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Unavoidably Unsafe Products and Strict Products Liability: What Liability Rule Should be Applied to the Sellers of Pharmaceutical Products?

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Table of Contents

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INTRODUCTION

Injuries from adverse drug reactions[1] have increased dramatically in recent years.[2] This increase is largely attributable to the changing nature of pharmaceutical products. First of all, more pharmaceutical products are currently available to physicians than ever in history. Presently, there are more than ten thousand prescription drugs on the market, and each year four hundred to five hundred new ones are introduced.[3] Second, modern drugs often

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[1] An adverse drug reaction is a harmful and undesirable response occurring at dosage levels ordinarily appropriate for their intended purpose. *See* Bennett & Lipman, *Comparative Study of Prospective Surveillance and Voluntary Reporting in Determining the Incidence of Adverse Drug Reaction*, 34 AM. J. HOSP. PHARM. 931 (1977); Note, *The Liability of Pharmaceutical Manufacturers for Unforeseen Adverse Drug Reactions*, 48 FORDHAM L. REV. 735 (1980).

[2] *See* Comment, *Drug Products Liability: Duty to Warn*, 49 U. PITT. L. REV. 283 (1987).

[3] *See* L. FRUMER & M. FRIEDMAN, PRODUCTS LIABILITY § 50.01[1], at 50-6 (1987).

are more potent than their older counterparts, thus increasing the likelihood of adverse reactions.[4]

It should come as no surprise that this rise in the number of drug-related injuries has led to a comparable increase in litigation.[5] Unfortunately, the courts seem unable to agree on a consistent set of liability rules to apply in drug injury cases. Sellers of defective pharmaceutical products[6] are theoretically subject to strict liability, just like other product sellers. However, in the case of pharmaceutical products, the principle of strict liability is qualified by a special rule for "unavoidably unsafe" products. According to this rule, which is derived from comment k to section 402A of the Restatement (Second) of Torts, sellers of unavoidably unsafe products are not held strictly liable to injured consumers as long as they warn the consumers of reasonably discoverable risks.[7]

Because comment k is unclear in many respects,[8] there is considerable disagreement about its nature and scope. For example, most courts have concluded that comment k essentially imposes a negligence standard on product sellers.[9] Nevertheless, a few courts seem to retain some vestiges of strict liability in comment k cases.[10]

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[4] *See* Irvey, *Validating Adverse Reaction Cases*, 1 J. LEGAL MED. 49 (Sept.-Oct. 1973).

[5] *See* Note, *An Escape from Strict Liability: Pharmaceutical Manufacturers' Responsibility for Drug-Related Injuries Under Comment K to Section 402A of the Restatement (Second) of Torts*, 23 DUQ. L. REV. 199 (1984).

[6] This Article uses the term "pharmaceutical products" to include chemical drugs, biologics such as blood or vaccines, and medical devices that are sold through prescription. Over-the-counter products are excluded from this definition, although many are produced by the same companies that manufacture prescription drugs.

[7] RESTATEMENT (SECOND) OF TORTS § 402A comment k (1979).

[8] Page, *Generic Product Risks: The Case Against Comment K and for Strict Tort Liability*, 58 N.Y.U.L. REV. 853, 866 (1983) ("Comment k . . . failed to delineate . . . either the breadth of its coverage or its purpose."); Comment, *Comment K Immunity to Strict Liability: Should All Prescription Drugs Be Protected?*, 26 HOUS. L. REV. 707, 721 (1989) (confusion in drug-related application stems from the conflict between comment k and the purposes underlying 402A).

[9] *See* Plummer v. Lederle Laboratories, 819 F.2d 349, 356 (2d Cir. 1987), *cert. denied*, 484 U.S. 898 (1987); Ferrigno v. Eli Lilly & Co., 420 A.2d 1305, 1318 (N.J. Super. 1980); Fischer, *Products Liability—The Meaning of Defect*, 39 Mo. L. REV. 339, 345-46 (1974); Mobilia, *Allergic Reactions to Prescription Drugs: A Proposal for Compensation*, 48 ALB. L. REV. 343, 345 (1983-84).

[10] Graham v. Wyeth Laboratories, 666 F. Supp. 1483, 1496 (D. Kan. 1987) ("[C]omment k . . . [does not stand] for the rule that all prescription drugs are unavoidably unsafe as a matter of law."); Kearl v. Lederle Laboratories, 218 Cal. Rptr. 453, 464-65 (1985) (discussing plaintiff's ability to prosecute her case under a strict liability theory); Toner v. Lederle Laboratories, 732 P.2d 297, 308 (Idaho 1987) ("We do not believe comment k was intended to provide nor should it provide all ethical drugs with blanket immunity from strict liability. . . ."); Johnson v. American Cyanamid Co., 718 P.2d 1318, 1323 (Kan. 1986), *aff'd*, 758 P.2d 206 (1988).

The courts also disagree about whether comment k applies to pharmaceutical products across the board or only on a case-by-case basis.[11]

The debate over comment k, however, is not limited to questions of interpretation. At a more basic level, it also involves a conflict over the proper liability standard to be imposed on sellers of pharmaceutical products. Critics of comment k argue that no group of product sellers should be subjected to a lesser standard of liability simply because of the products they sell.[12] In their view, consumers of pharmaceutical products should be entitled to the same legal protection as consumers of any other products.[13]

However, advocates of limited liability maintain that strict liability rules are best suited to mechanical products and cannot be applied willy-nilly to chemical or biological products, such as pharmaceuticals.[14] Proponents of comment k also contend that strict liability would have an undesirable adverse effect on the availability and price of pharmaceutical products.[15]

This Article discusses the role that comment k should play in the law of products liability. Part I reviews the fundamentals of strict products liability and examines the basic features of comment

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[11] Compare cases holding that the court should determine the applicability of comment k on an individual basis: Hill v. Searle Laboratories, 884 F.2d 1064, 1068-69 (8th Cir. 1989); Toner v. Lederle Laboratories, 779 F.2d 1429, 1433 (9th Cir. 1986); Feldman v. Lederle Laboratories, 479 A.2d 374, 383 (N.J. 1984); White v. Wyeth Laboratories, Inc., 533 N.E.2d 748, 752 (Ohio 1988) with cases holding that comment k applies to prescription drugs as a class: McElhaney v. Eli Lilly & Co., 575 F. Supp. 228, 230 (D.S.D. 1983); Fellows v. USV Pharmaceutical Corp., 502 F. Supp. 297, 300 (D. Md. 1980); Brown v. Superior Court, 751 P.2d 470, 482 n.11 (1988).

[12] *See* Note, *supra* note 5, at 218.

[13] Justice Traynor described the inadequacy of existing legal protection for consumers of health care products in the following words: "Thus ill health offers adventure; no one has a better chance to live dangerously than those who must take their medicine." *See* Traynor, *The Ways and Meanings of Defective Products and Strict Liability*, 32 TENN. L. REV. 363, 368 (1965).

[14] *See* Pratt & Parson, *Diagnosis of a Legal Headache: Liability for Unforeseeable Defects in Drugs*, 53 ST. JOHN'S L. REV. 517, 519-21 (1978-79) (discussing how pharmaceutical products differ from machines).

[15] *See* Comment, *The Diminishing Role of Negligence in Manufacturers' Liability for Unavoidably Unsafe Drugs and Cosmetics*, 9 ST. MARY'S L.J. 102, 110 (1977) (strict liability may discourage pharmaceutical companies from marketing new products); *see also* Epstein, *The Temporal Dimension in Tort Law*, 53 U. CHI. L. REV. 1175, 1204 (1986) (fear of excessive tort liability caused DTP vaccine manufacturers to withdraw their products from the market); Note, *supra* note 8, at 718 (fear of increased tort liability caused price of DTP vaccine to rise from 11 cents per dose in 1982 to $11.40 per dose in 1986, of which $8.00 was allocated to an insurance reserve).

k.[16] Part II identifies four types of product risks and discusses how each is treated under comment k's liability rules.[17] These risks include: (1) risks associated with the production process, (2) risks arising from a product's inherent nature or chemical composition, (3) risks created by particular design choices, and (4) scientifically unknowable risks.

Part III is concerned with the proper function of comment k in modern products liability law.[18] The first section compares the liability of pharmaceutical product sellers under both strict liability and comment k.[19] The next section reviews the various rationales that courts have relied upon to support the imposition of strict liability on product sellers.[20] This leads to the conclusion that strict liability is appropriate when consumers are harmed by production flaws and perhaps by product design, but not when their injuries are caused by some aspect of a product's inherent nature or chemical composition. The third section evaluates the merits of a hindsight rule in connection with the duty to warn.[21] The final section proposes a version of comment k that is consistent with the policies underlying strict products liability.[22]

I. OVERVIEW

A. Strict Products Liability

Strict liability, as codified in section 402A of the Restatement (Second) of Torts,[23] has now largely replaced negligence and im-

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[16] *See infra* notes 23-77 and accompanying text.
[17] *See infra* notes 78-186 and accompanying text.
[18] *See infra* notes 187-343 and accompanying text.
[19] *See infra* notes 191-217 and accompanying text.
[20] *See infra* notes 218-92 and accompanying text.
[21] *See infra* notes 293-328 and accompanying text.
[22] *See infra* notes 329-43 and accompanying text.
[23] Section 402A provides as follows:

(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.

plied warranty as the preferred theory of recovery against product sellers.[24] Under strict liability, the focus is on the product's condition, not the manufacturer's conduct.[25] Consequently, if a product is defective, an injured party can recover without showing that a manufacturer failed to exercise due care in the manufacture or design of the product.[26]

However, strict liability is not absolute liability,[27] nor does it require manufacturers to insure against all product-related injuries.[28] Section 402A requires that a product be "defective" for there to be liability.[29] This means that something must be "wrong"

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[24] The triumph of strict liability in tort over negligence and implied warranty in the law of products liability is recounted in Prosser, *The Fall of the Citadel (Strict Liability to the Consumer)*, 50 MINN. L. REV. 791 (1965-66).

[25] *See* Caterpillar Tractor Co. v. Beck, 593 P.2d 871, 883 (Alaska 1979); West v. Johnson & Johnson Prod., Inc., 220 Cal. Rptr. 437, 451 (Ct. App. 1985), *cert. denied*, 479 U.S. 824 (1986); Jackson v. Harsco Corp., 673 P.2d 363, 365 (Colo. 1983); Kerns v. Engelke, 390 N.E.2d 859, 862 (Ill. 1979); Phipps v. General Motors Corp., 363 A.2d 955, 958 (Md. 1976); Lenhardt v. Ford Motor Co., 683 P.2d 1097, 1099 (Wash. 1984).

[26] *See* Waterson v. General Motors Corp., 544 A.2d 357, 372 (N.J. 1988); Ulmer v. Ford Motor Co., 452 P.2d 729, 735 (Wash. 1965). *See generally* Albanese v. Emerson Elec. Co., 552 F. Supp. 694, 700 (D. Del. 1982).

[27] *See* Brown v. Sears, Roebuck & Co., 667 P.2d 750, 754 (Ariz. Ct. App. 1983) ("Strict liability . . . cannot be equated with absolute liability."); Vineyard v. Empire Mach. Co., Inc., 581 P.2d 1152, 1154 (Ariz. Ct. App. 1978) ("[S]trict liability is not synonymous with absolute liability."); Kaneko v. Hilo Coast Processing, 654 P.2d 343, 353 (Haw. 1982) ("Strict products liability was never intended to be absolute liability."); Prentis v. Yale Mfg. Co., 365 N.W.2d 176, 181 (Mich. 1984) ("[Courts] have never gone so far as to make sellers . . . absolutely liable for any and all injuries sustained from the use of those products."); Bellotte v. Zayre Corp., 352 A.2d 723, 724 (N.H. 1976) ("Sellers are not . . . subject to absolute liability."); Williamette Essential Oils, Inc. v. Herrold & Jensen Implement Co., 683 P.2d 1374, 1378 (Or. Ct. App. 1984) ("Strict liability is not absolute liability . . . ."); Shawver v. Roberts Corp., 280 N.E.2d 226, 231 (Wis. 1979) ("Strict liability does not . . . impose absolute liability.").

[28] *See* Gray v. Manitowac Co., Inc., 771 F.2d 866, 868-69 (5th Cir. 1985); Laney v. Coleman Co., Inc., 758 F.2d 1299, 1302 (8th Cir. 1985); Giordano v. Ford Motor Co., 299 S.E.2d 897, 899 (Ga. 1983); Coney v. J.L.G. Ind., Inc., 454 N.E.2d 197, 200 (Ill. 1983); Hunt v. Blasius, 384 N.E.2d 368, 372 (Ill. 1978); Suvada v. White Motor Co., 210 N.E.2d 182, 188 (Ill. 1965).

[29] Section 402A of the Restatement (Second) of Torts appears to require that a product be both defective *and* unreasonably dangerous for strict liability to apply. However, a growing number of courts now regard the "unreasonably dangerous" concept as unnecessary baggage and reject it as a requirement for strict liability. *See* M. SHAPO, THE LAW OF PRODUCTS LIABILITY ¶ 8.08 (1987); *see also* Butand v. Surburban Marine & Sporting Goods, Inc., 543 P.2d 209, 214 (Alaska 1975) ("[Requiring] plaintiff to prove that the product was unreasonably dangerous is burdensome and represents a step backward in this area."); Cronin v. J.B.E. Olson Corp., 501 P.2d 1153, 1161-62 (Cal. 1972) (requiring plaintiffs to prove that products are unreasonably dangerous burdens them "with proof of an element that rings of negligence."); Boudreau v. General Elect. Co., 625 P.2d 384, 389 (Haw. Ct. App. 1981); Suter v. San Angelo Foundry & Mach. Co., 406 A.2d 140, 153 (N.J. 1979);

with the product.[30] A manufacturing defect arises from some mishap in the production process,[31] while a design defect exists when the entire product line shares a common dangerous characteristic.[32] Additionally, strict liability may be imposed on a product seller who fails to provide adequate instructions or warnings.[33]

No single definition of defect can cover every type of dangerous condition in a product.[34] Therefore, most courts use several approaches depending on the circumstances involved. For example, under the "deviation from the norm" test,[35] a product that deviates from the manufacturer's intended design or that is inferior to products of the same description is considered defective.[36]

Another definition, known as the consumer expectation test, looks to the expectations of the ordinary consumer.[37] Under this

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Azzarello v. Black Bros. Co., 391 A.2d 1020, 1027 (Pa. 1978) ("[T]he term 'unreasonably dangerous' has no place in the instructions to a jury. . . ."); Berkebile v. Brantly Helicopter Corp., 337 A.2d 893, 899-900 (Pa. 1975) ("We hold today that the reasonable man standard in any form has no place in a strict liability case.").

[30] *See* Patterson v. Gesellschaft, 608 F. Supp. 1206, 1211 (N.D. Tex. 1985); *see also* Keeton, *Manufacturer's Liability: The Meaning of "Defect" in the Manufacture and Design of Products*, 20 SYRACUSE L. REV. 559, 566 (1968-69).

[31] *See* Birnbaum, *Unmasking the Test for Design: From Negligence [to Warranty] to Strict Liability to Negligence*, 33 VAND. L. REV. 593, 599 (1980) ("Manufacturing defects . . . may be evaluated against the manufacturer's own production standards, as manifested by other like products that roll off the assembly line."); Maynard & Crisci, *The Duty to Warn in "Toxic Tort" Litigation*, 33 CLEV. ST. L. REV. 69, 70 (1984-85).

[32] For a discussion of design defects, see Phillips, *A Synopsis of the Developing Law of Products Liability*, 28 DRAKE L. REV. 317, 345-47 (1978-79); Powers, *The Persistence of Fault in Products Liability*, 61 TEX. L. REV. 777, 782 (1982-83).

[33] *See* Wade, *On Product "Design Defects" and Their Actionability*, 33 VAND. L. REV. 551, 551-52 (1980).

[34] *See* Barker v. Lull Engineering Co., 573 P.2d 443, 453, (Cal. 1978); O'Brien v. Muskin Corp., 463 A.2d 298, 304 (N.J. 1983).

[35] *See* Jiminez v. Sears, Roebuck & Co., 4 Cal. 3d 379, 772, 482 P.2d 681, 684 (Cal. 1971); *see also Caterpillar Tractor Co.*, 593 P.2d at 881. The deviation from the norm test is derived from the implied warranty of merchantability. *See* UNIFORM COMMERCIAL CODE § 2-314(2)(d) ("Goods to be merchantable must be . . . of even kind, quality and quantity within each unit and among all units involved . . . .").

[36] For a discussion of the "deviation from the norm" test, see Traynor, *supra* note 13, at 367.

[37] *See* Boy v. ITT Grinnell Corp., 724 P.2d 612, 620 (Ariz. Ct. App. 1986); Dunham v. Vaughan & Bushnell Mfg. Co., 247 N.E.2d 401, 403 (Ill. 1969); Hancock v. Paccar, Inc., 283 N.W.2d 25, 37 (Neb. 1979); Kirkland v. General Motors Corp., 521 P.2d 1353, 1362-63 (Okla. 1974); Tinderman v. Fleetwood Homes, 684 P.2d 1302, 1305 (Wash. 1984); Estate of Ryder v. Kelly-Springfield Tire Co., 587 P.2d 160, 163-64 (Wash. 1978).

The consumer expectation test also is based on warranty principles. *See* Fischer, *supra* note 9, at 348; Wade, *On the Nature of Strict Torts Liability for Products*, 44 MISS. L.J. 825, 833-34 (1973).

approach, a product is defective if it is more dangerous than an ordinary consumer would expect it to be.[38] The consumer expectation test does not require a product to be risk-free;[39] rather, it is concerned with protecting buyers against unexpected product risks.[40]

A third definition of defect, often used in design defect cases, is concerned with the product's risks and benefits. This approach balances the risks and benefits of the product as designed with the risks and benefits of an alternative (and less risky) design proposed by the plaintiff. The product is considered defective if the overall utility of the alternative design exceeds that of the product's existing design.[41]

B. Comment K and "Unavoidably Unsafe" Products

Comment k is something of an anomaly in the law of products liability. It provides that strict liability will not apply to the sale of a product that is incapable of being made safe for its intended use as long as its utility outweighs its apparent risks and a proper warning is given.[42] Such products are characterized as "unavoid-

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[38] *See* RESTATEMENT (SECOND) OF TORTS § 402A comment i (1979).

[39] *See* Wade, *Strict Tort Liability of Manufacturers*, 19 Sw. L.J. 5, 16 (1965) ("Strict products liability clearly does not require a perfectly safe product.").

[40] *See* Dickerson, *Products Liability: How Good Does a Product Have to Be?*, 42 IND. L.J. 301, 306 (1966-67).

[41] *See Suter*, 406 A.2d at 150-51; *Barker*, 20 Cal. 3d at 429-30, 573 P.2d at 454; *Azzarello*, 391 A.2d at 1026; Wilson v. Piper Aircraft Corp., 577 P.2d 1322, 1326 (Or. 1978); Turner v. General Motors Corp., 584 S.W.2d 844, 851 (Tex. 1979); *see also* Henderson, *Renewed Judicial Controversy Over Defective Product Design: Toward the Preservation of an Emerging Consensus*, 63 MINN. L. REV. 773, 773-78 (1978-79).

[42] The RESTATEMENT (SECOND) OF TORTS § 402A comment k, declares:

> *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. 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 unavoidably high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such

ably unsafe." According to comment k, unavoidably unsafe products are neither defective nor unreasonably dangerous, even though they cause injury.[43]

Comment k does not define the term "unavoidably unsafe product," but instead gives a number of examples.[44] The first is the Pasteur vaccine, a product that provides protection against rabies, but occasionally causes harmful side effects.[45] The second category includes "drugs, vaccines, and the like" that are sufficiently dangerous that they can be sold only by prescription.[46] The third group consists of "new or experimental" drugs that are potentially dangerous because "lack of time and opportunity for sufficient medical experience" preclude the seller from providing any assurance of safety.[47]

Since all of the examples enumerated in comment k involve pharmaceutical products, one may reasonably conclude that the

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> experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

[43] *See* Mobilia, *supra* note 9, at 344; Note, *Mass Immunization Cases: Drug Manufacturers' Liability for Failure to Warn*, 29 VAND. L. REV. 235, 245 (1976).

[44] *See* Gershonowitz, *The Strict Liability Duty to Warn*, 44 WASH. & LEE L. REV. 71, 87 (1987) (proposing that comment k provides for a form of quasi strict liability).

[45] *See* Comment, *Torts—Strict Liability—A Hospital is Strictly Liable for Transfusions of Hepatitis*, 69 MICH. L. REV. 1172, 1182 (1971).

[46] Federal law requires that any medicine with toxic effects that render it unsafe for self-medication must be sold under prescription. See 21 U.S.C. § 353(b)(1)(B) (1982).

[47] This last example actually includes two distinct categories of drugs. "Experimental" drugs are products that are still undergoing clinical testing and are not available to the general public even under prescription. *See* Note, *supra* note 1, at 753-55 (discussion of FDA clinical testing procedures). These products have not really entered the stream of commerce, and it is questionable whether section 402A would apply to drug test subjects. Liability, if any, probably would be based on a theory of informed consent; this theory turns on whether the manufacturer or treating physician failed to provide test subjects with adequate information about potential risks.

