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COMMENT

STRICT LIABILITY FOR PRESCRIPTION DRUGS: WHICH SHALL GOVERN— COMMENT K OR STRICT LIABILITY APPLICABLE TO ORDINARY PRODUCTS?

I. INTRODUCTION

In 1963, California adopted Justice Traynor's theory of strict liability for products.¹ One year later, the Restatement followed his lead with the addition of section 402A which imposes liability upon manufacturers for selling defective products in conditions that are unreasonably dangerous.² To establish strict liability, under section 402A, a plaintiff must prove that a product was defective when it left a defendant's control and that the defect caused injury to a reasonably foreseeable user.³ It is this

1. *Greenman v. Yuba Power Products, Inc.*, 59 Cal. 2d 57, 377 P.2d 897, 27 Cal. Rptr. 697 (1963). Writing for a unanimous court, Justice Traynor expressed the court's belief that manufacturers should be strictly liable in tort for articles which they place in the market, knowing the articles will not be further inspected, and possibly cause injury to human beings. *Id.* at 62, 377 P.2d at 900, 27 Cal. Rptr. at 700.

2. RESTATEMENT (SECOND) OF TORTS § 402A (1964) [hereinafter cited as RESTATEMENT § 402A].

3. *Id.* In the Restatement § 402A, the defect requirement is expressed as follows:

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

defect⁴ requirement that distinguishes strict products liability from other forms of strict liability.⁵

Because of the far-reaching consequences of strict products liability, the Restatement authors added comments a through q to qualify, explain, and sometimes restrict the application of section 402A.⁶ Comment k is restrictive; it modifies the application of strict liability if unavoidably unsafe products are involved.⁷ Using the vaccine for rabies as an example, the authors of the Restatement explained how some products are so beneficial to society that the risk of using the product is superseded by its need.⁸ Specifically recognizing prescription drugs as such prod-

Id.

4. Defective, according to comment g, is a condition, not contemplated by the ultimate consumer, which will be unreasonably dangerous to him. *Id.* at comment g. This is commonly referred to as the consumer-expectation test. California courts have established that the defect can take one of three forms: a manufacturing flaw, a design defect, or an inadequate warning.

5. See Comment, *The Failure to Warn Defect: Strict Liability of the Prescription Drug Manufacturer in California*, 17 U.S.F.L. Rev. 743, 749 n.37 (1983).

6. See 38 American Law Institute (A.L.I.) Proc. 19, 90-98 (1961). During the discussion of § 402A, A.L.I. member, Harold Gross, offered an amendment to exclude prescription medicines as a class from the section's scope. He warned that including such products under strict liability would be "against the public interest" due to the "very serious tendency to stifle medical research and testing that would result." *Id.* at 91. Dean Prosser, the Reporter for the Restatement, replied that he was very concerned about this problem and that he had struggled unsuccessfully to solve it in drafting the text. He recommended that rather than including it in the text, these special problems posed by such medicines should be dealt with in the comments accompanying § 402A. The A.L.I. agreed. *Id.* at 94.

7. RESTATEMENT § 402A, *supra* note 2, at comment k. Comment k provides that a product will not be considered unreasonably dangerous if it is properly prepared, accompanied by proper directions and warnings; also, a seller will not be held to strict liability as a result of injury in those circumstances. *Id.* However, if the product is not prepared properly, a manufacturer will be held to strict liability. *Id.* The same is true with warnings and directions; they must be appropriate under the circumstances. *Id.* The law calls it strict liability but the reasonableness aspect requires a negligence analysis. *Id.*

8. *Id.* Comment k states:

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 defec-

ucts, the authors of the Restatement recognized that a product's makers should not be subjected to strict liability if a product is properly manufactured and accompanied by proper directions and appropriate warnings.⁹ Unless there is something wrong with such a product, apart from its unavoidable hazards, it will not be defective according to the standards of section 402A.¹⁰

The California appellate courts have traditionally treated prescription drugs as the primary group governed by comment k.¹¹ Although the California Supreme Court has not directly dealt with this issue, the court has recently acknowledged that it is looking for a case in which to consider the application of ordi-

tive, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which *for this very reason* cannot legally be sold except to physicians, or under the prescription of a physician 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. (Emphasis added.)

Id.

9. *Id.* Manufacturers of unavoidably unsafe products may incur strict liability only if there is a manufacturing flaw or an inadequate warning. Comment k, therefore, employs a combination of strict liability principles and negligence principles. The unavoidably unsafe product can not be deemed defective solely because it fails to perform as safely as an ordinary consumer would expect it to when used in an intended or reasonably foreseeable manner. *Id.*

10. See PROSSER, LAW OF TORTS § 99 (4th ed. 1971). Dean Prosser pointed out that there must be something wrong with a product to make it unreasonably dangerous to those who come in contact with it. He noted that an ordinary pair of shoes was not unreasonably dangerous just because the soles became slippery when wet; nor was a hammer unreasonably dangerous because one might smash a thumb. Likewise, knives and axes must be able to cut in order to be useful. *Id.* at 659.

11. In several decisions, California's courts of appeal have discussed comment k in a manner that indicates the court believes comment k should apply to all prescription drugs. See *McCreery v. Eli Lilly & Co.*, 87 Cal. App. 3d 77, 86-87, 150 Cal. Rptr. 730, 736 (1978) (comment k "implicitly recognizes the social policy behind the development of new pharmaceutical preparations"); *Carmichael v. Reitz*, 17 Cal. App. 3d 958, 987-91, 95 Cal. Rptr. 381, 398-402 (1971) (quoting and applying comment k); *Toole v. Richardson-Merrill, Inc.*, 251 Cal. App. 2d 689, 708-11, 60 Cal. Rptr. 398, 412-14 (1967) (quoting and applying comment k); *Christofferson v. Kaiser Foundation Hospitals*, 15 Cal. App. 3d 75, 79-80, 92 Cal. Rptr. 825, 827 (1971) (citing comment k with approval); *Grinnell v. Charles Pfizer & Company*, 274 Cal. App. 2d 424, 435 n.7, 79 Cal. Rptr. 369, 375 n.7 (1969) (citing comment k in dictum and stating that when "products, such as drugs, which are unavoidably unsafe . . . [are] properly prepared and accompanied by proper directions and warning, [they are] neither defective nor unreasonably dangerous").

