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Unavoidably Unsafe Products and the Design Defect Theory: An Analysis of Applying Comment K to Strict Liability and Negligence Claims

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UNAVOIDABLY UNSAFE PRODUCTS AND THE DESIGN DEFECT THEORY: AN ANALYSIS OF APPLYING COMMENT K TO STRICT LIABILITY AND NEGLIGENCE CLAIMS

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INTRODUCTION

One of the most difficult problems in understanding Minnesota products liability law is the erosion of the distinction between strict liability and negligence. The erosion of this distinction began as early as 1980,1 and it is unclear when the relationship between negligence and strict liability will be resolved conclusively by the Minnesota Supreme Court.

This Note will address Comment k of section 402A of the Restatement (Second) of Torts which provides an exception to strict liability for unavoidably unsafe products, which are primarily classified as prescription drugs. The Note will discuss the application of Comment k in both strict liability and negligence claims. In addition, the Note will dissect the different common law schemes utilized in applying Comment k. The overall purpose of this Note is to analyze and present alternatives regarding whether and to what extent Comment k should apply to strict liability and negligence claims in light of the merger of these two theories in Minnesota.

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I. STRICT LIABILITY

A. History

The doctrine of strict liability had its genesis in a concurring opinion by Justice Traynor in *Escola v. Coca Cola Bottling Co.* Justice Traynor suggested that a manufacturer should be absolutely liable if, in placing a product on the market, it knew that the product was to be used without inspection, and the product had a defect that caused an injury.

Several policy considerations underlie the doctrine of strict liability. First, unlike the public, the manufacturer can anticipate or guard against the recurrence of hazards. Second, the cost of injury may be an overwhelming misfortune to the injured person whereas the manufacturer can insure against the risk and distribute the cost among the consuming public. Finally, it is in the public interest to discourage the marketing of defective products.

In 1961, the members of the American Law Institute considered whether to adopt a rule of strict liability. Two years later, Justice Traynor, writing for the majority in *Greenman v. Yuba Power Products, Inc.*, held a manufacturer strictly liable in tort, based on his reasoning in the *Escola* decision. Finally, in 1965, the Restatement (Second) of Torts published section 402A setting forth the strict liability doctrine as enunciated in *Greenman*. Since the adoption of section 402A, almost all states have adopted some form of strict liability.

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3.  Id. at 461, 150 P.2d at 440.
4.  Id. at 462, 150 P.2d at 440–41.
5.  Id. at 462, 150 P.2d at 441.
6.  Id.
7.  For a description of the process by which the Restatements were drafted, see Goodrich, *The Story Of The American Law Institute*, 1951 Wash. U.L.Q. 283, 287.
9.  Id. at 63, 377 P.2d at 901, 27 Cal. Rptr. at 701.
10. Section 402A provides as follows:
(1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if (a) the seller is engaged in the business of selling such a product, and (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.
(2) The rule stated in Subsection (1) applies although (a) the seller has exercised all possible care in the preparation and sale of its product, and (b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.


B. Minnesota

In 1967, the Minnesota Supreme Court adopted section 402A of the Restatement (Second) of Torts in McCormack v. Hankscraft Co. In so doing, the court employed the general "consumer expectation" standard and held that a product is unreasonably dangerous "[i]f the product presents any danger that would not be contemplated by an ordinary (user) (consumer) who uses it with the knowledge common to the community as to the product's characteristics and common use. . . ."13

Under this standard, the manufacturer's conduct is irrelevant, regardless of whether it is egregious or highly responsible. Rather, focusing solely on the condition of the product, the fact finder can find a manufacturer liable even though the manufacturer could not reasonably know of the danger inherent in its product. Although this approach occasionally leads to a harsh result for a manufacturer who acts reasonably, "enlarging a manufacturer's liability to those injured by its products more adequately meets public policy demands to protect consumers from the inevitable risks of bodily harm created by mass production and complex marketing conditions."14

Since its inception, the distinctive feature of strict liability has been that the plaintiff is not required to establish negligence on the part of the manufacturer because the focus of the claim is on the condition of the product, not the manufacturer's conduct.15 While semantically correct, the Minnesota Supreme Court has adopted an approach which merges the concepts of negligence and strict liability when addressing a design defect claim.16

To say the plaintiff does not have to prove negligence does not mean the manufacturer is not in some sense at fault, only that the plaintiff does not have to prove it. And it is not the product that is sued, but the person who makes or markets it. At the bottom of a strict liability theory is still the notion (certainly shared by jurors) that the manufacturer did something wrong, and therefore, should pay.

This notion of "wrongness" surfaces when the law attempts to define what it means by a defect. A defect is something which makes the product "unreasonably dangerous." And something is unreasonably dangerous "if the product is dangerous when used by an ordinary user who uses it with knowledge common to the community as to the product's characteristics and common usage." So we come full circle back to something with negligence overtones. . . .

Id. at 215.

16. See Steenson, supra note 1, at 501. During the 1980s, the Minnesota Supreme
In *Bilotta v. Kelley Co.*, the Minnesota Supreme Court recognized the lack of distinction between strict liability and negligence in a design defect claim. The court completely rejected the "consumer expectation" standard of strict liability in favor of a negligence "reasonable care" standard which focuses on the conduct of the manufacturer rather than on the condition of the product.

