University of Dayton Law Review

Volume 14 | Number 2 Article 2

1-1-1989

The Erosion of Comment K

John P. Reilly

UNIVERSITY OF DAYTON LAW REVIEW

VOLUME 14 WINTER 1989 NUMBER 2

THE EROSION OF COMMENT K

*John P. Reilly**

I. INTRODUCTION

Comment k to Section 402A of the Restatement (Second) of Torts, exempts "unavoidably unsafe products" from strict liability.[1] This significant limitation to Section 402(A) reflects the controversial status of prescription drugs, which, though potentially dangerous, are enormously beneficial to society because of their potential to cure disease, relieve suffering and maintain and advance the quality of life for millions of people. Most jurisdictions in the United States have interpreted comment k as eliminating strict liability claims based upon design defect in cases involving prescription drugs.[2] Recent decisions by the highest courts of two states, Rhode Island and California, have focused attention on comment k's exemption from strict liability and its application in prescription drug litigation. In *Brown v. Superior Court,*[3] the California Supreme Court held that comment k applies, as a matter of law, to all prescription drugs.[4] In *Castrignano v. E.R. Squibb and*

---

* The author attended Cornell University where he received a B.A. in History and went on to acquire his J.D. from Cornell's School of Law.

1. *See, e.g.,* RESTATEMENT (SECOND) OF TORTS § 402A comment k (1965).

2. *See, e.g.,* Gaston v. Hunter, 121 Ariz. 33, 46, 588 P.2d 326, 339 (Ariz. Ct. App. 1978) ("[T]he availability of certain types of products is so important to society that the suppliers of the products should not be subject to strict liability for resulting injuries."); Tomer v. American Home Prod. Corp., 170 Conn. 681, 368 A.2d 35 (1976); Woodill v. Parke Davis & Co., 79 Ill. 2d 26, 402 N.E.2d 194, (1980); Ortho Pharmaceutical Corp. v. Chapman, 180 Ind. App. 33, 388 N.E.2d 541 (1979); Payton v. Abbott Labs, 38 Mass. 540, 570, 434 N.E.2d 171, 189 (1982); Seley v. G.D. Searle & Co., 67 Ohio St. 2d 192, 423 N.E.2d 831 (1981); McKee v. Moore, 648 P.2d 21 (Okla. Sup. Ct. 1982); Lewis v. Baker, 243 Or. 317, 321, 413 P.2d 400, 404 (1967) ("[A] drug, properly tested, labeled with appropriate warnings, approved by the Food and Drug Administration and marketed properly under federal regulation, is, as a matter of law, a reasonably safe product"); Leibowitz v. Ortho Pharmaceutical Corp. 224 Pa. Super. 418, 433, 307 A.2d 449, 458 (1973); Castrignano v. E.R. Squibb & Sons, Inc., 546 A.2d 775 (R.I. Sup. Ct. 1988); Terhune v. A.H. Robins Co., 90 Wash. 2d 9, 16, 577 P.2d 975, 978–9 (1978).

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

4. *Id.* at 1068–69, 751 P.2d at 482, 245 Cal. Rptr. at 424.

Sons,[5] the Rhode Island Supreme Court conditioned the application of comment k upon a risk/benefit test to be applied by the court.[6] These two decisions reflect the continuing dilemma in drug product liability litigation between providing easier redress for victims of adverse drug reactions and the concomitant desire to ensure that society benefits from therapeutic, albeit occasionally dangerous, ethical drugs. This comment reviews a recent series of decisions interpreting comment k and suggests that the *Castrignano* interpretation of comment k — requiring a manufacturer to earn the exemption — could well signal a new era in unnecessary complexity in prescription drug litigation. Rather than forcing a manufacturer to pass a rigorous risk/benefit test, this commentator argues that the manufacturers are, by virtue of compliance with the Food and Drug Administration's regulatory process, entitled to a rebuttable presumption indicating that at the time of a prescription drug's marketing, the apparent benefits of the product outweighed its apparent risks.

II. RECENT COMMENT K DECISIONS

Section 402(A) of the Restatement (Second) of Torts states that a manufacturer is liable for selling a product in a "defective condition" such that it is "unreasonably dangerous" to the user/consumer, irrespective of the level of care used in preparation of the product.[7] Comment k, one of seventeen comments to Section 402, exempts "unavoidably unsafe products" from the general rule, reasoning that such products are incapable of being made safe for their ordinary and intended use.[8] The marketing of unavoidably unsafe products is fully jus-

---

5. 546 A.2d 775 (R.I. Sup. Ct. 1988).

6. *Id.* at 780. In a recent decision which occurred after the completion of this article, the Eighth Circuit Court of Appeals held that comment k immunity is only available to manufacturers who demonstrate a showing of exceptional need. *See* Hill vs. Searle Laboratories, 884 F.2d 1064, 1069 (8th Cir. 1989).

7. 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 changes in the condition in which it is sold; 2) The rule stated in subsection (1) applies although (a) the seller has exercised all possible care in the preparation and sale of his product; and (b) the user and consumer has not brought the product from or entered into any contractual relation with the seller.

8. Comment k provides in full:

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

tified, despite the inherent risk, because such products are "especially common in the field of drugs" and strict products liability therefore does not apply.[9] Thus, such a product, properly prepared and accompanied by proper directions and warnings, is neither defective nor unreasonably dangerous.[10] The effect of comment k's application in most jurisdictions is to reduce strict liability in a design defect case to a negligence or fault-based standard.[11] By eliminating an action in strict

---

and the use of the vaccine are fully justified, notwithstanding the unavoidably high degree of risk which they involve. Such a product, properly prepared and accompanied by proper directions and warnings, 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 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.

Several commentators have analyzed comment k. *See* McCellan, *Strict Liability for Drug Induced Injuries: An Excursion through the Maze of Products Liability, Negligence and Strict Liability*, 25 WAYNE L. REV. 1 (1978); Schmidt, *Manufacturer's Liability for the Administration of an Experimental Drug*, S. M. U. PRODUCT LIABILITY INST. (1986); Schwartz, *Unavoidably Unsafe Products: Clarifying the Meaning and Police Behind Comment K*, 242 WASH. & LEE. L. REV. 1139 (1985); Selker, *An Escape from Strict Liability: Pharmaceutical Manufacturer's Responsibility for Drug Related Injuries under Comment K to Section 402A of the Restatement (Second) of Torts*, 23 DUQ. L. REV. 199 (1984); Willig, *The Comment K Character: A Conceptual Barrier to Strict Liability*, 29 MERCER L. REV. 545 (1978). *See generally* Magdan & McCall, *A Survey of Law Regarding the Liability of Manufacturer's and Sellers of Drug Products and Medical Devices*, 18 ST. MARY'S L.J. 395 (1986); Pratt & Parnon, *Diagnosis of Legal Headache: Liability for Unforseeable Defects in Drugs*, 53 ST. JOHN'S L. REV. 517 (1979); Note, *Can a Prescription Drug Be Defectively Designed? - Brochu v. Ortho Pharmaceutical Corp.*, 31 DE PAUL L. REV. 247 (1981) [hereinafter Note, *Brochu*]; Note, *The Liability of Pharmaceutical Manufacturers for Unforeseen Adverse Drug Reactions*, 48 FORDHAM L. REV. 735 (1980); Note, *The Impact of Product Liability Law on the Development of a Vaccine Against the AIDS Virus*, 55 U. CHI. L. REV. 943 (1988).

9. Comment k, *supra* note 1.

10. *Id.* Comment k's language is unclear as to whether the exemption applies to all prescription drugs. Some language suggests that comment k applies to all prescription drugs. *Id.* "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, while other language indicates a distinction among drugs such products are especially common in the field of drugs'." *Id.* (emphasis added) After citing examples such as the polio vaccine, the comment notes that "[t]he same is true of many other drugs . . . [and] in particular many new or experimental drugs." *Id. See generally* Schwartz, *supra* note 8, at 1141. ("[T]he basic message [of comment k] here is that, in general, ethical drugs and harms that arise out of their use should not subject their manufacturer, distributor or retailer to strict liability").