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nary strict products liability principles to prescription drugs, rather than section 402A and its comments.¹² Furthermore, Chief Justice Rose Bird has stated that she believes the standard generally applied in strict liability cases should also be applied to drug manufacturers.¹³

This change would be troublesome. For over two decades the California appellate courts have consistently allowed comment k to govern prescription drugs. If the court should decide to apply the strict liability standard for ordinary products instead of the strict liability standard for unavoidably unsafe products, it will refute its own reasoning that precedent should determine the standard for defectiveness in the products liability field;¹⁴ the purpose of comment k would be defeated.¹⁵

This Comment will review the history of strict products liability and the policies which have shaped its development. It will examine the state of the law today regarding strict liability for harm caused by prescription drugs, and demonstrate that comment k should continue to govern prescription drugs. Furthermore, it will point out that sound reasoning and public policy dictate that the modified strict products liability of comment k, rather than ordinary strict products liability, is the appropriate theory to establish liability for prescription drugs; it is also the method most beneficial to society's needs. Finally, this Comment

12. *Finn v. G.D. Searle & Co.*, 35 Cal. 3d 691, 694, 677 P.2d 1147, 1148, 200 Cal. Rptr. 870, 871 (1984). In the opinion, Justice Richardson stated:

Although we granted hearing in this case to consider the application of strict liability principles to injurious side effects allegedly produced by prescription drugs, our review of the record has convinced us that in light of the basis upon which plaintiff tried his case, this broader issue is not properly before us.

Id.

13. *Id.* at 720, 677 P.2d at 1166, 200 Cal. Rptr. at 889 (Bird, J., dissenting).

14. *Barker v. Lull Engineering Co., Inc.*, 20 Cal. 3d 413, 417, 573 P.2d 443, 446, 143 Cal. Rptr. 225, 228 (1978). In *Barker*, the court emphasized that "the defectiveness concept defies a simple, uniform definition applicable to all sectors of the diverse product liability domain." *Id.* The *Barker* court further explained that the question of what defect concept was appropriate could "best be resolved by resort to the 'cluster of useful precedents' which have been developed in the product liability field in the past decade and a half." *Id.* at 428, 573 P.2d at 453, 143 Cal. Rptr. at 235 (quoting *Cronin v. J.B.E. Olson Corp.*, 8 Cal. 3d 121, 134 n.16, 501 P.2d 1153, 1162 n.16, 104 Cal. Rptr. 433, 442 n.16 (1972)).

15. See *supra* note 7. To apply the same test to determine liability for prescription drugs and ordinary products would defeat the purpose of comment k.

will predict how the California Supreme Court will apply comment k to prescription drugs when the court is faced with the appropriate case.

II. STRICT PRODUCTS LIABILITY

A. AN HISTORICAL OVERVIEW

1. *Development of a Cause of Action*

Strict liability was first advocated as a basis of recovery for injuries related to defective products by former Justice Traynor in *Escola v. Coca Cola Bottling Co.*¹⁶ In *Escola*, the plaintiff, a waitress, was injured when a soda bottle broke in her hand as she carefully moved it from the case to the refrigerator.¹⁷ The defendant bottler used pressure to bottle carbonated beverages and had exclusive control over both the charging and the inspection of the bottle.¹⁸ Although it was not clear whether the explosion had been caused by an excessive charge or a defect in the glass, the court felt that neither problem would have ordinarily been present if the bottler had used due care.¹⁹ A majority of the court held that negligence could be inferred based upon the doctrine of *res ipsa loquitur*.²⁰

Justice Traynor, in a concurring opinion, asserted that a manufacturer's negligence should not provide the only basis for a plaintiff's right to recover.²¹ According to Justice Traynor, a manufacturer should be liable for any injury caused by a defect in a product which the manufacturer placed on the market knowing it would be used without further inspection.²² This type of liability would discourage manufacturers from marketing de-

16. 24 Cal. 2d 453, 461, 150 P.2d 436, 440 (1944) (Traynor, J., concurring).

17. *Id.* at 456, 150 P.2d at 437.

18. *Id.* at 459, 150 P.2d at 439.

19. *Id.* at 461, 150 P.2d at 441.

20. *Res ipsa loquitur* is a rule of evidence whereby negligence of the alleged wrongdoer may be inferred from the mere fact that the accident happened, provided: (1) the character of the accident and the circumstances attending it lead reasonably to the belief that in the absence of negligence it would not have occurred, and (2) the thing which caused the injury is shown to have been under the exclusive management of the alleged wrongdoer. The rule may not apply when direct evidence of negligence exists. BLACK'S LAW DICTIONARY (5th ed. 1979).

21. *Escola* at 461, 150 P.2d at 440.

