Providing Blanket Comment K Immunity to all FDA Approved Ethical Drugs: The Defect in Grundberg v. Upjohn Co.

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COMMENTS

PROVIDING BLANKET COMMENT K IMMUNITY TO ALL FDA APPROVED ETHICAL DRUGS: THE DEFECT IN GRUNDBERG v. UPJOHN CO.

For many years, courts have addressed various liability issues concerning personal injury, arising from the use of products made for internal consumption.¹ In an attempt to refine the law in this area, the American Law Institute ("ALI")² proposed section


² See RESTATEMENT, supra note 1, at vii-viii. The American Law Institute consists of a distinguished group of legal scholars from the academic, judicial and practicing areas. Id.; see also BLACK’S LAW DICTIONARY 1913 (6th ed. 1990). The American Law Institute’s purpose in writing the Restatement of Torts as well as other Restatements, was to “tell what
402A and comments to the Restatement (Second) of Torts. In jurisdictions that have adopted this section, plaintiffs suing manufacturers for injuries resulting from defective products are

the law in a general area is, how it is changing, and what direction the authors... think this change should take.” *Id.* See generally Kathleen H. Wilson, Note, *The Liability of Pharmaceutical Manufacturers for Unforeseen Adverse Drug Reactions*, 48 FORDHAM L. REV. 735, 735-39 (1980) (events leading to ALI’s adoption of strict liability).

* See RESTATEMENT, *supra* note 1, at vii. Section 402A was adopted as an amendment to the Restatement in 1964. *Id.* According to its authors, section 402A “states a special rule applicable to sellers of products. The rule is one of strict liability, making the seller subject to liability to the user or consumer even though he has exercised all possible care in the preparation and sale of the product.” *Id.* § 402A, at cmt. a; see also MARSHALL S. Shapo, 1 *THE LAW OF PRODUCTS LIABILITY* § 7.06 (2d ed. 1990) (increasing majority of states have adopted strict liability). *But see* Greenman v. Yuba Power Products, 377 P.2d 897, 900-01 (Cal. 1962) (Supreme Court of California adopted concept of strict liability before it was codified in Restatement § 402A).

* See RESTATEMENT, *supra* note 1, § 402A. The comments following section 402A were provided by the authors to aid in the interpretation and application of the sections. *Id.* Comments a, b and c describe the function and history of, and justification for the ALI’s amending the Restatement to include § 402A. *Id.* Comments d and e discuss the parameters and application of strict liability while comments f through n define relevant terms and provide exceptions to the section. *Id.*; see also Jason Scott Johnston, *Uncertainty, Chaos, and the Torts Process: An Economic Analysis of Legal Form*, 76 CORNELL L. REV. 341, 360 (1991) (effects of comments in implementing § 402A); Joseph A. Page, *Generic Product Risks: The Case Against Comment k and for Strict Liability*, 58 N.Y.U. L. REV. 853, 860-64 (1983) (effect of § 402A in light of accompanying comments); Richard L. Hasen, *Efficiency Under Informational Asymmetry: The Effect of Framing on Legal Rules*, 38 UCLA L. REV. 391, 406-08 (1990) (same).

* ReSTATEMENT, *supra* note 1, § 402A. Section 402A states in full:

(1) One who sells any product in a defective condition unreasonably dangerous to the user or customer 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 his product, and

(b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

*Id.* Although the Restatement is not the law per se, jurisdictions widely hold that section 402A is representative of their law. See M. STUART MADDEN, *PRODUCTS LIABILITY* § 6.1, at 192 n.12 (2d ed. 1988) (as of 1988, thirty-three jurisdictions have adopted Restatement position on strict liability in tort). *But see* Grundberg v. Upjohn Co., 813 P.2d 89, 95 (Utah 1991) (courts need not adhere to Restatement’s principles since it is not law per se).

* See Toner v. Lederle Lab., 732 P.2d 297, 302 (Idaho 1987) (defining defective product), *cert. denied*, 485 U.S. 942 (1988); Sidney H. Willig, *The Comment K Character: A Conceptual Barrier to Strict Liability*, 29 MERCER L. REV. 545, 550-51 (1978) (importance of Comment g). Comment g of section 402A states that a product which leaves the hands of the manufacturer in a condition not contemplated by the consumer can be called defective for purposes of the section. ReSTATEMENT, *supra* note 1, § 402A at cmt. g. However, certain products are unavoidably unsafe and cannot be defined as defective. See *infra* note 11.
equipped with an alternative theory of recovery. This alternative theory, strict products liability, relieves plaintiffs of the more substantial burden of proving negligence. Although most jurisdictions have adopted section 402A there have been differing inter-

(Comment k defines when product is unavoidably unsafe).


Strict liability claims consist of three theories: failure to warn, manufacturing defect, and design defect. See, e.g., Restatement, supra note 1, § 402A, at cmt. c. Comment c provides in relevant part:

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 the 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.


See Collins v. Eli Lilly Co., 342 N.W.2d 37, 45 (Wis.) (aside from actual damages and causation, negligence claim must establish manufacturer owed duty of care and breached that duty in manufacturing product in question), cert. denied, 469 U.S. 826 (1984). See generally Prosser & Keeton, supra note 7, at 700 (burdens of proof in negligence claim). In a strict liability claim, once the plaintiff proves that the product in question was defective, knowledge of such defect is imputed to the manufacturer as long as the plaintiff used the product in a manner that was foreseeable. Id. The plaintiff is not required to show that the manufacturer’s actions were unreasonable. Id.; see Savina v. Sterling Drug, Inc., 795 P.2d 915, 923 (Kan. 1990) (“Under the strict liability theory a plaintiff is not required to establish misconduct by the maker or seller but, instead, is required to impugn the product.”). But see Feldman, 479 A.2d at 385-86 (under certain standards strict liability claims and negligence claims require same proof (citing William Prosser, Law of Torts 659 n.72 (4th ed. 1971)));

interpretations by the courts. In particular, the application of section 402A, comment k ("Comment k"), which prohibits strict products liability suits against manufacturers of "unavoidably unsafe products," has resulted in a divergence of opinions in cases in-
volving ethical drugs. Recently, in *Grundberg v. Upjohn Co.*, the Utah Supreme Court expanded the literal interpretation of Comment k and held that in a strict products liability claim based on the theory of design defect, a drug approved by the United States Food and Drug Administration ("FDA") is "un-