11. Strict liability encompasses three theories: failure to warn of a product's dangers, manufacturing defect and design defect. *See* Frumer & Friedman, 2 *Products Liability*, § 16A.01(1)(b)(c)(4)(f) (1988). Comment k's exemption from strict liability is limited to the design

liability based on defective design, the only issue remaining after the application of comment k is whether the manufacturer issued adequate warnings as to the harmful risks and side effects of the drug.[12]

Until recently, most courts had respected the limitations of comment k and refrained from applying design defect theory to products liability cases involving prescription drugs. Beginning, however, with *Brochu v. Ortho Pharmaceutical Corp.*,[13] and continuing most recently with *Castrignano v. E.R. Squibb*,[14] a growing number of states have restricted the application of comment k and have permitted recovery for a strict liability claim based upon the theory that the drug was defectively designed.

In *Brochu*, the plaintiff suffered injury following the ingestion of an oral contraceptive containing 100 milligrams of estrogen.[15] The plaintiff presented evidence at trial that the defendant marketed an equally effective but far less dangerous contraceptive.[16] The other contraceptive contained only 50 milligrams of estrogen. The First Circuit Court of Appeals held that it was proper to instruct a jury that they could find the higher dosage pill to be "unreasonably dangerous" and thus defectively designed.[17]

While acknowledging that other courts have afforded comment k immunity from design defect claims to oral contraceptives, the *Brochu* court declined to do the same, suggesting that comment k's immunity against design defect liability did not extend to all prescription drugs.[18] The court noted that basing a strict liability claim on both design defect and inadequate warning, is "neither illogical nor inconsistent" since the comment itself suggests a balancing test.[19] If the danger is

---

defect claim: it preserves claims based on failure to warn and manufacturing defect.

12. Most courts hold that a manufacturer need only warn of those dangers that are reasonably foreseeable and knowable at the time of marketing. *See, e.g.*, Sterling Drug v. Yarrow, 408 F.2d 978, 992 (8th Cir. 1969); Ferrigno v. Eli Lilly & Co., 75 N.J. Super. 551, 420 A.2d 1305 (1980); Incollingo v. Ewing, 444 Pa. 263 n.205, 282 A.2d 206 n.220 (1971). *See generally* RESTATEMENT (SECOND) OF TORTS § 402A comment j (1965) ("[T]he seller is required to give warning against [risks], 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"). In short, there is little or no difference between negligent failure to warn and strict liability failure to warn - both focus on whether the manufacturer acted reasonably in light of scientific information available at the time of marketing.

13. 642 F.2d 652 (1st Cir. 1981).

14. 546 A.2d 775, 782 (R.I. Sup. Ct. 1988).

15. *Brochu*, 642 F.2d at 653.

16. *Id.* at 654.

17. *Id.* at 655.

18. *Id.* at 657.

19. *Id.* Before, other courts had applied a balancing test before applying comment k, but the *Brochu* court was the first to decide that the benefits did not outweigh the risks, thereby precluding comment k immunity. *See* E.R. Squibb & Sons, Inc. v. Cox, 477 So. 2d 532 (Fla. Dist. Ct. App. 1985); Ortho Pharmaceutical Corp. v. Chapman, 180 Ind. App. 33,

unavoidable, then the product is defective. However, if the danger is unavoidable and the utility is great, then design defect liability may be avoided with proper warnings.

The use of design defect analysis appears correct given the unusual facts of *Brochu*. The plaintiff had shown that another product, made by the same manufacturer, offered the same benefits as the injury-causing drug, yet with far less risk.[20] In this situation, the product causing the injury could have easily been labeled "unreasonably dangerous" because it could have been marketed at a lower dosage without an appreciable loss of therapeutic benefit.[21]

The *Brochu* holding on design defect was taken one step further by the Supreme Court of Colorado in *Belle Bonfils Memorial Blood Bank v. Hansen*.[22] In *Belle Bonfils*, Colorado's highest court set out a four-part risk/benefit analysis in determining the applicability of comment k.[23] The plaintiff in *Belle Bonfils* had contracted hepatitis after receiving a transfusion of blood supplied by the defendant, Memorial Blood Bank.[24] The defendant moved for summary judgment as to all claims including strict liability, negligence and breach of warranty on the ground that the contaminated blood was unavoidably unsafe pursuant to comment k.[25] The district court granted the motion but the court of appeals found comment k inapplicable and reversed.[26] The court of appeals held that the presence of the hepatitis virus constituted an "adultering substance," thereby rendering the blood defective.[27]

37, 388 N.E.2d 541, 545 (1979), the court held that comment k involves balancing availability of a product against its attendant risks; after such balancing, the court extended comment k immunity to Ortho-Novum, a "convenient and highly effective contraceptive." Similarly, in Davis v. Wyeth Laboratories, Inc., 399 F.2d 121, 128 (9th Cir. 1968), the court held that the Sabin vaccine, a "new and experimental" drug, qualifies for comment k immunity. Thus, the *Brochu* court was the first to decide after balancing risk versus benefit that the product was not worthy of comment k protection.

20. *Brochu*, 642 F.2d at 659.

21. *Id.* at 660.

22. 665 P.2d 118 (Colo. Sup. Ct. 1983).

23. *Id.* at 122.

24. *Id.* at 120.

25. The Memorial Blood Bank submitted the affidavits of two doctors establishing that in 1971 there was an unavoidable risk of hepatitis associated with blood transfusions, a risk commonly known in the medical profession and incapable of being eliminated. *Id.*

26. *Id.* at 121.

27. *Id.* (quoting Hansen v. Belle Bonfils Memorial Blood Bank, No. 80-CA-1173, slip op. at 2 (Colo. App. Sept. 10, 1981)). The appellate court stated:

> Comment k acknowledges only that a product may present a justifiable risk of harm even in the absence of a defect or some adulterating substance. Such products are neither defective nor unreasonably dangerous. However, blood supplied for the purpose of transfusion and which contains hepatitis virus is a defective product, dangerous to all. Hence the comment k exception does not apply here.

Hansen, 665 P.2d at 121.

On further appeal, the Colorado Supreme Court held comment k applicable, provided the defendant-manufacturer first passed a rigorous risk/benefit analysis.[28] Before the exemption to strict liability applies, the court stated the manufacturer must prove that the product's utility greatly outweighs its known risks.[29] In other words, the manufacturer must prove that the product's benefits could not be achieved in any other manner and that under the state of scientific knowledge at the time the risk was unavoidable.[30] The court also restricted comment k protection to "known" risks, meaning the exception to strict liability would not apply to risks not known at the time of marketing.[31]

The manufacturer must be held to the knowledge and experience of an expert in the field[32] and the product must conform to the highest standards of available scientific and technological knowledge, not merely the knowledge available to that particular manufacturer.[33] Finally, the Colorado Supreme Court held that the manufacturer must demonstrate that at the time the product was prepared and marketed, the risk involved with its continued use was unavoidable, and that the product's benefits could not be achieved by a substitute product or

---

28. *Id.* at 123.

29. *Id.*

30. *Id.* at 122.

31. *Id.* at 123. The court's restriction of comment k to "known" risks is a position emphatically rejected by other jurisdictions. *See, e.g.*, Chambers v. G.D. Searle, 441 F. Supp. 377, 380 (D. Md. 1975), *aff'd*, 567 F.2d 269 (4th Cir. 1977); Gaston v. Hunter, 121 Ariz. 33, 45, 588 P.2d 326, 338 (Ariz. Ct. App. 1978); Ortho Pharmaceutical Corp. v. Chapman, 180 Ind. App. 33, 388 N.E.2d 541, 545 (1979); *see also* Schwartz, *supra* note 8, at 1143–44. Professor Schwartz argues that the overall context of comment k suggests that it applies to risks not known at the time of marketing in addition to known risks. He points out that the application of comment k keeps the drugs within the ambit of negligence law:

> The pharmaceutical company must act as a reasonable person would have acted in the same or similar circumstances. The circumstances in which pharmaceutical manufacturers must deal directly involve severe risks to human life. Thus, their standard of care is not the reasonableness of a person who repairs a television set or drives a car — it is the most serious and intense obligation that one can find in the entire body of negligence law.