The *Bilotta* court rationalized its decision to adopt the "reasonable care" standard in strict liability design defect cases by noting that the "defect" in a design defect case "lies in a consciously chosen design" in which the manufacturer "deliberately added or omitted the challenged component and has presumably made that decision after balancing a variety of factors." Therefore, the key element in determining liability is the manufacturer's balancing of the product's risk against its utility.

Court's decisions show a steady reduction of distinctions between negligence and strict liability theories in design defect and failure to warn cases. Id.

17. 346 N.W.2d 616 (Minn. 1984). The plaintiff suffered severe injuries while working at a loading dock. The plaintiff had been assigned to general clean up chores near the loading dock. Another employee was unloading a semitrailer with a forklift at the same time. Somehow the forklift became stuck on the dock and the ramp. While the other employees were trying to free the forklift, the forklift tipped over and pinned the plaintiff at the neck against the warehouse doorjamb. The plaintiff was trapped for several minutes. Consequently, his brain was deprived of oxygen and he suffered permanent brain damage. Id. at 620. The plaintiff sued Kelley Company, the dockboard manufacturer under both strict liability and negligence theories. Id. at 619.

18. Id. at 622. See also *Holm v. Sponco Mfg. Inc.*, 324 N.W.2d 207, 212 (Minn. 1982). In *Holm*, the court first recognized the lack of distinction when the court overruled the "latent-patent danger" rule of strict liability, and adopted a reasonable care standard:

>a manufacturer is obligated to exercise that degree of care in his plan or design so as to avoid any unreasonable risk of harm to anyone... when the product is used in the manner for which the product was intended, as well as an unintended yet reasonably foreseeable use.

What constitutes "reasonable care" will, of course, vary with the surrounding circumstances and will involve "a balancing of the likelihood of harm, and the gravity of harm if it happens, against the burden of the precaution which would be effective to avoid the harm."


19. *Bilotta*, 346 N.W.2d at 622. The court used the same standard as in *Holm*, and removed any doubt that the reasonable care balancing approach should be applied in design defect cases. *Bilotta*, 346 N.W.2d at 622.

20. Id.

21. Id. In evaluating the manufacturer's conduct, the jury could consider several factors:

> (1) the usefulness and desirability of the product;
> (2) the availability of other and safer products to meet the same need;
> (3) the likelihood of injury and its probable seriousness;
> (4) the obviousness of the danger;
> (5) common knowledge and normal public expectation of the danger;
After *Bilotta*, strict liability and negligence merged into one negligence standard of recovery in design defect cases. This is best exemplified by the language of the jury instruction, from the Minnesota Jury Instruction Guide, intended for design defect cases:

A manufacturer has a duty to use reasonable care when designing a product, so as to avoid any unreasonable risk of harm to (anyone who) (property that) is likely to be exposed to harm when the product is put to its intended use or to any use that is unintended but is reasonably foreseeable.

What constitutes reasonable care will vary with the surrounding circumstances. Reasonable care is the care that a reasonably prudent person would exercise under the same or similar circumstances.

The reasonable care to be exercised by a manufacturer when designing a product will depend on all facts and circumstances, including, among others, the likelihood and seriousness of harm against the feasibility and burden of any precautions which would be effective to avoid the harm. You are instructed that the manufacturer is obligated to keep informed of scientific knowledge and discoveries in its field.

If the manufacturer did not use reasonable care when designing the product in question, then the product is in a defective condition unreasonably dangerous to the (user or consumer) (user's or consumer's property).

The establishment of this basic standard is still evolving, and while it may have resolved some of the problems that exist in design defect cases, several issues remain unanswered. One issue which has been left unanswered is the applicability of Comment k. It is that issue which this Note will now address.

II. COMMENT K

A. History and Public Policy

In the process of considering whether to adopt strict liability in 1961, the members of the American Law Institute (ALI) pondered, during a rather confusing discussion, whether the manufacturer of a prescription drug should be subject to the doctrine. One member

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(6) the avoidability of injury by care in use of the product (including the effects of instruction or warning); and
(7) the ability to eliminate the danger without seriously impairing the usefulness of the product or making it unduly expensive.

*See* Krein v. Raudabough, 406 N.W.2d 315, 318 (Minn. Ct. App. 1987); see also Holm, 324 N.W.2d at 212 (citing Wade, *Strict Tort Liability of Manufacturers*, 19 S.W. L.J. 5, 17 (1965)).

22. *See* Steenson, *supra* note 1 and accompanying text.
23. MINN. JURY INSTRUCTION GUIDES, CIVIL 3D JIG 117 (1986) [hereinafter MINN. JIG 3d].
of the institute made a motion that all prescription drugs should be exempt from strict liability on the ground that it would be "against the public interest" to apply the doctrine to such products because of the "very serious tendency to stifle medical research and testing."\(^{25}\)

Dean Prosser, the reporter at that time for the Restatement (Second) of Torts, responded with his own proposed exemption and suggested that it be dealt with in the comments to the section.\(^{26}\) The arguments and the discussion that followed were unfocused, and ultimately, both motions were defeated.\(^{27}\)