22. *Id.*

fective products that cause injury.²³

In *Greenman v. Yuba Power Products, Inc.*,²⁴ the California Supreme Court adopted Justice Traynor's position and held that the cost of injuries from defective products should be borne by the manufacturers of such products.²⁵ In *Greenman*, the plaintiff's wife bought, from a retailer, a power tool made by the defendant.²⁶ While using the tool as a lathe, the plaintiff was injured when a piece of wood he was shaping flew up and hit him in the face.²⁷ At trial, experts testified that the lathe was defective in design; the set screws were inadequate to hold certain adjustments. The harm could have been prevented by a different design.²⁸ Justice Traynor, writing for a unanimous court, reaffirmed his concurrence in *Escola*.²⁹ Manufacturers should be strictly liable for defective products which cause injury when such manufacturers place these articles on the market knowing they will be used without further inspection.³⁰

One year after *Greenman*, section 402A was added to the Restatement. Section 402A defines defective products as those products that cause injury due to a condition not contemplated by the ultimate consumer.³¹ The Restatement provides that a product will not be unreasonably dangerous if it is accompanied by appropriate directions or warning,³² the duty to warn is determined by the seller's knowledge.³³ Although the language of the Restatement seemed clear, the authors³⁴ went a step further

23. *Id.* at 462, 150 P.2d at 441.

24. 59 Cal. 2d 57, 377 P.2d 897, 27 Cal. Rptr. 697 (1963).

25. *Id.* at 63, 377 P.2d at 901, 27 Cal. Rptr. at 701.

26. *Id.* at 59, 377 P.2d at 898, 27 Cal. Rptr. at 698.

27. *Id.*

28. *Id.* at 60, 377 P.2d at 899, 27 Cal. Rptr. at 699.

29. *Id.* at 63, 377 P.2d at 901, 27 Cal. Rptr. at 701.

30. *Id.*

31. RESTATEMENT § 402A, *supra* note 2, at comment g.

32. According to the Restatement, in order to prevent a product from being unreasonably dangerous, it may be necessary for a seller to give directions or provide warnings on a product's container. *Id.* at comment j.

33. *Id.* A seller is required to give a warning if he has knowledge, or by the application of reasonable, developed human skill and foresight, should have knowledge of the risk. *Id.*

34. Roger J. Traynor, then Chief Justice of the California Supreme Court and the principal architect of California's product liability system, was one of the official advisors to the Restatement and was extremely concerned about this particular application of strict liability.

to ensure against the likelihood of liability for unavoidable injuries from drugs which are beneficial to society.³⁵ This emphasis demonstrated the authors' intent.

In less than a decade later, *Cronin v. J.B.E. Olson Corp.*,³⁶ rejected the Restatement's definition of defective for ordinary products; the defect no longer had to be unreasonably dangerous. Instead, the court decided that a plaintiff need only prove there was a defect in the product, and that the defect was the proximate cause of the plaintiff's injuries.³⁷ In *Cronin*, the driver of a nine year old bakery truck was forced off the road as he tried to pass another vehicle.³⁸ The impact broke the safety hasp that held bread trays, thereby freeing the trays.³⁹ The trays then fell forward, struck the plaintiff in the head, and knocked him through the front windshield.⁴⁰ The plaintiff alleged that the hasp was defective.⁴¹ The defendant appealed from a judgment for the plaintiff on the ground that the trial judge omitted the requirement that a defect must be "unreasonably dangerous."⁴²

According to the court, the unreasonably dangerous qualification was not in the original formulation of strict liability set forth in *Greenman*, but had its origin in the Restatement.⁴³ The *Cronin* court cited a number of cases to explain or support the general products liability rules articulated.⁴⁴ Significantly, none of those cases involved a prescription drug or any other unavoidably unsafe product.⁴⁵ Precedent, in the field of products liability law, was treating ordinary products and unavoidably unsafe products differently. The Restatement's definition of defect for unavoidably unsafe products was not rejected.

35. RESTATEMENT § 402A, *supra* note 2, at comment k. Comment k provides that unless an unavoidably unsafe product, such as a prescription drug, is improperly prepared or not accompanied by appropriate directions or warnings, it is not defective; therefore, the product's manufacturer will not be held strictly liable. *Id.*

36. 8 Cal. 3d 121, 501 P.2d 1153, 104 Cal. Rptr. 433 (1972).

37. *Id.* at 132-34, 501 P.2d at 1161-63, 104 Cal. Rptr. at 441-43.

38. *Id.* at 121, 501 P.2d at 1153, 104 Cal. Rptr. at 433.

39. *Id.*

40. *Id.*

41. *Id.*

42. *Id.* at 128-29, 501 P.2d at 1158-59, 104 Cal. Rptr. at 438-39.

43. *Id.*

44. *Id.* at 130-33, 501 P.2d at 1160-63, 104 Cal. Rptr. at 440-43.

45. *Id.*

2. *Defect Defined*

Although *Cronin* had established that, in order for a product to be defective, it need not be unreasonably dangerous, it was unclear what constituted a defect.⁴⁶ However, that issue was clarified in *Barker v. Lull Engineering Company, Inc.*⁴⁷ The *Barker* court established that there are at least two kinds of defects: manufacturing defects and design defects.⁴⁸ Manufacturing defects exist in products that are not as a manufacturer intended them to be, or which differ from other supposedly identical products of the same product line.⁴⁹ Design defects are determined according to *Barker's* two-prong test.⁵⁰ First, a product may be found defective in design if a plaintiff can show that a product does not function as safely as an ordinary consumer would expect it to function while using it for its intended or reasonably intended purpose.⁵¹ Second, as an alternate test, a product may be found defective in design if a plaintiff can show that a product's design was the proximate cause of his or her injuries.⁵² Once a plaintiff proves that a product was the proximate cause of his or her injuries, a defendant must establish that the benefits of the design outweigh the inherent risks.⁵³ If, through hindsight, a court determines that the risk of danger inherent in a challenged design outweighs the benefits of the design, the product is defective.⁵⁴

Barker examined the issues of products liability as they applied to a forklift. The plaintiff was injured when a high-lift loader he was operating overturned.⁵⁵ To support the court's application of the two-prong test in determining design defect, the *Barker* court cited approximately thirty cases; none of the cases involved an unavoidably unsafe product.⁵⁶ *Barker* established a

46. *Cronin*, 8 Cal. 3d 121, 501 P.2d 1153, 104 Cal. Rptr. 433.