Id. at 1143–44.

32. *Hansen*, 665 P.2d at 126 (quoting McEwen v. Ortho Pharmaceutical Corp., 270 Or. 375, 528 P.2d 522 (1974)). This standard, the court stated, holds the manufacturer to a higher standard than that which may be the custom in the industry. *Id.* at 126 n.13. While the use of trade customs would be permissible if the case were tried under negligence principles, such application would be inconsistent with strict liability. *Id.* (quoting Holloway v. J.B. Sys., 609 F.2d 1069 (3rd Cir. 1979)).

33. *Id.* at 126–27. The benefit offered by the product, the court argued, must be "unique or profound" and its benefit "should extend to the vast majority of the users of the product." *Id.* at 126. The court also rejected the defendant's argument that compliance with state of the art for processing blood was a complete defense to strict liability. *Id.* at 126–27. The court conceded that such evidence is "relevant and admissible" on the issue of whether the marketing of the product conformed to the highest known scientific and technical standards. Rather than operating as a complete defense, such evidence was "merely" a part of the defendant's burden of demonstrating comment k's relevance. *Id.* at 126.

through some other manner.[34]

Little of the exemption from strict liability remained after the court's tortured reading of comment k. Comment k deliberately exempts from strict liability the manufacturer of an unavoidably unsafe product, who supplies the public with an *apparently* useful and desirable product, attended with a known but *apparently* reasonable risk. The court in *Belle Bonfils,* astonishingly, interpreted a comment to the Restatement — one that patently recognizes that drugs are of a class of products deserving of leniency from strict liability — and managed to make the defense of a prescription drug case exceedingly more difficult than that of the ordinary product liability case.

The *Belle Bonfils* test requires a manufacturer to prove entitlement to an exemption to strict liability with a greater deal of certainty than that required of a plaintiff in proving a prima facie case. If the defendant fails to carry this burden, the ruling that the product was not "unavoidably unsafe" is, in effect, a ruling that the product was unreasonably dangerous.[35] Thus, a decision in favor of the plaintiff on the threshold issue of comment k's applicability essentially guarantees a verdict in favor of the plaintiff on the case in chief since the court and the jury will be assessing much of the same evidence on the negligence and breach of warranty claims. Unless a manufacturer is certain that he can carry this burden, he is, ironically, better off not seeking the exemption and allowing the plaintiff to prove a prima facie case of design defect. Forcing a manufacturer into this strategic dilemma is the most egregious result of the *Belle Bonfils* test.[36]

Another consequence of the *Belle Bonfils* decision is the likelihood that courts will reach inconsistent results in cases involving clear and undisputed facts. This specter of inconsistency became a reality in *Ortho Pharmaceutical Corporation v. Heath.*[37] In *Heath,* the plaintiff sued the manufacturer of an oral contraceptive, Ortho Novum 1/80, after she allegedly developed kidney failure and cervical cancer follow-

34. *Id.* at 122 n.6.

35. *Id.* at 126. The question of comment k's applicability would be decided by the judge unless, in rebuttal, the plaintiff produced any evidence that the product's dangerous aspect could have been avoided. Then, the question becomes one for the trier of fact. *Hansen,* 665 P.2d at 125 n.12 (quoting PROSSER, TORTS § 99 (4th ed. 1971)). *See generally* Schwartz, *supra* note 8, at 1148 (the interpretations of law and application of policy raised by comment k are particularly suited for discussion, analysis, and resolution by a court).

36. Also inexcusable was the court's rejection of COLO. REV. STAT. § 13-21-403(1)(a) (1982), which establishes a rebuttable presumption in product liability actions that the injury causing product is not defective if it conformed to state of the art at the time of sale. The court held that this presumption is unavailable to the manufacturer who asserts comment k as an affirmative defense. *Hansen,* 665 P.2d at 126 n.14.

37. 722 P.2d 410 (Colo. 1986).

ing her use of the product.[38] Prior to her use of Ortho Novum 1/80, the plaintiff had used a lower estrogen dosage contraceptive, Ortho Novum 1/50.[39] Her doctor advised her to use the higher dosage product after she had an episode of breakthrough bleeding.[40]

The defendant appealed from the jury's verdict for the plaintiff claiming, *inter alia,* that the trial judge had failed to instruct the jury that the contraceptive was an unavoidably unsafe product and thus exempt from strict liability.[41] The Colorado Supreme Court applied the *Belle Bonfils* risk/benefit test and found that the defendant had presented sufficient evidence to show that the benefits of Ortho Novum 1/80 greatly outweighed the risks created by its use.[42] The defendant specifically argued that Ortho Novum 1/80 prevented breakthrough bleeding, which was the problem encountered on plaintiff's use of the lower dosage product.[43]

The court also found that the risk was a known one.[44] Experts testified that as of 1974, medical studies indicated that higher estrogen dosage oral contraceptives increased the risk of serious side effects, including the renal failure that preceded plaintiff's blood clot.[45] Also, the defendant offered proof that no other product could prevent breakthrough bleeding and remain as efficacious as Ortho Novum 1/80.[46]

However, two dissenters in *Heath* concluded that a comment k instruction was not warranted.[47] Because breakthrough bleeding was "not

---

38. *Id.* at 411.

39. *Id.*

40. *Id.*

41. *Id.* at 415. The court did agree with the plaintiff that there was sufficient evidence to submit a design defect claim to the jury. *Id.* at 413. However, the court criticized the trial court's use of a "consumer expectation" test rather than a risk/benefit test, such as the one set forth in Barker v. Lull Engineering, 20 Cal. 3d 413, 426–27, 573 P.2d 443, 452, 143 Cal. Rptr. 225, 234 (1978). The court stated:

> We believe the second test as set forth in Barker is the appropriate standard here. The dangerousness of Ortho-Novum 1/80 is defined primarily by technical, scientific information. The consumer expectation test fails to address adequately this aspect of the problem. The risk/benefit test focuses on the practical policy issues characteristic of a product such as Ortho-Novum 1/80, which is alleged to be unreasonably dangerous despite being manufactured in precisely the form intended.

Id. at 414, 573 P.2d at 444, 143 Cal. Rptr. at 226.

42. *Heath,* 722 P.2d at 415–16.

43. *Id.* at 415. The facts in *Heath* are similar to the facts in *Brochu,* since the "unreasonably dangerous" product was a higher dosage oral contraceptive. Unlike *Brochu,* the Ortho-Novum in *Heath* did offer a demonstrably higher therapeutic benefit, albeit with a greater risk, than the lower dosage product. The question of whether the "extra" therapeutic benefit was worth the risk is the factor dividing the majority and dissent. *Id.*

44. *Heath,* 722 P.2d at 415.

45. *Id.* at 416.

46. *Id.*

47. *Id.* at 420.

a life-threatening or even a health-threatening condition,"[48] and because the risk of blood-clotting was indeed life-threatening, the dissenters argued that benefits relating to convenience could not outweigh risks involving critical health concerns.[49] Nor could it be said that the benefits of the products use could not be achieved in any other manner because of the various birth control alternatives that do not require ingestion of estrogen.[50] Finally, the dissenting judges argued that the risk was avoidable precisely because of the existence of other methods of birth control.[51] The dissent thus articulated a narrow view of comment k:

> In sum, Ortho-Novum is not the type of product to which comment k was intended to apply, and the trial court properly rejected Ortho's tendered instruction based on comment k. To hold otherwide would open the door to the use of a comment k defense in the absence of any 'unique or profound benefit . . . .' This would eliminate an essential element of the rationale for comment k as a plain reading of that comment makes clear.[52]

The dissent's view of comment k suggests a sliding scale approach to prescription drug cases, with "life saving" drugs such as a polio vaccine at one end, and so-called "convenience" drugs, such as contraceptives, at the other. Unless the drug offers a unique and profound benefit, comment k does not apply. Whether comment k was meant to apply to only those prescription drugs that offer a "unique and profound" benefit is debatable,[53] but the outcomes reached by the majority and dissent in *Heath* illustrate well the inconsistency resulting from *ex post facto* risk/benefit analyses.