13 See WEBSTER'S NINTH NEW COLLEGIATE DICTIONARY 427 (1983). Webster's defines "ethical" (drug) as those "restricted to sale only on a doctor's prescription." *Id.; see also PROSSER & KEETON, supra note 7, at 687 ("over-the-counter drugs and cosmetics are products that do not ordinarily involve risk of serious injury or death"); Selker, supra note 1, at 199 (defining "ethical"). See generally Proceedings, supra note 12, at 92-95. Ethical drugs, as opposed to over-the-counter and prescription drugs, can only be obtained by prescription. *Id. Prescription drugs can include over-the-counter and ethical drugs. *Id. Ethical drugs due to their strength and nature are considered dangerous enough to require a prescription by a physician. *Id.

This Comment discusses providing a blanket immunity to drugs approved by the FDA which due to their nature and value to society have been given protection from strict liability despite injuries associated with their use. Cases cited and discussed are those concerning drugs which can only be obtained through prescription.


16 *Id. at 89-90. Pursuant to Rule 41 of the Utah Rules of Appellate Procedure, the United States District Court for the District of Utah certified questions relating to this action to the Supreme Court of Utah. *Id.

18 *Id.: see West v. Searle & Co., 805 S.W.2d 608, 612 (Ark. 1991) ("We adopt this second view [as an affirmative defense] because of the wording of the comment itself and because it is the better public policy."); Adams v. G.D. Searle & Co., Inc., 576 So.2d 728, 732 (Fla. Dist. Ct. App. 1991) (Comment k from its wording denotes only possible exceptions to § 402A): *infra note 51 (drafters did not intend to provide blanket immunity).

Comment k states that there are certain products which when properly prepared and accompanied by proper directions and warnings are not defective. *Restatement, supra note 1, § 402A, at cmt. k. However, this wording has been used to justify a blanket immunity for prescription drugs. See Brown v. Superior Court, 751 P.2d 470, 482 n.11 (Cal. 1988).

17 See Brochu v. Ortho Pharmaceutical Corp., 642 F.2d 652, 655 (1st Cir. 1981). A claim for design defect arises in a situation where a product is manufactured according to a design but the design itself poses unreasonable dangers to consumers" (quoting Thibault v. Sears, Roebuck & Co., 395 A.2d 843, 846 (N.H. 1978)). *Id. The Court in *Grundberg* states that the three types of defects a product can have are (1) manufacturing flaws, (2) design defects, and (3) inadequate warnings regarding use. *Grundberg, 813 P.2d at 92.

21 21 U.S.C. § 321 (Supp. 1991). In 1940 the FDA was created and placed under the authority of the Department of Agriculture, and was transferred in 1980 to its current agency. *Id.: see id. § 301 (statutory definition of FDA); see also infra notes 83-93 and accompanying text (discussing FDA).
avoidably unsafe” and cannot, as a matter of law, be defective.\textsuperscript{19}

In Grundberg, plaintiff Ilo Grundberg suffered from chronic depression and anxiety\textsuperscript{20} for which her doctor prescribed Halcion,\textsuperscript{21} a drug manufactured by defendant Upjohn Company ("Upjohn") for use in treating insomnia.\textsuperscript{22} On June 19, 1988, after approximately one year of use, Mrs. Grundberg shot and killed her mother.\textsuperscript{23} As a defense to criminal charges which were brought against her, she claimed that side effects\textsuperscript{24} from Halcion caused her to commit the homicidal act.\textsuperscript{25} Subsequently, all criminal

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\textsuperscript{19} Grundberg, 813 P.2d at 90; see supra note 5 (text of § 402A).
\textsuperscript{20} Grundberg, 813 P.2d at 104 (Stewart, J., dissenting).
\textsuperscript{21} Id. at 104 n.4 (Stewart, J., dissenting). “Halcion is the trade name for triazolam, a prescription medication used for treatment of insomnia. Triazolam is one of a class of drugs known as benzodiazepines. Halcion, which is manufactured by Upjohn, was approved by the FDA in November 1982.” Id.; see PHYSICIANS’ DESK REFERENCE 2164-65 (43d ed. 1989). Halcion is an hypnotic agent in the benzodiazepine class that is meant to be used for short term management of insomnia. Id. The adverse reactions listed include confusional states and depression. Id. Paradoxical reactions include aggressiveness, inappropriate behavior and “other adverse behavioral effects.” Id.; see also TRIAL, Guide to Litigation Groups — Halcion, at S-13 (July 1991) [hereinafter TRIAL].

Halcion, an extremely popular drug prescribed to treat insomnia, has been reported to have adverse behavioral side effects. Dramatic withdrawal effects such as further insomnia and anxiety have been clinically observed not only after discontinued use but in the intervals between nightly use. Long-term use may produce organic changes in the brain. Because of the drug’s potency, overdosing is a potential problem.

Halcion has been associated with severely adverse central nervous system reactions, including psychosis, hallucinations, paranoia, depression, aggression, panic anxiety, and detachment from reality. Amnesia is another frequent side effect . . . .

Following widespread national publicity in 1988 about the behavioral side effects of Halcion, several lawsuits were filed against Upjohn.

\textsuperscript{22} Grundberg, 813 P.2d at 90.
\textsuperscript{23} Id. at 104 (Stewart, J., dissenting).
\textsuperscript{24} See id. at 90 (discussing side-effect defense); Johnson v. American Cyanamid Co., 718 P.2d 1318, 1321 (Kan. 1986) (discussing side-effects), aff’d, 758 P.2d 206 (1988). “Side-Effects” are adverse reactions to a particular drug, producing a secondary and unusual unfavorable result. MERRIAM-WEBSTER DICTIONARY 641 (2d ed. 1974); see also Wilson, supra note 2, at 735-38 (examination of adverse drug reactions).
\textsuperscript{25} See Grundberg, 813 P.2d at 90 (plaintiff in state of Halcion-induced intoxication when she shot mother). On the day of the shooting, Mrs. Grundberg was taking a variety of medications for depression and anxiety, including Halcion, Valium and Codeine. Id. at 104
chages were dropped.  

