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# Prescription Drugs and Strict Liability: The Flaw in The Ointment

California courts have led the nation in the development of strict products liability.<sup>1</sup> Imposing liability based on defect rather than fault, these modern judicial decisions attempt to protect consumers rendered vulnerable by an industrial society.<sup>2</sup> As the basis of liability has shifted so has the focus of the judicial inquiry. In a negligence action, which ties liability to fault, the jury focuses on the reasonableness of a manufacturer's conduct.<sup>3</sup> In a strict product liability action, which ties liability to defect, the jury focuses on the condition of the product.<sup>4</sup> Under the doctrine of strict products liability, a manufacturer is liable if the product is defective as manufactured, if the product is defective as designed or if the product lacks an adequate warning.<sup>5</sup> A manufacturing defect results from an error in the production process.<sup>6</sup> A design defect is endemic to an entire line of products.<sup>7</sup> A warning defect occurs when the product poses sufficient risks to the user without a suitable warning that the product becomes defective simply because the product lacks a warning.<sup>8</sup> If a

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1. *Kearl v. Lederle Laboratories*, 172 Cal. App. 3d 812, 821, 218 Cal. Rptr. 453, 458 (1985). See also *Greenman v. Yuba Power Prods., Inc.*, 59 Cal. 2d 57, 377 P.2d 897, 27 Cal. Rptr. 697 (1962). See Prosser, *The Assault on the Citadel, Strict Liability to the Consumer*, 69 YALE L.J. 1099 (1960) (discussing the early development of strict products liability).

2. *Barker v. Lull Eng'g. Co.*, 20 Cal. 3d 413, 435, 573 P.2d 443, 457, 143 Cal. Rptr. 225, 239 (1978) (quoting Keeton, *Product Liability and the Meaning of Defect*, 5 ST. MARY'S L.J. 30, 33 (1973)).

3. *Kearl*, 172 Cal. App. 3d at 822, 218 Cal. Rptr. at 458. See also *Feldman v. Lederle Laboratories*, 97 N.J. 429, 479 A. 2d 374, 385 (N.J. 1984).

4. *Barker*, 20 Cal. 3d at 418, 573 P.2d at 447, 143 Cal. Rptr. at 229. In *Barker* the court stated: "[I]n a product liability action, the trier of fact must focus on the product, not on the manufacturer's conduct. The plaintiff need not prove that the manufacturer acted unreasonably or negligently in order to prevail in such an action." *Id.*

5. *Cavers v. Cushman Motors*, 95 Cal. App. 3d, 338, 343, 157 Cal. Rptr. 142, 145 (1979).

6. *Barker*, 20 Cal. 3d at 429, 573 P.2d at 454, 143 Cal. Rptr. at 236.

7. *Id.*

8. *Cavers*, 20 Cal. 3d at 347, 157 Cal. Rptr. at 147. See also *Finn v. G.D. Searle & Co.*, 35 Cal. 3d 691, 700, 677 P.2d 1147, 1152, 200 Cal. Rptr. 870, 875 (1979).

defect exists, the manufacturer is liable even though the manufacturer has not been found negligent. Strict liability seeks to reduce consumer injuries caused by defective products.<sup>9</sup>

In considering prescription drugs, however, courts have been willing to sacrifice consumer protection. California appellate courts, for reasons of public policy, have often exempted prescription drugs from strict liability for design or warning defects.<sup>10</sup> Believing that prescription drugs are qualitatively different from other products, these courts have held pharmaceutical manufacturers strictly liable for only manufacturing defects.<sup>11</sup> Although recognizing the harm that drug side effects can cause, these courts have feared the consequences of applying strict liability to important life saving drugs.<sup>12</sup> While the California Supreme Court has never directly addressed the question whether prescription drugs are subject to strict liability for design or warning defects,<sup>13</sup> several appellate courts have recently decided cases involving prescription drugs.<sup>14</sup> These courts, however, have reached differing conclusions concerning the applicability of strict liability principles to prescription drugs.<sup>15</sup>

The purpose of this comment is to evaluate the application of strict liability in California to prescription drugs. The development of strict liability in California will be briefly discussed.<sup>16</sup> This com-

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9. *Greenman v. Yuba Power Products, Inc.*, 59 Cal. 2d 57, 60, 377 P.2d 897, 901, 27 Cal. Rptr. 697, 700 (1962).

10. *Brown v. Superior Court*, 182 Cal. App. 3d 1125, 1135, 227 Cal. Rptr. 768, 774 (1986) *review granted* Sept. 18, 1986. *See, e.g.*, *McCreery v. Eli Lilly & Co.* 87 Cal. App. 3d 77, 86-7, 150 Cal. Rptr. 730, 736 (1978), *Carmichael v. Reitz* 17 Cal. App. 3d 958, 987-89, 95 Cal. Rptr. 381, 400 (1971), *Toole v. Richardson-Merrell Inc.* 251 Cal. App. 2d 689, 708-11, 60 Cal. Rptr. 398, 412 (1967), *But see Finn v. G.D.Searle*, 35 Cal. 3d 691, 720, 677 P. 2d 1147, 1166, 200 Cal. Rptr. 870, 889 (1984) (dis. opn. of Bird, C.J.). *See infra* notes 59-78 and accompanying text for a discussion of the policy reasons.

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

12. *Id.* at 824, 218 Cal. Rptr. at 460.

13. *See Finn v. G.D. Searle & Co.*, 35 Cal. 3d 691, 698, 677 P.2d 1147, 1151, 200 Cal. Rptr. 870, 874 (1984) (expressly avoiding the issue).

14. *See Kearl*, 172 Cal. App. 3d 812, 218 Cal. Rptr. 453 (1985), *Brown v. Superior Court*, 182 Cal. App. 3d 1125, 227 Cal. Rptr. 768 (1986); *Flood v. Wyeth Laboratories, Inc.*, 183 Cal. App. 3d 1272, 228 Cal. Rptr. 700 (1986); *Collins v. Ortho Pharmaceutical Corp.*, 186 Cal. App. 3d 1194, 231 Cal. Rptr. 396 (1986), *review granted*, Feb 26, 1987.

15. *See Kearl*, 172 Cal. App. 3d 812, 829, 218 Cal. Rptr. 453, 463, (the decision to exempt prescription drugs from strict liability should be made on a case by case basis); *Brown*, 82 Cal. App. 3d 1125, 1137, n.4, 227 Cal. Rptr. 768, 775, n.4 (Restatement 402A comment k immunizes prescription drugs from strict liability); *Flood*, 183 Cal. App. 3d 1272, 1276, 228 Cal. Rptr. 700, 702 (manufacturers of vaccines are subject to strict liability for design defect); *Collins*, 186 Cal. App. 3d 1194, 1210, 231 Cal. Rptr. 396, 406 (when approved by the FDA and accompanied by a proper warning prescription drugs are exempt from strict liability for design defect).

16. *See infra* notes 19-55 and accompanying text.

ment will then analyze several appellate court decisions concerning prescription drugs and discuss the policies underlying those decisions.<sup>17</sup> Finally, this comment will propose that strict liability be applied to prescription drugs.<sup>18</sup>

#### EVOLUTION OF STRICT PRODUCTS LIABILITY IN CALIFORNIA

California pioneered the development and subsequent expansion of the theory that manufacturers are strictly liable in tort for injuries to persons caused by defects in their products.<sup>19</sup> Strict product liability first appeared in California in Justice Traynor's concurrence in *Escola v. Coca Cola Bottling Co.*<sup>20</sup> Justice Traynor stated that a manufacturer should incur absolute liability when a product that the manufacturer has placed on the market, knowing that the product is to be used without inspection, proves to have a defect that causes injury.<sup>21</sup>

Justice Traynor's theory became law in *Greenman v. Yuba Power Products, Inc.*<sup>22</sup> in which the Supreme Court established strict liability as California law.<sup>23</sup> The court stated that the purpose of strict liability is to insure that the costs of injuries resulting from defective products are borne by manufacturers who put products on the market rather than by injured persons who are unable to protect themselves.<sup>24</sup> The trend to strict liability was subsequently reflected in the Restatement of Torts, Second.

Section 402A of Restatement 2d provides that one is strictly liable in tort for selling any product in an unreasonably dangerous defective condition.<sup>25</sup> In *Cronin v. J.B.E. Olson Corp.*,<sup>26</sup> however, the California Supreme Court rejected the section 402A requirement that a product be both defective and unreasonably dangerous.<sup>27</sup> The court stated that the unreasonably dangerous requirement is an element of

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17. For the purposes of this comment both vaccines and prescription drugs will be considered prescription drugs since neither can be administered except under the auspices of a physician or a clinic. See *infra* notes 59-169 and accompanying text.