The term "new drug," on the other hand, is a term of art used for regulatory purposes. At the time comment k was drafted, a new drug was defined by statute as one "not generally recognized as . . . safe." *See* Sindell v. Abbott Laboratories, 26 Cal. 3d 588, 607 P.2d 924, 931-32 (Cal. 1980). A new drug could be marketed only after a new drug application was submitted to the FDA and approved by that agency. Once the FDA determined that a product generally was recognized as safe, it would no longer classify it as a new drug. Other manufacturers could then market such products without submitting an application to the FDA. *Id.* Although federal regulations have changed significantly since the 1960's, the statutory definition of a new drug is the same as it was when comment k was first drafted in 1961. *See* 21 U.S.C. § 321(p)(1) (1982).

drafters intended to limit the scope of this provision to drugs, vaccines, and similar products.[48] Moreover, this interpretation is amply supported by existing case law. Most comment k cases have involved either chemical drugs,[49] antibiotics,[50] vaccines,[51]

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[48] *See* Schwartz, *Unavoidably Unsafe Products: Clarifying the Reasoning and Policy Behind Comment K*, 42 WASH. & LEE L. REV. 1139, 1141 (1985).

[49] *See* Swayze v. McNeil Laboratories, Inc., 807 F.2d 464, 468 (5th Cir. 1987) (Fentanyl); De Luryea v. Winthrop Laboratories, 697 F.2d 222, 229 (8th Cir. 1983) (Talwin); Brochu v. Ortho Pharmaceutical Corp., 642 F.2d 652, 656-57 (1st Cir. 1981) (oral contraceptive); Needham v. White Laboratories, Inc., 639 F.2d 384, 402 (7th Cir. 1981) (Denostrol); Lindsay v. Ortho Pharmaceutical Corp., 637 F.2d 87, 90 (2d Cir. 1980) (oral contraceptive); Basko v. Sterling Drug, Inc., 416 F.2d 417, 425 (2d Cir. 1969) (Chloroquine); Raynor v. Richardson-Merrell, Inc., 643 F. Supp. 238, 247 (D.D.C. 1986) (Bendectin); Ramirez v. Richardson-Merrell, Inc., 628 F. Supp. 85, 87 (E.D. Pa. 1986) (Bendectin); Muniz Nunez v. American Home Prod. Corp., 582 F. Supp. 459, 462 (D. P.R. 1984) (Inderal); Fellows v. USV Pharmaceutical Corp., 502 F. Supp. 297, 300 (D. Md. 1980) (Doriden); McElhaney v. Eli Lilly & Co., 575 F. Supp. 22, 23 (D.S.D. 1983), *aff'd*, 739 F.2d 340 (8th Cir. 1984) (DES); Yarrow v. Sterling Drug, Inc., 263 F. Supp. 159, 161-62 (D.S.D. 1967) (Chloroquinine); Brown v. Superior Court, 227 Cal. Rptr. 768, 774 (Ct. App. 1986), *aff'd*, 751 P.2d 470 (Cal. 1988) (DES); McCreery v. Eli Lilly & Co., 150 Cal. Rptr. 730, 736 (Ct. App. 1979) (DES); Carmichael v. Reitz, 95 Cal. Rptr. 381, 399-400 (Ct. App. 1971) (oral contraceptive); Toole v. Richardson-Merrell, Inc., 60 Cal. Rptr. 398, 412 (Ct. App. 1967) (Triparanol); Ortho Pharmaceutical Corp. v. Heath, 722 P.2d 410, 415-16 (Colo. 1986) (oral contraceptive); Hamilton v. Hardy, 549 P.2d 1099, 1107 (Colo. 1976) (oral contraceptive); Woodhill v. Parke Davis & Co., 402 N.E.2d 194, 199 (Ill. 1980) (Pitocin); Lawson v. G.D. Searle & Co., 356 N.E.2d 779, 782-83 (Ill. 1976) (oral contraceptive); Ortho Pharmaceutical Corp. v. Chapman, 388 N.E.2d 541, 545 (Ind. Ct. App. 1979) (oral contraceptive); Moore v. Vanderloo, 386 N.W.2d 108, 117 (Iowa 1986) (oral contraceptive); McDaniel v. McNeil Laboratories, Inc., 241 N.W.2d 822, 827 (Neb. 1976) (Innovar); Ferrigno v. Eli Lilly & Co., 420 A.2d 1305, 1319 (N.J. 1980) (DES); Davila v. Bodelson, 704 P.2d 1119, 1127-28 (N.M. App. 1985) (Pitocin); Seley v. G.D. Searle & Co., 423 N.E.2d 831, 836 (Ohio 1981) (oral contraceptive); Vaughn v. G.D. Searle & Co., 536 P.2d 1247, 1248 (Or. 1975) (oral contraceptive), *cert. denied*, 423 U.S. 1054 (1976); Cochran v. Brooke, 409 P.2d 904, 906-07 (Or. 1966) (Chloroquinine); Lewis v. Baker, 413 P.2d 400, 402-03 (Or. 1966) (Triparanol); Leibowitz v. Ortho Pharmaceutical Corp., 307 A.2d 449, 457 (Pa. Super. Ct. 1973) (oral contraceptive); Crocker v. Winthrop Laboratories, 514 S.W.2d 429, 432-33 (Tex. 1974) (Talwin); Chambers v. G.D. Searle & Co., 441 F. Supp. 377, 380-81 (D. Md. 1975), *aff'd*, 567 F.2d 269 (4th Cir. 1977) (oral contraceptive). *But see* Collins v. Eli Lilly & Co., 342 N.W.2d 37, 52 (Wis.), *cert. denied*, 469 U.S. 826 (1984) (comment k not applicable to DES).

[50] *See* Werner v. Upjohn Co., 628 F.2d 848, 858 (4th Cir.), *cert. denied*, 449 U.S. 1080 (1980) (cleocin); Dalke v. Upjohn Co., 555 F.2d 245, 247 (9th Cir. 1977) (tetracycline); Feldman v. Lederle Laboratories, 479 A.2d 374, 383 (N.J. 1984) (tetracycline); Wolfgruber v. Upjohn Co., 72 A.D.2d 59, 423 N.Y.S.2d 95, 97 (1979) (cleocin); Incollingo v. Ewing, 282 A.2d 206, 220 (Pa. 1971) (chloromycetin).

[51] *See* Plummer v. Lederle Laboratories, 819 F.2d 349, 356 (2d Cir. 1987) (oral polio vaccine); Petty v. United States, 740 F.2d 1428, 1439 (8th Cir. 1984) (swine flu vaccine); Unthank v. United States, 732 F.2d 1517, 1522 (10th Cir. 1984) (swine flu vaccine); Givens v. Lederle Laboratories, 556 F.2d 1341 (5th Cir. 1977) (oral polio vaccine); Reyes v. Wyeth Laboratories, 498 F.2d 1264, 1274 (5th Cir. 1974) (oral polio vaccine); Alman Brothers Farm & Feed Mill, Inc. v. Diamond Laboratories, Inc., 437 F.2d 1295, 1302 (5th Cir. 1971)

blood,[52] or medical devices.[53] Although it has been suggested that other products may also merit comment k protection,[54] the courts generally have refused to extend comment k to nonmedical products.[55]

(hog cholera vaccine); Davis v. Wyeth Laboratories, 399 F.2d 121, 128-29 (9th Cir. 1968) (oral polio vaccine); Williams v. Lederle Laboratories, 591 F. Supp. 381, 384 (S.D. Ohio 1984) (oral polio vaccine); Sheehan v. Pima County, 660 P.2d 486, 487 (Ariz. Ct. App. 1982) (oral polio vaccine); Kearl v. Lederle Laboratories, 218 Cal. Rptr. 453, 463 (Ct. App. 1985) (oral polio vaccine); Johnson v. American Cyanamid Co., 718 P.2d 1318, 1323 (Kan. 1986) (oral polio vaccine); Dunn v. Lederle Laboratories, 328 N.W.2d 576, 579 (Mich. Ct. App. 1982) (oral polio vaccine); White v. Wyeth Laboratories, Inc., 533 N.E.2d 748, 754 (Ohio 1988) (DTP vaccine); Cunningham v. Charles Pfizer & Co., Inc., 532 P.2d 1377, 1380 (Okla. 1974) (oral polio vaccine); Calabrese v. Trenton State College, 392 A.2d 600, 604 (N.J. Super. Ct. 1978), *aff'd*, 413 A.2d 315 (1980) (Pasteur rabies vaccine); Samuels v. American Cyanamid Co., 130 Misc. 2d 175, 495 N.Y.S.2d 1006, 1011 (1985) (tetanus-typhoid-cholera vaccine).

[52] *See* Belle Bonfils Memorial Blood Bank v. Hansen, 665 P.2d 118, 125-26 (Colo. 1983) (blood); McMichael v. American Red Cross, 532 S.W.2d 7, 9 (Ky. 1975) (blood); Moore v. Underwood Memorial Hosp., 371 A.2d 105, 107 (N.J. Super. Ct. 1977) (blood); Hines v. St. Joseph's Hosp., 527 P.2d 1075, 1076-77 (N.M. 1974) (blood).

[53] *See* Coursen v. A.H. Robins Co., Inc., 764 F.2d 1329, 1337 (9th Cir. 1985) (IUD); Brooks v. Medtronic, Inc., 750 F.2d 1227, 1230 (4th Cir. 1984) (cardiac pacemaker); Collins v. Ortho Pharmaceutical Corp., 231 Cal. Rptr. 396, 405-06 (1986) (IUD); Racer v. Utterman, 629 S.W.2d 387, 393 (Mo. Ct. App. 1981) (antibacterial surgical drape); Perfetti v. McGhan Medical, 662 P.2d 646, 649-50 (N.M. Ct. App.) (mammary prosthesis), *cert. denied*, 662 P.2d 645 (N.M. 1983); McKee v. Moore, 648 P.2d 21, 24 (Okla. 1982) (IUD); Terhune v. A.H. Robins Co., 577 P.2d 975, 977 (Wash. 1978) (IUD).

[54] *See* Phillips, *supra* note 32, at 357 (the unavoidably unsafe doctrine may be applied broadly to any socially useful product that cannot be made safe).

[55] *See* Blevins v. Cushman Motors, 551 S.W.2d 602, 608 (Mo. Ct. App. 1977) (golf carts not unavoidably unsafe because they can be made safe for their intended use); Netzel v. State Sand & Gravel Co., 186 N.W.2d 258, 264 (Wis. 1971) (ordinary concrete mix not unavoidably unsafe merely because it contained caustic ingredients); *see also* Filler v. Rayex Corp., 435 F.2d 336, 338 (7th Cir. 1970) (baseball sunglasses might be unavoidably unsafe, but manufacturer held liable anyway for failure to warn that glasses were not shatterproof); Wilkinson v. Bay Shore Lumber Co., 227 Cal. Rptr. 327, 332-33 (Ct. App. 1986) (lumber may be an unavoidably unsafe product but defendant failed to produce sufficient evidence of this at trial); Walker v. Stuffer Chem. Corp., 96 Cal. Rptr. 803, 606 (1971) (sulfuric acid is a useful and desirable product that cannot be made entirely safe for its intended use).

Some courts have acknowledged that comment k might be applicable, at least in theory, to asbestos products. *See* Jackson v. Johns-Manville Sales Corp., 727 F.2d 506, 516 (5th Cir. 1984) (asbestos products may qualify as unavoidably unsafe); Moran v. Johns-Manville Sales Corp., 691 F.2d 811, 814 (6th Cir. 1982) (asbestos products may qualify as unavoidably unsafe); Borel v. Fibreboard Paper Prod. Corp., 493 F.2d 1076, 1088 (5th Cir. 1973), *cert. denied*, 419 U.S. 869 (1974) (some commercial products in addition to drugs might be deemed unavoidably unsafe if they possess both unparalleled utility and unquestioned danger); Neal v. Carey Canadian Mines, Ltd., 548 F. Supp. 357, 372 (E.D. Pa. 1982) (asbestos products may qualify as unavoidably unsafe); Daniels v. Combustion Eng'g, Inc., 583 S.W.2d 768, 772 (Tenn. App. 1978) (asbestos products may qualify as unavoidably unsafe).

At the same time, most courts have refused to characterize every pharmaceutical product as unavoidably unsafe; instead, they have chosen to evaluate each pharmaceutical product on a case-by-case basis.[56] Theoretically, a product risk must be "unavoidable" for comment k to apply. This means that the risk must be inherent in the nature of the product and incapable of being eliminated by the application of existing technology. Additionally, the benefits of the product must outweigh its apparent risks.[57] There is a superficial resemblance between comment k's risk-utility analysis and the approach employed in product design cases. In comment k cases, however, courts apparently seldom engage in a careful in-depth analysis of a product's risks and benefits.[58] Instead, courts generally assume that the therapeutic benefits of drugs and vaccines outweigh the risks associated with their use. Furthermore, in contrast with the usual practice in product design cases, courts tend to treat the risk-utility issue in comment k cases as a matter of law rather than leaving it to the jury to decide.

Even if a product's utility outweighs its risks, the product seller also must warn about known risks and will be held strictly liable if it fails to do so.[59] Generally speaking, the scope of the duty to warn is the same for producers of unavoidably unsafe products as it is for other product sellers.[60] Essentially, this means that a

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[56] Most courts maintain that the applicability of comment k to pharmaceutical products must be decided on a case-by-case basis. *See, e.g.*, Hill v. Searle Laboratories, 884 F.2d 1064, 1068-69 (8th Cir. 1989); Toner for Toner v. Lederle Labs., 779 F.2d 1429, 1433 (9th Cir. 1986); Graham v. Wyeth Laboratories, 666 F. Supp. 1483, 1496 (D. Kan. 1987); Martinkovic v. Wyeth Laboratories, 669 F. Supp. 212, 216-17 (N.D. Ill. 1987); *Feldman*, 479 A.2d at 383; *White*, 533 N.E.2d at 752; Senn v. Merrell-Dow Pharmaceuticals, 751 P.2d 215, 218 n.4 (Or. 1988); Castrignano v. E.R. Squibb & Sons, 546 A.2d 775, 781 (R.I. 1988); *Collins*, 342 N.W.2d at 52.

A few courts, however, have concluded that prescription drugs as a class are covered by comment k. *See McElhaney*, 575 F. Supp. at 230; *Fellows*, 502 F. Supp. at 300; *Brown*, 751 P.2d at 482 n.11. Apparently, these courts feel that an independent assessment of risks and benefits by the court is unnecessary in the case of prescription drugs because the FDA evaluates risks and benefits of all drugs before allowing them to be marketed. *See Collins*, 231 Cal. Rptr. at 404.

[57] The risks and benefits are evaluated in terms of what was known at the time of marketing. *See* Schwartz, *supra* note 48, at 1144; Note, *supra* note 1, at 743.

[58] *See* Burke, *DPT Vaccine Controversy: An Assessment of the Liabilities of Manufacturers and Administering Physicians Under Several Legal Theories*, 17 SETON HALL L. REV. 541, 558 (1987).

[59] *See Brochu*, 642 F.2d at 658-59; *Reyes*, 498 F.2d at 1282; Singer v. Sterling Drug, Inc., 461 F.2d 288, 290-91 (7th Cir.), *cert. denied*, 409 U.S. 878 (1972); Parke-Davis & Co. v. Stromsodt, 411 F.2d 1390, 1401 (8th Cir. 1969); *Samuels*, 495 N.Y.S.2d at 1011.

[60] A number of courts in comment k cases have relied expressly on the provisions of

warning must be adequate with respect to factual content, expression, and method of communication.[61]

Adequacy in terms of content requires that a warning be factually accurate and complete.[62] A product seller must disclose all known risks[63] and reveal the specific nature and magnitude of these risks.[64] Many courts have required sellers to warn only when a "substantial" or "appreciable number" of consumers are potentially affected by the dangerous condition.[65] However, in the case of prescription drugs, the seller may be required to warn of a risk even though it affects only a very small proportion of product users.[66]

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comment j, which sets forth the general duty to warn under section 402A. *See Needham*, 639 F.2d at 402; *McElhaney*, 575 F. Supp. at 231-32; *Brown*, 227 Cal. Rptr. at 776; *Chapman*, 388 N.E.2d at 546.

[61] *See Brochu*, 642 F.2d at 657; *Graham*, 666 F. Supp. at 1498; Finn v. G.D. Searle & Co., 35 Cal. 3d 691, 677 P.2d 1147, 1182 (Cal. 1984); Bristol-Myers Co. v. Gonzales, 561 S.W.2d 801, 823-24 (Tex. 1978); Mahr v. G.D. Searle & Co., 390 N.E.2d 1214, 1230 (Ill. Ct. App. 1979); *Chapman*, 388 N.E.2d at 552; *Seley*, 423 N.E.2d at 837; McEwen v. Ortho Pharmaceutical Corp., 528 P.2d 522, 529 (Or. 1974).

[62] *See Brochu*, 642 F.2d at 658 (warning about risk of stroke from oral contraceptive pill held to be inadequate because it failed to mention results of recent British study); *Alman Bros.*, 437 F.2d at 1302-03 (failure to warn that hog cholera vaccine might cause cholera in healthy hogs); Rumsey v. Freeway Manor Minimax, 423 S.W.2d 387, 393 (Tex. Civ. App. 1968) (warning on roach poison inadequate because it failed to disclose that no antidote existed); *Racer*, 629 S.W.2d at 394 (failure to warn about flammability of surgical drape).

[63] *See* Boyl v. California Chem. Co., 221 F. Supp. 669, 673-75 (D. Or. 1963) (warning of danger of direct physical contact not sufficient to warn about danger from contact with earth upon which product had been spilled); Bean v. Ross Mfg. Co., 344 S.W.2d 18, 23-24 (Mo. 1961) (warning that caustic drain cleaner was poisonous not adequate to warn that blinding explosion might result if too much cleaner was poured down drain).

[64] *See* Ellis v. International Playtex, Inc., 745 F.2d 292, 306-07 (4th Cir. 1984) (tampon manufacturer held liable for failure to warn about risk of toxic shock syndrome); Reid v. Eckerd Drugs, Inc., 253 S.E.2d 344, 349-50 (N.C. Ct. App. 1979) (warning inadequate for failure to disclose flammability risk of deodorant); Torsiello v. Whitehall Laboratories, 398 A.2d 132, 140 (N.J. Super. 1979) (direction on aspirin product to discontinue use if pain persisted not sufficient to warn about risk of ulcer).

[65] *See* Merrill v. Beute Vues Corp., 235 F.2d 893, 897 (10th Cir. 1956); Mountain v. Proctor & Gamble Co., 312 F. Supp. 534, 537 (E.D. Wis. 1970); Skaggs v. Clairol, Inc., 85 Cal. Rptr. 584, 587 (Ct. App. 1970); Oakes v. Geigy Agricultural Chemicals, 77 Cal. Rptr. 709, 713-14 (Ct. App. 1969) (manufacturer of weed killer not liable unless it knew that substantial number of persons were allergic to product); Howard v. Avon Products, Inc., 395 P.2d 1007 (Colo. 1964); Bonkowski v. Revlon, Inc., 100 N.W.2d 5, 8 (Iowa 1959); Alberto-Culver Co. v. Morgan, 444 S.W.2d 770, 776 (Tex. Civ. App. 1969) (No liability for injuries caused by allergic reaction to hair dye because manufacturer could not foresee injury to "appreciable number" of product users.); Esborg v. Bailey Drug Co., 378 P.2d 298 (Wash. 1963).

[66] *See Parke-Davis & Co.*, 411 F.2d at 1400; *Davis*, 399 F.2d at 129-30; Tomer v. American Home Prod. Co., 368 A.2d 35, 40 (Conn. 1976); *Cunningham*, 532 P.2d at 1381; *McEwen*, 528 P.2d at 529-30.

The manner of expression also is relevant to the question of adequacy. A warning must be communicated in language that is clear and understandable.[67] For this reason, a warning couched in technical language will not be appropriate when the intended recipient is unlikely to comprehend its meaning.[68] A warning also must be displayed so that it is readily visible.[69] Additionally, a warning must be phrased with sufficient emphasis to ensure that potential users will exercise caution.[70] However, a "watered down" warning that minimizes dangers or contains misleading assurances of safety will be considered inadequate.[71]

Finally, the seller must ensure that its warnings will reach anyone who may be endangered by the product. Normally, this duty can be met only if the seller communicates a warning to the ultimate user of the product.[72] However, where prescription drugs are involved, warnings may be directed at the medical profession rather than the ultimate users of such products.[73] The rationale for this rule is that lay persons often require the assistance of medical personnel to interpret warnings and make informed decisions about the risks of drug therapy. In addition, manufacturers, who typically draft product warnings, would find it difficult to warn consumers directly because prescription drugs are not sold to the general

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[67] *See Seley*, 423 N.E.2d at 837.

[68] *See* MacDonald v. Ortho Pharmaceutical Corp., 475 N.E.2d 65, 71-72 (Mass. 1985) (reference to "cerebral thrombosis" not sufficient to warn users of oral contraceptive pills about the danger of a stroke); Haberly v. Reardon Co., 319 S.W.2d 859, 867 (Mo. 1958) (statement that product contained calcium oxide not sufficient to warn of risk of blindness).

[69] *See* Noel, *Products Defective Because of Inadequate Directions or Warnings*, 23 SW. L.J. 256, 284 (1969).

[70] *See* Note, *supra* note 43, at 254-55; Note, *Alternatives to Manufacturer Liability for Injuries Caused by the Sabin-Type Oral Polio Vaccines*, 28 WM. & MARY L. REV. 711, 725 (1986-87); Note, *Products Liability—Drug Manufacturers—An Absolute Duty to Warn Exists Notwithstanding Miniscule Statistical Probability of Harm*, 18 DE PAUL L. REV. 829, 835 (1968-69).

