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Torts—Product Liability—Arkansas Adopts Comment K as an Affirmative Defense in Prescription Drug Actions. West v. Searle & Co., 305 Ark. 33, 806 S.W.2d 608 (1991).

Ian Birkett

NOTES

TORTS—PRODUCT LIABILITY—ARKANSAS ADOPTS COMMENT K AS AN AFFIRMATIVE DEFENSE IN PRESCRIPTION DRUG ACTIONS. *West v. Searle & Co.*, 305 Ark. 33, 806 S.W.2d 608 (1991).

In 1971, pursuant to a doctor's prescription, Mrs. Gari West began using Ovulen-28, an oral contraceptive manufactured by Searle & Co. and distributed by G.D. Searle & Co. and Searle Pharmaceuticals, Inc. (collectively referred to as "Searle").[1] Mrs. West, under the direction of her physician, used this contraceptive on and off until 1983.[2] In that year, she underwent extensive surgery when a benign liver tumor ruptured.[3]

Mrs. West and her husband sued Searle in a products liability action alleging that Ovulen-28 caused her to develop the benign liver tumor.[4] The plaintiffs' complaint alleged that Searle: (1) had defectively designed and manufactured the drug; (2) had breached the warranty of fitness; and (3) had been negligent in warning of the danger of the drug.[5] They sought recovery under theories of strict liability, breach of warranty, and negligence.[6] After limited discovery, the circuit court granted the defendant's motion for summary judgment, concluding that no question of fact existed.[7] The plaintiffs appealed to the Arkansas Supreme Court, which affirmed in part and reversed in part.[8]

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1. Brief for Appellants at 1, West v. Searle & Co., 305 Ark. 33, 806 S.W.2d 608 (1991) (No. 90-49).
2. *Id.*
3. West v. Searle & Co., 305 Ark. 33, 35, 806 S.W.2d 608, 609 (1991).
4. *Id.*
5. *Id.*
6. *Id.*
7. *Id.* at 36, 806 S.W.2d at 610.
8. *Id.* at 35, 806 S.W.2d at 610. The Arkansas Supreme Court reversed the dismissal of one count—strict liability for defective design. The court held that all of the claims failed to provide adequate factual pleading upon which relief could be granted, but Searle had tacitly admitted this one cause of action by answering with the defense of unavoidably unsafe products. *Id.* at 37, 806 S.W.2d at 611. The other claims, breach of warranty of fitness, negligence and strict liability for

The supreme court adopted comment k to the *Restatement (Second) of Torts* section 402A, also referred to as the "unavoidably unsafe products" exception to strict liability for defective products, into Arkansas law.[9] The court elected to apply comment k doctrine as an affirmative defense requiring the defendant to prove lack of an alternative feasible design.[10] It also held that a defendant must show that there was adequate warning of the risk of harm before it may raise this defense.[11] Finally, the court ruled that the "learned intermediary rule" applies to warnings regarding oral contraceptives.[12] *West v. Searle & Co.*, 305 Ark. 33, 806 S.W.2d 608 (1991).

Comment k of section 402A of the *Restatement (Second) of Torts* was written in response to the spectre of large liability judgments deterring the development and production of socially necessary and beneficial prescription products.[13] Dean Prosser cautioned about the dangers of imposing standard rules for strict liability with respect to prescription drugs:

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manufacturing defect, and negligence and strict liability for inadequate warning, were all dismissed with leave to amend. *Id.* at 36-37, 806 S.W.2d at 610-11.

9. *Id.* at 39, 806 S.W.2d at 612. The RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965) 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 and 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 direction 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.

10. 305 Ark. at 40, 806 S.W.2d at 612.

11. *Id.* at 42, 806 S.W.2d at 613.

12. *Id.* at 44, 806 S.W.2d at 614.

13. 38 A.L.I. PROC. 19, at 91-92 (1961) (as an example of potentially large judgments, one of the speakers noted that in spite of the obvious benefit to society of polio vaccination programs, the maker of the live polio vaccine faced potential liability in excess of $100 million).

> 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.[14]

Dean Prosser described these drugs as unavoidably dangerous because they cannot be made safe in the present state of human skill and knowledge.[15] Although there is unavoidable risk of harm, the utility of the product outweighs the risk of harm, and under strict liability the product is not considered defective or unreasonably dangerous.[16]

In 1961 the participants at the annual meeting of the American Law Institute initially discussed creating an exception to strict liability for prescription drugs.[17] They were concerned that large liability judgments might drive smaller drug companies out of business or persuade both larger and smaller drug companies not to pursue expensive research programs.[18] The membership also discerned a difference between nonessential prescription products, such as hair removal agents, and markedly beneficial products, such as drugs for treating cancer.[19]

As the reporter for the *Restatement (Second) of Torts*, Dean Prosser incorporated these concerns into comment k.[20] Under strict liability, a manufacturer that sold a product in a defective condition unreasonably dangerous to the user would be liable for resulting injury regardless

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14. WILLIAM L. PROSSER, HANDBOOK OF THE LAW OF TORTS, § 99, at 661 (4th ed. 1971). When a product is introduced into the stream of commerce, strict liability focuses upon the product itself, and an injured party does not have to prove that the manufacturer of the product was negligent. Three different types of product defects arise in the context of strict liability. First, there may be a flaw in the manufacturing process, such as a Coca Cola bottle that is made defectively and explodes. Next, the product may be manufactured correctly, but the design of the product is unreasonably dangerous. Finally, the product may be defective because there are inadequate instructions or warnings of danger. W. PAGE KEETON ET AL, PROSSER AND KEETON ON THE LAW OF TORTS, § 99 at 695 (5th ed. 1984). Comment k exempts certain prescription products from design defect claims, but the manufacturer is still liable for manufacturing defect and failure to warn claims. *See* John P. Reilly, *The Erosion of Comment K*, 14 U. DAYTON L. REV. 255, 257-58 (1989).

