 348 N.E.2d 571, 384 N.Y.S.2d 115 (1976), presents similar problems of interpretation. In *Micallef*, the plaintiff's hand was injured when he attempted to remove an imperfection from the plate of a printing machine he was operating. *Id.* at 379-80, 348 N.E.2d at 573, 384 N.Y.S.2d at 117. Discussing the scope of manufacturers' liability for design defects, the court enumerated several factors which should be considered by the trial court, such as matters of "cost, function, and competition as narrowing the design choices," *id.* at 386, 348 N.E.2d at 578, 384 N.Y.S.2d at 121 (quoting Rheingold, *Expanding Liability of the Product Supplier: A Primer*, 2 HOFSTRA

ity views *Bolm* as establishing a rule to be applied in strict products litigation.²⁷ More importantly, the case seems to govern where the injury-producing product is manufactured as intended and the alleged "defect" is inherent in its design. While *Codling* has never been expressly narrowed to instances of construction defects, such a limitation seems implicit in the *Bolm* opinion. Thus, without express acknowledgement, the New York decisions indicate that the essence of design defect liability is negligence, while strict liability will apply where "something has gone wrong"²⁸ in the manufacturing process.

If the test is to be negligence, a drug manufacturer invariably will be absolved from liability for injuries caused by unforeseeable defects in its products. Perhaps this is the proper result, but it should be noted that the New York cases have not yet considered the unique policy questions raised by drugs which are created and marketed with due care and yet, after years pass, turn out to be defective in design.²⁹ Accordingly, the following sections of this Article consider different approaches by other jurisdictions and authorities to the defective design problem.

L. Rev. 521, 537 (1974)), and "whether [the manufacturer] kept abreast of recent scientific developments . . . and the extent to which any tests were conducted to ascertain the dangers of the product." 39 N.Y.2d at 386, 348 N.E.2d at 578, 384 N.Y.S.2d at 121 (citations omitted). Just as in *Bolm*, it is unclear from the opinion which cause of action the court was referring to when it discussed these factors. It appears, however, that *Micallef* is susceptible of the same interpretation which has followed the court's earlier decision in *Bolm*. See note 27 and accompanying text *infra*.

²⁷ See *Cousins v. Instruments Flyers, Inc.*, 58 App. Div. 2d 336, 396 N.Y.S.2d 655 (1st Dep't 1977), *aff'd per curiam*, 44 N.Y.2d 698, 376 N.E.2d 914, 405 N.Y.S.2d 441 (1978); Weinberger, *Design Defect Litigation in New York: What is the Standard?*, 30 BROOKLYN BARRISTER 11 (1978); NEW YORK PATTERN JURY INSTRUCTIONS 2:141 (Supp. 1977).

²⁸ Wade, *supra* note 9, at 831.

²⁹ The plight of the helpless user in New York may have been increased by a recent decision of the New York Court of Appeals, *Thornton v. Roosevelt Hospital*, No. 135 (Ct. App. May 10, 1979), which held that a strict liability cause of action was time-barred where a cancer-causing drug had been injected 20 years before the cancer was discovered and suit filed. Reaffirming the vitality of *Victorson v. Bock Laundry Machine Co.*, 37 N.Y.2d 395, 373 N.Y.S.2d 39, 335 N.E.2d 275 (1975), the court of appeals in *Thornton* held that the product liability cause of action "accrued at the time of invasion of decedent's body, and not at the time the decedent's cancerous condition became apparent." *Thornton v. Roosevelt Hospital*, No. 135, slip op. at 1 (Ct. App. May 10, 1979). Under this decision, unforeseeable defects which surface more than 3 years after ingestion of a drug would be beyond the reach of strict product liability in New York. A large percentage of potential drug claims promise to be affected by this decision, and Judge Fuchsberg, the lone dissenter, may be correct in suggesting that there is need "for rescue from an unconscionable decisional law." *Id.* at 5.

OTHER APPROACHES TO DESIGN DEFECT CASES

The California Approach

Justice Traynor's landmark decision in *Greenman v. Yuba Power Products, Inc.*³⁰ began the development of a strict products liability theory spanning fifteen years in the California courts. The *Greenman* court announced a broad theory of strict liability: a "defect that causes injury to a human being" would be actionable without proof of the manufacturer's negligence.³¹ Justice Traynor later observed that the meaning of "defect" could vary according to the factual setting, and therefore suggested that the legal definition of the term should be developed through precedent.³² The *Greenman* theory was considered by many³³ to be equivalent to that set forth in the *Restatement (Second) of Torts* § 402A, which would impose

³⁰ 59 Cal. 2d 57, 377 P.2d 897, 27 Cal. Rptr. 697 (1962). In *Greenman*, the plaintiff was seriously injured while operating a lathe when the piece of wood he was working on flew off of the machine and struck him in the head. *Id.* at 58, 377 P.2d at 898, 27 Cal. Rptr. at 698. Ten months later he sued the manufacturer and the retailer for breach of express and implied warranties and negligence. *Id.* The trial court ruled that there was no evidence that the retailer was negligent or had breached any implied or expressed warranties. *Id.* at 59, 377 P.2d at 898-99, 27 Cal. Rptr. at 698-99. Without specifying the grounds, however, the jury found the manufacturer liable and awarded the plaintiff \$65,000. *Id.* at 59, 377 P. 2d at 899, 27 Cal. Rptr. at 699. On appeal, the defendant claimed that the warranty cause of action was barred because the plaintiff failed to give timely notice of the breach. Justice Traynor, writing for the California Supreme Court, concluded that the warranty action was not barred, *id.* at 61, 377 P.2d at 900, 27 Cal. Rptr. at 700, and then proceeded to outline the requirements for a strict products liability claim in California. *Id.* at 61, 377 P.2d at 901, 27 Cal. Rptr. at 701; see note 31 and accompanying text *infra*.

³¹ 59 Cal. at 61, 377 P.2d at 900, 27 Cal. Rptr. at 700. The *Greenman* court rejected the theory that strict products liability is predicated upon a breach of an express or implied warranty, *id.*, and thus departed from the then prevailing view in the majority of jurisdictions. See *id.*, and cases cited therein.

