Can a Prescription Drug Be Defectively Designed - Brochu v. Ortho Pharmaceutical Corp.

Britt Wesley Hanson

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It is well established that a manufacturer may be held liable for injuries caused by a defectively designed product. A product is defectively designed

1. W. Kimble & R. Lescher, Products Liability § 131, at 157 (1979) [hereinafter cited as Kimble & Lescher]; Twerski, Weinstein, Donaher & Piehler, Use and Abuse of Warnings in Products Liability—Design Defect Comes of Age, 61 Cornell L. Rev. 495 (1976) [hereinafter cited as Use and Abuse of Warnings]. See also Huddell v. Levin, 537 F.2d 726, 735 (3d Cir. 1976) (it is "beyond peradventure that an automobile manufacturer today has some legal obligation to design and produce a reasonably crashworthy vehicle"). Id. at 735.

The seminal products liability case, Greenman v. Yuba Power Prods., Inc., 59 Cal. 2d 57, 377 P.2d 897, 27 Cal. Rptr. 697 (1963), provided the impetus for modern design litigation. Writing for the majority, Justice Traynor stated that "[a] manufacturer is strictly liable in tort when an article he places on the market, knowing that it is to be used without inspection for defects, proves to have a defect that causes injury to a human being." Id. at 62, 377 P.2d at 900, 27 Cal. Rptr. at 700. Prevailing strict products liability doctrine is embodied in Restatement (Second) of Torts § 402A (1965) [hereinafter cited as Restatement]. Section 402A provides:

(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.

Id. At least 26 states have adopted Restatement § 402A, and others have imposed strict liability without expressly adopting § 402A. Kimble & Lescher, supra, § 2, n.41 (citing cases).

Manufacturers have been held strictly liable under § 402A in cases in which (1) the defect occurred in the manufacturing process; (2) the product design was unreasonably unsafe; and (3) adequate warnings of known defects were not provided. Epstein, Products Liability: The Search for the Middle Ground, 56 N.C. L. Rev. 643, 648-49 (1978) [hereinafter cited as Search for Middle Ground]. In manufacturing defect cases, the outcome may depend upon whether the plaintiff’s claim for relief is based upon a negligence theory or a strict liability theory. In cases where the plaintiff alleges either a design defect or inadequate warning, however, many courts and commentators have concluded that strict liability and negligence theories produce identical results. See, e.g., Wade, On Product Design Defects and Their Actionability, 33 Vand. L. Rev. 551, 552 (1980) (strict liability and negligence theories are in effect identical).

See also Sterling Drug, Inc. v. Yarrow, 408 F.2d 978, 992-93 (8th Cir. 1969) (in failure to warn cases, no difference exists between negligence standard under § 388 and strict liability standard under § 402A); Halvorson v. American Hoist & Derrick Co., 307 Minn. 48, 55-56, 240 N.W.2d 303, 307 (1976) (under either theory, the question is one of risks weighed against utility).

Differences may arise, however, if contributory negligence is a factor in the case. Ortho
if, although properly manufactured, it is unreasonably dangerous. A product is unreasonably dangerous if its risk of harm outweighs its utility.

Pharmaceutical Corp. v. Chapman, 388 N.E.2d 541, 551-52 (Ind. App. 1979). Dean Prosser has remarked that in a case against a manufacturer, "an honest estimate may very well be that there is not one case in a hundred in which strict liability would result in recovery where negligence does not." Prosser, The Assault Upon the Citadel (Strict Liability to the Consumer), 69 Yale L.J. 1099, 1114 (1960).


2. Restatement, supra note 1, § 402A(1). Although the Restatement uses the phrase, "defective condition unreasonably dangerous," in this Note the terms "defect" and "unreasonably dangerous" will be used interchangeably. There has been some confusion as to whether their meaning is identical. See Wade, On the Nature of Strict Tort Liability for Products, 44 Miss. L.J. 825, 829-32 (1973) [hereinafter cited as Wade] (the Restatement intended not to impose two separate requirements but rather only to ensure the viability of "unreasonably dangerous"). The confusion stems from § 402A(1) and the accompanying explanation: "[t]he rule stated in this section applies only where the defective condition of the product makes it unreasonably dangerous. . . ." Restatement, supra note 1, § 402A, Comment i. Most authorities construe the terms synonymously. See, e.g., Phillips v. Kimwood Mach. Co., 269 Or. 485, 491 n.3, 525 P.2d 1033, 1036 n.3 (1974); Keeton, Products Liability—Liability Without Fault and the Requirement of a Defect, 41 Tex. L. Rev. 855, 861 (1963).

Professor Wade explains that "[t]he only real problem is whether the product is 'unreasonably dangerous,' because 'defective condition,' if it is to be applied at all, depends on that." Wade, Strict Tort Liability of Manufacturers, 19 Sw. L.J. 5, 14-15 (1965). But see Cronin v. J.B.E. Olson Corp., 8 Cal. 3d 121, 132-34, 501 P.2d 1153, 1161-63, 104 Cal. Rptr. 433, 441-43 (1972) (plaintiff need only show that the product was defective because proof that defect was also unreasonably dangerous "rings of negligence"). The confused state of design litigation has caused one author to comment that "after fifteen years of decision making in the products liability area, courts have not only failed to fashion a legally sound definition of defect in design cases but have also failed in practice to separate conceptually the notions of strict liability, negligence, warranty, and absolute liability." Unmasking the Test, supra note 1, at 601.

Despite expansion in the area of design litigation courts have refused to evaluate the designs of drugs. This refusal stems from an exception derived from Comment k of section 402A of the Restatement (Second) of Torts which categorizes drugs as unavoidably unsafe products. Comment k has been judicially interpreted as absolving manufacturers from liability for injuries caused by unavoidably unsafe products, provided that consumers are adequately warned of the dangers inherent in the product’s use. Thus, the


The test for unreasonable danger as originally set out in the Restatement is “dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics.” Restatement, supra note 1, § 402A, Comment i. Although the “consumer’s expectations” definition retains some adherents, see, e.g., Vincer v. Esther Williams All-Aluminum Swimming Pool Co., 69 Wis. 2d 326, 332, 230 N.W.2d 794, 799 (1975), most courts have rejected it, reasoning that consumers’ expectations are subsumed in the jury’s deliberations when evaluating the product’s risks in light of its utility. See, e.g., Turner v. General Motors Corp., 584 S.W.2d 844, 851 (Tex. 1979). One scholar explains that “[a]n attempt to determine the consumer's reasonable expectations of safety concerning a technologically complex product may well be an exercise in futility, for the consumers have at most only a generalized expectancy . . . that the product will not harm him if he treats it with a reasonable amount of care.” Reflections on Defective Products, supra, at 823.

4. For a discussion of judicial reluctance to evaluate drug designs see Comment, The Diminishing Role of Negligence in Manufacturers’ Liability for Unavoidably Unsafe Drugs and Cosmetics, 9 St. Mary’s L.J. 102, 115 (1977) [hereinafter cited as Liability for Unavoidably Unsafe Drugs]. There is one trial court decision which has held that an oral contraceptive manufacturer could be strictly liable for injuries caused by use of its contraceptive. Oresman v. G.D. Searle & Co., 388 F. Supp. 1175 (D.R.I. 1975). The Oresman court found that both negligence in warning and defective design of the pills were questions of fact for the jury. Id. at 1180. See text accompanying notes 30-34 supra.

5. Basko v. Sterling Drug, Inc., 416 F.2d 417, 425 (2d Cir. 1969) (“comment k makes an exception to the strict liability rule in the case of products characterized as ‘unavoidably unsafe’”). See generally Willig, The Comment k Character: A Conceptual Barrier to Strict Liability, 29 Mercer L. Rev. 545 (1978). Comment k explains: Unavoidably Unsafe Products. There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. . . . Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. Restatement, supra note 1, § 402A, Comment k (emphasis in original). See notes 19 & 32-46 and accompanying text infra.


Because of the desirability of permitting drugs of proven value to be marketed despite known or suspected risks in said drugs, courts have uniformly held that “a drug, properly tested, labeled with appropriate warnings, approved by the Food and Drug Administration, and marketed properly under federal regulation, is, as a matter of law, a reasonably safe product. . . .” Id. (quoting Lewis v. Baker, 243 Or. 317, 324, 413 P.2d 400, 404 (1966)).
issue in virtually all prescription drug litigation has been the adequacy of manufacturers' warnings.  

In *Brochu v. Ortho Pharmaceutical Corp.*, however, the United States Court of Appeals for the First Circuit held that a drug manufacturer may be liable for injuries caused by a defectively designed drug, whether or not the warnings were adequate. The *Brochu* decision represents the first case in which a circuit court has permitted recovery from a drug manufacturer predicated upon a claim of defective design. On the basis of a medical study reporting a risk associated with an oral contraceptive, the *Brochu* court concluded that a jury could properly determine not only that the manufacturer failed in its duty to warn of the risk, but also that the product design was unreasonably dangerous.

Because this novel holding departs from the traditional basis of recovery, adequacy of warnings, it is first necessary to review the state of prescription drug liability prior to *Brochu*. An examination of the *Brochu* court's design defect rationale reveals that the holding is conceptually sound, and properly applied to the facts of the case. Indeed, it is precisely the peculiar facts of *Brochu* that obscure the difficulties that would be encountered in extending the design defect theory to prescription drugs in general. Thus, notwithstanding the ability of the court to properly apply the theory in the context of the case, a further appraisal of the holding mandates the conclusion that its extension is unwarranted and unnecessary.

**THE JUDICIAL TREATMENT OF PRESCRIPTION DRUG PRODUCT LIABILITY**

Although the Food and Drug Administration (FDA) requires a determination of safety and efficacy before a drug can be marketed, even the

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8. 642 F.2d 652 (1st Cir. 1981).