The defeat of Dean Prosser’s motion, however, is not reflected in the version of the comments he wrote that accompany section 402A.\(^{28}\) In particular, Comment k, which was approved by the members of the ALI and published along with section 402A in 1965,\(^{29}\) contains an exception for unavoidably unsafe products. The version of Comment k approved and published in 1965 provides as follows:

\[k. \text{ Unavoidably unsafe products.}\]

There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps

25. Id. at 98 (Harold B. Gross of New York City made the motion).
26. Id. at 96. Dean Prosser suggested that a better case could be made for excluding "relatively new, experimental, and uncertain drugs, of which there are a great many on the market. . . ." Id. at 93. He then defined the term "experimental drug" to include virtually all prescription drugs and even some over the counter medicines. Id. at 96.
27. 38 A.L.I. Proc. at 98.
28. See Page, supra note 26, at 866.
29. Restatement (Second) of Torts § 402A (1965).
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.\textsuperscript{30}

Although section 402A imposes strict liability on a seller who markets a product deemed to be defective and thereby unreasonably dangerous to the consumer, Comment k provides an exception to the strict liability rule in the case of “unavoidably unsafe” products.\textsuperscript{31} It is unclear, however, when the exception applies, and to which drugs. Thus, one needs to focus on several key phrases and also to understand the overall public policy of Comment k when applying the doctrine to different factual settings and legal principles.

In so doing, the first key phrase is the definition of an “unavoidably unsafe” product. Comment k defines this as a product which, “in the present state of human knowledge, [is] quite incapable of being made safe for [its] intended and ordinary use.”\textsuperscript{32} The second key phrase is that Comment k is particularly applicable to the “field of drugs,” where such products are “especially common” in three overlapping categories: (1) high-benefit, high-risk drugs, such as the vaccine used for rabies; (2) “many other drugs, vaccines and the like, many of which, because of high risk involved cannot legally be sold except to physicians, or under the prescription of a physician”; and (3) “many new or experimental drugs.”\textsuperscript{33}

Third, the focus must be where the comment declares that “such a product, properly prepared, and accompanied by proper directions and warning is not defective, nor is it unreasonably dangerous.”\textsuperscript{34} The fourth and final key phrase states that “the seller of such products . . . 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.”\textsuperscript{35}

In interpreting these key phrases, it is apparent that Comment k

\textsuperscript{30} Id. at Comment k (emphasis in original).


\textsuperscript{32} ReSTATEMENT (SECOND) OF TORTS § 402A comment k (1965).

\textsuperscript{33} Id.

\textsuperscript{34} Id. (emphasis in original).

\textsuperscript{35} Id. For a detailed analysis of comment k’s language, see Willig, The Comment k Character, A Conceptual Barrier to Strict Liability, 29 MERCER L. REV. 545 (1978).
furnishes no criteria for determining how risky and how beneficial a drug must be in order to qualify as "unavoidably unsafe." Equally troubling is that while Comment k emphasizes unreasonably dangerous, the wording suggests that the same characteristic that made the product unreasonably dangerous might also make it defective. Whatever the case may be, it is these literal ambiguities that have led to the onslaught of conflicting common law rules in interpreting and applying Comment k.

B. Common Law

Generally, there are three varieties of product defects: manufacturing flaws, design defects, and inadequate warnings. It is very common to plead claims of both design defect and inadequate warnings when asserting strict liability against prescription drug manufacturers. Accordingly, this Note focuses on only these two claims.

Courts and commentators universally agree, however, that the only unavoidably unsafe products by Comment k's terms which are exempt from strict liability are those which the plaintiff alleges contain a design defect, and not those which the plaintiff alleges contain an inadequate warning.

Some courts have taken the view that Comment k applies as a matter of law to all design defect claims involving prescription drugs. Others, however, have taken the view that Comment k does not provide blanket immunity to all prescription drugs; rather, the language of Comment k applies only to "some" products. These two vastly different approaches have left the application of Comment k in a constant state of flux.

37. See generally Page, supra note 26, at 867.
39. See Twerski, Weinstein, Donaher & Piehler, The Use and Abuse of Warnings in Products Liability—Design Defect Litigation Comes of Age, 61 CORNELL L. REV. 495, 501 (1976) [hereinafter Twerski]. Submitting a case on dual grounds of failure to warn and design defect results from the realization that if proper warning would result in the non-marketability of a product, then the true issue is acceptability of basic design.
41. See infra notes 70–90 and accompanying text.
42. See infra notes 43–69 and accompanying text.
1. The Feldman, Kearl, and Toner Approach

The Feldman, Kearl, and Toner approach proposes that in a strict products liability action based upon a design defect theory, courts must, on a case-by-case basis, condition the application of Comment k upon a prior showing that the drug was in fact "unavoidably dangerous."43 In Feldman v. Lederle Laboratories,44 the plaintiff's teeth became discolored turning to a gray-brown color as a result of taking a drug, tetracycline, produced by the defendant manufacturer.45 She commenced a strict products liability action against the manufacturer. At the trial level, the jury found for the defendant. On appeal, the jury's verdict was affirmed. The court reasoned that since prescription drugs are a special category of products, drug manufacturers would not be strictly liable for failure to warn of a side effect when it was unknown at the time the product was sold.46