³² Traynor, *The Ways and Meanings of Defective Products and Strict Liability*, 32 TENN. L. REV. 363, 371 (1965).

³³ *E.g.*, *Schenfeld v. Norton Co.*, 391 F.2d 420 (10th Cir. 1968); *Butaud v. Suburban Marine & Sporting Goods, Inc.*, 555 P.2d 42 (Alas. 1976); *Matter v. Coca-Cola Bottling Co.*, 311 So.2d 417 (Fla. App. 1974); *Suvada v. White Motor Co.*, 32 Ill. 2d 612, 210 N.E.2d 182 (1965); *Hawkeye-Security Ins. Co. v. Ford Motor Co.*, 174 N.W.2d 672 (Iowa 1970); *Brooks v. Dietz*, 218 Kan. 698, 545 P.2d 1104 (1976); *McCormack v. Hanksraft Co.*, 278 Minn. 322, 154 N.W.2d 488 (1967); *State Stove Mfg. Co. v. Hodges*, 189 So. 2d 113 (Miss. 1966), *cert. denied*, 386 U.S. 912 (1967); *Johnson v. American Motors Corp.*, 225 N.W.2d 57 (N.D. 1974); *Temple v. Wean United, Inc.*, 50 Ohio St. 2d 317, 364 N.E.2d 267 (1977); *Kirkland v. General Motors Corp.*, 521 P.2d 1353 (Okla. 1974); *Romano v. Westinghouse Elec. Co.*, 114 R.I. 451, 336 A.2d 555 (1975); *Seattle First National Bank v. Tabert*, 86 Wash. 2d 145, 542 P.2d 774 (1975); *Dippel v. Sciano*, 37 Wis. 2d 443, 155 N.W.2d 55 (1967); see *Garthwait v. Burgio*, 153 Conn. 290, 216 A.2d 189 (1965); *Stewart v. Budget Rent-A-Car Corp.*, 52 Haw. 71, 470 P.2d 240 (1970); *Perfection Paint & Color Co. v. Konduris*, 147 Ind. App. 106, 258 N.E.2d 681 (1970); *Dealers Transp. Co. v. Battery Distrib. Co.*, 402 S.W.2d 441 (Ky. 1966); *Buttrick v. Arthur Lessard & Sons Inc.*, 260 A.2d 111 (N.H. 1969).

liability when a product is "in a defective condition unreasonably dangerous to the user or consumer or to his property."³⁴ Under this approach, "defective" includes within its definition some "unreasonable danger" to the safety of the product's user, a definition subsequently adopted in numerous jurisdictions.³⁵ In *Cronin v. J.B.E. Olson Corp.*,³⁶ however, the California Supreme Court noted that the *Restatement (Second)* approach could burden "the injured plaintiff with proof of an element which rings of negligence,"³⁷ and concluded that such a burden would represent "a step backward" in the development of a strict tort liability theory.³⁸ Accordingly, the court rejected the "unreasonably dangerous" qualification of the *Restatement (Second)* and held that a showing of defectiveness

³⁴ RESTATEMENT (SECOND) OF TORTS § 402A (1965). Section 402A states:

(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 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 relationship with the seller.

Id.

³⁵ See, e.g., *Byrns v. Riddell, Inc.*, 113 Ariz. 264, 550 P.2d 1065 (1976); *Mattes v. Coca-Cola Bottling Co.*, 311 So. 2d 417 (Fla. App. 1974); *Farmer v. International Harvester Co.*, 97 Idaho 742, 553 P.2d 1306 (1976); *Perfection Paint & Color Co. v. Konduris*, 147 Ind. App. 106, 258 N.E.2d 681 (1970); *Hawkeye-Security Ins. Co. v. Ford Motor Co.*, 174 N.W.2d 672 (Iowa 1970); *Brooks v. Dietz*, 218 Kan. 698, 545 P.2d 1104 (1976); *Stenberg v. Beatrice Foods Co.*, 576 P.2d 725 (Mont. 1978); *Buttrick v. Arthur Lessard & Sons, Inc.*, 110 N.H. 36, 260 A.2d 111 (1969); *Cavan v. General Motors Corp.*, 280 Ore. 455, 571 P.2d 1249 (1977); *Webb v. Zern*, 422 Pa. 424, 220 A.2d 853 (1966); *Ritter v. Narragansett Elec. Co.*, 109 R.I. 176, 283 A.2d 255 (1971); *Zaleski v. Joyce*, 133 Vt. 150, 333 A.2d 110 (1975); *Lamon v. McDonnell Douglas Corp.*, 19 Wash. App. 515, 576 P.2d 426 (1978); *Vincer v. Esther Williams All-Aluminum Swimming Pool Co.*, 69 Wis. 2d 326, 230 N.W.2d 794 (1975).

³⁶ 8 Cal. 3d 121, 501 P.2d 1153, 104 Cal. Rptr. 433 (1972). Cronin was injured in an accident which occurred while he was driving a bread delivery truck. *Id.* at 124, 501 P.2d at 1155, 104 Cal. Rptr. at 435. His injuries were compounded when the bread trays, installed by the defendant and released by a defective latch, struck him and pushed him through the truck's windshield. *Id.* at 124, 501 P.2d at 1155, 104 Cal. Rptr. at 435. The trial court held for the plaintiff, *id.* at 124-25, 501 P.2d at 1156, 104 Cal. Rptr. at 436, and the defendant appealed, contending, *inter alia*, that the trial judge erroneously had refused to instruct the jury that the defect must be "unreasonably dangerous." *Id.* at 127-28, 501 P.2d at 1158, 104 Cal. Rptr. at 438. The California Supreme Court concluded that it was not necessary for the plaintiff to prove that the defect was unreasonably dangerous. See text accompanying note 39 *infra*.

³⁷ 8 Cal. 3d at 132, 501 P.2d at 1162, 104 Cal. Rptr. at 442.

