An Escape from Strict Liability: Pharmaceutical Manufacturers' Responsibility for Drug-Related Injuries under Comment k to Section 402A of the Restatement (Second) of Torts

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I. INTRODUCTION

Since the 1960’s there has been a continuing rise in litigation related to prescription drugs. Although pharmaceuticals have many salutary purposes and life-saving potential, the hazards of ethical drugs for therapeutic purposes have become patently clear in the past two decades. Diverse injuries, many of which are virtually nonexistent outside of their drug-related incidence, can have catastrophic effects on the lives of unsuspecting patients. When


2. Webster’s 9th New Collegiate Dictionary provides a definition of “ethical” in this context as follows: “When said of a drug, restricted to sale only on a doctor’s prescription.” WEBSTER’S 9TH NEW COLLEGIATE DICTIONARY 429 (9th ed. 1983).

3. Approximately 1.3 million drug reactions per year which demand medical care or lead to work loss include complications from blood transfusions and vaccinations. See Rheingold, supra note 1, at 947 n.2. For discussion concerning drug-related congenital defects, see 1 M. DIXON, DRUG PRODUCT LIABILITY, ch. 4A (MB) (1983).

4. A prime example of a drug-related malady, virtually unknown before it was linked with diethylstilbestrol (DES) exposure in utero is vaginal adenocarcinoma (clear cell cancer of the vagina). See Uelfelder, The Stilbestrol-Adenosis-Carcinoma Syndrome, 38 CANCER 426, 428-30 (1976). Problems associated with treating gynecological injuries and abnormalities which are typical of DES and related synthetic estrogens include mothers that may not be aware that they were given DES, medical records that may be lost or destroyed, and tissue abnormalities of the offspring that may not show up in routine pelvic exams until the cell changes have progressed to a dangerous stage. See generally Herbst, Scully & Robboy, Problems in the Examination of the DES-exposed Female, 46 OBSTET. & GYNECOL. 353 (1975) [hereinafter cited as Herbst, Problems]; Herbst, Cole, Robboy & Scully, Age Incidence and Risk for Diethylstilbestrol-related Clear Cell Adenocarcinoma of the Vagina and Cervix, 128 AM. J. OBSTET. & GYNECOL. 43 (1977) [hereinafter cited as Herbst, Age Incidence and Risk].

Another example of a drug which caused severe birth defects is Thalidomide, a sedative. Gross skeletal deformities such as flipper-like legs and hands (phocomelia) were associated with the drug. See McBride, Thalidomide embryopathy, 16 TERATOLOGY 79 (1977). The 1962 drug amendments were in part a reaction to the Thalidomide disaster. See Note, The Drug Amendments of 1962: How Much Regulation?, 18 RUTGERS L. REV. 101 (1963).

The anti-nauseant Bedectin has been associated with limb deformities and other congen-
such injury occurs, if a plaintiff cannot prove that the manufacturer was unreasonable in negligently marketing the drug, can he or she still obtain legal relief from the defendant drug house? If a seller of drugs is to be held to the same standard of liability as other manufacturers of consumer products, the answer is yes. Yet, much confusion has existed concerning the purpose and effect of comment k to Section 402A of the Restatement (Second) of Torts, an important guide to the resolution of the preceding question. Many courts and commentators have interpreted the comment as creating an exemption from strict liability for producers of pharmaceuticals, as the language suggests. The purpose of this

**5. Restatement (Second) of Torts, § 402A comment k (1965).** 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, 2 (1978). Professor McClellan's article provides an exhaustive treatment of these theories of products liability, and was a catalyst for the genesis of this comment. Section 402A sets forth the statutory basis of strict liability of suppliers of goods that cause physical harm to a user or consumer. Comment k of that section is the source of the problematic language concerning the liability of drug manufacturers for harm caused by their products. Comment k provides in pertinent part:

There are some products which . . . are quite incapable of being made safe for their intended and ordinary use. . . . Such a product, properly prepared and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. . . . It is also true in particular of many new or experimental drugs, as to which, because of the lack of time and opportunity for sufficient medical experience, there can be no assurance of safety. . . . 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.

**Restatement (Second) of Torts, § 402A comment k (1965) (emphasis in original).**

6. See Campbell, *Civil Liability for Investigational Drugs: Part II*, 42 Temp. L. Q. 289, 333 (1969). Although Professor Campbell admits that there may be a possible argument for imposing strict liability upon a manufacturer, he contends that drug manufacturers ought not to be made insurers of their products. *Id.* Furthermore, he argues that a drug should only be considered to be unreasonably dangerous in instances where no reasonable drug manufacturer would market such a drug, and where no reasonable physician would administer it. *Id.* Such a focus on the conduct of the manufacturer illustrates a major snarl in this area of products liability law. See also Note, *supra* note 1, at 759.

The following cases, which will be treated in detail in this comment, illustrate the fact that recent court decisions continue to use comment k as a basis to exempt drug manufacturers from liability for injuries resulting from their products: DeLuryea v. Winthrop Labs.,
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comment is to consider the goals of strict liability in drug-related injuries, how strict liability law differs in practice and concept from negligence law, and why favorable treatment in the terms of exemption from strict liability of drug companies for injurious products undermines the purpose of strict liability law.

II. THE ORIGINS OF STRICT LIABILITY AND ITS RELATIONSHIP TO FOOD AND DRUGS

A. Origins of the Relationship

In thirteenth century England those who were in the business of preparing or selling food did so at the risk of criminal sanctions for vending "corrupt" food and drink. In early twentieth century America, courts began to hold food merchants accountable to the consumer without proof of any negligence or privity of contract. These incipient stages of strict liability manifested themselves in complicated legal fictions, based ultimately on negligence or contract concepts. Finally, as judicial opinions began to assess liability in such cases on a theory straightforwardly independent of negligence or contract law, the beginnings of today's strict liability law started to emerge.