The Supreme Court of Idaho continued the restrictive interpretation of comment k in *Toner v. Lederle Laboratories*.[54] The court held that comment k applies to strict liability claims based on defective design but again conditioned the application of the exemption upon the manufacturer's ability to prove the benefits of the drug outweighed the risks at the time of marketing.[55]

In *Toner,* the plaintiff, who was a minor, brought suit against Lederle Laboratories after developing paralysis following administration of

---

48. *Id.* at 421.
49. *Id.*
50. *Id.*
51. *Id.* The dissenters did agree that the jury could have found that the risk of blood clotting through the use of Ortho-Novum 1/80 was known. *Id.*
52. *Heath,* 722 P.2d at 421.
53. *See supra* note 10.
54. 112 Idaho 328, 732 P.2d 297 (1987).
55. *Id.* at 339, 732 P.2d at 308.

a pertussis vaccine, Tri-Immunol.[56] The case proceeded on negligence, strict liability and breach of warranty causes of action, and the jury returned a verdict for the defendant on all claims except negligence.[57] On the appeal before the Ninth Circuit, Lederle argued that the evidence presented at trial was insufficient to support a finding of negligence.[58] The defendant specifically objected to the trial court's failure to include in the jury instructions any reference to comment k, arguing that the principles of comment k apply to negligence as well as strict liability.[59] Since the Idaho state courts had not yet interpreted comment k, the court of appeals certified four questions to the Idaho Supreme Court addressing the applicability of comment k to strict liability and negligence.[60]

The Supreme Court of Idaho agreed that comment k is a defense to strict liability claims but conditioned its application upon proof by the manufacturer that the product's risk was, in fact, unavoidable.[61]

---

56. *Id.* at 330, 732 p.2d at 308. Tri-Immunol was a "whole cell vaccine," so designated because it contains whole killed pertussis organisms. The whole organism containing fifteen or sixteen antigens is used because medical science has yet to isolate the single antigen that stimulates protection against the disease. *Id.* at 331, 732 P.2d at 308. Although the whole cell was the only licensed pertussis vaccine, plaintiff argued that Lederle should have developed a fractionated whole cell vaccine, that is, a vaccine, prepared by treating whole cells with salt. Eli Lilly had developed such a vaccine in the 1950's and studies indicated that this form resulted in fewer toxic reactions. *Id.* The plaintiff thus attacked Lederle's failure to develop a fractionated cell product. *See generally* Esaqui v. Dow Chem. Corp., 598 F.2d 727, 731 (2nd Cir. 1979) for a helpful discussion of vaccines.

57. *Toner,* 112 Idaho at 330, 732 P.2d at 299.

58. *Id.*

59. *See* Toner v. Lederle Labs., 779 F.2d 1429, 1431 (9th Cir. 1986). The instruction read:

> A manufacturer of vaccines has the duty to exercise ordinary and reasonable care not to expose the potential consumer to an unreasonable risk of harm from the use of its products. The failure to meet this standard of due care in light of all the attendant circumstances will constitute negligence and subject the manufacturer to liability for the resulting consequences. The fact that the consumer's injuries were proximately caused by the manufacturer's product does not in and of itself constitute a sufficient basis upon which to predicate the manufacturer's liability. When the cause of action sounds in negligence, a manufacturer's duty to additionally test and investigate the propensities of its product is dependent upon the foreseeable risk of harm to potential users in light of then current scientific or medical knowledge and discoveries.

Id. at 1431-32.

60. *Id.* at 1433. The four certified questions included:

> (1) Under Idaho law, do the principles set forth in Restatement (Second) of Torts § 402A comment k apply to strict liability and negligence claims, and in particular to the claims in this suit? (2) If yes, is there evidence from which a jury could find Tri-Immunol avoidably unsafe? (3) Under Idaho law, could the jury, on this record, find the defendant negligent for failure to develop a fractionated cell vaccine, or for any other reason? (4) Were the jury instructions on the issue of negligence in full accordance with Idaho law, given the contentions of the parties in the case?

Id.

61. *Toner,* 112 Idaho at 336, 732 P.2d at 305.

The manufacturer must show that the design of the drug was, at the time of distribution to the plaintiff, as safe as possible according to the best available testing and research.[62] Citing *Belle Bonfils,* the court held that in order to qualify as an unavoidably unsafe product, "there must be at the time of distribution no feasible alternative design which on balance accomplishes the product's purpose with a lesser risk."[63] In evaluating the alternative design, the court "should consider the magnitude of the subject product's risk that the alternative avoids, the financial costs of the compared designs, the benefits of the compared designs, and the relative safety of the compared designs, including any new risk that the alternative would pose."[64] Under this test, the court stated, the benefit must outweigh the risk and the weighing process should consider the value of the benefit, the seriousness of the risk and the likelihood of both.[65]

Finally, in a welcome departure from *Belle Bonfils* and *Heath,* the court held that strict liability will not apply to unknown risks and risks not scientifically discoverable at the time of distribution.[66] The court conceded that comment k's reference to a "known but apparently reasonable risk" could be read as limiting its coverage to only known risks.[67] However, citing the reference in comment k to drugs "for which there can be no assurance of safety" and other products whose benefits *appear* to outweigh risks at the time of distribution, the court had no trouble extending comment k to unknown risks as well as known risks.[68]

Despite the extension of comment k to unknown risks as well as known risks, Idaho's interpretation of comment k is unsatisfactory. As a result, in Idaho, as in Colorado, drug manufacturers are better off not pleading comment k as an affirmative defense because of the unreason-

---

62. *Id.* at 337, 732 P.2d at 306.

63. *Id.* (citing *Belle Bonfils,* 665 P.2d at 123); *Kearl v. Lederle Laboratories* 172 Cal. App. 3d 812, 830, 218 Cal. Rptr. 453, 464 (1985).

64. *Toner,* 112 Idaho at 336, 732 P.2d at 305.

65. *Id.*

66. *Id.* at 338, 732 P.2d at 307. The *Toner* court did not decide whether the issue of comment k's applicability would be decided by the trial judge or the jury but stated that the issue "would require a full evidentiary hearing." *Id.* at 339 n.8–9, 732 P.2d at 308 n.8–9.

67. *Toner,* 112 Idaho at 338, 732 P.2d at 307.

68. *Id.* The court emphatically rejected the argument that comment k shielded the manufacturer from negligence claims as well. While acknowledging that comment k concerns and the required balancing between risks and benefits are similar to those involved in a negligence claim, the majority declined to extend the immunity to claims based on negligence. *Id.* at 341, 732 P.2d at 310. Justice Bakes, in a concurring opinion, reasoned that comment k must apply to negligence as well as strict liability. *Id.* at 349, 732 P.2d at 318. Since there is little or no difference between Idaho's negligence test of "unreasonable risk of harm" and the strict liability test of "unreasonably dangerous to the consumer," the concurrence concluded that comment k must apply to both

able "burden" necessary to earn the exemption. Rather than trying to demonstrate that the benefits of the product outweighed the risk, the defendant manufacturer would have an easier time rebutting the plaintiff's prima facie case of design defect.

