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Brown v. Superior Court: Drug Manufacturers get Immunized from Strict Liability for Design Defects

Terrie Bialostok Brodie

BROWN V. SUPERIOR COURT: DRUG MANUFACTURERS GET IMMUNIZED FROM STRICT LIABILITY FOR DESIGN DEFECTS

I. INTRODUCTION

In *Brown v. Superior Court*[1] the California Supreme Court held that a drug manufacturer cannot be held strictly liable for harm caused by a prescription drug. In doing so, the court purported to adopt comment k of RESTATEMENT (SECOND) OF TORTS SECTION 402A[2] (*hereinafter* comment k), but interpreted the

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1. 44 Cal. 3d 1049, 751 P.2d 470, 245 Cal. Rptr. 412 (1988).
2. RESTATEMENT (SECOND) OF TORTS § 402A (1965) states:

> (1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer or to his property, if (a) the seller is engaged in the business of selling such a product, and (b) it is expected 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.
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> comment k
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> *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 unavoidable 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 very 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

comment as providing a blanket immunity from strict liability for design defects of prescription drugs.

The court's decision gives prescription drug manufacturers broad protection against liability. A consumer injured due to the defective condition of a prescription drug must now prove negligence or failure to warn of a known risk.

The *Brown* decision resulted from a suit filed by 69 women against numerous drug manufacturers who allegedly produced DES,[3] a substance ingested by the plaintiffs' mothers to prevent miscarriage. They alleged that DES was defective and caused them injury *in utero*.[4] The court's ruling will impact both men and women as consumers of prescription drugs. However, the decision has several ramifications which will impact specifically on womens' health. First, it appears that women have suffered the greatest ill-effects from their mothers' ingestion of DES.[5]

> sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such 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.

3. Diethylstilbestrol (DES) is a synthetic substance which duplicates the activity of estrogen, a female sex hormone. In 1947, the Food and Drug Administration (FDA) authorized the marketing of DES as a miscarriage preventative on an experimental basis. DES was made or distributed by 267 drug companies. The drug companies were all able to produce the drug because it was an unpatented generic product. By the mid-1950's studies had been conducted showing that DES did not prevent miscarriages. However, the drug remained on the market. In 1971, several physicians published an article associating DES with a rare form of vaginal cancer in young girls born to women who had taken the drug during pregnancy. The cancer, clear-cell adenocarcinoma, had previously been seen only in much older women. R. MEYERS, DES, THE BITTER PILL 17-19 (1983). In 1971, the FDA ordered that DES not be marketed or promoted for the purpose of preventing miscarriages. Sindell v. Abott Laboratories, 26 Cal. 3d 588, 607 P.2d 924, 163 Cal. Rptr. 132 (1980).

For a detailed history and information on DES, *see* D. FINK, DES TASK FORCE SUMMARY REPORT, (DHEW, PUB. No. (NIH) 84-1688 1978).

4. Brown v. Superior Court, 44 Cal. 3d 1049, 1054-1055, 751 P.2d 470, 473, 245 Cal. Rptr. 412, 414 (1988).

5. Some research has indicated that there is a slightly higher frequency of certain genital abnormalities among DES sons. Some examples include undescended testes, hypoplastic testes, epididymal cysts, and low or abnormal sperm counts. D. FINK, DES

Second, some prescription drugs such as birth control pills and pregnancy medications are designed and marketed specifically for women. In light of the *Brown* decision, women using these types of prescription drugs will be prohibited from bringing a strict liability action if a drug is defectively designed. Finally, if this decision reflects a trend by a new and more conservative California Supreme Court,[6] it may have an even greater impact on women. In *Collins v. Ortho Pharmaceutical Corporation*[7] the California Court of Appeals for the Fifth District held that an IUD (a prescription device) was exempt from strict liability design defect analysis. The *Collins* court stated, "[w]hen the product which allegedly caused a plaintiff's injury is a prescription product, *which is distributed with the approval of the FDA provided the manufacturer accompany the product with warnings of foreseeable risks*, we conclude the product must be considered unavoidably unsafe as a matter of law and thus outside the parameters of strict liability for defective design."[8] The California Supreme Court initially granted *Collins* review prior to its decision in *Brown*.[9] Subsequent to *Brown*, however, the California Supreme Court dismissed and remanded Collins back to the court of appeals.[10] If other appellate courts follow the *Collins*

TASK FORCE SUMMARY REPORT, (DHEW, PUB. NO. (NIH) 53844403 23 (1985)). There is no evidence yet of any increased risk of cancer of the testes, prostate or other sites among DES sons. D. FINK, DES TASK FORCE SUMMARY REPORT, (DHEW, PUB. NO. (NIH) 84-1688 65 (1978)).

6. For the first time in California's history, voters decided in November 1986 not to retain sitting justices—Chief Justice Rose Elizabeth Bird, Associate Justice Cruz Reynoso, and Associate Justice Joseph Grodin. Much of the campaign against them was fought on the death penalty issue, but the court's tort decisions were also attacked. Sugarman, *Taking Advantage of the Torts Crisis*, 48 OHIO ST. L.J. 329, 338 (1987).

7. *Review granted*, 186 Cal. App. 3d 1194, 732 P.2d 542, 234 Cal. Rptr. 596 (1987), dismissed 761 P.2d 102, 251 Cal. Rptr. 642 (1988). Plaintiff suffered uterine problems that ultimately resulted in a hysterectomy. The problems were allegedly caused by an intrauterine (IUD) birth control device.

8. Collins v. Ortho Pharmaceutical Corp., 195 Cal. App. 3d 1539, 1551, 231 Cal. Rptr. 396, 404 (1986).

9. *Collins* was granted review Feb. 26, 1987. Collins v. Ortho Pharmaceutical Corp., 186 Cal. App. 3d 1194, 732 P.2d 542, 234 Cal. Rptr. 596 (1987). *Brown* was decided April 1, 1988.

10. *Collins*, 761 P.2d 102, 251 Cal.Rptr. 642. The court dismissed the review pursuant to Rule 29.4(c) of California Rules of Court. Rule 29.4(c) states in part:

> "[Dismissal of review] The Supreme Court may dismiss review of a cause as improvidently granted and remand the cause to the Court of Appeal."

If the Supreme Court dismisses review as improvidently granted under subdivision (c), the cause is restored to the posture it had before the Supreme Court granted review: the decision of the Court of Appeal is final. CALIFORNIA RULES OF COURT 29.4(c) Advisory

rationale, women injured due to defectively designed prescription devices (e.g. prescription contraceptive devices) will be precluded from proceeding on a strict liability design defect theory.

II. BACKGROUND

The plaintiffs in *Brown* sought recovery on theories of strict liability for design defect, failure to warn, breach of express and implied warranty, fraud and negligence.[11] The California Supreme Court granted review to examine the conclusions of the court of appeals and its potential conflict with *Kearl v. Lederle Laboratories*[12] on the issue of strict liability of a drug manufacturer for a defect in the design of a prescription drug.[13]

The *Kearl* court disapproved the "rather routine and mechanical fashion by which many appellate courts have concluded that certain products, particularly drugs," are exempted from strict products liability.[14] That court held that the decision as to whether a drug, vaccine, or any other product is entitled to exemption from strict liability design defect analysis as an unavoidably unsafe product is a mixed question of law and fact. A trial court should take evidence as to: (1) whether, when distributed, the product was intended to confer an exceptionally important benefit that made its availability highly desirable; (2) whether the then-existing risk posed by the product both was "substantial" and "unavoidable";[15] and (3) whether the interest in availability (measured as of the time of distribution) outweighs the interest in promoting enhanced accountability through strict liability design defect review. If these factors ex-

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Committee's comment.

11. Brown v. Superior Court, 44 Cal. 3d 1049, 1055-1056, 751 P.2d 470, 473, 245 Cal. Rptr. 412, 414-415 (1988).

12. 172 Cal. App. 3d 812, 218 Cal. Rptr. 453 (1985).

13. *Brown*, 44 Cal. 3d at 1055-1056, 751 P.2d at 473, 245 Cal. Rptr. 415.