The Supreme Court of New Jersey, however, reversed and remanded. The court held that a manufacturer could be held strictly liable for failing to warn of a side effect that was unknown when the drug was sold where the manufacturer had sufficient information to warrant a warning.47 The court also addressed the applicability of Comment k, even though it was not addressed at trial.48 The court recognized that the unsafe nature of certain prescription drugs may be avoided through better manufacturing or design.49 Ultimately, the court concluded that the determination of whether a drug is unavoidably unsafe should be viewed on a case-by-case basis, rather than giving all prescription drug manufacturers a blanket immunity from strict liability under Comment k.50 The court held that only after considering several risk-utility factors51 and other relevant considerations should a court conclude that the strict liability principle should not be applied.52

In Kearl v. Lederle Laboratories,53 the plaintiff brought a strict prod-

43. See Brown, California Speaks Out on Prescription Drug Liability, FOR THE DEFENSE, August 1988, at 16.
45. Id. at 434, 479 A.2d at 376.
46. Id. at 435, 479 A.2d at 377.
47. Id. at 463–64, 479 A.2d at 392.
48. Id. at 441–42, 479 A.2d at 380.
49. Id. at 447, 479 A.2d at 383. The court saw "no reason to hold as a matter of law and policy that all prescription drugs that are unsafe, are unavoidably so. Drugs, like any other products, may contain defects that could have been avoided by better manufacturing or design." Id.
50. Id.
51. Id. at 444, 479 A.2d at 382. In a footnote, the court referred to the factors to be weighed as those set forth by Professor Wade.
52. Id.
ucts liability action against the manufacturer after contracting a disease and developing paralysis from her ingestion of an oral polio vaccine produced by the manufacturer.54 At trial, the jury determined that the defendant’s polio vaccine was defective and caused the plaintiff to contract the disease.55

On appeal, the Supreme Court of California reversed and remanded. The court held that “although in a standard products liability litigation a plaintiff may utilize a strict liability design defect theory, such a strict liability cause of action must be prohibited for public policy reasons if the court determines, after taking evidence, that the product complained of is ‘unavoidably dangerous.’”56

In line with Feldman, the court stated that “a drug, vaccine, or any other product [that] triggers the unavoidably dangerous product exemption [enunciated in Comment k] poses a mixed question of law and fact and can be made only after evidence is first taken out of the jury’s presence. . . .”57 This approach calls for a “mini-trial” by each trial judge to determine whether the particular drug in question was “unavoidably dangerous” before Comment k would be applied.58

The Kearl court provided a three part test to be used by trial judges when making their determination: (1) determine whether the drug conferred an “exceptionally important benefit” that made it “highly desirable”; (2) determine whether the risk posed by the product was both “substantial” and “unavoidable,” i.e. whether any alternate product would have as “effectively accomplished the full intended purpose” of the product; and (3) determine whether the interest in the drug’s availability outweighed the interest of applying strict liability.59

In effect, the Kearl approach, similar to Feldman, mandates a case-by-case analysis, incorporating a risk-benefit analysis to determine if the product will be unavoidably dangerous and exempt from a strict products liability design defect analysis.

In Toner v. Lederle Laboratories,60 the plaintiff received a vaccination of Tri-Immunol, a drug manufactured by the defendant designed to immunize children against diphtheria, pertussis and tetanus.61 The plaintiff then became paralyzed from the waist down and brought a suit against Lederle.62 At trial, the jury found that Lederle’s vaccine

54. Id. at 820, 218 Cal. Rptr. at 456–57.
55. Id. at 821, 218 Cal. Rptr. at 457. The plaintiff recovered $800,000. Id.
56. Id. at 817, 218 Cal. Rptr. at 454 (emphasis in original).
57. Id. at 829, 218 Cal. Rptr. at 463.
58. See Brown, supra note 43 and accompanying text.
61. Id. at 330, 732 P.2d at 299.
62. The suit was tried to the jury on theories of strict liability, negligence, breach of warranty and merchantability, and failure to warn. Id.
had caused the plaintiff's paralysis, and that the defendant was negligent. However, the jury also found that the vaccine was not in a "defective condition unreasonably dangerous to persons."\(^6\)

Lederle appealed to the United States Court of Appeals for the Ninth Circuit, which in turn certified four questions to the Supreme Court of Idaho.\(^6\) These questions centered on the applicability of the unavoidably unsafe product doctrine, as described in Comment k, to Idaho strict liability and negligence law.\(^6\)

In discussing the applicability of Comment k to strict liability claims, the Toner court, as in Feldman and Kearl, held that courts, after hearing evidence out of the jury's presence, must decide the applicability of Comment k on a case-by-case basis.\(^6\) The court in Toner reaffirmed the Feldman and Kearl principle that Comment k was not intended to provide nor should provide all ethical drugs with blanket immunity from strict liability design defect claims.\(^6\) Such a rule, the court noted, "runs counter both to the express language of comment k and to common sense."\(^6\) Accordingly, the court remanded the case back to the Idaho Court of Appeals requiring a utility-risk analysis before Comment k is applied.\(^6\)

2. The Brown Approach

In Brown v. Superior Court,\(^7\) a unanimous California Supreme Court rejected the Feldman, Kearl, and Toner approach and held that Comment k applies to all prescription drugs. In Brown, approximately seventy plaintiffs filed individual lawsuits against numerous drug manufacturers claiming they suffered injuries from using dieth-

\(^{63}\). Specifically, the jury found that the pertussis component of the vaccine had caused the plaintiff's paralysis, and awarded him $1,131,200 in damages. \textit{Id.}

\(^{64}\). \textit{See Toner}, 779 F.2d 1429, 1430 (9th Cir. 1986).