9. Id. at 655.

10. See note 4 supra.

11. 642 F.2d at 655, 659.

most stringent testing procedures cannot eliminate all dangers in otherwise useful drugs. The use of even the most beneficial drugs can result in serious illness or death. But because of the therapeutic value of drugs, it is axiomatic that drugs must be marketed and prescribed despite their inherent risks. Hence, the term unavoidably unsafe has attached to drugs.

Courts do not permit plaintiffs to recover simply because harm results from the use of a drug. Absolute liability, it is feared, would stifle

(concluding that the deterrent effect on introduction of beneficial new drugs has cost more lives than the heightened protection has saved).

13. Kimble & Lesher, supra note 1, § 375, at 394. A drug marketed today has undergone three phases of tests, subsequent to preliminary tests on plants and animals. The first phase constitutes testing on volunteers. The second requires tests on a limited and controlled number of patients, and the third involves clinical research. Id. § 373, at 386-93. The average time spent testing a drug is seven to ten years. Grabowski, The Impact of Regulation on Innovation, 34 Food Drug Cosm. L.J. 555 (1979). The average cost to the manufacturer to introduce a new drug is estimated at $50 million dollars. This figure includes the cost of developing unsuccessful drugs. Id. Despite thorough testing, not all dangers can be eliminated nor all adverse reactions identified. See Note, The Liability of Pharmaceutical Manufacturers for Unforeseen Adverse Drug Reactions, 48 Fordham L. Rev. 735, 745 (1980) (citing M. Silverman & P. Lee, Pills, Profits and Politics 266 (1974)) (estimating that between 20-30% of adverse reactions are caused by unknown side effects). For this reason, one commentator describes the drug market as the "ultimate laboratory" with the consumer as the "ultimate test subject." Id. at 757. (citing W. Wardall & L. Lasagna, Regulation and Drug Development 146 (1975).


15. Comment k illustrates:

An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve.

Restatement, supra note 1, § 402A, Comment k.

16. Restatement, supra note 1, § 402A, Comment k. See note 5 supra.


Because courts reject absolute liability, they have logically refused to hold manufacturers liable for harm caused by unforeseeable risks in drug products. See, e.g., O'Hare v. Merck & Co., 381 F.2d 286, 291-92 (8th Cir. 1967) (recovery denied because evidence indicating an adverse side effect was discovered after the injury occurred); Christofferson v. Kaiser Foundation Hosps., 15 Cal. App. 3d 75, 79-80, 92 Cal. Rptr. 825, 827 (1971) (manufacturer cannot be held liable for unforeseeable drug reactions); Woodill v. Parke Davis & Co., 79 Ill. 2d 26, 33-35, 402 N.E.2d 194, 198-99 (1980) (affirmed remand of complaint because plaintiff failed to
product innovation. Thus, for any product-related injury, strict liability is imposed only if the product is deemed unreasonably dangerous. Accordingly, Comment k of section 402A of the Restatement (Second) of Torts provides that an unavoidably unsafe product, properly tested and manufactured, and accompanied by proper warnings, is not unreasonably dangerous.

Because of the apparent exception for prescription drugs carved out of section 402A, the inadequacy of warnings provided by the manufacturer, rather than a design defect, has served as the basis for recovery in nearly every drug case. Courts in turn, have imposed strict warning requirements

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allege knowledge of the risk); Ortho Pharmaceutical Corp. v. Chapman, 388 N.E.2d 541, 548 (Ind. App. 1979) ("manufacturer cannot be required to warn of a risk unknown to science"). Only one court has held that a drug manufacturer could be liable for failure to warn regardless of whether the danger was foreseeable. See Hamilton v. Hardy, 37 Colo. App. 375, 383-84, 549 P.2d 1099, 1108 (1976) (under strict liability rubric, the test is whether there was a duty to warn assuming manufacturer's knowledge of dangerous propensities) (citing Phillips v. Kimberly-Clark Mach. Co., 269 Or. 485, 498, 525 P.2d 1033, 1039 (1974)). Cf. Crocker v. Winthrop Labs., Inc., 514 S.W.2d 429, 432 (Tex. 1974) (manufacturer liable for an unforeseeable risk of drug addiction because of express statement that Talwin was non-habit forming).

18. In Gaston v. Hunter, 121 Ariz. 33, 48-49, 588 P.2d 326, 341-42 ( Ct. App. 1978), the plaintiff proposed that the drug manufacturers should be held absolutely liable for injuries caused by new drugs. Id. The court rejected this suggestion, and remarked that:

... there 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 drugs would enlarge the latter risk to unacceptable proportions. . . .

Id. See also Liability for Unavoidably Unsafe Drugs, supra note 4, at 110 (rejecting absolute liability), But see Comment, Liability of Birth Control Pill Manufacturers, 23 Hastings L.J. 1526, 1545-46 (1972) (reactions from drugs that do not treat illnesses, such as oral contraceptives, should be compensated under absolute liability). This distinction has been expressly rejected by at least one court. See Ortho Pharmaceutical Corp. v. Chapman, 388 N.E.2d 541, 545 (Ind. App. 1979) (rejected suggestions that Comment k does not apply to oral contraceptives because there is no dire need for them).

19. RESTATEMENT, supra note 1, § 402A(1). See note 2 supra.

20. See note 5 supra.

21. Dixon, supra note 7, § 9.01(1), at 9-4. Although the phrase "unreasonably dangerous as marketed" is used by some courts to denote the drug warning issue, e.g., Reyes v. Wyeth Laboratories, 498 F.2d 1264, 1275 (5th Cir.), cert. denied, 419 U.S. 1096 (1974), this phrase is often loosely employed. Use and Abuse of Warnings, supra note 1, at 519-21. Some warnings merely inform the physician of risks inherent in the product and do not reduce the level of danger. Id. Recovery for inadequate warnings in these cases is akin to failure to comply with informed consent. Id. This concept is explained in Borel v. Fibreboard Prods. Corp., 493 F.2d 1076, 1088-89 (5th Cir. 1973). In Borel, the court stated:

The failure to give adequate warnings in these circumstances renders the product unreasonably dangerous. The rationale for this rule is that the user or consumer is entitled to make his own choice as to whether the product's utility or benefits justify exposing himself to the risk of harm. Thus, a true choice situation arises, and a duty to warn attaches, whenever a reasonable man would want to be informed of the risk in order to decide whether to expose himself to it.
on manufacturers. In Ortho Pharmaceutical Corp. v. Chapman, for example, the court stated that a manufacturer is viewed as possessing the knowledge of an expert, and must warn physicians of all risks of which it knows or should have known. The court added that this requirement includes a duty to warn physicians of all risks that are suspected, even if not medically proven. Finally, the Chapman court rejected the defendant's argument that FDA-approved oral contraceptive warnings are adequate as a matter of law, finding that, although technically accurate, the warnings

Id. at 1089. Other warnings should reduce danger, for example, by informing physicians of premonitory symptoms of disease. See, e.g., Singer v. Sterling Drug, Inc., 461 F.2d 288 (7th Cir. 1972) (failure to warn of premonitory symptom of blindness).

22. The trend has been to heighten the judicial standard of adequacy of warnings. DIXON, supra note 7, § 9.01[2], at 9-2. For example, courts originally adhered to the "appreciable number of persons test, so that manufacturers were not liable for hypersensitive and idiosyncratic reactions. See, e.g., Cudmore v. Richardson-Merrell, Inc., 398 S.W.2d 640, 644 (Tex. Civ. App. 1965), cert. denied, 385 U.S. 1003 (1967). More recently, however, courts have rejected this approach. See, e.g., Basko v. Sterling Drug, Inc., 416 F.2d 417, 430 (2d Cir. 1969) (trial court erred in referring to "appreciable number of users" in jury instructions); Sterling Drug, Inc. v. Cornish, 370 F.2d 82, 84-85 (8th Cir. 1966) (duty to warn small percentage of users). Indeed, plaintiffs have recovered where the manufacturer breached its duty to warn of extraordinarily remote risks. See, e.g., Givens v. Lederle, 556 F.2d 1341, 1345 (5th Cir. 1977) (failure to give adequate warning where the risk was one in three million); Stahlheber v. American Cyanamid Co., 451 S.W.2d 48, 58 (Mo. 1970) (failure to warn where risk was less than one in one million).


24. Id. at 548. Prescription drug warnings are unique in that manufacturers need only warn physicians, not consumers. Basko v. Sterling Drug, Inc., 416 F.2d 417, 426 (2d Cir. 1969). The Basko court described the reasons for this exception.

In such cases the choice is essentially a medical one involving an assessment of the medical risks in the light of the physician's knowledge of his patients' needs and susceptibilities. Further it is difficult under such circumstances for the manufacturer, by label or direct communication, to reach the ultimate consumer with a warning.

Id. (quoting Davis v. Wyeth Laboratories, Inc., 399 F.2d 121, 130 (9th Cir. 1968)). The Physician's Desk Reference and the package insert are the primary means of disseminating information concerning a product's medical peculiarities and instructions for use. DIXON, supra note 7, § 9.04, at 9-18. In a few instances, such as with the oral contraceptive, the FDA requires manufacturers to advise consumers as well as physicians of risks associated with the product. See 21 C.F.R. § 310.501 (1981). However, no reported opinion has imposed liability for failure to adequately warn a consumer directly. Cf. Ortho Pharmaceutical Corp. v. Chapman, 388 N.E.2d 541, 549 (Ind. App. 1979) (would not retrospectively consider failure to warn the consumer).