18. See *infra* notes 198-214 and accompanying text.

19. *Fluor Corp. v. Jepperson*, 170 Cal. App. 3d 468, 474, 216 Cal. Rptr. 68, 71 (1986).

20. 24 Cal. 2d 453, 150 P. 2d 436 (1944).

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

22. 59 Cal. 2d 57, 377 P.2d 897, 27 Cal. Rptr. 697 (1963).

23. *Id.* at 63, 377 P.2d at 901, 27 Cal. Rptr. at 700 (the liability is not governed by the law of contract warranties but by the law of strict liability in tort).

24. *Id.*

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

26. 8 Cal. 3d 121, 501 P.2d 1153, 104 Cal. Rptr. 433 (1972).

27. *Id.* at 133, 501 P.2d at 1162, 104 Cal. Rptr. at 442.

negligence that is unnecessary in a strict liability action.<sup>28</sup> Since one goal in developing the theory of strict liability was to relieve plaintiffs from the problems of proof inherent in pursuing negligence and warranty remedies,<sup>29</sup> the court held that in both manufacturing and design defect cases a plaintiff need only prove the existence of a defect in a product and prove that the defect proximately caused his injury.<sup>30</sup> However the court acknowledged the difficulty in giving meaning to the defectiveness standard.<sup>31</sup>

#### A. Design Defects

In *Barker v. Lull Engineering Company*,<sup>32</sup> the California Supreme Court defined design defect.<sup>33</sup> The court in *Barker* held that a product can be defective in design in two alternative ways. First, the product is defective when it fails to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner.<sup>34</sup> Second, the product is defective in design if in light of certain relevant factors<sup>35</sup> the benefits of the challenged design do not outweigh the risk of danger inherent in the design.<sup>36</sup> The product itself is the focus of attention rather than the reasonableness of the manufacturer's conduct.<sup>37</sup> The *Barker* court emphasized that a plaintiff proceeding under the risk benefit standard need establish only a prima facie showing of causation.<sup>38</sup> Once the plaintiff has made this showing, the defendant must prove that the product is not defective in light of the risk-benefit factors.<sup>39</sup>

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28. *Id.*

29. *Id.*

30. *Id.*

31. *Id.* at 134, 501 P.2d at 1163, 104 Cal. Rptr. at 443 (quoting Traynor, *The Ways and Meanings of Defective Products and Strict Liability*, 32 TENN. L. REV. 363, 373 (1965) (No single definition has proved adequate to define the scope of the manufacturer's strict liability. The strict liability of the manufacturer is limited, however, to physical injury to person's and property)).

32. 20 Cal. 3d 413, 573 P.2d 443, 143 Cal.Rptr. 225 (1978).

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

34. *Id.*

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

36. *Id.* at 32, 573 P.2d at 456, 143 Cal. Rptr. at 238.

37. *Id.* at 432, 573 P.2d at 456, 143 Cal. Rptr. at 238.

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

39. *Id.*

The *Barker* court identified three significant differences between strict liability and negligence in a design defect case. First, the strict liability inquiry focuses on the product, not the manufacturer's conduct.<sup>40</sup> Second, under strict liability the fact finder looks at the defect causing injury in hindsight.<sup>41</sup> Finally, once the plaintiff establishes causation, the burden shifts to the defendant to prove that the benefits of the product outweigh the risks.<sup>42</sup>

The concept of defect has been extended to a great variety of injury producing deficiencies. These defects range from products that cause injury because they deviate from the manufacturer's intended result<sup>43</sup> to products which, though perfectly manufactured, are unsafe because of a defect in their design or the absence of a safety device.<sup>44</sup> Products may also be defective because they lack adequate warning or instructions.<sup>45</sup>

### B. Warning Defects

In California, the failure to warn of dangers inherent in a product has been considered a category of defect separate from manufacturing or design defects.<sup>46</sup> Beginning with *Canifax v. Hercules Powder Co.*,<sup>47</sup> California courts have held that a product although faultlessly made may nevertheless be defective.<sup>48</sup> The court in *Canifax* held that a product is subject to strict liability if it is unreasonably dangerous to place the product in the hands of a user without a suitable warning and the product is supplied without a warning.<sup>49</sup>

Court of appeal decisions subsequent to *Canifax* do not clearly indicate whether in a warning defect case, unlike a design defect case, a product must be unreasonably dangerous to impose liability.<sup>50</sup> Where the only defect is the lack of an adequate warning, courts have differed in the standard used for the imposition of strict liability.<sup>51</sup> Some courts have held that where imposition of liability

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40. *Id.* at 434, 573 P.2d at 457, 143 Cal. Rptr. at 239.

41. *Id.*

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

43. *Id.* at 428, 573 P.2d at 453, 143 Cal. Rptr. at 235.

44. *Id.*

45. *Id.*

46. *Cavers v. Cushman Motors*, 95 Cal. App. 3d 336, 343, 157 Cal. Rptr. 142, 145.(1979).

47. 237 Cal. App. 2d 44, 46 Cal. Rptr. 552 (1965).

48. *Id.* at 53, 46 Cal. Rptr. at 558.

49. *Id.*

50. *Cavers*, 95 Cal. App. 3d at 345, 157 Cal. Rptr. 146.

51. *Finn v. G.D. Searle & Co.*, 35 Cal. 3d 691, 699, 677 P.2d 1147, 1151, 200 Cal. Rptr.

is contingent upon the finding of dangers which were or should have been known, concepts from negligence law have been amalgamated into the doctrine of strict liability.<sup>52</sup> Another appellate court has held that rules conditioning liability on knowledge of danger are rules fixing duties of care<sup>53</sup> and that rules expressed in comment j, Restatement 2d of Torts, although applicable to strict liability are well settled rules of negligence.<sup>54</sup> Another appellate court applied the *Barker* balancing test in determining warning defects.<sup>55</sup> Although strict liability for failure to warn is uniformly recognized by California appellate courts as a separate product defect, the courts have applied differing standards in determining defectiveness.

#### THE APPLICATION OF STRICT LIABILITY TO PRESCRIPTION DRUGS

Strict liability protects the consumer.<sup>56</sup> Because the manufacturer is liable for product defects, the manufacturer has an incentive to make safer products.<sup>57</sup> The manufacturer can, of course, simply not

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870, 874 (1979). The California Supreme Court has never decided whether strict liability should be imposed for a failure to warn regardless of the defendant's knowledge or ability to know of the side effect causing injury or whether strict liability should only be imposed based upon the manufacturer's actual or constructive knowledge. *Id.*

52. *Finn*, 35 Cal. 3d at 699, 700 P.2d at 1152, 200 Cal. Rptr. at 875 (citing *Carmichael v. Reitz*, 17 Cal. App. 3d 985, 988, 95 Cal. Rptr. 381, 400 (1971); *Ortho Pharmaceutical Corp. v. Chapman*, 388 N.E. 2d 541, 550 (1979)).

53. *Finn*, 35 Cal. 3d at 700, 677 P.2d at 1152, 200 Cal. Rptr. at 875 (citing *Oakes v. E.I. DuPont de Nemours & Co., Inc.*, 272 Cal. App. 2d 645, 650 n.4, 77 Cal. Rptr. 709, 713, n.4 (1969); *Christofferson v. Kaiser Foundation Hospitals*, 15 Cal. App. 3d 75, 79-80, 92 Cal. Rptr. 825, 827 (1971)).

54. RESTATEMENT (SECOND) OF TORTS § 402A comment j provides:

In order to prevent the product from being unreasonably dangerous, the seller may be required to give directions or warning, on the container, as to its use. The seller may reasonably assume that those with common allergies, as for example to eggs or strawberries, will be aware of them, and is not required to warn against them. Where, however, the product contains an ingredient to which a substantial number of the population are allergic, and the ingredient is one whose danger is not generally known, or if known is one which the consumer would reasonably not expect to find in the product, the seller is required to give warning against it, if the seller has knowledge, or by the application of reasonable, developed human skill and foresight should have knowledge, of the presence of the ingredient and the danger. Likewise in the case of poisonous drugs, or those unduly dangerous for other reasons warning as to use may be required. Where warning is given, the seller may reasonably assume that it will be read and heeded; and a product bearing such a warning, which is safe for use if it is followed, is not in defective condition, nor is it unreasonably dangerous.