15. PROSSER, *supra* note 14, § 99, at 660.

16. M. STUART MADDEN, PRODUCTS LIABILITY § 6.13, at 235 (2d ed. 1988).

17. 38 A.L.I. Proc. 19, 90 (1961).

18. *Id.* at 92.

19. *Id.* at 93.

20. *Id.* at 97-98.

of the exercise of reasonable care.[21] The comment k doctrine establishes an exception to strict liability for a special category of products, common in the field of medicine, in which the benefit of the product exceeds the risk of harm.[22] Comment k provides that even though these products are unavoidably hazardous, they should not be considered unreasonably dangerous when they are properly prepared and accompanied by proper directions and adequate warnings of the risk of harm.[23]

The American Law Institute members also debated whether this exception to strict liability should include all prescription drugs.[24] The participants, however, could not agree upon the wording of an exemption for prescription products, and Dean Prosser elaborated on the group's concerns in comment k.[25]

In the years since the drafting of comment k, drug companies' reactions have confirmed that potential liability deters drug manufacturers from marketing prescription products. In the 1970s, the manufacturers of a new influenza vaccine refused to supply it because of liability concerns.[26] The cost of the childhood vaccine for diptheria-pertussis-tetanus (DPT) skyrocketed in the 1980s, increasing from $0.11 in 1982 to $11.40 in 1986. The increase has been associated with the dramatic rise in the number of DPT lawsuits filed—from one in 1978 to 219 in 1985.[27] Benedictin, the only antinausea drug available to pregnant women, was withdrawn from the market in 1983 because of the outrageously high cost of insurance.[28]

In response to these potential liability problems, almost all jurisdictions adopted comment k.[29] Only one court has rejected the doc-

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21. MADDEN, *supra* note 16, § 6.13, at 235.

22. MADDEN, *supra* note 16, § 6.13, at 235. *See also* Plummer v. Lederle Lab., 819 F.2d 349, 356 (2d Cir. 1987) (even though the injection of a vaccine may result in damaging complications, the diseases prevented by the vaccine also produce terrible injuries).

23. RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965).

24. 38 A.L.I. PROC. 19, 95-96 (1961).

25. *Id.* at 96. *But see Unavoidably Unsafe Products and the Design Defect Theory: An Analysis of Applying Comment K to Strict Liability and Negligence Claims*, 15 WM. MITCHELL L. REV. 1049, 1054 (1989) (the A.L.I. membership's vote, *see supra* note 24, is not reflected in comment k).

26. Marc A. Franklin & Joseph E. Mais, Jr., *Tort Law and Mass Immunization Programs: Lessons from the Polio and Flu Episodes*, 65 CAL. L. REV. 754, 769 (1977).

27. Gina Kolata, *Litigation Causes those Price Increases in Childhood Vaccines*, SCI. June 13, 1986, at 1339.

28. Brown v. Superior Court, 751 P.2d 470, 479 (Cal. 1988) (repeating statements by defendant E.R. Squibb & Sons, Inc.).

29. *See, e.g.*, Reyes v. Wyeth Lab., 498 F.2d 1264 (5th Cir.) (applying Texas law), *cert. denied*, 419 U.S. 1096 (1974); Borel v. Fibreboard Paper Prods. Corp., 493 F.2d 1076 (5th Cir.

trine.[30] The comment k defense has been allowed when doctors have ordered or prescribed therapeutic drugs, vaccines, blood products, and intrauterine devices.[31]

Courts take two basic approaches when applying comment k. The majority of states use comment k as an affirmative defense,[32] requiring the defendant manufacturer to prove that the drug's benefit to society outweighs the risk of harm.[33] This view requires a case-by-case analysis of the drug compared to feasible, alternative products available at the time the drug was marketed.[34] A small number of courts have rejected this approach and instead apply comment k as a blanket exemption for all prescription drugs.[35] This interpretation of comment k insulates the drug manufacturer from strict liability and holds it to the basic negli-

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1973) (applying Texas law), *cert. denied*, 419 U.S. 869 (1974); Beetler v. Sales Affiliates, Inc., 431 F.2d 651 (7th Cir. 1970) (applying Illinois law); Helene Curtis Indus., Inc. v. Pruitt, 385 F.2d 841 (5th Cir. 1967) (applying Oklahoma law), *cert. denied*, 391 U.S. 913 (1968); Patten v. Lederle Lab., 676 F. Supp. 233 (D. Utah 1987) (applying Utah law); Hawkinson v. A.H. Robins Co., 595 F. Supp. 1290 (D. Colo. 1984) (applying Colorado law); Williams v. Lederle Lab., 591 F. Supp. 381 (S.D. Ohio 1984) (applying Ohio law); Gaston v. Hunter, 588 P.2d 326 (Ariz. Ct. App. 1978); Toole v. Richardson-Merrell, Inc., 60 Cal. Rptr. 398 (1967); Ortho Pharmaceutical Corp. v. Heath, 722 P.2d 410 (Colo. 1986); Payne v. Soft Sheen Prods., Inc., 486 A.2d 712 (D.C. 1985); Toner v. Lederle Lab., 732 P.2d 297 (Idaho 1987); Johnson v. American Cyanamid Co., 718 P.2d 1318 (Kan. 1986); Dunn v. Lederle Lab., 328 N.W.2d 576 (Mich. Ct. App. 1982); Racer v. Utterman, 629 S.W.2d 387 (Mo. Ct. App. 1981); Ferrigno v. Eli Lilly & Co., 420 A.2d 1305 (N.J. Super. Ct. App. Div. 1980); Davila v. Bodelson, 704 P.2d 1119 (N.M. Ct. App. 1985).