Mrs. Grundberg and her mother’s estate brought suit in the United States District Court for the District of Utah against Upjohn in strict products liability, claiming, inter alia, that Halcion was defectively designed. Upjohn moved for summary judgment on the strict liability claim contending that Halcion was an unavoidably unsafe product which came within the purview of Comment k. The district court, faced with the unanswered question of whether Utah adopts the “unavoidably unsafe products” exception to strict products liability as set forth in Comment k, certified this and related questions to the Supreme Court of

(Stewart, J., dissenting). Valium (which is Roche’s name for diazepam) is a benzodiazepine derivative used for anxiety disorders. PHYSICIANS’ DESK REFERENCE, supra note 21, at 1772. Adverse reactions include rage and depression. Id. Codeine accompanies a variety of different medications containing different chemical agents. Id. at 308.

See Grundberg, 813 P.2d at 104 (Stewart, J., dissenting) (upon recommendation of medical expert who testified as to Mrs. Grundberg’s state of mind at time of shooting, all criminal charges were dropped).

Grundberg, 813 P.2d at 90. Plaintiff also brought suit in strict products liability for failure-to-warn and in common law negligence. Id. Those causes of action were unaffected by the decision in Grundberg, Id.

See Prosser & Keeton, supra note 7, at 699 (“Under a danger-utility test, product is defective as designed if, but only if, the magnitude of the danger outweighs the utility of the product”). See generally Gary C. Robb, A Practical Approach to the Use of State of the Art Evidence in Strict Liability Cases, 77 NW. U. L. REV. 1, 20-35 (1982) (current defenses to design defect claims); Willig, supra note 6, at 572-78 (miscellaneous Comment k defense considerations in drug and cosmetic areas).

Grundberg, 813 P.2d at 90. There is no evidence in the Grundberg decision of Upjohn’s raising the defense of federal preemption by FDA approval of Halcion over plaintiff’s state-based tort claim. Id. For a discussion of this defense, see Feldman v. Lederle Lab., 592 A.2d 1176, 1183 (N.J. 1991). In Feldman, defendant raised federal preemption of state tort action as a defense to the plaintiff’s strict liability claim for inadequate warnings. The court held that there was no preemption. Id. Similarly, in Abbott v. American Cyanamid Co., 844 F.2d 1108, 1114 (4th Cir.), cert. denied, 488 U.S. 908 (1988), the court addressed federal preemption by FDA regulations over a design defect claim, and subsequently held that defendant’s contention of federal preemption was without merit. Id.

See also Joseph H. Page, Generic Product Risks: The Case Against Comment K and for Strict Tort Liability, 58 N.Y.U. L. REV. 853, 855 (1983) (“under the [Comment k] analysis, if the benefits of a product outweigh its known risks, and if the manufacturer has provided suitable warnings and directions for use, the defendant’s product will be deemed reasonably safe and the plaintiff will not recover”); supra note 11 (text of Comment k).

See Grundberg, 813 P.2d at 90-91. The district court certified the following questions: 1. Does Utah adopt the “unavoidably unsafe products” exception to strict liability as set forth in comment k to section 402A of the Restatement (Second) of Torts (1965)? (a) If Utah does adopt comment k, should FDA-approved prescription drugs be deemed as a matter of law to have satisfied the “unavoidably unsafe” prerequisite to the comment k exception, or should that determination be made on a case-by-case
Utah before ruling on the motion.\textsuperscript{32}

Justice Durham, writing for the majority in a 3-2 decision, stated that Comment k applies only to causes of action in strict products liability based on design defects.\textsuperscript{33} Furthermore, the court agreed with the basic-principles set forth in Comment k, specifically that there are certain products which are unavoidably unsafe.\textsuperscript{34} The court discussed the manner in which other jurisdictions have applied Comment k immunity, comparing jurisdictions that have adopted a case-by-case, risk-benefit analysis\textsuperscript{35} with those

\textsuperscript{32} Id. Subsequent to the Grundberg court's disposition on the certified questions, the parties settled. See Geoffrey Cowley et al., Sweet Dreams or Nightmare?, NEWSWEEK, Aug. 9, 1991, at 44 [hereinafter Sweet Dreams].

\textsuperscript{33} Grundberg, 813 P.2d at 92; see West v. G.D. Searle & Co., Inc., 806 S.W.2d 608, 613 (Ark. 1991) ("by its terms, Comment k exempts unavoidably unsafe products from strict liability only where the plaintiff alleges a design defect") (emphasis added); Toner v. Lederle Lab., 732 P.2d 297, 305 (Idaho 1987) (Comment k applies to strict liability actions claiming design defects), cert. denied, 485 U.S. 942 (1988).

\textsuperscript{34} Grundberg, 813 P.2d at 92; see, e.g., West, 806 S.W.2d at 612 (products with no feasible alternative design to accomplish product's purpose are unavoidably unsafe); Dunn v. Lederle Lab., 328 N.W.2d 576, 584 n.21 (Mich. App. 1982) (oral polio vaccine unavoidably unsafe). But see Reyes v. Wyeth Lab., 498 F.2d 1264, 1275 (5th Cir.) (drug is unreasonably dangerous due to inadequate warnings), cert. denied, 419 U.S. 1096 (1974).