Although the April 1961, Tentative Draft No. 6 of the Restatement (Second) included a strict liability section which extended only to "food for human consumption," courts since 1950 had been extending the rule of strict liability to "products intended for


8. Id. Such theories include an agency relationship between the retailer and consumer or retailer and original seller; a third party beneficiary relationship; and a warranty "running with the goods," Id. These complicated efforts by the courts to impose responsibility for manufacturing or design defects on the seller of goods, undertaken within the more familiar context of contract or negligence law, demonstrate the reluctance of the judiciary to expand strict products liability.

9. Id. See Betehia v. Cape Cod Corp., 10 Wis.2d 323, 103 N.W.2d 64 (1960) (liability for bone found in chicken sandwich); Food Fair Stores v. Macurda, 93 So.2d 860 (Fla. 1957) (worms in canned spinach); Cernes v. Pittsburgh Coca-Cola Bottling Co., 183 Kan. 758, 332 P.2d 258 (1958) (slime in soft drink); Willis v. Safeway Stores, 199 Misc. 821, 105 N.Y.S.2d 9 (1951) (cork pieces in drink).

intimate body use" including cosmetics and drugs. Tentative Draft No. 7 of the Restatement (Second) of Torts broadened the scope of strict liability law from food products only to drugs and other products "of an intimate character." Although the Restatement finally applied the rule of strict liability to all products, it is apparent that pharmaceuticals and other analogous commodities fell within the early contemplation of strict liability law. It is irony in its truest sense that drug manufacturers should now be excluded from strict liability by the courts on the basis of comment k when their products occupied a place in the original genre of commodities considered especially appropriate for the application of liability without fault.

B. The Purpose of Strict Liability

The goals of strict liability as contrasted to those of negligence were enunciated by Justice Traynor of the California Supreme Court in an early products liability case, Escola v. Coca Cola Bottling Co. of Fresno. In Escola, the plaintiff alleged that she was injured when a Coca-Cola bottle broke in her hand. The majority resolved the controversy on a theory of res ipsa loquitur, stating that the bottle must have been defective when it left the manufacturer's control, because the explosion of bottles of carbonated drink ordinarily would not occur outside of negligence on the part of the bottling company. Although the court's inference of negligence allowed recovery for the injured plaintiff, Justice Traynor wrote a concurring opinion which shifted the focus from the conduct of the manufacturer to the product itself:

Those who suffer injury from defective products are unprepared to meet its consequences. The cost of an injury, and the loss of time or health may be an overwhelming misfortune to the person injured, and a needless one, for the risk of injury can be insured by the manufacturer, and distributed among the public as a cost of doing business. . . . It is to the public interest to place the responsibility for whatever injury they may cause upon the manufacturer, who, even if he is not negligent in the manufacture of the product, is responsible for its reaching the market. . . . The inference of

12. RESTATEMENT (SECOND) OF TORTS, § 402A (Tent. Draft No. 7, 1962). Such items included chewing gum, chewing tobacco, snuff, cigarettes, clothing, soap, cosmetics, liniments, hair dye and permanent wave solutions, as well as drugs. See Putnam, 338 F.2d at 918-19 n.16.
14. Id. at 454, 150 P.2d at 437.
15. Id. at 456-57, 150 P.2d at 439-40.
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negligence may be dispelled by an affirmative showing of proper care. . . . An injured person, however, is not ordinarily in a position to refute such evidence or identify the cause of the defect, for he can hardly be familiar with the manufacturing process as the manufacturer himself is. In leaving it to the jury to decide whether the inference has been dispelled, regardless of the evidence against it, the negligence rule approaches the rule of strict liability. It is needlessly circuitous to make negligence the basis of recovery and impose what is in reality liability without negligence. If public policy demands that a manufacturer of goods be responsible for their quality regardless of negligence there is no reason not to fix that responsibility openly. (emphasis added)\(^1\)

Justice Traynor's discussion included the fact that food merchants were subject to strict liability on the basis of warranty, as well as criminal statutes, and that retailers, in general, were subject to absolute liability through the implied warranty of fitness and merchantability.\(^17\) The pervading theme of his opinion was that the manufacturer maintained the best position to test and control the quality of his product, as well as a superior position to cover any loss or damage that might result from his product.\(^18\) Justice Traynor's opinion in Escola anticipated the acknowledged purpose of Section 402A.\(^19\) The goal of strict liability derives from an economic and ethical allocation of responsibility for loss to the source of the defective, injury-producing product rather than from fault. It is the manufacturer who is most prepared to prevent damage or bear its burden should it occur. Such a perspective looks to the product which causes the harm, not the conduct of the one who places it in commerce.\(^20\)

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16. *Id.* at 458, 150 P.2d at 441 (Traynor, J., concurring).
17. *Id.* at 459-60, 150 P.2d at 441-42 (Traynor, J., concurring).
18. *Id.* at 459-61, 150 P.2d at 441-43 (Traynor, J., concurring).
19. *Restatement (Second) of Torts, § 402A comment c* (1965). Comment c provides a summary of the purpose of strict liability:
On whatever theory, the justification for the strict liability has been said to be that the seller, by marketing his product for use and consumption, has undertaken and assumed a special responsibility toward any member of the consuming public who may be injured by it; that the public has a right to and does expect, in the case of products which it needs and for which it is forced to rely upon the seller, that reputable sellers will stand behind their goods; that public policy demands that the burden of accidental injuries caused by products intended for consumption be placed upon those who market them, and be treated as a cost of production against which liability insurance can be obtained; and that the consumer of such products is entitled to the maximum of protection at the hands of someone, and the proper persons to afford it are those who market the products.