30. Collins v. Eli Lilly Co., 342 N.W.2d 37 (Wis.), *cert. denied*, 469 U.S. 826 (1984). In *Collins* the Wisconsin Supreme Court reasoned that comment k was too restrictive upon the use of strict liability in Wisconsin, although the court recognized that in some exigent circumstances it may be necessary to place the drug on the market without adequate testing. *Id.* at 52.

31. In discussions of comment k, the commentators loosely use the terms "prescription products" and "drugs" to include those things for which the Food and Drug Administration requires a doctor's order or prescription. *See, e.g.*, Sidney H. Willig, *The Comment k Character: A Conceptual Barrier to Strict Liability*, 29 MERCER L. REV. 545, 563-72 (1978).

32. *See* cases cited *supra* note 29.

33. *See, e.g.*, Ortho Pharmaceutical Corp. v. Heath, 722 P.2d 410 (Colo. 1986) (the manufacturer presented sufficient evidence to show that the benefits from an oral contraceptive outweighed the risks); Belle Bonfils Memorial Blood Bank v. Hansen, 665 P.2d 118 (Colo. 1983) (the manufacturer is held to the knowledge and experience of an expert in the field regarding known risks); Toner v. Lederle Lab., 732 P.2d 297 (Idaho 1987) (the court suggests parameters to evaluate risk-benefit, *see infra* text accompanying notes 39-45). *See also* Willig, *supra* note 31, at 556-57 (the defendant's responsibilities regarding knowledge of the risk of harm).

34. *See, e.g.*, Kearl v. Lederle Lab., 218 Cal. Rptr. 453, 464 (1985) (suggesting parameters to assist the trial judge in deciding whether the manufacturer is allowed to use the comment k defense).

35. *See, e.g.*, Lindsey v. Ortho Pharmaceutical Corp., 637 F.2d 87 (2d Cir. 1980) (applying New York law); Brown v. Superior Court, 751 P.2d 470 (Cal. 1988); McKee v. Moore, 648 P.2d 21 (Okla. 1982); Terhune v. A.H. Robins Co., 577 P.2d 975 (Wash. 1978).

gence or fault-based standard.[36]

By restricting the use of comment k to an affirmative defense, the majority rule encourages the manufacturer to produce only socially valuable drugs.[37] The selective application of the comment k doctrine promotes research and production of highly beneficial drugs needed to treat serious illness because the manufacturer is not held strictly liable for the unavoidable side effects of the treatment.[38] However, the pharmaceutical company must show that there was no safer, alternative treatment at the time the drug was marketed, which means the company is not shielded from strict liability if an alternative product posed a smaller risk of harm.[39] In this manner, the courts use comment k as an affirmative defense to balance the tort law considerations of promoting safety and compensating an injured party while simultaneously advancing the production of important products.[40]

Those courts adopting comment k as an affirmative defense were confronted with how to measure the value of the drug compared to the risk of harm. One method of analysis, which has received the endorsement of several other jurisdictions,[41] was proposed by the Supreme Court of Idaho in *Toner v. Lederle Laboratories*.[42] The plaintiff in *Toner* was a minor who developed paralysis after an injection of the pertussis vaccine.[43] The court reasoned that "unavoidably unsafe" under comment k requires that there must have been no feasible alternative to accomplish the vaccine's purpose with lesser risk.[44] The *Toner* court stated a four part test to be used in determining if a drug is "unavoidably unsafe" and found that the vaccine satisfied this test. The four factors are (1) the magnitude of the product's risk that the alternative avoids; (2) the financial costs of the product compared to the

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36. Reilly, *supra* note 14, at 257.

37. Victor E. Schwartz, *Unavoidably Unsafe Products: Clarifying the Meaning and Policy behind Comment K*, 42 WASH. & LEE L. REV. 1139, 1141 (1985). Schwartz concludes that comment k balances the basic tort law conditions of deterrence, incentives for safety, and compensation to favor socially valuable drugs. *Id.* at 1143 n.37.

38. Schwartz, *supra* note 37, at 1143.

39. *See, e.g.*, Toner v. Lederle Lab., 732 P.2d 297, 305 (Idaho 1987).

40. Schwartz, *supra* note 37, at 1141.

41. *See, e.g.*, Hill v. Searle Lab., 884 F.2d 1064, 1069 (8th Cir. 1989) (applying Arkansas law); Kociemba v. G.D. Searle & Co., 680 F. Supp. 1293, 1301 (D. Minn. 1988) (applying Minnesota law); Patten v. Lederle Lab., 676 F. Supp. 233, 237 (D. Utah 1987) (applying Utah law); White v. Wyeth Lab., Inc., 533 N.E.2d 748, 752 (Ohio 1988).

42. 732 P.2d 297 (Idaho 1987).

