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# THE RELEVANCY OF DRUG EFFICACY EVIDENCE IN STRICT LIABILITY ACTIONS: NEEDHAM v. WHITE LABORATORIES, INC.

MARY E. KELLY\*

## INTRODUCTION

Diethylstilbestrol (DES), a synthetic estrogen<sup>1</sup> widely prescribed in the past for the prevention of miscarriage,<sup>2</sup> is cur-

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1. U.S. DEP'T OF HEALTH, EDUCATION AND WELFARE, WOMEN AND ESTROGENS, PUB. NO. FDA 76-3022 (Apr. 1976) [hereinafter cited as WOMEN AND ESTROGENS].

2. It is estimated that between 1943 and 1959, estrogens were prescribed for nearly six million pregnant women resulting in the birth of at least three million children who had been exposed *in utero*. B. SEAMAN & G. SEAMAN, WOMEN AND THE CRISIS IN SEX HORMONES 16 (1977) [hereinafter cited as SEAMAN & SEAMAN]. In 1971, the FDA announced that DES was contraindicated in pregnancy. A 1974 survey of drug prescription practices, however, revealed that 11,000 prescriptions for DES were written for "threatened abortion" or "prenatal" care. *Diethylstilbestrol*, MED. WORLD NEWS 44 (Aug. 23, 1976) [hereinafter cited as *Diethylstilbestrol*].

Diethylstilbestrol (DES) was first synthesized in 1937, and used in the suppression of lactation in post-partum women and in treatment of the "menopausal syndrome." Brief for Defendant-Appellant White Laboratories, Inc. at 4, *Needham v. White Laboratories, Inc.*, 639 F.2d 394 (7th Cir. 1981) [hereinafter cited as *Needham*, Defendant's Brief]. In 1978, the FDA's advisory committee recommended that the indications for use of DES and other estrogens, including combinations with progesterones, for post partum breast engorgement be deleted from the product's labeling. FOOD AND DRUG ADMINISTRATION, 8 DRUG BULLETIN 10 (No. 2 Mar.-Apr. 1978) [hereinafter cited as *DES and Breast Cancer*]. The reason for this change was a preliminary report of a University of Chicago study indicating that DES increased the risk of breast cancer, and "to a lesser extent, the risk of cervical and ovarian cancer." *Id.* Although the data did not firmly establish a cause and effect relationship between DES and increased risk of breast cancer, it did give "reason for concern" since other estrogens have been associated with endometrial and breast cancer in certain patients. *Id.*

Currently, estrogens are indicated for only the vasomotor symptoms of menopause ("hot flashes"). PHYSICIANS' DESK REFERENCE 1055 (35th ed. 1981). Post menopausal use of estrogens has been excessive due to the belief that it would stave off aging, maintain youthfulness, prevent wrinkles, and stop deterioration of the bones (osteoporosis). WOMEN AND ESTROGENS, *supra* note 1, at 1. There is a lack of objective evidence that estrogen is effective for these major uses, and the current labeling indicates that estrogen should not be used to treat nervous or depressive symptoms of men-

rently the subject of much drug litigation.<sup>3</sup> The association between clear-cell adenocarcinoma of the vagina in young females, a rare cancer which was virtually unknown before the use of DES,<sup>4</sup> and prenatal exposure to DES is firmly established.<sup>5</sup> It is estimated that in the female DES-exposed popula-

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opause. PHYSICIANS' DESK REFERENCE 1055 (35th ed. 1981). The risk of endometrial cancer in women who have taken estrogens is 4 to 14 times greater than in women who have not taken synthetic estrogens. Rosenwaks, Wentz, Jones, Urban, Lee, Migeon, Pharmley & Woodruff, *Endometrial Pathology and Estrogens*, 53 OBSTETRICS AND GYNECOLOGY 403 (Apr. 1979). See also PHYSICIANS' DESK REFERENCE 1055 (35th ed. 1981) (risk estimated to be 4.5 to 13.9 times greater in estrogen users). DES is also indicated for use in atrophic vaginitis, female castration, primary ovarian failure, and as a palliative in advanced prostatic cancer and breast cancer. *Id.* at 1056.

In 1959, the Food and Drug Administration (FDA) withdrew approval of the use of DES in chicken feed on the ground that it was a well known carcinogen. The Second Circuit affirmed the order. *Bell v. Goddard*, 366 F.2d 177 (7th Cir. 1966). In 1971, the FDA notified all drug manufacturers of DES or closely related congeners such as dienestrol and hexestrol that they were required to change their products' labeling to list pregnancy as a contraindication to the use of these products. Other estrogen products also were required to be accompanied by a warning that estrogens are not indicated in pregnancy. Comment, *DES and a Proposed Theory of Enterprise Liability*, 46 FORDHAM L. REV. 963, 966 n.11 (1978) [hereinafter cited as *Enterprise Liability*]. Despite lack of FDA approval for use of DES as a post coital contraceptive (to cause abortion), it has been prescribed for this use since a study claiming 100% effectiveness in 1,000 females appeared in the American Medical Association Journal. Kuchera, *The Morning After Pill*, 224 J.A.M.A. 1038 (1973). This claim has been sardonically referred to as "an amazing statistic, considering the fact that no contraceptive, not even sterilization, has ever been 100 percent effective in a population of 1,000 people." SEAMAN & SEAMAN, *supra*, at 40. The use of DES as a morning after pill has been criticized, Editorial, "*Diethylstilbestrol as a Morning-After Contraceptive*", 15 MEDICAL LETTER 19 (1973), and Eli Lilly's DES labeling, in bold face type, warns against its use for this purpose. PHYSICIANS' DESK REFERENCE 1056 (35 ed. 1981). The FDA, however, has indicated that it "will approve" this use of DES "for emergency situations such as rape and incest if a manufacturer provides patient labeling and special packaging." *DES and Breast Cancer*, *supra*, at 10. Thus, it appears that the FDA will approve of this use despite the lack of any well-controlled studies indicating efficacy, and the lack of a pending new drug application. See, e.g., SEAMAN & SEAMAN, *supra*, at 40-45.

3. See, e.g., *Mink v. University of Chicago*, 460 F. Supp. 713 (N.D. Ill. 1978); *Sindell v. Abbott Laboratories*, 26 Cal. 3d 588, 607 P.2d 924, 163 Cal. Rptr. 132 (1980); *Morrissey v. Eli Lilly & Co.*, 76 Ill. App. 3d 753, 394 N.E.2d 1369 (1979); *Abel v. Eli Lilly & Co.*, 94 Mich. App. 59, 289 N.W.2d 20 (1979); *Lyons v. Premo Pharmaceutical Labs*, 170 N.J. Super. 183, 406 A.2d 185 (1979).

4. Herbst, Scully & Robboy, *Effects of Maternal DES Ingestion on the Female Genital Tract*, HOSPITAL PRACTICE 51 (Oct. 1975) [hereinafter cited as *Effects of Maternal DES*]. See also Schmitt, *The Stilbestrol Story*, 2 THE BULLETIN OF THE SOCIETY OF PHARMACOLOGICAL AND ENVIRONMENTAL PATHOLOGIST (No. 2, 1974) [hereinafter cited as Schmitt].

5. Sonek, Bibbo, & Wied, *Colposcopic Findings in Offspring of DES-Treated Mothers as Related to Onset of Therapy*, 16 J. OF REPRODUCTIVE MED. 65 (Feb. 1976).

tion, four in one thousand women will develop clear-cell adenocarcinoma.<sup>6</sup> Almost fifty deaths have resulted from prenatal exposure to DES.<sup>7</sup>

DES daughters, and DES sons as well, suffer from a variety of maladies which presently are considered benign, but are suspected to be precancerous.<sup>8</sup> For example, it is estimated that adenosis, the abnormal presence of benign glandular tissue in the vagina, occurs in eighty to ninety percent of the female population exposed *in utero* to DES,<sup>9</sup> yet adenosis is found histologically in over ninety-seven percent of DES daughters who have adenocarcinoma of the vagina.<sup>10</sup> DES daughters also may develop various abnormalities of the cervix.<sup>11</sup> Recent research reveals that a number of DES sons also suffer from abnormalities which may result in sterility,<sup>12</sup> and a preliminary study sug-

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6. This is one per 250 DES-exposed women, SEAMAN & SEAMAN, *supra* note 2, at 29. But see Herbst, Robboy, Scully, Poskanzer, *Clear-Cell Adenocarcinoma of the Vagina and Cervix in Girls: Analysis of 170 Registry Cases*, 119 AM. J. OF OBSTETRICS AND GYNECOLOGY 713, 722 (1973) [hereinafter cited as *Registry*] (risk of cancer may be less than 4 in 1,000). In the 1973 nationwide *Registry* study of clear-cell adenocarcinoma cases, stilbestrol, dienestrol, and hexestrol, all synthetic estrogens, were implicated in 95 of the 146 cases (65%) for which maternal histories were available. In another 19 cases, medication for bleeding or prior miscarriage was administered in early pregnancy but the specific drug could not be identified. *Id.* Thus, a history of some maternal medication for high-risk pregnancy was obtained in 114 of the 146 cases (78%). In all cases, treatment began before the eighteenth week of pregnancy, *id.* at 716, with dosages ranging between 25 mg. daily for 12 days to 100 mg. daily for 6½ months. By 1975, 250 cases had been reported, and of these, two-thirds had a confirmed exposure to DES; of the vaginal adenocarcinomas, the confirmed exposure was over 80%. Ulfelder, *The Stilbestrol Adenosis-Carcinoma Syndrome*, 38 CANCER 426, 428 (1976). Of the 170 cases in the 1973 *Registry* study, 154 were treated with surgery or radiation; of these, 37 (24%) had recurrences and 24 (16%) of these died. Most significant, one-third of the deaths and recurrences occurred within the two year follow-up period. *Registry, supra* at 720.

7. *Diethylstilbestrol, supra* note 2, at 46. This is a 1976 estimate, therefore the death rate is now probably higher.

8. *Effects of Maternal DES, supra* note 4, at 53.

9. Herbst, Scully, and Robboy, *Problems in the Examination of the DES-Exposed Female*, 46 OBSTETRICS AND GYNECOLOGY 353 (1975) [hereinafter cited as *DES-Exposed Female*].

10. Adam, Decker, Herbst, Noller, Tilley & Townsend, *Vaginal and Cervical Cancers and Other Abnormalities Associated with Exposure in Utero to Diethylstilbestrol and Related Synthetic Hormones*, 37 CANCER RESEARCH 1249, 1250 (1977) [hereinafter cited as *Vaginal and Cervical Cancers*].

11. *Id.* See also *DES-Exposed Female, supra* note 9, at 353.

12. See Bartke, Williams & Daltero, *Effects of Estrogens on Testicular Testosterone in Vitro*, 17 BIOLOGICAL REPRODUCTION 645 (1977); Gill, Schumacher & Bibbs, *Structural and Functional Abnormalities in the Sex Organs of Male Offspring of Mothers Treated with Diethylstilbestrol (DES)*, 16 J. REPRODUCTIVE MED. 147 (1976); see also *Diethylstilbestrol, supra* note 2, at 44.

gests the need for research on "whether *in utero* DES exposure may be associated with a risk for testicular cancer."<sup>13</sup>

DES mothers, also, are subject to an increased risk of endometrial cancer.<sup>14</sup> In addition, a recent follow-up study of DES mothers shows that they have an increased risk of breast cancer.<sup>15</sup> Researchers' views differ as to the significance of this increase,<sup>16</sup> however, animal studies demonstrate that estrogen increases the frequency of carcinomas of the breast, cervix, vagina, kidney, and liver.<sup>17</sup>

DES daughters have instituted a number of legal actions against drug manufacturers.<sup>18</sup> DES mothers who were unknowing participants in a 1953 study to determine the effectiveness of DES are litigating a class action suit against the University of Chicago Lying-in Hospital and Eli Lilly Company.<sup>19</sup> At least one

13. FDA, 8 FDA DRUG BULLETIN 31 (Oct.-Nov. 1978).

14. Women who have taken exogenous estrogens have been shown to have a risk of developing endometrial cancer four to fourteen times greater than women who have not taken exogenous estrogens. *Endometrial Pathology and Estrogens*, 53 OBSTETRICS AND GYNECOLOGY 403 (1979). See also FDA, *Estrogens and Endometrial Cancer* DRUG BULLETIN 18 (Feb.-Mar. 1976). The risk is a "highly significant" one because cancer of the endometrium has, in the past, been considered to occur infrequently. *Id.* at 19.

15. Bibbo, Haenszel, Wied, Hubby, Herbst, *A Twenty-Five-Year Follow-up Study of Women Exposed to Diethylstilbestrol During Pregnancy*, 298 NEW ENGLAND J. MED. 763 (1978) [hereinafter cited as Bibbo].

16. Compare Bibbo, *supra* note 15, at 764-65 (excess number of cases of breast cancer among exposed mothers in the Bibbo study "suggestive" but not statistically significant) and Letter from Joseph A. Califano to Sidney M. Wolfe, M.D. (Jan. 1978) ("the data suggest an excess risk of breast cancer that is of borderline statistical significance. . . . There also appears to be an excess cancer of the cervix and ovary . . . [but] the number of cases is small") and PHYSICIANS' DESK REFERENCE 1056 (35th ed. 1981) ("[t]here is no satisfactory evidence that . . . estrogen . . . increases the risk of cancer of the breast") with SEAMAN & SEAMAN, *supra* note 2, at 93-94, quoting MEDICAL LETTER (May 21, 1976) ("[n]o other drug effect so readily reproducible in such a wide variety of test animals has been generally regarded as not potentially applicable to man") and *DES and Breast Cancer*, *supra* note 2, at 10 ("[the Bibbo data] do not at this time firmly establish a cause and effect relationship between DES and increased risk of breast cancer . . . . But . . . there is reason for concern . . . since other estrogens have been associated with endometrial and breast cancer"); and Letter from Sydney A. Wolfe, M.D. to Joseph A. Califano (Dec. 12, 1977) ("[the Bibbo study shows] a substantial increase in breast cancer . . . [and] makes it imperative that you expedite federal action outlawing the use of estrogens as morning-after pills or additives to food.").

17. PHYSICIANS' DESK REFERENCE 1056 (35th ed. 1981).

18. See, e.g., *Sindell v. Abbott Laboratories*, 26 Cal. 3d 588, 163 Cal. Rptr. 132 (1980); *Morris v. Eli Lilly & Co.*, 76 Ill. App. 3d 753, 394 N.E.2d 1369 (1979); *Abel v. Eli Lilly & Co.*, 94 Mich. App. 59, 289 N.W.2d 20 (1979); *Lyons v. Premo Pharmaceutical Labs*, 170 N.J. Super. 183, 406 A.2d 185 (1979); *Bichler v. Eli Lilly & Co.*, 436 N.Y.S.2d 625 (1981).

19. *Mink v. University of Chicago*, 460 F. Supp. 713 (N.D. Ill. 1978).

suit has been filed by a DES son who is suffering from testicular cancer.<sup>20</sup>

DES litigation has fostered the articulation of new theory,<sup>21</sup> as well as the creative application of established theory,<sup>22</sup> in the

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20. Telephone interview with Sybil Shainwald, the plaintiff's attorney (July 7, 1981). Plaintiff wishes to remain anonymous.

21. See, e.g., *Sindell v. Abbott Laboratories*, 26 Cal. 3d 588, 607 P.2d 924, 163 Cal. Rptr. 132 (1980). In *Sindell*, the plaintiffs asserted that defendants acted in concert to produce the drug which their mothers ingested. Since plaintiffs were exposed *in utero*, specific product identification was impossible. Noting that all joined defendants produced a drug from an identical formula and that plaintiff was without fault in her inability to name the manufacturer of the DES which caused her injury, a majority of the court felt that "a modification of the rule of *Summers* is warranted." *Id.* at 611, 607 P.2d at 936, 163 Cal. Rptr. at 144. In *Summers*, plaintiff could not determine which of the defendants had fired the gunshot which actually caused the injury; nevertheless, both defendants were held jointly and severally liable for damages. The court shifted the burden of proof to defendants, each to absolve himself if possible. The *Sindell* majority modified the *Summers* rule of causation to allow a shifting of the burden of proof to the defendant drug manufacturers to demonstrate that they could not have made the substance which injured the plaintiffs. The *Sindell* majority held that the plaintiffs must join in the action a "substantial percentage" of the manufacturers of the DES which their mothers might have taken. *Id.* at 612, 607 P.2d at 937, 163 Cal. Rptr. at 145. The court believed that in the context of the case it was reasonable . . . "to measure the likelihood that any of the defendants supplied the product which allegedly injured the plaintiff by the percentage which the DES sold by each of them for the purpose of preventing miscarriages bears to the entire production of the drug sold by all for that purpose." Applying this formula to the facts in *Sindell*, the court reasoned that if plaintiff's allegations were established in fact at trial, that Eli Lilly & Co. and five or six other companies produced 90% of the DES marketed, then there was a corresponding likelihood that this comparative handful of producers had manufactured the DES which caused plaintiffs' injuries. Conversely, there was only a 10% likelihood that the offending producer would escape liability. Each defendant would be liable for the proportion of the judgment represented by its share of the market unless it could demonstrate that it could not have made the DES which caused plaintiffs' injuries. The court recognized that "it is probably impossible, with the passage of time, to determine market share with mathematical exactitude." Nevertheless, the difficulty of apportioning damages among the defendant manufacturers did not "militate seriously" against the adoption of the rule. *Id.* at 613, 607 P.2d at 937, 163 Cal. Rptr. at 145.