The *Belle Bonfils, Heath,* and *Toner* decisions, moreover, are likely to engender considerable confusion for juries. The *Heath* ruling in particular contemplates a jury instruction based on traditional design defect theory *and* an instruction based on comment k.[69] A jury is not likely to find a product avoidably unsafe but not unreasonably dangerous. So similarly, it is hardly likely that a jury could find a product unavoidably unsafe but still unreasonably dangerous. These inconsistencies will inevitably have to be sorted out at the appellate level. Such is the result when the jury receives two different instructions with different labels, avoidably unsafe and unreasonably dangerous, on what is essentially the same legal theory, strict liability based on design defect.

More than any other jurisdiction, California courts have come full circle in their treatment of prescription drugs under comment k. Although the state was one of the first to fashion a risk/benefit test to determine the drugs entitled to comment k protection,[70] the supreme court of that state, in *Brown v. Superior Court,*[71] recently extended comment k protection to *all* prescription drugs.

In *Kearl v. Lederle Laboratories,*[72] the plaintiff sued the manufacturer of a polio vaccine after developing a rare, but lethal form of paralysis following the administration of a live polio vaccine.[73] At trial, the jury returned a verdict for the plaintiff, finding the defendant liable for design defect strict liability.[74] The court of appeals reversed after a

---

69. Barker v. Lull Engineering, 20 Cal. 3d 413, 414, 573 P.2d 443, 444, 143 Cal. Rptr. 225, 226 (1978). Assuming that the jury is instructed, as Heath suggested, on traditional design defect theory using a risk-benefit analysis, the result will be that the jury will receive two instructions on the same theory.

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

71. 44 Cal. 3d 1049, 751 P.2d 470, 245 Cal. Rptr. 412 (1988).

72. 172 Cal. App. 3d at 812, 218 Cal. Rptr. at 453.

73. 172 Cal. App. 3d at 817–18, 218 Cal. Rptr. at 455–456. Two vaccines for polio are used in this country: "killed" polio vaccine, (IPV) which consists of a virus grown in a tissue culture, which is then "killed" but is capable of acting as an antigen to stimulate production of antibodies. *Id.* Dr. Tobin developed a "live" polio vaccine (OPV) consisting of living but weakened polio viruses which are *generally* incapable of causing the disease itself but are strong enough to produce antibodies to repel wild polio virus. *Id.* The plaintiff received the "live" polio virus which has a recognized though remote (about 1 in every 4 million vaccinations) risk of causing paralysis. *Id.*

74. *Id.* at 820–21, 218 Cal. Rptr. at 457. The trial judge instructed the jury on design defect theory as follows:

> The manufacturer and/or distributor of a product is liable for injuries a legal cause of which was a defect in its design which existed when it left possession of such a defendant provided that the injury resulted from a use of the product that was reasonably foreseeable by the defendant. A product is defective in design unless the benefits of the design of the

lengthy discussion of the relationship between strict liability and prescription drugs.[75] The court specifically addressed the dilemma of allowing redress for innocent plaintiffs injured by pharmaceutical products and the problems that society would face by subjecting drugs to the same accountability as other products.[76] Subjecting pharmaceuticals to the same standard, the court suggested, would not only delay availability of needed drugs, but would also place the cost of research, development and eventual marketing of new products beyond that which manufacturers, especially smaller manufacturers, are willing to risk.[77]

Nevertheless, the court expressed discomfort "with the rather routine and mechanical fashion by which many appellate courts have concluded that certain products, particularly drugs, are entitled to special treatment."[78] The decision to exempt such products could only be made after evidence is first taken out of the jury's presence on the relevant factors to be considered.[79] The evidence considered would include the following:

> (1) whether, when distributed, the product was intended to confer an exceptionally important benefit that made its availability highly desirable; (2) whether the then-existing risk posed by the product both was 'substantial and unavoidable;' and (3) whether the interest in availability

---

> product as a whole outweigh the risk of danger inherent in the design or if the product failed to perform as safely as an ordinary consumer of the product would expect when used in a manner reasonably foreseeable by the defendant. 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 could cause damage, the medical feasibility of a safer alternate design at the time of 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.

172 Cal. App. 3d at 820–21, 218 Cal. Rptr. at 457 (quoting Barker v. Lull Engineering, 20 Cal. 3d 413, 573 P.2d 443, 143 Cal. Rptr. 225 (1978)). The instructions did not mention comment k and the only modification made was substituting medical for mechanical before the word feasibility. *Barker* defined design defect claims in two ways. Under the first test, a plaintiff may establish a design defect by showing that the product failed to perform as safely as an ordinary consumer would expect. *Barker* 20 Cal. 3d at 429–30, 573 P.2d at 454, 143 Cal. Rptr. at 236–38. Under the second test, a plaintiff must show that the product's design proximately caused his injury, then, the burden then shifts to the defendant to establish that, viewed from information available at the time of trial, the benefits of the product's design outweigh the risks inherent in such a design. *Id.* at 430–32, 573 P.2d at 454–55, 143 Cal. Rptr. at 237–38; *see infra* note 76 and accompanying text.

75. *Kearl*, 172 Cal. App. 3d at 836, 218 Cal. Rptr. at 469.

76. 172 Cal. App. 3d at 823–25, 218 Cal. Rptr. at 459–60.

77. *Id.* at 823–24, 218 Cal. Rptr. at 459 (quoting Feldman v. Lederle Laboratories, 189 N.J. Super. 424, 435–36, 460 A.2d 203, 209 (1983), *rev'd on other grounds*, 97 N.J. 429, 479 A.2d 374 (1984)).

78. 172 Cal. App. 3d at 829, 218 Cal. Rptr. at 463.

79. *Id.* at 829–30, 218 Cal. Rptr. at 464.

(again measured at the time of distribution) outweighs the interest in promoting enhanced accountability through strict liability design defect review.[80]

In determining whether the risk posed was substantial, the court should consider whether, at the time of distribution, the risk posed permanent or long-term disability as opposed to mere temporary or insignificant inconvenience.[81] Furthermore, in considering whether the risk posed was unavoidable, the court should consider whether the product was designed to minimize, to the extent scientifically knowable at the time it was distributed, the risk inherent in the product, and the availability at the time of distribution of any alternative product that would have *as effectively* accomplished the *full intended purpose* of the subject product.[82]

Under the analysis set forth in *Kearl,* if the court concluded that the product was intended to provide an exceptionally important benefit, and the risk posed was substantial and unavoidable when distributed, the product would be deemed unavoidably unsafe and exempt from a strict products liability cause of action based on design defect.[83]

The test outlined by the *Kearl* court, however, was short lived. In March 1988, in *Brown,*[84] the California Supreme Court rejected the case-by-case application of comment k and held that all prescription drugs are entitled as a matter of law to the exemption from strict liability claims based upon design defect.[85]

In *Brown,* the plaintiffs sued several drug companies for injuries allegedly resulting from their mothers' *in utero* exposure to diethystilbestrol, a sythetic hormone marketed in the 1940's and 1950's for pregnancy-related indications.[86] The trial court made pretrial rulings in favor of the defendants, holding, *inter alia,* that the defendants could not be held strictly liable for defectively designing the drug.[87] The plaintiffs then sought a writ of mandate or prohibition in the court of appeals to review this and other rulings.[88] The appellate court upheld the trial court's rulings and the plaintiffs subsequently sought review from the California Supreme Court, which agreed to review the case for its potential conflict with *Kearl.*[89]

---

80. *Id.* at 830, 218 Cal. Rptr. at 464.
81. *Id.*
82. *Id.*
83. *Id.*
84. 44 Cal. 3d at 1068, 751 P.2d at 486, 245 Cal. Rptr. at 424.
85. *Id.*
86. *Id.* at 1054–55, 751 P.2d at 473, 245 Cal. Rptr. at 414.
87. *Id.* at 1055, 751 P.2d at 473, 245 Cal. Rptr. at 415.
88. *Id.*
89. *Id.* at 1055–56, 751 P.2d at 473, 245 Cal. Rptr. at 415.