14. Kearl v. Lederle Laboratories, 172 Cal. App. 3d 812, 829, 218 Cal. Rptr. 453, 463 (1985).

15. One commentator has suggested that courts should weigh the risks which exist at the time of trial. Keeton, *Manufacturer's Liability: The Meaning of "Defect" in the Manufacture and Design of Products*, 20 SYRACUSE L. REV. 559, 570-571 (1969). The rationale is that the fact-finding task in determining whether a risk is knowable is often impossible, especially when drugs are involved. The outcome "depends too much on the competency and skill of the advocates and investigators." *Id.* at 570. However, this is too great a burden to place on manufacturers as they should not be required to be clairvoyant. Toner v. Lederle Laboratories, 112 Idaho 328, 337-338, 732 P.2d 297, 306-307 (1987).

ist, the product will be deemed unavoidably dangerous and exempted from strict products liability design defect analysis.[16]

The *Brown* court rejected that portion of *Kearl*[17] which held that not all prescription drugs should be exempt from strict liability design defect analysis.[18] This note analyzes only that portion of the *Brown* decision relating to design defects[19] in prescription drugs.[20]

III. THE COURT'S REASONING

A. Prescription Drugs as Compared to Other Products

The *Brown* court attempted to distinguish prescription drugs from other products.

> In the latter cases [other products], the product is used to make work easier or to provide pleasure, while in the former [prescription drugs] it may be necessary to alleviate pain and suffering or to sustain life. Moreover, unlike other important medical products (wheelchairs, for example), harm to some users from prescription drugs is unavoidable.[21]

Once the court determined there was a distinction between prescription drugs and other products, it then balanced the public policies mitigating for and against imposition of strict liability for design defects of prescription drugs.

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16. *Kearl*, 172 Cal. App. 3d at 829-830, 218 Cal. Rptr. at 463-464.

17. 172 Cal. App. 3d at 829, 218 Cal. Rptr. at 463 (1984).

18. Brown v. Superior Court, 44 Cal. 3d 1049, 1068-1069, 751 P.2d 470, 482, 245 Cal. Rptr. 412, 424 (1988).

19. Two alternative tests have been adopted by the California Supreme Court by which to measure design defects. First, whether the product performed as safely as the ordinary consumer would expect when used in an intended and reasonably foreseeable manner. Second, whether the benefits of the challenged design outweighed the risk of danger inherent in the design. This second test is know as the risk/benefit analysis. Barker v. Lull Engineering, 20 Cal. 3d 413, 431-432, 573 P.2d 443, 455-456, 143 Cal. Rptr. 225, 237-238 (1978).

20. The *Brown* Court also dealt with the issues of failure to warn, fraud, breach of express and implied warranty, and whether the liability imposed on drug manufacturers in DES cases should be joint and several. *Brown*, 44 Cal. 3d at 1065-1066 and 1069-1075, 751 P.2d at 477-478 and 483-487, 245 Cal. Rptr. at 421-422 and 424-428.

21. *Id.* at 1063, 751 P.2d at 478, 245 Cal. Rptr. at 420.

B. Competing Public Policies

1. *Public Policies Favoring Strict Liability for Design Defects in Prescription Drugs*

The California Supreme Court first held a manufacturer strictly liable in tort in *Greenman v. Yuba Power Products, Inc.*[22] In that landmark decision, Justice Traynor stated the purpose of strict liability is to impose the cost of injuries on manufacturers who market the product rather than on "injured persons who are powerless to protect themselves."[23]

In addition to the public policy of placing the responsibility of a defective product on the manufacturer, the goals of risk reduction and risk distribution also underlay the imposition of strict liability. Risk reduction operates on the premise that manufacturers will work to make their products safer if they are liable for defective products.[24] Risk distribution spreads the cost of injury from those who are harmed by a defective product to consumers of the product who will pay a higher price to reflect the increased cost of insurance to the manufacturer.[25] The *Brown* court accepted that "[t]hese reasons could justify application of the doctrine to the manufacturers of prescription drugs."[26] However, because the court determined that prescription drugs are distinct from other products it proceeded to evaluate counter policy considerations.[27]

2. *Public Policies Opposing Strict Liability for Design Defects in Prescription Drugs*

The *Brown* court espoused three public policies mitigating

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22. 59 Cal. 2d 57, 58-59, 377 P.2d 897, 898, 27 Cal. Rptr. 697, 698 (1963). Plaintiff was injured by the defective design of a power tool. The court held that a manufacturer is strictly liable in tort when an article it places on the market, knowing the article is to be used without inspection for defects, proves to have a defect that causes injury to some human being.

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

24. Brown v. Superior Court, 44 Cal. 3d 1049, 1062, 751 P.2d 470, 478, 245 Cal. Rptr. 412, 419-420 (1988).

25. *Id.* at 1062-1063, 751 P.2d at 478, 245 Cal. Rptr. at 419-420.

26. *Id.* at 1063, 751 P.2d at 478, 245 Cal. Rptr. at 420.

27. *Id.* at 44 Cal. 3d at 1063-1065, 751 P.2d at 478-480, 245 Cal. Rptr. at 420-421.

against imposing strict liability for prescription drugs.[28] First, the court was concerned that drug manufacturers might stop producing valuable drugs because of lost profits resulting from lawsuits or the inability to obtain adequate insurance.[29]

Second, there is a consumer interest in getting new drugs on the market as quickly as possible. Imposition of strict liability might cause manufacturers to delay in putting new products on the market.[30]

Finally, the added expense of insuring against strict liability and additional research programs might cause the cost of medication to increase in price so that it would no longer be affordable to consumers.[31]

These policy considerations prompted the court to adopt comment k and to interpret it as providing drug manufacturers blanket immunity from strict liability for design defects.[32]

C. Comment k of Restatement (Second) section 402A

Comment k creates an exception to the Restatement (Second) of Torts section 402A for products which are "unavoidably unsafe" and should, therefore, not be subject to strict liability.[33] For over two decades, courts have almost universally concluded that some special products should not be subjected to design defect analysis.[34] The *Brown* court conceded that the language of comment k is unclear as to whether it should be interpreted as granting prescription drugs blanket immunity from strict liability.[35] However, the court chose to interpret the comment as exempting all prescription drugs from design defect analysis stating, "we are of the view that the comment was intended to and should apply to all prescription drugs."[36]

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28. *Id.* at 1063-1065, 751 P.2d at 478-480, 245 Cal. Rptr. at 420-421.
29. *Id.* at 44 Cal. 3d at 1063-1065, 751 P.2d at 479-480, 245 Cal. Rptr. at 420-421.
30. *Id.* at 44 Cal. 3d at 1063, 751 P.2d at 479, 245 Cal. Rptr. at 420.
31. *Id.*
32. *Id.* at 1061, 751 P.2d at 477, 245 Cal. Rptr. at 418 (1988).
33. *See supra*, note 2.
34. Kearl v. Lederle Laboratories, 172 Cal. App. 3d 812, 825, 218 Cal. Rptr. 453, 460-461 (1985).
35. *Brown*, 44 Cal. 3d at 1069, n.11, 751 P.2d at 482, 245 Cal. Rptr. at 424.
36. *Id.*

The court gave two reasons for this interpretation and application of comment k. First, it stated that "almost all jurisdictions that have adopted the rule stated in the comment view its provisions as granting immunity from strict liability to all such drugs."[37] Second, the court contended that granting drug manufacturers any protection short of blanket immunity from strict liability would result in valuable drugs being withheld from consumers. The court believed that the public interest in developing and marketing new drugs would be substantially impaired by the very process of attempting to distinguish which drugs should receive the protection of comment k because drug manufacturers would have no assurance as to whether a product placed on the market will be measured by the liability standard of comment k or a stricter standard.[38] "In order to vindicate the public's interest in the availability and affordability of prescription drugs, a manufacturer must have a greater assurance that his products will not be measured by a strict liability standard than is provided by the test stated in *Kearl*."[39]

The *Brown* court conceded that "[i]t seems unjust to grant the same protection from liability to those who gave us thalidomide as to the producers of penicillin."[40] However, the court permitted other policies to override this injustice, and therefore rejected the test set forth in *Kearl* which would determine if a prescription drug is entitled to comment k protection.

It is the opinion of this author that the *Brown* court erroneously allowed its concern for the availability and affordability of prescription drugs to completely overshadow other important public policy concerns favoring strict liability. This Note proposes that the availability and affordability of prescription drugs could have been properly balanced with the need to protect innocent consumers by following the test set forth in *Kearl v. Lederle Laboratories*.

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37. *Id.*

38. *Id.* at 1067-1068, 751 P.2d at 481-482, 245 Cal. Rptr. at 423-424.