*Id.*

20. For a scholarly analysis of this perspective, see Weinstein, Twerski, Piehler & Donaher, *Product Liability: An Interaction of Law and Technology*, 12 *Duq. L. Rev.* 425
III. JUDICIAL APPLICATION OF COMMENT K TO DRUG CASES

Since many drug controversies can be litigated and resolved on negligence grounds, not all courts address the complicated and seemingly contradictory issues\textsuperscript{21} germane to comment k's guidelines for strict liability of drug manufacturers.\textsuperscript{22} This section will highlight some recent opinions in the area of drug induced injuries with a view toward variations in judicial treatment of comment k.\textsuperscript{23}

A. Plaintiff's Recovery In Strict Liability Not Precluded By Comment k.

*Bichler v. Eli Lilly and Co.*\textsuperscript{24} tells the story of a young woman afflicted with DES-related adenocarcinoma at the age of seventeen. After a surgical bout with the disease which included a radical hysterectomy and partial vaginectomy, Bichler and her father sued the manufacturer, the pharmacist and prescribing physician. She recovered a verdict against Eli Lilly on a theory of concerted action among the drug manufacturers which sought Food and Drug Administration (FDA) approval of DES and marketed it for the prevention of miscarriage.\textsuperscript{25} Although the plaintiff won at the trial level, the case was appealed to the appellate division of the Su-
preme Court and later to the New York Court of Appeals. On appeal to the appellate division, defendant Eli Lilly contended that the trial court erred in not charging the jury properly on the issue of forseeability in strict liability. The president judge rejected this assertion in the appellate court opinion. The language of the jury instructions at issue are quite pertinent to this discussion, however. The trial court charged the jury that, in order to find whether DES was “reasonably safe”, the panel had to determine whether a reasonable manufacturer would have marketed the drug if present knowledge of the drug’s effect had been known in 1953. Such a charge accords with strict liability principles, and imputes knowledge of the drug’s carcinogenic and mutagenic qualities to the manufacturer. The court did not charge the jury on the issue of forseeability directly related to Lilly’s marketing of the drug, but rather on the issue of whether Lilly and other DES manufacturers should have foreseen that DES could have cancerous effects on offspring exposed in utero. Forseeability in this

26. Id. at 578-79, 450 N.Y.S.2d at 779, 436 N.E.2d at 185. See also supra note 4.
27. Id. at 579, 450 N.Y.S.2d at 779, 436 N.E.2d at 185.
28. Id. at 586, 450 N.Y.S.2d at 783, 436 N.E.2d at 189. The defendant contended that it could not have foreseen the occurrence of DES-caused cancer in human offspring in 1947. The New York Court of Appeals rejected this on two bases: First, the court hesitated to disturb the jury’s verdict which was based on proof offered by the plaintiff’s experts. Second, the court referred to testimony regarding medical research conducted in 1947 on mice concerning the transplacental effects on the offspring of an anesthetic administered during delivery. Id.
29. Id. at 587 n.10, 436 N.E.2d at 189 n.10, 450 N.Y.S.2d at 783 n.10. “Reasonably safe” was the court’s alternative to the negatively phrased “unreasonably dangerous” language of § 402A.
30. Id.
31. A landmark case where the manufacturer was imputed with knowledge of his product’s dangerous quality is Phillips v. Kimwood Machine Co., 269 Or. 485, 525 P.2d 1033 (1974), where the court noted their modification of jury instructions suggested by Professor Wade as follows:

The law imputes to a manufacturer [supplier] knowledge of the harmful character of his product whether he actually knows of it or not. He is presumed to know of the harmful character of his product whether he actually knows of it or not. He is presumed to know of the harmful characteristics of that which he makes [supplies]. Therefore a product is dangerously defective if it is so harmful to persons [or property] that a reasonably prudent manufacturer [supplier] with this knowledge would not have placed it on the market.

32. Id. at 501 n.16, 525 P.2d at 1040-41 n.16.
33. Carcinogenic refers to the drug’s cancer-producing effects, while mutagenic refers to the structural abnormalities with which it has been associated, especially adenosis. Adenosis is a non-cancerous gynecological abnormality in which glandular tissue normally growing only in the cervix is also found in the vagina. See generally Herbst, Problems, supra note 4; Herbst, Age incidence and risk, supra, note 4.
34. Bichler, 55 N.Y.2d at 587, 436 N.E.2d at 189-90, 450 N.Y.S.2d at 783-84. There
separate issue was linked to the drug manufacturer’s ability to test DES on pregnant mice, which it had failed to do.\textsuperscript{34} The appellate division found that these jury instructions complied with New York products liability law.\textsuperscript{35} In the court of appeals, Lilly again raised the comment k issue, contending that since all drugs are inherently unsafe, liability for effects can attach only where the “side effect”\textsuperscript{36} was foreseeable, and if the manufacturer omitted warnings in the product enclosures.\textsuperscript{37} Lilly’s second issue on appeal asserted that no liability can be found against a drug manufacturer if the physician did not rely on product literature or warnings when prescribing the drug.\textsuperscript{38} The court rejected both contentions, since it analyzed the plaintiff’s case as pleaded and proven on a failure to test theory.\textsuperscript{39} Therefore, the court of appeals did not fully analyze the relationship of comment k to the case, although two strong inferences can be drawn. First, on a strict liability theory, the manufacturer’s ability to foresee the harm does not necessarily have to be proven because foreseeability is imputed to the manufacturer. Secondly, the plaintiff does not necessarily have to show inadequate warning if improper marketing can be proven under another theory, in this case, failure to make adequate pre-market tests.\textsuperscript{40} Bichler, as we shall see, stands as a noticeable exception to many other pharmaceutical cases.