The California Supreme Court upheld the trial court's rulings, overruled *Kearl* and extended comment k protection to all prescription drugs as a matter of law.[90]

The court began by reviewing the relationship between strict liability and prescription drugs.[91] The court first considered whether the *Barker* test for determining design defect should apply to prescription drugs.[92] In *Barker v. Lull Engineering,*[93] the California Supreme Court set forth two alternative tests for design defect: "first, whether the product performed as safely as the ordinary consumer would expect when used in an intended and reasonably foreseeable manner, and second, whether, on balance, the benefits of the challenged design outweighed the risk of danger inherent in the design."[94] The court agreed that the "consumer expectation test" is inappropriate when considering prescription drugs because a patient's expectations regarding drugs are related by a physician, to whom the manufacturer relates the warnings on the properties of a particular drug.[95]

The defendants further argued that design defect analysis is inappropriate in the context of prescription drugs because the chemical composition that produces the desired effect also produces the negative side effect.[96] Thus, the argument goes, there is no possibility for an alternative design for a drug like diethystilbestrol (hereinafter DES) because the drug is a scientific constant compounded in accordance with a required formula.[97]

The court countered that it might be possible for a plaintiff to demonstrate at trial that a particular component of DES rendered it unsafe and that removal of that component would not have affected the efficacy of the drug.[98] "Or the plaintiff might be able to prove that other, less harmful drugs were available to prevent miscarriage."[99]

The court thought that the issue was not whether a prescription drug is capable of being defectively designed; rather, it identified the

---

90. *Id.* at 1068, 751 P.2d at 4855, 245 Cal. Rptr. at 424.
91. *Id.* at 1057–58, 751 P.2d at 475, 245 Cal. Rptr. at 416.
92. *Id.* at 1060–62, 751 P.2d at 476–78, 245 Cal. Rptr. at 418–19; *see supra* note 74.
93. 20 Cal. 3d 413, 573 P.2d 443, 143 Cal. Rptr. 225, (1978).
94. *Brown,*44 Cal. 3d at 1061, 751 P.2d at 477, 245 Cal. Rptr. at 419. The court stated:
> [W]hile the 'ordinary consumer' may have a reasonable expectation that a product such as a machine he purchases will operate safely when used as intended, a patient's expectations regarding the effects of such a drug are those related to him by his physician, to whom the manufacturer directs the warnings regarding the drugs properties.

Id. at 1061–62, 751 P.2d at 477, 245 Cal. Rptr. at 419.
95. *Id.* at 1062, 751 P.2d at 478, 245 Cal. Rptr. at 419.
96. *Id.* at 1061, 751 P.2d at 477, 245 Cal. Rptr. at 419.
97. *Id.*
98. *Id.*

issue as being whether imposition of strict liability on drug manufacturers comports with the traditional goals of tort law, namely, deterrence and cost distribution.[100] The court acknowledged that a drug might perhaps be made safer if it was withheld from the market until scientific skill and knowledge advanced to the point where all dangerous side effects could be discovered.[101] However, this delay, when added to the delay normally required for a new drug to pass muster under the Food Drug and Cosmetic Act, would not, in the court's view, serve the public welfare.[102] In a significant passage, the court cited examples of potentially useful drugs being withdrawn from the market because of the liability crisis:

> One producer of a diptheria-tetanus-pertussis vaccine withdrew from the market, giving as its reason extreme liability exposure, cost of litigation and the difficulty of continuing to obtain adequate insurance. There are only two manufacturers of the vaccine remaining in the market, and the cost of each dose rose a hundredfold from 11 cents in 1982 to $11.40 in 1986, $8 of which was for an insurance reserve. The price increase roughly paralleled an increase in the number of lawsuits from one in 1978 to 219 in 1985. Finally, a manufacturer was unable to market a new drug for the treatment of vision problems because it could not obtain adequate liability insurance at a reasonable cost.[103]

The court held that a drug manufacturer's liability for a defectively designed drug should not be measured by the *Kearl* test for determining when a pharmaceutical is unavoidably unsafe.[104] While agreeing that there is some appeal in the *Kearl* approach, the court set forth several specific criticisms of that test. First, under the *Kearl* "mini-trial," a drug manufacturer has no assurance that a product it places on the market will be measured by the standard of comment k.[105] Second, a manufacturer's incentive to develop what it considered to be a superior product would be diminished if, many years later, a trial court could decide that in fact another product which was available on the market could have accomplished the same result.[106] Third, the question of superiority could not be decided in the abstract since the advantages of a drug cannot be isolated by the condition of a particular patient.[107] In other words, the court would be deciding risk ver-

100. *Id.* at 1064, 751 P.2d at 479, 245 Cal. Rptr. at 421.
101. *Id.* at 1063, 751 P.2d at 479, 245 Cal. Rptr. at 420.
102. *Id.*
103. *Id.* at 1065–67, 751 P.2d at 480–81, 245 Cal. Rptr. at 421–22.
104. *Id.* at 1067, 751 P.2d at 481, 245 Cal. Rptr. at 423.
105. *Id.* at 1068, 751 P.2d at 482, 245 Cal. Rptr. at 423.
106. *Id.*
107. *Id.* at 1068, 751 P.2d at 482, 245 Cal. Rptr at 423–24. The court stated:

sus benefit for a particular patient, not the public at large.[108] The court cited possible inconsistent results among different judges as well as inconsistent verdicts between judges and juries.[109]

The policy underlying the *Brown* decision was straightforward: to allow design defect claims to go forward against drug manufacturers would only deprive the public of beneficial products. While recognizing a difference between "life saving" drugs and so-called "convenience" drugs, such as contraceptives, the *Brown* court suggested that judicially crafted risk/benefit tests to determine the applicability of comment k invite inconsistency, uncertainty and an inevitable rise in litigation costs for both plaintiffs and defendants.

Unfortunately, even as *Brown* augered a more realistic approach to comment k, the Rhode Island Supreme Court, in *Castrignano v. E.R. Squibb & Sons, Inc.*,[110] embraced yet another case-by-case approach to comment k. The plaintiff in *Castrignano* brought suit in the United States District Court for the District of Rhode Island against E.R. Squibb for injuries allegedly arising out of the plaintiff's *in utero* exposure to DES.[111] Before trial, the district court, Judge Boyle presiding, refused the defendant's suggested jury instruction that DES was "unavoidably unsafe" pursuant to comment k.[112] The jury specifically found the defendant liable under strict liability and breach of implied warranty.[113] The district court refused to entertain the defendant's post trial motions and instead certified the following three questions to the Rhode Island Supreme Court: 1) Does the State of Rhode Island recognize an action for damages for personal injuries in the circumstances presented in this action based upon theories of strict liability in tort and breach of warranty of merchantability? 2) Does comment k to Section 402A, Restatement of Torts, apply in Rhode Island to an action for damages for personal injuries in the circumstances presented in an action based upon a theory of strict liability in tort? 3) If comment k

---

> [S]ome of the factors considered by the judge in making his determination whether the issue should be submitted to the jury on the basis of strict liability or negligence appear so similar to the matters to be considered by the jury in making the subsequent risk/benefit analysis required by *Barker*, that the judge in effect makes a preliminary determination whether a drug contains a design defect. If he determines that strict liability is the appropriate standard, the jury is required to make a second determination, based on factors and evidence similar to those considered by the judge, whether the drug was defectively designed. The possibility of conflicting conclusions by judge and jury is real.

Id.