39. *Id.* at 1068, 751 P.2d at 482, 245 Cal. Rptr. at 424. The *Brown* court also gave other reasons for its rejection of the *Kearl* test but those seemed secondary to the reasons discussed here. For a response to these other reasons, *see* Toner v. Lederle Laboratories, 112 Idaho at 328, 340 n.10, 732 P.2d 297, 309 (1987).

40. *Id.* at 1067, 751 P.2d at 481, 245 Cal. Rptr. at 423.

IV. CRITIQUE

A. EFFECTS OF *BROWN* DECISION

The California Supreme Court's decision will often result in leaving a victim who is harmed by a defective drug without remedy. This unfortunate consequence will hold true regardless of how catastrophic the harm or how ineffective or unnecessary the drug. Although the victim can pursue a negligence cause of action, the hurdle is greater since the plaintiff must carry the evidentiary burden.[41] In the case of a drug manufacturer, a plaintiff may have a particularly difficult burden of proof. "The time and expense required to investigate all the procedures of those who make and sell a new drug is enormous, and may prevent an individual litigant from gathering the necessary facts to prove negligence when it does, in fact, occur."[42]

B. *BROWN*'S DISTINCTION OF PRESCRIPTION DRUGS

The distinctions made by the *Brown* court between prescription drugs and other products[43] are artificial. The distinction between products which make work easier or provide pleasure and prescription drugs which may be necessary to alleviate pain does not always hold true. For example, not all prescription drugs are intended to alleviate pain and suffering but fall more within the "providing pleasure" category. (e.g. minoxidol promotes hair growth[44] and Retin-A tightens wrinkles.[45]) As technology develops and knowledge increases, it is reasonable to expect an increase in prescription drugs which are cosmetic and would fit more within the "providing pleasure" classification. Also, strict liability applies to other products (non-prescription drugs) which alleviate pain and suffering. (e.g. arm and leg control devices enabling handicapped individuals to drive automobiles). The court's explanation for these differing standards was

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41. The burden of proof of the defendant's negligence is on the plaintiff. W. PAGE KEETON, PROSSER AND KEETON ON TORTS, P 139 (5th ed. 1984).

42. Keeton, *Products Liability—Drugs and Cosmetics*, 25 VAND. L. REV. 131, 141 (1972).

43. *Brown*, 44 Cal. 3d at 1063, 751 P.2d at 478-479, 245 Cal. Rptr. at 420.

44. Langone, *Gone Today, Hair Tomorrow*, TIME, Aug. 29, 1988, at 78.

45. Roberts, *Questions Raised About Anti-Wrinkle Cream*, SCIENCE, Feb. 5, 1988, at 564.

that "harm to some users from prescription drugs is unavoidable."[46]

The court's distinction based on the "unavoidability" of harm is not relevant to the issue of liability for design defects in prescription drugs. There is a difference between harm caused by design defects as compared to harm caused by other adverse drug reactions. Harm to some users of prescription drugs may indeed be unavoidable if the harm resulted from idiosincratic reactions or side effects of the drug which could not be anticipated by the manufacturer.[47] In contrast, if the harm is caused by a design defect in the drug itself the harm was avoidable because a safer alternative design was available. Therefore, by definition, harm caused by a design defect cannot be "unavoidable."

The court's attempt to distinguish prescription drugs from other products, either on the basis of the type of benefit they confer or the avoidability of harm, is tenuous. The court's argument is circular: all prescription drugs should receive the protection which comment k grants to unavoidably unsafe products because prescription drugs are unavoidably unsafe. The court's reasoning makes it appear as if it first decided to exempt all prescription drugs from strict liability, and then selected comment k as its vehicle to do so. Although the court has hung its hat on comment k, the comment fails to provide the support for which the *Brown* court searches to rest its policy based decision.

C. The Comment K Controversy

1. *The language of comment K*

Commentators have criticized comment k as being vague,

46. *Brown*, 44 Cal. 3d at 1063, 751 P.2d at 478, 245 Cal. Rptr. at 420.

47. A product which causes harm due to its interaction with a person's body chemistry does not exclude it from strict liability design defect analysis. The interaction of the product with the body chemistry should be part of safety considerations inherent in the design of the product. Thus, strict liability for design defect was applicable to a tampon manufacturer. West v. Johnson & Johnson Products, Inc., 174 Cal. App. 3d 831, 220 Cal. Rptr. 437 (1985). Plaintiff contracted toxic shock syndrome resulting from the use of a vaginal tampon manufactured by defendant. She received a judgment against the manufacturer based on a strict product liability design defect theory. The *West v. Johnson & Johnson* decision will presumably not be affected by *Brown* because it involved a non-prescription device.

obscure or even meaningless.[48] The *Brown* court conceded it is unclear whether comment k grants blanket immunity from strict liability to all prescription drugs or just to those that are unavoidably dangerous.[49] Despite this uncertainty, the court stated, "[n]evertheless, we are of the view that the comment was intended and should apply to all prescription drugs. . .[A]lmost all jurisdictions that have adopted the rule stated in the comment view its provisions as granting immunity from strict liability to all such drugs."[50]

The court's interpretation and application of comment k on the basis of other states' holdings is without merit. "The *Brown* court overlooked the mountain of decisions that limit comment k to drugs that are in fact 'unavoidably unsafe'. . . and relied instead on a handful of decisions that did not address the issue, let alone resolve it in the manner *Brown* purported to follow."[51]

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48. *See*, e.g., Page, *Generic Product Risks: The Case Against Comment k and For Strict Tort Liability*, 58 N.Y.U.L. REV. 853 (1983); Twerski, *National Product Liability Legislation: In Search for the Best of All Possible Worlds*, 18 IDAHO L. REV. 411, 430 (1982).

49. *Brown*, 44 Cal. 3d at 1069 n.11, 751 P.2d at 482, 245 Cal. Rptr. at 424.

50. *Id.* at 1069 n.11, 751 P.2d at 482, 245 Cal. Rptr. at 424.

51. Brief for Appellants at 46, White v. Wyeth, 40 Ohio St. 3d 390, 533 N.E. 2d 748 (1988)(No. 87-1657).

Appellants in *White v. Wyeth* analyzed the cases cited by the *Brown* court: In three of the cases cited in *Brown*, the court held only that the evidence established the particular drug was unavoidably unsafe. *See* DeLuryea v. Winthrop Laboratories, 697 F.2d 222, 229 (8th Cir. 1983) ("[t]he evidence in this case points to Talwin being an unavoidably unsafe product."); Stone v. Smith, Kline & French Laboratories, 447 So. 2d 1301, 1302 (Ala. 1984) (plaintiffs presented no facts that the drug was unavoidably unsafe); Gaston v. Hunter, 121 Ariz. 33, 588 P.2d 326, 338-41 (Ariz. 1987) (reviewing evidence to determine balance of risks and benefits).

In Basko v. Sterling Drug, Inc., 416 F.2d 417, 425-426 (2nd Cir. 1969) (applying Connecticut law), although the court relied on comment k, its discussion of the issue suggests that it understood Connecticut not to generally recognize a cause of action for strict liability design defect. *Id.* at n.12.

In Chambers v. G.D. Searle & Co., 441 F.Supp. 377, 380-381 (D.Md. 1975) *aff'd*, 567 F.2d 269 (4th Cir. 1977) (applying District of Columbia law), the court appeared to deal with a failure to warn issue rather than a design defect claim. Brief for Appellants at 46-47, n.39, White v. Wyeth, 40 Ohio St. 3d 390, 533 N.E. 2d 748 (1988)(No. 87-1657).

In Johnson v. American Cyanamid Co., 239 Kan. 279, 447 So. 2d 1301 (Ala. 1984) the court held only that the vaccine Orimune was an unavoidably unsafe product, not that all prescription drugs and vaccines are unavoidably unsafe. *Johnson*, 239 Kan. at 285-286, 447 So. 2d at 1323-1324. Subsequently, in Castrignano v. E.R. Squibb & Sons, Inc., 546 A.2d 775, 781-782 (1988), the Rhode Island Supreme Court cited *Johnson* to stand for the proposition that the question of whether a prescription drug is unavoidably unsafe is a ruling which the court allows the judge to make as a matter of law. *Castrignano*, 546 A.2d at 781-782. Obviously, this is contrary to the *Brown* court's use of

Even assuming, *arguendo*, that those decisions of other states gave all prescription drugs the protection of comment k, if the *Brown* court were truly persuaded by the decisions of other jurisdictions[52] it should have not simply followed their holdings but, more important, it should have been persuaded by their reasoning. Yet, as the *Brown* court itself noted, most cases which have embraced the rule of comment k have not given much consideration to its language.[53] Thus, these cases offer little reasoning which might assist in the interpretation and application of comment k. The *Kearl* court summarized this problem stating,

> [a]lthough. . .the rule against subjecting some special products to strict liability design defect analysis is well established, its application has not often been well explained. Instead, the rule is frequently stated in conclusory fashion accompanied by little more than a reference or citation to Restatement Second of Torts section 402A, comment k, which sets out the basic rule.[54]

"The statement that drugs are unavoidably unsafe, and therefore within the protection of comment k, has become almost tautological."[55] The decisions of other jurisdictions, then, do little to provide the *Brown* court a rationale for its interpretation and application of comment k.