[71] *See* Maize v. Atlantic Refining Co., 41 A.2d 850, 853 (Pa. 1945) (Words "Safety Kleen" prominently displayed on all four sides of cleaning fluid container diluted effect of small print warning). In addition, the force of a warning may be weakened by other language on the product label. *See* La Plant v. E.I. Dupont de Nemours & Co., 346 S.W.2d 231 (Mo. Ct. App. 1961) (labeling on weed killer created the impression that it was not harmful to humans).

[72] *See* Sales, *The Duty to Warn and Instruct for Safe Use in Strict Tort Liability*, 13 ST. MARY'S L.J. 521, 566 (1981-82).

[73] *See* Britain, *Product Honesty Is the Best Policy: A Comparison of Doctors' and Manufacturers' Duty to Disclose Drug Risks and the Importance of Consumer Expectations in Determining Product Defect*, 79 NW. U.L. REV. 342, 375-76 (1984); Comment, *The National Childhood Vaccine Injury Act of 1986: A Solution to the Vaccine Liability Crisis?*, 63 WASH. L. REV. 149 (1988).

public.[74] Although this "learned intermediary" rule has been criticized[75] and occasionally rejected,[76] it generally is still applied to prescription drugs.[77]

II. COMMENT K'S LIABILITY REGIME

There are several distinct risks associated with pharmaceutical products. These include: (1) risks associated with the production process; (2) risks arising from the inherent nature of the product; (3) risks created by conscious design choices; and (4) scientifically unknowable risks. Although each of these categories is different, courts rarely make any distinctions among them as far as the application of comment k to drug-related injuries is concerned.

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[74] *See* Note, *supra* note 70, at 728. As one court declared:

> Ordinarily in the case of prescription drugs warning to the prescribing physician is sufficient. In such cases the choice involved is essentially a medical one involving an assessment of medical risks in the light of the physician's knowledge of his patient's needs and susceptibilities. Further it is difficult under such circumstances for the manufacturer, by label or direct communication, to reach the consumer with a warning. A warning to the medical profession is in such cases the only effective means by which a warning could help the patient.

Davis, 399 F.2d at 130; *see also* Dunkin v. Syntex Laboratories, Inc., 443 F. Supp. 121, 123 (W.D. Tenn. 1977).

[75] *See* Comment, *Pharmaceutical Manufacturers and Consumer-Directed Information—Enhancing the Safety of Prescription Drug Use*, 34 CATH. U. L. REV. 117, 138-50 (1984-85).

[76] The learned intermediary rule is most often rejected in the case of vaccines that are administered on a mass basis where no individual physician-patient relationship exists. *See Petty*, 740 F.2d at 1440 (swine flu vaccine); *Givens*, 556 F.2d at 1345 (Sabin oral polio vaccine); *Reyes*, 498 F.2d at 1277 (oral polio vaccine); *Graham*, 666 F. Supp. at 1498 (DPT vaccine).

Recently, however, a Massachusetts court in MacDonald v. Ortho Pharmaceutical Corp., 475 N.E.2d 65 (Mass. 1985), extended the exception to oral contraceptives. The *MacDonald* court concluded that an oral contraceptive manufacturer was required to warn individual consumers of product risks by means of package inserts. The court rejected the learned intermediary rule because it felt that the patient, rather than the physician, played the dominant role in making decisions about methods of birth control. *Id.* at 70.

[77] *See Swayze*, 807 F.2d at 470-71; *Brooks*, 750 F.2d at 1232 (cardiac pacemaker); Stanback v. Parke-Davis & Co., 657 F.2d 642, 647 (4th Cir. 1981) (influenza vaccine); Timm v. Upjohn Co., 624 F.2d 536, 538 (5th Cir. 1980), *cert. denied*, 449 U.S. 1112 (1980) (Cleocin antibiotic); Sterling Drug, Inc. v. Cornish, 370 F.2d 82, 85 (8th Cir. 1966) (Aralen); *Dunkin*, 443 F. Supp. at 123 (oral contraceptives); Love v. Wolf, 38 Cal. Rptr. 183, 192 (Ct. App. 1964) (Chloromycetin antibiotic); *McKee*, 648 P.2d at 25 (IUD); Cobb v. Syntex Laboratories, Inc., 444 So. 2d 203, 205 (La. Ct. App. 1983) (oral contraceptives); Hill v. E.R. Squibb & Sons, 592 P.2d 1383, 1387-88 (Mont. 1979) (synthetic cortisone); Niemiera v. Schneider, 555 A.2d 1112, 1117 (N.J. 1989) (DTP vaccine); Bacardi v. Holzman, 442 A.2d 617, 619 (N.J. Super. Ct. 1981) (Diamox to treat glaucoma); *Ferrigno*, 420 A.2d at 1321 (DES); *Terhune*, 577 P.2d at 979 (IUD).

A. Risks Associated with the Production Process

Ordinarily, product sellers are strictly liable for harm caused by mishaps in the production process even though they could not have discovered the condition or eliminated defective products by the exercise of due care.[78] Strict liability is imposed on product sellers, particularly manufacturers, because they are in a good position to control production flaws.[79] Additionally, because claims arising from manufacturing defects are relatively small in relation to the number of units produced,[80] product sellers can usually obtain insurance at a reasonable cost.[81]

Production flaws also occur in the pharmaceutical industry. One class of production flaw involves drugs that deviate from their accepted chemical formula. Since comment k requires that products be "properly prepared," it usually does not immunize against liability in such cases.[82] Product contamination is another type of production flaw. Although quality control standards are high in the pharmaceutical industry,[83] impure or contaminated drugs sometimes enter the market.[84] Although comment k shields sellers of

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[78] *See* Page, *supra* note 8, at 883.

[79] *See* Note, *Strict Liability in Hybrid Cases*, 32 STAN. L. REV. 391, 394 (1980); Note, The Medical Malpractice Citadel Still Stands, 11 CREIGHTON L. REV. 1357, 1359 (1978). According to another theory of liability, since the manufacturer controls product quality, the decision to distribute products knowing that some of them will be dangerous amounts to a "taking" of the physical well-being of those who are injured by defective products. Fairness considerations support a liability rule that requires the manufacturer to provide compensation. *See* Henderson, *Coping With the Time Dimension in Products Liability*, 69 CALIF. L. REV. 919, 936-37 (1981).

[80] *See* McClellan, *Strict Liability for Drug Induced Injuries: An Excursion Through the Maze of Products Liability, Negligence and Absolute Liability*, 25 WAYNE L. REV. 1, 30 (1978); Owen, *Rethinking the Policies of Strict Products Liability*, 33 VAND. L. REV. 681, 691-92 (1980); Schwartz, *The Uniform Product Liability Act—A Brief Overview*, 33 VAND. L. REV. 579, 585 (1980).

[81] *See* Page, *supra* note 8, at 885. Liability insurance costs for manufacturers vary according to the nature of the product. However, for the typical manufacturer, the cost of insurance is about one percent of sales. *See* Schwartz, *New Products, Old Products, Evolving Law, Retroactive Law*, 58 N.Y.U.L. REV. 796, 812 (1983).

[82] *See* Morris v. Parke-Davis & Co., 667 F. Supp. 1332, 1336 (C.D. Cal. 1987); Toner v. Lederle Laboratories, 732 P.2d 297, 305 (Idaho 1987).

[83] *See* Note, *supra* note 1, at 742. Not only do most drug companies have rigorous quality control standards, but these internal safeguards are supplemented by the efforts of the FDA, which closely monitors the manufacture of prescription drugs. *See* Federal Food, Drug & Cosmetic Act, 21 U.S.C. § 351(a)(2) (1984) (Requiring producers to use "current good manufacturing practice."); 21 U.S.C. § 374(a)(1) (authorizing the FDA to inspect factories to ensure that statutory standard is met); Comment, *Warnings and the Pharmaceutical Companies: Legal Status of the Package Insert*, 16 HOUSTON L. REV. 140, 143 (1978) (the entire industrial process of drug manufacture is closely regulated by the FDA).

[84] *See* Note, *supra* note 43, at 240.

"new and experimental drugs" from liability even when "purity of ingredients" cannot be assured,[85] it does not protect the purveyors of ordinary pharmaceutical products against liability when their products are contaminated.[86]

A more common risk arises from the failure to remove harmful byproducts from the finished product. This problem sometimes occurs in the manufacture of vaccines and other biologics.[87] For example, injuries can occur when substances used to culture vaccines are not completely removed from the finished product.[88] This condition is associated with the Pasteur vaccine, which is cultured in the brains of small laboratory animals such as rats, mice, and rabbits.[89] Serious harm to the recipient can occur if small particles of animal brain material are left in the vaccine.[90] In such cases, however, the courts have found the Pasteur vaccine to be unavoidably unsafe.[91]

Virulent organisms in vaccines also can cause serious injuries. Vaccines typically use killed or weakened disease-producing organisms to create a natural immunity in the recipient's body.[92] A vaccine, however, can cause the very disease it is supposed to prevent if these harmful organisms are not neutralized. This problem has arisen in connection with the production of both Sabin and Salk polio vaccines.[93]

The Salk vaccine uses dead polio virus organisms to induce the formation of antibodies in the recipient's body. Killed polio virus

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[85] *See* RESTATEMENT (SECOND) OF TORTS § 402A comment k, *supra* note 42.

[86] *See* Abbott Laboratories v. Lapp, 78 F.2d 170, 174 (7th Cir. 1935) (manufacturer held liable in negligence for allowing virulent bacteria to contaminate sterilized milk formula); David v. McKesson & Robbins, 253 A.D. 728, 300 N.Y.S. 635, 636 (1937) (manufacturer held liable in negligence for sodium fluoride in bicarbonate of soda), *aff'd*, 278 N.Y.S. 622, 16 N.E.2d 127 (1938); *see also* Note, *supra* note 8, at 736 (plaintiff can recover in strict liability if drug is adulterated).

[87] Biologics are products that are cultured from living organisms. *See* Note, *supra* note 43, at 235 n.2.

[88] This condition should be distinguished from serum sickness, which is not caused by a production flaw, but instead is an antigen-antibody reaction to the injection of foreign protein into the body. *See* Petty v. United States, 740 F.2d 1428, 1433 (8th Cir. 1984).

[89] *See* Comment, *supra* note 45, at 1182.

[90] *Id.*

[91] *See* Calabrese v. Trenton State College, 162 N.J. Super. 145, 392 A.2d 600, 604 (1978), *aff'd*, 82 N.J. 321, 413 A.2d 315 (1980).

[92] *See* Note, *Vaccine Related Injuries: Alternatives to the Tort Compensation System*, 30 ST. LOUIS U.L.J. 919, 920-21 (1986); *see also* Parke-Davis & Co. v. Stromsodt, 411 F.2d 1390, 1392-93 (8th Cir. 1969).

[93] *See* Franklin & Mais, *Tort Law and Mass Immunization Programs: Lessons from the Polio and Flu Episodes*, 65 CALIF. L. REV. 754, 765-66 (1977).

is incapable of causing disease, but can act as an antigen to stimulate the production of antibodies that will attack any live polio viruses entering the body.[94] However, in *Gottsdanker v. Cutter Laboratories*,[95] Cutter Laboratories, a manufacturer of Salk vaccine, failed to exclude live polio virus from some of its vaccine even though it relied on government approved safety tests to prevent this from happening.[96] As a result, a number of vaccine recipients contracted polio from the vaccine.[97] The defendant contended that liability should not be imposed because the vaccine was a "new" drug, and thus not subject to a strict liability rule. The court, however, rejected this argument and held in favor of the plaintiffs.[98]

The Sabin vaccine uses a weakened live virus that causes the recipient's immune system to produce antibodies that are effective against ordinary polio virus.[99] As the weakened strain reproduces itself in the intestinal tract of the recipient, however, it occasionally produces a form of virulent strain instead.[100] This can cause the recipient, or those who come into close contact with the recipient, to contract polio.[101] Perhaps because the dangerous condition arises after the vaccine leaves the manufacturer's control, the courts generally have refused to impose strict liability in such cases.[102]

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[94] *See* Note, *supra* note 43, at 237.

[95] 6 Cal. Rptr. 320 (Ct. App. 1960).

[96] *See* Note, *Strict Liability for Drug Manufacturers: Public Policy Misconceived*, 13 STAN. L. REV. 645, 647 (1961). The Salk process had been developed and tested using small batches of vaccine produced under laboratory conditions. The Salk inactivation process proved to be less reliable under mass production conditions and several manufacturers had difficulties with it. *See* Note, *The Cutter Polio Vaccine Incident: A Case Study of Manufacturers' Liability Without Fault in Tort and Warranty*, 65 YALE L.J. 262, 262 n.2 (1955).

[97] *See* Note, *supra* note 43, at 238.

[98] Gottsdanker v. Cutter Laboratories, 6 Cal. Rptr. 320, 326 (Ct. App. 1960).

[99] *See* Schwartz & Mahshigian, *National Childhood Vaccine Injury Act of 1986: An Ad Hoc Remedy or a Window for the Future?*, 48 OHIO ST. L.J. 387, 388 (1987).

[100] *Id.*

[101] Plummer v. Lederle Laboratories, 819 F.2d 349, 351 (2d Cir. 1987).

[102] *See Plummer*, 819 F.2d at 356; Givens v. Lederle Laboratories, 556 F.2d 1341, 1345 (5th Cir. 1977); Reyes v. Wyeth Laboratories, 498 F.2d 1264, 1274 (5th Cir. 1974), *cert. denied*, 418 U.S. 1096 (1974); Davis v. Wyeth Laboratories, 399 F.2d 121, 128-29 (9th Cir. 1968); Williams v. Lederle Laboratories, 591 F. Supp. 381, 384 (S.D. Ohio 1984); Sheehan v. Pima County, 660 P.2d 486, 487 (Ariz. Ct. App. 1982); Johnson v. American Cyanamid Co., 718 P.2d 1318, 1323 (Kan. 1986); Dunn v. Lederle Laboratories, 328 N.W.2d 576, 579 (Mich. 1982); Cunningham v. Charles Pfizer & Co., 532 P.2d 1377, 1380 (Okla. 1975).

Grinnell v. Charles Pfizer & Co., 79 Cal. Rptr. 369 (1969), represents an exception to this approach. The plaintiff contracted polio from the defendant's vaccine. The court held that the vaccine was defective because it contained virulent polio virus instead of the harmless variety, apparently assuming that the virulent strain was introduced into the vaccine during the production process rather than afterwards. *Id.* at 374.

Another type of production flaw involves failure to detect and remove serum hepatitis from blood.[103] Only one case, *Cunningham v. MacNeal Memorial Hospital*,[104] has refused to apply comment k to serum hepatitis contamination. The Illinois Supreme Court declared in *Cunningham* that blood contaminated with serum hepatitis could not be treated as an unavoidably unsafe product because it was impure.[105] However, the *Cunningham* court's interpretation of comment k was widely criticized because comment k expressly mentioned impure drugs as one class of potentially unavoidably unsafe product.[106] For this reason, most courts apply comment k to cases involving blood impurities.[107]

B. Risks Arising from the Inherent Nature of a Product

The chemical or biological components of drugs and vaccines can cause a variety of adverse effects on patients. Generally speaking, these adverse reactions are classified as either Type A or Type B reactions.[108] Type A reactions, such as side effects or extension effects, are exaggerated but otherwise normal reactions to pharmaceutical products. A side effect or secondary effect is one that differs from the drug's intended or primary effect. Side effects often occur when a drug has more than one pharmacological action. For example, dextroamphetamine, which is used to control appetite, also may elevate blood pressure or cause insomnia, restlessness, or tachycardia because it also stimulates the central nervous system.[109] When the pharmacodynamic effect produced by a

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[103] Blood may be contaminated by serum hepatitis, a virus that cannot be detected in the blood under present medical technology. *See* Comment, *Blood Transfusions and the Transmission of Serum Hepatitis: The Need for Statutory Reform*, 24 AM. U. L. REV. 367, 368 (1976). This condition differs from the vaccine cases because the contaminant exists in the donor's blood before the blood comes within the producer's control.

[104] 266 N.E.2d 897 (Ill. 1970).

[105] *Id.* at 904; *see also* McDaniel v. Baptist Memorial Hospital, 352 F. Supp. 690 (W.D. Tenn. 1971), *aff'd*, 469 F.2d 230 (6th Cir. 1972). The *McDaniel* court questioned the application of comment k to contaminated blood. Apparently, the court felt that comment k should cover only characteristics that are common or indigenous to the product. *Id.* at 695.

[106] *See* Hines v. St. Joseph's Hosp., 527 P.2d 1075, 1077 (N.M. 1974); Comment, *supra* note 103, at 403.

[107] *See* Belle Bonfils Memorial Blood Bank v. Hansen, 665 P.2d 118, 125-26 (Colo. 1983); McMichael v. American Red Cross, 532 S.W.2d 7, 9 (Ky. 1975); Moore v. Underwood Memorial Hosp., 371 A.2d 105, 107 (N.J. Super. Ct. 1977).

[108] *See* Note, *supra* note 1, at 736.

[109] *See* E. MARTIN, HAZARDS OF MEDICATION 323 (1971); L. FRUMER & M. FRIEDMAN, *supra* note 3, at § 50.01[6][d][ii], at 50-38. In addition, a particular pharmacologic mecha-

drug is greater than intended, the result is known as an extension effect.[110] For example, insulin, which is used to lower blood sugar levels, may sometimes produce severe hypoglycemia instead.[111]

On the other hand, Type B reactions are totally aberrant effects that are unrelated to a drug's normal pharmacology.[112] Many Type B reactions are allergic in nature. Ordinarily, when a foreign substance is introduced into the bloodstream, the body creates antibodies to combat it.[113] These antibodies combine with and neutralize the antigen; however, if the body's defense mechanism fails to operate effectively, "the body's equilibrium is upset, the antigen prevails, and there is an allergic response."[114]

In the few reported cases where this issue has arisen, courts generally have refused to impose liability on drug manufacturers for injuries caused by an adverse reaction to the drug's chemical ingredients. For example, in *Fellows v. USV Pharmaceutical Corp.*,[115] a case involving the soporific drug Doriden, the court declared that comment k would protect a manufacturer against side effects that were inherent in the chemical composition of the drug as long as a proper warning was given.[116]

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nism may affect parts of the body outside the intended treatment area. For example, the primary effect of an antibiotic is antimicrobial. However, when ingested, an antibiotic may irritate the mucosa of the gastrointestinal tract and thereby cause diarrhea as a side effect. *See* E. MARTIN, *supra* note 109, at 322-23 (1971).

[110] *See* L. FRUMER & M. FRIEDMAN, *supra* note 3, at § 50.01[6][d][iii], at 50-38.

[111] *See* E. MARTIN, *supra* note 109, at 323.

[112] *See* Note, *supra* note 1, at 738 n.15 (citing M. RAWLINS & J. THOMPSON, *Pathogenesis of Adverse Drug Reactions*, in TEXTBOOK OF ADVERSE DRUG REACTIONS (D. Davies ed. 1977)).

[113] *See* Note, *Legal Aspects of Allergy*, 5 VAND. L. REV. 212, 213 (1952).

[114] *See* Freedman, *Allergy and Products Liability Today*, 24 OHIO ST. L.J. 479, 479 (1963).

Almost all allergic reactions fall into one of four categories. In Type I reactions, the allergen reacts with antibodies attached to tissue cells. Type I reactions occur almost immediately when the body comes into contact with an allergen to which it has previously been sensitized. Many food allergies produce Type I reactions.

Type II reactions occur when the antibody reacts with antigen that has come to adhere to cells or tissues. This reaction produces toxins that damage cells. Adverse reactions from the transfusion of incompatible blood are examples of Type II reactions.

Type III reactions result from deposits of soluble circulating antigen-antibody complexes in tissue or vessels. Serum sickness is a form of Type III reaction.

Type IV reactions do not involve a direct antigen-antibody reaction. Instead, these reactions occur when sensitized lymphocytes (T cells) come into contact with antigen. The reaction may directly produce cell-destroying toxins or it may release lymphokines that cause injury. Contact dermatitis is an example of a Type IV reaction. *See* K. TRESTMAN & C. HOWES, *Allergies* in 3 ATTORNEY'S TEXTBOOK OF MEDICINE, ¶¶ 65.11-.14, 65.9 (Gray 3d ed. 1985).

[115] 502 F. Supp. 297 (D. Md. 1980).

[116] *Id.* at 300.

In another case, *Davila v. Bodelson*,[117] a labor-inducing drug, Pitocin, caused injury to the infant plaintiff during birth. The trial court gave an instruction on comment k and the jury found in favor of the defendant. On appeal, the *Davila* court affirmed the lower court's finding that the drug was unavoidably unsafe.[118] The appellate court expressly declared that the utility of Pitocin outweighed its known risks.[119]

Vaccines also may possess inherent characteristics that can cause the patient's immune system to react violently.[120] In *Schindler v. Lederle Laboratories*,[121] for example, the plaintiff contracted polio after being administered the Sabin oral polio vaccine. The plaintiff suffered from agammaglobulinemia, a congenital immune system deficiency. This condition affected the plaintiff's ability to resist viral or bacterial attack. Consequently, his immune system apparently succumbed to the weakened polio virus in the vaccine instead of producing antibodies against it.[122] The trial court directed a verdict in the manufacturer's favor and this was affirmed on appeal.[123] Although the appellate court did not expressly refer to comment k, it no doubt regarded idiosyncratic responses, such as occurred here, as essentially unavoidable.[124]

At least one court has found the diptheria-tetanus-pertussis (DTP) vaccine to be unavoidably unsafe because of the inherent risks associated with one of its components. The plaintiff in *White v. Wyeth Labs, Inc.*[125] suffered from encephalopathy[126] as a result

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[117] 704 P.2d 1119 (N.M. Ct. App. 1985).