\(^{65}\). 112 Idaho at 334, 732 P.2d at 303. The certified questions were reformulated to read as follows:

(1) Under Idaho law, do the principles set forth in Restatement (Second) of Torts § 402A comment k (1965) apply to strict liability claims, and in particular to the claim in this suit? (2)(a) Under Idaho law, do the principles set forth in Restatement (Second) of Torts § 402A comment k (1965) apply to negligence claims, and in particular to the claims of this suit?

\textit{Id.}

\(^{66}\). \textit{Id.} at 340, 732 P.2d at 309.

\(^{67}\). \textit{Id.} at 339, 732 P.2d at 308. The court supported this conclusion through the literal language of Comment k by noting that the comment refers only to "'some' products which are unavoidably unsafe. . . ." Further, the court remarked that "the comment states such products are 'especially common in the field of drugs'. . . ." \textit{Id.} (emphasis in original). The court concluded that this language in and of itself certainly "does not apply to all drugs." \textit{Id.} (emphasis in original).

\(^{68}\). \textit{Id.} at 340, n.10, 732 P.2d at 309, n.10.


ylstilbestrol (DES), a prescription drug.71 The plaintiffs claimed that the drug was defective and injured them in utero when their mothers ingested it in order to prevent a miscarriage.72 Because each of the lawsuits raised several common issues, the actions were designated as “complex litigation” and assigned to the Honorable John E. Benson for resolution of various pre-trial motions.73 On appeal, the California Supreme Court unanimously upheld Judge Benson’s rulings. Specifically, the court held that negligence, not strict liability, governs actions involving injuries resulting from the use of prescription drugs.74

In affirming Judge Benson’s holdings, the California Supreme Court emphatically rejected the Kearl approach. First, the court noted that it would be unjust to allow Comment k protection exclusively to drugs which have proven useful to mankind and not to drugs which are “clearly harmful.” To do so would substantially impair the development and marketing of new drugs.75 The court noted that the harm to this interest arises in the very process of attempting to make the distinction.76

Second, the court found that the Kearl approach provides a disincentive to drug manufacturers to develop and produce new drugs because there is no assurance that strict liability standards would not be applied.77 For example, a particular judge may feel that the drug did not confer an “exceptionally important benefit,”78 that the risks were not “substantial” and “unavoidable,” or that another drug on the market would have accomplished the same result without the risks. Since the advantages of a drug cannot be isolated from a particular patient, the court also noted that any attempt to determine the “superiority” of one drug over another would have to be made in reference to a particular plaintiff and not in the abstract.79

71. Id. at 1055, 751 P.2d at 473, 245 Cal. Rptr. at 414.
72. Id. at 1054-55, 751 P.2d at 473, 245 Cal. Rptr. at 414.
73. Id.
74. Id. at 1061, 751 P.2d at 477, 245 Cal. Rptr. at 418. The court also ruled that (1) fraud and warranty are not viable causes of action where the plaintiff cannot identify the manufacturer of the product; and (2) a manufacturer’s potential liability under the market share doctrine is several not joint. Id. at 1069-75, 751 P.2d at 483-87, 245 Cal. Rptr. at 424-28. The California Court of Appeals also unanimously upheld Judge Benson’s holding. Brown v. Superior Court, 192 Cal. App. 3d 150, 227 Cal. Rptr. 768 (1986).
75. 44 Cal. 3d at 1067, 751 P.2d at 481, 245 Cal. Rptr. at 423. In particular, the court stated as an example that “it seems unjust to grant the same protection from liability to those who gave us thalidomide as to the producers of penicillin.” Id.
76. Id.
77. Id. at 1067-68, 751 P.2d at 482, 245 Cal. Rptr. at 423.
78. Id. at 1068, 751 P.2d at 482, 245 Cal. Rptr. at 423; see also supra note 59 and accompanying text.
79. 44 Cal. 3d at 1068, 751 P.2d at 482, 245 Cal. Rptr. at 423. “Thus, in one
Third, the court concluded that unpredictable and inconsistent judgments involving the same product would inevitably result. Therefore, a drug manufacturer would not have a basis to determine the extent of its liability when deciding whether or not to sell a new drug. These results, the court noted, could not be harmonized by appellate courts without threatening the fundamental rule that a trial court’s decision on the facts must be upheld if based on “substantial evidence.” The court reasoned further that each case which involves the same drug depends upon the evidence presented and the judge’s subjective perception of whether the three criteria were met. Thus, each jurisdiction could be riddled with inconsistent determinations about the same product, which could deter manufacturers from developing and offering new products.

Fourth, the *Brown* court ruled out the *Kearl* approach because of the danger of inconsistency between the findings of the judge and jury in the same case. This is due to the similarity between the *Kearl* and *Barker* risk/benefit analysis. The only difference is that in *Kearl*, the judge makes the determination of whether the product is defectively designed. Consequently, if the judge decides that the *Kearl* criteria have not been met and that the *Barker* standards should apply, the jury will be asked to make a second determination, based on similar factors and evidence, as to whether the drug is defectively designed.