55. *Cavers v. Cushman Motors*, 95 Cal. App. 3d 336, 348, 157 Cal. Rptr. 142, 148 (1979).

56. *Id.*

57. *Kearl v. Lederle Laboratories*, 172 Cal. App. 3d 812, 822, 218 Cal. Rptr. 453, 458 (1985). See also *Collins v. Eli Lilly Co.*, 342 N.W.2d 37, 49 (Wis. 1984) (the cost of damage awards will act as an incentive for drug companies to test adequately the drugs they place on the market).

market a product that cannot be made sufficiently safe. Thus, a trade off may occur. Products may be safer but fewer new products may be available.<sup>58</sup> Alternatively, the manufacturer may continue to market the product and pass the costs of liability to all consumers.

The possibility that increased accountability may lead to decreased product availability has caused some California courts to exempt prescription drugs from strict liability.<sup>59</sup> These courts have reasoned that holding drug manufacturers strictly liable for drug side effects, and incidently liable for large damage awards, would deter manufacturers from marketing other life saving drugs.<sup>60</sup> A policy of protecting consumers has collided with a policy of making prescription drugs readily available. On the one hand, pharmaceutical manufacturers argue that important new drugs may not be developed because of the costs of strict liability.<sup>61</sup> On the other hand, innocent consumers injured by unsafe drugs should not be singled out to bear the costs of society's interest in a ready supply of prescription drugs.<sup>62</sup> Although the California Supreme Court has never indicated that any class of products is exempt from strict liability, appellate courts have extended immunity to prescription drugs for both design and warning defects.<sup>63</sup>

#### *A. Design Defect Applied to Prescription Drugs*

A design defect is inherent in a line of products.<sup>64</sup> Because the flaw has been designed into the product, every unit in the line is unsafe. Prescription drugs have been considered unavoidably unsafe by some courts and exempted from strict liability on the authority

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58. *Kearl*, 172 Cal. App. 3d at 824, 218 Cal. Rptr. at 459-60.

59. *Id.*

60. *Id.* at 823, 218 Cal. Rptr. at 459.

61. Defendant's Brief on the Merits at 15, *Brown v. Superior Court*, 1 Civ. No. A032655 (Calif. Supreme Court Jan. 16, 1987).

62. Petitioner's Brief on the Merits at 27, *Brown v. Superior Court*, 1 Civ. No. A032655 (Calif. Supreme Court Nov. 3, 1986).

63. *Brown v. Superior Court*, 182 Cal. App. 3d 1125, 1134, 227 Cal. Rptr. 768, 773 (1986). See also *Toole v. Richardson Merrell, Inc.*, 251 Cal. App. 2d 689, 708-11, 60 Cal. Rptr. 398, 413 (1967) (manufacturer of Mer/29, a drug prescribed to treat arteriosclerosis, is strictly liable only for manufacturing or warning defects); *Christofferson v. Kaiser Found. Hosps.*, 15 Cal. App. 3d 75, 77-80, 92 Cal. Rptr. 825, 827 (1971) (in a prescription drug case defendant is only liable for warning defects); *Carmichael v. Reitz*, 17 Cal. App. 3d 958, 988-89, 95 Cal. Rptr. 381, 400 (1971) (manufacturer of prescription drug that assisted pregnancy is strictly liable only for manufacturing or warning defect).

64. *Barker v. Lull Eng'g. Co.*, 20 Cal. 3d 413, 427, 573 P.2d 443, 143 Cal. Rptr. 225, 234 (1978).



of the Restatement of Torts 402A comment k.<sup>65</sup> Comment k recognizes that although certain products like prescription drugs cannot be made completely safe, the products have value to society.<sup>66</sup> If an unavoidably unsafe product is accompanied by a warning, the product is not defective. Applying comment k, California courts have granted prescription drugs immunity from strict liability. However, a recent California decision has suggested that in some cases strict liability for dangerous defects could be applied to prescription drugs.<sup>67</sup>

### 1. *Kearl v. Lederle Laboratories*

In *Kearl v. Lederle Laboratories*<sup>68</sup> a patient who had received an oral polio vaccine subsequently contracted the disease and developed paralysis. The patient brought a products liability action against the manufacturer of the vaccine arguing that the vaccine was defective in design and warning.<sup>69</sup> The court held that an oral polio vaccine was an unavoidably dangerous product exempt from strict liability for design or warning defects. The court stated, however, that the decision to grant a drug immunity should be made on a case by case basis.<sup>70</sup>

In reaching this decision, the court began with the proposition that strict liability may not be appropriate for products that are extremely beneficial to society yet pose an inherent and substantial risk that is

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65. *Brown*, 182 Cal. 3d at 1140, 227 Cal. Rptr. at 777.

66. RESTATEMENT (SECOND) OF TORTS § 402A comment k addresses the problem of unavoidably unsafe products such as the Pasteur vaccine for rabies. Comment k states:

Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidably high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not 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 it has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

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

68. *Id.*

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

70. *Id.* at 829, 218 Cal. Rptr. at 463.

unavoidable at the time of distribution.<sup>71</sup> Acknowledging that the extent to which strict liability might inhibit drug availability has been questioned,<sup>72</sup> the court believed that the enhanced prospect of liability might substantially affect availability.<sup>73</sup> The court stated that the release of a new drug may be delayed or postponed indefinitely.<sup>74</sup> In addition, the cost of insuring against strict liability could place the cost of research and marketing of new drugs beyond what manufacturers, particularly small manufacturers, are willing to risk.<sup>75</sup> Further insurers might be unwilling to underwrite the increased risks at an affordable cost.<sup>76</sup> Finally the increased cost of drugs might place the price of drugs outside the reach of those who need them most.<sup>77</sup> In the case of certain drugs, the court stated, availability is more important than accountability.<sup>78</sup> These drugs should be judged by the manufacturer's actual or constructive knowledge at the time of distribution rather than under a strict liability standard.<sup>79</sup>

Despite these policy considerations, the court in *Kearl* refused to grant blanket immunity to all prescription drugs for design defects. Uncomfortable with the past mechanical application of comment k, the *Kearl* court ruled that in each case a trial court should determine whether a drug is unavoidably dangerous.<sup>80</sup> Only drugs that are found

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

72. See McClellan, *Strict Liability for Drug Induced Injuries: An Excursion Through the Maze of Products Liability, Negligence and Absolute Liability*, 25 WAYNE L. REV. 1, 33 (1978) (the suggestion that strict liability would deprive consumers of essential drugs is subject to serious doubts. In the absence of substantial data showing that the profit margin in the drug industry is so low that the industry could not bear the costs of the injuries drugs cause, strict liability should apply). Comment, *An Escape from Strict Liability: Pharmaceutical Manufacturers' Responsibility for Drug-Related Injuries Under Comment k to Section 402A of the Restatement (Second) of Torts*, 23 DUQ. L. REV. 199, 215-18 (1984) (questioning the extent to which strict liability would inhibit availability).

73. *Kearl*, 172 Cal. App. 3d at 823, 218 Cal. Rptr. at 459.

74. *Id.* See Reed & Watkins, *Product Liability Tort Reform: The Case for Federal Action*, 63 NEB. L. REV. 839, 848-49 (1984) (the prospect of strict liability may cause manufacturers to withhold needed vaccines).

75. *Kearl*, 172 Cal. App. 3d at 824, 218 Cal. Rptr. at 459 (1985). See Note, *The Liability of Pharmaceutical Manufacturers for Unforeseen Adverse Drug Reactions*, 48 FORDHAM L. REV. 735, 757-58 (1980) (small manufacturers will not risk the costs of developing new drugs if strict liability is imposed).

76. *Kearl*, 172 Cal. App. 3d at 825, 218 Cal. Rptr. at 459. See Baynes, *Liability for Vaccine Related Injuries: Public Health Considerations and Some Reflections on the Swine Flu Experience*, 20 ST. LOUIS U.L.J. 44, 66 (1977) (the federal government assumed responsibility for injuries resulting from strict liability for swine flu vaccine design defects when manufacturers were unwilling to underwrite the risks).

77. *Kearl*, 172 Cal. App. 3d at 824, 218 Cal. Rptr. at 459.

