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Comment k: A Prescription For The Over-The-Counter Drug Industry

Thomas M. Moore* and Scott L. Hengesbach**

As an illustration of the existing legal quagmire regarding the liability of drug manufacturers, consider the following scenarios: In one scenario, a middle-aged individual undergoes a yearly physical with his internist who determines that the patient is in a high risk category for stroke. In order to reduce the risk, the internist prescribes low doses of the anticoagulant warfarin. After taking the drug as prescribed over a period of time, the patient suffers not a stroke, but a significant adverse reaction to the drug. The patient files a lawsuit for damages contending that the drug manufacturer is strictly liable for defects in the design of the drug as well as the warnings provided by the drug manufacturer to the internist.

In the second scenario, a patient undergoes a similar physical examination by her internist with the same resulting diagnosis. For this patient, the internist “prescribes” low doses of acetylsalicylic acid, another well-known blood thinning agent. After taking the drug as directed for a period of time this patient also suffers a significant adverse reaction and files a lawsuit against the drug manufacturer on the theory of strict liability.

Although these hypotheticals seem nearly identical, for the purposes of determining the liability of the respective drug manufacturers there

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may be a significant distinction. In California, the manufacturer of the first drug, warfarin, could not be held strictly liable for defects in design or for its failure to warn about the resulting adverse reaction. The decision of the California Supreme Court in *Brown v. Superior Court*¹ precludes such a theory in actions involving prescription medications. The applicability of strict liability in the second scenario is somewhat more troublesome. Despite the fact that acetylsalicylic acid may be as efficacious as warfarin in reducing the risk of stroke² and, like warfarin, is inherently unsafe to some degree, the second manufacturer may not be favored with the protective holding in *Brown*. The reason is that acetylsalicylic acid (aspirin) is available directly to consumers over-the-counter.

In the arena of tort liability for pharmaceutical-related injuries, courts and commentators alike have focused their attention almost exclusively on medications which are available only upon the prescription of a licensed physician. This is largely attributable to the fact that, historically, most significant pharmaceutical cases have dealt with prescription drugs.³ The lack of over-the-counter (hereinafter OTC) liability analysis also stems from the relative ignorance of courts and lawyers about the origin of regulatory distinctions between prescription and OTC products, as well as the social and economic benefits of OTC medications.

First, this Article will analyze the development of liability for drug-related injuries in California.⁴ In that respect, its commentary is not unique. However, the foregoing analysis will focus on the applicability of traditional theories of product liability and their impact on the over-the-counter drug industry.⁵ Second, this Article analyzes the various approaches that courts may utilize in OTC drug cases in light of *Brown*.⁶ The Article concludes that since OTC products provide enormous social and economic benefits by encouraging self-medication, these products should be exempt from strict liability.

1. 1. 44 Cal. 3d 1049, 751 P.2d 470, 245 Cal. Rptr. 412 (1988).

2. 12 NEW ENG. J. OF MED. 863, 866-67 (1990).

3. For example, manufacturers of intrauterine devices (IUDs), diethylstilbestrol (DES) and Bendectine have been deluged by lawsuits alleging various adverse drug reactions.

4. See *infra* notes 6-75 and accompanying text.

5. The authors are aware of only one other commentary which attempts to analyze the liability of OTC manufacturers. See Rheingold, *The Expanding Liability of The Drug Manufacturer To The Consumer*, 40 FOOD DRUG COSM. L.J. 135 (1985). However, that article is essentially a case review which does not address the specific issue of whether strict liability principles should be applied to OTCs.

6. See *infra* notes 77-180 and accompanying text.

I. THE LIABILITY OF PHARMACEUTICAL MANUFACTURERS IN CALIFORNIA

Although *Brown* has been criticized as a radical departure from both the principles and analysis of the Restatement (Second) of Torts section 402A,⁷ and the court's seminal decision in 1962, *Greenman v. Yuba Power Products, Inc.*,⁸ a review of the historical development of strict tort liability, especially in the context of pharmaceutical products, demonstrates that *Brown* is more akin to a restatement of preexisting California drug liability law.

A. *The Evolution of Strict Products Liability in California*

Drawing from concepts first outlined in the concurring opinion of Justice Traynor in *Escola v. Coca-Cola Bottling Co.*,⁹ the California Supreme Court, in *Greenman*, set forth the doctrine of strict liability in tort.¹⁰ In *Greenman*, the court held that a product manufacturer is strictly liable in tort when the manufacturer places a product on the market, knowing that the product is to be used without inspection for defects, and the product proves to have a defect that causes injury to an individual.¹¹ The imposition of strict liability on mass product manufacturers was premised upon the policy that regardless of fault, the producers of defective products should bear the burden of compensating injured plaintiffs. The court reasoned that the manufacturers are in a better position to spread the economic losses resulting from such compensation through insurance and higher consumer prices.¹²

7. See RESTATEMENT (SECOND) OF TORTS § 402A (1965).

8. 59 Cal. 2d 57, 377 P.2d 897, 27 Cal. Rptr. 697 (1963). For cases and commentaries critical of *Brown*, see, e.g., Comment, *Comment k Immunity To Strict Liability: Should All Prescription Drugs Be Protected?*, 26 HOUS. L. REV. 707 (1989); Humphreys, *The Efficacy of Brown v. Superior Court: Should All Prescription Drugs Be Exempted From Strict Liability?*, PRODUCT SAFETY & LIABILITY REP. (Dec. 22, 1989); Hill v. Searle Laboratories, 884 F.2d 1064, 1068-69 (8th Cir. 1989).

9. 24 Cal. 2d 453, 461, 150 P.2d 436, 440 (1944) (Traynor, J., concurring).

10. *Greenman v. Yuba Power Prod.*, 59 Cal. 2d 57, 377 P.2d 897, 27 Cal. Rptr. 697 (1963).

11. *Id.* at 62, 377 P.2d at 900, 27 Cal. Rptr. at 700.

12. *Id.* at 63, 377 P.2d at 901, 27 Cal. Rptr. at 701. Other courts and commentators which have embraced the strict tort liability concept have attempted to justify the doctrine on other grounds. Most notably, it has been suggested that strict liability deters manufacturers

The strict product liability concept was subsequently developed nationally and, in 1965, after almost four years of refinement and debate, the American Law Institute adopted its version of strict products liability in section 402A of the Restatement (Second) of Torts. Section 402A provides:

(1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if (a) the seller is engaged in the business of selling such a product, and (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold. (2) The rule stated in subsection (1) applies although (a) the seller has exercised all possible care in the preparation and sale of the product, and (b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.¹³

Seven years after publication of the Restatement, the California Supreme Court articulated its unwillingness to be bound by the black-letter of section 402A. The court, in *Cronin v. J.B.E. Olson Corp.*,¹⁴ adopted a "modified" version of the Restatement. The court eliminated the dual requirement that a product be both "defective" and "unreasonably dangerous."¹⁵ The court dismissed the "unreasonably

from developing defective products. See, e.g., Rheingold, *Products Liability—The Ethical Drug Manufacturer's Liability*, 18 RUTGERS L. REV. 947, 1015 (1964). The deterrence argument has been rejected by a number of scholars and has never been explicitly approved by the Supreme Court in California. See generally Owen, *Rethinking the Policies of Strict Products Liability*, 33 VAND. L. REV. 681, 709-10 (1980); McClellan, *Strict Liability For Drug Induced Injuries: An Excursion Through The Maze of Products Liability, Negligence And Absolute Liability*, 25 WAYNE L. REV. 1, 25 (1978). The argument was put forth by Justice Traynor concurring in *Escola*, and again by Chief Justice Bird in her dissent in *Finn*. See *Escola v. Coca-Cola Bottling Co.*, 24 Cal. 2d at 462, 150 P.2d at 440-41 (1944) (Traynor, J., concurring); *Finn v. G.D. Searle & Co.*, 35 Cal. 3d 691, 705, 677 P.2d 1147, 1155, 200 Cal. Rptr. 870, 888 (1984) (Bird, C.J., dissenting). Moreover, deterrence would seem to have little significance in the case of an allegedly defective pharmaceutical product whose risk is unavoidable.

13. RESTATEMENT (SECOND) OF TORTS § 402A (1965). See Prosser, *The Assault Upon The Citadel (Strict Liability To The Consumer)*, 69 YALE L.J. 1099 (1960) (discussing the legal underpinnings of section 402A).

14. 8 Cal. 3d 121, 501 P.2d 1153, 104 Cal. Rptr. 433 (1972).

15. *Id.* at 134-35, 501 P.2d at 1163, 104 Cal. Rptr. at 443. *Cronin* is significant in its definition of the role of the Restatement. Many courts and commentators unjustifiably accord the Restatement almost precedential significance, whereas the document is intended to constitute a synthesis of opinions collected from many diverse jurisdictions, and is necessarily based only upon those decisions published up to the date on which the final draft is adopted. Accordingly, the Restatement is subject to severe analytic limitations. As Professor Page has noted:

While the A.L.I. is a distinguished body, it is a private non-governmental entity. The courts have ultimate responsibility for translating policy into common-law rules, and the matter of liability for generic risks, and for toxic products in particular,

dangerous” language of section 402A, finding that such language infused negligence concepts into the strict liability doctrine.¹⁶

Although *Cronin* refined the test for strict liability, *Cronin*, like *Greenman* before it, failed to define the defectiveness standard.¹⁷ The California Supreme Court first defined a defective product in the context of strict liability in *Barker v. Lull Engineering Co.*¹⁸ *Barker* specifically defined “design” defect. The court held that a product can be defective in design either if it fails to perform as safely as an ordinary consumer would expect when used in an intended and reasonably foreseeable manner,¹⁹ or if in light of certain factors²⁰ the risks posed by the design outweigh the benefits.²¹ Once the plaintiff makes a prima facie showing that the injury was proximately caused by the product’s design, the burden of proof shifts to the defendant to demonstrate that the benefits of the design are greater than the risks.²²

requires more comprehensive scrutiny than has been afforded by the Restatement. Page, *Generic Product Risks: The Case Against Comment k And For Strict Tort Liability*, 58 N.Y.U. L. REV. 853, 872 (1983).

16. *Cronin*, 8 Cal. 3d at 132, 501 P.2d at 1161-62, 104 Cal. Rptr. at 441-42.

17. *Id.* at 134, 501 P.2d at 1162, 104 Cal. Rptr. at 442 (quoting Traynor, *The Ways and Meanings of Defective Products and Strict Liability*, 32 TENN. L. REV. 363, 373 (1965)).

18. 20 Cal. 3d 413, 573 P.2d 443, 143 Cal. Rptr. 225 (1978). The *Barker* court identified three types of product defects. First, the *Barker* court isolated defects attributable to the manufacturing process, which resulted in individual product units that differed from the intended result of the manufacturer. *Id.* at 429, 573 P.2d at 454, 143 Cal. Rptr. at 236. Second, the *Barker* court indicated that there are products which are “perfectly” manufactured, but are unsafe in the absence of a safety device or alternative specification, such as a defect in design. *Id.* at 428, 573 P.2d at 453, 143 Cal. Rptr. at 235. Third, the *Barker* court noted that a product may be defective because it lacks adequate warnings or instructions. *Id.* at 428, 573 P.2d at 453, 143 Cal. Rptr. at 235.

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

20. *Id.* Several factors should be considered in balancing the risks and benefits of a product. These factors include the gravity of the danger posed by the challenged design, the likelihood that such danger would occur, the technical feasibility of a safer alternative design, the cost of an improved design, and the adverse consequences to the product and consumer that would result from an alternative design. *Id.* at 431, 573 P.2d at 455, 143 Cal. Rptr. at 237.

21. *Id.* at 432, 573 P.2d at 456, 143 Cal. Rptr. at 238. The *Barker* test has been incorporated into the California Form Jury Instructions as follows:

A product is defective in design: [1] if it fails to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner, or [2] if there is a risk of danger inherent in the design which outweighs the benefits of that design. In determining whether the benefits of the design outweigh such risks you may consider, among other things, the gravity of the danger posed by the design, the likelihood that such danger would cause damage, the mechanical feasibility of a safer alternate design at the time of the manufacture, the financial cost of an improved design, and the adverse consequences to the product and the consumer that would result from an alternate design.

B.A.J.I. 9.00.5.

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

The *Barker* court refused to apply the design defect test to products which are "inherently" or "unavoidably" unsafe, such as drugs.²³ While strict liability for the design of consumer goods such as machinery and appliances had been steadily developing along the lines of *Greenman* and section 402A, cases involving chemicals, especially drugs, were following a much different path.²⁴ The California pharmaceutical decisions during the period between *Greenman* and *Barker* focused exclusively on defects in the manufacturing process or the warnings provided to the medical community.²⁵ These cases all involved prescription drugs.²⁶ In cases involving product

23. *Id.* at 430 n.10, 573 P.2d 455 n.10, 143 Cal. Rptr. at 237 n.10.

24. See Comment, *Strict Liability For Prescription Drugs: Which Shall Govern—Comment k or Strict Liability Applicable To Ordinary Products?*, 16 GOLDEN GATE U.L. REV. 309 (1986) (explaining the history of pharmaceutical liability in California).

25. Many cases involve strict liability claims for manufacturing defects. See, e.g., *Fogo v. Cutter Laboratories*, 68 Cal. App. 3d 744, 137 Cal. Rptr. 417 (1977); *Grinnell v. Pfizer*, 274 Cal. App. 2d 424, 79 Cal. Rptr. 369 (1969). The following cases involve a purported failure to adequately warn: *Stevens v. Parke-Davis*, 9 Cal. 3d 51, 507 P.2d 653, 107 Cal. Rptr. 45 (1973); *Carmichael v. Reitz*, 17 Cal. App. 3d 958, 95 Cal. Rptr. 381 (1971); *Christoffersen v. Kaiser Hospital Foundations*, 15 Cal. App. 3d 75, 92 Cal. Rptr. 825 (1971); *Toole v. Richardson-Merrell*, 251 Cal. App. 2d 689, 60 Cal. Rptr. 398 (1967); *Love v. Wolf*, 226 Cal. App. 2d 378, 38 Cal. Rptr. 183 (1964); *Magee v. Wyeth Laboratories*, 214 Cal. App. 2d 340, 29 Cal. Rptr. 322 (1963). With the exception of *Stevens*, the plaintiffs in each of the warning cases pleaded causes of action for both strict liability and negligence. However, retrospective examination suggests that although these cases were purportedly analyzed under the rubric of strict liability, the underlying allegations of warning defect were founded on negligence. See *infra* notes 63-68 (discussing the lack of distinction between negligence and strict liability failure to warn theory).