2. *The interpretation and application of comment k by other state supreme courts*

Supreme court decisions in other states have challenged this routine application of comment k to all prescription drugs.[56]

Johnson as support for the proposition that comment k exempts all prescription drugs from strict liability design defect analysis.

52. The *Brown* court's list of cases contains primarily district and appellate citations. *Brown*, 44 Cal. 3d at 1059-1060, 751 P.2d at 476, 245 Cal. Rptr. at 417-418. It includes only two state supreme court decisions, Stone v. Smith, Kline & French Laboratories, 447 So. 2d 1301 (Ala. 1984) and Johnson v. American Cyanamid Co., 239 Kan. 279, 718 P.2d 1328 (Kan. 1986). Neither state supreme court decision holds that comment k protects all prescription drugs from design defect analysis. *See supra* note 51.

53. *Brown*, 44 Cal. 3d 1049, 1060, 751 P.2d 470, 476, 245 Cal. Rptr. 412, 418 (1988).

54. Kearl v. Lederle Laboratories, 172 Cal. App. 3d 812, 828, 218 Cal. Rptr. 453, 463 (1985).

55. Note, *Can A Prescription Drug Be Defectively Designed? Brochu v. Ortho Pharmaceutical Corp.*, 31 DE PAUL L. REV. 247, 254 (1981).

56. Seven state supreme courts have explicitly determined that not all prescription drugs should receive the protection of comment k:

These courts have refused to give prescription drug manufacturers blanket immunity from strict liability design defects.[57] Instead, they have held that the question as to whether a drug is unavoidably unsafe should be decided on a case-by-case basis.[58] In order for a prescription drug to receive the protection of comment k, the scale must clearly tip in favor of benefits.[59]

The Idaho Supreme Court stated the rationale of a case-by-case analysis: a rule providing blanket immunity to prescription drugs from strict liability design defect analysis without requiring a showing that comment k applies "runs counter both to the express language of comment k and to common sense."[60] That court explained,

> [w]e do not believe comment k was intended to provide nor should it provide all ethical drugs

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Colorado - Ortho Pharmaceutical Corp. v. Heath, 722 P.2d 410 (Colo. 1986); Idaho - Toner v. Lederle Laboratories, 112 Idaho 328, 732 P.2d 297 (1987); New Jersey - Feldman v. Lederle Laboratories, 97 N.J. 429, 479 A.2d 374 (1984); Ohio - White v. Wyeth, 40 Ohio St. 3d 390, 533 N.E. 2d 748 (1988); Oregon - Senn v. Wyeth, 305 Or. 256, 751 P.2d 215 (1988); Rhode Island - Castrignano v. E.R. Squibb & Sons, Inc., 546 A.2d 775 (R.I. 1988); Wisconsin - Collins v. Eli Lilly Co., 116 Wis. 2d 166, 342 N.W.2d 37 (1984).

In addition, a Kansas state Supreme Court decision, Johnson v. American Cyanamid, 239 Kan. 279, 718 P.2d 1318 (1986), has been interpreted as holding likewise. *See supra*, note 51.

Two state supreme courts might be interpreted as exempting all prescription drugs from strict liability design defect analysis, although neither specifically discussed the issue: Alabama - Stone v. Smith, Kline & French Laboratories, 447 So. 2d 1301, 1304 (Ala. 1984) ("[I]n the case of an 'unavoidably unsafe' yet properly prepared prescription drug, [footnote omitted] the adequacy of the accompanying warning determines whether the drug, as marketed, is defective, or unreasonably dangerous."); Nebraska - McDaniel v. McNeil Laboratories, 196 Neb. 190, 201, 241 N.W.2d 822, 828 (1976) ("An unavoidably unsafe drug approved for marketing by the United States Food and Drug Administration . . . as a matter of law, is not defective nor unreasonably dangerous. . .").

57. *See supra* note 56.

58. *See* Ortho Pharmaceutical Corp. v. Heath, 722 P.2d 410, 415-416 (Colo. 1986); Toner v. Lederle Laboratories, 112 Idaho 328, 340, 732 P.2d 297, 309 (1987); White v. Wyeth, 40 Ohio St. 3d 390, 395, 533 N.E. 2d 748, 752 (1989); Senn v. Merrell-Dow Pharmaceuticals, 305 Or. 256, 751 P.2d 215, 218 n.4, (1988); Feldman v. Lederle Laboratories, 97 N.J. 429, 447, 479 A.2d 374, 383 (1984); Castrignano v. E.R. Squibb & Sons, Inc., 546 A.2d 775, 781 (1988).

59. Brochu v. Ortho Pharmaceutical Corporation, 642 F.2d 652, 657 (1st Cir. 1981). Plaintiffs were a husband and wife who brought action against the manufacturer of oral contraceptives to recover for damages the woman sustained from taking the drug. The court held that the manufacturer could be held liable for a design defect in the drug.

60. *Toner*, 112 Idaho at 340, n.10, 732 P.2d at 309. Plaintiffs were parents of a child who was permanently paralyzed from the waist down resulting from a vaccination. The court analyzed comment k and determined that not all prescription drugs should receive its protection.

> with blanket immunity from strict liability design defects claims. The comment refers to '*some*' products which are unavoidably unsafe; . . . Obviously, the comment does not apply to *all* drugs. Rather the comment applies 'when the product is unavoidably unsafe,' . . . It is equally obvious that not all drugs are so perfectly designed that they cannot be made more pure or more safe, or that there are not safer, suitable alternatives; nor do the benefits of all drugs necessarily outweigh their risks.[61]

Similarly, the New Jersey Supreme Court stated, "we see no reason to hold as matter of law and policy that all prescription drugs that are unsafe are unavoidably so. Drugs, like any other products, may contain defects that could have been avoided by better manufacturing or design."[62] The Wisconsin Supreme Court has refused to adopt comment k because it "is too restrictive and, therefore, not commensurate with strict products liability law in Wisconsin."[63]

Four months after *Brown*, the Rhode Island Supreme Court considered the issue of whether all prescription drugs should receive the protection of comment k. Having the benefit of the reasoning of each of the supreme court decisions discussed, the Rhode Island Supreme Court rejected *Brown* stating, "[a]lthough both approaches have merit, we believe the societal interest in ensuring the development and marketing of prescrip-

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61. *Id.* at 339, 732 P.2d at 308.

62. Feldman v. Lederle Laboratories, 97 N.J. 429, 447, 479 A.2d 374, 383 (1984). Plaintiff suffered tooth discoloration caused by taking a tetracycline drug and brought a strict liability action against the manufacturer for failing to warn the physician about the drug's side effects. The court held that whether a prescription drug is unavoidably unsafe should be determined on a case-by-case basis.

63. Collins v. Eli Lilly Co., 116 Wis. 2d 166, 197, 342 N.W.2d 37, 52 (1984). Plaintiff claimed injuries from her mother's ingestion of DES while plaintiff was *in utero*. The court permitted her to proceed under a strict products liability cause of action. To prevail on this theory, the plaintiff had to prove: (1) DES was defective when it left the possession or control of the drug company; (2) that DES was unreasonably dangerous to the user or consumer; (3) that the defect was a cause of the plaintiff's injury; (4) that the drug company engaged in the business of producing or marketing DES; and (5) that the product was one which the company expected to reach the user or consumer without substantial change in the condition it was when sold. *Id.*, 116 Wis. 2d at 195-196, 342 N.W.2d at 51.