The *Brown* court’s rejection of the *Feldman*, *Kearl*, and *Toner* case-by-case risk/benefit analysis is significant since it implicitly rejected the idea that a manufacturer can be held liable for a drug’s “design,” regardless of whether in strict liability or negligence. The court in *Brown* focused on the manufacturer’s duty to warn. Specifically, it held that a manufacturer cannot be held liable for an injury caused by a properly manufactured drug which was accompanied by an adequate warning to physicians of risks that were known or reasonably, scientifically knowable at the time of distribution. Thus, even though the court discussed a drug’s “design” in terms of strict liability, its rejection of risk/benefit criteria as a standard for liability ap-

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80. Id.
81. Id.
82. Id. See also supra note 59 and accompanying text.
83. *Brown*, at 1067, 751 P.2d at 481, 245 Cal. Rptr. at 423.
84. Id. at 1068, 751 P.2d at 482, 245 Cal. Rptr. at 423.
85. Id.
86. See supra notes 50-56 and accompanying text.
87. *Brown*, at 1068, 751 P.2d at 482, 245 Cal. Rptr. at 424.
89. Id.
appears to make a claim for "negligent design" untenable in a prescription drug case.\footnote{Id. But see \textit{Brown}, 44 Cal. 3d at 424 n.12, 751 P.2d at 483 n.12, 245 Cal. Rptr. at 483 n.12. In this footnote, the California Supreme Court explains, "Our conclusion does not mean, of course, that drug manufacturers are free of all liability for defective drugs. They are subject to liability for manufacturing defects, as well as under general principles of negligence, and for failure to warn of known or reasonably knowable side effects." \textit{Id.} This statement suggests that, in California, Comment k does not preclude design defect claims based on negligence. However, the California Supreme Court does not discuss whether Comment k would apply where strict liability and negligence are merged, as in Minnesota.}

\section{Minnesota and Comment k}

The Minnesota appellate courts have not had an occasion to decide whether, and in what capacity, to adopt Comment k. The issue was, however, considered in Minnesota Federal District court by Judge Robert G. Renner in \textit{Kociemba v. G.D. Searle & Co.}\footnote{680 F. Supp. 1293 (D. Minn. 1988).}

In \textit{Kociemba}, the plaintiff had been inserted with a CU-7, which is an intrauterine contraceptive device produced by G.D. Searle.\footnote{Id. at 1295. On February 25, 1974, the FDA notified Searle that the CU-7 had been approved as a prescription drug for sale and distribution in accordance with Section 505 of the Federal Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. § 355 (1987).} After wearing the device for approximately one and one-half years, the plaintiff decided to start a family.\footnote{Id. at 1296. On June 6, 1977, the plaintiff was inserted with the CU-7 by Dr. Timothy Scanlan. Twelve days later the plaintiff awoke with severe cramping caused by an infection. Dr. Scanlan diagnosed the infection as mild endometritis, treated it, and it disappeared within a month. The plaintiff wore the CU-7 until November 1978, when Dr. Klotter removed the device. \textit{Id.}} Following an hysterosalpingogram test, the plaintiff was diagnosed as having blocked fallopian tubes—she was infertile.\footnote{Id. After being unable to determine why the Kociemba's were unable to conceive a child, Dr. Klotter referred the plaintiff to Dr. David Lees, a specialist in artificial insemination. It was on January 18, 1982, that the HSG test was performed determining Mrs. Kociemba's infertility. \textit{Id.}} After consulting several physicians who suggested that a pelvic inflammatory disease (PID) caused by the CU-7 resulted in her infertility, the plaintiff commenced a lawsuit against the manufacturer.\footnote{Id. at 1297. In April 1982, Dr. Lees referred the plaintiff to Drs. Tagatz and Nagel at the University of Minnesota Hospitals. It was some two years later, in June 1984, that Dr. Nagel informed Kociemba that her infertility was related to her use of the CU-7 and PID. On October 1, 1984, the Kociemba's commenced their action. \textit{Id.}}

The plaintiff's complaint contained several counts, but the focus of this Note is on the first two. In count one, the plaintiff alleged that the defendant negligently designed, tested, manufactured, pro-
moted, labeled, distributed and sold the CU-7, which resulted in providing an unsafe product to the plaintiff.\(^{96}\) Count two alleged that the defendant manufactured, sold, promoted, and distributed an unreasonably dangerous and defective product and was liable under the doctrine of strict liability.\(^{97}\)

On a motion for summary judgment brought by the defendants, the applicability of Comment k was considered.\(^{98}\) In denying the motion, Judge Renner predicted that the Minnesota courts would adopt Comment k if given the opportunity.\(^{99}\) The court stated that, assuming Comment k was adopted, it would nevertheless not apply to all prescription drugs as a matter of law (Brown approach), but only to "some" products (Feldman, Kearl, & Toner approach). Accordingly, the court concluded that material issues of fact existed and that summary judgment was therefore improper.\(^{100}\)

The court stated further that when the jury is deciding whether a product is unavoidably unsafe, the following three factors should be considered:

(i) whether the product could have been designed in a safer manner;
(ii) whether a safer alternative product could have been available at that time to accomplish the same intended purpose as the product in question; and
(iii) whether the benefits of the product outweigh the interest in promoting enhanced accountability on the part of the

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96. Id. "Count One further alleges that the defendant negligently, fraudulently, and intentionally misrepresented the effects of the CU-7 and failed to adequately warn physicians of said defects." Id.