³⁸ *Id.* at 133, 501 P.2d at 1162, 104 Cal. Rptr. at 442.

alone would satisfy a plaintiff's strict liability burden of proof.³⁹ Discussing the application of this revised liability formula to design cases, the court stated that since a "defect may emerge from the mind of the designer as well as from the hand of the workman,"⁴⁰ no distinction could be made between construction and design defects.⁴¹

Six years later, in *Barker v. Lull Engineering Co.*,⁴² the California Supreme Court, noting that misinterpretations of *Cronin* had flourished in the lower courts, set forth a two-part test for determining the *defectiveness* of a design:

[A] product is defective in design either (1) if the product has failed to perform safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner, or (2) if . . . the benefits of the challenged design do not outweigh the risk of danger inherent in such design.⁴³

Among the factors to be considered under the second part of the test are the gravity of the danger posed, the likelihood of it occurring, the feasibility and cost of an alternative design, and the adverse

³⁹ *Id.* *Cronin's* exclusion of "unreasonably dangerous" from the definition of "defective" led to considerable confusion in California's lower courts. See, e.g., *Buccery v. General Motors Corp.*, 60 Cal. App. 3d 533, 132 Cal. Rptr. 605 (1976); *Baker v. Chrysler Corp.*, 55 Cal. App. 3d 710, 127 Cal. Rptr. 745 (1976); *Self v. General Motors Corp.*, 42 Cal. App. 3d 1, 116 Cal. Rptr. 575 (1974); *Hyman v. Gordon*, 35 Cal. App. 3d 769, 111 Cal. Rptr. 262 (1973). This confusion was attributed to the court's failure to propose an alternative definition. See Hoenig, *Product Design and Strict Tort Liability: Is There a Better Approach?* 8 Sw. U.L. REV. 109 (1976); Keeton, *Product Liability and the Meaning of Defect*, 5 ST. MARY'S L.J. 30, 30 (1973); Keeton, *Manufacturer's Liability: The Meaning of "Defect" in the Manufacture and Design of Products*, 20 SYRACUSE L. REV. 559 (1969); Traynor, *The Ways and Meanings of Defective Products and Strict Liability*, 32 TENN. L. REV. 363 (1965); Wade, *On the Nature of Strict Tort Liability for Products*, 44 MISS. L. J. 825 (1973); Wade, *Strict Tort Liability of Manufacturers*, 19 Sw. L.J. 5 (1965).

⁴⁰ 8 Cal. 3d at 134, 501 P.2d at 1162, 104 Cal. Rptr. at 442.

⁴¹ *Id.* at 134, 501 P.2d at 1163, 104 Cal. Rptr. at 443.

⁴² 20 Cal. 3d 413, 573 P.2d 443, 143 Cal. Rptr. 225 (1978). *Barker* was injured while operating a forklift manufactured by the defendant, when the lift's load fell off the forks and hit *Barker* as he attempted to escape injury. *Id.* at 419, 573 P.2d at 447, 143 Cal. Rptr. at 229. The plaintiff alleged that his injuries were caused by design defects in the forklift which caused the machine to be unstable. *Id.* at 417, 573 P.2d at 445-46, 143 Cal. Rptr. at 227-28. The jury was instructed that strict liability is "based on a finding that the product was unreasonably dangerous for its intended use," *id.* at 417, 573 P.2d at 446, 143 Cal. Rptr. at 228 (emphasis added), and held for the defendant. *Id.* at 422, 573 P.2d at 446, 143 Cal. Rptr. at 231. On appeal, the California Supreme Court reversed, holding that the trial court's instructions to the jury were erroneous because they required the jury to find the defect to be unreasonably dangerous in light of the manufacturer's concept of intended use, rather than "defective" in light of a "reasonable use" as its prior decision in *Cronin* required. *Id.* at 435-36, 573 P.2d at 458, 143 Cal. Rptr. at 240.

⁴³ *Id.* at 418, 573 P.2d at 446, 143 Cal. Rptr. at 228 (emphasis added).

consequences that might result from an alternative design.⁴⁴ Attempting to conform the design defect action to the strict liability formula generally, the *Barker* court stressed that the emphasis would be on the product itself, rather than the conduct of the manufacturer.⁴⁵ The court concluded that "once the plaintiff makes a prima facie showing that the injury was proximately caused by the product's design, the burden should appropriately shift to the defendant to prove, in light of the relevant factors, that the product is not defective."⁴⁶

Despite its professed adherence to a strict liability scheme, the California Supreme Court has not eliminated negligence from design defect actions by vesting the plaintiff with a set of "rebuttable presumptions" as a part of his prima facie case.⁴⁷ By requiring the manufacturer to go forward with evidence of the relevant factors in its favor, the *Barker* court implicitly acknowledged the negligence character of a design defect action. While the court also stated that the balancing of relevant factors would not require a jury determination that the defendant was negligent before liability could be imposed,⁴⁸ it seems clear that the manufacturer must, in effect, disprove negligence.⁴⁹ Thus, despite appearances, the California courts take an approach similar to that utilized by the New York courts

⁴⁴ *Id.* at 431, 573 P.2d at 455, 143 Cal. Rptr. at 237 (citing *Horn v. General Motors Corp.*, 17 Cal. 3d 359, 551 P.2d 398, 131 Cal. Rptr. 78 (1976)); *Henderson v. Harnishchfeger Corp.*, 12 Cal. 3d 663, 527 P.2d 353, 117 Cal. Rptr. 1 (1974); *Luque v. McLean*, 8 Cal. 3d 136, 501 P.2d 1163, 104 Cal. Rptr. 443 (1972); *Heap v. General Motors Corp.*, 66 Cal. App. 3d 824, 136 Cal. Rptr. 304 (1977); *Buccery v. General Motors Corp.*, 60 Cal. App. 3d 533, 132 Cal. Rptr. 605 (1976); *Baker v. Chrysler Corp.*, 55 Cal. App. 3d 710, 127 Cal. Rptr. 745 (1976); *Self v. General Motors Corp.*, 42 Cal. App. 3d 1, 116 Cal. Rptr. 575 (1974); *Garcia v. Halsett*, 3 Cal. App. 3d 319, 82 Cal. Rptr. 420 (1970)).