[118] The court declared that Pitocin could cause the mother to have hypertonic contractions during labor. "Hypertonic contractions squeeze extremely hard and are too long in duration." *Id.* at 1128. Hypertonic contractions can injure an unborn child because they cut off blood supply to the mother's uterus. This interruption of the blood supply can cause a shortage of oxygen to the unborn child's brain, resulting in brain damage. *Id.*

[119] "Other evidence indicated that, despite the risk attending the use of Pitocin, Pitocin is a valuable and beneficial drug for the induction of labor. We conclude there was evidence supporting the giving of the instruction [on comment k.]" *Id.*

[120] *See* Comment, *supra* note 73, at 151; *see also* Toner v. Lederle Laboratories, 779 F.2d 1429, 1430 (9th Cir. 1986) (transverse myelitis); *Petty*, 740 F.2d at 1433 (serum sickness); Unthank v. United States, 732 F.2d 1517, 1519 (10th Cir. 1984) (transverse myelitis); Samuels v. American Cyanamid Co., 495 N.Y.S.2d 1006, 1009 (N.Y. 1985) (Guillain-Barre Syndrome).

[121] 725 F.2d 1036 (6th Cir. 1983).

[122] *Id.* at 1037.

[123] *Id.* at 1040.

[124] The court also concluded that the manufacturer had not breached its duty to warn. *Id.* at 1039-40.

[125] 533 N.E.2d 748 (Ohio 1988).

[126] The term "encephalopathy" is commonly used to describe various neurological

of receiving a DTP vaccine. The vaccine's pertussis component was made from whole Bordetella pertussis bacterium.[127] This bacterium contains two substances, endotoxin and pertussis toxin, that are suspected of having an adverse effect on the central nervous system.[128] The plaintiff contended that the manufacturer should not have used whole cell bacteria to produce its vaccine. The court, however, concluded that whole cell bacteria must be used because scientists had been unable to identify the specific antigens within the bacterium that must be included to produce an effective vaccine.[129] Consequently, the court found the whole cell DTP vaccine to be unavoidably unsafe and reversed a lower court judgment in favor of the plaintiff.[130]

C. Risks Created by Conscious Design Choices

Although some drug-related risks are unavoidable in the sense that they cannot be eliminated without changing the inherent nature of the product, other risks are at least partly within the product seller's control. These risks are analogous to product risks created by manufacturer design choices. Nevertheless, courts often employ comment k's risk-utility balancing approach in such cases rather than the more rigorous risk-utility analysis that is customarily utilized in product design cases.

Dosage levels are largely within a product seller's control. Therefore, one would expect courts to treat dosage cases like product design cases. However, some courts continue to apply comment k in cases where a product seller markets a product with more than one dosage level.

Brochu v. Ortho Pharmaceutical Corp.[131] represents the view that comment k is inapplicable to such products. In *Brochu*, the plaintiff claimed that high estrogen levels in the defendant's oral contraceptives caused her to suffer a stroke. The pills contained two milligrams of synthetic progestogen and 100 micrograms of synthetic estrogen. The plaintiff claimed that, at the time of her

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conditions such as encephalitis, Reyes syndrome, prolonged convulsions, acute infantile hemiplegia, and infantile spasms. *See* David & Jalilian-Marian, *DTP: Drug Manufacturers' Liability in Vaccine Related Injuries*, 7 J. LEGAL MED. 187, 197 (1986).

[127] White v. Wyeth Labs, Inc., 533 N.E.2d 748, 749 (Ohio 1988).

[128] *See* Note, *Tort Liability for DPT Vaccine Injury and the Preemption Doctrine*, 22 IND. L. REV. 655, 662 (1989).

[129] *White*, 533 N.E.2d at 749.

[130] *Id.* at 754.

[131] 642 F.2d 652 (1st Cir. 1981).

injury, the manufacturer was marketing oral contraceptives that were just as effective as the higher dosage pills, but much less risky. According to the plaintiff, the two milligram product was "defectively designed" since a safer but equally effective pill was available.[132] The trial court held in the plaintiff's favor.

On appeal, the court observed that "liability may attach if a manufacturer did not take available and reasonable steps to lessen or eliminate the danger of even a significantly useful and desirable product."[133] After reviewing the evidence, the federal appeals court upheld the lower court's finding that the two milligram contraceptive pill was defective.[134]

The plaintiff in *Ortho Pharmaceutical Corp. v. Heath*[135] also challenged a manufacturer's decision to market an oral contraceptive pill with high estrogen levels. The plaintiff's doctor prescribed Ortho-Novum 1/80 to prevent breakthrough bleeding, a condition that is uncomfortable but not health threatening.[136] The plaintiff claimed to have suffered massive kidney failure as a result of taking the higher dosage pills.[137] At trial, the plaintiff established that the defendant also manufactured Ortho-Novum 1/50, another oral contraceptive, which had a lower estrogen level than Ortho-Novum 1/80. Like the plaintiff in *Brochu*, Ms. Heath contended that Ortho-Novum 1/80 was defective because a safer but equally effective product, Ortho-Novum 1/50, was available.

The trial court refused to give an instruction on comment k, and the jury returned a verdict for the plaintiff. On appeal, the court held that comment k was applicable and reversed.[138] Nevertheless, the court acknowledged that a jury might reasonably conclude that Ortho-Novum 1/80 was not unavoidably unsafe. The court declared that the extra 30 micrograms of synthetic estrogen

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[132] *Id.* at 654.

[133] *Id.* at 655, quoting Thibault v. Sears, Roebuck & Co., 395 A.2d 843, 846 (N.H. 1978).

[134] *Id.* at 655. The court also held that the manufacturer failed to provide an adequate warning about the danger of a stroke. *Id.* at 659. However, the court made it clear that liability could be based on defective design alone. According to the *Brochu* court, "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 an adequate warning." *Id.* at 655.

[135] 722 P.2d 410 (Colo. 1986).

[136] *Id.* at 411.

[137] The plaintiff's condition is known as hemolytic uremic syndrome (HUS). *Id.* at 412.

[138] *Id.* at 415-16.

subjected users to risks that outweighed the benefits of the higher dosage product even though Ortho-Novum 1/80 was the only oral contraceptive on the market that would prevent breakthrough bleeding.[139]

Drug manufacturers also create risks when they combine several chemically distinct drugs into a single product. Examples of such drugs include Panalba, an antibiotic composed of tetracyline and novobiocine, and Bendectin, an antinausea drug composed of dicyclomine, an antispasmodic, doxylamin, an antihistamine, and pyridoxine.[140] Nevertheless, courts sometimes have treated such products as unavoidably unsafe even though the product seller played a significant role in creating the risk.

In *McDaniel v. McNeil Laboratories, Inc.*,[141] the plaintiff suffered a cardiac arrest and consequent brain damage after doctors administered Innovar, an anesthetic, during an operation. Innovar is a combination of fentanyl, a synthetic narcotic, and droperidol, a major tranquilizer. The plaintiff did not deny that a physician could properly administer either or both of these drugs to a patient during an operation. He contended, however, that the ratio of fentanyl to droperidol should be controlled by the anaesthesiologist on the spot, not by the pharmaceutical manufacturer.[142]

In the plaintiff's view, Innovar was defectively designed because the ratio of these drugs was fixed by the manufacturer and, therefore, could not be varied by doctors in accordance with the patient's individualized circumstances. The plaintiff contended that the manufacturer's decision to market Innovar in this fashion created an avoidable and unreasonable risk of injury to patients. The court, however, rejected this argument, relying instead on FDA approval of Innovar to conclude that the drug was unavoidably unsafe.[143]

Vaccine manufacturers also use the combination approach. *Parke-Davis & Co. v. Stomsodt*[144] is illustrative. The plaintiff in that case suffered brain damage as a result of being vaccinated with Quadrigen. Quadrigen is a combination of diptheria, tetanus, pertussis, and polio vaccines.[145] The addition of polio vaccine to

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[139] *Id.* at 414.
[140] See Note, *supra* note 5, at 216-17.
[141] 241 N.W.2d 822 (1976).
[142] *Id.* at 827.
[143] *Id.* at 828.
[144] 411 F.2d 1390 (8th Cir. 1969).
[145] *Id.* at 1391.

the more conventional combination of diptheria, tetanus, and pertussis vaccines (DTP) required the manufacturer to use Phemerol as a preservative instead of menthiolate, the preservative commonly used in DTP vaccine.[146] Unfortunately, Phemerol apparently affected the potency of the pertussis vaccine and this led to the plaintiff's injury.[147] The plaintiff alleged that the product was defective under a breach of warranty theory.[148] The jury apparently agreed that the risks of Phemerol outweighed the benefits of administering the vaccines together instead of separately.[149] A federal appeals court affirmed a lower court judgment for the plaintiff.[150]

Recently, a number of victims injured by the DTP vaccine have claimed that DTP vaccines are defectively designed because manufacturers have chosen to produce whole cell rather than split cell vaccines.[151] For example, the plaintiff in *MacGillivray v. Lederle Laboratories*[152] maintained that whole cell vaccine was riskier than split cell and acellular vaccines. In his complaint, the plaintiff alleged that use of the whole cell technique constituted a design defect because a safer alternative was possible.[153] The defendant moved to dismiss, arguing that FDA approval of the whole cell vaccine preempted common law claims based on state products liability law.[154] The court rejected the preemption claim, but failed to decide the design defect issue.[155]

The plaintiff in *White v. Wyeth Labs, Inc.*[156] also claimed that whole cell DTP vaccine was defectively designed because safer

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[146] *Id.* at 1393.

[147] *Id.*

[148] *Id.* at 1397.

[149] *Id.* at 1399.

[150] *Id.* at 1402. The court also concluded that the manufacturer's warning was inadequate. *Id.* at 1401.

[151] *See* Note, *Vaccine-Related Injury Actions: Federal Preemption Reconsidered*, 41 RUTGERS L. REV. 373, 378-79 (1988).

[152] 667 F. Supp. 743 (D.N.M. 1987).

[153] *Id.* at 744. The plaintiff in Toner v. Lederle Laboratories, 779 F.2d at 1430-31, made a similar argument.

[154] Manufacturers have raised the preemption defense in a number of DTP cases. Generally, they have been unsuccessful. *E.g.*, Abbott v. American Cyanamid Co., 844 F.2d 1108, 1113-14 (1988); Graham v. Wyeth Laboratories, 666 F. Supp. 1483, 1493-94 (D. Kan. 1987); Wack v. Lederle Laboratories, 666 F. Supp. 123, 128 (N.D. Ohio 1987); Martinkovic v. Wyeth Laboratories, Inc., 669 F. Supp. 212, 215 (N.D. Ill. 1987); Morris v. Parke-Davis & Co., 667 F. Supp. at 1340; White v. Wyeth Labs, Inc., 533 N.E.2d at 751. *Contra* Hurley v. Lederle Laboratories, 651 F. Supp. 993, 1007 (E.D. Tex. 1986) (allowance of failure to warn claim would destroy uniformity of FDA labeling regulations).

[155] MacGillivray v. Lederle Laboratories Division, American Cyanimid Co., 667 F. Supp. 743, 746 (1987).

[156] 533 N.E.2d 748.

alternatives, such as split cell and acellular vaccines, were technologically feasible to produce. The court in *White*, however, found no conclusive evidence to support the plaintiff's contention that these alternatives were actually safer. Therefore, it concluded that the whole cell vaccine was not defective.[157]

The courts have not limited comment k's protection to chemical drugs and vaccines; on occasion they have extended it to medical devices as well. For example, in *Coursen v. A.H. Robins Co., Inc.*,[158] the plaintiff claimed that the design of the Dalkon Shield IUD increased the risk of uterine infection. According to the plaintiff, the Dalkon Shield's fins had greater contact with the surface of the uterus than the fins of other IUDs, thereby increasing the chances of infection. The plaintiff also alleged that the defendant's use of multifilament line in the product's tailstring caused it to transmit bacteria from the vagina to the uterus more easily than the tailstrings of other IUDs.[159] Although the increased risk of infection was directly attributable to the IUD's design, the trial court instructed the jury on comment k instead of allowing the case to be tried on a design defect theory. Nevertheless, the jury concluded that the product was defective, even under the more relaxed risk-benefit standards of comment k.[160]

Even purely mechanical products have been characterized as unavoidably unsafe. For example, in *Brooks v. Medtronic, Inc.*,[161] the plaintiff was required to undergo a second operation after his cardiac pacemaker malfunctioned. The plaintiff claimed that the tines or prongs on the pacemaker's endocardial leads were too short to remain properly attached to the heart muscle.[162] The lower court, however, rejected this argument. On appeal, the court declared that comment k was applicable to the pacemaker even though it was entirely mechanical in nature.[163] At the same time, the court noted that the defendant had established at trial that the

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[157] *Id.* at 754.

[158] 764 F.2d 1329 (9th Cir. 1985).

[159] *Id.* at 1338.

[160] *Id.* at 1338-39. A number of courts have held that an IUD could qualify as an unavoidably unsafe product. *E.g.*, Collins v. Ortho Pharmaceutical Corp., 231 Cal. Rptr. 396, 405-06 (1986); McKee v. Moore, 648 P.2d 21, 24 (Okla. 1982); Terhune v. A.H. Robins Co., 577 P.2d 975, 977 (Wash. 1978).

[161] 750 F.2d 1227 (4th Cir. 1984).

[162] *Id.* at 1229. The cardiac pacemaker in question was made up of a pulse generator, an endocardial wire lead, and metal electrodes. The lead was run intervenously into the heart and attached to the heart tissue by the tines. *Id.* at 1229 n.1.

[163] *Id.* at 1230.

product's design conformed to the state of the art.[164] Although the court apparently felt that the pacemaker's risks were attributable to the product's design, it seems to have concluded that the risk of mechanical failure was unavoidable and was outweighed by the product's benefits.[165]

D. Scientifically Unknowable Risks

Drug manufacturers typically test their products on laboratory animals and human volunteers before marketing them to the general public.[166] However, some product risks cannot be discovered until the product has been on the market for some time.[167] Risks of this sort can be described as "scientifically unknowable" because product manufacturers cannot discover them prior to marketing by using existing scientific knowledge and technology. Most courts[168]

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[164] *Id.* at 1229 n.3.

[165] *See also* Racer v. Utterman, 629 S.W.2d 393, 394 (Mo. Ct. App. 1981) (flammable surgical drape found to be unavoidably unsafe but manufacturer held liable for failure to provide adequate warning); Perfetti v. McGhan Medical, 662 P.2d 646, 651 (N.M. Ct. App. 1983) (mammary prothesis that leaked saline solution apparently found to be unavoidably unsafe but manufacturer held liable for failure to provide adequate warning).

[166] First, chemical compounds are selected for laboratory study on the basis of molecular structure or relation to other compounds of known pharmacological characteristics. These compounds are then tried on small laboratory animals to determine pharmacological and pathological results. Also, a number of larger animals, usually dogs and monkeys, are used to determine the margin of safety (the difference between no effect and a lethal dose) for the drug. *See* Whitmore, *Allergies and Other Reactions Due to Drugs and Cosmetics*, 19 SW. L.J. 76, 77 (1965).

Next, the formula is tested on human subjects. Normally, there are three phases of human testing. First, preliminary trials are conducted on a small number of normal human subjects to determine human toxicity, metabolism, absorption, elimination, and other pharmacological reactions, as well as the preferred route of administration and safe dosage range. Then initial trials are conducted on a small number of patients for specific disease control or phrophylactic purposes. Finally, clinical trials are conducted on a large number of patients by different physicians, all of whom follow the same investigational procedures. This broad clinical trial permits the assessment of the drug's safety, effectiveness and optimum dosage schedules in the diagnosis, treatment or prophylaxis of a group of subjects with a given disease or condition. *See* Campbell, *Civil Liability for Investigational Drugs: Part I*, 42 TEMPLE L.Q. 99, 106-07 (1969). *See also* 21 CFR § 312.21 (1989).

[167] *See* Campbell, *supra* note 166, at 129.

[168] *See* Basko v. Sterling Drug, Inc., 416 F.2d 417, 426 (2d Cir. 1969) (manufacturer of chloroquinine not liable for failure to warn that product might impair vision); Chambers v. G.D. Searle & Co., 441 F. Supp. 377, 381 (D. Md. 1975), *aff'd*, 567 F.2d 269 (4th Cir. 1977) (manufacturer of oral contraceptives not liable for failure to warn about danger of stroke); McElhaney v. Eli Lilly & Co., 575 F. Supp. 228, 232 (D.S.D. 1983), *aff'd*, 739 F.2d 340 (8th Cir. 1984) (manufacturer of DES not liable for failure to warn about unforeseeable dangers); Brown v. Superior Court, 751 P.2d 470, 480 (Cal. 1988) (liability for failure to warn about unknown risks would be contrary to comment k); Woodhill v.

and commentators[169] agree that the duty to warn under comment k is limited to "scientifically knowable" risks.

Feldman v. Lederle Laboratories,[170] decided by the New Jersey Supreme Court in 1984, illustrates the reluctance of most courts to hold drug manufacturers liable for scientifically unknowable risks.[171] In *Feldman*, the plaintiff's teeth became discolored after she was treated with Declomycin, a tetracyline antibiotic drug.[172] The plaintiff sued the drug's manufacturer, claiming that it failed to provide an adequate warning about the risk of tooth discoloration. The defendant began to market Declomycin in 1959 and the plaintiff was first treated with the product in 1960. According to the defendant, the risk of tooth discoloration did not become known until 1962. The defendant claimed that it issued a warning as soon as it discovered the risk.[173]

The trial court held in favor of the defendant, and its decision was affirmed by the intermediate appellate court.[174] On appeal, the New Jersey Supreme Court declared that a hindsight test was inappropriate in comment k cases, endorsing instead the use of a "foresight" test.[175] Accordingly, the court ruled that the defendant

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Parke-Davis, 402 N.E.2d 194, 198 (Ill. 1980) (manufacturer of labor-inducing drug, Pitocin, not liable for failure to warn mother about risk of brain damage to unborn child); Ortho Pharmaceutical Corp. v. Chapman, 388 N.E.2d 541, 548 (Ind. App. 1979) (manufacturer of oral contraceptives not liable for failure to warn about risk of stroke); Cochran v. Brooke, 409 P.2d 904, 907 (Or. 1969) (manufacturer of chloroquinine not liable for failure to warn that product might impair vision); Gaston v. Hunter, 588 P.2d 326, 340 (Ariz. Ct. App. 1978) (manufacturer of experimental drug, chymopapain, not liable for subsequently discovered risk).

[169] *See* Schwartz, *Unavoidably Unsafe Products: Clarifying the Meaning and Policy Behind Comment K*, 42 WASH. & LEE L. REV. 1139, 1144 (1985); Comment, *Strict Liability for Prescription Drugs: Which Shall Govern—Comment K or Strict Liability Applicable to Ordinary Products?*, 16 GOLDEN GATE U. L. REV. 309, 324 (1986). *But see* Rheingold, *Products Liability—The Ethical Drug Manufacturer's Liability*, 18 RUTGERS L. REV. 947, 1017 (1964); Merrill, *Compensation for Prescription Drug Injuries*, 59 VA. L. REV. 1, 107 (1973).

[170] 479 A.2d 374 (1984).

[171] In 1982, the New Jersey Supreme Court in Beshada v. Johns-Manville Products Corporation, 447 A.2d 539, 549 (N.J. 1982), ruled that a manufacturer of asbestos insulation could be held strictly liable for failure to warn about the health risks of its products even if these risks were scientifically unknowable at the time the products were first marketed.

[172] Feldman v. Lederle Laboratories, 479 A.2d 374, 376 (N.J. 1984).

[173] *Id.* at 378-79.

[174] Feldman v. Lederle Laboratories, 450 A.2d 579 (1982). After the intermediate appellate court affirmed the trial court's decision, the plaintiff sought further review by the New Jersey Supreme Court. The New Jersey Supreme Court remanded the case back to the intermediate appellate court for reconsideration in light of *Beshada*. However, the intermediate appellate court reaffirmed its original decision in favor of the defendant.

[175] *Feldman*, 479 A.2d at 388.

would not be held strictly liable if it acted as a reasonably prudent manufacturer in discovering and warning about the risks associated with its products.[176]

Under the foresight test adopted in *Feldman* and followed in most other jurisdictions, product sellers are treated as experts in their field,[177] and existing scientific knowledge is imputed to them.[178] They must test their products prior to marketing in order to discover potential risks.[179] Furthermore, this duty is continuous;[180] sellers must keep abreast of scientific developments[181] and must search for previously undiscovered risks.[182] Warnings also must be timely,[183] and sellers must immediately warn of newly discovered risks or adverse reactions;[184] they cannot ignore reports of adverse reactions.[185] Furthermore, the product seller may be required to warn of a possible risk even before a causal connection has been definitely established.[186] However, product sellers who satisfy these

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[176] *Id.* at 386.