The most persuasive reason for the market share rule was the *Summers* rationale: as between innocent plaintiffs and negligent defendants, the latter should bear the cost of injury. In justifying its ruling on policy grounds the court asserted:

In our contemporary complex industrialized society, advances in science and technology create fungible goods which may harm consumers and which cannot be traced to any specific producer. The response of the courts can be either to adhere rigidly to prior doctrine, denying recovery to those injured by such products, or to fashion remedies to meet those changing needs.

*Id.* at 610, 607 P.2d at 936, 163 Cal. Rptr. at 144. The majority also noted that defendants were in a better position to bear the cost of injury and to guard against product defects.

22. In *Abel v. Eli Lilly & Co.*, 94 Mich. App. 59, 289 N.W.2d 20 (1979), the court held that if plaintiffs could prove by a preponderance of the evidence

area of tort law. The majority of the decisions favor DES de-

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that they suffered a certain amount of damages at the hands of defendants, all of whom were tortfeasors, then defendants would be "left to apportion the damages among themselves." *Id.* at 76, 289 N.W.2d at 26. In essence, once plaintiffs established that defendants are alternatively liable for their damages, the burden shifts to each defendant to absolve itself from liability as to any plaintiff or all plaintiffs, or to implead any other defendant. To establish alternative liability under *Abel*, each plaintiff must establish that each named defendant breached its duty of care in producing the product, that her harm was the result of her mother's ingestion of DES, and that one or more of the named defendants manufactured the DES so ingested.

Noting that the concert of action claim is a "true joint tort," the court set forth the rule that once the fact of the tortfeasor's liability is established, the tortfeasor is jointly and severally liable for the entire amount of damages. The tortfeasor may show that only the other tortfeasor acted wrongfully, but whether or not the other tortfeasor caused more or all of the damage is irrelevant to liability. That the tortfeasor personally caused no harm also is immaterial to the imposition of liability, since all tortfeasors acted jointly to bring about a result. *Id.* at 73, 289 N.W.2d at 25.

The court also discussed the alternative liability theory which applies where two or more tortfeasors have acted wrongfully but independently, and only one of them has injured the plaintiff, but it is impossible to determine which one is responsible. Here, defendant may prove the other defendants are responsible, despite defendant's own wrongful actions. Defendant has the burden of disproving causation. *Id.*

The majority characterized the problem as one of "apportioning damages," which would be defendants burden if plaintiffs could establish that all defendants breached their duty of care. In reaching its decision, the majority noted that products liability, "the remedy afforded consumers against sellers and manufacturers of defective goods," is a judicial development "which the courts should be free to develop further." *Id.* at 69, 289 N.W.2d at 23. The court also reasoned that if injustice is inevitable, the burden should fall on the wrongdoer rather than the innocent plaintiff. *Id.* at 76, 289 N.W.2d at 26.

*Lyons v. Premo Pharmaceutical Labs, Inc.*, 170 N.J. Super. 183, 190, 406 A.2d 185 (1979), however, rejected plaintiffs' claims based on alternative liability, enterprise liability, and concert of action. The first two theories could not apply because plaintiffs identified the manufacturer of the product DES which caused their daughter's death. Concert of action was not available because the court apparently did not view the conduct of the drug manufacturers as antisocial and the purpose of this theory, in the courts' view, is to deter antisocial conduct. Plaintiffs "overlook[ed] the fact that products containing DES are still in use today with [the] full approval of the FDA and Surgeon General." *Id.* at 194, 406 A.2d at 190.

Again, the court relied on this fact in holding that a broker, who arranged to have DES sent from one drug company to another company which added substances to the DES prior to its sale, could not be held strictly liable in tort. The court asserted:

What must be kept in mind here is that the drug whose sale Greeff arranged was then, and is now, a drug approved for use by the FDA. It is not DES which is defective as claimed by plaintiffs; it is only DES when used by pregnant women that has been shown to be carcinogenic. *It has never been demonstrated that the user of the drug herself, or himself, is harmed.* Use of this drug represents the tragedy of the harm being visited on the unborn child, *the daughter of the user.*"

*Id.* at 196, 406 A.2d at 191-92 (emphasis added). The statement that DES is not harmful to the user is factually incorrect. See notes 12-17 *supra*.

fendants.<sup>23</sup> The recent decision of the Seventh Circuit in *Needham v. White Laboratories, Inc.*,<sup>24</sup> reversing a jury's determination of drug manufacturer liability, deals a drastic blow to drug injured plaintiffs seeking to hold drug manufacturers strictly liable in tort. The reversal is significant because *Needham* is the first appellate reversal of a DES plaintiff's jury verdict and its impact on drug litigation is far reaching. This article will analyze the *Needham* decision within the context of strict liability principles appropriate to the drug industry.

*Needham v. White Laboratories, Inc.*<sup>25</sup>

Plaintiff Needham's mother ingested dienestrol, a synthetic estrogen similar to DES, while she was pregnant with the plaintiff.<sup>26</sup> At the age of twenty, plaintiff discovered she had the rare clear-cell adenocarcinoma of the vagina, which made surgical removal of all her reproductive organs necessary.<sup>27</sup> Plaintiff sued White Laboratories, the manufacturer of dienestrol, on theories

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23. See, e.g., *Needham v. White Laboratories, Inc.*, 639 F.2d 394 (7th Cir. 1981) (evidence of drug efficacy irrelevant and prejudicial); *Mink v. University of Chicago*, 460 F. Supp. 713 (N.D. Ill. 1978) (allegations of mental distress and increased risk of cancer to self and children did not state specific injury; but court did allow a battery action to proceed against the university hospital for 1953 experiment upon unknowing DES mothers); *Morrissy v. Eli Lilly & Co.*, 76 Ill. App. 3d 753, 394 N.E.2d 1369 (1979) (affirming dismissal of class action because common questions of fact did not predominate, court refused to recognize adenosis as an injury); *Lemire v. Garrard Drugs*, 95 Mich. App. 520, 291 N.W.2d 103 (1980) (no cause of action against druggist because successor pharmacist had no connection with the doctor or knowledge of the DES sale prior to defendant's purchase of the drug store, and had no connection with the former owner except to purchase the store); *Lyons v. Premo Pharmaceutical*, 170 N.J. Super. 183, 406 A.2d 185 (1979) (broker who arranged transfer and sale of DES from one drug company to second drug company, and second drug company, which added some substance to DES before distributing it, could not be held liable under negligence and strict liability theories as a matter of law); *Bichler v. Welling*, 397 N.Y.2d 2, 58 A.2d 331 (1977) (retail druggist cannot be held strictly liable for failure to warn; druggist was not registered).

DES plaintiffs, on the other hand, have only two pretrial decisions in their favor: *Sindell v. Abbott Laboratories*, 26 Cal. 3d 588, 607 P.2d 924, 163 Cal. Rptr. 132 (1980); *Abel v. Eli Lilly & Co.*, 94 Mich. App. 59, 289 N.W.2d 20 (1979); and one affirmance of a jury verdict, *Bichler v. Eli Lilly & Co.*, 436 N.Y.S.2d 625 (1981).

24. 639 F.2d 394 (7th Cir. 1981).

25. Federal jurisdiction was based on diversity of citizenship between Anne Needham and White Laboratories. Thus, the substantive law of Illinois governed.

26. Brief of Plaintiff-Appellee at 15-16, *Needham v. White Laboratories, Inc.*, 639 F.2d 394 (7th Cir. 1981) [hereinafter cited as *Needham*, Plaintiff's Brief].

27. Plaintiff underwent three surgical procedures: 1) a radical hysterectomy (removal of the uterus, cervix, and surrounding tissue), bilateral salpingectomy (removal of the fallopian tubes); 2) a partial vaginectomy (removal of 80% of the vagina); and 3) vaginal reconstruction, with skin



of negligence, strict liability in tort, and fraud and deceit.<sup>28</sup> Plaintiff's strict liability claim was based on two theories: failure to properly warn of the risk of cancer from exposure to dienestrol; and production of a drug which was defective in that it was useless and unreasonably dangerous in the treatment of threatened or habitual abortion.<sup>29</sup> Plaintiff's two theories of negligence were based on defendant's failure to test dienestrol in

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grafts and a plastic mold. Plaintiff continues to experience urinary incontinence and pain of an unknown origin. *Id.*

28. The jury was instructed on the negligence and strict liability actions. *Needham*, Plaintiff's Brief, *supra* note 26, at 2. In a memorandum order, the district court questioned whether plaintiff had standing to assert an alleged fraud perpetrated upon her mother, and whether there was a "connection" between the alleged fraud and plaintiff's injury. *Needham v. White Laboratories, Inc.*, No. 76 C 1101 (N.D. Ill., Aug. 13, 1979). The problem, however, is not whether plaintiff has standing to assert a fraud perpetrated upon her mother, but whether plaintiff's injuries were caused by the drug manufacturer's fraudulent representations. In any prescription drug action based on misrepresentation, the fraudulent representations would be made to the prescribing physician, not the patient, since such drugs can only be purchased with a prescription. The representations would induce the physician to prescribe a drug, which would cause the plaintiff to ingest the drug and suffer injury. *See Crocker v. Winthrop Laboratories*, 514 S.W.2d 429 (Tex. App. 1974) (plaintiff stated a cause of action for misrepresentation even though representations were made to doctor; court held that if a drug company makes positive and specific representations about a drug and those representations are relied upon by plaintiff's physician, the drug company is liable if the representation proves to be false and harm results); RESTATEMENT (SECOND) OF TORTS § 402B, Comment j (1965) (Sets forth cause of action for misrepresentation; injury must be caused by justifiable reliance on the misrepresentation although the reliance need not be that of the consumer; liability exists even though the representation is not fraudulently made and the consumer has not bought the chattel from the seller).

In *Needham*, the alleged fraudulent representations were made to the doctor of plaintiff's mother and the doctor, in turn, was induced to prescribe the drug for plaintiff's mother based on these representations. There is no logical distinction to be drawn between a plaintiff who ingests a drug and is injured because the prescribing physician relied on the drug company's false misrepresentations, and a plaintiff who is injured *in utero* by a drug prescribed for her mother by a doctor who relied on the same representations. Here, plaintiff was conceived when the tortious conduct occurred and the drug directly injured her. White's alleged representation that dienestrol was safe and effective caused the physician of plaintiff's mother to prescribe dienestrol, which caused plaintiff's mother to ingest dienestrol, and thereby caused plaintiff's exposure *in utero* to dienestrol and subsequent injury. Thus, the district court incorrectly characterized the problem as one of standing instead of causation. *See Renslow v. Mennonite Hospital*, 67 Ill. 2d 348, 367 N.E.2d 1250 (1977) (child born alive had cause of action for prenatal injuries resulting from another's preconception negligent conduct; that the negligence occurred prior to conception did not bar plaintiff's claim.) *But see Jorgensen v. Meade Johnson Laboratories, Inc.*, 483 F.2d 237, 239 (10th Cir. 1973) (no cause of action exists for a child's injuries which allegedly stem from a preconception injury to the mother because the tortious conduct occurred before the child's conception).

29. *Needham*, Plaintiff's Brief, *supra* note 26, at 2, 45-47.

accordance with 1952 medical research standards and to warn of its dangers.<sup>30</sup>

Before instructions were given to the *Needham* jury, the Illinois Supreme Court held in *Woodill v. Parke Davis Co.*,<sup>31</sup> that a manufacturer is strictly liable for failure to warn of a risk of injury if the manufacturer knew or should have known of the product's danger. The *Woodill* majority asserted that it was not imposing a negligence standard. Although a knowledge requirement injects an element of fault which, in theory, is absent in strict liability, in the court's view, failure to warn based on strict liability remains separate and distinct from failure to warn based on negligence.<sup>32</sup> The court did not clearly define this difference; however, given its extensive reliance on comment k to section 402A of the Restatement (Second) of Torts,<sup>33</sup> it seems reasonable to presume that the comment may provide an explanation.<sup>34</sup>

#### *Comment k and Evidence of Efficacy*

The comment k exception to strict liability is created for unavoidably unsafe products, and it applies particularly to drugs, "[w]hich in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use."<sup>35</sup> The sale of such products may be justified, provided a warning is given when necessary, because the benefit of using the product appears to outweigh the attendant risk.<sup>36</sup>

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30. *Id.* at 2. In several cases, courts have based liability on inadequate testing together with failure to warn. See *Roginsky v. Richardson-Merrell, Inc.*, 378 F.2d 832 (2d Cir. 1967); *Schenebeck v. Sterling Drug, Inc.*, 291 F. Supp. 368 (E.D. Ark. 1968); *Tinnerholm v. Parke-Davis & Co.*, 285 F. Supp. 432 (S.D.N.Y. 1968); *Stromsadt v. Parke-Davis & Co.*, 257 F. Supp. 991 (D.N.D. 1966), *aff'd*, 411 F.2d 1390 (8th Cir. 1969).

31. 79 Ill. 2d 26, 402 N.E.2d 194 (1980).

32. 79 Ill. 2d 26, 402 N.E.2d at 194.

33. RESTATEMENT (SECOND) OF TORTS § 402A, Comment k (1965).

34. The court stated that it is the inadequacy of the warning and the focus on the product which differentiates negligent and strict liability failure to warn actions. The proper inquiry in the strict liability action is whether it would have been reasonable for the drug manufacturer to have given a warning, and whether that warning would have been adequate. The court also cited Dean Keeton's formulation of the strict liability standard which describes a product as unreasonably dangerous if an ordinary person, knowing the risks and dangers involved, would not have marketed the product without informing consumers of the risks and dangers involved. 79 Ill. 2d at 34, 402 N.E.2d at 198. Keeton's interpretation compares favorably to Comment k which also focuses upon whether the manufacturer was justified in marketing the product as it did. See notes 150-70 and accompanying text *infra*.

35. RESTATEMENT (SECOND) OF TORTS § 402A, Comment k (1965).

36. *Id.*

Relying on both *Woodill* and the comment k strict liability exception for unavoidably unsafe products, the district court in *Needham* allowed plaintiff to present evidence of dienestrol's ineffectiveness to counter defendant's reliance on the comment k exception to strict liability. The district court reasoned that if comment k did not apply because the sale of dienestrol was not justified—*i.e.*, it had no apparent usefulness to outweigh any risk of harm—then the defendant could be liable for marketing the drug even if the plaintiff could not prove the defendant knew it was dangerous and yet failed to give a warning.<sup>37</sup> The relevant issue would be whether defendant knew or should have known that the drug was ineffective or not apparently useful, not whether defendant knew it was dangerous.<sup>38</sup> The district court also noted that evidence of dienestrol's ineffectiveness was relevant to plaintiff's alternate theory of strict liability that dienestrol was defective and unreasonably dangerous because it was ineffective and caused cancer.<sup>39</sup> The essence of this alternate theory is that dienestrol was not fit for its intended use.

#### *The Seventh Circuit's View*

The jury returned a general verdict against the defendant and assessed damages of \$800,000.<sup>40</sup> On appeal, the Seventh Circuit reversed and remanded for a new trial, holding that evidence of dienestrol's effectiveness or ineffectiveness was irrelevant and prejudicial.<sup>41</sup> The court's decision was premised

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37. *Needham v. White Laboratories, Inc.*, No. 80-1579, memorandum opinion at 1-3 (N.D. Ill. Aug. 13, 1979). The court assumed that Comment k applied because the product was a prescription drug and therefore an unavoidably unsafe product. Such is the practice of Illinois courts. See notes 239-40 and accompanying text *infra*.

38. *Id.*

39. *Needham v. White Laboratories, Inc.*, No. 80-1579, memorandum opinion at B-8 (N.D. Ill., Mar. 19, 1980).

40. *Needham v. White Laboratories, Inc.*, 639 F.2d 394 (7th Cir. 1981). The trial was trifurcated; the statute of limitations issue was decided first, liability second, and finally damages.

41. The court's decision distinguished between comments j and k of the Restatement (Second) of Torts § 402A (1965). The text of comment k is set forth in note 151 *infra*. The text of comment j is quoted in note 162 *infra*. The court also held that plaintiff failed to lay a proper foundation for the introduction of medical articles to show that White Laboratories should have had notice of the risk of cancer in dienestrol and therefore should have warned of the danger. *Id.* at 15. It is unlikely that reversal hinged on this singular ground since plaintiff's procedure for introducing the articles of evidence was virtually matched by the defendant. See *Needham*, Plaintiff's Brief, *supra* note 27, at 53. In fact, the error is nominal in the context of a jurisdictional defect which, very arguably, should have precluded appeal of the case.