47. 20 Cal. 3d 413, 573 P.2d 443, 143 Cal. Rptr. 225 (1978).

48. *Id.* at 426-30, 573 P.2d at 452-55, 143 Cal. Rptr. at 234-38.

49. *Id.* at 429, 573 P.2d at 454, 143 Cal. Rptr. at 236.

50. *Id.* at 432, 573 P.2d at 455-56, 143 Cal. Rptr. at 237-38.

51. *Id.*

52. *Id.*

53. *Id.*

54. *Id.*

55. *Id.* at 413, 573 P.2d at 443, 143 Cal. Rptr. at 225.

56. *Id.* Significantly, the court noted that the term defect was misleading because it was not defined. *Id.* at 428, 573 P.2d at 453, 143 Cal. Rptr. at 235. According to the

definition for defects in design and manufacturing only. Unavoidably unsafe products were presumably covered by comment k.⁵⁷

The third form of defect, inadequate warning, was not discussed in *Cronin* or *Barker*. In *Barker*, the court did not decide the warning issue because the issue was not properly before the court.⁵⁸ However, both before and after *Barker*, the standard for determining the adequacy or need for warning has been comment j to the Restatement; the duty to warn arises if a manufacturer knows or should have known of a dangerous condition.⁵⁹

The California Supreme Court has not addressed the warning issue, but the California appellate courts have continued to apply the Restatement in failure to warn cases.⁶⁰ *Christofferson v. Kaiser Foundation Hospital*,⁶¹ a leading drug injury case, was decided under section 402A.⁶² In *Christofferson*, the plaintiff suffered permanent visual impairment as a result of ingesting a prescription drug to treat a skin condition.⁶³ The court decided that, because the harmful side effect was not known at the time of the injury, the manufacturer was not strictly liable.⁶⁴ The Restatement and its comments were again affirmed as a basis for determining warning defect in *Carmichael v. Reitz*.⁶⁵ The appellate court approved the trial court's jury instructions pertaining to the strict liability of a drug manufacturer for failure to warn of a risk inherent in a drug; the instructions were based on the

court, it was easier to apply a definition of defect to manufacturing defects. *Id.* The court further noted that products likely to be injurious in their normal condition, would need a more specific definition of defect. *Id.* at 427, 573 P.2d 453-54, 143 Cal. Rptr. at 235-36.

57. *Id.* at 413, 573 P.2d at 443, 143 Cal. Rptr. at 225.

58. *Id.* at 420 n.1, 573 P.2d at 449 n.1, 143 Cal. Rptr. at 229 n.1.

59. RESTATEMENT § 402A, *supra* note 2, at comment j. The Restatement standard of strict liability for failure to warn was explained in *Cronin*, 8 Cal. 3d 121, 501 P.2d 1153, 104 Cal. Rptr. 433. Comment j was first used as the test of defectiveness for failure to warn in *Canifax v. Hercules Powder Co.*, 237 Cal. App. 2d 44, 46 Cal. Rptr. 552 (1965). In *Cavers v. Cushman*, 95 Cal. App. 3d 338, 157 Cal. Rptr. 142 (1979), a case following *Barker*, the court noted that *Cronin* did not alter the standard for defectiveness due to an inadequate warning. *Id.* at 343, 157 Cal. Rptr. at 145.

60. See Comment, *supra* note 5, at 746-47.

61. 15 Cal. App. 3d 75, 92 Cal. Rptr. 825 (1971).

62. *Id.*

63. *Id.*

64. *Id.*

65. 17 Cal. App. 3d 958, 95 Cal. Rptr. 381 (1971).

Restatement and its comments.⁶⁶

The California Supreme Court recently had an opportunity to determine the duty of a pharmaceutical manufacturer to warn of potential side effects of prescription drugs.⁶⁷ In *Finn v. G.D. Searle & Company*, the court instructed the jury that a manufacturer of a prescription drug was liable to a plaintiff if the manufacturer failed to warn the medical profession within a reasonable time after he or she knew of potentially harmful side effects.⁶⁸ The court further instructed the jury that a manufacturer was under a duty of due care to warn the medical profession of potential dangers even if the percentage of users who might be harmed was minor.⁶⁹ The duty, however, did not extend beyond warning the medical profession; the drug manufacturer had no duty to warn the patient.⁷⁰ To be adequate, a warning must be reasonable under the circumstances.⁷¹ The standard of strict liability for failure to warn used in defective product cases, and in defective drug cases, remained the standard set forth in the Restatement and its comments.

III. PHARMACEUTICAL DRUGS AND STRICT LIABILITY

Under present California law, the unavoidably unsafe product doctrine of section 402A of the Restatement governs all pharmaceutical medicines.⁷² Recently, however, in *Finn v. G.D. Searle & Company*, the California Supreme Court expressed an interest in reviewing strict products liability as applied to prescription drugs.⁷³ The court noted that failure-to-warn cases in

66. *Id.* at 987, 95 Cal. Rptr. at 398. In *Carmichael*, the plaintiff sued the manufacturer of the drug Enovid which was prescribed to the plaintiff by her physician to help her become pregnant. The plaintiff alleged, inter alia, that an inadequate warning by the drug manufacturer caused her to suffer blood clots in her lung and her leg. *Id.*

67. 35 Cal. 3d 691, 677 P.2d 1147, 200 Cal. Rptr. 870 (1984).