\textsuperscript{35} See Wade, supra note 7, at 837. The classic seven factors of the risk-utility analysis proposed by Professor Wade are:

1. The usefulness and desirability of the product—its utility to the user and to the public as a whole.
2. The safety aspects of the product—the likelihood that it will cause injury and the probable seriousness of the injury.
3. The availability of a substitute product which would meet the same need and not be as unsafe.
4. The manufacturer's ability to eliminate the unsafe character of the product without impairing its usefulness or making it too expensive to maintain its utility.
5. The user's ability to avoid danger by the exercise of care in the use of the product.
6. The user's anticipated awareness of the dangers inherent in the product and their avoidability, because of general public knowledge of the obvious condition of the product, or of the existence of suitable warnings or instructions.
7. The feasibility, on the part of the manufacturer, of spreading the loss by setting the price of the product or carrying liability insurance.

482
Grundberg v. Upjohn Co.

that have held all prescription drugs are entitled to immunity as a matter of law. While admitting that the language of Comment k "contemplates a weighing of the drug's risks and benefits," the majority concluded that the elaborate regulatory system overseen by the FDA was the proper forum in which to review the efficacy of a prescription drug. The court reasoned that the FDA tests provided a legally sufficient screening process to weigh the risks and benefits of a particular drug, and that the courthouse was ill-suited for the complexities of design defect claims in prescription drug cases. Furthermore, the court maintained that such

Id.: see also Toner, 732 P.2d at 308 (adopting risk-benefit analysis for Comment k application as a "sensible system [serving] . . . important policy considerations, particularly in the area of ethical drug manufacture"); Schwartz, supra note 1, at 43 ("[d]espite [the] uncertainties, the [risk-utility] standard itself is easily understood and fits within traditional principles of negligence which are familiar to the legal profession").

9 Grundberg, 813 P.2d at 96. That the FDA employs a comprehensive scheme of pre-market screening and post-market surveillance to ensure the safety and efficacy of all licensed medications.

10 Grundberg, 813 P.2d at 95 (citing Toner, 732 P.2d at 306).

11 Id. at 96. "[T]he FDA employs a comprehensive scheme of pre-market screening and post-market surveillance to ensure the safety and efficacy of all licensed medications." Id. (citing 50 Fed. Reg. 7452 (1985)). The FDA regulates the testing and marketing practices of drug companies through its new drug application regulations. Id.

The Grundberg court based its holding on the assumption that the drug manufacturer fully complied with FDA regulations in obtaining approval for the drug. Id. at 90. There is evidence, however, that Upjohn omitted the results from one clinical study which revealed adverse effects in fifty-eight patients taking Halcion. Mark Hansen, Does Halcion Spur Aggression?, A.B.A. J., Nov. 1991, at 25. If this omission is not sufficient to qualify as non-compliance with FDA regulations, it is submitted that the Grundberg decision implicitly endorses insignificant omissions from the reporting requirements of the FDA. It is further submitted that lower courts, faced with analogous factual situations, would be forced to determine what constitutes a significant omission thereby undermining the Grundberg court's primary motivation—uniform lower court rulings.

12 See Grundberg, 813 P.2d at 97; PROSSER & KEETON, supra note 7, at 688. ("the drug approval process involves a complex and often ad hoc balancing of imponderable and commensurate factors relating to danger and utility of marketing a specific new drug"). But see Feldman v. Lederle Lab., 479 A.2d 374, 383 (N.J. 1984), rev'd on other grounds, 592 A.2d 1176 (1991).

There has been no showing of the extent to which and how the FDA applies a risk-utility analysis in deciding whether a drug should be distributed or the effect of the FDA's determination on drug manufacturers' options to distribute or not distribute the drug with or without warnings. Indeed, the FDA's determination, even if it consisted of a risk-utility analysis it would not supplant the risk-utility balancing required in the judicial process.

13 Grundberg, 813 P.2d at 98-99. See generally James H. Henderson, Jr., Judicial Review of 483
deference to the FDA's judgment facilitated the development, affordability and expedient distribution of drugs, and provided guidance for future lower court rulings in this area.

In dissent, Justice Howe suggested a more discriminating application of Comment k. Under this approach, the Comment k immunity defense would be available only when use of a "life-saving drug" forms the basis of the lawsuit. In addition, Justice Howe argued that FDA approval in such an action should afford a defendant manufacturer only a rebuttable presumption that its product was safely designed.

In a separate dissent, Justice Stewart criticized the majority for its "abdication of judicial responsibility" through its unjustified deference to the FDA. He cited the inadequacy of the FDA approval process in preventing harmful drugs from reaching the market in past years and the subsequent injuries which arose from their introduction. He asserted that the better approach is one


Grundberg, 813 P.2d at 98.

Id. at 99 (Howe, J., dissenting).

Id. (Howe, J., dissenting).

Id. (Howe, J., dissenting).

Id. at 100 (Stewart, J., dissenting).

Id. (Stewart, J., dissenting); see Adams v. G.D. Searle & Co., Inc., 576 So. 2d 728, 792 (Fla. Dist. Ct. App. 1991) ("Applying comment k uniformly to all prescription drugs . . . rejects the comment's own approach to determining its scope."); cf. Belle Bonfils Memorial Blood Bank v. Hansen, 665 P.2d 118, 123 (Colo. 1983) (manufacturer must prove Comment k applicability). Determining the meaning behind Comment k has been the justification used by some courts in rationalizing their decisions in pharmaceutical cases involving claims of design defects. See Brown v. Superior Court, 751 P.2d 470, 482 n.11 (Cal. 1988) (construing language of Comment k to provide blanket immunity); Willig, supra note 6, at 549. The problem posed in design defect cases in recent years has been the extent to which Comment k applies and the conflicting public policy considerations. Id.; see also Feldman v. Lederle Lab., 479 A.2d 374, 383 (N.J. 1984) (case-by-case approach should be used because drugs have flaws like any other product), rev'd on other grounds, 592 A.2d 1176 (1991); Tim Moore, Comment, Comment K Immunity to Strict Liability: Should All Prescription Drugs Be Protected?, 26 Hous. L. REV. 707, 729 (1989) (discussing economic and social factors entering into court considerations of Comment k claims).