Brochu \textit{v. Ortho Pharmaceutical Corp.}\textsuperscript{41} is another case remarkable for its analysis of comment k in relation to design defects and failure to warn.\textsuperscript{42} The plaintiff wife suffered a stroke (cerebral

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\textsuperscript{34} Id. at 587 n.10, 436 N.E.2d at 189 n.10, 450 N.Y.S.2d at 783 n.10.

\textsuperscript{35} Id. at 587, 436 N.E.2d at 189, 450 N.Y.S.2d at 783. It was determined that such testing would have provided laboratory data which should have either prevented a manufacturer from marketing DES in 1947, or motivated the company to take it off the market by 1953. Id.

\textsuperscript{36} Id.

\textsuperscript{37} "Side-effect" appears to be a very understated term for carcinogenicity, since "side-effect" encompasses very mild effects such as drowsiness or lack of appetite. "Adverse reaction" or "contraindication" would more clearly convey the seriousness of a drug's cancer-causing propensity.

\textsuperscript{38} Id.

\textsuperscript{39} 55 N.Y.2d at 586, 436 N.E.2d at 189, 450 N.Y.S.2d at 783.

\textsuperscript{40} Id.

\textsuperscript{41} 642 F.2d 652 (1st Cir. 1981).

\textsuperscript{42} Id. at 656-57. The court emphasized that the hypothetical instance of the Pasteur vaccine in comment k suggests a balancing between the risk of certain death weighed against a high degree of risk posed by the treatment itself. Such a balancing was found.
thrombosis) which left her partially paralyzed and prone to grand mal seizures, depression, and difficulty in breathing and swallowing pursuant to taking defendant's Ortho Novum 2 contraceptive pills. At the time, defendants were also marketing birth control pills with lower estrogen content. The court noted that in 1970 a study had been released in the British Medical Journal concerning the relation between high ratios of estrogen content and increased risk of cerebral thrombosis. The court ruled that the manufacturer should be held liable for continuing to market a pill inherently defective in design due to its high estrogen content when it had another, less risky alternative. Moreover, the manufacturer was liable for its failure to warn physicians of the significantly higher risk of ingesting a pill with a higher estrogen content than from a lower dosage contraceptive. The First Circuit's analysis of the strict liability of the manufacturer in Brochu inheres in the policy which requires a product's social utility to outweigh its risks in order to be acceptable. Such a perspective on strict liability for drugs is invited by the Restatement's example of the Pasteur vaccine in comment k. The First Circuit's rationale, which attached liability where a less dangerous alternative was available when the offending product was purchased, and where the product's unreasonably dangerous condition caused the injury, has potentially extensive application in the field of drugs today. Not only are there a myriad of prescription drugs, which offer different options for treatment in many cases, but also alternative courses of treatment which are non-pharmaceutical in nature abound. When a drug company places the risk of loss on the patient through an inadequate warning, or non-disclosure of less dangerous, substitute therapies, helpful when determining what kind of warning would be reasonable under the circumstances. Id.

43. Id. at 657. The court referred to an unnamed study by Inman, Vessey, Westerholm and Engelund, found in the British Medical Journal. Id.

44. Id. at 658-59.

45. This policy is articulated in Donaher, Piehler, Twerski and Weinstein, The Technological Expert in Products Liability Litigation, 52 Tex. L. Rev. 1303, 1307 (1974) as follows:

The issue in every products case is whether the product qua product meets society's standards of acceptability. The unreasonable danger question, then, is posed in terms of whether, given the risks and the benefits of any possible alternatives to the product, we as a society will live with it in its existing state or will require an altered, less dangerous form.

Id.

46. See supra notes 22 & 42 and accompanying text.

47. Brochu, 642 F.2d at 659.
should it not be held strictly liable for harm resulting from its product?\footnote{48}  
The wording of comment \( k \) suggests that the absence of proper directions and warnings renders a prescription drug defective or unreasonably dangerous. The language of the preceding comment \( j \) also concerns warnings for prescription drugs.\footnote{49} A case interpreting comment \( j \) which merits discussion because of the parallels which can be drawn to drug cases and comment \( k \) is \textit{Little v. PPG Industries, Inc.}\footnote{50} In this wrongful death case, predicated on exposure to a toxic cleaning agent, the lower appellate court emphatically rejected any argument based on the reasonableness of the manufac-

\begin{quote}
\noindent 48. This view was set forth at length in Cowan, \textit{Some Policy Bases of Products Liability}, 17 \textit{STAN. L. REV.} 1077, 1091-92 (1965). He states:

If, however, the manufacturer is producing for the general public, he sets the level of consumer's risk himself and is restrained, if at all, only by market conditions and by the law. . . . [N]ow the question arises, why should the manufacturer be allowed to pass the so-called consumer's risk on to the consumer at all? Especially the risk of property loss or serious bodily injury resulting from a defective product? The answer of the manufacturer that he must pass \textit{some} risk on to the consumer is now met with the reply: then pay for the damages. This is not absolute liability. It has nothing to do with subjective fault. It has to do with compensation for a loss resulting from a deliberately assigned risk — assigned, that is, to the other fellow.