108. *Brown*, 44 Cal. 3d at 1068, 751 P.2d at 482, 245 Cal. Rptr. at 423.
109. *See supra* note 2.
110. *Castrignano*, 546 A.2d at 775.
111. *Id.* 546 A.2d 776.
112. *Id.* at 778.
113. *Id.* at 777.

applies to this type of action, is its application to the prescription drug DES a matter of law, or a question of fact, and, if a question of fact, which party has the burden of proof?[114]

In its opinion, the Rhode Island Supreme Court reviewed the cases advocating complete immunity from strict liability design defect claims and the cases advocating a case-by-case approach: the court acknowledged that both approaches have merit, but opted for the more restrictive interpretation of comment k.[115] Under the *Castrignano* test, if at the time of marketing, the apparent benefits outweighed the apparent risks, then comment k applies and recovery for design defect liability is precluded.[116] Proving that benefits outweigh risk will be the defendant's burden "because that defendant will invariably be expert in the field and have superior knowledge."[117]

The court adopted a directed verdict standard to balance the role of the judge and jury in the application of comment k. If a trial judge concludes that reasonable minds could not differ in deciding that a drug's benefits exceed its risks, then as a matter of law, the trial judge can extend comment k protection.[118] If the judge feels that reasonable minds could differ on the question, then the judge should submit the issue to the jury.[119]

III. ANALYSIS

The decisions embracing a risk/benefit comment k test were clearly influenced by the *Barker v. Lull Engineering*[120] case, which held that in a design defect case the burden of proof is on the defendant to establish that the benefits of the challenged design outweigh the inherent risk of danger.[121]

The factors cited by the *Barker* court are substantially similar to those cited in the *Belle Bonfils Memorial Blood Bank v. Hansen, Ortho Pharmaceutical Corporation v. Heath, Toner v. Lederle Laboratories* and the *Castrignano v. E.R. Squibb and Sons* holdings. They include the gravity of the danger posed by the challenged design, the likelihood that such danger would occur, the mechanical feasibility of the safer alternative design, the financial cost of an improved design and the adverse consequences to the product and to the consumer that

114. *Id.*
115. *Id.* at 781.
116. *Id.*
117. *Id.* at 782.
118. *Id.*
119. *Id.*
120. 20 Cal. 3d 413, 573 P.2d 443, 143 Cal. Rptr. 225 (1978).
121. *Id.* at 426-27, 573 P.2d at 452, 143 Cal. Rptr. at 234.

would result from an alternative design.[122]

Barker has been criticized because its holding shifted the burden of exculpation in a design defect case to the defendant.[123] Professor Henderson, for example, has suggested that *Barker* threatens the ability of courts to achieve integrity in the judicial treatment of product design cases:

> If the new [*Barker*] test for liability is applied literally, every plaintiff represented by at least minimally competent counsel should succeed in shifting the burden to the defendant; and no defendant however capably represented will succeed, other than by agreeing to settle, in avoiding the retrospective evaluation of its design choices by lay jurors. Directed verdicts for defendants, traditionally an important protection against arbitrary jury decisions in cases of doubtful merit, will occur even less frequently under the *Barker* rule literally applied than they occur under the existing majority rule.[124]

The same concerns for process expressed by Professor Henderson are equal, if not greater, in the comment k context. Colorado, Idaho and Rhode Island have taken the second prong of the *Barker* test for design defect and applied it in order to determine the applicability of the *exception* to design defect theory. In doing so, these states have thus ensured that defendants will find little success in establishing comment k as a matter of law. The irony in the transformation of the *Barker* test into a test to determine the applicability of comment k is that the California Supreme Court, the court that spawned *Barker,* has itself refused to extend *Barker* to cases involving prescription drugs.[125]

Other jurisdictions are not so reasonable. The nebulous standards proposed by the *Castrignano* and *Belle Bonfils* courts which determine

---

122. *Id.* at 431, 573 P.2d at 455, 143 Cal. Rptr. at 237. The factors cited in *Barker* were, in turn, influenced by Professor Wade's law review article. *See* Wade, *On the Nature of Strict Tort Liability for Products,* 44 MISS. L.J. 825 (1973). There, Professor Wade identifies seven factors to be considered in judging the conduct of a manufacturer, whether or not the case sounds in negligence or strict liability. The factors include: the usefulness and desirability of the product; the likelihood that the product will cause injury and the probable seriousness of the injury; the availability of a substitute product which would meet the same need and not be as unsafe; the manufacturer's ability to eliminate the unsafe character of the product without impairing its usefulness or making it too expensive; and the feasibility of spreading the loss by setting the price of the product or carrying liability insurance. *Id.* at 838. Although the *Barker* court did not cite the Wade article specifically for the "relevant factors" to be considered by the jury, the Wade article is cited three times elsewhere in the opinion. *See Barker,* 20 Cal. 3d at 426 n.8, 428, 430, 573 P.2d at 452 n.8, 453, 454, 143 Cal. Rptr. at 234 n.8, 235, 236.

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

124. *Id.* at 782.

125. *See supra* notes 84–109 and accompanying text.

when the question of comment k's application reaches the jury, leaves much room for plaintiff to maneuver cases to the jury.

One type of prescription drug litigation that will plague Colorado, Idaho and Rhode Island courts seeking to intelligently apply the comment k risk/benefit tests is the litigation involving oral contraceptives and other drugs, like DES, used for pregnancy related purposes. These products fall somewhere in the void between drugs like the polio vaccine, which possess enormous benefit and a quantifiable minute risk, and other drugs, such as an acne preventing medication, which offer some benefits, albeit slim ones, as compared to most other prescription drugs.[126]

Thus, the woman plaintiff suing for injuries allegedly caused by oral contraceptives, DES or pregnancy-related drugs, might argue that there were alternatives to these products available that posed less risk than their synthetic counterparts. The defendants might in response argue that their products offer substantial benefits over other available products. But, as the *Heath* dissent illustrates so well, in the case of oral contraceptives and other pregnancy related drugs, it is easy to argue that availability of safer alternatives exists.[127]

This example, though, is far removed from the *Brochu* plaintiff, who was able to show that another form of the same product offered exactly the same benefits with much less risk. In most cases involving oral contraceptives and other pregnancy related drugs, plaintiffs will not be able to demonstrate a specific dosage response relationship involving the same product. Instead, they will point to altogether different products offering similar advantages, but an ultimately dissimilar package of risks and benefits.[128]

Furthermore, analysis of the comment k tests set forth in *Bell Bonfils, Toner, Heath* and *Castrignano* illuminates the broader issue of

---

126. *See* Note, *Brochu, supra* note 8, at 272.

127. *Id.*

128. *Id.* at 267–68 n.121. This commentator, discussing the consequences of *Brochu,* has persuasively outlined the problems of comparing pregnancy related drugs:

> [A] women whose IUD causes a pelvic infection (a side effect of the IUD) could correctly claim that the injury would not have occurred had she used an alternative method of birth control, such as an oral contraceptive. Although she was fully informed of risks of the IUD, a prima facie design case would be established with expert testimony stating that the IUD was unreasonably dangerous because safer substitutes were available. The defense would argue that the widespread use of the IUD is conclusive evidence as to the reasonableness of the design. In accord with prevailing products liability doctrine, this defense would be rejected. Consequently, based on plaintiff's expert testimony, the case should be submitted to the jury. The jury could conceivably render a verdict for the plaintiff, purportedly on the ground that an IUD is unreasonably dangerous. Yet many women prefer the IUD over other methods of contraception because of its convenience (citations omitted).

Id.

whether the judicial system possesses the ability to adjudicate, rationally and justly, a manufacturer's conscious design choices. Professor Henderson, in particular, has forcefully argued that the courts are unsuited to render responsible judgments in the design defect area.[129] Decisions in this area, as a consequence, more often reflect arbitrary judgment rather than reasoned adjudication. These arbitrary results, Henderson suggests, occur because the judicial review of conscious design choices, without reliance on extrajudicially established standards, are necessarily polycentric.[130] This polycentricity presents courts with a series of judgmental tasks for which they are not well suited.[131] The result, Henderson concludes, does not augur well for the judicial system:

> The adjudicatory process is most appropriate for resolving issues by the application of rules sufficiently specific and defined to permit the parties

---

129. *See* Henderson, *Judicial Review of Manufacturer's Conscious Design Choices: The Limits of Adjudication*, 73 COLUM. L. REV. 1531, 1562–65 (1973) [hereinafter Henderson, *Judicial Review*]; Henderson, *Design Defect Litigation Revisited*, 61 CORNELL L. REV. 541 (1976) [hereinafter Henderson, *Design Defect Revisited*].