⁴⁵ 20 Cal. 3d at 432, 573 P.2d at 456, 143 Cal. Rptr. at 238.

⁴⁶ *Id.* at 431, 573 P.2d at 455, 143 Cal. Rptr. at 237.

⁴⁷ Under the *Barker* test, see text accompanying notes 43-46 *supra*, the defendant must prove that, in light of the relevant factors, liability should not be imposed. Should the defendant fail to meet this burden, the *Barker* test presumes the factors are in the plaintiff's favor and enables him to prevail. *Barker v. Lull Engineering*, 20 Cal. 3d 413, 573 P.2d 443, 143 Cal. Rptr. 225 (1978).

⁴⁸ *Id.* at 434, 573 P.2d at 457, 143 Cal. Rptr. at 239.

⁴⁹ "Likelihood" of injury implies foreseeability, "gravity of danger posed" conjures a standard of reasonableness in marketing, and "feasibility" of a different design implicates "state of the art" technology. Thus, the burden of proving these relevant factors, while at one time the plaintiff's, is now upon the defendant-manufacturer.

According to Dean Prosser, a plaintiff's burden of proof when seeking recovery against a manufacturer for injuries resulting from an "unsafe product" should be similar whether he is pursuing a negligence, warranty or strict liability theory. In any of these situations, the plaintiff must establish that the product was the proximate cause of the injury, the injury resulted from the product's defective condition and that the defect was present when the product left the manufacturer. W. PROSSER, *LAW OF TORTS* § 103 (4th ed. 1971).

and, therefore, generally would not impose liability on drug manufacturers for unforeseeable injuries.

Restatement (Second) of Torts § 402A

Entitled "Strict Liability," section 402A of the *Restatement (Second) of Torts* recommends that liability be imposed on the seller of a product which causes injury and is "in a defective condition unreasonably dangerous to the user or consumer."⁵⁰ This rule would apply even where "the seller has exercised all possible care in the preparation and sale of his product."⁵¹ With specific reference to drugs, Comment *h* states that where a manufacturer "has reason to anticipate that danger may result from a particular use," such a product is defective if not accompanied by a warning.⁵² Similarly, Comment *i* states that the seller may assume that a warning will be read and heeded, and that "a product bearing such a warning, which is safe for use if it is followed, is not in defective condition nor is it unreasonably dangerous."⁵³ Both the New York and California courts have rejected the standard set forth in section 402A of the

⁵⁰ RESTATEMENT (SECOND) OF TORTS § 402A(1) (1965); see *Dougherty v. Hooker Chemical Corp.*, 540 F.2d 174, 177-78 (3d Cir. 1976); *Schrib v. Seidenberg*, 80 N.M. 573, 458 P.2d 825, 829 (1969); *McGrath v. White Motor Corp.*, 258 Ore. 583, 484 P.2d 838, 844 (1971).

⁵¹ RESTATEMENT (SECOND) OF TORTS § 402A(2) (1965); see *Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1272 (5th Cir.), *cert. denied*, 419 U.S. 1096 (1974); *Reilly v. King County Central Blood Bank, Inc.*, 6 Wash. App. 172, 492 P.2d 246, 247 (1971).

⁵² RESTATEMENT (SECOND) OF TORTS § 402A(2), Comment *h* at 351 (1965); see *Jacobsen v. Ducommun, Inc.*, 87 Nev. 240, 484 P.2d 1095 (1971); *Incollingo v. Ewing*, 444 Pa. 263, 282 A.2d 206, 219 (1971).

⁵³ RESTATEMENT (SECOND) OF TORTS § 402A(2), Comment *j* at 353 (1965); see *Bryant v. Hercules Inc.*, 325 F. Supp. 241, 246 (W.D. Kan. 1970); *Incollingo v. Ewing*, 444 Pa. 263, 282 A.2d 206, 219 (1971).

Comment *k*, concerning "unavoidably unsafe products," reiterates this rule by stating that a properly prepared and marketed drug for which proper warning is given will not give rise to strict tort liability "merely because [the manufacturer] has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk." RESTATEMENT (SECOND) OF TORTS § 402A(2), Comment *k* at 354 (1965); see *Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1275 (5th Cir.), *cert. denied*, 419 U.S. 1096 (1974); *Fruge v. Blood Services*, 365 F. Supp. 1344, 1349 (W.D. La. 1973), *aff'd in part, rev'd in part*, 506 F.2d 841 (5th Cir. 1975). See also *Oresman v. G.D. Searle & Co.*, 321 F. Supp. 449, 457 (D.R.I. 1971). Directed towards products such as drugs "which, in the present state of human knowledge" cannot be made completely safe for ordinary use, this comment seeks to balance the overall public benefit against the injury which may attend the product's use. RESTATEMENT (SECOND) OF TORTS § 402A(2), Comment *k* at 353 (1965); see *Basko v. Sterling Drugs, Inc.*, 416 F.2d 417, 425-26 (9th Cir. 1969); *Brody v. Overlook Hospital*, 127 N.J. Super. 331, 317 A.2d 392, 397 (1974), *aff'd*, 66 N.J. 448, 332 A.2d 596 (1975); *Hines v. St. Joseph's Hospital*, 86 N.M. 763, 527 P.2d 1075, 1106 (1974); *Leibowitz v. Ortho Pharmaceutical Corp.*, 224 Pa. Super. 418, 307 A.2d 449, 457 (1973).

Restatement (Second). New York has rejected 402A in its entirety,⁵⁴ while California has refused to adopt its “unreasonably dangerous” qualification of “defective.”⁵⁵ Because the concept of unreasonable danger forms the heart of the *Restatement* approach, California’s rejection of that theory would appear to be as complete as New York’s.