See also David, *DTP: Drug Manufacturers' Liability*, 9 J. PROD. LIAB. 361, 396-397 (1986) which adopts the view that comment k does not provide blanket immunity for all prescription drugs.

tion drugs will be adequately served by extending the protection to prescription drugs on a case-by-case basis."[64] Most recently the Ohio Supreme Court held that whether a prescription drug "qualifies as 'unavoidably unsafe' under Comment k is a determination to be made on a case-by-case basis."[65] The Ohio Supreme Court explained, "[I]t is . . . obvious that not all drugs are so perfectly designed that they cannot be made more pure or more safe, or that there are not safer, suitable alternatives; nor do the benefits of all drugs necessarily outweigh their risks."[66] Thus, those state Supreme Courts faced with the issue of whether prescription drugs should be afforded blanket immunity from strict liability have opted for a case-by-case analysis.

3. *The interpretation and application of comment K by California appellate courts*

The *Brown* court also referred to three California appellate court decisions which have applied comment k.[67] The court apparently cited these appellate decisions to bolster its interpretation and application of comment k.[68]

First, the court referred to *Carmichael v. Reitz*.[69] However, *Carmichael* does not support the court's interpretation of comment k. This is evidenced by *Flood v. Wyeth*[70] which was de-

64. Castrignano v. E.R. Squibb & Sons, Inc., 546 A.2d 775, 781 (1988). Plaintiff sought to recover for injuries incurred *in utero* by mother's ingestion of DES. The Rhode Island Supreme Court certified three questions concerning injuries caused by prescription drugs: (1) Does the State of Rhode Island recognize an action for damages for personal injuries in the circumstances presented in that case based on theories of strict liability in tort and breach of warranty of merchantability? (2) Does comment k to section 402A of the Restatement of Torts apply in Rhode Island to an action for damages for personal injuries in the circumstances presented in that action based upon strict liability? (3) If comment k applies to that type of action, is its application to DES a matter of law or a question of fact, and, if a question of fact, which party has the burden of proof? *Id.* at 776-777.

65. White v. Wyeth Laboratories, Inc., 40 Ohio St. 3d 390, 395, 533 N.E.2d 748, 752 (1989).

66. *Id.* at 395, 533 N.E. 2d at 752 (citing Toner v. Lederle Laboratories, 112 Idaho 328, 339, 732 P.2d 297, 308 (1987)).

67. Brown v. Superior Court, 44 Cal. 3d 1049, 1059-1060, 751 P.2d 470, 476, 245 Cal. Rptr. 412, 417-418 (1988).

68. *Id.* at 1059-1060, 751 P.2d at 476, 245 Cal. Rptr. at 417-418.

69. 17 Cal. App. 3d 958, 95 Cal. Rptr. 381 (1971).

70. Flood v. Wyeth Laboratories, Inc., 183 Cal. App. 3d 1272, 228 Cal. Rptr. 700 (1986).

cided in the same district, fifteen years after *Carmichael*.[71] The *Flood* court recognized a strict liability cause of action for a vaccine and held the statutory scheme requiring immunization for all school-aged children did not grant immunity to vaccine manufacturers.[72] The *Flood* court, in fact, looked to *Kearl v. Lederle Laboratories*[73] in reaching its decision and cited *Kearl*'s holding that "[m]anufacturers of vaccines are subject to liability under a strict products liability design defect theory, unless the trial court makes certain evidentiary findings."[74] The California Supreme Court denied the manufacturer's petition for review in *Flood*.[75] *Flood*, then, appears to stand for the proposition that prescription drugs can be subject to design defect analysis.

The other two California appellate cases cited by the California Supreme Court as illustrative of courts which have adopted comment k, *Christofferson v. Kaiser*[76] and *Toole v. Richardson*,[77] dealt with the application of strict liability in the context of a duty to warn. Neither stood for the proposition that all prescription drugs should be protected by comment k. This is apparent from the later *Kearl* decision[78] (14 years after *Christofferson* and 18 years after *Toole*) which was decided in the same district as both of these cases. Because *Kearl* made no mention of breaking with precedent, it is reasonable to conclude that the *Kearl* court believed itself to be consistent with these previous decisions.

The *Brown* court is correct in stating that these courts applied comment k.[79] The comment, however, was not understood as exempting all prescription drugs from a strict liability design defect analysis. These cases do not bolster the *Brown* court's decision to protect all prescription drugs from strict liability design defect analysis.

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71. *Carmichael*, 17 Cal. App. 3d 958, 95 Cal. Rptr. 381 (1971).

72. *Flood*, 183 Cal. App. 3d at 1275, 228 Cal. Rptr. at 701.

73. *Id.* at 1276, 228 Cal. Rptr. at 702 (*citing* Kearl v. Lederle Laboratories, 172 Cal. App. 3d 812, 218 Cal. Rptr. 453 (1985)).

74. *Id.*

75. *Id.* at 1280, 228 Cal. Rptr. at 700.

76. Christofferson v. Kaiser Foundation Hospitals, 15 Cal. App. 3d 75, 92 Cal. Rptr. 825 (1971).

77. Toole v. Richardson-Merrell Inc., 251 Cal. App. 2d 689, 60 Cal. Rptr. 398 (1967).

78. Kearl v. Lederle Laboratories, 172 Cal. App. 3d 812, 218 Cal. Rptr. 453 (1985).

79. Brown v. Superior Court, 44 Cal. 3d 1049, 1059-1060, 751 P.2d 470, 476, 245 Cal. Rptr. 412, 417-418 (1988).

In summary, the *Brown* court's interpretation of comment k apparently was not gleaned from the ambiguous language of the comment, the rationale of other jurisdictions or its prior application in California. Further, state supreme courts which have specifically considered the issue as to whether comment k should exempt all prescription drugs from design defect analysis have held contrary to *Brown*.

D. THE *KEARL* TEST: BALANCING CONSUMER PROTECTION WITH MANUFACTURER LIABILITY

1. *A case-by-case "Kearl analysis" relieves the injured plaintiff of two evidentiary burdens*

One of the purposes behind the strict product liability doctrine is to relieve an injured plaintiff of evidentiary burdens inherent in a negligence cause of action.[80] Application of a *Kearl* analysis would effectuate this public policy.

First, once the plaintiff makes a prima facie case showing that the drug's design was the proximate cause of the plaintiff's injury, the burden of proof shifts to the manufacturer[81] who would have the burden of showing that the drug is unavoidably unsafe and, thus, should receive the protection of comment k.[82] Comment k, then, would be an affirmative defense to a claim based on strict liability.[83] As a matter of policy, the burden of proving the status of the knowledge at the time of distribution should be placed on the manufacturer since it is in a superior position to know the technological information in the particular field.[84] The drug manufacturer could use the criteria set forth in *Kearl* to prove that the product is entitled to comment k protection. If the manufacturer is able to sustain its burden of proof

80. Barker v. Lull Engineering Co., 20 Cal. 3d 413, 431-432, 573 P.2d 443, 455, 143 Cal. Rptr. 225, 237 (1978). Plaintiff was injured while operating a piece of heavy construction equipment and claimed that a safety device would have prevented the accident. The court found that the defendant could be held liable for a defect in design. The court held that the once the plaintiff proves that a product's design was the proximate cause of the plaintiff's injury, the burden then shifts to the defendant to prove that the utility of the product outweighs the danger. *Id.*

81. *Id.*

82. Toner v. Lederle Laboratories, 112 Idaho at 328, 338, 732 P.2d 297, 307 (1987).

83. *Id.* at 339, 732 P.2d at 308.

84. Feldman v. Lederle Laboratories, 97 N.J. 429, 455-456, 479 A.2d 374, 388 (1984).

that the drug is unavoidably unsafe, the plaintiff cannot proceed on a strict liability cause of action. Second, if the manufacturer cannot prove that its product should receive the protection of comment k, the plaintiff can proceed on a strict liability cause of action and the drug would be treated like other products to which strict liability applies. Assuming the plaintiff has made out a prima facie showing that the product's design was the proximate cause of his/her injury, the burden of proof would shift to the defendant to prove that the product is not defective.[85]

2. *The Kearl test would not cause drug manufacturers to stop the development of needed drugs*

The *Kearl* test was unacceptable to the *Brown* court because drug manufacturers would not know whether a particular drug would be judged as conferring an exceptional benefit to receive the protection of comment k.[86] The court felt that this potential exposure to greater liability would diminish a manufacturer's incentive to develop and distribute new drugs.[87] The concern that tighter reigns of liability on drug manufacturers would impede development of new drugs or cause bankruptcy has been rejected by other courts.[88] In 1960, a drug manufacturer unsuccessfully argued that public policy will best be served by denying recovery in warranty for "new drugs" because development of medicines will be retarded if manufacturers are held to strict liability for their defects.[89] Similarly, an Illinois court rejected an argument by drug manufacturers that a market share theory would render pharmaceutical companies uninsurable, and thus unable to absorb the costs of liability, stating, "[t]hese economic considerations have arisen where courts have contemplated any expansion of products liability law."[90]

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85. Barker v. Lull Engineering Co., 20 Cal. 3d 413, 431-432, 573 P.2d 443, 455, 143 Cal. Rptr. 225, 237 (1978).