See, e.g., Williams v. Ciba-Geigy Corp., 686 F. Supp 573, 574 (W.D. La.) (plaintiff got serious skin condition after ingesting Tegretol), aff'd, 864 F.2d 789 (5th Cir. 1988); West v. G.D. Searle & Co., Inc., 806 S.W.2d 608, 609 (Ark. 1991) (birth control pill caused benign
Grundberg v. Upjohn Co.

that utilizes the risk-benefit analysis embodied in Comment k, which weighs a drug's apparent benefits against its apparent risks at the time of the drug's introduction. Under this test, a drug providing more benefits than risks would receive Comment k immunity, while a drug not qualifying for immunity would be "subject to the traditional design-defect analysis set forth in [section] 402A." Justice Stewart endorsed this approach rather than the majority's decision which, he asserted, would deprive injured consumers of a means of obtaining compensation.

This Comment will address the inappropriateness of substituting a products liability analysis, traditionally and properly posited in the judicial system, with the product-marketability standards of the FDA. Part One will analyze the ALI's purpose in promulgating Comment k, as well as other jurisdictions' approaches construing its language. Part Two will briefly review the FDA's approval process for prescription drugs. Part Three will compare and contrast the purposes of the ALI and the FDA in employing their respective risk-benefit analyses. Finally, Part Four will discuss the ramifications of the Utah Supreme Court's decision in Grundberg.

See generally Nelson, supra note 41, at 469 (injuries resulting despite FDA approval of thalidomide); Willig, supra note 6, at 545 (discussing recall of DES, Dalkon Shield and MER-29).

49 Grundberg, 813 P.2d at 103 (Stewart, J., dissenting); see supra notes 11 and 35 (text of Comment k and risk-benefit test).

50 Grundberg, 813 P.2d at 103 (Stewart, J., dissenting).

51 Id.: see West, 806 S.W.2d at 612. "[I]t is obvious that the drafters did not intend to grant all manufacturers of prescriptive drugs a blanket exception to strict liability." Id.: see Toner, 752 P.2d at 306. "[T]he scales must clearly tip in favor of the benefits for comment k to apply." Id. "[T]he comment refers to "some" products which are unavoidably unsafe: obviously it does not apply to all drugs." Id. at 308; see also Castrignano, 546 A.2d at 782 (adopted modification of risk-benefit test).


53 Id. (Stewart, J., dissenting); see Selker, supra note 1, at 215. "[T]he 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." Id.
I. DETERMINING THE MEANING BEHIND COMMENT K

As written by the ALI, Comment k provides an exception to strict liability claims for design defects against manufacturers of "unavoidably unsafe" products. The ALI recognized that there are some cases in which, given the limits of technology or the urgent need for a specific product, manufacturers may find it necessary to distribute products that are "incapable of being made safe for their intended and ordinary use." According to the intended meaning of Comment k, for a product to gain "unavoidably unsafe" status, a defendant manufacturer must prove that the product's utility outweighed its risks, that a safer product was unavailable, and that the product was unadulterated and effective for its prescribed use. Despite the clarity of both the language and the intent of Comment k, courts have disagreed as to its application.

A. The Case-by-Case Approach

Justice Stewart's dissenting opinion in Grundberg advocated a li-
Grundberg v. Upjohn Co.

eral adherence to Comment k which would inevitably involve some form of risk-benefit analysis, with the burden placed on the defendant-manufacturer to affirmatively prove the Comment’s applicability. For example, in Castrignano v. Squibb & Sons, Inc., the plaintiff sustained personal injuries due to her mother’s ingestion of DES and brought a strict liability design defect claim against manufacturer Squibb & Sons, Inc. The court held that the proper application of Comment k required the trial judge to conduct an initial risk-utility analysis. If the trial judge concluded that, at the time of its manufacture, the benefits of the drug clearly outweighed its attendant risks to the extent that reasonable minds could not differ, then Comment k immunity should be granted as a matter of law. Alternatively, if the judge decided that reasonable minds could differ, the issue would be resolved by the finder of fact.

Many jurisdictions have similarly interpreted Comment k and despite some variation in application, the underlying risk-benefit analysis has been preserved. Notwithstanding the wide acceptance of the case-by-case approach, the majority in Grundberg concluded that this approach was “unworkable,” would lead to a

62 See supra note 16 (risk-benefit analysis built into Comment k).
64 546 A.2d 775 (R.I. 1988).
65 Id. at 777.
66 Id. at 778. The decision in Castrignano was in response to questions certified to the Supreme Court of Rhode Island following the jury’s finding defendant Squibb liable for the damages suffered by the plaintiff. Id. The court responded that “[t]he application of Comment k is a mixed question of law and fact. The defendant who uses comment k as a defense bears the burden of proving that the comment applies. If reasonable minds could only reach one conclusion, the judge may rule on comment k’s application. Otherwise, the question should be submitted to the jury.” Id.; see supra note 35 (risk-utility test).
67 Id. at 782.
68 Id.
disparity of lower court rulings, and could deter drug manufacturers from producing new and valuable medicines. Nevertheless, it is submitted that the case-by-case approach better preserves both plaintiff's remedy for an avoidably unsafe drug and manufacturer's defense for a highly beneficial, though dangerous, drug.

B. The Blanket Immunity Approach

The Grundberg court provided blanket Comment k immunity to all ethical drugs approved by the FDA. The decision was premised on Brown v. Superior Court, where the plaintiff was injured in utero by her mother's ingestion of DES. In Brown, the California Supreme Court rejected the case-by-case approach which it had previously developed in Kearl v. Lederle. The Brown court, finding the approach "unworkable" because it gave the trial judge "mixed questions of law and fact," held that Comment k