Defendant's appeal was not timely filed. *Needham v. White Laboratories, Inc.*, 639 F.2d 394, 398 (7th Cir. 1981). The defect was, however, excused

on the notion that Illinois recognizes two types of strict liability drug actions involving warnings which are set forth in comments j and k to section 402A: complete failure to give a warning; and failure to give an adequate warning. In the Seventh Circuit's view, comment k contemplates only the latter instance in which some warning is given but is inadequate. Here, a manufacturer is entitled to comment k protection only if the product's benefits outweigh its risks. If no warning at all is given, comment j governs the action. The court reasoned that efficacy evidence is relevant only in a comment k case because, in that instance, the drug's benefits must be balanced against its risks.<sup>42</sup> In a comment j case, where no warning is given, efficacy evidence is irrelevant, according to the court, because the manufacturer's liability turns on whether it had knowledge of the risk about which it failed to warn.<sup>43</sup> Concluding that the defendant in *Needham* failed to give a warning of the risk of cancer from ingesting its product, the circuit court held that comment j governed, and evidence of dienestrol's ineffectiveness was therefore irrelevant and prejudicial to the defendant. The court also asserted that Illinois law did not support plaintiff's alternate theory of strict liability,<sup>44</sup> and accordingly efficacy evidence was not relevant to this theory.

The court's decision rests on an erroneous interpretation of *Woodill*. The court characterized *Woodill* as a comment j case and announced flatly that Illinois had not yet decided a com-

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by the Circuit on the theory that defendant relied upon the trial court's assurance that the statute of limitations had been tolled by an earlier motion to reconsider denial of a timely filed post-trial motion. *Id.* at 397.

It is submitted, that in its acceptance of jurisdiction, the Seventh Circuit mistakenly relied upon *Thompson v. Immigration and Naturalization Service*, 375 U.S. 384 (1964) (per curiam). In *Thompson*, plaintiff filed a late post-trial motion to which its adversary failed to object and which the court said was timely. The Supreme Court ruled that where a litigant relies upon the lower court's assurance that a motion is timely, and where the motion is one which, if properly made, would have postponed the appeal time, the reviewing court may grant jurisdiction.

*Needham* does not, however, fit within the exception created by the *Thompson* case. A motion for reconsideration of a post-trial motion never tolls the time for appeal and hence, is not a motion which, if properly made, would postpone the time for appeal. See, e.g., *Wansor v. George Hantsho Co.*, 570 F.2d 1202 (5th Cir. 1978), *cert. denied*, 439 U.S. 953 (1979). Cf. *Martinez v. Trainor*, 556 F.2d 818, 820 (7th Cir. 1977); *Mottelier v. J.A. Constr. Co.*, 447 F.2d 954, 955 (7th Cir. 1971); *Files v. City of Rockford*, 440 F.2d 811 (7th Cir. 1970); *Fine v. Paramount Pictures*, 181 F.2d 300 (7th Cir. 1950). These cases reflect the Seventh Circuit's, usually rigid, adherence to the *Thompson* requirement of an act which, if properly done, would suspend the statute of limitations.

42. *Needham v. White Laboratories, Inc.*, 639 F.2d 394, 402 (7th Cir. 1981).

43. *Id.* at 400.

44. *Id.* at 14.

ment k case. In fact, comments j and k may be read together for the purpose of determining whether any given case should be governed by a strict liability standard. Thus, in actions against the manufacturers of concededly beneficial drugs, liability must be premised on defendant's knowledge of the risk of injury. These cases, unlike *Needham*, have not involved a challenge to the claimed benefits of the drug. In the absence of such a challenge, an initial presumption that benefits outweigh risks is made.<sup>45</sup> Once this presumption is made, the manufacturer's liability for failure to warn, under comment k, turns on whether the drug is properly prepared and accompanied by warnings of known dangers. If the drug is accompanied by a warning of known risks of injury and is properly prepared, the manufacturer is not liable for harm caused by its dangerous product. If, on the other hand, the manufacturer knows or should know of the drug's risks, and fails either to warn or to properly prepare the drug, the drug is considered to be unreasonably dangerous and the manufacturer is liable for harm caused.

Where the assumption that a drug is beneficial is challenged, as in *Needham*, the court must initially determine whether or not the drug's usefulness is outweighed by its risks. Efficacy evidence is crucial to this determination. If the drug's risks outweigh its usefulness, the manufacturer will be liable for its unreasonably dangerous product irrespective of its ignorance of the risk of injury.<sup>46</sup>

The Seventh Circuit failed to note that Illinois courts had never been confronted with a strict liability, failure to warn action involving a challenge to the drug's usefulness. Whether comment k protection from strict liability should be extended to such a case had never been called into question. Comment k imposes a knowledge of risk requirement for failure to warn cases which involve beneficial drugs. Thus, comment k expresses a policy of not imposing strict—where knowledge is irrelevant—liability where a manufacturer has undertaken to supply the public with a useful drug. Where, however, the drug manufacturer has not marketed a useful drug, the rationale for protecting the manufacturer from strict liability is absent. Public policy negates the argument that comment k protection may be invoked before it is established that defendant marketed a relatively beneficial drug. But for the principal case, no Illinois precedent would support such an expansive interpretation of comment k.

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45. See notes 239-40 and accompanying text *infra*.

46. See notes 250-52 and accompanying text *infra*.

## THE NATURE OF THE DRUG INDUSTRY

*High Profits; Few Losses*

An understanding of the nature of the drug industry is essential to understanding the legal, factual, and policy issues that the *Needham* cases raises. The drug industry has been described as “one of both high profits and high returns.”<sup>47</sup> During congressional hearings in 1972, the drug industry was characterized as practically unique in that “[l]osses or even low profits, are virtually unheard of among larger companies.”<sup>48</sup> Although drug companies attempt to justify high profits by pointing to the extreme risks inherent in the development of new drugs, critics note that if extreme risks justify high profits, one would expect to see “occasional losses” by some firms instead of “consistently high industrywide profits.”<sup>49</sup>

The fear that imposing strict liability on the sellers of drugs would result in depriving consumers of essential drugs,<sup>50</sup> has little basis in reality. One commentator has argued that this fear should not shape the development of strict liability law in the absence of substantial empirical supporting data showing that the profit margin in the drug industry is so low that the industry could not bear the cost of compensation for the injuries it produces.<sup>51</sup> This argument is especially persuasive when the industry produces, promotes, and obtains large profits from a drug like DES,<sup>52</sup> whose efficacy and concomitant benefits are questionable, and which is also capable of causing serious injury. Such products are particularly appropriate subjects for strict liability.

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47. *Enterprise Liability*, *supra* note 2, at 975.

48. Senate Subcommittee on Monopoly, Select Committee on Small Business, Competitive Problems in the Drug Industry, 92d Cong. 2d Sess. 33 (Comm. Print 1972) [hereinafter cited as SENATE MONOPOLY] (quoting the then chief economist to the Federal Trade Commission).

49. *Id.* at 35. Since 1961, the drug industry has ranked first or second in terms of returns on investors' equity. *Id.* at 34.

50. Note, *The Liability of Pharmaceutical Manufacturers for Unforeseen Adverse Drug Reactions*, 48 FORDHAM L. REV. 735, 756 (1980) [hereinafter cited as *Drug Reactions*].

51. McClellan, *Strict Liability for Drug Induced Injuries: An Excursion through the Maze of Products Liability, Negligence and Absolute Liability*, 25 WAYNE L. REV. 1, 33 (1978) [hereinafter cited as McClellan].

52. For example, from 1950-52, 100% of the 25 mg. units of DES manufactured by Lilly was sold; from 1953-55, 95% was sold; from 1956 to 1958, 78% was sold, and from 1959 to 1961, 48% was sold. Herbst, Cole, Colton, Robbay & Scully, *Age Incidence and Risk of Diethylstilbestrol-Related Clear-cell Adenocarcinoma of the Vagina and Cervix*, 128 AM. J. OF OBSTETRICS AND GYNECOLOGY, 43, 50 (1978).

*"Me Too" Practices*

Another unusual feature of the drug industry is the "me too" practice of developing new drugs.<sup>53</sup> "Me too" drugs are typically made by slightly deviating from the molecular make-up of an already marketed drug.<sup>54</sup> Molecular manipulation is of no significant therapeutic value. The practice does, however, enable a manufacturer to market a theoretically "new" drug without violating a patent or obtaining a licensing agreement from the manufacturer who invented the original product.<sup>55</sup> Thus, drug companies expend considerable research money to develop drugs which vary only slightly from the original product.<sup>56</sup>

The result is a proliferation of company trade names for essentially one product. The Health, Education and Welfare (HEW) task force on prescription drugs determined that important new chemical entities represent "only a fraction, perhaps 10-20%, of all new products introduced each year, while the remainder consist merely of minor modifications of combination products."<sup>57</sup> The task force concluded that many of the drug industry's research and development activities "would appear to provide only minor contributions to medical progress."<sup>58</sup> A more important concern, especially in the case of DES-related products, is that "a single defect in the original drug may be common to all similar products subsequently manufactured."<sup>59</sup>

DES, dienestrol, and related DES products are poignant examples of drug industry "me too" practices. DES was unpatented by its original inventor.<sup>60</sup> In 1941, twelve drug companies submitted a joint clinical file to the Food and Drug Administration (FDA) as part of their New Drug Application (NDA) request for permission to market DES.<sup>61</sup> These companies also agreed on common chemical standards, uniform labeling, and product literature for the drug to be manufactured by each of

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53. *Enterprise Liability*, *supra* note 2, at 976. See also M. DIXON, DRUG PRODUCT LIABILITY § 6.03 (1977).

54. SENATE SUBCOMMITTEE ON MONOPOLY, SELECT COMMITTEE ON SMALL BUSINESS, COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY, 90th Cong. 2d Sess. 3750 (1968) (Task Force on Prescription Drugs, Second Interim Report and Recommendations) [hereinafter cited as Task Force on Prescription Drugs].

55. *Enterprise Liability*, *supra* note 2, at 976.

56. *Id.*

57. Task Force on Prescription Drugs, *supra* note 54.

58. *Id.*

59. *Enterprise Liability*, *supra* note 2, at 976.

60. *Id.*

61. *Id.*

them.<sup>62</sup> The companies did not request permission to market DES to prevent threatened or habitual abortion until 1947.<sup>63</sup>

In 1946, White Laboratories obtained permission to market dienestrol for the same use as DES.<sup>64</sup> DES and dienestrol are virtually identical in action and toxicity; dienestrol, specifically marketed to be competitive with DES, was described by the former medical director of White Laboratories as a “me too” drug.<sup>65</sup>

In 1948, a year after other companies received permission to market DES for use in the treatment of threatened abortion, White Laboratories submitted a supplemental NDA requesting permission to market dienestrol for the same use in pregnancy.<sup>66</sup> Its intent in marketing dienestrol was to compete with DES; dienestrol had no advantages over DES for use in pregnant women. Moreover, when White Laboratories requested permission to market dienestrol, it did no independent testing of dienestrol’s safety in pregnant women or their offspring.<sup>67</sup> The supplemental NDA contained only two summaries of case reports by two different doctors to show that dienestrol would do what White Laboratories claimed it could do—prevent habitual or threatened abortion.<sup>68</sup> These case reports were characterized by two eminent researchers as grossly inadequate demonstrations of these claims.<sup>69</sup>

### *The FDA Then and Now*

White Laboratories argued that FDA approval of dienestrol absolved the company of responsibility for failure to test dienestrol adequately before marketing it.<sup>70</sup> While some authority exists for this proposition,<sup>71</sup> most courts have held that FDA approval does not discharge the obligation of the drug manufacturer to test adequately for and warn of its product’s risks of danger.<sup>72</sup>

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62. *Id.* A dispute exists as to the significance of the common or joint application.

63. *Enterprise Liability, supra* note 2, at 976. *See also* Lyons v. Premo Pharmaceutical Labs, Inc. 170 N.J. Super. 183, 406 A.2d 185 (1979).

64. *See Needham*, Plaintiff’s Brief, *supra* note 26, at 9.

65. *Id.*

66. *Id.*

67. *Id.* at 10-11.

68. *Id.* at 9.

69. *Id.* at 28-29.

70. *Needham*, Defendant’s Brief, *supra* note 2, at 13.

71. *E.g.*, Lewis v. Baker, 243 Ore. 317, 404, 413 P.2d 400 (1966) (FDA approval as a matter of law—reasonably safe drug).

72. Stevens v. Parke, Davis & Co., 9 Cal. 3d 51, 507 P.2d 653, 661, 107 Cal. Rptr. 45, 53 (1973); Lawson v. G. D. Searle & Co., 64 Ill. 2d 543, 356 N.E.2d 779 (1976); Mahr v. G.D. Searle, 72 Ill. App. 3d 540, 390 N.E.2d 1214 (1979); Ortho



The premise underlying the argument that FDA regulations define only minimal standards, may well be an accurate assessment of the FDA's role in the 1950s and today. Prior to 1962, a drug manufacturer's NDA was automatically approved if the FDA did not object to the marketing of the drug.<sup>73</sup> While the FDA must now act positively to approve a drug for marketing, it still only reviews a report of data provided by the drug manufacturer.<sup>74</sup> The FDA does not test the drug independently, and the drug manufacturer, consequently, has complete control over what data is submitted. While the FDA may refuse to approve a drug until a manufacturer performs additional tests, the ultimate responsibility for providing the clinical data upon which the agency will make its final determination rests with the party who has the greatest interest in a favorable response.<sup>75</sup>

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Pharmaceutical Corp. v. Chapman, 388 N.E.2d 541 (1979); Bristol-Myers Co. v. Gonzales, 561 S.W.2d 801, 804 (Tex. Sup. Ct. 1978).

73. See, e.g., Drug Amendments of 1962, § 104(b), amending Food & Drug Act of 1938, § 505(c), 21 U.S.C. § 355(c) (1960). Section 505 changed the data requirements to require submission of data showing efficacy. Drug Amendments of 1962 § 102(b), amending Federal Food Drug Cosmetic Act of 1938, § 505(b), 21 U.S.C. § 355(c) (1964). For a discussion of the 1962 Amendment, see Note, *Drug Efficacy and the 1962 Drug Amendments*, 60 GEO. L.J. 185 (1971) [hereinafter cited as *Drug Efficacy*].

The drug industry and the AMA were hostile to the 1962 efficacy amendments requiring premarketing efficacy testing. The industry position was that the efficacy requirements were unnecessary because safety review under the 1938 Act already included considerations of efficacy. See Mintz, *FDA and Panalka: A Conflict of Commercial Therapeutic Goals?* 165 SCIENCE 875, 876-77 (1969) [hereinafter cited as Mintz]. See also Pharmaceutical Mfr. Ass'n v. Finch, 307 F. Supp. 858 (D. Del., 1970). The AMA's opposition to efficacy requirements is, perhaps, related to the substantial income it receives from drug advertising in its journal. Mintz, *supra* at 875. The AMA also opposes patient product information with birth control prescriptions. See Blair, *Liability of Birth Control Pill Manufacturers*, 23 HASTINGS L. J. 1532 (1972) [hereinafter cited as *Birth Control*]; Merrill, *Compensation for Prescription Drug Injuries*, 59 VA. L. REV. 1, 92 (1973) [hereinafter cited as Merrill]. Historically, organized medicine has fought any proposals that threatened the "physician's prerogative" to prescribe whatever drug he believes is appropriate for the patient. The drug industry also fights for the physician's "right to prescribe." The principal reason for the drug industry's concern is the recognition that success of a particular brand name drug depends on physician cooperation. "So long as physicians can be persuaded to prescribe by brand name and no pharmacist may legally substitute a less expensive drug, large manufacturers need not fear competition based on price." Merrill, *supra* at 92 n.341.

Although the FDA requires premarketing evidence of efficacy prior to approval, this does not ensure that only effective drugs will be marketed. Aside from the problems with false data and researcher bias, see notes 76-84, and accompanying text *infra*, the FDA has indicated it will approve the use of DES as a post-coital contraceptive in emergency situations despite the lack of a pending NDA or studies showing DES to be effective for this use. See *DES and Breast Cancer*, *supra* note 2, at 10; SEAMAN & SEAMAN, *supra* note 2, at 40-45.

74. Merrill, *supra* note 73, at 73; *Birth Control*, *supra* note 73, at 1533.

75. Merrill, *supra* note 73, at 13-18. Another factor may be the lure of a

Data submitted by drug manufacturers has often been criticized by the FDA as scientifically inadequate;<sup>76</sup> some has even been shown to be fraudulently concealed<sup>77</sup> or “rigged.”<sup>78</sup> Clinical investigators hired by drug companies to investigate their drugs have also been criticized as tending to skew data in favor of their employers.<sup>79</sup> Many articles extolling a drug’s virtues or minimizing its harmful effects, which are published in respectable medical journals, have been sponsored by the drug company that manufactured the drug.<sup>80</sup> A “substantial number”

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lucrative career in the private industry. FDA officials have had something of a “reputation” for leaving for well-paying positions in the private drug and hospital industry. SEAMAN & SEAMAN, *supra* note 2, at 14, 82, 84-85.