43. *Id.* at 299.

44. *Id.* at 306.

alternative design; (3) the benefits of the product compared to the alternative design; and (4) the safety of the product compared to the alternative design, including the risks of the alternative design.[45]

The great majority of jurisdictions determine whether to allow the defendant manufacturer to raise the comment k defense by using a risk-benefit analysis similar to *Toner*.[46] The courts attempt to quantify the benefit from the drug compared to the risk of harm.[47] Then the courts decide whether the manufacturer is allowed to use the affirmative defense of comment k as a matter of law.[48]

A small minority of jurisdictions reject the affirmative defense approach and instead apply comment k to exempt all prescription drugs from strict liability.[49] In *Brown v. Superior Court*[50] the California Supreme Court outlined three basic policy reasons supporting the minority view. First, the court reasoned that a case-by-case analysis of drug products is a disincentive to the development and production of new drugs because the manufacturer cannot predict whether the drug would be eligible for favorable treatment.[51] Second, the manufacturer is deterred from providing a superior product if a trial court might decide, years later, that another product could have accomplished the same result with less risk.[52] Finally, the Food and Drug Administration must test and approve the new prescription drug before it is sold. Any further delay while the manufacturer tests for unknown risks would not serve the public interest since the new drug might save lives or reduce pain and suffering.[53]

Whether comment k is applied to all prescription drugs or only as an affirmative defense, the manufacturer must show that adequate warning was given about the harmful risks and side effects of the drug before the defense is allowed.[54] Usually, the prescription product manu-

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45. *Id.*

46. *See* cases cited *supra* notes 29 & 41.

47. *See, e.g.*, Kearl v. Lederle Lab., 218 Cal. Rptr. 453, (Ct. App. 1985), *overruled in part by*, Brown v. Superior Court, 751 P.2d 470 (Cal. 1988).

48. *Id.*

49. *See, e.g.*, Brown v. Superior Court, 751 P.2d 470 (Cal. 1988); Lindsey v. Ortho Pharmaceutical Corp., 637 F.2d 87 (2d Cir. 1980) (applying New York law); McKee v. Moore, 648 P.2d 21 (Okla. 1982); Terhune v. A.H. Robins Co., 577 P.2d 975 (Wash. 1978).

50. 751 P.2d 470 (Cal. 1988).

51. *Id.* at 482.

52. *Id.*

53. *Id.* at 479.

54. The RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965) requires that the product is "accompanied by proper directions and warning." See *supra* note 9 for full text of comment k.

facturer is shielded from an inadequate warning claim by the learned intermediary rule.[55]

According to the learned intermediary rule, the physician is interposed between the drug manufacturer and the user of the drug.[56] Rather than a direct warning to the patient, the company's duty to warn can be satisfied by warning the physician who selects the drug.[57] Since the physician makes an independent judgment in the patient's interest, early cases concluded that patient labelling was superfluous.[58] The common policy was to allow the drug manufacturer to rely upon the physician to warn the patient of the risks of the drug.[59]

Several courts have outlined the advantages of allowing the drug manufacturer to use the learned intermediary rule. A direct warning to the patient may interfere with the doctor-patient relationship and the independent judgment of the doctor, violating the ethical practice of medicine.[60] Also, the warning of possible side effects often contains information that is too technical for the patient to understand.[61] Additionally, direct communication from the drug manufacturer to the patient may be virtually impossible.[62] Finally, a direct warning to the user may be impractical because it does not fully reflect the individual factors involved in selecting a treatment.[63]

For prescription drugs generally, the majority of jurisdictions have

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55. *See, e.g., In re* Certified Questions, 358 N.W.2d 873, 881 n.4 (Mich. 1984) (Boyle, J., dissenting) (listing 31 jurisdictions adopting the "learned intermediary rule" for prescription drugs). *See also* Margaret Gilhooley, *Learned Intermediaries, Prescription Drugs, and Patient Information*, 30 ST. LOUIS U. L.J. 633, 644 (1986) (The learned intermediary doctrine is a general rule with virtually unanimous acceptance.).

56. Gilhooley, *supra* note 55, at 642-44. The term "learned intermediary" was first used in Sterling Drugs, Inc. v. Cornish, 370 F.2d 82 (8th Cir. 1966). The term was used to describe the physician's role in warning the patient. 370 F.2d at 85.

57. Gilhooley, *supra* note 55, at 642-44.

58. *See, e.g.*, Stottlemire v. Cawood, 213 F. Supp. 897, 899 (D.C. Cir. 1963). *See also* Paul D. Rheingold, *Products Liability—The Ethical Drug Manufacturer's Liability*, 18 RUTGERS L. REV. 947, 987 (1964).

59. Gilhooley, *supra* note 55, at 642-44.

60. *See, e.g.*, Hill v. Searle Lab., 884 F.2d 1064, 1070 (8th Cir. 1989); Drunkin v. Syntex Lab., Inc., 443 F. Supp. 121, 123 (W.D. Tenn. 1977); Carmichael v. Reitz, 95 Cal. Rptr. 381, 400 (Ct. App. 1971).

61. *See, e.g., Hill*, 884 F.2d at 1070; Reyes v. Wyeth Lab., 498 F.2d 1264, 1276 (5th Cir.), *cert. denied*, 419 U.S. 1096 (1974).

62. *See, e.g., Hill*, 884 F.2d at 1070; *Terhune*, 577 P.2d at 978 (Although this case concerns a prescription intrauterine device, rather than a prescription drug, the principles are the same.).