25. Ortho Pharmaceutical Corp. v. Chapman, 388 N.E.2d at 548. The court rejected the notion that drug manufacturers should be held liable for unforeseeable dangers. Id. at 547-48. See note 17 supra.


may not have effectively communicated the serious nature of the risk.28

This duty, the court held, rests solely upon the manufacturer.29

Although courts have allowed plaintiffs to demonstrate that FDA-approved warnings may be inadequate, no court prior to Brochu had recognized a plaintiff's assertion that an FDA-approved drug is unreasonably dangerous as designed.30 The statement that drugs are unavoidably unsafe, and therefore within the protection of Comment k, has become almost tautological.31 Some courts have rejected the design defect


28. 388 N.E.2d at 554. See also Incollingo v. Ewing, 444 Pa. 263, 288-89, 282 A.2d 206, 220 (1971) (overpromotion of the drug may have diluted the warnings and rendered them ineffective).

29. 388 N.E.2d at 554. It should be noted that the Chapman court purported to apply a § 402A strict liability standard to the warnings issue. Id. The court acknowledged that it has been a matter of some debate whether Comment k implies a strict liability or negligence warning standard, and whether there is any difference in result depending on which standard is applied. Id. at 549-52. The Chapman court's analysis revealed that the terminology could make a difference if contributory negligence was an issue. Id. at 552 n.8. The court concluded that although it chose to term its standard as one of strict liability, such a label would not alter the outcome in the case. Id. at 552-53.

It is not apparent that a " stricter" warning requirement is applied under strict liability than negligence. For instance, the court that applied perhaps the strictest warning standard—manufacturers must warn by the "most effective method,"—did so after concluding that there was no difference between strict liability and negligence. See Sterling Drug, Inc. v. Yarrow, 408 F.2d 978, 992, 993 (8th Cir. 1969). Because use of the strict liability rubric appears to apply a different duty to warn standard than negligence, however, one court expressly stated that it was proper to submit to the jury only one set of instructions. Smith v. E.R. Squibb & Sons, Inc., 405 Mich. 79, 90-91, 273 N.W.2d 476, 480 (1979) (submitting both instructions could have misled the jury). Accord, Ortho Pharmaceutical Corp. v. Chapman, 388 N.E.2d 541, 552 (Ind. App. 1979).

30. See note 4 supra.

31. See, e.g., Lindsay v. Ortho Pharmaceutical Corp., 637 F.2d 87, 90-91 (2d Cir. 1980) (to recover under Comment k a plaintiff must prove a breach of duty to warn for a drug-caused injury); Dalke v. Upjohn Co., 555 F.2d 245, 247 (9th Cir. 1977) (unavoidably unsafe products not defective or unreasonably dangerous if properly prepared and accompanied by adequate directions and warnings); Basko v. Sterling Drug, Inc., 416 F.2d 417, 425 (2d Cir. 1969) (Comment k suggests that a drug is not defective nor unreasonably dangerous if the manufacturer provides adequate warning of the risks involved); Lawson v. G.D. Searle & Co., 64 Ill. 2d 543, 551, 356 N.E.2d 779, 783 (1976) (Comment k indicates that adequacy of warning is central issue in drug cases); Wolfgruber v. Upjohn Co., 72 A.D.2d 59, 61, 423 N.Y.S.2d 95, 97 (1979) (warning is key in drug cases because prescription drugs are unavoidably unsafe); Cochran v. Brooke, 243 Or. 89, 94-95, 409 P.2d 904, 906 (1966) (Comment k applies to drugs and therefore refused to apply § 402A).

An examination of the authorities cited above reveals that the "protection" Comment k has traditionally afforded is from liability resulting from harm caused by dangers inherent in the drug's design, not from liability for failure to warn properly. These cases also suggest that inadequate warnings, negligent manufacture, or failure to sufficiently test a drug before marketing are the only bases for drug product liability. The Court in Basko v. Sterling Drug, Inc., 416 F.2d 417 (2d Cir. 1969), sums up the prevailing interpretations of the Comment k im-
theory by holding that, as a matter of law, an FDA-approved product is not unreasonably dangerous.\(^3\) A few courts, however, have recognized that Comment k does not exempt drug products from judicial scrutiny of their design, stating that Comment k implies the use of a risk-utility balancing test to determine whether a drug's presence on the market is justified.\(^3\) None of these courts, however, has found a drug to be defectively designed.\(^4\)

**Gaston v. Hunter**\(^3\) illustrates the relaxed scrutiny afforded drug designs. In *Gaston*, the plaintiff was treated with an experimental drug as an alternative to a back operation. The treatment, however, resulted in severe complications and further injuries.\(^3\) The plaintiff's expert claimed that the drug was defective because it not only lacked therapeutic value in alleviating back problems, but contained highly dangerous substances.\(^3\) Describing Comment k rules of liability as "more lenient" than other section 402A rules,\(^3\) the appellate court summarily concluded that the potential benefits of the drug outweighed its hazards.\(^3\) Accordingly, the *Gaston* court affirmed

\(^{32}\) See McDaniel v. McNeil Laboratories, Inc., 196 Neb. 190, 201, 241 N.W.2d 822, 828 (1976) (unless the manufacturer withheld information from the FDA, a drug approved by that agency is not defectively designed as a matter of law); Lewis v. Baker, 243 Or. 317, 324, 413 P.2d 400, 404 (1966) (Federal agency approval will not safeguard a drug where fraud or culpable nondisclosure is proven); Leibowitz v. Ortho Pharmaceutical Corp., 224 Pa. Super. 418, 433-34, 307 A.2d 449, 458 (1973) (absent impurity or inadequacy in labeling, FDA approved drug is reasonably safe as a matter of law).

\(^{33}\) See Davis v. Wyeth Laboratories, Inc., 399 F.2d 121, 129 (9th Cir. 1968) (must determine whether on balance the benefits justify its use); Ortho Pharmaceutical Corp. v. Chapman, 388 N.E.2d 541, 545 (Ind. App. 1979) (public interest in availability of a drug must be weighed against risks).

\(^{34}\) In Ortho Pharmaceutical Corp. v. Chapman, 388 N.E.2d at 545, the court had "no difficulty" in finding oral contraceptives, specifically Ortho-Novum 2 mg., reasonably safe, and therefore under the protection of Comment k. See also Reyes v. Wyeth Laboratories, 498 F.2d 1264, 1274 (5th Cir. 1974) (Salk polio vaccine not unreasonably dangerous); Cudmore v. Richardson-Merrell, Inc., 398 S.W.2d 640, 645 (Tex. Civ. App. 1965), cert. denied, 385 U.S. 1003 (1967) (MER/29 not "unfit and unmerchantable" after weighing utility against potential danger).


\(^{36}\) Id. at 38, 588 P.2d at 331. Because it was debated whether the physicians negligently prescribed the drug or whether the toxic effect of the drug itself caused the injuries, the plaintiff sued the physicians and the manufacturer. *Id.*

\(^{37}\) *Id.* at 47, 588 P.2d at 340.

\(^{38}\) *Id.* at 46, 588 P.2d at 339.

\(^{39}\) *Id.* at 47, 588 P.2d at 340. Importantly, the court did not examine the actual benefits of the drug. Instead, because the drug was experimental, the court only speculated as to the potential benefits of the drug at the time of the injury, regardless of whether the benefits were subsequently realized. *Id.*
the trial judge's refusal to instruct the jury on strict liability for defective design.\footnote{40}{Id. at 46-47, 588 P.2d at 39-40. The court further concluded that the manufacturer had properly instructed the physician on the proper use of the drug. Id.} The approach in Gaston stands in stark contrast with that in Self v. General Motors Corp.,\footnote{41}{42 Cal. App. 3d 1, 116 Cal. Rptr. 575 (1974).} a case involving the design of a product falling outside the purview of Comment k. In Self, the gas tank of the plaintiff's automobile ruptured and burst into flames when the car was rear-ended at a high speed.\footnote{42}{Id. at 4-5, 116 Cal. Rptr. at 577.} The plaintiff's expert alleged that the automobile was defectively designed because the rupture would not have occurred had the tank been located in the less damaged area beneath the floor of the car.\footnote{43}{Id. at 9, 116 Cal. Rptr. at 580.} The defense countered that if all possible types of accidents were considered, the proposed "redesign" would not improve safety.\footnote{44}{Id. The dissent queried: "what if the angle of the collision had been different or Prior's vehicle had been a low-slung sports car that went beneath the rear bumper and struck the area which plaintiff contends is the 'safe' area." Id. at 15-16, 116 Cal. Rptr. at 585 (Compton, J., dissenting).} Furthermore, the gas tank of the other auto involved in the crash, located beneath the floor of the car, had also ruptured and burst into flames.\footnote{45}{Id. at 8-9, 116 Cal. Rptr. at 580.} Rather than examining the merits of the arguments, the court held that the conflict in expert testimony created a jury issue as to whether the plaintiff's auto was unreasonably dangerous.\footnote{46}{Id. at 6, 116 Cal. Rptr. at 578. The jury had rendered a verdict for the plaintiffs, but the manufacturer was given a new trial due to prejudicial remarks concerning the amount of insurance available to the defendant. Id. at 14, 116 Cal. Rptr. at 584.} As illustrated by Self, courts customarily delegate the risk/utility balancing test to juries for resolution of design defect claims.\footnote{47}{See notes 113-20 and accompanying text infra.} In contrast, the casual assessments of the risk and utility of allegedly defective drugs have effectively prevented drug design defect claims from reaching the jury.\footnote{48}{See cases cited in note 33 supra. In these cases, the risk-utility balancing test was given cursory treatment at the appellate level, but was not submitted as a jury issue at trial.} Comment k, courts have maintained, explains this disparity in treatment.\footnote{49}{See note 31 and accompanying text supra.} Thus, until Brochu, Comment k had removed drugs from the otherwise common adjudication of design issues.