68. *Id.* at 697-98, 677 P.2d at 1150-51, 200 Cal. Rptr. at 873-74.

69. *Id.*

70. *Id.*

71. *Id.*

72. *See supra* note 11.

73. 35 Cal. 3d at 694, 677 P.2d at 1149, 200 Cal. Rptr. at 871 (1984). In *Finn*, the trial court rejected the plaintiff's proposed instruction for a manufacturer's duty to warn. The modified instruction provided, in part, that a drug manufacturer is under a duty to exercise reasonable care to warn of potential dangers reasonably foreseeable from the use of the manufacturer's drug. The plaintiff argued that, by modifying the proposed instruction, the trial court introduced negligence principles which impaired the plaintiff's

California have been subject to a distinct form of analysis regarding strict liability.⁷⁴ Some California courts have held that concepts of negligence are absorbed by the doctrine of strict liability; other courts have decided that although the rules expressed in comment j are referred to as strict liability rules, they are merely well settled rules of negligence.⁷⁵

A California trial court recently ruled on the applicable strict liability law in DES litigation.⁷⁶ The court stated that because *Finn* had not provided suitable precedent to decide the issues, it would look to other authority for their resolution. The court relied upon those cases that deal with the application of strict liability to prescription drugs and which have accepted the Restatement's section 402A and comments j and k.⁷⁷ The court further determined that the design defect standards of *Barker* are not applicable to prescription drugs.⁷⁸

strict liability claim. The California Supreme Court noted, however, that these assertions were founded upon the proposition that there is a significant difference between negligence claims and strict liability claims due to failure to warn. The court pointed out that if one determined liability for failure to warn of defects discovered after a product caused injury (i.e., a *Barker* hindsight analysis) there would be a substantial distinction between a negligence standard and strict liability. *Id.*

74. *Id.* at 699, 677 P.2d at 1151, 200 Cal. Rptr. at 874.

75. *Id.* at 700, 677 P.2d at 1152, 200 Cal. Rptr. at 875. The court noted that both common sense and experience dictate that it would be impractical to impose a need to warn based on every piece of information in a manufacturer's possession. According to the court, to overwarn is to reduce the effectiveness of all warnings. *Id.*

76. DES is the abbreviation for Diethylstilbestrol, an estrogen preparation that was prescribed to prevent miscarriages. See *infra* note 77. *In re* DES Litigation, No. 830-109 (Cal. Super. Ct., San Francisco, Aug. 16, 1985) (General Order No. 11) (petition for writ pending hearing of April 21, 1986) [hereinafter cited as *In re* DES Litigation]. With the concurrence of all parties to the DES litigation, common issues were submitted to the Complex DES Litigation Judge, after briefing and argument, for decisions that would have common application to the DES cases before the court. *Id.*

77. *In re* DES Litigation, at 5. After analysis of those cases and the Restatement, the court concluded:

there is substantial legal authority in [California] adopting comments j and k standards in strict liability litigation involving ethical drugs and their potentially injurious side effect. Diethylstilbestrol, prescribed for the purpose of treatment of threatened and habitual miscarriage, is a prescription drug and falls within the ambit of comments j and k.

Id.

78. *Id.* Initially, the court maintained that the product would fail to meet the threshold requirement of the first prong of *Barker* or the "consumer-expectation" test because it was not a product within the common experience of ordinary consumers. *Id.* at 11-12. The court pointed out that such a product was made according to a scientific formula and prescribed according to a physician's judgment. *Id.* Likewise, the court ex-

The California Appellate Court recently affirmed its position on strict liability and unavoidably unsafe products in *Kearl v. Lederle Laboratories*.⁷⁹ The *Kearl* court ruled that although unavoidably unsafe products, like all other products, are subject to strict liability for manufacturing defects, they are not subject to strict liability for design or warning defects.⁸⁰ The court noted that even though defective warning in products liability cases may be a basis for strict liability, the appropriate analysis is based on negligence.⁸¹

In *Kearl*, a child developed paralysis about four weeks after receiving an oral polio vaccine.⁸² The child's parents alleged that the drug was defective due to design and warning and asserted a strict products liability theory at trial.⁸³ The trial court allowed strict products liability design defect testimony, and instructed the jury on the *Barker* theory of design defect.⁸⁴ Although the child's mother had read and signed a warning noting the risk of contracting polio from the vaccine, she alleged that the warning was inadequate; she contended that the warning failed to inform her that oral polio vaccine was "the best way to get polio today."⁸⁵

On appeal by the drug manufacturer, the court found that the trial court erred in allowing the child's parents to present a strict products liability design defect case. According to the court, the lower court should have first determined whether or not the product was unavoidably unsafe, and therefore, exempt

plained that the second *Barker* test, the risk-benefit analysis, was equally inappropriate because the object of that test is to determine if the risk of danger inherent in the design outweighs the benefit of that design. *Id.* at 12. Such a test was premised primarily on the likelihood of a different design posing less risk. The court pointed out that in most prescription drugs there is no alternate design available. *Id.* The court further argued that to adopt either of the tests set forth in *Barker* would require abandoning the policy considerations of comments j and k which have become a part of the strict liability law of California and that the court had neither the inclination nor authority to do so. *Id.* at 12-13. The court concluded, therefore, that since there was no allegation of a manufacturing or production defect in the DES cases, strict liability will apply only when a defect is based on a failure to warn. *Id.* at 13.

79. 172 Cal. App. 3d 812, 218 Cal. Rptr. 453 (1985).

80. *Id.* at 817, 218 Cal. Rptr. at 454.

81. *Id.* at 832, 218 Cal. Rptr. at 465.

82. *Id.* at 820, 218 Cal. Rptr. at 456.