63. *See, e.g., Reyes*, 498 F.2d at 1276 (5th Cir. 1974); Davis v. Wyeth Lab., 399 F.2d 121, 130 (9th Cir. 1968).

concluded that the manufacturer's duty to adequately warn is satisfied by warning the prescribing physician.[64] The rationale for allowing the learned intermediary rule is that injury to the patient is best avoided by warning the physician because the selection and treatment with a prescription product is a medical decision and not a patient decision.[65]

An exception to the learned intermediary rule was developed by the Fifth Circuit Court of Appeals in *Reyes v. Wyeth Laboratories*.[66] The court held that the manufacturer of a polio vaccine did have a duty to directly warn the patient when the vaccine was used in a mass inoculation program because the policy considerations for the learned intermediary rule were not present.[67] In *Reyes*, the court explained that the manufacturer must either directly warn the recipient of the prescription drug or warn the prescribing physician in those cases in which the doctor makes an independent judgment as to selection of and treatment with the drug.[68] The court applied this test to the facts regarding the polio vaccination program and concluded that the mass inoculation program did not involve an individualized medical decision, so the manufacturer could not use the learned intermediary rule to satisfy its duty of adequate warning.[69]

Using similar analysis to the *Reyes* decision, a small number of courts held that the manufacturer of contraceptive products must warn patients directly rather than use the learned intermediary rule.[70] These courts observed that, unlike most other prescription products, the use of contraceptives is a decision actively made by the patient rather than the physician.[71] After the initial decision and treatment, there is little

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64. *See supra* note 55.

65. Gilhooley, *supra* note 55, at 643-45.

66. 498 F.2d 1264 (5th Cir.), *cert. denied*, 419 U.S. 1096 (1974).

67. *Id.* at 1294.

68. *Id.* at 1295. Often referred to as the *Reyes* test, the court reasoned:

> [I]n the case of a prescription drug which is unavoidably unsafe, and as to which there is a certain, though small, risk throughout the population, there must be *either* a warning—meaningful and complete so as to be understood by the recipient—*or* an individualized medical judgment that this treatment or medication is necessary and desirable for this patient.

Id. (emphasis in original).

69. *Id.*

70. *See, e.g.*, Odgers v. Ortho Pharmaceuticals, 609 F. Supp. 867 (E.D. Mich. 1985) (applying Michigan law); Stephens v. G.D. Searle, 602 F. Supp. 379 (E.D. Mich. 1985) (applying Michigan law); MacDonald v. Ortho Pharmaceutical Corp., 475 N.E.2d 65 (Mass.), *cert. denied*, 474 U.S. 920 (1985).

71. Hill v. Searle Lab., 884 F.2d 1064, 1070-71 n.11 (8th Cir. 1989) (summarizing the cases cited *supra* note 70).

contact between the patient and doctor.[72] The courts in these jurisdictions concluded that the learned intermediary rule should not be used for contraceptive products because the physician does not make an individualized medical decision.[73]

The large majority of courts concluded that contraceptive products should not be an exception to the learned intermediary rule.[74] These courts cogently argued that the physician makes an individualized medical decision in selection and treatment involving contraceptive products.[75] For example, the court in *Allen v. Searle Laboratories*[76] asserted that "the physician makes the ultimate decision as to whether a particular contraceptive requested by a patient is appropriate."[77] The learned intermediary rule has been applied to both oral contraceptives and intrauterine devices.[78]

Until the *West* decision, the Arkansas Supreme Court avoided ruling upon comment k or the learned intermediary rule. The court declined to adopt strict liability for any products until the Arkansas legislature passed Act 111 in 1973.[79] The legislature further defined strict

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72. *Id.*

73. *Id.*

74. *See, e.g.*, Beyette v. Ortho Pharmaceutical Corp., 823 F.2d 990 (6th Cir. 1987) (applying Michigan law); Brochu v. Ortho Pharmaceutical Corp., 642 F.2d 652 (1st Cir. 1981) (applying New Hampshire law); Lindsay v. Ortho Pharmaceutical Corp., 637 F.2d 87 (2d Cir. 1980) (applying New York law); Kociemba v. G.D. Searle & Co., 680 F. Supp. 1293 (D. Minn. 1988) (applying Minnesota law); Tarallo v. Searle Pharmaceutical, Inc., 704 F. Supp. 653 (D.S.C. 1988) (applying South Carolina law); Goodson v. Searle Lab., 471 F. Supp. 546 (D. Conn. 1978) (applying Connecticut law); Drunkin v. Syntex Lab, Inc., 443 F. Supp. 121 (W.D. Tenn. 1977) (applying Tennessee law); Stafford v. Nipp, 502 So.2d 702 (Ala. 1987); Carmichael v. Reitz, 95 Cal. Rptr 381 (Ct. App. 1971); Hamilton v. Hardy, 549 P.2d 1099 (Colo. Ct. App. 1976); Lacy v. G.D. Searle & Co., 567 A.2d 398 (Del. 1989); Ricci v. Parke-Davis & Co., 491 So.2d 1182 (Fla. Dist. Ct. App. 1986); Lawson v. G.D. Searle & Co., 356 N.E.2d 779 (Ill. 1976); Ortho Pharmaceutical Corp. v. Chapman, 388 N.E.2d 541 (Ind. Ct. App. 1979); Moore v. Vanderloo, 386 N.W.2d 108 (Iowa 1986); Rhoto v. Ribando, 504 So.2d 1119 (La. Ct. App. 1987); Seley v. G.D. Searle & Co., 423 N.E.2d 831 (Ohio 1981); McKee v. Moore, 648 P.2d 21 (Okla. 1982); McEwen v. Ortho Pharmaceutical Corp., 528 P.2d 522 (Or. 1974); Leibowitz v. Ortho Pharmaceutical Corp., 307 A.2d 449 (Pa. Super. Ct. 1973); Terhune v. A.H. Robins Co., 577 P.2d 975 (Wash. 1978).