71 Id. at 98.
72 Id. at 99.
73 Id.; see Brown v. Superior Court, 751 P.2d 470, 482-83 (Cal. 1988) (Comment k provides immunity for all prescription drugs); accord Adams v. G.D. Searle & Co., Inc., 576 So.2d 728, 732 (Fla. Dist. Ct. App. 1991). In Adams, the court stated:
74 751 P.2d at 470 (Cal. 1988).
75 Plaintiff was one of "at least 69" patients who filed personal injury actions in the San Francisco Superior Court due to their mothers' ingestion of DES during pregnancy. Id.
76 Id. at 473. Plaintiff was one of "at least 69" patients who filed personal injury actions in the San Francisco Superior Court due to their mothers' ingestion of DES during pregnancy. Id.
77 751 P.2d 470 (Cal. 1988).
78 Id. at 482; see Kearl v. Lederle Lab., 218 Cal. Rptr. 453, 464 (1985), overruled by Brown v. Superior Court, 751 P.2d 470 (Cal. 1988). According to the Kearl test, the judge was to determine:
79 Brown, 751 P.2d at 481.
80 Id. at 482. "In order to vindicate the public's interest in the availability and af-
Grundberg v. Upjohn Co.

was intended and should apply to all prescription drugs.\textsuperscript{80}

The \textit{Grundberg} court disregarded the factual arguments asserting Halcion's propensity for causing substantial adverse side effects,\textsuperscript{81} concluding that the judicial system need not inquire further into a particular drug's design because the FDA's approval process is extensive enough to ensure that only safe drugs reach the marketplace.\textsuperscript{82} It is submitted that this blanket immunity approach deprives plaintiffs of a vital cause of action while indiscriminately allowing defendants to avoid liability once their products receive FDA approval.

\textbf{II. THE FDA APPROVAL PROCESS}

Pursuant to congressional legislation, the FDA instituted a comprehensive regulatory system to assure manufacturers' compliance with the Federal Food, Drug and Cosmetic Act.\textsuperscript{83} The purpose of this regulatory system is to protect the public health and welfare from misbranded and adulterated articles of medicine and food.\textsuperscript{84} In furtherance of this objective, the FDA maintains its own Center for Drug Evaluation and Research\textsuperscript{85} which must approve

fordability of prescription drugs, a manufacturer must have a greater assurance that his products will not be measured by a strict liability than is provided by the test stated in \textit{Kearl}.” \textit{Id. But see} Adams v. G.D. Searle & Co., Inc., 576 So.2d 728, 732 (Fla. Dist. Ct. App. 1991) (denying cause of action for design defects will not stop poor marketing practices); Selker, \textit{supra} note 1, at 216. “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.” \textit{Id. See generally} Wilson, \textit{supra} note 2, at 757-58 (deterrent effect on drug manufacturers).

\textsuperscript{80} Brown, 751 P.2d at 482 n.11.


\textsuperscript{82} Grundberg v. Upjohn Co., 813 P.2d 89, 97 (Utah 1991).

\textsuperscript{83} \textit{Id.} at 96. “The federal government has established an elaborate regulatory system, overseen by the FDA, to control the approval and distribution of these drugs. No other class of products is subject to such special restrictions or protections in our society.” \textit{Id.; see} 21 U.S.C. §§ 301-393 (1988) (text of Federal Food, Drug and Cosmetic Act).

\textsuperscript{84} See, \textit{e.g.}, United States v. Kordel, 164 F.2d 913, 917 (7th Cir.) (liberal interpretation given to statutes which promote public health), \textit{aff'd}, 335 U.S. 345 (1947); Barnes v. United States, 142 F.2d 648, 651 (9th Cir. 1944) (purpose of Act is protection of consuming public); \textit{cf.} Upjohn Mfg. Co. v. Schweiker, 681 F.2d 480, 484 (6th Cir. 1982) (regulations governing FDA approval not intended to provide manufacturers with patent-like protection).

\textsuperscript{85} 21 C.F.R. § 5.100 (1990). The Center for Drug Evaluation and Research is located in
all drugs before they may be sold in the United States.\textsuperscript{86} To comply with the FDA’s approval process, manufacturers must submit a New Drug Application\textsuperscript{87} asserting the proposed drug’s safety and effectiveness for its purported use.\textsuperscript{88} Approval is given to new drugs if substantial evidence\textsuperscript{89} shows that the proposed drug is as effective as the proposed labeling represents and is safe according to New Drug Application tests and expert medical opinion.\textsuperscript{90} In addition, an abbreviated approval process is available when a new drug’s active ingredient is identical to that of a drug which is already FDA approved.\textsuperscript{91} After receiving approval, the manufacturer is further obligated to periodically submit reports pertaining to any adverse reactions associated with the drug’s use discovered through “post-marketing studies, reports in scientific literature and foreign marketing experience.”\textsuperscript{92} Depending on the severity of the adverse reactions reported, the FDA may either require the manufacturer to indicate such reactions on the product’s label or it may mandate the drug’s removal from the American market.\textsuperscript{93}

Rockville, Maryland and consists of eight specialized offices with several divisions under each office. \textit{Id.}


\textsuperscript{87} See \textit{id.} § 355(b). All experiments conducted in support of an NDA must be performed in accordance with FDA’s rigid testing requirements. \textit{Id.}

\textsuperscript{88} See \textit{id.} § 355(d) (defining FDA approval process); Victor E. Schwartz, \textit{Unavoidably Unsafe Products: Clarifying the Meaning and Policy Behind Comment K,} 42 \textit{Wash. & Lee L. Rev.} 1139, 1142 (1985) (same). “New” drug is defined as “[a]ny drug the composition of which is such that such drug is not generally recognized among qualified experts \ldots as safe and effective for use under the condition prescribed \ldots.” 21 U.S.C. § 321(h).

\textsuperscript{89} 21 U.S.C. § 335(d). “Substantial evidence” is defined as:

\textit{[C]onsisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.}

\textit{Id.}

\textsuperscript{90} \textit{Id.}

\textsuperscript{91} 21 U.S.C. § 355(i); see Grundberg v. Upjohn Co., 813 P.2d 89, 104 (Utah 1991) (Stewart, J., dissenting) (Halcion neither unique nor essential); cf. Selker, \textit{supra} note 1, at 216 (“The drug [Panalba] had negligible therapeutic value, but, rather, was merely a new substance created by combining two other antibiotics. [I]t was clearly an instance of a drug created for a market rather than a medical purpose.”).