97. Id.

98. Id. at 1300. Searle maintained that the CU-7, and for that matter, all prescription drugs are "unavoidably unsafe." Thus, it argued that the Comment k protection should apply to the CU-7 as a matter of law, and that the strict liability count should be dismissed. Searle further argued that since Minnesota appellate courts have merged the concepts of negligence and strict liability in product design defect cases, summary judgment was appropriate for all counts alleging design defects. Id.

99. Id. The court noted that the Minnesota Supreme Court has adopted or approved several other Comments under section 402A. See id. (citing Farr v. Armstrong Rubber Co., 288 Minn. 83, 89-91, 179 N.W.2d 64, 69-70 (1970) (comments g, h, i, and m); Olson v. Village of Babbitt, 291 Minn. 105, 109-111, 189 N.W.2d 701, 705 (1971) (comment 1); Magnuson v. Rupp Mfg. Inc., 285 Minn. 32, 38-40, 171 N.W.2d 201, 206 (1969) (comments g, h, i, j); Holm v. Sponco Mfg. Inc., 324 N.W.2d 207, 213 (Minn. 1982) (comment c)).

100. Kociemba, 680 F. Supp. at 1301. The court specifically found that there are genuine issues of material fact as to whether Searle gave adequate warnings to Dr. Scanlan, as well as to the medical community-at-large. Id. at 1300-01. In addition, the court found that, even if the fact finder concludes that Searle provided adequate warnings on the CU-7, a factual question remains as to whether CU-7 is "unavoidably unsafe" and therefore subject to Comment k protection. Id. at 1300.
After two months of trial, and some 4000 exhibits, both sides rested, at which time the defendants made a motion for a directed verdict. This motion forced the court to reconsider the applicability of Comment k. Upon review, Judge Renner reaffirmed his initial ruling rejecting Brown, but modified significantly the jury instruction. Specifically, the court recognized that Bilotta had merged strict liability and negligence in design defect claims. The court concluded that the negligence based standard of Bilotta, as reflected in the JIG 117, implicitly contained the policy considerations underlying Comment k. As noted by the court, analysis of the texts of JIG 117 and Comment k both require a risk/utility balancing test to determine the reasonableness of the manufacturer's conduct in producing a given product. An important difference between the tests, however, is that Comment k explicitly provides that a manufacturer may act reasonably in manufacturing an unavoidably unsafe product while JIG 117 merely implies the same.

Because it found the tests to be essentially the same, the court held that two separate special verdict questions reflecting the same balancing test should not be given. Thus, the jury received only one special verdict question on whether the CU-7 was defectively designed, and received an additional instruction after JIG 117 was read. That instruction reads as follows:

A product prescribed by a physician is not negligently designed merely because it may have side effects.

Some products, given the present state of human knowledge cannot be made totally safe for their intended and ordinary use. Because of the nature of the ingredients or natural characteristics of the product, their use involves substantial risk of injury, and some users will necessarily be harmed. Thus, a manufacturer is not negligent merely because it supplies the public with an apparently useful and desirable product that has a known but apparently

101. Id. (citing Patten v. Lederle Laboratories, 676 F. Supp. 233, 237 (D. Utah 1987)).
103. Id.
104. Id. at 434. See also supra notes 16–23 and accompanying text for a full discussion and impact of the merger of the two doctrines.
106. Id. at 435. See also supra note 23 and accompanying text. For a full discussion of Comment k's language, see supra notes 24–37 and accompanying text.
108. Id.
109. Id. The court stated that it adopted a position in which the jury can consider unavoidable but reasonable risks of a desirable product at the same time it considers the reasonableness of the manufacturer's conduct. Id.
reasonable risk.110

By taking this course of action, the court was trying to reduce the possibility of perverse verdicts.111 At the same time, the court was trying to strike a fair balance between the policy encouraging a manufacturer to produce useful but unavoidably dangerous products and the policy that holds a manufacturer accountable for unreasonable conduct.112

In furthering these objectives, the court also concluded that since the above considerations are best reserved for the fact finder, the Brown approach would not be applied in Minnesota.113 In addition, the court rejected the applicability of Brown because California's "consumer expectation" standard is different from Minnesota's "reasonable care" standard.114 Accordingly, in light of Bilotta, the court declined to adopt Brown because it would eliminate both negligent and strict liability design defect claims in prescription drug cases, except to the extent that a manufacturer is liable for its failure to warn the user of the inherent dangers of the drug.115

IV. ANALYSIS

The legal repercussions resulting from the merger of strict liability into negligence for design defect claims in Minnesota are unresolved. A problematic offshoot from this merger is the Comments to the now rejected 402A, and more specifically, Comment k.