\textit{Id.}

49. \textit{Restatement (Second) of Torts, § 402A comment j} (1965). Comment \( j \) addresses the issue of warnings. Warnings are required when a product contains a harmful ingredient that the consumer would not expect to encounter, or the danger of which he would not know. This comment sets the stage for comment \( k \) in several ways. First, it acknowledges that a proper warning may transform an unreasonably dangerous product into an acceptable one. Secondly, it sets forth certain types of products which should require warnings. Finally, its language appears to include negligence terminology of foreseeability which corresponds to the "present state of human knowledge" language of comment \( k \). Comment \( j \) is set forth in pertinent part:

\begin{quote}
\textit{Directions or Warning.}

In order to prevent the product from being unreasonably dangerous, the seller may be required to give directions or warning, on the container, as to its use. The seller may reasonably assume that those with common allergies . . . will be aware of them. . . . Where, however, the product contains an ingredient and the ingredient is one whose danger is not generally known, or if known is one which the consumer would reasonably not expect to find in the product, the seller is required to give warning against it, if he has knowledge, or by the application of reasonable, developed \textit{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.

\textit{Restatement (Second) of Torts § 402A comment j} (1965) (emphasis added).

turer's knowledge of the dangerous condition of its product.51 The manufacturer then sought to reverse the ruling that its knowledge of the danger should be assumed.52 The Washington Supreme Court then set forth an opinion which defined the problem inherent in applying a negligence rationale in strict liability cases.53 It reasoned that the objective of strict liability is defeated if the plaintiff must prove the defendant's negligence or if the manufacturer may defend on the grounds of lack thereof. As the court stated, "It is the adequacy of the warning which is given, or the necessity of such a warning which must command the jury's attention, not the defendant's conduct."54 The court went on to discuss the role of "reasonableness" in such a case and asserted that "it is a role which concerns itself with the sufficiency of the warning and the expectations of the user."55 Summing up further policies in favor of true strict liability (liability without fault) the court stated that proof of an inadequate warning will usually be a much simpler task than proof of the defendant's negligence, because of the accessibility of the evidence. Further, the question of whether or not a warning is adequate invokes an element of common knowledge within the province of the jury.56 It is apparent from this discussion that the Washington court would treat any exemption from negligence under a comment k analysis in a similar manner.

B. Plaintiff's Recovery under Strict Liability Precluded by Comment k.

Ferrigno v. Eli Lilly & Co.57 is one of the few prescription drug cases where the court pursued an in-depth analysis of the role of strict liability law in relation to pharmaceuticals. This case involved another claim based on cancer and other gynecological injuries related to in utero DES exposure. In its analysis, the court addressed the fact that under New Jersey law foreseeability of danger is imputed to the manufacturer of a defective machine, even if it was in fact unknowable at the time of manufacture and distribution.58

52. 92 Wash.2d at 120, 594 P.2d at 913.
53. Id.
54. Id. at 121, 594 P.2d at 914.
55. Id. at 122, 594 P.2d at 914.
56. Id. at 122, 594 P.2d at 915.
58. Id. at 576, 420 A.2d at 1318.
According to the court, however, comment k effectively rules out the question of imputed knowledge of the danger in drug cases, since the language concerning liability of drug manufacturers for dangerous defects frames the issue in terms of "the present state of human knowledge" and "such experience as there is," thus referring to the time of marketing and purchase. This court proposed that although comment k is couched in strict liability principles it sets forth no more than tenets of negligence. Concluding its analysis of comment k, the court reasoned that strict liability can apply to only two situations in pharmaceutical cases: either to those cases where the drug could not reasonably have appeared to be useful and "desirable at the time of manufacture," or to cases where a "medically recognizable risk foreseeably outweighed its utility ... despite some apparent efficacy." The irony of this analysis is that one test for strict liability is whether the risk to society outweighs the societal benefits of the product. If there is a threshold requirement that the risk outweighs the benefit at the time of manufacture in order to escape the comment k exemption and permit a claim to be brought on a strict liability theory, in effect, the plaintiff must prove his or her case twice. The plaintiffs in the case under question did argue that the risk of DES outweighed its benefit at the time of manufacture. However, the court dismissed their argument that if DES was ineffective in preventing miscarriage, it was defective. This argument is cogent if analyzed

59. Id. (quoting Restatement (Second) of Torts § 402A comment k (1965)). The relevant portion of comment k provides as follows:

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. ... Such a product, properly prepared, and accompanied by proper directions and warning, is not defective. ... It is ... 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.

Id. (emphasis added).

60. 175 N.J. Super. at 576, 420 A.2d at 1318.

61. Id. at 577, 420 A.2d at 1319. Compare Rheingold, supra note 1, at 1001 n.304.

62. See supra note 45.

63. 175 N.J. Super. at 576, 420 A.2d at 1318. Compare Rheingold, supra note 1, at 1008-09, where the author draws a graphic analogy between ineffective drugs and mechanical safety devices which do not work properly:

In a situation in which an ethical drug fails to cure a certain disease which it purports to cure, reliance upon the drug by the doctor and his patient may aggravate the patient's condition and leave him with a permanent disability which he would not have suffered had he been administered another, more effective medicine. Such a lack of efficacy in a drug may be caused either by an inherent lack of ability to cure or by a
in the light that there can be no real benefit if a drug is ineffective for the purpose for which it is marketed and used by the consumer. Such a lack of effectiveness is tantamount to design defect.\textsuperscript{64} Furthermore, if a manufacturer induces reliance on a product which fails to be effective for that purpose, there appears to be a breach of warranty. Using Comment language, such a drug could not be considered to be "apparently useful and desirable." From any perspective, it would seem that the risk of such a drug must necessarily tip the scales against being beneficial.