76. Merrill, *supra* note 73, at 17; *Hearings on Drug Safety before the Subcommittee on Intergovernmental Relations of the House Committee, Intergovernmental Relations of the House Committee on Governmental Operations*, 88th Cong. 2d Sess., Pt. at 568-600 (1964) [hereinafter cited as *Drug Safety Hearings*].

77. SEAMAN & SEAMAN, *supra* note 2, at 74. An investigation of the tests of products of G. D. Searle & Co. revealed that a fibroadenoma of the abdomen (a benign tumor consisting of glandular tissue) had been removed also from a test dog in a study involving Ovulen, a contraceptive; other data had also been withheld. *Id.* at 75. MER 29 is perhaps the most litigated prescription drug; the manufacturer falsified research results in its NDA and was convicted of making false statement to the FDA in its NDA. Rheingold, *The MER/29 Story—An Instance of Successful Mass Disaster Litigation*, 56 CALIF. L. REV. 116 (1968). See also *Toole v. Richardson-Merrill, Inc.*, 251 Cal. App. 2d 689, 60 Cal. Rptr. 398 (1967) (manufacturer did not disclose full extent of its knowledge with respect to significant blood and serious eye changes in test animals treated with the drug).

78. See generally *Editorial*, 265 NEW ENGLAND J. MED. 1116 (1961).

79. The drug company stands to gain from a favorable investigation. Rheingold, *Products Liability—The Ethical Drug Manufacturer’s Liability*, 18 RUTGERS L. REV. 947, 955-56 (1964) [hereinafter cited as *Rheingold*]. In 1966, the FDA notified G. D. Searle that one of its investigations of estrogen for menopause was unacceptable because it had been promoting the drug to remedy conditions, such as prevention of menopause, for which it had never been proven effective. The investigator was being paid by several drug companies while he was publishing promotional articles in popular magazines. SEAMAN & SEAMAN, *supra* note 2, at 288-89.

Dr. Abraham Rakoff, one of White Laboratories’ “clinical investigators” of DES for use in pregnant women and a personal friend of Dr. Neary, the medical director, had observed that endometrial hyperplasia in human beings could be a precancerous lesion. *Needham*, Plaintiff’s Brief, *supra* note 27, at 9, 29-30. Since endometrial hyperplasia was known to be an expected response to estrogen, *id.* at 30, it is not clear why he advocated the use of large doses in pregnant women. *Id.* at 14, 37. Despite four dead births out of 12 births, no pathology tests were done by Rakoff or ordered by White Laboratories, even though there was no understanding of why the deaths resulted. *Id.* at 29. As early as 1949, however, the medical community was aware that, in the pregnant rat, “estrogen is very deleterious to the fetus. In early pregnancy [it] will prevent implantation or produce abortion, and during later stages, it leads to death of the fetus.” Smith & Smith, *The Influence of Diethylstilbestrol on the Progress and Outcome of Pregnancy As Based on a Comparison of Treated with Untreated Primigravidas*, 58 AM. J. OF OBSTETRICS & GYNECOLOGY 994, 1007 (1949).

80. E.G. Drill and D.W. Calhoun, *Oral Contraceptives and*

of these articles have been written within the confines of the pharmaceutical houses concerned."<sup>81</sup> Moreover, medical journals rely on drug advertising as a major source of financing.<sup>82</sup> Some medical journals which, by virtue of their ownership, are captives of certain drug houses, have printed inaccurate articles on the miraculous effects of new drugs.<sup>83</sup> Once a drug has been authenticated by publication, the drug manufacturer cites the article as authority for its advertising claims.<sup>84</sup>

### Promotional Practices

Not only is the FDA dependent upon drug manufacturers for information about their drugs, but the prescribing physician also relies on the drug manufacturer for information about a drug's safety and instructions for use.<sup>85</sup> Medical practitioners simply cannot keep abreast of numerous medical articles, scattered in hundreds of journals, on each new drug which appears on the market.<sup>86</sup> Consequently, doctors rely on product infor-

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*Thromboembolic Disease*, 206 J.A.M.A. 77 (1968). Dr. Victor Drill was the director of biological research for G.D. Searle & Co. The article argues that there is evidence that the birth control pill is not the cause of thromboembolic disease. The article was published simultaneously with an FDA warning to physicians about the increase in thromboembolic disease associated with use of the pill. *Birth Control*, *supra* note 73, at 1528-29.

81. SENATE COMMISSION ON THE JUDICIARY, ADMINISTERED PRICES IN THE DRUG INDUSTRY, 78 S. REP. NO. 448, 87th Cong., 1st Sess. 182 (1961) [hereinafter cited as Senate Commission].

82. Journal of the American Medical Association, (J.A.M.A.) has been criticized as favoring drug companies because its major source of income is from drug advertising in its journal. See Rheingold, *supra* note 79, at 659 n.66; Mintz, *supra* note 73, at 875.

83. Rheingold, *supra* note 79, at 659 n.66.

84. An expert from one of the country's largest drug companies described the cyclical process:

Frequently the physician involved merely makes the observations and his data, which sometimes are sketchy and uncritical, are submitted to a medical writer employed by the company. The writer prepares the article which is returned to the physician who makes the overt effort to submit it for publication. The article is frequently sent to one of the journals which looks to the pharmaceutical company for advertising and rarely is publication refused. . . . The primary concern is to have the article published in any place in order to have reprints available. There is a rather remarkable attitude prevalent that if a paper is published then its contents become authoritative even though before publication the same contents may have been considered nonsense.

Senate Commission, *supra* note 81, at 182. Once authenticated by publication, the drug company cites the research as an advertising technique to promote the drug's safety and effectiveness.

85. *Needham*, Plaintiff's Brief, *supra* note 27, at 13. The Physician's Desk Reference, extensively relied upon by the prescribers of drugs, is subsidized by the drug companies' purchases of advertising space. SENATE MONOPOLY, *supra* note 48, at 56.

86. The problem is compounded by the considerable period between the time when a highly advertised new drug is put on the market and the

mation supplied by the drug companies through advertising in drug brochures and medical journals, and detail men who personally visit a doctor to promote a specific drug.<sup>87</sup>

### *Advertising*

The proliferation of “me too” drugs, each with its own brand name, makes advertising the important variable in the fight for increased sales.<sup>88</sup> Drug companies spend enormous amounts of money to influence a doctor’s choice of a brand name drug.<sup>89</sup> A brand name often is easier to remember than the more complex generic name.<sup>90</sup> Drug manufacturers inundate doctors daily with a “torrent of new drug advertising” which is “confusing” and “misleading.”<sup>91</sup> Frequently, warnings appearing in a brochure about drug side effects are tucked neatly away behind a “stream of literature which extols the claimed virtues of the drug so glowingly” that it takes attention away from the hazards of the drug.<sup>92</sup> The physician simply is “bombarded with seductive advertising which fails to tell the truth;” which often misleads him or her to prescribe a new drug without adequate information about possible side effects and without any “solid clinical evidence that the drug is effective or even as safe as the advertisers claim.”<sup>93</sup>

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time when knowledge becomes widely disseminated among the medical profession that its performance falls seriously short of its claims. *Upjohn Co. v. Finch*, 422 F.2d 944, 952-53 (6th Cir. 1970), quoting S. REP. NO. 1744, 87th Cong. 2d Sess. 37, reprinted in [1962] U.S. CODE CONG. & AD. NEWS 2902.

87. In 1962, drug manufacturers spent \$5,000 a year per physician to send out detail men with product samples and other promotional items. *Id.* quoting 108 CONG. REC. 16,320 (Aug. 23, 1962).

88. The prescribing physician is . . . under siege from magazines, from direct mail . . . unsolicited and frequently unwanted samples, from symposia sponsored by the drug company, . . . and from the manufacturer’s detail men . . . . *It is a fact of life in this industry that sheer volume of promotion and advertising is what sells a drug.* *Drug Safety Hearings*, *supra* note 76, at 1995-91 (emphasis added).

89. See note 87 *supra*. In the early 1970s, the drug industry reported spending one billion dollars per year on advertising. M. DIXON, *DRUG PRODUCTS LIABILITY* § 6.10[2] (1979).

90. Drug manufacturers have been accused of choosing generic names which are difficult to pronounce and spell so that physicians would rely upon and remember only the manufacturer’s brand name when they prescribed. *SENATE MONOPOLY*, *supra* note 48, at 44.

91. *Upjohn Co. v. Finch*, 422 F.2d 944, 953 (6th Cir. 1970), quoting 108 Cong. Rec. 19,925 (Sept. 27, 1962).

92. *Id.*

93. *Id.* During the Kefauver investigation, the Library of Congress surveyed drug advertisements appearing in six of the leading medical journals, including the *JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION*, the *NEW ENGLAND JOURNAL OF MEDICINE*, and *LANCET*, during a nine-month period in 1959. The survey covered 34 brand names which appeared on 2,033 pages of advertisements. Fourteen drug companies completely ignored side effects,

The advertising practices of DES manufacturers are subject to these criticisms. Claims of DES's safety and effectiveness in the treatment of threatened and habitual abortion abounded in advertisements within reputable medical journals.<sup>94</sup> Some advertisements recommended DES as a routine prophylaxis in all pregnancies.<sup>95</sup>

### *Detail Men*

Since drug manufacturers daily send physicians more drug information than they can possibly read or remember,<sup>96</sup> physicians rely on detail men for drug information.<sup>97</sup> Detail men frequently minimize their product's dangers while emphasizing its effectiveness and wide acceptance.<sup>98</sup> This practice has resulted in drug manufacturer liability despite a printed warning.<sup>99</sup>

White Laboratories utilized detail men to distribute a brochure to doctors about dienestrol's indicated use. The brochure was a promotional effort which White Laboratories knew would be relied upon by doctors.<sup>100</sup> The distribution was a form of salesmanship,<sup>101</sup> and the dienestrol brochure was the product information provided to doctors. This brochure only

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twenty contained at least some reference to side effects, although the language was less a warning than a reason for prescribing, and seven had warnings of side effects. Senate Committee, *supra* note 81 at 199.

In 1976, Ayerst, the manufacturer of Preniarin, an estrogen, sent a letter to physicians clouding the risk of cancer issue. The Ayerst letter did not mention the results of three "well-designed case controlled studies" indicating an increased risk of endometrial cancer from estrogen replacement therapy. *Estrogens and Endometrial Cancer, supra* note 14 at 19-20. The letter merely asserted that a controversy had arisen and that it was "simplistic" to attribute the increased risk of endometrial cancer solely to estrogen therapy. The FDA, in a later letter to physicians, stated that this attribution was not simplistic but "consistent" with the studies' results. *Id.* at 20. Thus, the Ayerst letter sought to assure physicians that estrogen was safe when, in fact, the risk of cancer had been established.

94. *See, e.g.*, 70 AM. J. OF OBSTETRICS AND GYNECOLOGY 24 (December, 1955) ("no side effects in pregnant patients . . . in either low or massive dosage; safe, effective").

95. *See, e.g.*, 71 AM. J. OF OBSTETRICS AND GYNECOLOGY 30 (June 1956) (no side effects, recommended for routine prophylaxis in all pregnancies).

96. Merrill, *supra* note 73, at 25; *Drug Safety Hearings, supra* note 76, at 1995 or 995.

97. *See* Sterling Drug, Inc. v. Yarrow, 408 F.2d 978, 991-92 (8th Cir. 1969); Love v. Wolf, 226 Cal. App. 2d 378, 399, 38 Cal. Rptr. 183, 185 (1964); Incollingo v. Ewing, 444 Pa. 263, 299, 282 A.2d 206, 220 (1971); *see also* Birth Control, *supra* note 73, at 1535. Note that "detail man" is a drug industry term of art.

98. *See* Love v. Wolf, 226 Cal. App. 2d 378, 38 Cal. Rptr. 183 (1964); Incollingo v. Ewing, 444 Pa. 263, 299, 282 A.2d 206, 220 (1971).

99. *See also* Sterling Drug, Inc. v. Yarrow, 408 F.2d 978 (8th Cir. 1969).

100. Needham, Plaintiff's Brief, *supra* note 26, at 13.

101. *Id.*

contained references to studies and a personal communication which reported estrogen to be an effective method of preventing accidents of pregnancy.<sup>102</sup> Although the medical director and management of White Laboratories were aware of studies which indicated that DES had no value in preventing threatened abortion and studies which demonstrated that estrogens caused cancer and fetal abnormalities, these studies were not included in the dienestrol brochure.<sup>103</sup> Although a statement that use of estrogen was considered investigational was included, any reference to risk was omitted.<sup>104</sup>

## HISTORY OF THE MEDICAL CONTROVERSY SURROUNDING DES

### *DES As a Carcinogen*

At trial, plaintiff presented "extensive evidence describing studies prior to 1952" which suggested a causal relationship between synthetic estrogen and cancer in animals.<sup>105</sup> Dr. Michael Shimkin, "one of the earliest and still among the most eminent researchers in the field," testified that by 1940 the scientific community viewed the eventual demonstration of synthetic estrogen's carcinogenic effects in humans to be a "lead pipe cinch."<sup>106</sup> In his view, any drug manufacturer should have been aware of this. Dr. Shimkin also described in extensive detail several pre-1952 studies which demonstrated that the introduction of estrogen into the system of a pregnant animal could affect her offspring, and that the introduction of other carcinogens into the system of a pregnant animal could cause cancer in the offspring.<sup>107</sup> Dr. Shimkin concluded that, in 1952, any drug firm planning to market a drug like dienestrol for use in pregnant women should have viewed animal testing for intergenerational effects as essential.<sup>108</sup> The drug company also should have warned of the risk of cancer in 1952.<sup>109</sup>

Dr. Neary, White Laboratories' medical director at the time dienestrol was marketed, testified that it was "standard practice" when dealing with a new drug to consider publications on both clinical use of the drug and animal experimentation with the drug.<sup>110</sup> At the time dienestrol was marketed, Dr. Neary was

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102. *Id.*

103. *Id.* at 14.

104. *Id.*

105. *Needham*, Defendant's Brief, *supra* note 2, at B-7.

106. *Id.* at A-14.

107. *Id.* at A-14-15, B-4 to B-5.

108. *Id.* at 14-15.

109. *Id.* at A-15.

110. *Needham*, Plaintiff's Brief, *supra* note 26, at 8.

familiar with a 1940 study which revealed abnormalities in male and female offspring of female rats injected with estrogen.<sup>111</sup> He acknowledged that estrogens had been shown to induce tumor formation in animals.<sup>112</sup> He also knew, at that time, of a warning issued by the editors of the *Canadian Medical Journal* that since synthetic estrogens were chemically related to some carcinogenic substances, notably coal tar, a warning was justified on purely theoretical grounds.<sup>113</sup>

In 1948, a doctor who was later employed by White Laboratories<sup>114</sup> had written that endometrial hyperplasia in humans could be considered a precancerous lesion.<sup>115</sup> Dr. Neary acknowledged that endometrial hyperplasia was an expected pharmacological effect of estrogen use.<sup>116</sup> He also admitted that he knew the tissue of the developing fetus was more susceptible than adult tissue to carcinogenic transformation.<sup>117</sup> Yet, prior to marketing dienestrol for use in pregnant women, Dr. Neary did not commission any research to determine whether estrogens caused cancer in the mother or the child.<sup>118</sup>

At trial, and on appeal, White Laboratories disputed the importance and applicability of animal studies to the human experience and argued that these studies could not provide notice of the need for human testing.<sup>119</sup> Dr. Shimkin, however, was "unequivocal" in his assertions that the animal studies were known at that time to indicate potential danger to humans.<sup>120</sup> Although Dr. Neary recognized the relevance of animal research to certain

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111. *Id.* at 6.

112. *Id.* at 29-30.

113. *Id.* at 29.

114. *Id.* Dr. Rakoff was hired by White Laboratories as a clinical investigator to evaluate the use of dienestrol in the treatment of threatened or hospital abortion.

115. *Id.*

116. *Id.* at 30. Although Dr. Rakoff, who was hired by White to investigate the use of dienestrol in pregnant women, considered endometrial hyperplasia a precancerous lesion, and Dr. Neary was aware that endometrial hyperplasia was an expected effect of estrogen use, neither Dr. Rakoff nor Dr. Neary performed any pathology tests on dead babies born to four of twelve mothers treated with dienestrol during their pregnancies. Dr. Rakoff did not understand why his investigation resulted in four deaths, nevertheless, he did not do any testing and White Laboratories did not request any further investigation or testing.

117. *Id.* at 28-29.

118. Dr. Neary testified that before dienestrol was first marketed in 1946 for uses other than in pregnancy that White Laboratories hired Dr. Teague to test for dienestrol's carcinogenicity by injecting mice with estrogen. The mice were sacrificed after 90 days and found to be free from tumor formation. Ninety days, however, is an insufficient time for mice to develop cancer. *Id.* at 29. Thus, the project was useless as a test for carcinogenicity.

119. *Needham*, Defendant's Brief, *supra* note 2, at B-4.