86. Brown v. Superior Court, 44 Cal. 3d 1049, 1067, 751 P.2d 470, 481, 245 Cal. Rptr. 412, 423 (1988).

87. *Id.* at 1067-1068, 751 P.2d at 482, 245 Cal. Rptr. at 423.

88. *See infra* notes 89 and 90.

89. Gottsdanker v. Cutter Laboratories, 182 Cal. App. 2d 602, 611-612, 6 Cal. Rptr. 320, 326 (1960). Plaintiff prevailed in an action based on a breach of implied warranty of merchantability against the manufacturer of a Salk vaccine. Plaintiffs contracted poliomyelitis after being inoculated with the vaccine. *Id.* at 605, 612, 6 Cal. Rptr. at 322, 326.

90. Smith v. Eli Lilly & Co., 527 N.E.2d 333, 349 (1988). Plaintiff was a DES daugh-

"[D]rug manufacturers are not nonprofit or charitable institutions. They are commercial profit-making enterprises . . ."[91] Drug manufacturers are in the business of developing and promoting new drugs and, as in any other enterprise, it pays to produce new products.[92] Drug manufacturers are in competition with one another, just as any other industry. Therefore, they must search for and develop new drugs to stay in business.[93] This concept is more than just academic rhetoric. Merck, a drug manufacturer which has emerged as the leader in new drug development,[94] was ranked number one as the most admired company in 1986, 1987 and 1988.[95] "I think Merck is a very competitive company, and I push our people to be competitive. . .we challenge people to get into new fields, and we tell them that the objective is to make a drug, not just to discover facts and publish in trade journals."[96]

Of course, a desire to remain competitive and produce new

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ter who brought an action against manufacturers who produced DES.

91. Feldman v. Lederle Laboratories, 97 N.J. 429, 444, 479 A.2d 374, 382 (1984). *See e.g.*, STANDARD & POORS INDUSTRY SURVEYS, April 1988, Volume No. 1 at H 16. "Earnings of many leading pharmaceutical companies have also benefited from extensive corporate restructuring programs, which have involved the divestiture of unprofitable or marginal non-drug businesses and stressed investment in high-profit drug operations." *Id.*

92. Selker, *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. LAW REV. 199, 216 (1984). Drug manufacturers rely on research and development as the key to future growth. STANDARD & POORS INDUSTRY SURVEYS, April 1988, Volume No. 1 at H 19. Drug patent laws should also encourage continued development of new drugs. New prescription drugs generally receive a patent for 17 years. After the patent expires, generic drugs may enter the market for that drug. Generic drugs are copies of established brand-name drugs whose patent lives have expired. Prices for generic drugs are less than the original brand name drugs because there is no need to recoup costs such as research and development, FDA approval and advertising. STANDARD & POORS INDUSTRY SURVEYS, April 1988, Volume No. 1 at H 22. Consequently, drug manufacturers must continue to come up with new drugs because they cannot rely on continuing large profits from older drugs once the patents expire and competitive prices enter the market.

93. Rheingold, *Products Liability—The Ethical Drug Manufacturer's Liability*, 18 RUTGERS L. REV. 947, 1017 (1964).

94. STANDARD & POORS INDUSTRY SURVEYS, April 1988, Volume No. 1 at H 20.

95. Davenport, *America's Most Admired Corporations*, FORTUNE, Jan. 30, 1989, at 68.

96. Schultz, America's Most Admired Corporations, Fortune, Jan. 18, 1988, at 38. "Merck's ambitious research and development program spawned an unprecedented list of new drug products, which are now beginning to be translated into sales and profits . . . By the end of this decade, the drugs mentioned above could generate over $1 billion in new revenues for Merck." STANDARD & POORS INDUSTRY SURVEYS, April 1988, Volume No. 1 at H 20.

drugs is not enough. It must also be financially feasible for drug manufacturers to absorb increased insurance costs which may result from potential litigation. Statistics indicate that drug manufacturers have the necessary financial resources.[97] Sixteen pharmaceutical companies are ranked in the top 500 companies in the United States.[98] The industry median for pharmaceutical companies in 1986 for return to investors was 27.90%.[99] Net income rose as high as $779 million.[100] Overall profits increased 20.3% from the previous year.[101] It has been said that "[i]f ever there were an industry which could easily withstand the impact of liability . . . it is the drug industry."[102]

Finally, the *Brown* court's belief that the development of new drugs will be facilitated by holding drug manufacturers to a

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97. American Cyanamid Co., a drug manufacturer, discussed the financial impact of lawsuits on the company in its 1984 annual report.

> The company and its subsidiaries are parties to numerous suits and claims arising out of the conduct of the business. Included among such suits are approximately sixty-six involving personal injury occurring in connection with administration of the company's DPT and oral polio vaccines; these vaccines involve very large damage claims, including claims for punitive damages in many cases. In the opinion of management, the ultimate liability resulting from all pending suits and claims (after taking into account insurance coverage) will not have a material adverse effect upon the consolidated financial position of the company or its subsidiaries.

American Cyanamid Annual Report, 1984, page 39.

98. *Who did best and worst among the 500*, FORTUNE, Apr. 27, 1987, at 404.

99. *Id.* at 384. In this "return to investors" category, pharmaceuticals ranked number six out of twenty-five industries. The return ranged from a low of -9.50% in metals to a high of 48.74% in tobacco. The industry breakdowns are as follows: tobacco 48.74%, rubber products 38.5%, food 36.50%, textiles 35.96%, forest products 30.88%, pharmaceuticals 27.90%, scientific and photo equipment 22.87%, chemicals 21.84%, metal products 21.73%, apparel 21.51%, furniture 17.83%, soaps, cosmetics 16.67%, beverages 16.37%, computers and office equipment 14.64%, publishing, printing 14.47%, building materials 14.07%, transportation equipment 9.32%, industrial and farm equipment 7.33%, electronics 6.55%, motor vehicles and parts 5.16%, petroleum refining 4.00%, aerospace -.04%, mining -.51%, toys, sporting goods -1.11%, metals -9.50%. *Id.* In the "return on stockholder's equity" category, the pharmaceutical industry emerged as the leader with an median of 23.6% followed by the tobacco industry with a median of 22.1%. The low in this category was the toy, sporting goods industry with a median of .3%. *Id.* at 385.

100. *Id.* at 404. Also, Abbott Laboratories reported record sales and profits for the second quarter of 1987. Net income for the period rose to $155.1 million, from $133.7 million in the year-earlier period. Chicago Tribune, July 10, 1987, § 3, at 2, col. 1.

101. *Id.* at at 386.

102. Note, *Strict Liability in Tort: Its Applicability to Manufacturers of Prescription Drugs*, 7 U.C. DAVIS L. REV. 487, 508 (1974).

lesser standard of liability is unrealistic because most drug manufacturers distribute nationwide, including those states which have held that prescription drugs are not automatically exempted from strict liability design defect analysis.[103] Consequently, in the development of new drugs, manufacturers must not only consider liability under California law, but also the tighter reins of liability in other states.[104]

3. *The Kearl test would not cause a delay in marketing new drugs that confer exceptional benefits*

There are some drugs which should get to the consuming public quickly. But that is why it is necessary to analyze each new drug on a case-by-case basis. If there were exigent circumstances or the drug was to confer an exceptional benefit, the *Kearl* test would not subject a drug manufacturer to a strict liability standard.[105]

In contrast, speed is less important in cases where the drug does not confer an exceptional benefit. For example, the public can wait longer for prescription drugs which are primarily cosmetic, if additional testing might ensure greater safety.

4. *Insurance costs for high risk drugs*

The *Brown* court cited several examples of drugs that had to be taken off the market (or could not be put on the market) because of the inability to obtain liability insurance at a reasonable cost.[106] The court stated, "[w]e express no opinion whether the products to which these examples relate were in fact beneficial to the public health."[107] It is absurd not to consider this factor since obtaining insurance is a way of allocating risk and if a product is uninsurable, that implies a high risk. In a high risk

103. *See supra* note 56.