26. Indeed, the authors are unaware of any California decision where the liability of an OTC drug manufacturer has been specifically delineated. *Hutchinson v. Revlon Corp.*, 256 Cal. App. 2d 517, 65 Cal. Rptr. 81 (1967), was cited by the court of appeal in *Kearl v. Lederle Laboratories*, 172 Cal. App. 3d 812, 828, 218 Cal. Rptr. 453, 463 (1985), as a case involving application of strict liability to an OTC drug. The same case was cited by former Chief Justice Bird in her dissent in *Finn v. G.D. Searle & Co.*, 35 Cal. 3d 691, 712, 677 P.2d 1147, 1160, 200 Cal. Rptr. 870, 884 (1984) (Bird, C.J., dissenting). However, this characterization would appear to be inaccurate. First, the *Hutchinson* court did not refer to the product therein (an external deodorant) as a "drug." Moreover, a deodorant generally would not fall into the category of "drug" as defined by the Food, Drug and Cosmetic Act (however, a few internally ingested deodorants used therapeutically in ostomy patients are considered drugs by the FDA). This mischaracterization typifies the general ignorance of the courts in understanding the distinction between drugs and other products, and between OTC drugs and prescription medications in particular. In a recent case, the Court of Appeal for the Fifth District was asked to consider application of comment k to OTC products. *Rodriguez v. Superior Court*, 90 Daily Journal D.A.R. 7610 (to be reported at 271 Cal. Rptr. 204) (July 2, 1990). However, the court did not reach the issue in that case. *Id.*, 90 Daily Journal D.A.R. at 7611. See *infra* notes 78-79 (discussing *Rodriguez*). Other jurisdictions have analyzed at least the failure to warn aspect of an OTC drug manufacturer's liability. These cases have generally imposed a negligence analysis based on comments k and j to Restatement Section 402A, although the analogy (or lack thereof) between OTC products and prescription drugs has not been discussed. See *Wells v. Ortho Pharmaceutical Corp.*, 788 F.2d 741 (11th Cir. 1986) (applying Georgia

warnings, the courts held the manufacturer liable if the manufacturer had actual or constructive knowledge of a particular risk of injury and failed to adequately inform physicians of the risk, regardless of whether the plaintiff claimed a negligence, breach of warranty, or strict liability cause of action.²⁷ The courts analyzed the failure to warn defect using non-drug case law,²⁸ and comments k and j to the Restatement (Second) of Torts section 402A.²⁹

law); *Griggs v. Combe, Inc.*, 456 So. 2d 790 (Ala. 1984); *Ferrigno v. Eli Lilly & Co.*, 175 N.J. Super. 551, 420 A.2d 1305 (1980); *Torsiello v. Whitehall Laboratories, Etc.*, 165 N.J. Super. 311, 398 A.2d 132 (1979).

27. *See, e.g.*, *Love v. Wolf*, 226 Cal. App. 2d 378, 402, 38 Cal. Rptr. 183, 197-98 (1964) (stating that no rule of strict liability has been applied to a failure to adequately warn of the risks inherent in the use of a drug). *See also* *Brown v. Superior Court*, 44 Cal. 3d 1049, 1065-66, 751 P.2d 470, 480-81, 245 Cal. Rptr. 412, 421-22 (1988); *Kearl v. Lederle Laboratories*, 172 Cal. App. 3d 812, 831-34, 218 Cal. Rptr. 453, 465-67 (1985).

28. *See, e.g.*, *Oakes v. E.I. DuPont de Nemours & Co., Inc.*, 272 Cal. App. 2d 645, 646-47 Cal. Rptr. 709, 710 (1969) (finding that a chemical manufacturer is not liable for failing to warn of unknown toxicity).

29. Comments k and j read as follows:

k. *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 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.

j. *Directions or warning.* In order to prevent the product from being unreasonably dangerous, the seller may be required to give directions or warning, on the container, as to its use. The seller may reasonably assume that those with common allergies, as for example to eggs or strawberries, will be aware of them, and he is not required to warn against them. Where, however, the product contains an ingredient to which a substantial number of the population are allergic, and the ingredient is one whose danger is not generally known, or if known is one which the consumer would reasonably not expect to find in the product, the seller is required to give warning against it, if he has knowledge, or by the application of reasonable, developed human skill and foresight should have knowledge, of the presence of the ingredient and the danger. Likewise in the case of poisonous drugs, or those unduly dangerous for other reasons, warning as to use may be required.

RESTATEMENT (SECOND) OF TORTS § 402A (1965).

B. The Development of the Liability of Pharmaceutical Manufacturers Prior to the Brown Decision

There is a conspicuous absence of design defect cases involving pharmaceutical products in California prior to the 1978 *Barker* decision. However, in *McCreery v. Eli Lilly & Co.*,³⁰ an appellate court refused to hold the defendant drug manufacturer liable since the plaintiff failed to identify the defendant as the manufacturer of the actual pills her mother ingested.³¹ The plaintiff claimed that her mother's ingestion of diethylstilbestrol (DES) caused the plaintiff to suffer a benign cell disorder of the cervix described as vaginal adenosis.³² The court partially justified its decision by finding that comment k "compels rejection of the imposition of liability."³³ The court reasoned that comment k discourages the imposition of liability.³⁴ The court, out of cited concern for research and development of new chemotherapeutic agents and reduction in the costs of medical care, rejected strict liability.³⁵

Despite the addition of the *Barker* design defect analysis to the armament of the plaintiffs' bar, the issue of the application of strict tort liability to manufacturers of pharmaceutical products was not discussed again in California until 1984 in *Finn v. G.D. Searle & Co.*³⁶ In *Finn*, the California Supreme Court affirmed a defense verdict in favor of a prescription drug manufacturer. The lawsuit was brought on behalf of a child who allegedly became permanently and almost totally blind subsequent to treatment for a skin ailment with high doses of a prescription drug.³⁷ The plaintiff proceeded to trial on a complaint sounding in negligence and strict liability,

30. 87 Cal. App. 3d 77, 150 Cal. Rptr. 730 (1978).

31. *Id.* at 82-84, 150 Cal. Rptr. at 733-35. The supreme court subsequently eliminated the identification element in cases where the plaintiff cannot prove who manufactured the drug she actually ingested in situations where the same drug was marketed by more than one company. See *Sindell v. Abbott Laboratories*, 26 Cal. 3d 588, 607 P.2d 924, 163 Cal. Rptr. 132 (1980).

32. *McCreery*, 87 Cal. App. 3d at 79-80, 150 Cal. Rptr. at 732.

33. *Id.* at 80, 150 Cal. Rptr. at 732.

34. *Id.* at 86-87, 150 Cal. Rptr. at 736. This portion of the court's opinion is arguably dicta since the reference to comment k was unnecessary given the inability of the plaintiff to identify the defendant's drug. Nevertheless, the case is significant as the first reported opinion discussing the liability of a drug manufacturer for defective design.

35. *Id.*

36. 35 Cal. 3d 691, 677 P.2d 1147, 200 Cal. Rptr. 870 (1984).

37. *Id.* at 695, 677 P.2d at 1149, 200 Cal. Rptr. at 872.

although both causes of action were predicated on an alleged failure to warn.³⁸ On review, when the California Supreme Court was asked to consider whether jury instructions modified by the trial court erroneously failed to articulate a cause of action for failure to warn based on strict liability, the majority refused to decide the strict liability issue, observing that the plaintiff's own proposed instructions, which conditioned liability on the manufacturer's actual or constructive knowledge of drug risks, were based not upon strict liability, but on negligence.³⁹

The *Finn* case is probably most noteworthy for the dissent of former Chief Justice Bird. Chief Justice Bird vigorously argued that a prescription drug manufacturer may be held strictly liable for both warning inadequacies as well as defects in design.⁴⁰ Subsequently, several cases addressing strict liability of prescription drugs began to proceed through the appellate courts, but only one decision, *Kearl v. Lederle Laboratories*,⁴¹ was ordered published.

Kearl was the first California decision since *McCreery* to specifically address the strict liability design defect issue in a prescription drug case. In *Kearl*, a California court of appeal held that only those

38. The jury instructions proffered by the plaintiff, as well as those modified by the court, indicated that the manufacturer was liable only for dangers about which the manufacturer "knew or should have known" prior to the plaintiff's ingestion of the drug. The court also deleted the word "strict" from the proposed instructions. *Id.* at 697-98, 677 P.2d at 1150-51, 200 Cal. Rptr. at 873-74.

39. *Id.* at 698, 677 P.2d at 1151, 200 Cal. Rptr. at 874. Arguably, the majority was unjustified in skirting the strict liability issue. In analyzing the failure to warn defect, the court pointed out that other jurisdictions considering the issue were divided on whether *foreseeability* is a necessary element in a failure to warn case ostensibly based on strict liability. *Id.* at 699, 677 P.2d at 1151, 200 Cal. Rptr. at 874. By holding that the proposed instructions of the plaintiff sounded in *negligence*, the majority impliedly (1) adopted the foreseeability requirement, and (2) recognized that in view of that requirement there is no theoretical distinction between negligence and strict liability when the issue is failure to warn. *See infra* notes 63-68 and accompanying text (discussing the lack of distinction between negligence and strict liability failure to warn theory).

40. *Finn*, 35 Cal. 3d at 705, 677 P.2d at 1155, 200 Cal. Rptr. at 878 (Bird, C.J., dissenting). Chief Justice Bird's dissent in *Finn* is significant in that it provides a detailed analysis of those theories which were ultimately rejected by the supreme court in *Brown*. The former Chief Justice suggested that California ought not follow comment k to the extent that the comment exempts drug manufacturers from design defect liability. *Id.* at 720-22, 677 P.2d at 1166-68, 200 Cal. Rptr. at 889-91 (Bird, C.J., dissenting). The dissent alternatively argued that if comment k is adopted, a manufacturer should continue to be held "strictly liable" to the extent that the plaintiff can demonstrate that the manufacturer's warning is inadequate. *Id.* In the authors' opinion, this contention is based upon an erroneous interpretation of comment k owing to an ambiguity in the language of the Restatement. The ambiguity may arguably have survived *Brown* and is responsible for several inconsistent decisions subsequent to that case. *See infra* note 68 and accompanying text (discussing recent strict liability failure to warn case law).

41. 172 Cal. App. 3d 812, 218 Cal. Rptr. 453 (1985).

prescription drugs which are sufficiently beneficial yet substantially and unavoidably unsafe, and which possess an interest in availability which outweighs the interest in promoting enhanced accountability via strict liability, should be protected by comment k.⁴² In *Kearl*, the plaintiff contracted polio after receiving an oral polio vaccine.⁴³ The plaintiff contended that the vaccine manufacturer was strictly liable for marketing a defectively designed product and for failing to adequately warn about the attendant risks.⁴⁴

The court of appeal stated that the trial court must first determine whether the vaccine was "unavoidably unsafe." If so, the drug is exempt from strict liability pursuant to comment k.⁴⁵ Further, the court found that the manufacturer could be held liable only for failure to warn of known or constructively known risks (i.e., negligence).⁴⁶

42. *Id.* at 829-30, 218 Cal. Rptr. at 463-64. The court was "uncomfortable with the rather routine and mechanical fashion by which many appellate courts have concluded that certain products, particularly drugs, are entitled to such special treatment." *Id.* at 829, 218 Cal. Rptr. at 463. The court proposed a mixed analysis of law and fact to be made by the trial court after an evidentiary hearing outside of the jury's presence. The trial court would 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 was both "substantial" and "unavoidable"; and (3) whether the interest in availability outweighs the interest in promoting enhanced accountability through strict liability design defect review. If the answer to all three threshold questions was in the affirmative, the manufacturer would be exempt from strict products liability design defect analysis. *Id.* at 829-30, 218 Cal. Rptr. at 464.

43. *Id.* at 817-20, 218 Cal. Rptr. at 454-56.

44. *Id.* at 820, 218 Cal. Rptr. at 456-57. Although vaccines are rarely "prescribed" in the usual sense of the term, vaccines have traditionally been treated the same as prescription drugs for the purposes of liability analysis (except in failure to warn cases where the learned intermediary doctrine has not been employed). See, e.g., *Reyes v. Wyeth Laboratories*, 498 F.2d 1264, 1275-78 (5th Cir. 1974) (applying Texas law). Additionally, vaccines would appear to be protected by comment k independently and without regard to their prescription or non-prescription status. See *supra* note 29 (providing the language of comment k).

45. In dicta contained in a footnote, the court suggested that the defendant would still be theoretically liable for a negligent design even if comment k applied. *Kearl*, 172 Cal. App. 3d at 831 n.15, 218 Cal. Rptr. at 465 n.15. However, the viability of such a theory should be seriously questioned in view of *Brown*. See *infra* note 63 (discussing the viability of a negligent design cause of action after *Brown*).

46. *Kearl*, 172 Cal. App. 3d at 832, 218 Cal. Rptr. at 465-66. Consistent with prior drug-liability decisions, *Kearl* appears to go beyond comment k in analyzing the "warning defect." The court discussed one of its previous decisions, *Cavers v. Cushman Motor Sales, Inc.*, 95 Cal. App. 3d 338, 157 Cal. Rptr. 142 (1979), often cited by other courts for the proposition that product manufacturers could be held strictly liable for warning defects. *Cavers* figured prominently in the dissent of Chief Justice Bird in *Finn*. The *Kearl* court noted that "contrary to dicta in *Finn v. G.D. Searle & Co.* and the *Finn* dissent suggestion . . . nothing in *Cavers* suggests, nor was it intended to imply, that failure to warn can or should be subject to an analysis different from negligence simply because it happens to be alleged as a basis of product

The *Kearl* court recognized that subjecting manufacturers of unavoidably unsafe products to either of *Barker's* two standards for determining defectiveness might cause delay in the marketing of products, deter the research and development of new chemical entities, or deter the manufacturing and marketing of certain agents altogether.⁴⁷ The court also found that the increased costs of production—resulting in part from larger insurance premiums—might so increase the price of drugs that they would be placed outside the reach of those who need them most.⁴⁸ However, while the court painstakingly drew a nexus between the ultimate imposition of strict design defect liability and a potential decrease in pharmaceutical development and availability, the court failed to analyze the impact of its ad hoc “mini-trial” approach on that same societal goal.

Although the court of appeal in *Kearl* did not determine whether the vaccine at issue qualified for comment k protection,⁴⁹ at least one jurisdiction has imposed strict design defect liability on a prescription drug manufacturer.⁵⁰ Given the somewhat unique approach to comment k advanced by the court of appeal in *Kearl*, and the increasing number of prescription drug cases meandering their way through the judicial system at the time, it was inevitable that the California Supreme Court would have to address the issue it so deftly avoided in *Finn*.

defect. [*Cavers*] simply attempts to give the jury guidance in determining the reasonableness of a warning or the reasonable need for a warning in a typical products liability case.” *Kearl*, 172 Cal. App. 3d at 833 n.17, 218 Cal. Rptr. at 466 n.17.

47. *Kearl*, 172 Cal. App. 3d at 822-24, 218 Cal. Rptr. at 458-60.

48. *Id.* at 823-24, 218 Cal. Rptr. at 459. The cases and commentary in support of the policy of encouraging development and availability of drug products, as well as the litany of examples of the deleterious effect of products liability on the drug industry cited by the *Kearl* court, were adopted almost verbatim by the supreme court in *Brown*. See *Brown v. Superior Court*, 44 Cal. 3d 1049, 1063-64, 751 P.2d 470, 479, 245 Cal. Rptr. 412, 420-21 (1988).

49. *Kearl* was ultimately settled before a mini-trial was held on whether comment k applied to the vaccine at issue. Telephone conversation with Richard J. Siggins, Esq., partner in the firm of Gudmundson, Siggins & Stone, attorneys for defendant Lederle Laboratories, April 24, 1990 (notes on file at the *Pacific Law Journal*).

50. See *Brochu v. Ortho Pharmaceutical Corp.*, 642 F.2d 652 (1st Cir. 1981). In *Brochu*, the plaintiff allegedly suffered a stroke during the time she was taking an oral contraceptive and contended that the manufacturer could have decreased the product's milligram content of estrogen, arguably making a stroke less likely, without any accompanying decrease in efficacy. *Id.* at 654. The court held that the plaintiff had set forth a claim under New Hampshire law for design defect based on the high content of estrogen in the product and the danger resulting from the estrogen level. *Id.* at 655. *Brochu* has been criticized and arguably constitutes a misapplication of comment k and a tortured interpretation of the phrase “unavoidably unsafe.” See Comment, *Can A Prescription Drug Be Defectively Designed?*—*Brochu v. Ortho Pharmaceutical Corp.*, 31 DE PAUL L. REV. 247 (1981).