[177] *See Dunn*, 328 N.W.2d at 580; O'Hare v. Merck & Co., 381 F.2d 286, 291 (8th Cir. 1967); *Toner*, 732 P.2d at 307; Mahr v. G.D. Searle & Co., 390 N.E.2d 1214, 1231 (Ill. App. Ct. 1979); *Ortho Pharmaceutical Corp.*, 388 N.E.2d at 549; Krug v. Sterling Drug, Inc., 416 S.W.2d 143, 152 (Mo. 1967); McDaniel v. McNeil Labs, Inc., 241 N.W.2d 822, 830 (Neb. 1976); *Feldman*, 479 A.2d at 386; McEwen v. Ortho Pharmaceutical Corp., 528 P.2d 522, 528 (Or. 1974); Barson v. E.R. Squibb & Sons, Inc., 682 P.2d 832, 835 (Utah 1984).

[178] *See Barson*, 682 P.2d at 826; Dalke v. Upjohn Co., 555 F.2d 245, 248 (9th Cir. 1977).

[179] *See* Ferrigno v. Eli Lilly & Co., 420 A.2d 1305, 1320 (N.J. Super. Ct. 1980); Tinnerholm v. Parke-Davis & Co., 285 F. Supp. 432, 446 (S.D.N.Y. 1968); *Barson*, 682 P.2d at 836; Dayton v. Jiffee Chem. Corp., 395 F. Supp. 1081, 1090 (N.D. Ohio 1975).

[180] *See* Muilenberg v. Upjohn Co., 320 N.W.2d 358, 366 (Mich. App. 1982).

[181] *See* Lindsay v. Ortho Pharmaceutical Corp., 637 F.2d 87, 91 (2d Cir. 1980); Schenebeck v. Sterling Drug, Inc., 423 F.2d 919, 922 (8th Cir. 1970); O'Hare v. Merck & Co., 381 F.2d 286, 291 (8th Cir. 1967); *Graham*, 666 F. Supp. at 1498-99; *Krug*, 416 S.W.2d at 152; *Samuels*, 495 N.Y.S.2d at 1011; *Barson*, 682 P.2d at 835.

[182] *See* Borel v. Fibreboard Paper Products Corp., 493 F.2d 1076, 1089-90 (5th Cir. 1973); Noel, *Manufacturer's Negligent Design or Directions for Use of a Product*, 71 YALE L.J. 816, 853 (1962); Placitella & Darnell, *Beshada v. Johns-Manville Products Corp.: Evolution or Revolution in Strict Products Liability?*, 51 FORDHAM L. REV. 801, 805 (1983).

[183] *See Schenebeck*, 423 F.2d at 922; Mobilia, *Allergic Reactions to Prescription Drugs: A Proposal for Compensation*, 48 ALB. L. REV. 343, 360-62 (1984); Comment, *Unavoidably Unsafe Drugs and the Duty to Warn*, 29 ARK. L. REV. 71, 75 (1975).

[184] *See Schenebeck*, 423 F.2d at 922; Baker v. St. Agnes Hospital, 421 N.Y.S.2d 81, 85 (1979); Incollingo v. Ewing, 282 A.2d 206, 222 (Pa. 1971); *Barson*, 682 P.2d at 835.

[185] *See Schenebeck*, 423 F.2d at 922; *Ferrigno*, 420 A.2d at 1320.

[186] *See* McCue v. Norwich Pharmacal Co., 453 F.2d 1033 (1st Cir. 1972); Skill v. Martinez, 91 F.R.D. 498, 514 (D.N.J. 1981), *aff'd on other grounds*, 677 F.2d 368 (3d Cir. 1982); Hamilton v. Hardy, 549 P.2d 1099 (Colo. Ct. App. 1976); Mahr v. G.D. Searle & Co., 390 N.E.2d 1214, 1231 (Ill. App. Ct. 1979); Seley v. G.D. Searle, 423 N.E.2d 831, 837 (Ohio 1981).

conditions will not be held liable for the consequences of unknown risks.

E. Effect of Comment K on Producer Liability

Although comment k does not completely insulate sellers of pharmaceutical products from liability, in many instances it allows them to avoid responsibility for drug-related injuries. For example, comment k protects sellers against liability for injuries caused by dangerous byproducts that cannot be removed from a finished product. This allows product sellers to escape liability for harm caused by the presence of animal brain material in Pasteur rabies vaccine, virulent polio virus in Sabin polio vaccine, or serum hepatitis in transfused blood.

Comment k also protects sellers against liability for adverse drug reactions caused by inherent characteristics of chemical drugs or vaccines. If an adequate warning is provided, product sellers are not liable for a drug's known side effects, nor are they responsible for allergic reactions to pharmaceutical products.

Additionally, a number of courts refuse to impose liability on product sellers who voluntarily choose to increase the risk associated with their product. For example, comment k apparently applies to manufacturers that combine several separate chemical drugs or vaccines to create a single product even though this increases the risk of injury from the product. Moreover, some courts have applied comment k to injuries caused by medical devices, such as IUDs and cardiac pacemakers, even though injuries resulted from design choices by the product manufacturer.

Finally, comment k limits the duty to warn to risks that were scientifically knowable when the product was sold. Consequently, consumers often are unprotected against risks discovered after a drug has been introduced into the market.

III. IMPACT OF STRICT LIABILITY ON PHARMACEUTICAL PRODUCT SELLERS

Some commentators have suggested that comment k, by subjecting sellers of pharmaceutical products to a lesser standard of liability, gives them preferential treatment in comparison with other product sellers.[187] Implicit in this criticism is an assumption that

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[187] *See* Comment, *An Escape from Strict Liability: Pharmaceutical Manufacturers' Responsibility for Drug Related Injuries Under Comment K to Section 402A of the Restatement (Second) of Torts*, 23 DUQ. L. REV. 199, 215 (1984).

pharmaceutical product sellers should be subjected to the same liability standard as other product sellers. This portion of the Article considers whether comment k has any useful role to play in a strict liability regime. First, Part A discusses how strict liability will increase the liability of product sellers.[188] Next, Part B examines the policy bases of strict products liability.[189] Finally, Part C evaluates the concept of absolute liability and considers whether it is a viable alternative to strict liability in some cases.[190]

A. Strict Liability for Sellers of Pharmaceutical Products

A shift from comment k to strict liability would increase the liability exposure of pharmaceutical product sellers in every product risk category except scientifically unknowable risks.

1. *Risks Associated with the Production Process*

As mentioned earlier, comment k often insulates product sellers from liability for injuries caused by failure to remove harmful byproducts from the finished product. Conversely, sellers of pharmaceutical products would enjoy no such immunity under strict liability in states that apply the deviation-from-the-norm test to production flaws. Under this approach, individual units that deviate from the rest of the product line are considered defective.[191] If this test were applied to pharmaceuticals, then products such as vaccines or blood that contained harmful byproducts, or polio vaccine that contained virulent strains of polio virus, would be regarded as defective since they differ from uncontaminated products of the same description.[192]

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[188] *See infra* notes 191-217 and accompanying text.

[189] *See infra* notes 218-92 and accompanying text.

[190] *See infra* notes 293-328 and accompanying text.

[191] *See* Caterpillar Tractor Co. v. Beck, 593 P.2d 871, 881 (Alaska 1979); Jiminez v. Sears, Roebuck & Co., 482 P.2d 681, 684 (Cal. 1971); *see also* Traynor, *The Ways and Meanings of Defective Products and Strict Liability*, 32 TENN. L. REV. 363, 367 (1965).

[192] The consumer expectation test, discussed below, might also be applicable to harmful byproduct cases. This test is often used in cases where food is contaminated with byproducts of the production process. *See* Hochberg v. O'Donnell's Restaurant, Inc., 272 A.2d 846, 848-49 (D.C. Ct. App. 1971) (olive pit in martini olive); Zabner v. Howard Johnson's, Inc., 201 So. 2d 824, 826 (Fla. Ct. App. 1967) (walnut shell in maple nut ice cream); Bryer v. Rath Packing Co., 156 A.2d 442, 446 (Md. 1959) (chicken bone in chicken chow mein); Allen v. Grafton, 164 N.E.2d 167, 174 (Ohio 1960) (oyster shell in fried oysters); Williams v. Braum Ice Cream Stores, Inc., 534 P.2d 700, 702 (Okl. Ct. App. 1974) (cherry pit in cherry ice cream); Betehia v. Cape Cod Corp., 103 N.W.2d 64, 69 (Wis. 1960) (chicken

2. *Risks Arising from the Inherent Nature of a Product*

In the absence of comment k, liability might also be imposed on product sellers for injuries caused by risks that are attributable to a product's inherent chemical or biological character. Traditionally, courts have applied either the consumer expectation test or a risk-utility test in inherent risk cases. Under the consumer expectation test, a product is regarded as defective if it is more dangerous than the ordinary consumer would expect it to be.[193] The consumer expectation test does not require the manufacturer to produce a perfectly safe product, but it does protect against *unexpected* risks.[194] Therefore, products are not defective under the consumer expectation test simply because some inherent characteristic makes them dangerous to consumers; however, products must conform to accepted community norms of safety in order for product sellers to avoid liability.

Comment i to section 402A of the Restatement (Second) of Torts illustrates the distinction between known and unknown risks.[195]

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bone in chicken sandwich).

However, unlike common processed food products, consumers are often unfamiliar with pharmaceutical products and have little knowledge about the risks associated with the production process. Thus, while consumers may expect to find a cherry pit in cherry pie, they almost certainly would not expect to find a virulent strain of polio virus in a polio vaccine. *See* Dickerson, *Products Liability: How Good Does a Product Have to Be?*, 42 IND. L.J. 301, 305 (1967), which suggests that drug manufacturers might be held strictly liable under the consumer expectation test for injuries resulting from the existence of harmful byproducts in biologics.

[193] *See* Boy v. ITT Grinnell Corp., 724 P.2d 612, 620 (Ariz. Ct. App. 1986); Dunham v. Vaughan & Bushnell Mfg. Co., 247 N.E.2d 401, 403 (Ill. 1969); Hancock v. Paccar, Inc., 283 N.W.2d 25, 37 (Neb. 1979); Kirkland v. Gen. Motors Corp., 521 P.2d 1353, 1362-63 (Okla. 1974); Tinderman v. Fleetwood Homes, 684 P.2d 1302, 1305 (Wash. 1984); Estate of Ryder v. Kelly-Springfield Tire Co., 587 P.2d 160, 163-64 (Wash. 1978).

[194] *See* Wade, *Strict Tort Liability of Manufacturers*, 19 Sw. L.J. 5, 16 (1965).

[195] *See* RESTATEMENT (SECOND) OF TORTS § 402A comment i (1979). Comment i declares:

> The rule stated in this Section applies only where the defective condition of the product makes it unreasonably dangerous to the user or consumer. Many products cannot possibly be made entirely safe for all consumption, and any food or drug necessarily involves some risk of harm, if only from overconsumption. Ordinary sugar is a deadly poison to diabetics, and castor oil found use under Mussolini as an instrument of torture. That is not what is meant by "unreasonably dangerous" in this Section. The article sold must be dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics. Good whiskey is not unreasonably dangerous merely because it will make some people drunk, and is especially dangerous to alcoholics; but bad whiskey, containing a dangerous amount of fusel oil, is unreasonably dangerous. Good tobacco is not unreasonably dan-

Comment i mentions "good" butter, whiskey, and tobacco as examples of products that are potentially harmful, but not defective, under the consumer expectation test. These products are considered defective only if they create a different risk from the risk consumers would expect to encounter when they use the product.[196] Arguably, uncontaminated and properly formulated pharmaceutical products are analogous to "good" butter, whiskey, and tobacco and, therefore, should not be regarded as defective when inherent characteristics cause injury to consumers.

On the other hand, one may contend that comment i reflects the notion that product sellers are not liable for risks that are widely known and understood by the general population because consumers voluntarily "assume" these risks when using the product.[197] However, consumers are unlikely to be as familiar with the inherent risks associated with pharmaceutical products as they are with the risks associated with ordinary consumer goods.[198] Absent such knowledge, consumers are likely to assume that pharmaceutical products are generally safe.[199] If this assumption is correct, sellers of pharmaceutical products may not avoid responsibility for risks that are not matters of common knowledge in jurisdictions that follow the consumer expectation test of comment i in inherent risk situations.

Some courts have proposed that, in inherent risk cases, the risk-utility test, normally associated with product design cases, be

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> gerous merely because the effects of smoking may be harmful; but tobacco containing something like marijuana may be unreasonably dangerous. Good butter is not unreasonably dangerous merely because, if such is the case, it deposits cholesterol in the arteries and leads to heart attacks; but bad butter, contaminated with poisonous fish oil, is unreasonably dangerous.

Id.

[196] Thus, whiskey contaminated with a dangerous amount of fusel oil, tobacco contaminated with marijuana, or butter contaminated with poisonous fish oil all would be considered defective under this principle. *See id.*

[197] *See* Wade, *On the Nature of Strict Tort Liability for Products*, 44 MISS. L.J. 825, 843 (1973).

[198] *See* Dickerson, *supra* note 192, at 307.

[199] *See* Fischer, *Products Liability—The Meaning of Defect*, 39 MO. L. REV. 339, 350 (1974); Rheingold, *What Are the Consumer's "Reasonable Expectations"?*, 22 BUS. LAW. 589, 595 (1967). Perhaps the consumer expectation test could be qualified by imputing to consumers knowledge of all risks disclosed in product warnings. To be sure, warnings are normally communicated to physicians rather than to consumers, but physicians are expected to inform their patients of any risks known to them. *See* Tietz, *Informed Consent in the Prescription Drug Context: The Special Case*, 61 WASH. L. REV. 367, 370-71 (1986); Comment, *Drug Product Liability: Duty to Warn*, 49 U. PITT. L. REV. 283, 291-94 (1987). Another way to limit the liability of product sellers would be to focus on the expectations of physicians and other health care experts rather than those of consumers.

used instead of comment k.[200] In design defect cases, the court determines by considering various factors whether an alternative design should have been employed. These factors include: (1) the likelihood that the product would cause harm; (2) the seriousness of that harm; (3) the technological feasibility of using an alternative design; (4) the relative costs of producing and marketing an alternatively designed product; and (5) any new or increased risks that may result from the alternative design.[201]

The risk-utility test used in product design cases, however, does not seem to be well-suited to inherent risk cases. In a design defect case, the court or the jury can compare the product as designed with an alternative design for the same product and thereby reach (in theory) a principled decision. However, in an inherent risk case, there is seldom any obvious alternative with which to compare the product. Either the jury must evaluate the product's social risks and benefits in a vacuum or it must compare the product's risks and benefits with those of an entirely different product. The latter approach almost certainly would lead to inconsistent results. For example, if an oral contraceptive user suffers a stroke, a jury might decide that IUDs or diaphragms are superior to oral contraceptives as a means of birth control; but if the victim is injured by an IUD, the jury might just as easily conclude that oral contraceptives are better.[202]

3. *Risks Created by Manufacturer Design Choices*

Risks in pharmaceutical products that result from manufacturer choice strongly resemble design risks in ordinary products. Consequently, in the absence of comment k, courts probably would subject pharmaceutical products to the same risk-utility balancing

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[200] *See* Toner v. Lederle Laboratories, 779 F.2d 1429 (9th Cir. 1986); Brochu v. Ortho Pharmaceutical Corp., 642 F.2d 655 (1st Cir. 1981); Brown v. Superior Court, 245 Cal. Rptr. 412, 751 P.2d 470, 477-78 (Cal. 1988); Murphy v. E.R. Squibb & Sons, 710 P.2d 247, 262 (Cal. 1985); Finn v. G.D. Searle & Co., 677 P.2d 1147, 1167 (Cal. 1984).

[201] *See* Uniform Product Liability Act § 104(B), 44 C.F.R. 60,714-21 (1979).

[202] *Compare* Note, *The Intrauterine Device: A Criterion of Governmental Complaisance and an Analysis of Manufacturer and Physician Liability*, 24 CLEV. ST. L. REV. 247, 292 (1975) (risks of IUD may outweigh utility since other methods of birth control are available) *with* Note, *Liability of Birth Control Pill Manufacturers*, 23 HASTINGS L.J. 1526, 1545 (1972) (birth control pills should not be considered unavoidably unsafe since other methods of birth control are available).

test that is used in ordinary product design cases.[203] Under this approach, the court or jury determines whether the risks and benefits of the product as designed outweigh the risks and benefits of an alternative design proposed by the plaintiff.[204]

Comment k also uses a risk-utility approach. In theory, therefore, it should not matter which test is used in drug design cases since either test should lead to the same result. However, there are some significant differences in the way these two risk-utility tests operate in practice.[205] Sellers of pharmaceutical products are more likely to be held liable under a product design risk-utility standard than under the approach typically applied by the courts under comment k.

First, the risk-utility analysis tends to be somewhat perfunctory in comment k cases.[206] For example, the courts often find a product to be socially useful as a matter of law rather than leaving the matter up to the jury. In contrast, in product design cases, risks and benefits are examined more thoroughly by the court, and the design defect issue usually is decided by the jury.[207] Moreover, courts in comment k cases rarely make any explicit comparisons between the product in question and possible alternatives. In conventional product design cases, however, the product as designed is explicitly compared with an alternative (safer) design suggested by the plaintiff.

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[203] A few courts continue to use the consumer expectation test in design defect cases. *E.g.*, Barker v. Lull Engineering Co., 573 P.2d 443, 454 (Cal. 1978) (alternative test); Young v. Tide Craft, Inc., 242 S.E.2d 671, 680 (S.C. 1978); Vincer v. Esther Williams All-Aluminum Swimming Pool Co., 230 N.W.2d 794, 798-99 (Wis. 1975).

Another approach is the prudent manufacturer test. Under this alternative, the jury is asked to determine whether a prudent manufacturer, with knowledge of the product's dangerous characteristics, would place it into the stream of commerce. *See* Nicholas v. Union Underwear Co., 602 S.W.2d 429, 433 (Ky. 1980); Phillips v. Kimwood Machine Co., 525 P.2d 1033, 1037 (Or. 1974); Birmbaum, *Unmasking the Test for Design Defect: From Negligence [to Warranty] to Strict Liability to Negligence*, 33 VAND. L. REV. 593, 618-31 (1980).

[204] *See* Henderson, *Renewed Judicial Controversy Over Defective Product Design: Toward the Preservation of an Emerging Consensus*, 63 MINN. L. REV. 773, 773-78 (1979).

[205] *See* Edell, *Risk Utility Analysis of Unavoidably Unsafe Products*, 17 SETON HALL L. REV. 623, 638-46 (1987).

[206] *See* Burke, *DPT Vaccine Controversy: An Assessment of the Liabilities of Manufacturers and Administering Physicians Under Several Legal Theories*, 17 SETON HALL L. REV. 541, 558 (1987).

[207] *See* Note, *Can a Prescription Drug Be Defectively Designed?—Brochu v. Ortho Pharmaceutical Corp.*, 31 DE PAUL L. REV. 247, 267-68 (1981) (design defect risk-utility approach usually would cause case to go to jury, thereby placing manufacturer at a disadvantage in comparison with comment k approach).

Plaintiffs' chances of recovery are enhanced even more in states that follow the rule of *Barker v. Lull Engineering Co.*[208] According to the prevailing view, plaintiffs in product design cases must prove that their proposed alternative design is superior in cost-benefit terms to the design actually employed by the product seller. A plaintiff who fails to sustain this burden of proof will not recover against the product seller.[209] *Barker*, however, places this burden on the defendant instead of the plaintiff in product design cases.

In *Barker*, the California Supreme Court held that plaintiffs could use either the consumer expectation test or the risk-utility test to establish that a product was defectively designed.[210] Under the risk-utility aspect of *Barker*, the court would consider the usual risk-utility factors,[211] but the burden of persuasion would fall on the defendant rather than on the plaintiff. Thus, once the plaintiff showed that the product in question caused his or her injury, the defendant would have to prove that the utility of the product as designed outweighed the utility of an alternatively designed product.[212] In effect, the *Barker* approach penalizes the defendant, rather than the plaintiff, when information is unavailable about the feasibility, cost, and benefits of alternative designs. In drug liability cases, since information on alternative designs is frequently difficult for either party to obtain, product sellers would lose cases under the *Barker* rule that they probably would win under comment k.

4. *Scientifically Unknowable Risks*

As mentioned earlier, the product seller's duty to warn under comment k is limited to risks that fall within the scope of existing scientific knowledge or that can be discovered by the application of existing technology.[213] However, this principle is not limited to comment k cases, but applies to product warnings generally. Consequently, the seller of an unavoidably unsafe product would not

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[208] 573 P.2d 443 (Cal. 1978).

[209] *See* Wilson v. Piper Aircraft Corp., 577 P.2d 1322, 1327 (Or. 1978).

[210] *Barker*, 573 P.2d at 455-56.

[211] The *Barker* court declared that "a jury may consider, among other relevant factors, the gravity of the danger posed by the challenged design, the likelihood that such danger would occur, the mechanical feasibility of a safer alternative design, the financial cost of an improved design, and the adverse consequences to the product and to the consumer that would result from an alternative design." *Id.* at 455.

[212] *Id.*

[213] *See Brown*, 751 P.2d at 480; Feldman v. Lederle Labs, 479 A.2d 374, 386 (N.J. 1984).

be held liable for failing to provide a warning about a scientifically unknowable risk even if comment k were abolished.