83. *Id.*

84. *Id.*

85. *Id.* at 834, 218 Cal. Rptr. at 467.

from strict product design liability.⁸⁶ The court noted that for over two decades courts have decided that some special products should not be subjected to a strict liability design defect analysis; those products are often prescription drugs.⁸⁷ Furthermore, the court contended that a *Barker* standard for determining design defect may result in a delay of marketing products because of further testing.⁸⁸ The court pointed out that these considerations suggested that special unavoidably unsafe products tip the scales away from holding a manufacturer strictly liable so as to ensure a product's availability.⁸⁹

The *Kearl* court required a determination as to whether a product, including a drug, is to be viewed as unavoidably unsafe.⁹⁰ These special products should not be judged in light of ordinary consumer expectations or present scientific knowledge; they should be reviewed according to a manufacturer's actual or constructive knowledge at the time of marketing.⁹¹ Consistently, for over two decades, the courts have concluded that these products, including prescription drugs, should be exempt from the normal strict products liability design defect analysis.⁹²

IV. A *BARKER* ANALYSIS SHOULD NOT BE APPLIED TO PRESCRIPTION DRUGS

A. PHARMACEUTICAL DRUGS ARE UNIQUE

Barker determined that a product is defective in design if it fails one of two alternate tests.⁹³ First, if the product does not function as an ordinary consumer would expect when the con-

86. *Id.* at 836, 218 Cal. Rptr. at 468. The court also ruled that the warning was, as a matter of law, adequate under the circumstances.

87. *Id.*

88. *Id.* at 823-24, 218 Cal. Rptr. at 458-59. The court conceded that whereas this delay may be beneficial to society as far as general products were concerned, in the case of some special products, such as prescription drugs, a delay in marketing may prolong suffering or deny a needed cure. *Id.* at 823, 218 Cal. Rptr. at 459. Furthermore, the court stated, increased production costs, which will stem from increased insurance costs as well as from extended testing, can conceivably cause manufacturers to withdraw or decline to develop certain products. *Id.* at 824, 218 Cal. Rptr. at 459.

89. *Id.* at 824-25, 218 Cal. Rptr. at 460.

90. *Id.* at 829, 218 Cal. Rptr. at 463-64.

91. *Id.* at 825, 218 Cal. Rptr. at 460.

92. *Id.* See also *supra* note 11.

93. *Barker v. Lull Engineering Co.*, 20 Cal. 3d 413, 432, 573 P.2d 443, 462, 143 Cal. Rptr. 225, 244 (1978).

sumer uses the product in a reasonably foreseeable manner, or second, if a plaintiff can show, from a hindsight perspective, that the product's design was the proximate cause of injury and that the risks inherent in the design outweigh its benefits.⁹⁴

A prescription drug is not designed. Drugs are produced according to a formula, the component parts of which combine to create the desired results.⁹⁵ The inclusion of each component is necessary to produce the formula.⁹⁶ To change the formula is to produce a different drug. Therefore, liability based on the premise that an alternate design would have avoided the harm caused by the drug used is not applicable to prescription drugs. As set forth in the Restatement, drugs were never intended to be found defective in design under a strict liability standard, only under a negligence standard.⁹⁷

Under strict liability, a manufacturer can be held liable simply for manufacturing a product; this is because liability is based on unforeseeable risks as well as foreseeable risks. Because drugs are chemical compounds, they contain components that may adversely affect certain individuals.⁹⁸ As Dean Prosser observed:

The argument that industries producing potentially dangerous products should make good the harm, distribute it by liability insurance, and add the cost to the price of the product, encounters reason for pause, when we consider that two of the greatest medical boons to the human race, penicillin and cortisone, both have their dangerous side effects, and that drug companies might well have been deterred from producing and selling them.⁹⁹

Comment k cites prescription drugs and vaccines as examples of products that are unavoidably unsafe, and therefore, are not unreasonably dangerous as long as they are properly manu-

94. *Id.*

95. Amicus Brief (Pharmaceutical Manufacturers Association) for Appellant, *Kearl v. Lederle Laboratories*, 172 Cal. App. 3d 812, 218 Cal. Rptr. 453 (1985).

96. *Id.* at 41-42.

97. RESTATEMENT § 402A, *supra* note 2, at comment k.

98. *See* Amicus Brief, *supra* note 95.

99. *See* PROSSER, *supra* note 10.

factured and a proper warning given.¹⁰⁰ To apply the consumer-expectation text to an unavoidably unsafe product, such as a prescription drug, is illogical. A prescription drug is a chemical compound; the very chemical formula that produces a desired result is the same formula that causes the unwanted side effect. Liability for a manufacturer's inability to alter unique chemical compounds should not be premised upon a consumer's expectation that an unwanted but unpreventable side effect will not occur.

The consumer-expectation test requires that a product perform as an ordinary consumer would expect under reasonable circumstances.¹⁰¹ Prescription drugs are only available to an ordinary consumer by prescription written by a physician; a physician should determine a consumer's expectations. A physician decides when a medicine and when and if certain warnings should be given. Once a manufacturer has warned a physician of any known risks, a manufacturer's control over consumer-expectation has ended. To hold a manufacturer liable for a consumer's independently conceived expectations would be unreasonable.

An example, used by the authors of comment k, as to why it would be illogical and unjust to hold manufacturers liable for unavoidable harmful side effects is demonstrated by the rabies vaccine.¹⁰² As was observed in comment k, a person who has been exposed to rabies has two choices: he can decline to take the vaccine treatment, thereby risking the occurrence of a disease which invariably leads to a dreadful death, or he can take the treatment which may cause serious consequences.¹⁰³ A patient and his physician are in the best position to make that decision. If the courts held a drug manufacturer liable for all resultant injuries, they would interfere with the treatment for rabies.