**FACTS AND REASONING OF BROCHU**

In 1971, Ortho Pharmaceutical Corporation (Ortho) was selling an oral contraceptive, Ortho-Novum 2 mg. (Novum 2), that contained 100 mcg. of estrogen.\footnote{50}{Brochu v. Ortho Pharmaceutical Corp., 642 F.2d 652, 654 (1st Cir. 1981). Most oral contraceptives contain two active ingredients, synthetic estrogen and progestogen. Id. at 654 n.1. Ortho-Novum 2 mg. (Novum 2) contained 2 mg. of progestogen. Id. at 654.} Ortho was simultaneously marketing other oral contraceptives,
including a pill that contained only 50 mcg. of estrogen, Ortho-Novum 1 mg. (Novum 1). 51 It was recognized that the estrogen in oral contraceptives exposed users to an increased risk of stroke, and consequently, the FDA required manufacturers to warn of this risk. 52 Moreover, a medical study (Inman-Vessey Study) 53 published in 1970 suggested a positive correlation between higher doses of estrogen in oral contraceptives and the risk of stroke. 54

Mrs. Brochu had been using Novum 2 for four years when a stroke rendered her partially incapacitated. 55 The Brochus brought suit against Ortho claiming that the oral contraceptive caused her injury. 56 Specifically, the plaintiffs alleged that Novum 2 was unreasonably dangerous because lower dose pills, such as Novum 1, which were less dangerous yet no less effective in preventing pregnancy, were available. 57 The plaintiffs also argued that Ortho fraudulently withheld from physicians the information regarding the link between the dosage level and the increased risk of stroke, or in any event, failed in their duty to warn physicians of the possible link. 58 The trial judge instructed the jury on fraudulent misrepresentation, and section 402A strict liability for failure to warn and defective design. 59 The jury returned a verdict of $700,000 for Mrs. Brochu and her husband. 60

On appeal, Ortho claimed that it was erroneous as well as unprecedented to submit the drug design issue to the jury. 61 Ortho also argued that the

51. Id. at 654. Ortho also marketed pills containing 60 mcg. and 80 mcg. of estrogen. Id. at 654 n.1.
52. The FDA-approved warnings given by Ortho to physicians stated that a statistical study in Great Britain had found that the risk of thromboembolic disease was seven times higher for "pill" users than non-users, and that a similar study in the United States had found the risk to be 4.4 times greater for "pill" users. Brief for Appellee at 8, Brochu v. Ortho Pharmaceutical Corp., 642 F.2d 652 (1st Cir. 1981). The warnings accompanying Novum 2 were identical to those for all other oral contraceptives on the market. Brochu v. Ortho Pharmaceutical Corp., 642 F.2d at 658.
54. 642 F.2d at 657.
55. The technical name for the stroke that Mrs. Brochu suffered is cerebral vascular accident, which occurs when a blood clot forms in an artery of the brain. Brief for Appellant at 1, Brochu v. Ortho Pharmaceutical Corp., 642 F.2d 652 (1st Cir. 1981). This is a subcategory of thromboembolism, which is the term sometimes referred to in other cases involving oral contraceptives.
56. 642 F.2d at 653.
57. Id. at 654. Both pills were about 99% effective in preventing pregnancy. Id. at 655 n.4. In essence, plaintiff's claim was that there was no need to have the 100 mcg. pill on the market. Id. at 654. There had been some evidence produced at trial that the higher dose pills may have been more effective in preventing breakthrough bleeding. Id. at 655 n.4.
58. Id. at 653. The Brochu's had withdrawn their claims of negligence prior to submission of the case to the jury. Id.
59. Id. at 660-62.
60. Id. at 653.
61. Id. at 653-54.
evidence suggesting the dosage level link to stroke was insufficient to create a duty to warn, and therefore, the FDA-approved warnings were adequate as a matter of law.62

In sustaining the verdict, the First Circuit held that submission of the design defect issue to the jury was not improper.63 In reaching this conclusion, the court relied upon Thibault v. Sears, Roebuck & Co.,64 which had considered a strict liability action for defective design of a lawn mower.65 Thibault held that "when an unreasonable danger could have been eliminated without excessive cost or loss of product efficiency, liability may attach even though the danger was obvious or there was adequate warning."66 The Brochu court reasoned that this holding was equally applicable to prescription drug products, and rejected the defendant's claim that Comment k precluded scrutiny of drug design.67 The court stated that Comment k itself suggests a risk-benefit balancing test to determine whether a drug is unreasonably dangerous.68 Therefore, it was appropriate to hold Ortho liable under section 402A for defective design.69

The Brochu court also held that Ortho's failure to inform physicians of the potentially higher risk of stroke associated with Novum 2 was sufficient evidence upon which the jury could conclude that the warnings were not "reasonable under the circumstances."70 In analyzing the adequacy of warnings issue, the court first rejected Ortho's claim that approval of the warn-

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62. Id. at 657-58. Ortho also claimed that the trial court had erred in three other respects: (1) the submission of the fraudulent misrepresentation issue to the jury was prejudicial; (2) the judge failed to adequately answer a jury question on the issue of damages; and (3) the charge to the jury improperly intermixed negligence and strict liability concepts. Id. at 653-54. The Brochu court rejected all claims of error. Id. at 661-63. In regard to the latter claim, Ortho specifically objected to the instruction that a manufacturer may be liable despite "all possible care." Brief for Appellant at 22, Brochu v. Ortho Pharmaceutical Corp., 642 F.2d 652 (1st Cir. 1981). The Brochu court conceded that the instructions were not "a model of clarity," but emphasized that this instruction was proper with respect to the design defect claim. 642 F.2d at 661.

63. Id. at 655. The First Circuit was interpreting New Hampshire law. Id. Although New Hampshire courts had not previously ruled on the issue, the Brochu court explained that it believed that New Hampshire would apply the design defect theory to drug products. Id.


65. Id. The Thibault court ultimately affirmed a jury verdict for the defendant manufacturer. Id. at 814, 395 A.2d at 850.

66. 118 N.H. at 808, 395 A.2d at 847.

67. 642 F.2d at 655, 657.

68. 642 F.2d at 657 (citing Reyes v. Wyeth Laboratories, 498 F.2d 1264, 1274 (5th Cir.), cert. denied, 419 U.S. 1096 (1974)). The Reyes court stated that a drug should not be marketed "if the potential harmful effects of the product—both qualitative and quantitative—outweigh the legitimate public interest in its availability." 498 F.2d at 1274. See notes 33-34 and accompanying text supra.

69. 642 F.2d at 655. Because Ortho challenged only the legal grounds of the design defect claim, it was not necessary for the court to review the sufficiency of evidence supporting the claim. Id. at 657-58.

70. Id. at 657-58.
nings by the FDA established their adequacy as a matter of law. The court further determined that a duty to warn arises when "a seller . . . has reason to believe that danger may result from a particular use of his product." Thus, the plaintiffs were not required to demonstrate that Novum 2 actually presented an increased risk of stroke. Rather, they needed to demonstrate only a sufficient possibility that the risk existed.

ANALYSIS OF THE DESIGN DEFECT HOLDING

Although Brochu represents the first decision in which an appellate court has applied the design defect theory to drugs, the holding that a drug may be unreasonably dangerous regardless of whether warnings are adequate is not conceptually startling. As with any product, the utility of a drug may not always justify the potential harm that results from its use. Alternative drugs, as Brochu illustrates, may perform the same therapeutic task while posing less risk of injury. Thus, the court's perception that Comment k exempts a drug from section 402A rules of strict liability only if its benefits exceed its risks is conceptually sound.

The court further reasoned that it is logical to submit a case to the jury on both design defect and adequacy of warnings grounds, stating that "if proper warnings would result in nonmarketability of the product, then the

71. Id. at 658. See note 27 supra.
72. 642 F.2d at 657 (quoting Reyes v. Wyeth Laboratories, Inc., 498 F.2d 1264 (5th Cir.), cert. denied, 419 U.S. 1096 (1974)).
73. 642 F.2d at 659. The court noted that Ortho's own Adverse Reaction Reports indicated that there might have existed a higher risk associated with higher estrogen doses. Id. at 658 n.13. Additionally, the warnings that accompanied Novum 2 informed physicians of other risks that were not medically proven. Id. at 659 n.14. This prompted the court to remark that "[t]he standard actually followed for inclusion [in the warnings] appears to have been considerably less than medical certainty, and choosey in the wrong direction." Id.
74. See note 4 supra.
75. 642 F.2d at 657. The court analogized to the example of the Pasteur rabies vaccine in Comment k. Id. See note 15 supra. The court stated that the example suggests that "certain death is weighed against the high degree of risk posed by the [Pasteur] treatment itself." Id. Comment k concludes with the statement that a manufacturer should not be liable for marketing a drug "attended with a known but apparently reasonable risk." RESTATEMENT, supra note 1, § 402A, Comment k. It can be inferred from the use of the phrase "reasonable risk" that Comment k leaves open the possibility that courts can make a determination of reasonableness. In this regard, courts commonly determine the reasonableness of risks associated with other products. See note 1 supra. But see text accompanying notes 106-23 infra.
true issue is acceptability of basic design." That is, because the alleged risk that created the duty to warn is precisely the same risk that may have made the drug unreasonably dangerous, the jury should consider both theories. However sound that logic may be, the implication is that the design issue theoretically added nothing to the Brochu case. If the jury found that the "extra" 50 mcg. of estrogen presented an increased risk, then the warning issue alone would be dispositive of the case in the plaintiff's favor. On the other hand, to find that Novum 2 was defectively designed, the jury would have had to find that not only did the "extra" 50 mcg. present an increased risk, but in addition that the risk was unreasonably dangerous. In short, a finding of defective design required the additional element of unreasonable danger. Because a finding of a defective design necessarily included a determination of the warning issue, the Brochu court's finding of a design defect did not provide an alternative ground of recovery.

By affirming recovery on grounds of design defect as well as warnings, however, the Brochu court broke new ground in drug product liability. Even if the design defect theory did not provide an alternative ground of recovery in Brochu, the holding should spur rethinking of the restricted bases of recovery in drug litigation.