78. *Id.*

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

80. *Id.* at 829, 218 Cal. Rptr. at 463. The court found the routine application of comment

to be unavoidably dangerous should be immune from strict liability.<sup>81</sup>

Cautious about conferring special protection on a product, the court recommended a pretrial hearing out of the jury's presence to determine whether a product is unavoidably dangerous.<sup>82</sup> The trial court should consider three questions in determining that a drug is unreasonably dangerous and exempt from strict liability analysis.<sup>83</sup> First, the court must determine whether the drug, when distributed,<sup>84</sup> was intended to confer an exceptionally important benefit that made the availability of the product particularly necessary.<sup>85</sup> Second, the court must determine whether the risk posed by the drug at the time of distribution, was substantial and unavoidable.<sup>86</sup> The third question is whether the interest in product availability as measured at the time of distribution outweighs the interest in promoting enhanced accountability through strict liability design defect review.<sup>87</sup>

The *Kearl* test is similar to the *Barker* risk benefit test in that each test focuses on the product rather than on the manufacturer's conduct.<sup>88</sup> *Kearl* differs from *Barker*, however, in three ways. First, the *Barker* test asks whether the product is defective,<sup>89</sup> while *Kearl* asks whether the product is unavoidably dangerous.<sup>90</sup> Second, in *Kearl*, the court determines whether the product is unavoidably dangerous.<sup>91</sup>

k immunity to prescription drugs "tautological." The rule that prescription drugs should be immune from strict liability is often stated in conclusory fashion accompanied by little more than a reference to Restatement (Second) of Torts § 402A, comment k. See also Comment, *Can a Prescription Drug Be Defectively Designed?—Brochu v. Ortho Pharmaceutical Corp.*, 31 DE PAUL L. REV. 247, 254 (1980) (prescription drugs should not be exempt from strict liability design defect analysis if an alternative product was available at the time of distribution that could have accomplished the same purpose).

81. *Kearl*, 172 Cal. 3d at 829, 218 Cal. Rptr. at 463 (the decision to grant immunity poses a mixed question of law and fact and can be made only after evidence is heard, out of the jury's presence, on certain relevant factors).

82. *Id.*

83. See Wade, *On the Effect in Product Liability of Knowledge Unavailable Prior to Marketing*, 58 N.Y.U.LAW.REV. 734, 753-54 (1983) (time of distribution or marketing is when the manufacturer relinquishes control of the product).

84. *Kearl*, 172 Cal. 3d at 829, 218 Cal. Rptr. at 464.

85. *Id.* In determining substantiality, 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. In deciding unavoidability the court should consider whether the product was designed to minimize the risk inherent in the product and the availability of any alternative product that would have as effectively accomplished the full intended purpose of the subject product. *Id.* at 830, 218 Cal. Rptr. at 464.

86. *Id.* at 829, 218 Cal. Rptr. at 430.

87. *Id.*

88. See *Barker v. Lull Eng'g. Co.*, 20 Cal. 3d 413, 432, 573 P.2d 443, 455, 143 Cal. Rptr. 225, 238 (1978).

89. *Id.*

90. See *Kearl*, 172 Cal. App. 3d at 829, 218 Cal. Rptr. at 463.

91. *Id.*

In *Barker* the jury decides whether the product is defective.<sup>92</sup> Third, *Kearl* requires an analysis of the risks and benefits at the time of distribution,<sup>93</sup> rather than at the time of trial.<sup>94</sup>

Under *Kearl*, therefore, a drug would be judged first by the court by one standard and then by the jury by a different standard. If a drug were not found to be unavoidably dangerous, after a *Kearl* hearing, the drug would be subject to strict liability. The attempt to balance the competing policy interests in the *Kearl* test raises the possibility that a prescription drug would be subject to strict liability for design defect. The approach of the *Kearl* court was subsequently considered by another appellate court in the same district.

## 2. *Brown v. Superior Court*

In *Brown v. Superior Court*,<sup>95</sup> the court directly rejected the *Kearl* proposal.<sup>96</sup> In *Brown* the plaintiffs in "complex litigation" against manufacturers of DES, a prescription drug, challenged several pretrial rulings of the Superior Court.<sup>97</sup> The Court of Appeal held that manufacturers could not be held strictly liable for injuries allegedly caused by design or warning defects in the drug.<sup>98</sup> The *Brown* court found no reason to impose a condition on comment k immunity.<sup>99</sup> The *Brown* court stated that comment k and *Barker* were not completely reconcilable.<sup>100</sup> Comment k suggests design immunity for all prescription drugs.<sup>101</sup> *Barker* does not provide immunity for any product, but tests every product either under a consumer expectation or a risk benefit analysis.<sup>102</sup> *Brown* interpreted *Kearl* as advocating a variant of the *Barker* risk benefit analysis to determine whether

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92. *Barker*, 20 Cal. 3d at 434, 573 P.2d at 457, 143 Cal. Rptr. at 239.

93. *Kearl*, 172 Cal. App. 3d at 830, 218 Cal. Rptr at 464.

94. *Barker*, 20 Cal. 3d at 430, 573 P.2d 454, 143 Cal. Rptr. at 236.

95. 182 Cal. App. 3d 1125, 227 Cal. Rptr. 768 (1986).

96. *Id.* at 1137, 227 Cal. Rptr. at 775.

97. *Id.* at 1129, 227 Cal. Rptr at 769. DES, diethylstilbestrol, is a synthetic estrogen used to prevent miscarriages and alleged to have caused injury to plaintiffs exposed to the drug *in utero*. Some 69 cases have been designated complex litigation and assigned to one judge to hear all pretrial rulings. Although each action has its own case number and independent existence, all the law and motion rulings are made in the complex litigation case. These rulings are binding on the individual cases. Plaintiffs in *Brown* were petitioning for writ of mandate and/or prohibition. *Id.* at 1129, 227 Cal. Rptr. at 770.

98. *Id.* at 1137, 227 Cal. Rptr. at 774 (the plaintiffs are suing the manufacturers of the prescription drug, DES, alleging injury to plaintiffs exposed to the drug *in utero*).

99. *Id.* at 1140, 227 Cal. Rptr. at 774.

100. *Id.* at 1140, 227 Cal. Rptr. at 773.

101. *Id.* at 1137, 227 Cal. Rptr. at 774.

102. *Id.* at 1137, 227 Cal. Rptr. at 773.

comment k immunity should be accorded.<sup>103</sup> The court in *Brown* stated that comment k is an implied exception to the design defect analysis and flatly held that comment k should be followed since decision law prior to *Kearl* had uniformly supported comment k immunity.<sup>104</sup>

The *Brown* court found the *Kearl* approach to strict liability for prescription drugs unnecessary, novel and unworkable.<sup>105</sup> The court suggested that the *Kearl* approach was flawed in several respects. First of all, the *Kearl* mini-trial would require that courts determine an essentially factual question.<sup>106</sup> The first two *Kearl* inquiries raise only questions of fact.<sup>107</sup> The *Brown* court stated that the jury, properly instructed about the meaning of the terminology in the factual questions, could determine the existence of risks and benefits.<sup>108</sup> Moreover, the court in *Brown* stated that the third question on which *Kearl* focuses, whether availability is outweighed by accountability,<sup>109</sup> is an open ended policy question that should not be decided by the court.<sup>110</sup> Another flaw in the *Kearl* approach is that different courts could reach inconsistent results with regard to the same drug.<sup>111</sup> No uniformity can be expected in the treatment of a particular drug if lower courts are permitted to weigh the pros and cons of immunity on a case by case basis.<sup>112</sup> The *Brown* court objected strenuously to the *Kearl* requirement that the court rule on factual questions and weigh and balance evidence central to a plaintiff's case.<sup>113</sup>

While rejecting the *Kearl* mini-trial the *Brown* court did not, however, analyze the reasons for applying comment k. The *Brown* court stated in a footnote<sup>114</sup> that if the supreme court held comment

103. *Id.*

104. *Id.*

105. *Id.* at 1135, 227 Cal. Rptr. at 774.

106. *Id.* at 1136, 227 Cal. Rptr. at 774.

107. *Id.* at 1134, 227 Cal. Rptr. at 773 (whether the product was intended to confer an exceptionally important benefit and whether there was a substantial and unavoidable risk posed by the product). See *Kearl v. Lederle Laboratories*, 172 Cal. App. 3d at 820, 218 Cal. Rptr. at 464.

108. *Brown*, 182 Cal. App. 3d at 1134, 227 Cal. Rptr. at 773.

109. *Kearl*, 172 Cal. App. 3d at 830, 218 Cal. Rptr. at 464 See also *Brown*, 182 Cal. App. 3d at 1136, 227 Cal. Rptr. at 775 where the court stated: "What degree of benefit should outweigh what level of risk? How far must the scales tip in order to provide design immunity for a particular drug." *Id.*

110. *Brown*, 182 Cal. App. 3d at 1136, 227 Cal. Rptr. at 774.