In another recent case, \textit{Gaston v. Hunter},\textsuperscript{65} a plaintiff's disc disease was aggravated through the use of chymopapain, an investigational drug intended to provide an alternative to disc surgery. The plaintiff asserted that the drug was unreasonably dangerous and defective in that it was ineffective for the purpose for which it was marketed and prescribed, and, secondly, that it was highly toxic and injurious to human tissue.\textsuperscript{66} Although some evidence of product defect was erroneously excluded at trial,\textsuperscript{67} and the trial court below refused to give strict liability jury instructions, the Arizona Appellate Court ruled that this was not prejudicial to the plaintiff

defective batch from which the active ingredient has been omitted. The question posed in this section is whether there is or should be manufacturer liability in such a situation, or in one in which a vaccine fails to give immunity to a disease, or where an oral contraceptive fails to prevent an unwanted pregnancy? . . . As to the inherent lack of drug efficacy—alogous to design fault—such a suit is virtually without precedent in the ethical drug area. Other types of products liability cases predicated upon safety devices that did not function might be analogized to inefficacious drug cases and thus provide a basis for liability. While it is true that in safety device cases liability has been found because of unsafeness and not inefficacy, still it was the failure to live up to the created expectations of positive performances that underlay liability. Inducing use and creating reliance based upon a false sense of usefulness constitute the culpable conduct of the supplier. Beyond an action for negligence or for negligent misrepresentation, an express warranty action might also be available in the case of an ineffective drug, since such a drug is used only because the manufacturer has claimed it to be proper for a certain condition, and it has not lived up to that express promise.

\textit{Id.} at 1008-09 (emphasis added).

Rheingold's analogy between non-functional safety devices and drugs that are ineffective for their claimed purpose makes sense. The \textit{Ferrigno} court also drew a logical comparison between machines and drugs, but stopped short of the rational outcome of its reasoning. Comment \textit{k} became an effective roadblock to imputing knowledge to the manufacturer of an injurious product. The \textit{Ferrigno} court claimed that the comment \textit{k} phrases "[i]n the present state of human knowledge" and "such experience as there is" distinguish drug cases from the machine cases. See 175 N.J. Super. at 576, 420 A.2d at 1318. See also supra note 59.

64. See Rheingold, \textit{supra} note 1, at 1008-09.
66. \textit{Id.} at 40, 588 P.2d at 331.
67. \textit{Id.} at 46 n.10, 588 P.2d at 339 n.10.
because "none of the erroneously excluded evidence would tend to provide that missing element of breach of the drug companies' duty." Breach of duty is obviously a negligence concept, foreign to product liability doctrine. This court would seem to draw no distinction between negligence and strict liability actions for drug injuries, because it proceeds to use the prudent person standard in judging the manufacturer's conduct. This is a far cry from *Kimwood* in which knowledge was imputed to the manufacturer.

In another contraceptive pill case, *Seley v. G.D. Searle*, a woman of twenty-six suffered a stroke which left her numb and partially paralyzed. The plaintiffs asserted that the manufacturer failed to adequately warn of the dangers associated with its birth control pill, Ovulen. The Ohio Court of Appeals reversed a verdict for the manufacturer on the grounds that the trial court committed error by introducing negligence theories into the language of the jury charge which read in pertinent part:

[If Searle] made available adequate warnings to the medical profession to summarize medical or scientific information reasonably known or discoverable by said defendants in the exercise of ordinary care at the time Ovulen-21 was prescribed for the plaintiff, the defendants Searle complied with their duty to give warning.

[When I use the words 'ordinary care,' I mean the care that a reasonably careful pharmaceutical company would use under circumstances similar to those shown by the evidence.

The court of appeals objected to such language, in that it diverted the jury's attention from the condition of the product itself to the conduct of the manufacturer, thus evading the purpose of strict liability law. The *Seley* court underscored its point with language from a Colorado court in a similar case where it was stated that "[i]t is of no import whether this drug manufacturer's warning comported with the warning a reasonably prudent drug manufacturer would have given." Nevertheless, on appeal the Ohio Su-

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68. *Id.* at 45, 588 P.2d at 338.
69. *Id.*
70. See supra note 31.
71. 67 Ohio St.2d 192, 423 N.E.2d 831 (1981).
72. *Id.* at 194, 423 N.E.2d at 835.
73. *Id.* at 195, 423 N.E.2d at 835. The basis of the plaintiff's claim was that Searle provided no information concerning the dangers of the pill to women who had a history of toxemia in pregnancy. *Id.*
74. *Id.* at 198, 423 N.E.2d at 837.
75. Hamilton v. Hardy, 37 Colo. App. 375, 549 P.2d 1099 (1976). See *Seley*, 67 Ohio St.2d 199, 423 N.E.2d 837. *Hamilton* was also a Searle birth control case in which an appeals court reversed the trial court for refusal to instruct the jury that the manufacturer
Drug-Related Injuries

The Supreme Court shifted the standard back to one of reasonableness, asserting that such language does not necessarily transform the measure of proof into that of negligence. Such disagreement between two appellate courts in the same state graphically illustrates the confusion comment k has generated. While some courts hold that comment k exempts drug companies from strict liability, others assert that it merely employs the same language as negligence concepts.