\textsuperscript{92} Grundberg, 813 P.2d at 97; see Nelson, \textit{supra} note 41, at 463 (regulations regarding post marketing procedures).

\textsuperscript{93} See \textit{infra} note 99 (powers of FDA to recall products).
III. The Policies of the American Law Institute and the Food and Drug Administration Are Distinct

As contemplated by Comment k, the design of a drug "must be as safe as the best available testing and research permits," and the attendant risks of the drug must be unavoidable. Thus, by the terms of Comment k, a risk would not be "unavoidable" if there were another drug available with the same benefits and lesser risks than the drug in question. In contrast, the FDA's New Drug Application makes no inquiry as to the existence of other comparable drugs having equal or greater utility with fewer attendant risks. Therefore, as defined by Comment k, FDA approval is not indicative of an "unavoidably unsafe" drug.

Moreover, Comment k status is not perpetual. Drugs that at

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95 Id.
96 Id. at 306. Justice Bistline's reasoning in Toner best highlights the difference between an FDA approved drug and a drug deserving comment k immunity:

As an additional element of an "unavoidable risk," there must be, at the time of the subject production's distribution, no feasible alternative design which on balance accomplishes the subject product's purpose with a lesser risk... If there were, than the risk would not be "unavoidable" or "apparently reasonable."

Id.
98 Feldman v. Lederle Lab., 479 A.2d 374, 379 (N.J. 1984), rev'd on other grounds, 592 A.2d 1176 (1991). It is submitted that this case is particularly illustrative of the FDA's fallibility. In Feldman, the defendant had contacted the FDA regarding the possibility of placing a warning on its drugs containing tetracycline concerning that compound's tendency to cause tooth discoloration. Id. The FDA advised the defendant against circulating such a warning until the FDA had completed its investigation of one of the defendant's drugs, Declomycin, an antibiotic that contained tetracycline. Id. It was not until over one year after the FDA received the defendant's request that the FDA approved the warning. Id. In the interim, plaintiff continued to use Declomycin to control her upper respiratory infections. Id.; see also Savina v. Sterling Drug, Inc., 795 P.2d 915, 929 (Kan. 1990) (doctor on cross-examination testified that FDA prohibits release of any unsubstantiated comment or concern regarding drug regardless of reports of adverse incidents).
99 Toner v. Lederle Lab., 732 P.2d 297, 307 (Idaho 1987), cert. denied, 485 U.S. 942 (1988). FDA approval is likewise not perpetual. Section 355(e) of Title 21 of the United States Code, in relevant part, describes the conditions by which a drug may lose its approval:

The Secretary shall, after due notice and opportunity for hearing to the applicant, withdraw approval of an application with respect to any drug under this section if the Secretary finds (1) that clinical or other experience, tests, or other scientific data show that such drug is unsafe for use under the conditions of use upon the basis of which the application was approved; (2) that new evidence of clinical experience, not contained in such application or not available to the Secretary until after such application was approved, or tests by new methods, or tests by methods not deemed rea-
one time qualify for Comment k immunity may lose that status in subsequent litigation if reports of adverse reactions indicate a greater risk than benefit, or if a comparable drug with a safer design is made available. In contrast, the FDA will not withhold its approval of a drug merely because potentially safer alternative drugs exist, nor will it withdraw approval if such an alternative becomes available. Halcion, approved despite the FDA’s own characterization of the drug as having “no therapeutic advantage over existing sleeping pills,” has been permitted to retain FDA approval notwithstanding the existence of more effective alternative drugs. It is submitted that this illustrates perfectly the need for a court to independently evaluate each drug’s deservedness of

sonably applicable when such application was approved, evaluated together with the evidence available to the Secretary when the application was approved, shows that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved; or (3) on the basis of new information before him with respect to such drug, evaluated together with the evidence available to him when the application was approved, that there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof; or... (5) that the at the [sic] application contains any untrue statement of a material fact: Provided, That if the Secretary finds that there is an imminent hazard to the public health, he may suspend the approval of such application immediately, and give the applicant prompt notice of his action and afford the applicant the opportunity for an expedited hearing under this subsection...

Id. Although the means exist for taking a drug off the market, the FDA is not noted for its swiftness: see, e.g., American Cyanamid Co. v. Young, 770 F.2d 1213, 1215 n.4 (D.C. Cir. 1985) (“The pace of proceedings at the Food and Drug Administration [FDA], for whatever reasons does not rival that of, say, a turn-of-the-century sweatshop in New York City.” (quoting General Medical Co. v. United States Food and Drug Admin., 770 F.2d 214, 216 (D.C. Cir. 1985))).

100 Toner, 732 P.2d at 307. In Toner, the court stated:

Where the balancing [of a risk-benefit analysis] results in the application of comment k’s immunity from strict liability, the immunity is not perpetual. If new information later tips the balance toward the risk of a product, or if new developments make possible a safer design, at that point further distributions of the product are not protected by comment k.

Id.: see also Schwartz, supra note 88, at 1147 (public policy not compromised by requiring manufacturers to keep abreast of developments affecting drug industry).

101 Grundberg v. Upjohn Co., 813 P.2d 89, 104 (Utah 1991) (Stewart, J., dissenting) (nine other hypnotic agents are available).


103 Grundberg, 813 P.2d at 104 (Stewart, J., dissenting).

104 Id. (Stewart, J., dissenting).
Grundberg v. Upjohn Co.

Comment k immunity regardless of FDA approval.

IV. RAMIFICATIONS OF THE GRUNDBERG DECISION

In holding that all prescription drugs should receive Comment k immunity based solely on FDA approval, it is submitted that the Grundberg court chose convenience over reason. The court eliminated the necessity of litigating on a case-by-case basis, design defect issues and Comment k applicability by holding as a matter of law, that a drug with FDA approval cannot be defective. Such mechanical adherence to the standards of a government agency undermines the role of the judicial system to provide plaintiffs with a form of redress. In addition, the court's rationale for granting Comment k immunity to all prescription drugs ignores the profit-motivated aspect of the drug industry. In manufacturing a drug, the minimizing of costs and marketing in a compet-

106 Grundberg, 813 P.2d at 99. "[W]e conclude that a broad grant of immunity from strict liability claims based on design defects should be extended to FDA-approved prescription drugs in Utah." Id.