The second prong of *Barker* states that products are defective if the benefits from their design do not outweigh the risks.¹⁰⁴ Comment k, likewise, requires a balancing; a plaintiff has the

100. RESTATEMENT § 402A, *supra* note 2, at comment k.

101. *Id.* at comment g.

102. *Id.* at comment k.

103. *Id.*

104. *Barker v. Lull Engineering Co., Inc.*, 20 Cal. 3d 413, 573 P.2d 443, 143 Cal. Rptr. 225 (1978).

option to show that an unreasonable risk was present when he used a product.¹⁰⁵ A significant difference between the risk-benefit analysis of comment k and *Barker* is that *Barker* determined the risk according to hindsight.¹⁰⁶ If at the time of trial it is known that the risks of using a product outweigh the benefits, the product is determined defective. Comment k, however, expressly rules out hindsight liability even as to new or experimental drugs for which unforeseen side effects are always a possibility. It merely provides that knowledge, by a manufacturer, at production time should justify the marketing and use of a drug.¹⁰⁷ A hindsight analysis of risk would deter research and production of experimental drugs.¹⁰⁸

The comment k requirement also differs from *Barker* procedurally. Once a plaintiff establishes that a product's design proximately caused his injury, *Barker* places upon a manufacturer of ordinary products the burden of establishing that the benefits of a product's design outweigh its risks.¹⁰⁹ *Barker's* threshold requirement that a plaintiff prove that a *design*, as opposed to a product, proximately caused his injury,¹¹⁰ contemplates that the product could have been designed in some other fashion. When a product is unavoidably unsafe, by definition, it cannot be designed differently.

Additionally, the *Barker* court shifted the burden of proof to a manufacturer because evidence relevant to determining risks and benefits, such as the cost of an alternate design, involve technical matters often within the knowledge of a manufacturer.¹¹¹ However, the question of an alternate design is not at issue in an unavoidably unsafe product. Therefore, the only question remaining, determining risks and benefits, involves empirical evidence compiled not only by manufacturers but by the Food and Drug Administration, the Centers for Disease Control, and other entities that conduct such studies.¹¹² This information

105. RESTATEMENT § 402A, *supra* note 2, at comment k.

106. *Barker*, 20 Cal. 3d 413, 573 P.2d 443, 143 Cal. Rptr. 225.

107. RESTATEMENT § 402A, *supra* note 2, at comment k.

108. *See supra* note 88.

109. *Barker*, 20 Cal. 3d 413, 573 P.2d 443, 143 Cal. Rptr. 225.

110. *Id.* at 426-27, 573 P.2d at 453, 143 Cal. Rptr. at 235.

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

112. *See Amicus Brief, supra* note 95, at 41-42.

is readily available to product liability plaintiffs.¹¹³ The risk-benefit analysis that precedes approval of any prescription drug is sufficient; it does not warrant the imposition of an additional burden of proof upon manufacturers.¹¹⁴

B. PHARMACEUTICAL DRUG SHORTAGES DUE TO FEAR OF LIABILITY

Application of a *Barker* analysis to prescription drugs will have a negative effect upon the supply of necessary pharmaceutical drugs.¹¹⁵ If drug companies are held liable for unforeseeable or unavoidable injuries, the fear of such liability can extend testing of new drugs and delay marketing. Further, manufacturers of unavoidably unsafe drugs may cancel drug production because of the fear of liability.

Illustrative of the negative effect strict liability will have upon drug manufacturers is the case of the swine flu vaccine shortage.¹¹⁶ In 1976, President Gerald Ford announced plans to conduct a national vaccination program against a newly discovered influenza virus, the swine flu.¹¹⁷ A swine flu vaccine was ready for production, but fear of liability by drug manufacturers caused insurance companies to deny liability coverage to manufacturers of the vaccine.¹¹⁸ Consequently, manufacturers were unwilling to supply the vaccine.¹¹⁹ Production of the vaccine proceeded only after Congress passed legislation naming the United States as the defendant in any action by recipients of the vaccine.¹²⁰

Recently, a major drug company stopped production of diphtheria, pertussis, and tetanus (DPT) vaccine because of the "extreme liability exposure, cost of litigation and the difficulty

113. *Id.*

114. *Id.*

115. *See supra* note 88.

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

117. *Id.* Scientists had warned this was necessary to avoid a devastating epidemic.

Id.

118. *Id.*

119. *Id.*

120. *Id.*

of continuing to obtain adequate insurance."¹²¹ Subsequently, another major drug company acted similarly.¹²² The company informed the federal government's Centers for Disease Control that, due to the unwillingness of its liability carriers to renew coverage of DPT vaccine sales, the company would be unable to respond to new requests to supply the vaccine to state and local health departments.¹²³ One vaccine manufacturer remained in the market and announced it would attempt to make up the resulting shortage of vaccine.¹²⁴ However, this manufacturer experienced production problems which prompted the Director of the Centers for Disease Control to advise Congress that, unless drastic measures were taken, there would be shortages of DPT in the early months of 1985 in many areas of the country.¹²⁵

At a house committee hearing, a physician, speaking on behalf of the American Academy of Pediatrics, suggested that instead of spreading the cost of a very limited risk, expanded liability would greatly increase the risk to the public.¹²⁶ After noting that high liability awards had driven several vaccine producers out of the market and that remaining producers had significantly increased prices, the physician expressed concern that either an insufficient supply or cost of the DPT vaccine would make the vaccine unobtainable to a large segment of the population.¹²⁷ He placed the blame on "the deteriorating liability situation" and noted that the tort process has not served us well.¹²⁸ Additionally, he asserted that many vaccines are still needed even though the diseases are rare; if parents stopped immunizing their children, the diseases would reappear.¹²⁹

For example, oral polio vaccine has been deemed an effective method for preventing polio in the vast majority of those who use it.¹³⁰ Without the vaccine, there would be many victims

121. *Vaccine Injury Compensation: Hearings Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce*, 98th Cong., 2d Sess. 122 (1984).