THE IMPACT OF EXPANDING DRUG DESIGN LITIGATION

The obvious nature of the design defect in Brochu demonstrates that prescription drugs are not necessarily unavoidably unsafe. Furthermore, an

76. 642 F.2d at 657 n.6 (citing Use and Abuse of Warnings, supra note 1, at 501). Professor Twerski illustrates this idea with a case, McCormack v. Hankscraft Co., 278 Minn. 322, 154 N.W.2d 488 (1967), involving a steam vaporizer that was tipped off a chair, causing hot water to gush out and scald a young child. Use and Abuse of Warnings, supra note 1, at 501. The decision for the plaintiff was grounded on two theories: (1) the design of the vaporizer was unreasonably dangerous because it could have been fitted with a screw-on cap that would have prevented the water from pouring out; and, (2) the manufacturer had failed to warn of the danger of hot water pouring out when the vaporizer is tipped over. Professor Twerski then suggests that the true issue in the case was the design, because an adequate warning of the risk would have resembled the following: "This vaporizer when operating is filled with scalding hot water—if this vaporizer is tipped, the water will pour out and one could be seriously injured or killed—do not use in the vicinity of children." Use and Abuse of Warnings, supra note 1, at 503. The author concludes that if this warning was attached to the product it would be unmarketable, and, therefore, the true issue is design. Id. at 503-04. But see note 77 infra.

77. See Henderson, Judicial Review of Manufacturers' Conscious Design Choices: The Limits of Adjudication, 73 COLUM. L. REV. 1531, 1562-65 (1973) [hereinafter cited as Henderson]. Professor Henderson contends that whenever both theories are presented to the jury, the warning issue inevitably undercuts and displaces the design issue as the basis for determining recovery. Id. at 1562. He explains that "the issue of unreasonable design is open-ended, polycentric and relatively difficult, while, in contrast the issue of defendant's failure to warn is focused and relatively easy." Therefore, he reasons, a jury truly bases liability on defective design only if the jury also concludes that it was impossible for the manufacturer to warn the plaintiff of the danger. Id. at 1563.

78. See notes 21-40 and accompanying text supra.

79. In 1977, the FDA mandated warnings that advised physicians that oral contraceptives
analysis of the *Brochu* design defect holding reveals that, conceptually, Comment k does not exempt drugs from a risk/utility balancing test. Indeed, having willingly embraced this balancing test for other products, it appears quite logical for courts to apply it to drugs. There are practical reasons, however, that should preclude courts from doing so.

The peculiar facts of the *Brochu* case conceal the impracticalities of extending the risk/utility balancing test to prescription drug litigation. Because the 100 mcg. of estrogen offered no apparent advantages over lower doses, Novum 1 provided an objective standard against which to compare Novum 2. Consequently, the design defect claim centered upon a mere factual dispute, the statistical risk of harm, rather than upon a risk/utility assessment of design trade-offs. This aspect of *Brochu* should not, however, tempt other courts to expand product design litigation to encompass all types of drug cases. Unlike *Brochu*, the overwhelming majority of prescription drug cases are likely to involve products for which there is no objective standard of safety. Therefore, the effect of applying the design defect theory to drugs can best be assessed in a context in which no objective standard exists. That is, the impact of the *Brochu* holding must be examined as it affects the cases in which a risk/utility balancing test would truly be necessary.

To demonstrate a prima facie design defect case, a plaintiff must prove that a feasible alternative design would have reduced or eliminated the injury-causing danger. Comparable products are commonly used to demonstrate the feasibility of the proposed alternative. Expert testimony containing amounts of estrogen greater than 50 mcg. should not be prescribed for contraceptive purposes. FDA CONSUMER, Feb. 1977, at 21. Ortho now warns physicians of the correlation between risk of thromboembolism and higher doses of estrogen in oral contraceptives. Brief for Appellant at 34 n.39, *Brochu v. Ortho Pharmaceutical Corp.*, 642 F.2d 652 (1st Cir. 1981).

80. See notes 74-78 and accompanying text *supra*.
81. See note 1 and accompanying text *supra*.
82. See *Brochu v. Ortho Pharmaceutical Corp.*, 642 F.2d at 655 n.4. At trial, Ortho did not controvert testimony that no matter the estrogen dosage, oral contraceptives were 99% effective. *Id.* Ortho did present some testimony that women using lower dose pills experienced a higher degree of breakthrough bleeding, but that line of testimony was not extensively pursued. *Id.*
83. Comparing Novum 2 to Novum 1 is akin to comparing a particular design to the industry custom. See Henderson, *supra* note 77, at 1556-57, 1571. That is, the “norm” of safety provides an objective standard to which a product design can be compared. *Id.* at 1556. If the safety is lower than the norm, it may be said to be defective. *Id.*
84. See notes 106-12 and accompanying text *infra*.
85. See notes 87-105 and accompanying text *infra*.
86. See notes 106-23 and accompanying text *infra*.
87. Lolie v. Ohio Brass Co., 502 F.2d 741, 744 (7th Cir. 1974).
provides the evidence utilized to determine whether the alternative product would have presented less risk of the precise danger that caused the injury.89

In many cases, however, evaluation of the harm-causing risk is not the only consideration. The alternatives suggested 'may differ in efficiency, usefulness, and cost, and may present dangers other than that which injured the plaintiff.90 It then becomes necessary to evaluate the full range of design trade-offs.91 The inability to meaningfully compare alternatives complicates

gas tank in Ford Pinto compared to foreign autos). See notes 45-46 and accompanying text supra. Cf. Unmasking the Test, supra note 1, at 603 (the concept of defect is meaningful only if compared to a similar product).

89. Huddell v. Levin, 537 F.2d 726, 736 (3d Cir. 1976) (expert testimony required to determine defectiveness where product design is at issue). See Donaher, Piehler, Twerski and Weinstein, The Technological Expert in Products Liability Litigation, 52 TEX. L. REV. 1303 (1974). According to the authors, the expert must address the following elements in a design defect case:

(1) the identification of the design flaw or flaws that occasioned the injury; (2) the enumeration of alternative design features proposed to reduce the danger; (3) the evaluation of these features relative to the expected performance standards of the product, as well as their effect upon the product's subsequent usefulness and cost; (4) the comparison of this product with other similar products; and (5) the causal link between the design deficiency and the injury.

Id. at 1310-11.


91. This type of evaluation has been described as involving the adjudication of conscious design choices. See Bowman v. General Motors Corp., 427 F. Supp. 234, 241 (E.D. Pa. 1977). See generally Henderson, supra note 77. This type of design case is distinguished from those cases involving inadvertent design errors, wherein the product fails to meet the intended design objective. Id. at 1542-52. For instance, when a roof collapses, e.g., Guffie v. Erie Strayer Co., 350 F.2d 378 (3d Cir. 1965) (build-up of sand and rock on roof designed to hold the aggregate caused it to collapse), or when a plane fails to fly, e.g., Noel v. United Aircraft Corp., 342 F.2d 232 (3d Cir. 1964) (overspeeding propeller caused the plane to crash), it can be said that the actual design failed to meet the design objective. Moreover, in these cases the standard for judicial determination of defectiveness, the intended design, is objective. These cases are similar to manufacturing defect cases in which the product also failed to meet the design objective. See Henderson, supra note 77, at 1542-43.

On the other hand, where the case involves a conscious design choice, the issue of design defect is subjective. See, e.g., Garst v. General Motors Corp., 207 Kan. 2, 484 P.2d 47 (1971) (claim that safer hydraulic brake design could have stopped the earth-mover more quickly and possibly averted the accident not meritorious where evidence insufficient to establish that another design was in fact safer). In Bowman v. General Motors Corp., 427 F. Supp. 234 (E.D. Pa. 1977), the plaintiff alleged that fuel tank on a Toronado could have been more safely located so as to prevent injury. The court recognized the subjective nature of determining whether the design was unreasonably dangerous:

Where however, a conscious design choice has caused the injury, we are faced with
the balancing process in many cases. In Dreisonstock v. Volkswagenwerk, A.G.,92 for example, the court rejected plaintiff's attempt to compare a microbus to ordinary front-engine passenger cars.93 In so doing, the court recognized that the rear-engine design that rendered the microbus less crashworthy than an ordinary auto, was also responsible for allowing the extra cargo space that made the vehicle unique and popular.94 Similarly, in Seattle-First National Bank v. Volkswagen of America, Inc.,95 the dissent questioned the propriety of comparing the relatively inexpensive microbus to higher-priced vehicles.96 Thus, Dreisonstock and Seattle-First National Bank illustrate that in some instances no valid safety comparisons can be made. Without an objective standard of safety, the question essentially posed in such cases becomes "how much safety is enough?"97 To answer this open-ended question courts employ a risk/utility balancing test.98

quite a different problem; for there is no built-in objective standard by which the jury can measure the alleged defect. This result stems, at least in part, from the fact that a conscious design choice necessarily involves a trade-off among safety, utility, and cost. The trade-off may be obvious and may also be acceptable to the consumer. At the very least, it reflects the manufacturer's judgment of what would be acceptable if the terms of the trade-off were publicly known. However, the process of evaluating the trade-off, which represents the manufacturer's distillation of the forces of the marketplace, is a sophisticated one which complicates the process of products liability adjudication.