C. *The Brown Decision*

*Brown v. Superior Court*⁵¹ provided the first opportunity for the California Supreme Court to consider, in detail, the liability of a pharmaceutical manufacturer.⁵² In *Brown*, the court rejected strict liability for design defects in drugs, finding that a prescription drug manufacturer can be liable only if a drug is improperly manufactured or if the manufacturer failed to adequately warn of “known or knowable” side effects.⁵³

In *Brown*, the plaintiffs contended that the prescription drug diethylstilbestrol (DES), a miscarriage preventative, was defectively designed and the defendants knew of its dangerous propensities and failed to warn the medical community.⁵⁴ The drug manufacturer contended that DES comported with the “state of the art” when developed and distributed, and that similarly, the warnings disseminated to the medical community reflected the risks which were known at the time of distribution. Both the trial court and court of appeals rejected the design defect analysis in *Barker* and the ad hoc approach of *Kearl*, and embraced the policy and analysis of comment k.⁵⁵

With respect to the issue of design defect, the supreme court found that it would be inappropriate to apply the analysis of *Barker* to drug manufacturers.⁵⁶ In rejecting the first prong of the *Barker* test, the court noted that the expectations of an “ordinary consumer” of prescription drugs are normally those expectations the physician relates to the consumer, and the physician may not disseminate all

51. 44 Cal. 3d 1049, 751 P.2d 470, 245 Cal. Rptr. 412 (1988).

52. In *Stevens v. Parke-Davis*, 9 Cal. 3d 51, 507 P.2d 653, 107 Cal. Rptr. 45 (1973), the court upheld a jury verdict against a prescription drug manufacturer. However, that case primarily concerned questions of evidence and attorney misconduct. *Id.* at 63-73, 507 P.2d at 660-67, 107 Cal. Rptr. at 52-59. Additionally, plaintiff's claim in that case was predicated solely on a theory of negligent failure to warn. *Id.* at 64-65, 507 P.2d at 660-61, 107 Cal. Rptr. at 52-53.

53. *Brown*, 44 Cal. 3d at 1069, 751 P.2d at 482-83, 245 Cal. Rptr. at 424. The holding of the court is potentially much more far-reaching. The court arguably eliminated any theory of design defect, including a cause of action predicated on negligence. See *infra* note 63 (analyzing the viability of a negligent design cause of action after *Brown*).

54. *Id.* at 1055, 751 P.2d at 473, 245 Cal. Rptr. at 414.

55. See *Brown v. Superior Court*, 182 Cal. App. 3d 1125, 227 Cal. Rptr. 768 (1986) (depublished when review granted).

56. *Brown*, at 1061-62, 751 P.2d at 477-78, 245 Cal. Rptr. at 419. See *supra* note 21 (providing the complete language of the *Barker* test).

of the warnings included in the manufacturer's label.⁵⁷ The *Brown* court gave far more consideration to the second prong of the *Barker* test, the risk-benefit analysis.⁵⁸

The court rejected the defendant's claim that the *Barker* risk-benefit analysis is inapposite to prescription drugs because it contemplates that a safer alternative design is feasible. The court observed that it is at least theoretically possible to "re-design" a drug such as DES to make the drug safer.⁵⁹ Further, there may be less harmful drugs available to prevent miscarriage.⁶⁰ Nevertheless, the court rejected extension of the *Barker* analysis to pharmaceutical products by looking to the broader question of whether strict liability ought to be imposed on drug manufacturers in the first instance.⁶¹ The court balanced the policy of imposing strict liability for design defects as originally articulated in *Greenman* against the policy of encouraging development and availability of drugs at a reasonable price. The court found an important distinction between prescription drugs and machinery, namely the public interest in the development, availability, and reasonable price of drugs.⁶²

57. *Brown*, 44 Cal. 3d at 1061-62, 751 P.2d at 477-78, 245 Cal. Rptr. at 419. This analysis is open to question since some prescription drugs are provided to consumers with little or no physician input and may require direct warning to patients pursuant to Food and Drug Administration rule-making. See *Kearl v. Lederle Laboratories*, 172 Cal. App. 3d 812, 833 n.18, 218 Cal. Rptr. 453, 466 n.18 (1985); *Reyes v. Wyeth Laboratories*, 498 F.2d 1264, 1275-78 (5th Cir. 1974), cert. denied 419 U.S. 1096 (1974); Comment, *Pharmaceutical Manufacturers And Consumer-Directed Information—Enhancing The Safety Of Prescription Drug Use*, 34 CATH. U.L. REV. 117 (1984). Conversely, many OTC products, such as aspirin given to prevent stroke, require a significant amount of physician intervention. See *infra* note 119. Nevertheless, it is clear that the *Brown* court was more concerned with whether the *Barker* test should apply than whether it *could* apply. See *Brown*, 44 Cal. 3d at 1062, 751 P.2d at 478, 245 Cal. Rptr. at 419.

58. *Brown*, 44 Cal. 3d at 1062-65, 751 P.2d at 478-80, 245 Cal. Rptr. at 419-21. This is understandable in that the reasons for the court's rejection of *Barker's* risk-benefit examination provided a springboard for an attack on the *Kearl* mini-trial approach, which shares a number of common elements.

59. *Brown*, 44 Cal. 3d at 1062, 751 P.2d at 478, 245 Cal. Rptr. at 419.

60. *Id.*

61. *Id.* at 1062-65, 751 P.2d at 478-80, 245 Cal. Rptr. at 419-21.

62. *Id.* at 1063, 751 P.2d at 478, 245 Cal. Rptr. at 420. The supreme court's reliance on this broader social policy, reflecting both the application of *Barker* and the threshold test for comment k protection espoused by *Kearl*, has led some commentators and courts to suggest that *Brown* goes beyond comment k and potentially exempts from strict liability any product which benefits society through alleviation of pain and suffering without regard to whether the product could have been designed to be safer; that is, unavoidably unsafe. See *Humphreys*, *supra* note 8, at 1276; *Hill v. Searle Laboratories*, 884 F.2d 1064, 1068-69 (8th Cir. 1989). Such a conclusion would appear to be erroneous on several counts. First, *Brown's* interpretation of comment k, which by definition applies only to "unavoidably unsafe" products, is that comment k extends at least to all prescription drugs. *Brown*, 44 Cal. 3d at 1069 n.11, 751 P.2d at 482 n.11, 245 Cal. Rptr. at 424 n.11. Second, the court recognized that while some

To determine the liability of a pharmaceutical manufacturer for injuries, the court looked to the test outlined in comment k.⁶³ The

drugs could arguably be made "safer," they cannot be made "safe," which is the terminology used in the comment. *Id.* at 1062, 751 P.2d at 478, 245 Cal. Rptr. at 419. As the *Brown* court observed, in addition to their social benefit, an important distinction between drugs and other products is that "unlike other important medical products (wheelchairs, for example), harm to some users from prescription drugs is unavoidable." *Id.* at 1063, 751 P.2d at 478, 245 Cal. Rptr. at 420. Thus, in *Brochu* for example, a decrease in the amount of estrogen contained in the birth control pills at issue might have reduced the risk of stroke but would not have eliminated it. Finally, unlike the manufacturer of a machine who could at least contemplate the nature and range of potential product risks on a pre-market basis (even though identification of the actual defects in the product giving rise to those risks might not be affected at the time of distribution), a drug manufacturer may have no idea of the character of the side effects of its products, as such side effects may not manifest themselves until years or even decades after initial marketing. Such a manufacturer, unlike the producer of a machine who can simply "design out" the defect once it is identified, may have to choose between subjecting itself to at least some liability for unforeseen dangers or pulling the drug from the market.

63. *Brown*, 44 Cal. 3d at 1061, 751 P.2d at 477, 245 Cal. Rptr. at 418. By omitting the phrase "strict liability" from its holding, the court arguably turned to comment k for a standard by which all forms of design defect liability are to be litigated in the pharmaceutical context. Although the issue of negligent design was not specifically raised on appeal, the opinion certainly leaves open the question of whether such a theory remains viable in a prescription drug case. In a latter portion of the opinion, the court noted that drug manufacturers may still be liable for manufacturing defects, as well as "under general principles of negligence, and for failure to warn of known or reasonably knowable side effects." *Id.* at 1069 n.12, 751 P.2d at 483 n.12, 245 Cal. Rptr. at 424 n.12. Since both the risk-benefit prong of *Barker* and the *Kearl* mini-trial focus on primarily the same factors as the traditional risk-utility test in negligent design cases, the *Brown* court's rejection of the *Barker* risk-benefit prong would seem to apply with equal significance to all theories of recovery based on an allegedly defective design. See generally Birnbaum, *Unmasking The Test for Design Defect: From Negligence [to Warranty] to Strict Liability to Negligence*, 33 VAND. L. REV. 593 (1980) (discussing negligence principles). Indeed, the *Brown* court refused to pass on whether the benefits of certain pharmaceutical agents justified their development and marketing. *Brown*, 44 Cal. 3d at 1065 n.10, 751 P.2d at 480 n.10, 245 Cal. Rptr. at 421 n.10. A negligent design defect cause of action would compel the jury to conduct just such an assessment. The court of appeal in *Kearl* noted in dicta that a negligent design defect cause of action would continue to be viable. *Kearl v. Lederle Laboratories*, 172 Cal. App. 3d 812, 827, 218 Cal. Rptr. 453, 462 (1985). However, that observation was consistent with the court's holding since under the mini-trial approach there would already be a "risk-benefit" issue. The only cases of which the authors are aware specifically addressing the effect of comment k on design defect actions sounding in negligence are *Graham v. Wyeth Laboratories*, 666 F. Supp. 1483 (D. Kan. 1987), *White v. Wyeth Laboratories*, 40 Ohio St. 3d 390, 533 N.E.2d 748 (1988), and *Toner v. Lederle Laboratories*, 112 Idaho 328, 732 P.2d 297 (1987). In *Toner*, a divided court held that comment k was *not* a defense to a negligent design defect case, although it acknowledged that a jury analysis of the issue under a negligence theory was indistinguishable from strict liability, the application of which is precluded by comment k. *Id.*, 732 P.2d at 305. *But see id.*, 732 P.2d at 314 (Bakes, J., specially concurring in part) (comment k should be a defense). In *Graham*, the district court pointed out that, by "comment k's own terms, the comment bars only strict liability claims . . ." *Graham*, 666 F. Supp. at 1497. However, the court noted that the question of whether a manufacturer acted negligently "is, in a general sense, similar to the comment k inquiry of whether a drug is unavoidably unsafe." *Id.* at 1498. The court went on to note that a judicial determination of whether a drug is unavoidably unsafe would involve the "same evidence" that a jury would hear in determining whether a drug was negligently designed. *Id.*

court noted that although comment k is located in the Restatement section encompassing strict liability, comment k is in fact an articulation of a negligence standard.⁶⁴ Comment k focuses on the manufacturer's conduct in warning or failing to warn of the risks within the manufacturer's actual or constructive knowledge.⁶⁵ Contrary to prior California decisions and cases in other jurisdictions, which have interpreted comment k as a "shield" from strict liability,⁶⁶ the *Brown* court interpreted in comment k an exemption,⁶⁷ whereby cases involving "unavoidably unsafe" products are funneled back into the realm of negligence.⁶⁸

64. *Brown*, 44 Cal. 3d at 1059, 751 P.2d at 475, 245 Cal. Rptr. at 417. This is consistent with prior California cases, as well as the majority of cases in other jurisdictions which have analyzed the comment. See, e.g., *Kearl v. Lederle Laboratories*, 172 Cal. App. 3d 812, 218 Cal. Rptr. 453 (1985); *Carmichael v. Reitz*, 17 Cal. App. 3d 958, 95 Cal. Rptr. 381 (1971); *Christofferson v. Kaiser Foundation Hospitals*, 15 Cal. App. 3d 75, 92 Cal. Rptr. 825 (1971); *Toole v. Richardson-Merrell Inc.*, 251 Cal. App. 2d 689, 60 Cal. Rptr. 398 (1967). Other jurisdictions have analyzed the comment as well. See, e.g., *DeLuryea v. Winthrop Laboratories, Etc.*, 697 F.2d 222 (8th Cir. 1983); *Werner v. Upjohn Co. Inc.*, 628 F.2d 848 (4th Cir. 1980) cert. denied 449 U.S. 1080 (1981); *Lindsay v. Ortho Pharmaceutical Corp.* 637 F.2d 87 (2d Cir. 1980) (applying New York law); *Chambers v. G.D. Searle & Co.*, 441 F. Supp. 377 (D. Md. 1975) (interpreting District of Columbia law) aff'd 567 F.2d 269 (1977); *Basko v. Sterling*, 416 F.2d 417 (2nd Cir. 1969) (applying Connecticut law); *Ortho Pharmaceutical Corp. v. Chapman*, 180 Ind. App. 33, 388 N.E.2d 541 (Ind. App. 1979). See generally Schwartz, *Unavoidably Unsafe Products: Clarifying the Meaning And Policy Behind Comment k*, 42 WASH. & LEE L. REV. 1139 (1985); Merrell, *Compensation for Prescription Drug Injuries*, 59 VA. L. REV. 1 (1973).

65. *Brown*, 44 Cal. 3d at 1065-66, 751 P.2d at 480, 245 Cal. Rptr. at 421-22. In analyzing the "failure to warn" aspect of comment k, *Brown*, like *Kearl* and prior pharmaceutical liability cases, cited both drug and non-drug precedent for the proposition that the applicable analysis is one of negligence, regardless of whether plaintiff proceeds on a strict liability theory. *Id.* The authors are aware of only one published opinion in California which attempts to draw a clear-cut distinction between negligence and strict liability for failure to warn, *Anderson v. Owens-Corning Fiberglass Corp.*, 217 Cal. App. 3d 772, 266 Cal. Rptr. 204 (1990) petition for review granted and opinion superseded, 790 P.2d 238, 269 Cal. Rptr. 74 (1990). *Anderson* was decided after *Brown* and interprets *Brown* as having limited its negligence analysis to prescription drug cases decided pursuant to comment k. *Id.* at 783, 266 Cal. Rptr. at 211. The dissenting justice criticized the majority for departing from precedent in both pharmaceutical and non-pharmaceutical cases, and for failing to recognize that comment j, which is not limited to unavoidably unsafe products, contains the same elements of foreseeability and reasonable conduct. *Id.* at 787-88, 266 Cal. Rptr. at 214-15. (Goertzen, J., dissenting). The argument advanced by the dissent was similar to the reasoning of the majority in another post-*Brown* non-drug case, *Persons v. Salomon North America, Inc.*, 217 Cal. App. 3d 168, 265 Cal. Rptr. 773 (1990). See also *Vermeulen v. Superior Court*, 204 Cal. App. 3d 1192, 251 Cal. Rptr. 805 (1988). The *Anderson* case would appear to be an aberration and is more in line with the former Chief Justice's dissent in *Finn*, which has never been adopted by the California Supreme Court.

66. See *infra* note 76 (discussing the cases employing the affirmative defense approach).

67. *Brown*, 44 Cal. 3d at 1059, 751 P.2d at 476, 245 Cal. Rptr. at 417. Accord, *Patten v. Lederle Laboratories*, 676 F. Supp. 233 (D. Utah 1987) (applying Utah law).