It is the position of this author, that since the Minnesota Supreme Court has stated that there is little difference between strict liability and negligence claims for improper design, and in effect has merged the two theories together, Comment k and its rationale should apply to the now available cause of action in negligence.116 If the court

110. Id.
111. Id. The possibility of perverse verdicts, or inconsistent determinations, was also a concern for the Brown court in overruling Kearl's mini-trial approach. See supra text accompanying note 84.
112. Id.
113. Id.
114. Id. at 436.
115. See id.
116. See Hill v. Searle Laboratories, 884 F.2d 1064, 1069 (8th Cir. 1989) (applying Arkansas law). In Hill the Eighth Circuit Court of Appeals affirmed the district court's determination that Arkansas courts would join the majority of jurisdictions and adopt the defense to strict liability contained in Comment k. The court of appeals, however, reversed the district court on its determination that all prescription drugs, including the CU-7, fall within the scope of Comment k. Judge Heaney, writing for the majority, distinguished the Brown case and decided to agree with Kociemba's rational and held that the unavoidably unsafe product exception should apply only upon a showing of exceptional social need. Id. In addition, the court held that Comment k only applies to "some" prescription drugs, not all prescription drugs, which must be determined on a case by case basis. Id.
adopted such a position, it would be recognizing that, by definition, a
product which may be "unavoidably unsafe" would be neither "un-
reasonably dangerous" to the consumer (the strict liability standard)
nor would it create an "unreasonable risk of harm" to the consumer
(the negligence standard). Accordingly, Comment k could exclude
"unavoidably unsafe products" as being not defective or unreasona-
bly dangerous.

Assuming, arguendo, that the court would adopt the proposition
that the Comment k exception to strict liability applies to negligence
causes of action, the court should additionally decide whether Com-
ment k applies to prescription drugs as a matter of law, or whether
this is a question of fact, and, if a question of fact, which party has the
burden of proof. In resolving this question, the court will have to
wrestle with whether to adopt the blanket "as a matter of law" ap-
proach as stated in Brown,117 or, whether to fashion some other
mixed question of law and fact approach as in Kociemba.118

In choosing between these two alternatives, the supreme court
may decide to fashion a more stringent mixed question of law and
fact approach than Kociemba, while not going quite as far as Brown.119
In adopting such an approach, the court could enable the trial judge
to apply Comment k as a matter of law only after weighing the fol-
lowing considerations: (1) if reasonable minds could not differ in de-
ciding that the drug's benefits exceed its risks, with deference being
given to the FDA's earlier risk/benefit analysis; (2) if there are no
genuine issues of material fact surrounding any fraud or misrepre-
sentation to the FDA regarding the drug's design and safety; and (3)
if the plaintiff's case primarily lies in failure to adequately warn of
risks that were known or reasonably scientifically knowable at the
time of distribution.

Under this approach, the court would not make a negligent design
defect claim for prescription drugs totally baseless in Minnesota, but
would allow the trial judge more flexibility and at the same time bal-
ance the competing interests of plaintiffs and manufacturers. For in-
stance, if the trial judge were to find that an application of the
risk/benefit analysis allows reasonable minds to differ despite the
FDA approval, then the issue should go to the jury. Similarly, if
there was evidence and material fact questions regarding fraud and
misrepresentation to the FDA, or if in fact the alleged defect may

117. See supra notes 70–90 and accompanying text.
118. See Kociemba, 695 F. Supp. at 493.
The Supreme Court of Rhode Island adopted a mixed question of law and fact ap-
proach similar to Kociemba, but less stringent than the one proposed, and couched in
strict liability terms. See id.
have been avoidable, then the judge should submit the issue to the trier of fact.

By allowing this flexibility, the burden of proof would shift to the "superior knowledge" of the defendants, and require them to show that the benefits outweighed the risks at the time the product was prescribed; that there are no material questions of fact regarding fraud or misrepresentation; and that the alleged defect was in fact unavoidable given the scientific knowledge and testing at the time the product was approved.

As is evident from the above discussion, there certainly is some practical merit in conferring immunity through Comment k to design defect claims for all prescription drugs as stated in Brown. Nevertheless, the literal interpretation of Comment k applies only to "some" products, and in light of the merger of strict liability and negligence, the mixed question of law and fact approach would be a realistic alternative given the differences of Minnesota and California product liability law.120

CONCLUSION

Prescription drugs today are the most heavily regulated consumer products in our society.121 Vaccine research, an area in which the United States was once a leader, has slowed to a trickle.122 We cannot permit liability doctrines to slow drug development, cause enormous price increases, and inevitably drive beneficial products off the market. As stated by one major pharmaceutical president, "Who in his right mind would work on a product today that would be used by pregnant women?"123 We cannot tolerate this reality, we need to encourage, not stifle drug manufacturers from developing lifesaving, disease preventing, and illness curing drugs.

How to simultaneously protect the interests of society, the drug industry, and the innocent victims of certified drugs on the market, is one of the most difficult problems facing our tort system today. As a state we should be a leader in curtailing the liability crisis that has and will deprive the public of safe, effective products that help make life easier, healthier and longer.

Inevitably there will be many more prescription drug related cases in the years to come. Based upon the foregoing analysis, it seems clear that this issue is ripe for consideration in Minnesota, and may

120. For a complete discussion of the differences between Minnesota and California design defect law, see Kallio v. Ford Motor Co., 407 N.W.2d 92, 95 (Minn. 1987).
123. Id. at 155.
be a candidate for accelerated review or certification to resolve expeditiously this important social and legal dilemma.

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