Id. at 241.
92. 489 F.2d 1066 (4th Cir. 1974).
93. Id. at 1074-75. The passenger compartment had been unable to withstand a head on crash at approximately 40 miles per hour. Id. at 1068. The plaintiff alleged that the front end was insufficiently crashworthy to protect the passenger compartment. Id.
94. Id. at 1073-74.
96. 11 Wash. App. 929 at 935-36, 525 P.2d at 290 (Green, C.J., dissenting). Criticizing the majority's judgment that the issue of reasonableness of the microbus design should be submitted to the jury, the dissent stated: "The effect of this case, if universally applied, will be to eliminate the less-expensive products from the market or drive up the price to cover losses...." Id. at 936, 525 P.2d at 290.
97. Henderson, supra note 77, at 1540; Reflections on Defective Products, supra note 3, at 811. Optimal safety, not maximum safety, is the goal of product design and, consequently, products liability. See Calabresi & Hirschoff, Toward a Test for Strict Liability in Torts, 81 YALE L.J. 1055, 1056-58 (1972). According to the authors, the liability test should be algebraically formulated "to minimize the sum of accident costs and the costs of accident avoidance." Id. at 1057 (citing Posner, A Theory of Negligence, 1 J. LEGAL STUD. 29 (1972)). Professor Henderson, with the same idea in mind, states that the question of design liability is resolved by answering the question: "What portion of society's limited resources are to be allocated to safety, thereby leaving less to be devoted to other social objectives?" Henderson, supra note 77, at 1540.
98. See note 3 and accompanying text supra. See, e.g., Schell v. AMF, Inc., 567 F.2d 1259, 1262-63 (3d Cir. 1977) (jury must balance trade-offs in adding a safety interlock that could have prevented plaintiff's injury from dough-making machine); Melia v. Ford Motor Co., 534 F.2d 795, 799 (8th Cir. 1976) (probability and gravity of harm when an auto door latch opens from collision must be weighed against cost of avoiding harm); Dorsey v. Yoder Co., 331 F. Supp. 753 (E.D. Pa. 1971), aff'd sub nom. Yoder Co. v. General Copper and Brass Co., 474
Dreisonstock v. Volkswagenwerk, A.G.,98 exemplifies the frustration courts encounter in subjectively determining a reasonable standard of safety.100 Dreisonstock involved injuries sustained when a rear-engined microbus travelling at forty miles per hour crashed head-on into a pole.101 In finding for the plaintiffs, the trial court had reasoned that a passenger compartment should be able to withstand a collision at that speed.102 The Court of Appeals for the Fourth Circuit reversed, querying: "Does ordinary care demand that the manufacturer provide against impacts at a speed of 40 miles per hour? Is this the 'reasonable risk' as it has been defined? And why '40 miles per hour' anyway?"103 In concluding that the crashworthiness of the microbus was legally sufficient, however, the appellate court was unable to articulate its reasons for so holding any better than the trial court was able to support its contrary result.104 As demonstrated by the Dreisonstock deci-

F.2d 1339 (3d Cir. 1973) (jury verdict for plaintiff proper where cost-benefit analysis of adding guard to metal slitter was utilized).

Professor Wade has delineated seven risk-utility balancing factors:

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.


99. 489 F.2d 1066 (4th Cir. 1974).
100. See also Owens v. Allis-Chalmers Corp., 83 Mich. App. 74, 82, 268 N.W.2d 291, 295 (1978). The Owens court remarked that "[w]e are no longer on the frontier of products liability litigation. The time has approached when we must begin to refine the role of the judiciary in such controversies with deference to its limitations. . . ." Id.
101. 489 F.2d at 1068.
102. Id. at 1075.
103. Id.
104. The appeals court termed the trial court's standard as "improper," referring to the comparison of the microbus to a more crashworthy ordinary front-engined passenger auto. Id. at 1076. Nonetheless, the court could suggest no better alternative standard. Conversely, in Seattle-First Nat'l Bank v. Volkswagen of Amer., Inc., 11 Wash. App. 929, 525 P.2d 286 (1974), a case concerning a similar microbus, but where the accident occurred at a speed of only 20 miles per hour, the court concluded that the design issue should be submitted to the jury. Id. at 935, 525 P.2d at 290.
sion, where a comparative norm of safety is absent, the subjective court-imposed standard is unavoidably arbitrary.\footnote{105}

The typical drug design defect case, unlike Brochu, would resemble these cases in which the lack of an objective standard is manifest. The physician is nearly always faced with a selection of drugs in which safety is but one of several variables considered in choosing the appropriate prescription.\footnote{106} In Fritz v. Parke Davis & Co.,\footnote{107} for example, a physician selected Dilantin, one of five drugs available, to treat epilepsy.\footnote{108} When the patient subsequently died from an adverse reaction to the drug, the plaintiffs brought suit against the manufacturer and physician claiming the Dilantin was unreasonably dangerous as designed, and that the physician was negligent in prescribing the drug.\footnote{109} The plaintiff's assertions were supported by expert testimony that two alternative drugs for treating epilepsy were preferable because they contained fewer side effects.\footnote{110} Other experts contradicted this

\footnote{105} See generally Henderson, supra note 77. Professor Henderson maintains that courts are incapable of responsibly adjudicating conscious product designs unless they rely upon extra-judicially established standards. \textit{Id.} at 1534. He concludes that such adjudication unavoidably results in arbitrary verdicts. \textit{Id.} at 1558.

Assuming the validity of the hypothesis that adjudication is unsuited to answering the question of "How much design safety is enough?," it follows that a broad-scale judicial commitment to the independent review of conscious design choices would bring with it a very real threat to the integrity of the judicial process. Confronted with the hopeless difficulties of trying to redesign products via adjudication, and presumably unable to resist the social pressures generally favoring injured plaintiffs, courts would inevitably resort to some form of judicial coin-flipping, \textit{i.e.}, they would begin to determine defendants' liability on some arbitrary basis rather than on the purported basis of the reasonableness of the product designs brought before them. Efforts to establish meaningful design standards would be abandoned in favor of allowing juries to determine defendants' liability upon no more substantial grounds than their own untutored "good judgment," or whim. The shift in the basis of manufacturers' liability would be disguised, consciously or otherwise, by heavy reliance upon the unsupported opinions of experts relating to the ultimate issue of the reasonableness of defendants' conscious design choices. The absence of any viable product safety standards with which to decide these cases, however, would be obvious even to the casual observer. In effect, the adjudicative process would largely become a sham. Although such tactics might render these cases manageable in the short run, they would do so at the cost of a serious erosion of confidence in the courts by those litigants who would correctly come to realize that they have been denied effective access to the adjudicative process by such subterfuge.

\textit{Id.} at 1558.

\footnote{106} A physician, of course, can be liable for selecting the wrong drug for treatment of an illness, \textit{e.g.}, Rotan v. Greenbaum, 273 F.2d 830 (D.C. Cir. 1959) (administered penicillin which was ineffective for treatment of mumps); or prescribing doses too large for the illness, \textit{e.g.}, Koury v. Follo, 272 N.C. 366, 758 S.E.2d 555 (1968) (administering an adult drug to a child).

\footnote{107} 277 Minn. 210, 152 N.W.2d 129 (1967).

\footnote{108} \textit{Id.} at 212, 152 N.W.2d at 130-31.

\footnote{109} \textit{Id.}

\footnote{110} \textit{Id.}
testimony, however, stating that they preferred Dilantin. The Minnesota Appellate Court affirmed the directed verdict for the manufacturer and the physician, holding that the widespread use of Dilantin by physicians conclusively established the reasonableness of its safety.

Significantly, according to modern products liability law the design issue in Fritz should have been submitted to the jury for resolution. Contrary to the Fritz holding, widespread usage does not establish the reasonableness of a design. Instead, a conflict in expert testimony, such as that in Fritz, creates a jury issue. In Huddell v. Levin, for example, although the court expressed skepticism of plaintiff's expert testimony that a headrest was defectively designed, it was held that the issue should be resolved by the trier of fact. In the court's view, because public policy requires liberal

111. Id.
112. Id. at 213, 152 N.W.2d at 131. If the drug manufacturer misleads the physician into prescribing a drug for an ailment when less dangerous drugs are available, the manufacturer may be liable. See Bristol-Myers v. Gonzalez, 548 S.W.2d 416 (Tex. Civ. App. 1977). In Gonzalez the manufacturer had indicated in the warnings that Kantrex could be used for irrigating wounds. Id. at 424. The warnings did not indicate, however, that the drug was not proper for continuous irrigation. Id. Relying on the manufacturer's recommendations, the physician used Kantrex for continuous irrigation in treating the patient's injury, and the patient subsequently suffered loss of hearing from the toxic effects of the drug. Id. at 422. Based on testimony that less toxic drugs were available for continuous treatment, the manufacturer was held liable for inadequately warning physicians. Id. at 424.


114. See, e.g., Schell v. AMF, Inc., 567 F.2d 1259, 1262-63 (3d Cir. 1977) (judge erred in directing a verdict for the manufacturer where conflicting testimony existed); Melia v. Ford Motor Co., 534 F.2d 795, 798-99 (8th Cir. 1976) (jury must resolve design issue from conflicting testimony); Spurlin v. General Motors Corp., 528 F.2d 612, 616-17 (5th Cir. 1976) (reasonable minds can draw differing conclusions from conflicting evidence); Nanda v. Ford Motor Co., 509 F.2d 213, 220 (7th Cir. 1974) (plaintiff demonstrates prima facie case where expert testifies as to unreasonableness of design); Self v. General Motors Corp., 42 Cal. App. 3d 1, 6, 116 Cal. Rptr. 575, 578 (1974) (conflict in expert testimony is sufficient to create a jury issue). But see Garst v. General Motors Corp., 207 Kan. 2, 484 P.2d 47 (1971). In Garst, the plaintiff argued that an improved steering system on an 80-ton earth-moving scraper could have provided sufficient maneuverability so that the accident that injured the plaintiff could have been avoided. Id. at 14, 484 P.2d at 56. The plaintiff's expert proposed three alternative designs. Id. The appellate court, doubting the feasibility of the alternatives, reversed the jury verdict for the plaintiff. Id. at 23, 484 P.2d at 62-63. The dissent admonished the majority for ignoring the rule that a conflict in expert testimony creates a jury issue. Id. at 24, 484 P.2d at 63-64 (Fatzer, J., dissenting).