68. See RESTATEMENT (SECOND) OF TORTS § 388 (1965) (outlining the negligence doctrine). There has been an enormous amount of confusion both before and after *Brown* concerning whether any form of strict liability remains for either defective design or failure to warn. This

Although both *Brown* and *Kearl* adopted comment k and reached a similar drug liability policy and analysis of warning defects, the

confusion has stemmed from an ambiguity in comment k which has been paraphrased in many decisions, including *Brown*. Specifically, comment k would appear to exempt manufacturers of unavoidably unsafe products from strict liability, but only if the manufacturer gives proper warning of a product's dangerous propensities. See *supra* note 29 (providing the text of comment k). In dealing with this language, a number of cases and commentators have simply regurgitated the phrase and have concluded that a drug manufacturer *may* be held "strictly liable" to the extent its warnings are inadequate, without explaining how this can be the case when, admittedly, the analysis to be employed by the jury is predicated upon a standard of reasonable care; that is, negligence. See *e.g.*, *Rodriguez v. Superior Court*, 90 Daily Journal D.A.R. 7610 (to be reported at 271 Cal. Rptr. 114 (July 2, 1990)) (interpreting *Brown* and *Finn*); *Daubert v. Merrell Dow Pharmaceutical, Inc.*, 711 F. Supp. 546 (S.D. Ca. 1989) (interpreting *Brown*); *Hill v. Searle Laboratories*, 884 F.2d 1064 (8th Cir. 1989) (applying Arkansas law); *Coursen v. A.H. Robbins*, 764 F.2d 1329 (9th Cir. 1985) (applying Oregon law); *Kirk v. M. Reese Hosp. & Medical Center*, 117 Ill. 2d 507, 513 N.E.2d 387 (1987); *Toner v. Lederle Laboratories*, 112 Idaho 328, 732 P.2d 297 (1987) *cert. denied* 485 U.S. 942 (1988); *Feldman v. Lederle Laboratories*, 97 N.J. 429, 479 A.2d 374 (1984); *McKee v. Moore*, 648 P.2d 21 (Ok. 1982); *Leibowitz v. Ortho Pharmaceutical Corp.*, 224 Pa. Super. 418, 307 A.2d 449 (1973); Comment, *Brown v. Superior Court: A Tonic For Prescription Drug Manufacturers*, 16 W. St. L. Rev. 753, 762 (1989); *Kelly, The Relevancy of Drug Efficacy Evidence In Strict Liability Actions: Needham v. White Laboratories, Inc.*, 14 J. MARSHALL L. Rev. 629, 640 (1981). One theory emanating from the ambiguous terminology that has been adopted in at least two jurisdictions was outlined in detail by Chief Justice Bird in her dissent in *Finn*. The Chief Justice suggested that although comment k arguably introduces the element of "foreseeability" into an action for strict liability based on failure to warn, the focus continues to be on the product, as opposed to the reasonableness of the manufacturer's conduct. *Finn v. G.D. Searle & Co.*, 35 Cal. 3d 691, 705, 677 P.2d 1147, 1155, 200 Cal. Rptr. 870, 878 (1984) (Bird, C.J., dissenting). Accordingly, while the manufacturer utilizing comment k could attempt to prove its lack of knowledge with regard to the drug risk at issue, the defendant's conduct in obtaining information or in using such information, for the purpose of product labeling, would be irrelevant. See also *Toner v. Lederle Laboratories*, 112 Idaho 398, 732 P.2d 297 (1987); *Woodhill v. Parke-Davis & Co.*, 79 Ill. 2d 26, 402 N.E.2d 194 (1980). The view espoused in the *Finn* dissent ignores the clear meaning of comments k and j which focus, as the *Brown* court clearly recognized, on the reasonableness of the manufacturer's conduct both in terms of gleaning scientific data and in disseminating that information. The disputed language in comment k indicates that the manufacturer must provide warnings "where the situation calls for it," a significant caveat suggesting that there may be instances where a manufacturer has knowledge of a risk, but where such knowledge may not trigger a duty to warn. *Finn*, 35 Cal. 3d at 701, 677 P.2d at 1153, 200 Cal. Rptr. at 876. See also *Basko v. Sterling*, 416 F.2d 417, 426 (2nd Cir. 1969). Certainly the court in *Brown* was not amenable to such theoretical hair-splitting as it unabashedly referred to the "comment k negligence standard." *Brown*, 44 Cal. 3d at 1067, 751 P.2d at 481, 245 Cal. Rptr. at 423. It appears that the only case to have specifically addressed the effect of the ambiguity in comment k is *Kearl*. After explaining that the test contained in comment k is predicated upon a negligent failure to warn analysis, the *Kearl* court noted that: "[I]t would be incorrect to view an unavoidably dangerous product as subject to strict products liability design defect analysis, or as presumptively defective, simply because such a product may lack a warning The test for whether a warning must be given is one of reasonableness; because there may be unavoidably dangerous products that reasonably required no warning, such products would not be defective by mere absence of warning." *Kearl v. Lederle Laboratories*, 172 Cal. App. 3d at 831 n.15, 218 Cal. Rptr. at 465 n.15 (1985) (citations omitted). It is clear that for the policy recognized by *Brown* to be fully implemented, a drug manufacturer must not have to wait until trial to know whether it will be subjected to strict liability. *Brown v. Superior Court*, 44 Cal. 3d at 1068-69, 751 P.2d at 482, 245 Cal. Rptr. at 424 (1988).

cases differ on the scope of comment k. The supreme court advocated blanket protection for prescription drugs in *Brown*, while *Kearl* espoused a drug-by-drug examination.

The *Brown* court embraced the “unavoidably unsafe” concept from *Kearl* but disapproved of the *Kearl* procedure for implementing the concept.⁶⁹ The *Brown* court recognized the general appeal of the premise behind the mini-trial approach, observing that “it seems unjust to grant the same protection from liability to those who gave us thalidomide as to the producers of penicillin.”⁷⁰ The court indicated that it would seriously consider a workable method to confine the benefit of the comment k negligence standard to clearly beneficial drugs while denying the privilege to those that are clearly harmful. Nevertheless, the court concluded that “[w]e know of no means by which that can be accomplished without substantially impairing the public interest in the development and marketing of new drugs, because the harm to this interest arises in the very process of attempting to make the distinction.”⁷¹ Therefore, the court concluded that all prescription drugs must be protected by comment k, and exempt from strict liability, as a matter of law.⁷²

69. *Brown*, 44 Cal. 3d at 1067, 751 P.2d at 481, 245 Cal. Rptr. at 423.

70. *Id.*

71. *Id.* In a detailed critique of the *Kearle* approach, the court pointed out that an ad hoc determination of pharmaceutical risks and benefits as a prerequisite to protection from strict liability would mean that a drug manufacturer would have

no assurance that a product he places on the market will be measured by the liability standard of comment k because a trial judge could decide that the benefit of the drug was not “exceptionally important” so as to make its availability “highly desirable,” or that the interest in its availability did not outweigh the public’s interest in subjecting the producer from strict liability.

Id. The court referred to several examples where the *Kearle* approach would lead to gross inconsistencies in the application of the strict liability doctrine to drug manufacturers. The court noted that there would be a disincentive to introduce potentially superior competing products onto the market if the manufacturer would be held strictly liable for harmful side effects because a trial court could decide “perhaps many years later” that another product previously or subsequently available could have accomplished the same therapeutic result. *Id.* at 1068, 751 P.2d at 482, 245 Cal. Rptr. at 423. Additionally, the court recognized that individual drugs may have several therapeutic indications, and that while the risk-benefit assessment might favor a drug given to one plaintiff, the balance could tip in favor of a plaintiff in another case where the drug was used to treat a dissimilar, less threatening condition. *Id.* The court was most concerned about potentially inconsistent findings by different judges, different juries, and by the judge and jury in the same case. *Id.*

72. *Id.* at 1068-69, 751 P.2d at 482-83, 245 Cal. Rptr. at 424. It is clear that instead of rejecting the requirement that a product, in order to qualify for comment k protection, be deemed unavoidably unsafe, the court made a determination that prescription drugs as a class of products fulfill that prerequisite. This conclusion is inescapable inasmuch as the court held that while the scope of comment k appears “unclear,” it “was intended to and should apply to all prescription drugs.” *Id.* at 1069 n.11, 751 P.2d at 482 n.11, 245 Cal. Rptr. at 424 n.11. Such intent is derived from the critical observation that in order for the policy of comment k

The blanket protection of *Brown* is consistent with cases from a number of other jurisdictions.⁷³ However, while the California Supreme Court casually suggested that its comment k analysis has been adopted by "almost all our sister states,"⁷⁴ there appears to be substantial division among those courts.⁷⁵ Given the prominent role of California in the development of product liability law, the *Brown* decision will unquestionably become a focal point in the disposition of pharmaceutical litigation all across the country. Indeed, *Brown* has been analyzed by courts outside of California as well as in legal commentary, and predominantly has been criticized for its categorical exemption of prescription drugs.⁷⁶

While courts in other jurisdictions continue to grapple with *Brown* and the scope of comment k in the context of prescription drugs, it

to be fully implemented, the industry must be assured prior to the undertaking of research and development that it will not be subject to strict liability. *See also supra* notes 42-50 and accompanying text (discussing the impact of the *Kearl* mini-trial on the pharmaceutical industry).

73. *See Basko v. Sterling Drug, Inc.*, 416 F.2d 417 (2nd Cir. 1969) (applying Connecticut law); *McDaniel v. McNeil Laboratories, Inc.*, 196 Neb. 190, 241 N.W.2d 822 (1976); *Leibowitz v. Ortho Pharmaceutical Corp.*, 224 Pa. Super. 418, 307 A.2d 449 (1972).

74. *Brown*, 44 Cal. 3d at 1069; 751 P.2d at 482-83, 245 Cal. Rptr. at 424.

75. *Compare* cases cited *supra* note 73 (applying the blanket approach) *with Hill v. Searle Laboratories*, 884 F.2d 1064 (8th Cir. 1989) (applying Arkansas law); *Coursen v. A.H. Robbins Co., Inc.*, 764 F.2d 1329 (9th Cir. 1985); *Kociemba v. G.D. Searle & Co.*, 695 F. Supp. 432 (D. Minn. 1988) (applying Minnesota law); *Patten v. Lederle Laboratories*, 676 F. Supp. 233 (D. Utah 1987) (applying Utah law); *White v. Wyeth Laboratories, Inc.*, 40 Ohio St. 3d 390, 533 N.E.2d 748 (1988); *Castrignano v. E.R. Squibb & Sons, Inc.*, 546 A.2d 775 (R.I. 1988); *Señn v. Merrell-Dow Pharmaceuticals*, 305 Or. 256, 751 P.2d 215 (1988); *Toner v. Lederle Laboratories*, 112 Idaho 328, 732 P.2d 297 (1987) *cert. denied* 485 U.S. 942 (1988); *Feldman v. Lederle Laboratories*, 97 N.J. 429, 479 A.2d 374 (1984). Interestingly, while the Rhode Island Supreme Court opted for the case-by-case approach, the court, citing *Brown*, noted without direct refutation that, "[t]he threat of the imposition of strict liability even on a case-by-case basis, would undermine the public interest in the development and availability of drugs." *Castrignano*, 546 A.2d at 781 (citation omitted).

76. *See, e.g., Hill v. Searle Laboratories*, 884 F.2d 1064 (8th Cir. 1989) (applying Arkansas law); *Kociemba v. G.D. Searle & Co.*, 695 F. Supp. 432 (D. Minn. 1988) (interpreting Minnesota law); *Hawkinson v. A. H. Robbins Co., Inc.*, 595 F. Supp. 1290 (D. Colo. 1984) (applying Colorado law). These cases embrace the comment k concept but inappropriately treat comment k as an affirmative defense which essentially compels the manufacturer to justify, as a threshold matter, its decision to market the drug. *See, e.g., Hill*, 884 F.2d at 1068. Ironically, but not surprisingly, these cases help to underscore the inherent difficulties in approaching comment k protection on an ad hoc basis. For example, *Hill* adopts comment k but refuses to extend the comment's protection to the manufacturer of a "prescription" intrauterine device. *Id.* at 1069-70. Several other jurisdictions, including California, have applied comment k to precisely the same device. *See, e.g., Collins v. Ortho Pharmaceutical Corp.*, 195 Cal. App. 3d 1539, 231 Cal. Rptr. 396 (1986), *cause dismissed, remanded*, *Collins v. Karoll*, 761 P.2d 102, 251 Cal. Rptr. 642 (1988); *McKee v. Moore*, 648 P.2d 21 (Okla. 1982). The manufacturer of such a product is thus left with no real benefit, even in those jurisdictions which have extended comment k protection, since liability is contingent upon venue rather than the policy of encouraging research and development. Some commentators have been critical of the *Brown* decision. *See, e.g., Humphreys, supra* note 8.

is highly likely that California will move forward to consider the more far-reaching implications of the decision. These implications include, most prominently, the question of how the courts are to deal with non-prescription medications.

II. THE APPLICATION OF BROWN TO OVER-THE-COUNTER PHARMACEUTICAL PRODUCTS

Although most reported adverse drug reactions involve prescription products,⁷⁷ the regulatory trend towards increased self-medication, and the marketing of increasingly potent over-the-counter medicines, will inevitably thrust the strict liability issue into the OTC arena.⁷⁸

77. Comment, *Strict Liability In Tort: Its Applicability To Manufacturers of Prescription Drugs*, 7 U.C. DAVIS L. REV. 487, 487 n.2 (1974) (finding that 95% of reported adverse drug reactions involve prescription drugs). This figure probably understates current statistics since it does not take into account the effect of a number of prescription drugs that have been converted to OTC status in the past fifteen years. The figure also fails to reflect significant new areas of potential litigation involving "old" OTC products including aspirin (Reyes Syndrome), acetaminophen (kidney damage), and L-tryptophan (blood dyscrasia).

78. In *Rodriguez v. Superior Court*, 90 Daily Journal D.A.R. 7610 (to be reported at 271 Cal. Rptr. 114) (July 2, 1990), the Fifth District Court of Appeal had the opportunity to determine for the first time the applicability of comment k and *Brown* to an over-the-counter product. This case involved a child who allegedly contracted Reyes Syndrome after ingesting aspirin. The plaintiff brought suit against the aspirin manufacturer in a complaint stating causes of action predicated, *inter alia*, on strict liability for alleged defects in the drug's design as well as in the warnings provided by the company. *Id.*, 90 Daily Journal D.A.R. at 7610. The defendant manufacturer brought a motion for judgment on the pleadings prior to trial seeking to preclude the strict liability counts on the grounds that comment k, and the policies identified by the Supreme Court in *Brown v. Superior Court*, were applicable to some non-prescription drugs such as aspirin. *Id.* The trial court granted the motion and the plaintiff petitioned the court of appeal for a writ of mandate. *Id.* In a unanimous opinion, the court of appeal refused to determine whether comment k should be applied to non-prescription medications concluding that "such a consideration is premature." *Id.* The court (erroneously) interpreted comment k as leaving open the possibility of a strict liability cause of action to the extent that a plaintiff alleges that the manufacturer's warnings were inadequate. *See id.* at 7611. In addition, the court mistakenly construed a prior court of appeal decision in *Cavers v. Cushman Motor Sales, Inc.*, 95 Cal. App. 3d 338, 157 Cal. Rptr. 142 (1979), as establishing strict liability for failure to warn. *See Rodriguez*, 90 Daily Journal D.A.R. at 7611. The holding in *Rodriguez* is unfortunate. First, the court side-stepped the still unanswered question of whether comment k will apply to OTC medications. *Id.* Moreover, the decision adds to the already significant confusion surrounding the nature of the failure to warn defect both in terms of general product liability litigation and in pharmaceutical cases in particular. The court inexplicably ignored critical language contained in *Kearl v. Lederle Laboratories*, 172 Cal. App. 3d 812, 218 Cal. Rptr. 453 (1985) in which the First District Court of Appeal endeavored to clarify its earlier decision in *Cavers* noting that failure to warn analysis is firmly rooted in the doctrine of "negligence." *Kearl*, 172 Cal. App. 3d at 831 n.15, 218 Cal. Rptr. at 465 n.15. *See supra* note 46 and accompanying text (discussing *Kearl* and *Cavers*). Most troublesome, however, is the court's failure to discuss the effect of its holding on the policies espoused by the supreme court in *Brown*, which are explicitly designed to provide assurances to the pharmaceutical industry that it will not be held strictly liable for defects in design and warnings.