*De Luryea v. Winthrop Laboratories* is a case set in Arkansas in which the plaintiff sued for injuries resulting from the use of Talwin, a prescribed pain killer. De Luryea not only suffered mental and physical injuries from addiction to the drug, but also developed tissue ulceration and necrosis at the injection sites. The case was brought on a failure to warn theory in strict liability. When the Eighth Circuit heard the case on appeal to determine whether evidence of the manufacturer's change in warnings on the package insert should have been admitted below, the court stated that the rule barring evidence of subsequent remedial changes had not been extended to products cases brought in strict liability in the Eighth Circuit. The rationale was that the evidence would not be used to prove negligence in such cases. Prescription drug cases, however, demand different treatment, according to the court. A plaintiff must prove negligence in drug cases brought on a strict liability theory. Supporting this proposition, the court compared the jury instructions used in the district court which were nearly identical to those used in negligence cases. Further, they looked to the reasoning of the Fourth Circuit in *Werner v. Upjohn Company*, where it was decided that the difference between strict liability and negligence in a warning case disappeared under close analysis. The Eighth Circuit further reasoned that a claim regarding an "unavoidably dangerous drug" closed the gap between negligence and strict liability completely. Therefore, a plaintiff in

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the circumstances similar to those in *De Luryea* must prove culpable conduct. Total deterioration of the purpose and intent of the strict liability standard is therefore shown in *De Luryea*. The plaintiff is severely impeded from proving negligence because of the nature of the evidence which is probative in the case. Although such evidence would be admitted in other strict products liability cases to demonstrate the unreasonably dangerous quality of the product, the plaintiff here is effectively prevented from making her case because an exemption from strict liability has been created for the defendant.

C. Summary of the Strict Liability Concepts in the Foregoing Cases

The array of policies and legal concepts exemplified in the previous cases can be distilled into a group of principles representing the vacillating status of strict liability law in regard to ethical drug companies today.

First, present scientific knowledge of a drug's dangerous propensities is imputed to a drug manufacturer under a failure to test theory. Yet, a jury must determine if the manufacturer would have been "reasonable" in putting the drug on the market. This approach applies strict liability principles coupled with negligence doctrine.

Second, risk-benefit assessment of a product and whether or not the accompanying warning was reasonable in light of the availability of a much less dangerous alternative product utilizes strict liability principles. Further, the imputation to the manufacturer of scientific knowledge about the product's contents is consonant with strict liability doctrine in a failure to warn case.

Third, the reasonableness of a manufacturer's knowledge of a dangerous condition in its product is irrelevant in a failure to warn theory. Rather, the adequacy of the warning itself as a part of the total concept of the marketed product is at issue.

Finally, a policy that drug companies should not be charged with knowledge of a dangerous defect at the time of manufacture is cur-

85. 697 F.2d at 229.
86. Compare this decision to the court's rationale in *Hamilton*, supra note 71.
88. *Id.* at 587, 436 N.E.2d at 190, 450 N.Y.S.2d at 784.
90. *Id.* at 657. See *Phillips*, supra note 31; *Hamilton*, supra note 75.
rent law in many jurisdictions. Foreseeability, reasonableness, breach of duty, ordinary care and other aspects of negligence law have been deemed appropriate measures of culpable conduct in pharmaceutical cases espousing this viewpoint.93

IV. DRUG COMPANIES AND COMMERCIAL PRACTICE: WILL HOLDING DRUG COMPANIES TO STRICT LIABILITY INHIBIT THE DEVELOPMENT OF NEW DRUGS?

One of the reasons behind the reluctance of courts to hold drug manufacturers to strict liability standards is the fear that such accountability would deter pharmaceutical companies from developing new drugs.93 When viewing policies underlying strict liability, it must be realized that no matter what precautions are taken, and regardless of the extent to which pre-market research and testing is engaged in, some risk will be passed to the consumer.94 Yet, the purpose of strict liability is to assure that the entity which transfers the risk to the consumer will ultimately pay for the injuries caused by the products.95

Comment k of section 402A implies a policy which favors giving preferential treatment to drug companies because of the kind of products they manufacture and market.96 Therefore, rather than objectively viewing the pharmaceutical industry as the profit-oriented business that it is, an exemption from strict liability has placed the industry in the category of those entities which can only be sued on the basis of professional negligence.97 A close look at

93. See Note, supra note 1, where it is contended that any impediment to drug companies placing new drugs on the market would inevitably result in detriment to the consumer. See also Feldman v. Lederle Labs., 189 N.J. Super. 424, 428-29, 460 A.2d 203, 205 (1983), where the court stated that:

The underlying reason for special exemption of prescription drugs is the public policy concern that imposition of strict liability, or, perhaps more accurately stated, the almost absolute liability, principle of the Beshada approach would chill, if not smother, the research, development, production and marketing of new or experimental drugs necessary to alleviate or cure the ills to which we are all subject.

Id. (referring to the approach taken in an earlier case involving workers exposed to asbestos, Beshada v. Johns-Manville Corp., 90 N.J. 191, 447 A.2d 539 (1982)).
94. See Cowan, supra note 48.
95. Id. See also Rheingold, supra note 1; Keeton, supra note 1; McClellan, supra note 5.
96. See supra notes 6 & 20.
97. These include physicians, nurses, pharmacists, hospitals, and lawyers. See also McClellan, supra note 5, at 33, for a discussion of the “wealth distribution preference” given drug companies to the detriment of consumers.
the pharmaceutical industry should mitigate the fear that strict liability would deter pharmaceutical companies from developing new drugs. First, the industry, although it produces an array of beneficial commodities for public health, has a strong profit motive which it readily acknowledges. Obviously, drug companies are in the business of developing and promoting new drugs, and, as in any other enterprise, it pays to have new products to put on the market. A striking and essential difference exists between the development of the Pasteur treatment for rabies (the named example of an unavoidably unsafe product set forth in comment k), penicillin, the polio vaccines, and most ethical drugs on the market today. Those early examples of medical pioneering were developed with a view toward urgent public health needs by independent scientists with no apparent motive for pecuniary gain, whereas today most pharmaceuticals are developed in large drug houses on the basis of potential market value. A clear example of the underlying profit motive in drug development and marketing is found in the development of the drug Panalba. Panalba was a fixed ratio combination of tetracycline with novobiocin, a dangerous antibiotic. The drug had negligible therapeutic value, but, rather, was merely a new substance created by combining two other antibiotics. Although the two-drug combination was less effective than tetracycline itself, it was clearly an instance of a drug created for a market rather than a medical purpose. The unsuspecting patient obviously bears the risk of harm in such an instance.