120. *Id.*

aspects of new drug development, he believed that the application of animal studies to human beings was controversial.<sup>121</sup> Consequently, prior to marketing dienestrol for use in pregnant women, the management of White Laboratories consciously decided not to do any testing to determine whether dienestrol was safe for use in human beings.<sup>122</sup>

The district court's ruling in *Needham* which upheld the evidentiary use of animal studies to show knowledge of a risk of injury in humans was correct. In other drug cases, courts have considered the results of animal tests which revealed injuries similar to but not the same as the injuries sustained by a plaintiff to be evidence of knowledge or notice of the risk of injury which required a warning about that risk.<sup>123</sup> A manufacturer is deemed to constructively know the results which testing and inspection of its product could have revealed.<sup>124</sup> Courts accordingly have based liability on inadequate testing, together with failure to warn.<sup>125</sup> It hardly seems fair to the consuming public to allow a drug manufacturer which has failed to test its product to escape liability for failure to warn about dangers which could have been discovered by adequate testing. "The claim that a hazard was not foreseen is not available" to a drug manufacturer who does not "use foresight appropriate to his enterprise."<sup>126</sup>

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121. *Needham*, Plaintiff's Brief, *supra* note 26, at 8.

122. *Id.* at 11, 19, 1980.

123. *Toole v. Richardson Merrill, Inc.*, 251 Cal. App. 2d 689, 60 Cal. Rptr. 398, 404-05 (1967); *E. R. Squibb & Sons, Inc. v. Heflin*, 579 S.W.2d 19, 21 (Texas Cir. Ct. App. 1979). See also *Hoffman v. Sterling Drug, Inc.*, 485 F.2d 132, 140-41 (3d Cir. 1973).

124. *Borel v. Fibreboard Paper Products Corp.*, 493 F.2d 1076, 1089-90 (5th Cir. 1973); *Hoffman v. Sterling Drug*, 485 F.2d 132, 140-41 (3d Cir. 1973). Plaintiff's expert, Dr. Shimkin, testified that White Laboratories should have done more testing prior to marketing dienestrol because estrogen was known to be a carcinogenic agent. *Needham*, Plaintiff's Brief, *supra* note 26, at 28. He also asserted that defendant should have viewed the tests for inter-generation effects as essential and should have warned of the risk of cancer. White did not claim to have taken either of these steps. *Needham*, Defendant's brief, *supra* note 2, at A14-15.

The duty to warn can arise only where there is knowledge of the hazard. *Dalke v. Upjohn Co.*, 555 F.2d 245, 248 (9th Cir. 1977); *Basko v. Sterling Drug, Inc.*, 416 F.2d 417, 426 (2d Cir. 1969); *Woodill v. Parke Davis & Co.*, 79 Ill. 2d 26, 33, 402 N.E.2d 194, 199 (1980). The knowledge imputed to the manufacturer is that which exists at the time of the injury. *Daly v. McNeil Laboratories, Inc.*, 509 F.2d 617, 618 (6th Cir. 1975); *Chambers v. G. D. Searle*, 441 F. Supp. 377, 381 (D. Md. 1976), *aff'd per curiam*, 567 F.2d 269 (4th Cir. 1977); *Torner v. American Home Prods. Corp.*, 170 Conn. 681, 687, 368 A.2d 35, 38 (1976).

125. See note 30 *supra*.

126. *Hoffman v. Sterling Drug, Inc.*, 485 F.2d 132, 141 (3d Cir. 1973), quoting *Dalenite v. United States*, 346 U.S. 15, 51-52 (1953) (Jackson, J., dissenting).



*Risks versus Benefits: Dienestrol as an Ineffective  
Therapeutic Agent*

*Standards for Testing Drugs*

Dr. Shimkin testified that recognized testing methods existed in 1948 to determine drug safety and efficacy.<sup>127</sup> He identified the principle method of scientific testing as the controlled experiment, which scientists viewed as an important means to eliminate bias.<sup>128</sup> Controlled experiments were considered essential to evaluate the ability of estrogen to prevent threatened abortion because pregnancy is affected by many factors, such as diet and psychological state.<sup>129</sup> Consequently, it would be imperative to design a study which would control for these factors by treating all research subjects in the same manner.<sup>130</sup> Use of a placebo in the nonmedicated group compared to use of the experimental drug in the medicated group is an example of such a control. The paradigm of controlled experiments, and the most favored testing method in 1952, is the double blind study<sup>131</sup> in which neither the researcher nor the research subject knows whether the drug given is a placebo or a real drug—in all respects both groups being compared are treated and evaluated in the same manner.<sup>132</sup>

*Claims of Effectiveness from Poorly Controlled Studies*

Articles published by Drs. Olive and George Smith in the late 1940s were primarily responsible for the belief that DES would reduce the incidence of threatened abortion.<sup>133</sup> The Smiths theorized that a lack of the hormone progesterone caused early termination of pregnancy, and that DES could stimulate production of progesterone, thereby preventing abortion.<sup>134</sup> Other scientists severely criticized both the theory that reduced progesterone caused abortion,<sup>135</sup> and the method that

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127. *Needham*, Plaintiff's Brief, *supra* note 26, at 7.

128. *Id.*

129. *Id.*

130. *Id.* at 8.

131. *Id.*

132. *Id.*

133. Smith & Smith, *Diethylstilbestrol on Prevention and Treatment of Complications of Pregnancy*, 56 AM. J. OF OBSTETRICS AND GYNECOLOGY 821 (1948); Smith & Smith, *Increase of Pregnandiol in Pregnancy from DES with Special Reference to the Prevention of Late Pregnancy Accidents*, 57 AM. J. OF OBSTETRICS AND GYNECOLOGY 411 (1946) [hereinafter cited as *Pregnandiol*].

134. *Pregnandiol*, *supra* note 133, at 414.

135. Davis & Fugo, *Effects of Various Sex Hormones on Excretion of Pregnandiol Early in Pregnancy*, 65 PROC. SOC. EXP. BIOL. & MED., 283, 289 (1947) [hereinafter cited as *Effects of Sex Hormones*].

the Smiths used to measure the efficacy of DES and its alleged “progesterone stimulating qualities.”<sup>136</sup> As early as 1949,<sup>137</sup> the Smiths were severely criticized for lack of adequate controls, and controlled studies performed in the early 1950s refuted the Smiths’ claims of DES effectiveness in preventing threatened abortion.<sup>138</sup>

### *White Laboratories’ Decision to Market Dienestrol to Treat Threatened Abortion*

The medical director of White Laboratories, Dr. Neary, relied on the Smiths’ articles to establish DES effectiveness in the treatment of threatened abortion.<sup>139</sup> Before submitting the sup-

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136. Davis & Fugo, *Does Administration of Diethylstilbestrol to Pregnant Women Result in Increased Output of Urinary Pregnandiol?* 69 PRAC. SOC. EXP. BIOL. & MED., 436 (1948) [hereinafter cited as *Administration of Diethylstilbestrol*]. To test whether DES would stimulate the production of progesterone, the Smiths measured how much pregnandiol was excreted in the urine of pregnant women treated with DES. When they found that the pregnandiol level was elevated, they assumed that it was the result of increased progesterone production which had been stimulated by DES. The Smiths acknowledged that they could not determine what amount of the excreted pregnandiol was actually produced by the body and what amount was due to DES. *Pregnandiol*, *supra* note 130, at 414. Nevertheless, they concluded that their results indicated an increased stimulation of progesterone from DES.

137. In a discussion following the Smiths’ 1949 presentation, Dr. Dieckman criticized them for utilizing an inadequate study design. Smith & Smith, *The Influence of Diethylstilbestrol on the Progress and Outcome of Pregnancy Based on a Comparison of Treated and Untreated Primigravidas*, 58 AM. J. OF OBSTETRICS & GYNECOLOGY 994, 1008 (1949). The untreated group was not given a placebo, hence the two groups were not treated the same. See also *Effects of Sex Hormones*, *supra* note 135.

138. See, e.g., Davis & Fugo, *Steroids in the Treatment of Early Pregnancy Complications*, 142 J.A.M.A. 778 (1950); Robinson & Shettles, *The Use of Diethylstilbestrol in Threatened Abortion*, 63 AM. J. OF OBSTETRICS & GYNECOLOGY 1330 (1952).

In 1953, a double blind study of DES effectiveness for preventing accidents of pregnancy was conducted at the University of Chicago Lying In Hospital. Dieckmann, Davis, Rynkiewicz, & Potter, *Does the Administration of Diethylstilbestrol during Pregnancy Have Therapeutic Value?* 66 AM. J. OF OBSTETRICS & GYNECOLOGY, 1062 (1953). Pregnant mothers were unknowing participants in the study. Both the DES- and the placebo-treated mothers were told the pills were vitamins. A class action on behalf of these DES mothers has withstood a motion to dismiss plaintiff’s battery claim against the hospital. *Mink v. University of Chicago*, 460 F. Supp. 713 (N.D. Ill. 1978). The products liability count was dismissed because the mothers did not allege a specific injury, but rather an increased risk of developing cancer. Unfortunately, the Dieckmann study results were barred from the *Needham* trial. All efficacy evidence pertaining to the years after 1952 was restricted by the district court.

139. *Needham*, Defendant’s Brief, *supra* note 2, at 6. Dr. Neary also relied on the research of Doctors White and Karnaky. *Id.* Plaintiff’s experts criticized the studies for lack of adequate controls. *Needham*, Plaintiff’s Brief, *supra* note 26, at 10.

plemental NDA to the FDA, Dr. Neary reviewed the published material concerning the use of estrogen in experimental animals and humans.<sup>140</sup> He knew that the usefulness of DES in treating threatened abortion was controversial, and he informed the management of White Laboratories of this controversy.<sup>141</sup> The supplemental NDA, however, did not list any publication which indicated that the use of DES was controversial.<sup>142</sup>

In a letter to White Laboratories, the American Medical Association questioned the effectiveness of dienestrol and criticized the NDA data as "completely uncontrolled," resulting in "obscure" criteria for the use of estrogen in treating threatened abortion. Nevertheless, Dr. Neary failed to conduct further tests to determine the effectiveness of dienestrol.<sup>143</sup> He did inform management of two studies indicating that DES was of no value and a "dismal failure" in preventing threatened abortion, and also told management that pregnant animals treated with estrogen had aborted.<sup>144</sup> These facts, however, were not included in the supplemental NDA or the product information brochure, although White Laboratories and Dr. Neary knew that doctors would rely on the brochure to determine dosage and instructions for use.<sup>145</sup>

Dr. Albert Schmitt, an obstetrician who has done extensive work with DES-related problems, described these reports as "inadequate testing," and also characterized as irresponsible the Smiths' suggested hundredfold increase in dosage for pregnant women.<sup>146</sup> Both Dr. Schmitt and Dr. Shimkin criticized White Laboratories' reliance on the Smiths' articles to determine dienestrol's safety and efficacy in the treatment of threatened abortion.<sup>147</sup> a review of articles which favored estrogen use in pregnant women and which were of questionable

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140. *Needham*, Plaintiff's Brief, *supra* note 26, at 14.

141. *Id.* Other researchers had found bed rest and psychological factors effective in preventing miscarriage. *See, e.g.* Bevis, *Treatment of Habitual Abortion*, 2 LANCET 207 (1951); Javert, *Repeated Abortion*, 3 OBST. AND GYNEC. 420 (1954).

142. *Id.* Instead, the supplemental NDA contained only two summaries of "clinical reports" from two doctors who had been commissioned by White Laboratories to report on dienestrol's effectiveness. In one report of twelve women treated with dienestrol who carried their pregnancies to term, eight women delivered live babies, and four delivered dead babies; in the other report, five of the seven women treated with dienestrol delivered live babies and two delivered dead babies. These case reports were criticized as poorly controlled. *Id.* at 14.

143. *Id.* at 14.

144. *Id.*

145. *Id.* at 29.

146. *Id.*

147. *Id.* at 10, 28-29.

authority because of poor testing methodology was unacceptable premarketing practice. In Dr. Shimkin's view, more premarket testing of dienestrol was required because estrogens were well known to be carcinogenic.<sup>148</sup>

RELEVANCE OF DRUG EFFICACY EVIDENCE IN  
STRICT LIABILITY ACTIONS

*The District Court's Ruling in Needham*

*Comment k*

Before determining *when* the comment k exception to strict liability applies, it is necessary to examine the products to which it applies. By its terms, comment k covers "unavoidably unsafe products;" those products which, "in the present state of human knowledge," are "incapable of being made safe for their ordinary and intended use."<sup>149</sup> Unavoidably unsafe products are "especially common in the field of drugs."<sup>150</sup>

Comment k separates drugs into three categories.<sup>151</sup> An example of the first category is the rabies vaccine. Because it prevents death, marketing and use of the vaccine are "fully

148. *Id.*

149. RESTATEMENT (SECOND) OF TORTS § 402A, comment k (1965).

150. *Id.*

151. The three categories of vaccines (such as the rabies vaccine), prescription drugs, and new drugs, are discussed in § 402A, comment k:

Unavoidably unsafe products. There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. *These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs* as to which because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

RESTATEMENT (SECOND) OF TORTS § 402A, comment k (1965) (emphasis added).

justified" despite the high degree of risk which the vaccine itself presents.<sup>152</sup> In the second category are drugs which cannot legally be sold except to a physician or under prescription of a physician.<sup>153</sup> The third category consists of new or experimental drugs in which, because of "insufficient time and opportunity for medical experience," there can be no assurance of safety.<sup>154</sup> The seller of these three types of products is not to be held strictly liable in tort simply because the seller has undertaken to supply the public with an *apparently useful and desirable* product, as long as the product is accompanied by proper directions and warnings and is properly prepared.<sup>155</sup>

Comment k, accordingly, has been referred to as an "exception" to strict liability which applies to the sellers of "established" but unavoidably unsafe, and new or experimental drugs.<sup>156</sup> The obvious intent of comment k is to preclude drugs and other inherently dangerous products from being characterized as defective merely because of their inherently dangerous features.<sup>157</sup> Consequently, when a plaintiff sues a drug manufacturer for strict liability in tort for failure to warn of a risk of injury from a drug, the courts and commentators assume that a drug is an unavoidably unsafe product which must be analyzed according to the provisions of comment k.<sup>158</sup> This assumption accurately perceives that all drugs involve some risk of danger, and hence are unavoidably unsafe.<sup>159</sup>

The district court in *Needham*, therefore, was correct in assuming that dienestrol was an unavoidably unsafe product which should be analyzed within the comment k framework. White Laboratories' defense throughout the trial was that dienestrol was a new or investigational drug, the dangers of

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152. *Id.*

153. *Id.*

154. *Id.*

155. *Id.*

156. McClellan, *supra* note 51, at 2.

157. *Id.*

158. *E.g.*, *Davis v. Wyeth Laboratories, Inc.*, 399 F.2d 121, 127-28 (9th Cir. 1968); *Mink v. University of Chicago* 460 F. Supp. 713, 719 (N.D. Ill. 1978); *Carmichael v. Reetz*, 17 Cal. App. 3d 958, 988, 95 Cal. Rptr. 381, 399-400 (1971); *Woodill v. Parke Davis & Co.*, 79 Ill. 2d 26, 402 N.E.2d 194, 199 (1980); *Lawson v. G. D. Searle & Co.*, 64 Ill. 2d 343, 356 N.E. 2d 779 (1976); *Mahr v. G.D. Searle & Co.*, 72 Ill. App. 3d 540, 390 N.E.2d 1214, 1228 (1979); *Chapman v. Ortho Pharmaceutical Co.*, 388 N.E.2d 541 (Ind. 1979). *See generally* Cassidy, *The Prescription Drug Exception to the Doctrine of Strict Liability*, 58 ILL. B.J. 268 (1969); Willig, *The Comment K Character: A Conceptual Barrier to Strict Liability*, 29 MERCER L. REV. 545, 550 (1978) [hereinafter cited as Willig].

159. *Drug Reactions*, *supra* note 50, at 742; W. PROSSER, *THE LAW OF TORTS* § 99, at 661 (4th ed. 1971).

which were unknown in 1952 when plaintiff was exposed to it.<sup>160</sup> If this were true, and if dienestrol were an apparently useful and desirable drug, White Laboratories could escape liability for failure to warn of the danger since it did warn that dienestrol was an investigational drug. If the defendant did know of the risk of harm, the jury could determine that this warning was inadequate.

The district court also properly construed comment k as interpreted by the Illinois Supreme Court in *Woodill v. Parke Davis*.<sup>161</sup> In that case the court held that when a plaintiff sues a drug manufacturer based on strict liability in tort for failure to warn of a danger the plaintiff must, in accordance with comments j<sup>162</sup> and k, plead and prove that the manufacturer knew or should have known of the risk inherent in the drug.<sup>163</sup> Thus, a drug manufacturer in Illinois cannot be held strictly liable for failure to warn of a risk unless liability can also be based on negligent failure to warn, that is, unless the evidence would support a finding that the seller should have foreseen the danger.<sup>164</sup>

The *Woodill* decision, however, did not involve a challenge to the drug's usefulness and the manufacturer's decision to market it was tacitly assumed to be reasonable despite the attendant risk. Consequently, the comment k knowledge standard was properly applied. Comment k does not, however, limit drug manufacturer liability under all conditions. The protection from strict liability afforded by comment k might be lost if a drug that offered no substantial benefit caused an injury, even if the injury

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160. See Needham, Defendant's Brief, *supra* note 2, at B-4.