115. 537 F.2d 726 (3d Cir. 1976).
116. Id. at 735-37.
treatment of an expert’s opinion, the jury must determine the credibility of expert testimony.117

Because Ortho did not challenge the evidentiary basis of the design defect claim,118 the Brochu court did not need to address the infirmities of this policy as applied to drugs. In any event, this policy would necessarily apply to drug design issues because there is no means of limiting its application.119 The liberal policy is the natural result of courts’ inability to articulate an objective standard by which to determine whether a design defect claim has sufficient merit to warrant submission to the jury.120

Applied to drugs, the potentially disastrous results of this liberal policy are apparent. Despite the advantages a drug may possess, if an available alternative exists that poses less risk of a particular injury, under a design defect theory the claim would warrant submission to the jury regardless of its merits.121 Absent any standard by which to judge the reasonableness of a

117. Id. at 737.
119. See Oresman v. G.D. Searle & Co., 388 F. Supp. 1175 (D.R.I. 1975). In Oresman, the trial court concluded, without discussion, that "there was sufficient evidence for the submission to the jury for its determination [on] the issue of whether defendant’s [oral contraceptives] were in a defective condition, unreasonably dangerous to the user or consumer. . . ." Id. at 1180-81. The court gave no indication of the nature of evidence that was "sufficient." It can be concluded that the evidence in Oresman was not similar to that proffered in Brochu regarding the extra risk posed by the 100 mcg. pill. The plaintiff in Oresman incurred her injury in 1968, before the Inman-Vessey Study suggested the link between dosage levels of estrogen and increased risk of stroke.

In any event, it is likely that the judge in Oresman was willing to extend the liberal policy to drugs. In an earlier opinion, the court ruled that res ipsa loquitur should apply so that negligence could be inferred from the fact that the injury resulted from the ingestion of the oral contraceptives. See Oresman v. G.D. Searle & Co., 321 F. Supp. 449, 454-55 (D.R.I. 1971) (denying summary judgment for defendant). Applying res ipsa loquitur to such a situation is strikingly similar to the imposition of absolute liability. Not surprisingly, the jury ultimately rendered a verdict of $500,000 for the plaintiff. See Oresman v. G.D. Searle & Co., 388 F. Supp. 1175, 1181 (D.R.I. 1975) (denying manufacturer’s request for judgment n.o.v.).

120. See note 105 supra. See also Search for Middle Ground, supra note 1, at 651. Professor Epstein concludes that by virtue of this policy, and by isolating the harm-causing feature of a product, nearly any product-related injury is actionable. Id. In addition, he contends that the more complicated a product, the more defects that can be invented. Id. Indeed, at least one court has affirmatively stated that to create a jury issue, the plaintiff need only demonstrate that the product proximately caused the injury. See Barker v. Lull Eng’r Co., 20 Cal. 3d 413, 431, 573 P.2d 443, 455, 143 Cal. Rptr. 225, 237 (1978). If the plaintiff can demonstrate proximate cause, the court held, the burden then shifts to the defendant to prove that the product is not defectively designed. Id.

121. A hypothetical example could involve an IUD. A woman whose IUD causes a pelvic infection (a side effect of the IUD) could correctly claim that the injury would not have occurred had she used an alternative method of birth control, such as an oral contraceptive. Although she was fully informed of risks of the IUD, a prima facie design case would be established with expert testimony stating that the IUD was unreasonably dangerous because safer substitutes were available. The defense would argue that the widespread use of the IUD is conclusive evidence as to the reasonableness of design. In accord with prevailing products liability doctrine, this defense would be rejected. See note 113 and accompanying text supra. Consequently, based on plaintiff’s expert testimony, the case should be submitted to the jury. See
drug's design, and in light of the financial burdens caused by drug injuries, it is probable that juries will arbitrarily afford recovery in many cases. Regardless of the conceptual soundness of inferring a risk/utility balancing test from Comment k, the practical effect is to accord drugs the same status as other products, thereby destroying the Comment k exception.

**THE POLICY ARGUMENTS**

Both courts and commentators recognize the problems that pervade subjective design litigation. They maintain, however, that despite the sometimes arbitrary results, there are overriding policy reasons that justify judicial scrutiny of product designs. One policy goal, enhanced product safety, is

notes 113-17 and accompanying text supra. The jury could conceivably render a verdict for the plaintiff, purportedly on the ground that an IUD is unreasonably dangerous. Yet many women prefer the IUD over other methods of contraception because of its convenience. See *Contraception: Comparing the Options*, 11 FDA CONSUMER, July-August, 7, 9 (1977).

122. The determining factor in many products liability cases may be sympathy for the plaintiff. See Strause & Hedden, *Liability for Product Design in Ohio—A First Step Toward Solution*, 11 AKRON L. REV. 663, 670 (1978). The authors attribute this to the lack of an objective standard. Id. Where the jury has no standard for determining the reasonableness of design, it may instead rely on the ability of the manufacturer to absorb the loss. See note 105 supra.

Another commentator ascribes the propensity to favor plaintiffs to the manner in which the trial is conducted. See Weinstein, Twerski, Piehler & Donaher, *Product Liability: An Interaction of Law and Technology*, 12 DUQ. L. REV. 425, 445 (1974) (focus of the trial on the injury-causing feature of the product creates a strong inference that the product is unreasonably dangerous). Moreover, these authors insist that "[i]f the only input the jury has provided for its consideration is two conflicting expert opinions without the supporting reasoning processes . . ., the jury is in no position to intelligently choose between them." Id. at 438. One commentator concludes that the modern standardless design litigation results in a "glorious" and "expensive game of chance." *Search for Middle Ground*, supra note 1, at 652. Perhaps the most pristine example of a jury finding a manufacturer liable in an improbable situation is Moran v. Faberge, Inc., 273 Md. 538, 332 A.2d 11 (1975) (failure to warn of cologne's flammability where plaintiff for fun poured cologne on a candle, causing the candle to flame up and scorch the girl's neck and breasts).

123. Oresman v. G.D. Searle & Co., 321 F. Supp. 449 (D.R.I. 1971) (denying summary judgment for the manufacturer), illustrates this result. In *Oresman*, the defendant contended that oral contraceptives are unavoidably unsafe products and are, therefore, protected by Comment k. The court ruled that it would reserve judgment on the matter until the trial progressed further. Id. at 457. Apparently, the court decided that the jury should determine the issues of whether the oral contraceptive was unavoidably unsafe and whether it was unreasonably dangerous. In subsequent case development, the same judge found that there was sufficient evidence to warrant the jury conclusion that the oral contraceptive was unreasonably dangerous. In so doing, the judge made no mention of Comment k. See Oresman v. G.D. Searle & Co., 388 F. Supp. 1175 (D.R.I. 1975) (denying manufacturer's request for judgment n.o.v.).

124. See, e.g., Self v. General Motors Corp., 42 Cal. App. 3d 1, 8, 116 Cal. Rptr. 575, 579 (1974) (design litigation may freeze product innovation but it is necessary to promote safe designs); *Use and Abuse of Warnings*, supra note 1, at 539-40 (after criticizing design litigation, authors conclude that there is no alternative to judicial review of conscious design choices if societal goals are to be met). In contrast, several courts have concluded that an objective standard, such as custom of the industry or government standards, must be employed to
furthered by increasing the potential liability of manufacturers. Moreover, even if liability is sometimes imposed capriciously, the manufacturer is in a better position than the individual to absorb the loss and spread the costs resulting from product-related injuries. These justifications undoubtedly apply with equal force to prescription drug products. The underlying presumption that compels courts to set safety standards, however, does not apply to prescription drugs.

Consumers, it is presumed, are often unable to adequately assess a product’s risks. This inability occurs when a product’s risks are hidden and reduce the subjectivity in design litigation. See, e.g., Owens v. Allis-Chalmers Corp., 83 Mich. App. 74, 81, 268 N.W.2d 291, 295 (1978); Temple v. Wean United, Inc., 50 Ohio St. 2d 317, 326-27, 364 N.E.2d 267, 273 (1977).


126. See Restatement, supra note 1, § 402A, Comment c (manufacturer is the proper party to afford protection and absorb risks). See also Greenman v. Yuba Power Prods., Inc., 59 Cal. 2d 57, 377 P.2d 897, 27 Cal. Rptr. 697 (1963). The Greenman court stated “[t]he purpose of such liability is to insure that the costs of injuries resulting from defective products are borne by the manufacturers that put such products on the market rather than by the injured persons who are powerless to protect themselves.” Id. at 63, 377 P.2d at 901, 27 Cal. Rptr. at 701. Accord, Price v. Shell Oil Co., 2 Cal. 3d 245, 251, 466 P.2d 722, 726, 85 Cal. Rptr. 178, 182 (1970) (manufacturers’ liability can spread risks throughout society).

This “deep pocket” rationale has been harshly condemned. See Unmasking the Test, supra note 1, at 643. The author argues that “[t]he time has come to ask candidly whether some courts, in their eagerness to provide recovery for injured plaintiffs, have not overzealously emphasized and relied upon the risk-spreading rationale of strict products liability. . . .” Id. An example of this “overzealous emphasis” is apparent in Dimond v. Caterpillar Tractor Co., 65 Cal. App. 3d 173, 183, 134 Cal. Rptr. 895, 902 (1976), where the court stated that “[t]o deny the plaintiff the benefit of the inference of proximate cause would frustrate that [loss-spreading] policy.” Professor Epstein recognized the limits of the court’s logic when he noted that “[o]ne might as well say that any judgment for the defendant frustrates that policy.” Search for Middle Ground, supra note 1, at 659-60.

127. See Woodill v. Parke Davis & Co., 79 Ill. 2d 26, 31, 402 N.E.2d 194, 196 (1980) (if strict product liability applies to food products and tractors, it certainly applies to drugs).