The effect of the *Restatement’s* requirement of “proper warnings” of “anticipated dangers” is to place emphasis upon the manufacturer’s conduct in producing and marketing the drug. As noted by several commentators, the *Restatement* apparently carves out an exception in its strict liability theory, applying standard negligence principles when the product is a drug.⁵⁶

The Uniform Product Liability Act

Recognizing the inherent differences between construction and design defects, the proposed Uniform Product Liability Act (the Draft)⁵⁷ treats them separately⁵⁸ and offers no single definition of “defective.”⁵⁹ The Draft suggests five factors to be weighed in determining whether a product’s design is defective:

- (1) The likelihood at the time of manufacture that the product would cause the harm suffered by the claimant;
- (2) The seriousness of that harm;
- (3) The technological feasibility of manufacturing a product designed so as to have prevented claimant’s harm;
- (4) The relative costs of producing, distributing, and selling such an alternative design; and
- (5) The new or additional harms that may result from such an alternative design.⁶⁰

⁵⁴ *Micallef v. Miehle Co.*, 39 N.Y.2d 376, 388, 348 N.E.2d 571, 579, 384 N.Y.S.2d 115, 122 (1976).

⁵⁵ *Cronin v. J.B.E. Olson Corp.*, 8 Cal. 3d 121, 133, 501 P.2d 1153, 1162, 104 Cal. Rptr. 433, 442 (1972).

⁵⁶ See RESTATEMENT (SECOND) OF TORTS § 402A(2), Comment *h* at 353 (1965); Keeton, *Products Liability—Inadequacy of Information*, 48 TEX. L. REV. 398, 408 (1970); Comment, *The Diminishing Role of Negligence in Manufacturers’ Liability for Unavoidably Unsafe Drugs and Cosmetics*, 9 ST. MARY’S L.J. 102, 105 (1977).

⁵⁷ UNIFORM PRODUCT LIABILITY ACT (U.P.L.A.), reprinted in 44 Fed. Reg. 2996 (1979).

⁵⁸ See U.P.L.A. § 104(A)-(B), reprinted in 44 Fed. Reg. 2998 (1979). The draft recommends that determination of a construction defect should consider both the manufacturer’s specifications and peculiarities of the particular product. More detailed criteria are offered to determine whether or not a design is defective. *Id.* See generally *Cepeda v. Cumberland Engineering Co.*, 76 N.J. 152, 386 A.2d 816 (1978).

⁵⁹ See U.P.L.A. § 104, reprinted in 44 Fed. Reg. 2998 (1979).

⁶⁰ *Id.*

These are, in essence, the same factors which the California Supreme Court proposed in *Barker*.⁶¹ Unlike *Barker*, however, the Draft places on the plaintiff the burden of proving that the factors weigh in his favor.⁶²

The analysis accompanying the Draft points out that "no court yet has imposed true strict or absolute liability on product sellers for defects in design appreciating, no doubt, the unlimited liability potential inherent in such cases where it is almost always possible to design a product more safely."⁶³ On this premise, the Draft accepts the notion that a strict liability action for design defects is impossible and opts instead for a negligence-based standard. For example, not only is the state of the art as it existed at the time of manufacture relevant,⁶⁴ but conformity with the state of the art and legislative standards raises a rebuttable presumption of nondefectiveness.⁶⁵

The Draft is less than innovative in its approach to the design defect problem. It is, in fact, merely a synopsis of the majority views in the area of product manufacturer's liability. Although the sources consulted by the Draft's task force were many and varied,⁶⁶ the Draft suffers from a "machine perspective." Applied to machines and most other products, it provides a sound standard by which the trier of the fact may determine defectiveness but provides little help in determining drug defectiveness. In light of present drug testing practice,⁶⁷ it is likely that industry custom will be observed and hazardous aspects, known at the time of manufacture, will be

⁶¹ See 20 Cal. 3d 413, 573 P.2d 443, 445, 143 Cal. Rptr. 225, 237 (1978); note 39 *supra*.

⁶² U.P.L.A. § 104, reprinted in 44 Fed. Reg. 2998 (1979). The *Barker* court held that once the plaintiff has shown that the product's design proximately caused the injury, the defendant has the burden of showing that the product was not defective. 20 Cal. 3d at 432-33, 573 P.2d at 455, 143 Cal. Rptr. at 237; see text accompanying notes 42-46 *supra*.

⁶³ U.P.L.A. § 104(B) (analysis), reprinted in 44 Fed. Reg. 3004-05 (1979).

⁶⁴ U.P.L.A. § 106(b), reprinted in 44 Fed. Reg. 2998 (1979); see *Bruce v. Martin-Marietta Corp.*, 544 F.2d 442, 447 (10th Cir. 1976).

⁶⁵ U.P.L.A. § 106(d), reprinted in 44 Fed. Reg. 2999 (1979). The *Restatement (Second)* approach, see note 53 *supra*, is adopted for those products which are "unavoidably unsafe." U.P.L.A. § 105, reprinted in 44 Fed. Reg. 2998 (1979). See generally *Cochran v. Brooke*, 243 Or. 89, 409 P.2d 904 (1966); Willig, *The Comment k Character: A Conceptual Barrier to Strict Liability*, 29 MERCER L. REV. 545 (1978). If adequate warning is provided, the manufacturer is absolved from liability for any ensuing injuries. U.P.L.A. § 105(c), reprinted in 44 Fed. Reg. 2998 (1979); see *Givens v. Lederle*, 556 F.2d 1341, 1345 (5th Cir. 1977); *Dalke v. Upjohn Co.*, 555 F.2d 245, 247-48 (9th Cir. 1977); *Davis v. Wyeth Labs., Inc.*, 399 F.2d 121, 130 (9th Cir. 1968); *Fogo v. Cutter Labs., Inc.*, 68 Cal. App. 3d 744, 755, 137 Cal. Rptr. 417, 423 (1977).

⁶⁶ 44 Fed. Reg. 2996 (1979). Among the sources used to produce this draft were the Interagency Task Force on Product Liability, recent cases, and recent law review material. *Id.*

⁶⁷ See note 10 *supra*.

either eliminated or adequately warned of. In short, the Draft's design defect standard offers little guidance in the drug context, particularly in the area of unforeseeable hazards. While it attempts to supply a comprehensive scheme for determining manufacturer's liability, the Draft promises to leave uncompensated a potentially large number of persons injured by defective drugs.