130. *See* Henderson, *Judicial Review*, *supra* note 129, at 1536. Polycentric problems, Henderson explains, are "many centered problems," in which "each point for decision is related to all the others as are the strands of a spider web." *Id.* He further states why polycentric issues are difficult to litigate:

> If one strand is pulled, a complex pattern of readjustments will occur throughout the entire web. If another strand is pulled, the relationships among all the strands will again be readjusted. A lawyer seeking to base his argument upon established principle and required to address himself indiscourse to each of a dozen strands, or issues, would find his task frustratingly impossible. As he moved from the first point of his argument to the second and then to the third, he would find his arguments regarding the earlier points shifting beneath him. Unlike most of the traditional types of cases in which litigants are able, in effect, to freeze the rest of the web as they concentrate upon each separate strand, the web here retains its natural flexibility, adjusting itself in seemingly infinite variations as each new point, or strand, in the argument is reached.

Id.

Rather than developing design defect analysis, Henderson suggests that the same objective, increased product safety, can be achieved through strict liability failure to warn theory. He explains:

> The questions, "How much warning is enough?" and "How much warning is too much?" are fundamentally different from the "How much product safety is enough?" question involved in a product design case. The former questions are decided along a single value axis (i.e., maximum information to the user or consumer), whereas the latter question is decided by balancing the various competing values in the society. The inquiry in a duty-to-warn or duty-to-disclose case is essentially factual- i.e., "What are the limits of the recipient's understanding and ability to under-stand, and how may the objective of informing the recipients best be accomplished in light of those limits?" The inquiry in a design defect case, on the other hand, is substantially normative - i.e., "What is a reasonable mix of the competing values at stake in setting the minimally acceptable level of design safety?"

Henderson, *Design Defect Revisited*, *supra* note 129, at 546. For an illuminating rebuttal to Professor Henderson, see Twerski, Weinstein, Donaher & Piehler, *The Use and Abuse of Warnings in Product Liability-Design Defect Litigation Comes of Age*, 61 CORNELL L. REV. 495 (1976).

131. *See* Henderson, *Renewed Judicial Controversy*, *supra* note 123, at 790.

> to argue rationally that a proper application of the rules dictates a certain result. The adjudicatory process is inadequate as a method of resolving, on a case-by-case basis, the vague question of whether or not risks presented by a particular product are unreasonable. When forced to make such decisions, courts must resolve complex and often times highly technical issues of design alternatives equipped only with legal principle reduced to its most basic degree of generalization: a balancing test. In effect, the courts are forced to second guess the designers; they are forced to redesign the product themselves. The result is to push the adjudicatory process to the brink of arbitrariness.[132]

Design defect adjudication, Henderson suggests, is appropriate when the task of setting standards has already been accomplished by government agencies and industry custom.[133] Reliance on these standards thus enables courts to find liability without having to engage in a task for which they are unsuited.[134]

Henderson's thesis—that courts are incapable of rationally reviewing a manufacturer's conscious design choice—is particularly relevant in considering judicially crafted comment k tests. As the *Heath* case demonstrates, charging judges (and juries) with the task of weighing the benefits of a particular drug against its risks invites widely divergent conclusions over undisputed facts.[135]

Perhaps the greatest irony in the growth of such tests is that there is an appropriate extrajudicially prescribed standard for judging the "design" of prescription drugs: the detailed, fact specific standards set forth by the Food and Drug Administration (hereinafter FDA). Before a prescription drug can be marketed, the manufacturer must present detailed testing data demonstrating that the product is both safe and effective.[136] The process can take years. The question persists, then, why courts continue to give little attention to the findings of the FDA

---

132. *Id.* at 780.

133. *See* Henderson, *Judicial Review, supra* note 129, at 1534 n.15 ("[T]his technique [applying extrajudicial standards] is employed when a court adopts and applies a standard devised by one of the federal regulatory agencies").

134. *Id.*

135. For two articles that persuasively argue that courts give insufficient weight to FDA approval, see Gibbs & Mackler, *Food and Drug Administration Regulation and Products Liability: Strong Sword, Weak Shield,* 22 TORT & INS. L.J. 194 (1987); Walsh & Klein, *The Conflicting Objectives of Federal and State Tort Law Drug Regulation,* 41 FOOD DRUG. COSM. L.J. 171, 180 (1986).

136. This view of the presumptive effect of FDA approval has been accepted by a few courts. *See, e.g.,* Collins v. Ortho Pharmaceutical Corp., 186 Cal. App. 3d 1194, 1206, 231 Cal. Rptr. 396, 405 (1986) (FDA approval precludes design defect action); McDaniel v. McNeil Laboratories, 196 Neb. 190, 241 N.W.2d 822 (1976) (FDA determination of safety not subject to challenge unless there is some proof of fraud or nondisclosure of relevant information by the manufacturer at the time of obtaining or retaining such federal approval).

in developing design defect theory. None of the jurisdictions advocating a risk/benefit test to determine whether comment k applies have advanced any compelling reason why the findings of the FDA should not at least provide the defendent with a rebuttable presumption of safety. A plaintiff can rebut the presumption by demonstrating that the manufacturer negligently or fraudulently withheld information from the FDA. Absent such information, it makes little sense to submit a design defect theory to the jury. One explanation for the growth of design defect theory and the diminishment of comment k is the "deep pocket" character of drug companies. Although courts readily concede that drugs are enormously beneficial to society, their decisions are influenced by the view that the drug industry is basically only in pursuit of profits. Thus, one commentator demonstrates the "preferential treatment" given drug manufacturers since the drug industry "is as much a profit-oriented business as any other."[137] Another notes that past studies have revealed a high profit margin for drugs.[138] With decision-making colored by this view, it is not surprising that courts devise imaginative ways to burden defendants with obfuscatory risk/benefit tests. The *Brown*, decision commendably, is the first major state court decision to challenge this view by citing specific examples of useful prescription drugs being withdrawn from the market in response to rising litigation insurance costs. Of course, the *Brown* court did not suggest that its decision would solve the insurance crisis, but its holding adds a welcome dosage of reality into a difficult area of decision making.

IV. CONCLUSION

Judicially crafted risk/benefit tests to determine the applicability of comment k are on the rise. These tests place the burden of proving that a product was unavoidably unsafe on the manufacturer of the product. Despite having survived the rigors of the Food and Drug Administration regulations in getting the drug marketed, the manufacturer must reconstruct and rejustify the original marketing decision to avoid having a jury second guess the original "design choice." In justifying this original decision, the manufacturer faces a perplexing open-ended standard that can be applied to either justify or condemn any design defect decision. Rather than seek the comment k exemption from strict liability, the drug manufacturer has an easier time merely rebutting a traditional design defect strict liability theory where the

137. *See* Selker, *supra* note 8, at 218.

138. *See* McCellan, *supra* note 8, at 33 n.102 (quoted in Finn v. G.D. Searle & Co., 35 Cal. 3d 691, 719 n.12, 677 P.2d 1147, 1165 n.12, 200 Cal. Rptr. 870, 888 n.12 (1984) (Bird, C.J., dissenting)).

burden of proof rests on the plaintiff. The comment k tests also threaten to make a drug product liability action infinitely more complex. Bewildering jury instructions, inconsistency among judges and juries and an undue emphasis on efficacy are some of the more unfortunate consequences of these tests. The California Supreme Court in the *Brown v. Superior Court*[139] decision displayed considerably more appreciation for these process concerns. It is hoped that other jurisdictions will follow suit.

139. *Brown*, 44 Cal. 3d 1049, 751 P.2d 470, 245 Cal. Rptr. 412.