111. *Id.* at 1136, 227 Cal. Rptr. at 775.

112. *Id.*

113. *Id.*

114. *Id.* (citing *Akers v. Kelley Co.*, 173 Cal. App. 3d 633, 651, 219 Cal. Rptr. 513 (1985)).

k inapplicable in California, there would be no reason not to apply the *Barker* two prong test for design defect.<sup>115</sup>

Thus, the *Brown* court would go further than the *Kearl* court if comment k immunity were found not to apply to prescription drugs. *Brown* would subject every drug to a *Barker* strict liability test under either a consumer expectation or risk/benefit theory. Recently two other appellate courts have cited the *Kearl* decision in reaching two opposite results.

### C. Recent Appellate Decisions

In *Flood v. Wyeth Laboratories, Inc.*,<sup>116</sup> a DPT vaccination allegedly caused the plaintiff severe brain damage.<sup>117</sup> The court held that the statutory scheme that required immunization for school age children did not extend a grant of immunity to the manufacturer of the vaccine.<sup>118</sup> The court stated that if the legislature had intended to grant immunity to drug manufacturers the statute would explicitly include an exemption provision.<sup>119</sup> The court cited *Kearl* for the proposition that manufacturers of vaccine are subject to liability under the strict products liability design defect theory unless the trial court finds that the product is unavoidably dangerous.<sup>120</sup>

In *Collins v. Ortho Pharmaceutical Corporation*,<sup>121</sup> the plaintiff alleged that she was injured by an IUD.<sup>122</sup> The court held that a prescription drug or device, distributed with FDA approval and

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The trial court had rejected the *Barker* test stating that the consumer expectation test did not fit because DES was not within the common experience of ordinary consumers. The risk-benefit test was inappropriate because the weighing process involves consideration of possible alternative designs, whereas the formula for DES is a scientific constant, and the product could not be designed differently. *Id.* at 1134, n.4, 227 Cal. Rptr. at 773, n.4.

115. *Brown*, 182 Cal. App. 3d at 1136, 227 Cal. Rptr. at 775. The consumer expectation prong of *Barker* does not require that the product be within the common experience of the ordinary consumer. Alternatively, a risk benefit analysis would consider whether other miscarriage medicine was available, not the narrow question of whether an alternative formula for DES could have been used. *Id.*

116. 183 Cal. App. 3d 1272, 228 Cal. Rptr. 700 (1986).

117. *Id.* at 1273, 228 Cal. Rptr. at 701. Every child in this state must receive the DPT vaccine before being admitted into any school. See CAL. HEALTH AND SAFETY CODE §§ 3380-3390. No person shall be unconditionally admitted "as a pupil of any private or public elementary or secondary school, child care center, day nursery, nursery school, or development center, unless prior to his or her first admission to that institution he or she has been fully immunized against diphtheria, pertussis (whooping cough), and tetanus. *Id.* § 3381. Some exceptions, not pertinent to this discussion, are permitted. See *id.* §§ 3385 and 3386.

118. *Flood*, 183 Cal. App. 3d at 1274, 228 Cal. Rptr. at 702.

119. *Id.*

120. *Id.* at 1275, 228 Cal. Rptr. at 703.

121. 186 Cal. App. 3d 1194, 231 Cal. Rptr. 396 (1986), review granted, Feb 26, 1987.

122. *Id.* at 1206, 231 Cal. Rptr. at 402.

accompanied by requisite warnings, is unavoidably unsafe as a matter of law and thus cannot be the basis for a cause of action based on strict liability for a design defect.<sup>123</sup> The *Collins* court held that the FDA tests were similar to both the *Barker* risk benefit analysis and the *Kearl* mini-hearing.<sup>124</sup> In deciding whether the product was defective in design, the *Collins* court emphasized that the plaintiff was injured by the precise risk about which the manufacturer had warned.<sup>125</sup> The court expressly did not decide whether an action in strict liability is barred when the plaintiff's injury is caused by a risk not warned against.<sup>126</sup>

The preceding cases demonstrate that appellate courts in California reach different conclusions on the issue of blanket immunity from strict liability for design defects for prescription drugs. In addition to suing on a design defect theory, many plaintiffs sue for injuries allegedly caused by prescription drugs on a warning defect theory.<sup>127</sup> In a warning defect case, the injured plaintiff does not allege that the manufacture or design of the product was faulty, but that the manufacturer failed to warn of potential dangers in the use of its product.<sup>128</sup>

#### *D. Warning Defect Applied To Prescription Drugs*

In California the concept of defect has been expanded to include products that are dangerous because they lack adequate warning or instructions.<sup>129</sup> The failure to warn of dangers inherent in a product is a category of defect separate from manufacturing or design defects.<sup>130</sup> The applicability of strict liability for a failure to warn has been troublesome for the courts in prescription drug cases.

In a strict liability action for manufacturing defect the jury looks at a product in hindsight and ignores the question of the manufacturer's actual or constructive knowledge of the risk.<sup>131</sup> In a warning

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123. *Id.* at 1199, 231 Cal. Rptr. at 398.

124. *Id.* at 1208, 231 Cal. Rptr. at 404.

125. *Id.*

126. *Id.*

127. *Kearl v. Lederle Laboratories*, 172 Cal. App. 3d 812, 826, 213 Cal. Rptr 453, 461 (1985).

128. *Cavers v. Cushman Motor Sales, Inc.*, 95 Cal. App. 3d 338, 343, 157 Cal. Rptr. 142, 145 (1979).

129. *Id.*

130. *Campbell v. General Motors*, 32 Cal. App. 3d 112, 649 P.2d 224, 228, 184 Cal. Rptr. 891 (1982).

131. *Kearl*, 172 Cal. App. 3d at 832, 218 Cal. Rptr. at 465.

defect case courts have been reluctant to hold manufacturers liable for risks that were unknown and undiscoverable at the time the drug was distributed.<sup>132</sup> Side effects of a drug may not be known until long after the time the drug is placed on the market. Consequently negligence concepts have been incorporated into the strict liability analysis.<sup>133</sup>

The court in *Cavers v. Cushman Motors*<sup>134</sup> offered one solution to the question of how to apply strict liability to a warning defect.<sup>135</sup> The court stated that a warning defect is difficult to define since the jury can neither compare the product to similar products nor weigh alternative designs.<sup>136</sup> Finding the principles formulated by the California Supreme Court in *Barker* helpful in defining defect, the *Cavers* court adapted the risk-benefit test to a warning defect.<sup>137</sup> Under the *Cavers* test, a jury weighs the degrees of danger inherent in a product in order to determine if the product requires a warning.<sup>138</sup> While *Cavers* was not a prescription drug case, the California Supreme Court cited the *Cavers* approach approvingly in *Finn v. G. D. Searle*.<sup>139</sup>

### 1. *Finn v. G. D. Searle*

In *Finn*, the court considered the applicability in a prescription drug case of strict liability principles for known or knowable de-

132. See, e.g., *Kearl*, 172 Cal. App. 3d 812, 218 Cal. Rptr. 453 (1985). *Brown v. Superior Court*, 182 Cal. App. 3d 1125, 227 Cal. Rptr. 768 (1986).

133. *Finn v. G.D. Searle*, 35 Cal. 3d 691, 700, 671 P.2d 1147, 1152. 200 Cal. Rptr. 870, 875 (1984).

134. 95 Cal. App. 3d 336, 157 Cal. Rptr. 142 (1979).

135. *Id.* at 346, 157 Cal. Rptr. at 147. (There is no precise definition of the term "defect." The concept of defect is more elusive in a design or warning case than in a manufacturing case).

136. *Id.* See also Wade, *On the Nature of Strict Tort Liability for Products*, 44 Miss. L.J. 825, 832 (1973) (to apply the term defective to a case where a warning is not attached to the product and to use the term without defining it to the jury is to insure that the they will be misled).

137. *Cavers*, 95 Cal. App. 3d at 346, 157 Cal. Rptr. at 147. The court also stated: "the consumer expectation text may be out of place in a design defect or warning case since the consumer would not know how safe the product could be made." *Id.* at 347, 157 Cal. Rptr. at 148.