Courts considering the strict liability design issue⁷⁹ after *Brown* will likely choose between three possible approaches in handling OTC products: (1) No protection for non-prescription drugs, (2) protection limited to some, but not all, OTC drugs, or (3) "blanket" protection extended to all drugs, prescription and OTC, as defined by the Food and Drug Administration.

A. *The "No Exemption" Approach*

Given the lack of explicit precedent for extending comment k protection to OTC medications, it would not be surprising for a court, relying on a literal interpretation of *Brown* and its progeny, to preclude any OTC exemption from strict liability. This approach would be based on the contentions that (1) comment k was not intended to apply to non-prescription drugs, and (2) the social policy underlying the *Brown* court's decision to protect prescription drugs does not apply to non-prescription pharmaceutical products.

1. *The Scope of Comment k*

Although there has been a great deal of debate on the issue,⁸⁰ California case law seems to favor the interpretation that, at the very least, comment k was intended to exempt all prescription products from strict design defect liability.⁸¹ The question of whether comment

If the *Rodriguez* analysis is to be applied literally, manufacturers will not know until the jury returns a verdict on the failure to warn cause of action whether they will be subject to strict liability. *Rodriguez*, therefore, totally circumvents *Brown* by allowing a plaintiff to plead around *Brown* by asserting a strict liability failure to warn cause of action. See *infra* note 68 and accompanying text (discussing the nature of the failure to warn "defect" and its effect on the application of comment k).

79. Since virtually all California non-drug failure to warn cases analyze that defect under the rubric of negligence, there should be no theoretical distinction between prescription drugs and OTC products, regardless of whether comment k is extended into the OTC arena. Cf. *Rodriguez v. Superior Court*, ___ Cal. App. 3d ___, 90 Daily Journal D.A.R. 7611 (to be reported at 271 Cal. Rptr. 114 (July 2, 1990)); *Anderson v. Owens-Corning Fiberglass Corp.*, 217 Cal. App. 3d 772, 266 Cal. Rptr. 204 (1990), *petition for review granted and opinion superseded*, 790 P.2d 238, 269 Cal. Rptr. 74. See *supra* note 27 and cases cited therein (discussing California failure to warn doctrine).

80. See, e.g., Comment, *supra* note 8; Schwartz, *supra* note 64; Page, *supra* note 15; McClellan, *supra* note 12; Willig, *The Comment k Character: A Conceptual Barrier to Strict Liability*, 29 MERCER L. REV. 545 (1978).

81. See generally *Brown v. Superior Court*, 44 Cal. 3d 1049, 751 P.2d 470, 245 Cal. Rptr. 412 (1988).

k protection should be extended to OTC products appears to be an open question.

In fact, support for the application of comment k to OTC medications can be gleaned from language which suggests that unavoidably unsafe products are “especially common in the field of drugs.”⁸² The comment observes that such products are not defective or unreasonably dangerous and cites as specific examples “[d]rugs, vaccines, and the like, many of which for this very reason can not legally be sold except to physicians, or under the prescription of a physician.”⁸³ That Dean Prosser, in drafting the language of comment k, did not intend to limit the comment’s ambit to prescription drugs, is borne out by statements he made during debate over an initial draft of section 402A at a meeting of the American Law Institute’s section on the Restatement of Torts in 1961. Specifically, Prosser was concerned that proposed amendments to section 402A, which would have explicitly exempted all *prescription* drugs, would inappropriately leave the task of determining those products to be protected from strict liability to what he perceived as a non-uniform and sometimes illogical regulatory scheme.⁸⁴ While some commentators have suggested that rejection of the amendments by the A.L.I. evidenced the A.L.I.’s intention not to provide blanket protection for prescription drugs,⁸⁵ the conclusion which is best supported by Dean Prosser’s testimony, as well as the other language which he drafted into comment k, is that the scope of comment k was intended to cover all prescription drugs as well as at least some non-prescription medications.⁸⁶ To the extent that the language of comment k is unclear as to its scope, this ambiguity is largely explained by the lack of knowledge on the part of Dean Prosser and the drafters of

82. See *supra* note 29 (providing the language of comment k).

83. *Id.*

84. Prosser’s comments were in response to two proposed amendments to section 402A submitted by another member of the Committee on Torts. A.L.I. Proc. (1961), at 90-92. While Prosser was sympathetic to the policy underlying the proposed amendments, the late Dean expressed some difficulty with the definition of “drug” and the limitations of the amendments to prescription products. He observed: “I am not happy about the limitation of prescription. It seems to me that what you are doing is tossing it back to a lot of local regulations which vary enormously and frequently do not make any sense.” *Id.* at 95-96.

85. Comment, *supra* note 8 at 722; Humphreys, *supra* note 8, at 1274.

86. Schwartz, *supra* note 64, at 1145-46. Professor Page, whose interpretation of comment k was cited with approval by the supreme court in *Brown*, has noted that the comment “[m]ay be read to remove from the reach of section 402A any product that is unavoidably unsafe as long as the manufacturer will not be subject to liability under a negligence rule for injury caused by the product. Such an exemption includes but is not limited to prescription drugs” Page, *supra* note 15, at 867.

the Restatement regarding the regulatory distinction between prescription and non-prescription medications.⁸⁷ To his credit, Prosser refused to promote any definitive line-drawing in the pharmaceutical area, presumably leaving that task to further common law developments in pharmaceutical product litigation.

2. *Application of the Brown Policy to Over-the-Counter Drugs*

In holding that comment k should apply to all prescription medications, the *Brown* court emphasized the need to encourage research and development of affordable drugs and to protect the marketing of existing products from the deterrent effect of strict liability. Any future limitation or extension of the comment k doctrine to OTC drugs should ultimately turn on the supreme court's policy analysis in *Brown*.

Three significant themes appear to form the basis for the categorical application of comment k to prescription drug products in *Brown*: (1) The products, while inherently unsafe, confer great social benefit,⁸⁸ (2) the products are subject to intense regulation by the federal government,⁸⁹ and (3) the industry which manufactures the products is particularly susceptible to the effects of liability in terms of research, development, and marketing decisions.⁹⁰

To preclude protection for OTC drugs under the *Brown* analysis, a court would have to conclude that: (1) OTC drugs, by definition, are not sufficiently beneficial, (2) such products are not subject to equivalent federal scrutiny, and (3) the OTC drug industry is not uniquely affected by the imposition of strict liability. However, an analysis of the origin, regulation, and social impact of OTC drugs demonstrates that all three of the considerations in *Brown* apply to non-prescription medications.

87. Page, *supra* note 15, at 866 n.66. Indeed, the A.L.I. Proceedings between 1961 and 1964 were devoid of any detailed analysis of the federal regulatory process.

88. *Brown v. Superior Court*, 44 Cal. 3d 1049, 1063, 751 P.2d 470, 479, 245 Cal. Rptr. 412, 420 (1988). It is important to note that the court assessed the benefits of prescription drugs as a "class", and refused to engage in ad hoc determinations of whether a particular drug is, in isolation, in fact beneficial to the public health. *Id.* at 1065 n.10, 751 P.2d at 480 n.10, 245 Cal. Rptr. at 421 n.10.

89. *Id.* at 1069 n.12, 751 P.2d at 483 n.12, 245 Cal. Rptr. at 424 n.12.

90. *Id.* at 1063-1065, 751 P.2d at 478-80, 245 Cal. Rptr. at 420-21.

a. OTC or Prescription Classification? The Role of Drug Benefit

According to the California Supreme Court, a significant difference between prescription drugs and other consumer goods, such as machinery, is that the non-drug goods are used "to make work easier or to provide pleasure," while drugs may be necessary "to alleviate pain and suffering or to sustain life."⁹¹ In order for a rational distinction to be drawn between OTC and prescription products in the context of the application of strict liability, it must be demonstrated that the Food and Drug Administration (FDA) distinguishes between the two classes on the basis of the benefits the products provide. By this classification, the prescription drugs would be the more beneficial drugs (i.e., those which alleviate pain and suffering or which sustain life) and OTC drugs would be the less beneficial drugs (i.e., those which provide only minor comfort). If the FDA does not classify drugs in this manner, the regulatory distinction between prescription and over-the-counter medications cannot logically serve as a basis for determining which products are deserving of comment k protection.

Under the current statutory and regulatory scheme, the federal government, through the FDA, engages in a generalized risk-benefit examination of *all* new drugs as a condition to marketing, regardless of their prescription or OTC status.⁹² As Professor James O'Reilly noted:

The judgment of marketability made by both the manufacturer and the Food and Drug Administration for a drug product takes into account the benefits of the product and the relative risk presented

91. *Id.* at 1063, 751 P.2d at 478, 245 Cal. Rptr. at 420. As noted earlier, while there may be other non-drug products which confer the same type of benefit, they would not be protected by comment k unless they were shown to be unavoidably unsafe. *Id.* For example, contaminated blood may fall within the ambit of comment k. See *Miles Laboratories v. Doe*, 315 Md. 704, 556 A.2d 1107 (1989); *Belle Bonfills Memorial Blood Bank v. Hansen*, 665 P.2d 118 (Colo. 1983).

92. Indeed, all new drugs are presumed to be destined for the OTC market. Their status when ultimately marketed will turn on; (1) whether the manufacturer desires to distribute the drug over-the-counter, and (2) whether FDA approves of such intention. O'Reilly, *The Food and Drug Administration*, (Regulatory Manual Series), v.2, 1989, at 14-9. See *Initial Decision, Benylin Expectorant*, Docket 76N-0483 (FDA 1979), and *Parke-Davis & Co. v. Califano*, 564 F.2d 1200 (6th Cir. 1977) *cert. denied*, 435 U.S. 942 (1978).

in light of other available remedies and the particular therapeutic situation to which the drug is addressed.⁹³

Such an assessment by the FDA, in the context of prescription drugs, partly formed the foundation for the *Brown* court's application of comment k to those products, although it is clear that the same analysis is utilized by the FDA in determining the risks and benefits of OTC medications.

After conducting a risk-benefit assessment, the FDA determines if the drug should be marketed to the consumer or to the physician. This secondary examination focuses on whether the medication, or the underlying condition which necessitates the drug, requires medical supervision. The FDA determines whether written directions for the drug's use will be adequate and understandable by the lay consumer.⁹⁴ This distinction of whether the consumer can understand the drug's directions is the most critical and fundamental distinction between prescription and OTC drugs. This distinction does not bear directly on drug benefits, since all drugs must demonstrate efficacy in treating or preventing the conditions for which they are indicated.

i. The Historical Origins of the Prescription/OTC Distinction

A historical analysis of the regulatory framework demonstrates that the classification of a drug as "prescription" or "over-the-counter" was never based on an assessment of medical import.⁹⁵ Prior to 1938, there was no distinction between prescription and OTC medications, with the exception of certain habit-forming narcotics.⁹⁶ In 1938, Congress passed sweeping legislation in the form

93. O'Reilly, *The Food and Drug Administration*, (Regulatory Manual Series), v.2, 1979, at 14-7.

94. Willig, *supra* note 80, at 557. Dr. John Archer noted that the distinction between OTC and prescription drugs involves a labeling decision. Archer, *Instrument Or Impediment? The Regulatory Monograph In Medical Communications*, 120 J. A.M.A. 1474, 1474-75 (1972). If the directions can be written for a lay person, the drug is marketed OTC. *Id.*

95. In reviewing the historical development of the regulatory distinction between OTC and prescription drugs, one commentator was moved to quip:

I am not certain whether to analogize this distinction to Pallas Athena who sprang full-grown from Zeus' head or to Topsy, who "just growed." In any event, it was only shortly after the enactment of the 1938 Federal Food, Drug and Cosmetic Act that any general distinction was drawn under federal law concerning the dispensing status of a drug product.

Kaplan, *Over-The-Counter And Prescription Drugs: The Legal Distinction Under Federal Law*, 37 FOOD DRUG COSM. L.J. 441, 441 (1982)

96. The 1906 Food and Drugs Act was the first comprehensive federal law regulating

of the Federal Food, Drug & Cosmetic Act (Act),⁹⁷ which was largely designed to broaden FDA powers to ensure product safety. Whereas previous federal law subjected manufacturers to regulatory scrutiny only for the “fraudulent misbranding” of their products,⁹⁸ the new Act provided that any “new drug” must be tested for safety and approved by FDA prior to marketing.⁹⁹ The “new drug” definition drew no distinction between products for sale over-the-counter or by prescription. This was a logical outcome since most drugs were sold directly to consumers at the time of the Act.¹⁰⁰ In addition to providing for a pre-market safety screen, the Act required warnings and adequate directions for use on drug product labels, unless the FDA determined that such labeling was unnecessary.¹⁰¹

The new Act itself did not specifically create separate drug categories. However, shortly after the Act’s passage, internal debate at the FDA regarding how the agency should enforce the new legislation resulted in the first prescription/OTC distinction.¹⁰² Some FDA regulators felt that the new labeling requirements of the Act created a potential conflict with related provisions.¹⁰³ Specifically, they felt that adequate warnings and directions for use intended for lay consumers could not be written for some drugs.¹⁰⁴ Since the Act deemed any drug which failed to provide adequate labeling to be “misbranded,”

drugs. 1906 Food and Drugs Act, ch. 3915, 34 STAT. 768, as amended. This law was designed to curtail fraudulent claims made by patent medicine distributors. The 1914 Harrison Narcotic Act required that opium and coca leaf derivatives be dispensed only upon a physician’s written order, although the number of refills was unregulated. 38 STAT. 785 (1914)

97. 2 STAT. 1040 (1938), as amended 21 U.S.C.A. §§ 301-392 (West Supp. 1990).

98. See *infra* note 101.

99. 2 STAT. 1040, as amended, 21 U.S.C. § 321(p) (1982). New drugs are defined as those products which have the following characteristics: (1) Classification as a drug; (2) absence of general recognition of safety and effectiveness for the drug, a recognition of those attributes among qualified scientists rather than among the public or all practitioners, or absence of such general recognition as to any particular use for which it is proposed to be used and prescribed; and (3) absence of a record of pre-1938 uses for that drug which match identically the uses for which the drug is now represented to be useful. *Id.* § 355(a)-(b).

100. Indeed, it appears that the intent of Congress in passing the Act was to improve and facilitate self-medication by safeguarding the consumer through pre-market clearance and more detailed labeling. Temin, *The Origin of Compulsory Drug Prescriptions*, 22 J. of L. & Econ. 91, 96 (1979).