122. *Id.*

123. *Id.*

124. *Id.*

125. *Id.*

126. *Id.*

127. *Id.*

128. *Id.*

129. *Id.*

130. *Id.*

of this disease. However, the very nature of the live vaccine means that on rare occasions, and without any way of predicting, some unfortunate recipients contract the disease from the vaccine.¹³¹

C. APPLICATION OF COMMENT K

Comment k does not grant pharmaceutical manufacturers immunity from strict product liability rules.¹³² On the contrary, these manufacturers may be held strictly liable for any medicine that they improperly prepare; improper preparation is considered a manufacturing defect.¹³³ Furthermore, drug manufacturers may be liable for inadequate warnings. Comment k mandates that the medicine in question must present only a "reasonable risk" to the public; the benefits from its use must outweigh the attendant risks.¹³⁴ However, manufacturers under comment k are required to provide warnings against even unavoidable risks although the user can do nothing to reduce those risks.¹³⁵ Additionally, a pharmaceutical manufacturer must provide warnings against preventable dangers.¹³⁶ Warnings must be given by the person most capable of making a decision regarding the risk to any given individual—the physician who will prescribe the drug.¹³⁷

Comment k imposes a modified strict liability standard which is more properly adapted to unavoidably unsafe products. Manufacturers of these products may incur strict liability for manufacturing defects or inadequate warnings. However, manufacturers may not incur strict liability solely because they fail the consumer-expectation test nor may they be subject to a design defect analysis; unavoidable hazards are not deemed defects.

Comment k is largely premised upon public policy.¹³⁸ The

131. *Id.*

132. RESTATEMENT § 402A, *supra* note 2, at comment k.

133. *Id.*

134. *Id.*

135. *Id.*

136. *Finn v. G.D. Searle & Co.*, 35 Cal. 3d 691, 697, 677 P.2d 1147, 1153, 200 Cal. Rptr. 870, 876 (1984).

137. *Id.*

138. *See supra* note 6.

authors of comment k were concerned with the population's health. They did not want drug research and manufacturing to be infringed upon due to fear of liability.¹³⁹ Comment k was tailored by experts to fit the body of pharmaceutical medicines as well as other unavoidably unsafe products. The system has worn well for over twenty years. Society's need for development of new drugs has, if anything, increased. There is no need to alter the design.

D. PREDICTIONS AND RECOMMENDATIONS

In light of the fact that the California appellate courts have traditionally applied comment k to determine liability for prescription drugs, it seems unlikely that the Supreme Court of California will abandon that standard in favor of a *Barker* analysis. The policy reasons which underlie comment k will weigh heavily in the decision-making process. As has been shown, there is considerable data to support the fear that drug research and manufacturing will be severely handicapped with a broader application of liability. Additionally, the often expressed desire of the authors of comment k that manufacturers not become insurers of their products¹⁴⁰ is a persuasive reason to continue comment k protection for prescription drugs.

According to the *Finn* decision, the court is unwilling to reject the reasonableness language of the Restatement as a standard for determining strict liability for failure to warn in drug injury cases.¹⁴¹ The *Finn* court also asserted that this was not the appropriate case to consider the broader issue of "application of strict liability principles to injurious side effects allegedly produced by prescription drugs."¹⁴² Therefore, in light of the *Finn* decision, it is unlikely that the court will reject comment k in favor of a *Barker* analysis.

It is more likely that the court will grant some protection to certain drugs such as vaccines which either prevent a disease or reduce the spread of a disease among a significant number of

139. *Id.*

140. RESTATEMENT § 402A, *supra* note 2, at comment k.

141. *Finn*, 35 Cal. 3d 691, 677 P.2d 1147, 200 Cal. Rptr. 870.

142. *Id.*

individuals. These drugs will continue to receive comment k protection. In order for a drug manufacturer to be held strictly liable, a plaintiff must show either a manufacturing flaw or an inadequate warning. The remaining unavoidably unsafe products or prescription drugs will be subject to a standard of liability to be determined on a case-by-case basis; those drugs must be determined to be unavoidably unsafe and beneficial enough to outweigh the risks involved with their use.

Concededly, this method of determining liability is not without fault. Initially, there is the question of who shall make the determination, judge or jury? Either alternative presents further litigation problems to an already overloaded judicial system. However, the problem can be avoided if the California Supreme Court will acknowledge that which has long been established in the appellate courts—comment k should govern liability for prescription drugs.

A compelling proposal is for the government to indemnify those individuals who are injured as a result of vaccination programs. Not only are these programs beneficial, they are often mandatory. This, however, is a legislative matter, not a judicial matter.

V. CONCLUSION

The unavoidably unsafe product doctrine of comment k was intended to apply to all strict products liability cases involving pharmaceutical medicines. It has served, thus far, as the basis for establishing liability in the California courts and should continue to do so. Additionally, imposition of strict products liability is likely to result in a shortage or elimination of needed drugs.

Furthermore, certain aspects of the strict products liability standard governing ordinary products are not applicable to pharmaceutical medicines. For instance, drugs are unique products. They are chemical compounds with characteristics inherent to their very nature. These characteristics occasionally cause problems. However, a change in the compound would alter the effectiveness of the drug.

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Finally, comment k does not immunize manufacturers from strict products liability. Rather, it imposes a modified strict liability standard which is more properly adapted to unavoidably unsafe pharmaceutical drugs. The troublesome result of strict liability would be a heavy price to pay for compensation of those unfortunately injured as a result of lifesaving drugs.

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