138. *Id.* The trial court may assist the jury's determination by suggesting various factors to consider. Factors to be considered in determining whether the product is defective because of the lack of a warning are: the normal expectations of the consumer as to how the product will perform, degrees of simplicity or complication in the operation or use of the product, the nature and magnitude of the danger to which the user is exposed, the likelihood of injury, and the feasibility and beneficial effect of including a warning. *Id.* at 347, 157 Cal. Rptr. at 148.

139. 35 Cal. 3d 691, 677 P.2d 1147, 200 Cal. Rptr. 870 (1979).



fects.<sup>140</sup> The plaintiff in *Finn* was blinded as a side effect of the drug Diodoquin.<sup>141</sup> The plaintiff argued that Searle was strictly liable for failing to warn of the side effects of Diodoquin at the time plaintiff took the drug.<sup>142</sup> The California Supreme Court reviewed the general approaches to product liability for a warning defect.<sup>143</sup>

The decisions in other jurisdictions have developed two theories.<sup>144</sup> The first theory imposes strict liability for a failure to warn regardless of defendant's knowledge or ability to know of the side effect causing injury.<sup>145</sup> The second theory focuses on the defendant's actual or constructive knowledge.<sup>146</sup> The *Finn* court stated that under the hindsight theory in which the manufacturer's knowledge is ignored, there is a substantial distinction between a negligence standard and strict liability.<sup>147</sup> The *Finn* court did not choose between these two positions.<sup>148</sup>

The *Finn* court then discussed the type of warning that a drug may be required to have.<sup>149</sup> First, the manufacturer may be required to adequately instruct the consumer as to how the product should be used.<sup>150</sup> In this case, a warning may reduce the risk of injury.<sup>151</sup> A second option is to require a manufacturer to inform the consumer

140. *Id.* at 698, 677 P.2d at 1151, 200 Cal. Rptr. at 874 (the court did not decide whether liability for a failure to warn could be imposed for failure of the product to warn of defects discovered and reasonably discoverable only after the product has caused injury). *See also* Wade, *On the Effect in Product Liability of Knowledge Unavailable Prior to Marketing*, 58 N.Y.U.L. REV. 734 (1983) (extensive discussion of the time when defect should be determined).

141. *Finn*, 35 Cal. 3d at 695, 677 P.2d at 1149, 200 Cal. Rptr. at 872 (1984).

142. *Id.* The trial court deleted the word strictly from the proposed instruction, and the plaintiff appealed. The California Supreme Court held that no prejudicial error occurred because the instructions did not reflect the theory on which plaintiff argued the case. *Id.* The Court did not reach the question whether a manufacturer is liable for defects that are unknowable at the time of distribution. *Id.* *See* Wade, *supra* note 139, at 749 (a product related danger is knowable if the available scientific data give rise to a reasonable inference that the danger is likely to exist).

143. *Finn*, 35 Cal. 3d at 698, 677 P.2d at 1151, 200 Cal. Rptr. at 874.

144. *Id.*

145. *See, e.g.*, *Woodill v. Parke Davis & Co.* 79 Ill.2d 26, 402 N.E.2d 194, 197 (1980); *Bristol-Myers Co. v. Gonzales*, 561 S.W.2d 801, 804 (Tex. 1978); *Singer v. Sterling Drug, Inc.* 461 F.2d 288 (7th Cir. 1972).

146. *See, e.g.*, *Leibowitz v. Ortho Pharmaceutical Corp.* 307 A.2d 449, 457-58 (Pa. 1973); *Berkebile v. Brantly Helicopter Corp.* 462 Pa. 83, 101, 337 A.2d 893, 902 (1975).

147. *Finn*, 35 Cal. 3d at 699, 677 P.2d at 1151, 200 Cal. Rptr. at 874. A court makes a hindsight decision when it determines liability based upon failure to warn of defects discovered and reasonably discoverable only after the product has caused injury. *Id.*

148. *Id.*

149. *Id.* at 699, 677 P.2d at 1152, 200 Cal. Rptr. at 875.

150. *Id.* (citing *Midgley v. S.S. Kresge Co.* 55 Cal. App. 3d 67, 127 Cal. Rptr. 217, (1976) (strict liability imposed when the manufacturer failed to advise users on the proper use and assembly of a telescope).

151. *Finn*, 35 Cal. 3d at 700, 677 P.2d at 1152, 200 Cal. Rptr. at 875.

or the physician of potential risks or side effects which may follow the foreseeable use of the product.<sup>152</sup> The second type of warning is particularly applicable in claims involving prescription drugs,<sup>153</sup> since it affords the consumer an opportunity to make an informed choice.<sup>154</sup>

The *Finn* court suggested that the *Cavers* balancing test would be appropriate in determining whether a drug was defective because it lacked a warning or had an inadequate warning.<sup>155</sup> A strict liability test focuses on the product and asks whether the product has been rendered defective because applying an objective standard and weighing the relevant costs and benefits a warning was required.<sup>156</sup> This warning would be based on the information the manufacturer had "in hand."<sup>157</sup>

## 2. *Kearl v. Lederle Laboratories*

The court in *Kearl v. Lederle Laboratories*<sup>158</sup> rejected the *Finn* proposal for a balancing test.<sup>159</sup> The court in *Kearl* held that an oral polio vaccine manufacturer's warning adequately informed the patient of the reasonably foreseeable risk associated with the vaccine.<sup>160</sup> Dismissing the *Finn* discussion of *Cavers* as dicta, the *Kearl* court stated that nothing in *Cavers* suggested that failure to warn should be subject to an analysis different from negligence.<sup>161</sup> The court questioned the proposition that in a product liability case failure to warn or inadequacy of a warning could be the basis of imposition of strict liability.<sup>162</sup> In warning cases, according to *Kearl*, liability is condi-

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152. *Id.* See generally Twerski, *The Use and Abuse of Warnings in Products Liability—Design Defect Litigation comes of Age*, 61 CORNELL L. REV. 495, 520-21 (1976) (different kinds of warnings will be required as a result of the different functions the warnings serve).

153. *Finn*, 35 Cal. 3d at 700, 677 P.2d at 1152, 200 Cal. Rptr. at 875, *See supra* note 137 (the *Cavers* test balances the risks of the product against the benefits to determine whether the degree of danger in a product is sufficient to require a warning).

154. *See* McClellan, *supra* note 72 at 32. Inadequate warning claims protect the interest of the consumer in personal autonomy as well as safety. An important consumer interest is violated if a material risk or direction is not disclosed. *Id.*

155. *Finn*, 35 Cal. 3d at 700, 677 P. 2d at 1152- 53, 200 Cal. Rptr. at 875-76.

156. *Id.* Under a negligence standard, the jury focuses on the reasonableness of the manufacturer's conduct. Under a strict liability standard, the jury focuses on whether the product has been rendered defective because the required warning was lacking. *Id.* at 700, 677 P. 2d at 1152, 200 Cal. Rptr. at 875.

157. *Id.* at 701, 677 P.2d at 1153, 200 Cal. Rptr. at 876.

158. 172 Cal. App. 3d 812, 218 Cal. Rptr. 453 (1985).

159. *Kearl*, 172 Cal. App. 3d at 832, n.17, 218 Cal. Rptr. at 466, n.17.

160. *Id.* at 836, 218 Cal. Rptr at 469.

161. *Id.* at 832, n.17, 218 Cal. Rptr at 466, n.17.

162. *Id.* at 831-32, 218 Cal. Rptr at 465.

tioned on the defendant having actually or constructively known of the risk that triggers the warning.<sup>163</sup>

The *Kearl* court concluded that the adequacy of a warning should be judged under a reasonableness standard.<sup>164</sup> The adequacy of the warning is measured by the reasonably foreseeable risks associated with the product.<sup>165</sup>

### 3. *Brown v. Superior Court*

Similarly the court in *Brown v Superior Court*<sup>166</sup> held that manufacturers of prescription drugs should not be strictly liable for failure to warn of risks that were not known or reasonably discoverable at the time of distribution.<sup>167</sup> The court stated that adoption of comment k immunity for prescription drugs would be a meaningless act without also embracing comment j to section 402A.<sup>168</sup> Comment j states that a warning is required where the danger is known or should have been known.<sup>169</sup> The *Brown* court held that the policy reasons for providing design defect immunity for prescription drugs also counsel against imposing strict liability upon manufacturers for failure to warn of risks not known or reasonably knowable.<sup>170</sup> The court saw no difference between applying strict liability for design defect and failure to warn.<sup>171</sup>

Both *Kearl* and *Brown* focused on the conduct of the manufacturer rather than the safety of the product and held that the relevant time for determining defect was at the time of distribution.<sup>172</sup> Neither court adopted the *Finn* suggestion that a test balancing the cost and benefits of a warning be used.