The general duty to warn under section 402A of the *Restatement (Second) of Torts* is set forth in comment j. Comment j essentially applies negligence principles to the duty to warn.[214] These principles not only determine a warning's adequacy with respect to factual content, expression, and method of communication,[215] but they also limit the product seller's liability to risks that were either known or reasonably foreseeable.[216]

In the past, the courts have invoked comment j to determine the duty of a pharmaceutical product seller to warn, either independently or in conjunction with comment k.[217] Therefore, they are likely to rely on comment j in duty to warn cases even if comment k is replaced by a rule of strict liability. If this assumption is correct, sellers of pharmaceutical products would remain free from liability for scientifically unknowable risks.

B. Policy Considerations

Over the years, courts and commentators have relied on several rationales to justify the imposition of strict liability on product

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[214] *See* DuLuryea v. Winthrop Laboratories, 697 F.2d 222, 229 (8th Cir. 1983); *Brochu*, 642 F.2d at 656-58; Lindsay v. Ortho Pharmaceutical Corp., 637 F.2d 87, 92 (2d Cir. 1980); Borel v. Fibreboard Paper Products Corp., 493 F.2d 1076, 1088-90 (5th Cir. 1973), *cert. denied*, 419 U.S. 869 (1974); Basko v. Sterling Drug, Inc., 416 F.2d 417, 426 (2d Cir. 1969); Sterling Drug, Inc. v. Yarrow, 408 F.2d 978, 992 (8th Cir. 1969); Graham v. Wyeth Laboratories, 666 F. Supp. 1483, 1499 (D. Kan. 1987); Chambers v. G.D. Searle & Co., 441 F. Supp. 377, 381 (D. Md. 1975), *aff'd*, 567 F.2d 269 (4th Cir. 1977); Smith v. E.R. Squibb & Sons, Inc., 273 N.W.2d 476, 480 (Mich. 1979); Wolfgruber v. Upjohn Co., 423 N.Y.S. 95, 97 (N.Y. App. Div. 1979). *But see* Petty v. United States, 740 F.2d 1428, 1441 (8th Cir. 1984); Brooks v. Medtronic, Inc., 750 F.2d 1227, 1233 n.13 (4th Cir. 1984); *Finn*, 677 P.2d at 1160 (Bird, J., dissenting); Hamilton v. Hardy, 549 P.2d 1099, 1108 (Colo. Ct. App. 1976); *see also* Kidwell, *The Duty to Warn: A Description of the Model of Decision*, 53 TEX. L. REV. 1375, 1384-85 (1974-75); Robb, *A Practical Approach to the Use of State of the Art Evidence in Strict Product Liability Cases*, 77 NW. U. L. REV. 1, 13 (1982); Comment, *Drug Products Liability: Duty to Warn*, 49 U. PITT. L. REV. 283, 288 (1987); Comment, *New Jersey Supreme Court Rejects State of the Art Defense in Strict Liability Actions Alleging Failure to Warn*, 17 SUFFOLK U. L. REV. 1071, 1075-76 (1983).

[215] *See supra* notes 42-186 and accompanying text.

[216] *See* Comment, *Requiring Omniscience: The Duty to Warn of Scientifically Undiscoverable Product Defects*, 71 GEO. L.J. 1635, 1638-39 (1983); Britain, *Product Honesty is the Best Policy: A Comparison of Doctors' and Manufacturers' Duty to Disclose Drug Risks and the Importance of Consumer Expectations in Determining Product Defect*, 79 NW. U. L. REV. 342, 378-80, 396-98 (1984).

[217] *See, e.g.*, Needham v. White Laboratories, Inc., 639 F.2d 394, 402 (7th Cir. 1981); McElhaney v. Eli Lilly & Co., 575 F. Supp. 228, 231-32 (D.S.D. 1983), *aff'd*, 739 F.2d 340 (8th Cir. 1984); *Brown*, 227 Cal. Rptr. at 776; Ortho Pharmaceutical Corp. v. Chapman, 388 N.E.2d 541, 546 (Ind. Ct. App. 1979).

sellers. For example, strict liability eliminates the plaintiff's need to prove negligence in order to recover and also encourages product honesty. Additionally, strict liability promotes allocative efficiency and provides a mechanism for spreading losses.[218] This section considers whether these policies would also support a shift from comment k to strict liability for sellers of pharmaceutical products. To some degree, each of these rationales supports strict liability as opposed to comment k's less burdensome liability standard. At the same time, other considerations militate against excessive liability for sellers of pharmaceutical products.

1. *The "Burden of Proof" Rationale*

One justification for strict liability is that it permits injured parties to recover against product sellers without having to prove negligence.[219] By relieving plaintiffs of this burden, strict liability enhances the chances of recovery for those with meritorious claims and reduces the costs of litigation.[220]

This "burden of proof" rationale also appears to support the imposition of strict liability on sellers of pharmaceutical products. Plaintiffs who are injured by defective pharmaceutical products might have great difficulty establishing wrongdoing on the part of product sellers as required under the law of negligence. With its focus on the product, rather than on the conduct of the product seller,[221] the theory of strict liability provides a better chance of recovery for injured parties than negligence.

For example, in production flaw cases, under comment k, the plaintiff must prove that more effective production or detection techniques are technologically and economically feasible. In contrast, under the deviation-from-the-norm test used to evaluate pro-

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[218] *See generally* Powers, *Distinguishing Between Products and Services in Strict Liability*, 62 N.C.L. REV. 415, 423-28 (1984).

[219] *See* Cronin v. J.B.E. Olson Corp., 501 P.2d 1153, 1155 (Cal. 1972); Greenman v. Yuba Power Products, Inc., 377 P.2d 897, 901 (Cal. 1962); Beshada v. Johns-Manville Prods. Corp., 447 A.2d 539, 547 (N.J. 1982).

[220] *See* Henderson, *Coping with the Time Dimension in Products Liability*, 69 CALIF. L. REV. 919, 933 (1981). Strict liability avoids "circuity of actions" by allowing the injured party to sue the manufacturer directly instead of having to show negligence on the part of some other party in the distributive chain. *See* Prosser, *The Fall of the Citadel (Strict Liability to the Consumer)*, 50 MINN. L. REV. 791, 816 (1966).

[221] *See Caterpillar*, 593 P.2d at 883; Kerns v. Engelke, 390 N.E.2d 859, 862 (Ill. 1979); Phipps v. Gen. Motors Corp., 363 A.2d 955, 958 (Md. 1976); Little v. PPG Indus., Inc., 92 Wash. 2d 118, 594 P.2d 911, 913 (1979).

duction flaws under strict liability, the plaintiff would merely have to show that the product causing the harm was different from other units sold by the defendant.

Likewise, under comment k, the plaintiff who is injured because of some inherent characteristic of the product must establish that the risk of such injuries outweighs the product's therapeutic benefits. Expert testimony on this issue is likely to be difficult and expensive to obtain. On the other hand, if the rules of conventional strict liability are applied, the plaintiff merely has to show that the product failed to meet ordinary consumer expectations. Since juries can determine ordinary consumer expectations without the aid of expert testimony, litigation costs for the plaintiff are likely to be lower if this approach is used.

Where the pharmaceutical product's design is at issue, the approach used under strict liability is also more favorable to the plaintiff than that employed under comment k. This is because, as mentioned earlier, courts applying comment k tend to view a product's risks and benefits in isolation, while courts applying ordinary design defect principles place more emphasis on the risks and benefits of an alternative design. This improves a plaintiff's chances of recovery because it is easier for a jury to conclude that a product is defective when evidence about safer alternatives is given a prominent role in the case.

Of course, the plaintiff in a design defect case still has a difficult burden to overcome if the conventional risk-utility test is used. On the other hand, the plaintiff's chances of prevailing in design defect cases are greatly increased in states that apply the *Barker* approach since it shifts the burden of proof with respect to risk-utility to the defendant.[222]

If the burden of proof rationale is based on the notion that injured parties generally should prevail against those who caused their injuries, then this rationale supports strict liability, as opposed to negligence or comment k's liability standard. That is, plaintiffs will win more often if strict liability is applied than if a lesser standard of liability is applied to sellers of pharmaceutical products. On the other hand, one can argue that the burden of proof rationale is based on the assumption that most product-related injuries are caused by unprovable acts of negligence by product

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[222] *See Barker*, 573 P.2d at 455.

sellers.[223] This version of the burden of proof rationale is much less persuasive as a justification for strict liability where product sellers often lack control over product risks. Sellers of pharmaceutical products lack control over risks arising from the inherent nature of a product and risks that are scientifically unknowable. Consequently, one cannot impute negligent or blameworthy conduct to them simply because their products cause injury. For this reason, the burden of proof rationale does not support strict liability in cases that involve truly unavoidable risks.

2. *The "Product Honesty" Rationale*

Courts also have held product sellers strictly liable to injured consumers under a "representational" theory of liability.[224] According to this rationale, sellers may impliedly represent products to be safe for their intended functions simply by placing them in the stream of commerce.[225] Advertising reinforces this implied representation of safety and often engenders a misplaced sense of security in the minds of consumers.[226] Since product sellers create false expectations of safety in order to increase sales, they should be required to compensate injured consumers when their products are found to be less safe than represented.[227]

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[223] *See* Prosser, *The Assault on the Citadel (Strict Liability to the Consumer)*, 69 YALE L.J. 1099, 1114 (1960) (there is not more than one case in a hundred in which strict liability would result in recovery where negligence would not); *see also* Schwartz, *New Products, Old Products, Evolving Law, Retroactive Law*, 58 N.Y.U.L. REV. 796, 802-10 (1983) (manufacturing defects are often the result of negligence and the high correlation between product defects and manufacturer negligence makes it wasteful to litigate the negligence issue in product liability cases).

[224] *See* Johnson v. Marshall & Huschart Mach. Co., 384 N.E.2d 141, 143 (Ill. App. Ct. 1978); *Phipps*, 363 A.2d at 958; Suter v. San Angelo Foundry & Mach. Co., 406 A.2d 140, 149 (N.J. 1979); Markle v. Mulholland's, Inc., 509 P.2d 529, 532-33 (Or. 1973); Hall v. Armstrong Cork, Inc., 692 P.2d 787, 791 (Wash. 1984).

[225] *See* Shapo, *A Representational Theory of Consumer Protection: Doctrine, Function and Legal Liability for Product Disappointment*, 60 VA. L. REV. 1107, 1242-45 (1974); Schwartz, *Products Liability and Bankruptcy: Toxic Substances and the Remote Risk Relationship*, 14 J. LEGAL STUD. 689, 730 n.59 (1985).

[226] *See* Owen, *Rethinking the Policies of Strict Products Liability*, 33 VAND. L. REV. 681, 684 (1980); Henderson, *supra* note 220, at 939. Arguably, representations of safety made in advertisements not only cause consumers to underestimate product risks, but in some cases they may even nullify a consumer's consent to assume such risks. *See* Page, *Generic Product Risks: The Case Against Comment k and for Strict Liability*, 58 N.Y.U.L. REV. 853, 889 (1983).

[227] *See* Hubbard, *Reasonable Human Expectations: A Normative Model for Imposing Strict Liability for Defective Products*, 29 MERCER L. REV. 465 (1978).

Arguably, the product honesty rationale is not applicable to sellers of ethical[228] drugs because they normally direct their promotional activities at health care professionals rather than the general public. Unlike the sellers of ordinary consumer goods, drug companies do not generate public demand for their products by advertising or other promotional efforts.[229] Furthermore, consumers presumably are aware that some prescription drugs are dangerous since drug manufacturers continually warn about product risks.[230]

Still, pharmaceutical companies vigorously promote their products to physicians through personal contacts by sales representatives and advertisements in professional journals. In this manner, they project a favorable image of their products to the public indirectly through the medical profession.[231] Consequently, the representational theory of liability does provide some support for a strict liability rule in the case of pharmaceutical products.

3. *The Allocative Efficiency Rationale*

The goal of allocative efficiency is to distribute society's economic resources in a way that maximizes social welfare.[232] Strict liability promotes allocative efficiency by encouraging product sellers to invest in product safety and thereby reduce the number of product-related injuries.[233] Additionally, strict liability causes product prices to reflect the true costs of production, including the cost of unavoidable product injuries, and thus ensures that members of the public will not "overconsume" dangerous products.[234]

Many courts agree with the "safety incentive" theory of strict liability.[235] According to this view, product sellers have little incen-

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[228] Ethical, "[w]hen said of a drug[, means] restricted to sale only on a doctor's prescription." WEBSTER'S 9TH NEW COLLEGIATE DICTIONARY 429 (9th ed. 1983).

[229] Although drug companies do not advertise to the general public, they aggressively promote their products within the medical profession. These promotional efforts obviously affect product sales. Moreover, drug companies are beginning to advertise certain prescription drugs, such as hair treatment products, in media directed at the general public.

[230] *See* Rheingold, *supra* note 199, at 597.

[231] *See* Shapo, *supra* note 225, at 1225.

[232] *See* R. POSNER, ECONOMIC ANALYSIS OF LAW 4 (1972).

[233] *See* Owen, *supra* note 226, at 711-13; Note, *Prescription Drugs and Strict Liability: The Flaw in the Ointment*, 19 PAC. L.J. 193, 198 (1987).

[234] *See* Ausness, *Cigarette Company Liability: Preemption, Public Policy and Alternative Compensation Systems*, 39 SYRACUSE L. REV. 897, 946-47 (1988); Henderson, *supra* note 220, at 933.

[235] *See, e.g.*, Salt River Project Agric. Improv. & Power Dist. v. Westinghouse Elec. Corp., 694 P.2d 198, 205-06 (Ariz. 1984); Palmer v. A.H. Robins Co., Inc., 684 P.2d 187, 218 (Colo. 1984); Ellithorpe v. Ford Motor Co., 503 S.W.2d 516, 521 (Tenn. 1973).

tive to spend money on product safety where they bear no responsibility for product-related injuries.[236] By requiring product sellers to compensate injured consumers, strict liability forces them to choose between paying for the cost of product injuries or spending money on injury-prevention measures.[237]

Of course, strict liability does not compel sellers to make their products safe at any cost; product sellers will spend money to prevent harm when it is cost-effective to do so, but they will simply pay damage claims when the cost of compensation is less than the cost of preventing injuries.[238] In this manner an optimal level of product safety, based on what the public is actually willing to pay for, ultimately will be achieved.

Strict liability also is justified in terms of "market deterrence." The theory of market deterrence presupposes that the prices of goods must reflect their true social costs, including the costs of product-related injuries, if the market is to allocate goods efficiently within a society.[239] If these costs are not placed on the product seller, the price of the product will be artificially low and demand for the product will be higher than market forces ordinarily would support.[240] However, if the product seller is forced to raise

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[236] *See* Cowan, *Some Policy Bases of Product Liability*, 17 STAN. L. REV. 1077, 1090-92 (1965) (from a producer's standpoint, the object of quality control is to maximize profits, not to optimize quality). In such a case, the costs of injuries are said to be externalized. Externalities arise when the private costs of an activity are not equivalent to its social costs (including the costs of injuries); *see also* Coleman, *Efficiency, Exchange, and Auction: Philosophic Aspects of the Economic Approach to Law*, 68 CALIF. L. REV. 221, 231-32 (1980).

[237] Because assembly line production is well adapted to the use of safety tests and other quality control measures, manufacturers are able to calculate accident costs and improve product safety when it is cost effective to do so. *See* Note, *Strict Liability in Hybrid Cases*, 32 STAN. L. REV. 391, 394 (1980); Comment, *Strict Liability—The Medical Malpractice Citadel Still Stands*, 11 CREIGHTON L. REV. 1357, 1359 (1978). However, wholesalers, retailers, and others in the distribution chain also can protect consumers from unsafe products, either by inspecting them before sale, by dealing only with reputable manufacturers, or by exerting pressure on manufacturers to make their products safer. *See* Vandermark v. Ford Motor Co., 391 P.2d 168, 171-72 (Cal. 1964); Prosser, *supra* note 220, at 816.

[238] *See* Green & Moore, *Winter's Discontent: Market Failure and Consumer Welfare*, 82 YALE L.J. 903, 912 (1973); Note, *Sales of Defective Used Products: Should Strict Liability Apply?*, 52 S. CAL. L. REV. 805, 815 (1978-79).

[239] *See* McKean, *Product Liability: Trends and Implications*, 38 U. CHI. L. REV. 3, 41-42 (1970-71); Klemme, *The Enterprise Liability Theory of Torts*, 47 U. COLO. L. REV. 153, 159 (1976). It is assumed that consumers tend to underestimate product risks. Therefore, unless they are reminded of these risks by means of pricing signals, consumers will overconsume relatively risky products. *See* Henderson, *supra* note 220, at 933.

[240] *See* G. CALABRESI, THE COSTS OF ACCIDENTS 70 (1970).

prices to reflect the costs generated by product-related injuries, demand for the product will fall accordingly in response to these higher prices.

Note that the market theory rationale supports the imposition of strict liability on product sellers even when they cannot eliminate a product-related risk. If product-related injuries cannot be prevented, sellers will be forced to raise their prices to pay the costs of compensating injured consumers. However, since higher prices usually decrease consumer demand for the product, fewer products will be produced. As the production of dangerous products falls, the number of product-related injuries also should decline.[241]

In general, the safety incentive rationale seems to support the imposition of strict liability on suppliers of pharmaceutical products. Product sellers are responsible for the development and testing of new products and, as such, are in a good position to discover and reduce the risks associated with their products. Strict liability creates an incentive to invest in research and product testing; it also encourages product sellers to take other precautionary measures to minimize harm to consumers.[242]

The argument for market deterrence is less obvious where pharmaceuticals are concerned than it is in the case of dangerous products with relatively little social utility. Indeed, most people would find it hard to believe that society is in danger of "overconsuming" pharmaceutical products because they are too cheap. Nevertheless, higher prices for drugs would serve a legitimate allocative function by creating an economic incentive to develop safer alternatives. In theory, this ultimately would reduce "unavoidable" injuries to an optimal level.

The allocative efficiency rationale seems particularly applicable to production flaws in pharmaceutical products. Presently, suppliers of blood and vaccines often escape liability for production-related injuries because such injuries are considered unavoidable. However, if strict liability were imposed on product sellers, they would attempt to improve current production and detection technology in order to reduce or eliminate the risk of injury from harmful byproducts.

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[241] *See* Henderson, *Extending the Boundaries of Strict Products Liability: Implications of the Theory of Second Best*, 128 U. PA. L. REV. 1036, 1040 (1980).

[242] Note, *The Duty to Warn Under Strict Products Liability as Limited by the Knowledge Requirement: A Regretful Retention of Negligence Concepts*, 26 ST. LOUIS U.L.J. 125, 149 (1981-82).

The contamination of transfused blood by serum hepatitis virus is an example of a risk that comment k treats as unavoidable. At the present time, serum hepatitis virus cannot be physically removed from the blood. Although tests can detect the presence of serum hepatitis in the blood, these tests are not completely accurate.[243] Arguably, strict liability would encourage blood banks and hospitals to support the development of better detection methods.[244] Strict liability also would provide an incentive for blood suppliers to implement better donor screening procedures.[245] It is universally acknowledged that volunteer donors are much less likely to transmit hepatitis virus than paid donors.[246] Strict liability would encourage blood suppliers to search for new sources of volunteer donors and thereby reduce the risk of injury from impure blood.[247]

The allocative efficiency rationale is less compelling where products with inherent risks are concerned. Since these risks cannot be eliminated without changing the product's essential nature, holding product sellers liable provides no direct incentive for sellers to make their products safer. Furthermore, because of their familiarity with individual patient characteristics, physicians and other health care providers might be better able to reduce the risk of injury from side effects or allergic reactions than product sellers.

Nevertheless, even if the product itself cannot be made safer, product sellers could develop other risk reduction strategies to lessen the number of injuries. For example, since product sellers routinely monitor the performance of their products after the products are approved for sale by the FDA,[248] strict liability might promote better reporting and analysis of adverse drug reactions

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[243] *See* Comment, *Blood Transfusions and the Transmission of Serum Hepatitis: The Need for Statutory Reform*, 24 AM. U.L. REV. 367, 376-81 (1974-75).

[244] *See* Note, *Liability for Serum Hepatitis in Blood Transfusions*, 32 OHIO ST. L.J. 585, 598-99 (1971).

[245] *See* Discussion, *Strict Liability—A Hospital is Strictly Liable for Transfusions of Hepatitis Infected Blood*, 48 CHI.[-]KENT L. REV. 292, 297 (1971); Comment, *Hepatitis and Strict Liability*, 25 U. MIAMI L. REV. 349, 353 (1971).

[246] Paid donors are about ten times more likely to transmit hepatitis than volunteer donors. *See* Franklin, *Hepatitis, Blood Transfusions, and Public Action*, 21 CATH. U.L. REV. 683, 684 (1972).

[247] Presently, paid donors account for about one-third of the blood supply. The risk of serum hepatitis contamination could be considerably reduced if blood suppliers made an effort to increase the share of blood obtained from volunteer sources. *Id.* at 683-84.

[248] *See* Mobilia, *Allergic Reactions to Prescription Drugs: A Proposal for Compensation*, 48 ALB. L. REV. 343, 373 n.153 (1984); Merrill, *Compensation for Prescription Drug Injuries*, 59 VA. L. REV. 1, 109 (1973).

and encourage manufacturers to disseminate this information to the medical profession.[249]

Furthermore, because strict liability would increase the price of inherently dangerous pharmaceutical products, it also would provide an economic incentive to develop safer alternatives.[250] Theoretically, a safer alternative would be cheaper since it would cause fewer adverse reactions, and thus would generate less liability for the product seller. In view of the competitive nature of the pharmaceutical industry,[251] other manufacturers presumably would be encouraged by strict liability to develop safer and less expensive substitutes.