Bendectin, another example of a combination drug, was a pill first marketed in 1956 for the treatment of nausea and vomiting in pregnancy. Bendectin’s original ingredients were: dicyclomine,

98. As one pharmaceutical executive has stated:
Searle Laboratories’ philosophy for the promotion and sale of our pharmaceutical products is based on the concept that the generation of profit as a result of marketing pharmaceuticals is not only legally acceptable, but is morally and ethically desirable. We take the position that marketing and sales activities are essential to the discovery and development of new methods of improving the well-being of patients both now and in the future.


100. See id. at 138 (statement of Senator Gaylord Nelson).

101. Id.

102. Id.

103. Bendectin was originally marketed by Merrell National Laboratories, now Merrell
an antispasmodic, doxylamine, an antihistamine, and Vitamin B6, pyridoxine. In 1976, dicyclomine was removed, as it was shown not to contribute to the effectiveness of the pill.\textsuperscript{104} Since that time many birth defects have been associated with the drug,\textsuperscript{105} and it was withdrawn from the market in 1983. Although the marketing of Bendectin had a legitimate medical purpose, the practice of including an extra, ineffective ingredient in any pill, especially one to be promoted for use in pregnancy is clearly questionable. Hopefully not all pharmaceutical developments are so blatantly unbalanced in their risk-benefit proportions. Yet, even those drugs which have a very high value in the treatment of serious illnesses are often ruthlessly marketed. Mellaril, a psychotropic drug often used in the treatment of manic-depression and other psychic disorders offers an example of aggressive marketing techniques. The following is an excerpt from the marketing directives given to salesmen who promoted Mellaril:

Continue to detail Mellaril until you have convinced the physician to use this drug. This is your sole mission. In many cases, you will be able to remind the physician about our headache line along with selling him Mellaril. But do not let anything interfere with your doing a complete sales job on Mellaril.

It is imperative that you get Mellaril stocked in every possible hospital. This is the first big hurdle.

The tests showed that what a buyer hears first, he retains the longest. If the benefits are listed before the drawbacks, a 'that's for me' state of mind is created. If the drawbacks are given first, a 'no thanks' attitude is created.\textsuperscript{106}

Although these marketing strategies may not differ greatly from those used in other industries, it is apparent that the psychological techniques used in such sales ploys cannot help but undermine the value of any warnings. That such marketing techniques are successful is not denied. The fiscal strength exhibited by the leading drug companies was set forth by a former F.D.A. Commissioner, Dr. James Goddard:

Profitability has long been the hallmark of the pharmaceutical industry.

Year after year the industry ranks first or second in after-tax income as a


\textsuperscript{105} \textit{See supra} note 4.

\textsuperscript{106} \textit{Pharmaceutical Hearings, supra} note 98, at 141 (statement of Senator Gaylord Nelson).
percentage of net worth. This profitability has been maintained by the drug industry even though drug prices have not climbed as rapidly as consumer prices in general.\textsuperscript{107}

At the same congressional hearings wherein Dr. Goddard’s comments were introduced, the drug companies rebuttal to Dr. Goddard’s views were discussed as follows:

The drug companies generally argue that they are entitled to such high profits because of the risks involved in developing new drugs. Indeed, drug companies do spend a sizeable 6.5\% of their revenue on Research and Development. However, the risk dollars for Research and Development are dwarfed by the safe dollars for marketing. A full 25\% of the total sales dollar goes for marketing. . . . Even if there was a “risk” in developing drugs, the kind of marketing clout the drug companies have would reduce it to zero.

. . . .

No major pharmaceutical house has been forced out of business in the past 25 years; if there were a significant risk, enough to justify these enormous profits, we would expect to see occasional losses.\textsuperscript{108}

The polio vaccine crisis is an excellent case in point of the buoyancy of drug companies in the face of extensive verdicts and settlements.\textsuperscript{109} Richardson-Merrell, for example, evidences another instance of continuing fiscal viability in spite of the numerous actions that have been brought against it in the past twenty years as the producer of both MER/29 and Bendectin.\textsuperscript{110}

VI. CONCLUSION

The drug industry is as much a profit-oriented business as any other in this country. That drugs are dangerous commodities in themselves is patently clear. Whereas other ultrahazardous activities must finance their own way in the marketplace through absolute liability standards,\textsuperscript{111} pharmaceutical companies have been given preferential treatment by the judiciary on the basis that drugs are unavoidably unsafe. Drug companies do have the financial means to diminish the unsafe qualities of many of the


\textsuperscript{108} \textit{Pharmaceutical Hearings}, supra note 98, at 240 (testimony of Herbert S. Denenberg, Pennsylvania Insurance Commissioner).


\textsuperscript{110} See Toole v. Richardson-Merrell, 251 Cal. App. 2d 639, 60 Cal. Rptr. 398 (1967).

\textsuperscript{111} \textit{Restatement (Second) of Torts}, §§ 519-524A (1978).
drugs they market. Furthermore, drug companies have the capability and the responsibility as the prime source of drug information to physicians to advise and warn of other less risky courses of treatment when a particular drug is especially dangerous. Not only must drug companies demonstrate integrity in a willingness to accept responsibility for their products through adequate testing, research, development and physician education, but especially in accepting financial responsibility for injuries created by these products.

The confusion of negligence concepts and strict liability in the judicial resolution of drug-related litigation can only undermine the purpose of strict liability law. Pharmaceutical companies should be held to the same standard of liability as other industries or a great disservice to injured victims will continue.

Patty Coleman Selker