### STRICT LIABILITY FOR PRESCRIPTION DRUGS IN OTHER JURISDICTIONS

Courts and commentators have exhaustively discussed the reasons for and against granting drugs immunity from strict liability for

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163. *Id.* at 832, 218 Cal. Rptr. at 466. In a strict liability action the court ignores the question of a manufacturer's actual or constructive knowledge of risk or imputes to the manufacturer current scientific knowledge of the risk caused by his product. *Id.*

164. *Id.* at 833, 218 Cal. Rptr. 466.

165. *Id.*

166. 182 Cal. App. 3d 1125, 227 Cal. Rptr. 768 (1986).

167. *Id.* at 1140, 227 Cal. Rptr. at 776.

168. *Id.*

169. *Id.*

170. *Id.* at 1138, 27 Cal. Rptr. at 776.

171. *Id.* at 1139, 227 Cal. Rptr. at 777. See RESTATEMENT (SECOND) OF TORTS § 402A comment j *supra* note 54.

172. *Id.* at 1139, 227 Cal. Rptr. at 777.

design and warning defects. Life saving drugs are particularly beneficial to society. Yet it is impossible to make risk free drugs.<sup>173</sup>

Many courts have wrestled with the applicability of strict liability to prescription drugs. In *Feldman v. Lederle Laboratories*,<sup>174</sup> the New Jersey Supreme Court first considered whether comment k should immunize prescription drugs from strict liability for design defect.<sup>175</sup> The court held that the principle of strict liability is generally applicable to manufacturers of prescription drugs.<sup>176</sup>

In *Feldman* the court discussed instances in which certain groups have been exempted from strict liability analysis. Doctors and dentists, who render to consumers professional service involving skills in judgment and diagnosis are exempt from strict product liability.<sup>177</sup> On the other hand, drug manufacturers produce goods and place them in the stream of commerce.<sup>178</sup> While their products are valuable to society, the drug manufacturers are profit making enterprises upon whom product responsibility properly rests.<sup>179</sup> Since drugs, like any other product, may contain defects that could have been avoided by better manufacturing or design.<sup>180</sup> The court in *Feldman* reasoned that drug manufacturers should not be treated differently from other manufacturers.<sup>181</sup> Moreover, the FDA's determination of safety should not replace the risk benefit analysis required in the judicial process.<sup>182</sup> Although some drugs are more vital to the public health than other drugs, comment k immunity would treat all drugs the same regardless of their utility.<sup>183</sup>

Finding no justification for giving prescription drug manufacturers blanket immunity from strict liability for design defect claims, the

173. *Kearl v. Lederle Laboratories*, 172 Cal. App. 3d 812, 825, 218 Cal. Rptr 453, 459 (1985). See also *Feldman v. Lederle Laboratories*, 97 N.J. 429, 435, 479 A.2d 374, 380 (1984).

174. 97 N.J. 429, 479 A.2d 374 (1984).

175. *Id.* at 435, 479 A.2d at 380.

176. *Id.* at 437, 479 A.2d at 382.

177. *Id.* at 437, 479 A.2d at 382 (when the essential nature of a transaction involves a service rather than a product, public policy may dictate that the general welfare is better served by inapplicability of strict liability doctrine). See also *Murphy v. E.R. Squibb & Co.*, 40 Cal. 3d 672, 677, 710 P.2d 247, 221 Cal. Rptr. 447 (1985) (in providing prescription drugs, a pharmacy is a service and exempt from strict liability). See CAL. BUS. & PROF. CODE § 4046 (defining a pharmacy as a health service). *Carmichael v. Reitz* 17 Cal. App. 3d 958, 95 Cal. Rptr. 381 (1971) (a doctor when prescribing a drug is providing a service and exempt from strict liability).

178. *Feldman v. Lederle Laboratories*, 97 N.J. 429, 436, 479 A.2d 374, 383 (1984).

179. *Id.* See also *Collins v. Eli Lilly Co.* 116 W. 2d 166, 171, 342 N.W.2d 37, 52 (1984) (drug companies like other manufacturers have a duty to produce and market safe products).

180. *Feldman*, 97 N.J. at 437, 479 A.2d at 383.

181. *Id.* at 437, 479 A.2d at 383.

182. *Id.* at 436, 479 A.2d at 382.

183. *Id.* 479 A.2d at 436, at 383.

*Feldman* court held that the decision whether a drug is unavoidably unsafe should be made on a case-by-case basis.<sup>184</sup> The *Feldman* court then stated that even if a prescription drug were unavoidably unsafe, the comment k immunity would not eliminate liability for failure to provide a proper warning.<sup>185</sup> The proper test for a defective warning is whether the manufacturer knew or should have known of the danger at the time that the product was distributed.<sup>186</sup> Both actual and constructive knowledge acquired after distribution of the product, however, obligates the manufacturer to warn consumers of the newly discovered danger.<sup>187</sup> The *Feldman* court required the manufacturer to bear the burden of proving that the information was not reasonably available or obtainable.<sup>188</sup>

The Supreme Court of Wisconsin in *Collins v. Eli Lilly Co.*,<sup>189</sup> rejected 402A comment k.<sup>190</sup> In *Collins*, the plaintiff sued several drug manufacturers for injuries to her in utero after her mother ingested DES.<sup>191</sup> The court stated that drug companies were like other manufacturers having a duty to produce and market reasonably safe products.<sup>192</sup> Drug companies can either insure themselves against liability, absorb the damage award, or pass the cost along to the consumer as a cost of doing business.<sup>193</sup> The court argued that imposing liability on drug companies would not affect the availability of drugs to the public, but would simply encourage drug companies to produce and market safe drugs.<sup>194</sup>

In a recent decision, *Toner v. Lederle Laboratories*,<sup>195</sup> the Idaho Supreme Court held that comment k was not intended to provide blanket immunity to all prescription drugs.<sup>196</sup> After receiving a DPT vaccination, the plaintiff in *Toner* became paralyzed.<sup>197</sup> Stating that

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184. *Id.*

185. *Id.* at 439, 479 A.2d at 386 (a manufacturer is deemed to know information available in the industry or the particular field). See also Wade, *supra* note 139 at 760 (the court should determine available scientific knowledge as of the time of distribution).

186. *Feldman*, 97 N.J. at 439, 479 A.2d at 386.

187. *Id.* at 437, 479 A.2d at 388.

188. *Id.*

189. *Id.* 116 Wis.2d 166, 342 N.W.2d 37 (1984).

190. *Id.* at 181, 342 N.W.2d at 52 (1984).

191. *Id.* at 171, 342 N.W.2d at 42.

192. *Id.* at 181, 342 N.W.2d at 52.

193. *Id.* at 178, 342 N.W.2d at 49.

194. *Id.* See also, Page, *Generic Product Risks: The Case against Comment k and for Strict Tort Liability*, 54 N.Y.U.L. REV. 856, 884 (1982) (further testing might reveal injurious side effects of a drug before it reaches the market).

195. 55 U.S.L.W. 2456, 732 P.2d 297 (1987).

196. *Toner*, at 308.

197. *Id.* at 298.

comment k only applies to design defects where no alternative design is available, the Idaho court held that comment k clearly contemplates that the benefits of the product should outweigh the risks.<sup>198</sup> Reasoning from the language of the comment, the *Toner* court rejected the argument that blanket immunity should be granted all prescription drugs.<sup>199</sup> The *Toner* court said that obviously not all drugs are so perfectly designed that they cannot be made purer or safer or that the benefits of the drugs outweigh their risks.<sup>200</sup>

## PROPOSAL FOR CALIFORNIA COURTS

### A. Design Defect

A societal policy encouraging the increased availability of inexpensive, life saving drugs is often in conflict with the policies underlying strict product liability. To hold manufacturers absolutely liable for the side effects of drugs could discourage research and marketing of drugs.<sup>201</sup> On the other hand, holding manufacturers liable only for negligence would cause many plaintiffs to bear the burden of society's interest in promoting the availability of prescription drugs.<sup>202</sup> As the court in *Brown v. Superior Court*<sup>203</sup> recognized, the *Barker v. Lull* tests provide an effective standard by which to balance the benefits of a drug against the risks to the consumer.<sup>204</sup> Under *Barker* if the ordinary consumer would not have taken the drug if the consumer had known of the risk or if the risks of the drug outweigh the benefits, the drug is defective.<sup>205</sup> In order to adhere to the policies

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198. *Id.* at 308. See also Willis, *The Comment K Character: A Conceptual Barrier to Strict Liability*, 29 MERCER L. REV. 545 (1978) (society is not served when an unavoidably unsafe product with occasional benefit is insulated from strict liability when the product's predominant effect is harmful to the individual and society).