Finally, the allocative efficiency rationale appears to support the application of strict liability in product design cases. The economic incentive provided by strict liability is especially necessary in the case of combination drugs because marketing advantages, rather than therapeutic benefits, often lie behind the decision to combine ingredients into a single product.[252]

The risk-utility test used in ordinary product design cases explicitly takes the cost of product injuries into account when the risks and benefits of existing and alternative designs are weighed by the court. This protects manufacturers whose design decisions promote allocative efficiency but penalizes those who fail to take the costs of product injuries sufficiently into account when designing their products.

Of course, the courts also weigh risks and benefits when they apply comment k. However, as mentioned earlier, comment k's approach is more favorable to product manufacturers than the risk-utility test in strict liability.[253] Because product manufacturers are more likely to escape liability for improper design when comment k is applied, as compared with the liability standard used in product design cases, the latter approach is more likely than comment k to encourage cost-effective design decisions.

4. *The Loss-Spreading Rationale*

Loss-spreading provides yet another rationale for strict products liability. A large number of courts endorse strict liability

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[249] *See* Note, *Vaccine Related Injuries: Alternatives to the Tort Compensation System*, 30 ST. LOUIS U.L.J. 919, 936 (1986).

[250] *See* Note, *supra* note 238, at 813.

[251] *See* Note, *The Liability of Pharmaceutical Manufacturers for Unforeseen Adverse Drug Reactions*, 48 FORDHAM L. REV. 735, 758 n.191 (1979-80).

[252] *See* Comment, *supra* note 187, at 216.

[253] *See* Burke, *supra* note 206, at 558; Edell, *supra* note 205, at 638-46.

because it shifts the costs of injuries from accident victims to product sellers, who can spread these costs among product buyers.[254] Loss-spreading is based partly on the notion that those who benefit from an injury-producing activity should compensate those who suffer harm.[255] Loss-spreading also may be justified on secondary accident cost-avoidance grounds. According to this theory, the "secondary" or dislocation costs of injuries are reduced when they are spread among a large group of people instead of borne entirely by individual victims.[256]

Loss-spreading generally is most effective if liability for injuries is placed on the party who can best absorb and spread the cost of compensation.[257] In the case of product-related injuries, product sellers are usually the best loss-spreaders because they can insure against such losses[258] and treat them as a cost of production.[259] Moreover, since product sellers typically sell to a mass market, the

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[254] *See, e.g.*, Corporate Air Fleet v. Gates Learjet, Inc., 589 F. Supp. 1076, 1079 (M.D. Tenn. 1984); Becker v. IRM Corp., 698 P.2d 116, 123 (Cal. 1985); Immergluck v. Ridgeview House, Inc., 368 N.E.2d 803, 804 (Ill. App. Ct. 1977); Berry v. Beech Aircraft Corp., 717 P.2d 670, 673 (Utah 1985).

[255] *See Beshada*, 447 A.2d at 547; Suvada v. White Motor Co., 210 N.E.2d 182, 186 (Ill. 1965). In the words of Professor Fleming James, "[i]t is both just and expedient that the enterprise which causes losses should lift them from the individual victims and distribute them widely among those who benefit from the activities of the enterprise." James, *General Products—Should Manufacturers Be Liable Without Negligence?*, 24 TENN. L. REV. 923, 924 (1956-57).

Specifically, since pre-market testing cannot reveal all product risks, consumers act as human "guinea pigs," at least during the first few years after a pharmaceutical product is marketed. Since future consumers benefit from the information generated by those who use the product during this period, it seems fair to impose compensation costs on them in the form of higher prices for the product. *See* Pratt & Parnon, *Diagnosis of a Legal Headache: Liability for Unforeseeable Defects in Drugs*, 53 ST. JOHN'S L. REV. 517, 538 (1979); Note, *supra* note 251, at 757.

[256] *See* Calabresi, *Some Thoughts on Risk Distribution and the Law of Torts*, 70 YALE L.J. 499, 517-18 (1960-61); Kidwell, *supra* note 214, at 1386.

[257] *See* Ray v. Alad Corp., 560 P.2d 3, 8 (Cal. 1977); Price v. Shell Oil Co., 466 P.2d 722, 726 (Cal. 1970); Greenman v. Yuba Power Products, Inc., 377 P.2d 897, 901 (Cal. 1962); Calabresi, *supra* note 256, at 517-27; Montgomery & Owen, *Reflections on the Theory and Administration of Strict Tort Liability for Defective Products*, 27 S.C.L. REV. 803, 809-10 (1976).

[258] *See* Keeton, *Products Liability—Some Observations About Allocation of Risks*, 64 MICH. L. REV. 1329, 1333 (1966); Mallor, *Liability Without Fault for Professional Services: Toward a New Standard of Professional Accountability*, 9 SETON HALL L. REV. 474, 478 (1978).

[259] *See* Keeton, *Products Liability—Liability Without Fault and the Requirement of a Defect*, 41 TEX. L. REV. 855, 856 (1962-63); Greenfield, *Consumer Protection in Service Transactions—Implied Warranties and Strict Liability in Tort*, 1974 UTAH L. REV. 661, 691 (1974). *But see* Britain, *supra* note 216, at 410 (manufacturer not always the best loss-spreader).

incremental cost to each consumer from such price increases is likely to be small.[260]

Sellers of pharmaceutical products appear to be good loss-spreaders.[261] The pharmaceutical industry is profitable,[262] and the demand for its products is relatively inelastic.[263] In theory, sellers of pharmaceutical products, like other product sellers, can obtain liability insurance and spread the cost of premiums through the pricing mechanism.[264]

This reasoning seems especially applicable to risks associated with the production process. Production flaws in the manufacturing process are relatively rare and can be accurately predicted by statistical methods.[265] Arguably, production flaws in pharmaceutical products are similar to manufacturing defects.[266] Consequently, the loss-spreading arguments that are made with respect to manufacturing defects in ordinary products also can be applied to production flaws in pharmaceutical products.[267]

The loss-spreading rationale also supports strict liability in cases where consumers are injured as a result of the product manufacturer's design choices. In particular, fairness considerations dictate that producers who make a conscious decision to increase profits at the expense of consumer safety should be required to compensate

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[260] *See* Note, *Liability of a Manufacturer for Products Defectively Designed by the Government*, 23 B.C.L. REV. 1025, 1080 (1982); Sales, *Service-Sales Transactions: A Citadel Under Assault*, 10 ST. MARY'S L.J. 13, 16 (1978).

[261] *See* Merrill, *Compensation for Prescription Drug Injuries*, 59 VA. L. REV. 1, 88 (1973).

[262] *See* Comment, *supra* note 187, at 217-18; Note, *Comment K Immunity to Strict Liability: Should All Prescription Drugs Be Protected?*, 26 HOUSTON L. REV. 707, 733 (1989).

[263] *See* Mobilia, *supra* note 183, at 367.

[264] *See* Connolly, *The Liability of a Manufacturer for Unknowable Hazards Inherent in His Product*, 32 INS. COUNSEL J. 303, 307 (1965).

[265] *See* McClellan, *Strict Liability for Drug Induced Injuries: An Excursion Through the Maze of Products Liability, Negligence and Absolute Liability*, 25 WAYNE L. REV. 1, 30 (1978-79).

[266] *See* Keeton, *Products Liability—Inadequacy of Information*, 48 TEX. L. REV. 398, 409 (1969-70).

[267] Contamination of blood by serum hepatitis virus may constitute an exception to this generalization because the incidence of hepatitis injuries is relatively high. *Cf.* Note, *supra* note 244, at 585 (2% of blood transfusion recipients contract hepatitis); R. TITMUSS, THE GIFT RELATIONSHIP: FROM HUMAN BLOOD TO SOCIAL POLICY 146 (1971) (3.5% of blood transfusion recipients contract hepatitis). According to one estimate, the cost of blood would double if blood suppliers were held strictly liable for injuries caused by contaminated blood. Note, *supra* note 244, at 597.

injured parties, particularly when their design choices are not cost effective.[268]

However, the loss-spreading rationale is less persuasive when it comes to inherent product risks. Obviously, the imposition of strict liability for injuries arising from inherent product risks would place a much greater financial burden on product sellers.[269] Both the aggregate annual number of adverse drug reactions and the percentage of adverse effects from such products are relatively high.[270] For example, an estimated 1.3 million serious adverse drug reactions occur annually in the United States.[271] Another study concluded that 3.6% of all drug exposures result in a serious adverse reaction.[272] Estimates of the economic costs of adverse drug reactions range from $3 billion to $4.5 billion.[273] Sellers of pharmaceutical products may have a difficult time spreading costs of this magnitude through the pricing mechanism.

Furthermore, even when product risks are relatively low, product sellers may be unable to obtain insurance at a reasonable cost.[274] Recently, for example, vaccine manufacturers have been unable to purchase insurance at affordable rates even though the number of adverse reactions to vaccines was extremely low.[275] In the words of one commentator, "[t]he presumption in the courts has been that insurance will solve everything. But it hasn't, because insurance companies are no more eager to lose their shirts to unpredictably generous juries than are the vaccine manufacturers themselves."[276]

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[268] Of course, the product seller has no duty to compensate, even under strict liability, if the utility of the chosen design outweighs its costs, including the costs of consumer injuries.

[269] *See* McClellan, *supra* note 265, at 31.

[270] Page, *supra* note 226, at 885-86.

[271] *See* Comment, *supra* note 187, at 199 n.3.

[272] *See* JICK, *The Boston Collaborative Drug Surveillance Programme*, in ADVERSE DRUG REACTIONS 61, 64 (D. Richards & R. Rondel, ed. 1972).

[273] *See* Note, *supra* note 251, at 737.

[274] *See* Note, *Alternatives to Manufacturer Liability for Injuries Caused by the Sabin-Type Oral Polio Vaccines*, 28 WM. & MARY L. REV. 711, 721-22 (1986-87).

[275] *See* Huber, *Safety and Second Best: The Hazards of Public Risk Management in the Courts*, 85 COLUM. L. REV. 277, 287 n.49 (1985) (swine flu vaccine); Note, *supra* note 262, at 718 n.73 (DTP vaccine). According to one commentator, administration of the oral polio vaccine causes serious injury about once per 3.2 million doses (5 cases per year); DTP vaccine also causes serious injury once every 3.2 million doses (43 cases per year). Cases of anaphylactic shock from all vaccines occur once every ten million doses (10 cases per year). *See* Comment, *The National Childhood Vaccine Injury Act of 1986: A Solution to the Vaccine Liability Crisis?*, 63 WASH. L. REV. 149, 149 n.3 (1988). Another commentator estimates the number of deaths and serious injuries from vaccines at 52 per year. *See* Note, *supra* note 249, at 919.

[276] Huber, *supra* note 275, at 287.

All of this suggests that loss-spreading may provide less support for strict liability in inherent risk cases than it does in the case of other product risks.[277]

5. *Other Policy Considerations*

In addition to the considerations discussed above, a number of other issues are relevant to the question of whether strict liability should be imposed on the sellers of pharmaceutical products. In particular, it is important to assess the administrative costs of operating a strict liability regime and it also is necessary to evaluate the effect of strict liability on the price and availability of pharmaceutical products.

One concern is that the "administrative" or "transaction" costs of implementing a strict liability regime may be excessive.[278] As Dean Calabresi points out, sometimes it is cheaper to effectuate societal goals by direct means (specific deterrence) than by relying on indirect methods (general deterrence), such as the imposition of tort liability, to achieve them.[279] Arguably, the FDA's licensing process ensures that the social costs and benefits of pharmaceutical products are properly evaluated. If that is so, the additional administrative costs of subjecting pharmaceutical product sellers to strict liability probably may exceed any marginal improvements in allocative efficiency that strict liability could achieve.

A second concern is strict liability's potential effect on the availability and price of pharmaceutical products. A number of

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[277] This suggests that other loss-spreading mechanisms may be superior to strict liability for compensating injuries caused by inherent conditions in pharmaceutical products. One possibility is first-party insurance, like medical or disability insurance, paid for by potential victims. *See* Note, *Strict Liability for Drug Manufacturers: Public Policy Misconceived*, 13 STAN. L. REV. 645, 648 (1960-61) (victims can obtain low-cost medical insurance to protect against injury). *But see* Note, *supra* note 242, at 151-52 (it is unreasonable to expect individual consumers to insure against catastrophic loss from drug-related injuries).

Another option is to provide relief to injured parties through government-financed compensation programs. Congress has authorized such a compensation scheme for certain vaccine-related injuries. *See* National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 to 300aa-33 (1989); Schwartz & Mahshigian, *National Childhood Vaccine Injury Act of 1986: An Ad Hoc Remedy or a Window for the Future?*, 48 OHIO ST. L.J. 387, 389-93 (1987); Comment, *supra* note 275, at 157-58. Some foreign countries, such as West Germany, Sweden and Japan, also provide compensation from public funds to victims of drug-related injuries. *See* Fleming, *Drug Injury Compensation Plans*, 30 AM. J. COMP. L. 297, 298-304 (1982).

[278] Administrative costs are the costs of operating a particular compensation system, including litigation costs. *See* G. CALABRESI, *supra* note 240, at 28. Dean Calabresi refers to administrative costs as "tertiary" costs. *Id.* at 28.

[279] *Id.* at 102-03.

commentators have warned that the prospect of strict liability might cause manufacturers to refrain from marketing risky but otherwise beneficial products.[280] In fact, this problem arose in the 1970's when pharmaceutical companies refused to produce swine flu vaccine until the federal government agreed to indemnify them against tort liability.[281] Fear of excessive tort liability also may cause manufacturers to take useful products off the market. For example, the producer of Bendectin stopped producing the drug because it was unable to obtain liability insurance, even though FDA studies concluded that there was no health reason to withdraw it from the market.[282] In addition, some firms have abandoned production of vaccines because of the potential liability associated with such products.[283]

Perhaps these are exceptional cases. In theory, competitive forces within the industry should ensure a continuing supply of new pharmaceutical products even if strict liability is imposed on product sellers.[284] However, strict liability no doubt will cause product sellers to subject their products to more extensive testing[285] and this will delay the introduction of new drugs into the market.[286] These delays carry a social cost, and in some cases, the costs of delay may exceed the benefits of increased knowledge that are obtained from additional testing.[287]

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[280] *See* Reed & Watkins, *Product Liability Tort Reform: The Case for Federal Action*, 63 NEB. L. REV. 389, 438-39 (1984); Comment, *The Diminishing Role of Negligence in Manufacturers' Liability for Unavoidably Unsafe Drugs and Cosmetics*, 9 ST. MARY'S L.J. 102, 110 (1977-78); Note, *Mass Immunization Cases: Drug Manufacturers' Liability for Failure to Warn*, 29 VAND. L. REV. 235, 261 (1976).

[281] *See* Franklin & Mais, *Tort Law and Mass Immunization Programs: Lessons from the Polio and Flu Episodes*, 65 CALIF. L. REV. 754, 769 (1977); Huber, *supra* note 275, at 287 n.49.

[282] *See* Epstein, *Products Liability as an Insurance Market*, 14 J. LEGAL STUD. 645, 648 (1985). *But see* Comment, *supra* note 187, at 216-17 (Bendectin should have been taken off the market because risks of birth defects outweighed its utility as an anti-nausea drug); Note, *supra* note 262, at 731 (harmful ingredient in Bendectin did not contribute to the drug's effectiveness).

[283] *See* Epstein, *The Temporal Dimension in Tort Law*, 53 U. CHI. L. REV. 1175, 1204 (1986) (DTP); Huber, *supra* note 275, at 288-89 (DTP); Comment, *Informed Consent to Immunization: The Risks and Benefits of Individual Autonomy*, 65 CALIF. L. REV. 1286, 1286 n.2 (1977) (oral polio vaccine).

[284] *See* Note, *supra* note 251, at 758 (new drugs are necessary to maintain competitive position within pharmaceutical industry); Rheingold, *Products Liability—The Ethical Drug Manufacturer's Liability*, 18 RUTGERS L. REV. 947, 1017 (1963-64) (drug manufacturers need to develop new drugs in order to stay in business).

[285] *See* Merrill, *supra* note 261, at 113.

[286] *See* Note, *supra* note 274, at 721.

[287] *See* Gaston v. Hunter, 588 P.2d 326, 341 (Ariz. Ct. App. 1978); Kearl v. Lederle

Strict liability also could lead to drastic increases in the prices of pharmaceutical products. Obviously, any additional testing that resulted from the imposition of strict liability would increase expenses.[288] In addition, product sellers would try to pass compensation costs on to consumers.[289] Competitive forces may counteract this tendency somewhat.[290] However, as the recent experience with DTP vaccine illustrates, the threat of increased tort liability sometimes can cause sudden and dramatic increases in the price of pharmaceutical products. In 1982, manufacturers charged eleven cents per dose for DTP vaccine; by 1986, the price had risen to $11.40 per dose. Reportedly, $8.00 of this increase was used to provide for an insurance reserve against future liability for product-related injuries.[291]

The prospect of substantial price increases for pharmaceutical products is a disturbing one. To a sick person, drugs are not luxuries; they are necessities. If the cost of pharmaceutical products does rise significantly, these products will be placed out of the reach of many who need them most.[292]

C. *Absolute Liability and the Duty to Warn*

A rule of "absolute" liability would make manufacturers responsible for all injuries caused by the use of their products.[293] Under this approach, injured parties could recover against product sellers merely by establishing that the defendants' products caused their injuries. The party would not have to prove that the harm was avoidable or that the product in question was defective in any way.[294] Although neither courts[295] nor

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Laboratories, 218 Cal. Rptr. 453, 459 (1985); *Feldman*, 460 A.2d at 209; Note, *Strict Liability for Drug Manufacturers: Public Policy Misconceived*, 13 STAN. L. REV. 645, 649 (1961).

[288] *See* Note, *supra* note 251, at 755.

[289] *See* Merrill, *supra* note 261, at 115; Note, *Mass Immunization Cases: Drug Manufacturers' Liability for Failure to Warn*, 29 VAND. L. REV. 235, 261-62 (1976).

[290] *See* Note, *supra* note 274, at 736-37.

[291] *See* Note, *supra* note 262, at 718.

[292] *See* Mobilia, *supra* note 248, at 367; Note, *supra* note 233, at 201.

[293] *See* Schwartz, *supra* note 223, at 809.

[294] *See* Schwartz, *Foreword: Understanding Products Liability*, 67 CALIF. L. REV. 435, 441 (1979).

[295] *See* Phillips v. Kimwood Machine Co., 525 P.2d 1033, 1036 (Or. 1974) ("No one wants absolute liability where all the article has to do is cause injury."); Morningstar v. Black & Decker Mfg. Co., 253 S.E.2d 666, 684 (W. Va. 1979) ("We thus decline to adopt [absolute liability for inherently dangerous but not otherwise defective products] into our tort product liability law.").

commentators[296] have shown much enthusiasm for absolute liability, it nevertheless remains the most viable alternative to strict liability and comment k. For this reason, this Article briefly discusses the potential impact of an absolute liability rule on pharmaceutical product sellers, with particular emphasis on the duty to warn.

1. *Liability for Inherent Risks and Product Design Choices*

Obviously, a shift from strict liability to absolute liability would increase the liability of product sellers for most product risks.[297] For example, a rule of absolute liability would make product sellers responsible for all adverse reactions attributable to a product's inherent biochemical properties. Absolute liability also would impose liability on product sellers for injuries associated with product design, even though the design chosen was superior to every available alternative. Finally, under absolute liability, product sellers would be required to compensate those who were injured by risks that were scientifically unknowable at the time the product was sold.

Unless one believes that compensating injured consumers is an overriding consideration, the case for absolute liability is rather weak, especially where inherent risks are concerned. Earlier, this Article concluded that strict liability is inappropriate for injuries attributable to the inherent nature of a product. The primary concern was that the cost of compensating for such injuries would be too great for product sellers to spread effectively through the pricing mechanism. If this occurred, product sellers would be reluctant to market new products and also might raise prices excessively. Since absolute liability would impose even greater costs on product sellers, this reasoning suggests that it would be even more undesirable in inherent risk cases.

The argument against absolute liability in product design cases proceeds along different lines. The earlier discussion of risks associated with design choices suggested that a rule of strict liability was preferable to comment k's liability standard. This conclusion

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[296] *See* Keeton, *Products Liability—The Nature and Extent of Strict Liability*, 1964 ILL. L. F. 693, 701 ("No one would be so reckless as to argue that a user can recover anytime he is injured in the course of the use of a product.").

[297] One exception to this would be risks associated with the production process. Since product sellers already would be liable for production-related injuries under strict liability, a rule of absolute liability would not affect producer liability in such cases.

was based on the assumption that strict liability would encourage producers to make product design decisions that minimized social costs. A rule of absolute liability, however, would impose liability on sellers even when a product is designed properly. If a strict liability rule is sufficient to achieve allocative efficiency in product design cases, a rule of absolute liability will not cause product sellers to allocate resources any better; it will only increase their liability to consumers. Although this additional liability might allow more loss-spreading to occur, it also could adversely affect the availability and price of pharmaceutical products. For these reasons, an absolute liability rule should not be used to resolve product design cases.