161. 79 Ill. 2d 26, 402 N.E.2d 194 (1980).

162. Comment j provides:

*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, as for example to eggs or strawberries, will be aware of them, and he is not required to warn against them. Where, however, the product contains an ingredient to which a substantial number of the population are allergic, and the ingredient is one whose danger is not generally known, or if known is one which the consumer would reasonably not expect to find in the product, the seller is required to give warning against it, if he has knowledge, or by the application of reasonable, developed human skill and foresight should have knowledge, of the presence of the ingredient and the danger. Likewise in the case of poisonous drugs, or those unduly dangerous for other reasons, warning as to use may be required.

RESTATEMENT (SECOND) OF TORTS § 402A, comment j (1965).

163. *Woodill v. Parke Davis & Co.*, 79 Ill. 2d 26, 35, 402 N.E.2d 194, 199 (1980).

164. To recover in negligence, plaintiff must show that the manufacturer's conduct exposed plaintiff to an unreasonable risk of harm and that this was the proximate cause of plaintiff's injuries. See Merrill, *supra* note 73, at 29.

were not foreseeable.<sup>165</sup> Such a drug would be considered unreasonably dangerous as marketed or unreasonably dangerous per se.<sup>166</sup>

To determine whether a drug provides a substantial benefit, and therefore comes within the comment k exception to strict liability, the drug's benefits or apparent usefulness and desirability must be weighed against its risks. If the "risk/benefit" analysis under comment k renders a product unreasonably dangerous, sale of the drug results in strict liability regardless of the manufacturer's ignorance of the dangers.<sup>167</sup> Where a seller has marketed an apparently useless drug, the reason for the comment k exception—to give sellers of drugs an incentive to continue producing useful and beneficial drugs—is not present. The seller of such a product should not be entitled to greater protection than the seller of a product which has a manufacturing defect. Society's interests are not served if an unavoidably

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165. See, e.g., *Tinnerholm v. Parke Davis & Co.*, 285 F. Supp. 432 (S.D.N.Y. 1968), *aff'd*, 411 F.2d 48 (2d Cir. 1969); *Stromst v. Parke-Davis & Co.*, 257 F. Supp. 991, 994-97 (D. N. 1966), *aff'd*, 411 F.2d 1390 (8th Cir. 1969). Both cases recognized a breach of warranty theory to permit recovery for harm caused by quadrigen, a quadruple antigen vaccine designed to inoculate against tetanus, pertussis, poliomyelitis, and diphtheria in one inoculation. Both plaintiff children developed encephalopathy with permanent brain injury, and based their actions on implied warranty and negligence theories. Neither court required proof of manufacturer fault for the implied warranties actions. Proof of a defect in the product and proof that the defective condition caused the injury are the necessary elements of warranty. The *Tinnerholm* court also quoted the Restatement defect test as the best working definition of a defect: "the product is . . . in a condition not contemplated by the ultimate consumer, which will be unreasonably dangerous to him," 285 F. Supp. at 443, quoting RESTATEMENT (SECOND) OF TORTS § 402A, comment g (1965). In characterizing quadrigen as defective, the court noted that no recognized medical need justified the risk of marketing because the product was not a marked improvement over any other drug. Consequently, the manufacturer was not entitled to be shielded from liability as provided by comment k. Although there was evidence that quadrigen was beneficial to the patient and doctor in reducing the number of injections, "[w]hen balancing this with the tragic occurrence . . . the reduction of injections argument pales into insignificance." *Id.* at 446.

The similarity between implied warranty, where the law implies a warranty by the seller that its product is fit for its intended use, and strict liability, where the law imposes liability for a defective product, renders the *Tinnerholm* and *Stromsodt* cases persuasive authority for drug actions based on a strict liability defect. Implied warranty, without the contract defenses of privity and notice, has been used to permit recovery in those jurisdictions which have not yet adopted strict liability. The test to determine whether a drug is defective in an implied warranty action—the balancing of benefits against risks—is the same test which is required to determine whether the comment k exception to strict liability applies.

166. See, e.g., *Reyes v. Wyeth Laboratories*, 498 F.2d 1264 (5th Cir. 1974); *Davis v. Wyeth Laboratories, Inc.*, 399 F.2d 121, 129-31 (9th Cir. 1968). See also Willig, *supra* note 158, at 568.

167. See also *Borel v. Fibreboard Paper Prods. Corp.*, 493 F.2d 1076 (5th Cir. 1973).

unsafe product has a high degree of risk and an occasional or nonexistent benefit, yet enjoys insulation from strict liability in tort despite its predominantly detrimental effects.<sup>168</sup> This is the reason the comment k exception to strict liability requires a predominant character of usefulness and beneficiality.<sup>169</sup>

Strict liability in tort is particularly appropriate where this beneficial character is lacking in a drug. The drug industry is highly competitive; new drugs must be produced to ensure a drug company's continued existence.<sup>170</sup> The potential profits from a commercially successful new drug are enormous. In an economic sense then, strict liability is justified by the manufacturer's superior ability to absorb the costs of minimizing risks and ensuring drug efficacy.<sup>171</sup> Although production of safe and useful drugs can only be accomplished through more extensive testing, which would increase the price of drugs, consumers directly benefit from the availability of a drug whose benefits far outweigh its risks, and from escaping exposure to drugs which are ineffective and dangerous. The possibility of strict liability may provide drug manufacturers with an incentive to market drugs which are effective and beneficial as well as profitable.<sup>172</sup> It may also encourage drug companies to divert a portion of their huge advertising and promotion budgets to researching and testing of their products.<sup>173</sup>

It is readily apparent that the risk/benefit analysis required under comment k to determine whether a product's marketing was justified, necessitates evidence of the product's efficacy or lack of efficacy. When the efficacy of a drug is manifestly outweighed by its risks, or is nonexistent, proof of fault—knowledge of a risk of injury and failure to warn—is unnecessary to a finding of liability.<sup>174</sup>

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168. Willig, *supra* note 158, at 545.

169. *Id.* Cf. *Tinnerholm v. Parke, Davis & Co.*, 285 F. Supp. 432. (S.D.N.Y. 1968), *aff'd*, 411 F.2d 48 (2d Cir. 1969) (efficacy of drug manifestly outweighed by its risk, therefore it was defective; court stressed that there was no urgent need for the product since other safer products were available).

170. See *Rheingold*, *supra* note 79, at 1009.

171. *Needham v. White Laboratories, Inc.*, No. 76-C 1101 (N.D. Ill. Aug. 13, 1979).

172. Sheer volume of promotion and advertising is what sells a drug. *Drug Safety Hearings*, *supra* note 76, pt. 5 at 1995-97.

173. See W. PROSSER, *THE LAW OF TORTS* § 75, at 494 n.27 (4th ed. 1971).

174. The deterrence theory of strict liability for drug manufacturers has been criticized by Professor McClellan who argues that strict liability must be purged of negligence overtones. This can be accomplished, in his view, if the focus of the loss spreading principle of strict liability is turned away from the deterrence goal of loss shifting. "Adherence to the view that deterrence is an essential goal of loss shifting in a strict liability case impels



In *Needham*, the district court ruled that evidence of dienes-trol's lack of efficacy was relevant. A pretrial ruling noted that drugs are commonly considered unavoidably unsafe products under comment k.<sup>175</sup> Citing the language of comment k, the district court noted that such products are not unreasonably dangerous, and therefore do not come within the purview of strict liability, if they are properly prepared and accompanied by directions and warnings:

The seller of [unavoidably unsafe] products, again with the qualification that they are properly prepared and marketed and a proper warning is given, where the situation calls for it, is not to be held to strict liability for the 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.<sup>176</sup>

The district court interpreted this language to mean conversely that strict liability may be imposed upon a manufacturer, irrespective of warnings, if the product at the time of marketing was not apparently useful. Accordingly, evidence of efficacy was relevant to determine whether or not dienes-trol was apparently useful when marketed. The precise question to be addressed, in the court's view, was whether there were sufficient technological experience and testing standards in 1952 to justify the marketing and use of dienes-trol. The issue to be resolved was not whether dienes-trol was *actually* useful, but whether dienes-trol was *ap-parently* useful.<sup>177</sup>

In later opinions, the district court affirmed its ruling that evidence of dienes-trol's ineffectiveness was relevant to foreclose reliance on the lack of knowledge defense provided by comment k.<sup>178</sup> If there was no reason to believe in 1952 that dienes-trol was useful in preventing threatened or habitual abortion, the court reasoned, the marketing of dienes-trol was not justified. Consequently, the comment k curtailment of the normal strict liability standard could not be applied. The absence of any apparent utility would render the drug unreasonably dangerous, and irrespective of its knowledge of dienes-trol's danger, White Laboratories could be held strictly liable in tort. Evidence of efficacy

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courts to cling to the concept of foreseeability of risks which in turn produces a confused evaluation of the strict liability claim." McClellan, *supra* note 51, at 25.

175. In the early 1970s the drug industry reported spending one billion dollars per year on advertising. The industry used 20,000 detail men, paying them salaries totalling 700 million dollars. M. DIXON, DRUG PRODUCT LIABILITY § 6.10[2].

176. *Id.* (emphasis added).

177. *Id.* at 2.

178. See *Needham*, Defendant's Brief, *supra* note 2, at A-16-17, B-7-8.

was deemed crucial to the case and its omission, in the court's view, could require reversal.

### *Strict Liability Based on a Drug Defect*

To recover under section 402A of the Restatement (Second) of Torts,<sup>179</sup> a plaintiff must prove that the proximate cause of his or her injury was a defect in the product which rendered the product unreasonably dangerous.<sup>180</sup> The rationale for imposing strict liability is set forth in comment c:

[T]he 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.

[P]ublic 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.<sup>181</sup>

Certainly, drugs are necessary products for which the consumer must rely upon the seller who markets them for consumption.<sup>182</sup> Thus it would seem that a drug manufacturer has a special responsibility under section 402A to a member of the consuming public who is injured by its drug. The design and manufacturing process must yield a product which reflects the proper balance of efficiency and safety.<sup>183</sup> The Restatement test to determine whether particular risks posed by a product make it defective and unreasonably dangerous is whether the article is more dangerous than would be contemplated by the reasonably informed consumer.<sup>184</sup> Under this test, drugs which are ineffective and unsafe would be defective and unreasonably dangerous.<sup>185</sup>

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

180. *Suvada v. White Motor Co.*, 32 Ill. 2d 612, 210 N.E.2d 182 (1965). See also *Durham v. Vaughan & Bushnell Mfg. Co.*, 42 Ill. 2d 339, 247 N.E.2d 401 (1969).

181. RESTATEMENT (SECOND) OF TORTS § 402A, comment c (1965).

182. In a failure to warn action against a drug manufacturer, the physician is deemed the "learned intermediary." Because the doctor administers or prescribes the drug, the manufacturer's duty is to alert doctors to potential hazards. *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82, 85 (8th Cir. 1965).

183. *Accord*, *Davis v. Wyeth Laboratories, Inc.*, 399 F.2d 121 (9th Cir. 1968).

184. RESTATEMENT (SECOND) OF TORTS § 402A, comment c (1965).

185. An ordinary consumer would expect that a drug he or she ingested would be effective and safe for its intended use.

### Design Defects

The defect asserted by the plaintiff in *Needham* was that dienestrol was ineffective and unreasonably dangerous as marketed for its intended use. This description comes within the Restatement's consumer-expectation definition of a defective and unreasonably dangerous product. The difficulty with using the Restatement test in a prescription drug case is that the consumer does not purchase the drug directly from the seller, but through a learned intermediary, the prescribing physician.<sup>186</sup> Substituting the word "physician" for "consumer" would resolve this difficulty. If the risks of a drug manifestly outweigh its benefits, the drug is dangerous beyond the extent contemplated by either the consumer or the prescribing physician.

The drug was in the condition the manufacturer intended, hence the injury resulting from its use can be analogized to an injury caused by a defect in design. In a design defect case, the product conforms to the manufacturer's plan or design, but certain intended characteristics render the product not reasonably safe.<sup>187</sup> In the case of drugs, something in the formula makes the product dangerous.<sup>188</sup> In a strict liability sense, the product defect in drugs is, in most instances, due to a laggard approach to research design formulation. Design defect claims protect the consumer's interest in avoiding exposure to a product posing risks which so far outweigh its benefits that it should not continue to be marketed.<sup>189</sup>

Although the definition of defect in a drug may differ from the definition of defect in a machine, the theory of strict liability is the same in both cases.<sup>190</sup> As Justice Traynor cogently noted:

If we scrutinize deviations from a norm of safety as a basis for imposing liability, should we not scrutinize all the more the product

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186. *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82, 85 (8th Cir. 1965).

187. *Harins v. Caterpillar Tractor Co.*, 80 Ill. App. 3d 262, 264, 399 N.E.2d 722, 723 (1980). Manufacturing defects result from a quality of a product not intended by the manufacturer. The unreasonably dangerous condition which gives rise to strict liability in tort includes both defects in manufacture and defects in design. *Kerns v. Engelke*, 54 Ill. App. 3d 323, 369 N.E.2d 1284 (1977), *aff'd*, 76 Ill. 2d 154, 390 N.E.2d 859 (1979). See also Pratt & Parnon, *Diagnosis of a Legal Headache: Liability for Unforeseeable Defects in Drugs*, 53 ST. JOHN'S L. REV., 51, 519 n.10 (1979) [hereinafter cited as Pratt & Parnon].

188. See, e.g., *Tinnerholm v. Parke Davis & Co.*, 285 F. Supp. 43 (S.D.N.Y. 1968), *aff'd*, 411 F.2d 48 (2d Cir. 1969); *Stromsodt v. Parke Davis & Co.*, 257 F. Supp. 991 (D. N.D. 1966), *aff'd*, 411 F.2d 1390 (8th Cir. 1969).

189. McClellan, *supra* note 51, at 32.

190. *Id.* at 29-30. The reason for the court's different treatment of drug and machine defect cases is that the principle by which machines work is understood, while a drug may affect different individuals in different ways. Pratt & Parnon, *supra* note 187, at 533.

whose norm is danger? Such scrutiny is especially sensible for drugs for which a reasonably safe substitute exists. Thalidomide sleeping pills afford a recent dramatic example of such a dangerous product. Other drugs, which must be used despite the danger, perhaps should be treated differently.<sup>191</sup>

Despite a lack of negligence, public policy demands that responsibility be fixed wherever it will most effectively reduce the hazards to life and health inherent in defective drug products. The responsibility is appropriately fixed on the drug manufacturer because "the manufacturer can anticipate some hazards and guard against the occurrence of others as the public cannot."<sup>192</sup> In addition to being in a superior position to reduce the injury, the manufacturer is in the best position to spread the cost of the injury; the consumer can least afford the devastating impact of disability.

Where a product is inherently unsafe, strict liability requires that the marketer face the test of usefulness and reasonable purpose for the product in the marketplace. "To the degree a product is unsafe, a similar degree of justification will have to be found for offering it for use or consumption."<sup>193</sup> Marketing a drug which lacks therapeutic potential is unreasonable when that drug also presents a risk of harm. "The less effective a drug is, the more its risks become unreasonable."<sup>194</sup> This formulation is reflected in the design defect theory articulated by the California courts.<sup>195</sup> Other courts have held that proof of the manufacturer's fault is unnecessary where the efficacy of the drug is manifestly outweighed by its risks<sup>196</sup>—the drug is defective and unreasonably dangerous in a strict liability sense.<sup>197</sup>

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191. Traynor, *The Ways & Meanings of Defective Products & Strict Liability*, 32 TENN. L. REV. 363, 368-69 (1965).

192. *Id.* See also, *Escola v. Coca Cola Bottling Co. of Fresno*, 24 Cal. 2d 453, 150 P.2d 436 (1944) (Traynor, J., concurring).

193. *Willig*, *supra* note 158, at 553.

194. *Id.* at 545-46.

195. To determine whether a design is defective, the California Supreme Court adopted a two-part test:

[A] product is defective in design either (1) if the product has failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner, or (2) if . . . the benefits of the challenged design do not outweigh the risk of danger inherent in such design.

*Barker v. Lull Engineering Co.*, 20 Cal. 3d 413, 418, 573 P.2d 443, 446, 143 Cal. Rptr. 225, 228 (1978).

196. See, e.g., *Tennerholm v. Parke Davis & Co.*, 285 F. Supp. 43 (S.D.N.Y. 1968) *aff'd*, 411 F.2d 48 (2d Cir. 1969); *Stromsodt v. Parke Davis & Co.*, 257 F. Supp. 991 (D.N.D. 1966), *aff'd*, 411 F.2d 1396 (8th Cir. 1968). See also *Davis v. Wyeth Laboratories, Inc.*, 399 F.2d 121 (9th Cir. 1968).