New York's Pattern Jury Instructions

The authors of New York's Pattern Jury Instructions (PJI) describe a defective product as one which is "not reasonably safe."⁶⁸ The suggested instruction specifically eliminates the need to prove manufacturer's knowledge of the product's harmful character and asks instead whether the product is "so likely to be harmful . . . that a reasonably prudent person who had *actual knowledge* of its harmful character would conclude that it should not have been marketed in that condition."⁶⁹ Apparently, then, liability could be imposed for unforeseen drug injuries under the PJI test because, although the *Restatement's* "unreasonably dangerous" definition is used, it is here joined with time-of-trial hindsight.

The PJI suggests that whether a design is defective depends on a "balancing of the alternative designs available against the existing risk while taking into account the cost of the proposed alternative."⁷⁰ These factors fairly approximate those suggested by the Cal-

⁶⁸ NEW YORK PATTERN JURY INSTRUCTIONS (PJI) 2:141 (Supp. 1977).

⁶⁹ *Id.* (emphasis added).

⁷⁰ PJI 2:141, comment at 78 (Supp. 1977). In determining whether a product is "not reasonably safe," the *Pattern Jury Instructions* (PJI) suggests consideration of the seven factors proposed by Professor Wade. See Wade, *supra* note 9. A brief discussion of these factors will highlight some of the policy considerations inherent in any disposition of the unforeseeable side effect issue.

(1) "*The usefulness and desirability of the product—its utility to the use and to the public as a whole.*" *Id.* at 837. Perhaps another means of expressing this first factor is to ask—"How valuable is the product?" A lifepreserving drug gains favor under this consideration, while one producing a no-essential therapeutic effect suffers a disadvantage when weighed against attendant risks of injury.

(2) "*The safety aspects of the product—the likelihood that it will cause injury and the probable seriousness of the injury.*" *Id.* While a mechanical design can often be scrutinized for its "safety aspects," a drug's design is hardly amenable to such practical analysis. In light of the current regulations of the Food and Drug Administration and the practices of the drug industry, however, the statistical likelihood of serious injury from use of a new drug is relatively low, almost certainly below ten percent. See W. Ross, *supra*, note 11. Even if it is as low as one percent or a small fraction thereof, at least one school of thought believes that the user is entitled to know the risks he is confronting. See generally Gardner, *Increasing Patient Awareness in Drug Therapy: Ramifications of a Patient Package Insert Requirement*, 66 GA.

ifornia Supreme Court in *Barker*.⁷¹ The difference between the two approaches lies in application rather than substantive content. New York's PJI asks whether, in light of the relevant factors known at trial, the product should have been marketed. In California, the plaintiff need only allege injury due to design and will succeed if the defendant cannot show that the relevant factors weigh in his favor. The PJI approach is preferable from the plaintiff's viewpoint, notwithstanding that the California standard substantially reduces the plaintiff's burden of proof. Under both analyses the essence of the action remains negligence, but the PJI element of time of trial hindsight greatly erodes the action's negligence character.⁷²

Curiously, it appears that no reported New York decision has commented upon, much less applied, the PJI's knowledge-at-trial

L.J. 837 (1978). From the perspective of a plaintiff who has suffered serious, possibly crippling harm, "statistical unlikelihood" has a hollow ring.

(3) "*The availability of a substitute product which would meet the same need and not be as unsafe.*" Wade, *supra* note 9, at 837. In the context of drug-related injuries this is a relatively unimportant factor, because while there are usually a variety of "substitute products" for a particular drug, these substitutes function with varying degrees of effectiveness and safety.

(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.*" *Id.* Although redesign of a drug to circumvent, eliminate or minimize side effects might be theoretically possible, as a practical matter the manufacturer cannot focus his resources in that direction until the existence of the side effect is known.

(5) "*The user's ability to avoid danger by the exercise of care in the use of the product.*" Wade, *supra*, at 837. Careful use presupposes that the consumer knows the potential risks. This element greatly favors the plaintiff in the context of unforeseeable drug injuries, since the danger to be avoided is not known at the time of use.

(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.*" *Id.* Overlapping the concept of user's knowledge, this factor becomes particularly relevant in the context of warnings and instructions accompanying a drug product. With unforeseeable side effects, of course, a user's knowledge will not result from a specific warning, but only from a generalized realization that all drugs are potentially dangerous.

(7) "*The feasibility, on the part of the manufacturer, of spreading the loss by setting the price of the product or carrying liability insurance.*" *Id.* A 1972 Senate report states that "[l]osses, or even low profits, are practically unheard of among large drug companies." SENATE SUBCOMM. ON MONOPOLY, SELECT COMM. ON SMALL BUSINESS, COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY, 92d Cong., 2d Sess. 33. (Comm. Print 1972). Coupled with the high volume of sales in the drug industry, the loss-spreading ability of drug manufacturers is amply illustrated. Indeed, these profits have been justified by manufacturers on the grounds of the risk undertaken in new drug development. *Id.* at 31.

⁷¹ See notes 43-46 *supra*.

⁷² See PJI 2:141, comment at 79 (Supp. 1978).

standard.⁷³ Other courts, however, have used similar methods of analysis in determining manufacturer's liability. For example, in *Hamilton v. Hardy*,⁷⁴ the plaintiff suffered a stroke as a side effect of using the defendant's birth control pill.⁷⁵ Noting that the evidence required to establish inadequacy of warning is identical under strict liability and negligence theories,⁷⁶ the Colorado Court of Appeals succinctly illustrated that the two actions are nonetheless dissimilar:

In a strict liability case we are talking about the condition (dangerousness) of an article which is sold without any warning, while in negligence we are talking about the reasonableness of the manufacturer's action in selling the article without a warning. The article can have a degree of dangerousness because of a lack of warning which the law of strict liability will not tolerate even though the actions of the seller were entirely reasonable in selling the article without a warning considering what he knew or should have known at the time he sold it.⁷⁷

Implicitly, the *Hamilton* court determines dangerousness by knowledge at trial; otherwise the two principles would be identical.