199. *Toner*, at 308.

200. *Id.*

201. See Schwartz, *Unavoidably Unsafe Products: Clarifying the Meaning & Policy Behind Comment K*, 42 WASH. & LEE L. REV. 1139, 1141 (1985) (society wishes to encourage research and marketing of new drugs and strict liability would stifle this goal).

202. *Collins v. Eli Lilly Co.*, 34 N.W.2d 37, 49 (Wis. 1984) (It is better to have drug companies or consumers share the cost of the injury than to place the burden solely on the innocent plaintiff. Strict liability is particularly important in the case of mass marketed drugs because consumers and their physicians rely upon advice given by the supplier and consequently are virtually helpless to protect themselves from serious injuries caused by deleterious drugs).

203. 182 Cal. App. 3d 1125, 227 Cal. Rptr. 768 (1986).

204. *Id.*

205. *Barker v. Lull Eng'g. Co.*, 20 Cal. 3d 413, 432, 573 P.2d 443, 456, 143 Cal. Rptr. 225, 238 (1978).

underlying strict products liability doctrine<sup>206</sup> the California Supreme Court should hold that prescription drugs may be subject to strict liability for design defect.<sup>207</sup> Comment k, while providing guidance in making a decision, should not provide blanket immunity for all prescription drugs. An unavoidably unsafe product under comment k is a product that cannot be made safer yet the benefits of the product outweigh the risks of the product.<sup>208</sup> Since different drugs have different risks and benefits, the determination whether the benefits outweigh the risks should be made on a case by case basis at the time of trial.

In *Sindell v Abbott Laboratories*,<sup>209</sup> the first DES case in California, the California Supreme Court stated that the manufacturer is in the best position to discover and guard against defects in its product and to warn of injurious side effects.<sup>210</sup> The court stated that these considerations are particularly significant where medication is involved.<sup>211</sup> Consumers cannot protect themselves from serious, sometimes permanent or even fatal injuries caused by dangerous drugs.<sup>212</sup>

By testing for design defect at the time of trial, plaintiffs injured by drugs whose risks outweigh their benefits will be allowed to recover where the risk is endemic to the drug. However, manufacturers who produce drugs whose benefits outweighed their risk will not be strictly liable under a design theory for the occasional adverse reaction to a drug.

If the benefits of the drug outweigh the risks and the design is not defective, the injured party could still proceed under a failure to warn theory. Comment k immunity does not eliminate strict liability

206. McClelland, *supra* note 72, at 34 (strict liability is society's mechanism for effectuating cost-spreading to sellers and a wealth distribution preference in behalf of an injured consumer).

207. See *Barker*, 20 Cal. 3d at 432, 573 P.2d at 456, 143 Cal. Rptr. at 237.

208. Unavoidably unsafe is a conclusion that the Restatement applies to the rabies vaccine based upon a balancing of the risks and benefits of the vaccine. RESTATEMENT (SECOND) OF TORTS § 402A (1964). Comment k says that many prescription drugs will be unavoidably unsafe. Comment k does not say that all prescription drugs are unavoidably unsafe. *Id.* Comment k analysis of the rabies vaccine is similar to the risk benefit analysis of *Barker* since it, like *Barker* focuses on the product. *Id.*

209. 26 Cal. 3d 588, 607 P.2d 924, 163 Cal. Rptr. 132 (1980).

210. *Id.* at 611, 607 P.2d at 942, 163 Cal. Rptr. at 150 (1980). See also *Collins v. Eli Lilly Co.* 342 N.W. 2d 37, 49 (Wis. 1984). In that case, entirely innocent plaintiffs may have been severely harmed by a drug that they had no control over. *Id.* The interests of justice demand that the defendant who provided the product should bear the cost of injury. *Id.* Each defendant contributed to the risk of injury; thus each defendant shares a degree of culpability in producing and marketing a drug with possibly harmful side effects. *Id.*

211. *Sindell*, 26 Cal. 3d 588, 611, 607 P.2d 924, 942, 163 Cal. Rptr. 132, 150.

212. *Id.*

for failure to provide a proper warning.<sup>213</sup> While the presence of a warning is one factor in determining whether a design is defective,<sup>214</sup> the absence of a warning is also a separate basis of liability.

### B. Warning Defects

Strict liability for a failure to warn has often confused California courts because two questions remain unanswered. The first question is whether strict liability can be imposed for undiscoverable defects.<sup>215</sup> Holding a product liable for not warning of unknowable defects would make a manufacturer absolutely liable.<sup>216</sup> Since absolute liability for prescription drugs might impede the development of new drugs,<sup>217</sup> manufacturers should be held liable only for known or knowable defects. The manufacturer, however, should bear the burden of proving that information concerning the defect was not available or obtainable at the time of distribution. If knowledge of a defect is acquired subsequently the manufacturer must notify consumers of the newly discovered defect.

The second question is whether negligence and strict liability tests are the same in a failure to warn case. A difference exists between strict liability and negligence depending on the focus of the inquiry.<sup>218</sup> In a warning defect claim, The focus should be on the product itself not the reasonableness of the conduct of the manufacturer.

The applicability and adequacy of a warning would be judged at the time of distribution.<sup>219</sup> In determining the liability for failure to warn, California courts should apply a *Cavers* balancing approach based upon the manufacturer's actual or constructive knowledge at the time the injury occurred. The manufacturer will have the burden of showing that the manufacturer did not know or could not know

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213. *Feldman v. Lederle Laboratories*, 97 N.J. 429, 436, 479 A.2d 374, 383 (1984).

214. Under both comment k and *Barker* one of the factors to consider in determining whether a design is defective is the presence or absence of a warning of the side effect causing injury. Comment k says that a prescription drug whose benefits outweigh its risks is not defective or unreasonably dangerous when accompanied by proper directions and warning. Under *Barker*, one of the factors to consider in determining whether the benefits outweigh the risks is the presence of a warning.

215. *Finn v. G.D. Searle*, 35 Cal.3d 691, 698, 677 P.2d 1147, 1151, 200 Cal. Rptr. 870, 874.

216. *But see* Schwartz, *Understanding Products Liability*, 67 CAL. L. REV. 435, 488 (1979) (suggesting that strict liability is appropriate for prescription drugs).

217. *Id.* (manufacturers often know of a defect from an early date).

218. *Finn v. G.D. Searle & Co.*, 35 Cal. 3d 691, 698, 677 P.2d 1147, 1151, 200 Cal. Rptr. 870, 874 (1979).

219. *Id.* at 701, 677 P.2d at 1153, 200 Cal. Rptr. at 877.



with the aid of further testing that the drug caused the side effect producing injury.

Judging a failure to warn case on the basis of actual or constructive knowledge will protect manufacturers from being insurers of their drugs. At the same time consumers will be protected because manufacturers will have to show that it was impossible for them to know of the injurious side effect or to warn of it adequately. In the absence of legislative guidance, the court should attempt to balance the two competing societal interests.<sup>220</sup> Society needs life saving drugs and society needs protection from the injurious side effects caused by those drugs.

### CONCLUSION

Strict products liability has sought to protect injured consumers who are unable to protect themselves. Courts have attempted to relieve plaintiffs of their traditional burden of proof under negligence law by shifting that burden to defendant manufacturers who have control of the evidentiary material.

In actions against prescription drug manufacturers, however, this policy of protecting consumers conflicts with the development and manufacture of life-saving or life-enhancing drugs. These drugs often have attendant risks. Many courts have chosen to shield prescription drug manufacturers from strict product liability analysis for design or warning defects. These courts have argued that the interest of society as a whole in the development of prescription drugs outweighs the interest of an injured individual.

This comment has concluded that California courts should reaffirm their commitment to the principles of strict liability by applying strict liability for design defects to prescription drugs. At the same time, society's interest in life saving drugs should be protected by only requiring manufacturers to be liable for known or knowable defects in a failure to warn claim.

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220. *But see* Wildman, *Strict Products Liability in California: An Ideological Overview*, 19 U.S.F.L. REV 139, 157 (1985) (suggesting that strict liability has created a myth that people are being taken care of because of a progressive judicial system, yet prevention of injury is still relegated to unimportant status).