197. An action based on negligent design is also possible. See, e.g., *Brooks v. Allis Chalmers Mfg. Co.*, 163 Cal. App. 2d 410, 329 P.2d 575 (1958).

Illinois courts have defined defective products to be those products which are dangerous because they fail to perform in the manner reasonably to be expected in light of their nature and intended function.<sup>198</sup> Proof that, in the absence of abnormal use or reasonable secondary causes, the product failed so to perform establishes a prima facie case that the product was defective.<sup>199</sup> Whether a product has failed to perform in the manner that would reasonably have been expected, and whether this failure caused plaintiff's injury, are questions for the jury.<sup>200</sup> Although the Illinois cases that produced this definition involved hammers, ladders, and brakes, the strict liability principles articulated in these design defect cases apply as well to defects in the design of drugs. The policy reasons for imposing strict liability are the same in each instance.

The strict liability rationale was set forth in *Suvada v. White Motor Co.*<sup>201</sup> before Illinois adopted the Restatement view of strict liability. In *Suvada* the supreme court discussed the rationale in terms of the consumption of food, but the reasoning is especially applicable to drugs. First, the public interest in human life and health demands all the protection the law can give against unwholesome food.<sup>202</sup> This policy applies equally to unwholesome drugs—drugs which are of questionable efficacy and a high risk of harm. Second, the manufacturer solicits and invites the use of its product by packaging, advertising, or otherwise representing to the public that it is safe and suitable for use.<sup>203</sup> With respect to drugs, the inducement is aimed at the

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The third circuit recently articulated the policy differences between strict liability and negligence actions:

The choice between holding a manufacturer liable only for negligence and holding it strictly liable for any dangerous products or design is, practically speaking, a matter both of searching for optimal deterrence of harmful conduct and of allocating the costs of injuries either to producers or consumers. A negligence standard is, broadly speaking, more protective of producers, while strict liability is more solicitous of consumers.

*Reyno v. Piper Aircraft Co.*, 630 F.2d 149, 167 (3d Cir. 1980).

198. *Gillespie v. R. D. Werner Co., Inc.*, 71 Ill. 2d 318, 321, 375 N.E.2d 1294, 1295-96 (1978); *Tweedy v. Wright Ford Sales, Inc.*, 64 Ill. 2d 570, 571, 357 N.E.2d 449, 452 (1976); *Dunham v. Vaughan & Bushnell Mfg. Co.*, 42 Ill. 2d 339, 342-43, 247 N.E.2d 401, 403 (1969).

199. *Dunham v. Vaughan & Bushnell Mfg. Co.*, 42 Ill. 2d 339, 342-43, 247 N.E.2d 401, 403 (1969). The defect must have existed at the time the product left the manufacturer's control, which does not mean the defect must manifest itself at once.

200. *Id.*

201. 32 Ill. 2d 612, 210 N.E.2d 182 (1965).

202. *Id.* at 618-19, 210 N.E.2d at 186.

203. *Id.*

prescribing physician, who then orders the drug for the consumer.

Third, the losses caused by unwholesome food should be borne by those who have created the risk and reaped the profit by placing the product in the stream of commerce.<sup>204</sup> In the case of drugs, the manufacturer's high profits and few losses render this reason particularly forceful, especially since the profits are justified by asserting that a risk exists in developing new drugs. Moreover, where a drug manufacturer has placed a drug on the market which has been inadequately tested for efficacy and safety, the manufacturer has certainly created the risk. Consequently, the manufacturer should bear the losses caused by the drug. To quote *Suvada*:

[I]t seems obvious that public interest in human life and health, the invitations and solicitations [to the doctors to prescribe the product for a consumer] and the justice of imposing the loss on the one creating the risk and reaping the profit are present and as compelling in cases involving motor vehicles, [food], and other products, where the defective condition makes them unreasonably dangerous to the user, as they are in [drug] cases.<sup>205</sup>

The strict liability principles were later affirmed by the Illinois Supreme Court in *Liberty Mutual Insurance Co. v. Williams Machine and Tool Co.*<sup>206</sup> The court asserted that the major purpose of strict liability is to place the loss caused by defective products on those who create the risk and reap the profit from placing defective products on the market.<sup>207</sup> This rationale should apply to drug actions which assert strict liability based on a defect.

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204. *Id.* This reflects the consumer orientation of the strict liability loss-shifting principle.

205. *Id.* Before adopting § 402A, the *Suvada* court discussed the development of implied warranty theory to allow recovery against a manufacturer despite a lack of privity of contract and notice of the claim. The court quoted Justice Traynor's analysis for the imposition of strict liability:

[T]he abandonment of the requirement of a contract between [the manufacturer and the plaintiff], the recognition that the liability is not assumed by agreement but imposed by law . . . and the refusal to permit the manufacturer to define the scope of its own responsibility for defective products . . . made clear that liability is not one governed by the law of contract warranties but by the law of strict liability in tort.

*Id.* at 619, 210 N.E.2d at 187.

206. 62 Ill. 2d 77, 338 N.E.2d 857 (1975).

207. *Id.* at 82, 338 N.E.2d at 860. The other policy considerations are (1) that the public interest in human life and health requires protection of the law, and (2) that the manufacturer solicits and invites use of the product, thereby representing to the public that it is safe and suitable for use.

### *Efficacy Evidence*

It is readily apparent that to determine whether a product is defective, evidence of efficacy or lack of efficacy together with evidence of danger is necessary. For example, in one product defect case, evidence of both brake failure and brake effectiveness was introduced to determine whether the product failed to perform in the manner reasonably to be expected in light of its nature and intended function.<sup>208</sup> Similarly, evidence of efficacy must be presented in addition to evidence of dangers in a drug defect case to determine whether a drug performed in a manner reasonably to be expected. Accordingly, the district court correctly ruled that evidence of efficacy was relevant to plaintiff's claim for strict liability based on a defect. The plaintiff claimed that the drug was defective because it was not safe for its intended use and was ineffective. Consequently, dienestrol failed to perform in the manner reasonably to be expected in light of its nature and intended function.

The district court relied on the Illinois Supreme Court's refusal in *Woodill v. Parke Davis & Co.*<sup>209</sup> to impose a requirement that defendant have knowledge of the potential danger in design defect cases.<sup>210</sup> The district court also referred to the *Woodill* court's reliance on the comment k balancing of benefits against risks and, citing *Cunningham v. MacNeal Memorial Hospital*, noted that if the product was not "one of those useful but unavoidably dangerous" products described in comment k, then liability could be imposed "even in the absence of the knowledge of the dangers involved."<sup>211</sup> The district court concluded that the principles of strict liability based on a defect remained substantively unchanged by the *Woodill* decision.<sup>212</sup> Unfortunately, the court expressed no opinion on whether the evidence would have supported a verdict for plaintiff on the defect theory.<sup>213</sup> The district court merely reaffirmed its ruling that efficacy evidence was admissible under this theory.

### *Authority for the District Court's Ruling*

*Cunningham v. MacNeal Memorial Hospital*<sup>214</sup> involved a transfusion of blood contaminated by hepatitis virus. The Illi-

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208. *Tweedy v. Wright Ford Sales, Inc.*, 64 Ill. 2d 570, 357 N.E.2d 449 (1976). See also *Melancon v. Western Auto Supply Co.*, 628 F.2d 395 (5th Cir. 1980).

209. 79 Ill. 2d 26, 402 N.E.2d 194 (1980).

210. *Id.* at 35, 402 N.E.2d at 199.

211. *Needham*, Defendant's Brief, *supra* note 2, at B-8.

212. *Id.*

213. *Id.*

214. 47 Ill. 2d 443, 266 N.E.2d 897 (1970).

nois Supreme Court held the hospital supplier of the blood strictly liable and refused to apply the comment k exception for unavoidably unsafe products.<sup>215</sup> The court held that blood containing hepatitis virus is impure and therefore in an unreasonably dangerous defective condition.<sup>216</sup> Comment k was construed to apply only to products which are not impure and which, even if properly prepared, involve substantial inherent risk of injury to the user.<sup>217</sup>

Later, in *Woodill v. Parke Davis & Co.*,<sup>218</sup> the Illinois Supreme Court referred to the distinction between strict liability based on a defect in a product “such as was involved in [Cunningham]” and an unavoidably unsafe product such as the one involved in *Woodill*.<sup>219</sup> *Woodill* made it clear that the knowledge of risk requirement was not a “weakening” of the *Cunningham* rule that proof of a defect suffices for strict liability<sup>220</sup>; comment k applies only to unavoidably unsafe products. The court also refused to extend the knowledge requirement to design defect cases.<sup>221</sup>

The district court interpreted the *Woodill* court’s reaffirmation of *Cunningham* as authority for premising strict liability for a drug injury on a defect in the drug. The defect in dienestrol was not an impurity, as in *Cunningham*, but rather a design defect. The court therefore inferred that *Cunningham*’s applicability to strict liability actions for other types of defects such as design defects should be broadly construed.<sup>222</sup> There is language in *Woodill*<sup>223</sup> and in another drug case, *Lawson v. G.D. Searle*,<sup>224</sup> which supports this inference. Interpreting this language together with the strict liability principles articulated in design defect cases involving products other than drugs,<sup>225</sup> it is reasonable to conclude that the Illinois courts would uphold a claim based on a design defect in a drug such as that alleged in *Needham*.<sup>226</sup> Consequently, the admission of efficacy evidence on this basis was correct.

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215. *Id.* at 456-57, 266 N.E.2d at 904.

216. *Id.*

217. *Id.*

218. 79 Ill. 2d 26, 402 N.E.2d 194 (1980).

219. *Id.* at 36, 402 N.E.2d at 199.

220. *Id.* at 35, 402 N.E.2d at 199.

221. *Id.* at 37, 402 N.E.2d 199.

222. *Needham*, Defendant’s Brief, *supra* note 2, at B-1.

223. 79 Ill. 2d 26, 402 N.E.2d 194, 199 (1980).

224. 64 Ill. 2d at 547-48, 356 N.E.2d at 779 (1976) (“[A] product faultlessly made may be deemed to be unreasonably dangerous if it is not safe for such use that is expected to be made of it and no warning is given”).

225. *See* note 198 *supra*.

226. *See* notes 198-207 and accompanying text *supra*.



*Reversal by the Court of Appeals**Comment k Risk/Benefit Analysis*

On appeal, the Seventh Circuit criticized the district court's ruling on the admissibility of efficacy evidence as an erroneous interpretation of Illinois law. In the Seventh Circuit's view, only three possible kinds of defective products could result in strict liability in Illinois,<sup>227</sup> and none of these include the design defect: (1) a product contaminated by an impurity;<sup>228</sup> (2) a product unaccompanied by a warning of the product's dangerous propensities, also called a comment j case;<sup>229</sup> and (3) a product which is accompanied by a warning but in which the risk of danger outweighs the benefit of use, also described as a comment k case.<sup>230</sup> The court further explained that a comment k case exists only where the manufacturer warns of the danger, and yet the product remains dangerous even if the warning is followed.<sup>231</sup> Evidence of efficacy is relevant, in the Seventh Circuit's opinion, only to this third kind of defect, a comment k case. Only here is it necessary to weigh the drug's apparent usefulness against its risk to determine whether the drug is unreasonably dangerous. The court found it necessary to adopt another jurisdiction's analysis of comment k since the Illinois Supreme Court had not "yet decided a comment k case" but had only "commented" on the applicability of comment k to products which are not impure and involve substantial inherent risk of injury even if properly prepared.<sup>232</sup>

Citing *Woodill*, the Seventh Circuit determined that comment j, rather than comment k, governed the *Needham* action because no warning accompanied dienestrol.<sup>233</sup> Efficacy evidence was therefore held to be irrelevant to the "dispositive issue," in the case: "[W]hether White should be held liable for its failure to warn of the risk of cancer to offspring of pregnant women who [ingested] Dienestrol."<sup>234</sup>

The Court of Appeals reasoning is faulty for several reasons. First, it ignores the existence of liability for a design defect in

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227. *Needham v. White Laboratories, Inc.*, 639 F.2d 394, 400 (7th Cir. 1981).

228. Such as the blood contaminated by hepatitis in *Cunningham v. MacNeal Memorial Hosp.* 47 Ill. 2d 443, 266 N.E.2d 897 (1970).

229. Such as the drugs involved in *Needham* and *Woodill*. 79 Ill. 2d 26, 402 N.E.2d 194 (1980).

230. Such as the vaccine in *Reyes v. Wyeth Laboratories*, 498 F.2d 1263 (5th Cir. 1974), *cert. denied*, 419 U.S. 1096 (1974).

231. *Needham v. White Laboratories, Inc.*, 639 F.2d 394, 402 (7th Cir. 1981).

232. *Id.* at 401.

233. *Id.* at 402.

234. *Id.* The court's statement of the issue ignores plaintiff's strict liability claim.

Illinois. Second, the court incorrectly interpreted Illinois case law to distinguish between comment k and comment j cases. Third, the court erroneously asserted that the Illinois Supreme Court had not yet decided a comment k case. Fourth, the court ignored the new-drug provisions of comment k which apply to diethystrol.

### *Comment k and Comment j*

Illinois drug cases based on strict liability for failure to warn do not support the Seventh Circuit's distinction between comments j and k. The Illinois courts have not dichotomized the comments to apply comment j only in cases where a warning of a risk is lacking, and comment k only in cases where a warning is given. Rather, the Illinois courts have construed comments j and k together to determine that a manufacturer of a beneficial drug must have actual or constructive knowledge of a risk of danger before it can be held strictly liable for failure to warn of that risk.<sup>235</sup>

Furthermore, it is simply incorrect to say that Illinois has not yet decided a comment k case. Several Illinois drug cases based on strict liability for failure to warn have expressly relied on comment k to resolve the issues.<sup>236</sup> In *Woodill v. Parke Davis & Co.*,<sup>237</sup> the Illinois Supreme Court placed great reliance on comment k for resolution of the strict liability failure to warn issue.<sup>238</sup> Despite the absence of a warning accompanying the drug, the court, adopting comment k language, described the product as an unavoidably unsafe product.<sup>239</sup> Other drug cases reveal a tacit assumption by Illinois courts that prescription drugs, by their nature, are unavoidably unsafe products which must be analyzed according to the provisions of comment k.<sup>240</sup> A discussion of *Woodill* will exemplify these issues.

In *Woodill*, the plaintiff sued the drug manufacturer, alleging strict liability for failure to warn physicians and consumers of the danger in using the drug pitocin to induce labor in preg-

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235. See, e.g., *Woodill v. Parke Davis & Co.*, 79 Ill. 2d 26, 402 N.E.2d 194 (1980); *Lawson v. G. D. Searle*, 64 Ill. 2d 543, 356 N.E.2d 779 (1976); *Mahr v. G. D. Searle & Co.*, 72 Ill. App. 3d 540, 390 N.E.2d 1214 (1979).

236. See note 235 *supra*.

237. 79 Ill. 2d 26, 402 N.E.2d 194 (1981).

238. *Id.* at 35-38, 402 N.E.2d at 199-200.

239. *Id.* at 29, 402 N.E.2d at 199.

240. See *Mink v. University of Chicago*, 460 F. Supp. 713, 719 n.7 (N.D. Ill. 1978); *Mahr v. G. D. Searle*, 72 Ill. App. 3d 540, 390 N.E.2d 1214 (1979). Accord *Woodill v. Parke Davis & Co.*, 79 Ill. 2d 26, 402 N.E.2d 194 (1980). The Circuit referred to comment k as an "affirmative defense" rather than a legal standard. *Needham v. White Laboratories, Inc.*, 639 F.2d 394, 402 (7th Cir. 1981).

nant women when the fetus is in a certain position.<sup>241</sup> As in *Needham*, there was no warning given about this danger. The court, nevertheless, characterized pitocin as an unavoidably unsafe product.<sup>242</sup> In so doing, it did not distinguish between comments j and k, but did distinguish between the nonapplicability of comment k in strict liability defective product cases. Citing *Cunningham*,<sup>243</sup> the *Woodill* court stated:

Later in *Cunningham* we distinguished between strict liability based on a defect in a product, such as was involved therein, and where, as here, *warning may be required because a product is unavoidably unsafe*. We referred to the "exception" created by comment k to Section 402A of the Restatement (Second) of Torts:

k. *Unavoidably Unsafe Products*.

There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified . . . Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous . . . We believe it clear that the exception set forth in the quoted comment relates only to products which are not impure and which, even if properly prepared, inherently involve substantial risk of injury to the user.<sup>244</sup>

The *Woodill* court went on to hold:

Therefore, the pleading requirement that a manufacturer know or should know of the dangerous propensity of the product is limited to complaints which allege a breach of the duty to warn adequately. Whether it is necessary to allege knowledge where liability is predicated on the defective design of the product is not before us.<sup>245</sup>

The *Woodill* discussion of the knowledge requirement is replete with references to the language of comment k. For example, to describe the pleading and proof requirements of a strict liability failure to warn action, the court stated that "the inquiry becomes whether the manufacturer, because of the 'present state of human knowledge, . . . knew or should have known of the danger presented by the use or consumption of the product."<sup>246</sup> Again using the language of comment k, the court expressed one of the reasons for imposing the knowledge

241. *Woodill v. Parke Davis & Co.*, 79 Ill. 2d 26, 28-29, 402 N.E.2d 194, 195 (1980).