Some courts, however, have hesitated to impose a knowledge-at-trial standard upon a manufacturer. In *Crocker v. Winthrop Laboratories, Inc.*,⁷⁸ for example, the Supreme Court of Texas stated that, although under certain circumstances "the manufacturer should be liable for resulting harm though he did not and could not have known of the danger at the time of marketing,"⁷⁹ it was "not prepared to hold . . . that in the case of a generally beneficial or good product the manufacturer's liability can be predicated upon . . . those facts known at the time of trial."⁸⁰ Other courts have been less ambivalent and absolved the manufacturer simply on the basis of the defect's unforeseeability.⁸¹

⁷³ See Wade, *supra* note 9, at 835.

⁷⁴ 549 P.2d 1099 (Colo. Ct. App. 1976).

⁷⁵ *Id.* at 1102.

⁷⁶ *Id.* at 1106.

⁷⁷ *Id.* at 1107.

⁷⁸ 514 S.W.2d 429 (Tex. 1974).

⁷⁹ *Id.* at 432.

⁸⁰ *Id.* at 433.

⁸¹ See, e.g., *Bichler v. Willing*, 58 App. Div. 2d 331, 397 N.Y.S.2d 57 (1st Dep't 1977); *Friedman v. Medtronic, Inc.*, 42 App. Div. 2d 185, 345 N.Y.S.2d 637 (2d Dep't 1973); *Hoover v. Franklin Serum Co.*, 444 S.W.2d 596 (Tex. 1969); *Cudmore v. Richardson-Merrell, Inc.*, 398 S.W.2d 640, 643 (Tex. Civ. App.), *cert. denied*, 385 U.S. 1003 (1967).

POLICY AND ALTERNATIVES

None of the foregoing authorities provides an adequate framework for apportioning losses from injuries caused by unforeseeable drug defects.⁸² The New York cases on strict liability for design defects, focusing as they do on negligence, would effectively shield the drug manufacturer from all liability. The California cases shift the burden of proof, but maintain the negligence character of the strict liability action. Section 402A of the *Restatement (Second)*, despite its broad language about "unreasonably dangerous" products, would apply standard negligence principles to drugs. The draft of the Uniform Product Liability Act lists five factors to be considered under what is still a negligence test. The only authority to depart from the standard negligence framework is the New York PJI, which would evaluate the drug at the time of trial, not when it was manufactured and marketed, and then apply negligence principles. The PJI would permit the imposition of liability on manufacturers of defective drugs whose defects could not reasonably have been foreseen.

There are undoubtedly less extreme alternatives which would neither shield the manufacturer from all liability nor leave the manufacturer completely exposed to suit. It is unlikely that either of these extremes represent a proper apportionment of losses from unforeseen drug defects.⁸³ The proper apportionment ultimately

⁸² Although a definition of "defect" unique to unknown drug hazards is required before strict liability can be imposed, the theory of liability remains the same. As the New York Court of Appeals in *Codling* noted, the rationale for imposing strict liability applies to those products "with an alluring exterior . . . [whose] validity and usefulness . . . depend upon the application of . . . chemical . . . principles far beyond the ken of the average consumer." 32 N.Y.2d 330, 340, 298 N.E.2d 622, 627, 345 N.Y.S.2d 461, 468. Thus, drugs seem particularly susceptible to the strict liability theory and rationale. As Professor Wade has noted, however, the question of design defectiveness is a theoretical vexation:

[T]he term "defective" raises many difficulties. Its natural application would be limited to the situation in which something went wrong in the manufacturing process, so that the article was defective in the sense that the manufacturer had not intended it to be in that condition. To apply it also to the case in which . . . the design turns out to be a bad one or the product is likely to be injurious in its normal condition, is to use the term in a Pickwickian sense, with a special, esoteric meaning of its own.

Wade, *supra* note 9, at 831-32.

⁸³ The dilemma posed by these extremes can be approached from the traditional perspective articulated by Professor James: "[W]hen unexpected dangers develop from the use of a valuable new product, the industry producing it. . . [should] compensate the innocent victims of those dangers." James, *Products Liability*, 34 *Tex. L. Rev.* 192, 215 (1955). Interestingly, although the *Restatement (Second)* authors apparently have seen fit to absolve drug manufacturers where the injury is the result of an unanticipated danger, Comment c to

must rest on a complex policy determination, best performed by a legislature, weighing economic, social and political factors. Among the factors to be considered is the possibility that new product development and marketing might be brought to a halt for fear of potential lawsuits.⁸⁴ A greater potential for liability might prompt manufacturers to purchase substantially more insurance, the cost of which might be passed on to consumers in the form of higher prices, an undesirable result in light of already spiralling medical costs. Additionally, the cost of adequate liability insurance could make operation unprofitable for the small manufacturer, while the alternative of carrying no insurance at all could destroy a smaller business in the event of a costly lawsuit.⁸⁵

On the other hand, it might be argued that the threat of personal injury suits would encourage the development of more precise and thorough research and testing methods.⁸⁶ Moreover, it may be more desirable to spread the loss among all consumers rather than

section 402A adopts the same view as Professor James:

Public policy demands that the burden of accidental injuries caused by products intended for consumption be placed upon those who market them, and be treated as a cost of production against which liability insurance can be obtained.

RESTATEMENT (SECOND) OF TORTS § 402A, Comment c (1965); see Comment, *The Diminishing Role of Negligence in Manufacturer's Liability for Unavoidably Unsafe Drugs and Cosmetics*, 9 ST. MARY'S L.J. 102, 115-16 (1977).

Other commentators have analogized drug manufacturers' liability to the earlier tort concept of ultrahazardous activity, see, e.g., Rheingold, *Products Liability—The Ethical Drug Manufacturer's Liability*, 18 RUTGERS L. REV. 947, 1001 & n.308 (1964); Wade, *supra* note 9, at 835-36, and conclude that liability for injuries caused by unforeseeable hazards is the price that manufacturers should pay for engaging in such a business. Rheingold, *supra*, at 1001-02, 1017. In the end, it would not be incorrect to say that sufficient authority and precedent exists for the imposition of strict liability upon the drug manufacturer for injuries resulting from unforeseeable hazards.