101. The United States Code provides that a drug is “misbranded” unless its label provides the user with adequate directions and adequate warnings. 21 U.S.C. 352(f) (1982). The directions and warnings must be in a manner and form that will protect the users. *Id.* The Sec. of Health, Ed. & Welfare may exempt any drug from the directions and warnings requirement if the Secretary finds the directions and warnings unnecessary to protect the consumers. *Id.*

102. See Kaplan, *supra* note 95, at 441-42.

103. See Temin, *supra* note 100, at 99.

104. *Id.* at 96-100.

the FDA was concerned that some beneficial medicines might have to be taken off the market.¹⁰⁵

In order to provide protection for the manufacturers of these as yet unidentified drugs, the FDA promulgated regulations which exempted from the labeling requirements of the Act, *any drug* which bore the legend: "Caution: To be used only by or on the prescription of a physician."¹⁰⁶ There was no explicit articulation of which drugs were incapable of being properly labeled. The FDA left the decision up to individual manufacturers.

Between 1938 and 1951, there was little uniformity in the classification of drug products as either prescription or OTC. Indeed, many drugs were sold by prescription only by some manufacturers, with other companies selling an identical drug over-the-counter, the only difference being in the content of the label. Congressional response to this inconsistency, developed largely in order to protect pharmacists, came in the form of the 1951 Humphrey-Durham Amendments to the Food, Drug & Cosmetic Act of 1938.¹⁰⁷ The amendments outlined for the first time the definitional criteria which FDA was to use in determining prescription drug status, although the new law left the determination of who could prescribe such products up to the individual states.¹⁰⁸

In the wake of the thalidomide disaster, the next significant drug legislation was the 1962 amendment to the 1938 Act which added, in addition to pre-existing safety regulations, a requirement that all "new drugs" demonstrate substantial evidence of *efficacy* in the context of their indications for use.¹⁰⁹ The 1962 legislation imposed

105. *Id.* Professor Temin concludes that FDA rule-making in this respect was contrary to the intent of Congress, which was to encourage the availability of safe drugs without a prescription. *Id.* at 96.

106. 3 Fed. Reg. 3168 (Dec. 28, 1938).

107. 21 U.S.C. § 353(b) (1976).

108. As the FDA noted: "The prescription requirements were enacted for the sake of uniformity of labeling and the protection of retail druggists . . . not [as] a result of a congressional decision that the government rather than the manufacturers was best able to determine which drugs were most appropriately marketed on a prescription basis . . ." Initial decision, Docket No. 76N-0483, *In Matter of Benylin Expectorant: Proposal to Deny Approval of Supplemental New Drug Application* at 6-7 (May 31, 1978).

109. Pub. L. No. 87-781, 6 Stat. 780 (1962) (amending 21 U.S.C. §§ 301 *et seq.*). As was the case when the 1938 Act was enacted to require premarket "safety" testing, the 1962 amendments imposed an efficacy requirement on all "new drugs," including those destined for the OTC market. Under the OTC Review regulations, efficacy is defined as follows:

Effectiveness means a reasonable expectation that, in a significant proportion of the target population, the pharmacological effect of the drug, when used under adequate directions for use and warnings against unsafe use, will provide clinically significant relief of the type claimed.

21 C.F.R. § 330.10(a)(4)(ii) (1990).

a requirement that drugs demonstrate actual medical benefit, in addition to safety, as a prerequisite for marketing approval. Previously, neither prescription products nor over-the-counter drugs were required to prove efficacy. The new efficacy-testing regulations similarly failed to draw a distinction between OTC and prescription medications.

Thus, the current regulatory scheme implements a two-tiered approach to pharmaceutical approval and marketing. Prior to FDA approval, manufacturers must submit well-controlled studies demonstrating both safety and efficacy. Only after these studies have been completed and reviewed by the FDA is a secondary decision made concerning how a particular product will be marketed.¹¹⁰ Certainly, this secondary analysis indirectly involves drug risks and benefits, but only to the extent that those factors impact the ability of lay consumers to use a drug safely and effectively without medical supervision. It is the medical supervision issue which has ultimately determined the overall makeup of the over-the-counter drug marketplace.

ii. The Parameters of the OTC Marketplace

Since 1951 the primary impact of the Humphrey-Durham Amendments has been to enhance uniformity in the marketing classification of identical drug products. The effect of the amendments has not been to create dichotomous categories of medicinal products on the basis of relative social import since the criteria which control the prescription definition turn on the need for medical supervision, rather than the risk-benefit profile of a chemotherapeutic agent.

Moreover, the prescription drug criteria contained in the 1951 amendments were not intended to constitute a "static" definition, but are ideally applied consistent with the evolution of social, eco-

110. Of course, some drugs may be principally targeted for either prescription or OTC status early in their development. See generally O'Reilly, *supra* note 93, § 13.10. Additionally, any question about safety during the NDA process may lead to an accelerated decision that prescription distribution is required. *Id.* § 13.09, at 13-51. Once the FDA determines that a drug requires a prescription, over manufacturer objection, judicial review may be taken under 21 United States Code section 505. See Weinberger v. Bentex Pharmaceuticals, Inc., 412 U.S. 645 (1973). In general, however, courts are likely to defer to the expertise of the agency. See National Nutritional Foods Association v. Matthews, 423 U.S. 827 (1975), *dismissed on remand*, 418 F. Supp. 394 (S.D. N.Y. 1976), *revd. and remanded*, 557 F.2d 325 (2d Cir. 1977).

nostic, and scientific data.¹¹¹ The FDA's implementation of the prescription drug criteria largely reflects this policy of flexibility, although the agency has been criticized for individual decisions which have occasionally been inconsistent or arbitrary.¹¹²

The fact that a particular drug is "toxic" or "may lead to harmful results" does not mean that the drug will automatically be restricted to prescription status.¹¹³ Virtually all drugs can have harmful effects on susceptible individuals, even when used according to directions.¹¹⁴ Nevertheless, if those risks can be adequately disseminated via product labeling to consumers, OTC status may be justified. Even drugs with especially significant potential risks may be marketed OTC where the benefits largely outweigh the costs of restricted access.¹¹⁵

Similarly, the "collateral measures"¹¹⁶ and "medical diagnosis"¹¹⁷ criteria of the 1951 amendments have not been uniformly applied. Insulin (diabetes), antacids (ulcers), and inhalation bronchodilators (asthma) are all highly beneficial products which are used to treat conditions which require an initial medical diagnosis and subsequent monitoring, yet all these drugs are, to a large extent, available over-the-counter.¹¹⁸

Several other important categories of pharmaceutical products underscore the lack of substantive differences between many OTC and prescription drugs, and demonstrate why comment k, and the *Brown* policy to encourage expanded availability of such products, cannot be rationally limited to prescription medications. A multitude of OTC

111. Hutt, *A Legal Framework for Future Decisions on Transferring Drugs From Prescription to NonPrescription Status*, 37 FOOD DRUG COSM. L.J. 427, 433 (1982). Such information may include new information regarding a drug's toxicity. For example, the antibacterial agent hexachlorophene was switched from OTC to prescription status after reports of neurological toxicity. Baumgartner, *A Historical Examination of the FDA's Review of The Safety and Effectiveness of Over-the-Counter Drugs*, 43 FOOD DRUG COSM. L.J. 463, 475 (1988).

112. Pinco & Cogan, *Prescription to Over-the-Counter Switches: An Example of the New Procedures In the Post-Monograph Era*, 39 FOOD DRUG COSM. L.J. 230, 234-35 (1984).

113. Hutt, *supra* note 111, at 434.

114. Note, *Picking Your Poison: The Drug Efficacy Requirement And The Right Of Privacy*, 25 UCLA L. REV. 577, 585-86 (1978). See also Hess & Clark Division of Rhodia, Inc. v. FDA, 495 F.2d 975, 993 (D.C. Cir. 1974).

115. Rchanow, *The Switch of Drugs From Prescription To Over-the-Counter Status*, 39 FOOD DRUG COSM. L.J. 201, 205 (1984). A good example involves common aspirin. That drug is associated with development of Reyes Syndrome, a rare, but often fatal disease afflicting children. Nevertheless, FDA has rejected proposals to restrict children's aspirin sales to a doctor's prescription, concluding that information regarding the potential risk can be adequately disseminated in product labeling. 53 Fed. Reg. 21633, 21635 (1988).

116. See *supra* note 111.

117. See *id.*

118. Wuest & Gossel, *How—And Why—Prescription Drugs Become OTC*, U.S. PHARMACIST, (September, 1982) at 23.

drugs are prescribed by physicians in this country on a daily basis.¹¹⁹ Drawing a liability distinction between cases where an OTC product was “prescribed” by a physician and where the same drug was self-administered to treat the same illness by a more sophisticated and cost-conscious consumer would be difficult to justify.

Many products have been put into a special category by the FDA because of their potential for misuse.¹²⁰ This is especially true of some medications which contain codeine, a potent cough suppressant. Such products may be sold over-the-counter at the discretion of the individual states.¹²¹ Were comment k restricted to prescription drugs, the application of strict liability to these medications would depend exclusively on venue, a result which, as the court in *Brown* noted, would circumvent the comment’s underlying policy.¹²²

A significant number of medications are sold *both* over-the-counter and by prescription, although each OTC product is *identical* in terms of ingredients, dosage and strength to its prescription counterpart. Here the FDA distinction is based on a difference in indications for use. For example, the drug meclizine is used to treat vertigo as well as nausea accompanying motion sickness. One version of the drug, Bonnine, is sold OTC and is indicated for motion sickness. The same drug (manufactured by the same company) is marketed in a prescription form known as Antivert. The reason: Bonnine is indicated for vertigo, which requires, according to FDA, a medical diagnosis.¹²³ Again, this dichotomy bears no relation to either the risks or benefits of a drug per se, and points to the difficulty in limiting comment k protection to prescription drugs.

The OTC category with the most to win or lose in a debate over the extension of *Brown* to non-prescription drugs includes those products which have been reclassified by the FDA from prescription to OTC status. These products are referred to by the FDA and the

119. Liebowitz, *Substitution Between Prescribed and Over-the-Counter Medications*, 27 MEDICAL CARE 85, 93 (1989). “National data indicate that physicians routinely suggest OTC drugs during office visits; aspirin ranks sixth among the drugs most frequently ordered or provided in office practice.” *Id.*

120. 21 U.S.C.A. § 812 (West 1990).

121. These so-called schedule products include preparations with up to one grain per ounce of codeine. *See id.* § 812(c).

122. *See supra* notes 42-50 and accompanying text (discussing the *Kearl* mini-trial).

123. Wuest & Gossel, *supra* note 118, at 23. In recent years, there has been a clear trend at the FDA towards liberalizing the agency’s policy to allow more simultaneous OTC/prescription marketing of identical products for different indications. Some likely candidates for the future include climetidine, sucralfate, and clotrimazole. F-D-C Reports, *Pink Sheet*, August 8, 1988 at 3.

pharmaceutical industry as "switch-overs."¹²⁴ They include former prescription products which have been moved entirely from prescription to OTC status, as well as low-dose versions of prescription chemicals.¹²⁵

Perhaps the best example of an OTC switch-over, for the purposes of this article, is the drug hydrocortisone. Hydrocortisone is used to treat many dermatologic disorders and is now sold over-the-counter in concentrations up to .5 percent.¹²⁶ Hydrocortisone is significant in that it was specifically cited by the California Supreme Court in *Brown* as an example of a product with unquestionable and significant social value and as a justification for exempting "prescription drugs" from strict liability.¹²⁷

As of January, 1989, the FDA switched over more than forty-three prescription ingredients and dosages to OTC status.¹²⁸ A more sophisticated public is demanding that the FDA consider more OTC switch-overs.¹²⁹ The trend has led one observer to suggest that:

[T]here is virtually no limit to the number of prescription drugs that are potential candidates for transfer to non-prescription status. By far the three most important considerations involved are the margin of safety, the abuse potential, and the availability of adequate labeling. The considerations of self-diagnosis and self-treatment are waning in importance, and indeed are already of minor significance. Social policy concerns may well regulate the speed at which transfers are made from prescription to non-prescription

124. See generally Cusick & Downs, *The Prescription to Over-the-Counter Switch*, AMERICAN DRUGGIST, June 1986 at 101-13.

125. A "switch-over" can be accomplished through a number of procedural mechanisms and can be initiated both by FDA and industry or upon the petition of "any interested person."

126. F-D-C Reports, *Pink Sheet*, March 5, 1990 at 1. Additional concentrations up to one percent have been tentatively cleared for OTC switch-over by FDA and are likely to be introduced sometime in 1991. *Id.* at 90-91.

127. *Brown v. Superior Court*, 44 Cal. 3d 1049, 1064, 751 P.2d 470, 479, 245 Cal. Rptr. 412, 420 (1988). The *Brown* reference takes on added significance since it in turn cited Dean Prosser who concluded in a famous quote: "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." *Id.* (citing PROSSER, TORTS § 99 at 661 (4th Ed. 1971)). It should be noted that Dean Prosser's other example, penicillin, has been, and continues to be, a candidate for switch-over, at least at low dose levels. See Temin, *Costs and Benefits In Switching Drugs From Rx to OTC*, 2 J. OF HEALTH ECON. 187, 199-201 (1987).

128. Proprietary Association data (copy on file at the *Pacific Law Journal*).

129. A recent industry survey revealed that 24 pharmaceutical firms which responded to the survey will make 170 submissions to the FDA in the next four years, of which 57 will be switch-over requests. Soller, *Introduction*, 24 DRUG INFO. J. 1, 1-2 (1990).

status, but ultimately can be expected to reinforce that process.¹³⁰

Every drug, regardless of this marketing status, has a unique risk-benefit profile. Some OTC products have enormous benefit but relatively few risks and this largely justifies their direct sale to consumers. Some prescription drugs on the other hand, have less qualitative or quantitative benefit than their OTC cousins, but may involve significantly greater risks or are indicated for more complex pathologies necessitating medical supervision and thus prescription status. In both cases however, the marketing classification distinction does not directly turn on drug benefits. Indeed, even the risk factor is playing a less important role in marketing decisions as demand for over-the-counter medications increases. The clear trend is towards OTC distribution of increasingly potent, and thus inherently dangerous, chemicals.

b. FDA Regulation of OTC Drugs: Proof of Safety and Efficacy

Along with the general belief that there is a significant difference in the risks and benefits of prescription and OTC medications is the common misperception among lay persons that OTC drugs are not subjected to the kind of rigorous governmental scrutiny imposed on the manufacturers of prescription products.¹³¹ Obviously, this concern is unfounded with respect to “dual category” or “switch-over” drugs since these products, by virtue of their current or former prescription status, have already been subjected to the approval process for that classification. Moreover, all “new” drugs developed for the OTC market are screened according to the same criteria and protocol for approval applicable to prescription medications.¹³²

130. Hutt, *supra* note 111, at 440. It is anticipated that by 1995 newly switched prescription products will consume 24 percent of the OTC analgesic market. Some potential switch candidates which have both significant risks as well as benefits include naproxen, diflusal, piroxicam, and fenoprofen. F-D-C Reports, *Pink Sheet*, March 12, 1990 at 13.

131. The United States drug regulatory scheme has been called the “most stringent” in the world. O’Reilly, *supra* note 93, at 13-7, 13-8. Indeed, pre-market testing protocols are so time-consuming and expensive that they, in addition to liability concerns, often delay drug introduction until years after identical products are marketed in other countries. See generally WARDELL, 24 CLINICAL PHARMACOLOGY AND THERAPEUTICS 499 (1978); PELTZMAN, THE BENEFITS AND COSTS OF NEW DRUG REGULATION, (R. Landau, Ed. 1973).