242. *Id.* at 79 Ill. 2d 26, 36, 402 N.E.2d 194, 199.

243. *Id.*

244. *Id.* (emphasis added).

245. *Id.* at 37, 402 N.E.2d at 199.

246. *Id.* at 35, 402 N.E.2d at 198.

limitation: If a manufacturer is held liable for failure to warn of a danger which it would be impossible to know about “based on the present state of human knowledge,” then the manufacturer would become “an insurer of its product.”<sup>247</sup> Finally, in language which parallels the rationale of comment k, the court set forth the policy reasons for imposition of a knowledge requirement in strict liability failure to warn cases:

This court is acutely aware of the social desirability of encouraging the research and development of *beneficial* drugs. We are equally aware that risks, often grave, may accompany the introduction of these drugs into the market place. We simply *think, however, in accordance with comments j and k* of Section 402A. . . that where liability is framed by the manufacturer’s duty to warn adequately of dangers which may arise from the use of a drug that liability should be based on there being some manner in which to know of the danger.<sup>248</sup>

The Illinois appellate court also has relied “particularly” on comment k to conclude that “without doubt, Section 402A . . . comment k, discloses that a *prescription* drug may be deemed unreasonably dangerous if it is manufactured and distributed without adequate warnings. . . .”<sup>249</sup> Implicit in this formulation is the assumption that comment k applies to all prescription drugs because these products are inherently dangerous by nature and therefore unavoidably unsafe products. The presence or absence of warnings determines whether the useful product is unreasonably dangerous, not whether it is unavoidably unsafe. Before a warning is required under *Woodill*, however, the manufacturer of a beneficial drug must have known or have been able to discover the risk of danger. If knowledge of a risk exists and a warning is provided, the product is not unreasonably dangerous; if such knowledge exists but a warning is not given, the product *is* unreasonably dangerous.

*Woodill’s* reliance on comment k belies the notion that it can be characterized as a comment j, as opposed to a comment k case. *Woodill* also demonstrates that a warning is not a prerequisite to comment k applicability. The Seventh Circuit’s conclusions concerning comment k directly oppose those of the Illinois Supreme Court. Although the Seventh Circuit recognized its responsibility to apply the substantive law of Illinois, it evaded this obligation.

To justify the application of another jurisdiction’s substantive law, the Seventh Circuit simply asserted that the Illinois Supreme Court had not decided a comment k case. Perhaps

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247. *Id.* at 37, 402 N.E.2d at 199.

248. *Id.* (emphasis added).

249. *Mahr v. G. D. Searle*, 72 Ill. App. 3d 540, 390 N.E.2d 1214, 1228 (1979).

what the court meant was that the Illinois courts had not been confronted with a case like *Needham*, that is, a strict liability failure to warn action in which the plaintiff claimed that the drug involved was not beneficial—not an apparently useful product—in addition to asserting that it posed a risk of harm about which there was no warning. Consequently, Illinois courts have not been asked to balance a drug's risk of harm against its benefits to determine whether the manufacturer's decision to market the drug was justified. In the Illinois drug cases decided thus far, the drug has been presumed to be beneficial.<sup>250</sup> Thus the comment k rationale for imposing a knowledge requirement applies to those cases, and the courts accordingly have imposed liability in these circumstances in accordance with the comment k exception to strict liability: The manufacturer of a beneficial drug is liable for failure to warn only of known dangers.

It seems likely, however, that if the Illinois Supreme Court were faced with a challenge to a drug's benefits, it would resolve the issue using efficacy evidence, in the same manner as other courts have resolved it.<sup>251</sup> If, as in *Needham*, the drug's risks manifestly outweigh its benefits, then under the comment k analysis, the knowledge requirement, which protects or excepts the manufacturer from strict liability, would not be applied. In relaxing the strict liability rule in failure to warn cases, the *Woodill* court clearly indicated that the underlying policy of this rule was to favor the development of *beneficial* drugs.<sup>252</sup> Conversely, then, if a drug's benefits were manifestly outweighed by its risk, that is, if the drug were ineffective and caused serious harm, the policy favoring the development of beneficial drugs would not be furthered by allowing comment k protection to the manufacturer. The manufacturer would be held strictly liable for failure to warn, irrespective of its knowledge of dangers.

#### *The Seventh Circuit's Comment k Analysis*

Instead of applying Illinois law, the Seventh Circuit adopted the comment k analysis articulated in *Reyes v. Wyeth Laboratories*, which it mistakenly interpreted as a case in which a warning of risks is given and yet the product remains dangerous even if the warning is followed.<sup>253</sup> The manufacturer is exempt from

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250. See, e.g., *Woodill v. Parke Davis & Co.*, 79 Ill. 2d 26, 402 N.E.2d 194 (1980); *Lawson v. G. D. Searle & Co.*, 64 Ill. 2d 543, 356 N.E.2d 779 (1976); *Mahr v. G. D. Searle & Co.*, 72 Ill. App. 3d 540, 390 N.E.2d 1214 (1979).

251. See cases cited *supra* note 158.

252. *Woodill v. Parke Davis & Co.*, 79 Ill. 2d 26, 37, 402 N.E.2d 194, 199 (1980).

253. *Needham v. White Laboratories, Inc.*, 639 F.2d 394, 401 (7th Cir. 1981).

liability only if the product's benefits outweigh its risks.<sup>254</sup> In *Reyes*, however, *no warning* was provided, although the risk of danger was known. Nevertheless, the court found that the vaccine was an unavoidably unsafe product and thus that comment k applied.<sup>255</sup> Because no warning as to the vaccine's dangers was provided, the *Reyes* court held Wyeth Laboratories strictly liable under a comment k analysis.<sup>256</sup> The Seventh Circuit was therefore mistaken in indicating that a warning must have been given for comment k to be applicable.

In analyzing the issue within the comment k framework, the *Reyes* court first determined whether the vaccine was unreasonably dangerous per se by determining whether marketing it was justified despite the danger involved in its use.<sup>257</sup> After concluding that marketing the vaccine was justified, the court went on to decide whether the drug was unreasonably dangerous *as marketed*, which in a drug case translates to "a duty to provide proper warnings."<sup>258</sup>

According to the *Reyes* comment k analysis, the first, rather than last, step is to determine whether the drug's apparent usefulness outweighs its known risk. If it does, then the marketing of the drug is justified; if it does not, the drug is unreasonably dangerous per se. At this juncture, the question of warnings, whether given or not, need not be addressed. To determine whether a product is unreasonably dangerous per se, it is apparent that evidence of efficacy or lack of efficacy must be adduced. Without this evidence, it is impossible to determine whether the drug's apparent usefulness outweighs its known risks. Thus, under *Reyes*, the evidence of dienestrol's ineffectiveness clearly was not irrelevant or prejudicial. Rather, this evidence was a crucial aspect of the case. The *Reyes* analysis supports the district court's ruling that evidence of dienestrol's efficacy or lack of efficacy is relevant to the *Needham* action.

If the Seventh Circuit had correctly applied the *Reyes* court's analysis to the facts adduced during the *Needham* trial, it would be hard pressed to escape the conclusion that dienestrol was unreasonably dangerous per se. As of 1952, the efficacy of dienestrol in preventing threatened abortion was admittedly "controversial" according to White Laboratories' medical director, and White Laboratories was aware that other scientists had concluded that dienestrol was a dismal failure. Thus, White

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254. *Id.* at 12.

255. *Reyes v. Wyeth Laboratories*, 498 F.2d 1264, 1270, 1273 (5th Cir. 1974).

256. *Id.* at 1276.

257. *Id.*

258. *Id.* at 1274.

Laboratories knew or should have known that dienestrol was not apparently useful. The additional knowledge that DES-related estrogens such as dienestrol caused tumor formation and abnormal anatomical changes in the offspring of pregnant animals, as well as cancer, leads to the conclusion that the known risks far outweighed its benefits. Even if the Seventh Circuit viewed animal studies as inconclusive proof of actual danger to humans, the jury was entitled to believe the testimony of plaintiff's experts that animal studies were viewed as reliable indicators of risks to humans. Although the *Needham* district court did not make a finding as to the sufficiency of the efficacy evidence, it did find that the evidence supported a jury verdict for plaintiff on the basis of White Laboratories' knowledge of the risk of cancer to female offspring exposed *in utero* to dienestrol. The Seventh Circuit did not refute this finding. Under the *Reyes* analysis, the evidence presented at the *Needham* trial established that White Laboratories' decision to market dienestrol was not justified. Given the gravity of the potential harm, the controversial and questionable efficacy of dienestrol could not possibly be found to outweigh its known risk. Dienestrol is unreasonably dangerous per se within the meaning of *Reyes*.

*Another Seventh Circuit View of Comment k: Singer v. Sterling Drug*

The requirement that comment k be applied only when the manufacturer has warned of the risk and the product remains dangerous even if the warning is followed is supported by the Seventh Circuit's earlier decision in *Singer v. Sterling Drug*,<sup>259</sup> which established two classifications of drugs which fall within the comment k exception to strict liability. First, comment k applies to drugs in which there is a known but apparently reasonable risk of injury and the user has been warned of the risk.<sup>260</sup> An example of this drug is the Pastuer vaccine for rabies. The second class to which comment k applies is the new or experimental drug for which there is no knowledge of risk and the user has been warned that the drug is new or experimental.<sup>261</sup> An example of this type of drug is dienestrol.

The Seventh Circuit's decision in *Needham* addresses only the first category of comment k drugs; the second category is notably missing from the court's discussion of comment k. This omission is significant because White Laboratories relied on the second category as a defense. Throughout the trial, White Labo-

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259. 461 F.2d 288 (7th Cir. 1972).

260. *Id.* at 290.

261. *Id.*

ratories maintained that knowledge of dienestrol's risks had not and could not be discovered in 1952, and that White Laboratories had warned that the use of dienestrol in the treatment of threatened abortion was investigational. The Seventh Circuit simply ignored this evidence and did not address the second comment k category formulated in *Singer*. In categorizing comment k drugs in two classes, *Singer* itself made a notable omission. The text of comment k refers to prescription drugs, which *Singer* ignored, apparently because the court viewed with disfavor the applicability of the comment k knowledge requirement in all prescription drug cases based on strict liability for failure to warn. The *Woodill* court imposes this requirement on all failure to warn cases which involve beneficial drugs.<sup>262</sup> Thus, *Singer* rejects the underlying premise of *Woodill*, and therefore is questionable authority for Illinois strict liability law.

#### *Strict Liability Based on a Defect*

In *Needham*, the plaintiff's second theory of strict liability was that dienestrol was defective because it was useless and unreasonably dangerous. The Seventh Circuit held that the district court's alternative ruling, which allowed evidence of lack of efficacy to prove dienestrol defective, was not supported by *Cunningham v. MacNeal Memorial Hospital*. The district court relied on *Woodill* to support its view that the knowledge of risk requirement applied in strict liability failure to warn cases, and that the usual rule in other strict liability cases, that proof of a defect suffices, remained undisturbed. *Cunningham* was cited as authority for the usual strict liability rule that proof of a defect is sufficient. The district court's interpretation was correct. The *Woodill* court clearly stated that it was not imposing a knowledge requirement in either a product defect or design defect case.<sup>263</sup> In reaching this decision, the *Woodill* court cited the *Cunningham* distinction between strict liability based on a defect and strict liability based on the manufacturer's failure to warn, and noted that comment k only applied to the failure to warn action.

Despite the *Woodill* references to defect cases such as *Cunningham*, and to design defect cases, the Seventh Circuit essentially held that an impurity such as that in *Cunningham* was the only kind of product defect on which strict liability could be based. Since the plaintiff in *Needham* did not claim that dienestrol contained any impurity as did the plaintiff in *Cunningham*, the *Cunningham* case did not "govern." The Seventh Circuit in-

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262. *Id.*

263. *Woodill v. Parke Davis & Co.*, 79 Ill. 2d 26, 402 N.E.2d 194 (1980).



terpreted the district court's citation to *Cunningham* as a ruling that an ineffective product is a defective product. Citing section 402A, the Seventh Circuit held that ineffectiveness of a product is not actionable under strict liability theory.<sup>264</sup>

The district court, however, had not ruled that plaintiff's case was governed by *Cunningham*. Rather, the district court extrapolated from *Cunningham* the principle that proof of a defect, without proof of knowledge of the defect, is sufficient to establish strict liability based on that defect. Likewise, the district court did not hold that an ineffective product is necessarily a defective product. The plaintiff's alternate theory of strict liability was premised on the claim that dieneestrol was defective because it was ineffective *and* unreasonably dangerous. If the drug was *both* ineffective and the cause of plaintiff's cancer, as the jury was instructed, then the drug was defective. The theory is supported by Illinois case law. To distinguish between an ineffective drug and an ineffective brake, both of which subsequently cause injury, is not legally justified for purposes of strict liability.

The real difference between these products is in their nature; the brake is only dangerous if it is ineffective, while the drug is always potentially dangerous. A drug is ingested despite its danger because it is an effective therapeutic agent against some other harm. Such a drug is not unreasonably dangerous. If, however, the drug does not prevent some other harm, that is, if it is useless, then the danger it poses is unreasonable. In the first situation there is reason for exposing oneself to potential danger—the drug is taken to avoid some other harm. If the drug does not prevent this other harm, then it follows that it is not reasonable to expose oneself to the drug's potential dangers. Such a drug is unreasonably dangerous.

These differences in the kinds of product defects are not of sufficient import to deny strict liability for drug defects. "The response of the courts can be either to adhere rigidly to prior doctrines, denying recovery to those injured by such products, or to fashion remedies to meet these changes."<sup>265</sup> From a strict liability policy standpoint, the manufacturer of drugs is better able to bear the cost of injuries resulting from defective products. The manufacturer is in the best position to test for and discover, as well as guard against, defects in its products. The threat of strict liability will provide an incentive to produce safer drugs. The drug-consuming public needs protection from defec-

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264. *Needham v. White Laboratories, Inc.*, 639 F.2d 394, 402 (7th Cir. 1981).

265. *Sindell v. Abbott Laboratories*, 26 Cal. 3d 588, 610, 607 P.2d 924, 936, 163 Cal. Rptr. 132, 144 (1980).

tive drug products. The Seventh Circuit's holding creates a blanket protection from strict liability for drug manufacturers who develop, promote, and profit from an ineffective and dangerous drug. This decision is contrary to Illinois strict liability consumer protection goals.

#### CONCLUSION

The protection afforded by comment k to drug manufacturers applies only if the drug's benefits outweigh its risks. Where a plaintiff challenges the manufacturer's decision to market the drug as unjustified by asserting that the drug is not beneficial, evidence of efficacy or inefficacy is relevant to decide the claim. If the decision to market the drug was not justified because its apparent usefulness was outweighed by its risks the manufacturer loses the protection of comment k and may be held strictly liable. Comment k protection was intended for manufacturers of beneficial drugs only.

On the other hand, if a drug had no apparent usefulness and it caused injury, the manufacturers may be held strictly liable for manufacturing a defective product in an unreasonably dangerous condition. The result under either theory, the loss of comment k protection, is the same, and evidence of efficacy or lack of efficacy is relevant to both theories. These theories are supported by Illinois case law and by decisions in other jurisdictions.

Moreover, the imposition of strict liability on the drug manufacturer who develops, promotes, and profits from an apparently useless and dangerous drug is a just result. It would be manifestly unfair to thrust upon the consumer the burden of paying for the treatment of injuries caused by such drugs. The high profits and few losses in the drug industry reveal that a drug company is in a better position than the injured consumer to absorb and spread the cost of compensating for drug injuries. It is time to make the justification for these high drug profits a reality; manufacturers who develop, for profit, apparently useless and dangerous drugs must also accept the risk in such developments. The district court's ruling promotes this goal; the Seventh Circuit's decision defeats it. The *Needham* reversal signified another victory for the drug companies, and yet another disaster for the consumer.

The Seventh Circuit's opinion in effect allows drug companies to develop and sell useless drugs with no concern about whether or not these drugs are dangerous, since the manufacturers will not be strictly liable in tort for injured caused by such drugs. And as long as neither the drug manufacturer nor

anyone else tests for the drug's dangers, the manufacturer will not be liable for failure to warn because it will not know of the danger until some time after the drug has been on the market—in the case of cancer, perhaps twenty years. During this time the manufacturer will have made an enormous profit. Of course, one would assume that after the manufacturer learns of injury caused by its product, it would warn consumers of the danger. But if the birth control pill experience is any indication, this assumption is grossly naive. The risk of cancer from estrogen consumption has only recently surfaced in the warnings accompanying the pill. Time may well prove that the development and promotion of estrogen products has been the greatest fraud ever perpetrated by drug companies. The courts should allow the victims of DES injuries to bring strict liability actions based either on a theory of defect or of failure to warn. Evidence of efficacy or usefulness should be deemed pivotal in such actions. Strict liability for drug injuries should exist in fact, not just in theory.