128. See Buchanan, In Defense of Caveat Emptor, 38 U. CHI. L. REV. 64, 71 (1970) (impetus for strict liability is inability of consumers to rationally judge quality of complex technological products and to compensate third parties); Henderson, supra note 77 at 1562-67 (“marketplace negotiation breakdown” accounts for entry of judiciary into safety standard-setting); Keeton, Products Liability—Inadequacy of Information, 48 TEX. L. REV. 398, 399 (1970) (“the underlying basis for the conclusion . . . that a product is defective and
warnings are impossible, impractical, or ineffective, as is typically the case with highly technological products. If it is impossible to warn of risks, thereby exposing unwitting consumers to a product's hidden dangers, the only way to ensure that the consumer can choose a reasonably safe product is to demand a safe design. Courts, therefore, intervene to establish product safety standards, albeit on a case-by-case basis.

Because prescription drugs are extremely complex products, they are often comprised of hidden dangers and uncertain benefits. It is precisely because of the vagaries of prescription drugs that the physician is positioned between the manufacturer and the consumer. The duty of the "learned intermediary" is to consciously weigh the therapeutic value of available alternatives against their potential side effects. Because the physician performs this risk assessment, the drug consumer is not helplessly exposed to product dangers. Accordingly, the justification for adjudicating product designs—consumers' inability to assess risks—is therefore inapplicable to prescription drug products.

unreasonably dangerous is the ignorance of the user about the dangerous characteristics of the product.

129. It is significant that the seminal case holding a manufacturer (other than food manufacturers, etc.) liable for implied warranty of merchantability was justified based on the inability of consumers to adequately assess complex modern products. See Henningsen v. Bloomfield Motors, Inc., 32 N.J. 358, 375, 161 A.2d 69, 78 (1960) (consumer cannot decide for himself whether autos are reasonably fit for the designed purpose). Similarly, in the seminal strict liability case, the court held that "[a] manufacturer is strictly liable in tort when an article he places on the market, knowing that it is to be used without inspection for defects, proves to have a defect that causes injury to a human being." Greenman v. Yuba Power Prods., Inc., 59 Cal. 2d 57, 62, 377 P.2d 897, 900, 27 Cal. Rptr. 697, 700 (1962) (emphasis supplied).

There are instances where the plaintiff could not know of the danger and it would be impossible to warn of the danger. See, e.g., Long v. Burdette Mfg. Co., 460 F.2d 448 (4th Cir. 1972) (plaintiff's heel cut on unnecessary sharp edge of bottom shelf of library cart); Passwaters v. General Motors Corp., 454 F.2d 1270 (8th Cir. 1972) (plaintiff passenger on motorcycle injured when her leg came into contact with unshielded metal flanges protruding from car manufactured by defendant).

130. One scholar explains that courts feel peculiarly compelled to adjudicate design safety of heavy industrial equipment, autos, and power lawn mowers. He estimates that these categories account for 80% of design defect cases, because in these cases injured parties are particularly unsuited to avoiding risks associated with those products. See Henderson, supra note 77 at 1565-66.

131. Reyes v. Wyeth Laboratories, 498 F.2d 1264, 1276 (5th Cir. 1974) ("[p]rescription drugs are likely to be complex medicines, esoteric in formula and varied in effect").

132. See note 24 supra.

133. Reyes v. Wyeth Laboratories, 498 F.2d 1264, 1276 (5th Cir. 1974); Wolfgruber v. Upjohn Co., 72 A.D.2d 59, 61, 423 N.Y.S.2d 95, 96 (1979). The Reyes court explained that it is precisely because prescription drugs are complex that the physician's presence is necessary. 498 F.2d at 1276. The physician's task is "weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative." Id.

134. Cf. RESTATEMENT, supra note 1, § 402A, Comment k. "[A] [drug] product . . . accompanied by proper directions and warning is not defective, nor is it unreasonably dangerous." Id. (emphasis in original).
Moreover, even without the advantage of the design defect theory, a drug consumer that is needlessly exposed to excessive dangers will not be left without a legal remedy. The physician is legally obligated to ensure that patients are shielded from unnecessary risks. The presence of the physician enables manufacturers to communicate remote or suspected risks. In short, if a risk is identifiable, a duty to warn arises. Thus, if the physician does not adequately assess the risks associated with a drug, it is either because he was negligent in performing his duty or because the manufacturer failed to inform him of the risks.

This dual rationale was illustrated in *Gaston v. Hunter*. In that case, the manufacturer had informed physicians of the experimental nature of a drug. When injury resulted from the administration of the drug, the patient sued the manufacturer, alleging that the drug was defectively designed and that the warnings issued were inadequate. Claiming that the drug was not suited to her condition, the plaintiff also contended that the physicians had negligently failed to follow the warnings regarding the type of patient

135. See note 137 and accompanying text infra.

136. See Krug v. Sterling Drug, Inc., 416 S.W.2d 143, 151 (Mo. 1967) (differentiating duty to warn for drugs from that required for cosmetics because physician's presence allows manufacturers to warn of idiosyncratic drug reactions to prescription drugs). See cases cited in note 22 supra.

137. See, e.g., Ohligschlager v. Proctor Community Hosp., 55 Ill. 2d 411, 418, 303 N.E.2d 392, 396 (1973) (physician's deviation from manufacturer's recommendations constitutes a prima facie case of negligence); Sanzari v. Rosenfeld, 34 N.J. 128, 143, 167 A.2d 625, 633 (1961) (dentist "who knows a drug is potentially harmful to a certain type of patient should take adequate precaution before . . . deciding whether to administer [the drug]"); Oppenheimer v. Sterling Drug, Inc., 7 Ohio App. 2d 103, 108-09, 219 N.E.2d 54, 58-59 (1964) (doctor who failed to read warnings that would have alerted him to side effects was negligent).

138. See notes 21-29 and accompanying text supra. Moreover, as Brochu illustrates, manufacturers have demonstrated a propensity for failing to warn of risks that render drugs unreasonably dangerous. See Brief for Appellee at 23-24, Brochu v. Ortho Pharmaceutical Corp., 642 F.2d 652 (1st Cir. 1981). The plaintiff alleged that Ortho withheld information of the increased risk from Novum 2 for fear that releasing it would dent sales. Id. See also Tinnerholm v. Parke Davis & Co., 285 F. Supp. 432, 452 (S.D.N.Y. 1968), modified, 411 F.2d 48 (2d Cir. 1969) (marketed drug without warnings although reports indicated substantially increased risks); Toole v. Richardson-Merrell Inc., 251 Cal. App. 2d 689, 695-96, 60 Cal. Rptr. 398, 404 (Dist. Ct. App. 1967) (failed to warn of various reactions despite massive test findings); Krug v. Sterling Drug, Inc., 416 S.W.2d 143, 148-49 (Mo. 1967) (failed to warn despite medical studies and doctor reports indicating drug could cause cataracts). Each of the above-cited cases was tried on the adequacy of warning issue as well as an alternative ground.

In discussing the relationship between the defective design and warnings issue, the court in Larsen v. General Motors Corps., remarked 391 F.2d 495 (8th Cir. 1968): "Admittedly, [the manufacturer] would not sell many cars of this particular model if its sales 'pitch' included the cautionary statement that the user is subjected to an extra hazard or unreasonable risk in the event of a head-on collision." Id. at 506.


140. Id. at 47, 588 P.2d at 340. Also, the plaintiff had signed a consent form stating that she was aware of the investigational nature of the drug. Id. at 38, 588 P.2d at 331.

141. Id. at 38, 588 P.2d at 331.
for whom the drug was appropriate. The court noted that if this contention was valid, the physicians would be liable, but the claim against the manufacturer would be barred. Alternatively, the court pointed out that if the warnings had been inadequate, the manufacturer would be held liable. Under either alternative, even if the drug administered was unreasonably dangerous, the plaintiff would have legal recourse without resorting to the design defect theory. Consequently, in prescription drug cases, the design defect theory adds no significant weapon to plaintiffs' legal arsenal.

CONCLUSION

By taking the stance that a drug manufacturer may be held strictly liable based upon a claim of defective drug design, regardless of the warnings, the Brochu decision purports to extend to plaintiffs an alternative ground of recovery. Although Brochu represents the first circuit court decision applying the design defect theory to prescription drugs, the court's inference of a risk/utility balancing test from Comment k is conceptually sound. The soundness of this reference reflects, however, that the facts in Brochu were peculiarly susceptible to the application of that rationale. In contrast to Brochu, the overwhelming majority of drug cases involve products for which there is no "norm" of safety. Applying the design defect theory to those cases would allow drug-related injuries to become presumptively actionable, and, in effect, would abolish the policy role of Comment k. Furthermore, because of the presence of the physician, the presumption that underlies design litigation—the inability of consumers to assess risks—does not apply to prescription drug products. Finally, the distinctive ability of prescription drug manufacturers to warn of risks renders adjudication of drug designs unnecessary. The prescription drug user who is subjected to unwarranted dangers will find an adequate ground of legal relief either through negligence of the physician, or through the manufacturer's failure to adequately warn. In short, if application of the design defect theory to drugs is unnecessary, and would engender largely arbitrary results, courts should forego attempts to scrutinize drug designs altogether.

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142. Id.
143. Id. at 45 n.9, 588 P.2d at 338 n.9.
144. Id. at 47, 588 P.2d at 340. In some situations, however, both the physician and the manufacturer may be liable. For example, in Incollingo v. Ewing, 444 Pa. 263, 282 A.2d 206 (1971), the physicians were held liable for indiscriminately prescribing a drug, and the manufacturer was held liable for its overpromotion of the drug that contributed to the physicians' carefree use of it. Id. at 282, 288-89, 282 A.2d at 217, 220.