75. *See, e.g.*, *Seley*, 423 N.E.2d at 840 (the patient relies upon the physician's judgment in selecting the drug and advising the patient in its use); *Lacy*, 567 A.2d at 401 (the patient relies upon her physician's expertise in selecting and fitting an intrauterine device).

76. 708 F. Supp. 1142 (D. Or. 1989).

77. *Id.* at 1148.

78. *See* cases cited *supra* note 75.

79. ARK. CODE ANN. § 4-86-102 (Michie 1987). The Arkansas Supreme Court avoided adopting strict liability in Gatlin v. Cooper Tire & Rubber Co., 252 Ark. 839, 481 S.W.2d 338 (1972) and in Higgins v. General Motors Co., 250 Ark. 551, 465 S.W.2d 898 (1971). *See also*

liability in Act 511 of 1979, the Arkansas Products Liability Act.[80] Both of these acts were substantially the same as the strict liability concepts outlined in section 402A of the *Restatement (Second) of Torts*.[81] The Arkansas Supreme Court has used the comments to section 402A when interpreting these laws even though the comments were not part of the 1973 or 1979 acts.[82]

In 1989 the Eighth Circuit Court of Appeals attempted to predict how the Arkansas courts would address strict liability issues involving comment k, the learned intermediary rule, and the exception for oral contraceptives. In *Hill v. Searle Laboratories*,[83] an intrauterine device (IUD) was inserted into the patient's uterus by a physician who had received appropriate warnings of possible complications.[84] It was discovered three years later that the IUD had perforated the patient's uterus and was partially embedded in the small bowel.[85] The patient and her husband brought a products liability action against the manufacturer of the IUD.[86] The trial court granted summary judgment for the manufacturer, reasoning that the IUD was a prescription product under comment k of section 402A.[87] The trial court further reasoned that the learned intermediary rule applied to IUDs and that the patient's doctor received adequate warning of the risk of perforation.[88] The patient and her husband appealed.[89]

The Eighth Circuit Court of Appeals first considered whether the Arkansas courts would adopt comment k. They observed that most other jurisdictions have adopted the comment k doctrine, and that the Arkansas Supreme Court implicitly adopted some of the comments to section 402A.[90] The Eighth Circuit agreed with the trial court and the

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Blagg v. Fred Hunt Co., 272 Ark. 185, 612 S.W.2d 321 (1981) (discussing past strict liability cases in Arkansas).

80. ARK. CODE ANN. §§ 16-116-101 to -107 (Michie 1987).

81. Henry Woods, *Product Liability: Is Comparative Fault Winning the Day?*, 36 ARK. L. REV. 360, 364 (1982).

82. *See, e.g.*, Berkeley Pump Co. v. Reed-Joseph Land Co., 653 S.W.2d 128, 133 (1983) (refers to the comments to § 402A in construing the Arkansas Products Liability Act); General Motors Corp. v. Tate, 257 Ark. 347, 353, 516 S.W.2d 602, 606 (1974) (refers to comment m to Section 402A in construing Act 111).

83. 884 F.2d 1064 (8th Cir. 1989).

84. *Id.* at 1065-66.

85. *Id.* at 1065.

86. *Id.*

87. *Id.*

88. *Id.*

89. *Id.*

90. *Id.* at 1067.

defendant manufacturer that the Arkansas courts would adopt comment k as a defense to strict liability for prescription products.[91]

Next, the court discussed whether the Arkansas courts would use comment k as an affirmative defense. The Eighth Circuit agreed with jurisdictions that considered it an affirmative defense, requiring a case-by-case analysis that the benefit outweighed the risk of the product before allowing the use of comment k.[92] The court reasoned that the wording of comment k itself suggests that it is limited to special products that fill an "exceptional social need."[93] Also, public policy considerations justified limiting comment k to an affirmative defense because it would be inconsistent to have a blanket exemption for prescription products and not other products having life-bettering or life-saving characteristics.[94] The appeals court reversed the summary judgment on this issue and ruled that an IUD is not within the scope of comment k.[95]

The Eighth Circuit predicted that Arkansas would adopt the test in *Reyes* when applying the learned intermediary rule to prescription products.[96] The court noted that the physician is interposed between the manufacturer and the patient, that the warning of risks is often too technical for the patient to analyze, and that the manufacturer is often incapable of directly warning the patient.[97] The court concluded that an individualized medical decision by the physician is required before the manufacturer could satisfy its duty of warning with the learned intermediary rule.[98]

In applying the *Reyes* test to the facts in *Hill*, the Eighth Circuit concluded that the selection and use of the IUD did not require an intervening, individualized medical decision.[99] The court discussed the minority rule which emphasized the limited input by the physician when prescribing contraceptive products.[100] It incorrectly predicted that Arkansas would not allow the application of the learned intermedi-