132. All new drugs, which by definition include reformulations of old products, as well as existing drugs with new indications, are subject to FDA approval via the New Drug Application (NDA) process which requires manufacturers to submit to the agency extensive toxicologic and

c. *The Impact of Strict Liability on the OTC Drug Industry*

In light of the similar benefits and regulations of OTC drugs, a court must determine whether imposing strict liability will adversely affect the OTC drug industry. As the court in *Brown* concluded, strict liability may negatively deter a manufacturer from allocating money to research and develop new chemotherapeutic agents.¹³³ The impact of such liability on the drug industry, insofar as it relates to "new drugs," should affect OTC and prescription products equally since the ultimate marketing status of a drug may not be determined until the end of the New Drug Application process. Accordingly, the *Brown* policy of encouraging research and development by exempting prescription drugs should apply to all new products including those slated for over-the-counter distribution.

efficacy data accumulated as a result of animal and clinical studies. *See generally* O'Reilly, *supra* note 93, at §§ 13.03, 13.11. All drugs introduced subsequent to implementation of the 1938 Act were required to have FDA approval through the NDA process on the basis of well-controlled clinical data demonstrating safety. The 1962 amendments added an efficacy requirement so that drugs introduced subsequent to that date must establish both safety and efficacy in their NDA. Prescription drugs introduced between 1938 and 1962, which had only been tested for safety, were re-examined for efficacy by scientific panels designated by the National Academy of Sciences through a process known as the Drug Efficacy Study Implementation (DESI) Review. *See generally id.* § 13.07. Given the enormous number of OTC products on the market in 1962 (estimated to be around 500,000), but with the knowledge that the *active ingredients* contained in those products was relatively small (between 300 and 700), the FDA instituted a similar, but separate examination of all OTC active ingredients known as the OTC Review. Pursuant to the review, all OTC ingredients on the market prior to 1972 have been evaluated by scientific panels drawing their membership primarily from relevant areas of academic expertise which review the world's literature as well as data submitted by manufacturers. These panels are designated according to product category and the results of their review are ultimately formulated into a written monograph which determines; (1) a drug's safety, (2) drug efficacy for particular indications, and (3) appropriate labeling. As a function of the review process, an OTC ingredient may be found to be safe and effective for a particular indication (Class I) or lacking in one or both of those elements (Class II) and thus subject to removal from the OTC market by the FDA. *See generally id.* § 13.08; Harlow, *The FDA's OTC Drug Review: The Development and an Analysis of Some Aspects of the Procedure*, 32 FOOD DRUG COSM. L.J. 248 (1977). The OTC review process is largely complete and the remaining product monographs are likely to be finalized by the end of 1991.

133. *Brown v. Superior Court*, 44 Cal. 3d 1049, 1063, 751 P.2d 470, 479, 245 Cal. Rptr. 412, 420 (1988). A recent study undertaken by the Center for the Study of Drug Development at Tufts University demonstrates how risky investment in pharmaceutical innovation can be. Analogizing drug development to the oil industry, the investigators noted that drug research and development will inevitably encounter "more dry holes than wet holes. The fate of a project cannot be known with certainty at the outset." The study estimates that, on average, new chemical entity (NCE) research and development takes twelve years from synthesis of a compound to marketing approval and costs \$231 million in 1987 dollars. Even more significant is the fact that the average success rate for drug companies ultimately gaining FDA approval is a scant 23 percent. Remarks of Joseph A. Diamasi, Ph.D. (pre-publication press release April 19, 1990) (copy on file at the *Pacific Law Journal*).

A second critical consideration is whether imposing strict liability affects the range and affordability of products. Given the present regulatory scheme, the answer is definitely in the affirmative.¹³⁴ FDA switch-over decisions are a low priority and tend to be made on an ad hoc basis.¹³⁵ The FDA has yet to articulate a definitive switch-over policy relating to all drugs.¹³⁶ Accordingly, a great deal of uncertainty already exists in the pharmaceutical industry, making manufacturer commitment of the significant resources needed to effectuate switch approval an inherently risky business.¹³⁷

Given an already uncertain regulatory climate, the potential effect of liability incurred as a result of an OTC switch has become a critical factor for the industry to consider.¹³⁸ As long as the nature of most OTC drug-related injuries remains relatively innocuous, at least when compared to prescription drugs, specific examples of manufacturers withdrawing products from the market in the face of increasing liability may not be readily apparent. However, this should not lead courts to conclude that since incidents do not exist, since imposition of strict liability is more likely to affect a manufacturer's decision to market a drug over-the-counter rather than by encouraging outright product removal. Thus, the damage to the public interest in imposing strict liability on OTC manufacturers may ultimately be manifested by restriction in the availability of affordable new products for self-medication.¹³⁹

Undoubtedly, the strict liability factor will drastically increase in significance as consumer demand for more potent forms of self-

134. A recent study concluded: "Recent experience indicates that pharmaceutical innovation is sensitive to risk. The increased risk of financial losses created by lawsuits has already slowed innovation in the areas of vaccines and contraceptives. Only one major pharmaceutical firm is conducting R&D on new contraceptives." National Pharmaceutical Council Report: *Pharmaceutical Research: Therapeutic and Economic Value of Incremental Improvements*, 39 (1990). There is little reason to believe that the imposition of strict liability will have any different effect on the over-the-counter drug industry. This is especially true given the fact that many companies which market vaccines and contraceptives also market over-the-counter drugs.

135. Pinco & Cogan, *supra* note 112, at 234. For a brief history of the FDA's treatment of switch-overs, see generally Pinco, *A Legal Perspective on Regulatory Approaches to Switch*, 24 DRUG INFO. J. 5, 5-10 (1990).

136. See Pinco & Cogan, *supra* note 112, at 234.

137. O'Reilly, *The State of GRACE: God Only Knows the Future of Over-the-Counter Drug Regulation*, 1 REGULATORY AFFAIRS 239, 242 (1989).

138. See *id.* at 244; Hutt, *supra* note 111, at 439.

139. Not only does greater access to OTC drugs reduce medical costs by decreasing the amount of physician visits, the actual cost of OTC switch-over products is normally far below the price of identical prescription drugs because of wider distribution and more direct competition. O'Reilly, *supra* note 137, at 240. Both cost and availability were important factors in the *Brown* analysis. See *supra* notes 59-62 and accompanying text (discussing the policy rationale of *Brown*).

medication grows in the face of increased buyer sophistication, spiraling costs of primary health care, and the lack of comprehensive health insurance.¹⁴⁰

In sum, a tort compensation system which refuses to extend comment k protection in cases involving non-prescription drugs cannot be justified based on the language contained in the Restatement. Moreover, for the policies underlying the comment to be fully implemented, the judiciary must avoid conditioning comment k application on common misperceptions regarding the nature of OTC and prescription drugs.

B. The "Limited Exemption" Approach

Since the OTC drug classification encompasses a significant range of products from insulin to cough drops, a court considering application of comment k may choose to extend the *Brown* analysis to some, but not all OTC medications. However, any interpretation of the comment's scope which fails to cover all OTC drug products is liable to suffer from the same analytical inconsistencies and inadequacies which beset the *Kearl* "mini-trial" approach; a standard which was rejected by the court in *Brown*. First, courts will be unable to effectively formulate a bright line test which can rationally exempt some OTC drugs from strict liability while excluding others from such protection. The changing nature of drug products, e.g., switch-over and dual category drugs, and the inherent difficulty in making extra-regulatory assessments of individual product benefits, precludes adoption of a fixed rule governing ad hoc application of comment k to OTC products. Second, the policy of promoting research and development would be ill-served by such an approach because a manufacturer must decide to allocate research and development funds before a new chemical entity is classified by the FDA.

1. Regulatory Line-Drawing

Courts wishing to maintain a semblance of the status quo while providing comment k protection to some OTC products could limit the application of comment k to medications with the same charac-

140. Hutt, *supra* note 111, at 439.

teristics as prescription drugs. Courts could protect *any* drug which was “prescribed” by a doctor, even if the product is available over-the-counter; for example, aspirin prescribed for patients at high risk for stroke. However, such a limitation would be inappropriately based on the assumption that a “learned intermediary” is a necessary prerequisite for the comment k exemption.¹⁴¹ Such a limitation would also penalize a manufacturer for making a drug available for use by more sophisticated consumers who self-medicate as an alternative to seeing a doctor. Finally, such a limitation fails to take into account the major use for most OTC products: the treatment of *symptoms* which are readily recognizable by consumers, even if their underlying medical causes are not.¹⁴²

Courts might also consider limiting comment k protection to OTC ingredients which are also sold in prescription form or as part of a prescription compound (dual category drugs).¹⁴³ Along the same lines, courts could extend the exemption to OTC “switch-overs” based on their history of prescription status. Limiting protection to “dual category” products or “switch-overs” is unsatisfactory because it assumes that over-the-counter drugs without a prescription counterpart or historical prescription status do not deserve exemption from strict liability. In fact, most OTC ingredients, including some of the most beneficial drugs in our therapeutic arsenal, were marketed prior to 1938 when the initial prescription/OTC distinction was developed by the FDA.¹⁴⁴ More importantly, this approach will not provide protection for *new* drugs developed specifically for the OTC market in an age of increasing consumer demand for such products.¹⁴⁵

141. It is the law in California as well as most other jurisdictions that, as a general matter, the manufacturer of a prescription drug is under a duty only to disseminate warnings to prescribing physicians, who act as “learned intermediaries” by passing along to their patients information they believe is necessary for safe and effective use. *See e.g.*, *Carmichael v. Reitz*, 17 Cal. App. 3d 958, 95 Cal. Rptr. 381 (1971). However, the input of a “learned intermediary” is not always apparent even in prescription drug cases. Indeed, two of the most widely litigated prescription drug products, vaccines and oral contraceptives, normally involve little physician input, and as a result, manufacturers of these products may be under a duty to disseminate warnings to patients themselves. *See, e.g.*, *Reyes v. Wyeth Laboratories*, 498 F.2d 1264 (5th Cir. 1974) (vaccine case); *Odgers v. Ortho Pharmaceutical Corp.*, 609 F. Supp. 867 (D.C. Mich. 1985) (oral contraceptive case). *See generally* Gilhooley, *Learned Intermediaries, Prescription Drugs, And Patient Information*, 30 St. Louis U.L.J. 633 (1986).

142. *Rachanow, supra* note 115, at 205-6.

143. For example, there are many OTC analgesic ingredients which are combined with narcotics to form prescription compounds, including aspirin and acetaminophen with codeine.

144. McLeod, *Non-Prescription Drug Approval: Therapeutic Strategy or Marketing Decision?*, 23 THE ANNALS OF PHARMACOTHERAPY 607 (1989). A prominent example is insulin.

145. It is conceivable that a drug might be developed with certain known or unknown risks but with a benefit side which justifies immediate OTC marketing. Many such products

2. Case-By-Case Determination

A second possible approach to non-prescription drug liability would involve examining individual OTC drug benefits on a case-by-case basis. A number of jurisdictions outside of California established the theoretical basis for this case-by-case analysis.¹⁴⁶ Specifically, several decisions which have rejected blanket protection of prescription drugs in favor of a *Kearl* analysis probably do not deny comment k protection for at least some OTC drugs, since these cases candidly admit that there are non-prescription medications whose benefits would arguably meet the criteria for comment k inclusion articulated by the court in *Brown*.

Under an ad hoc approach, courts could attempt to limit comment k protection to OTC products whose medicinal benefits are readily apparent, such as analgesics, while allowing a strict liability design defect analysis to apply in cases involving seemingly less important preparations, such as wart removers and foot powders. However, as is the case for virtually all prescription drugs, it is likely that even these latter products would ultimately receive comment k protection once a judge or jury closely examined their risk-benefit profiles.¹⁴⁷

Despite the relative ease with which prescription drug manufacturers have prevailed on the comment k issue in jurisdictions employing the ad hoc approach, the supreme court in *Brown* rejected any form of risk-benefit balancing as a prerequisite to exemption from strict design defect liability.¹⁴⁸ The *Brown* court observed that the very process of making a medical and legal distinction between avoidably

are currently in the developmental pipeline in the diagnostic field, including self-test kits for AIDS.

146. See, e.g., *Hill v. Searle Laboratories*, 884 F.2d 1064 (8th Cir. 1989); *White v. Wyeth Laboratories*, 40 Ohio St. 3d 390, 533 N.E.2d 748 (1988). *White* expressly extended its holding to prescription drugs, vaccines or similar products. *White*, 533 N.E.2d at 752. The *Hill* court noted that non-prescription drug products create a similar benefit to society. *Hill*, 884 F.2d at 1069 n.8. It is interesting that in their attempt to limit the application of comment k by rejecting an across-the-board exemption for prescription drugs, these cases, from a theoretical standpoint, arguably go beyond the holding in *Brown*.

147. Empirically, few, if any, prescription drugs fail to garner comment k protection in jurisdictions employing an ad hoc risk-benefit balancing test. See Comment, *supra* note 8, at 731. But see *Brochu v. Ortho Pharmaceutical Corp.*, 642 F.2d 652 (1st Cir. 1981). If indirect benefits from an OTC drug are presented to the jury, such as affordability and effects on health care availability and insurance rates, the likelihood of comment k protection from seemingly innocuous non-prescription drugs may be significantly increased.

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

and unavoidably unsafe medications would substantially impair the public interest in the development and marketing of chemotherapeutic agents.¹⁴⁹

The *Brown* court's analysis and ultimate rejection of the ad hoc approach stemmed directly from the social policy underlying comment k. The court interpreted the comment as exempting classes of products from a strict design defect standard where the policies advanced by imposition of such liability are outweighed by its potentially deleterious effect on competing social goals.¹⁵⁰ In the context of the class of pharmaceutical products, these competing social goals include: (1) maintenance of currently available prescription drugs, (2) encouragement of resource allocation towards the development of new medications, and (3) increased affordability of drug products. From a liability standpoint, facilitation of these three goals, and thus the effectiveness of comment k itself, turns largely upon one overriding factor: certainty. The *Brown* court recognized that an ad hoc risk-benefit analysis would leave manufacturers with little or no assurance that their products would not be subject to strict liability.¹⁵¹ Accordingly, the *Brown* court did not categorically exempt prescription drugs because of the somewhat ambiguous language of comment k, but because anything less than blanket protection would render the underlying policy of comment k moot.

In California, the imposition of a risk-benefit analysis as an initial hurdle to comment k protection for non-prescription medications would do little to facilitate the goals articulated by the supreme court in *Brown*. The maintenance of current products in the marketplace would not be enhanced, since the comment k "defense" would be subject to the whims of individual judges and juries in unrelated cases involving potentially dissimilar claims. An aspirin manufacturer in one case could be subject to strict liability where the product was taken for a minor headache, while in another case, comment k might be applied where the indication was to reduce the risk of stroke.

The goals of encouraging research and development of new chemotherapeutic agents and of promoting greater affordability of medications would be uniquely affected by uncertainty in the application of comment k to OTC drugs. By drawing a distinction between prescription and non-prescription medications, the imposition of a

149. *Id.*

150. *Id.*

151. *Id.*

risk-benefit analysis on the non-prescription class would effectively constitute a judicial referendum on a manufacturer's and the FDA's decision to market a product over-the-counter. Conceivably, a manufacturer developing a new drug, faced with uncertain liability in the OTC market, might well choose to forego the economic benefits of non-prescription distribution. If the product possesses only limited prescription potential, the manufacturer might abandon development altogether.