2. *The Duty to Warn: Hindsight versus Foresight*

One of the most interesting issues in products liability is the potential impact of an absolute liability rule on a product seller's duty to warn. Both comment k and strict liability require the product seller to warn about scientifically discoverable product risks. An absolute liability rule, on the other hand, would hold a manufacturer liable for failure to warn even though the risk involved was scientifically unknowable. This approach is commonly referred to as a "hindsight" rule. Proponents of a hindsight rule claim that it would ameliorate the plaintiff's burden of proof in failure to warn cases and also would promote resource allocation and loss-spreading goals.[298]

a. The "Burden of Proof" Rationale

The New Jersey Supreme Court relied heavily on the "burden of proof" rationale several years ago when it adopted a hindsight rule in *Beshada v. Johns-Manville Products Corp.*[299] In *Beshada*, a group of workers sued an asbestos manufacturer, arguing that it failed to warn them that exposure to asbestos insulation might

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[298] *See Beshada*, 447 A.2d at 547-49. It also has been suggested that product sellers should be held liable when reasonable consumer expectations of safety are disappointed by injuries caused by risks that are scientifically unknowable at the time the product was sold. *See* Page, *Generic Product Risks: The Case Against Comment K and for Strict Liability*, 58 N.Y.U.L. REV. 853, 889 (1983).

[299] 447 A.2d 539, 549 (N.J. 1982). The *Beshada* case was followed in Kisor v. Johns-Manville Corp., 783 F.2d 1337 (9th Cir. 1986), Halphen v. Johns-Manville Sales Corp., 737 F.2d 462, 465 (5th Cir. 1984), and Elmore v. Owens-Illinois, Inc., 673 S.W.2d 434 (Mo. 1984).

cause cancer. The defendant, Johns-Manville, contended that the risk of cancer from asbestos insulation was scientifically unknowable when the product in question left its control. According to the defendant, its duty to warn was confined to risks that were discoverable by existing knowledge and technology at the time the product was sold.[300] The court, however, disagreed with the defendant and held that the "state of the art" defense was not applicable to failure to warn claims.[301]

The *Beshada* court declared that plaintiffs should not be required to bear the burden of proof with respect to state of the art issues. The court felt that plaintiffs would have a difficult time obtaining evidence on the state of the art and that juries would be confused by undue focus on this issue.[302] Others also have expressed doubts about the propriety of requiring plaintiffs to establish what the state of the art was when the product was sold.[303]

The *Beshada* court is no doubt correct that the burden of proof rationale does support the adoption of a hindsight rule in failure to warn cases.[304] However, if a hindsight rule is rejected for other reasons, it may be possible to retain the foresight rule, but shift the burden of persuasion on the state of the art issue to defendants.[305] This approach would meet the requirements of the burden of proof rationale while retaining many of the benefits of a foresight rule.

b. *The Allocative Efficiency Rationale*

Advocates of absolute liability also claim that a hindsight rule would promote an efficient allocation of economic resources.[306] According to this view, the state of the art largely is determined by an industry's willingness to invest resources in research.[307] An absolute liability rule will induce product sellers to commit more

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[300] *Beshada*, 447 A.2d at 545-47.

[301] *Id.* at 549.

[302] *Id.* at 548-49.

[303] *See* Note, *New Jersey Advances the State of the Art in Products Liability: Beshada v. Johns-Manville Prod. Corp.*, 15 CONN. L. REV. 635, 676 (1983); Schwartz, *supra* note 225, at 693.

[304] *See* Schwartz, *supra* note 223, at 824-25.

[305] *See* Comment, *supra* note 214, at 1083; Comment, *supra* note 216, at 1656-57.

[306] Several commentators have evaluated the hindsight rule in terms of economic theory. *See generally* Calabresi & Klevorick, *Four Tests for Liability in Torts*, 14 J. LEGAL STUD. 585 (1985); Schwartz, *supra* note 225.

[307] *See Beshada*, 447 A.2d at 548.

resources to research and thereby advance the frontiers of scientific knowledge.[308] This, in turn, will lead to discovery and avoidance of product risks that otherwise would remain undetected until consumer injuries were reported.

In response, critics of the hindsight approach contend that the allocative efficiency rationale requires a product seller to invest in safety research only if it reduces the costs of injuries by more than the costs of research.[309] If a particular risk is unknown, the amount of research needed to discover the risk cannot be known in advance either. Therefore, it will be extremely difficult for a product seller to estimate how much research is optimal.[310]

This argument was raised by Johns-Manville in the *Beshada* case.[311] The court, however, declared that liability still should be imposed on the product seller (in the form of a hindsight rule) because it was the "cheapest cost avoider."[312] According to this theory, when it is difficult or expensive to determine the costs and benefits of a particular activity, the best way to achieve allocative efficiency, or at least move in that direction, is to impose liability on the cheapest cost avoider—that is, the party that is "in the best position to make a cost-benefit analysis between accident costs and accident avoidance costs and act on that decision once it is made."[313] Applying this cheapest cost avoider analysis to pharmaceuticals, one could argue that product sellers are best able to determine how much research is cost-effective.

However, the cheapest cost avoider theory implicitly assumes the existence of someone who can assess costs and benefits with some degree of accuracy. If we believe that product sellers will be unable to perform meaningful cost-benefit calculations, there is no reason to assume that their decisions about research will promote allocative efficiency. In fact, product sellers may be more likely to

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[308] *See* Henderson, *supra* note 220, at 940; Schwartz, *Understanding Products Liability*, 67 CALIF. L. REV. 435, 484-85 (1979); Comment, *Strict Products Liability: The Irrelevance of Foreseeability and Related Negligence Concepts*, 14 TULSA L.J. 338, 353-54 (1978).

[309] *See* R. POSNER, *supra* note 232, at 90-91; Comment, *supra* note 216, at 1648.

[310] *See* Schwartz, *supra* note 225, at 696-703. For that matter, it also may be difficult to determine *post hoc* how much research was optimal. *See* Epstein, *supra* note 283, at 1205.

[311] *See Beshada*, 447 A.2d at 548.

[312] *Id.* (quoting Suter v. San Angelo Foundry & Machine Co., 406 A.2d 140, 151-52 (N.J. 1979), in turn quoting Calabresi & Hirschoff, *Toward a Test for Strict Liability in Torts*, 81 YALE L.J. 1055, 1060 (1971-72)).

[313] *See* Calabresi & Hirschoff, *Toward a Test for Strict Liability in Torts*, 81 YALE L.J. 1055, 1060 (1972).

misallocate economic resources under a hindsight rule than under a foresight rule. For example, product sellers who are highly risk-adverse are likely to overinvest in research and testing.[314] Not only would this waste corporate resources, but it also would impose costs on society as the result of delays in the marketing of beneficial products.[315]

Other product sellers, however, might underinvest in research if they were subjected to a hindsight rule.[316] In particular, manufacturers of existing products might feel that engaging in additional research would merely turn up evidence of risks that otherwise would have remained undiscovered.[317] Product sellers also might choose to put their resources into additional liability insurance (assuming that it could be obtained) instead of investing more corporate resources into research that ultimately might prove worthless.[318]

Finally, imposition of a hindsight rule could cause market distortions if product sellers overpriced pharmaceutical products to cover unknown, but possibly significant, future liability costs.[319] Depending on market conditions, product sellers also might try to shift some of these anticipated future liability costs on to other products.[320] In either case, the prices charged for pharmaceutical products would not reflect their true social costs.[321]

c. *The Loss-Spreading Rationale*

According to some commentators, the need to spread losses fairly dictates that a hindsight rule be applied to sellers of phar-

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[314] *See* Henderson, *supra* note 220, at 942; Comment, *supra* note 216, at 1648-49.

[315] *See* Comment, *supra* note 216, at 1649; Note, *supra* note 274, at 721.

[316] *See* Henderson, *supra* note 220, at 940-41.

[317] *See* Note, *Strict Liability in Tort—State-of-the-Art Defense Inapplicable in Design Defect Cases*, 13 SETON HALL L. REV. 625, 638 (1982-83); Berry, *Beshada v. Johns-Manville Products Corp.: Revolution—or Aberration—in Products Liability Law*, 52 FORDHAM L. REV. 786, 797 (1984); Wade, *On the Effect in Product Liability of Knowledge Unavailable Prior to Marketing*, 58 N.Y.U.L. REV. 734, 755 (1983). On the other hand, this disincentive is somewhat offset by the fact that others may be generating information as well. *See* Schwartz, *supra* note 308, at 485.

[318] *See* Comment, *Defeat for the State-of-the-Art Defense in New Jersey Product Liability: Beshada v. Johns-Manville Products Corp.*, 14 RUTGERS L.J. 953, 974 (1983).

[319] *See* Note, *supra* note 317, at 637.

[320] *See* Berry, *supra* note 317, at 794; Henderson, *supra* note 220, at 943.

[321] *But see* Page, *supra* note 226, at 878-79 (market distortions are more likely to occur under noncompetitive market conditions than in a competitive market environment).

maceutical products.[322] They claim that the number of injuries from undiscovered risks is small in relation to the number of injuries from known risks.[323] Consequently, proponents of the hindsight rule maintain that product sellers can obtain liability insurance easily and thereby spread the costs of compensating those injured as the result of unknown product risks.[324]

However, this view has been vigorously challenged by other commentators.[325] They point out that liability insurers often overestimate the consequences of unknown risks.[326] Therefore, insurers may be unwilling to insure against such liability arising out of undiscovered product risks,[327] or they may charge unreasonably high premiums for adequate coverage against such liability.[328]

D. A Proposed Rule for "Unavoidably Unsafe" Products

Presently, the liability of pharmaceutical products sellers is largely governed by the provisions of comment k. However, comment k's language and structure leave much to be desired. For example, it is unclear whether comment k can be properly applied to products that are technologically capable of being made safer or whether the term "unavoidably unsafe" should be taken literally.[329] The language of comment k is also vague about the extent of its coverage. In particular, it is unclear whether the drafters of comment k intended to restrict its application to pharmaceutical

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[322] *See* Note, *The Cutter Polio Vaccine Incident: A Case Study of Manufacturers' Liability Without Fault in Tort and Warranty*, 65 YALE L.J. 262, 264 (1955-56).

[323] *See* Rabin, *Indeterminate Risk and Tort Reform: Comment on Calabresi and Klevorick*, 14 J. LEGAL STUD. 633, 637 (1985); Note, *supra* note 242, at 145.

[324] *See* Wade, *supra* note 197, at 826.

[325] *See* Henderson, *supra* note 220, at 949; Note, *New Jersey Advances the State of the Art in Products Liability: Beshada v. Johns-Manville Prod. Corp.*, 15 CONN. L. REV. 661, 679 (1982-83); Note, *supra* note 251, at 757.

[326] *See* Note, *Tort Liability for DPT Vaccine Injury and the Preemption Doctrine*, 22 IND. L. REV. 655, 673-74 (1989).

[327] *See* Henderson, *supra* note 220, at 949; Note, *supra* note 318, at 974.

[328] *See* Comment, *Beshada v. Johns-Manville Products Corp.: Adding Uncertainty to Injury*, 35 RUTGERS L. REV. 982, 1011 (1983).

[329] Most courts seem willing to apply comment k to product risks that are not literally unavoidable. For example, virtually every court has absolved blood suppliers from liability for injuries caused by serum hepatitis in blood even though the risk of serum hepatitis contamination can be significantly reduced by improved screening procedures. *See supra* notes 78-107 and accompanying text. A number of courts also have applied comment k to product risks caused by conscious design choices. *See supra* notes 131-65 and accompanying text.

products or whether they believed that comment k should protect any seller whose product was incapable of being made safe.[330]

Furthermore, there is considerable disagreement about the proper role, if any, that comment k should play in the law of products liability. Generally, courts have applied comment k rather generously, at least as far as pharmaceutical products are concerned.[331] At the same time, however, some courts have exhibited a certain amount of hostility to the concept of comment k and have proposed that it be replaced with the risk-utility standard that is employed currently in product design cases.[332]

Considering comment k's obvious flaws, it is surprising that the American Law Institute has made no effort to rewrite the provision since its adoption in 1963. The only serious alternative treatment of the unavoidably unsafe product issue is section 105 of the Department of Commerce's Model Uniform Product Liability Act.[333] Section 105, entitled "Unavoidably Dangerous Aspects of Products," provides that sellers will not be held strictly liable for the unavoidably unsafe aspects of their products as long as they provide adequate warnings.[334]

Although section 105 is better drafted than comment k, its substantive provisions are essentially the same.[335] Section 105 defines an unavoidably unsafe product as one that cannot be made safe because of current technological limitations. In effect, it ex-

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[330] *See supra* notes 42-75 and accompanying text.

[331] For example, some courts have held that comment k applies across-the-board to all prescription drugs. *See id.*

[332] *See Brochu*, 642 F.2d at 655; *Finn*, 677 P.2d at 1166-67 (Bird, C.J., dissenting); *Murphy*, 710 P.2d at 262 (Bird, C.J., dissenting); Ortho Pharmaceutical Corp. v. Heath, 722 P.2d 410, 414 (Colo. 1986).

[333] *See* MODEL UNIFORM PRODUCT LIABILITY ACT, *reprinted in* 44 Fed. Reg. 62,714 (Dept. of Commerce offered Oct. 31, 1979).

[334] Section 105 declares:

> (a) An unavoidably unsafe aspect of a product is that aspect incapable of being made safe in light of the state of scientific and technological knowledge at the time of manufacture.
>
> (b) A product seller may be subject to liability for failing to provide an adequate warning or instruction about an unavoidably unsafe aspect of the seller's product, if the factors set forth in Section 104, subdivision (C) indicate that such warnings or instructions should have been given. This obligation to warn or instruct may arise after the time the product is manufactured.
>
> (c) If Section 104(C) is not applicable, the product seller shall not be subject to liability for harm caused by an unavoidably unsafe aspect of a product unless the seller expressly warranted by words or actions that the product is free of such unsafe aspects.

[335] *See* Page, *supra* note 226.

empts from strict liability: (1) products whose risks arise out of the production process if these risks are technologically unavoidable; (2) products with inherent risks; and (3) products whose risks are scientifically undiscoverable at the time of marketing.[336]

Like comment k, section 105 places losses from unavoidable product risks on consumers rather than on product sellers. As the commentary to section 105 points out, "[t]he approach taken in Section 105 recognizes that there may be circumstances where a seriously injured person is left without compensation for an injury caused by an unavoidably unsafe aspect of a product."[337] The commentary also declares, "[i]f the costs of these harms are to be shifted from the individual, they should be borne by society at large."[338]

The policies discussed earlier in this article support some limitations on strict liability for pharmaceutical product sellers. However, I would propose a somewhat narrower exemption than either comment k or section 105 provide. My proposal[339] would read as follows:

(1) The sellers of a chemical drug, biologic, or medical device licensed by the federal Food and Drug Administration for sale by prescription shall not be subject to liability for harm caused by an unavoidable product risk unless the seller has expressly warranted by words or actions that the product is free from such risk.

(2) An unavoidable product risk is one that is solely attributable to the product's inherent physical, chemical, or biological condition and that is incapable, under existing or reasonably achievable technology, of being reduced or eliminated. A product risk also shall be regarded as unavoidable if, at the time the product was marketed, the risk was unknown to the scientific community and could

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[336] The comment to § 105 clearly extends the duty to warn only to scientifically knowable risks. The comment states that:

> The factual question underlying the legal issue of whether warnings or instructions were adequate is whether product sellers meet their duty to promulgate warnings and instructions commensurate with their *actual* knowledge gained from research and adverse reaction reports and their constructive knowledge as measured by scientific literature and other available means of communication.

See 44 Fed. Reg. 3006 (Jan. 12, 1979) (emphasis in original).

[337] *Id.*

[338] *Id.*

[339] Although this proposal is drafted in "legislative" form, this Article is not necessarily recommending that the American Law Institute substitute it in place of comment k's existing language. The substance of the proposal just as easily could take the form of a judicial gloss on the common law doctrine of strict liability in tort.

not have been discovered by the application of existing, or reasonably achievable, scientific knowledge or technology. The product seller who alleges that a product risk is unavoidable shall have the burden of establishing this allegation by a preponderance of the evidence.

(3) A product seller may be subject to liability for failing to provide an adequate warning or instruction about a known unavoidable product risk or about a product risk that could be discovered by the application of existing, or reasonably achievable, scientific knowledge or technology.

There are four significant aspects to this proposal. First, it focuses on unavoidable product *risks*, rather than attempting to characterize the product itself as unavoidably unsafe. Second, it is limited to pharmaceutical products licensed by the FDA. Third, only *inherent* and *unavoidable* product risks are immunized from strict liability. Finally, scientifically unknowable risks are treated as if they were unavoidable.

The proposal is similar to section 105 in that it focuses on the unavoidably unsafe aspects of a product rather than attempting, like comment k, to classify the product itself as unavoidably unsafe. This approach is preferable because it avoids placing undue emphasis on the product's overall risks and benefits and instead directs attention to the specific risk involved. By concentrating on a particular product risk, this approach also makes it easier for courts to confine the unavoidable risk rule to product risks that are truly unavoidable.

This proposal also limits the exemption from strict liability to pharmaceutical products licensed by the FDA for sale by prescription. The proposal is narrower in this respect than comment k because nonpharmaceutical products are clearly excluded from coverage, as are "over the counter" drugs. One could argue that unavoidable risks should be treated the same, regardless of the product. While there is some merit to this position, special protection is warranted for FDA-approved pharmaceutical products because of their high social utility and because of legitimate concerns about the effect of excessive tort liability on the price and availability of such products. Possibly, these same concerns apply to certain other products as well. However, if this is the case, similar protection against liability can be provided for such products.

It should be noted that this proposal avoids any explicit balancing of risks and benefits. This omission seems appropriate in the case of pharmaceutical products because risks and benefits are

already evaluated by the FDA as part of the licensing process. Once the FDA has determined that a product's therapeutic benefits outweigh its known inherent risks, it serves no purpose for courts to engage in a similar endeavor.[340]

Furthermore, this proposal would insulate only inherent and unavoidable product risks from liability. As mentioned earlier, comment k supposedly is limited to unavoidable danger, but as a practical matter, the courts have extended its provisions to product risks that are not truly unavoidable. For example, comment k has been applied to production flaws, such as contaminated blood, on the theory that such conditions are unavoidable. Some courts have also applied comment k to risks resulting from conscious design choices by product sellers. By restricting protection to inherent conditions, my proposal excludes virtually all production flaws since the product risk would be artificial, rather than being part of the product's inherent nature. It also excludes risks created by design choice since these risks are not unavoidable.[341]

Finally, my proposal creates an exception from strict liability for scientifically unknowable risks. As concluded earlier, holding product sellers liable for scientifically unknowable risks under a failure to warn theory is contrary to many of the policies that underlie strict products liability. Consequently, like comment k, this proposal treats scientifically unknowable risks as if they were unavoidable. Still, recognizing that injured consumers are unlikely to be able to prove that a risk was scientifically knowable at a particular time, this proposal shifts the burden of persuasion on the "knowability" or "state of the art" issue to the product seller, who is more likely to be able to offer expert testimony on this issue.[342]

Perhaps the issue of scientifically unknowable risks should be treated separately from the issue of known unavoidable product risks.[343] However, most courts have considered that lack of know-

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[340] *See* Henderson, *Judicial Review of Manufacturers' Conscious Design Choices: The Limits of Adjudication*, 73 COLUM. L. REV. 1531, 1555-56 (1973) (arguing that administrative agencies often are better suited than courts to make, or evaluate, polycentric decisions).

[341] These risks, of course, would be treated like any other risk that arises out of a conscious design choice by the product seller.

[342] *See* Comment, *supra* note 214, at 1083; Note, *supra* note 325, at 677; Comment, *supra* note 216, at 1656-57.

[343] *See* Note, *Strict Liability and the Scientifically Unknowable Risk*, 57 MARQ. L. REV. 660, 661 (1973-74) (discussing the difference between scientifically unknowable risks and risks that are known, but physically unavoidable).

ledge prior to marketing makes a product just as unavoidably unsafe as any inherent aspect of its physical, chemical, or biological condition. Consequently, despite some misgivings, this proposal adopts a similar approach.

CONCLUSION

Comment k exempts sellers of unavoidably unsafe products from the normal rules of strict products liability. Because the language of comment k is ambiguous in many respects, the courts have not always agreed on its proper purpose or scope. Most courts, however, have concluded that comment k is applicable primarily to risks associated with pharmaceutical products. These risks include (1) risks attributable to some mishap in the production process, (2) risks arising from the inherent nature of a product, (3) risks created by conscious design choices, and (4) scientifically unknowable risks.

Earlier, this Article described the various rationales that courts and commentators have traditionally relied on to justify the imposition of strict liability on product sellers. These rationales also seem applicable to at least some of the risks associated with pharmaceutical products. In certain cases, however, these rationales are much less persuasive, or they are outweighed by countervailing considerations.

This Article proposes an alternative to comment k that, if accepted by the courts, would protect sellers from liability for unavoidable risks that arise from the inherent nature of pharmaceutical products. It also advocates that product sellers be insulated from liability for scientifically unknowable risks. On the other hand, this proposal would remove the protection, currently afforded by comment k in certain cases, against liability for risks associated with the production process and for risks created by conscious design choices.

Allocating risks between product sellers and their potential victims is a difficult task. Hopefully, this proposal gives appropriate recognition to the interests of both producers and consumers of pharmaceutical products.