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91. *Id.*
92. *Id.* at 1069.
93. *Id.*
94. *Id.*
95. *Id.* at 1070.
96. *Id.*
97. *Id. See also supra* notes 60-63 and accompanying text.
98. 884 F.2d at 1070.
99. *Id.* at 1070-71.
100. *Id. See also supra* notes 70-73 and accompanying text.

ary rule in cases involving contraceptives.[101] The Eighth Circuit reversed summary judgment on this issue because there was a dispute in the record whether the patient had received adequate direct warning of the risks of harm.[102]

In *West v. Searle & Co.* the Arkansas Supreme Court adopted comment k.[103] The court further held that the comment should be applied as an affirmative defense which requires the defendant manufacturer to prove the product was unavoidably dangerous.[104] Finally, the court ruled that on the issue of adequate warning, the learned intermediary rule should be applied in cases involving oral contraceptives.[105]

The supreme court first addressed the policy reasons for adopting comment k. The court reasoned that comment k represents a judgment that some prescription drugs, despite unavoidable risk of harm, are so beneficial to society that their manufacturers should not be held strictly liable for providing them.[106] Otherwise, the potential liability from the inherent risk of harm might increase the costs of these important products beyond the reach of the people who need them.[107] The court was influenced by the fact that only one court has declined to adopt comment k.[108]

After adopting comment k, the court was faced with choosing between applying it to all prescription drugs or treating it as an affirmative defense.[109] Once again, the court elected to follow the majority approach and interpret the comment as an affirmative defense.[110] The court reasoned that the wording of the comment itself indicates that only "some" drugs out of all prescription drugs were intended to be

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101. 884 F.2d at 1070-71.

102. *Id.* at 1071.

103. 305 Ark. 33, 40, 806 S.W.2d 608, 612 (1991). Rather than affirming the trial court's summary judgment for the defendants, the supreme court ordered dismissal without prejudice for all but one of the claims, because the pleadings provided issue rather than factual notice as required by ARK. R. CIV. P. 8. *Id.* at 36, 806 S.W.2d at 610. The defendants answered the claim of strict liability for defective design by raising the defense of comment k. The court reasoned that their answer implied a tacit assumption that the claim was valid, if the comment k defense is valid in Arkansas. Thus, the supreme court addressed whether to adopt comment k and how to apply it under Arkansas law. *Id.* at 37-38, 806 S.W.2d at 611.

104. 305 Ark. at 41, 806 S.W.2d at 612-13.

105. *Id.* at 44, 806 S.W.2d at 614.

106. *Id.* at 39, 806 S.W.2d at 611.

107. *Id.*

108. *Id. See also supra* note 30 and accompanying text.

109. 305 Ark. at 39-40, 806 S.W.2d at 612.

110. *Id.* at 40, 806 S.W.2d at 612.

protected by the comment k exception.[111] The court was also influenced by the rejection of a blanket exemption for all prescription drugs by the American Law Institute membership when discussing the adoption of section 402A.[112]

In using comment k as an affirmative defense, the manufacturer must show that the prescription product is unavoidably unsafe.[113] In determining whether the manufacturer has satisfied this burden of proof, the court referred to the guidelines in *Toner* to evaluate whether there is an alternative feasible product with lesser risk.[114] The Arkansas court observed that risk-benefit analysis only requires that the "balance 'apparently' tip toward the benefit of a product at the time of distribution."[115]

Having adopted comment k as an affirmative defense, the court moved on to the issue of what constitutes adequate warning of the unsafe nature of the product.[116] According to the wording of comment k, the seller of a proven unavoidably unsafe product may avoid strict liability for the consequences of the product's use by providing "proper directions and warning."[117] The court noted that the duty of adequate warning, as a general rule, requires that the manufacturer directly warn the consumer of a product of its risks.[118] However, almost all jurisdictions recognize the learned intermediary rule as an exception to the general requirement of direct warning.[119] The court agreed that a drug manufacturer should be allowed to rely upon the prescribing doctor to warn the patient of the risks of a prescription drug.[120] Finally, the Arkansas Supreme Court recognized that three cases have rejected the learned intermediary doctrine in cases involving contraceptives.[121] The court rejected the reasoning of those cases that a physician fills only a passive role in a patient's decision to take an oral contracep-

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111. *Id.*

112. *Id. See* 38 A.L.I. PROC. 19, at 97-98 (1961).

113. 305 Ark. at 41, 806 S.W.2d at 612.

114. *Id. See also supra* notes 41-45 and accompanying text.

115. 305 Ark. at 41, 806 S.W.2d at 613.

116. *Id.* at 42, 806 S.W.2d at 613 (quoting RESTATEMENT (SECOND) TORTS § 402A cmt. k (1977)).

117. *Id.* Usually the manufacturer has a duty to warn the consumer of a product under both negligence and strict liability theories. *See Madden, supra* note 16, §§ 10.3-10.4.

118. 305 Ark. at 42, 806 S.W.2d at 613.

119. *Id.*

120. *Id. See also supra* notes 54-59 and accompanying text.