Perhaps the most significant effect of the uncertainty fostered by an ad hoc application of comment k protection would be its impact on prescription switch-over decisions. It is clear that consistency, both in terms of regulatory climate and potential liability, are important factors in a company's decision to begin switch-over proceedings. In view of the enormous cost savings generated by these products, a case-by-case approach would not encourage switch-overs, and could potentially provide a disincentive to OTC marketing in California.

While there may be some OTC medications which at first glance seem significantly less important than others, they are not unique to the non-prescription drug market.¹⁵² Certainly, the "social utility" of drug products when examined individually varies considerably, and depends to a large extent on indications for use in a given clinical situation. However, in choosing to forego a drug-by-drug evaluation as to the risk-benefit profiles of prescription products, the *Brown* court impliedly recognized the "apparently useful and desirable" characteristics of prescription drugs as a class. By refusing to determine the actual medical benefits of individual prescription drugs, the *Brown* court obviously intended its categorical exemption of these medications from strict design defect liability to be potentially over-inclusive since "the benefit of the negligence standard stated in [comment k] would be greatly diminished if all drugs were required to run the gauntlet of risk-benefit analysis in order to qualify for application of the standard."¹⁵³ Accordingly, if comment k is to be applied to non-prescription medications, protection should be granted unconditionally.

152. One needs only to look at the Physicians Desk Reference (PDR) to identify drugs which include prescription preparations of dental rinses (sodium fluoride), foot powders (aluminum chlorhydroxide), wart removers (topical salicylic acid), antiperspirants (aluminum chloride), acne medications (benzoyl peroxide), dandruff shampoos (chloroxine), skin bleaches (hydroquinone), not to mention hair restorers (menoxidil).

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

C. The “Blanket Exemption” Approach

Although the *Brown* court’s determination that all prescription drugs should be exempted from strict design defect liability pursuant to comment k was predicated primarily on the observation that anything less than categorical protection would fail to effectuate the comment’s underlying policy, the policy itself would be meaningless if it was not based on the assumption that these products, as a class, are highly useful and desirable. Indeed, courts have consistently rejected the extension of comment k protection to other non-drug products which, as a class, are not perceived as having equivalent social import.¹⁵⁴ Thus, the question of whether non-prescription drug products should be categorically exempted from strict design defect liability depends on the social benefits of these products as a class, as well as their unavoidably unsafe characteristics.

The medicinal benefits of certain non-prescription medications are somewhat obvious, even when determined on an individual basis. However, as Professor Willig has noted, application of comment k principles to a particular class of products involves an analysis which “goes beyond an individual decision and contemplates a weighing of values on a community basis against the known danger involved.”¹⁵⁵ The court in *Brown* utilized this macro-analysis by shifting the focus from an assessment of individual drug benefits in isolated cases to an assessment of the overall societal role of prescription medications in general.¹⁵⁶

154. In addition to prescription drugs, medical devices, and vaccines, comment k has been applied to one other class, namely, blood products. *See, e.g., Miles Laboratories v. Doe*, 315 Md. 704, 556 A.2d 1107 (Md. 1989). Even where an argument can be made that individual products within a larger class have unique social benefits, courts have refused to apply comment k where the class as a whole cannot claim equivalent social import. *See, e.g., Kennan v. Dow Chemical Co.*, 717 F. Supp. 799, 812 (M.D. Fla. 1989) (pesticides), *Wilkinson v. Bayshore Lumber Co.*, 182 Cal. App. 3d 594, 602-3, 227 Cal. Rptr. 327, 332-33 (1986) (lumber).

155. Willig, *supra* note 80, at 556.

156. *Brown*, 44 Cal. 3d at 1063, 751 P.2d at 478, 245 Cal. Rptr. at 420. It would be ill-advised to read *Brown* as confining its analysis of drug benefits to those products which “eliminate pain and suffering” or which “sustain life.” Although these are the general goals of virtually all pharmaceutical products, they may be achieved in different ways. For example, drugs may be used to *prevent* rather than treat conditions. Other products may be used to *diagnose* diseases and allow for earlier medical intervention. Finally, many products, including most non-prescription drugs, are used to alleviate symptoms. Accordingly, the primary definition of “drugs” utilized by the FDA, without regard to prescription or OTC status, includes, “articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man. . . .” 21 U.S.C. § 321(g)(1)(B) (West 1972). Because of the enormous cost and

While the risk-benefit profiles of individual drugs may be subject to medical controversy on a situational basis, compensation for injuries suffered by a relatively small number of individuals predicated upon strict liability may have the effect of reducing the availability of drugs whose overall benefits are unquestionable. Similarly, precluding comment k protection for OTC drugs with relatively low direct medicinal value would fail to take into account significant but indirect social benefits which exemplify the uniquely interdependent nature of the marketing of prescription and OTC products in the pharmaceutical industry. Prescription drugs as a class are generally intended to assist medical practitioners in treating the underlying etiology of diseases and their symptomatology. OTC medications as a class provide similar medical benefits, although their utility emanates more from the treatment of symptoms than of underlying causative conditions. However, non-prescription drugs, even the most innocuous, create indirect benefits by reducing overall health costs and by freeing up primary health care resources so that they become increasingly affordable and available. It is these indirect benefits which help to justify an across-the-board application of comment k to all drugs, including those sold over-the-counter.

Courts must recognize that a clear, yet subtle trend toward the increasing use of self-medication, or self-care, is rapidly developing in America. The growing consensus among health care experts is that self-care is the "wave of the future"¹⁵⁷ in modern medicine. Former FDA Commissioner, Dr. Frank Young, recently declared:

I think we are about to move into one of the larger expansions of self-care in the use of diagnostic, monitoring and self-care medicinals that we have seen in the history of the United States. . . . The future will undoubtedly see an acceleration of the trend towards greater self-care.¹⁵⁸

A number of social and economic forces combine to propel the current trend toward self-care. Prominent among these forces is the

complexity of federal drug regulations, including stringent requirements relating to safety (risks) and efficacy (benefits), manufacturers of chemical products are *discouraged* from making unsupported health-related claims since they would automatically result in such products being classified as drugs. See O'Reilly, *supra* note 93, at 13-9; McNamara, *When Is A Cosmetic Also A Drug—What You Need To Know, And Why*, 35 FOOD DRUG COSM. L.J. 467 (1980); Rodriguez, *Cosmetic or Drug? The Minotaur's Labyrinth Revisited*, 44 FOOD DRUG COSM. L.J. 63 (1989).

157. Statement of Matt Clark, Symposium: New Resources in Self-Medication, November 1, 1982, at 25.

158. Statement of Frank Young, Symposium: Self-Care, Self-Medication in America's Future, February 8, 1988, at 4.

increasing sophistication of the American consumer. Today's consumer is more knowledgeable about handling everyday health care problems, and consequently more interested in over-the-counter medicines and technology.¹⁵⁹ Moreover, the American consumers' desire for greater nutrition and physical fitness perpetuates a desire for greater autonomy in the management of their health-related problems.¹⁶⁰ Public suspicion of the medical industry, and the development of home health services, further perpetuates this self-care mentality.¹⁶¹

The economics of health care also contribute to a stronger desire for self-care. The rising cost of physician visits, coupled with cutbacks by third party payers (i.e., government and private insurers) is encouraging more consumers to undertake self-care.¹⁶² These economic forces will in turn lead to an increase in demand for new self-care medicines and technologies including OTC medications.¹⁶³

Switch-over drugs will also play a major role in the self-care surge. The demand for self-care alternatives will be aided by the switch-over of drugs from prescription to over-the-counter status.¹⁶⁴ Consumer costs will fall as drugs are switched over to OTC status, providing greater impetus to the self-care trend.¹⁶⁵

Self-care already plays a vital role in our health care system. Approximately seventy-five percent of all medical care is self-care.¹⁶⁶ A recent survey found that ninety-seven percent of all health care problems are handled without any physician contact.¹⁶⁷ One expert estimates that ninety percent of primary care is amendable to some form of self-care.¹⁶⁸

Over-the-counter drugs, because they play such a critical role in facilitating self-care, are absolutely essential to the nation's health

159. Statement of Isadore Rosenfeld, Symposium: Self-Care, Self-Medication in America's Future, February 8, 1988, at 36; Statement of William Bergman, *Id.*, at 51; Lessing, *The OTC Drug Phenomenon: Double-Edged Clinical Implications*, 152 *MILITARY MED.* 577 (1987).

160. Statement of Isadore Rosenfeld, *supra* note 159, at 36.

161. Smay and Wertheimer, *A Review of Over-the-Counter Drug Therapy*, 5 *J. OF COMMUNITY HEALTH* 54, 55 (1979).

162. Statement of Isadore Rosenfeld, *supra* note 159, at 36.

163. *Id.* at 38.

164. Statement of Donald M. Vickery, Symposium: New Resources in Self-Medication, November 1, 1982, at 30.

165. Temin, *supra* note 100, at 189-90.

166. Statement of Donald M. Vickery, *supra* note 162, at 29; U.S. Department of Commerce, *1978 U.S. Industrial Outlook* 131 (Washington: Government Printing Office, 1978).

167. Health Care Practices and Perceptions: A Consumer Survey of Self-Medication, Heller Research Corporation, 1984, at 52.

168. Statement of Dr. John Fry, Symposium: Self-Medication: The New Era, March 31, 1980, at 5.

care system.¹⁶⁹ According to the FDA, 500,000 OTC drugs are currently on the market in the United States.¹⁷⁰ Six of every ten medicines purchased by U.S. consumers are over-the-counter drugs.¹⁷¹ The World Health Organization estimates that forty million Americans take an over-the-counter drug every day.¹⁷² Consequently, Americans spend at least ten billion dollars annually on over-the-counter medicines,¹⁷³ which amounts to forty percent of consumer expenditures on medicinal products.¹⁷⁴

From a broader perspective, safe, effective, and inexpensive over-the-counter drugs are critical to the stability of the health care system. The continuing improvement in the health of Americans has come at an increasingly higher price. Aside from immediate health benefits, the greatest contribution of over-the-counter drugs is in helping consumers control their health care costs.¹⁷⁵ Self-care also frees up valuable resources necessary for effective primary care. A study found that a majority of doctors believe that at least twenty-five percent of patient visits were for conditions that people could treat themselves.¹⁷⁶ A reversal in the self-care trend could spell disaster for the health care industry. Professor Simon Rottenberg has noted:

Self-medication, where appropriately used, releases professional care resources to higher and better uses [A]s the price of physicians' services has been rising, relative to the cost of other commodities and services, prudence in the use of professional, medical care services is increasingly urgent. . . . If only 2% of OTC drug consumers in the United States chose to visit primary care practitioners, rather than using self-medication, the annual increase in patients' office visits would be 292 million, a 62% rise. To maintain the same quality of consultive care, the number of primary care prac-

169. In the FDA's proposal for the OTC review process it was stated that, "[b]ecause self-medication is essential to the nation's health care system, it is imperative that OTC drugs available for human use be safe and effective and bear fully informative labelling." 37 Fed. Reg. 85 (1972).

170. Gilbertson, *The OTC Drug Review—FDA's Viewpoint*, 8 AGENTS ACTIONS 422, 422 (1978).

171. Statement of Frank Young, Symposium: Self-Care, Self-Medication in America's Future, February 8, 1988, at 9.

172. Statement of Donald M. Vickery, Symposium: New Resources in Self-Medication, November 1, 1982, at 30.

173. Goldberg, *How Risky Is Self-Care With OTC Medicines?*, GERIATRIC NURSING, November/December 1980, at 279.

174. Smay and Wertheimer, *supra* note 161, at 55.

175. Statement of William Bergman, Symposium: Self-Care, Self-Medication in America's Future, February 8, 1988, at 51; Temin, *supra* note 100, at 189.

176. Statement of Donald M. Vickery, Symposium: New Resources in Self-Medication, November 1, 1982, at 29.

tioners would have to be increased from the present 91,000 to 147,400. The increased cost to produce the additional 56,400 needed doctors would be . . . a total of \$10 billion.¹⁷⁷

The overall economic value of self-medication further illuminates the importance of a prosperous over-the-counter drug industry. Health care spending now accounts for eleven percent of our gross national product.¹⁷⁸ The gross savings from OTC drugs, in terms of lost time from work, professional visits, and use of prescription drugs, is estimated at \$24 billion annually.¹⁷⁹

The continued growth of the OTC drug market has been projected to result in \$73 billion in gross savings by the year 2000, with a net benefit to the economy of \$34 billion.¹⁸⁰ However, future growth in the non-prescription drug market will depend to a large extent on the willingness of manufacturers, as well as the FDA, to allow distribution of more potent medications directly to consumers. Uncertainty regarding liability will be a major factor in future decisions in that regard. Accordingly, courts should act now to ensure comment k application to OTC drugs so this uncertainty can be effectively mitigated. Only a blanket approach can achieve this end.

CONCLUSION

Litigation involving the liability of pharmaceutical manufacturers has largely focused on the effects of prescription medications. So far, little scrutiny has been given to the principles which govern compensation for injuries attributable to over-the-counter medications. Given the increased consumer demand for more potent non-prescription drugs, inevitably courts will ultimately face the question of how liability for these products should be imposed.

The California Supreme Court's landmark decision in *Brown v. Superior Court* does not specifically address whether strict design defect liability should apply to OTC product injuries. However, the

177. Statement of Simon Rottenberg, Symposium: Self-Medication: The New Era, March 31, 1980 at 30-33.

178. Statement of William Roper, Symposium: Self-Care, Self-Medication in America's Future, February 8, 1988, at 11.

179. Statement of Charles Kline, *id.* at 16.

180. *Id.* at 18. Professor Temin estimates that the switch-over of hydrocortisone alone will result in some \$400 million in net benefits. Professor Temin also estimates that the potential switch-over of low doses of oral penicillin could result in a saving of over \$1 billion. Temin, *supra* note 100, at 194, 199.

court's opinion does provide an analytic framework which courts may use to determine whether products other than prescription drugs should be exempted from strict liability.

When over-the-counter medications are analyzed as a class, their exclusion from the ambit of comment k seems difficult to justify. Categorically, the OTC products are virtually indistinguishable from many prescription drugs. All drugs are unavoidably unsafe to some degree even when used according to directions. They confer significant direct and indirect benefit both on an individual and societal scale. Finally, since they are developed and manufactured by an industry which predicates allocation of research and development resources, to a large extent, on marketing certainty and stability, their introduction to, and maintenance on the market place may be uniquely affected by the imposition of certain forms of liability.

Courts considering the application of comment k to preclude strict design defect liability in litigation involving non-prescription drugs will be faced with precisely the same issues which influenced the California Supreme Court's decision in *Brown*. Those issues will largely concern the scope and practical implementation of the comment k exemption.

The language and history of comment k suggest that comment k was intended to apply to at least some non-prescription medications. Some courts, focusing primarily on the wording of the comment, have advocated an ad hoc approach to its application in cases involving prescription medications. The *Brown* court went beyond the admittedly ambiguous language of the comment and determined that, in order for its underlying policies to be adequately facilitated, prescription drugs as a class must be exempted from strict design defect liability. Similarly, if courts are to grant non-prescription medications relief from such liability, it must be provided across the board. The liability for injuries attributable to any drug product approved for market by the Food and Drug Administration should only be imposed where a jury finds that the warnings provided to consumers or to the medical community failed to reflect risks which were known, or should have been known, by manufacturers prior to a plaintiff's ingestion of the drug.