104. *Id.*

105. Kearl v. Lederle Laboratories, 172 Cal. App. 3d 812, 829-830, 218 Cal. Rptr. 453, 463-464 (1985).

106. Brown v. Superior Court, 44 Cal. 3d 1049, 1064-1065, 751 P.2d 470, 479-480, 245 Cal. Rptr. 412, 421 (1988). The court gave examples of an influenza vaccine, a diphtheria-tetanus-pertussis vaccine, a new drug for treatment of vision problems, and an anti-nauseant drug, Bendectin.

107. *Id.* at 1065 n.10, 751 P.2d at 480, 245 Cal. Rptr. at 421.

situation, the manufacturer should then consider how high a benefit the drug is intended to confer. Even more absurd is that the court gave Bendectin, an anti-nauseant drug for pregnant women, as an example of a drug that had to be removed from the market because the cost of insurance almost equalled the entire income from the sale of the drug.[108] Bendectin has been associated with limb deformities and other congenital defects in children of mothers who took the drug.[109] The example of Bendectin, rather than supporting the court's proposition, instead illustrates one of the goals of adopting the *Kearl* test: when the risk becomes so high that the drug is difficult to insure, it forces the manufacturer to consider whether an anti-nauseant drug such as Bendectin is conferring an especially important benefit. If not, the drug should be removed from the market.

The *Brown* court gave an example of a situation in which a manufacturer was unable to market a new drug to treat vision problems because it could not obtain adequate insurance.[110] This illustration is misleading, however, because the drug, Oculinum, is an experimental one and has not been licensed by the FDA.[111] The FDA does not allow patients to be charged for experimental drugs whose value has not been firmly proven.[112] Naturally, the situation is greatly altered when a drug cannot be charged for because the principle of risk distribution is not applicable. That is, the cost of insurance cannot be spread to the consuming public. This is obviously different from the profit-making drug manufacturer who may spread the cost of insurance to consumers of the drug.

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108. *Id.* at 1064, 751 P.2d at 479, 245 Cal. Rptr. at 421.

109. Selker, *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. LAW REV. 199, n.4 (1984).

110. Brown v. Superior Court, 44 Cal. 3d 1049, 1065, 751 P.2d 470, 480, 245 Cal. Rptr. 412, 421 (1988).

111. The drug is made from botulinum, the same toxin that poisons improperly canned food. N.Y. Times, Oct. 14, 1986, at C1, col. 3.

112. Dr. Alan B. Scott, a proponent of Oculinum, sought permission to charge for the drug so he could pay for his insurance. N.Y. Times, Oct. 14, 1986, at C1, col. 3.

5. *The price of prescription drugs will still be affordable to the consuming public*

The *Brown* court gave two examples of dramatic price increases, one case involving a vaccine and the other, a prescription drug.[113]

Although drug price inflation exceeds the overall inflation rate,[114] the example of Bendectin[115] cited by the court is extreme and atypical of the general price increases of prescription drugs. The average prescription cost increased 4.6% from 1985 to 1986 and the average actual cost increased from $9.73 to $10.18.[116] One survey estimated that, for persons using prescription drugs, the average annual expenditure for those under sixty-five was $46 per person and for those over sixty-five, $93 per person.[117]

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113. *Brown*, 44 Cal. 3d at 1064-1065, 751 P.2d at 479, 245 Cal. Rptr. at 421.

114. STANDARD & POORS INDUSTRY SURVEYS, April 1988, Volume No. 1 at H 18. The overall consumer price index rose 1.9% in 1986. Medical care rose 7.5%. *Id.* at H 15. During the same year, the average wholesale price for prescription drugs rose by 8.7%. Budiansky, *The cost of new drugs raises the roof*, U.S. NEWS AND WORLD REPORT, Apr. 6, 1987, at 47.

115. Brown v. Superior Court, 44 Cal. 3d 1049, 1064, 751 P.2d 470, 479, 245 Cal. Rptr. 412, 421 (1988). The price of Bendectin rose 300% before it was removed from the market. *Id.* The actual cost went from 30 cents per tablet to $1.00 per tablet. *Lawsuits Kill Off a Pregnancy Drug*, CHEMICAL WEEK, June 22, 1983, at 14. Bendectin, as a pregnancy prescription drug, is different than many prescription drugs. First, it is reasonable to expect that any drug taken by a pregnant woman may affect the fetus and insurance companies are legitimately fearful about insuring such drugs. Second, even though $1.00 per tablet is expensive, the drug was to be taken only on a temporary basis to prevent nausea.

116. STANDARD & POORS INDUSTRY SURVEYS, April 1988, Volume No. 1 at H 20. As of November 1986, selected prescription drug groups showed the following year-to-year increases: analgesics, 13.0%; antiarthritics, 11.2%; systemic anti-infectives, 6.4%; antispasmodic/antisecretory, 12.1%; bronchial therapy, 13.6%; cancer therapy, 6.9%; cardiovascular, 11.5%; central nervous system stimulants, 25.8%; contraceptives, 13.3%, cough and cold preparations, 8.7%; and dermatological preparations, 2.8%. *Id.* at H 19.

The following reflect price increases of prescription drugs as compared to all other consumer goods between 1981 and 1986 (ratio represented by prescription drugs:all other products): 1981 11.7%:10.4%, 1982 11.0%:6.1%, 1983 10.5%:3.2%, 1984 9.5%: 4.3%, 1985 9.1%:3.6%, 1986 8.7%:1.9%. Budiansky, *The Cost of New Drugs Raises the Roof*, U.S. NEWS AND WORLD REPORT, Apr. 6, 1987, at 47.

117. PMA Statistical Factbook, 1986 at 2-9 to 2-10. The statistics for this study were gathered in 1977. *Id.* A later study was done in 1980 but statistics were reported on a per capita basis rather than the "average charge per user" that the 1977 study reflected. Per capita charges are averaged over all persons in the population, whether they used prescription drugs or not, and thus are lower than average charges per user. That study showed that the per capita cost for prescription drugs was $35 in 1980. Costs of Illness United States, 1980, National Medical Care Utilization and Expenditure Survey,

The *Brown* court also used the cost and the predicted shortage of the diphtheria-tetanus-pertussis (DPT) vaccine[118] to illustrate its point.[119] The vaccine rose in cost from 11 cents in 1982 to $11.40 in 1986.[120] This is a drastic increase, but it is not representative of typical price increases in prescription drugs. The *Brown* court cannot reasonably draw inferences about the cost of prescription drugs based on vaccine statistics because they are not analogous situations. This is evidenced by legislative intervention to deal specifically with problems of liability and compensation for vaccine injuries.[121] In contrast, Congress has not found it necessary to intervene in the area of prescription drugs.

Rising costs are not limited to the pharmaceutical industry.[122] Even outside the pharmaceutical industry, there has been a surge of product related lawsuits.[123] "Premiums paid by companies for protection against product-related litigation have been soaring—and in the last year alone, increases of 300% or more have not been uncommon."[124] Difficulties faced by pharmaceutical companies in obtaining insurance at a reasonable cost is not unique to that industry, but is a problem faced by

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Rising costs of prescription drugs may present a genuine hardship to the elderly. People over 65 consume about 30% of all prescription drugs. *The Big Lie About Generic Drugs*, CONSUMER REPORTS, Aug. 1987, at 480. It is important to ensure the availability of prescription drugs to these people. A discussion of this issue is beyond the scope of this article except to note some available alternatives. Many prescription drugs are available in generic form. *Id.* at 481-482. Brand names cost 70% more than generics. *Id.* at 481.

118. The pertussis component of DPT is made from the whole Bordetella pertussis bacterium. The bacterium contain two toxins which are suspected of causing adverse effects on the central nervous system. White v. Wyeth, 40 Ohio St. 3d 390, 391, 533 N.E.2d 748, 749 (1988).

119. Brown v. Superior Court, 44 Cal. 3d 1049, 1064-1065, 751 P.2d 470, 479-480, 245 Cal. Rptr. 412, 421 (1988).

120. *Id.*

121. In 1986 Congress passed and the President signed into law the National Childhood Vaccine Injury Act of 1986, Pub. L. 99-660, Title III, Section 2101-2128, 100 Stat. 3755-84, 42 U.S.C. Section aa-1 et seq, amended by the Vaccine Compensation Amendments of 1987, P.L. 100-203, 133 Cong. Rec. H 12103, at 12166 (Dec. 21, 1987). In the Act, Congress created a "no-fault" compensation system to assure children injured by vaccines could secure recovery.