121. 305 Ark. at 43-44, 806 S.W.2d at 613-14. *See also supra* notes 70-73 and accompanying text.

tive.[122] In contrast, the court concluded that although the patient may make the initial choice regarding birth control, "after that, the physician would exercise his medical judgment concerning the best method of contraception for his patient."[123] Therefore, the court found the learned intermediary rule applicable to cases involving oral contraceptives.[124]

The Arkansas Supreme Court elected not to decide whether it would follow *Reyes* and require an individualized medical decision before allowing the use of the learned intermediary rule.[125] The court determined that it was unnecessary to make that decision because the "stated public policy reasons for the learned intermediary doctrine are present with respect to oral contraceptives."[126]

Although it did not address the scope of the *Reyes* test, *West v. Searle & Co.* is still one of the court's more significant recent rulings. The Arkansas Supreme Court for the first time explicitly adopted the comment k doctrine of unavoidably unsafe products and provided guidelines for its application.

The court followed the vast majority of jurisdictions in adopting comment k as an affirmative defense. Also, the court rejected the *per se* application of comment k to all prescription drugs, as advocated by the California Supreme Court in *Brown*.[127]

The Arkansas court's decision to limit comment k to an affirmative defense has important implications for plaintiffs and defendants in prescription product cases. In a typical case involving an allegedly defective design, the plaintiff is often required to use risk-utility analysis and show the existence of a feasible alternative product.[128] In contrast, when a drug manufacturer raises the comment k defense in response to

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122. *Id.* at 44, 806 S.W.2d at 614.

123. *Id.*

124. *Id.*

125. *Id.*

126. *Id. See also supra* notes 75-77 and accompanying text.

127. 305 Ark. at 40, 806 S.W.2d at 612 (the court cites and rejects the decision in *Brown*, 751 P.2d 470 (Cal. 1988)). One justice dissented from the majority opinion. He would adopt comment k as a blanket exemption for all prescription drugs for the reasons outlined in *Brown*. 305 Ark. at 45-46, 806 S.W.2d at 615 (Hayes, J., dissenting). *See also supra* notes 50-53 and accompanying text.

128. MADDEN *supra* note 16, § 6.12, at 233. However, Arkansas does not require the plaintiff to prove the feasibility of an alternative safer design, but rather lets the jury consider it as a factor in determining if the product was in a defective condition unreasonably dangerous. *See* ARK. CODE ANN. § 16-116-104 (Michie 1987); French v. Grove Mfg. Co., 656 F.2d 295, 298-99 (8th Cir. 1981).

a claim that one of its products was defectively designed, the *West* court allocated the burden of showing utility greater than risk to the defendant manufacturer.[129] In evaluating the drug manufacturer's proof of risk-utility, the court also shifted the burden of showing the lack of a feasible alternative product from the plaintiff to the manufacturer.[130]

The Arkansas Supreme Court's choice of risk-utility analysis contrasts with the statutory incorporation of the consumer contemplation test by the Arkansas Products Liability Act.[131] The risk-utility test defines unreasonably dangerous as the magnitude of the risk of harm outweighing the benefit of the product.[132] On the other hand, the consumer contemplation test evaluates whether the product is dangerous to an extent beyond that which would be considered by an ordinary user with common knowledge of the product's characteristics.[133] When the drug manufacturer raises the comment k defense, the ruling in *West* changed the emphasis from the plaintiff's proof of what a reasonable consumer would contemplate to the defendant's focus upon risk-utility.

In *West* the court also required the drug manufacturer to prove that the warning was adequate prior to using the comment k defense.[134] Usually, the plaintiff must prove inadequate warning to recover under a failure to warn theory of strict liability.[135] The *West* decision shifted the burden of proof that is usually borne by the plaintiff to the drug manufacturer raising comment k as an affirmative defense.

Finally, the court addressed the learned intermediary rule and declined to decide whether to adopt the Eighth Circuit's limited approach in *Reyes*, which requires an individualized medical decision before ap-

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129. 305 Ark. at 41, 806 S.W.2d at 612. The court ruled "for the comment to protect the designer of the product, the benefit of the product must outweigh the risk." *Id.*

130. *Id.* The court reasoned "the designer of the drug must show that the product is 'unavoidably unsafe.' Necessarily then, there must be no feasible alternative design . . . ." *Id.*

131. ARK. CODE ANN. § 16-116-102 (Michie 1987) provides:

> Unreasonably dangerous means that a product is dangerous to an extent beyond that which would be contemplated by the ordinary and reasonable buyer, consumer, or user who acquires or uses the product, assuming the ordinary knowledge of the community or of similar buyers, users, or consumers as to its characteristics, propensities, risks, dangers, and proper and improper uses . . . .

132. KEETON *et al.*, *supra* note 14, § 99, at 699.

133. KEETON *et al.*, *supra* note 14, § 99, at 698.

134. 305 Ark. at 42, 806 S.W.2d 608, 613. The court ruled "adequate warning of danger . . . must be proved before a judgment is granted on the basis of the affirmative defense set out in comment k." *Id.*

135. KEETON *et al.*, *supra* note 14, § 99, at 697.

plying the rule.[136] This approach provides the court greater flexibility in future cases, allowing it to balance the goals of patient autonomy and informed consent with the benefits of the learned intermediary rule.

The Arkansas Supreme Court's interpretation of comment k promotes consistency in the law and good public policy. Under the court's approach, prescription drugs of limited social value, such as depilatory agents, will be treated like most other commercial products, and the consumer has increased protection from the product's risk of harm through the application of strict liability. The protective umbrella of comment k will be reserved for highly beneficial prescription products for which the defendant manufacturer can show benefit exceeding risk and that there is no safer alternative product available serving the same needs.

Ian Birkett

136. 305 Ark. at 44, 806 S.W.2d at 614. *See also supra* notes 66-69 and accompanying text.