106 See Selker, supra note 1, at 203 (goal of strict liability is derived "from an economic and ethical allocation of responsibility for loss to the source of the defective, injury producing product" regardless of fault).

107 See Gina Kolata, Records Indicate Company Ignored Warning on Drug, N.Y. TIMES, July 4, 1991, at A1. As reported by one journalist:

[Manufacturer F. Hoffmann-La Roche, despite warnings from its Swiss affiliate] went ahead with what the affiliate correctly predicted would be a dangerously concentrated formulation, and more than 40 deaths and about as many injuries resulted. The drug, known as Versed, was designed to replace injectable Valium as its patent expired. [Internal] documents, made available to The New York Times by a person who said he was outraged at the company's conduct, include a memorandum from the company's own legal advisers stating that it might have disregarded safety concerns for economic reasons. Id.; see also A.D. Twerski et al., The Use and Abuse of Warnings in Products Liability — Design Defect Litigation Comes of Age, 61 CORNELL L. REV. 495, 527 (1976).

The industrial design engineer pays first allegiance to the trilogy of cost, marketability and competitive position within the context of product function. Although safety is a factor in his design plan, it cannot and does not become the focal point of his endeavors. The engineer does not sit down to design a product with safety at the head of his list of features or concerns. The products liability case provides that shift in focus whereby society reexamines the design, taking into account all the factors that the design engineer must account for, with one difference: in this forum they are viewed in light of their ultimate impact on product safety.

Id.: see Feldman v. Lederle Lab., 479 A.2d 374, 408 (N.J. 1984), rev'd on other grounds, 592 A.2d 1176 (1991). "Granted, drug production is a commercial enterprise but it has a unique and intimate relationship to the health and even survival of many people." Id.
itive industry often eclipse safety considerations.\textsuperscript{108}

The ramifications of \textit{Grundberg} are clear.\textsuperscript{109} Halcion, a drug with low utility and potentially high risks, received immunity under the court's decision.\textsuperscript{110} It is submitted that when low-utility drugs injure individuals—and the drug companies who manufacture the drugs receive immunity—the majority's own public policy arguments are defeated. The majority sought to provide drug manufacturers with an incentive to develop new and important drugs,\textsuperscript{111} but in the instant case, a drug which was neither new nor valuable\textsuperscript{112} was given immunity. It is submitted the \textit{Grundberg} decision illustrates that the benefit conferred by granting blanket immunity inures to the benefit of the drug manufacturers at the expense of the public health and welfare.

Although the case-by-case approach might seem complicated and resulting divergent decisions might cause drug companies to hesitate in marketing certain new drugs, it is nevertheless suggested that this approach better serves public policy by providing an additional remedy to injured persons in the event the FDA's testing is flawed.\textsuperscript{113} Furthermore, if a court is to grant Comment k immunity based solely on FDA determinations, complete deference should be given to those determinations only in cases involving experimental new drugs needed for the treatment of deadly diseases. This would effectuate the clear intent of Comment k and more adequately serve public policy.\textsuperscript{114}

\textsuperscript{108} See Selker, \textit{supra} note 1, at 204 (drug manufacturers do not make drugs merely to benefit mankind, but to realize a profit); see also Rosenthal, \textit{supra} note 81, at 18 (Britain banned Halcion from market). Despite the problems associated with its use, Dr. Theodore Cooper, Upjohn's Chairman maintains that "[t]here is absolutely no scientific evidence that warrants withdrawal of Halcion." Geoffrey Cowley & Karen Springen, \textit{Hard Times for Halcion}, \textit{Newsweek}, Oct. 14, 1991, at 61.

\textsuperscript{109} See generally \textit{Sweet Dreams}, \textit{supra} note 81, at 44-46 (discussing details of Grundberg case).

\textsuperscript{110} Grundberg, 813 P.2d at 99.

\textsuperscript{111} Id.

\textsuperscript{112} See supra note 21 (describing Halcion).

\textsuperscript{113} See supra note 48 (recalling of products approved by FDA). It is submitted that the very existence of FDA recall procedures evidences the fact that FDA approval is not error free and that serious adverse effects can occur after a product reaches the market, therefore under the Court's decision in Grundberg, these injured people would have little recourse to seek compensation.

\textsuperscript{114} See Adams v. G.D. Searle & Co., Inc., 576 So.2d 728, 732 (Fla. Dist. Ct. App. 1991). "We believe that the policy reasons for supporting a blanket approach are countervailed by
CONCLUSION

The ALI's purpose for including Comment k with Restatement section 402A was to provide a narrow exception to the harshness of strict liability for products that cannot be manufactured more safely. When it was suggested during the drafting of section 402A that all drugs should be granted Comment k immunity, the ALI drafters specifically rejected this notion. The Grundberg majority unjustifiably expanded the literal meaning of Comment k, effectively becoming a judicial rubber stamp of the FDA, relinquishing its duty to determine liability by checking manufacturers' designs in accordance with the risk-benefit analysis contemplated by the authors of Comment k. Instead, the Grundberg court succumbed to the seduction of convenience and expedience. The majority failed to show any confidence in the judiciary to analyze complex issues found in most design defect cases. The decision reached by the majority is dangerous because it precludes the judicial process from its traditional obligation to protect society. Individuals injured by this new generation of drugs may have no recourse against the manufacturers without carrying the burden of proving negligence. It is submitted that with its decision, the majority obliterated the strict products liability doctrine with respect to manufacturers of ethical drugs. Plaintiffs injured by these drugs can only hope that the Grundberg decision is not followed by their jurisdiction.

Christopher J. Albee & Dawn Kilgallen

those supporting a more selective application of the comment.” Id.; see also West v. G.D. Searle & Co., Inc., 806 S.W.2d 608, 612 (Ark. 1991) (wording of Comment k calls for case-by-case analysis).