122. *The Sue Syndrome*, NEWSWEEK, Apr. 4, 1977, at 61-62.

123. *Id.* The cause and cure for this trend are beyond the scope of this article. For detailed analysis, *see* 5 PROD. LIAB. REP. (CCH), 623-638 app. G.

124. *The Sue Syndrome*, NEWSWEEK, Apr. 4, 1977, at 61-62.

other industries as well.[125] As long as pharmaceutical products are still available and affordable, it is unreasonable to draw an artificial line at the boundaries of prescription drugs.

Finally, the threat that drug manufacturers may face a stricter standard will encourage greater honesty and a faster response in removing a drug from the market if it is discovered that the drug is potentially defective. Drug manufacturers must recoup their investments quickly because of the threat that a competitor may produce a superior drug.[126] Consequently, once a drug has been released, there is incentive for manufacturers to suppress adverse information and delay FDA regulatory action.[127] However, in a strict liability design defect analysis, the focus is on the product, not the manufacturer's standard of care. A manufacturer's incentive to continue marketing a potentially defective drug is, therefore, diminished because the issue will be whether the product was defective, not whether the manufacturer was negligent.

E. A LEGISLATIVE SOLUTION: CODIFICATION OF A *Kearl* TYPE ANALYSIS

Oliver Wendell Holmes once stated, "it must be remembered that legislatures are ultimate guardians of the liberties and welfare of the people in quite as great a degree as the

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125. *Id.*

126. Comment, *Drug Product Liability and Health Care Delivery Systems*, 40 STAN. L. REV. 989, 1017 (1988). Moving a drug from the initial discovery stage through FDA approval can take from seven to ten years and cost over $100 million. STANDARD & POORS INDUSTRY SURVEYS, April 1988, Volume No. 1 at H 19.

127. *Id.* at 1017, n.113. There are several examples of drug manufacturers' "slow reflex time" in removing drugs from the market. In 1969, Upjohn challenged an FDA order removing the combination antibiotic Panalba from the market. Upjohn earned $1.5 million per month from Panalba sales until the court affirmed FDA's order several months later. *Id.* at 1017, n.113 (citing S. Greenberg, THE QUALITY OF MERCY 269, at 273-74 (1971)). "Despite conclusive evidence of the drug's danger and the fact that it was superior to other antibiotics in only a handful of emergencies, Parke-Davis downplayed the drug's toxicity so effectively that ten years after the discovery of its adverse effects, Chlormycetin was being prescribed wrongly in about 90% of cases. . ." *Id.* at 1018, n.118 (citing M. Silverman and P. Lee, PILLS, PROFITS, AND POLITICS at 59-61, 283-88 (1974)). In marketing MER/29, "Richardson-Merrell falsified results of animal tests, withheld negative outside reports, prepared 'scientific papers' signed by 'independent' investigators, and bribed physicians not to criticize the drug." *Id.* at 1019, n.127 (citing M. Silverman and P. Lee, PILLS, PROFITS, AND POLITICS at 89-94).

courts."[128] The *Brown* decision may be an appropriate occasion for the California legislature to intervene and exercise its "guardian" role. A possible solution to remedy the effect of *Brown* is that the legislature codify a *Kearl* type analysis. This will enable courts to determine on a case-by-case basis whether a prescription drug is unavoidably unsafe and entitled to exemption from strict liability design defect analysis. The following is a suggested model statute:[129]

> (1) Except as provided in paragraph (2) below, a manufacturer of an FDA-approved prescription drug that is sold, delivered, administered or dispensed in California shall be held strictly liable for all damages proximately or legally caused by a design defect in the drug.
> (2) A manufacturer of an FDA-approved prescription drug that is sold, delivered, administered or dispensed in California shall not be held liable for any damages proximately or legally caused by a design defect in the drug if the trial judge determines that the drug is unavoidably unsafe. A prescription drug is unavoidably unsafe if the trial judge determines that each of the criteria set forth in (A), (B) and (C) below are conjunctively met.
>
> (A) The drug was intended to confer an exceptionally important health benefit on society that made its availability highly desirable.
>
> (B) The risk posed by the product was both substantial and unavoidable.
>
> (i) In deciding whether the risk posed was substantial as stated in section (2)(B), a court should consider whether, at the time of distribution, the risk posed permanent or long-term disability (e.g. loss of body functions, organs, or death) as opposed to temporary inconvenience (e.g. skin rash).
>
> (ii) In deciding whether the risk posed

128. Missouri, K. & T. R. Co. v. May, 194 U.S. 267, 270, 48 L.Ed. 971, 973, 24 S.Ct. 638 (1904).

129. The language of this model statute is taken primarily from the test set forth in Kearl v. Lederle Laboratories, 172 Cal. App. 3d 812, 829-830, 218 Cal. Rptr. 453, 463-464 (1985).

was unavoidable as stated in section (2)(B) a court should consider:

(a) If the product design minimized risks inherent in the product, and

(b) The availability of any alternative product that would have as effectively accomplished the full intended purpose of the product.

(C) The interest in availability of the prescription drug outweighs the interest in promoting enhanced accountability through strict liability design defect review.

(3) The trial court shall rule as a matter of law[130] as to whether a prescription drug shall be considered unavoidably unsafe according to the criteria as set forth in section (2) above.

(4) Each of the criteria (A), (B) and (C) above are to be determined as of the time the drug was distributed.

(5) Nothing in this statute effects the liability of a manufacturer on issues pertaining to failure to warn.

V. CONCLUSION

For over thirty years the California Supreme Court has pioneered the way of product liability law in seeking ways to provide a remedy to protect those injured by defective products. This consumer protection strand has guided the court to cut through the citadel of privity,[131] limitations of warranty,[132] the

130. Some courts have emphasized the factual determinations necessary and believe it is proper for the jury to decide whether a product is unavoidably unsafe. Toner v. Lederle Laboratories, 112 Idaho 328, 339, n.9, 732 P.2d 297, 308-309 (1987). Others consider it a decision for the court to decide as a matter of law. *Id.*

131. MacPherson v. Buick Motor Co., 217 N.Y. 382, 111 N.E. 1050 (1916). Plaintiff was injured as a result of a defect in one of the wheels of an automobile. The issue of the case was whether the defendant manufacturer owed a duty of care to anyone but the immediate purchaser, the retailer. The court held that the manufacturer was liable to the plaintiff.

132. Henningsen v. Bloomfield Motors, Inc., 32 N.J. 358, 161 A.2d 69 (1960). Plaintiff was injured when the steering gear of the automobile she was driving malfunctioned. *Id.* at 369, 161 A.2d at 75. The court held that the manufacturer's attempt to disclaim an implied warranty of merchantability was so harmful to the public good that it would be considered invalid. *Id.* at 408, 161 A.2d at 97.

burden of proof,[133] and causation.[134] The court's decision in *Brown* reflects a retreat from the its consumer protection orientation and a diversion from the sentiments expressed in *Sindell* just eight years ago. At that time, the court stated that the considerations underlying strict liability are "particularly significant where medication is involved, for the consumer is virtually helpless to protect himself from serious, sometimes permanent, sometimes fatal, injuries caused by deleterious drugs."[135]

The public policies of availability and affordability of prescription drugs are important, but they should not override the policies underlying strict liability. A *Kearl* type analysis fairly balances a drug manufacturer's liability with consumer protection by providing drug manufacturers an opportunity to escape a strict liability standard if a drug qualifies as "unavoidably unsafe." Thus, this balance facilitates the aim that the obligation of the manufacturer will continue to be based upon "the demands of social justice."[136]

*Terrie Bialostok Brodie**

133. Barker v. Lull Engineering Co., 20 Cal. 3d 413, 431-432, 573 P.2d 443, 455, 143 Cal. Rptr. 225, 237 (1978).

134. Sindell v. Abbott Laboratories, 26 Cal. 3d 588, 607 P.2d 924, 163 Cal. Rptr. 132 (1980). Plaintiff could not identify which drug manufacturer produced the DES ingested by her mother. The court adopted the market share theory to deal with the impossibility plaintiff would otherwise have in establishing causation.

135. *Id.* at 611, 607 P.2d at 936, 163 Cal. Rptr. at 144.

136. Henningsen v. Bloomfield Motors, Inc., 32 N.J. 358, 384, 161 A.2d 69 (citing Mazetti v. Armour & Co., 75 Wash. 622, 627, 135 P. 633, 635 (1913)).

* Golden Gate University, Class of 1990.