⁸⁴ See *Leibowitz v. Ortho Pharmaceutical Corp.*, 244 Pa. Super. 418, 307 A.2d 449, 458 (Pa. 1973); Connolly, *The Liability of a Manufacturer For Unknowable Hazards Inherent in His Product*, 32 INS. COUNSEL J. 303, 306 (1965); Comment, *The Diminishing Role of Negligence in Manufacturer's Liability For Unavoidably Unsafe Drugs and Cosmetics*, 9 ST. MARY'S L.J. 102, 112 (1977). *Contra*, Rheingold, *Products Liability—The Ethical Drug Manufacturer's Liability*, 18 RUTGERS L. REV. 947, 1017 (1964). In connection with this argument, it has been asserted that society's need for life-preserving drugs demands that the best production environment possible be made available to drug manufacturers. W. PROSSER, *LAW OF TORTS* § 99, at 661-62 (4th ed. 1971).

⁸⁵ As Professor Rheingold has noted, however, "it is hard to imagine any drug company today whose financial situation is so marginal that it is unable to purchase insurance and itself be a self-insurer beyond the limits of the coverage." Rheingold, *Products Liability—The Ethical Drug Manufacturer's Liability*, 18 RUTGERS L. REV. 947, 1016-17 (1964).

⁸⁶ See Merrill, *Compensation for Prescription Drug Injuries*, 59 VA. L. REV. 1, 107-09 (1973); Rheingold, *Products Liability—The Ethical Drug Manufacturer's Liability*, 18 RUTGERS L. REV. 947, 1015 (1964); Comment, *The Diminishing Role of Negligence in Manu-*

force the injured party to bear the burden. Indeed, under certain circumstances the injured party may be the "guinea pig" whose injury causes the product to be redesigned in the form of revised warnings or withdrawn from the market to prevent injury to others.

Yet, without making a sweeping policy decision for or against drug manufacturers' liability, a legislature might make various minor changes to better apportion losses. Several commentators, for example, have suggested partial governmental responsibility for unforeseeable injuries, particularly when the losses are catastrophic such as in a "Thalidomide"-type disaster.⁸⁷ This suggestion is founded upon the belief that government participation in the marketing of a drug through FDA testing and approval should carry with it some measure of financial responsibility.⁸⁸

On the issue of damages, limits or "caps" could be placed on plaintiffs' recoveries. Several states already have enacted liability-limiting legislation in the area of medical malpractice.⁸⁹ While these statutes present constitutional questions that are beyond the scope of this Article,⁹⁰ it seems clear that this type of limitation could ameliorate the economic consequences of expanded manufacturers' liability.

Other more drastic methods include arbitration,⁹¹ elective no-fault insurance⁹² and governmentally funded social compensa-

facturer's Liability for Unavoidably Unsafe Drugs and Cosmetics, 9 ST. MARY'S L.J. 102, 110 (1977); Comment, *Strict Liability in Tort: Its Applicability to Manufacturers of Prescription Drugs*, 7 U. CAL. D.L. REV. 487, 506 (1974). See generally G. CALABRESI, *THE COSTS OF ACCIDENTS* 73 (1970).

⁸⁷ See, e.g., Teff, *Products Liability in the Pharmaceutical Industry at Common Law*, 20 MCGILL L.J. 102, 121 (1974). In the context of governmental responsibility for drug injuries, it has been stated that "the government should accept at least joint responsibility with a manufacturer, whose product has met standards of safety set by the government, but from the use of which any injury or loss has arisen." *Id.*, n.87 (quoting *The Pharmaceutical Journal* (1973), Vol 211, No. 5727, 84). See also Rheingold, *supra* note 80, at 1016.

⁸⁸ Teff, *Products Liability in the Pharmaceutical Industry at Common Law*, 20 MCGILL L.J. 102, 121-22 & n.87 (1974).

⁸⁹ See, e.g., ILL. REV. STAT. ch. 70 § 101 (Supp. 1978) (\$500,000); IND. STAT. ANN. § 16-9.5-2-2 (Cum. Supp. 1978) (\$500,000); OHIO REV. CODE ANN. § 2307.43 (Supp. 1978) (\$200,000).

⁹⁰ See *Wright v. Central DuPage Hosp. Assoc.*, 63 Ill. 2d 313, 347 N.E.2d 736 (1976) (Illinois statute limiting malpractice awards to \$500,000 held unconstitutional).

⁹¹ As one commentator has noted, however, arbitration merely replaces one system with another, without correcting the problems which are inherent in the typical drug injury case. See O'Connell, *An Alternative to Abandoning Tort Liability: Elective No-Fault Insurance for Many Kinds of Injuries*, 60 MINN. L. REV. 501, 513 (1976).

⁹² See *id.*; Freedman, *No-Fault and Products Liability: An Answer to a Maiden's Prayer*, 1975 INS. L.J. 199; O'Connell, *An Alternative to Abandoning Tort Liability: Elective No-*

tion schemes.⁹³ In contrast to the alternatives already mentioned, which in varying degrees alter the judicial framework, these proposals constitute entirely new methods of compensation wholly independent of the judicial system.

The alternatives mentioned are not without their practical imperfections. They are suggested merely to demonstrate that unforeseeable drug injuries need not go entirely uncompensated and that compensation for those injuries need not destroy the manufacturer. Of course, future legislative possibilities do not help judges who must charge juries and make decisions today. To do justice to both injured user and non-negligent manufacturer, the judge seeks a legal standard which will properly apportion losses between the parties for injuries resulting from unforeseeable drug hazards. Unfortunately, the prevailing legal theories of negligence and strict liability, developed in machinery litigation, are tools too crude for this delicate job.

Fault Insurance for Many Kinds of Injuries, 60 MINN. L. REV. 501, 513 (1976); O'Connell, *Elective No-Fault by Liability Contract With or Without an Enabling Statute*, 1975 U. ILL. L.F. 59, 72; Schwartz, *Professor O'Connell's No-Fault Plan for Products and Services: Have New Problems Been Substituted for Old?*, 70 NEV. U.L. REV. 639 (1975).

⁹³ See Teff, *Products Liability in the Pharmaceutical Industry at Common Law*, 20 MCGILL L.J. 102, 121-22 (1974).